# Guidance of EFSA

# Risk Assessment for Birds and Mammals




On request from EFSA, Question No EFSA-Q-2009-00223
First published on 17 December 2009

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**Acknowledgement:** EFSA wishes to thank the members of the Joint Working Group for the preparation of this EFSA scientific output: Lilian Tornqvist (chair, DG SANCO), Apolonia Novillo (Spain), Brian Woolacott (United Kingdom), Elisabeth Dryselius (Sweden) Henry (Her) de Heer (The Netherlands), Manousous Foudoulakis (Greece), Martin Streloke and Andreas Höllrigl-Rosta (Germany), Robert Luttik (technical expert), Andy Hart (technical expert), and EFSA's staff member Christine Füll for the support provided to this EFSA scientific output. The final GD was edited by Andy Hart, Robert Luttik and EFSA's staff member Christine Füll. Further, EFSA wishes to thank all PPR Panel members (2006-2009) and all experts involved in the preparation of the underlying opinion. For a complete list of acknowledgements please refer to that opinion (EFSA, 2008). EFSA also wishes to thank its staff member Jane Richardson (Assessment and Methodology Unit) for the development of the tool (Excel spreadsheets) for Tier 1 calculations.

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doi: 10.2903/j.efsa.2009.1438



Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

# About EFSA

The European Food Safety Authority (EFSA) was established and funded by the European Community as an independent agency in 2002 following a series of food crises that caused the European public to voice concerns about food safety and the ability of regulatory authorities to fully protect consumers.

In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides objective scientific advice on all matters with a direct or indirect impact on food and feed safety, including animal health and welfare and plant protection. EFSA is also consulted on nutrition in relation to Community legislation.

EFSA's work falls into two areas: risk assessment and risk communication. In particular, EFSA's risk assessments provide risk managers (EU institutions with political accountability, i.e. the European Commission, European Parliament and Council) with a sound scientific basis for defining policy-driven legislative or regulatory measures required to ensure a high level of consumer protection with regard to food and feed safety.

EFSA communicates to the public in an open and transparent way on all matters within its remit.

Collection and analysis of scientific data, identification of emerging risks and scientific support to the Commission, particularly in case of a food crisis, are also part of EFSA's mandate, as laid down in the founding Regulation (EC) No 178/2002 of 28 January 2002.

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# Abstract

The revised Guidance Document on Risk Assessment for Birds and Mammals on the basis of the Scientific Opinion of the PPR Panel on the Science behind the Guidance Document on Risk Assessment for Birds and Mammals (The EFSA Journal (2008) 734: 1-181) and its Appendices has been finalised based on the decisions of the Joint WG consisting of representatives from the European Commission, nominated Member States and technical experts from EFSA.

**Key words**

Birds, mammals, risk assessment, pesticide, plant protection product, active substance, refinement, level of protection.

# Summary

The European Food Safety Authority (EFSA) asked its Scientific Panel on Plant protection products and their Residues Unit (PPR Panel Unit) to prepare the revised Guidance Document on Risk Assessment for Birds and Mammals on the basis of the Scientific Opinion of the PPR Panel on the Science behind the Guidance Document on Risk Assessment for Birds and Mammals (The EFSA Journal (2008) 734: 1-181) and its Appendices (EFSA, 2008).

This Guidance Document (GD) is further based on the decisions made by a Joint Working Group (WG) of nominated representatives from Member States, assisted by technical experts from EFSA and chaired by a representative of DG Health and Consumers. This Joint WG took necessary risk management decisions not within the remit of EFSA and decided on the options given in the Scientific Opinion. A record of their work and decisions is provided in the report of the Joint WG submitted to the Standing Committee on the Food Chain and Animal Health (SCFCAH) meeting on 2 October 2009 (EC, 2009). An editorial team then implemented these decisions and rewrote the GD.

This GD addresses approaches to risk assessment for birds and mammals. In both cases, a tiered approach is used to assess the risk of mortality and reproductive effects.

A first-tier assessment procedure for a large range of scenarios including different crops and different types of pesticide uses (e.g. granules, seed treatment, and sprays) has been developed. Each scenario is a combination of the ecological characteristics of exposed species and other factors relevant to exposure, e.g. the type and structure of crop, and the type of formulation of the pesticide product. The best available data to define each scenario have been used. The Tier 1 assessment is supported by a calculation tool that has been developed during the revision of the GD.

The level of protection provided by each first-tier procedure, taking account of the conservatism of the assumptions used has been evaluated, uncertainties arising from factors omitted from the assessment (e.g. dermal exposure) and, where available, evidence on actual effects in field studies or from incident monitoring given.

Guidance on the range of options available for higher-tier risk assessment, e.g. refined dietary exposure assessments using realistic data on the ecology of relevant species; or field studies in order to get better residue data, better ecological data, or to measure effects are provided.

Further, guidance on how to combine different types of evidence from higher-tier risk assessment to form an overall judgement on the level of risk, giving appropriate weight to the strengths and uncertainties of each type of evidence, is presented.

More detailed guidance on specific aspects of higher risk assessment is given in a series of Appendices to this Guidance Document as well as to the opinion forming the basis of this GD (EFSA, 2008). Further Appendices provide detailed scientific background and underlying data for the first-tier assessment procedures. Worked examples for the reproductive risk assessment and comparisons of the outcome of the proposed new assessment procedures with the existing risk assessment scheme are available.

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The CD-ROM enclosed in this report contains the full guidance document in pdf format, appendices (as listed on page 125) and a calculator tool for Tier 1 calculations.

# Background as provided by EFSA

EFSA's Scientific Panel on Plant Protection Products and their Residues (PPR Panel) had completed a comprehensive scientific opinion (EFSA, 2008) for the revision of the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (SANCO/4145/2000 – final of 25 September 2002).

The scientific opinion contains various modules, some of which are alternative approaches for the same risk assessment area. The decision on which of these approaches to choose is a risk management decision and is therefore not within the remit of the EFSA PPR Panel, since EFSA is responsible for risk assessment and risk communication but not risk management.

As a result of the close cooperation and involvement of Member States (MS) and industry during the whole drafting process (two public consultations, the participation of representatives from MS and industry in the Core Working Group, a field-based consultation workshop in May 2007, a meeting with Member States in Dec 2007) together with the extensive comments received from the public consultations on the draft scientific opinion on the revised GD, it was understood that the users of the GD would prefer and need a GD that does not contain different options to choose from.

In a meeting on 31st Jan 2008, the EFSA Director on Risk Assessment decided to deal with risk management options by asking the PPR Panel to adopt a two-stage approach and to first prepare a scientific Opinion on the Science behind the GD on risk assessment for birds and mammals (*The EFSA Journal* (2008) 734: 1-181) using a modular approach. In a second stage, a Joint Working Group of nominated risk managers from Member States, assisted by technical experts from EFSA's PPR Panel, and chaired by a representative of the European Commission (DG Health and Consumers), was invited to consider the risk management issues and make respective decisions for the revised/new Guidance Document on risk assessment for birds and mammals to be finalised.[1] The role of the PPR Panel members and EFSA staff in this WG was to assist in interpretation and understanding of the science in the Opinion, and not to participate in the risk management decisions.

Nominations had been received from the following Member States: Germany, Greece, Spain, Sweden, The Netherlands, and the United Kingdom.

# Terms of reference as provided by EFSA

Based on the PPR Panel's scientific opinion on the science behind the proposed new GD on risk assessment for birds and mammals (*The EFSA Journal* (2008) 734: 1-181) the specific Working Group is tasked by EFSA to prepare a revised Guidance Document on Risk Assessment for Birds and Mammals which will be used for the risk assessment of pesticides under Council Directive 91/414/EEC.

The task of the group is to produce a clear Guidance Document, without the alternative options presented in the PPR Panel's scientific opinion, to address the risk management decisions required. The published scientific opinion has taken account of the extensive comments from the public consultation and the scientific principles have been agreed. The PPR Panel has written the opinion in such a way that each module is self-contained in order to help the choice for the revised Guidance Document to meet the risk management requirements.

1 The Working Group "Legislation" of the Standing Committee on the Food Chain and Animal Health (SCFCAH) was officially informed by the Head of the PPR Panel Unit about the situation during their meeting on 12th March 2008 and was asked to nominate risk managers from Member States for this new Working Group. This specific Working Group should consist of approximately ten people (at least one from the Commission, two members from the PPR Panel, one from the EFSA PPR Secretariat, and up to six risk managers from MS). In case of too many nominations from Member States, up to six with the most relevant experience were to be chosen. The Working Group ought to be chaired by either the Commission or a Member State representative.

# Implementation of the Guidance Document

The Commission recommends that it is acceptable that an applicant applies already this current Guidance Document. For all dossiers submitted as of 1 July 2010 this current Guidance Document should be applied. This Guidance Document should be revised in 2012 taking into account experience from using it. Member States are encouraged to use a questionnaire that will be made available to provide feedback to EFSA.

# Guidance

## 1. Introduction

In 2006, the responsibility for producing new or for revising already-existing Guidance Documents (GDs) addressing risk assessment of pesticides was transferred from the European Commission to the European Food Safety Authority (EFSA). The Scientific Panel on Plant Protection Products and their Residues (PPR Panel) was asked by EFSA's Unit for the pesticide risk assessment peer-review (PRAPeR Unit) to start with the revision of the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (SANCO/4145/2000 – final of 25 September 2002), hereafter referred to as EC, 2002.

**Use of term 'pesticide'**

The term 'pesticides' is often used as a synonym for plant protection products, which are mainly used in agriculture to keep crops healthy and to prevent them from being destroyed as a consequence of disease and infestation. The active substances (a.s.) used in plant protection products are the chemicals or micro-organisms, including viruses, that are the essential component enabling the product to affect.[2] To facilitate the reading of this document, the term 'pesticide' has been used throughout the text were possible.

### 1.1. The process

The revision process of the existing GD (EC, 2002) started off in summer 2006 with a public consultation on EFSA's website[3]. Based on these comments a Core Working Group (Core WG) and several sub WGs drafted a first document, taking into consideration input regarding scope and scale for the revision from risk managers received via a questionnaire. This document was discussed during a scientific workshop with Member States and other stakeholders in May 2007[4] and further developed. In winter 2007 a second public consultation of the updated document[5] took place and EFSA organised a meeting with Member States to exchange views on that document.

In the course of the revision, it became apparent that the task embraced several risk management issues which are not within EFSA's and the PPR Panel's remit. Therefore, the PPR Panel adopted a two-stage approach and first prepared a "Scientific Opinion on the Science behind the GD on risk assessment for birds and mammals", which was adopted in June 2008 (EFSA, 2008).

In the second stage, a Joint Working Group of representatives from Member States, chaired by the European Commission and assisted by EFSA technical experts considered the risk management issues and produced a report (EC, 2009)[6] including all their decisions and recommendations on how to finalise the revision of the Guidance Document on risk assessment for birds and mammals. On the basis of this report, an editorial team[7] produced the present Guidance Document.

2 See http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620925075.htm
3 See http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178660551795.htm
4 See http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592142.htm
5 At this time still named 'first draft of the revised GD'.
6 Available at: http://ec.europa.eu/food/plant/protection/evaluation/guidance/report_birds_mammals_guidance_doc_sanco10997_2009_31_07_09.pdf
7 Christine Füll, Andy Hart, Robert Luttik.

## 1.2. Scope of the Guidance Document

Annex II and III of Directive 91/414/EEC[8] state that information should be provided to enable an assessment of the direct impact on birds and mammals likely to be exposed to the active substance, plant protection product and/or its metabolites. These impacts may result from either single long-term or repeated exposure and can be reversible or irreversible. In order to determine the risk, toxicity data are taken, along with an estimate of the likely exposure concentrations. This document provides a tiered approach to assessing both, direct acute and reproductive risk to birds and mammals.

Risk managers should be aware that two main issues have not been considered in the following risk assessment scheme: indirect effects and overspraying of eggs of ground nesting birds. Further work is required in this area to develop suitable schemes as well as risk mitigation measures.

Further, risk assessment for a rice scenario is not included in this document because it is envisaged that it will be addressed in a separate guidance document.

## 1.3. Risk assessment approach

The traditional acute and reproductive risk assessments schemes are based on a TER approach comprising three tiers. The first step in the process is a 'screening step'. It makes use of an 'indicator species'[9] along with worst-case assumptions regarding exposure. The aim of this step is to highlight those substances that do not require further consideration as their associated uses pose a low risk. Further, this step should identify, with sufficient certainty, false negatives (i.e. cases of undetected risks).

If a substance and its associated use do not pass the screening step, then the next step is the first-tier risk assessment. This uses more realistic exposure estimates along with a 'generic focal species'[10]. For the reproductive risk assessment, a variety of toxicity endpoints can be used. If this step is not successful, then further refined risk assessment is required. This involves a greater degree of realism and uses more realistic exposure estimates as well as a 'focal species'[11] approach. Further details regarding each of these steps are provided in sections 4, 5 and 6 of this Guidance Document.

Indicator and generic focal species are representatives of real species occurring in a particular crop at a particular time. Data describing the feeding habits and other ecological needs have been collected by the PPR Panel from existing literature and compiled in Appendix A.[12] The respective values for the indicator and generic focal species have been selected from these tables and compiled in the tables of Annex I to this GD and in section 4. They can be used directly in the exposure calculations and are called 'shortcut values'.

8 On 24 Sep 2009, the Council adopted a new Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. This new legislation was published in the Official Journal of the European Union on 24 Nov 2009 and will become fully applicable as from 18 months following the date of publication (i.e. mid 2011). Annexes II and III have been incorporated into the new Regulation and are currently under revision.

9 An 'indicator species' is not a real species but, by virtue of its size and feeding habits is considered to have higher exposure than (i.e. to be protective of) other species that occur in the particular crop at a particular time. It has a high food intake rate, and consumes one type of food which in turn has high residues on/in it.

10 A 'generic focal species' is not a real species, however it is considered to be representative of all those species potentially at risk, i.e. it is based on ecological knowledge of a range of species that could be at risk. It has a high food intake rate and may consume a mixed diet rather than just one as for the indicator species. The diet is not real but is considered to be representative of the species represented and hence a quartile approach has been used where only the 2, 3 or 4 largest food types have been extrapolated to either 25 % or 50 % of the total diet. The 'generic focal species' is also considered to be a representative of the types of birds or mammals that occur across Member States.

11 A 'focal species' is a real species that actually occurs in the crop when the pesticide is being used. The aim of using a 'focal species' is to add realism to the risk assessment insofar as the assessment is based on a real species that uses the crop. It is essential that the species actually occurs in the crop at a time when the pesticide is being applied. It is also essential that this species is considered to be representative of all other species that may occur in the crop at that time. As a 'focal species' needs to cover all species present in the crop, it is possible that there may be more than one 'focal species' per crop.

12 Appendices on the basis on EFSA (2008) that form part of this GD because they will be used on a day-to-day basis have been renamed to Appendix A, B, C etc. Some of them are updated, others remained unchanged. Letters "I" and "O" have been omitted in the naming.

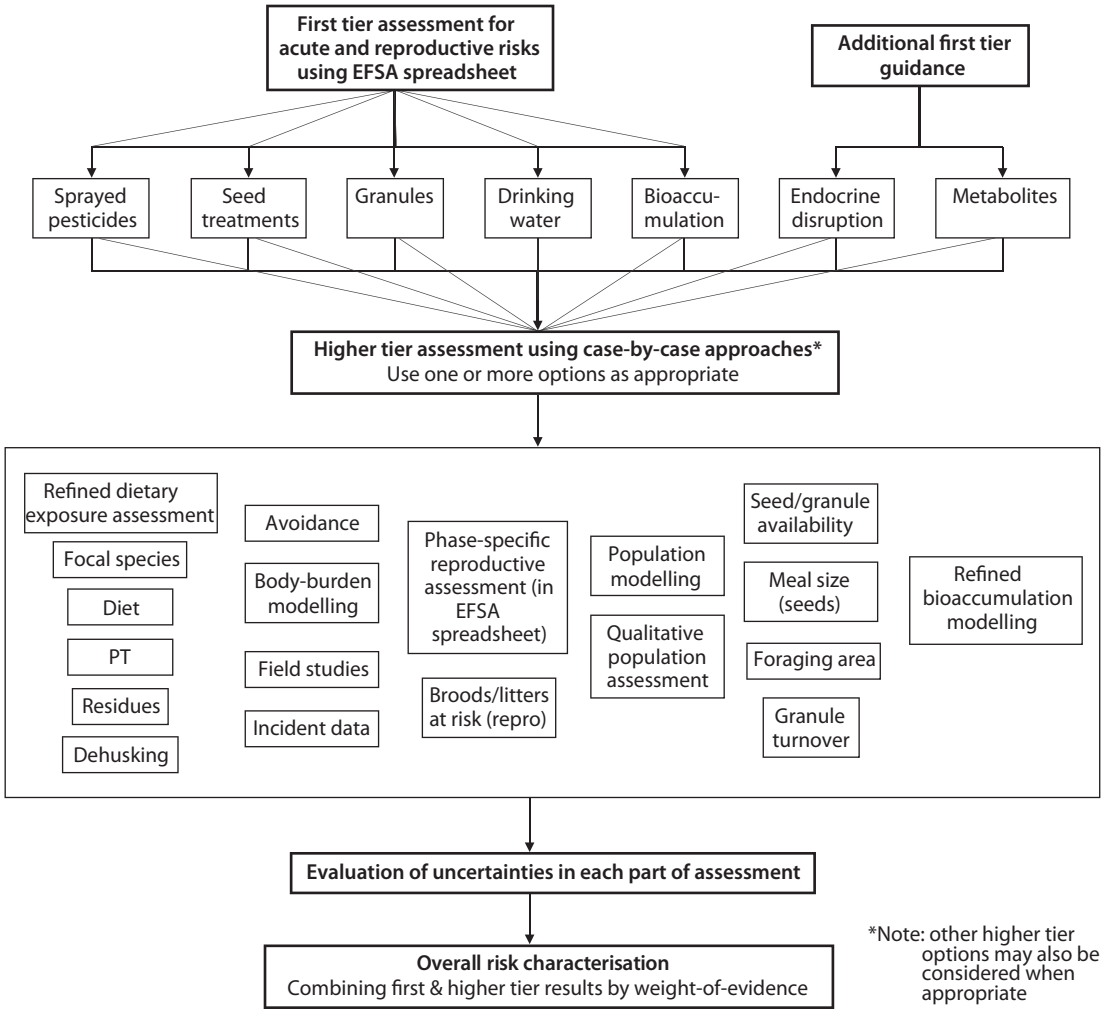


**Figure 1.** Flowchart for the risk assessment. Please note that for some types of assessment there is an optional screening step.

Please note that a calculation tool (spreadsheet) for Tier 1 risk assessment has been developed and is made available together with this Guidance Document.

# 2. Standard toxicity tests and the derivation of toxicity data for risk assessment

In order to assess the risk of pesticides to birds and mammals, data on the acute and reproductive toxicity are required. Details regarding which avian studies should be provided are given in Annex II Section 8.1 and Annex III Section 10.1 of Directive 91/414/EEC. Details regarding which mammalian studies should be considered are provided in Annex II Section 5 and Annex III Section 7. Details of which studies are available and which key points need to be considered are outlined below.

The PPR Panel adopted and published 12 opinions related to data requirements of Annex II and III of Directive 91/414/EEC. In particular, the two opinions on ecotoxicological studies (EFSA, 2007, 2009a) provide recommendations concerning avian toxicity studies. These recommendations are currently considered by the European Commission in the revision process of Annexes II and III.

## 2.1. Acute toxicity to birds and mammals

Where possible, the test should provide for birds and mammals, the $LD_{50}$ values, the lethal threshold dose, time courses of response and recovery and the no observed effect level (NOEL) for lethality, and must include relevant gross pathological findings. Study design should be optimised for the achievement of an $LD_{50}$ rather than for any secondary endpoint.

### Birds

According to Annex II of Directive 91/414/EEC, the acute oral toxicity of an active substance to a quail species (Japanese quail, *Coturnix coturnix japonica* or bobwhite quail, *Colinus virginianus*) or to mallard duck (*Anas platyrhynchos*) must be determined. The highest dose used in tests need not normally exceed 2000 mg/kg body weight. Due to issues of regurgitation it is recommended not to use the mallard duck (EFSA, 2007). Where regurgitation or emesis occurs at doses used for risk assessment, additional information is essential to complete the risk assessment. The amount of regurgitated material should be assessed for determination of the ingested dose. In the absence of this information, the lowest overall no observed effect level (NOEL) must be used for risk assessment purposes. Where more than one study has been submitted, the study/studies where no regurgitation has occurred should be used. If, however, mortalities appear in the study in which regurgitation has occurred (at dose levels at or around the $LD_{50}$ value for the non-regurgitation study), then it is proposed to use the NOEL (for regurgitation or mortality, whichever is lower) from the study where regurgitation has occurred.

Avian acute oral $LD_{50}$ studies generally are conducted with a minimum of 50 birds. A new draft guideline of the Organisation for Economic Cooperation and Development (OECD, 2002), which is currently under development, appears likely to deliver the same endpoints with similar precision using fewer birds (e.g. 12 – 24 individuals). In view of the policy goal of minimising animal testing, it is recommended that support be given to completing the development and evaluation of this guideline, and to ensuring that, when available, it can readily be assumed under Directive 91/414/EEC and Regulation (EC) 1107/2009, respectively.

The opinion of the PPR Panel on pirimicarb (EFSA, 2005a) showed that it would be useful to obtain additional information from acute oral toxicity studies, specifically, measurement of food consumption on the day of dosing, and the approximate times of onset and disappearance of overt clinical signs. This requires increased visual observations, e.g. every 1 - 2 hours on the day of dosing. Such information can be used for a refined assessment of the influence on risk of food avoidance responses and metabolism of the pesticide, as illustrated in EFSA (2005a). It was recommended that consideration should be given to requiring this information from acute oral studies (including OECD, 2002) as standard, in order to avoid the need to repeat studies in cases in which such an assessment becomes necessary.

**Mammals**

The following acute oral toxicity test methods with mammals are available ($LD_{50}$ mg/kg bw):

- OECD Test 420 (OECD, 2001a): Acute oral toxicity – fixed dose procedure
- OECD Test 423 (OECD, 2001b): Acute oral toxicity – acute toxic class method
- OECD Test 425 (OECD, 2006c): Acute oral toxicity – up-and-down procedure

The fine details of the above studies vary but the underlying principles are the same. Animals (normally rats, but data from studies with other mammals including mice and dogs are also relevant) are dosed once by oral gavage and observed for 14 days. Observations include body weight, clinical signs, death and necropsy findings. A limit dose of 2000 mg/kg bw or 5000 mg/kg bw (depending on study) should not be exceeded.

The fixed dose procedure and the acute toxic class method are range estimators and are useful for mammalian wildlife risk assessment only in cases where they can be used as a limit test (e.g. > 2000 mg/kg bw), or to provide a conservative surrogate for the $LD_{50}$ (i.e. lowest value of range).

An acute neurotoxicity study based on a US EPA procedure[13] may also provide useful information. The basic design is that of the OECD Test 424, i.e. animals (normally rats; 5/sex/group) are dosed once, normally by oral gavage and observed for up to 14 days, but in addition, observations for neurological function (a functional observation battery) are taken pre-dosing and at the time of peak effect (up to 8 h post dose), day 7 and day 14. Other observations are body weight and specific histopathological investigation of nervous tissue.

If the result of the acute mammalian toxicity assessment does not pass the trigger value of Annex VI of Directive 91/414/EEC for Tier 1, the estimate of toxicity could be refined with a more precise test (e.g. up and down procedure of Test 425). Only in cases where there is a thoroughly justified need for more precision in estimating the acute mammalian $LD_{50}$ and slope, consideration could be given to performing studies using more animals (e.g. acute oral test, OPPTS[14] 870-110).

### 2.1.1. Selection of acute endpoints

Occasionally, $LD_{50}$ values may be quoted for males and females separately. Some guidance on which endpoints to use is given below.

**Birds**

In the acute oral $LD_{50}$ study with birds, males and females normally are not tested separately; hence the endpoint is a combined one for both sexes. In the unlikely event that separate values for males and females are measured, it is proposed that the geometric mean be used unless there is a clear indication of a difference in sensitivity between the sexes (e.g. > 25 % in the $LD_{50}$; EPCO, 2005) – in which case the data from the more sensitive sex should be taken.

**Mammals**

The current OECD guideline 420 for acute mammalian oral toxicity states that only females should be tested except where there is evidence that males are likely to be more sensitive (OECD, 2001a). In cases where this guideline has been used, it is assumed that the more sensitive sex has been tested. However, it is likely that endpoints are derived from a range of guidelines and hence endpoints for males and females may be available. It is proposed that the geometric mean be used unless there is a clear indication of a difference in sensitivity between the sexes. In order to determine if one sex is more sensitive than the other, it is proposed to use the guidance in the EPCO manual (EPCO, 2005). One sex is considered more sensitive if the difference in the $LD_{50}$ value is >25 %. If this is the case then the lower $LD_{50}$ value should be used for risk assessment purposes.

13 United States Environmental Protection Agency (870.6200 – Neurotoxicity screening battery: http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/870-6200.pdf

14 US EPA's Office of Pesticide Programs and Toxic Substances

### 2.1.2. Extrapolated LD50 values from limit dose tests for birds

It is permissible to extrapolate an $LD_{50}$ value upwards in cases where there is no mortality or a single mortality at a limit dose in an acute avian toxicity study. The proposed extrapolation factors in Table 1 assume an average probit slope (5.43 – log dose against probit-transformed mortality) generated from a large sample of pesticides tested in the bobwhite quail and mallard duck (see EFSA 2008, Appendix 5). The extrapolation is carried out assuming a 50 % binomial probability bound that mortality could have occurred but had simply been missed by chance in the test. The extrapolation may therefore be underprotective, especially in the case of pesticides having steeper than average slopes of the dose-response-curve, and it is hence inadvisable to use this extrapolation where clear signs of toxicity are observed in the surviving individuals.

**Table 1.** Extrapolation factors based on the number of individuals tested at limit dose.

| Number of animals tested at limit dose | Extrapolation factor for no mortality at a limit dose | Extrapolation factor for a single mortality at a limit dose |
|---|---|---|
| 5 | 1.614 | 1.228 |
| 10 | 1.888 | 1.518 |
| 15 | 2.051 | 1.685 |
| 20 | 2.167 | 1.802 |

After choosing an extrapolation factor from Table 1, the extrapolated $LD_{50}$ value is calculated by multiplying the limit dose with the extrapolation factor:

$$LD_{50} = limit\ dose \times extrapolation\ factor$$

The method of calculating an extrapolated $LD_{50}$ from a limit dose could be equally applied to mammals. However, a requirement of this method is, being able to calculate an average probit slope from a sample of toxicity tests with a variety of substances. These data were available for birds but not for mammals. Hence, until the proper factors can be calculated for mammals, this method can only be applied to birds.

## 2.2. Short term toxicity to birds

The following short term dietary test method with birds is often available ($LC_{50}$ mg/kg food):

- OECD Test 205 (OECD, 1984): Avian dietary toxicity test

This risk assessment scheme does not routinely use output from this $LC_{50}$ study. In two opinions on the revision of Annexes II & III (EFSA, 2007, 2009a), the PPR Panel identified a number of scientific limitations and welfare issues concerning this study and therefore recommended that it should be conducted only for those pesticides where the mode of action and/or results from mammalian studies indicate a potential for the dietary $LD_{50}$ measured by the short term study to be lower than the $LD_{50}$ based on an acute oral study. This would apply, for instance, to many of the organochlorines compounds and anticoagulants. In such cases, where it is lower than the acute $LD_{50}$, the dietary $LD_{50}$ should be used in the acute risk assessment.

Although this test is no longer part of the core data packet, it is very often still available in the dossier. Information from the dietary toxicity test could be used on a case-by-case basis in higher-tier assessments when appropriate, e.g. in particular for body burden modelling (section 6.3). It can also provide an indication of whether avoidance is worth considering in higher tier assessment, but is not sufficient on its own to demonstrate that avoidance will prevent mortality. However, these types of information are also available from other studies, so in general new dietary $LC_{50}$ studies should not be conducted due to their scientific limitations and welfare issues (EFSA, 2007, 2009a).

## 2.3. Reproductive toxicity to birds and mammals

The following overview on toxicity studies available to assist in the reproductive risk assessment is based on Mineau (2005). If the substance being assessed is an endocrine-disrupting substance[15], section 5.3 should be consulted.

### Birds

A test for effects on reproduction in birds is currently requested if birds are likely to be exposed during the breeding season. There are two standard studies, OECD Test 206 (avian reproduction study; OECD, 1993) and the US EPA 71.4 study (US EPA, 1996). The US EPA protocol recommends that tests be carried out on first-time breeders of an upland game species, preferably the northern bobwhite quail (*Colinus virginianus*), and a wild waterfowl species, preferably the mallard duck (*Anas platyrhynchos*). The OECD version states that the Japanese quail (*Coturnix coturnix japonica*), preferably experienced breeders, is also acceptable. However, there are concerns regarding the appropriateness of this species due to its greater sensitivity and ability to attain breeding readiness under short daylight conditions.

Birds are acclimated to laboratory conditions. The substance to be tested is mixed into the diet. The birds are fed *ad libitum* for a recommended period of 10 weeks before they begin laying in response to a change in photoperiod. The egg-laying period should last 8 - 10 weeks. Eggs are removed from the adults the day they are laid, stored and then artificially incubated. Variables recorded during the study include:

- Adult body weight and food consumption;
- The number of eggs laid per hen;
- The mean eggshell thickness;
- The proportion of eggs set (placed in the incubator) that are fertile at 11 (bobwhite) or 14 days (mallard);
- The proportion of fertile eggs containing viable embryos one week later (i.e. days 18 and 21, respectively);
- The proportion of eggs that hatch and produce chicks;
- The survival of the chicks at 1 and 14 days of age;

15 Here: Materials that cause effects on bird and mammal reproduction through disruption of endocrine-mediated processes.

**Mammals**

Outlined below is background information on the range of studies that may be considered in assessing the reproductive risk to mammals. Not all the studies are reproductive studies. This is due to the fact that some of these studies are used to address specific steps in the reproductive cycle in the phase-specific approach, which is one of the options for higher tier risk assessment (see section 6.6). Mammalian tests relevant for the reproductive risk assessment include the following:

- OECD Test 416 (OECD, 2001c) – Two-generation reproduction toxicity study (adopted 22 January, 2001).

With this test, two or sometimes more generations can be assessed. It is specifically designed to address male and female reproductive performance including gonadal function, oestrous cycling, mating behaviour, conception, parturition, lactation and weaning. The results of such tests are the ones most often available for assessing long-term toxicity in mammals. The test uses rats or (less frequently) mice. Males are dosed during growth and, at least, during a complete spermatogenic cycle (56 days in mice, 70 days in rats). Females are dosed for two complete oestrous cycles. The animals are then mated. The pesticide is given throughout the study, typically in the diet. Sufficient pregnancies and offspring must be produced to enable assessment of maternal behaviour as well as of suckling, growth and development of the initial offspring generation (F1) right up to weaning. As the name implies, the two-generation test means that the F1 pups are kept on-dose and bred to produce a second generation, the F2 generation. The highest dose level should induce toxicity, but not mortality, in the parent animals. If necessitated by a decrease in food consumption, a pair-fed group could be added. Other than the functional endpoints such as fertility, litter size and survival, test endpoints include gross necropsy and pathology of the reproductive tract as well as histopathology where indicated (especially if reproductive organ histopathology was not performed on the shorter-term studies). The latest revisions to the test emphasized more detailed examinations of sperm parameters, sexual maturation and functional measurements of the reproductive output. The two-generation study allows an examination of the full growth, development and sexual maturation of the F1.

- OECD Test 414 (OECD, 2001d) – Prenatal developmental toxicity study (adopted 22 January, 2001).

This test doses pregnant female animals from the approximate day of implantation (ca. day 5 or 6 of gestation in rats and rabbits) to the day before delivery (ca. day 21 of gestation in rats). An earlier protocol used a shorter dosing period, restricted to the time of major organ and system differentiation. Doses are normally given by oral gavage. The study is designed to determine adverse effects on the dam such as reduced body weight, clinical signs and ability to maintain pregnancy. The study also identifies structural abnormalities in the foetus (e.g. thalidomide type effects). The foetuses are examined for viability, size, weight, sex ratio and specifically, for abnormalities of the skeleton and soft tissues/organs. The highest dose tested should produce some degree of maternal toxicity or be the limit dose of 1000 mg/kg bw/d. Foetal abnormalities are normally divided into severe cases (malformations), i.e. those ones that would compromise the ability to survive or function normally, and minor cases (variations/anomalies) that would have a minimal impact on the animal. For some endpoints it is also important weighing the maternal toxicity.

- OECD Test 407 (OECD, 1998a) – Repeated dose 28-day oral toxicity in rodents (adopted 27 July, 1995).
- OECD Test 408 (OECD, 1998b) – Subchronic oral toxicity – rodent 90 day study (adopted 21 September, 1998).

The above two tests are essentially the same except for the duration of the dosing period and among others the number of animals per group. They consist of repeated oral dosing of the test substance either by gavage or in the diet.

The use of gavage dosing can result in high systemic levels that induce adverse findings that cannot be produced when equivalent doses (in mg/kg bw/d) are given via the diet.

### 2.3.1. Determining toxicity endpoints from avian and mammalian reproductive toxicity studies

Future scientific developments may support changes to current practice in the ecotoxicological starting point for the risk assessment. It may be, for example, that benchmark doses or $EC_x$/$ED_x$ (concentration/dose where x % effect was observed/calculated) will come to be viewed as an alternative and often preferable reference point to the no-observed-effect concentration/level (NOEC/NOEL). Because a benchmark dose/concentration stands for a certain magnitude of effect, the replacement of the NOEC/NOEL/NOAEL by such benchmark value would have an impact on the level of protection which is achieved by the risk assessment scheme. This impact would have to be evaluated, and the scheme adjusted accordingly.

For the time being, this document refers to the no-observed-adverse-effect level (NOAEL) rather than either no-observed-effect concentration (NOEC) or no-observed-effect level (NOEL). This is due to the latter terms referring to levels or concentrations where there is no effect.[16]

In determining a NOAEL there may not be a consideration of the effect or its biological relevance. Therefore, it is proposed to use endpoints that are based on a consideration of the biological and/or ecological relevance. This needs to be considered case-by-case, as illustrated by the following examples:

(a) Endpoint is statistically significantly different from the control but does not fit a dose/treatment response. In this case, the endpoint can be ignored. In the example below, the value 72 is considered to be statistically significantly different (*) from the control but there is no dose response and this endpoint can therefore be ignored.

| Dose (mg a.s./kg bw/d) | 0 | 10 | 30 | 100 |
|---|---|---|---|---|
| Biological response | 100 | 72* | 98 | 95 |

(b) Endpoint is not statistically significantly different from the control but does fit a dose/treatment response. In this case, it may be appropriate to consider it as a NOAEL. In the example below, the effects in the top two doses are statistically significant (*) and dose/treatment related – while the response at 10 mg a.s./kg bw/d is not statistically significant from the control. However it would appear to be dose/treatment related and hence the NOAEL for this endpoint *could* be 5 mg a.s./kg bw/d. However, before deciding on this as the NOAEL, it is necessary to determine if the endpoint is biologically relevant (see below for details).

| Dose (mg a.s./kg bw/d) | 0 | 5 | 10 | 30 | 100 |
|---|---|---|---|---|---|
| Biological response | 100 | 98 | 75 | 55* | 30* |

(c) Endpoint is statistically significantly different from the control but may not be biologically relevant. In order to determine the biological relevance of an effect it should be considered whether the effect could lead to a functional deficit later on in the study, e.g. if a reduction in the weight of pups at birth leads to a decrease in level of survival. If not, then the effect may not be biologically relevant, however if there is a carry over of effects into the number of survivors, it can be considered biologically relevant.

It has been argued that a slight eggshell thinning should be ignored if there is no effect on hatchability. In a sample of 49 recent studies with mallard ducks, Mineau (2005) found that, 4 % of studies had a NOEC related to eggshell thickness but no evidence of increased breakage. Indeed, population effects in the wild tend to come about after thinning of 18 % or more (Blus, 2003).

16 It may be possible to use a 'bench mark dose' rather than a NOAEL. Further details regarding 'benchmark dose' see EFSA (2005c).

However, before deciding that endpoints are not biologically relevant, the following must be taken into consideration:

- Because of high variability in inter-pair performance, the avian reproduction test is not a statistically robust test. The likelihood of false positives typically is not high.
- Interspecies differences mean that a mild effect in one of the two test species may be much more pronounced in a wild exposed species. Knowledge that a mechanism of toxicity exists should not be dismissed without consideration of this possible variation in sensitivity. An example of this variation is DDE-induced eggshell thinning, which is known to vary across bird orders by orders of magnitude (see Cooke, 1973 and Blus, 2003 for reviews).
- An effect may be higher in the field than in the laboratory. Again, with eggshell thickness, a shortage of readily available calcium in the wild would exacerbate toxic effects on eggshell thickness.

(d) Endpoint is statistically significantly different (*) from the concurrent control but is within the range of comparable historical control levels. It should be noted that the comparable controls must be from studies carried out following the same protocol/guideline and conducted within an appropriate timeframe (e.g. ±2 years). In determining whether the effects can be discounted it is important to consider any effects in other test concentrations in the concurrent study. This is illustrated by the following:

**Test 1**

| Dose (mg a.s./ kg) | 0 | 5 | 10 | 30 |
|---|---|---|---|---|
| Biological response | 6 | 5 | 6 | 12* |

**Test 2**

| Dose (mg a.s./ kg) | 0 | 5 | 10 | 30 |
|---|---|---|---|---|
| Biological response | 4 | 11 | 10 | 12* |

Historical control ranges from 4 to 13.

Since the control, low dose and mid-dose are consistent, the findings at the top dose of Test 1 can be considered as relevant. In Test 2 the low and mid-dose findings do not appear to be dose or treatment related and hence the findings at the top dose is considered to be within normal variation and hence can be discounted.

#### 2.3.1.1. *Conversion of endpoints from ppm to mg a.s./kg bw/d*

In the following risk assessment, it is necessary to have all toxicity endpoints in mg a.s./kg bw/d, i.e. in a daily dose format to be consistent with the units used in the exposure assessment. Endpoints from mammalian toxicity studies are usually presented in this way. However most avian reproduction studies and some mammalian reproduction/development studies tend to be reported in terms of parts per million (ppm) or mg a.s./kg diet and therefore their endpoints need to be converted into daily dose. For avian reproduction studies, a generic factor can be used. The results of nine studies were examined and the lowest conversion factor was calculated to be 0.1 (Appendix 6 of EFSA, 2008). On the basis of this work, as well as information from the French Food Safety Authority (AFSSA) and the Agritox database (discussed in Appendix 6 of EFSA, 2008), this figure is used in the first instance (e.g. in the screening step). For this conversion to be used, no food avoidance should have occurred in the study. If refinement is required, then food consumption data from the actual study should be applied. For this, the overall mean value for food consumption and body weight at the NOAEL must be used and this value be applied for conversion of the NOAEL to a daily dose.

Regarding mammalian toxicity studies, it is likely that for newer substances the endpoints tend to be presented as daily doses. However, daily food consumption can vary during a study and hence conversions can be based either on the average food consumption, or on the consumption specific to that phase. It is more appropriate to use the consumption relevant to the specific reproductive phase and therefore it is essential to discuss this with a toxicology specialist.

Table 2 presents a standard set of factors that can be used to provide internal consistency when converting concentrations in diet into mg/kg bw/d dose levels for mammals. This should be used only in the absence of specific information in a study report or summary (it can, however, be used to give a rough check of values cited in a study). Only routine study types, species and ages have been considered.

**Table 2.** Factors for converting endpoints from mammalian toxicity studies from ppm to mg a.s./kg bw/d. Endpoints reported as ppm should be multiplied by the relevant factor from the table to convert them to mg/kg bw/d.

| Species | Age/study | Conversion factor from ppm to mg/kg bw/d |
|---|---|---|
| Rat | 28 d and 90 d | 0.1 |
| Rat | Two-generation study first mating* | 0.08 |
| Rat | Two-generation study overall (females)* | 0.12 |
| Mouse | 28 d and 90 d | 0.20 |
| Dog | adult/all | 0.025 |

* The first mating value for a two-generation study should be used for assessment when effects (general or on reproduction) are seen to relate to the pre-mating phase of the first mating of a study, or effects seen only in male F0 parents at any time. For all other aspects of a two-generation study the overall conversion figure should be used.

## 2.4. Incorporation of additional toxicity information

According to Annex II (Directive 91/414/EEC), an acute toxicity study for one species of bird or mammal is required. The endpoint from this study is then applied in a risk assessment and the resulting TER is compared to the decision making criteria in Annex VI of Directive 91/414/EEC. If the TER is less than 10, then no authorization is permitted "unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product". If the TER is greater than 10, then the acute risk to birds is considered to be "acceptable". This implies that the acute toxicity data on one species together with an uncertainty factor of 10 gives a level of protection which is 'acceptable'. Similarly, it can be assumed that as Annexes II stipulates reproductive data on one species of bird and mammal, then an appropriate level of protection is provided by applying an uncertainty factor or assessment factor of 5 to the appropriate toxicity endpoint for a single species.

### 2.4.1. How to deal with toxicity data from more than one species

If additional species are tested, it is necessary to consider which endpoint should be used in the risk assessment. In the past, it has been normal practice to take the lowest available endpoint. This means that, as more species are tested, the risk assessment is based on increasingly sensitive species. Consequently, the average level of protection exceeds the level implied by the provisions of Directive 91/414/EEC and Regulation (EC) 1107/2009, respectively.

In a previous opinion, the PPR Panel proposed an alternative approach of taking the geometric mean when more than one species is tested (Method 1 in EFSA, 2005b[17]). It was shown that this would ensure at least the same average level of protection as implied by the Directive, and avoid most of the increase in conservatism when additional species are tested. This was based on the assumption that toxicity data were normally distributed on a logarithmic scale.

17 Method 1 is appropriate for taxonomic groups where the minimum requirement is a single tested species, as is the case for birds and for mammals.

As part of the work in preparing this Guidance Document, new research was undertaken to examine the sensitivity of the proposed approach to the assumption of normality. The analysis used the same measure of level of protection as the earlier opinion (the Mean Fraction Exceeded) and applied also an additional measure: the probability of the Fraction Exceeded being greater than a given percentile, e.g. the hazardous dose to 5 % of the species ($HD_5$). The details are reported in Appendix 7 of EFSA (2008). The results show that using the geometric mean of multiple species is conservative (achieves at least the same average level of protection as a single species). This is true for a wide range of distributions that are symmetric and unimodal (single peak) on a logarithmic scale, and also for asymmetric unimodal distributions where the long tail is to the left. It is also true for asymmetric distributions with long tails to the right[18] and for some examples of bimodal distributions, provided that the standard uncertainty factor includes sufficient allowance for between-species variation in toxicity, which seems likely.

The Joint Working Group noted that in some cases, the $LD_{50}$ for most sensitive species might be lower than the geometric mean divided by the standard assessment factor of 10. As the standard factor of 10 is considered sufficient to provide appropriate allowance for between-species variation when only one species is tested, this implies that a small frequency of such cases is already taken into account, in which case the geometric mean approach is still appropriate. However, it was recognised that there could be concerns for situations where the variation between species was particularly wide. The Joint Working Group therefore decided on the following approaches:

- The geometric mean should be used for the acute assessment, except when the endpoint for the most sensitive species is more than a factor of 10 below the geometric mean of all the tested species. Where this is the case, the most sensitive species will be used for the risk assessment but generally without any assessment factor[19] (unless there are specific reasons to believe that this is not appropriate).

The new work also investigated how bias and measurement errors in toxicity data affect the use of the geometric mean when multiple species are tested. The results (see section 2.3.1 of EFSA, 2008) imply that using the geometric mean of multiple species will be conservative, however this depends on the measurement errors in NOECs following roughly a normal distribution, which requires further investigation. Therefore the Joint Working Group (EC, 2009) decided that, until further work is completed:

- For reproductive studies, the endpoint from the most sensitive tested species should be used.

The above highlights the possible application of endpoints if data on additional species are available. This refinement step should be used only if, for historical reasons, data on additional species are already available, i.e. data should **not routinely** be generated to specifically refine the endpoint. This is due to concerns with regard to animal welfare and to minimise the use of animals.

18 Distributions of acute toxicity data often have long tails to the right on the natural scale, but this is reduced or removed on the logarithmic scale, which is used for the geometric mean.

19 No assessment factor is generally needed in such cases, because the most sensitive species is already more than a factor of 10 below the geometric mean, so the level of protection provided by using this endpoint should already be greater than that provided by the standard factor of 10. If there was specific reason to believe that between-species variation is greater for the substance under assessment than is allowed for by the standard factor of 10, then a suitable factor could be applied to the lowest endpoint. However, this factor should be less than 10, because taking the lowest endpoint already incorporates more protection than the standard factor. Note that the finding of a single endpoint more than a factor of 10 below the geomean is not in itself strong evidence that between-species variation is unusually large, because such cases are expected to occur occasionally.

### 2.4.2. How to deal with more than one acute study on the same species

In cases where more than one acute study on the same species is available, it is proposed that the geometric mean of the endpoints for the same species should be taken (including only those studies that are considered suitable for use in risk assessment). This endpoint is then used in the overall geometric mean (see Table 3). The studies should be equivalent in terms of guideline and in particular the vehicle/solvent since, e.g. there may be a marked reduction in apparent toxicity of pyrethroids when using an aqueous rather than an oil based vehicle.

**Table 3.** LD50 [mg/kg bw] for various bird species and their use in the calculation of the geometric mean.

| Species | $LD_{50}$ mg/kg bw | $LD_{50}$ to be used in calculation of geometric mean |
|---|---|---|
| Mallard duck (study 1) | 25 | 30 |
| Mallard duck (study 2) | 36 | |
| Bobwhite quail | 21 | 21 |
| Japanese quail | 36 | 36 |
| Red winged blackbird | 5 | 5 |
| **Overall geometric mean to be used in RA** | | **18.3** |

### 2.4.3. How to deal with more than one reproduction study on the same species

Sometimes there may be more than one reproduction or developmental study on the same species available. In these cases it may be possible to merge the two datasets as if it were one study (JMPR, 2004)[20]. However, in order to allow for the merger of the two studies, they should be conducted according to a similar protocol or guideline. It is also important to ensure that the key endpoints have been assessed in all studies and that the studies are similar, e.g. the two studies have similar dose-responses, the same species has been used, the same protocol followed, similar number of animals used, and same endpoints and same test conditions applied. It should also be checked whether the test substances are chemically equivalent (EC, 2005). It is not considered appropriate to use the output from the pilot study for this exercise nor to take the geometric means of the NOAEL.

This procedure is in line with how mammalian toxicologists deal with such data. An example of this is illustrated in Tables 4a, 4b and 4c.

**Table 4a.** Illustration of how to combine two studies on the same species (example a).

| **Study 1** Test concentration [mg/kg bw/d] | **Effect** | **Study 2** Test concentration [mg/kg bw/d] | **Effect** |
|---|---|---|---|
| 100 | Yes | 50 | Yes |
| 30 | Yes | 25 | No |
| 3 | No | 10 | No |
| 0 | No | 0 | No |
| **NOAEL** | **3** | | **25** |

From the above example the NOAEL that could be used in the risk assessment would be 25 mg/kg bw/d. Presented below is another example of merging data sets. In this example, it is not possible to ignore the lower finding.

20 http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/DOWNLOAD/2004_rep/report2004jmpr.pdf

**Table 4b.** Illustration of how to combine two studies on the same species (example b).

| **Study 1** Test concentration [mg/kg bw/d] | **Effect** | **Study 2** Test concentration [mg/kg bw/d] | **Effect** |
|---|---|---|---|
| 100 | Yes | 50 | Yes |
| 30 | Yes | 35 | No |
| 3 | No | 10 | No |
| 0 | No | 0 | No |
| **NOAEL** | **3** | **NOAEL** | **35** |

**Table 4c.** Results following the combination of all these results as if it were one study.

| **Combined results from studies 1 and 2** | |
|---|---|
| **Test concentration mg/kg bw/d** | **Effect** |
| 100 | Yes |
| 50 | Yes |
| 35 | No |
| 30 | Yes |
| 10 | No |
| 3 | No |
| 0 | No |
| **NOAEL** | **10** |

As the NOAEL of 35 mg/kg bw /d from study 2 is higher than the LOAEL of 30 mg/kg bw/d from study 1, it is considered that the overall NOAEL from the above studies would be 10 mg/kg bw/d.

## 2.5. Combined effects of simultaneous exposure to several active substances

This assessment is not carried out for decisions on the inclusion of active substances in Annex I of Directive 91/414/EEC, but is important for national authorisation procedures for products that could contain more than one active substance. From the scientific point of view, combined action of several toxicants must be specifically considered in the risk assessment when it is obvious that such exposure situations will occur for animals. If an assessment is made for such a product in the context of national authorisation, the simultaneous exposure of animals to residues of two or more potential toxicants should also be considered in the risk assessment. Further information is given in Appendix B.

# 3. Level of protection provided by the assessment procedures

Directive 91/414/EEC does not contain a precise definition nor detailed specifications of the level of protection that is required. Therefore, in developing this Guidance Document, careful consideration was given to how this should be addressed.

In summary, the procedures for **first-tier assessment** (described in sections 4 and 5) are designed to achieve a *"surrogate" protection goal of making any mortality or reproductive effects unlikely*. At **higher tiers**, assessments may be directed either at the surrogate protection goal or at the *actual protection goal of clearly establishing that there will be no visible mortality and no long-term repercussions for abundance and diversity*. If the actual protection goals are defined more precisely by risk managers or legislators in future, then the protection goals and assessment procedures should be reviewed and revised accordingly.

The level of protection provided at Tier 1 is determined by the standard assessment procedures set out in this document and therefore does not need to be reconsidered case by case. However, since there is no standardised approach for higher tier assessments, the level of protection needs to be evaluated case by case for every higher tier assessment. Guidance for this is given in section 6.8.

A full account of these issues is provided in Appendix C, together with evaluations of the levels of protection provided by the first-tier assessment procedures set out in this Guidance Document. These evaluations are provided both for reference and as a starting point for evaluating the level of protection in higher tier assessments.

In addition to the level of protection, the impact of the assessment procedures on the proportions of pesticides requiring higher-tier assessment may be a relevant consideration for risk managers. An analysis of this is presented in Appendix D.

# 4. Risk assessment modules for spray applications

There are four different risk assessment modules for dietary exposure due to the use of sprayed products:

Module 1 Acute risk assessment for birds

Module 2 Acute risk assessment for mammals

Module 3 Reproductive risk assessment for birds

Module 4 Reproductive risk assessment for mammals

All four modules must be completed.

In bird and mammal risk assessment three categories of species have been defined: the indicator species, the generic focal species and the focal species. The **'indicator species'** is used in the first screening step and for eliminating all those substances that clearly pose a low risk to birds and mammals. This 'indicator species' is not a real species but, by virtue of its size and feeding habits is considered to have higher exposure than (i.e. to be protective of) other species that occur in a particular crop (see Table 5 below) at a particular time.

In the first-tier risk assessment, a **'generic focal species'** will be used for further risk assessment. Again it is not a real species, however it is considered to be representative of all those species potentially at risk. Instead of the one single food item approach of the screening step in this assessment a mixed diet is applied when appropriate for the generic focal species. In addition, interception of the spray by the crop is taken into account by calculating the residue level on the several food types for the birds and the mammals (see Appendix E).

In refined risk assessment it is appropriate to use **'focal species',** i.e. a real species that actually occurs in the crop when the pesticide is being used (see section 6.1.3 for identification of focal species.).

The approach used to select both, indicator and generic focal species, is described in Appendix 10 of EFSA (2008).

For the first-tier risk assessment it is not necessary that the generic focal species only eats part of the crop. Even when the crop is unpalatable it is assumed that weeds and weed seeds will be available as food for birds and mammals. Often these weeds and weeds seeds will be covered by the crop and therefore crop interception has been taken into account. The degree of interception is defined by the growth stages (BBCH[21] stages) for each crop category (BBA, 2001).

Rice is not included in this document because it is envisaged that it will be addressed in a separate guidance document.

It should be noted that the screening steps are based on worst-case assumptions and should be used to identify those substances and associated uses that do not pose a risk to birds and mammals and for which no further acute risk assessment is therefore required. The screening steps are an option and the assessment may as well start at the first-tier assessment.

In the assessment for the potential risk of bird and mammals in the screening step and the first-tier, crop groups have been defined. Those groups consist of crop species that have similar growing patterns and therefore it is assumed that the exposure of the indicator species and generic focal species will be the same. This list (see Table 5) is not exhaustive, but covers most of the larger crops.

21 Biologische Bundesanstalt, Bundessortenamt und CHemische Industrie

To facilitate the assessment process, shortcut values are provided to assist with the exposure calculations. These are data describing the feeding habits and other ecological needs for the indicator and generic focal species that can be used directly in the exposure calculations. Shortcut values based on mean residue unit doses (RUDs) are used for reproductive assessments. Shortcut values based on 90$^{th}$ percentile RUDs are used for acute assessments to take account of the likelihood that individual animals may feed in one field for all or most of a single day. Over the longer periods that are relevant for some reproductive endpoints, animals may feed on several fields and thus tend to average out variation in residues, although it is also possible that an individual may continue to feed in a single field with high (or low) residues over multiple days. Considering this together with other factors affecting the level of protection, it was deemed reasonable to use the 90$^{th}$ percentile RUD for the acute assessment and the mean RUD for the reproductive assessment (see Appendix C for detailed evaluation of the levels of protection).

**Table 5.** Crop groups and crop species

| Crop group | Crop species |
|---|---|
| Bare soil | All arable crops (BBCH < 10) |
| Bulbs and onion like crops | Bulbs (like tulips etc.), onions, garlic, shallots, etc. |
| Bush and cane fruit | Blackberry, dewberry, loganberry, raspberry, gooseberry, red and blackcurrant, etc. |
| Cereals | Wheat, barley, oats, rye, rice, millet, sorghum, triticale, etc. |
| Cotton | Cotton |
| Fruiting vegetables | Tomatoes, peppers, chilli peppers, aubergines, cucumber, gherkins, courgettes, melons, squashes, watermelons, etc. |
| Grassland | Grass |
| Hops | Hops |
| Leafy vegetables | Broccoli, cauliflower, Brussels sprouts, cabbage, Chinese cabbage, kale, cress, lambs lettuce, lettuce, escarole, spinach, chicory, chervil, chives, parsley, artichokes, cardoons, rhubarb, asparagus, etc. |
| Legume forage | Alfalfa, clover, etc. |
| Maize | Maize, sweet corn, etc. |
| Oilseed rape | Oilseed rape, linseed, field (faba) beans, quinoa, poppy, mustard, sesame, etc. |
| Orchards | Grapefruit, lemon, lime, mandarins, oranges, pomelos, olives, almonds, chestnuts, hazelnuts, macademia, pecans, pine, pistachios, walnuts, apple, pear, quinces, apricots, cherries, peaches, nectarines, plums, avocado, date, kiwi, mango, pomegranate, fig, kumquat, litchi and passion fruit, etc. |
| Ornamentals/nursery | Flowers and plants for transplanting |
| Potato | Potato, sweet potatoes, etc. |
| Pulses | Peas, lentils, French beans, soybeans, buckwheat, etc. |
| Root and stem vegetables | Beetroot, carrot, celeriac, horseradish, Jerusalem artichoke, parsnips, parsley root, radishes, salsify, Swedes, turnips, celery, kohlrabi, fennel, etc. |
| Strawberries | Strawberry, bilberry, cranberry, etc. |
| Sugarbeet | Sugarbeet |
| Sunflower | Sunflower |
| Vineyards | Grape |

## 4.1. Module 1: Acute dietary risk assessment for birds

The 'daily dietary dose' (DDD) is defined by the food intake rate of the species of concern (i.e. the indicator species, the generic focal species or the focal species), the body weight of the species of concern, the concentration of a substance in/on fresh diet (see Appendix F) and the fraction of diet obtained in the treated area.

The estimated food intake rates are based on the daily energy expenditure of the species of concern, the energy in the food, the 'energy' assimilation efficiency of the species of concern, and the moisture content of the food (see Appendix G).

The above information is combined into a single value for a specific species-crop-combination and termed a 'shortcut value' (SV).

### Screening assessment

#### Step 1

Identify which of the indicator species listed in Table 6 is relevant to the crop

**Table 6.** Acute shortcut values (based on 90$^{th}$ percentile residues) for avian indicator species.

| Crop | Indicator species | Shortcut value for acute assessment |
|---|---|---|
| Bare soils and hop | Small granivorous bird | 24.7 |
| Grassland | Large herbivorous bird | 30.5 |
| Bush and cane fruit | Small frugivorous bird | 46.3 |
| Orchards and ornamentals/nursery | Small insectivorous bird | 46.8 |
| Vineyard | Small omnivorous bird | 95.3 |
| Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower | Small omnivorous bird | 158.8 |
| Cotton | Small omnivorous bird | 160.3 |

#### Step 2

Calculate the daily dietary dose (DDD) for a single application by multiplying the shortcut value based on the 90$^{th}$ percentile residue (presented in Table 6) with the application rate in kg/ha.

$$DDD_{\text{single application}} = application\ \ rate\ \ [kg/ha] \times\ shortcut\ \ value$$

#### Step 3

Multiply the daily dietary dose for a single application with an appropriate multiple application factor for 90$^{th}$ percentile residue data ($MAF_{90}$) when the substance is applied two or more times (see Table 7). Or calculate a specific $MAF_{90}$ according to Appendix H for non-standard application intervals.

$$DDD_{\text{multiple applications}} = DDD_{\text{single application}} \times MAF_{90}$$

$MAF_{90}$ values for other application intervals can be calculated either using the formula in Appendix H with the input parameters for 'grass + cereals (adjusted)' or using the values for the next lower application interval. The limit value in the rightmost column should be used for higher number of applications with one of the tabulated intervals.

**Table 7.** Multiple application factors for 90th percentile residue data ($MAF_{90}$) for selected application intervals and *n* = 1-8 applications (considering a default $DT_{50}$ of 10 d on foliage).

| Application interval (d) | $MAF_{90}$ for 90th percentile residue data for *n* applications | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | ∞ |
| 7 | 1.0 | 1.4 | 1.6 | 1.8 | 1.9 | 1.9 | 1.9 | 1.9 | 2.0 |
| 10 | 1.0 | 1.3 | 1.5 | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 |
| 14 | 1.0 | 1.2 | 1.3 | 1.3 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 |

**Step 4**

Take the appropriate $LD_{50}$ (mg/kg bw/d) for birds (see section 2).

**Step 5**

Calculate the toxicity-exposure-ratio

$$TER = \frac{LD_{50}}{DDD}$$

**Step 6**

Compare the TER to the respective trigger value.

**TER ≥ 10** — **No refinement required**
**TER < 10** — **Go to first-tier risk assessment (Step 7)**

**Tier 1 risk assessment**

All pesticides should be subjected to Tier 1 assessment, unless they are shown by a screening assessment (Steps 1-6) to pose a low risk. Tier 1 uses the same general approach as the screening assessment, but requires more specific exposure scenarios.

**Step 7**

Identify all of the generic focal species listed in Table I.1 (Annex I) that are relevant for the crop.

**Step 8**

Calculate the daily dietary dose (DDD) for a single application for each generic focal species by multiplying the shortcut value based on the 90th percentile residue (presented in Table I.1, Annex I) with the application rate in kg/ha.

$$DDD_{\text{single application}} = application\ \ rate\ \ [kg/ha] \times\ shortcut\ \ value$$

**Step 9**

Multiply the DDD for a single application with an appropriate multiple application factor for 90th percentile residue data ($MAF_{90}$) when the substance is applied two or more times (see Table 7). Or calculate a specific $MAF_{90}$ according to Appendix H for non-standard application intervals.

$$DDD_{\text{multiple applications}} = DDD_{\text{single application}} \times MAF_{90}$$

**Step 10**

Take the appropriate $LD_{50}$ for birds (same as Step 4).

**Step 11**

Calculate the toxicity-exposure-ratio:

$$TER = \frac{LD_{50}}{DDD}$$

**Step 12**

Compare the TER to the respective trigger value.

**All TERs ≥ 10** — **No refinement required**
**One or more of the TERs < 10** — **Higher tier risk assessment required**

For higher tier options see section 6.

## 4.2. Module 2: Acute dietary risk assessment for mammals

The 'daily dietary dose' (DDD) is defined by the food intake rate of the species of concern (i.e. the indicator species, the generic focal species or the focal species), the body weight of the species of concern, the concentration of a substance in/on fresh diet (see Appendix F) and the fraction of diet obtained in the treated area.

The estimated food intake rates are based on the daily energy expenditure of the species of concern, the energy in the food, the 'energy' assimilation efficiency of the species of concern, and the moisture content of the food (see Appendix G).

The above information is combined into a single value for a specific species-crop-combination and termed a 'shortcut value' (SV).

**Screening assessment**

**Step 1**

Identify which of the indicator species listed in Table 8 is relevant to the crop.

**Table 8.** Acute shortcut values (based on 90$^{th}$ percentile residues) for mammalian indicator species.

| Crop | Indicator species | Shortcut value for acute assessment |
|---|---|---|
| Bare soil | Small granivorous mammal | 14.4 |
| Bush and cane fruit | Small herbivorous mammal | 81.9 |
| Bulbs and onion like crops, cereals, oilseed rape, potatoes, root and stem vegetables, strawberries, sugar beet, and sunflower | Small herbivorous mammal | 118.4 |
| Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard | Small herbivorous mammal | 136.4 |

**Step 2**

Calculate the daily dietary dose (DDD) for a single application by multiplying the shortcut value based on the 90$^{th}$ percentile residue (presented in Table 8) with the application rate in kg/ha.

$$DDD_{\text{single application}} = application\ \ rate\ \ [kg/ha] \times\ shortcut\ \ value$$

**Step 3**

Multiply the DDD for a single application with an appropriate multiple application factor for 90$^{th}$ percentile residue data ($MAF_{90}$) when the substance is applied two or more times (see Table 9). Or calculate a specific $MAF_{90}$ according to Appendix H for non-standard application intervals.

$$DDD_{\text{multiple-applications}} = DDD_{\text{single-application}} \times MAF_{90}$$

**Table 9.** Multiple application factors for 90$^{th}$ percentile residue data ($MAF_{90}$) for selected application intervals and $n$ = 1 – 8 applications (considering a default $DT_{50}$ of 10 d on foliage).

| Application interval (d) | $MAF_{90}$ for 90$^{th}$ percentile residue data for *n* applications | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | ∞ |
| 7 | 1.0 | 1.4 | 1.6 | 1.8 | 1.9 | 1.9 | 1.9 | 1.9 | 2.0 |
| 10 | 1.0 | 1.3 | 1.5 | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 |
| 14 | 1.0 | 1.2 | 1.3 | 1.3 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 |

$MAF_{90}$ values for other application intervals can be either calculated using the formula in Appendix H with the input parameters for 'grass + cereals (adjusted)' or the values for the next lower application interval should be used. For higher number of applications with one of the tabulated intervals, the limit value in the rightmost column should be used.

**Step 4**

Take the appropriate $LD_{50}$ in mg/kg bw/d for mammals (see section 2).

**Step 5**

Calculate the toxicity-exposure–ratio.

$$TER = \frac{LD_{50}}{DDD}$$

**Step 6**

Compare the TER to the respective trigger value.

**TER ≥ 10** — **No refinement required**
**TER < 10** — **Go to first-tier risk assessment (Step 7)**

### Tier 1 risk assessment

All pesticides should be subjected to Tier 1 assessment, unless they are shown by a screening assessment (Steps 1-6) to pose a low risk. Tier 1 uses the same general approach as the screening assessment, but requires more specific exposure scenarios.

#### Step 7

Identify which of the generic focal species listed in Table I.2 (Annex I) are relevant for the crop.

#### Step 8

Calculate the daily dietary dose (DDD) for a single application for each generic focal species by multiplying the shortcut value based on the 90$^{th}$ percentile residue (presented in Table I.2, Annex I) with the application rate in kg/ha.

$$DDD_{\text{single application}} = application\ \ rate[kg/ha] \times shortcut\ \ value$$

#### Step 9

Multiply the DDD for a single application with an appropriate multiple application factor for 90$^{th}$ percentile residue data ($MAF_{90}$) when the substance is applied twice or more times (see Table 9). Alternatively, calculate a specific $MAF_{90}$ according to Appendix H for non-standard application intervals.

$$DDD_{\text{multiple applications}} = DDD_{\text{single application}} \times MAF_{90}$$

#### Step 10

Take the appropriate $LD_{50}$ for mammals (same as Step 4)

#### Step 11

Calculate the toxicity-exposure-ratio:

$$TER = \frac{LD_{50}}{DDD}$$

#### Step 12

Compare the TER to the respective trigger value.

**All TERs ≥ 10** — **No refinement required**
**One or more of the TERs < 10** — **Higher tier risk assessment required**

For higher tier options see section 6.

## 4.3. Module 3: Reproductive risk assessment for birds

An avian reproductive toxicity study and associated risk assessment should not be necessary if it can be demonstrated that exposure will not occur during the reproductive season for birds. This is based on the assumption that if a bird is not in a reproductive phase then exposure to pesticides is unlikely to cause an adverse effect on reproduction.

However, delayed effects on reproduction from exposure during the non-reproductive period may be unlikely but they are possible. Therefore, if the proposed use of the product under assessment is to be made outside the breeding season of birds, the mammalian toxicity data package should be examined to determine if the active substance has either antiandrogenic or antiestrogenic activity. If such activity is indicated then there is a need for a reproductive risk assessment even if exposure during the breeding season is unlikely (see section 5.3 on endocrine disruption).

### Screening assessment

The screening assessment may be useful to identify quickly those substances that pose very low reproductive risk, for which more detailed assessment is unnecessary. If preferred, assessors may proceed directly to Tier 1 (Step 5).

### Step 1

Determine if breeding birds could be exposed to either the active substance or the associated product. If not, no further assessment is required.

### Step 2

If exposure is possible, determine the lowest NOAEL from the available avian reproduction study/studies. See section 2.3.1 for details on how to determine a NOAEL.

It should be noted that the endpoints from the current guidelines are presented as ppm diet or mg a.s./kg diet. Therefore, it is necessary to convert the endpoints to daily doses, i.e. mg a.s./kg bw/d. In the first instance a generic factor of 0.1 can be used and applied to the ppm or mg a.s./kg food endpoint (see section 2.3.1.1).

In addition, obtain the acute oral $LD_{50}$ value used in the acute avian assessment (either the $LD_{50}$ for a single species, or the geometric mean for multiple species) and divide it by 10 to obtain $LD_{50}/10$. The $LD_{50}/10$ is used as an endpoint in the reproductive assessment to take account of the possibility of reproductive impairment due to sublethal effects on pair formation and breeding site selection, incubation, parental care of nestlings, and survival of fledgling birds (see Appendix J)[22].

For the screening assessment, take the lowest of the $LD_{50}/10$ and the lowest NOAEL from the avian reproduction study/studies.

22 Note that division of the $LD_{50}$ by 10 is for extrapolation from lethal to sublethal endpoints (see Appendix 11 of EFSA, 2008) and is not related to the normal assessment factor of 10 used in acute assessments. When $LD_{50}/10$ is used in the reproductive assessment, the resulting TER should be compared to the normal reproductive assessment factor of 5 (see Steps 4 and 8).

**Step 3**

Identify the appropriate indicator species and shortcut value for the crop under assessment from Table 10. If multiple applications are to be made, then Table 11 should be consulted and the appropriate 'multiple application factor' ($MAF_m$) should be used. Calculate the daily dietary dose (DDD):

$$DDD = application\ rate \times shortcut\ value \times TWA \times MAF_m$$

The value to be used for the time-weighted average factor (TWA) depends on whether the toxicity endpoint from Step 2 could be caused by a short-term exposure (STE) or only by a long-term exposure (LTE)[23].

- If the toxic effect is considered to be caused by LTE, use TWA = 0.53 (estimates time-weighted exposure over 21 days, assuming a default $DT_{50}$ of 10 days).
- If the toxic effect is considered to be caused by STE, use TWA = 1 (one day exposure).

**Table 10.** Indicator species and shortcut values (based on mean residues) for the avian reproductive assessment.

| Crop | Indicator species | Shortcut value for reproductive assessment |
|---|---|---|
| Bare soils and hop | Small granivorous bird | 11.4 |
| Grassland | Large herbivorous bird | 16.2 |
| Orchards and ornamentals/nursery | Small insectivorous bird | 18.2 |
| Bush and cane fruit | Small frugivorous bird | 23.0 |
| Vineyard | Small omnivorous bird | 38.9 |
| Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower | Small omnivorous bird | 64.8 |
| Cotton | Small omnivorous bird | 65.4 |

**Table 11.** Multiple application factors assuming mean residues ($MAF_m$), for use in reproductive assessments.

$MAF_m$ are shown for selected application intervals and $n$ = 1-8 applications, assuming a default $DT_{50}$ of 10 d on foliage. $MAF_m$ values for other application intervals can be either calculated either using the formula in Appendix H or using the values for the next lower application interval. The limit value in the rightmost column should be used for higher numbers of applications with one of the tabulated intervals. These MAF factors should be used for all food types (i.e. arthropods and vegetation). Further information on this issue is provided in Appendix H.

| Application interval (d) | $MAF_m$ for n applications | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | n = 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | Limit |
| 7 | 1.0 | 1.6 | 2.0 | 2.2 | 2.4 | 2.5 | 2.5 | 2.5 | 2.6 |
| 10 | 1.0 | 1.5 | 1.8 | 1.9 | 1.9 | 2.0 | 2.0 | 2.0 | 2.0 |
| 14 | 1.0 | 1.4 | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 |

23 It is intended to develop further guidance on criteria for determining which effects could be caused by short-term exposures. The Joint Working Group decided that, until such guidance is available, it should be assumed as a default that the effects are caused by LTE, unless there is specific evidence for the pesticide under assessment that the effect could be caused by STE.

**Step 4**

Calculate the toxicity-exposure-ratio and compare the TER to the respective trigger value.

$$TER = \frac{\text{lowest endpoint (Step 2)}}{\text{relevant } DDD \text{ (Step 3)}}$$

**TER ≥ 5** — **No further assessment required**
**TER< 5** — **Go to Tier 1 (Step 5)**

**Tier 1 risk assessment**

All pesticides should be subjected to Tier 1 assessment, unless they are shown by a screening assessment (Steps 1-4) to pose a low risk. Tier 1 uses the same general approach as the screening assessment, but requires more detailed consideration of the relevance of toxicity endpoints and more specific exposure scenarios.

**Step 5**

Obtain the acute oral $LD_{50}$ value used in the acute avian assessment (either the $LD_{50}$ for a single species, or the geometric mean for multiple species) and divide it by 10 to obtain $LD_{50}/10$ (see Step 2 and Appendix J for more explanation of the relevance of $LD_{50}/10$ for reproductive assessments).

For each available reproduction study, identify the NOAEL for reproductive effects, ignoring purely parental effects (e.g. changes in parental body weight and food consumption[24]).

It is normal for toxicity endpoints to be determined statistically. In the vast majority of cases it is acceptable to use these endpoints. However, occasionally care needs to be exercised to ensure that the endpoint is appropriate. Further information on this issue is provided in section 2.1.1.

Endpoints that are presented as ppm diet or mg a.s./kg diet must be converted to daily doses, i.e. mg a.s./kg bw/d. At Tier 1, this should be done using the actual body weight and food consumption data from the study under consideration. In order to do this, take the mean value for food consumption over the whole study and average body weight over the duration of the study at the NOAEL and use these figures to convert the NOAEL to a daily dose.

After converting the lowest reproductive endpoint from each study or merged dataset to a daily dose, identify the lowest of the converted endpoints[25]. If the $LD_{50}/10$ (from Step 5) is lower than the lowest reproductive endpoint, then use the $LD_{50}/10$ as the endpoint for the Tier 1 reproductive assessment. Otherwise, use the lowest reproductive endpoint. Proceed to Step 6.

**Step 6**

Identify the appropriate crop and **generic focal bird species** in Annex I. Where more than one generic focal species is relevant for the crop, the one that is relevant in terms of time of application or growth stage should be selected. Where there is more than one generic focal species in terms of timing etc. Tier 1 risk assessments (and refined assessments, if necessary) should be carried out for all the relevant generic focal species.

24 These endpoints are excluded because, for birds, $LD_{50}/10$ is considered a more appropriate indicator of the NOAEL for parental effects with potential to disrupt reproduction.

25 The geometric mean of LD50s across species is used in the acute risk assessment. It is intended to investigate further whether the geometric mean is also suitable for use in reproductive risk assessment. Until further guidance is developed, the most sensitive species should be used in the reproductive assessment (see section 2.3.1).

**Step 7**

For each relevant generic focal species, calculate the daily dietary dose (DDD):

$$DDD = application\ rate \times shortcut\ value \times TWA \times MAF_m$$

The relevant shortcut value (based on mean residues) for each generic focal species should be obtained from the tables in Annex I.

If multiple applications are to be made, then Table 11 (see Step 3 above) should be consulted and the appropriate 'multiple application factor' or $MAF_m$ should be used.

The value to be used for the time-weighted average factor (TWA) depends on whether the toxicity endpoint from Step 2 could be caused by a short-term exposure (STE) or only by a long-term exposure (LTE)[26].

- If the toxic effect is considered to be caused by LTE, use TWA = 0.53 (estimates time-weighted exposure over 21 days, assuming a default $DT_{50}$ of 10 days).
- If the toxic effect is considered to be caused by STE, use TWA = 1 (one day exposure).

**Step 8**

For each relevant generic focal species, calculate the toxicity-exposure-ratio and compare the TER to the respective trigger value.

$$TER = \frac{\text{lowest endpoint (Step 2)}}{\text{relevant } DDD \text{ (Step 3)}}$$

| | |
|---|---|
| **TER ≥ 5** | **No further assessment required for this generic focal species** |
| **TER< 5** | **Refined assessment required for this generic focal species – go to Step 9** |

**Step 9**

**Refinement options**

Refined assessments should be carried out for all generic focal species that have a TER < 5 at Step 8.

Outlined below is a summary of selected options for refinement steps that can be used individually or combined together. Before considering any of the following refinement steps it is important to take account of the general principles for refinement steps in higher-tier risk assessment (section 6), and in particular to ensure that the likely level of protection resulting from a refined risk assessment reflects the expectations of the risk manager.

26 It is intended to develop further guidance on criteria for determining which effects could be caused by short-term exposures. Until such guidance is available, it should be assumed as a default that the effects are caused by LTE, unless there is specific evidence for the pesticide under assessment that the effect could be caused by STE.

Re-assessment of the exposure period relevant to the toxicity endpoints. – The screening and Tier 1 assessments use time-weighted averages over 21 days, except where there is specific evidence that the effects could be caused by short-term exposures. The default periods of 21 days for long-term effects and 1 day for short-term effects are arbitrary choices without specific scientific justification. In refined assessments the evidence for the exposure period relevant to each endpoint should be reviewed in more detail. See Appendix J for more information.

Refine the residue element of the initial DDD calculation. – For this, data are required on either the initial residue values and/or the residue decline. Details regarding refining the risk using specific residue data are provided in Appendix J and the respective refinement section (6.1.4) of this Guidance Document.

Refine ecological parameters. – It is possible to refine the DDD by using more relevant data on the ecological components of the risk assessment, i.e. focal species (FS), proportion of an animal's daily diet obtained in habitat treated with pesticide (PT) and composition of diet obtained from treated area (PD) (see sections 6.1.3, 6.1.5 and 6.1.6).

Phase-specific risk assessment. – The screening and Tier 1 assessments do not distinguish between different phases of reproduction. In reality, different phases of reproduction may differ both in their exposure and their toxicological sensitivity to the pesticide. Furthermore, only a proportion of birds will be exposed and, for those that are exposed, the peak exposure may not occur during the most sensitive reproductive phase. These factors may be addressed by phase-specific risk assessment. To gain the full benefits of this approach requires detailed data that may not be available in some cases (e.g. time of application of the pesticide, time of breeding phases for focal species etc). However, the phase specific approach may be an effective approach if these data are available. For further information see Appendix J.

Field trials. – Theoretically, it is possible to carry out a field study to assess the potential effects on reproduction. However, from a practical point of view, this refinement step is not really viable for avian reproduction (see section 6.4).

Population modelling. – If, despite the above refinements, there is still concern regarding the risk to birds, then one option would be to assess the risk at the population level. Unfortunately there are no population models that can be readily used or adapted for use in pesticide risk assessment. This should not, however, preclude their use. Possible examples of population models are presented in Topping et al. (2005), Sibly et al. (2005), Roelofs et al. (2005) and Wang and Grimm (2007). It should be noted that the models included in these references are not endorsed but are provided as an indication of the types of studies that are available. Due to the complexity of this issue, it is envisaged that each assessment would be on a case-by-case basis. For further discussion of assessing population level effects, see section 6.7.

Modified toxicity studies. – If the substance under consideration 'passes' the assessment assuming that the effects are the result of long-term exposure, but 'fails' if it is assumed that effects are the result of short-term exposure, then it may be possible to carry out further toxicity studies to determine if effects are due to short or long-term exposure. It should be noted that due to animal welfare reasons, this refinement step should only be used if the above exposure orientated refinements have not provided sufficient information to identify an 'acceptable' TER.

## 4.4. Module 4: Reproductive risk assessment for mammals

A mammalian reproductive risk assessment is not necessary if it can be demonstrated that exposure will not occur during the breeding season. If exposure is possible then a risk assessment is required.

### Screening assessment

The screening assessment may be useful to identify quickly those substances that pose very low reproductive risk, for which more detailed assessment is unnecessary. If preferred, assessors may proceed directly to Tier 1 (Step 5).

### Step 1

Determine if breeding mammals could be exposed to either the active substance or the associated product. If not, no further assessment is required.

### Step 2

If exposure is possible, then the same endpoint as in the human risk assessment should be used (without the assessment factor applied as part of the human risk assessment[27]). If the endpoint is in ppm or mg a.s./kg bw then Table 2 should be used to convert the endpoint to a daily dose, or mg a.s./kg bw/d.

### Step 3

Identify the appropriate indicator species and shortcut value for the crop under assessment from Table 12. If multiple applications are to be made, then Table 13 should be consulted and the appropriate 'multiple application factor' or $MAF_m$ should be used. Calculate the daily dietary dose (DDD):

$$DDD = application\ rate \times shortcut\ value \times TWA \times MAF_m$$

The value to be used for the time-weighted average factor (TWA) depends on whether the toxicity endpoint from Step 2 could be caused by a short-term exposure (STE) or only by a long-term exposure (LTE)[28].

- If the toxic effect is considered to be caused by LTE, use TWA = 0.53 (estimates time-weighted exposure over 21 days, assuming a default $DT_{50}$ of 10 days).
- If the toxic effect is considered to be caused by STE, use TWA = 1 (one day exposure).

**Table 12.** Indicator species and shortcut values (based on mean residues) for the mammalian reproductive assessment.

| Crop | Indicator species | Shortcut value for reproductive assessment |
|---|---|---|
| Bare soil | Small granivorous mammal | 6.6 |
| Bush and cane fruit | Small herbivorous mammal | 43.4 |
| Bulbs and onion like crops, cereals, oilseed rape, potatoes, root and stem vegetables, strawberries, sugar beet, and sunflower | Small herbivorous mammal | 48.3 |
| Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard | Small herbivorous mammal | 72.3 |

27 The standard Annex VI trigger value of 5 should be used for the non-target mammal assessment (see Step 4).

28 It is intended to develop further guidance on criteria for determining which effects could be caused by short-term exposures. The Joint Working Group decided that, until such guidance is available, it should be assumed as a default that the effects are caused by LTE, unless there is specific evidence for the pesticide under assessment that the effect could be caused by STE.

**Table 13.** Multiple application factors assuming mean residues ($MAF_m$), for use in reproductive assessments.

$MAF_m$ are shown for selected application intervals and *n* = 1-8 applications, assuming a default $DT_{50}$ of 10 d on foliage. $MAF_m$ values for other application intervals can be either calculated either using the formula in Appendix H or using the values for the next lower application interval. The limit value in the rightmost column should be used for higher numbers of applications with one of the tabulated intervals. These MAF factors should be used for all food types (i.e. arthropods and vegetation). Further information on this issue is provided in Appendix H.

| Application interval (d) | $MAF_m$ for n applications | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | n = 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | Limit |
| 7 | 1.0 | 1.6 | 2.0 | 2.2 | 2.4 | 2.5 | 2.5 | 2.5 | 2.6 |
| 10 | 1.0 | 1.5 | 1.8 | 1.9 | 1.9 | 2.0 | 2.0 | 2.0 | 2.0 |
| 14 | 1.0 | 1.4 | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 |

### Step 4

Calculate the toxicity-exposure-ratio and compare the TER to the respective trigger value.

$$TER = \frac{\text{lowest endpoint (Step 5)}}{\text{relevant } DDD \text{ (Step 7)}}$$

**TER ≥ 5** — **No further assessment required**
**TER< 5** — **Go to Tier 1 (Step 5)**

### Tier 1 risk assessment

All pesticides should be subjected to Tier 1 assessment, unless they are shown by a screening assessment (Steps 1-4) to pose a low risk. Tier 1 uses the same general approach as the screening assessment, but requires more detailed consideration of the relevance of toxicity endpoints and more specific exposure scenarios.

### Step 5

Identify the endpoint from the developmental study that is used in the human risk assessment. Check if the developmental study contained lower endpoints that were considered rodent-specific and, if so, take the lowest of these instead of the endpoint used for human risk assessment.

Identify the lowest NOAEL from the 2-generation rat study[29]. If there is no 2-generation rat study, identify the lowest NOAEL from the extended 1-generation rat study.

Note that relevant rodent-specific endpoints should not be disregarded (as they are in human risk assessment).

Endpoints that are presented as ppm diet or mg a.s./kg diet must be converted to daily doses, i.e. mg a.s./kg bw/d. At Tier 1, this should be done using the actual body weight and food consumption data from the study under consideration. In order to do this, take the mean value for food consumption over the whole study and average body weight over the duration of the study at the NOAEL and use these figures to convert the NOAEL to a daily dose.

If the lowest relevant endpoint from the developmental study is lower than the lowest endpoint from the 2-generation rat study, then use the developmental study endpoint as the endpoint for the Tier 1 reproductive assessment. Otherwise, use the lowest relevant endpoint from the 2-generation rat study. Proceed to Step 6.

29 The lowest endpoint is taken to avoid the need for detailed re-evaluation of the mammalian studies in Tier 1 of the ecotoxicological assessment. The relevance of the endpoints for wild mammals may be reconsidered as a refinement option (see Step 9).

**Step 6**

Identify the appropriate crop and **generic focal mammal species** in Annex I. Where more than one generic focal species is relevant for the crop, the one that is relevant in terms of time of application or growth stage should be selected. Where there is more than one generic focal species in terms of timing etc., Tier 1 risk assessments (and refined assessments, if necessary) should be carried out for all the relevant generic focal species.

**Step 7**

For each relevant generic focal species, calculate the daily dietary dose (DDD):

$$DDD = application\ rate \times shortcut\ value \times TWA \times MAF_m$$

The relevant shortcut value (based on mean residues) for each generic focal species should be obtained from Annex I.

If multiple applications are to be made, then Table 13 (see Step 3 above) should be consulted and the appropriate multiple application factor (MAF) assuming mean residues ($MAF_m$) should be used.

The value to be used for the time-weighted average factor (TWA) depends on whether the toxicity endpoint from Step 2 could be caused by a short-term exposure (STE) or only by a long-term exposure (LTE)[30].

- If the toxic effect is considered to be caused by LTE, use TWA = 0.53 (estimates time-weighted exposure over 21 days, assuming a default $DT_{50}$ of 10 days).
- If the toxic effect is considered to be caused by STE, use TWA = 1 (one day exposure).

**Step 8**

For each relevant generic focal species, calculate the toxicity-exposure-ratio and compare the TER to the respective trigger value.

$$TER = \frac{\text{lowest endpoint (Step 5)}}{\text{relevant } DDD \text{ (Step 7)}}$$

**TER ≥ 5** — **No further assessment required for this generic focal species**
**TER< 5** — **Refined assessment required for this generic focal species – go to Step 9**

30 It is intended to develop further guidance on criteria for determining which effects could be caused by short-term exposures. Until such guidance is available, it should be assumed as a default that the effects are caused by LTE, unless there is specific evidence for the pesticide under assessment that the effect could be caused by STE.

**Step 9**

**Refinement options**

Refined assessments should be carried out for all generic focal species that have a TER < 5 at Step 8.

Outlined below is a summary of selected options for refinement steps that can be used individually or combined together. Before considering any of the following refinement steps it is important to read section 6 on refinement options, and in particular ensure that the likely level of protection that will result from the refined risk assessment is the level wanted by the risk manager.

Re-examination of the relevance of mammalian toxicity endpoints for wild mammals. - Evaluate the 2-generation (or if absent, extended 1-generation) rat study/studies in detail, and determine for each study (or merged dataset, where it is appropriate to merge studies, see section 2.4.3) the endpoints that are considered relevant for reproductive performance, as listed below[31]:

- NOAEL for body weight change[32], behavioural effects and systemic toxicity;[33]
- NOAEL for indices of gestation, litter size, pup and litter weight;[34]
- NOAEL for indices of viability, pre- and post-implantation loss;
- NOAEL for embryo/foetal toxicity including teratological effects;
- NOAEL for number aborting and number delivering early;
- NOAEL for systemic toxicity and effects on adult body weight;
- NOAEL for indices of post-natal growth[35], indices of lactation and data on physical landmarks;
- NOAEL for survival and general toxicity up to sexual maturity.

31 For information on why these endpoints are considered relevant, see Appendix J.

32 This is included as an indicator of parental effects with potential to disrupt reproduction. It is considered in the reproductive assessment for mammals but not for birds, where LD50/10 is used instead.

33 Effects derived from absorption of the substance that causes modification of an organ or an apparatus (biochemical, physiological and/or morphological). Examples include behavioural or physiological impairment (e.g. reduced locomotive activity, altered reflexes).

34 Any effects in foetal body weight should be evaluated in the context of all pertinent data including other developmental effects as well as maternal toxicity.

35 For example body weight gain, ear and eye opening, tooth eruption, hair growth and effects on sexual maturation such as age and body weight at vaginal opening or balano-preputial separation.

Effects on other endpoints are considered not relevant for reproductive performance and may be disregarded.

Note that slight delays, e.g. 1 day, in obtaining a particular endpoint or developmental milestone can be ignored. However, longer delays could be considered as adverse effect. This is based on the frequency of measuring and hence is a pragmatic approach. Note that a 1-d delay may be of importance for certain substances. It should be checked that this is not treatment related before discounting it. Further discussion of the ecological relevance of test endpoints for wild mammals may be found in Appendix J and EFSA (2006).

Examination of additional mammalian toxicity studies. – The Tier 1 assessment concentrates on endpoints from the 2-generation rat study and the developmental study. In refined assessments it is desirable also to examine other mammalian toxicity studies to check whether they contain lower NOAELs for relevant endpoints. The lowest relevant NOAEL should be used for assessment[36].

Re-assessment of the exposure period relevant to the toxicity endpoints. – The screening and Tier 1 assessments use time-weighted averages over 21 days, except where there is specific evidence that the effects could be caused by short-term exposures. The default periods of 21 days for long-term effects and 1 day for short-term effects are arbitrary choices without specific scientific justification. In refined assessments the evidence for the exposure period relevant to each endpoint should be reviewed in more detail, in consultation with a mammalian toxicologist. See Appendix J for more information.

Refine the residue element of the initial DDD calculation. – To do this, data are required on either the initial residue values or/and the residue decline. Details regarding refining the risk using specific residue data are provided in section 6.1.4.

Refine ecological parameters. – It is possible to refine the DDD by using more relevant data on the ecological components of the risk assessment, i.e. focal species (FS), proportion of an animal's daily diet obtained in habitat treated with pesticide (PT) and composition of diet obtained from treated area (PD) (see sections 6.1.3, 6.1.5 and 6.1.6).

Phase-specific risk assessment. – The screening and Tier 1 assessments do not distinguish between different phases of reproduction. In reality, different phases of reproduction may differ both in their exposure and their toxicological sensitivity to the pesticide. Furthermore, only a proportion of mammals will be exposed and, for those that are exposed, the peak exposure may not occur during the most sensitive reproductive phase. These factors may be addressed by phase-specific risk assessment. To gain the full benefits of this approach requires detailed data that may not be available in many cases (e.g. time of application of the pesticide, time of breeding phases for focal species etc.). However, the phase specific approach may be an effective approach if these data are available. For further information see Appendix J.

Field trials. – Effects on reproduction for small mammals may be studied by using capture-mark-release-recapture techniques to monitor population density and age structure (see section 6.4).

Population modelling. – If, despite the above refinements, there is still concern regarding the risk to mammals, then one option would be to assess the risk at the population level. Unfortunately, there are no population models that can be readily used or adapted for use in pesticide risk assessment. Existing possible examples of population models are presented in Topping et al. (2005), Sibly et al. (2005), Roelofs et al. (2005) and Wang and Grimm (2007). It should be noted that the models included in these references are not endorsed but are provided as an indication of the types of studies that are available. Due to the complexity of this issue, it is envisaged that each assessment would be on a case-by-case basis. For further discussion of assessing population-level effects, see section 6.7.

36 The geometric mean of $LD_{50}$s across species is used in the acute risk assessment. It is intended to investigate further whether the geometric mean is also suitable for use in reproductive risk assessment. Until further guidance is developed, the most sensitive species should be used in the reproductive assessment (see section 2.3.1).

# 5. Special topics

## 5.1. Risk assessment for granular formulations

The following approach for assessing the risk for granular formulations is closely based on the method presented in EPPO/OEPP (2003) and the method presented in the fosthiazate opinion of the Scientific Committee on Plants (SCP, 2002).

It is possible that birds and mammals may be exposed to granules in different ways:

a) Birds and mammals may ingest granules as a source of food.

b) Birds may ingest granules as grit.

c) Birds may mistake granules for small seed.

d) Birds and mammals may ingest granules when they eat food contaminated with soil.

e) Birds and mammals may consume food contaminated with residues resulting from granular applications.

Assessments for these are addressed in sections 5.1.1 - 5.1.5. It is important that all relevant routes are considered. In addition, route b) above should also be considered for pelleted seeds.

During the development of the granule risk assessment scheme it became apparent that birds, predominately dabbling ducks, may be at risk from dabbling in puddles[37] that have formed on slow- or poorly drained fields recently treated with granules. This scenario is relatively rare, but has caused incidents in the past. Ideally this scenario should be assessed if conditions similar to those that caused previous incidents are likely to occur. It should be noted that this scenario is due to the correct use of substances and cannot be attributed to misuse. Unfortunately, due to a lack of information, it has not been possible to develop a risk assessment for this scenario.

An animal visiting a field treated with granules might be exposed via several routes in the same period of time, e.g. by ingesting granules and through drinking water. In principle, it would be logical to combine such exposures by adding them together (SCP, 2002). If this is done, account should be taken of the probability of each combination of routes occurring for the same individual. In practice, this will be very uncertain. A practical solution to this would be to estimate total exposure for each plausible combination of routes. If any combination raised a concern, then the risk assessor together with the risk manager could decide to require new data to confirm/refute the concern, or to accept the additional risk if the concern was not very high, and/or the probability of the combination was likely to be low (provided the individual routes were not of concern when considered separately).

Assessing the exposure of birds to granules presents special difficulties. Scientific knowledge in this area has continued to develop since the presentation of the first decision-making sub-scheme for the environmental risk assessment of plant protection products for terrestrial vertebrates by the OEPP/EPPO in 1994 (ECOFRAM, 1999; SCP, 2002; Luttik, 2003; OEPP/EPPO 2003; Luttik and de Snoo, 2004).

37 Since at least the early 1970s, pesticide poisoning from granular insecticide formulations has been documented as an important cause of wildlife mortality in British Columbia, Canada. Incidents have occurred where it would appear that waterfowl, primarily dabbling ducks (family *Anatinae*), have foraged extensively in puddles that have formed in slow-draining agricultural fields during autumn and winter following the application of the pesticide to potatoes and other root crops. In the wet highly acidic soils of the delta, granular formulations have been found to persist for several months beyond projected post application intervals (Wilson et al., 2002). A review of incident cases elsewhere, e.g. kills of waterfowl in US rice fields, suggests that these conditions may not be unique (Mineau, 1993). It is thought that waterfowl may be exposed through drinking from these puddles as well as when they are sifting through the saturated sediments for food. Granules appear to have the right size to be retained by the bill lamellae and they are ingested along with weed seeds, debris and grit. Raptors and other scavengers in turn are poisoned by the insecticides after scavenging on dead or dying waterfowl that have consumed the granules. The majority of raptors poisoned by anti-cholinesterase pesticides in the Fraser Delta have waterfowl remains in their ingesta. A few poisoned waterfowl carcasses can attract large numbers of scavengers (Peterson et al., 2001). All available information suggests that the poisonings are not the result of poor use, or misuse, and that a solution to the problem does not reside with a more careful use of the granular products but, rather, with choosing products of lower toxicity.

### 5.1.1. Animals ingesting granules as source of food

If there is a possibility that birds and mammals will mistake granules for food (e.g. in the case of granular products formulated on corncob carrier, carriers to which oil is added or carriers having some calorific value), it is appropriate to run the same procedure as for contaminated food (e.g. oversprayed). For this type of assessment it is necessary to know the caloric value of the granular material. With this value and the daily caloric demand of a bird or mammal of concern, the amount of granules and therefore the amount of active substance can be calculated to which the animal will be exposed. Species of concern, appropriate for the first-tier assessment are an omnivorous bird (e.g. house sparrow of 27.7 g) and an omnivorous mammal (e.g. wood mouse of 21.7 g).

### 5.1.2. Birds ingesting granules with/as grit

Grit consumption by farmland birds is an important constituent of dietary intake both for mineral content and mastication (Best and Gionfriddo, 1994). Significant differences exist between granivorous and non-granivorous species with respect to the size of grit ingested, with non-granivorous generally taking in grit indiscriminately with soil particles, while granivorous species pick up grit particles selectively (Luttik and de Snoo, 2004). Accordingly, the type of soil and its constituent composition can substantially influence the extent to which birds may be exposed to granular products. For seed-eating birds, e.g. finches, pigeons, partridges and pheasants that need grit for mastication of their food, the method for assessing the potential risk for the ingestion of granules follows the method proposed in the OEPP/EPPO (2003).

**Acute risk assessment**

**Step 1**

Calculate the acute daily grit dose ($DGritD_{acute}$)[38] for small and large granules.

$$DGritD_{acute}\,(\text{small granules})^{43} = 651 \times \frac{G_{density}}{(15200 + G_{density})} \times G_{loading}$$

$$DGritD_{acute}\,(\text{large granules})^{44} = 2453 \times \frac{G_{density}}{(71 + G_{density})} \times G_{loading}$$

With:

$G_{density}$ = number of granules on soil surface (this number should be based on real practice and not on theoretical incorporation efficiencies; see Appendix 21 of EFSA, 2008)

$G_{loading}$ = the amount of the active substance in one granule

**Step 2**

Take the appropriate $LD_{50}$ value (see section 2).

**Step 3**

Calculate the toxicity-exposure ratio for the relevant granule size and compare the TER to the respective trigger value.

$$TER_{acute} = \frac{LD_{50}}{DGritD_{acute}}$$

**$TER_{acute} > 10$** — **No refined acute risk assessment required**

**$TER_{acute} \leq 10$** — **Refined acute risk assessment required**

38 See note 1 in section 5.1.6.

39 Size of small granules: between 0.75 and 2 mm.

40 Size of large granules: between 2 and 6 mm.

**Reproductive risk assessment**

It is acknowledged that granules will only be present on a soil surface for a short time; however, reproductive RA is still required as there may be a long-term effect due to short-term exposure. The methodology outlined in section 4 should be followed. The initial exposure estimates should be based on the concentration in the granule. Where a TWA approach is required the degradation/dissipation of the active substance of the granule will be necessary.

**Step 4**

Calculate the daily grit dose ($DGritD_{repro}$)[41] for small and large granules for reproductive risk assessment.[42]

$$DGritD_{repro}\,(\text{for small granules}) = 386 \times \frac{G_{density}}{(15200 + G_{density})} \times G_{loading}$$

$$DGritD_{repro}\,(\text{for large granules}) = 1306 \times \frac{G_{density}}{(71 + G_{density})} \times G_{loading}$$

When sufficient information is available, apply a time-weighted average (TWA) correction for the number of granules and for the active substance.[43]

**Step 5**

Take the appropriate NOAEL (mg/kg bw/d) (see section 4.3 and 2.3.1).

**Step 6**

Calculate the toxicity-exposure ratio for the relevant granule size and compare the TER to the respective trigger value.

$$TER_{repro} = \frac{NOAEL}{DGritD_{repro}}$$

**$TER_{repro} > 5$** — **No refined reproductive risk assessment required**
**$TER_{repro} \leq 5$** — **Refined reproductive risk assessment required**

Steps 4–6 must be repeated for each relevant reproductive endpoint and associated time of exposure (see section 4.3 and Appendix J).

41 See note 1 of section 5.1.6.

42 The number of soil particles is based on three samples from three Dutch soils, two sands and one clay. If appropriate, replace these numbers with data for other soils. This should be done in the case of applications to peaty soils as they probably have lower grit estimates (see SCP, 2002: estimated density of available for 0.5–0.85-mm grit particles is approximately 5000 per square meter).

43 See note 3 of section 5.1.6.

### 5.1.3. Birds ingesting granules when seeking seeds as food

If it appears possible that the granules could be mistaken for weed seeds by seed-eating birds[44], then the granules should be assessed using the method described previously in the opinion of the Scientific Committee on Plants on fosthiazate (SCP, 2002). The potential risk can be illustrated by estimating a TER in a manner analogous to that used for ingestion of granules accidentally as part of soil ingestion, i.e. by assuming that granules and seeds are ingested in proportion to their availability.

**Acute risk assessment**

**Step 1**

Calculate the acute daily granule dose ($DGD_{acute}$) for a small granivorous bird.[45]

$$DGD_{acute} = 620 \times \frac{G_{density}}{(100 + G_{density})} \times G_{loading}$$

With:

$G_{density}$ = number of granules on soil surface
$G_{loading}$ = the amount of the active substance in one granule

**Step 2**

Take the appropriate $LD_{50}$ (mg/kg bw/d) for birds (see section 2).

**Step 3**

Calculate the acute toxicity-exposure ratio and compare the TER to the respective trigger value.

$$TER_{acute} = \frac{LD_{50}}{DGD_{acute}}$$

**$TER_{acute} > 10$** — **No refined acute risk assessment necessary**
**$TER_{acute} \leq 10$** — **Refined acute risk assessment necessary**

**Reproductive risk assessment**

It is acknowledged that granules will only be present on a soil surface for a short time; however, reproductive RA is still required as there may be a long-term effect due to short-term exposure. The methodology outlined in section 3 should be followed. The initial exposure estimates should be based on the concentration in the granule. If a TWA approach is required, then the degradation/dissipation of the active substance of the granule will be necessary.

**Step 4**

Calculate the daily granule dose ($DGD_{repro}$) for a small granivorous bird for the reproductive risk assessment (see note 4 of section 5.1.6).

$$DGD_{repro} = 620 \times \frac{G_{density}}{(100 + G_{density})} \times G_{loading}$$

When sufficient information is available, apply a time-weighted average (TWA) correction for the number of granules and for the active substance (see note 3 of section 5.1.6).

44 There are no indications available that mammals do forage on small seeds.
45 See note 4 of section 5.1.6.

**Step 5**

Take the appropriate NOAEL (mg/kg bw/d) (see sections 4.3 and 2.3.1).

**Step 6**

Calculate the toxicity-exposure-ratio and compare the TER to the respective trigger value:

$$TER_{repro} = \frac{NOAEL}{DGD_{repro}}$$

| | |
|---|---|
| $TER_{repro} > 5$ | **No refined reproductive risk assessment required** |
| $TER_{repro} \leq 5$ | **Refined risk assessment for chronic exposure required** |

Steps 4–6 must be repeated for each relevant reproductive endpoint and associated time of exposure (see section 4.3).

### 5.1.4. Animals ingesting granules when eating soil-contaminated food

The method for assessing the potential risk for birds and mammals exposed to granules as part of ingested soil when seeking food follows the one proposed in the EPPO scheme of 2003 (OEPP/EPPO, 2003).

**Acute risk assessment**

**Step 1**

Calculate the acute daily dry soil dose ($DDSD_{acute}$) for a small omnivorous bird and mammal[46].

$DDSD_{acute}$ for mammal = 0.097 × dosage [kg a.s./ha].

$DDSD_{acute}$ for bird = 0.283 × dosage [kg a.s./ha].

**Step 2**

Take the appropriate $LD_{50}$ value (see section 2).

**Step 3**

Calculate the acute toxicity-exposure ratios and compare the TERs to the respective trigger values:

$$TER_{acute} = \frac{LD_{50}}{DDSD_{acute}}$$

| | |
|---|---|
| $TER_{acute} > 10$ | **No refined acute risk assessment required** |
| $TER_{acute} \leq 10$ | **Refined acute risk assessment required** |

46 See note 5 of section 5.1.6.

**Reproductive risk assessment**

It is acknowledged that granules will only be present on a soil surface for a short time. However, reproductive RA is still required as there may be a long-term effect due to short term exposure. The methodology outlined in section 3 should be followed. The initial exposure estimates should be based on the concentration in the granule. If a TWA approach is required the degradation/dissipation of the active substance of the granule will be necessary.

**Step 4**

Calculate the daily dry soil dose ($DDSD_{repro}$) for the reproductive risk assessment for a small omnivorous bird and mammal[47].

$DDSD_{repro}$ for mammals = 0.005 × dosage in kg a.s./ha.

$DDSD_{repro}$ for birds = 0.025 × dosage in kg a.s./ha.

When sufficient information is available, apply a time-weighted average (TWA) correction for the active substance.[48]

**Step 5**

Take the appropriate NOAEL (mg/kg bw/d), described in section 4.4 and 2.3.1.

**Step 6**

Calculate the toxicity-exposure ratios for mammals and birds and compare the TERs to the respective trigger values:

$$TER_{repro} = \frac{NOAEL}{DDSD_{repro}}$$

| | |
|---|---|
| $TER_{repro} > 5$ | **No refined reproductive risk assessment required** |
| $TER_{repro} \leq 5$ | **Refined reproductive risk assessment required** |

Steps 4–6 must be repeated for each relevant reproductive endpoint and associated time of exposure (see sections 4.3 and 4.4).

### 5.1.5. Animals consuming other food items with residues from granular applications

At present, no standardised schemes are available for assessing the risk of residues of granular formulations in other food items such as earthworms and plant seedlings. This is mainly due to the lack of transfer factors for calculating concentrations in the food items for birds and mammals, e.g. transferring the load of granules to a concentration in the earthworm and the seedling.

If it is expected that the substance will be taken up by the worm via the pore water, the same route should be followed as for bioaccumulation. If it is expected that the substance will be taken up via seedlings, e.g. systemic substances, the same risk assessment method as for oversprayed food items should be applied (see section 4.1). Appropriate generic focal species are a 28.5-g lark and a 21.7-g mouse.

47 See note 5 of section 5.1.6.
48 See note 3 of section 5.1.6.

No standardised scheme is available for assessing the possible exposure of birds and mammals to granules adhered to the surface of worms. This is a route of exposure, which has caused poisoning incidents in the past and should therefore be considered in every case. Again, the same approach could be used as for oversprayed food items. This will require information on the number of adhered granules or the load of active substance per g of earthworm. Appropriate species of concern for earthworm-eating birds and mammals are a 10-g shrew and a 100-g thrush.

As described in section 4.1, the 'daily dietary dose' (DDD) is defined by the food intake rate (FIR) and the body weight (bw) of the species of concern. FIR/bw values for the generic focal species are provided in Table 14. The risk for these generic bird and mammal species can be calculated by dividing the appropriate toxicity value [mg/kg bw] by the FIR/bw value multiplied by the concentration of the compound in the plant or on the earthworm [mg/kg food].

**Table 14.** FIR/bw values for generic focal species exposed to pesticide residues via ingestion of plant seedlings or by granules sticking to earthworms.

| Generic focal species | Food | FIR/bw | Body weight bw [g] | Daily energy expenditure DEE [kJ] | Food energy FE [kJ] | Moisture content MC (%) | Assimilation efficiency AE (%) |
|---|---|---|---|---|---|---|---|
| Shrew | earthworms | 1.34 | 10 | 33.8 | 19.3 | 84.6 | 85 |
| Thrush | earthworms | 0.96 | 100 | 242 | 19.3 | 84.6 | 85 |
| Lark | leaves | 2.26 | 28.5 | 104 | 17.8 | 88.1 | 76 |
| Mouse | leaves | 1.68 | 21.7 | 58.8 | 17.8 | 88.1 | 76 |

### 5.1.6. Explanatory notes to risk assessment for granules

**Note 1. Selection of input parameters for exposure scenarios (ingestion of granules as part of grit ingestion).**

Table 15 gives estimations for acute and reproductive risk assessment scenarios for a small generic bird (e.g. finches) and a large bird (e.g. partridge or woodpigeon).

**Table 15.** Estimation of input parameters for acute reproductive risk assessment for birds ingesting granules intentionally when seeking grit.

| Exposure duration | Size of birds | Number of grit per day (DGritI) | Number of soil particles ($SP_{surface}$) | $f_{TWA}$ for number of granules | $f_{TWA}$ for the active substance |
|---|---|---|---|---|---|
| Acute exposure | Large | 2453 | 71 | No | No |
| | Small | 651 | 15200 | No | No |
| Long-term exposure | Large | 1306 | 71 | Yes | Yes |
| | Small | 386 | 15200 | Yes | Yes |

It is assumed in the assessment that small granules (size between 0.75 and 2 mm) are taken by small birds (e.g. finches) and that large granules (size between 2 and 6 mm) are taken by large birds (e.g. partridge and wood pigeon).

The acute exposure scenario (90$^{th}$ percentile) and reproductive scenario (geometric mean) estimates of the numbers of grit particles in the gizzards of a small and a large bird are based on research carried out by de Leeuw et al. (1995). For small birds, data on six European, predominantly granivorous species were available. Greenfinch had 95 grit particles in the gizzard, chaffinch 65, linnet 100, twite 122, brambling 188 and goldfinch 43 (mean values). The geometric mean is 92 and the 90$^{th}$ percentile is 155 grit particles. For larger birds data on three species were available. The grey partridge had 676, woodpigeon 208 and pheasant 214 particles (geometric mean 311 and 90$^{th}$ percentile 584). To convert these gizzard counts into a daily intake, a conversion factor of 4.2 is used (see note 2). Sensitivity or influence is based on incorporation efficiency.

For the number of soil particles in the same size classes as the granules (i.e. 0.75 to 1.5 mm and 2 to 6 mm) the geometric mean of three Dutch soils have been used as default (Luttik and de Snoo, 2004). On average (geometric) 15200 soil particles of the size 0.75 to 1.5 mm can be found per m$^2$ and 71 soil particles of the size 2 to 6 mm.

The daily grit dose (DGritD) can be calculated with the following equation:

$$DGritD = DGritI \times \frac{G_{density}}{(SP_{surface} + G_{density})} \times G_{loading} [mg/kg/bw/d]$$

In which:

DGritI = daily grit intake of birds

$G_{density}$ = number of granules at soil surface

$SP_{surface}$ = number of soil particles at soil surface in the same size classes as granules

$G_{loading}$ = the amount of the active substance in one granule.

In the first-tier assessment it is assumed that the birds will obtain their entire daily granule dose (DGritD) from the treated area (PT = 1), lower values could be used when appropriate in higher tier assessments. In the reproductive risk assessment it is appropriate to include time weighted average factors (TWA); one for the decline in numbers of granules over time and one for the degradation of the active substance (see note 3).

The estimate of soil particle density is based on just one sample from each of three Dutch soils, one clay and two sands, which would be expected to have relatively high grit contents. Peaty soils contain much less grit and would therefore lead to a higher estimate of daily granule dose. Therefore, if granules may be used on peaty soils and peaty soils are considered as relevant in agriculture, data on grit densities on relevant soils should be obtained and used to modify the assessment calculations. Even for clay and sandy soils, it would be desirable to base the assessment on larger numbers of samples; however, these are currently not available.

### Note 2. Grit turnover rate

On basis of Fischer and Best (1995), a 4.2 conversion factor will be used to take account for the turnover rate of grit. It should be noted that this value is only based on one experimental design using only one species. Further, the blank silica granules were intermixed with dog food and there was a great deal of scatter in the data depicting the relationship between granule consumption and gizzard granule counts.

Additional research is needed to validate the general applicability of using a conversion factor and to determine the degree to which such a factor may vary among species and under different environmental conditions.

### Note 3. Time weighted average factors (fTWA)

In the reproductive risk assessments it is appropriate to use time weighted average residues rather than initial residues. The time weighted average factor *($f_{TWA}$)* depends on the half-life of the compound or the half-life of the granules:

$$f_{TWA} = \frac{1 - e^{-kt}}{k}$$

With:

k = $\ln 2/DT_{50}$

t = averaging time in days

### Note 4. Selection of input parameters for exposure scenarios (ingestion of granules as part of seed ingestion)

Granules are often smaller than most seeds taken by birds but are of comparable size to some of the smaller seeds of arable weeds e.g. *Stellaria media, Capsella bursa-pastoris, Veronica arvensis* and *Urtica dioica*. Some of these (e.g. *Stellaria*, *Capsella*) are among the plant species most commonly taken by birds. Plant groups known to be important in the diet of the seed-eating linnet include Polygonaceae, Chenopodiaceae, Gramineae, Caryophyllaceae, Cruciferae, and Compositae. It is therefore possible that granules may be ingested by birds searching for seeds as food.

Studies on UK arable fields show varying densities of crop and weed seeds up to about 20,000/$m^2$, based on soil cores to a depth of 20 cm (Jones, 1998; Jones and Maulden, 1999; Jones *et al*., 1997). It is assumed that seeds taken by small birds average about 1 mm diameter and are therefore visible to birds only if they are contained in the top 1 mm of soil. Ploughing is intended to invert the soil and has been shown to bury over 90 % of new seeds from the surface to a depth of 5 cm or more, but additional ploughing in successive years tends to redistribute surviving seeds more evenly (Moss, 1998). Therefore, a uniform distribution of seeds is assumed in the top 20 cm, and 20000 seeds/$m^2$ in the top 20 cm would correspond to about 100 seeds/$m^2$ in the top 1 mm.

It is assumed that a linnet of 15.3 g will eat small seeds with an average caloric content of 21.7 kJ/g dry weight, an average water content of 9.9 % and an average assimilation efficiency of 80 % for birds. Based on allometric equations for dry food intake (see Appendix G) and an estimated moisture content of 9.9 %, a 15.3 g linnet would require 4.35 g/day or about 620 seeds per day (based on an average weight for canary seeds of 7 mg).

If the generic species is adequate for carrying out the first-tier risk assessment, the daily granule dose (DGD) can be calculated by using the following equation:

$$DGD = DGI \times G_{loading}$$

$$DGI = 620 \times \frac{G_{density}}{(100 + G_{density})}$$

In which:

DGI = daily granule intake

$G_{density}$ = density of granules at surface (including incorporation efficiency when the product label recommends incorporation of granules)

$G_{loading}$ = amount of active substance in one granule

In the first-tier assessment it is assumed that the birds will obtain their entire daily granule dose (DGD) from the treated area (PT = 1), lower values could be used when appropriate in higher tier assessments. In the reproductive risk assessment it is appropriate to include time weighted average factors (TWA): one for the decline in numbers of granules over time and one for the degradation of the active substance (see note 3).

### Note 5. Selection of input parameters for exposure scenarios (ingestion of granules as part of soil ingestion)

Table 16 gives estimations for the acute and reproductive risk assessment scenarios for a generic bird and mammalian omnivorous species of 25 g. It is assumed that the animals will eat equal parts on dry weight consisting of non-grass herbs, insects and seeds with a caloric content of 17.8, 22.7 and 21.7 kJ/g dry weight respectively, and an assimilation efficiency of 76, 76 and 80 % for birds and 74, 88 and 83 % for mammals.

**Table 16.** Estimation of shortcut values for acute and long-term exposure via contaminated soil for a generic bird and mammalian omnivorous species of 25 g.

| Exposure duration | Species | Daily Dry Food Intake (DDFI) [g $kg^{-1}$ bw $d^{-1}$] | % of soil in diet | Daily Dry Soil Intake (DDSI) [g $kg^{-1}$ bw $d^{-1}$] | RUD [mg/kg dry soil] | Shortcut value |
|---|---|---|---|---|---|---|
| Acute | Mammal | 153 | 9.4 | 14.5 | 6.667 | 0.097 |
| | Bird | 236 | 18 | 42.5 | 6.667 | 0.283 |
| Long-term | Mammal | 153 | 3.8 | 5.8 | 1.333 | 0.005 × fTWA |
| | Bird | 236 | 7.9 | 18.6 | 1.333 | 0.025 × fTWA |

If the generic species are adequate for carrying out the first-tier risk assessment, the daily dry soil dose (DDSD) can be calculated by using the shortcut value(s) for soil ingestion:

DDSD = Shortcut value × dosage in kg a.s./ha [mg a.s./kg bw/d].

The underlying equation for calculating the shortcut value is:

$$\text{Short cut value} = DDSI \times \frac{RUD}{1000}$$

In which:

DDSI = Daily dry soil intake of the indicator species [g/kg bw/d]

RUD = Residue unit dose (concentration in soil as a result of an application rate of 1 kg a.s./ha in a soil layer of 1 cm in acute scenario and 5 cm in long-term scenario, see also note 6)

Further:

$$DDSI = DDFI \times \frac{\%\text{soil}}{100 - \%\text{soil}}$$

In which:

DDFI = Daily dry food intake of the indicator species [g/kg bw/d]

%soil = Percentage of dry soil in dry diet of indicator species (see note 7)

And:

$$DDFI = \frac{DEE}{FE} \times \frac{AE}{100} [\text{g dry weight/d}]$$

In which:

DEE = Daily energy expenditure of the indicator species [kJ/d]

FE = Food energy [kJ/dry g]

AE = Assimilation efficiency [%]

Mean estimates for factors DEE, FE and AE can be found in Appendix G on food intake.

In the first-tier assessment it is assumed that the birds will obtain their entire daily dry soil dose (DDSD) from the treated area (PT = 1), lower values could be used when appropriate in higher tier assessments. In the reproductive risk assessment it is appropriate to include time weighted average factors (TWA) for the degradation of the active substance (see note 3).

### Note 6. Residue per unit dose (RUD) for soil-applied pesticides

The values for RUDs in Table 16 of note 5 are based on an application rate of 1 kg a.s./ha and assuming broadcast seeding (no incorporation). For the acute exposure assessment, it is assumed that the compound is equally mixed in a layer of 1 cm soil, for the long-term exposure it is assumed that the compound is mixed over a layer of 5 cm. If other incorporation depths are specified by the product label, the RUD value and shortcut values for a number of depths are presented in Table 17. The calculations are based on a dry bulk density of 1500 kg/$m^3$.

### Note 7. Estimation of soil ingestion by birds and mammals

For acute risk assessment and for reproductive risk assessment it is assumed that respectively the 90$^{th}$ percentile and the geometric mean estimates of the percentages of soil in the daily diet are appropriate to use. These values are based on data collected by Beyer et al. (1994). For mammals the following data are available: <2, <2, <2, <2, <2, <2, 2.3, 2.4, 2.7, 2.8, 5.4, 6.3, 6.8, 7.7, 9.4, 9.4 and 17 % (geometric mean 3.8 % and 90$^{th}$ percentile 9.4 % (17 different species)). For birds data on 11 species are available (no data on passerines): <2, <2, 3.3, 7.3, 8.2, 9.3, 10.4, 11, 17, 18 and 30 % (geometric mean 7.9 % and 90$^{th}$ percentile 18 %). It is important to note that Beyer et al. estimates are expressed as dry weight/dry weight.

**Table 17.** Shortcut values for different incorporation depths (e.g. 10, 15, 20 and 25 cm).

| Exposure duration | Species | RUD mg/kg soil (in layer of x cm) | | | | Shortcut value | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 10 cm | 15 cm | 20 cm | 25 cm | 10 cm | 15 cm | 20 cm | 25 cm |
| Acute | Mammal | 0.667 | 0.444 | 0.333 | 0.267 | 0.010 | 0.006 | 0.005 | 0.004 |
| | Bird | 0.667 | 0.444 | 0.333 | 0.267 | 0.028 | 0.0191 | 0.014 | 0.011 |
| Repro | Mammal | 0.667 | 0.444 | 0.333 | 0.267 | $0.004 \times f_{TWA}$ | $0.003 \times f_{TWA}$ | $0.002 \times f_{TWA}$ | $0.002 \times f_{TWA}$ |
| | Bird | 0.667 | 0.444 | 0.333 | 0.267 | $0.012 \times f_{TWA}$ | $0.008 \times f_{TWA}$ | $0.006 \times f_{TWA}$ | $0.005 \times f_{TWA}$ |

### 5.1.7. Possible options for refinement

General guidance on refinement and higher-tier assessment is provided in section 6. The following options are most likely to be relevant:

- Avoidance studies in pens (laboratory) with animals that have been grit deprived for a few days and reasonable numbers of available grit and granules (section 6.2).
- Field studies to test for sublethal effects and mortality following application of granules (section 6.4).

In addition to the options described above, specialised field or laboratory studies could be conducted to obtain refined estimates of parameters used in the first-tier calculations like, e.g. the incorporation efficiency or the turnover rate. These studies should be designed to cover the range of values occurring in practice, including a realistic worst case. The results can then be used to carry out revisions of the first-tier exposure calculations.

## 5.2. Risk assessment for treated seed

Tier 1 assumes that granivorous birds and mammals feed entirely on readily available, freshly treated seeds. The failure rate of pesticides used as seed treatments to meet the standard EU triggers for acute and reproductive risks under such a scenario is likely to be high. Therefore, many cases will require refined assessment. At present, it is not possible to recommend standardised approaches for refined assessment. Therefore, a range of options for refinement are presented.

The outcome of a refined assessment would, in most cases, take the form of a weight-of-evidence approach, rather than a quantitative assessment (e.g. TER). Risk managers will have to decide on whether the evidence provided is sufficient to allow for a decision whether the intended level of protection is reached. Guidance is provided on the method for such a weight-of-evidence approach.

### 5.2.1. Selection of relevant risk assessment scenarios

Exposure of birds and mammals to pesticides used as seed treatment is primarily via dietary intake. Dermal exposure to seed treatments is unlikely to occur, especially when seeds are incorporated into the soil. Pesticides used as seed treatments are unlikely to be volatile since the protection of the seed would not be long-lasting. Hence, the contribution to exposure of birds and mammals from inhalation of pesticides from treated seeds is considered to be low. Significant contamination of drinking water after the use of a pesticide as seed treatment seems equally unlikely to be a critical route or to lead to TER greater than direct dietary consumption. Therefore, the following risk assessment focuses on the dietary route of exposure.

It should be noted that in early sections of this Guidance Document, the risk assessment process has started with a screening step. In this scheme there is no screening step and the assessment starts at Tier 1.

Pesticides used as seed treatment are normally applied to soils that have been specifically prepared (seed beds). Minimum tillage practices have increased throughout EU in the last decade, but even in case of seed treatment use in minimum tillage practices the soil surface is 'worked' to a depth up to 5 cm. No-tillage practices are rare (< 5 %) in Europe. Therefore, for potential 'consumers' in bird and mammal populations the scenario represented by a seed treatment resembles a bare-soil scenario. Herbivorous birds and mammals are not considered to be attracted to fields immediately after treated seed has been drilled. However it is possible that birds and mammals may consume seedlings that contain residues of the active substance or consume the seedling and the remaining seed. These issues are discussed below.

In general granivorous birds and mammals prefer a certain type of seed for their diet. Not all birds are attracted to all sizes and shapes of seeds. Therefore, in a Tier 1 assessment, small granivorous birds that feed on small seeds, and larger, medium-size birds that feed on large seeds such as maize, sugar beets and beans should be considered separately.

Work by Prosser (2001) indicated that some pelleted seeds were not readily taken as a food source by birds. However, the potential for pelleted seeds to be taken as source of grit must also be considered when making a risk assessment for birds. Mammals are not known to ingest grit.

**Step 1**

For pelleted seeds, an assessment for mammals is not required[49], but an assessment for birds must be conducted according to the scheme presented in section 5.1.2.

For non-pelleted seeds the standard scenario for risk assessment is a bird or mammal feeding on freshly drilled seeds. Throughout the present document, first-tier scenarios are set in which diets consist of a single food item. Therefore, at Tier 1, it can be assumed that seed-eating birds and mammals feed on treated seeds only (100 % diet).

**Step 2**

For non-pelleted seeds, select the appropriate generic focal species from Table 18.

**Table 18.** Type of seeds, corresponding generic focal species and their food intake rate per body weight.

| Type of seeds | Indicator species | FIR/bw |
|---|---|---|
| 'Large seeds'<br>(maize/beans/peas) | Large granivorous bird<br>Small omnivorous mammal | 0.1<br>0.24 |
| 'Small seeds'<br>(not maize, beans or peas) | Small granivorous bird<br>Small omnivorous mammal | 0.3<br>0.24 |

**Step 3**

For all seed treatments, including pelleted seeds, an additional scenario of birds and mammals feeding on crop seedlings should be considered in the risk assessment.

When consumption of newly emerged crop shoots (including roots and remaining seed) is likely to occur, it is necessary to conduct an additional risk assessment for herbivorous birds and mammals according to the methods provided in the modules for acute and reproductive risk assessment for spray products (section 4). In such an assessment, any information on the amount of substance likely to be present in newly emerged crop shoots should be taken into consideration. The scenario assessed here resembles mostly the 'newly-sown grassland' or 'early-post emergence uses on cereals' scenario for spray products. Relevant indicator species for this scenario are as such large herbivorous birds and mammals and small omnivorous birds and mammals. The generic focal species and the appropriate shortcut values for the risk assessment for pesticides present in newly emerged crop shoots can be selected from Table 19. Insectivorous birds and mammals are unlikely to present a critical case for this scenario. The FIR/bw needs to be multiplied by the concentration expected in the seedling to obtain a shortcut value suitable for use in the first-tier RA. As a conservative default for the Tier 1, it is assumed that the applied amount of pesticide is contained in a total mass of seedling that is five times the weight of the original seed (based on the relative water contents of seeds and the newly emerged grass and cereal shoots – see Appendix G). The values in Table 19 assume that root, seed and seedling are ingested by the animal and that all of the applied substance remains available. If data can be provided to justify less conservative values this could be considered in a refinement step. The acute and reproductive risk assessments for birds and mammals have to be carried out in the same way as for spray applications, outlined in sections 4.1 - 4.4, but using the shortcut values from Table 19. This is in addition to, and not a replacement for, the assessment for ingestion of treated seed (Step 4).

49 Pelleted seeds may be consumed by wood mice (e.g. Pelz, 1989) but the Joint Working Group considered that the risk in these cases may be reduced due to animals cracking and discarding the pellet with most of the residue before ingesting the seed.

**Table 19.** Generic focal species and corresponding shortcut values for assessment of residues present in newly emerged crop shoots.

| Generic focal species | Short-cut values for acute risk* |
|---|---|
| Small omnivorous bird | 0.5 × NAR/5 |
| Small omnivorous mammal | 0.24 × NAR/5 |

NAR = Nominal loading/application rate of active substance in mg/kg seed.
* For the reproductive assessment, these shortcut values should be combined with appropriate time windows and default degradation/dissipation rates for residues (see sections 4.3 and 4.4).

### 5.2.2. First-tier RA and refinement options for birds and mammals feeding on treated seeds

For products used as seed treatment, risk assessments for acute as well as reproductive effects are needed.

**Step 4**

Calculate the acute and long-term TER values for generic focal species using the FIR/bw values from Table 18 and appropriate estimates of exposure.

$$TER_{acute} = \frac{LD_{50}}{(NAR \times FIR / bw)}$$

$$TER_{longterm} = \frac{NOAEL}{\text{Appropriate exposure estimate}}$$

With:

NAR = Nominal loading/application rate of active substance [mg/kg seed].

Information on how to determine appropriate NOAELs for different reproductive phases is provided in sections 4.3 and 4.4. For exposure estimates, the same time windows as in the sections on reproductive effects should be used, together with the nominal application rate and appropriate dissipation and degradation rates of the active substance on the treated seed.

Compare the resulting toxicity-exposure ratios to the respective trigger values:

| | |
|---|---|
| $TER_{acute} \geq 10$ *and* $TER_{longterm} \geq 5$ | **No refined risk assessment required.** |
| $TER_{acute} < 10$ *and/or* $TER_{longterm} < 5$ | **Select one or a combination of refinement options (section 5.2.3) and perform a weight-of-evidence assessment** |

### 5.2.3. Refinement options

The above procedures represent realistic but worst-case scenarios for individual animals. Based on currently used loading rate (NAR) for most seed treatment products, a large majority of cases will fail this first-tier assessment, so refined risk assessment will frequently be required. At present, it is not possible to provide advice on a fixed refinement approach. Therefore, a set of refinement options is outlined below. This set of options is not necessarily exhaustive and further refinement tools may be available or be developed in the future. General guidance on higher-tier assessment is provided in section 6.

Regardless of the options selected for refinement, the uncertainties associated with each option should be evaluated (see section 6.8) and the overall weight-of-evidence (WoE) should be assessed (see section 6.9). A summary of the main sources of uncertainty affecting the different refinement options is provided in Table 21.

**Focal species (FS), PT and mixed diet composition**

Actual focal species information may be available for the crop/region under assessment. Refinements can be performed using the food intake rate (FIR) and body weight data of the actual focal species rather than the generic FS in Table 19. PT values for the actual crop-specific FS as well as any information on the (mixed) diet of those species may be used for further refinements of the dietary exposure and TER. In any refinement of these factors, account should be taken of the guidance provided in section 6.1 on approaches and limitations of refined dietary exposure assessments. Additional care is required for treated seeds. First, simple dietary assessments assume that food obtained on treated fields follows the same dietary composition as measured for the general population in all habitats. This will probably underestimate the intake of crop seed for animals feeding on newly drilled fields. Therefore, the conservative assumption of taking only treated seed should be retained unless there is specific data on the foods taken on relevant fields. Second, when refining PT for seed treatments, it is important to take account of the range of variation between individuals and between days (not average values), because acute risks and also reproductive effects caused by short-term exposures depend on the amount of seed taken by an individual on a given day.

**Availability of non-treated seeds**

Bare soil and/or prepared seed beds are likely to contain a natural seed bank of weed seeds. The first-tier assumption of a bird/mammals diet consisting of 100 % treated seeds is likely to represent a worst-case approach. At higher tiers, where mixed diets are considered, it is therefore possible to adjust the percentage of treated seed in the diet. This is based on the availability of alternative seeds from the natural seed bank on the treated field, assuming that relevant data exist or can be generated for the scenario under consideration. However, it cannot be assumed that birds or mammals simply take treated seeds and weed seeds in proportion to their relative densities. Account must be taken of other factors that may influence relative uptake, including the relative visibility to birds and mammals of the seeds against the soil background, their relative energy contents and palatability. Modelling these factors is likely to be very uncertain and it may be more practical to study seed intake of animals directly (e.g. by analysis of faecal samples from animals known to be foraging entirely or mainly on the relevant fields).

### Dehusking behaviour

Granivorous mammals and birds are known to dehusk seeds prior to consumption. In such cases the actual intake of a substance after feeding on treated seeds may be considerably less than was estimated from the nominal treatment rate. The extent of dehusking behaviour may vary among different species of birds and mammal as well as for different types of seed (crop). Therefore, in looking at any available experimental data on dehusking, the representativeness of the studies to the situation likely to arise in the field should be taken into consideration. Further discussion and guidance on this issue is provided in section 6.1.7.

### Foraging area

It stands to reason that the risk for birds and mammals presented by a product used as a seed treatment is correlated with the area that a bird or mammal will have to forage to find sufficient seeds that add up to a lethal dose. Therefore, an indication of the degree of risk may be obtained by estimating the area that needs to be foraged by a bird or mammal to obtain a lethal dose.

This approach requires information on the density of seeds available on the soil surface after application (including an assessment of field incorporation rate). De Snoo and Luttik (2004) reported that the soil incorporation rates achieved in different crops, with different machineries and different periods of the season, vary by 90 – 99.5 %. It is important to take into account that the scatter of treated seeds left on the soil surface after using a 'soil-incorporation' seed treatment is unlikely to be homogeneous. Larger densities of available seeds may remain on the soil surface, especially at those points where the applicator either enters or leaves the soil (due to turning of machinery or uneven soil surface), even when the overall incorporation efficiency of the treatment is high. Birds and mammals may be specifically attracted to these 'hot-spots' and any effect seen may be more related to those than to the incorporation-efficiency-adjusted nominal application rate (NAR). The potential of risk mitigation measures that are mentioned on the label may also be taken into account. These require e.g. the immediate (end-of-row) removal of spills after application in order to lower the availability of treated seeds on the soil surface

Data on incorporation rates should be relevant to the crop, soil type and conditions under assessment. Data from multiple sites may be needed to represent the range of variation. Sampling within each site should be designed to reflect within-field variation including any differences between end-row, field edge and field centre areas. Since animals are likely to concentrate their foraging in areas of higher seed density, the area containing sufficient exposed seeds to provide a lethal dose should be calculated for the higher densities encountered as well as the average. Appropriate allowance should be made for variation of toxicity between and within species, i.e. by estimating the lethal dose as the $LD_{50}$ for test species divided by a part or all of the standard uncertainty factor of 10[50].

50 Unfortunately, there is no generally accepted view on how much of the standard uncertainty factor of 10 should be considered as allowing for variation in toxicity between and within species.

If the area that must be foraged to obtain a lethal dose is clearly unfeasibly large for any relevant focal species, even at the upper end of expected seed densities, it may be possible to conclude that the risk is low. If a lethal dose can be obtained from an area that is clearly small enough for a focal species to forage in a short period of time, this will indicate a cause for concern unless it can be demonstrated that other factors such as avoidance and metabolism will reduce the risk. However, interpretation of intermediate results may be very uncertain, unless they can be compared to good information on the range of foraging areas that can be covered by relevant species in relevant conditions. If existing information is inadequate to make this judgement, then consideration could be given to conducting quantitative observations in the field.

### Meal size approach

The typical numbers of seeds that a bird can ingest in a single feeding bout has been investigated by Prosser (1999). Comparison of the number of seeds needed to attain a lethal dose with the data provided by Prosser may provide useful information on the likely risk of mortality. Appropriate allowance should be made for variation of toxicity between and within species, e.g. by estimating the lethal dose as the $LD_{50}$ for test species divided by part or all of the standard uncertainty factor of 10, or dividing the relevant endpoint by up to 5 for reproductive effects caused by one-day exposures.

Prosser's (1999) data on seed intakes are summarized in Table 20 below. It should be stressed that the methodology used by Prosser to derive these numbers was conservative in some aspects (e.g. it was a spill scenario) but not in others (the same bird may have returned to the feeding site several times a day, and one bout may not equate to a 'meal'). Therefore, before using these data, one needs to assess the degree of 'comparability' between the numbers derived under the set of experimental conditions and the field situation to be assessed. The range of variation in feeding bout size (as indicated in Table 20 will assist in evaluating the proportion of bouts that may approach a lethal dose. If it appears from the 90$^{th}$ percentile and maximum values that some bout sizes could be sufficient to provide a lethal dose, this will indicate a cause for concern unless it can be demonstrated that other factors such as avoidance and metabolism will reduce the risk.

**Table 20.** Mean and maximum number of large and small seeds taken by birds in a single feeding bout in field studies, summarised from Prosser (1999).

| | Number of large seeds | | | Number of small seeds | | |
|---|---|---|---|---|---|---|
| | Mean* | 90$^{th}$ percentile** | Maximum | Mean* | 90$^{th}$ percentile** | Maximum |
| Large granivorous bird | 12 | 116 | 266 | 75 | 1744 | 4487 |
| Small granivorous bird | 3 | 11 | 11 | 12 | 85 | 240 |

* Geometric mean of mean values for different species and seed types.
** 90$^{th}$ percentile of maximum values for relevant species and seed types.

### Food item preference and avoidance

Granivorous birds and mammals may be able to distinguish treated seeds from non-treated seeds and may show a preference for either treated or untreated seeds in their diet. This may be influenced by various factors including appearance, taste or surface texture of the treated seed, and aversive reactions to the active substance. Information on such preferences/avoidance behaviour can, in combination with data on the availability of treated and non-treated seeds on the soil surface, be used to refine the risk assessment.

No standard guideline for testing avoidance is as yet available. Studies conducted in the past were performed under choice as well as no-choice situations, with and without food-deprived animals (hunger stress). In applying a weight-of-evidence approach on avoidance studies the severity of the test method should be compared with the field scenario likely to arise. Important factors to consider when assessing avoidance are discussed in section 6.2.

### Metabolism and body burden modelling

The rate of absorption, distribution, metabolism and elimination (ADME) of substances in the gastrointestinal tract of birds and mammals influences the toxicity of the product. In the first-tier risk assessment above, $LD_{50}$ values from gavage studies are used as an estimate of the toxicity of the substance. ADME-factors may be different for dietary uptake of products from seed treatment than in the gavage experiments. Therefore, metabolism and body burden models (see also section 6.3 of this GD and Appendix 23 of EFSA, 2008) can be used as a potential refinement step at higher tiers. The EFSA opinion on pirimicarb gives an example as to how such models may be applied in a weight-of-evidence approach (EFSA, 2005a).

### Field studies

Since the screening assessment for seed treatments has not been calibrated by field studies, as is the case for the acute assessment on spray-product, classical field 'effect' studies can be used to refine assessments on the acute risk of seed treatments. Quality criteria should be applied to the studies regarding the relevance of the species that are present (e.g. diet, use of field), the representativeness of the field situation and the power of the study to detect effects (e.g. carcass search efficiency). Note that, although the lack of vegetative cover makes it easier to find carcasses in newly sown fields, it may also make intoxicated animals more likely to seek cover away from the field. Other important factors to consider when designing and interpreting field studies are discussed in section 6.4.

### Historical data on poisoning incidents

When reviewing a previously authorised product, information on historical incidents may be available from official surveillance schemes and/or the scientific literature. Such data are very relevant to evaluating the protection goal of avoiding 'visible mortality', although only a fraction of visible casualties may be reported or documented. Furthermore, only a fraction of actual casualties will be visible, and therefore incident records are a very uncertain indication of the degree of undetected mortality. This is relevant when assessing the protection goal of avoiding long-term repercussions for abundance and diversity. These issues and the interpretation of incident data are discussed further in section 6.5.

### Comparison to well-studied historical examples

Comparisons between the product under assessment and other products that have been well studied in the past may provide some assistance in characterising the possible risk, provided the uncertainties inherent in 'reading across' between products and scenarios are carefully assessed. For example, extensive information is available on the organophosphorus insecticide fonofos, which was used as a seed treatment on wheat in the UK. This was associated with a small number of bird poisoning incidents over a number of years (Prosser et al., 2006). Authorisation of the product was not withdrawn, so it may be inferred that the level of incidents was not considered clearly unacceptable, but it may have been close to the borderline of acceptability. Therefore, it may provide a useful, although approximate benchmark for the evaluation of other products with similar characteristics. For example, if another product required a smaller area of exposed seeds to obtain a lethal dose, when compared to the same calculation for the historical use of fonofos, then this would be a cause for concern. On the other hand, if the new product required a much larger area to obtain a lethal dose, this might be an indication of lower risk provided that the avoidance and metabolism properties of the two substances were similar. In making such comparisons it would also be relevant to consider the anticipated extent of use of the new product, because fonofos was used on a relatively small area of wheat and would presumably have caused more incidents if used more widely. The validity of extrapolations implied by comparative inferences of this sort must be considered very carefully. Differences in avoidance and metabolism between products could have large effects. Uncertainty will be increased for comparisons involving different crops, different focal species, or different regions.

A more subtle, but important uncertainty arises from between-species variation in toxicity. As indicated in Appendix C, (Figure 1, histogram of variation between species), a sensitive species may be up to one or two orders of magnitude more sensitive than the standard test species. If the test species for the benchmark pesticide was itself a relatively sensitive one, and the test species for the new pesticide was a relatively insensitive one, then the benchmark comparison could severely underestimate the risk. A conservative work-around for this would be to apply part or all of the normal uncertainty factor of 10 to the new pesticide, but not the benchmark pesticide, when calculating the areas required for a lethal dose.

If, when all the uncertainties are considered, a comparison of this sort is still clear enough to form a judgement about risk relative to a well-studied 'benchmark' example, it may make a useful contribution to the overall weight-of-evidence.

### Weight-of-evidence (WoE) approach

All the options above can potentially be used to refine a first-tier risk assessment. However, none of them is considered as the 'preferred' way forward in all cases, and a combination of several options may often be used. Therefore, higher-tier assessments should take the form of a weight-of-evidence approach, in which an overall conclusion on the characterisation of risk is formed, giving appropriate weight to each of the available lines of evidence. In principle, the weights given to different lines of evidence should be proportional to their degree of certainty. If one line of evidence shows with high certainty that effects are (or are not) expected, then this should be given more weight than a more uncertain line of evidence that indicates the possibility of either a positive or negative outcome. A general indication of the degree of uncertainty associated with different types of evidence is shown in Table 21, but this depends critically on the details of the evidence available in each case. Further guidance on evaluating uncertainty for each line of evidence is provided in section 6.8. Guidance on weight-of-evidence approaches for combining lines of evidence is given in section 6.9. The implications of uncertainty for decision-making and risk management are discussed in section 7.1.

**Table 21.** Summary of most important types of uncertainty affecting different types of evidence that may be available in higher-tier assessment of seed treatments. The actual magnitudes of the uncertainties will depend on the quantity and quality of data available in each case.

| Line of evidence | Type of output | Major sources of uncertainty | |
|---|---|---|---|
| | | Dietary exposure | Toxicity |
| First-tier dietary assessment | TER | Realistic for worst-case individual | Focal species can be up to 1 or 2 orders of magnitude more or less sensitive than test sp. |
| Refinement of focal species and PT | Refined TER | More realistic for some individuals but refinement must still take account of variation between individuals | Focal species can be up to 1 or 2 orders of magnitude more or less sensitive than test sp. |
| Availability of non-treated seeds | Refined TER | Increased realism, but relation between availability and intake is very uncertain | Focal species can be up to 1 or 2 orders of magnitude more or less sensitive than test sp. |
| Dehusking | Refined TER | Need to take account that proportion of seeds dehusked varies between individuals and species. | Focal species can be up to 1 or 2 orders of magnitude more or less sensitive than test sp. |
| Foraging area = Estimation of field area containing exposed seeds carrying toxic dose | Area containing $LD_{50}$ (acute) or NOAEL (repro) ($m^2$) | Takes account of seed availability but this is highly variable and may be very uncertain. | Focal species can be up to 1 or 2 orders of magnitude more or less sensitive than test sp. |
| Meal size approach*** | One meal = a % of $LD_{50}$ | Meal size is highly variable and will be very uncertain unless there are extensive data for focal species. | Focal species can be up to 1 or 2 orders of magnitude more or less sensitive than test sp. |
| Metabolism and body burden modelling*** | Peak net dose = a % of $LD_{50}$ | Less important than other sources of uncertainty for this approach. | Focal species can be up to 1 or 2 orders of magnitude more or less sensitive than test sp. |
| Avoidance studies*** | Number of species tested, number showing lethal and subletal effects | Test scenario should be realistic worst case. Proportion of real exposures approaching this is very uncertain. | Focal species can be up to 1 or 2 orders of magnitude more or less sensitive than test sp. |
| Field study*** | Number of sites, number showing evidence of mortality | Species exposed and degree of exposure vary widely between sites. It needs multiple sites to capture this. | Multiple sites reduce uncertainty by representing a wider range of species sensitivity. |
| Data on historical poisoning incidents*** | Numbers of suspected and confirmed incidents | Representative of actual exposures, if data relate to product under assessment. | Representative of actual sensitivities, if data relate to product under assessment. |
| Comparison to a well-studied 'benchmark' example. | Critical comparison of some or all of the lines of evidence listed above. | Uncertainty depends on similarity of dietary scenarios for the two pesticides considered. | Ratio of tested to sensitive species could differ substantially between the two pesticides. An uncertainty factor has to be applied to allow for this. |

* Refined TERs may be compared to the standard first-tier trigger values but the level of protection they achieve will generally be lower than in Tier 1 and should therefore be re-evaluated in every refined assessment (see section 6.8).
** If part of the standard uncertainty factor is considered to address other issues, then only the part relating to between-species variation in toxicity should be used here.
*** These lines of evidence are usually applicable only for assessment of acute risks.

| Major sources of uncertainty | | Overall uncertainty |
|---|---|---|
| Avoidance/metabolism | Uncertainty factor* | |
| Ignored. May reduce risk little or very substantially, depending on pesticide. | 10 (acute)<br>5 (reproductive) | Realistic worst-case individual for non-avoided pesticides. Conservative to very conservative for others. |
| Ignored. May reduce risk little or very substantially, depending on pesticide. | 10 (acute)<br>5 (reproductive) | May underestimate risk for non-avoided pesticides. Probably conservative for others. |
| Ignored. May reduce risk little or very substantially, depending on pesticide. | 10 (acute)<br>5 (reproductive) | High uncertainty. May underestimate risk if animals actually focus on treated seed. |
| Ignored. May reduce risk little or very substantially, depending on pesticide. | 10 (acute)<br>5 (reproductive) | May underestimate risk if overestimate degree of dehusking or its impact on residues. |
| Ignored. May reduce risk little or very substantially, depending on pesticide. | Divide toxicity endpoint by 10 (acute) or 5 (reproductive)** | Uncertainty depends on how incorporation is assessed. In addition, interpretation of result may be very uncertain. |
| Simple way to allow for avoidance. May be conservative if meal size estimate is worst case, and metabolism and recovery are rapid. | Divide toxicity endpoint by 10** | Uncertainty and conservatism depend critically on quality of meal size data and rate of metabolism and recovery. |
| Parameters required by body burden model are usually very uncertain | Use $LD_{50}$/10 or other suitable estimate for toxicity to sensitive species** | Very uncertain unless conservative estimates for most/all inputs give peak dose < $LD_{50}$ |
| Conservative for test species only if test design is worst case. Extrapolation to other species is highly uncertain (see section 6.2). | No uncertainty factor. | Conservative for test species only if test design is worst case. Extrapolation of result to other species is highly uncertain. |
| Multiple sites reduce uncertainty by representing a wider range of species and conditions. | No uncertainty factor. | Low uncertainty if number of sites high. Extrapolation of results from single/few sites is highly uncertain. |
| Representative of actual conditions, if data relate to product under assessment. | No uncertainty factor. | Reliability as measure of visible mortality depends on quality of surveillance scheme. Underestimates total (hidden) mortality. |
| Uncertainty will be high unless comparable data on avoidance and metabolism exist for both pesticides. | Apply uncertainty factor to assessed pesticide but not benchmark to allow for possible difference in relative sensitivity of standard species. | Reliability of comparison depends critically on comparability to benchmark in terms of scenario, avoidance, metabolism, etc. |

## 5.3. Risk assessment for substances with endocrine-disrupting properties in birds and mammals

Annex II, 3.6.5. of (EC) 1107/2009, the new Regulation on pesticides states that "An active substance, safener or synergist shall only be approved if, (…) it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans (…), under realistic proposed conditions of use, is negligible, (…)." 3.8.2. relates to non-target organisms: "An active substance, safener or synergist shall only be approved if, (…) it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible."

Taking this inclusion of cut-off criteria within the new Regulation into account, the risk assessment for endocrine-disrupting properties in birds and mammals might no longer be needed. Before carrying out the RA steps below, notifiers should therefore check the latest state of regulatory practice and discuss with their competent national authority.

In the context of risk assessment for birds and mammals endocrine-disrupting substances can be defined as materials that cause effects on bird and mammal reproduction through disruption of endocrine-mediated processes (see also Appendix 26 of EFSA, 2008). The environmental risk assessment performed under EC, 2002, is based on the ecological relevance of the observed effects, independent of the mode of action that are (or may be) responsible for such effects. Therefore the general procedure for risk assessment can also be used for substances with endocrine-disrupting properties.

**Step 1**

Study the information available from tests performed on other taxa (fish, amphibians, mammals and birds) for the substance under assessment. Information from structurally related substances may also be considered. If the data give rise to concerns of potential endocrine-mediated effects of the substance, then mammalian screening tests should be assessed to clarify the mechanism of action, and/or the potential of the test substance to cause endocrine-mediated effect in birds/mammals (*in vivo*). With regard to mammals, and in contrast to birds, a number of *in vitro* and *in vivo* screening tests for assessing endocrine-disrupting properties have become available in recent years and are in various stages of (pre-) validation (OECD, 2007a; NIEHS, 2002; US EPA, 2005; OECD, 2007b). In order to begin the assessment of endocrine-mediated effects in mammals and birds, further specific steps to be followed are given below.

**Step 2**

Study the information available from mammalian screening studies to clarify any potential of the substance to influence known endocrine mechanisms. In case (*in vitro*) screening studies in mammals show that the substance has an effect on a known endocrine mechanism, further assessment is needed to allow for the evaluation or generation of data relevant to risk assessment. The mammalian multi-generation study, performed for pesticide risk assessment, covers the entire reproductive cycle and therefore is able to provide information on overall productivity at the population level. In addition to mammalian screens, fish and amphibian screens exist that can address the question of the likelihood of a material to be an endocrine disruptor, as well as its probable mode of action (OECD, 2005; OECD, 2007c). This information should also be taken into account for the assessment as further weight of evidence. In cases where screens are 'positive', or where no screens are available but concerns for potential endocrine-mediated effects remain, Step 3 should be taken.

**Step 3**

Assess the standard (multi-generation) mammalian reproductive study or any available relevant mammalian *in vivo* study for potential endocrine-mediated effects on reproduction. Derive an endpoint value for these effects to be used in risk assessment for wild mammals.

Mammals and birds have similar hormones, hormone receptors and fundamental feedback mechanisms. However, one important difference between mammals and birds lies in the mechanism of sex differentiation. Both testosterone and estradiol, in appropriate relative concentrations, are required for reproductive development in birds (Ottinger and Abdelnabi, 1997; Ottinger et al., 2001). In the absence of estrogens the development is masculine. In mammals, however, embryos require sufficient levels of androgens to induce gonadal differentiation into testicular tissue. There are further important differences between birds and mammals regarding hormonal systems existing. Hence, if mammalian screening tests reveal the potential of a substance to influence endocrine processes, the absence of endocrine-mediated effects in mammalian *in vivo* studies is not sufficient to conclude a risk assessment on birds. It is not possible to use the endpoints from a mammalian risk assessment in an avian assessment. Such endpoints can only be used as a source of information.

**Step 4**

Asses all information available from the standard one-generation avian reproduction study or a specific modified one-generation study modified to include endocrine endpoints. The information provided may help in determining an appropriate strategy for further testing but will, in general, not provide conclusive information on endocrine-mediated effects. This is partly due to the fact that the one-generation avian reproduction study does not include exposure during all relevant stages of the bird's development or the measurement of other relevant endocrine-sensitive endpoints such as behaviour (e.g. parental care, nesting behaviour, territoriality and mounting behaviour). Currently, no internationally accepted testing methodology is available, that can be used to adequately assess the impact of endocrine meditated effects of a substance on the reproduction of birds.

A test design aimed specifically at the evaluation of endocrine effects that is currently under discussion in an OECD process is a two-generation study with Japanese quail (OECD, 2006a). While the ultimate objective of the test is still to be determined, the most likely objective of the study is to characterise dose-response relationships with subsequent conclusion on immediate and more long-term adverse consequences associated with exposure to potential endocrine-disrupting substances. In addition to the avian two-generation test, more targeted and smaller tests (e.g. partial life cycle or critical life-stage tests) may be developed in the future. Such tests should allow the evaluation of the impact of potential endocrine-disrupting substances on a specific portion of the avian life cycle and its associated endpoints. Smaller tests that focus on specific endpoints (including behaviour) may be more sensitive in evaluating the potential endocrine effect of a substance than a two-generation study, since the range of concentrations can be focussed around a specific endpoint. Individual studies of this nature have been performed (OECD, 2006a), but no test protocols have been developed to date.

**Step 5**

Assess any specific two-generation or sensitive life stage study in birds for endocrine-mediated endpoints. When assessing/selecting the appropriate test design and the appropriate endpoints, it is essential to evaluate all the available information on avian and/or other species. If available information allows, the likely mode of action and the part of the avian life-cycle likely to be the most sensitive (with associated behaviours) should be identified. Subsequently, an appropriate test design should be selected. There is no single test design that should automatically be followed. In addition, only those techniques should be applied that have been developed sufficiently to assess the various endpoints. While extensive work has been performed on a number of potentially relevant endpoints (OECD, 2006a; OECD, 2006b) there is still a substantial amount of development and validation work required. Hence, in using end-points from such studies in avian risk assessment the uncertainty related to the fact that they are currently in a research stage and therefore lack validation should be taken into consideration as a source of uncertainty when interpreting the assessment outcome.

## 5.4. Assessment of the risk from metabolites formed in potential food items

The primary focus of this document is to provide a framework on how to assess the risk of active substances to birds and mammals. It is, however, important to ensure that the risk from any metabolite(s) is also fully addressed. Birds and mammals can be exposed to metabolites that are formed in plants, fish and other birds or mammals that are consumed. Metabolites can also occur in soil which, in turn, can occur in soil organisms (e.g. earthworms) that are also eaten. Outlined below is a procedure that should be followed to ensure that the risk from metabolites in potential items of avian or mammalian food is assessed.

**Step 1**

Determine the metabolites present in plants, fish, other birds or mammals and other relevant food items that may be consumed by the relevant focal species.

**Step 2**

In order to assess the risk to **mammals**, it is necessary to refer to the evaluation of the mammalian toxicology data package. Information from studies on the metabolism of the active substance by the rat (or goat) will indicate whether the metabolite of concern occurs in mammals. If the metabolite of concern does occur at significant levels in a rat metabolism study then its toxicity may have been addressed as part of the assessment of the active substance. One important point to note is that the metabolite may occur at much higher levels, or proportions, in the plant or food item than in the rat or goat. If this is the case, care must be exercised, since the assumption that its presence in rats sufficiently addresses the risk may result in underestimation of the risk. This is illustrated by a substance that is formed in low levels in rats, however is formed in high levels in plants. Assuming that the risk is addressed by the metabolism study may underestimate the risk. In such a situation Step 3 should be taken. However, if the metabolite is adequately addressed in the mammalian toxicity data package, then still the risk to birds must be assessed (see Step 4).

**Step 3**

If the metabolite occurs at much higher levels, or proportions, in the plant or food item than in the rat, the availability of an acute rat or mouse study on the metabolite in the mammalian toxicology data package should be checked. Before requesting such a study, if it is not at hand, a reassessment of the amount of metabolite formed and the risk from the parent substance is required. This assessment should include an indication of how much more toxic the metabolite would need to be to raise concerns, i.e. to produce an acute TER of < 10.

**Step 4**

For **birds**, a similar approach to that outlined in Steps 1-3 for mammals should be used. The hen metabolism study should be consulted and the same approach as outlined above should be used. If a hen metabolism study is not available, it is recommended to consult the rat or goat metabolism studies. If the metabolite is detected in the study, then this may be sufficient for the assessment, depending upon the toxicity of the parent substance, the risk posed and the likely metabolic pathway, i.e. if the metabolite is likely to be formed in birds as well. These factors should be evaluated by a weight-of-evidence approach (see section 6.8).

Occasionally, there may be a soil or plant metabolite that does not occur at all or not at significant levels in either bird or mammal metabolism studies. This means that the potential effects have not been assessed in studies using the active substance. Birds and mammals may, however, be exposed to this metabolite when consuming plants or organisms containing soil. In this situation it is necessary to assess the risk in the following ways:

- Carry out a quantitative structure-activity relationship (QSAR) assessment although there are no 'off the shelf' QSAR or structure-activity relationships (SAR) for pesticide metabolites. However, this should not preclude their use. When using a QSAR or SAR, it is necessary to ensure that the model is appropriate for the key chemical structures of the metabolite, i.e. that substances of the type being assessed have been included in the original training set. If not, this will cause much uncertainty regarding the output. One QSAR that was designed to model pesticide toxicity and might be useful for metabolites is the DEMETRA model.[51]
- Carry out an SAR assessment. If the toxiphore is no longer present in the metabolite, this may indicate that the metabolite is of lower toxicity. However, it should be noted that a toxiphore to one organism (the target pest) may not be a toxiphore to another. Therefore, this approach should be justified, e.g. with reference to similar active substances with similar metabolic pathways, etc.
- Carry out an avian toxicity study on the metabolite. This should only be used for those metabolites that pose a potential high risk and where it is not possible to address this risk by other means.

## 5.5. Risks for birds and mammals through drinking water

Exposure of birds or mammals via drinking water is not explicitly included in the DDD calculations of the dietary risk assessment. Therefore, an approach is presented that allows estimating the possible risk arising from uptake of contaminated drinking water for two basic scenarios. Due to the incidental nature of occurrence of drinking water reservoirs on agricultural fields (as compared to the contamination of food items growing or dwelling on those fields), a separate assessment of this exposure route is considered appropriate at least on the first-tier level.

Most birds and mammals can in principle satisfy (at least parts of) their daily water demand via uptake of food. However, this potential depends on the water content of the diet items, which is lowest for seeds. Therefore, the assessment methodology for the risk to birds and mammals of pesticides in drinking water as provided below uses small granivorous animals as indicator species at Tier 1.

The two scenarios covered by the assessment both refer to small and smallest water reservoirs, namely pools in leaf whorls and puddles on soil (see Step 1 for the selection of scenarios and Step 2 for calculating exposure concentrations in water). Experience has shown that uptake of drinking water from larger water bodies is unlikely to pose a relevant risk. Uptake of drinking water by animals is estimated using allometric equations (Step 3). For situations where the calculated TER values suggest a risk, options for refinement and/or management are provided (Step 4). For further details see Appendix K.

51 Details of this can be found at http://www.demetra-tox.net/index.php?option=com_frontpage&Itemid=1.

**Step 1**

**Selection of relevant scenarios.** Two scenarios were identified as relevant for assessing the risk of pesticides via drinking water to birds and mammals:

- **Leaf scenario.** Birds taking water that is collected in leaf whorls after application of a pesticide to a crop and subsequent rainfall or irrigation.
- **Puddle scenario.** Birds and mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil.

A leaf scenario is clearly the worst-case situation. It is relevant for spray applications only and should be considered for the following crop types and growth stages:

- Leaf vegetables (forming heads) at principal growth stage 4 until harvest (classification according to BBCH[52]).
- Other leaf vegetables (e.g. cauliflower) at principal growth stage 4 or later, with a morphology that facilitates collection of rain/irrigation water in reservoirs that are large enough and easily accessible to attract birds and sufficiently stable over some hours.

A leaf scenario is not deemed relevant for small mammals. The equations for calculating exposure concentrations can be found under Step 2a. A leaf scenario is only deemed to be relevant for acute risk assessment. This is due to the fact that such pools in whorls are not likely to be formed very frequently in a field, since they require a specific combination of leaf morphology, weather conditions, formulation type and water volumes. Also a puddle scenario reflects events that may or may not occur on a single agricultural field, unlike the contamination of potential food items growing or dwelling on the fields. It is, however, likely to be more common than a leaf scenario and puddles may remain present in fields for longer periods of time. Therefore a puddle scenario is also recommended to be used in a first-tier approach towards the assessment of any risk to reproduction of birds and mammals. The lower probability of exposure on a population-relevant level as compared to dietary exposure may be considered when estimating overall uncertainties in the course of a refined risk assessment.

A puddle scenario, on the other hand, is relevant for all types of application that may cause contamination of soil. This also includes non-foliar applications of pesticides. If necessary, a puddle scenario may further be applied for a risk assessment for metabolites and degradation products, according to their toxic potential. The equations for calculating exposure concentrations can be found under Step 2b.

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**Step 2a**

**Calculation of exposure concentrations for a leaf scenario.** A leaf scenario assumes a situation in which rainfall or irrigation occurs shortly after the application event. Based on measurements conducted at the sites of incidents, it was concluded that the worst-case concentration in water would correspond to the concentration in the spray solution (i.e. the product already diluted in the required amount of water) diluted by a factor of 5 (Hommes et al., 1990).

$$PEC_{pool} = \frac{C_{spray}}{5}$$

**Step 2b**

**Calculation of exposure concentrations for a puddle scenario.** To obtain an estimate for pesticide concentrations in puddles formed on a field after rainfall (predicted environmental concentration, $PEC_{puddle}$), it may be assumed that this concentration would be the same as the concentration in runoff water as calculated for the assessment of surface water exposure. Taking into account a relevant subset of parameters from FOCUS[53] surface water modelling (FOCUS, 2003), a simplified model can be proposed to calculate $PEC_{puddle}$ in mg/L as a function of application rate and the organic carbon adsorption coefficient ($K_{OC}$) of a substance. Provided that the full application rate is considered, this approach assumes application to bare soil without degradation and thus reflects a worst case for crop-directed applications. Where appropriate, crop interception may be considered in the same way as for calculation of $PEC_{soil}$, $PEC_{gw}$ and $PEC_{sw}$, in order to increase realism.

$$PEC_{puddle} = \frac{AR/10}{1000(w + Koc \times s)}$$

With:

AR = application rate [g/ha]; divisor of 10 to achieve rate in mg/m$^2$

*w* = 0.02 (pore water term: volume)

*s* = 0.0015 (soil term: volume, density, organic carbon content)

When multiple spray applications are considered, a MAF based on the $DT_{50}$ in soil (single first order kinetics, geometric mean as used for $PEC_{gw}$ and $PEC_{sw}$) may be applied to achieve the effective application rate $AR_{eff}$.

$$AR_{eff} = AR \times MAF_m = AR \times \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

With:

*k* = $\ln(2)/DT_{50}$ (rate constant)

*n* = number of applications

*i* = application interval (d)

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals (see below), no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

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**Step 3**

**Drinking water uptake by birds and mammals and calculation of TER values.** The respective calculations for birds and mammals are performed on a level of generic focal species, i.e. basic ecological traits already form part of the considerations. According to the relatively low water content of their diet, granivorous species will face the greatest necessity to satisfy their daily water demand by additional uptake of drinking water. In line with the proposals made for dietary exposure, the following generic species should be considered for estimating the uptake of drinking water:

- Small granivorous bird (bw = 15.3 g)
- Small granivorous mammal (bw = 21.7 g)

For birds, drinking water rates (DWR) as published by DEFRA (2007) should be used. They are based an allometric equations for total water flux (WF) in different categories of birds and on data on the contribution of other sources on birds' water balance. For mammals, no DWRs are included in the report by DEFRA (2007), but it is possible to use the data on water flux from Nagy and Peterson (1988) and calculate DWR in the same way as for birds.

- Small granivorous bird
  $\log_{10}(WF) = -0.195 + 1.003 \times \log_{10}(bw)$ for passerines
  linnet: WF = 9.8 mL/d; DWR = WF – (food water + metabolic water) = 7.0 mL/d,
  equivalent to 0.46 L/kg bw/d
- Small granivorous mammal
  $\log_{10}(WF) = -0.110 + 0.734 \times \log_{10}(bw)$ for non-desert species
  wood mouse: WF = 7.4 mL/d; DWR = WF – (food water + metabolic water) = 5.1 mL/d,
  equivalent to 0.24 L/kg bw/d

TER values are calculated by division of the relevant ecotoxicological endpoint (leaf scenario: acute; puddle scenario: acute and reproduction) by the product of $PEC_{pool}$ or $PEC_{puddle}$, in summary termed $PEC_{dw}$ and the DWR related to bodyweight. It is suggested that the same acceptability criteria should apply as for the dietary risk assessment.

**Step 4**

**Options for refinement or management**

*Leaf scenario*

As regards calculated TER values, the leaf scenario obviously constitutes an extreme worst-case scenario. It can be shown that even active substances of moderate to low toxicity ($LD_{50}$ > 1000 mg/kg) will often fail this scenario. However, incidents reported in the pasts confirm that in fact a potential for adverse effects exists that may be realised when several conditions (application of pesticides followed by rainfall or irrigation in a period of relative drought) are simultaneously met. In such cases, typical approaches for refining the risk assessment, e.g. the estimation of a PT factor, are not possible, because birds will be attracted by the water source in a way that is not observed under more regular conditions. As a consequence, a risk identified in a leaf scenario will typically have to be managed.

In Germany, where incidents corresponding to this scenario did occur in the 1980s, risk mitigation options were studied. Specific label statements exist that both warn the user that a product is hazardous for birds, and provide measures to mitigate the risk:

- Apply only at early stages of crop development;
- Provide bird netting on the crop after application;
- Avoid sprinkling/irrigation of the crop until one day after application.

The puddle scenario should be considered for assessments where the leaf scenario is not relevant, e.g.:

- Mammals (all crops);
- Application on cereals and grasses for birds;
- Applications where the morphology of the crop at the time of application makes it unlikely for pools in whorls to be formed (e.g. early stages); and
- Non foliar applications.

A puddle scenario should also be applied if the risk with regard to a leaf scenario is managed by measures that would not prevent animals from drinking from contaminated puddles on soil.

*Puddle scenario*

Refinements to the exposure part of this scenario can be made by using runoff concentrations directly from relevant FOCUS step 3 scenarios. This would address degradation of the active substance in a dry period after application according to FOCUS weather data. Due to the incidental nature of puddle occurrence on agricultural fields, the potential for refinement of the assessment using the 'ecological parameters' for indicator/focal species (PT) is deemed very limited.

## 5.6. Bioaccumulation and food chain behaviour

Bioconcentration is defined as the net result of the uptake, distribution and elimination of a substance in an organism due to waterborne exposure, whereas bioaccumulation includes all routes, i.e. air, water, soil and food (EC, 2003). Bioaccumulation often correlates with lipophilicity, thus, for organic chemicals, a log $K_{ow} \geq 3$ indicates a potential for bioaccumulation. If this condition is met, the three issues described below (a-c) should be considered. As bioaccumulation processes often are slow and substances may be persistent, a long-term assessment is appropriate. Relevant metabolites must also be considered. For background information with regard to food chain modelling see Romijn et al. (1993, 1994), Traas et al. (1996), Jongbloed et al. (1996) and Luttik (2003).

### a) Food chain from earthworm to earthworm-eating birds and mammals

For the food chain 'earthworm to earthworm-eating birds and mammals' two different approaches are presented. The first is the same as in EC (2002) based on dry soil concentrations (see Steps 1a-5a below). The PPR Panel concluded in 2009 that for soft bodied soil organisms (earthworms, enchytraeids, nematodes) and plants in close contact with the soil solution, pore water mediated uptake of pesticides seems mainly responsible for the effects caused, and would therefore be the relevant metric for effects assessment, and consequently also for exposure assessment (EFSA, 2009). The second approach is based on pore water concentrations and includes the gut content of the earthworms (see Steps 1b-5b below). The inclusion of the gut content of worms is particularly of importance for soils with > 1 % organic matter. This approach is equivalent to the approach taken in the Technical GD for existing chemicals (EC, 2003).

#### *Dry soil approach*

#### Step 1a

Select a predicted environmental concentration for dry soil ($PEC_{soil}$ with an appropriate TWA according to the reproductive assessment) from the environmental fate section.

#### Step 2a

Calculate the bioconcentration factor for the earthworm ($BCF_{earthworm}$):

$$BCF_{earthworm} = \frac{0.84 + 0.012K_{OW}}{f_{OC} \times K_{OC}}$$

With:

$K_{oc}$ = Organic carbon adsorption coefficient

$f_{oc}$ = Organic carbon content of soil (take 0.02 as a default value)

The equation originates from works of Jager (1998). There, the bioconcentration[54] factor for the earthworm ($BCF_{earthworm}$) is defined as concentration in earthworm related to fresh weight to concentration in soil related to dry weight ($PEC_{worm\ fresh\ weight}/C_{soil\ dry\ weight}$). The model is empirically based on non-ionised, organic chemicals in the log $K_{ow}$-range from 1 to 8, and it should not be applied to other types of substances or highly reactive substances. If modelling seems inappropriate it may be necessary to determine bioconcentration factors experimentally.

**Step 3a**

Estimate residues in earthworms:

$$PEC_{earthworm} = PEC_{soil} \times BCF_{earthworm}$$

**Step 4a**

Convert residue ($PEC_{worm}$) to daily dose by multiplying with 1.28 (mammals) and 1.05 (birds) respectively, and compare with relevant long-term NOAEL. Multiplicators are based on a 10-g mammal eating 12.8 g worms (fresh) per day, and a 100-g bird eating 104.6 g per day, according to Smit (2005) (see Appendix L).

**Step 5a**

Compare the toxicity-exposure ratio to the respective trigger value:

| | |
|---|---|
| **TER > 5** | **No further refinement required.** |
| **TER < 5** | **Further refinement required (see section 6).** |

In addition to the refinement options in section 6, another option would be to carry out a BCF study with earthworms rather than to rely on the QSAR approach used at the Tier 1.

Further, rather than assuming equilibrium and calculating BCF values, another option is the modelling of the internal body burden of earthworms by using information on uptake and elimination kinetics in earthworms as well as information on dissipation kinetics in soil.

***Pore water approach***
(method equivalent to EC, 2003)

**Step 1b**

Select a pore water concentration ($C_{porewater}$ with an appropriate TWA according to the reproductive assessment) from the environmental fate section.

**Step 2b**

Calculate the bioconcentration factor for the earthworm ($BCF_{earthworm}$) related to porewater:

$$BCF_{earthworm} = \frac{(0.84 + 0.012 \cdot K_{OW})}{RHO_{earthworm}}$$

Where for $RHO_{earthworm}$ by default a value of 1 [$kg_{wwt} \times L^{-1}$] can be assumed (Jager, 1998).

54 Process leading to a higher concentration of a substance in an organism than in environmental media to which it is exposed. (http://sis.nlm.nih.gov/enviro/iupacglossary/glossaryb.html#bioconcentration)

**Step 3b**

Calculate the concentration in earthworms:

$$C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut} \times CONV_{soil}}{1 + F_{gut} \times CONV_{soil}}$$

Where:

$$CONV_{soil} = \frac{RHO_{soil}}{F_{solid} \times RHO_{solid}}$$

With:

| | | |
|---|---|---|
| $CONV_{soil}$ | conversion factor for soil concentration wet-dry weight soil | [$kg_{wwt}$ $kg_{dwt}^{-1}$] |
| $F_{solid}$ | volume fraction of solids in soil | [$m^3$ $m^{-3}$] |
| $F_{gut}$ | fraction of gut loading in worm | [$kg_{dwt}$ $kg_{wwt}^{-1}$] |
| $RHO_{soil}$ | bulk density of wet soil | [$kg_{wwt}$ $m^{-3}$] |
| $RHO_{solid}$ | density of solid phase | [$kg_{dwt}$ $m^{-3}$] |

**Step 4b**

Convert residue ($C_{earthworm}$) to daily dose by multiplying with 1.28 (mammals) and 1.05 (birds) respectively, and compare with relevant long-term NOAEL. Multiplicators are based on a 10-g mammal, eating 12.8 g worms (fresh) per day, and a 100-g bird, eating 104.6 g per day, according to Smit (2005) (see Appendix L).

**Step 5b**

Compare the toxicity-exposure ratio to the respective trigger value:

| | |
|---|---|
| **TER > 5** | **No further refinement required.** |
| **TER < 5** | **Further refinement required (see section 6).** |

In addition to the refinement options in section 6, another option would be to carry out a BCF study with earthworms rather than to rely on the QSAR approach used at the Tier 1.

Further, rather than assuming equilibrium and calculating BCF values, another option is the modelling of the internal body burden of earthworms by using information on uptake and elimination kinetics in earthworms as well as information on dissipation kinetics in soil.

**b) Food chain from fish to fish-eating birds and mammals**

A simple worst-case assessment can be conducted according to the following steps:

**Step 1**

Take the highest $PEC_{water}$ based on the regulatory acceptable concentration ($RAC^{55}$) from the environmental fate section and multiply this value with an appropriate TWA value according to the reproductive assessment.

**Step 2**

Take the whole-body $BCF_{fish}$ from the aquatic section.

**Step 3**

Estimate residues in fish:

$$PEC_{fish} = PEC_{water} \times TWA \times BCF$$

**Step 4**

Convert residue ($PEC_{fish}$) to daily dose by multiplying with 0.142 (mammals) and 0.159 (birds) respectively, and compare with the relevant long-term NOAEL. Multiplicators are based on a 3000-g mammal, eating 425 g fresh fish per day, and a 1000-g bird, eating 159 g per day, according to Smit (2005) (see Appendix L).

**Step 5**

Compare the toxicity-exposure ratio to the respective trigger value:

| | |
|---|---|
| **TER > 5** | **No further refinement required.** |
| **TER < 5** | **Further refinement required (see section 6).** |

In addition to the refinement options in section 6, and rather than assuming equilibrium and calculating BCF values, another option is the modelling of the internal body burden of fish using information on uptake and elimination kinetics in fish as well as information on dissipation kinetics in water.

55 It might be impractical to have to wait for the RAC to be determined in the aquatic ecotoxicology section; instead the highest relevant PEC for bioaccumulation could be used. The RAC could be used as a refinement option.

### c) Biomagnification in terrestrial food chains

Substances that have a potential for biomagnification, i.e. the whole-body residue in an animal at steady state is higher than the residue in its food (biomagnification factor BAF > 1)[56], are of concern for terrestrial food chains. For substances with such a property, exposure may increase along the food chain, and top predators are particularly at risk. In Annex VI of Directive 91/414/EEC a trigger value of 1 is provided for the BAF (not quite correctly termed 'BCF') which is specified as related to fat tissue. This trigger implies some degree of precaution since, when exposed to lipophilic organic chemicals the whole body residue is lower than the residue in fat tissue. The following step-wise approach is proposed:

**Step 1**

Obtain the information from the toxicology section on the ADME studies and from the residue section on the metabolism studies with livestock. A brief conclusion from these assessments with regard to bioaccumulation is reported in the list of endpoints. If the bioaccumulation potential is stated as being low then, no further assessment is required. If this is not the case, Step 2 has to be followed.

**Step 2**

Estimate the food-to-organism bioaccumulation factor according to the following equation:

$$BAF_{organisms,\ food} = \frac{\alpha \times FIR}{k_2}$$

With

| | |
|---|---|
| $\alpha$ = | Fraction of ingested dose that is absorbed; available from toxicokinetic studies |
| $k_2 = \ln(2)/T_{½}$ | Rate constant for depuration; should also be available from toxicokinetic studies ($T_{½}$ = elimination half-life) |
| *FIR* = | Food intake rate relative to body weight. |

**Step 3**

With the information provided in Appendix G, the FIR/bw can be calculated for any carnivorous or insectivorous species of concern.

**Step 4**

If the BAF according to this calculation is clearly below 1, no further assessment is required. If it is higher, possibilities for conducting a detailed food chain modelling as described in Appendix S should be considered.

56 See also IUPAC-definition: http://sis.nlm.nih.gov/enviro/iupacglossary/glossarya.html

# 6. Higher tier risk assessment – refinement steps

A higher-tier assessment is required when the results of assessments at lower tiers breach the relevant trigger values (e.g. TER < 10 for acute risks, 5 for reproductive risks[57]). The general aim of higher-tier assessment is defined by the 'unless' clause in point 2.5.2.1 of Annex VI of Directive 91/414/EEC. There it states that "no authorisation shall be granted … unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product under the proposed conditions of use."

The definition of 'unacceptable impacts' is discussed in detail in Appendix C. It indicates that unacceptable impacts include 'long-term repercussions for abundance and diversity of non-target species' and 'visible mortality'. The term 'clearly established' is not defined, but suggests that a high level of certainty is required. However, as discussed in Appendix C, it is not practical to assess these protection goals directly in first-tier assessments. Therefore this Guidance Document has defined a surrogate protection goal for use in first-tier assessments. The actual and surrogate protection goals are defined as follows:

- The actual protection goal is to provide a high certainty that no visible mortality and no long-term repercussions on abundance and diversity will occur.
- The surrogate protection goal is to make any mortality or reproductive effects unlikely.

The surrogate protection goal is more conservative than the actual protection goal, but the actual protection goal is impractical[58] to assess at Tier 1.

In higher-tier assessments, either protection goal can be used. It may be possible to show by refined assessment that the surrogate protection goal can be satisfied. However, if this is not possible then it would be necessary to address the actual protection goal directly. This could be done by assessing for example the percentage of mortality and the likelihood that it would be 'visible', or the probability of long-term repercussions for abundance and diversity. However, higher-tier assessments may also be based on the more conservative surrogate protection goal, if that is a more practical option for the case under assessment (e.g. a refined TER calculation, see section 6.1.).

A key first step before commencing any refined assessment is to define the objectives and scope for the case under consideration. This includes the types of effects (acute or reproductive) and scenarios to be considered and should be guided by the results of the first-tier assessments. It may be efficient to start by focussing on those scenarios which gave the worst (i.e. highest risk) results in the first-tier assessment. However, if refined assessment shows the risk for those scenarios to be acceptable, it may be necessary to conduct additional refined assessments for all other scenarios which breach the first-tier trigger values, unless it can be justified that the refined assessment can be extrapolated between scenarios.

In the following sections, specific options for higher-tier assessment are described in more detail. They are summarised in Table 22, with an indication of their possible contribution and some of the issues to consider when choosing between them.

57 Or alternative triggers if new ones are adopted.

58 Visible mortality doesn't relate to any particular percentage of mortality, which could be predicted. Likewise, long-term population impacts require refined assessments and cannot be done at Tier 1 (see Appendix C).

There are no general rules for choosing which option(s) to adopt for refined assessment. However, it may be helpful to consider the following factors, together with any others which appear relevant:

- The degree by which the lower tier trigger values were breached. Stronger evidence is likely to be required if the triggers were breached by a large margin. This is especially true for assessment of acute risks from sprayed pesticides, as the field study analysis implies a rather strong expectation of mortality for pesticides which fail Tier 1 by more than a small margin (see Figure 4 in Appendix C). Removing this expectation would require correspondingly strong evidence in the higher-tier assessment.
- The general potential of each option to reduce the estimate of risk, and/or reduce uncertainty. Refinements of dietary exposure assessment may provide only limited benefit, but this may be sufficient if the first-tier triggers were not breached by a large margin. Field studies are much more effective for reducing uncertainty, but also more costly. Population modelling has the advantage of addressing long-term repercussions directly, but this may be outweighed by uncertainty about the extra parameters that have to be estimated.
- Indications from first-tier studies, e.g. indications of strong avoidance, rapid metabolism or rapid degradation may indicate that these would be fruitful targets for refinement.
- The availability and relevance of existing data, and the cost and practicality of generating new data.
- Ethical and policy preferences for minimising animal testing.

It might also be advisable to consult with the relevant authorities before finalising the choice of refinement options.

Since the variation in toxicity between species is one of the largest sources of uncertainty affecting risk assessment, it is a general issue that may influence the choice of refinement method. There is up to one or two orders of magnitude variation in acute $LD_{50}$ between the most and least sensitive bird species (Luttik and Aldenberg, 1997; also see Figure 1 in Appendix C). This implies up to one or two orders of magnitude uncertainty in estimating the $LD_{50}$ for the focal species[59], and therefore up to one or two orders of uncertainty in those refinement options that involve modelling effects on a focal species (including refined TERs and body burden modelling). It also implies up to one or two orders of magnitude uncertainty in the relation between any species chosen for testing and the species actually exposed in the field. This, in turn, implies at least[60] one or two orders of magnitude uncertainty in extrapolating from higher-tier studies with captive animals (e.g. avoidance studies and pen studies) to species actually exposed in the field. It also implies up to one or two orders of magnitude uncertainty when extrapolating from a single field study site to other study sites where different species may be present. The only refinement options that avoid this problem are wildlife incident data (which underestimate risk for other reasons, see section 6.5) and field studies with multiple sites in a sufficient diversity of conditions to encounter a representative range of species. This does not mean that field studies on multiple sites are the best option, because simpler or less costly options may be sufficient in many cases, but it does make it essential to take careful account of uncertainty about toxicity when using other options.

Regardless of the choice of options for the refinement of the assessment, it should be noted that, they are not sufficient on their own but should be considered as inputs to the final steps of risk characterisation and decision-making. Because there is often more than one line of evidence for characterising the risk, this will often require a weight-of-evidence approach. Practical approaches for risk characterisation and weight-of-evidence assessment are discussed in section 6.9. It is emphasised that weight-of-evidence assessment is not itself a method of refined assessment, nor is it a substitute for refinement options such as those listed in Table 22. Instead, it is an approach for weighing and combining the results of first-tier and refined assessments to form an overall characterisation of risk, as described in section 6.9. Guidance on risk management considerations in decision-making is included in section 7.1.

59 This uncertainty is progressively reduced when LD50s are available for more than one species.

60 This will be increased by additional sources of uncertainty such as lab to field differences in exposure patterns and sensitivity.

**Table 22.** Overview of options for higher-tier assessment. (Continued on next page.)

| Refinement option | Possible objectives | Issues to consider | Section |
|---|---|---|---|
| Refined model of exposure for dietary route | Demonstrate that effects due to dietary exposure will not exceed an unacceptable level | • Addresses only dietary exposure (unless combined with estimation of other routes, see below)<br>• Does not remove high uncertainty due to variation in toxicity between tested and focal species<br>• Is difficult to interpret level of impact (e.g. mortality or population effects) implied by TER<br>• Is difficult to assess level of protection without probabilistic calculations (comparison of refined TER with lower tier trigger value is not valid). | 6.1 |
| Modelling non-dietary routes of exposure | Demonstrate that non-dietary routes are negligible, or estimate their contribution | • Equations exist for approximate estimates of drinking water intake and inhalation<br>• Equations also exist for dermal exposure but require estimation of contact areas and transfer rates that will vary with species and habitat and would be very uncertain to estimate<br>• High uncertainty estimating effects, due to variation in toxicity between tested and focal species. | 5.5 (dw only) |
| Specialised avoidance/ repellency studies with captive birds | Demonstrate that avoidance is sufficiently strong to ensure that lethal effects will not exceed an acceptable level | • Only addresses dietary route of exposure<br>• Need to ensure test species is among the most sensitive for this pesticide (generally not known), or test at elevated concentrations to simulate situation for more sensitive species (which could introduce other factors, e.g. taste repellency not present at normal concentrations)<br>• Need to ensure initial feeding rate is close to maximal not just for test species but also other sensitive species<br>• Need to assume that the effect of other relevant factors, e.g. avoidance threshold and delay time, uptake, metabolism (EFSA, 2005a), is the same in untested species. | 6.2 |
| Body burden modelling | Demonstrate that the ADME characteristics of the pesticide will prevent an unacceptable level of effects | • Can address all exposure routes IF non-dietary uptakes can be modelled with sufficient certainty<br>• Extrapolation of avoidance threshold and lethal dose between species is highly uncertain<br>• Estimates of ADME parameters have substantial uncertainty even for tested species (EFSA, 2005a)<br>• Almost no knowledge of how ADME parameters vary between species and whether they do so in a correlated way. | 6.3 |
| Field studies | Demonstrate that effects occur on acceptable proportion of occasions, or that the number of individuals and species affected is acceptable | • Addresses all routes of exposure<br>• Need sufficient number and size of sites, and sufficient variety of ecological conditions, to ensure opportunity for sensitive species to be present and to be exposed in a representative range of conditions, and to give adequate statistical power to detect effects and/or quantify their frequency. | 6.4 |
| Semi-field studies (pen studies) | Demonstrate that under realistic exposure conditions, effects will not exceed an acceptable level | • Potentially addresses all exposure routes, if appropriately designed<br>• Captive animals are confined to the treated area, so this aspect of exposure is conservative<br>• Other aspects of exposure and effects may be unconservative (tend to underestimate risk):<br>  • Energy expenditure and hence food intake and exposure are reduced<br>  • The rate of feeding is unlikely to approach levels achieved by free-living animals, unless conditions are manipulated to achieve this (e.g. restriction of feeding time)<br>  • There is no way to ensure that the study species is more sensitive (has a lower $LD_{50}$) than other species exposed in the wild<br>• Level of protection achieved is very uncertain, could be either conservative or very unconservative. | 6.4.5 |

| Refinement option | Possible objectives | Issues to consider | Section |
|---|---|---|---|
| Data on wildlife incidents | Demonstrate that acute mortality occurs at least under some circumstances | • Reported incidents may be a very small fraction of those that occur, so absence of reported incidents does not imply no occurrence. | 6.5 |
| Population modelling | Demonstrate acceptably low risk of long-term repercussions for abundance and diversity | • Can provide quantitative estimates of long-term repercussions for abundance and diversity, the measure of population impact specified in Annex VI of Directive 91/414/EEC.<br>• Relatively complex methodology requiring specialist population modelling expertise.<br>• No guidance or officially-accepted methods for use in pesticide registration, so studies have to be produced and evaluated case-by-case.<br>• Requires data on population parameters which may be difficult to obtain or very uncertain.<br>• Requires estimates of impact on individuals as input, so uncertainty of these will also be included.<br>• Overall uncertainty in estimated population impacts likely to be very uncertain. | 6.7 |
| Refinements of phase-specific reproductive assessment | Demonstrate reduction in estimated risk when account is taken of relative timing of reproduction and pesticide applications | • Avoids highly conservative and unrealistic first-tier assumption that reproduction always coincides with period of maximum exposure.<br>• Addresses only dietary exposure (unless combined with estimation of other routes, see above).<br>• Does not remove high uncertainty due to variation in toxicity between tested and focal species. | 6.7 and App. 16 |
| Additional toxicity studies | Reduce uncertainty about the distribution of toxicity between species, e.g. to justify reduction of uncertainty factors | • Although this reduces one of the most important sources of uncertainty, it has been discouraged for policy reasons, to minimise animal testing.<br>• Even when more species are tested, there is still substantial uncertainty in estimating the $LD_{50}$ for any particular untested species (i.e. a focal species).<br>• No established guidance on how to reduce uncertainty factors when more species are tested. | 2.3 |
| Additional toxicity study on the identified critical life stage | Addresses the major concern highlighted in lower tier assessment, and generates more appropriate end-points for that phase | • Avoids the mismatch between the length of exposure in the study (e.g. 22 weeks for bird report study) and the length of the exposure estimate (1 or 21 day) in the risk assessment.<br>• Difficult to decide as to how long the birds/mammals should be dosed before the sensitive stage is reached (in case of accumulating substances).<br>• Subject to the normal uncertainty about extrapolation of toxicity between species. | 4.3, 4.4 |

## 6.1. Refined modelling of dietary exposure and risk

Under the former Guidance Document (EC, 2002), the most commonly used option for higher-tier assessment of both acute and reproductive risks was refinement of the worst-case dietary exposure model, replacing the default values with others that were considered more realistic, e.g. replacing PT (the proportion of food obtained from treated fields) = 1 with a value estimated from field observations or radio-tracking. This continues to be an option under this revised Guidance Document. However, it is essential that such refinements are supported by relevant evidence (see the following sections).

In addition, careful consideration must be given to how refined dietary risk estimates can be used in risk characterisation and decision-making. It is not valid simply to compare a refined TER to the same trigger value used at Tier 1 and assume that the same level of protection is achieved. Due to the importance of this issue, it is discussed first, followed by an overview of refined dietary assessment and then a series of sections providing guidance on individual components of the assessment.

### 6.1.1. Level of protection in refined dietary exposure assessment

The first-tier assessments have been carefully constructed to provide an appropriate level of protection (section 3 and Appendix C). This level of protection is a result of both the particular inputs used in calculating the first-tier TER and the size of the trigger value. If a refined TER is calculated with less conservative inputs, then the level of protection will decrease[61]. Therefore it is essential that the level of protection should be reassessed for every higher-tier assessment, to ensure that it is still sufficient to meet the protection goals. This may be done by starting with the weight-of-evidence assessment carried out for the first-tier assessment (see Appendix C), and adjusting it to take account of the changes made to the dietary exposure parameters in the higher-tier assessment.

The need to re-evaluate the level of protection for every higher-tier assessment applies to all types of assessment (acute and reproductive risks for all types of pesticides). However, it requires different considerations in assessments for acute risks to birds from sprayed products, because for these assessments the level of protection has been established partly by comparison to the field data (section 3 and Appendix C).

For example, in the past, one of the most common refinements has been to reduce the value used for PT (e.g. based on radio tracking data) on the grounds that most individuals have PT less than 1. However, the birds that were present in the field studies used to evaluate the level of protection (LoP) for acute assessments of sprayed pesticides also had values of PT less than 1. Therefore the effect of lower values of PT in reducing acute risk is already reflected in the outcomes of the field studies. Consequently, the evaluated level of protection for Tier 1 (Appendix C) already takes account of lower PT values, so replacing PT = 1 with lower values in a refined TER will double-count their effect[62]. The same logic applies to other common refinements including changes to PD and using pesticide-specific residue data, or arguments based on avoidance and/or metabolism: the same factors would also have been operating in the field studies (to varying extents) and will therefore be double-counted (to varying extents) if a refined acute TER is compared to the Tier 1 trigger value. This does not mean that refined TER calculations should not be done. Specifically, if there is evidence that one (or more) of the inputs to the TER calculation for a particular pesticide consistently differs from the range of values expected for the pesticides in the original field studies, in a way that reduces the risk, then the refinement can be supported. This might be the case if, for example, it could be shown that the distribution of PT (and particularly its upper tail, which is most relevant for acute risk), is lower than most of the distributions that would have been expected in the original field studies; or if, the pesticide is more strongly avoided in field conditions than most of the pesticides in the original field studies (organophosphates and carbamates). It is clear, then, that the level of protection provided by refined acute assessments must be re-evaluated case by case, including careful comparison with the field study calibration (Appendix C).

61 It can be assumed that the relation between TER and level of protection asymptotes at some point. If the first-tier assessment was beyond this point, i.e. was extremely conservative, then moderate changes in the TER might not reduce the level of protection, but the field study analysis suggests that for acute risks to birds at least the first-tier assessment is not so conservative (Appendix C, Figure 4).

62 To explain this another way: consider the points in the graph relating evidence of mortality in field studies to acute TER (Appendix C). The TERs in this graph are based on default TER of 1. If the default PT was set to a lower value, all the TERs will increase by the same factor, so all the points on the graph would shift to the right by the same amount. However, the probabilities of mortality for each point would remain unchanged as they reflect the actual outcomes of the field studies. Therefore, to retain the same level of protection, the TER threshold for acceptable risk would also need to be increased, again by the same factor.

For all other types of assessment (apart from acute/spray), the level of protection for Tier 1 was based only on qualitative evaluation (due to lack of sufficient field data). For those types of assessments there is more scope for refinement, if they provide real evidence that can improve on the evidence and judgements that were available for the original evaluation of level of protection in Appendix C. This should therefore be done by starting with the weight-of-evidence assessment that was carried out for the first-tier assessment (see section 3 and Appendix C), and adjusting it to take account of the specific evidence provided by the refined assessment. Note that this requires reviewing not only the evaluation for the specific parameter for which refined data is provided (e.g. PT), but also the level of protection considering all parameters and uncertainties. This is necessary because, in reaching a judgement about the level of protection overall, account was taken of the fact that the default assumptions for some parameters (e.g. PT = 1) are conservative while others (e.g. exclusion of non-dietary routes) are unconservative (see Tables in Appendix C for detail).

In summary, **a refined TER calculation is one option for characterising the risk, but it is not valid to compare the resulting TER with the first-tier trigger value and assume that the same level of protection will automatically be achieved. Rather, the level of protection achieved by refined TERs must be re-evaluated in every higher-tier assessment** to evaluate whether the 'unless' clause is satisfied, i.e. whether it is established with sufficient certainty that no unacceptable impact will occur. Practical approaches for making this evaluation are discussed in section 6.8.

### 6.1.2. Overview of refined dietary exposure assessment

This section describes how to plan a higher-tier assessment of dietary exposure and introduces the sub-sections, which provide guidance on individual components of the assessment.

The first step of any higher-tier assessment should be to define the type(s) of effect, focal species, population, spatial scale and time period to be considered; define the measure of risk that will be produced; specify an appropriate assessment model to generate it; and decide how to deal with variability and uncertainty. Currently, there is no single established approach so this must be defined case by case according to the needs of the situation. Among the factors to be considered are the ones listed below. Note that some of the factors are more readily refined with existing methodologies (e.g. selection of focal species, inputs for exposure assessment) whereas others require methodology that is not yet well established for regulatory use (e.g. probabilistic modelling), or the use of additional animal studies which is discouraged for animal welfare and policy reasons.

**Type of effects.** The survey of Member States and stakeholders undertaken by EFSA (2008, Appendices 1a and 1b) indicated that visible mortality and population effects should be the focus of concern. Assessing population effects will require qualitative or quantitative assessment of the relationship between test endpoints (lethality, reproductive performance) and appropriate measures of population effect. The time period for exposure assessment is generally dictated by the type of effect considered (e.g. 1 day for mortality, 1 day or longer periods for reproductive effects).

**Focal species.** For higher-tier assessment of the risk for birds and mammals it is usual to focus on 'focal' species to avoid modelling exposure for multiple species. These FS are selected to represent a realistic worst case and could comprise more than one species. See section 6.1.3 for guidance on how to identify appropriate focal species.

**Population and spatial scale.** The first-tier assessment implies a hypothetical population of animals confined to a single treated field. Higher tier assessment often uses data on the proportion of an animal's daily diet obtained in habitat treated with pesticide' (PT). This implies a population of animals moving in landscape with both treated and untreated areas. This opens up additional questions. Should the assessment refer only to the subset of individuals which visit treated fields, or include also individuals which never do so? Should it be assumed that a pesticide is applied to every field of the relevant crop? Should it be assumed that these fields are treated simultaneously or over a period of time? Is it assumed that food availability and dietary choices of the focal species are different or the same in different crops and habitats, and in treated versus untreated crops? These questions have significant implications for the design of the exposure model (see below). Introducing increasing realism rapidly makes the exposure model very complex, so it is common to start with a relatively simple scenario that is designed to be conservative, and only incorporate more complex representations of reality when this proves necessary.

**Measure of risk to be produced.** In the past, refined assessments for birds and mammals have generally used the same measure for risk characterisation as the first-tier assessment: the toxicity-exposure-ratio (TER). Consideration could also be given to alternative measures of risk such as percentage of mortality, percentage of reproduction attempts affected, or higher level endpoints such as population change over a specified period. These may be more interpretable for risk managers, but require additional data or assumptions (e.g. slope of the dose-response to estimate percentage of mortality).

**Exposure model.** The form of model required to estimate dietary exposure depends on the population considered, how the assessor decides to represent spatial scale (see above), and on the timescale of the assessment. Other influential factors include the number of food types considered and whether these are the same in each part of the landscape. Crocker (2005) shows how the assumptions made can influence the form of dietary exposure model required. However, it must be noted that the equations presented by Crocker (2005) include a factor to represent avoidance, although Crocker identifies several problems with this in his text. EFSA (2004, 2005a) have concluded that including avoidance in exposure modelling in this way (at least for substances where avoidance is determined by a threshold dose, rather than by a concentration-related sensory response) is not appropriate. Appendix G includes a simple form of dietary exposure model that allows for multiple foods and the presence of untreated habitat. Consideration should also be given to the inclusion of other routes of exposure in the assessment. Otherwise these must be considered as significant sources of uncertainty (potential under-estimation of risk) in the overall characterisation of risk (section 6.8). See Appendix 2 of EFSA (2008) for a discussion of the importance of dermal exposure.

**Toxicity model.** The form of the model required for toxicity depends upon the measure of risk required, and on how extrapolation between species will be accounted for. If the desired output for a risk assessment is a TER, its calculation requires an estimate of the $LD_{50}$ or NOAEL. In principle, this should be an estimate of the relevant toxicity endpoint ($LD_{50}$ or NOAEL) for the focal species being assessed. In practice, the focal species is never tested, so its $LD_{50}$ or NOAEL is uncertain and could lie either above or below the tested species. This uncertainty can be represented by a distribution in a probabilistic risk assessment, although the shape and parameters (mean and variance) of the distribution are uncertain. In deterministic assessments it is usual to make the conservative assumption that the focal species is more sensitive than the tested species, and use an extrapolation factor to allow for this. The TER trigger value used in first-tier assessments is (or includes) such an extrapolation factor. In higher-tier assessments, one option is to continue using the geometric mean of the $LD_{50}$s or NOAELs for the tested species, and divide it by the same extrapolation factor as in Tier 1. This should provide at least the same average level of protection in the effects assessment as was present in Tier 1, but does not quantify that level of protection (EFSA, 2005a; and section 2.3.1 and Appendix 7 of EFSA, 2008). Another option is to use one of the other methods 3-5 as described by EFSA (2005a). These methods are designed to achieve a specified level of protection and to take account of the decreased uncertainty when more species are tested. However, for birds and mammals, methods 3 - 5 are currently applicable only to the $LD_{50}$, because they require estimates of variation between species that are not available for other bird and mammal endpoints[63].

63 See Luttik et al. (2005) for a discussion of inter-species extrapolation of long-term toxicity.

If the required output is not a TER but another measure of risk, different model structures and data or assumptions may be required. For example, the estimation of the percentage of mortality would require an estimate of the slope of the dose-response as well as the $LD_{50}$, and again these should refer to the focal species. Slopes are available from some but not all $LD_{50}$ studies, and extrapolating the slope to untested focal species will be very uncertain. There is even less information about variation between individuals in other responses (e.g. reproductive effects).

**Methods for dealing with variability and uncertainty.** Consideration of variability and uncertainty is an essential requirement for addressing the 'unless' clause. The variability of impacts must be considered to decide whether they are acceptable, and uncertainties in the assessment must be considered to decide whether acceptability is 'clearly established'.

At Tier 1, variability and uncertainty are addressed by including some conservative assumptions in the assessment and comparing the result with a trigger value that is considered to provide an appropriate level of protection. An indication of the level of protection achieved by the first-tier acute assessment is provided by the analysis of field study data in Appendix 2 of EFSA (2008).

As explained at the start of this section, the first-tier trigger values are not applicable in higher-tier assessments. Therefore, other methods must be used to take account of variability and uncertainty. The range of different impacts that are made possible by the variability and uncertainty of exposure and effects needs to be taken into account. There are two options for doing so:

- *Scenario analysis*. This is a practical approach that simply involves repeating the assessment for a limited number of selected scenarios. In each scenario, a single value is assumed for each variable or uncertain parameter, leading to a single estimate of impact. Different values can be selected for different scenarios, e.g. a $90^{th}$ percentile residue might be assumed in one scenario and a $50^{th}$ percentile residue in another. Each scenario can be described in terms of its assumptions, e.g. when residues and PT are at their $90^{th}$ percentiles, and an uncertainty factor of 10 is applied to the geometric mean of the $LD_{50}$s, the TER is X. If the scenarios include a range from worst case to 'best case' assumptions then the range of results gives an indication of the range of possible impacts.
- *Probabilistic modelling*. This uses probability distributions to represent sources of variability and uncertainty that influence the assessment, and produces a distribution that estimates the variability and uncertainty of the impact.

Scenario analysis has the advantage of being simple to compute, and is useful for indicating the range of possible impacts. If even the worst-case impact is acceptable, no further assessment is required. However, if the best-case impact is acceptable but the worst-case is not, the relative probability of the different scenarios needs to be considered. Scenario analysis may not be sufficient for this, since it only shows that a range of impacts are possible. It does not provide any quantitative estimate of how often a given impact will occur, nor of how uncertain the impact is for each scenario. Therefore the assessor will have to make a subjective assessment, based on the nature of the assumptions made for each parameter[64]. This is very difficult, because the influence of different parameters depends not only on the value that is chosen, but also on the shape and width of their distributions and how they are combined in the model. For example, it might be thought that taking the $99^{th}$ percentile of one parameter and means for all other inputs would result in a conservative estimate of impact, but if the model were insensitive to the parameter that is set to the $99^{th}$ percentile then the result could actually be close to the mean impact. The difficulty of evaluating the conservatism of a refined dietary assessment subjectively is illustrated by Figure 2.

64 It is suggested that this should be done using the approaches outlined in sections 6.8 and 6.9 for weight of evidence and qualitative evaluation of uncertainty.

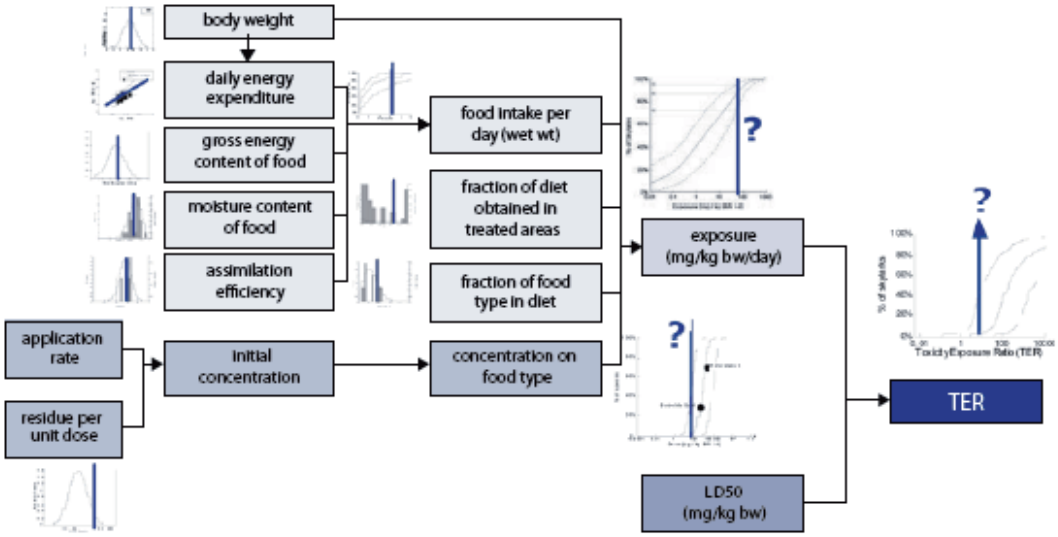


**Figure 2.** A deterministic refined assessment of dietary exposure and risk involves choosing a single value for each of the parameters and using them to estimate a single value for the output (e.g. TER or % mortality). These single values are illustrated by the thick lines in the graphs for each input and output. The conservatism of the output (i.e. where the deterministic TER sits within the 'true' distribution of TERs) depends on the combined effect of the conservatism of all the inputs and is difficult to judge without quantitative (probabilistic) modelling.

Probabilistic modelling is a more complex approach but may be worth considering if scenario analysis proves insufficient for decision-making. Probabilistic modelling takes account of the full distribution of values for each input and uses them to estimate a distribution for the output. Thus it estimates both the range of possible impacts and their relative probabilities, providing a quantitative basis for addressing the 'unless' clause. However, it is much more complex than scenario analysis and requires significant statistical expertise to be applied correctly. Also, it is not yet generally accepted for use in regulatory assessment, and there is no established guidance for its use in relation to pesticide risks (although useful guidance has been published in other areas, e.g. US EPA, 1997).

Regardless of the use of either scenario analysis or probabilistic modelling, it will never be practical to quantify all sources of variability and uncertainty. Therefore, in order to properly address the 'unless' clause, it is essential for every refined assessment to be accompanied by a list of unquantified sources of variation and uncertainty, and a qualitative evaluation of their potential influence on the assessment outcome. Some approaches for this are discussed in section 6.7.

Whatever the outcome of a refined assessment, it should not be the sole basis for decision-making. Instead, decision-making should consider all relevant lines of evidence, including the outcome of the first-tier assessment. The outcome of the first-tier assessment is especially important in the case of acute risks from sprayed pesticides, because its relevance to effects in the field has been characterised by the analysis of field studies (Appendix 2, EFSA, 2008). Some approaches for weighing different lines of evidence to form an overall characterisation of risk are discussed in section 6.9. It is emphasised that weight-of-evidence assessment is not a replacement for quantitative refinement of the dietary exposure assessment. Instead, it is an approach for weighing and combining the results of first-tier and refined dietary assessments, together with the results of any other refinement options that may be used, to form an overall characterisation of risk.

The following sections provide guidance on methods to assess some of the parameters required for a refined exposure assessment. Some of these methods can be costly to implement, therefore it is advisable to consider carefully the contribution they might make to refine the assessment. In general, it will be efficient to concentrate resources on those parameters that contribute most to the uncertainty of the assessment outcome. However, the choice of which parameters to refine will also be influenced by other factors. For example, toxicity is probably the biggest source of uncertainty in bird and mammal assessments, but for ethical and policy reasons testing of additional species is strongly discouraged. This limits the contribution that refined modelling of exposure and effects can make to higher-tier assessment.

### 6.1.3. Identification of focal species

This chapter describes the identification and selection of species used in the risk assessment for birds and mammals.

**Indicator species**

The risk assessment starts by using 'indicator species'. This is a realistic worst case and acts as a screening step by eliminating all those substances that clearly pose a low risk to birds and mammals. This 'indicator species' is not a real species but it is representative of all species that may occur in a particular crop at a particular time. It has a high food intake rate, and consumes one type of food which in turn has high residues on or in it (see Tables 6 and 8). The indicator species is fixed and can not be altered, if refinement is required, then it is necessary to progress to the next stage and use a 'generic focal species'.

**Generic focal species**

If the active substance, and associated product and its use, fails the screening step, it is possible to refine the risk via the use of a 'generic focal species'. This is not a real species, however it is considered to be representative of all those species potentially at risk. A 'generic focal species' is based on ecological knowledge of a range of species that could be at risk. It should be noted that this species still has a high food intake rate, however it may consume a range of food types rather than just one as for the indicator species. The 'generic focal species' is also considered to be a representative of the types of birds or mammals that occur across Member States (see tables in Annex I). The generic focal species is fixed and can not be altered. If refinement is required, then it is necessary to progress to the next tier and to use a 'focal species'.

**Focal species**

If an active substance, and its associated product and use, fails when the 'generic focal species' is used, it is possible to further refine the exposure element of risk via the use of a 'focal species' (FS). This is a real species that actually occurs in the crop when the pesticide is being used. The aim of using a 'focal species' is to add realism to the risk assessment insofar as the assessment is based on a real species that uses the crop. It is essential that the species actually occurs in the crop at a time when the pesticide is being applied. Further, it is essential that this species is considered to be representative of all other species from the feeding guild that may occur in the crop at that time highlighted at earlier stages of the risk assessment. As a 'focal species' needs to cover all species present in the crop, it may become necessary to assess the risk for more than one species (considering different feeding guilds or different breeding times) to ensure that the chosen 'focal species' has the highest exposure. Details on how to determine a focal species for a specific crop are presented in Appendix M of this Guidance Document.

#### 6.1.3.1. *Identification of focal species using targeted observation data*

The identification of focal species using targeted observation data can involve one of two methods, i.e. the transect method and the field survey method. Both methods involve surveying fields with the appropriate crop, its correct growth stage and at a time of the year that is relevant to the proposed use. It should be noted that it is necessary to survey a range of fields to enable an indication of the range of birds that may occur as well as the frequency with which they occur in each field and per survey. Once the survey data have been collected it is necessary to determine the focal species. The selection of the species 'covering' all other species present in the field, needs to take into account issues such as feeding strata, food intake rate, body weight of potential focal species and diet to ensure species with the highest potential exposure are considered. It should be noted that a focal species is not automatically the species that was most frequently seen, but that it should represent the feeding guild(s) that has/have raised concern at earlier stages in the risk assessment as well as other species.

#### 6.1.3.2. *Extrapolation of study results from one MS or zone to another*

Studies to determine a focal species in one Member State or one zone, may possibly be taken into account to support uses of pesticides in other zones, however, straight 'read across' is not possible. A focal species occurring in one MS or one zone could only be used for the risk assessment for another zone if it satisfies the criteria outlined above, i.e. the species being present, prevalent, occurring frequently and, more importantly, representing the feeding guild(s) that has/have raised concern at earlier stages in the risk assessment.

In summary:

- In order to refine the risk assessment a focal species should be identified and be determined using appropriate techniques (see Appendix M of this Guidance Document).
- In determining a focal species, it is important to consider the risk highlighted and hence select a species that is representative of the feeding guild highlighted at lower tiers.
- In selecting a focal species, it is essential to ensure that the chosen species covers all other species. It may be necessary to have more than one focal species, to ensure that all appropriate species are covered.

It is possible to extrapolate from a focal species from one MS or one zone to another, providing it satisfies all relevant criteria in terms of being present, prevalent, occurring frequently and representing feeding guilds at risk.

#### 6.1.3.3. *Identification of focal species using other sources of information*

The ideal and most reliable way to determine a focal species is via field work (see section 6.1.3). However, it may be possible to determine a focal species by evaluating published data. In the grey literature, data are available for which the aim has been to determine focal species in certain crops at certain times of the year[65]. If these data are to be used, it is essential to ensure that the crop and time of the year, as well as the agricultural environment are relevant for the assessment.

Other data that may be used to determine focal species may include survey or census information. When considering such data, it is important to ensure that it includes information not only on the identity of species that are present in a particular crop but also their quantity. It should be noted that a simple absence- or presence- correct/type survey alone will not provide sufficient information. It is also important to ensure that the survey or census was carried out at an appropriate time of the year and that the crop in question was at an appropriate growth stage. Finally, it is also essential to ensure that there are sufficient sites visited. A survey on one field only is unlikely to provide sufficient information on the prevalence and abundance of potential focal species.

65 See e.g. http://www.pesticides.gov.uk/uploadedfiles/Surveys_short1.pdf

### 6.1.4. Measured residues and residue dynamics

The most relevant substance-related parameters that determine the exposure term in the DDD equation are the initial residue unit doses (RUD) on food items and the dissipation rate of the substance. Application rate and number of applications also determine exposure, but are fixed according to the intended use. In principle, additional information provided by applicants on substance- and use-specific residue levels can be used to refine the RUDs for each food category mentioned in Appendix F or for a food item introduced in higher-tier assessment. Recommendations on arthropod residue field studies to refine food residues in higher-tiered bird and mammal risk assessments can be found in Appendix N. In the same way, substance- and use-specific information on the decline of residues on plant food items can be used to refine the current default $DT_{50}$ of 10 d (see section 6.1.4.1).

It should be noted that, in particular the RUD values for cereals and grass, non-grass herbs and for insects as presented in Appendix F are already derived from relatively large (in the case of plant food items) datasets comprising GLP studies carried out according to the label. Therefore, any additional residue study conducted according to normal standards would tend to rather broaden this existing database than to replace a RUD derived from it. However, refinement of RUDs is still possible if it can be clearly justified[66] that the deviating new residue data mainly reflect substance- or use-specific properties rather than normal variation.

#### 6.1.4.1. *Measured residues and residue dynamics in plant food items*

**Level of residues.** The exposure assessment in the DDD equation is in first instance based on measured residue levels in food items, in this case plants. It has already been stated above that the RUDs from Appendix F may in principle be replaced by more substance- and use-specific parameters if these are available from experiments and fulfil certain criteria.

- The confined residue studies performed for the residue risk assessment are considered a valuable source of information also for an assessment of bird or mammal exposure. For this reason, the default RUDs for 'grass and cereals' as well as for 'non-grass herbs' are now based on 132 and 230 individual confined residue studies, respectively, for different active substances. Nonetheless, it should be kept in mind that these studies are targeted at deriving maximum residue levels (MRL) and pre-harvest intervals (PHI) for human consumption risk assessment. It must be carefully checked whether the worst case for MRLs and PHIs is also a worst case for bird and mammal exposure, e.g. with respect to application timing. Trials with the first sampling point at day 0 should typically allow reliable conclusions on residue levels under realistic conditions, provided that plant parts sampled were those that can actually be eaten by birds or mammals.
- If an intended use comprises more than one application and respective confined residue trials are available with sampling that begins immediately after the last application, the results can be used directly in the exposure assessment. No additional multiple application factor (MAF) is required.
- It should be kept in mind that the RUDs for crop plants also act as a surrogate for residues on other potentially contaminated plants on the field. If the crop in question is not eaten, but residue studies for other crop plants indicate occurrence of significant residues in non-crop plants, this information should not be neglected in the risk assessment.

66 This justification could logically take one of two main forms: *either* sufficient field data (on multiple sites and under varying conditions) *or* clear mechanistic evidence (e.g. on spray deposition or retention), confirmed by at least some field data, to demonstrate that the substance or use under consideration *differs from the general pattern* represented by the data underlying the default values.

There may be reasons for applicants to perform additional studies explicitly targeted at the ecotoxicological risk assessment. Factors to consider when designing such a study to determine more realistic residue levels on potential food items are outlined below:

- The proposed treatment regime should be in line with the worst case 'good agricultural practice'. For example, if the product is to be used at 1000 g/ha on cereals from growth stage BBCH 60 onwards, then the study should be carried out at growth stage BBCH 60.
- The sites and conditions should be representative of the proposed usage. Data from a field study conducted in a northern Member State should in general be used for a northern MS risk assessment. However, it may be possible to use data from a region A to support uses in a region B if it is obvious that the conditions in region A tend to be worse than in region B so that the risk will not be underestimated. The acceptability of this should be considered on a case-by-case basis.
- More than one site should be used as between-site variations are likely to be greater than within one site. The number of sites should cover an appropriate range of situations to ensure that the data are representative of the proposed uses. Also, statistical advice should be sought when establishing the number of sites and the sampling scheme.

The result of any measurement program will be a distribution of residue data accompanied by descriptive statistics. The selection of values ($90^{th}$ percentiles or arithmetic means) should be the same as for the generic RUD data, provided that the parameters are reliable from a statistical point of view. If a time-weighted average residue concentration is required for the risk assessment, it can be either determined parametrically with an estimated $DT_{50}$ or by considering the observed area-under-curve.

**Dissipation and degradation of residues.** Dissipation and degradation of residues from plant material may be more rapid than in other environmental media. The different routes of residue decline comprise physical parameters like volatilization or wash-off, physico-chemical factors like photolysis, abiotic chemical degradation as well as biotic metabolisation and dilution due to plant growth. The integrated result of these processes is usually visible in form of an initial rapid decline in surface residues followed by a phase of slower dissipation (Willis and McDowell, 1987). In principle, the assumption of first order kinetics is less appropriate for such type of processes. Nevertheless, only very few data are typically available on residue decline on the scale of hours during the first day. However, these would be required for achieving a reliable fit of a more complex kinetical model. Since the $DT_{50}$ from first order kinetics tends to underestimate dissipation at earlier time points for the described overlap of partly very rapid processes, but will not overestimate it, this approach is recommended to ensure a worst case.

Willis and McDowell (1987) presented a review of approximately 450 $DT_{50}$ values (81 chemicals) for a broad spectrum of vegetative plant materials (grass, cereals, forage crops, cotton, vegetables, tobacco, and foliage of fruit trees). Mean $DT_{50}$ values and standard deviations for total residues were as follows:

- Organochlorines: $5.8 \pm 6.0$ d
- Organophosphates: $3.3 \pm 2.6$ d
- Carbamates: $2.7 \pm 1.2$ d
- Pyrethroids: $5.9 \pm 5.0$ d

Due to the time schedule of sampling in the original studies the authors expect that many of the half-lives may be overestimates. This bias in mind and taking into account that the data base includes very stable substances such as organochlorines, it is reasonable to use a $DT_{50}$ of 10 days as a default value if the $DT_{50}$ comes into play in the exposure assessment.

With regard to the level of residues, it is possible to replace the default $DT_{50}$ by a more appropriate substance- and use-specific value based on experimental evidence.

- Risk depends upon the rate of dissipation and degradation under practical use conditions. Thus data from confined residue studies covering all routes of loss are more relevant than plant metabolism studies which are focussed on metabolisation.
- The confined residue studies performed for the residue risk assessment include also studies with several sampling points to allow conclusions on residue decline in plants. However, they are usually not targeted at deriving a $DT_{50}$ or at describing residue dynamics on a time scale of few days after the initial exposure peaks. Still, studies with sampling starting directly after the initial application often exist and allow kinetical analyses. Care must be taken that the concentrations at individual data points refer to the same plant item (e.g. whole plant or green plant parts). With a change from fresh to dried samples or from whole plants to, e.g. grains only the consistent parts of the dataset can be used for deriving kinetical parameters.
- When only few sampling points are available for analysis of results from one trial site, the fit of the model, and consequently, the kinetical parameters become very uncertain. In such cases, pooling of data from comparable trial sites may be considered, but it must be accompanied by a justification why those trial sites can be considered comparable.

Due to the mentioned limitations of confined residue studies, it may be advantageous to conduct targeted plant dissipation studies if refinement of the $DT_{50}$ is intended.

- As regards the representativeness of sites and conditions, the same requirements as for the determination of residue levels are valid. However, like the default $DT_{50}$, the analysis does not aim at plant-specific kinetics, but at a value that can be used also for plant food items not tested in the analysis.
- To ensure that a meaningful $DT_{50}$ is determined, sampling points should primarily cover the first few days after application, e.g. day 0, 1, 2, 5, 10 and 20. If there is evidence from the residues package that the substance is likely to have a short half-life, for example from the residues or fate and behaviour, then the number of sampling points may be reduced. It should be noted that the number of sampling points should be justified. If the substance is applied several times per season, it is not always necessary to repeat sampling through the season. However, if the product is likely to accumulate, then repeat sampling should be conducted.

After determination of a $DT_{50}$, the MAF and TWA factors can be adjusted accordingly.

#### 6.1.4.2. *Measured residues and residue dynamics in arthropod food items*

Much less is known about residue levels and residue dynamics of pesticides in arthropods than in plants. First, this is related to the problems connected with the sampling of small mobile targets and with the analysis of low sample masses. Second, this is due to the fact that these data are not requested as plant residue studies within the risk assessment for human health assessment. Nevertheless, increased concern about the risk to birds and mammals has triggered various activities to elucidate the questions on the fate of pesticide residues in and on arthropods populations.

As the most distinct difference to the earlier concept, the RUDs for arthropods are no longer based on residues on surrogate items, but on results from targeted laboratory, semi-field and field studies. Instead of former size classes, biological aspects such as foraging strata of birds or mammals now form the relevant background of the exposure assessment. If a refinement of these standard parameters is intended, comparable approaches and concepts like those used for obtaining the current default values should be used.

The state of knowledge and the state of agreement between stakeholders at the time of writing this document is reflected in Appendix N. Only few core points will be mentioned and discussed below. For more detailed information, readers are referred to Appendix N and to possible future revisions of that document.

**Laboratory vs. field.** Although studies in the laboratory take place under better controlled conditions and allow tight sampling schemes, factors determining height and time course of residues like uptake from vegetation, food-web interactions etc. can only be observed in field studies. However, field studies are subject to much more natural variation than laboratory studies, so it is essential to conduct sufficient studies (at different sites and under varying conditions) to demonstrate that differences from the default values are statistically significant.

**Selection of study sites.** One test site is considered to represent an individual study[67]; however, to obtain information on intra-site variability of the residue values, 3-5 replicates should be planned per site. To minimise bias due to immigration and emigration, the replicates must be sufficiently large and arthropod sampling should be avoided in the border structures.

**Application of the test item.** The application(s) should be performed according to the recommendations of the product label and according to good agricultural practice.

**Test organisms.** Attention should focus on organisms likely to be consumed by the potential focal species and also the composition of the species' diet. This information is thus needed before initiation of the study. In order to obtain a meaningful classification, it is recommended that arthropods are sampled according to typical foraging strata of birds or mammals.

**Sampling.** Sampling techniques should be selected and performed in a way to minimise bias in test results. Desiccation of samples and cross-contamination should be avoided. Composition of individual samples must be recorded to allow meaningful interpretation of results. In case of insecticides, taking knock-down samples is recommended for obtaining information on residue levels in dead or dying arthropods directly after application. Sample numbers must be high enough to allow statistical evaluation.

**Reporting and data interpretation.** The main results from tests are initial and/or peak residue concentrations, as well as data on residue dynamics. Due to a number of reasons, first order kinetics is not considered appropriate for describing residue dynamics in arthropod populations. The most important of these reasons is the potential uptake of residues by arthropods in the first days after application. Thus, quantitative description of residue dynamics should not simply be based on MAF or TWA factors alone. If refinement is intended, it is necessary that the relevant application scenario is appropriately reflected in a test. Only if that is ensured, a $MAF_{90}$ can be derived from the highest peak measured or a $MAF_m \times TWA$ from the area under the residue vs. time curve. Care must be taken that the quality of the data (e.g. application pattern, number of sampling points) is sufficient to support conclusions on average residue levels.

67 Note that, as for residues on plant food items, more than one site should be used to take account of between-site variation (see section 6.1.4.1).

### 6.1.5. Steps to refine the PT factor

PT is defined as the 'proportion of an animal's daily diet obtained in habitat treated with pesticide'.

#### 6.1.5.1. *Criteria for performing radio tracking studies and evaluating observational data*

At the screening step as well as the generic focal species step, it is assumed that individuals find all their food in the treated area, therefore PT = 1. In reality, birds and mammals in the agricultural landscape may visit a variety of habitats within a single day and may obtain their food from a variety of fields. Therefore, in higher-tier risk assessment, it may be possible to use more realistic estimates of PT. In order to do this, it is necessary to obtain a measure of the amount of treated food ingested by individual birds and mammals in a particular field. This measure can be obtained by radio-tracking individuals, however, this is an indirect measure and certain assumptions need to be made, namely:

- That the amount of active time spent by an animal in a given crop is directly proportional to the food it eats there; and
- That the crop has been recently treated with pesticide.

If these assumptions are accepted, it can be further assumed that 50 % of the daily food intake of an individual bird that spends 50 % of its day in a given crop is likely to be contaminated with pesticide. Likewise, an individual that spends 70 % of its day will obtain 70 % of its food from the treated crop.

Details on the use of radio-tracking data to estimate PT are provided in Appendix P however, outlined below is a brief summary of the key issues that should be considered.

#### 6.1.5.2. *Radio-tracking and inclusion of individuals in the estimate of PT*

Radio-tracking should be carried out on those species considered to be 'focal species' (FS). There are two main methods for the selection of individuals to radio-track:

a) To focus on the crop and to radio-track only those individuals that were caught in (or in close proximity to) the target crop;

a) To focus on the species and to radio-track individuals captured in local farmland habitats where they are most abundant.

Both approaches provide useful data. However, it is necessary to consider that the estimated PT will generally be different. This will be a reflection of the fact that they are derived from different populations. The birds or mammals studied in (b) represent the whole farmland population whereas the birds or mammals in (a) are a subset that spends potentially more time in the crop of concern.

Having selected either (a) or (b) and obtained radio-tracking on the birds or mammals, it is necessary to further consider which individuals from this dataset are used to determine PT. One option is to consider all birds or mammals that visited the crop or had the potential to visit the crop. This would give an indication of the risk to the population at a farmland scale. Alternatively, only those birds that visited the crop, i.e. consumers only, could be selected to assess their risk. Using consumers only will not give an indication of the risk to the wider population that was in the vicinity of the target crop but did not happen to visit it during the observation period. Alternatively, considering all birds that had the potential to forage in the crop of concern will give an indication of the risk to the wider farmland population. It may perhaps include birds that were quite unlikely to visit the crop, e.g. because their breeding territories did not overlap the target crop or they had a strong preference for some other feeding habitat.

Considering all of the above, it is recommended that for focal species caught within the crop, PT should be estimated from all individuals - whether they used the crop of concern or not. For the focal species caught in the general farmland, PT should be estimated from only those individuals proved by radio-tracking to be consumers, i.e. PT > 0. It should be noted that the inclusion or exclusion of individuals with PT = 0 is a trivial calculation. It is further recommended that the risk from both groups is included, i.e. if radio-tracking data are available from birds or mammals caught in the general landscape, then two PT values should be calculated, one for all the birds and one for only those with PT > 0. Likewise, for those birds or mammals caught in the crop of concern, PT should be calculated for those individuals with a PT > 0 as well as for all individuals.

Whichever choices are made in collecting data and deriving refined estimates for PT, it is essential in all cases to evaluate the impact of the refinement on the overall level of protection provided by the assessment, taking account of the issues discussed in section 6.1.1.

#### 6.1.5.3. *Radio-tracking contact time as an estimate of foraging time*

Data from radio-tracking studies are used to provide an indication of the exposure through the consumption of treated food. Therefore, it is necessary to distinguish between the time spent in the crop 'actively or potentially foraging' and the time spent in the crop 'inactive or not foraging' for food. Therefore, the output from a radio-tracking study is the amount of (potential) foraging time in the crop expressed as a proportion of the total time spent (potentially) foraging during the day.

#### 6.1.5.4. *How long should individuals be followed?*

Ideally, radio-tracking of an individual should encompass the activity period of a single day; however, this might not always be possible. In this case it is necessary to consider the following questions:

- Is the sampling regime likely to introduce biases into the estimation of PT, such as by favouring particular times of day when the animal is engaged in particular behaviours or by leading to greater sampling of the animal when it is either in or outside the crop?
- Does the shorter observation time produce a significant bias on estimates of PT? Can the likely bias that shorter observation may have on the estimation of PT be estimated and corrected for? Can it be indicated whether the bias will have conservative or non-conservative effects on the risk assessment?

#### 6.1.5.5. *How to use PT in deterministic case calculations*

In selecting a suitable refinement of PT, it is necessary to determine what level of protection is required. For example, if the first-tier PT of 1 was replaced by a median or mean, this would suggest that the risk assessment will only relate to those 50 % individuals that fall under this PT, provided that no other parameters drive the risk assessment. However, in reality other variables contribute significantly to the overall risk and therefore the true proportion protected will be a result of the combined effect of all the input parameters (see Figure 2 in section 6.1.2).

Therefore, selecting a percentile for PT does not automatically provide the same percentile of TERs, due to the potential affect of the other parameters. Therefore, selecting the 90$^{th}$ percentile does not mean that 90 % of the population will be protected. If it is desired to know the level of protection provided by a certain PT percentile, it would be possible to estimate this by using probabilistic methods to take account of the combined effect of all the parameters.

#### 6.1.5.6. *Use of other sources of information in refining PT*

Radio-tracking studies will not be available for every combination of crop and focal species. In cases where radio-tracking data are not available, an attempt may be made to refine PT using other types of information. However, it should be recognised that this will generally involve a much higher level of uncertainty, which must be taken into account in risk characterisation and decision-making.

If radio-tracking data are available for other species or crops, this may provide a useful starting point from which to extrapolate to the species and crop of interest. In some cases, it might be reasonable to treat the available data as a direct surrogate for the species and crop of interest, but with additional uncertainty due to the extrapolation. In other cases it might be considered that some adjustment should be applied to the data to make it more relevant to the species and crop of interest. In both situations, the extrapolation should be clearly documented and justified with reference to relevant supporting evidence, e.g. regarding the ecological similarity of the species and crops involved, or from other types of data (e.g. observational studies).

Many types of information other than radio-tracking may contribute to the assessment of PT. The most useful are systematic visual observations (e.g. transect surveys) and mark-release-recapture studies, but even these are subject to substantial uncertainties. For example, visual observations of unmarked individuals cannot determine how PT varies between individuals, and can estimate average PT (which may not be sufficient for risk assessment) only if the size of the local population is known. Less systematic data, such as informal or incidental observations, nest locations and general ecological or natural history knowledge can contribute to expert judgements about PT, but these are inevitably highly uncertain. Other difficulties affecting interpretation of information on PT are listed in section 2.1 of EFSA (2004).

It is therefore recommended that:

- Every estimate of PT (apart from the conservative default PT = 1) be based on a detailed and critical evaluation of all the relevant evidence and be fully justified and documented;[68]
- The evaluation should always include consideration of the range of PT for individual animals, which for many species may actually extend from 0 to 1, as well as the average;
- Every estimate of PT be accompanied by a realistic indication of its uncertainty;
- Estimates that have been developed for one species-crop combination should not be extrapolated to other species-crop combinations without a fully documented and justified reassessment of the relevant evidence.

68 The documentation should be concise but sufficiently detailed to enable readers to critically evaluate the basis for the estimates taken for use in the risk assessment. An example of the degree of detail and depth that may be required is provided by the combination of section 2.2 and Appendix 1 in EFSA (2004).

### 6.1.6. Steps to refine the information on composition of vertebrate diet (PD factor)

PD is defined as "composition of diet obtained from treated area". Birds and mammals will be exposed to pesticide residues on or in food items obtained from crops or areas where pesticides are used. Outlined below is brief information regarding the dietary composition of both the indicator and generic focal species (see Appendix Q for detailed information) and energy, moisture content and assimilation efficiency of diets (Appendix L).

#### 6.1.6.1. *Diet used in the screening step*

For the screening step, the diet is deemed to be a single type of food (e.g. only seeds or only arthropods etc.) that is considered to be both realistic and worst case in terms of amount required to fulfil the dietary requirements as well as the initial residues. The screening step diet is fixed and cannot be changed. For further details of the screening step diet, see Annex I, and Tables 6 and 8.

#### 6.1.6.2. *Diet used for the 'generic focal species'*

The diet used for the risk assessment for 'generic focal species is a more realistic one. The methodology used to develop these diets is outlined in Appendix Q. In determining these diets, all available literature has been considered, and a quartile approach has been adopted to try and account for the range of a particular food item that may occur in the diet. Hence, in determining the diet of the generic focal species 'lark', use was made of all the published information on the diet of all lark species so as to obtain a generic diet. With regard to the screening step, these diets are fixed and should not be altered. If there is concern, i.e. the TER is breached, it is necessary to progress to the next step.

#### 6.1.6.3. *Diet used for the 'focal species'*

If a more refined assessment of diet is required, this should be based on the focal species. In order to do this, two approaches are possible. The first and most robust way is to carry out specific studies to determine the diet of focal species. The second approach is to consult published studies, some of which may have been used to determine the diet for the indicator and generic focal species. Details of these two approaches are outlined below.

1. Specific studies on the diet of focal species are conducted in appropriate landscapes (crop or agricultural mosaic) according to a robust methodology as described in Appendix Q for birds. In principle, the method of faeces analysis can also be used for mammals but more common is the analysis of stomach content for mammals caught in snap-taps (mice, voles etc.) or shot by hunters (hares, rabbits etc.) There are two types of methodology for birds - namely faecal analysis and stomach flushing. Both methods rely on catching birds in or close to the crop of concern and then determining what they have eaten. Since dietary composition may vary between crops, it is essential that the birds have access to the crop of concern and are known to have actually foraged in the crop of concern. For several small mammal species the analysis of faeces and of contents of dissected stomachs is recommended and the same rules and methods can be applied as for birds (see Appendix Q).
2. Alternatively, additional published literature may be used, but only if it takes account of the crop or agricultural mosaic as well as variability and uncertainties in time and space that may be due to preference and availability.

In both cases, it must be taken into account that there is not a single true value of PD, rather it varies between individuals, between sites/habitats and over time. If multiple studies are available, differences between them may represent either true variation and/or uncertainty due to differences in measurement methods. If a single value is used for refined assessment the impact of the variability of PD in the field must be taken into account when evaluating the overall level of protection provided by the assessment.

In summary, it is therefore concluded that:

- It is possible to refine the diet that a focal species obtains from the treated area by conducting specifically designed studies. These studies should be conducted using the appropriate focal species, the correct crop and during the correct time of year.
- It is possible to refine the diet using published data. However, the underlying studies need to be relevant in terms of the species, the crop, and the relevance of the agricultural mosaic.

### 6.1.7. Dehusking

Residues on treated seeds (direct treatment, pelleted or incrusted seeds) will be mainly located on the outside of the seeds (husk, testa, pericarp), whereas concentrations in the inner parts of the seeds (endosperm, embryo) will be significantly lower. Thus, exposure of granivorous birds or mammals may be markedly reduced when they dehusk seeds before consumption. However, incorporation of dehusking as a mitigating factor in the DDD equation requires careful consideration of various parameters.

In the case of birds, dehusking is mainly observed in smaller species. Some respective observations have been reported, e.g. by Prosser (1999), comprising species such as finches, sparrows and yellowhammer. Studies have shown that dehusking of seeds can substantially reduce avian exposure to pesticides in some cases. Nevertheless, it is important to note that dehusking is not all-or-nothing: not all small species dehusk, and some species dehusked some but not all of particular seed types. In the wild, the actual amount of seeds dehusked may be dependent on stressors such as feeding pressure, predation or competition (Prosser, 1999). For birds with a bodyweight above 50 g, it must be assumed that dehusking does not occur (Edwards et al., 1998). Larger granivorous birds typically have the capability to destroy even hard-shelled seeds within their gizzard.

For granivorous mammals such as rodents, dehusking or cracking of seed or fruit shells is often a part of their typical behaviour. Distinct anatomical features such as incisors or folds of skin that prevent material from entering the mouth while being gnawed (DEFRA, 2005) indicate that rodents will probably minimise the uptake of husks when eating seeds. Ludwigs et al. (2007) presented some experimental indications for the occurrence and efficiency of dehusking with regard to mice and cereal seeds. Qualitative data on wood mice dehusking cereal or weed seeds or cracking sugar beet seeds can be found in Barber et al., 2003; Westerman et al., 2003; Tew et al., 2000; and Pelz, 1989.

Quantitative information on the actual effectiveness of dehusking is very scarce. In the study of Edwards et al. (1998), seeds were manually dehusked before analysis. The data of Ludwigs et al. (2007) are based on seeds actually dehusked by animals. These data further indicate that not only the amount of dehusked seeds but also the exposure mitigation achieved by dehusking is very dependent on seed structure.

Due to the lack of reliable data and the known uncertainties, dehusking should only be considered in higher-tier assessments with case-specific justifications. Evidence must be provided that dehusking may actually play a role under field conditions for the relevant focal species. If this is the case, the available information should be checked for the conditions under which dehusking occurs and the extent to which it has been observed for this species. Specific care should be taken for seed treatments with a high toxicity per single seed. If the $LD_{50}$ is already reached with one or few seeds/particles, consideration of dehusking in the risk assessment might not be justified.

To obtain an estimate on the actual efficiency of dehusking, studies with the relevant focal species, the relevant seed type and the relevant product are preferable, since extrapolation is always connected with increasing uncertainty. If specific data are not available, the risk assessment can start with more generic information, in order to identify the general potential of this mitigating effect. Particularly in the case of birds, the assessment should always be performed for a second species that does not dehusk. If this assessment indicates a higher risk for the non-dehusking species, this species should become the species of concern. Further considerations on dehusking are not meaningful in such a case, unless it can be proven that the risk to the non-dehusking species is acceptable in a further refined assessment. If the overall risk is still determined by the potential effects on the dehusking species, careful reconsideration of any generic assumptions made in the first instance is required. It may become necessary to conduct targeted studies on the actual exposure of focal species under realistic conditions to conclude on an acceptable risk.

It is therefore recommended that:

- If dehusking is to be considered in a higher-tier assessment, case-specific evidence must be provided that it may actually play a role under field conditions for the relevant focal species;
- Available information on actual extent of dehusking and on relevant environmental conditions for such behaviour should be thoroughly discussed;
- Studies with the relevant focal species, the relevant seed type and the relevant product should be considered in preference to other studies requiring extrapolation;
- Particularly for birds, a risk assessment for a dehusking species should always be accompanied by an assessment for a second species that does not dehusk, in order to conclude on the actual species of concern.

## 6.2. Avoidance

A degree of avoidance of food contaminated with pesticides, commonly seen in dietary studies with captive animals, has the potential to reduce exposure and hence risk in the field. It can be a combination of several different responses including (a) a reduction in the rate of feeding due to novel or unpleasant characteristics of the contaminated food (e.g. taste or odour) and (b) temporary cessation of feeding due to sublethal intoxication. It is hard to determine the precise mechanism(s) of avoidance for a given pesticide, so attention should focus on its effectiveness in reducing exposure and effects, and on how this may vary under field conditions. Avoidance can occur with treated seeds and granular formulations as well as sprayed pesticides; and the principles of this section apply equally to each. The majority of this section focuses on evaluating the impact of avoidance on acute risks; consideration of avoidance for reproductive risks is discussed more briefly at the end of the section.

In the former Guidance Document (EC, 2002), a multiplicative factor (AV) to represent the effect of avoidance was included in the equation for estimating exposure. This might be appropriate if the degree of avoidance was constant over time, as might (or might not) apply if the avoidance response was purely of type (a) above. However, for many substances (including but not restricted to organophosphate and carbamate pesticides), where the type (b) response is important, avoidance is absent or limited at the start of feeding and becomes significant only after the animal reaches a certain threshold dose. This cannot be represented appropriately by a simple multiplicative factor in the exposure model (EFSA, 2004), which is the reason for the current exclusion of AV from the standard exposure model (section 4). This does not mean that avoidance cannot be considered in risk assessment. But it does mean that avoidance cannot generally be characterised by a simple multiplicative factor such as AV.

In cases where avoidance occurs as a threshold effect, the threshold is likely to be less than the lethal dose. Nevertheless, mortality can still occur in an acute exposure scenario: since the avoidance response is not immediate, animals that feed rapidly may ingest a lethal dose before the onset of the response. For less toxic substances, where several feeding bouts would be required to ingest a lethal dose, the availability of uncontaminated foods and the ability of the animal to select them become more important. Many other factors that may influence the avoidance response and its potential to reduce risk in the field are discussed in section 4.1 of EFSA (2004).

Currently, no internationally accepted guidelines for testing avoidance exist. Two national guidelines exist (INRA, 1990; BBA, 1993) but neither of these ensures a high feeding rate, which, as mentioned above, is a critical factor in acute exposures. Reductions in food consumption may also be measured in dietary toxicity tests (Luttik, 1998), but again these do not ensure a high feeding rate. Various other methods exist, including some intended for testing the efficacy of avian repellents for protecting crops (discussions see OECD, 1996). However, due to the complexity of factors affecting avoidance, interpreting data on avoidance from captive studies and assessing its implications for risk in the field is difficult and uncertain, as shown by the example of EFSA (2004).

Since it is not generally appropriate to represent avoidance as a multiplicative factor reducing consumption, consumption should not be the primary endpoint of avoidance studies for acute risk assessment. Instead, any new studies should focus on the critical question for avoidance, i.e. on whether it is able to prevent mortality and serious sublethal effects under realistic worst-case conditions. Thus, mortality and serious sublethal effects should be the primary endpoints, unless the aim is to generate data on other parameters for use in a modelling approach (see section 6.3).

An alternative to testing avoidance for acute exposures is to model the avoidance response and its interactions with other key factors such as metabolism. This involves modelling the effects of feeding rates and ADME processes on body burdens of the active substance as well as the threshold doses for avoidance responses and lethality. Approaches for body burden modelling are discussed in section 6.3 and an example of its use in a regulatory context is provided by EFSA (2005a). However, there is no standard approach, therefore the appropriateness of any model must be fully documented and justified in each case.

When data or models on avoidance are used as part of an acute risk assessment, careful consideration must be given to the substantial uncertainties involved. Particular attention should be paid to uncertainties that concern the relevance of the study or model to the exposure situation in the field, and to uncertainties that affect extrapolation between species. Questions to consider include:

- What rates of feeding occur in the field?
- Do the feeding rates achieved in laboratory studies or assumed in models correspond to the maximum rates occurring in the field? If not, how much higher will risk be at the maximum rates? If avoidance will not prevent adverse effects at the maximal rate, it will be necessary to consider the distribution of feeding rates in the field to assess how often adverse effects may occur.
- Does the availability of untreated foods provided in studies or assumed in models correspond to realistic worst cases in the field? For acutely toxic substances, absence of untreated food is a realistic worst case[69]. For longer-term exposures, what evidence is there that animals could learn to avoid contaminated food?
- Is the species tested in studies or considered in a model among the most sensitive to the substance? This is critical for acute scenarios, because the opportunity for an avoidance response to prevent mortality (i.e. the time interval between reaching the avoidance and reaching lethal doses) will be smallest for the most sensitive species. This is a serious problem for avoidance testing, because the relative sensitivity of the tested species (i.e. its position in the species sensitivity distribution for that substance) is extremely uncertain (1 or 2 orders of magnitude). Therefore, even if no adverse effects are seen in a tested species, more sensitive species may be adversely affected in the field. Potentially, this issue could be addressed by testing multiple species, but this option raises concerns of ethics and policy. In a modelling approach, it may be possible to account for variation in sensitivity between species by using a species sensitivity distribution[70].
- What assumptions are made or implied about extrapolation between species of the many other factors affecting the avoidance response? Even if a tested species is known to be sensitive, could other factors affecting avoidance (e.g. metabolism) be less favourable in other species? This could be addressed by testing multiple species, but as mentioned above, this raises concerns of ethics and policy. This problem is also serious for modelling approaches, since almost nothing is known about between-species variation in the avoidance threshold dose and the various ADME processes. In the absence of such information, a possible approach is the exploration of the effect of a range of plausible but conservative assumptions. If the risk appears low when using conservative assumptions, this may be sufficient for a conclusion (e.g. section 2.3.2.7 in EFSA, 2005b).

69 This is because it is a realistic worst case to assume that an animal encountering a contaminated food source in the field will continue to feed on that single food until its appetite is satisfied, unless avoidance occurs.

70 See EFSA (2005, section 2.3.2.2) for an example of this.

In the light of these issues, the recommendations with regard to consideration of avoidance in refined assessments of acute risk are as follows:

- Reductions in food consumption in the standard 5-day dietary $LC_{50}$ study are not sufficient to demonstrate that avoidance will prevent mortality in the field. They only indicate that avoidance may be worth to be considered further, using the following approaches.
- If specialised avoidance studies with the substance exist already, their implications for risk should be interpreted very carefully, taking full account of the issues discussed above.
- Before undertaking any new animal studies, it should first be considered whether modelling can provide sufficient certainty for decision-making, following the approaches outlined in section 6.3 and illustrated by EFSA (2005b).
- If new animal studies are to be carried out, they should be designed, justified, conducted and interpreted very carefully, taking account of the issues discussed above[71]. The test species should be chosen or trained to feed at the maximum rate expected in the field, ideally based on suitable field observations. The primary test endpoint should be the occurrence of mortality and serious sublethal effects, unless the aim is to generate other data for use in a modelling approach. If no adverse symptoms are seen, it is important to determine whether this is due to avoidance or simply due to the low sensitivity of the test species[72]. It is recommended to consult the competent authorities before proceeding with any new studies.
- If there is evidence from one or more of the above approaches that avoidance will reduce the risk of mortality, it should be considered carefully whether it is reasonable to extrapolate this conclusion to other species in the field. If there is significant doubt about this, the testing of additional species could be considered (if justified).
- All of the above approaches require very detailed documentation and justification, including explicit discussion and analysis of the uncertainties, as illustrated by the examples of EFSA (2004, 2005b). The uncertainties should be considered when evaluating the level of protection provided by the refined assessment (see sections 6.7 and 6.8).

Reproductive risk may be reduced if avoidance causes reductions in exposure over longer time periods, e.g. if it results in the animal learning to select less contaminated food items, or moving to untreated areas. This could be caused by either of the mechanisms mentioned at the start of this section (type (a) or (b)). Demonstrating this type of response experimentally requires a different type of study design than avoidance in acute scenarios, e.g. longer time periods and access to both treated and untreated food, rather than short time periods with treated food only. However, as for avoidance in acute scenarios, it is essential to consider the realism of the test conditions and how responses may differ in the field. For example, a test with treated and untreated portions of an attractive food presented concurrently side-by-side may significantly exaggerate the degree of avoidance that would be seen in the field, where animals may have to switch to less-preferred foods, or leave the treated area, to obtain untreated food. It is also essential to consider how responses seen in tested species extrapolate to other species. Devising test methods and assessment approaches to take account of such factors requires further research, so in the meantime any consideration of avoidance in reproductive assessments should be undertaken case by case and with special care.

71 Note also that avoidance studies should not be performed for treated seeds or granules where it is expected that a lethal dose is contained in a single seed or granule. In such cases avoidance cannot prevent mortality, although it is possible regurgitation may do so, and attention should focus instead on assessing what proportion of the population will be exposed (and hence the possible level of mortality).

72 This may be determined from the $LD_{50}$ for the species, if available. If a new toxicity study is required, an approximate lethal dose study (e.g. up-and-down method) should be chosen, to minimise animal use.

## 6.3. Metabolism & avoidance – application of body-burden models and dietary toxicity data

In EC (2002) and in this Guidance Document, risk assessments models, at least at lower tiers, use the daily dietary dose (DDD) as main input parameter. Implicitly, the use of the DDD brings along some restrictions:

A. The animal (bird or mammal) itself is considered a black-box. 'Dose' refers only to the amount of substance administered to the animal, and ignores internal process such as absorption in the gastrointestinal tract, elimination (faeces and urine) and metabolism and their kinetics.

B. The assessment is made based on the 'day' as a unit of time, and as such precludes the use of other (shorter) time scales as the basis for the risk assessment.

Within the registration process of plant protection products under Directive 91/414/EEC, often data from metabolism studies (ADME) within rat, live-stock or hen are available. These would allow for an alternative in risk assessment to avoid the above mentioned restrictions. Where risk-refinement is necessary based on results from lower tier assessments, 'metabolism' data should be evaluated by the risk assessor for options to reduce the uncertainty associated with the risk assessment. ADME studies may provide information on:

- Data on adsorption rates in the gastrointestinal tract
- Data on metabolism (kinetics/rate of formation)
- Data on elimination rates
- Data on potential de-activation/de-toxification steps

Besides the specific 'metabolism/ADME' studies on rat, livestock or hen, available toxicity studies (gavage/dietary) can be re-evaluated to potentially obtain useful information allowing the risk-assessor to overcome the restrictions of the DDD approach. A comparison of data from gavage and dietary studies can be particularly useful, since large differences between these two types of dosing may indicate metabolism playing a significant role in the expression of the intrinsic toxicity of a substance. Therefore, even cases where specific ADME studies are not available for the substance under assessment, metabolism is a refinement option.

Metabolism data may provide a way to include food avoidance as a refinement factor at higher tiers. The use of the avoidance factor (AV) as it was included in the standard algorithm in the previous Guidance Document (EC, 2002) is no longer considered suitable. However, there is wide agreement among scientists that food avoidance is an important factor, that frequently occurs in the field, and which, as such, should be considered when refining risk assessments (but see also section 6.2). ADME data and comparison of gavage with dietary studies can provide a means to take account of avoidance in risk assessment.

Several publications were made over the last years, presenting models, which allowed for the use of absorption, metabolism and elimination in the refinement of the risk assessment for birds and mammals (EFSA, 2005a). A more in-depth overview and discussion of the body burden (BB) model is given in Appendix 23 to EFSA (2008). This Appendix also specifies which type of data is required as input to BB-models and provides the assessor with information on the type of output that is gained with these models, as well as information on the manner in which this output can be used in risk assessment.

The body burden model(s) provide(s) the risk assessor with a tool:

- To include potential activation or de-activation (de-toxification) and elimination processes of a substance within the animal in the risk-assessment;
- To study the influence of absorption rates of a substance in the gastrointestinal tract on avoidance and risk posed to terrestrial vertebrates;
- To use the experience gained in human risk assessment and pharmaceutical research;
- To refine the assessment of the bioaccumulation potential of any substance and/or its metabolites;
- To include other routes of exposure (dermal/inhalation) into the risk assessment. However there are currently no examples for this being used in regulatory assessment of risks to wildlife.

Since ADME studies are not always available, and due to the fact that subtracting metabolism relevant information from available toxicity studies can be complex, BB-type models may not be a suitable tool for lower-tier assessment for terrestrial vertebrates. However, they are potentially a powerful tool for risk refinement. Currently available data could be used as input parameters for the BB-model. Alternatively, relatively simple dietary studies could be designed that would provide the input data needed. Such studies use relatively low numbers of individuals and often do not inflict stress (toxic effects, starvation) on the test animals. Therefore, for animal welfare reasons, BB-type models may form an alternative refinement option to conducting further laboratory toxicity and field studies.

BB-type models could be considered as a potential tool for higher-tier risk assessment. It should be stressed however, that BB-type models are a research area rather than an established methodology in environmental risk assessment. Moreover, extrapolation of ADME data from one species to another is hampered by uncertainty due to the lack of research on this topic. Therefore, when such models are to be used, the assessment should always be accompanied with a justification of why this model is considered to be applicable for the specific case one is dealing with. Furthermore, if an assessor wishes to use BB-type models, it is strongly recommended to consult with a toxicologist/metabolism specialist.

## 6.4. Field studies to detect or quantify mortality or reproductive effects

This section focuses on the use of field studies to detect or quantify mortality or reproductive impairment of wild birds and mammals[73]. The use of field tests for other purposes is considered in other sections (to identify focal species, section 6.1.3; to measure residues on wildlife foods, section 6.1.4; to quantify use of treated crops, section 6.1.5; to quantify dietary composition, section 6.1.6). Sometimes, a single field study may serve several of these purposes.

Field studies of mortality and reproductive effects are neither simple nor inexpensive but they have some important advantages. Aimed at the direct measurement of the effects of concern under realistic field conditions, such studies can take account of all routes of exposure and – depending on the number of study sites – all relevant sources of variation.

An internationally agreed standard protocol for avian and mammalian field studies does not exist. The US EPA protocol (OPPTS 850.2500 - Field testing of terrestrial wildlife) is still current, although field studies are no longer requested by US EPA as part of higher-tier assessment. For Europe, papers and recommendations from two workshops held in the 1980s are available (Greaves et al., 1988; Somerville and Walker, 1990; Anonymous, 1990), but no official guidance or protocol exists.

73 In this section, 'field studies' refers both to studies of effects following experimental pesticide applications (i.e. applications made as part of a regulatory study) and also to 'active monitoring' of effects following applications of approved products in agricultural practice. It excludes 'passive' wildlife incident monitoring or surveillance, involving investigation of suspected incidents reported by farmers and members of the public, which are dealt with in section 6.5.

### 6.4.1. Field study objectives

In view of the potential costs and difficulties of field studies, it is essential to ensure that the objectives of such studies are clearly defined and appropriate for the needs of the risk assessment they will serve. Specification of the objectives should include the type(s) of effects that are to be assessed, the population in question and spatial and temporal scales. To enable the design of a study of appropriate power, it is desirable to know in advance the levels of effects that are considered acceptable, as well as the degree of certainty that is required to prevent the acceptable limit being exceeded. Since such questions address risk management, it is desirable to discuss them in advance with the relevant authorities.

### 6.4.2. Number of study sites: intensive versus extensive approach

A key issue in a workshop held in 1988 was the contrast between 'extensive' and 'intensive' approaches (Somerville and Walker, 1990). The 'extensive' approach uses simple techniques such as carcass searching and census methods but employs a large number of sites to cover a broad spectrum of use conditions. It provides true replicates for statistical evaluation and thus allows for estimation of the probability of effects. The 'intensive' approach on the other hand involves more detailed investigations but on a smaller number of sites, or on one site only. It puts more emphasis on evaluating the potential for effects by using a combination of methods to study factors influencing exposure and risk.

The recommendations of the 1988 workshop tended to favour the intensive approach (Anonymous, 1990). However, this should be reconsidered in the light of developments since that time. Research has demonstrated wide variation in PT between individuals, of residues between sites and of toxicity between species. Each of these conditions will contribute to wide variation of exposure and effects between sites. Consistent with this observation, the analysis of field studies suggests that the same pesticide use may cause lethal effects on some occasions but not others (Appendix 2 of EFSA, 2008). This implies that studies on small numbers of sites could be very misleading. Failure to detect lethal effects at one or a few sites cannot be interpreted as a reliable indication of the frequency of lethal effects over many sites. Furthermore, this cannot be addressed by selecting 'worst-case' sites, as it is not possible to know in advance which sites will have high residues or which species will be most sensitive, nor is it possible to ensure that individuals of sensitive species with high PT will be present. However, these issues can be addressed by assessing the occurrence of effects at a larger number of sites, as in the 'extensive' approach.

It may be objected that a high quality study done with modern methods on a small number of sites should be sufficient to refute a potential risk indicated by the first-tier assessment, given that the latter has been 'calibrated' with historical field studies of variable quality. This would be true if most or all of variation in existing field studies is due to variable quality. However, due to the wide variation in residues, PT and toxicity and other factors influencing risk, it is clear that a large part of the variation must be real. Effects may occur at some sites but not others. Therefore, even when high quality modern methods are used, it will still be necessary to study multiple sites to determine with adequate certainty whether effects will occur. It is concluded that an 'extensive approach' with suitable methods and an appropriate number of sites (see below) is preferable to field studies with fewer sites.

The number of sites required will depend on a number of factors. These include the sensitivity of the field study methods for detecting effects, the level of effects that is considered acceptable (this might be defined in various ways, e.g. as the percentage of sites with any effects, the percentage of individuals affected over multiple sites, or the percentage of sites exceeding some specified level of effects), and the level of certainty required. Statistical methods for determining the number of sites required are included in the US EPA guidance (OPPTS 850.2500). However, it was suggested at the 1988 workshop that these methods could lead to a high frequency of false positives and required further consideration (Gould, 1990). Therefore, if field studies of effects became more frequently used, it would be desirable to undertake a new initiative (e.g. research and/or a workshop) to develop appropriate methods for determining number of sites. It would also be desirable to develop guidance on how to take account of the number of sites used when evaluating the results of studies (including existing studies with small numbers of sites). In the meantime, expert statistical help should be sought on a case by case basis, both to determine and justify the number of sites for new studies, and to evaluate the results of existing studies.

### 6.4.3. Methods for detecting effects in the field

The choice of methods and their detailed implementation in each case should be driven by the study objectives, including the type of effects that are of interest and the degree of certainty required in detecting and quantifying them. It should be noted that using multiple sites does not remove the need for adequate methods to detect effects at each site. Available methods include (but are not limited to):

- Systematic searching for dead or sublethally-affected individuals. This should include the treated area as well as adjacent habitats where exposed individuals might go to rest, roost or take cover (see Fryday et al., 1996). Searches should be carried out at appropriate times to maximise detection of casualties, taking account of the mode of action of the substance, while minimising disturbance that could artificially reduce exposure. Pre-treatment searches on at least two occasions are advisable to remove pre-existing animal remains and assess the level of natural mortality to aid interpretation or analysis of post-treatment mortalities. Search efficiency and rate of carcase removal by scavengers should be estimated using dummy carcasses.
- Radio-tracking to monitor activity and survival of tagged individuals (e.g. Prosser et al., 2006). The number of individuals should be sufficient to measure the level of mortality with the desired level of certainty. Casualties must be recovered very promptly and in a condition that is adequate to diagnose the cause of death.
- Post-mortem examination to diagnose cause of death: this may include residue analysis, biomarker assays (e.g. enzyme inhibition) and histology.
- Capture-mark-release-recapture studies to monitor population changes, which include changes in age structure, especially in small mammals.
- Monitoring of sublethal effects using biomarkers (e.g. enzyme inhibition). Repeated sampling from the same individuals may be desirable to control for high natural variability in biomarker levels, although this must be balanced against the risk that repeated capture will alter the behaviour of the animals and hence will bias the results.
- Visual observations to monitor populations and activity of birds and large mammals. Interpretation of results is difficult if the animals are not individually marked.
- Monitoring of reproductive performance of birds. Large samples of nests are required to ensure that an adequate number are active at the time of pesticide application.

Before choosing and using study methods, relevant literature should be consulted. Such literature includes the US EPA guidance (OPPTS 850.2500) and workshop publications cited earlier (Greaves et al., 1988; Somerville and Walker, 1990). However, in order to address the objectives of each study, the methods described or recommended in these sources should be considered, modified and justified case by case.

Careful consideration should also be given to other aspects of study design, including the following:

- Selection of appropriate study sites, e.g. should they be representative or aim towards a worst case? In order to take account of variation in sensitivity between species[74], sites with contrasting species assemblages (e.g. in different regions) may be preferable to similar sites in a single region.
- A broad range of species should be studied to take account of the wide variation in toxicity between species.
- Representativeness of the method, timing and rate of pesticide applications: should these be highly controlled or reflect normal variations in agricultural practice?
- The number and type of control sites and pre-application observations.
- The manner in which the cause of mortality or other observed effects will be determined, and how uncertainty in attributing effects to the pesticide will be addressed when interpreting the results (e.g. will carcasses with low residues, or those that were not analysed, be considered as pesticide casualties or not?).
- The way to ensure that the activities of investigators on the treated area do not cause under-estimation of exposure and risk, e.g. by reducing the time wildlife spend in the treated area or by reducing the rate at which they feed.

74 The number of species associated with a crop in one region may be high, but only a few species in each region will have high PT in that crop. Therefore in order to have a reasonable chance of encountering a species with both high PT and high sensitivity, sites in multiple regions may be needed.

### 6.4.4. Interpretation of existing field studies

In principle, all of the issues discussed above in relation to study design, e.g. number of sites, representativeness of sites and methods, attribution of cause of effects, the need for statistical advice, should also be considered when interpreting existing studies. Primary focus should be placed on the evaluation of (a) the certainty that effects did or did not occur at the sites studied, (b) what can be inferred about the occurrence of effects in general (over many sites). These evaluations will usually require expert statistical advice as well as expertise in biology, ecology and residue chemistry. In particular, it should be remembered that, because of the intrinsic variability of exposure and effects between sites, a small number of sites, even when subjected to high quality study, provide a very uncertain estimate of the occurrence or frequency of effects over many sites. This impact of this and other uncertainties affecting the outcome of field studies may be evaluated using the approaches described in section 6.8. This can then provide a basis for evaluating the weight that should be given to the field evidence, relative to the first-tier assessment and other types of higher tier evidence (weight of evidence assessment, section 6.9).

### 6.4.5. Pen studies

Pen tests are a form of semi-field study in which the product is applied according to practical use conditions, either by applying it within an aviary or pen or by setting up an open-bottom cage in the field after treatment. Such tests are only rarely conducted with mammals and birds, and there is no currently-recognised standard method. Detection of effects is facilitated by the confinement of the study animals within the pen, and by the use of replicated treated pens and controls. Formerly, these studies were considered as worst-case because the captive animals are confined to the treated area. However, this is invalidated by other factors. First, energy expenditure and hence food intake are reduced. More importantly, the rate of feeding is unlikely to approach levels achieved by free-living animals[75]. Finally, there is no practical way to ensure that the study species is more sensitive (has a lower $LD_{50}$) than other species exposed in the wild. This last issue is critical, because the wide variation in toxicity between species means that untested species could be up to one or two orders of magnitude more sensitive than those used in the study. Therefore, it is recommended that new pen studies should not be conducted, unless for very specific purposes such as to investigate avoidance responses[76]. For the same reasons, great care should be exercised when interpreting existing pen studies. The ecological realism of the study for the tested species should be carefully assessed, and the results should not be extrapolated to other species.

### 6.4.6. Conclusions and recommendations for use of field studies

The above considerations lead to the following conclusions and recommendations regarding field studies:

- Field studies that measure effects in the wild have a substantial advantage over other refinement options, because they avoid uncertainties associated with extrapolation from models or laboratory studies to the field. Further, they reduce uncertainties associated with extrapolating sensitivity (toxicity) from studied species to those exposed in the field. Semi-field studies (pen studies) do not have these advantages and are not recommended.
- Despite their advantages in reducing uncertainty, field studies of effects are not always the best option for refined risk assessment. In many cases, especially when the first-tier assessment 'fails' by only a small margin, other simpler and less costly options for refinement may be sufficient.
- Field studies to detect or quantify avian reproductive effects are significantly more difficult than field studies to detect or quantify mortality.
- When field studies are conducted, it is essential to define the objectives very clearly in advance. It is further desirable to discuss these with the relevant authorities if possible.
- An 'extensive' approach with multiple field study sites is recommended in preference to 'intensive' approaches where fewer sites are studied in more detail. More work (research and/or a workshop) would be desirable to develop guidance on how to determine an appropriate number of sites. In the meantime, expert statistical advice should be sought case-by-case on this issue.

75 Low feeding rates may greatly reduce risk by increasing the opportunity for avoidance responses and metabolism of the pesticide (EFSA, 2005a). This probably explains the failure of some existing pen studies (e.g. Pascual and Hart, 1997) to show mortality despite mortalities being documented for the same species in the wild.

76 If the purpose of a pen study is to investigate avoidance, the PPR Panel's recommendations in section 6.2 apply.

- Care is required to ensure that the methods chosen for detecting effects in field studies are appropriate to the study objectives and provide adequate statistical power to be useful for risk assessment and decision-making.
- Results of new or existing field studies require critical evaluation, which will frequently require expert statistical advice. The primary focus should generally be to evaluate (a) the certainty that effects did or did not occur at the sites studied, and (b) what can be inferred about the occurrence of effects in general (over many sites).
- Uncertainties affecting the interpretation of field studies may be evaluated using the approaches described in section 6.8. This can then provide a basis for evaluating the weight that should be given to the field evidence, relative to the first-tier assessment and other types of higher tier evidence (weight of evidence assessment, section 6.9).

## 6.5. Use of wildlife incident data

When reviewing an authorised substance, it may be possible to use data from incidents involving wildlife (see e.g. Hardy and Stanley, 1984, Hardy et al., 1986, Fletcher and Grave, 1992; Mineau et al., 1999)[77]. These generally relate to lethal effects. For countries that have organised schemes to investigate and document reported incidents, the frequency of incidents can be regarded as a measure of visible mortality, which is one of the protection goals for higher-tier assessment. However, incident reporting is unlikely to be useful when assessing reproductive effects. Severe and widespread reproductive impacts have been detected in the past, e.g. the historical declines of raptor populations due to eggshell-thinning caused by DDT[78] and DDE[79]. However, much lower levels of effect would be sufficient to breach the protection goal of 'no long-term repercussions on abundance and diversity', and it is extremely unlikely that these lower levels of effect would be detected by casual observation.

It is important to recognise that the recorded frequency of poisoning incidents can be regarded as a measure of 'visible mortality'. It is very likely to underestimate the level of mortality actually occurring. This is due to the fact that the probability of victims being noticed, collected, reported to an authority and identified as being affected by plant protection products is likely to be low (Baillie, 1993). This depends on numerous factors, including:

- Large animals are more conspicuous than small animals (Baillie, 1993);
- Mass mortality (e.g. of species which feed in flocks) is more conspicuous, and more likely to be reported, than single carcasses;
- Specimens with a high conservation interest are more likely to be reported than common species;
- Animals receiving a life-threatening exposure to pesticide are likely to seek cover before they die (Fryday et al., 1996), making them unlikely to be found by casual observers;
- Birds are highly mobile and after exposure may travel a significant distance before becoming incapacitated. This reduces the likelihood that their deaths (if observed) will be suspected of association with pesticides and hence reduces the likelihood that they will be reported and investigated. On the other hand, birds exposed to very fast acting substances (a few minutes) are more likely to be found on the treated field;
- Passive monitoring is extremely unlikely to detect effects other than severe overt symptoms (e.g. incapacitation or convulsions) and mortality, and therefore provides virtually no information on reproductive effects;
- Incident investigation schemes do not exist in all countries and their organisation varies between countries (de Snoo et al., 1999).

77 This section refers to 'passive' wildlife incident monitoring or surveillance, involving investigation of suspected incidents reported by farmers and members of the public. It excludes 'active monitoring' which is a form of field study and is dealt with in section 6.4.

78 DDT = dichlorodiphenyltrichloroethane

79 DDE = dichlorodiphenyl dichloroethylene

For these reasons, an absence of incidents does not necessarily indicate the absence of risk or of impact. Conversely, the reporting of incidents confirms that effects occur at least under some circumstances. Furthermore, information on the types of species involved and nature of the effects and the circumstances under which they occur may be helpful when planning refined risk assessment, e.g. by identifying potential focal species, potentially relevant routes of exposure, and possible options for mitigating the risk.

It is concluded that assessments of existing (previously authorised) active substances should always include documentation and interpretation of any incidents of mortality or reproductive effects that have been reported via passive monitoring, but that absence of such reports for a particular pesticide should not be interpreted as evidence of low risk. Nevertheless, absence of such data for large-scale uses on bare soils is a stronger indication for low mortality than absence of such data for uses on smaller areas of growing crops. These and other uncertainties affecting the interpretation of incident data should be assessed using the approaches of section 6.8 and taken into account when weighing incident data against first-tier assessments and other types of higher tier evidence (section 6.9).

## 6.6. Phase-specific reproductive risk assessment

The screening and Tier 1 assessments do not distinguish between different phases of reproduction. In reality, different phases of reproduction may differ both in their exposure and their toxicological sensitivity to the pesticide. Furthermore, only a proportion of birds will be exposed and, for those that are exposed, the peak exposure may not occur during the most sensitive reproductive phase. These factors may be addressed by phase-specific risk assessment. To gain the full benefits of this approach requires detailed data that may not be available in some cases (e.g. time of application of the pesticide, time of breeding phases for focal species etc.). However, the phase specific approach may be an effective approach if the data are available. For further information see Appendix J.

## 6.7. Assessment of population-level effects

The survey of Member States and stakeholders undertaken by EFSA (2008) indicated that visible mortality and population effects should be the focus of concern for bird and mammal risk assessment. In principle, it would be desirable to assess these effects directly. This is not practical in first-tier assessments, but may be an option at higher tiers.

Assessing population effects quantitatively by population modelling is possible but very challenging. The methodology is complex and requires specialist population modelling expertise. Examples of population models exist in the research literature, e.g. Topping et al. (2005), Sibly et al. (2005), Roelofs et al. (2005) and Wang and Grimm (2007)[80]. However, there is no established guidance on population modelling, and there are no officially-accepted models for use in pesticide registration, so models have to be produced and evaluated/approved case-by-case.

Population modelling requires data on population parameters, which vary between species and countries and may be difficult to obtain and/or very uncertain. It may also require data on the spatial distribution of bird or mammal populations relative to the spatial distribution of pesticide use; information that is lacking or highly uncertain in most Member States. All these uncertainties have to be seen as additions to the usual uncertainties affecting estimates of exposure and effects for individuals, since these are needed as inputs for modelling population effects. Furthermore, the individual effects need to be provided in terms of the incidence of mortality (not just exposure relative to $LD_{50}$) and the incidence of different types of reproductive effect (not just exposure relative to NOAEL for most sensitive endpoint). This again requires additional parameters, which introduce additional uncertainties. Overall, therefore, estimates of population impacts are likely to be extremely uncertain. Nevertheless, quantitative modelling of population effects is an option for higher tier assessment, provided that the necessary expertise and data are available and provided that proper account is taken of all the uncertainties involved (methods for dealing with uncertainty are discussed in section 6.8). However, due to the complexity of these approaches it is recommended that they be discussed with the relevant authorities before proceeding.

80 These examples are provided as an indication of the types of approaches that are available, no endorsement is implied.

It is also possible to consider the potential for population effects in a qualitative way, i.e. a reasoned argument expressed in words. Of course, all of the complexities mentioned above are still present, and it is not possible to account accurately for these in a qualitative evaluation. Therefore, a qualitative argument should concentrate on major factors that influence the population consequences of individual effects. Factors that could potentially reduce the risk of population consequences include:

- The proportion of the population that is exposed to an active substance at any one time (including the area likely to be treated in relation to population distribution);
- Extrapolation from no-effect to effect levels for reproductive effects; and
- The potential for an affected population to recover through reproduction (in unexposed periods) or immigration (from unexposed areas).

However, consideration must also be given to factors that may increase risk, e.g. multiple exposures from return visits to the treated field or other adjacent fields, and the likelihood that species that are already declining (as many farmland species are) will have little or no ability to absorb additional effects.

Any qualitative evaluation of population effects will be extremely uncertain, due to the large uncertainties affecting the magnitude of the factors involved, the way they interact, and their impact on population effects, and the contribution of other factors that it is not possible to include in a qualitative evaluation. Therefore it is essential that the evidence, reasoning and uncertainties are fully documented in every case. This should include a table such as that illustrated in section 6.8, to list the uncertainties and indicate their potential impact on the assessment outcome. The degree of uncertainty should be clearly explained to risk managers so they can take proper account of it in decision-making (see section 7).

## 6.8. Approaches for characterising uncertainty in higher-tier assessments

Point 2.5.2.1 in Annex VI to Directive 91/414/EEC states that no authorisation shall be granted unless it is "clearly established" that no unacceptable impact occurs. The term 'clearly establish' implies a requirement for some degree of certainty. First-tier assessments use standardised scenarios and decision rules which are designed to provide an appropriate degree of certainty (see section 3 and Appendix C). Higher tier assessments are not standardised, and so the degree of certainty they provide has to be evaluated case by case. The need for risk assessments to include characterisation of uncertainty has also been emphasised at senior policy levels in the EU[81].

Methods for characterising uncertainty can be grouped into three main types:

- Qualitative methods: using words to describe the certainty of an outcome, or to describe how different the true outcome might be compared to an estimate.
- Deterministic methods: generating deterministic quantitative estimates of impact for a range of possible scenarios. This shows the range of possible outcomes (e.g. a range of TERs) and can be accompanied by qualitative descriptions of their relative probabilities (traditional 'worst-case' assessments are an example of this).
- Probabilistic methods: these give numeric estimates of the probabilities of different outcomes. These probabilities may be estimated statistically (e.g. when quantifying measurement or sampling uncertainty, or as outputs from probabilistic modelling). However, they may also be estimated subjectively, by expert judgement.

All uncertainties affecting an assessment should be considered at least qualitatively. To reduce the risk of overlooking important uncertainties, it is recommended to systematically consider each part of the assessment (e.g. different lines of evidence, different inputs to calculations, etc.) and list all of the sources of uncertainty together with a description of the magnitude and direction of their potential influence on the expected level of impact. As well as evaluating each individual source of uncertainty, it is also essential to give an indication of their combined effect. It is recommended to use a tabular approach to facilitate and document this process, as illustrated in Table 23. This is based on an approach used in some recent EFSA opinions (EFSA, 2005a; 2007b; 2007c; 2008), but adapted to increase clarity by introducing separate columns to describe uncertainties that act in different directions.

81 E.g. "Even though it is not a subject that lends itself easily to quantification, I would urge you to take account of the risk manager's need to understand the level of uncertainty in your advice and to work towards a systematic approach to this problem." (Madelin, 2004).

Research in social science has shown that there is a general tendency for experts to underestimate uncertainties. It is therefore important that risk assessors should be aware of the potential magnitude of common uncertainties in the assessment of risks to birds and mammals. For example, the ratio between the acute $LD_{50}$ for tested and untested species can be over one order of magnitude different (Luttik and Aldenberg, 1997). This implies up to 1 or 2 orders of magnitude uncertainty in estimating the $LD_{50}$ for the focal species in a refined risk assessment. Similarly, assessors should be aware of the potential magnitude of measurement uncertainties (e.g. in residue or radio-tracking data), and of the potential magnitude of sampling uncertainty associated with small and moderate sized datasets.

In some cases, a qualitative evaluation of uncertainties may be sufficient to establish clearly (i.e. with sufficient certainty) that unacceptable levels of impact will not occur, as is required by the 'unless' clause in Annex VI. In other cases, a purely qualitative evaluation of uncertainty may not give a sufficiently clear picture of the range of possible outcomes. In such cases, one option is to obtain additional data to reduce uncertainty. This may usefully be targeted on the uncertainties that appeared largest in the qualitative evaluation. However, an alternative option is to refine the characterisation of the uncertainties progressively, by evaluating some of them using first deterministic methods and then, if necessary, probabilistic methods. This implies a tiered approach to the treatment of uncertainties, which starts by evaluating all uncertainties qualitatively and progresses either by reducing uncertainty (by obtaining additional data) or by refining the evaluation of selected uncertainties (either deterministically or probabilistically), until the point where it can be 'clearly established' whether an unacceptable impact will occur (as required by the 'unless clause in Annex VI).

**Table 23.** Tabular approach recommended for qualitative evaluation of uncertainties in refined assessments.

The +/- symbols indicate whether each source of uncertainty has the potential to make the true risk higher (+) or lower (-) than the outcome of the refined assessment. The number of symbols provides a subjective relative evaluation of the magnitude of the effect (e.g. +++ indicates an uncertainty that could make the true risk much higher). If the effect could vary over a range, lower and upper evaluations are given (e.g. + / ++). If possible, the user should indicate the meaning of different numbers of symbols (e.g. two symbols might be used to represent a factor of 5, and three symbols a factor of 10). See Appendix C for some practical examples.

| Source of uncertainty | Potential to make true risk lower | Explanation | Potential to make true risk higher | Explanation |
|---|---|---|---|---|
| Concise description of first source of uncertainty | Degree of negative effect (e.g. - - -) | Short narrative text explaining how this factor could make true risk lower | | |
| Second source of uncertainty | | | Degree of positive effect (e.g. +++) | Short narrative text explaining how this factor could make true risk higher. |
| Add extra rows as required for additional sources of uncertainty | - | Note: many uncertainties may act in both positive and negative directions | + | |
| **Overall assessment** | **Narrative text describing the assessor's subjective evaluation of the overall degree of uncertainty affecting the assessment outcome, taking account of all the uncertainties identified above. The overall assessment should be a balanced judgement and not simply a summation of the plus and minus symbols.** | | | |

It is unlikely that it will ever be practical – or necessary – to quantify all uncertainties, so every deterministic or probabilistic assessment should be accompanied by a qualitative evaluation of the unquantified uncertainties. Also, it should be remembered that deterministic and probabilistic methods often require assumptions (e.g. about distribution shapes) that are themselves uncertain, and these additional uncertainties should be included in the qualitative evaluation. Therefore, every refined assessment should contain at least a qualitative evaluation of uncertainties. Individual first-tier assessments do not require an evaluation of uncertainty, because the uncertainties affecting the first-tier procedure have already been evaluated; furthermore, entries in the tables established for the first-tier procedures (in Appendix C) may be a useful starting point when evaluating uncertainty for refined assessments.

The overall magnitude of uncertainty associated with an assessment will often be very large. This should not be regarded as implying a failure of risk assessment; on the contrary, it provides essential information for decision-making (Madelin, 2004).

It should be noted that for pesticides where several different types of refined assessment are used (e.g. refined dietary modelling followed by an avoidance study or field study), the uncertainties affecting each one will be different. In such cases it is recommended to evaluate the uncertainties affecting each approach separately, including a separate version of Table 24 for each. The contribution of the multiple assessment approaches (multiple lines of evidence) in reducing overall uncertainty can then be evaluated by weight-of-evidence in the final risk characterisation (see next section).

In summary, it is recommended that:

- Every refined risk assessment should be accompanied by at least a qualitative evaluation of the uncertainties affecting it, using a systematic tabular approach such as that illustrated in Table 23. Evaluations already done for the first-tier assessment procedures (Appendix C) may be useful as a starting point when evaluating uncertainty in refined assessments. In assessments with multiple lines of evidence, the uncertainties affecting each line of evidence should be evaluated separately.
- In cases where qualitative evaluation of uncertainty is not sufficient to determine whether it is clearly established that no unacceptable impact will occur, the assessor may either (a) seek further data to reduce the uncertainty, or (b) refine the evaluation of the existing uncertainties using quantitative methods (which can be either deterministic or probabilistic).

## 6.9. Risk characterisation and weight-of evidence assessment

Risk characterisation is the final step of risk assessment. At this point, all relevant information or evidence that has been gathered is used to produce an overall characterisation or description of the risk, in a form that is suitable for decision-making.

To be useful for decision-making, the risk characterisation should focus on evaluating whether the relevant protection goals are satisfied for the pesticide under assessment. As explained in the introduction to section 6, higher-tier assessment may address one or both of the following protection goals:

- The actual protection goal - to ensure a high certainty that there will be no visible mortality and no long-term repercussions on abundance and diversity;
- The surrogate protection goal - to make any mortality or reproductive effects unlikely.

The surrogate protection goal is more conservative than the actual protection goal, but more practical to assess.

Most refined assessments do not measure or estimate visible mortality and long-term repercussions directly. Evaluating these by extrapolation from simpler measures of risk (e.g. a TER) is very uncertain. Furthermore, neither the level of certainty required, nor all other aspects of the decision-making criteria[82] are defined. It is therefore recommended to adopt a tiered approach to risk characterisation, as follows:

1. First, to consider whether the evidence provided by the risk assessment is sufficient to satisfy the surrogate protection goal of making any mortality or reproductive effects unlikely. If so, it can be assumed there is also a high certainty that no visible mortality or long-term repercussions, nor short-term population effects will occur. This is a more conservative criterion than is implied by the 'unless' clause, but it is more practical to assess and enables firm conclusions to be reached without requiring more precise definition of the 'unless' clause criteria.
2. If the evidence does not satisfy the surrogate protection goal of making any effects unlikely, then attention should shift from establishing the lack of effects to assessing the *levels* of mortality and reproductive effects that may occur, as well as their implications for the likelihood of visible mortality and long-term repercussions on abundance and diversity. It should be recognised that the additional uncertainty inherent in this more complex assessment may make it difficult to meet the Annex VI criterion of 'clearly establish'.

Often, risk characterisation will involve combining several different types of refined assessment, each providing a separate indication of the risk. For example, an applicant might submit a refined dietary exposure assessment, together with some avoidance studies. These need to be integrated in an overall risk characterisation that takes appropriate account of each, so as to provide the best basis for decision-making. This process of combining available 'lines of evidence' to form an integrated conclusion or risk characterisation is frequently referred to as 'weight-of-evidence' assessment (e.g. EC, 2002; Hull and Swanson, 2006). This term reflects the principle that the contribution of each line of evidence should be considered in proportion to its weight.

It is emphasised that weight-of-evidence assessment is not itself a method of refined assessment, nor is it a substitute for refinement options such as those listed in Table 22. Instead, it is an approach for weighing and combining lines of evidence resulting from first-tier and refined assessments to form an overall characterisation of risk.

In the context of this document, a line of evidence might be the completed output of any of the refinement options, such as a refined dietary exposure assessment, an avoidance study (or several avoidance studies considered together), a body-burden model, or a field study designed to measure mortality. Note that some refinement options, such as field studies to measure PT, are not lines of evidence in themselves but rather contributions to a line of evidence (PT is an input for refined exposure modelling).

A qualitative[83] approach to weight-of-evidence assessment is recommended, as follows:

- Consider all relevant lines of evidence, including the first-tier assessment. Retention of the first-tier assessment is appropriate in all cases, as it is relevant to consider whether it was borderline or failed by a large margin. In addition, the first-tier assessment of risk for sprayed pesticides deserves special consideration in weight of evidence, because it is given increased weight as a predictor of mortality in the field (see below) in the analysis of field studies (see Appendix C).
- Evaluate the uncertainties associated with each line of evidence. This should be done by applying the approaches described in the preceding section to each line of evidence separately. The characterisation of overall uncertainty for each line of evidence is then used in the weight-of-evidence assessment, as in principle the weight given to each line of evidence should be proportionate to its certainty (see below).
- Form overall conclusions by using expert judgement to combine all lines of evidence, weighted according to their certainty, and give more weight to the most certain, but also take due account of the less certain. High certainty implies high weight. If one line of evidence implies a much narrower range for the risk than another line of evidence (i.e. higher certainty), then the true risk is most likely to fall inside the range of the former.

82 E.g. there is no firm definition of the spatial and temporal scale for assessing 'long-term repercussions', nor of what constitutes 'visible' mortality, nor of the acceptable magnitude for short-term population effects.

83 Quantitative approaches could also be used to combine lines of evidence, but this requires each line of evidence to be expressed in the same units together with a quantitative measure of its certainty.

- Be sure to take full account of the uncertainties and to include a fair description of the range of possible outcomes in the final risk characterisation. Identify the outcome that is considered most likely, but do not give it more emphasis than is justified by the evidence.
- If different lines of evidence conflict (e.g. a low TER but no effects in a field study), this should be considered a form of uncertainty. No line of evidence should be completely discounted unless it is wholly invalid or irrelevant. Instead, as stated above, each line of evidence should contribute to the overall conclusion in proportion to its certainty.
- If the overall characterisation of risk is expressed qualitatively, choose words very carefully to describe the outcome and its uncertainty as clearly as possible. For example the phrase 'on balance' is often used to focus on one of several possible outcomes, e.g. "on balance, it is concluded there will be no mortality". This type of statement is not appropriate, because it fails to communicate the degree of certainty (e.g. 'on balance' could mean 51 % certainty, or 99 %)[84].
- A weight-of-evidence assessment is inevitably subjective. Different assessors may vary in their weighing of the evidence, especially when uncertainty is high. Therefore, it is essential to document the assessment in detail, including the outcome and uncertainty for each lines of evidence considered, and explaining how they were combined to reach conclusions about the overall outcome and its uncertainty.

A systematic tabular approach is recommended for documenting the weight-of-evidence assessment, such as that illustrated in Table 24. The tabular format provides a concise yet clear summary of the lines of evidence considered and how they were combined. It also helps the reader to evaluate whether the assessment was balanced, and aids consistency of approach between pesticides.

It should be noted that Table 24 summarises the major types of uncertainty for each line of evidence, and not just the overall uncertainty. This is recommended because it helps the assessor to take account of some important strengths and weaknesses of different types of refined assessment, as can be seen from the example in Appendix C (Table 4). Note that uncertainty entries for the first-tier assessment may be copied from the corresponding uncertainty table shown in Appendix C.

The subjectivity of weight-of-evidence assessment can impede the formation of an independent view when this is based on the assessment of another person. Therefore, when a weight-of-evidence assessment is submitted by an applicant, it would be prudent for the regulatory authority to conduct their own weight-of-evidence assessment separately, compare their conclusion with that of the applicant, and consider the reasons for any differences.

It is sometimes objected that characterising uncertainty is unhelpful in decision-making. In fact, it is essential for risk assessors to characterise uncertainty, as is clear from Directive 91/414/EEC ('clearly establish') and from policy statements by the European Commission (Madelin, 2004; EC, 2000). Furthermore, practical options exist for dealing with uncertainty in decision-making. As stated in section 6.8, two of the principal options are to request more data to reduce uncertainty, or to request more refined evaluation or analysis of the existing uncertainty. A third option is to counter the uncertainty by applying risk mitigation options (see section 7), so that the chance of adverse impacts is limited to an acceptable level[85]. However, choosing between options for dealing with uncertainty involves risk management considerations outside the scope of this document such as the acceptability of effects, the degree of certainty required and potentially other factors such as the cost and time required for further refinement, the need to respect legal deadlines for authorisations, and the consequences of risk mitigation or non-authorisation (e.g. reduced efficacy, reduced choice of pest control options in agriculture, risk of resistance, etc.).

84 Note that the standard of evidence required by the 'unless' clause is 'clearly establish', which is much stronger than 'on balance'.

85 "In cases where both the potential risk and scientific uncertainties are high, the risk manager may conclude that a precautionary approach is appropriate." (Madelin, 2004).

In summary, it is recommended that:

- Every refined risk assessment should conclude with an overall characterisation of risk, in terms relevant for decision-making. It is recommended to begin with the consideration of whether the evidence makes any mortality or reproductive effects unlikely (the surrogate protection goal). Where this is not satisfied, attention should turn to characterising the levels of mortality and reproductive effects that may occur, and using this to evaluate whether there is a high certainty of no visible mortality and no long-term repercussions on abundance and diversity (the actual protection goal).
- The overall characterisation of risk should be derived by a qualitative weight-of-evidence assessment considering all relevant lines of evidence and their uncertainties using a systematic tabular approach (see e.g. Table 24). If the overall characterisation is expressed qualitatively (in words) rather than quantitatively, great care should be taken to describe the outcome and its uncertainty as clearly as possible.
- The first-tier assessment should always be included as one of the lines of evidence, and given appropriate weight (this will be higher for acute risks of sprayed pesticides than for other types of assessment).

**Table 24.** Tabular approach recommended for qualitative weight-of-evidence assessment, summarising the conclusion and uncertainties for several lines of evidence and using them to develop an overall conclusion (see Appendix C, Table 4) for a practical example.

The +/- symbols indicate whether each source of uncertainty has the potential to make the true risk higher (+) or lower (-) than the indicated outcome. The number of symbols provides a subjective relative evaluation of the magnitude of the effect (e.g. - - - might indicate an uncertainty that could reduce risk by an amount equivalent to reducing a TER by about a factor of 10). If the effect could vary over a range, lower and upper evaluations are given (e.g. - / ++ or + / ++).

| | **Lines of evidence *(add more columns if appropriate)*** | | |
|---|---|---|---|
| | **First-tier assessment *(should always be included)*** | Second line of evidence | *Add one column for each line of evidence* |
| **Main contributions to uncertainty:** | | | |
| Concise description of first major source of uncertainty | + and – symbols (see legend) | | |
| Second uncertainty | | | |
| | | | |
| | | | |
| Add one row for each major source of uncertainty | | | |
| | | | |
| | | | |
| **Conclusions for individual lines of evidence** | **Insert overall assessment for each line of evidence** | | |
| **Overall conclusion** | **Insert overall conclusion giving appropriate weight to each line of evidence, taking account of their relative certainty (more uncertainty = less weight). The overall conclusion should be a balanced judgement and not simply a summation of the plus and minus symbols.** | | |

# 7. Risk management and decision-making

## 7.1. Risk management considerations[86]

The survey of Member States and stakeholders undertaken by EFSA (2008) indicated that visible mortality and population effects should be the focus of concern for bird and mammal risk assessment. Due to the difficulties of assessing these directly the approach taken in the procedures for first-tier assessments, and in most of the options for refined assessments, is to focus on individual effects, such that the population is protected (see section 3 and Appendix C for a full discussion of these issues). This introduces a degree of conservatism as a means of dealing with the many and large uncertainties that would affect assessments of effects at the population level. In cases where the assessment outcome breaches the standard decision-making criteria, risk managers may wish to consider whether the degree of conservatism is appropriate.

This question could be approached from two quite different directions. The first is for risk assessors to refine their assessment. This could be done via any of the options for refinement considered in section 6, including moving from assessing individual effects to assessing population effects. Population effects may be assessed either quantitatively or qualitatively, although both involve substantial uncertainties that must be taken into account (section 6.8). Of course, any scientific evaluation of population effects should be fully documented and justified, as a separate section of the risk assessment (as for any refined assessment). Any additional assessments should not be considered in isolation but should be weighed against evidence from the first-tier assessment and any other refined assessment options, to form an overall characterisation of the predicted effects and their associated uncertainties (section 6.9) [87].

The second possibility (which may be used in conjunction with the first) is for risk managers to weigh the scientific assessment of risk against other risk management considerations. Plant protection products are applied for the benefits they provide. Where risk managers consider that these benefits outweigh any predicted adverse effects from the risk assessment (taking account of their uncertainty), they may take the decision that authorisation is justifiable. For example, use of a plant protection product on a minor crop may be deemed essential and pose a lower threat to a population than use on a major crop, although the potential for aggregation of effects over multiple minor crops may also be relevant. Any risk management considerations affecting the final decision, either for no authorisation or for authorisation, must be explained in full. One of the benefits of this approach will be to assist other competent authorities when making their decisions on applications for mutual recognition or, in future, zonal authorisations.

## 7.2. Risk mitigation options

If at least one substantial area of use has been identified as acceptable in the risk assessment at the EU level, i.e. the TER is higher than the appropriate Annex VI trigger values, but a high risk is still indicated for other areas of use, it may be appropriate to consider risk mitigation options. These options are use-specific. It must be assessed in each case if their effectiveness can be determined on a Member State basis (e.g. in the context of a national authorisation) or if it must be determined during the process of Annex I inclusion of the active substance. In any case, the effectiveness of risk mitigation measures must be demonstrated before Annex I inclusion, as prescribed by the European Court[88]. Outlined below are possible options which could be considered if a high risk is indicated.

86 Risk management is outside the remit of EFSA. The guidance in this section was developed by the Joint Working Group (see also EC, 2009).

87 Assessments of population consequences tend to be very uncertain and must therefore be weighed carefully against other lines of assessment that address individual effects but with less uncertainty (see sections 6.7-6.9).

88 Judgement of the Court of First Instance in Case T-229/04 of 11 July 2007 - Kingdom of Sweden v Commission of the European Communities; annulation of the inclusion of paraquat into Annex I of Directive 91/414/EEC; paras 224 and 227, among others.

### 7.2.1. Risk from seed treatments

If a high risk from a seed treatment is predicted, labelling should instruct the immediate removal of spills. Furthermore, it may be appropriate to consider that the seed be drilled or incorporated immediately after application. If seed is incorporated, its availability to birds and mammals will be reduced and hence if an acute risk has been highlighted, this will be reduced as birds and mammals will take longer to find and consume treated seed. It has to be assessed, of course, whether consumption is reduced sufficiently thereby to conclude that the risk is acceptable. In order to do so, agronomic practices should be considered, for example, the likelihood of seed germination and the effectiveness of seed treatment on incorporated seeds. This risk management option has been considered in detail by Pascual et al. (1999b) and further information regarding risk management options for cereal seed is presented in Pascual et al. (1999a and b).

### 7.2.2. Risk from granules

If a high risk from granules has been highlighted, the removal of spills should be required and the feasibility of incorporating them at the time of application be considered in order to reduce their availability to birds. As for seed treatment, agronomic implications should be considered when assessing this as a risk management option.

### 7.2.3. Risk from spray applications

If a risk to birds and mammals has been indicated from the use of a spray, this risk may be reduced by decreasing the application rate and/or application frequency. However, this may significantly affect the efficacy of the product. Alternatively, spot or row treatment may be appropriate depending upon the pest or disease being treated. Changing the method of application from spray to a more targeted approach, e.g. bait or paste/paint may reduce the risk to birds and mammals but the success of this approach will depend upon the disease or pest being treated. If a reproductive risk to birds or mammals has been highlighted, then it may be appropriate to restrict the time of application to the non-breeding time of birds or mammals or to limit the number of applications and hence reduce exposure.

Regardless of the ultimate choice that is made between options of risk management, any impact on the effectiveness and usefulness of the product should be evaluated so it can be taken into account in decision making.

# Recommendations

The Commission recommends that it is acceptable that an applicant applies already this current Guidance Document. For all dossiers submitted as of 1 July 2010 this current Guidance Document should be applied. This Guidance Document should be revised in 2012 taking into account experience from using it. Member States are encouraged to use a questionnaire that will be made available to provide feedback to EFSA.

# Documentation provided to EFSA

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# Appendices

Appendices are available in the enclosed CD-ROM.

| Name | Appendix title |
|---|---|
| A | Bird and mammals Tier 1 tables |
| B | Combined effects of simultaneous exposure to several active substances |
| C | Evaluation of the level of protection provided by the proposed first-tier assessment procedures |
| D | Proportions of List 3a substances failing under current and proposed lower tier procedures for acute risk assessment |
| E | Impact of crop interception on residues on plant food items |
| F | Residues of plant protection products on food items for birds and mammals |
| G | Calculating exposure for the dietary intake approach |
| H | Multiple applications and residue dynamics in the environment |
| J | Detailed guidance on how to carry out the repro risk assessment |
| K | Background information on the assessment of uptake via drinking water |
| L | Energy, moisture content and assimilation efficiency of bird and mammal food |
| M | How to determine a focal species |
| N | Recommendations on arthropod residue field studies |
| P | How to estimate PT |
| Q | How to determine bird and mammal diets |
| R | Nestling scenarios for long-term assessments |
| S | Bioaccumulation of chemicals in terrestrial vertebrates |

# Abbreviations

| | |
|---|---|
| ADME | absorption, distribution, metabolism and excretion |
| AE | Assimilation efficiency |
| AFSSA | Agence française de sécurité sanitaire des aliments |
| AR | Application rate |
| a.s. | Active substance |
| AV | Avoidance factor |
| BAF | Bioaccumulation factor |
| BB | Body burden |
| BBCH | Biologische Bundesanstalt, Bundessortenamt and Chemical industry |
| BCF | Bioconcentration factor |
| bw | body weight |
| C | Concentration |
| CSL | Central Science Laboratory (now: The Food and Environment Research Agency) |
| d | Day |
| DDD | Daily dietary dose |
| DEE | Daily energy expenditure |
| $DT_{50}$ | Time for 50 % degradation |
| dw | Drinking water |
| DWR | Drinking water rates |
| EC | European Commission |
| EEC | European Economic Community |
| EFSA | European Food Safety Authority |
| EPCO | EFSA Peer Review Co-Ordination |
| EPPO | European and Mediterranean Plant Protection Organization |
| ETE | Estimated theoretical exposure |
| EU | European Union |
| F1 | Initial offspring generation |
| F2 | Second generation |
| FE | Food energy |
| FIR | Food intake rate |
| FOCUS | Forum for the Co-ordination of pesticide fate models and their Use |
| FS | Focal species |
| g | Gram |
| GD | Guidance Document |
| GLP | Good Laboratory Practice |
| gw | Ground water |
| HD5 | hazardous dose to 5 % of the species |
| IUPAC | International Union of Pure and Applied Chemistry |
| *k* | rate constant |
| kg/ha | Kilogram per hectare |
| kJ | Kilojoule |
| $K_{OC}$ | Organic carbon absorption coefficient |
| $K_{OW}$ | Octanol-water partition coefficient |
| L | Litre |
| $LC_{50}$ | Lethal concentration; the concentration at which 50 % of the test organisms die. |

## ABBREVIATIONS

| | |
|---|---|
| $LD_{50}$ | Lethal dose; the dose at which 50 % of the test organisms die. |
| LoP | Level of protection |
| lt | Long-term |
| LTE | long-term exposure assessment |
| MAF | Multiple application factor |
| MC | Moisture Content |
| mg/kg | Milligram per kilogram |
| mg/L | Milligram per litre |
| MRL | Maximum residue levels |
| MS | Member State |
| n | Sample size |
| NAR | Nominal application rate |
| NIEHS | National Institute of Environmental Health Sciences |
| NOAEL | No observed adverse effect level |
| NOEC | No observed effect concentration |
| NOED | No observed effect dose |
| NOEL | No observed effect level |
| OECD | Organisation for Economic Co-operation and Development |
| OPPTS | US EPA's Office of Pesticide Programs and Toxic Substances |
| PD | Composition of diet obtained from treated area |
| PEC | Predicted environmental concentration |
| PHI | pre-harvest interval |
| ppm | Parts per million |
| PPR Panel | Scientific Panel on Plant Health, Plant Protection Products and their Residues |
| PRAPeR | EFSA's unit for the pesticide risk assessment peer-review |
| PSD | Pesticide Safety Directorate |
| PT | Proportion of an animal's daily diet obtained in habitat treated with pesticide |
| QSAR | Quantitative structure-activity relationship |
| RA | Risk assessment |
| RAC | Regulatory acceptable concentration |
| RIVM | Netherlands National Institute of Public Health and the Environment |
| RUD | Residue unit dose |
| SANCO | European Commission Health and Consumer Protection Directorate General |
| SAR | Structure-activity relationship |
| SCFCAH | Standing Committee on the Food Chain and Animal Health |
| SCP | Scientific Committee on Plants |
| SETAC | Society of Environmental Toxicology and Chemistry |
| SP | Soil particle |
| STE | short-term exposure assessment |
| SV | shortcut value |
| sw | Surface water |
| TER | Toxicity-exposure-ratio |
| TWA | Time weighted average |
| US EPA | United States Environmental Protection Agency |
| WF | Water flux |
| WG | Working Group |
| WoE | Weight of evidence |

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# Annexes

## Annex I Shortcut values for generic focal species

**Table I. 1.** Shortcut values for avian generic focal species. The shortcut value based on mean RUDs should be used for reproductive assessments, and the shortcut value based on 90$^{th}$ percentile RUDs should be used for acute assessments.

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90$^{th}$ percentile RUDs |
|---|---|---|---|---|---|
| Bare soils | BBCH < 10 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 11.4 | 24.7 |
| Bare soils | BBCH < 10 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 8.2 | 17.4 |
| Bare soils | BBCH < 10 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 5.9 | 10.9 |
| Bulbs & onion like crops | BBCH 10 - 39 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 11.4 | 24.7 |
| Bulbs & onion like crops | BBCH ≥ 40 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 6.9 | 14.8 |
| Bulbs & onion like crops | BBCH 10 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Bulbs & onion like crops | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 6.5 | 14.4 |
| Bulbs & onion like crops | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Bulbs & onion like crops | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 9.7 | 25.2 |
| Bush & cane fruit | Fruit stage BBCH 71-79 currants | Frugivorous bird "blackcap" | Blackcap (Sylvia atricapilla) | 23.0 | 46.3 |
| Bush & cane fruit | Whole season BBCH 00-79 Currants | Small insectivorous bird "warbler" | Willow warbler (Phylloscopus trochilus) | 20.3 | 52.2 |
| Cereals | Late post-emergence (May-June) BBCH 71-89 | Small insectivorous bird "passerine" | Fan tailed warbler | 22.4 | 57.6 |
| Cereals | Early (shoots) autumn-winter BBCH 10-29 | Large herbivorous bird "goose" | Pink-foot goose (Anser brachyrhynchus) | 16.2 | 30.5 |
| Cereals | BBCH 10 - 29 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Cereals | BBCH 30 -39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 5.4 | 12.0 |
| Cereals | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 3.3 | 7.2 |
| Cereals | Late season- S eed heads | Small granivorous/ insectivorous bird "bunting" | Yellowhammer (Emberiza citronella) | 12.5 | 27.0 |
| Cotton | BBCH 10 - 19 | Medium insectivorous bird "pranticole" | Collared Pratincoles Glareola pratincola | 2.3 | 4.2 |
| Cotton | BBCH ≥ 20 | Medium insectivorous bird "pranticole" | Collared Pratincoles Glareola pratincola | 1.1 | 3.0 |
| Cotton | BBCH 10 - 49 | Small omnivorous bird "sparrow" | House sparrow (Passer domesticus) | 11.2 | 17.7 |
| Cotton | BBCH ≥ 50 | Small omnivorous bird "sparrow" | House sparrow (Passer domesticus) | 2.8 | 4.4 |

## Table I.1 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Fruiting vegetables | Fruit stage BBCH 71-89 | Frugivorous bird "crow" | Crow (Corvus brachyrhynchos) | 32.0 | 57.4 |
| Fruiting vegetables | BBCH 10 - 49 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 11.4 | 24.7 |
| Fruiting vegetables | BBCH ≥ 50 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 3.4 | 7.4 |
| Fruiting vegetables | BBCH 10 - 49 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Fruiting vegetables | BBCH ≥ 50 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 3.3 | 7.2 |
| Fruiting vegetables | Fruit stage BBCH 71-89 | Frugivorous bird "Starling" | Starling (Sturnus vulgaris) | 20.7 | 49.4 |
| Fruiting vegetables | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Fruiting vegetables | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 9.7 | 25.2 |
| Grassland | New sown grass seeds | Small granivorous bird "Sparrow" | House sparrow (Passer domesticus) | 9.4 | 20.4 |
| Grassland | Late season (seed heads) | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 11.4 | 24.7 |
| Grassland | Growing shoots | Large herbivorous bird "goose" | Pink-foot goose (Anser brachyrhynchus) | 16.2 | 30.5 |
| Grassland | Growing shoots | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Hop | BBCH 10 - 19 | Small insectivorous bird "finch" | Chaffinch (Fringilla coelebs) | 9.1 | 23.8 |
| Hop | BBCH ≥ 20 | Small insectivorous bird "finch" | Chaffinch (Fringilla coelebs) | 10.6 | 25.3 |
| Hop | BBCH 10 - 19 | Small granivorous bird "finch" | Goldfinch (Carduelis carduelis) | 11.4 | 24.6 |
| Hop | BBCH 20 - 39 | Small granivorous bird "finch" | Goldfinch (Carduelis carduelis) | 5.7 | 12.3 |
| Hop | BBCH ≥ 40 | Small granivorous bird "finch" | Goldfinch (Carduelis carduelis) | 3.4 | 7.4 |
| Leafy vegetables | BBCH 10 - 49 | Small granivorous bird "finch" | Serin (Serinus serinus) | 12.6 | 27.4 |
| Leafy vegetables | BBCH ≥ 50 | Small granivorous bird "finch" | Serin (Serinus serinus) | 3.8 | 8.2 |
| Leafy vegetables | BBCH 10 - 49 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Leafy vegetables | BBCH ≥ 50 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 3.3 | 7.2 |
| Leafy vegetables | Leaf development BBCH 10-19 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | 37.0 | 90.6 |
| Leafy vegetables | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Leafy vegetables | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 9.7 | 25.2 |
| Legume forage | BBCH 10 - 49 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 11.4 | 24.7 |

## Table I.1 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Legume forage | BBCH ≥ 50 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 3.4 | 7.4 |
| Legume forage | BBCH 10 - 49 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Legume forage | BBCH ≥ 50 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 3.3 | 7.2 |
| Legume forage | Leaf development BBCH 21-49 | medium herbivorous/ granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | 22.7 | 55.6 |
| Legume forage | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Legume forage | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 9.7 | 25.2 |
| Maize | BBCH 10 - 29 | Medium granivorous bird "gamebird" | Partridge (Perdix perdix) | 3.0 | 6.6 |
| Maize | BBCH 30 - 39 | Medium granivorous bird "gamebird" | Partridge (Perdix perdix) | 1.5 | 3.3 |
| Maize | BBCH ≥ 40 | Medium granivorous bird "gamebird" | Partridge (Perdix perdix) | 0.8 | 1.6 |
| Maize | Leaf development BBCH 10 to 19 | Small insectivorous/ worm feeding species "thrush" | Robin (Erithacus rubecula) | 5.7 | 10.5 |
| Maize | BBCH 10 - 29 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Maize | BBCH 30 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 5.4 | 12.0 |
| Maize | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 2.7 | 6.0 |
| Maize | BBCH 10 - 29 | medium herbivorous/ granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | 22.7 | 55.6 |
| Maize | BBCH 30 - 39 | medium herbivorous/ granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | 11.4 | 27.8 |
| Maize | BBCH ≥ 40 | medium herbivorous/ granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | 5.7 | 13.9 |
| Maize | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Maize | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 4.8 | 12.6 |
| Oilseed rape | late – late (with seeds) (BBCH 30-99) | Small insectivorous bird "dunnock) | Dunnock (Prunella modularis) | 2.7 | 7.4 |
| Oilseed rape | early (shoots) (BBCH 10-19) | Large herbivorous bird "goose" | Greylag goose (Anser anser) | 15.9 | 39.0 |
| Oilseed rape | late (with seeds) (BBCH 80-99) | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 11.4 | 24.7 |
| Oilseed rape | BBCH 10 - 29 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Oilseed rape | BBCH 30 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 3.3 | 7.2 |
| Oilseed rape | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 2.7 | 6.0 |
| Oilseed rape | BBCH 10 - 19 | medium herbivorous/grani-vorous bird "pigeon" | Wood pigeon (Columba palumbus) | 22.7 | 55.6 |
| Oilseed rape | BBCH 20 - 29 | medium herbivorous/grani-vorous bird "pigeon" | Wood pigeon (Columba palumbus) | 3.5 | 4.0 |

## Table I.1 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Oilseed rape | BBCH 30 - 39 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | 1.1 | 2.4 |
| Oilseed rape | BBCH ≥ 40 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | 0.9 | 2.0 |
| Oilseed rape | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 5.9 | 10.9 |
| Oilseed rape | BBCH 20 - 29 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 2.8 | 7.7 |
| Orchard | Spring Summer, | Small insectivorous bird "tit" | Bluetit (Parus caeruleus) | 18.2 | 46.8 |
| Orchard | Not crop directed application all season | Small insectivorous/ worm feeding species "thrush" | Robin (Erithacus rubecula) | 2.7 | 7.4 |
| Orchard | Crop directed application BBCH 10 - 19 | Small insectivorous/ worm feeding species "thrush" | Robin (Erithacus rubecula) | 2.1 | 5.9 |
| Orchard | Crop directed application BBCH 20 - 39 | Small insectivorous/ worm feeding species "thrush" | Robin (Erithacus rubecula) | 1.6 | 4.4 |
| Orchard | Crop directed application BBCH ≥ 40 | Small insectivorous/ worm feeding species "thrush" | Robin (Erithacus rubecula) | 0.8 | 2.2 |
| Orchard | Not crop directed application all season | Small granivorous bird "finch" | Serin (Serinus serinus) | 12.6 | 27.4 |
| Orchard | Crop directed application BBCH 10 - 19 | Small granivorous bird "finch" | Serin (Serinus serinus) | 10.1 | 21.9 |
| Orchard | Crop directed application BBCH 20 - 39 | Small granivorous bird "finch" | Serin (Serinus serinus) | 7.6 | 16.4 |
| Orchard | Crop directed application BBCH ≥ 40 | Small granivorous bird "finch" | Serin (Serinus serinus) | 3.8 | 8.2 |
| Ornamentals/ nursery | Application to plant | Small insectivorous bird "tit" | Bluetit (Parus caeruleus) | 18.2 | 46.8 |
| Ornamentals/ nursery | Application to plant – exposure to underlying ground | Small insectivorous/worm feeding species "thrush" | Robin (Erithacus rubecula) | 2.7 | 7.4 |
| Potatoes | BBCH 10 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Potatoes | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 3.3 | 7.2 |
| Potatoes | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Potatoes | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 9.7 | 25.2 |
| Pulses | BBCH 10 - 49 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 11.4 | 24.7 |
| Pulses | BBCH ≥ 50 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 3.4 | 7.4 |

## Table I.1 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Pulses | BBCH 10 - 49 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Pulses | BBCH ≥ 50 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 3.3 | 7.2 |
| Pulses | Leaf development BBCH 10-19 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | 22.7 | 55.6 |
| Pulses | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Pulses | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 9.7 | 25.2 |
| Root & stem vegetables | BBCH 10 - 39 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 11.4 | 24.7 |
| Root & stem vegetables | BBCH ≥ 40 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 3.4 | 7.4 |
| Root & stem vegetables | BBCH 10 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Root & stem vegetables | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 3.3 | 7.2 |
| Root &stem vegetables | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Root & stem vegetables | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 9.7 | 25.2 |
| Strawberries | BBCH 10 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Strawberries | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 4.4 | 9.6 |
| Strawberries | Late (Flowering/ development of fruit/ Maturity of fruit) BBCH 61-89 | Frugivorous bird "Starling" | Starling (Sturnus vulgaris) | 13.4 | 27.0 |
| Strawberries | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |
| Strawberries | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 9.7 | 25.2 |
| Sugar beet | late (summer/ autumn) (BBCH 30-49) | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | 11.4 | 24.7 |
| Sugar beet | early (spring) (BBCH 10-19) | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Sugar beet | BBCH 10-19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 5.9 | 10.9 |
| Sugar beet | BBCH 20 - 49 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 2.8 | 7.7 |
| Sugar beet | BBCH 10-19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 5.9 | 10.9 |
| Sugar beet | BBCH 20 - 49 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 9.7 | 25.2 |
| Sunflower | Early Germination/ leaf development) BBCH 00-19 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | 10.9 | 24.0 |
| Sunflower | Early (Germination/ leaf development) BBCH 00-19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | 11.3 | 26.8 |

## Table I.1 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Sunflower | Late (Flowering, seed ripening) BBCH 61-92 | Small granivorous/ insectivorous bird "bunting" | Yellowhammer (Emberiza citronella) | 10.0 | 21.7 |
| Vineyard | BBCH 10 - 19 | Small insectivorous species "Redstart" | Black Redstart (Phoenicurus ochruros) | 11.5 | 27.4 |
| Vineyard | BBCH ≥ 20 | Small insectivorous species "Redstart" | Black Redstart (Phoenicurus ochruros) | 9.9 | 25.7 |
| Vineyard | BBCH 10 - 19 | Small granivorous bird "Finch" | Linnet (Carduelis cannabina) | 6.9 | 14.8 |
| Vineyard | BBCH 20 - 39 | Small granivorous bird "Finch" | Linnet (Carduelis cannabina) | 5.7 | 12.4 |
| Vineyard | BBCH ≥ 40 | Small granivorous bird "Finch" | Linnet (Carduelis cannabina) | 3.4 | 7.4 |
| Vineyard | Ripening | Frugivorous bird "Trush/ starling" | Song Thrush (Turdus philomelos) | 14.4 | 28.9 |
| Vineyard | BBCH 10 - 19 | Small omnivorous bird "lark" | Wood Lark (Lullula arborea) | 6.5 | 14.4 |
| Vineyard | BBCH 20 - 39 | Small omnivorous bird "lark" | Wood Lark (Lullula arborea) | 5.4 | 12.0 |
| Vineyard | BBCH ≥ 40 | Small omnivorous bird "lark" | Wood Lark (Lullula arborea) | 3.3 | 7.2 |

**Table I. 2.** Shortcut values for mammalian generic focal species. The shortcut value based on mean RUDs should be used for reproductive assessments, and the shortcut value based on 90$^{th}$ percentile RUDs should be used for acute assessments.

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90$^{th}$ percentile RUDs |
|---|---|---|---|---|---|
| Bare soils | BBCH < 10 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 5.7 | 14.3 |
| Bulbs & onion like crops | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Bulbs & onion like crops | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Bulbs & onion like crops | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 43.4 | 81.9 |
| Bulbs & onion like crops | BBCH 10 - 39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Bulbs & onion like crops | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 4.7 | 10.3 |
| Bush & cane fruit | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Bush & cane fruit | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Bush & cane fruit | BBCH 10-19 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 43.4 | 81.9 |
| Bush & cane fruit | BBCH 20 - 39 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 36.1 | 68.2 |
| Bush & cane fruit | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Bush & cane fruit | Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | Garden dormouse (Eliomys quercinus) | 9.7 | 19.4 |
| Bush & cane fruit | BBCH 10-19 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 4.7 | 10.3 |
| Bush & cane fruit | BBCH 20 - 39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 3.9 | 8.6 |
| Bush & cane fruit | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Cereals | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Cereals | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Cereals | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Cereals | Early (shoots) | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 22.3 | 42.1 |
| Cereals | BBCH 10-29 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Cereals | BBCH 30 - 39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 3.9 | 8.6 |

## Table I.2 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Cereals | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Cotton | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Cotton | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Cotton | BBCH 40 - 49 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Cotton | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 18.1 | 34.1 |
| Cotton | BBCH 10-49 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Cotton | BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 1.9 | 4.3 |
| Fruiting vegetables | Fruit stage BBCH 71-89 | Frugivorous mammal "rat" | Brown rat (Rattus norvegicus) | 25.2 | 45.2 |
| Fruiting vegetables | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Fruiting vegetables | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Fruiting vegetables | BBCH 10 - 49 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Fruiting vegetables | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Fruiting vegetables | BBCH 10-49 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Fruiting vegetables | BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Grassland | All season | Large herbivorous mammal "lagomorph" | Brown Hare (Lepus europaeus) | 17.3 | 32.6 |
| Grassland | late | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Grassland | All season | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Grassland | Late season (seed heads) | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 6.6 | 14.4 |
| Grassland | New sown grass seeds | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 6.6 | 14.4 |
| Hop | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Hop | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Hop | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |

## Table I.2 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Hop | BBCH 10-19 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Hop | BBCH 20 - 39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 3.9 | 8.6 |
| Hop | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Leafy vegetables | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Leafy vegetables | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Leafy vegetables | BBCH 40-49 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Leafy vegetables | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Leafy vegetables | All season | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 14.3 | 35.1 |
| Leafy vegetables | BBCH 10-49 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Leafy vegetables | BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Legume forage | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Legume forage | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Legume forage | BBCH 40 - 49 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Legume forage | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Legume forage | Leaf development BBCH 21-49 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 14.3 | 35.1 |
| Legume forage | BBCH 10-49 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Legume forage | BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Maize | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Maize | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Maize | BBCH 10 -29 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Maize | BBCH 30 - 39 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 36.1 | 68.2 |
| Maize | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 18.1 | 34.1 |
| Maize | BBCH 10-29 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Maize | BBCH 30 - 39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 3.9 | 8.6 |

## Table I.2 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Maize | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 1.9 | 4.3 |
| Oilseed rape | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Oilseed rape | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Oilseed rape | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 18.1 | 34.1 |
| Oilseed rape | All season | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 14.3 | 35.1 |
| Oilseed rape | BBCH 10-29 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Oilseed rape | BBCH 30 - 39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Oilseed rape | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 1.9 | 4.3 |
| Orchards | Application crop directed BBCH <10 or not crop directed | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Orchards | Application crop directed BBCH <10 or not crop directed | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Orchards | Application crop directed BBCH 10- 19 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 57.8 | 109.2 |
| Orchards | Application crop directed BBCH 20- 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 43.4 | 81.9 |
| Orchards | Application crop directed BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Orchards | Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | Garden dormouse (Eliomys quercinus) | 22.7 | 47.9 |
| Orchards | Application crop directed BBCH <10 or not crop directed | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 14.3 | 35.1 |
| Orchards | Application crop directed BBCH 10- 19 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 11.5 | 28.1 |
| Orchards | Application crop directed BBCH 20- 40 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 8.6 | 21.1 |
| Orchards | Application crop directed BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 4.3 | 10.5 |
| Orchards | Application crop directed BBCH <10 or not crop directed | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Orchards | Application crop directed BBCH 10- 19 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 6.2 | 13.8 |
| Orchards | Application crop directed BBCH 20- 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 4.7 | 10.3 |
| Orchards | Application crop directed BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |

## Table I.2 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Ornamentals/ nursery | Application to plant – exposure to underlying ground | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Ornamentals/ nursery | BBCH 40 - 49 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Ornamentals/ nursery | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 36.1 | 68.2 |
| Ornamentals/ nursery | Application crop directed BBCH 10 - 49 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Ornamentals/ nursery | Application crop directed BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 3.9 | 8.6 |
| Potatoes | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Potatoes | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Potatoes | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Potatoes | BBCH 10 - 40 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 14.3 | 35.1 |
| Potatoes | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 4.3 | 10.5 |
| Potatoes | BBCH 10 - 39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Potatoes | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Pulses | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Pulses | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Pulses | BBCH 40 - 49 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Pulses | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Pulses | BBCH 10 - 49 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 14.3 | 35.1 |
| Pulses | BBCH ≥ 50 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 4.3 | 10.5 |
| Pulses | Pre harvest seed BBCH 81-99 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 6.6 | 14.4 |
| Pulses | BBCH 10 - 49 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |

## Table I.2 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Pulses | BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Root & stem vegetables | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Root & stem vegetables | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Root & stem vegetables | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Root & stem vegetables | BBCH 10-39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Root & stem vegetables | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| Strawberries | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Strawberries | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Strawberries | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 28.9 | 54.6 |
| Strawberries | BBCH 10-39 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 14.3 | 35.1 |
| Strawberries | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 5.7 | 14.0 |
| Strawberries | BBCH 10-39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Strawberries | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 3.1 | 6.9 |
| Sugar beet | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Sugar beet | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Sugar beet | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 18.1 | 34.1 |
| Sugar beet | BBCH 10-39 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 14.3 | 35.1 |
| Sugar beet | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 3.6 | 8.8 |
| Sugar beet | BBCH 10-39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Sugar beet | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 1.9 | 4.3 |
| Sunflower | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |

## Table I.2 (contd.)

| Crop | Scenario | Generic focal species | Representative species | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|
| Sunflower | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Sunflower | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 18.1 | 34.1 |
| Sunflower | BBCH 10-19 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 14.3 | 35.1 |
| Sunflower | BBCH 20 - 39 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 7.2 | 17.6 |
| Sunflower | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (Oryctolagus cuniculus) | 3.6 | 8.8 |
| Sunflower | BBCH 10-19 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Sunflower | BBCH 20 - 39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 3.9 | 8.6 |
| Sunflower | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 1.9 | 4.3 |
| Vineyard | Application ground directed | Large herbivorous mammal "lagomorph" | Brown Hare (Lepus europaeus) | 11.1 | 27.2 |
| Vineyard | BBCH 10-19 | Large herbivorous mammal "lagomorph" | Brown Hare (Lepus europaeus) | 6.7 | 16.3 |
| Vineyard | BBCH 20 - 39 | Large herbivorous mammal "lagomorph" | Brown Hare (Lepus europaeus) | 5.5 | 13.6 |
| Vineyard | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Brown Hare (Lepus europaeus) | 3.3 | 8.1 |
| Vineyard | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 4.2 | 7.6 |
| Vineyard | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| Vineyard | Application ground directed | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| Vineyard | Application crop directed BBCH 10 - 19 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 43.4 | 81.9 |
| Vineyard | Application crop directed BBCH 20 - 39 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 36.1 | 68.2 |
| Vineyard | Application crop directed BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (Microtus arvalis) | 21.7 | 40.9 |
| Vineyard | Application ground directed | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| Vineyard | Application crop directed BBCH 10 - 19 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 4.7 | 10.3 |
| Vineyard | Application crop directed BBCH 20 - 39 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 3.9 | 8.6 |
| Vineyard | Application crop directed BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |

**Annex II Review questionnaire on the ease of use of the Guidance Document**

The Commission recommends that for all dossiers submitted as of 1 July 2010 this Guidance Document should be applied. This Guidance Document should be revised in 2012 taking into account experience from using it. Member States are encouraged to use this questionnaire to provide feedback to EFSA.

| | | |
|---|---|---|
| 1 | Have you found the guidance on Tier 1 risk assessments simple to use? | Yes/No |
| 2 | If your response was NO, please offer thoughts for improvements. | |
| 3 | Have you found the higher tier guidance straight-forward to use? | Yes/No |
| 4 | If your response was NO, please offer thoughts for improvements. | |
| 5 | Have you used the EFSA risk assessment tool? | Yes/No |
| 6 | If your response was NO, can you please explain why you have chosen not to use it? | |
| 7 | If your response was YES, have you found it simple to use? | Yes/No |
| 8 | If your response was NO, please offer thoughts for improvements. | |
| 9 | If there are key scientific considerations that are not addressed by the Guidance Document, please provide a short outline. | |
| 10 | Please present any evidence of bird populations which have been adversely affected by or benefitted from decisions made using the Guidance Document. | |

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# APPENDIX A

## TIER 1 TABLES FOR BIRDS AND MAMMALS

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix A. EFSA Journal 2009; 7(12):1438. [2 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

**BIRD TIER 1 TABLES**

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Bare soils | BBCH < 10 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.7 |
| 2 | Bare soils | BBCH < 10 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 3 | Bare soils | BBCH < 10 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 4 | Bare soils | BBCH < 10 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.35 | 50% seeds, 50% ground arthropods | Combination (ground invertebrates without interception) | 1 | 23.9 | 50.4 | 8.2 | 17.4 |
| 5 | Bare soils | BBCH < 10 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.9 | 10.9 |
| 6 | Bulbs and onion like crops | BBCH 10 - 39 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.7 |
| 7 | Bulbs and onion like crops | BBCH ≥ 40 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 0.6 | 40.2 | 87 | 6.9 | 14.8 |
| 8 | Bulbs and onion like crops | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 9 | Bulbs and onion like crops | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 10 | Bulbs and onion like crops | BBCH 10 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 11 | Bulbs and onion like crops | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.6 | 28.7 | 70.3 | 38.9 | 95.3 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 12 | Bulbs and onion like crops | BBCH 10 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 13 | Bulbs and onion like crops | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.6 | 40.2 | 87 | 5.6 | 12.1 |
| 14 | Bulbs and onion like crops | BBCH 10 - 39 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 16 | Bulbs and onion like crops | BBCH ≥ 40 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.6 | 21.0 | 46.2 | 6.5 | 14.4 |
| 17 | Bulbs and onion like crops | BBCH 10 - 19 | Small insectivorous bird “wagtail” | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 18 | Bulbs and onion like crops | BBCH ≥ 20 | Small insectivorous bird “wagtail” | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.7 | 25.2 |
| 19 | Bush and cane fruit | Fruit stage BBCH 71-79 currants | Frugivorous bird "blackcap" | Blackcap (Sylvia atricapilla) | Frugivorous | Fruit | 15.5 | 2.77 | 100% fruit | Berries | 1 | 8.3 | 16.7 | 23.0 | 46.3 |
| 20 | Bush and cane fruit | Whole season BBCH 00-79 Currants | Small insectivorous bird "warbler" | Willow warbler (Phylloscopus trochilus) | Insectivorous | Foliar | 9.5 | 0.96 | 100% foliar insects | Foliar insects | 1 | 21 | 54.1 | 20.3 | 52.2 |
| 21 | Cereals | Late post-emergence (May-June) BBCH 71-89 | Small insectivorus bird "passerine" | Fan tailed warbler | Insectivorous | Foliar | 7 | 1.06 | 100% foliar insects | Foliar insects | 1 | 21 | 54.1 | 22.4 | 57.6 |
| 22 | Cereals | Early (shoots) autumn-winter BBCH 10-29 | Large herbivorous bird "goose" | Pink-foot goose (Anser brachyrhynchus) | Herbivorous | Ground | 2645 | 0.30 | 100% cereal shoots | Grass + cereals | 1 | 54.2 | 102.3 | 16.2 | 30.5 |
| 23 | Cereals | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 24 | Cereals | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 25 | Cereals | BBCH 10 - 29 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% non-grass herbs | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 26 | Cereals | BBCH 30 -39 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% non-grass herbs | Non-grass herbs | 0.5 | 28.7 | 70.3 | 32.4 | 79.4 |
| 27 | Cereals | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% non-grass herbs | Non-grass herbs | 0.3 | 28.7 | 70.3 | 19.4 | 47.6 |
| 28 | Cereals | BBCH 10 - 29 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 29 | Cereals | BBCH 30 -39 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.5 | 40.2 | 87 | 4.7 | 10.1 |
| 30 | Cereals | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 2.8 | 6.1 |
| 31 | Cereals | BBCH 10 - 29 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates with interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 33 | Cereals | BBCH 30 -39 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates with interception) | 0.5 | 21.0 | 46.2 | 5.4 | 12.0 |
| 34 | Cereals | BBCH ≥ 40 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates with interception) | 0.3 | 21.0 | 46.2 | 3.3 | 7.2 |
| 35 | Cereals | Late season-Seed heads | Small granivorous/insectivorous bird “bunting” | Yellowhammer (Emberiza citronella) | granivorous | Ground | 23 | 0.31 | 100% cereal seeds | Grains/ear | 1 | 15 | 13 | 4.7 | 4.0 |
| 36 | Cotton | BBCH 10 - 19 | Medium insectivorous bird "pranticole" | Collared Pratincoles Glareola pratincola | Insectivorous | Ground | 75 | 0.31 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 2.3 | 4.2 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 37 | Cotton | BBCH ≥ 20 | Medium insectivorous bird "pranticole" | Collared Pratincoles Glareola pratincola | Insectivorous | Ground | 75 | 0.31 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 1.1 | 3.0 |
| 38 | Cotton | BBCH 10 - 19 | Single diet for T1 | House sparrow (Passer domesticus) | Insectivorous | Ground | 27.7 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.4 |
| 39 | Cotton | BBCH ≥ 20 | Single diet for T1 | House sparrow (Passer domesticus) | Insectivorous | Ground | 27.7 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 40 | Cotton | BBCH 10 - 49 | Single diet for T1 | House sparrow (Passer domesticus) | Herbivorous | Ground | 27.7 | 2.28 | 100% non-grass herbs | Non-grass herbs | 1 | 28.7 | 70.3 | 65.4 | 160.3 |
| 41 | Cotton | BBCH ≥ 50 | Single diet for T1 | House sparrow (Passer domesticus) | Herbivorous | Ground | 27.7 | 2.28 | 100% non-grass herbs | Non-grass herbs | 0.25 | 28.7 | 70.3 | 16.4 | 40.1 |
| 42 | Cotton | BBCH 10 - 49 | Single diet for T1 | House sparrow (Passer domesticus) | Granivorous | Ground | 27.7 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.4 | 20.4 |
| 43 | Cotton | BBCH ≥ 50 | Single diet for T1 | House sparrow (Passer domesticus) | Granivorous | Ground | 27.7 | 0.23 | 100% seeds | Small seeds | 0.25 | 40.2 | 87 | 2.4 | 5.1 |
| 44 | Cotton | BBCH 10 - 49 | Small omnivorous bird “sparrow” | House sparrow (Passer domesticus) | Omnivorous | Ground | 27.7 | 0.38 | Weed seeds 50% weed plant matter 25%, animal matter 25% | Combination (invertebrates without interception) | 1 | 29.2 | 46.2 | 11.2 | 17.7 |
| 46 | Cotton | BBCH ≥ 50 | Small omnivorous bird “sparrow” | House sparrow (Passer domesticus) | Omnivorous | Ground | 27.7 | 0.38 | Weed seeds 50% weed plant matter 25%, animal matter 25% | Combination (invertebrates without interception) | 0.25 | 29.2 | 46.2 | 2.8 | 4.4 |
| 47 | Fruiting vegetables | Fruit stage BBCH 71-89 | Frugivorous bird "crow | Crow (Corvus brachyrhynchos) | Frugivorous | Fruit | 448 | 0.93 | 100% fruit | Gourds | 1 | 34.3 | 61.5 | 32.0 | 57.4 |
| 48 | Fruiting vegetables | BBCH 10 - 49 | Small granivorous bird “finch” | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.7 |
| 49 | Fruiting vegetables | BBCH ≥ 50 | Small granivorous bird “finch” | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87 | 3.4 | 7.4 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 50 | Fruiting vegetables | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 51 | Fruiting vegetables | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 52 | Fruiting vegetables | BBCH 10 - 49 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% non-grass herbs | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 53 | Fruiting vegetables | BBCH ≥ 50 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% non-grass herbs | Non-grass herbs | 0.3 | 28.7 | 70.3 | 19.4 | 47.6 |
| 54 | Fruiting vegetables | BBCH 10 - 49 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 55 | Fruiting vegetables | BBCH ≥ 50 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 2.8 | 6.1 |
| 56 | Fruiting vegetables | BBCH 10 - 49 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 58 | Fruiting vegetables | BBCH ≥ 50 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.3 | 21.0 | 46.2 | 3.3 | 7.2 |
| 59 | Fruiting vegetables | Fruit stage BBCH 71-89 | Frugivorous bird “Starling” | Starling (Sturnus vulgaris) | Frugivorous | Fruit | 82.3 | 1.62 | 100% fruit | Tomato | 1 | 12.8 | 30.6 | 20.7 | 49.4 |
| 60 | Fruiting vegetables | BBCH 10 - 19 | Small insectivorous bird “wagtail” | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 61 | Fruiting vegetables | BBCH ≥ 20 | Small insectivorous bird “wagtail” | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.7 | 25.2 |
| 62 | Grassland | New sown grass seeds | Small granivorous bird "Sparrow" | House sparrow (Passer domesticus) | Granivorous | Ground | 27.7 | 0.23 | 100% grass seeds | Small seeds | 1 | 40.2 | 87 | 9.4 | 20.4 |
| 63 | Grassland | Late season (seed heads) | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.7 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 64 | Grassland | Growing shoots | Large herbivorous bird "goose" | Pink-foot goose (Anser brachyrhynchus) | Herbivorous | Ground | 2645 | 0.30 | 100% grass leaves | Grass + cereals | 1 | 54.2 | 102.3 | 16.2 | 30.5 |
| 65 | Grassland | Growing shoots | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 66 | Hop | BBCH 10 - 19 | Small insectivorous bird "finch" | Chaffinch (Fringilla coelebs) | Insectivorous in relevant period | Foliar/ ground | 21 | 0.75 | 50% ground arthropods 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.1 | 23.8 |
| 67 | Hop | BBCH ≥ 20 | Small insectivorous bird "finch" | Chaffinch (Fringilla coelebs) | Insectivorous in relevant period | Foliar/ ground | 21 | 0.75 | 50% ground arthropods 50% foliar arthropods | Combination (ground arthropods without interception) | 1 | 14.3 | 34.0 | 10.6 | 25.3 |
| 68 | Hop | BBCH 10 - 19 | Small granivorous bird "finch" | Goldfinch (Carduelis carduelis) | Granivorous | Ground | 15.6 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.6 |
| 69 | Hop | BBCH 20 - 39 | Small granivorous bird "finch" | Goldfinch (Carduelis carduelis) | Granivorous | Ground | 15.6 | 0.28 | 100% weed seeds | Small seeds | 0.5 | 40.2 | 87 | 5.7 | 12.3 |
| 70 | Hop | BBCH ≥ 40 | Small granivorous bird "finch" | Goldfinch (Carduelis carduelis) | Granivorous | Ground | 15.6 | 0.28 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87 | 3.4 | 7.4 |
| 71 | Leafy vegetables | BBCH 10 - 49 | Small granivorous bird "finch" | Serin (Serinus serinus) | Granivorous | Ground | 11.2 | 0.31 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 12.6 | 27.4 |
| 72 | Leafy vegetables | BBCH ≥ 50 | Small granivorous bird "finch" | Serin (Serinus serinus) | Granivorous | Ground | 11.2 | 0.31 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 3.8 | 8.2 |
| 73 | Leafy vegetables | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 74 | Leafy vegetables | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 75 | Leafy vegetables | BBCH 10 - 49 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |

Bird Tier 1

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 76 | Leafy vegetables | BBCH ≥ 50 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.3 | 28.7 | 70.3 | 19.4 | 47.6 |
| 77 | Leafy vegetables | BBCH 10 - 49 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 78 | Leafy vegetables | BBCH ≥ 50 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 2.8 | 6.1 |
| 79 | Leafy vegetables | BBCH 10 - 49 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 81 | Leafy vegetables | BBCH ≥ 50 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.3 | 21.0 | 46.2 | 3.3 | 7.2 |
| 82 | Leafy vegetables | Leaf development BBCH 10-19 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Herbivorous | Ground | 490 | 1.29 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 37.0 | 90.6 |
| 83 | Leafy vegetables | BBCH 10 - 19 | Small insectivorous bird “wagtail” | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 84 | Leafy vegetables | BBCH ≥ 20 | Small insectivorous bird “wagtail” | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.7 | 25.2 |
| 85 | Legume forage | BBCH 10 - 49 | Small granivorous bird “finch” | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.7 |
| 86 | Legume forage | BBCH ≥ 50 | Small granivorous bird “finch” | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87 | 3.4 | 7.4 |
| 87 | Legume forage | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 88 | Legume forage | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 89 | Legume forage | BBCH 10 - 49 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |

Bird Tier 1

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 90 | Legume forage | BBCH ≥ 50 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.3 | 28.7 | 70.3 | 19.4 | 47.6 |
| 91 | Legume forage | BBCH 10 - 49 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 92 | Legume forage | BBCH ≥ 50 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 2.8 | 6.1 |
| 93 | Legume forage | BBCH 10 - 49 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 95 | Legume forage | BBCH ≥ 50 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.3 | 21.0 | 46.2 | 3.3 | 7.2 |
| 96 | Legume forage | Leaf development BBCH 21-49 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Herbivorous | Ground | 490 | 0.79 | 100% crop | Non-grass herbs | 1 | 28.7 | 70.3 | 22.7 | 55.6 |
| 97 | Legume forage | BBCH 10 - 19 | Small insectivorous bird “wagtail” | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 98 | Legume forage | BBCH ≥ 20 | Small insectivorous bird “wagtail” | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.7 | 25.2 |
| 99 | Maize | BBCH 10 - 29 | Medium granivorous bird "gamebird" | Partridge (Perdix perdix) | Granivorous | Ground | 390 | 0.08 | 100% seed | Small seeds | 1 | 40.2 | 87 | 3.0 | 6.6 |
| 100 | Maize | BBCH 30 - 39 | Medium granivorous bird "gamebird" | Partridge (Perdix perdix) | Granivorous | Ground | 390 | 0.08 | 100% seed | Small seeds | 0.5 | 40.2 | 87 | 1.5 | 3.3 |
| 101 | Maize | BBCH ≥ 40 | Medium granivorous bird "gamebird" | Partridge (Perdix perdix) | Granivorous | Ground | 390 | 0.08 | 100% seed | Small seeds | 0.25 | 40.2 | 87 | 0.8 | 1.6 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 102 | Maize | Leaf development BBCH 10 to 19 | Small insectivorous/worm feeding species "thrush" | Robin (Erithacus rubecula) | Omnivorous | Ground | 19.7 | 0.76 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.7 | 10.5 |
| 103 | Maize | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 104 | Maize | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 105 | Maize | BBCH 10 - 29 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 106 | Maize | BBCH 30 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.5 | 28.7 | 70.3 | 32.4 | 79.4 |
| 107 | Maize | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.25 | 28.7 | 70.3 | 16.2 | 39.7 |
| 108 | Maize | BBCH 10 - 29 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 109 | Maize | BBCH 30 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.5 | 40.2 | 87 | 4.7 | 10.1 |
| 110 | Maize | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.25 | 40.2 | 87 | 2.3 | 5.1 |
| 111 | Maize | BBCH 10 - 29 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 113 | Maize | BBCH 30 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.5 | 21.0 | 46.2 | 5.4 | 12.0 |
| 114 | Maize | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.25 | 21.0 | 46.2 | 2.7 | 6.0 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 115 | Maize | BBCH 10 - 29 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Herbivorous | Ground | 490 | 0.79 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 22.7 | 55.6 |
| 116 | Maize | BBCH 30 - 39 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Herbivorous | Ground | 490 | 0.79 | 100% leaves | Non-grass herbs | 0.5 | 28.7 | 70.3 | 11.4 | 27.8 |
| 117 | Maize | BBCH ≥ 40 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Herbivorous | Ground | 490 | 0.79 | 100% leaves | Non-grass herbs | 0.25 | 28.7 | 70.3 | 5.7 | 13.9 |
| 118 | Maize | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 119 | Maize | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates with interception | 0.5 | 12.3 | 31.9 | 4.8 | 12.6 |
| 120 | Oilseed rape | late – late (with seeds) (BBCH 30-99) | Small insectivorous bird "dunnock) | Dunnock (Prunella modularis) | Insectivorous | Ground | 19.7 | 0.76 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.7 | 7.4 |
| 121 | Oilseed rape | early (shoots) (BBCH 10-19) | Large herbivorous bird "goose" | greylag goose (Anser anser) | Herbivorous | Ground | 3108 | 0.55 | 100% crop shoots | Non-grass herbs | 1 | 28.7 | 70.3 | 15.9 | 39.0 |
| 122 | Oilseed rape | late (with seeds) (BBCH 80-99) | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.7 |
| 123 | Oilseed rape | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 124 | Oilseed rape | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 125 | Oilseed rape | BBCH 10 - 29 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 126 | Oilseed rape | BBCH 30 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.3 | 28.7 | 70.3 | 19.4 | 47.6 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 127 | Oilseed rape | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.25 | 28.7 | 70.3 | 16.2 | 39.7 |
| 128 | Oilseed rape | BBCH 10 - 29 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 129 | Oilseed rape | BBCH 30 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 2.8 | 6.1 |
| 130 | Oilseed rape | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.25 | 40.2 | 87 | 2.3 | 5.1 |
| 131 | Oilseed rape | BBCH 10 - 29 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25 % crop leaves 25 % weed seeds 50 % ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 133 | Oilseed rape | BBCH 30 - 39 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25 % crop leaves 25 % weed seeds 50 % ground arthropods | Combination (invertebrates without interception) | 0.3 | 21.0 | 46.2 | 3.3 | 7.2 |
| 134 | Oilseed rape | BBCH ≥ 40 | Small omnivorous bird “lark” | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25 % crop leaves 25 % weed seeds 50 % ground arthropods | Combination (invertebrates without interception) | 0.25 | 21.0 | 46.2 | 2.7 | 6.0 |
| 135 | Oilseed rape | BBCH 10 - 19 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Omnivorous | Ground | 490 | 0.79 | 100% crop shoots | Non-grass herbs | 1 | 28.7 | 70.3 | 22.7 | 55.6 |
| 136 | Oilseed rape | BBCH 20 - 29 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Omnivorous | Foliar/ ground | 490 | 0.10 | 50 % crop leaves 50 % weed seeds | Comby to be calculated | 1 | 34.5 | 39.3 | 3.5 | 4.0 |
| 137 | Oilseed rape | BBCH 30 - 39 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Omnivorous | Foliar/ ground | 490 | 0.10 | 50 % crop leaves 50 % weed seeds | Comby to be calculated | 0.3 | 34.5 | 78.7 | 1.1 | 2.4 |
| 138 | Oilseed rape | BBCH ≥ 40 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Omnivorous | Foliar/ ground | 490 | 0.10 | 50 % crop leaves 50 % weed seeds | Comby to be calculated | 0.25 | 34.5 | 78.7 | 0.9 | 2.0 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 139 | Oilseed rape | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.9 | 10.9 |
| 140 | Oilseed rape | BBCH 20 - 29 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.8 | 7.7 |
| 141 | Orchard | Spring Summer, | Small insectivorous bird "tit" | Bluetit (Parus caeruleus) | Insectivorous | Foliar | 13.3 | 0.86 | 100% foliar insects | Foliar insects | 1 | 21 | 54.1 | 18.2 | 46.8 |
| 142 | Orchard | Not crop directed application all season | Small insectivorous/worm feeding species "thrush" | Robin (Erithacus rubecula) | Omnivorous | Ground | 19.7 | 0.76 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.7 | 7.4 |
| 143 | Orchard | Crop directed application BBCH 10 - 19 | Small insectivorous/worm feeding species "thrush" | Robin (Erithacus rubecula) | Omnivorous | Ground | 19.7 | 0.76 | 100% soil dwelling invertebrates | ground invertebrates with interception | 0.8 | 3.5 | 9.7 | 2.1 | 5.9 |
| 144 | Orchard | Crop directed application BBCH 20 - 39 | Small insectivorous/worm feeding species "thrush" | Robin (Erithacus rubecula) | Omnivorous | Ground | 19.7 | 0.76 | 100% soil dwelling invertebrates | ground invertebrates with interception | 0.6 | 3.5 | 9.7 | 1.6 | 4.4 |
| 145 | Orchard | Crop directed application BBCH ≥ 40 | Small insectivorous/worm feeding species "thrush" | Robin (Erithacus rubecula) | Omnivorous | Ground | 19.7 | 0.76 | 100% soil dwelling invertebrates | ground invertebrates with interception | 0.3 | 3.5 | 9.7 | 0.8 | 2.2 |
| 146 | Orchard | Not crop directed application all season | Small granivorous bird "finch" | Serin (Serinus serinus) | Granivorous | Foliar/ ground | 11.2 | 0.31 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 12.6 | 27.4 |
| 147 | Orchard | Crop directed application BBCH 10 - 19 | Small granivorous bird "finch" | Serin (Serinus serinus) | Granivorous | Foliar/ ground | 11.2 | 0.31 | 100% seeds | Small seeds | 0.8 | 40.2 | 87 | 10.1 | 21.9 |
| 148 | Orchard | Crop directed application BBCH 20 - 39 | Small granivorous bird "finch" | Serin (Serinus serinus) | Granivorous | Foliar/ ground | 11.2 | 0.31 | 100% seeds | Small seeds | 0.6 | 40.2 | 87 | 7.6 | 16.4 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 149 | Orchard | Crop directed application BBCH ≥ 40 | Small granivorous bird "finch" | Serin (Serinus serinus) | Granivorous | Foliar/ ground | 11.2 | 0.31 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 3.8 | 8.2 |
| 150 | Ornamental s/nursery | Application to plant | Small insectivorous bird "tit" | Bluetit (Parus caeruleus) | Insectivorous | Foliar | 13.3 | 0.86 | 100% foliar insects | Foliar insects | 1 | 21 | 54.1 | 18.2 | 46.8 |
| 151 | Ornamental s/nursery | Application to plant – exposure to underlying ground | Small insectivorous/worm feeding species "thrush" | Robin (Erithacus rubecula) | Omnivorous | Ground | 19.7 | 0.76 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.7 | 7.4 |
| 152 | Potatoes | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 153 | Potatoes | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 154 | Potatoes | BBCH 10 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 155 | Potatoes | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.3 | 28.7 | 70.3 | 19.4 | 47.6 |
| 156 | Potatoes | BBCH 10 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 157 | Potatoes | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 2.8 | 6.1 |
| 158 | Potatoes | BBCH 10 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 160 | Potatoes | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.3 | 21.0 | 46.2 | 3.3 | 7.2 |
| 161 | Potatoes | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 162 | Potatoes | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.7 | 25.2 |
| 163 | Pulses | BBCH 10 - 49 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.7 |
| 164 | Pulses | BBCH ≥ 50 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87 | 3.4 | 7.4 |
| 165 | Pulses | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 166 | Pulses | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 167 | Pulses | BBCH 10 - 49 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 168 | Pulses | BBCH ≥ 50 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.3 | 28.7 | 70.3 | 19.4 | 47.6 |
| 169 | Pulses | BBCH 10 - 49 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 170 | Pulses | BBCH ≥ 50 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 2.8 | 6.1 |
| 171 | Pulses | BBCH 10 - 49 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 173 | Pulses | BBCH ≥ 50 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.3 | 21.0 | 46.2 | 3.3 | 7.2 |
| 174 | Pulses | Leaf development BBCH 10-19 | medium herbivorous/granivorous bird "pigeon" | Wood pigeon (Columba palumbus) | Herbivorous | Ground | 490 | 0.79 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 22.7 | 55.6 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 175 | Pulses | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 176 | Pulses | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.7 | 25.2 |
| 177 | Root and stem vegetables | BBCH 10 - 39 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.7 |
| 178 | Root and stem vegetables | BBCH ≥ 40 | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87 | 3.4 | 7.4 |
| 179 | Root and stem vegetables | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 180 | Root and stem vegetables | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 181 | Root and stem vegetables | BBCH 10 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 182 | Root and stem vegetables | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.3 | 28.7 | 70.3 | 19.4 | 47.6 |
| 183 | Root and stem vegetables | BBCH 10 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 184 | Root and stem vegetables | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 2.8 | 6.1 |
| 185 | Root and stem vegetables | BBCH 10 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 187 | Root and stem vegetables | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.3 | 21.0 | 46.2 | 3.3 | 7.2 |
| 188 | Root and stem vegetables | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 189 | Root and stem vegetables | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.7 | 25.2 |
| 190 | Straw-berries | BBCH 10 - 19 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 191 | Straw-berries | BBCH ≥ 20 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 192 | Straw-berries | BBCH 10 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 193 | Straw-berries | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.4 | 28.7 | 70.3 | 25.9 | 63.5 |
| 194 | Straw-berries | BBCH 10 - 39 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 195 | Straw-berries | BBCH ≥ 40 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.4 | 40.2 | 87 | 3.7 | 8.1 |
| 196 | Straw-berries | BBCH 10 - 39 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 198 | Straw-berries | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 0.4 | 21.0 | 46.2 | 4.4 | 9.6 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 199 | Straw-berries | Late (Flowering/ development of fruit/ Maturity of fruit) BBCH 61-89 | Frugivorous bird "Starling" | Starling (Sturnus vulgaris) | Frugivorous | Fruit | 82.3 | 1.62 | 100% fruit | Berries | 1 | 8.3 | 16.7 | 13.4 | 27.0 |
| 200 | Straw-berries | BBCH 10 - 19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 201 | Straw-berries | BBCH ≥ 20 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.7 | 25.2 |
| 202 | Sugar beet | late (summer/ autumn) (BBCH 30-49) | Small granivorous bird "finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 1 | 40.2 | 87 | 11.4 | 24.7 |
| 203 | Sugar beet | early (spring) (BBCH 10-19) | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 204 | Sugar beet | early (spring) (BBCH 10-19) | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 205 | Sugar beet | early (spring) (BBCH 10-19) | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 206 | Sugar beet | early (spring) (BBCH 10-19) | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 207 | Sugar beet | BBCH 10-19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.9 | 10.9 |
| 208 | Sugar beet | BBCH 20 - 49 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.8 | 7.7 |
| 209 | Sugar beet | BBCH 10-19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.9 | 10.9 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 210 | Sugar beet | BBCH 20 - 49 | Small insectivorous bird "wagtail" | yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.7 | 25.2 |
| 211 | Sunflower | Early Germination/ leaf development) BBCH 00-19 | Single diet for T1 | Woodlark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 212 | Sunflower | Early Germination/ leaf development) BBCH 00-19 | Single diet for T1 | Woodlark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 64.8 | 158.8 |
| 213 | Sunflower | Early Germination/ leaf development) BBCH 00-19 | Single diet for T1 | Woodlark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 1 | 40.2 | 87 | 9.3 | 20.2 |
| 214 | Sunflower | Early Germination/ leaf development) BBCH 00-19 | Small omnivorous bird "lark" | Woodlark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground arthropods | Combination (invertebrates without interception) | 1 | 21.0 | 46.2 | 10.9 | 24.0 |
| 215 | Sunflower | Early (Germination/ leaf development) BBCH 00-19 | Small insectivorous bird "wagtail" | Yellow wagtail (Motacilla flava) | Insectivorous | Ground | 17.6 | 0.79 | 50% ground arthropods, 50% foliar arthropods | Combination (ground invertebrates without interception) | 1 | 14.3 | 34.0 | 11.3 | 26.8 |
| 216 | Sunflower | Late (Flowering, seed ripening) BBCH 61-92 | Small granivorous/insectivorous bird "bunting" | Yellowhammer (Emberiza citronella) | granivorous, insecti-vourous | Ground | 23 | 0.25 | 100% crop seeds | Small seeds | 1 | 40.2 | 87 | 10.0 | 21.7 |
| 217 | Vineyard | BBCH 10 - 19 | Small insectivorous species "Redstart" | Black Redstart (Phoenicurus ochruros) | Insectivorous | Foliar/ ground | 16.5 | 0.81 | 50% ground arthropods 50% foliar arthropods | ground invertebrates without interception | 1 | 14.3 | 34.0 | 11.5 | 27.4 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 218 | Vineyard | BBCH ≥ 20 | Small insectivorous species "Redstart" | Black Redstart (Phoenicurus ochruros) | Insectivorous | Foliar/ ground | 16.5 | 0.81 | 50% ground arthropods 50% foliar arthropods | ground invertebrates with interception | 1 | 12.3 | 31.9 | 9.9 | 25.7 |
| 219 | Vineyard | BBCH 10 - 19 | Small granivorous bird "Finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 0.6 | 40.2 | 87 | 6.9 | 14.8 |
| 220 | Vineyard | BBCH 20 - 39 | Small granivorous bird "Finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 0.5 | 40.2 | 87 | 5.7 | 12.4 |
| 221 | Vineyard | BBCH ≥ 40 | Small granivorous bird "Finch" | Linnet (Carduelis cannabina) | Granivorous | Ground | 15.3 | 0.28 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87 | 3.4 | 7.4 |
| 222 | Vineyard | Ripening | Frugivorous bird "Trush/starling" | Song Thrush (Turdus philomelos) | Frugivorous | Fruit | 66.6 | 1.73 | 100% grapes | Berries | 1 | 8.3 | 16.7 | 14.4 | 28.9 |
| 223 | Vineyard | BBCH 10 - 19 | Single diet for T1 | Wood Lark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates without interception | 1 | 7.5 | 13.8 | 5.1 | 9.3 |
| 224 | Vineyard | BBCH ≥ 20 | Single diet for T1 | Wood Lark (Lullula arborea) | Insectivorous | Ground | 28.5 | 0.68 | 100% soil dwelling invertebrates | ground invertebrates with interception | 1 | 3.5 | 9.7 | 2.4 | 6.6 |
| 225 | Vineyard | BBCH 10 - 19 | Single diet for T1 | Wood Lark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.6 | 28.7 | 70.3 | 38.9 | 95.3 |
| 226 | Vineyard | BBCH 20 - 39 | Single diet for T1 | Wood Lark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.5 | 28.7 | 70.3 | 32.4 | 79.4 |
| 227 | Vineyard | BBCH ≥ 40 | Single diet for T1 | Wood Lark (Lullula arborea) | Herbivorous | Ground | 28.5 | 2.26 | 100% leaves | Non-grass herbs | 0.3 | 28.7 | 70.3 | 19.4 | 47.6 |
| 228 | Vineyard | BBCH 10 - 19 | Single diet for T1 | Wood Lark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.6 | 40.2 | 87 | 5.6 | 12.1 |
| 229 | Vineyard | BBCH 20 - 39 | Single diet for T1 | Wood Lark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.5 | 40.2 | 87 | 4.7 | 10.1 |
| 230 | Vineyard | BBCH ≥ 40 | Single diet for T1 | Wood Lark (Lullula arborea) | Granivorous | Ground | 28.5 | 0.23 | 100% seeds | Small seeds | 0.3 | 40.2 | 87 | 2.8 | 6.1 |
| 231 | Vineyard | BBCH 10 - 19 | Small omnivorous bird "lark" | Wood Lark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves 25% weed seeds 50% ground | Combination (invertebrates without interception) | 0.6 | 21.0 | 46.2 | 6.5 | 14.4 |

| n | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Interception | Mean | 90th | Shortcut value for mean RUDs | Shortcut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | arthropods | | | | | | |
| 232 | Vineyard | BBCH 20 - 39 | Small omnivorous bird "lark" | Wood Lark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves<br>25% weed seeds<br>50% ground arthropods | Combination (invertebrates without interception) | 0.5 | 21.0 | 46.2 | 5.4 | 12.0 |
| 233 | Vineyard | BBCH ≥ 40 | Small omnivorous bird "lark" | Wood Lark (Lullula arborea) | Omnivorous | Ground | 28.5 | 0.52 | 25% crop leaves<br>25% weed seeds<br>50% ground arthropods | Combination (invertebrates without interception) | 0.3 | 21.0 | 46.2 | 3.3 | 7.2 |

**MAMMAL TIER 1 TABLES**

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Bare soils | BBCH < 10 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 2 | Bare soils | BBCH < 10 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 3 | Bare soils | BBCH < 10 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.24 | 50% weed seeds, 50% ground arthropods | Combination (ground invertebrates without interception) | 1 | 23.8 | 59.4 | 5.7 | 14.3 |
| 4 | Bulbs & onion like crops | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 5 | Bulbs & onion like crops | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 6 | Bulbs & onion like crops | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.6 | 54.2 | 102.3 | 43.4 | 81.9 |
| 7 | Bulbs & onion like crops | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 8 | Bulbs & onion like crops | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 9 | Bulbs & onion like crops | BBCH 00-40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 10 | Bulbs & onion like crops | BBCH 40 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.6 | 40.2 | 87.0 | 4.0 | 8.6 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 11 | Bulbs & onion like crops | BBCH 00-40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 12 | Bulbs & onion like crops | BBCH 40 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.6 | 28.7 | 70.3 | 29.0 | 71.0 |
| 13 | Bulbs & onion like crops | BBCH 10 - 39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 14 | Bulbs & onion like crops | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.6 | 29.2 | 64.5 | 4.7 | 10.3 |
| 15 | Bush & cane fruit | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 16 | Bush & cane fruit | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 17 | Bush & cane fruit | BBCH 10-19 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.6 | 54.2 | 102.3 | 43.4 | 81.9 |
| 18 | Bush & cane fruit | BBCH 20 - 39 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.5 | 54.2 | 102.3 | 36.1 | 68.2 |
| 19 | Bush & cane fruit | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 20 | Bush & cane fruit | Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | Garden dormouse (*Eliomys quercinus*) | Frugivorous | Fruit | 57.5 | 1.16 | 100% fruit | Berries | 1 | 8.3 | 16.7 | 9.7 | 19.4 |
| 21 | Bush & cane fruit | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 22 | Bush & cane fruit | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 23 | Bush & cane fruit | BBCH 10-19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.6 | 40.2 | 87.0 | 4.0 | 8.6 |
| 24 | Bush & cane fruit | BBCH 20 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.5 | 40.2 | 87.0 | 3.3 | 7.2 |
| 25 | Bush & cane fruit | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 26 | Bush & cane fruit | BBCH 10-19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.6 | 28.7 | 70.3 | 29.0 | 71.0 |
| 27 | Bush & cane fruit | BBCH 20 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.5 | 28.7 | 70.3 | 24.2 | 59.2 |
| 28 | Bush & cane fruit | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 29 | Bush & cane fruit | BBCH 10-19 | Small omnivorous mammal “mouse” | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.6 | 29.2 | 64.5 | 4.7 | 10.3 |
| 30 | Bush & cane fruit | BBCH 20 - 39 | Small omnivorous mammal “mouse” | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.5 | 29.2 | 64.5 | 3.9 | 8.6 |
| 31 | Bush & cane fruit | BBCH ≥ 40 | Small omnivorous mammal “mouse” | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 32 | Cereals | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 33 | Cereals | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 34 | Cereals | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 35 | Cereals | Early (shoots) | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.41 | 100% cereal shoots | Grass + cereals | 1 | 54.2 | 102.3 | 22.3 | 42.1 |
| 36 | Cereals | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 37 | Cereals | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 38 | Cereals | BBCH 10-29 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 39 | Cereals | BBCH 30 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.5 | 40.2 | 87.0 | 3.3 | 7.2 |
| 40 | Cereals | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 41 | Cereals | BBCH 10-29 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 42 | Cereals | BBCH 30 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.5 | 28.7 | 70.3 | 24.2 | 59.2 |
| 43 | Cereals | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 44 | Cereals | BBCH 10-29 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 45 | Cereals | BBCH 30 - 39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 0.5 | 29.2 | 64.5 | 3.9 | 8.6 |
| 46 | Cereals | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 47 | Cotton | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 48 | Cotton | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 49 | Cotton | BBCH 40 - 49 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 50 | Cotton | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.25 | 54.2 | 102.3 | 18.1 | 34.1 |
| 51 | Cotton | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 52 | Cotton | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 53 | Cotton | BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 54 | Cotton | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.25 | 40.2 | 87.0 | 1.7 | 3.6 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 55 | Cotton | BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 56 | Cotton | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.25 | 28.7 | 70.3 | 12.1 | 29.6 |
| 57 | Cotton | BBCH 10-49 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 58 | Cotton | BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 0.25 | 29.2 | 64.5 | 1.9 | 4.3 |
| 59 | Fruiting vegetables | Fruit stage BBCH 71-89 | Frugivorous mammal "rat" | Brown rat (*Rattus norvegicus*) | Frugivorous | Fruit | 290 | 0.73 | 100% fruit | Gourds | 1 | 34.3 | 61.5 | 25.2 | 45.2 |
| 60 | Fruiting vegetables | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 61 | Fruiting vegetables | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 62 | Fruiting vegetables | BBCH 10 - 49 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 63 | Fruiting vegetables | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 64 | Fruiting vegetables | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 65 | Fruiting vegetables | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 66 | Fruiting vegetables | BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 67 | Fruiting vegetables | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 68 | Fruiting vegetables | BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 69 | Fruiting vegetables | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 70 | Fruiting vegetables | BBCH 10-49 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 71 | Fruiting vegetables | BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds50% weed seeds25% ground arthropods | Combination (invertebrates without interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 72 | Grassland | All season | Large herbivorous mammal "lagomorph" | Brown Hare (*Lepus europaeus*) | Herbivorous | Ground | 3800 | 0.32 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 17.3 | 32.6 |
| 73 | Grassland | late | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 74 | Grassland | All season | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 75 | Grassland | Late season (seed heads) | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 76 | Grassland | New sown grass seeds | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Foliar/ ground | 21.7 | 0.17 | 100% grass seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 77 | Hop | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 78 | Hop | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 79 | Hop | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 80 | Hop | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 81 | Hop | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 82 | Hop | BBCH 10-19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 83 | Hop | BBCH 20 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.5 | 40.2 | 87.0 | 3.3 | 7.2 |
| 84 | Hop | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 85 | Hop | BBCH 10-19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 86 | Hop | BBCH 20 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.5 | 28.7 | 70.3 | 24.2 | 59.2 |
| 87 | Hop | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 88 | Hop | BBCH 10-19 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds50% weed seeds25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 89 | Hop | BBCH 20 - 39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.5 | 29.2 | 64.5 | 3.9 | 8.6 |
| 90 | Hop | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 91 | Leafy vegetables | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 92 | Leafy vegetables | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 93 | Leafy vegetables | BBCH 40-49 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 94 | Leafy vegetables | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 95 | Leafy vegetables | All season | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 14.3 | 35.1 |
| 96 | Leafy vegetables | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 97 | Leafy vegetables | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 98 | Leafy vegetables | BBCH 00-49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 99 | Leafy vegetables | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 100 | Leafy vegetables | BBCH 00-49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 101 | Leafy vegetables | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 102 | Leafy vegetables | BBCH 10-49 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 103 | Leafy vegetables | BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds50% weed seeds25% ground arthropods | Combination (invertebrates without interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 104 | Legume forage | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 105 | Legume forage | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 106 | Legume forage | BBCH 40 - 49 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 107 | Legume forage | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 108 | Legume forage | Leaf development BBCH 21-49 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 1 | 28.7 | 70.3 | 14.3 | 35.1 |
| 109 | Legume forage | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 110 | Legume forage | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 111 | Legume forage | BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 112 | Legume forage | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 113 | Legume forage | BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 114 | Legume forage | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 115 | Legume forage | BBCH 10-49 | Small omnivorous mammal “mouse” | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 116 | Legume forage | BBCH ≥ 50 | Small omnivorous mammal “mouse” | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 117 | Maize | BBCH 10 - 19 | Small insectivorous mammal “shrew” | Common shrew (*Sorex araneus*) | Omnivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 118 | Maize | BBCH ≥ 20 | Small insectivorous mammal “shrew” | Common shrew (*Sorex araneus*) | Omnivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 119 | Maize | BBCH 10 -29 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | All maize shoots + later grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 120 | Maize | BBCH 30 - 39 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | All maize shoots + later grass | Grass + cereals | 0.5 | 54.2 | 102.3 | 36.1 | 68.2 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 121 | Maize | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | All maize shoots + later grass | Grass + cereals | 0.25 | 54.2 | 102.3 | 18.1 | 34.1 |
| 122 | Maize | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 123 | Maize | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 124 | Maize | BBCH 10 -29 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 125 | Maize | BBCH 30 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.5 | 40.2 | 87.0 | 3.3 | 7.2 |
| 126 | Maize | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.25 | 40.2 | 87.0 | 1.7 | 3.6 |
| 127 | Maize | BBCH 10 -29 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 128 | Maize | BBCH 30 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.5 | 28.7 | 70.3 | 24.2 | 59.2 |
| 129 | Maize | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.25 | 28.7 | 70.3 | 12.1 | 29.6 |
| 130 | Maize | BBCH 10-29 | Small omnivorous mammal “mouse” | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 131 | Maize | BBCH 30 - 39 | Small omnivorous mammal “mouse” | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 0.5 | 29.2 | 64.5 | 3.9 | 8.6 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 132 | Maize | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds<br>50% weed seeds<br>25% ground arthropods | Combination (invertebrates with interception) | 0.25 | 29.2 | 64.5 | 1.9 | 4.3 |
| 133 | Oilseed rape | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 134 | Oilseed rape | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 135 | Oilseed rape | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.25 | 54.2 | 102.3 | 18.1 | 34.1 |
| 136 | Oilseed rape | All season | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus*) | Herbivorous | Ground | 1543 | 0.50 | 100% crop leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 14.3 | 35.1 |
| 137 | Oilseed rape | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 138 | Oilseed rape | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 139 | Oilseed rape | BBCH 10-29 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 140 | Oilseed rape | BBCH 30 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 141 | Oilseed rape | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.25 | 40.2 | 87.0 | 1.7 | 3.6 |
| 142 | Oilseed rape | BBCH 10-29 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 143 | Oilseed rape | BBCH 30 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 144 | Oilseed rape | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.25 | 28.7 | 70.3 | 12.1 | 29.6 |
| 145 | Oilseed rape | BBCH 10-29 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 146 | Oilseed rape | BBCH 30 - 39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 147 | Oilseed rape | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 0.25 | 29.2 | 64.5 | 1.9 | 4.3 |
| 148 | Orchards | Application crop directed BBCH <10 or not crop directed | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | Ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 149 | Orchards | Application crop directed BBCH <10 or not crop directed | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 150 | Orchards | Application crop directed BBCH 10- 19 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.8 | 54.2 | 102.3 | 57.8 | 109.2 |
| 151 | Orchards | Application crop directed BBCH 20- 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.6 | 54.2 | 102.3 | 43.4 | 81.9 |
| 152 | Orchards | Application crop directed BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 153 | Orchards | Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | Garden dormouse (*Eliomys quercinus*) | Frugivorous | Fruit | 57.5 | 1.16 | 100% fruit | larger fruits | 1 | 19.5 | 41.1 | 22.7 | 47.9 |
| 154 | Orchards | Application crop directed BBCH <10 or not crop directed | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus*) | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 1 | 28.7 | 70.3 | 14.3 | 35.1 |
| 155 | Orchards | Application crop directed BBCH 10- 19 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus*) | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 0.8 | 28.7 | 70.3 | 11.5 | 28.1 |
| 156 | Orchards | Application crop directed BBCH 20- 40 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus*) | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 0.6 | 28.7 | 70.3 | 8.6 | 21.1 |
| 157 | Orchards | Application crop directed BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus*) | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 0.3 | 28.7 | 70.3 | 4.3 | 10.5 |
| 158 | Orchards | Application crop directed BBCH <10 or not crop directed | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 159 | Orchards | Application crop directed BBCH 10- 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 0.8 | 3.5 | 9.7 | 1.2 | 3.4 |
| 160 | Orchards | Application crop directed BBCH 20- 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 0.6 | 3.5 | 9.7 | 0.9 | 2.6 |
| 161 | Orchards | Application crop directed BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 0.3 | 3.5 | 9.7 | 0.5 | 1.3 |
| 162 | Orchards | Application crop directed BBCH <10 or not crop directed | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 163 | Orchards | Application crop directed BBCH 10- 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.8 | 40.2 | 87.0 | 5.3 | 11.5 |
| 164 | Orchards | Application crop directed BBCH 20- 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.6 | 40.2 | 87.0 | 4.0 | 8.6 |
| 165 | Orchards | Application crop directed BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 166 | Orchards | Application crop directed BBCH <10 or not crop directed | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 167 | Orchards | Application crop directed BBCH 10- 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.8 | 28.7 | 70.3 | 38.7 | 94.7 |
| 168 | Orchards | Application crop directed BBCH 20- 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.6 | 28.7 | 70.3 | 29.0 | 71.0 |
| 169 | Orchards | Application crop directed BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 170 | Orchards | Application crop directed BBCH <10 or not crop directed | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 171 | Orchards | Application crop directed BBCH 10- 19 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.8 | 29.2 | 64.5 | 6.2 | 13.8 |
| 172 | Orchards | Application crop directed BBCH 20- 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.6 | 29.2 | 64.5 | 4.7 | 10.3 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 173 | Orchards | Application crop directed BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds50% weed seeds25% ground arthropods | Combination (invertebrates without interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 174 | Ornamen-tals/nursery | Application to plant – exposure to underlying ground | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | Ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 175 | Ornamen-tals/nursery | BBCH 40 - 49 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 176 | Ornamen-tals/nursery | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.5 | 54.2 | 102.3 | 36.1 | 68.2 |
| 177 | Ornamen-tals/nursery | Application crop directed BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | Ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 178 | Ornamen-tals/nursery | Application crop directed BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | Ground dwelling invertebrates with interception | 0.5 | 3.5 | 9.7 | 0.8 | 2.1 |
| 179 | Ornamen-tals/nursery | Application crop directed BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 180 | Ornamen-tals/nursery | Application crop directed BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.5 | 40.2 | 87.0 | 3.3 | 7.2 |
| 181 | Ornamen-tals/nursery | Application crop directed BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 182 | Ornamen-tals/nursery | Application crop directed BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.5 | 28.7 | 70.3 | 24.2 | 59.2 |
| 183 | Ornamen-tals/nursery | Application crop directed BBCH 10 - 49 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 184 | Ornamen-tals/nursery | Application crop directed BBCH ≥ 50 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 0.5 | 29.2 | 64.5 | 3.9 | 8.6 |
| 185 | Potatoes | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 186 | Potatoes | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 187 | Potatoes | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 188 | Potatoes | BBCH 10 - 40 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 1 | 28.7 | 70.3 | 14.3 | 35.1 |
| 189 | Potatoes | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 0.3 | 28.7 | 70.3 | 4.3 | 10.5 |
| 190 | Potatoes | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 191 | Potatoes | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 192 | Potatoes | BBCH 10 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 193 | Potatoes | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 194 | Potatoes | BBCH 10 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 195 | Potatoes | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 196 | Potatoes | BBCH 10 - 39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds50% weed seeds25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 197 | Potatoes | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 198 | Pulses | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 199 | Pulses | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 200 | Pulses | BBCH 40 - 49 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 201 | Pulses | BBCH ≥ 50 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 202 | Pulses | BBCH 10 - 49 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 1 | 28.7 | 70.3 | 14.3 | 35.1 |
| 203 | Pulses | BBCH ≥ 50 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 0.3 | 28.7 | 70.3 | 4.3 | 10.5 |
| 204 | Pulses | Pre harvest seed BBCH 81-99 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 205 | Pulses | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 206 | Pulses | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 207 | Pulses | BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 208 | Pulses | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 209 | Pulses | BBCH 10 - 49 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 210 | Pulses | BBCH ≥ 50 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 211 | Pulses | BBCH 10 - 49 | Small omnivorous mammal “mouse” | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 212 | Pulses | BBCH ≥ 50 | Small omnivorous mammal “mouse” | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds50% weed seeds25% ground arthropods | Combination (invertebrates without interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 213 | Root &stem vegetables | BBCH 10 - 19 | Small insectivorous mammal “shrew” | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 214 | Root & stem vegetables | BBCH ≥ 20 | Small insectivorous mammal “shrew” | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 215 | Root & stem vegetables | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 216 | Root & stem vegetables | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 217 | Root & stem vegetables | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 218 | Root & stem vegetables | BBCH 10-39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 219 | Root & stem vegetables | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |
| 220 | Root & stem vegetables | BBCH 10-39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 221 | Root & stem vegetables | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 222 | Root & stem vegetables | BBCH 10-39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 223 | Root & stem vegetables | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |
| 224 | Straw-berries | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 225 | Straw-berries | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 226 | Straw-berries | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.4 | 54.2 | 102.3 | 28.9 | 54.6 |
| 227 | Straw-berries | BBCH 10-39 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 1 | 28.7 | 70.3 | 14.3 | 35.1 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 228 | Straw-berries | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 0.4 | 28.7 | 70.3 | 5.7 | 14.0 |
| 229 | Straw-berries | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 230 | Straw-berries | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 231 | Straw-berries | BBCH 10-39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 232 | Straw-berries | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.4 | 40.2 | 87.0 | 2.7 | 5.7 |
| 233 | Straw-berries | BBCH 10-39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 234 | Straw-berries | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.4 | 28.7 | 70.3 | 19.3 | 47.4 |
| 235 | Straw-berries | BBCH 10-39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 236 | Straw-berries | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds50% weed seeds25% ground arthropods | Combination (invertebrates without interception) | 0.4 | 29.2 | 64.5 | 3.1 | 6.9 |
| 237 | Sugar beet | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 238 | Sugar beet | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 239 | Sugar beet | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.25 | 54.2 | 102.3 | 18.1 | 34.1 |
| 240 | Sugar beet | BBCH 10-39 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus*) | Herbivorous | Ground | 1543 | 0.50 | 100% crop leaves | Non-grass herbs | 1 | 28.7 | 70.3 | 14.3 | 35.1 |
| 241 | Sugar beet | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus*) | Herbivorous | Ground | 1543 | 0.50 | 100% crop leaves | Non-grass herbs | 0.25 | 28.7 | 70.3 | 3.6 | 8.8 |
| 242 | Sugar beet | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 243 | Sugar beet | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 244 | Sugar beet | BBCH 10-39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 245 | Sugar beet | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.25 | 40.2 | 87.0 | 1.7 | 3.6 |
| 246 | Sugar beet | BBCH 10-39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 247 | Sugar beet | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.25 | 28.7 | 70.3 | 12.1 | 29.6 |
| 248 | Sugar beet | BBCH 10-39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 249 | Sugar beet | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates with interception) | 0.25 | 29.2 | 64.5 | 1.9 | 4.3 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 250 | Sunflower | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |
| 251 | Sunflower | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 252 | Sunflower | BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.25 | 54.2 | 102.3 | 18.1 | 34.1 |
| 253 | Sunflower | BBCH 10-19 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 1 | 28.7 | 70.3 | 14.3 | 35.1 |
| 254 | Sunflower | BBCH 20 - 39 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 0.5 | 28.7 | 70.3 | 7.2 | 17.6 |
| 255 | Sunflower | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Rabbit (*Oryctolagus cuniculus)* | Herbivorous | Ground | 1543 | 0.50 | 100% Non-grass herbs | Non-grass herbs | 0.25 | 28.7 | 70.3 | 3.6 | 8.8 |
| 256 | Sunflower | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 257 | Sunflower | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 258 | Sunflower | BBCH 10-19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 259 | Sunflower | BBCH 20 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.5 | 40.2 | 87.0 | 3.3 | 7.2 |
| 260 | Sunflower | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.25 | 40.2 | 87.0 | 1.7 | 3.6 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 261 | Sunflower | BBCH 10-19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 262 | Sunflower | BBCH 20 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.5 | 28.7 | 70.3 | 24.2 | 59.2 |
| 263 | Sunflower | BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.25 | 28.7 | 70.3 | 12.1 | 29.6 |
| 264 | Sunflower | BBCH 10-19 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.5 | 29.2 | 64.5 | 7.8 | 17.2 |
| 265 | Sunflower | BBCH 20 - 39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.25 | 29.2 | 64.5 | 3.9 | 8.6 |
| 266 | Sunflower | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 1.9 | 4.3 |
| 267 | Vineyard | Application ground directed | Large herbivorous mammal "lagomorph" | Brown Hare (*Lepus europaeus*) | Herbivorous | Ground | 3800 | 0.39 | 100% Plant matter | Non-grass herbs | 1 | 28.7 | 70.3 | 11.1 | 27.2 |
| 268 | Vineyard | BBCH 10-19 | Large herbivorous mammal "lagomorph" | Brown Hare (*Lepus europaeus*) | Herbivorous | Ground | 3800 | 0.39 | 100% Plant matter | Non-grass herbs | 0.6 | 28.7 | 70.3 | 6.7 | 16.3 |
| 269 | Vineyard | BBCH 20 - 39 | Large herbivorous mammal "lagomorph" | Brown Hare (*Lepus europaeus*) | Herbivorous | Ground | 3800 | 0.39 | 100% Plant matter | Non-grass herbs | 0.5 | 28.7 | 70.3 | 5.5 | 13.6 |
| 270 | Vineyard | BBCH ≥ 40 | Large herbivorous mammal "lagomorph" | Brown Hare (*Lepus europaeus*) | Herbivorous | Ground | 3800 | 0.39 | 100% Plant matter | Non-grass herbs | 0.3 | 28.7 | 70.3 | 3.3 | 8.1 |
| 271 | Vineyard | BBCH 10 - 19 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 4.2 | 7.6 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 272 | Vineyard | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | Insectivorous | Ground | 9.7 | 0.55 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.9 | 5.4 |
| 273 | Vineyard | Application ground directed | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 1 | 54.2 | 102.3 | 72.3 | 136.4 |
| 274 | Vineyard | Application crop directed BBCH 10 - 19 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.6 | 54.2 | 102.3 | 43.4 | 81.9 |
| 275 | Vineyard | Application crop directed BBCH 20 - 39 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.5 | 54.2 | 102.3 | 36.1 | 68.2 |
| 276 | Vineyard | Application crop directed BBCH ≥ 40 | Small herbivorous mammal "vole | Common vole (*Microtus arvalis*) | Herbivorous | Ground | 25 | 1.33 | 100% grass | Grass + cereals | 0.3 | 54.2 | 102.3 | 21.7 | 40.9 |
| 277 | Vineyard | BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates without interception | 1 | 7.5 | 13.8 | 3.3 | 6.1 |
| 278 | Vineyard | BBCH ≥ 20 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Insectivorous | Ground | 21.7 | 0.44 | 100% ground arthropods | ground dwelling invertebrates with interception | 1 | 3.5 | 9.7 | 1.5 | 4.3 |
| 279 | Vineyard | Application ground directed | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 1 | 40.2 | 87.0 | 6.6 | 14.4 |
| 280 | Vineyard | Application crop directed BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.6 | 40.2 | 87.0 | 4.0 | 8.6 |
| 281 | Vineyard | Application crop directed BBCH 20 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.5 | 40.2 | 87.0 | 3.3 | 7.2 |
| 282 | Vineyard | Application crop directed BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Granivorous | Ground | 21.7 | 0.17 | 100% weed seeds | Small seeds | 0.3 | 40.2 | 87.0 | 2.0 | 4.3 |

| N | Crop | Scenario | Generic focal species | Representative species | Diet guild | Foraging strata | bw (g) | FIR/BW | Diet of generic focal species in crop (%) | RUD unit | Deposition factor | Mean RUD | 90th percentile RUD | Short cut value for mean RUDs | Short cut value for 90th percentile RUDs |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 283 | Vineyard | Application ground directed | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 1 | 28.7 | 70.3 | 48.3 | 118.4 |
| 284 | Vineyard | Application crop directed BBCH 10 - 19 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.6 | 28.7 | 70.3 | 29.0 | 71.0 |
| 285 | Vineyard | Application crop directed BBCH 20 - 39 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.5 | 28.7 | 70.3 | 24.2 | 59.2 |
| 286 | Vineyard | Application crop directed BBCH ≥ 40 | Single diet for T1 | Wood mouse (*Apodemus sylvaticus*) | Herbivorous | Ground | 21.7 | 1.68 | 100% weeds | Non-grass herbs | 0.3 | 28.7 | 70.3 | 14.5 | 35.5 |
| 287 | Vineyard | Application ground directed | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 1 | 29.2 | 64.5 | 7.8 | 17.2 |
| 288 | Vineyard | Application crop directed BBCH 10 - 19 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.6 | 29.2 | 64.5 | 4.7 | 10.3 |
| 289 | Vineyard | Application crop directed BBCH 20 - 39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.5 | 29.2 | 64.5 | 3.9 | 8.6 |
| 290 | Vineyard | Application crop directed BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | Omnivorous | Ground | 21.7 | 0.27 | 25% weeds 50% weed seeds 25% ground arthropods | Combination (invertebrates without interception) | 0.3 | 29.2 | 64.5 | 2.3 | 5.2 |

# APPENDIX B

# COMBINED EFFECTS OF SIMULTANEOUS EXPOSURE TO SEVERAL ACTIVE SUBSTANCES

The basic concept of the risk assessment for birds and mammals is that animals are exposed to residues of active substances in the environment, e.g. via their food. Thus, the following steps do not refer to an assessment of formulation toxicity as such, but of the expected effects from exposure to a mixture of active substances (and possibly also toxic co-formulants) in the environment resulting from use of that formulation.

## General assessment scheme

Typically, toxicity studies for birds with formulated products or mixtures of active substances are not available. For the assessment of acute effects (mortality), a surrogate $LD_{50}$ should be calculated according to Step 1. Sublethal effects and effects on reproduction should be assessed on a case-by-case basis according to Step 2. If formulation studies are available, their results should be checked against the active substance data before they are used in the risk assessment (Step 3).

Acute mammalian toxicity tests with formulated products are more often available than for birds, because they are used for classification and labelling. Nevertheless, a surrogate $LD_{50}$ for the assessment of acute effects (mortality) should normally be calculated according to Step 1. This will serve as a basis for checking the applicability of the available formulation toxicity for the risk assessment (Step 2). As for birds, sublethal effects and effects on reproduction should be assessed on a case-by-case basis according to Step 3.

Finally, Step 4 provides guidance on the calculation of appropriate exposure estimates for a risk assessment based on calculated or experimentally determined mixture toxicity.

## Step 1

## Calculation of surrogate $LD_{50}$ values for acute effects (mortality)

An often used model for estimating the toxicity of mixtures is the assumption of dose or concentration additivity of toxicity (Loewe and Muischnek, 1926; frequently referred to as 'Finney's equation'). There is evidence that such $LD_{50}$ values predicted on the assumption of a similar mode-of-action should normally give a more conservative estimate of actual mixture toxicity than models based on the assumption of independent action (Junghans *et al.,* 2006; Van Leeuwen and Vermeire, 2007; EFSA, 2007; EFSA, 2008). The following equation can be used for deriving a surrogate $LD_{50}$ for a mixture of active substances with known toxicity assuming dose additivity:

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix B. EFSA Journal 2009; 7(12):1438. [5 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

$$LD_{50}(\text{mix}) = \left( \sum_i \frac{X(\text{a.s.}_i)}{LD_{50}(\text{a.s.}_i)} \right)^{-1}$$

With:

$X(\text{a.s.}_i)$ = fraction of active substance [$i$] in the mixture;
(please note that the sum $\sum X(\text{a.s.}_i)$ must be 1)

$LD_{50}(\text{a.s.}_i)$ = acute toxicity value for active substance [$i$]

It should be noted that it might be necessary to include also formulants with known toxicity in the equation to achieve a reliable result.

Measured $LD_{50}$ values should only be replaced in the risk assessment by modelled data if a significant change of the predicted risk is to be expected. To achieve a basis for a comparison of single active substance and mixture toxicity in terms of potential risk, a "tox per fraction" quotient can be calculated for each active substance and compared to the corresponding quotient for the mixture.

$$\text{tox per fraction (a.s.)} = \frac{LD_{50}(\text{a.s.}_i)}{X(\text{a.s.}_i)}$$

$$\text{tox per fraction (mix)} = \frac{LD_{50}(\text{mix})}{\sum_i X(\text{a.s.}_i)}$$

Note that these "tox per fraction" quotients themselves have no biological meaning; they are only to be used for comparison. If one active substance can be identified where the two quotients "tox per fraction (a.s.)" and "tox per fraction (mix)" deviate by $\leq 10$ %, this indicates that this active substance will contribute to $\geq 90$ % to mixture toxicity, while the other components of the mixture will only have a marginal impact on the predicted risk. Consequently, the risk assessment can be performed for the most toxic active substance alone. No further considerations according to Steps 2 - 4 are necessary. Otherwise, the predicted $LD_{50}$(mix) should be used in the risk assessment together with appropriate exposure estimates (Step 4).

When different environmental fate parameters are considered for individual active substances in a higher tier assessment, this might result in a changed composition of residues as compared to the initial mixture. In that case, the equations above have to be expanded as follows using multiple application factors (MAF):

$$LD_{50}(\text{mix}) = \left( \sum_i X(\text{a.s.}_i) \times MAF_i \right) \times \left( \sum_i \frac{X(\text{a.s.}_i) \times MAF_i}{LD_{50}(\text{a.s.}_i)} \right)^{-1}$$

$$\text{tox per fraction (a.s.)} = \frac{LD_{50}(\text{a.s.}_i)}{X(\text{a.s.}_i) \times MAF_i}$$

$$\text{tox per fraction (mix)} = \frac{LD_{50}(\text{mix})}{\sum_i X(\text{a.s.}_i) \times MAF_i}$$

With:

$MAF_i$ = multiple application factor for active substance [$i$]

To be consistent with the assessment for single active substances, always their respective relevant LD50 values should be considered in the calculation of mixture toxicity, regardless for what species they were

determined. Data for other species should only be used where clear evidence is available for a different specific mechanism of toxicity in one of the tested species for one of the active substances considered.

Neither occurrence nor magnitude of synergistic effects can be predicted with Finney's equation. Therefore, if synergism is expected, targeted studies may be required. See also EFSA (2008).

**Step 2a**

**Assessment of available formulation toxicity data (dose/response tests)**

Where the $LD_{50}$ of a formulated product with more than one active substance is available, this value should be compared with the predicted mixture toxicity assuming dose additivity (see Step 1). A different form of the equation than in Step 1 is used.

$$\sum_i \frac{X(\text{a.s.}_i)}{LD_{50}(\text{a.s.}_i)} = \frac{1}{LD_{50}(\text{mix})}$$

With:

$X(\text{a.s.}_i)$ = fraction of active substance [$i$] in the mixture (here: formulation)

$LD_{50}(\text{a.s.}_i)$ = acute toxicity value for active substance [$i$]

$LD_{50}(\text{mix})$ = measured acute toxicity value for the mixture (here: formulation)

A greater value on the right side of the equation indicates that the formulation is more toxic than predicted from the toxicity of the individual components (active substances and co-formulants of known toxicity). This may be due to, e.g. further toxic co-formulants, toxicokinetic interaction or synergism/potentiation of effect. It may also reflect the inherent variability of toxicity testing. In all these cases, the use of the $LD_{50}$ for the formulation (together with appropriate exposure estimates, see Step 4) is recommended for the first-tier assessment, because it cannot be excluded that such effects would also occur after exposure of animals to residues in the environment.

Dismissing the $LD_{50}$ of the formulation from the risk assessment would only be acceptable at a higher tier if any observed greater toxicity in the test could be clearly and unambiguously ascribed to a factor that would not be relevant under environmental exposure conditions.

If, in contrast, the measured toxicity of a formulation is lower than predicted, the predicted mixture toxicity according to Step 1 should be used in the first-tier risk assessment, together with appropriate exposure estimates (Step 4).

It is obvious that the predicted mixture toxicity calculated according to the model of dose or concentration additivity will always be greater than the individual measured toxicity of each contributing compound. It will also be greater than the toxicity predicted with other models (independent action) as long as synergism is excluded (Junghans *et al.*, 2006). As there is currently no clear evidence for synergistic effects to become manifest under environmental conditions, the use of the predicted mixture toxicity values is, for the time being, acknowledged to constitute a sufficiently conservative starting point for the first-tier assessment. The use of alternative prediction models or experimental data may be considered on a case-by-case basis at higher tier.

**Step 2b**

**Assessment of available formulation toxicity data (limit tests for classification and labelling)**

Acute toxicity studies with formulations in mammals are mainly performed for classification and labelling and normally are not designed for the derivation of a precise $LD_{50}$. Still, these studies should be considered in the ecotoxicological risk assessment as they might provide indications for greater toxicity than expected from the studies with active substances due to, e.g. toxic co-formulants or synergism. In such cases, the use of 'greater than' $LD_{50}$ from a formulation study would be more precautionary and appropriate than a predicted $LD_{50}$.

**Step 3**

**Consideration of mixture toxicity for sublethal effects and effects on reproduction**

As regards the risk to reproduction from exposure to more than one active substance, it is currently not recommended to consider the use of predicted toxicity values as surrogates in the risk assessment. Although it would be, in principle, possible to apply the concept of dose or concentration additivity of toxicity also to effect data for biological endpoints from long-term and reproductive toxicity testing, reliable results would only be expected for combinations of $EC_x$ values for the same biological endpoint. Moreover, additional bias would be introduced in the calculations if the values applied do not represent $EC_x$ values with defined x, but NOAELs, since these may represent varying risk or response levels for different compounds, depending on dose-spacing.

Nevertheless, there is also evidence that mixtures of chemicals can cause effects even though all their constituents were present in the environment at concentration levels around their individual NOECs ("something from nothing"). This has to be expected for mixtures of compounds acting in the same way on defined molecular targets, e.g., the estrogen receptor (ER-α) (Kortenkamp, 2007). If a given formulation contains several active substances all known to cause similar effects via a similar biochemical mechanism (e.g. aromatase inhibition) and if this type of effects is actually driving the risk assessment, it is thus recommended to perform an assessment for combined effects on a case-by-case basis.

In a simple approach, all active substances belonging to the same group could be expressed in terms of the most toxic representative (on a molar basis to account for differences in molar weight) and the risk assessment performed for the group applying the corresponding NOEC for the most toxic compound. The potential for more elaborated modelling (e.g., quantification of toxicity relative to an index compound; see relative potency approach in EFSA, 2008) depends on the availability and quality of data.

**Step 4**

**Appropriate exposure estimates for a risk assessment based on calculated or experimentally determined mixture toxicity**

An $LD_{50}$ for a mixture of active substances calculated assuming dose additivity can be conceived as an $LD_{50}$ of a single virtual compound. It is thus deemed the most logical approach to also base the exposure side of the risk assessment on the same assumption. Content in the formulation and application rate per hectare should thus be expressed in terms of this virtual compound. As long as only a single application is intended or considered, no changes in the composition as compared to the formulated product will occur and no adjustment of environmental residues is necessary.

If several applications must be considered, the default MAF values of Tier 1 can also be applied to the mixture as a single virtual compound. However, if the assessment should be refined using specific environmental fate data for individual active substances, the composition of the residues might be changed as compared to the original mixture. Using substance-specific MAF values, a residue level C(mix) after two or more applications can be calculated as follows.

$$C(\text{mix}) = \sum_i C_0(\text{a.s.}_i) \times \text{MAF}_i$$

With:

$C_0(\text{a.s.}_i)$ = residue levels of active substance [$i$] after one application of the original mixture

$\text{MAF}_i$ = multiple application factor for active substance [$i$]

The $\text{MAF}_i$ values are then also required for adjusting the mixture toxicity according to the changed composition as compared to the original mixture – see Step 1 for the respective equation.

If the risk assessment is based on experimental toxicity data for the formulated product, no differentiation according to environmental fate parameters of individual active substances is possible. As

described above for mixtures in general, also a formulation may be conceived as a single virtual compound and the default MAF values of Tier 1 may be applied.

In principle, the concept of the single virtual compound could also be applied to calculate time-weighted average concentrations for mixtures or formulations. However, the current proposed approach for assessing combined effects of simultaneous exposure to several active substances is restricted to the assessment of acute effects where time-weighted averages are not considered.

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# APPENDIX C

# EVALUATION OF THE LEVEL OF PROTECTION PROVIDED BY THE FIRST-TIER ASSESSMENT PROCEDURES

This Appendix documents the basis on which the first-tier risk assessments provided in the Guidance Document were judged to provide an appropriate level of protection. In addition, the tables presented in this Appendix may be a useful starting point for case-by-case consideration of the level of protection achieved in refined (higher tier) assessments (see section 6.9 of Guidance Document).

## Protection goals for first-tier assessment procedures

*Interpretation of actual protection goals*

Directive 91/414/EEC does not contain a precise definition of the level of protection in first-tier assessments. Annex VI to this Directive specifies a decision rule (TER ≥ 10 for acute risks, TER ≥ 5 for long-term risks). However, the level of protection actually achieved also depends on the precise manner in which the toxicity endpoints for the TER are selected and how the exposure component of the TER is calculated. This is not specified in detail by the Directive. Therefore, in developing the first-tier assessment procedures, careful consideration was given to how this should be addressed.

The first-tier assessment should be designed to ensure at least the same level of protection as is required in higher-tier assessments, as it would not be logical to authorise at Tier 1 substances that would fail at higher tiers. The level of protection required at higher tiers is indicated by C.1 point 2.5.2.1 in Annex VI of Directive 91/414/EEC (the 'uniform principles'). This states that when a refined assessment for birds is required, "no authorisation shall be granted … unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product under the proposed conditions of use."

The meaning of 'no unacceptable impact' is not defined in the Directive. However, Annex VI C.1, Number 5 to the Directive specifies a particular responsibility for Member States: "…MS shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species". This makes clear that long-term effects on

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix C. EFSA Journal 2009; 7(12):1438. [60 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

abundance and diversity[1] are not acceptable. However, this still does not precisely define the protection goal. For example, it does not define the temporal scale (how long is long-term?) nor the spatial scale (local, regional, etc.) on which changes in abundance and diversity should be assessed[2]. This is important because it makes it uncertain what level of short-term impacts on mortality or reproduction can be tolerated without threatening the long-term population goal. Furthermore, the directive does not state explicitly whether short-term effects can be unacceptable in themselves.

The previous Guidance Document stated that "appreciable mortality without population level consequences may be judged unacceptable" (EC, 2002, page 3). A survey conducted by EFSA (2008) confirmed that both individual mortality and population effects are of concern. The Commission and some Member States stated concern about mortality related to 'visible' mortality (e.g. animals dying in public places or in noticeable numbers)[3].

The 'unless clause' in Annex VI (quoted above) states that no authorisation shall be granted unless it is 'clearly established' that the unacceptable impacts will not occur. Although it is not defined, 'clearly established' suggests that a high level of certainty is required.

Based on these considerations, it is concluded that approaches for first-tier assessment should be designed to provide a high level of certainty and that there will be no visible mortality and no long-term repercussions for abundance and diversity.

*Addressing the protection goals*

In principle, it would be desirable to assess or model visible mortality or population impacts directly, since these are protection goals. This is currently not practical for first-tier assessments[4], although it may be an option for higher tiers. Therefore, this opinion continues the approach of previous guidance, using TERs as the primary quantitative measure of risk in first-tier assessments, except for acute risk of sprayed pesticides, where TER and $LD_{50}$s/m² are presented as alternative options. Consequently, it is necessary to design these procedures in such a way that the protection goals are achieved, e.g. in order to ensure a high certainty of the absence of visible mortality or of long-term repercussions if the relevant TER trigger value in Annex VI is exceeded. This requires judgements about the levels of TER or $LD_{50}/m^2$ that would lead to visible mortality or population impacts. These judgements are inevitably very uncertain. For example, it is often suggested that animal populations are sufficiently resilient to absorb some level of mortality or reproductive failure but (a) it is uncertain what levels could be tolerated, and (b) given that farmland bird populations have been declining in any case, it is possible that any resilience they possess is already exhausted.

*Definition of surrogate protection goal for first-tier assessments*

It is concluded that the uncertain definition of the protection goals and their uncertain relationship to the measures of risk that are practical for first-tier assessment makes it very difficult to achieve the required level of certainty ('clearly establish'). The practical solution is to design the first-tier assessment procedures in order to make any mortality or reproductive

[1] It is assumed that 'abundance' refers to population size or density for individual species and 'diversity' refers to the number and variety of different species.
[2] In EFSA's survey of Member States and stakeholders, some respondents indicated that population effects should be considered at local level, whereas others indicated they should be considered at regional level.
[3] 'Visible mortality' is a social or political criterion, rather than an ecological one.
[4] Modelling population impacts requires data on population parameters and the spatial distributions of wildlife and pesticide use that are not available in many Member States. Estimating visible mortality would require modelling the factors that influence the visibility of casualties, which would be difficult to quantify.

effects unlikely. This is referred to as a 'surrogate protection goal'. It allows a scientific judgement on the appropriate design of the first-tier assessment with much more confidence than would be possible if the actual protection goals were assessed directly. Additionally, the first-tier assessment should be sufficient to ensure a high certainty of avoiding visible mortality and long-term population repercussions. It should also ensure that there will be no short-term repercussions, the acceptability of which is not defined (see above).

The surrogate protection goal of making any mortality or reproductive effects unlikely is more conservative than the actual protection goal of clearly establishing that there will be no visible mortality and no long-term repercussions for abundance and diversity. Specifically, it means that first-tier procedures should assess exposure and effects for a *realistic worst-case individual*, i.e. a sensitive individual of a sensitive species, experiencing the upper end of realistic exposures. This degree of conservatism is necessary in the first tier because of the uncertain definition of the actual protection goals and the uncertainty in assessing them with the simple risk measures that are practical for first-tier assessments. It is consistent with normal practice in risk assessment, i.e., for first-tier assessment procedures to be more protective than higher-tier assessments.

It is essential to emphasise that the surrogate protection goal is not a replacement for the actual protection goal but is a surrogate for use in first-tier assessments. The actual protection goal remains the ultimate criterion. Higher-tier assessments may address the actual protection goal directly (e.g. assess the probability of visible mortality or the probability of long-term repercussions for abundance and diversity). However, higher-tier assessments may also be based on the surrogate protection goal, if that is a more practical option for the case in hand (e.g. a refined TER calculation, see section 6 of Guidance Document).

*Cumulative effects*[5]

It is current practice to assess the ecological risks of different pesticides independently, unless they are coformulated in a single product. However, there is some ambiguity about whether or not the actual protection goal relates to individual pesticides and/or to the cumulative effects of multiple products. As mentioned above, Annex VI C.1, Number 5 states: "…MS shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species". The 'use of plant protection products' (plural) could be interpreted as implying that the goal is to ensure no long-term repercussions when authorised products are considered collectively. However, it is also possible that this clause was intended to refer to the effects of pesticides considered individually. The former is consistent with the aspiration, expressed by some Member States when responding to the EFSA (2008) survey, that ideally they would like to address the combined effects of multiple pesticides[6]. The latter interpretation is consistent with current practice and also with the recognition by the above mentioned respondents that assessing effects of individual pesticides is more practical. Deciding between these interpretations is a risk management issue. However, the surrogate protection goal is compatible with both interpretations, because if effects are unlikely for individual pesticides they should also be unlikely if pesticides were considered collectively.

*Summary*

[5] Note that in this section 'cumulative' is used in the general sense of the cumulation of impacts of pesticide use as a whole, including for example effects on different individuals exposed to different pesticides, and not in the narrower sense of the combined toxic effect for (an) individual exposed simultaneously to multiple pesticides,

[6] Note that assessing cumulative effects for multiple pesticides is an explicit aspiration in the legislation relating to consumer risk assessments and MRL-setting (Regulation (EC) 396/2005).

In summary, the procedures described in the Guidance Document for first-tier assessment are designed to achieve the surrogate protection goal of making any mortality or reproductive effects unlikely. At higher tiers, assessments may be directed either at the surrogate protection goal or at the actual protection goal of clearly establishing that there will be no visible mortality and no long-term repercussions for abundance and diversity. If the actual protection goals are defined more precisely in future, then the surrogate protection goal and first-tier procedures should be reviewed and revised accordingly.

**Methods used for evaluating the level of protection**

For each first-tier assessment procedure, it was evaluated whether the surrogate protection goal (i.e. to make *any* mortality or reproductive effects unlikely) was met. This was based mainly on expert judgement of the conservatism of the data and assumptions used in the first-tier assessment. For each element of the assessment, the extent to which the element could be lower or higher for the most at-risk individuals was evaluated: in other words, the degree to which the first-tier assumptions are distanced from a realistic worst case[7]. This evaluation was conducted by constructing uncertainty tables in the format recommended for higher-tier assessments (section 6.8 of Guidance Document). In the case of acute risks from sprayed pesticides, additional lines of evidence were provided. These came from historical records of poisoning incidents and comparison of the first-tier assessment with data on mortality in field studies. These three lines of evidence were evaluated together using the weight-of-evidence approach recommended in section 6.9 of the Guidance Document.

The following sections document the basis on which it was judged that this goal is met by the procedures proposed for first tier assessment procedures. To illustrate the approach, the evaluation for acute risks to birds is presented in detail in the following section. The justification for other first-tier procedures is documented more briefly but uses the same principles.

**Acute risk to birds from sprayed pesticides, assessed using TERs**

This section documents the judgements made regarding the level of protection (LoP) for the first-tier assessment using a TER calculation. An alternative first-tier approach for acute risks based on lethal doses applied per square meter ($LD_{50}/m^2$) is considered more briefly in the following section.

Three lines of evidence are available for evaluating the LoP: the conservatism of the assessment assumptions (Table 1); comparison between calculated TERs and evidence on the occurrence of mortality in field studies (Table 2); and historical records of poisoning incidents (Table 3). Overall conclusions about the conservatism of the proposed procedure were derived by considering the relative weights of these three lines of evidence (Table 4).

The left hand column of Table 1 lists all of the factors used in calculating exposure for the acute TER for sprayed pesticides, including the parameters used to estimate daily food intake (daily energy requirement, food energy and moisture contents, energy assimilation efficiency, and body weight), residues on foods eaten by birds (residue per unit dose, half-life, multiple application factor, interception factor) and behaviour (dietary composition and proportion of diet obtained from treated area). It also enumerates factors that affect the conservatism of the toxicity endpoint used in the assessment (variation between and within species, regurgitation), and the

[7] As explained in the previous section, it is necessary to focus on the most at-risk individuals in order to make any mortality or reproductive effects unlikely.

uncertainty factor of 10 that is implied by comparing the final TER to the decision criterion from Annex VI of the Directive. It also lists three important factors that are not included in the first-tier TER assessment, i.e. avoidance, metabolism and non-dietary routes of exposure.

The second and third columns of Table 1 evaluate the extent to which the 'true' worst case for each parameter could make the risk lower than implied by the first-tier calculation. Similarly, the fourth and fifth columns of Table 1 evaluate the extent to which the 'true' worst case for each parameter could heighten the risk. It is recognised that, although some variables have an identifiable realistic upper or lower bound (e.g. the proportion of diet obtained in treated area can realistically be one but not higher), for other variables the realistic worst case is much harder to judge (e.g. residues). Nevertheless it was possible to make the approximate, relative judgements that are required in Table 1.

Focussing on a 'true' or realistic worst-case individual is necessary to address the surrogate protection goal of making any mortality unlikely, as explained in preceding sections. For example, although an estimate of the 90$^{th}$ percentile is used for determining the residue per unit dose, this nonetheless allows the true worst case to be higher since a small proportion of individuals will experience higher residues. This, together with other factors (summarised in column 5 of Table 1), lead the to the conclusion that for some pesticides the true worst-case RUD could be five times higher than the default value (hence two plus symbols in column 4). On the other hand, it is also possible that the worst-case is overestimated for some pesticides. This is because the estimated 90$^{th}$ percentile RUD is based on data for multiple pesticides, so it is probable that the true 90$^{th}$ percentile varies between pesticides to some extent and it is possible that the realistic worst-case for some individual pesticides is less than the 90$^{th}$ percentile averaged across all pesticides (hence a minus symbol in column 2). These evaluations take account of the range of variation of each parameter and its influence on the TER. For example, only an average value is used for body weight but the range of variation for this parameter is small. As it appears twice in the exposure calculation (once to estimate food intake, and once to convert absolute to relative dose), its effect nearly cancels out. Therefore, its influence on exposure is small (no symbols for effect via exposure, although it has more influence via toxicity as shown further down the table).

**Table 1.** Evaluation of conservatism of the first-tier assessment of acute avian risks assessed using a TER, in relation to the surrogate protection goal of making any mortality unlikely. Each row evaluates a separate input, assumption or omission of the TER calculation. Symbols are used to indicate the extent to which it is judged the 'true worst' case for that element could decrease (-) or increase (+) the risk of causing any mortality. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect: three symbols (e.g. - - -) indicates a factor that would change the risk by an amount equivalent to changing the TER by about a factor of 10, two symbols indicates a factor of about 5, and one symbol indicates a factor of about 2. The number of symbols does not reflect the variability of that particular parameter but its potential influence on the risk. The overall evaluation at the bottom of the table gives an overall judgement on the combined effect of the various factors on the overall conservatism of the assessment. This is based on expert judgement of how the factors interact and is not a simple summation.

| Parameter, assumption or omission | Potential to lower 'true worst-case' risk | Explanation | Potential to highten 'true worst-case' risk | Explanation |
|---|---|---|---|---|
| Screening assessment indicator species and type of food | _ | Realistic worst case – relatively small species eating only the most contaminated food type. Real worst case could be lower in some scenarios. | | Realistic worst case – relatively small species eating only the most contaminated food type. Negligible potential to be worse. |
| Tier 1 generic focal species and type of food | | Mixed diet based on average of available data on dietary composition. Worst case cannot be lower than average. | + | Mixed diet based on average of available data on dietary composition. Some individual birds will eat more than average proportion of most contaminated food on individual days. |
| Body weight (impact on exposure) | _ | In some scenarios such small species may not occur. However, this has only a limited impact on risk due to scaling of food intake with body weight. | | For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight. |
| Body weight (impact on toxicity) | | Relatively few exposed species are larger than species used in toxicity tests. | + | Focal species tend to be smaller than species used in toxicity tests. General trend for smaller species to be more sensitive (Mineau et al., 1996) is not taken into account in assessment. This is unlikely to exceed a 3-times difference in most cases. |
| Daily food intake | _ | Average, but taken from demanding period (e.g. breeding season). Energy expenditure and risk could be lower in less demanding periods. | + | True worst case unlikely to be more than two times more than assumed value except in extreme cases, e.g. fattening for migration. |
| Percent of diet taken by individual in treated area | _ | Likely only a few scenarios where true worst case individual is less than 0.5 (i.e. factor of 2 reduction). | | Absolute worst case; cannot be higher. |
| Residue per unit dose | _ | $90^{th}$ percentile of data for multiple pesticides and application events. True distribution for pesticide under assessment could be lower than generic distribution used in assessment, so true worst case could be lower than generic $90^{th}$ percentile. | ++ | $90^{th}$ percentile of data for multiple pesticides and application events. True $90^{th}$ percentile for pesticide under assessment could be higher than generic $90^{th}$ percentile used in assessment. In addition, 10 % of concentrations are expected to be higher than $90^{th}$ percentile. Furthermore, measuring RUD values relate to pooled samples and may underestimate peak concentration on highly-exposed food types. |

| Parameter, assumption or omission | Potential to lower 'true worst-case' risk | Explanation | Potential to highten 'true worst-case' risk | Explanation |
|---|---|---|---|---|
| Half-life on food ($DT_{50}$) | _ _ | Affects only multiple applications, and then only part of total exposure. Default value of 10 days is conservative: most pesticides have $DT_{50}$s below 10. | + | Affects only multiple applications, and then only part of total exposure. Some pesticides have $DT_{50}$s longer than 10 days (e.g. 19 % of pesticides registered in Canada in 2005[8]). Also dissipation in first few days is often faster than implied by assumption of first order kinetics. |
| Model for deriving multiple application factor from $DT_{50}$ and RUD | | | + | Affects only multiple applications, and then only part of total exposure. Uncertainty about what proportions of variability in existing RUD data represent within and between field variation. Maximum difference between $MAF_{90}$ and $MAF_{mean}$ does not exceed 30 % under realistic scenarios so any increase in risk would be minor. |
| Interception factors | | Interception factors are based on those used in FOCUS Step 2, which were derived from field measurements and are considered to be a realistic worst case for spray reaching the ground. | | Interception factors are based on those used in FOCUS Step 2, which were derived from field measurements and are considered to be conservative for spray reaching the ground. Within each growth stage a conservative (early) value is used. |
| Non-dietary exposure | | | +/++ | Ignored. True contribution uncertain, but could increase risk by up to two times or more (Driver et al., 1991). |
| Variation of toxicity between species | _ _ _ | Focal species could be over one order of magnitude more or less sensitive than standard species (Fig. 1). | +++ | Focal species could be over one order of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases. |
| Variation of toxicity between individuals | | | +/+++ | Most sensitive individuals could be 2 – 10 times (i.e. + to +++) more sensitive than $LD_{50}$ (Fig. 2). |
| Uncertainty factor | _ _ _ | TER is compared with trigger value of 10. | | |
| Avoidance of contaminated food | - / - - - | Ignored. True contribution varies between pesticides and species. Could be negligible, or could prevent mortality even for most sensitive species. | | |
| Effect of metabolism | _ _ _ | Ignored. True contribution varies between pesticides and species. Could be negligible or very substantial. | | |

[8] Based on http://www.wsi.nrcs.usda.gov/products/W2Q/pest/winpst.html#pst%20ppd

| Parameter, assumption or omission | Potential to lower 'true worst-case' risk | Explanation | Potential to highten 'true worst-case' risk | Explanation |
|---|---|---|---|---|
| Regurgitation | – | Should not cause under-estimation of risk if use of $LD_{50}$ studies where regurgitation occurred is avoided. May partially reduce mortality for some species in field, although not all individuals will regurgitate. | | |
| **Overall** | **Biases connected with the exposure calculation are relatively small (mostly within a factor of about 2) compared to the influence of toxicity, avoidance and metabolism. For pesticides with strong avoidance and rapid metabolism[9], Tier 1 will substantially overestimate risk. For substances with little or no avoidance and slow metabolism, true risk for a sensitive species could be higher and some mortality could occur above TER = 10.** | | | |

[9] No general statement can be made about the degree of avoidance and metabolism required for this, but it could be an option for case-by-case investigation in higher-tier assessments.

The overall evaluation at the bottom of the table gives an overall judgement on the combined effect of the various factors on the overall conservatism of the assessment. This is based on expert judgement of how the factors interact. It is not a simple summation of the plus and minus symbols.

Overall, it is considered that the calculation of dietary exposure might be relatively close to a realistic worst case, but that the conservatism of other aspects is much more uncertain. Possibly the largest single source of uncertainty is the extrapolation of toxicity from a test species to the species exposed in the field, which for some pesticides may be over an order of magnitude more or less sensitive (shown in Table 1 as +++ and - - -). Evidence for this is illustrated in Figure 1, which shows the manner in which the ratio of the geometric mean of two standard test species to the HD5 (estimated fifth percentile species) varies between pesticides. Another important factor affecting the conservatism of the assessment is that within a species, sensitive individuals may be 2 – 10 times more sensitive than the $LD_{50}$ value that is used in the TER calculation (see Figure 2). On the other hand, both avoidance and metabolism are ignored in the TER calculation but could greatly reduce the risk for some pesticides. Consequently, the overall conservatism of the first-tier TER calculation will vary widely between pesticides. If the focal species happens to be much more sensitive than the standard test species, and if there is little or no avoidance and metabolism, then the true risk could be higher than implied by the first-tier assumptions, and some mortality might then occur when the Tier 1 TER = 10. For pesticides that are subject to strong avoidance and metabolism, the first-tier assessment will substantially over-estimate risk.

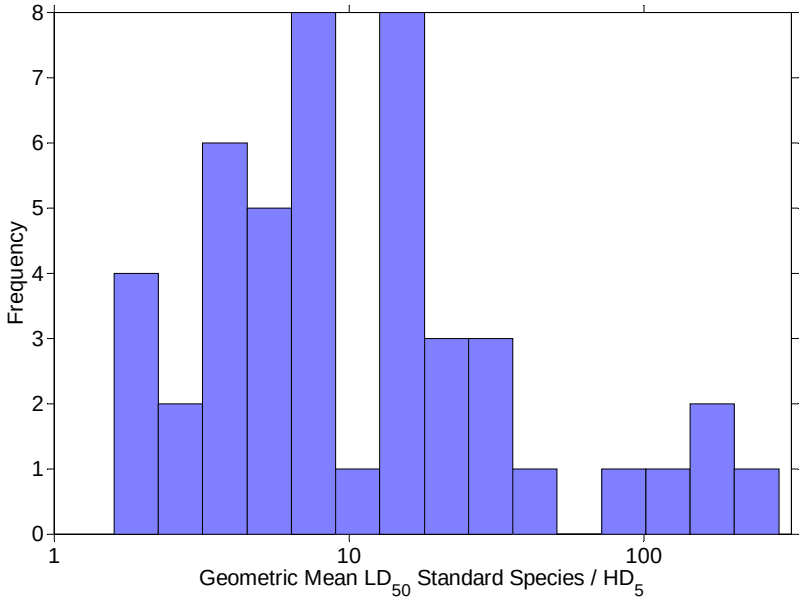



**Figure 1.** Frequency histogram for the ratio of the geometric mean of the $LD_{50}$ valuesfor two standard test species (which is used in TER calculations) to the estimated HD5 in 46 different pesticides, plotted on a log10 scale. The HD5 is taken as an arbitrary example of a sensitive species. For some pesticides, the estimated HD5 is nearly 100 times more sensitive than the $LD_{50}$ used in the TER calculation[10].

[10] HD5 is 5th percentile of variation in $LD_{50}$ between species for the same pesticide, estimated by the method of Aldenberg and Slob (1993). Analysis restricted to pesticides with over 10 tested species, in order to limit sampling error in estimating the HD5 from small samples.

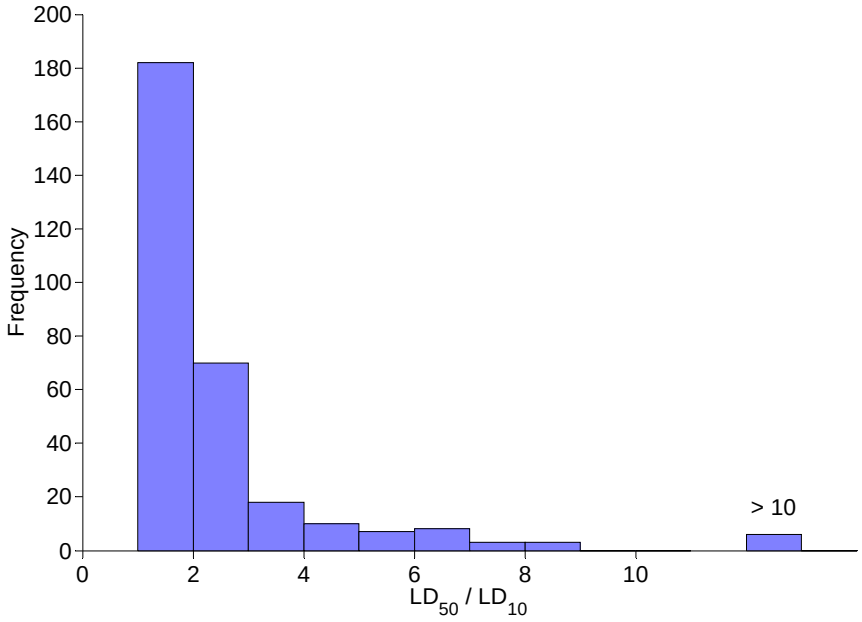



**Figure 2.** Frequency histogram for the ratio of the $LD_{50}$ to the $LD_{10}$ in 307 different toxicity studies with different species and pesticides, plotted on a $\log_{10}$ scale. The $LD_{10}$ is taken as an arbitrary example of a sensitive individual. The lethal dose for sensitive individuals is within a factor of 2 of the $LD_{50}$ in about 50 % of cases, and is nearly always within an order of magnitude.[11]

The second line of evidence for evaluating the LoP of the acute avian assessment for sprayed pesticides is derived from the comparison between calculated TERs and evidence on the occurrence of mortality in a total of 99 field studies with 28 different pesticides (seven carbamates, 19 organophosphorus pesticides, and two others). Uncertainties affecting extrapolation from organophosphates (OPs) and carbamates to other pesticides are discussed in detail below. A detailed account of the analysis is presented in Appendix 2 of EFSA, 2008.

The details and quality of the methods varied between field studies, as did the level of detail contained in the study reports. As a consequence, interpretation of the studies is inevitably subjective and uncertain. The evaluation addressed this in two ways. First, a method of evaluation was devised that allowed the evaluator to reflect their uncertainty about the attribution of effects. Second, each study was evaluated independently by three or four separate evaluators. In addition, the uncertainties affecting this and other aspects of the analysis are evaluated in detail below.

The measure used for evidence of field effects is the subjective probability of lethal effects. This was obtained by asking each assessor to evaluate the results of each field study, and to judge whether direct acute toxic effects on birds actually occurred in each study. Specifically, the evidence for the truth of each of the following statements was evaluated:

1. The pesticide application(s) caused no direct acute impact on adult birds. Absence of obvious sublethal or lethal effects.

[11] Analysis for same pesticides as Figure 1, but restricted to toxicity studies for which both an $LD_{50}$ and slope were available. $LD_{10}$ is the dose lethal to 10 % of animals tested.

2. The pesticide application(s) caused direct sublethal effects on adult birds. Changes in behaviour or physiology (e.g. choline esterase inhibition) were present but no immediate lethality.
3. The pesticide application(s) caused mortality of adult(s) in a single bird species.
4. The pesticide application(s) caused mortality of adults in two to five species of birds.
5. The pesticide application (s) caused mortality of adults in more than five species of birds.

The evaluators each expressed their own evaluation of each study by stating their subjective probability (i.e. degree of belief) for each statement being true. Because the protection goals relate to mortality and population effects (see earlier), it was decided to sum the probabilities assigned by each evaluator to statements 3 – 5 for each study, as an estimate of their subjective probability that the pesticide caused any mortality. Comparison of the results for the four evaluators showed a high degree of consistency in their interpretation of nearly all the studies (see Appendix 2 of EFSA, 2008). Consequently, the probabilities were averaged across evaluators for each study.

Caution is required in interpreting these probabilities. They express the likelihood (as assessed by four evaluators) that mortality occurred in each field study. This is a measure of the *strength of evidence* that mortality had actually occurred in that particular field study. It is not a measure of frequency. For example, a probability of 0.9 for a particular study means that after reviewing the reported results, the evaluators were (on average) 90 % sure that mortality caused by the pesticide had occurred in that study. It is not, and should not be interpreted as, an estimate of how often mortality would occur if the field study was repeated many times.

A histogram of the mean subjective probabilities assigned by the evaluators is shown in Figure 3. The probabilities fall mainly in two groups, one group between 0 and 0.4, and the other group between 0.8 and 1. The group between 0.8 and 1 relate to field studies where the evaluators considered the evidence of lethal effects to be strong (e.g. dead birds were found), with some evidence that they were caused by the pesticide (e.g. residues, cholinesterase inhibition, or comparison with unsprayed control sites). Probabilities in the lower group (between 0 and 0.4) imply less evidence of lethal effects. Those between 0 and 0.2 relate mostly to field studies with reasonable methodology that found no evidence of lethal or sublethal effects. Some of the probabilities around 0.2 – 0.3 relate to field studies without evidence of direct toxic effects but in which the methodology was not strong enough to provide confidence of detecting effects. Probabilities from 0.3 to 0.4 mostly relate to studies with evidence of sublethal effects (cholinesterase inhibition, the finding of a single debilitated bird founding a few cases, and indications of reduced nestling success in a few cases).

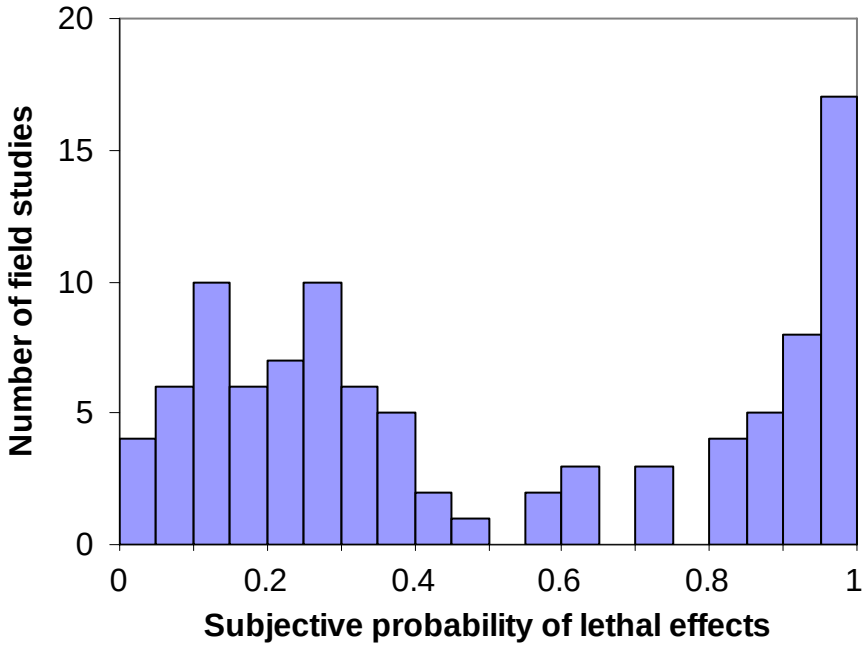
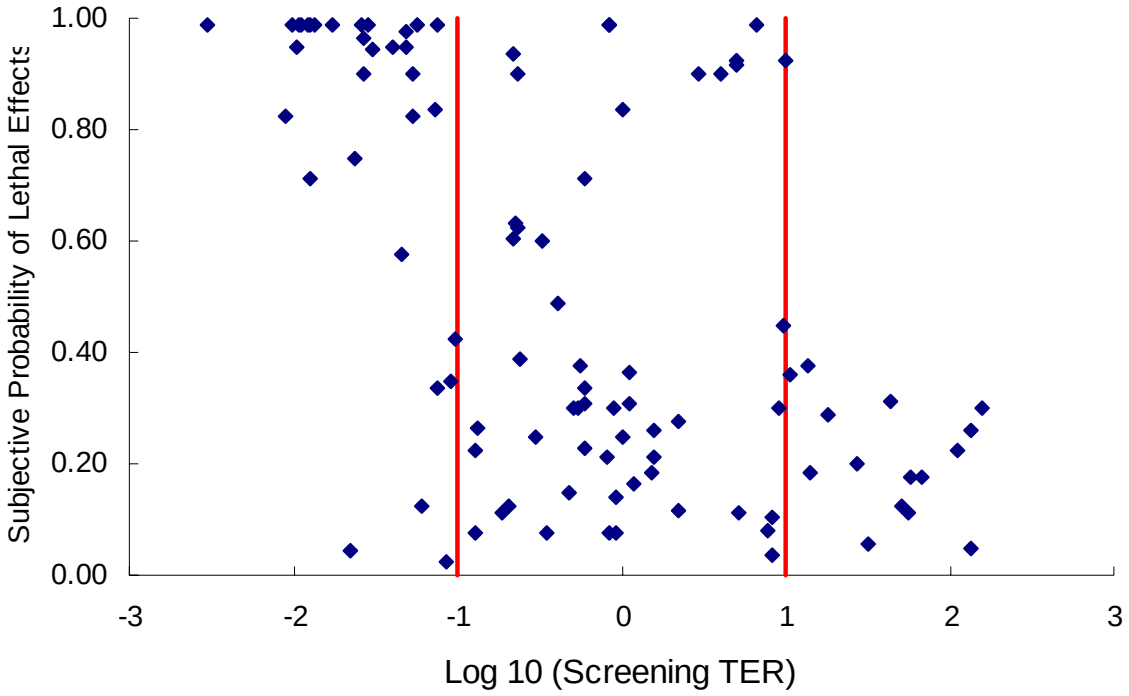



**Figure 3.** Histogram of subjective probabilities of lethal effects evaluated for a total of 99 field studies with 28 different sprayed pesticides. Each probability is the mean of values assigned by three or four evaluators, and represents their assessment of the strength of evidence that lethal effects were caused by the pesticide under study.

The probabilities assigned by the evaluators take account of the fact that the detection of sublethal effects increases the chance that lethal effects occurred but were not detected. Therefore, probabilities below 0.5 cannot be interpreted as implying absence of any mortality. On the other hand, they can be interpreted with reasonable confidence as implying an absence of 'visible mortality', if this is interpreted as birds dying in numbers noticeable to the public, since the methods employed in the field studies involved active searching and monitoring that substantially increase the chance of detection.

To evaluate the level of protection provided by proposed assessment procedures, screening and first-tier TERs were calculated[12] for the pesticides and crops involved in each field study, and were compared to the subjective probabilities of effects in the field studies. The results of these comparisons are shown in Figure 4. The TERs are shown on the horizontal axis, and the field study results on the vertical axis.

[12] TERs were based on exposures calculated according to the Guidance Document, and geometric means of LD50s for bobwhite quail and mallard duck, as these are the standard species most commonly submitted for risk assessment. Where data for bobwhite quail were lacking, Japanese quail was substituted if available.



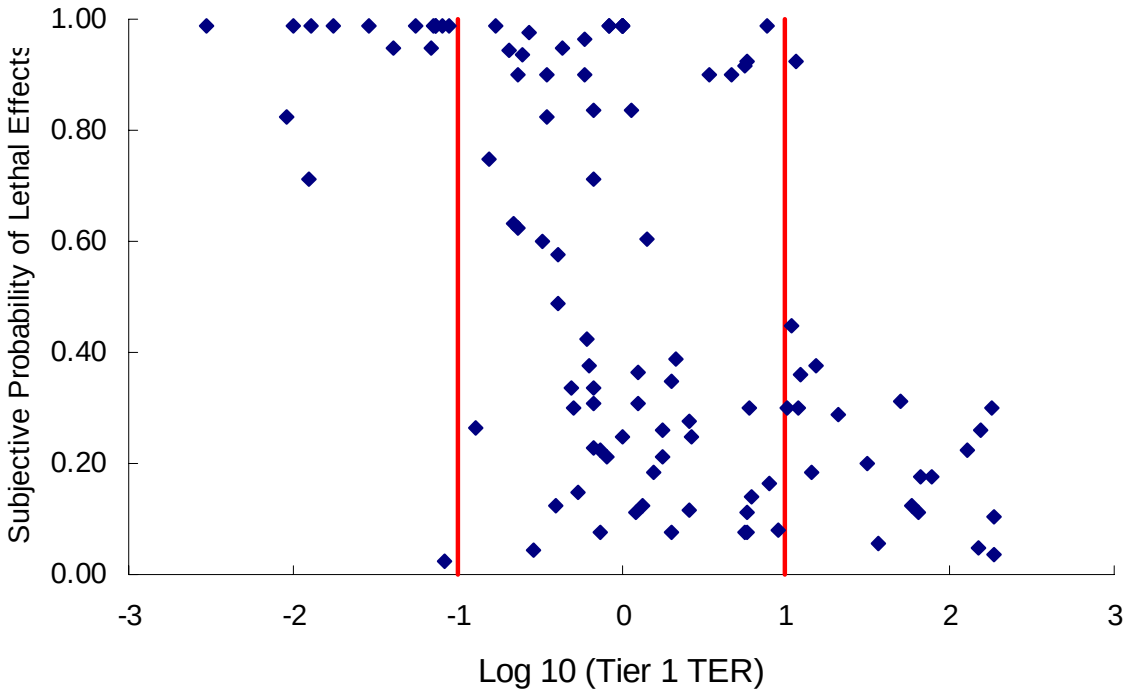




**Figure 4.** Relationship between evidence of lethal effects in field studies and the TER for each field study, calculated using the proposed default values for screening assessments (top graph) and first-tier assessments (bottom graph). Excludes avicidal applications. Horizontal axis is plotted on log10 scale. Vertical lines are at –1 and +1 (i.e. TER = 0.1 and 10).

The two graphs in Figure 4 are each divided into three regions, as illustrated by the vertical lines:

1. an area above about TER = 10, in which one or none of the field studies had a high probability of lethal effects;
2. an area below about TER = 0.1, in which most of the studies had a high probability of lethal effects;
3. an intermediate area between TER = 0.1 and 10, in which some studies had a high probability of lethal effects and others a low probability.

With regard to the pesticide uses represented in the field studies, these results are interpreted as suggesting that those with TER > 10 would rarely cause visible mortality. This conclusion takes account of the fact that, although some of the field studies with TER > 10 had probabilities of lethal effects in the region of 0.3, this overestimates the probability of visible mortality. This is due to the greater detectability of effects in field studies (which involve active searching) compared to normal use.

Pesticide uses with TERs between 0.1 and 10 caused detectable mortality in some of the field studies but not others, while those with TER < 0.1 caused detectable mortality in a high proportion of field studies. It is difficult to assess how often this mortality would reach a sufficient level to be 'visible'. It seems clear, however, that uses with TERs below 10 cannot be regarded as achieving the surrogate protection goal of any mortality being unlikely.

It is essential to consider the uncertainties affecting this use of the field study data. Uncertainties are summarised in Table 2, evaluated in terms of their potential to make the critical TER (at which any mortality becomes unlikely) higher or lower than the value of 10 specified in Annex VI of Directive 91/414/EEC. Uncertainties relating to the field studies and their interpretation are evaluated first, followed by uncertainties relating to differences between pesticides and use scenarios. The latter includes an evaluation of differences between the pesticides and scenarios found in the field studies and those encountered in EU regulatory assessments.

It is considered that most of the uncertainties have only minor impacts (factor of 2 or less) on identification of the critical TER value. Two factors stand out as potentially causing larger increases in the critical value. First, the possibility that some undetected mortality occurred in some of the field studies with TER > 10. Although it is considered that such mortality is unlikely to be 'visible', it would breach the surrogate protection goal of making any mortality unlikely. Second, all but two of the pesticides in the field studies were OPs or carbamates, all of which are likely to elicit moderate or strong avoidance responses. If these responses were much reduced or absent, as may occur for some other types of pesticide, then it would be expected that mortality – perhaps visible mortality – would occur at higher TERs than seen in the field studies, i.e. higher than 10. If it were desired to guard against these possibilities, then it might be prudent to increase the conservatism of the screening and first-tier TER calculations. This could be done by taking a more conservative value for any of the inputs, or by adding an extra factor to the calculation. If it was decided not to increase the conservatism of the assessment, it would mean that some undetected mortality could occur occasionally for pesticides with TER > 10, and that visible mortality might occur for such pesticides if they had little or no avoidance.

In some cases, it might be possible to apply for some pesticides a lower critical TER value than for others, if a reliable way could be found to identify them (e.g. based on common toxicological properties). There are some signs in the data that such differences may exist. For example, in seven field studies with methiocarb that showed TER values in the region of 0.1,

only one of them was evaluated as indicating a high probability of lethal effects. However, even if the critical TER is lower for methiocarb, the causing factors are not clear (possible candidates include avoidance, reversibility, rapid metabolism, and reduced dermal exposure or uptake). Therefore, it is not possible to identify with confidence other pesticides to which the same factors apply. Statistical analyses show that a combination of the octanol-water partition coefficient ($K_{ow}$) and the need for activation[13] substantially improve the prediction of mortality in the field studies (Appendix 2 of EFSA, 2008). However, the form and mechanism of these relationships are very uncertain and, on the basis of current evidence, there is insufficient confidence that these can be extrapolated to other pesticides (see Appendix 2 of EFSA, 2008). Furthermore, it is possible that much or all of the broad range of TER values over which both high and low probabilities of mortality occur (Figure 4) could be due to factors that are common to all pesticides. These include variation in the sensitivity of species and individuals present in any given field study, as well as variation in exposure between field studies (e.g. species and individuals with high PT may be present in some field studies but not others, and residues may vary between different applications of the same pesticide).

[13] Some pesticides require activation within the body to produce their toxic metabolite, e.g. some OPs, see Appendix 2 of EFSA (2008).

**Table 2.** Evaluation of uncertainties affecting comparison of the first-tier TER assessment of acute avian risks with data on mortality in field studies. The aim is to find the critical TER value above which any mortality will be unlikely (surrogate protection goal). Symbols are used to indicate the extent to which the true critical TER could be lower (-) or higher (+) than 10. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that could increase the critical value by a factor of 10.

| Source of uncertainty | Potential to decrease critical TER | Explanation | Potential to increase critical TER | Explanation |
|---|---|---|---|---|
| *Uncertainties affecting the evaluation of the field studies* | | | | |
| Variable quality of field studies | _ | Evaluators took account of study quality when assigning subjective probabilities. It is possible that in doing so they might have overstated the probability of effects for poorer studies. | + | It is possible that evaluators might have understated the probability of effects for poorer studies. |
| Matching field studies to TER scenarios | | Two of the field study evaluators matched the field studies to the TER scenarios, which were then checked by a third person. | | |
| Subjectivity of evaluation | | Four evaluators gave similar results. Average values used for analysis. | | |
| Relationship of results to actual effects | | | + | Probable that some field studies with TER > 10 caused some undetected (hence not visible) mortality (see discussion in text). |
| *Uncertainties affecting the form of the relationship between TER and field effects and its extrapolation from the available studies to other pesticides and scenarios* | | | | |
| Toxicity | | Most field study pesticides had mean $LD_{50}$ <100 mg/kg bw but relationship of TER to field effects is expected to be similar for less toxic pesticides | + | The geometric mean is more uncertain if LD50 is available for only one species, but in most cases at least 2 species are available. |
| Molecular weight | | Larger substances with lower uptake may present less hazard, but this should be reflected in $LD_{50}$. | | |
| Other pesticide properties | _ _ | Field study pesticides cover the general range for Kow, need for activation, and reversibility of effects. It is possible that these or other factors reduce critical TER substantially for some pesticides but they are not well enough understood to be included in the first-tier assessment (see text). | + | Field study pesticides cover the general range for Kow, need for activation, and reversibility of effects. It is possible that these or other factors increase critical TER to a limited extent for some pesticides (see text). |
| Application method | | Many field studies used aerial applications but in a separate analysis, effect of application method was not significant ($p > 0.05$). | | |
| Multiple applications | _ | Few studies with multiple applications, no obvious difference. TER calculations include theoretically appropriate adjustment. However, possible that MAF factors over-represent the contribution of repeat applications, which would cause critical TER to be lower. | | Possible that more studies with multiple applications might have indicated a higher critical TER. Possible that MAF factors under-represent the contribution of repeat applications, which would cause critical TER to be higher. |
| Crops | _ | Studies cover wide range of crops, no sign of consistent differences. Possible some crops not included in field studies may have lower critical TER. | + | Possible that some crops not included in field studies may have higher critical TER. |

| Source of uncertainty | Potential to decrease critical TER | Explanation | Potential to increase critical TER | Explanation |
|---|---|---|---|---|
| Bird species exposed | _ | Mostly North American studies, but ecological equivalents to EU. Possibly, some EU scenarios have species with lower potential for exposure, hence critical TER could be a little lower for those scenarios. Field studies on rangeland may have had higher bird densities than EU agricultural land, leading to increased effects and thus over-estimating critical TER. | + | Possible that some EU scenarios have species with higher potential for exposure, hence critical TER could be a little higher for those scenarios. |
| Dietary exposure | | Variation in factors affecting dietary exposure (e.g. diet, use of treated area, residues, etc.) in field studies is expected to be representative for the scenarios that were included. | | |
| Non-dietary exposure | _ | Contributions from non-dietary exposure routes (dermal, water, etc.) in field studies expected to be representative for the scenarios that were included. May have been increased to some extent in the studies with aerial spraying (though not detectable in analysis). | | |
| Variation of toxicity between species | _ | Sufficient field studies to include representative range of variation in extrapolation from test species to those exposed in field. Possible that in some cases the sensitivity of field species relative to test species could be still lower, making critical TER a little lower. | + | Possible that in some cases the sensitivity of field species relative to tested species could be higher than in the field studies, making critical TER a little higher. |
| Variation of toxicity between individuals | | Sufficient field studies to ensure that some include sensitive individuals. | | |
| Uncertainty factor | | Standard uncertainty factor is taken into account by examining evidence for mortality above TER = 10 (see Figure 4). | | |
| Avoidance of contaminated food | _ | Field study pesticides are mostly moderately or strongly avoided. Unlikely that new pesticides with similar toxicity will be more avoided than the most strongly avoided examples in the analysis. Less toxic pesticides will have more opportunity for avoidance. | +++ | Risk could be higher for pesticides that are less avoided than those in the field study analysis, and much higher for any which are not avoided at all. |
| Effect of metabolism | _ | For pesticides with lower toxicity but similar metabolism to those in the field studies, the opportunity for avoidance to occur before obtaining a lethal dose is increased, hence risk is decreased. | + | Field study pesticides cover a range of metabolism rates but some newer pesticides have lower metabolism rates, which would increase risk and imply a higher critical TER. |
| Regurgitation | _ | Field studies expected to include representative range of species with regard to regurgitation ability. Regurgitation may have increased some of the LD50s used in the analysis. If this was reliably identified in regulatory evaluations, the critical TER might decrease. | | |
| **Overall** | **The field studies include a range of crops and species and the critical TER for other scenarios is not expected to differ much. The field studies relate almost entirely to OPs and carbamates but in most respects their properties cover the range of variation seen in other pesticides. For pesticides with similar toxicity and avoidance responses to OPs and carbamates, visible mortality is unlikely above TER = 10 but some undetected mortality may occur. For pesticides with low toxicity, there is more opportunity for avoidance to reduce risk. For pesticides that elicit little avoidance, some visible mortality may occur above TER = 10.** | | | |

The third line of evidence available for evaluating the level of protection for the assessment of acute risks to birds is the historical record of reported poisoning incidents in practical use. In general, the frequency of such reports has been extremely low in Europe during the last 20 years. Even in countries with organised systems for investigation of reported incidents, very few are reported each year and of these even fewer (e.g. one or two per year per country) are attributed to approved use of pesticides (e.g. Fletcher and Grave 1992; de Snoo et al., 1999). For countries with organised schemes, the frequency of incidents can be regarded as a measure of visible mortality. When considering the total areas treated with pesticides, the frequency of incidents suggests that the frequency of 'visible mortality' has been very low, at least in those European countries where systematic records are kept, and that the risk assessment procedures used in the last 20 years have been adequate to achieve the protection goal of a high certainty of no visible mortality. This conclusion is likely to hold also for the acute risk assessment procedures proposed in this opinion, as they provide a level of protection similar to the existing procedures (Appendix D).

However, there are important reasons why the number of reported incidents is certain to underestimate the number of mortalities actually occurring, and furthermore is likely to underestimate it to a substantial degree. These factors are summarised in Table 3. The fact that some visible mortalities have occurred, and that they are likely to be a substantial underestimate of the true level of mortality, makes it probable that the risk assessment procedures of the last 20 years have not achieved the surrogate protection goal of making any mortality unlikely.

The factors listed in Table 3 also make the incident record an uncertain indicator for the other actual protection goal, of preventing long-term repercussions on abundance and diversity. This is because the factors in Table 3 show that it is possible that the frequency of undetected mortality could be quite high. It cannot be ruled out that this would be sufficient to cause some level of sustained decrease in bird populations, at least on a local scale. This might not be compatible with the protection goal of achieving a high certainty of no long-term repercussions on abundance and diversity, given that the temporal and spatial scales of that goal are undefined.

It is concluded that the historical record of incidents provides good evidence regarding the actual protection goal of preventing visible mortality, weaker evidence regarding the actual protection goal of preventing long-term population effects, and very weak evidence regarding the surrogate protection goal of making any mortality unlikely. Hence it is important to consider the historical record together with other lines of evidence when making an overall evaluation of the level of protection expected from the proposed procedures (see below).

**Table 3.** Evaluation of uncertainties affecting interpretation of historical record of reported poisoning incidents involving birds and mammals. Symbols are used to indicate the extent to which the true frequency of individual mortality could be lower (-) or higher (+) than the level recorded. The number of symbols provides a subjective evaluation of the potential magnitude of the effect, e.g. +++ indicates a factor that could make the true frequency of mortalities much higher than the recorded frequency.

| Source of uncertainty | Effect on true level of impacts | Explanation |
|---|---|---|
| Low probability of dead animals being visible to humans | +++ | Animals dying in dense crops are unlikely to be visible to casual observers. For small animals, even a low crop cover will prevent visibility. Animals receiving a life-threatening exposure in open habitats are likely to seek cover before they die (demonstrated for birds by Fryday *et al*. 1996 and likely to be true also for mammals). Carcasses in the open are rapidly removed by scavengers. Kills involving small numbers (e.g. non-flocking species) of small-bodied individuals unlikely to be found. Flocking species may not be the most vulnerable. |
| Low probability of dead animals being reported by public | ++ | Members of the public are unlikely to consider reporting single dead bodies but more likely to report larger kills. Even in countries with organised incident schemes, public awareness of them is low. Kills involving small numbers of small-bodied individuals are unlikely to be reported. |
| Proportion of reported incidents investigated for pesticide involvement | + | Even in countries with organised incident schemes, involvement of pesticides is only investigated where there is circumstantial evidence to suggest it (e.g. known application in direct vicinity of location where animal was found). Kills involving small numbers of individuals are unlikely to be fully investigated. |
| Probability of a pesticide mortality being positively identified as such | +/+++ | When chemical analysis is carried out, it is usually limited to a subset of pesticides that have historically caused incidents (e.g. OPs and carbamates, organochlorines, anticoagulants). Incidents caused by other pesticides are less likely to be detected. Even if the correct pesticide is analysed, there may be insufficient remaining residue for officials to record it as a lethal exposure. There is a potential bias in that there may be inadequate methods of analysis for new chemistries and hence they are unlikely to be looked for and hence detected. |
| Lack of organised schemes in most countries | +++ | Organised schemes for investigating and documenting reported incidents exist in only a small number of EC Member States (e.g. UK and France). |
| **Overall** | **In countries with an organised scheme for investigating and documenting incidents, the frequency of incidents can be regarded as a measure of the frequency of visible mortality. However, the factors evaluated above imply that the frequency of incidents could greatly underestimate the frequency of undetected mortality. For individual pesticides, incidents can confirm a high predicted risk, but absence of incidents does not necessarily indicate a low risk.** | |

Tables 1 to 3 evaluate three separate lines of evidence on the conservatism of the proposed screening and Tier 1 TER assessment procedures for acute risks to birds from sprayed pesticides. It is important to give appropriate weight to each line of evidence in reaching an overall conclusion. To assist with this, the three lines of evidence are summarised together in Table 4, together with the main uncertainties affecting them.

The pattern of uncertainties affecting the three lines of evidence is markedly different. In particular, the general magnitude of uncertainties is lower for the assessment based on comparison with field studies, because the field studies take account of some factors that are very uncertain or omitted in the TER calculation. Furthermore, the historical record of incidents underestimates the frequency of undetected mortality. On the other hand, in those countries with organised schemes, the historical incident record may be regarded as a measure of visible mortality. These differences are taken into account in reaching overall conclusions.

The field studies showed evidence of mortality occurring below about TER=10, but little evidence of mortality at TER > 10 (Figure 4). Evaluation of the TER calculation is subject to large uncertainties, but is compatible with the finding in the field studies of mortality below TER = 10. In addition the evaluation of the TER calculation indicates that, for some pesticides, mortality might occur above TER = 10. Although this was not seen in the field studies, they do not rule it out since there might have been undetected mortality, and since the studies were restricted mostly to OPs and carbamates. For both these lines of evidence, mortality above TER = 10 is more likely for pesticides with high toxicity, and that elicit low avoidance and slow metabolism. These conclusions are compatible with the historical incident record, because it is likely to greatly underestimate the level of undetected mortality. Overall, it is therefore concluded that some mortality can be expected below TER = 10, and that, especially for pesticides with high toxicity, low avoidance and slow metabolism, some undetected mortality may occur when TER > 10.

On the other hand, the historical incident record provides good evidence that, in general, visible mortality is unlikely when TER > 10. The other two lines of evidence both leave open the possibility that mortality could occur above TER = 10 for pesticides with high toxicity, low avoidance and slow metabolism. Overall, it is concluded that visible mortality is unlikely when TER > 10 for pesticides in general.

The conclusion that some mortality may occur when TER > 10 implies a possibility that the proposed assessment procedure may not satisfy the surrogate protection goal of making any mortality unlikely, especially for pesticides with high toxicity, low avoidance and slow metabolism. If it were desired to protect against these possibilities, then it might be prudent to increase the conservatism of the screening and first-tier TER calculations. This could be done by taking a more conservative value for any of the inputs, or by adding an extra factor to the calculation.

The conclusion that visible mortality is unlikely when TER > 10 suggests that the proposed assessment procedure might be regarded as satisfying the actual protection goal of ensuring high certainty that no visible mortality will occur (depending on the interpretation of 'clearly establish'). It might be thought that this would over-ride the surrogate protection goal of making any mortality unlikely, but this is not necessarily true. This is because the uncertainties affecting the historical incident record (Table 3) make it possible that the frequency of undetected mortality could be quite high, and it cannot be ruled out that this would be sufficient to cause some level of sustained decrease in bird populations, at least on a local scale. Three types of uncertainty combine here, the uncertainty about the level of undetected mortality, the uncertainty about the level of mortality required to cause sustained population reductions, and the uncertainty about what temporal and spatial scale of population change would be of concern to risk managers. These uncertainties imply that even though the assessment procedure may be regarded as satisfying the protection goal of no visible mortality, it is uncertain whether it achieves the protection goal of no long-term repercussions on abundance and diversity. As above, if it were desired to protect against this uncertainty, then it might be prudent to increase the conservatism of the screening and first-tier TER calculations, by taking a more conservative value for any of the inputs, or by adding an extra factor to the calculation.

In summary, it is concluded that the proposed first-tier assessment procedure for acute risks to birds from sprayed pesticides could be regarded as satisfying the protection goal of no visible mortality. However, it probably does not achieve the surrogate protection goal of making any mortality unlikely, and it is uncertain whether it achieves the actual protection goal of no long-

term repercussions on abundance and diversity. If it were desired to have a high certainty of achieving both actual protection goals, as well as the surrogate protection goal for all pesticides, then it might be prudent to increase the conservatism of the screening and first-tier TER calculations, by taking a more conservative value for any of the inputs, or by adding an extra factor to the calculation. Determining the level of certainty required involves risk management judgements.

*Risk management considerations*

The preceding paragraph summarises the outcome of the scientific assessment of the level of protection provided by the proposed first-tier TER assessment procedure for acute risks to birds from sprayed pesticides. There is some uncertainty whether the procedure will meet both of the protection goals. Deciding whether this uncertainty is sufficient to merit increasing the conservatism of the assessment procedure involves risk management judgements.

In addition to the assessment of the level of protection, risk managers may also wish to consider the impact that the proposed procedures would have on the proportions of pesticides requiring higher-tier assessment. An analysis of this is presented in Appendix D of the Guidance Document.

**Table 4.** Comparison of three lines of evidence on conservatism of the first-tier TER assessment of acute avian risks. The bottom rows of the table summarise the overall conclusions. The upper part of the table summarises the main uncertainties that have taken into account (see Tables 1-3 for details). Symbols indicate the potential for the 'true' critical TER value for ensuring any mortality is unlikely (surrogate protection goal) to be higher (+) or lower (-) than 10.[14]

| | **Lines of evidence** | | |
|---|---|---|---|
| | **Assessment of TER assumptions** | **Comparison of TERs with evidence from field studies** | **Historical record of poisoning incidents** |
| **Main contributions to uncertainty:** | | | |
| Dietary exposure | -/+ | | |
| Non-dietary exposure | +/++ | - | |
| Variation of toxicity between species | - - - /+++ | - /+ | |
| Variation of toxicity between individuals | +/+++ | | |
| Uncertainty factor | - - - | | |
| Avoidance of contaminated food | - / - - - | - /+++ | |
| Effect of metabolism | - - - | - /+ | |
| Other properties of some pesticides | ? | - - /+ | |
| Relationship of field study results to actual effects | | + | |
| Low probability of dead animals being visible | | | +++ |
| Low probability of dead animals being reported, investigated and confirmed | | | +++ |
| Lack of organised schemes for documenting incidents in most countries | | | +++ |
| **Conclusions for individual lines of evidence** | For pesticides with strong avoidance and rapid metabolism, Tier 1 will substantially over-estimate risk. For substances with little or no avoidance and slow metabolism, the true risk for a sensitive species might be higher and some mortality might occur above TER = 10. | For pesticides with toxicity and avoidance responses similar to those of OPs and carbamates, visible mortality is unlikely above TER = 10 but some undetected mortality might occur. For pesticides with little avoidance, some visible mortality might occur above TER=10. | The very low frequency of documented incidents suggests a very low frequency of visible mortality, but might greatly underestimate the frequency of undetected mortality. |
| **Overall conclusion regarding likelihood of any mortality above TER = 10** | Some undetected mortality may occur when TER > 10, especially for pesticides with high toxicity, low avoidance and slow metabolism. | | |
| **Overall conclusion regarding likelihood of visible mortality above TER = 10** | Visible mortality is unlikely when TER > 10 for pesticides in general. Theoretically it might occur for pesticides with high toxicity, low avoidance and slow metabolism but there is no evidence of this from the incident record. | | |

[14] Athough the -/+ symbols are defined in different ways in Tables 10a-c, they actually have comparable meaning, because they are all equivalent to indicating the potential for the 'true' critical TER value (for ensuring any mortality is unlikely) to be higher (+) or lower (-) than 10. Number of symbols indicates magnitude of effect.

**Evaluation of level of protection for first-tier assessment of reproductive risk to birds**

Only one line of evidence is available to evaluate the LoP of the proposed procedure for assessing reproductive risk to birds. Evaluation by comparison with field studies is not useful since too few field studies exist on the reproductive effects of pesticides on birds. Evaluation by comparison with historical incidents is also not useful. Severe and widespread reproductive impacts have been detected in the past: the historical declines of raptor populations due to eggshell-thinning caused by DDT and DDE. However, much lower levels of effect would be sufficient to breach the protection goal of no long-term repercussions on abundance and diversity, and it is extremely unlikely that these lower levels of effect would be detected by casual observation.

Consequently, the only line of evidence for evaluating the LoP of the reproductive risk assessment is to examine the conservatism of the inputs and assumptions of the assessment procedure. This is done using the same approach as in the first line of evidence when evaluating the LoP of the TER assessment procedure for acute risks (see above).

The first tier reproductive assessment allows two alternative choices for the time-weighted average to use in the TER calculations, depending the mechanism of effects (see section 4.3 in the Guidance Document). This in effect leads to two alternative assessments:

- The long-term exposure assessment (LTE), which assumes reproductive effects are caused only by long-term exposures, assessed using an exposure period of 21 days. (It should be noted that the selection of a 21-day time window is arbitrary and has only been selected to try to differentiate between those substances that may cause an effect following a short-term exposure and those that may cause an effect following long-term exposure.)
- The short-term exposure (STE) assessment, which assumes reproductive effects are caused by 1-day exposures[15].

The LoP of assessments using these alternative assumptions is evaluated in Tables 5a and 5b respectively. The inputs, assumptions and omissions of the assessment are listed in the left hand column of each table, and the remaining columns evaluate the conservatism of each one in relation to a 'true' realistic worst case. Factors that were evaluated to cause relatively minor uncertainty are listed separately in Table 5c.

As explained at the start of this Appendix, the focus on a true or realistic worst-case scenario is necessary to address the surrogate protection goal of making any reproductive effects unlikely. For acute risks, the availability of field studies and historical incident data made it possible to evaluate one of the actual protection goals more directly (prevention of visible mortality). This is, however, not possible for reproductive risks due to the absence of adequate field studies or incident data. Therefore the evaluation in this section is focussed on the surrogate protection goal of making any reproductive effects unlikely.

The STE assessment (Table 5a) makes an extreme worst-case assumption regarding the exposure duration required to cause NOAEL effects. Uncertainties exist in both directions, but most will tend to make the 'true' worst-case risk lower. One exception is the use of mean RUD

[15] It is intended to develop further guidance on criteria for determining which effects could be caused by short-term exposures. The Joint Working Group decided that, until such guidance is available, it should be assumed as a default that the effects are caused by LTE, unless there is specific evidence for the pesticide under assessment that the effect could be caused by STE.

for residues, which is likely to underestimate worst-case exposure if effects really are caused by 1-d exposures. Another exception is the overspray of eggs and nestlings, which may be significant in some cases. However, these factors may be outweighed by the collective effect of uncertainties working in the other direction, and some species may be able to recover part or all of any lost reproductive output by re-nesting. Overall it is concluded that when TER ≥ 5 the STE assessment is likely to achieve the surrogate protection goal for most pesticides. However, reproductive effects may occur for some individuals of sensitive species after application of pesticides that are slowly metabolised, weakly avoided, or have high non-dietary exposure.

The LTE assessment (Table 5b) assumes that the exposure duration required to cause NOAEL effects is 21 days. (It should be noted that the time window is arbitrary.) Uncertainties exist in both directions, but most will tend to make the 'true' worst-case risk lower. One exception is the use of 1/10 $LD_{50}$ as a proxy for longer-term effects, although this is likely to be outweighed by the collective effect of uncertainties working in the other direction. Some species may be able to recover part or all of any lost reproductive output by re-nesting. Overall it is concluded that when TER ≥ 5 the LTE assessment is likely to achieve the surrogate protection goal for those pesticides that do not cause reproductive effects through short-term exposures. However, reproductive effects may still occur for some individuals of the most sensitive species.

*Risk management considerations*

This section presents an assessment of the likelihood that the reproductive assessment procedure for birds will satisfy the protection goals. Deciding whether this provides an appropriate level of protection involves risk management judgements.

In addition to the level of protection, risk managers may also wish to know what impact the proposed procedures would have on the proportions of pesticides requiring higher-tier assessment (see Appendix D).

**Table 5a.** Evaluation of conservatism of the STE (short term exposure) scenario first-tier assessment of avian reproductive risks. The STE scenario assumes that all reproductive effects are caused by 1-day exposures. Each row evaluates a separate input, assumption or omission of the screening and first-tier assessment procedure. + and - are used to indicate the extent to which it is judged that the 'true worst' case for that parameter could decrease or increase the risk of causing any reproductive effect (the surrogate protection goal). The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that would increase the risk by an amount equivalent to reducing the TER by about a factor of 10. If the effect varies between pesticides or is uncertain, lower and upper evaluations are given (e.g. + /+++).

| Parameter, assumption or omission | Potential for 'true worst-case' risk to be lower | Explanation | Potential for 'true worst-case' risk to be higher | Explanation |
|---|---|---|---|---|
| Screening assessment indicator species and type of food | 0 to - | Realistic worst case – relatively small species eating only the most contaminated food type. Real worst case could be lower in some scenarios. | | Realistic worst case – relatively small species eating only the most contaminated food type. Negligible potential to be worse. |
| Tier 1 generic focal species and type of food | | Mixed diet based on average of available data on dietary composition. Worst case cannot be lower than average. | + | Mixed diet based on average of available data on dietary composition. Some individual birds will eat more than average proportion of most contaminated food on individual days. |
| Body weight (impact on exposure) | 0 to - | In some scenarios such small species may not occur. However, this has only a limited impact on exposure due to scaling of food intake with body weight. | | For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight. |
| Body weight (impact on toxicity) | | Relatively few exposed species are larger than species used in toxicity tests. | 0 to + | Focal species tend to be smaller than species used in toxicity tests. General trend for smaller species to be more sensitive (Mineau et al., 1996) is not taken into account in assessment. Relevant to endpoints based on $1/10^{th}$ $LD_{50}$. Bias can be up to four times but only one + given because this is partly represented by overall between-species variability (see below). |
| Percent of diet taken by individual in treated area | 0 to - - | Likely only a few scenarios where true worst-case individual is less than 0.5 (i.e. factor of 2 reduction) for short term exposures, could be lower for longer term exposures. | | Absolute worst case is used, hence cannot be higher. |
| Half-life of residues on food ($DT_{50}$) | | $DT_{50}$s often lower but only affect multiple applications in STE assessments and only part of the total exposure. | + | Some pesticides have $DT_{50}$s longer than 10 days (e.g. 19 % of pesticides registered in Canada in 2005[16]). |

[16] Based ondata from http://www.wsi.nrcs.usda.gov/products/W2Q/pest/winpst.html.

| Parameter, assumption or omission | Potential for 'true worst-case' risk to be lower | Explanation | Potential for 'true worst-case' risk to be higher | Explanation |
|---|---|---|---|---|
| Residue per unit dose | | Average of data for multiple pesticides and application events. True average for pesticide under assessment could be lower. However, if reproductive effects are caused by short-term exposure, realistic worst case could still be close to or even above general average. | ++ | True distribution for pesticide under assessment could be higher than average RUD used in assessment, so true worst case could be higher than average RUD. Also, RUD values may underestimate peak concentration on highly-exposed food items. Any under protection would be more pronounced where reproductive effects are the result of short-term exposure. |
| Non-dietary exposure of adults | | | + to ++ | This parameter is ignored, however, the true contribution uncertain, but could, increase risk by up to two times or more (Driver et al. 1991). |
| Duration of exposure required to cause reproductive effects | 0 to - - - | STE assessment assumes NOAEL effects can be caused by 1-d exposures: could be true for some pesticides but greatly over-estimating risk for others. | | STE assessment assumes NOAEL effects can be caused by 1-d exposures: this is an extreme worst case. |
| Relevance of reproduction toxicity study design | | | + | Not all critical phases of avian reproduction are adequately covered by existing protocol. Altricial species especially may differ – e.g. parental care is much more important for these species and not assessed in the current study. |
| Uncertainty of no-effect levels | 0 to - | Reproduction study has limited power to detect differences between dose levels. True NOAEL could be higher or lower. | 0 to + | |
| Relevance of 1/10 $LD_{50}$ as proxy for chick toxicity | - | True 'incapacitation' of chicks may not occur until higher levels than 1/10 $LD_{50}$. | | 1/10 $LD_{50}$ is realistic worst case for LOEL for incapacitation (protective for 95 % of studies). Potential for individual variability is considered below. |
| Variation of toxicity between individuals | | | + to ++ | Most sensitive individuals could be more sensitive for both 1/10 $LD_{50}$ and NOAEL endpoints (n.b. NOAELs used are based on average and not individual effects). |
| Variation of toxicity between species and/or stages within species | - - - | Focal species could be up to two orders of magnitude more or less sensitive than standard species (Fig. 1). If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (Luttik et al., 2005) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity. | ++/+++ | Focal species could be up to two orders of magnitude more or less sensitive than standard species (Fig. 1), although the potential for this is reduced when assessment is based on the most sensitive of several species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (*Luttik* et al., 2005) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity. |
| Uncertainty factor | - - | TER is compared with trigger value of 5. | | |

| Parameter, assumption or omission | Potential for 'true worst-case' risk to be lower | Explanation | Potential for 'true worst-case' risk to be higher | Explanation |
|---|---|---|---|---|
| Avoidance of contaminated food or of treated area as a whole | 0 to - - | Parameter is ignored, which would be realistic for non-avoided pesticides. Potential effect of avoidance less than for acute mortality. In STE assessments, 1/10 $LD_{50}$ represents sublethal effects which occur at doses closer to avoidance threshold and thus less likely to be prevented. | | |
| Effect of metabolism | - to - - - | In the STE assessment, risk for the 1/10 $LD_{50}$ endpoints would be reduced by metabolism; reduction could be very substantial for rapidly metabolised pesticides. | | |
| Recovery from effects | 0 to - - - | Affected individuals may be able to recover and reproduce at a later date. This may partially or wholly replace the reproductive output that was lost. | | |
| **Overall** | **The STE assessment makes an extreme worst-case assumption regarding the exposure duration required to cause effects. Uncertainties exist in both directions, but most will tend to make the 'true' worst-case risk lower. One exception is the use of mean RUD for residues, which is likely to underestimate worst-case exposure if effects really are caused by 1d exposures, although this may be outweighed by the collective effect of uncertainties working in the other direction. Some species may be able to recover part or all of the any lost reproductive output by re-nesting. Overall it is concluded that when TER ≥ 5 the STE assessment is likely to achieve the surrogate protection goal for most pesticides, but reproductive effects may occur for some individuals of sensitive species for pesticides that are slowly metabolised, weakly avoided, or have high non-dietary exposure.** | | | |

**Table 5b.** Evaluation of conservatism of the LTE (long-term exposure) scenario first-tier assessment of avian reproductive risks. The LTE scenario assumes that all reproductive effects are caused by long-term (21-d) exposures. + and - are used to indicate the extent to which it is judged that the 'true worst' case for that element could decrease or increase the risk of causing any reproductive effect (the surrogate protection goal). See Table 5a legend for more details.

| Parameter, assumption or omission | Potential for 'true worst-case' risk to be lower | Explanation | Potential for 'true worst-case' risk to be higher | Explanation |
|---|---|---|---|---|
| Screening assessment indicator species and type of food | 0 to - | Realistic worst case – relatively small species eating only the most contaminated food type. Real worst case could be lower in some scenarios. | | Realistic worst case – relatively small species eating only the most contaminated food type. Negligible potential to be worse. |
| Body weight (impact on exposure) | 0 to - | In some scenarios such small species may not occur. However, this has only a limited impact on exposure due to scaling of food intake with body weight. | | For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight. |
| Percent of diet taken by individual in treated area | 0 to - - | Likely only a few scenarios where true worst-case individual is less than 0.5 (i.e. factor of 2 reduction) for short term exposures, could be lower for longer term exposures. | | Absolute worst case is used, hence cannot be higher. |
| Half-life of residues on food ($DT_{50}$) | 0 to - - | Default value of 10 days for the various time-weighted average (TWA) measurements is conservative: most pesticides have $DT_{50}$s below 10. Also dissipation in first few days is often faster than implied by assumption of first order kinetics. | + | Some pesticides have $DT_{50}$s longer than 10 days (e.g. 19 % of pesticides registered in Canada in 2005[17]). |
| Non-dietary exposure | | | 0 to ++ | Dermal and inhalation routes will increase exposure to some degree, but limited to first few days after spray application and therefore less important if effects require longer exposure. |
| Duration of exposure required to cause reproductive effects | 0 to - | LTE assessment uses a TWA exposure over 21 d (an arbitrary choice). For some pesticides NOAEL endpoints might require longer exposures, but the reduction in TWA would be limited. | 0 to + | For some pesticides, reproductive effects might result from exposures shorter than 21 d, but the increase in TWA would be limited (e.g. two times with default $DT_{50}$ of 10 d). |
| Relevance of reproduction toxicity study design | - - | Exposure over 21 weeks in current protocol is much longer than is likely in most field situations and than considered in the 21-d LTE assessment. NOAELs likely to be lower over more relevant exposure periods, so true risk is lower. | + | Not all critical phases of avian reproduction are adequately covered by existing protocol. Altricial species especially may differ – e.g. parental care is much more important for these species and not assessed in the current study. |

[17] Based on data from http://www.wsi.nrcs.usda.gov/products/W2Q/pest/winpst.html.

| Parameter, assumption or omission | Potential for 'true worst-case' risk to be lower | Explanation | Potential for 'true worst-case' risk to be higher | Explanation |
|---|---|---|---|---|
| Uncertainty of no-effect levels | 0 to - | Reproduction study has limited power to detect differences between dose levels. True NOAEL could be higher or lower. | 0 to + | |
| Variation of toxicity between individuals | | | + to ++ | Most sensitive individuals could be more sensitive for NOAEL endpoints, as they are based on average and not individual effects. |
| Relevance of 1/10 $LD_{50}$ as an endpoint in LTE scenario | | | + to ++ | 1/10 $LD_{50}$ endpoint is derived from acute study and not strictly relevant to LTE scenario. Effects may occur at lower levels when caused by longer exposures. |
| Variation of toxicity between species and/or stages within species | - - - | Focal species could be up to two orders of magnitude more or less sensitive than standard species (Fig. 1). If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (Luttik et al., 2005) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity. | ++/+++ | Focal species could be up to two orders of magnitude more or less sensitive than standard species (Fig. 1), although the potential for this is reduced when assessment is based on the most sensitive of several species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (*Luttik* et al., 2005) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity. |
| Uncertainty factor | - - | TER is compared with trigger value of 5. | | |
| Avoidance of contaminated food or of treated area as a whole | 0 to - - | Parameter is ignored, which would be realistic for non-avoided pesticides. Potential effect of avoidance less than for acute mortality. Longer time scales increase potential for learned avoidance, but area under curve effects may occur at intakes below avoidance threshold. | | |
| Recovery from effects | 0 to - - - | Affected individuals may be able to recover and reproduce at a later date. This may partially or wholly replace the reproductive output that was lost. | | |
| **Overall** | **The LTE assessment assumes the exposure duration required to cause NOAEL effects is 21 days. Uncertainties exist in both directions, but most will tend to make the 'true' worst-case risk lower. One exception is the use of 1/10 $LD_{50}$ as a proxy for longer-term effects, although this is likely to be outweighed by the collective effect of uncertainties working in the other direction. Some species may be able to recover part or all of any lost reproductive output by re-nesting. Overall it is concluded that when TER > 5 the LTE assessment is likely to achieve the surrogate protection goal for those pesticides that do not cause reproductive effects through short-term exposures. However, reproductive effects may still occur for some individuals of the most sensitive species.** | | | |

**Table 5c.** Factors assessed as causing minor uncertainty, likely to cause less than two times difference between assessment and 'true worst-case' risk. They are listed separately to facilitate reading of Tables 5a and 5b. See legend of Table 5a for explanation of symbols.

| Parameter, assumption or omission | Potential for 'true worst-case' risk to be lower | Explanation | Potential for 'true worst-case' risk to be higher | Explanation |
|---|---|---|---|---|
| Daily food intake | | Data taken from breeding season. | | Data taken from breeding season. |
| Interception factors | | | | Interception factors are based on those used in FOCUS Step 2, which were derived from field measurements and are considered to be realistic worst case for spray reaching ground. Within each growth stage a conservative (early) value is used. |
| Proportion of the population exposed | | The surrogate protection goal relates to a realistic worst case individual, which would be exposed. | | |
| Timing of applications | | Assessment assumes worst-case exposure in all phases of reproduction for same individual, whereas in practice exposure is likely to peak in different phases for different individuals. However, it is likely that at least some individuals will be exposed in most sensitive phase, so not over-conservative for surrogate protection goal. | | The model assumes that every phase of reproduction coincides with spray time, so true worst case cannot be worse. |
| Regurgitation | | Regurgitation unlikely at sublethal doses (1/10 $LD_{50}$) so unlikely to reduce risk in field. | | Should not cause under-estimation of risk if avoid using $LD_{50}$ studies where regurgitation occurred. |
| **Overall** | **These factors are not thought to add significantly to the uncertainties considered in Tables 5a and 5b.** | | | |

**Acute risk to mammals from sprayed pesticides, assessed using TERs**

Three lines of evidence are available for evaluating the level of protection (LoP) of the acute mammalian assessment based on TER (toxicity-exposure-ratio):

- the conservatism of the assessment assumptions;
- the historical record of reported impacts attributed to pesticide use;
- the comparison between calculated TERs and evidence on effects in field studies.

The first two of these lines of evidence are very similar to those for birds (see earlier), so only differences are discussed here.

The first line of evidence is evaluation of the conservatism of the assessment assumptions. The conservatism of the TER calculation for birds is documented in Table 1 above. Only two items differ for mammals:

- Acute $LD_{50}$ scales positively with body weight for birds (average scaling factor about 1.2, small species are more sensitive, Mineau et al., 1996, 2001) but scaling is absent or slightly negative for mammals (scaling factor 0.94, Sample and Arenal, 1999).
- Regurgitation in toxicity tests is less common for mammals than birds. It is therefore not a source of bias in mammalian acute toxicity data, and unlikely to provide significant protection to mammals in the wild.

Therefore, both these factors have little impact on the LoP for mammals, whereas they have minor but opposite effects on the LoP for birds. Taking this into account, the overall assessment of the TER calculation for mammals is the same as for birds (copied from Table 1 above):

- Biases connected with the exposure calculation are relatively small (mostly within a factor of about two) compared to the influence of toxicity, avoidance and metabolism. For pesticides with strong avoidance and rapid metabolism[18], Tier 1 will substantially over-estimate risk. For substances with little or no avoidance and slow metabolism, true risk for a sensitive species could be higher and some mortality could occur above TER = 10.

The second line of evidence, based on the historical record of poisoning incidents, is essentially the same for mammals and birds. The conclusion, copied from Table 3 above, is:

- In those countries that have an organised scheme for investigating and documenting incidents, the frequency of incidents can be regarded as a measure of the frequency of visible mortality. However, the factors evaluated (in Table 3 above) imply that the frequency of incidents could greatly underestimate the frequency of undetected mortality. For individual pesticides, incidents can confirm a high predicted risk, but absence of incidents does not necessarily indicate a low risk.

The third line of evidence is comparison between calculated TERs and evidence on the occurrence of population changes in field studies. This differs substantially from the analysis of field studies for birds, and is therefore evaluated separately here. More details on these data are presented in Appendix 19 of EFSA (2008), which also contains an exploration of other assessment approaches.

[18] No general statement can be made about the degree of avoidance and metabolism required for this, but it could be an option for case-by-case investigation in higher tier assessments.

Fewer studies on effects in the field were available for mammals than birds. Of 23 studies with sprays, eight were unenclosed field studies and 15 were studies in experimental enclosures. They included a total of eight active substances. One substance, azinphos-methyl, was the subject of eight studies at various application rates[19].

All the studies used trapping methods to monitor changes in small mammal populations (nearly all with voles, some including also mice). Consequently the effects measured in these studies are population changes, which could be the result of mortality, reproductive effects, or both. The results are therefore relevant to evaluating the surrogate protection goal of making any mortality or reproductive effects unlikely. They also have some relevance to the actual protection goal, in that they measure changes in abundance.

Due to limitations of time, these studies were evaluated in a simpler way than the bird studies: a single evaluator scored the outcome of each study as positive (1) where the evidence indicated a population response (14 studies), and negative (0) where it did not (9 studies). A population response was defined as reductions in some age or sex cohorts which could indicate mortality, or changes in reproductive rates (e.g. pregnancy rates etc…) indicative of a more targeted effect on the reproductive process. With the selection of compounds represented in the dataset, the majority of effects were of the first type with only a few pesticides (e.g. carbaryl) showing reproductive effects per se.

Figure 5 shows these results plotted against Tier 1 TER for the focal species scenario relevant for each study, calculated with the rat $LD_{50}$.

We first consider the results in Figure 5 in relation to the surrogate protection goal of making any mortality and reproductive effects unlikely. Population effects were seen at TERs between 1 and 10, implying that mortality and/or reproductive effects occurred at this level. The positive studies in this range were all enclosure studies, an effect of which is to restrict the study animals to the treated area (PT = 1)[20]. This is a worst case, but it is a realistic worst case, because radio-tracking studies of free-ranging small mammals in arable crops showed that some individuals stayed within the crop during the whole period they were followed (e.g. EFSA, 2004). Given the limited number of studies and the very limited range of active substances, crops and focal species examined, it is clearly conceivable that other cases might show population effects above TER = 10. This implies that a TER trigger of 10 might not be sufficient to achieve the surrogate protection goal of making any mortality or reproductive effects unlikely. The field data can neither refute nor confirm this, because only one (negative) study had a TER above 10.

The fact that population responses were seen at TERs between 1 and 10, and that they might conceivably occur above TER = 10, might be considered to threaten the actual protection goal of preventing long-term repercussions on abundance and diversity. However, this is subject to several uncertainties. First, as already stated, there is only one study above TER = 10. Second, it is uncertain how long the population responses seen in the studies persisted[21]. Third, the positive studies with TERs between 1 and 10 were all conducted in enclosures: as well as restricting the study animals to the treated area, this prevents losses being replaced by immigration and therefore increases the chance that a measurable decrease in abundance will occur. It is notable that of the eight unenclosed studies, all four that showed population responses had TER < 1, and all four that showed no response had TER > 1. These studies are clearly too few to form firm conclusions, but they do make it conceivable that the TER trigger of 10 might be high enough to meet the actual protection goal of preventing long-term repercussions on abundance and

[19] Five of these studies were positive for population effects; three at lower application rates were negative.
[20] PT = Proportion of an animal's daily diet obtained in habitat treated with pesticide
[21] Also, the Directive and its Annexes do not define what duration would be regarded as 'long term'.

diversity. Again, the very limited range of pesticides, crops and focal species examined makes extrapolation to other cases very uncertain.

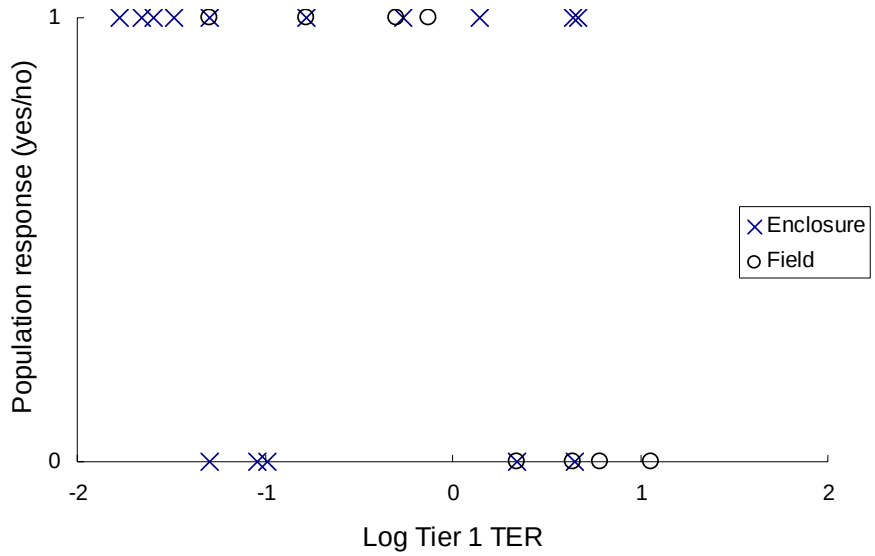



**Figure 5.** Relationship between the occurrence of a population response of small mammals in field studies and the Tier 1 TER for those studies, calculated with rat $LD_{50}$. Each data point represents a single field study, using different symbols for field and enclosure studies.

No field studies were available for larger mammal species. However, it might be expected that a trigger value chosen on the basis of the results for small mammals would also be protective for acute risks to large mammals, considering their larger size (lower relative exposure) and larger home ranges (lower PT).

Uncertainties affecting interpretation of these studies are summarised in Table 6, evaluated in terms of their potential to make the critical TER for achieving the surrogate and actual protection goals higher or lower than the value of 10 specified in Annex VI of Directive 91/414/EEC. Overall it is concluded that the results could be compatible with a critical TER in the region of 10, but that there are very substantial uncertainties due to limited number of species, pesticides and studies, so the 'true' critical value could be significantly higher or lower.

**Table 6.** Evaluation of uncertainties affecting comparison of the first-tier TER assessment of acute mammalian risks with data on population effects in field studies. The aim is to find the critical TER value above which any population response will be unlikely (this is intermediate between the surrogate and actual protection goals). Symbols are used to indicate the extent to which the true critical TER could be lower (-) or higher (+) than 10. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that could increase the critical value by a factor of about10.

| Source of uncertainty | Potential to decrease critical TER | Explanation | Potential to increase critical TER | |
|---|---|---|---|---|
| *Uncertainties affecting the evaluation of the field studies* | | | | |
| Only one study with TER>10 | | | 0 to +++ | Studies provide almost no direct test of whether critical TER could be higher than 10. |
| Effect of enclosures | 0 to - - - | Restrict animals to treated area, but this is realistic worst case for individual free-ranging small mammals. Prevents replacement of losses through immigration, thus exaggerating and prolonging population effects compared to unenclosed populations. | | |
| Matching field studies to TER scenarios | _ | Studied habitats (pasture, alfalfa, millet, clover, forest litter) match loosely to TER scenarios, based on structural similarity. | + | |
| Subjectivity of evaluation and quality of studies | _ | Precise nature and strength of effects varied between studies and were subjectively evaluated and summarised as positive/negative by a single evaluator. Other evaluators might differ. | + | |
| Duration of population responses | 0 to - - - | Uncertain how long the effects seen in the field studies would persist, and what duration risk managers would consider unacceptable. | | |
| *Uncertainties affecting the form of the relationship between TER and field effects and its extrapolation from the available studies to other pesticides and scenarios* | | | | |
| Limited range of pesticides studied | - to - - | Only eight pesticides studied: five OPs, two carbamates and endrin. Other pesticides might have lower critical TER due to different properties e.g. $DT_{50}$, vapour pressure, metabolism. | + to ++ | Only eight pesticides studied: five OPs, two carbamates and endrin. Other pesticides might have higher critical TER due to different properties e.g. $DT_{50}$, vapour pressure, metabolism. |
| Limited range of crops studied | - to - - | Only five 'crops' studied (pasture, alfalfa, millet, clover, forest litter). Possible other crops may have lower critical TER due to e.g. higher interception and differing vegetative structure. | + to ++ | Only five 'crops' studied (pasture, alfalfa, millet, clover, forest litter). Possible other crops may have higher critical TER due to e.g. lower interception and differing vegetative structure. |
| Limited range of species exposed | - to - - | Each study focuses on one to two small mammal species, mostly voles and mice. Other species might have lower critical TER due to e.g. differing diet (see below for toxicity) | + to ++ | Each study focuses on one to two small mammal species, mostly voles and mice. Other species might have higher critical TER due to e.g. differing diet (see below for toxicity) |
| Routes of exposure | | Studies include dietary and non-dietary routes. | | |
| Variation of toxicity between species | _ _ _ | Most studies focussed on one to two species. Other species might be one to two orders of magnitude more or less sensitive to the same pesticides. | +++ | |

| Source of uncertainty | Potential to decrease critical TER | Explanation | Potential to increase critical TER | |
|---|---|---|---|---|
| Variation of toxicity between individuals | | Field studies sufficiently large to include sensitive individuals. | | |
| Uncertainty factor | | Standard uncertainty factor is taken into account by examining evidence for effects above TER=10. | | |
| Avoidance of contaminated food | _ | Most of the studied pesticides are moderately to very toxic and moderately or strongly avoided, although opportunity for avoidance limited in enclosure studies. Less toxic pesticides will have more opportunity for avoidance. | ++ | Risk could be higher for pesticides that are less avoided than those in the field studies, although opportunity for avoidance may be less than birds due to lower mobility (less easy to move to untreated area). |
| **Overall** | **Study results compatible with a critical TER in the region of 10, but substantial uncertainties due to limited number of species, pesticides and studies, so true critical value could be significantly higher or lower.** | | | |

The preceding pages evaluate three separate lines of evidence on the conservatism of the proposed screening and Tier 1 TER assessment procedures for acute risks to mammals from sprayed pesticides. It is important to give appropriate weight to each line of evidence in reaching an overall conclusion. To assist with this, the three lines of evidence are summarised together in Table 7, together with the main uncertainties affecting them.

The pattern of uncertainties affecting the three lines of evidence is markedly different from one another. In addition, it is different from that for birds: in the case of birds, the general magnitude of uncertainties was lower for the assessment based on comparison with field studies, whereas for mammals the much smaller scope of the field studies makes their interpretation much more uncertain. The different degrees of uncertainty affecting the three lines of evidence for mammals are taken into account in reaching overall conclusions.

In summary, it is concluded that the first-tier assessment procedure for acute risks to mammals from sprayed pesticides probably satisfies the protection goal of no visible mortality, but it probably does not achieve the surrogate protection goal of making any mortality unlikely, and it is uncertain whether it achieves the protection goal of no long-term repercussions on abundance and diversity. If it were desired to have a higher certainty of achieving both actual protection goals for all pesticides, then the conservatism of the screening and Tier 1 TER calculations could be increased, by taking a more conservative value for any of the inputs, or by adding an extra factor to the calculation. Determining the level of certainty required involves risk management judgements.

**Table 7.** Comparison of three lines of evidence on conservatism of the first-tier TER assessment of acute risks to mammals for sprayed pesticides. The bottom rows of the table summarise the overall conclusions. The upper part of the table summarises the main uncertainties that have taken into account (see preceding pages for details). Symbols indicate the potential for the 'true' critical TER value for ensuring any mortality is unlikely (surrogate protection goal) to be higher (+) or lower (-) than 10.

| | **Lines of evidence** | | |
|---|---|---|---|
| | **Assessment of TER assumptions** | **Comparison of TERs with evidence from field studies** | **Historical record of poisoning incidents** |
| **Main contributions to uncertainty:** | | | |
| Non-dietary exposure | +/++ | | |
| Variation of toxicity between species | - - - /+++ | - - - /+++ | |
| Variation of toxicity between individuals | +/+++ | | |
| Uncertainty factor | - - - | | |
| Avoidance | - / - - - | - /++ | |
| Effect of metabolism | - - - | (included in next row) | |
| Other properties of some pesticides | ? | - - /++ | |
| Other crops | | - - /++ | |
| Other focal species | | - - /++ | |
| Effect of enclosures | | - - - / 0 | |
| Duration of effects | | - - - / 0 | |
| Lack of studies with TER>10 | | 0 / +++ | |
| Low probability of dead animals being visible | | | +++ |
| Low probability of dead animals being reported, investigated & confirmed | | | +++ |
| Lack of organised schemes for documenting incidents in most countries | | | +++ |
| **Conclusions for individual lines of evidence** | For pesticides with strong avoidance and rapid metabolism, Tier 1 will substantially over-estimate risk. For substances with little or no avoidance and slow metabolism, the true risk for a sensitive species could be higher and some mortality could occur above TER=10. | Study results compatible with a critical TER in the region of 10, but substantial uncertainties due to limited number of species, pesticides and studies, so true critical value could be significantly higher or lower. | The very low frequency of documented incidents suggests a very low frequency of visible mortality, but might greatly underestimate the frequency of undetected mortality. |
| **Overall conclusion regarding likelihood of any mortality above TER=10** | Some undetected mortality may occur when TER>10, especially for pesticides with high toxicity, low avoidance and slow metabolism. | | |
| **Overall conclusion regarding likelihood of visible mortality above TER=10** | Visible mortality is unlikely when TER>10 for pesticides in general. Theoretically it might occur for pesticides with high toxicity, low avoidance and slow metabolism but there is no evidence of this from the incident record. | | |

**Level of protection for assessment of reproductive risks to mammals for sprayed pesticides**

Many of the factors affecting the LoP for reproductive risks to mammals are similar to those for birds (see earlier). However, an important difference is that, in the assessment for mammals, uncertainty about the mode of action and relevant timescale for exposure is reduced because more information on this is available from the toxicology assessment done for human health purposes.

See Table 8 for evaluation and conclusions.

**In this and subsequent sections, LoP evaluation tables are presented with limited discussion text, but the principles of the approach are the same as in preceding examples above.**

**Table 8.** Evaluation of conservatism of the first-tier assessment of mammalian reproductive risks. Each row evaluates a separate input, assumption or omission of the screening and first-tier assessment procedure. + and - are used to indicate the extent to which it is judged that the 'true worst' case for that element could decrease or increase the risk of causing any reproductive effect (the surrogate protection goal). The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that would increase the risk by an amount equivalent to reducing the TER by about a factor of about 10. If the effect varies between pesticides or is uncertain, lower and upper evaluations are given (e.g. + /+++).

| | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Relevance of reproduction toxicity study | -/- - | The ecological relevance of some of the endpoints to the goal of preventing reproductive effects is difficult to determine. This may lead to possible overprotection. | | |
| Screening assessment indicator species and type of food | - | Realistic worst case – relatively small species eating only the most contaminated food type. Real worst case could be lower in some scenarios. | | Realistic worst case – relatively small species eating only the most contaminated food type. Negligible potential to be worse. |
| Tier 1 generic focal species and type of food | | Mixed diet based on average of available data on dietary composition. Worst case cannot be lower than average. | + | Mixed diet based on average of available data on dietary composition. Some individual mammals will eat more than average proportion of most contaminated food on individual days. |
| Body weight (impact on exposure) | - | In some scenarios such small species may not occur. However, this has only a limited impact on risk due to scaling of food intake with body weight. | | For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight. |
| Body weight (impact on toxicity) | | Less effect than for birds. Scaling of toxicity with body weight is close to 1 (0.94, Sample and Arenal, 1999). | | |
| Daily food intake | | | + | According to the raw data for non-marine, non desert, eutherian mammals, 72% of records make no mention of breeding status or season., 22% of records indicate winter or non-breeding status and only 6% make a definite mention of animal in engaged in breeding (e.g. pregnant or lactating). On the basis of this information, it is likely that the daily food intake for an individual during breeding could be greater than used. |
| Percent of diet taken by individual in treated area | - | Likely only a few scenarios where true worst case individual is less than 0.5 (i.e. factor of 2 reduction). | | Absolute worst case, cannot be higher. |
| Residue per unit dose | | Average RUD is used for the reproductive assessment. It is not likely that a true worst case has a lower RUD. | ++ | True distribution for pesticide under assessment could be higher than average RUD used in assessment, so true worst case could be higher than average RUD. |

| | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| | | | | Also, RUD values may underestimate peak concentration on highly-exposed food items. Any underprotection would be more pronounced where long term effects are the result of short-term exposure. |
| Half-life on food ($DT_{50}$) | - - | Default value of 10 days for the various TWA measurements is conservative: most pesticides have $DT_{50}$s below 10. | + | Some pesticides have $DT_{50}$s longer than 10 days (e.g. 19% of pesticides registered in Canada in 2005[22]). Also dissipation in first few days is often faster than implied by assumption of first order kinetics. |
| Interception factors | | Interception factors are based on those used in FOCUS Step 2, which were derived from field measurements and are considered to be conservative for spray reaching ground. Within each growth stage a conservative (early) value is used. | | |
| Non-dietary exposure | | | + /++ | This parameter is ignored, however, the true contribution uncertain, but could, in short term, increase risk by up to two times or more although this is very uncertain as based on bird studies (Driver et al., 1991). |
| Variation of toxicity between species and/or stages within species | - - - | There is very little data on toxicity in mammalian species other than the standard species used for human toxicology. There is in principle no reason to believe variation in sensitivity between tested mammals and wild mammal species will be different to that for birds. | +++ | |
| Variation of toxicity between individuals | | | +/++ | Most sensitive individuals could be more sensitive (most NOAELs used are based on tests of significance between treatment group averages and not individual effects). |
| Uncertainty factor | - - | TER is compared with trigger value of 5. | | |
| Avoidance of contaminated food or of treated area as a whole | 0 to - - | Parameter is ignored, which would be realistic for non-avoided pesticides. Potential effect of avoidance less for sublethal effects which occur at doses closer to avoidance threshold and thus less likely to be prevented. Longer time scales increase potential for learned avoidance, but effects may occur at intakes below avoidance threshold. | | |
| Effect of metabolism | | Effect of metabolism is incorporated in non-acute toxicity studies. | | |
| Proportion of the population exposed | | The surrogate protection goal relates to a realistic worst case individual, which would be exposed. | | |
| Timing of applications | | Assessment assumes worst case exposure in all phases of reproduction for same individual, whereas in practice exposure is | | The model assumes every phase of reproduction coincides with spray time so true worst case cannot be worse. |

[22] Based on data from http://www.wsi.nrcs.usda.gov/products/W2Q/pest/winpst.html.

| | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| | | likely to peak in different phases for different individuals. However, it is likely at least some individuals will be exposed in most sensitive phase, so not over-conservative for surrogate protection goal. | | |
| Recovery from effects | - - -/0 | Affected individuals may be able to recover and successfully reproduce at a later date. | | |
| **Overall** | **There are uncertainties in both directions. Because of the potential for wide variation in toxicity between species, some individuals in sensitive species may experience reproductive effects at TER>5, potentially breaching the surrogate protection goal. The assessment procedure is more likely to fulfil the actual protection goal of preventing long-term repercussions on abundance and diversity, due to variation in exposure between individuals and over space and time, and the potential for replacement through recovery and immigration.** | | | |

**Risk to birds and mammals from granular pesticides**

This section documents judgements regarding the level of protection achieved for the first-tier assessment for the use of granules. It is based on the scenarios used in the TER calculation and applicable for acute risk assessment and reproductive risk assessment.

The evaluation of the assessment assumptions (Tables 9-11) suggests that the calculation of granular exposure might be relatively close to a realistic worst case, but the conservatism of other aspects is much more uncertain. Possibly the largest single source of uncertainty is the extrapolation of toxicity from one or two standard test species to the species exposed in the field, which could be up to two orders of magnitude more or less sensitive (see Figure 1 above). Another important factor affecting the conservatism of the assessment is that within a species, sensitive individuals may be up to ten times more sensitive than the $LD_{50}$, which is used in the TER calculation (see also Figure 2 above). On the other hand, both avoidance and metabolism are ignored in the TER calculation but could greatly reduce the risk for some pesticides. Consequently, the overall conservatism of the Tier 1 TER calculation will vary widely between pesticides. If the focal species happens to be much more sensitive than the standard test species, and if there is little or no avoidance and metabolism, then the true risk could be higher than implied by the Tier 1 assumptions, and some mortality might then occur when the Tier 1 TER of 10 or effects on reproduction could be noticed when using the Tier 1 TER of 5. For pesticides with strong avoidance and metabolism, Tier 1 will substantially over-estimate risk.

**Table 9.** Conservatism for granules ingestion by birds seeking grit (see for explanation legend of Table 1 above).

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Number of grit taken by a bird per day | | | | |
| • Acute risk assessment | * | 90%-ile of distribution taken, for the specific generic focal species the actual worst case value may be lower | * | 90%-ile value taken, actual worst case for an individual bird may be higher |
| • Reproductive risk assessment | | | ** | Geometric mean of distribution, the actual worst case for an individual may be significantly higher especially in case of reproductive effects after short term exposure |
| Turn over rate in gizzards | ** | Distribution of true values unknown, default value is from a single study | ** | Distribution of true values unknown, default value is from a single study |
| Number of soil particles | | | ** | Default value is mean of 3 Dutch soils, the actual risk in peat soils may be higher due to the absence of natural grit sources |
| Density of granules at soil surface | * | Average density of granules (actual density may be lower) | * | Average density of granules (actual density may be higher) |
| Loading of granules | | | * | Nominal value taken, actual loading may be slightly higher |
| PT | * | Default PT is 1, actual value may be lower | | |
| Half-life of active substance | | Reported value from non-standard study, variability of such values are unknown | | Reported value from non-standard study, variability of such values are unknown |
| Half-life of granules | | Reported value from non-standard study, variability of such values are unknown | | Reported value from non-standard study, variability of such values are unknown |
| Toxicity parameters, metabolism, uncertainty factor | | see Table 1 above | | |

**Table 10.** Conservatism for granules ingestion by birds seeking seeds as food (see for explanation legend of Table 1 above)

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Daily energy expenditure, Food energy, Moisture content and Assimilation efficiency | | see Table 1 above | | |
| Density of granules at soil surface, loading of granules and PT | | see table 9 above | | |
| Number of available seeds at soil surface (seed bank) | | ?? | upper limit of known range (not conservative) | ?? |
| Choice of generic focal Species (influence on exposure) | * | Relatively small worst case species as default, actual focal species may be larger | | |
| Half-life of active substance and granules | | see table 9 above | | |
| Non-dietary exposure | | . | * | Ignored. True contribution probably small |
| Toxicity parameters, metabolism, uncertainty factor | | see Table 1 above | | |

**Table 11.** Conservatism granules ingestion by birds and mammals as part of the soil ingested with food (see for explanation legend of Table 1 above).

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Daily energy expenditure, Food energy, Moisture content and Assimilation efficiency | | see Table 1 above | | |
| Body weight | | Average body weight value for a small bird or mammals chosen as default. Actual focal species may be larger | | Average body weight value for a small bird or mammals chosen as default. Individual at risk may be smaller |
| PT | * | Default PT is 1, actual value may be lower | | |
| Concentration of a.s. in soil | | | | |
| • Acute risk assessment | ** | Active substance assumed to be homogenously mixed over layer of 1cm. Since granule application normally requires working the soil at or after treatment the actual mixing depth of the substance may be larger | * | Active substance assumed to be homogenously mixed over layer of 1cm. Acute exposure may be in a 'hot-spot' of the field where the actual concentration is somewhat higher |
| • Reproductive risk assessment | * | Active substance assumed to be homogenously mixed over layer of 5cm. Since granule application normally requires working the soil at or after treatment the actual mixing depth of the substance may be larger | * | Active substance assumed to be homogenously mixed over layer of 5cm.Where repro effects are due to short-term exposure the actual concentration in a 'hot-spot' in the field may be somewhat higher |
| Bulk density of soil | | Assumed to be 1.5 kg/l, but actual densities in agricultural soil may vary 1.2-1.8 kg/l | | Assumed to be 1.5 kg/l, but actual densities in agricultural soil may vary 1.2-1.8 kg/l |
| Half-life in soil | * | Average reported value used, but actual value in a particular soil-type may differ by factor 2 | ** | Average reported value used, but actual worst-case value in a particular soil-type may differ by factor 3 |
| Type of food | | | * | Mixed diet (not worst case type of food) |
| Daily dry soil intake | | | | |
| • Acute risk assessment | | | * | 90$^{th}$ percentile value of available information taken, but because data-base is relatively small, actual worst-case may be higher |

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| • Reproductive risk assessment | | | ** | Geometric mean value of available information taken, but because data-base is relatively small, actual worst-case may be higher, especially where reproductive effects are caused by short-term exposure |
| Non-dietary exposure | | . | * | Ignored. True contribution probably small |
| Toxicity parameters, metabolism, regurgitation, avoidance and uncertainty factor | | see Table 1 above | | |

**Risk to birds and mammals from bioaccumulating pesticides**

This section documents judgements regarding the level of protection achieved for the first-tier assessment for pesticides that could be accumulating through the food chain (e.g. soil – earthworm – earthworm eating birds and mammals and water – fish – fish eating birds and mammals). It is based on the scenarios used in the TER calculation and applicable reproductive risk assessment.

The evaluation of the assessment assumptions (Table 12) suggests that the calculation of bioaccumulative potential via the earthworm route might be relatively close to a realistic worst case (e.g. the choice of a relative small indicator species, the assumption that the species will spend 100 % of its time in the treated area, and by using the highest expected concentration in the season), but the conservatism of other aspects is much more uncertain. Possibly the largest single source of uncertainty is the extrapolation of toxicity from 1 or 2 standard test species to the species exposed in the field and that sensitive individuals may be up to ten times more sensitive than the $LD_{50}$, which is used in the TER calculation (see Figure 2 above). On the other hand, metabolic clearance is ignored in the TER calculation but could greatly reduce the risk for some pesticides. Avoidance and regurgitation is believed not to play a role in this particular part of the risk assessment. Consequently, the overall conservatism of the Tier 1 TER calculation will vary widely between pesticides. If the focal species happens to be much more sensitive than the standard test species, and if there is little metabolism, then the true risk could be higher than implied by the Tier 1 assumptions, and some effects on reproduction could be noticed when using the Tier 1 TER of 5. For pesticides that are quickly cleared, Tier 1 will substantially over-estimate risk.

The evaluation of the assessment assumptions (Table 13) suggests that the calculation of bioaccumulative potential via the fish route might be relatively close to a realistic worst case (e.g. the assumption that the species will spend 100 % of its time in the treated area, by using the highest expected concentration in the season and the assumption that the indicator species will be present in the relative small water body), but the conservatism of other aspects is much more uncertain (see for analysis of toxicity above). Metabolic clearance of the compound is ignored in the TER calculation but could greatly reduce the risk for some pesticides (and presumably if activating the compound could increase it for others?). Avoidance and regurgitation is believed not to play a role in this particular part of the risk assessment. Consequently, the overall conservatism of the Tier 1 TER calculation will vary widely between pesticides. If the focal species happens to be much more sensitive than the standard test species, and if there is little metabolism, then the true risk could be higher than implied by the Tier 1 assumptions, and some effects on reproduction could be noticed when using the Tier 1 TER of 5. For pesticides that are quickly cleared, Tier 1 will substantially over-estimate risk.

**Table 12.** Evaluation of conservatism of the first-tier risk assessment of potentially bioaccumulating compounds for earthworm eating birds and mammals. Each row evaluates a separate input, assumption or omission of the first-tier assessment procedure. – and + signs are used to indicate the extent to which it is judged that the 'true worst' case for that element could decrease or increase the risk of causing any reproductive effect. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that would reduce or increase the risk by an amount equivalent to reducing the TER by about a factor of about 10, ++ by a factor of about 5 and + by a factor of about 2. If the effect varies between pesticides or is uncertain, lower and upper evaluations are given (e.g. + /+++).

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Relevance of reproduction toxicity study | | Not all critical phases of avian reproduction are adequately covered by existing protocol. | +++ | Not all critical phases of avian reproduction are adequately covered by existing protocol. Alticial species especially may differ – e.g. parental care much more important. |
| Relevance of 1/10 $LD_{50}$ as proxy for chick toxicity | -- | True 'lethal incapacitation' of chicks may occur at lower level than 1/10 $LD_{50}$ based on adult signs of intoxication. | ++ | True 'lethal incapacitation' of chicks may occur at higher level than 1/10 $LD_{50}$ based on adult signs of intoxication. |
| Body weight (impact on exposure) | | | | For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight. |
| Body weight (impact on toxicity) | | Relatively few exposed species are larger than species used in toxicity tests. | + (for birds only) | Focal species tend to be smaller than species used in toxicity tests. General trend for smaller species to be more sensitive (Mineau et al., 1996) is not taken into account in assessment. |
| Daily energy expenditure DEE | - | Average, but from demanding period (e.g. breeding season). True worst case unlikely to be more than two times more or less than assumed value. | + | Average, but from demanding period (e.g. breeding season). True worst case unlikely to be more than two times more or less than assumed value. |
| Food energy FE | - | Average value. Best case unlikely to exceed two times. | + | Average value. Worst case unlikely to exceed two times. |
| Moisture content MC | - | Average value. Best case unlikely to exceed two times. | + | Average value. Worst case unlikely to exceed two times. |
| Assimilation efficiency AE | - | Average value. Best case unlikely to exceed two times. | + | Average value. Worst case unlikely to exceed two times. |
| Percent of diet taken by individual in treated area | - (for birds) | 100%; for birds probably less than 100% (a reduction of a factor of 2 is possible), the home range of the small mammals could be rather small and therefore believed to fall sometimes completely in the treated area. | | For each dietary guild a relatively small species has been chosen (reasonable worst case). Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight. |
| Concentration in soil | -/-- | Period with highest concentration in the season (worst case) rather thin layer of soil | | |

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Half-life in soil | -- | Average (range between lowest and highest values two orders of magnitude) | ++ | Average (range between lowest and highest values two orders of magnitude) |
| Bulk density of soil | - | Average (range between lowest and highest values one order of magnitude) | + | |
| Partitioning coefficient octanol water | - | Average (range between lowest and highest values one order of magnitude) | + | |
| Organic carbon content | - | Average (range between lowest and highest values one order of magnitude) | + | |
| Organic carbon adsorption coefficient | - | Average (range between lowest and highest values one order of magnitude) | + | |
| Bioconcentration factor (BCF) | -/-- | The BCF is normally calculated by using a QSAR (a real BCF study is seldomly carried out. The 'true' BCF could be lower than the estimated factor and therefore the risk could be lower (No information available for the expected range)) | +/++ | The BCF is normally calculated by using a QSAR (a real BCF study is seldomly carried out. The 'true' BCF could be lower or higher than the estimated factor and therefore the risk could different (No information available for the expected range)) |
| Non-dietary exposure | | Ignored. True contribution uncertain, but could, in short term, increase risk by up to two times or more (Driver et al., 1991). | ++ | Ignored. True contribution uncertain, but could, in short term, increase risk by up to two times or more (Driver et al., 1991). |
| Variation of toxicity between species and/or stages within species | --- | Focal species could be up to 2 orders of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (York workshop) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity. | +++ | Focal species could be up to 2 orders of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (York workshop) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity. |
| Variation of toxicity between individuals | | A logical extension of the above comment would suggest that this holds true for intra-specific variance as well. | +/+++ | Most sensitive individuals could be two to ten times more sensitive than $LD_{50}$. |
| Uncertainty factor | -- | TER is compared with trigger value of 5. | | |
| Avoidance of contaminated food or of treated area as a whole | -/--- | Ignored. True contribution varies between pesticides and species. Could be negligible, or could prevent reproductive effects for most sensitive species. Likely to be most important in case of short term exposure leading to long term effects; likely less important where long term exposure required to cause effect. | | |
| Effect of metabolism | -/--- | Ignored. True contribution varies between pesticides and species. Could be negligible or very substantial for both short and long term exposure. | | |

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Regurgitation | - | Should not cause under-estimation of risk if avoid using $LD_{50}$ studies where regurgitation occurred. May partially reduce the estimate of chick toxicity (1/10 $LD_{50}$). | | |
| Proportion of the population exposed | -- | The compound may only be used on a small area and hence only a small proportion of the population exposed. Similarly the proportion of birds co-existing with the crop at time of treatment may be small. | | It is assumed all birds are similarly exposed |
| Timing of applications | --- | The breeding phases of birds may not overlap directly with application of the pesticides. | | The model assumes every breeding phase coincides with spray time |
| **Overall** | **Biases connected with the exposure calculation are potentially large where overlap between application and breeding stages is minimal, The influence of toxicity, avoidance and metabolism is still potentially large. For pesticides with strong avoidance and rapid metabolism[23], Tier 1 will substantially over-estimate risk. For substances with little or no avoidance and slow metabolism, or with effects not currently covered by the reproduction study, true risk for a sensitive species could be higher and some reproductive effects could occur above TER=5.** | | | |

[23] No general statement can be made about the degree of avoidance and metabolism required for this, but it could be an option for case-by-case investigation in higher tier assessments.

**Table 13.** Evaluation of conservatism of the first-tier risk assessment of potentially bioaccumulating compounds for fish-eating birds and mammals. Each row evaluates a separate input, assumption or omission of the first-tier assessment procedure. – and + signs are used to indicate the extent to which it is judged that the 'true worst' case for that element could decrease or increase the risk of causing any reproductive effect. The number of symbols provides a subjective evaluation of the approximate magnitude of the effect, e.g. +++ indicates a factor that would reduce or increase the risk by an amount equivalent to reducing the TER by about a factor of about 10, ++ by a factor of 5 and + by a factor of 2. If the effect varies between pesticides or is uncertain, lower and upper evaluations are given (e.g. +/+++).

| **Parameter, assumption or omission** | **Potential for 'true worst case' risk to be lower** | **Explanation** | **Potential for 'true worst case' risk to be higher** | **Explanation** |
|---|---|---|---|---|
| Relevance of reproduction toxicity study | | Not all critical phases of avian reproduction are adequately covered by existing protocol. | +++ | Not all critical phases of avian reproduction are adequately covered by existing protocol. Alticial species especially may differ – e.g. parental care much more important. |
| Relevance of 1/10 $LD_{50}$ as proxy for chick toxicity | -- | True 'lethal incapacitation' of chicks may occur at lower level than 1/10 $LD_{50}$ based on adult signs of intoxication. | ++ | True 'lethal incapacitation' of chicks may occur at higher level than 1/10 $LD_{50}$ based on adult signs of intoxication. |
| Body weight of focal mammalian species in the Tier 1 assessment | | Realistic case – The otter serves as the model species in the mammalian scenario. Sometimes smaller mammals do eat fish like the Pyrenean Desman (***Galemys*** *pyrenaicus*) but are not considered as relevant in the risk assessment for pesticides. | | Sometimes smaller mammals do eat fish like the Pyrenean Desman (***Galemys*** *pyrenaicus*) but are not considered as relevant in the risk assessment for pesticides. |
| Body weight of focal mammalian species in the Tier 1 assessment | | The cormorant serves as the model species in the avian scenario. | + | There are smaller avian species that are sometimes eating fish (and sometimes only fish, particular in the winter period) like the Little Grebe (*Tachybaptus ruficollis*). Because of the higher daily energy expenditure of this species the 'true risk' could be higher (at the most a factor of 2) |
| Body weight (impact on toxicity) | - (only for birds) | Focal species tend to be larger than species used in toxicity tests. General trend for larger species to be less sensitive (Mineau et al., 1996) is not taken into account in assessment | | |
| Body weight (impact on exposure) | | | | Within the species some individuals are smaller but this has limited impact on exposure due to scaling of food intake with body weight. |
| Daily energy expenditure DEE | - | Average, but from demanding period (e.g. breeding season). True worst case unlikely to be more than two times more or less than assumed value. | + | Average, but from demanding period (e.g. breeding season). True worst case unlikely to be more than two times more or less than assumed value. |
| Food energy FE | - | Average value. Worst case unlikely to exceed two times. | + | Average value. Worst case unlikely to exceed two times. |
| Moisture content MC | - | Average value. Worst case unlikely to exceed two times. | + | Average value. Worst case unlikely to exceed two times. |
| Assimilation efficiency AE | - | Average value. Worst case unlikely to exceed two times. | + | Average value. Worst case unlikely to exceed two times. |

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Percent of diet taken by individual in treated area | -- | 100% very probably less of the diet is taken from the treated ditch, fish eating species normally can be found in larger water body than the ditch that is used in the scenario | | |
| Concentration in water | -- | Period with the highest concentration in the season (which is based on an overall 90$^{th}$ percentile drift value. Fish eating species are normally found in larger water bodies and therefore will be exposed to lower concentrations than assumed in the scenario. | + | Period with highest concentration in the season based on the 90$^{th}$ percentile drift values, in 10 percent of the case higher values can be expacted in the surface water |
| Half-life in water | - | Average (one order of magnitude between lowest and highest values) | + | Average (one order of magnitude between lowest and highest values) |
| Dimensions of water body | -- | Relative small (water body of target species is probably much larger) | | |
| Bioconcentration factor | - | Average (normally only one study available, one order of magnitude between lowest and highest values) | + | Average (normally only one study available, one order of magnitude between lowest and highest values) |
| Non-dietary exposure | | Ignored. True contribution uncertain, but could, in short term, increase risk by up to two times or more (Driver et al., 1991). | ++ | Ignored. True contribution uncertain, but could, in short term, increase risk by up to two times or more (Driver et al. ,1991). |
| Variation of toxicity between species and/or stages within species | +++ | Focal species could be up to 2 orders of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (York workshop) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity. | +++ | Focal species could be up to 2 orders of magnitude more or less sensitive than standard species. If there are several species with similar ecology the chance that one is sensitive increases. Recent expert opinion (York workshop) concluded that variation in acute toxicity should be used as estimate of variation in reproductive toxicity. |
| Variation of toxicity between individuals | | A logical extension of the above comment would suggest that this holds true for intra-specific variance as well. | +/+++ | Most sensitive individuals could be two to ten times (i.e. * to ***) more sensitive than $LD_{50}$. |
| Uncertainty factor | ++ | TER is compared with trigger value of 5. | | |
| Avoidance of contaminated food or of treated area as a whole | +/+++ | Ignored. True contribution varies between pesticides and species. Could be negligible, or could prevent reproductive effects for most sensitive species. Likely to be most important in case of short term exposure leading to long term effects; likely less important where long term exposure required to cause effect. Unknown whether it plays a role at all for fish eating birds and mammals (no information available). | | |
| Effect of metabolism | +/+++ | Ignored. True contribution varies between pesticides and species. Could be negligible or very substantial for both short and long term exposure. | | |
| Regurgitation | + | Should not cause under-estimation of risk if avoid using $LD_{50}$ studies where regurgitation occurred. May partially reduce the estimate of chick toxicity (1/10 $LD_{50}$). | | |

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Proportion of the population exposed | -- | The compound may only be used on a small area and hence only a small proportion of the population exposed. Similarly the proportion of birds co-existing with the crop at time of treatment may be small. | | It is assumed all birds are similarly exposed |
| Timing of applications | --- | The breeding phases of birds may not overlap directly with application of the pesticides. | | The model assumes each phase coincides with spray time |
| **Overall** | **Biases connected with the exposure calculation are potentially large where overlap between application and breeding stages is minimal, The influence of toxicity, avoidance and metabolism is still potentially large. For pesticides with strong avoidance and rapid metabolism[24], Tier 1 will substantially over-estimate risk. For substances with little or no avoidance and slow metabolism, or with effects not currently covered by the reproduction study, true risk for a sensitive species could be higher and some reproductive effects could occur above TER=5.** | | | |

[24] No general statement can be made about the degree of avoidance and metabolism required for this, and whether avoidance plays an important role, but it could be an option for case-by-case investigation in higher tier assessments.

### Acute risk to birds and mammals from treated seeds at Tier 1

The level of protection provided by the Tier 1 assessment procedure for acute risks to birds and mammals from treated seeds is evaluated in Table 14.

**Table 14.** Evaluation of the level of protection provided by the Tier 1 assessment procedure for acute risks to birds and mammals from treated seeds. See earlier tables for key to symbols.

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Choice of species (effect on exposure) | - | Relatively small species chosen as default. Actual focal species may be larger | ++ | Relatively small species chosen as default, except for large seeds (maize, peas and beans) that are not assumed to be consumed by small birds. Data from Prosser (1999) show that even when small birds do not readily feed on large seeds, individual cases may occur. |
| PT | | Default PT is 1, which is ok as a worst-case estimate for the individual | | |
| Diet | - | Assumed to be 100% treated seeds. Actual worst-case focal species a mixed diet | | |
| Availability of untreated seeds | - | Diet at Tier 1 assumed to consist of 100% treated seeds, Actual feeding even for of the worst-case individual may be a mix of treated seeds and other non-treated seeds from the natural seed-bank | | |
| Loading rate on seed | | Nominal loading rate cannot be higher than worst case | + | Nominal value taken, actual loading may be slightly higher |
| Dissipation and degradation of active of seeds | - | Assessment assumes bird/mammal to feed on freshly drilled seeds | | |
| Mammals feeding on Pelleted seeds | | | ++ | Not considered a relevant scenario. Even if individual mammals may do so occasionally, they will probably 'crack' the pill before feeding on the seed and hence avoid exposure to a significant extent |
| Birds feeding on pelleted seeds | | Scenario includes as equivalent to grit uptake | | Scenario includes as equivalent to grit uptake |
| Herbivorous birds and mammals feeding on seedlings | - | Dilution factor between active ingredient present in the seed to active ingredient in the seedling is conservatively set at five (NAR/5) based on water content difference between seeds and seedlings. Actual information on concentration in seedlings is largely unknown<br>The scenario assumes that when birds/mammal feed on seedlings they always consume the left-over of the seeds with it. This may be an overestimate | + | Dilution factor between active ingredient present in the seed to active ingredient in the seedling is conservatively set at five (NAR/5) based on water content difference between seeds and seedlings. Actual information on concentration in seedlings is largely unknown |
| Dehusking | -/- - | No de-husking assumed at Tier 1 | | |
| Avoidance | -/- - - | Ignored, true contributions varies between species and pesticides. Could be negligible or could prevent mortality even for the most sensitive species | | |

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Variation of toxicity between species | - - - | Focal species could be up to 2 orders of magnitude less sensitive than standard species. | +++ | Focal species could be up to 2 orders of magnitude more sensitive than standard species. |
| Variation of toxicity between individuals | | | +/+++ | Most sensitive individuals could be two to ten times more sensitive than reported $LD_{50}$. |
| Uncertainty factor | - - - | TER is compared with trigger value of 10. | | |
| **Overall** | **Although conservative, the scheme appropriately represents the risk to the worst case individuals, therefore it may often be necessary to refine the assessment in order to assess the product against the ultimate protection goals of visible mortality and long term repercussions for abundance and diversity** | | | |

**Risk to birds and mammals from contaminated drinking water**

This section documents judgements how the level of protection is affected by the assumptions made for assessing the risk for birds and mammals due to uptake of contaminated drinking water. Generic issues on toxicity parameters and uncertainty factors are documented in Table 1 above.

As regards the expected concentrations of active substances in drinking water, the evaluation of the assessment assumptions (Table 15) suggests that these are likely to reflect a worst case. In particular, the settings of the proposed leaf scenario (pools in whorls) are fully based on observed incidents and values measured at the incident sites. The proposed puddle scenario makes use of equivalent assumptions as employed in $FOCUS_{SW}$ for estimation of runoff to surface water bodies. Higher $PEC_{puddle}$ values would result for soils with a lower content of organic carbon; however, it is deemed less likely that longer-lasting puddles will be formed on such soils to a significant extent.

On the level of individuals, no combined exposure to residues in food and drinking water is currently considered. This is due to the incidental nature of occurrence of drinking water reservoirs on agricultural fields (as compared to the contamination of food items growing or dwelling on those fields). Combined exposure may occur for granivorous animals in case of toxic seed treatments, but there, the contribution of drinking water to the overall risk (according to the relevant puddle scenario) is probably low. For herbivorous and insectivorous animals, the calculated drinking water rates (DWR) are negative as long as the food uptake rates are based on the current DEE estimates (see Appendix L). Hence, the dietary risk assessment will most probably also cover a theoretical risk from drinking water uptake, due to typically higher residues in the food items.

**Table 15.** Evaluation of conservatism of the first-tier assessment of risk for birds and mammals due to uptake of contaminated drinking water

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Parameters for scenario A | | | | |
| Concentration in spray solution | | Fixed value, adjusted by spray operator, no distribution | | Fixed value, adjusted by spray operator, no distribution |
| Dilution factor | * | Relative worst case (set to five), minimum dilution found in measured data from incident sites | | Relation to spray solution concentrations does not necessarily reflect true driving forces for concentrations in leaf whorl pools. However, formation of such pools requires significantly higher water volumes than those used in standard spray applications (200-400 L water/ha). Pool formation without additional irrigation/precipitation may occur with high-volume sprays (≥ 1000-1500 L water/ha) |
| Parameters for scenario B | | | | |
| Pore water term (reflects pore water volume at run-off) | | Soil field capacity 0.4 $m^3/m^3$ – typical value for soil with high clay content.<br>50 % field capacity soil water content before precipitation reflects relative worst case.<br>10 mm precipitation is considered the minimum amount for causing run-off.<br>Effect of each single parameter on $PEC_{puddle}$ remains < 10 % | | Soil field capacity 0.4 $m^3/m^3$ – sandy soils may have lower field capacity, but this results in lower likelihood of puddle formation<br>Effect of each single parameter on $PEC_{puddle}$ remains < 10 % |
| Soil term (reflects soil density and sorptive capacity) | * | Bulk soil density 1.5 kg/L – standard assumption for $PEC_{soil}$ calculation<br>2 % organic carbon content represents a typical value for agricultural soils, actual values may be as high as 4-6 % (higher adsorption)<br>Effect of each single parameter unlikely to result in a factor > 3 for $PEC_{puddle}$ | * | Bulk soil density 1.5 kg/L – standard assumption for $PEC_{soil}$ calculation – actual values may range from 1.2 to 1.8<br>2 % organic carbon content represents a typical value for agricultural soils, actual values may be as low as 0.5 % (lower adsorption)<br>Effect of each single parameter unlikely to result in a factor > 3 for $PEC_{puddle}$ |
| Adsorption coefficient ($K_{OC}$) | ** | Using of average value is proposed, relevant concentrations in puddles only expected for compounds with $K_{OC}$ < 500, actual values may be higher by 1 order of magnitude (interactions with soil clay content or due to electrostatic forces may result in higher variance of measured adsorption coefficients, however, this would typically weaken correlation to OC content of soil) | ** | for compounds with $K_{OC}$ < 500, actual values may be lower by 1 order of magnitude (interactions with soil clay content or due to electrostatic forces may result in higher variance of measured adsorption coefficients, however, this would typically weaken correlation to OC content of soil) |

| Parameter, assumption or omission | Potential for 'true worst case' risk to be lower | Explanation | Potential for 'true worst case' risk to be higher | Explanation |
|---|---|---|---|---|
| Indicator species (impact on water intake) | * | Granivorous species represent worst case guild with highest additional water demand, other feeding guilds will satisfy higher fraction of water demand via food intake | | |
| Drinking water rate | | | * | Average, no reliable information available on dependency of water demand from typical environmental conditions. |
| Combined exposure to residues in food and drinking water | | | ** | Not considered, due to incidental nature of puddle formation |
| Toxicity parameters, metabolism, uncertainty factor – | | see table for dietary exposure assessment | | |

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[26] Available at: http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Research_PN0907.pdf

# APPENDIX D

## PROPORTIONS OF LIST 3A SUBSTANCES FAILING UNDER CURRENT AND PROPOSED LOWER TIER PROCEDURES FOR ACUTE AND REPRODUCTIVE RISK ASSESSMENTS

Surveys and consultations identified the number of substances failing Tier 1 as an issue of concern to Member States and stakeholders, and the failure rate may be a legitimate consideration for policy-makers. Therefore, the proportions of assessments that would fail for List 3a substances[1] (listed in Table 1) were determined for both the acute and reproductive risks to birds and mammals. Note that, in this Appendix, "fail" refers only to the outcome of the first tier assessment, i.e. it refers to uses or substances that would require a higher tier assessment.

Only field spray uses were considered. Greenhouse and indoor uses, granular formulations and seed treatments were excluded. In addition, toxicity data were not available for a few substances.

Toxicity data and key uses were extracted for each substance from their respective EU Endpoint Lists and Draft Assessment Reports (DAR), and used to assign relevant scenarios for the assessments. The proposed assessment procedures were applied as described in the Guidance Document. For comparison, assessments were also carried out according to the previous guidance document (EC, 2002). For the previous procedure, the lowest $LD_{50}$s listed in the EU endpoint list were used. For the new procedures the geometric mean is used;[2] for birds, this was based on all the tested species found in the DAR (excluding any that were identified as unsuitable for use). The geometric mean approach was not used for reproductive toxicity. Due to lack of time it was not possible to search the DAR for all mammalian $LD_{50}$s, so only those listed in the EU Endpoint List were considered. Similarly, it was not practical to access the original studies for each endpoint so it was not possible to apply the new procedure for extrapolating avian $LD_{50}$s beyond limit doses (as provided for in section 2.1.2 of the new Guidance Document). This means that the results shown below might overestimate the proportion of substances that would fail under the new procedures, although probably not by a large degree. Also due to limited time, it was not possible to consider the selection of focal species in the same detail as would be done in a full regulatory assessment. Where the selection was doubtful (e.g. due to uncertainty about the precise growth stages where the pesticide is used), the more conservative option was taken, as might be done in a regulatory assessment.

The new reproductive assessment, at both screening and Tier 1 levels, require consideration of whether reproductive effects could be caused by short-term exposures. It is intended to develop further guidance on criteria for this issue. The Joint Working Group of the Commission, Member States and EFSA decided that, until such guidance is available, it should be assumed as a default that the effects are caused

[1] Substances for which authorisation under Directive 91/414/EEC was reviewed in 'List 3a'.
[2] In no case did the most sensitive species have an $LD_{50}$ more than a factor of 10 below the geometric mean.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix D. EFSA Journal 2009; 7(12):1438. [4 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

by long-term exposure (LTE), unless there is specific evidence for the pesticide under assessment that the effect could be caused by short-term exposure (STE). In the assessments for this Appendix, it was not practical to consider in detail the evidence on causation of reproductive effects, so the assessments were done twice, once assuming effects are caused by short-term exposures (STE) and once assuming effects are caused by long-term exposure (LTE). STE assessments use a time-weighted average (TWA) factor of 1, whereas LTE assessments use a TWA factor of 0.53 (see sections 4.3 and 4.4 of Guidance Document).

The results are summarised in Tables 2-5. The grey cells show the proportions of uses that "fail", i.e. give toxicity-exposure ratios (TERs) above the trigger values of 10 and 5, for acute and reproductive assessment respectively. Results are also shown for other TER values, to show how sensitive the outcome would be to a change in the trigger value or to changes or refinements in the TER calculations.

**The principal findings** are that the "failure" rates under the new Tier 1 procedures are 7% for birds and 14% for mammals for acute assessments, 35% for birds and 68% for mammals for reproductive assessments (with the default assumption that reproductive effects are caused by long term exposure). The corresponding failure rates under the previous guidance are 15% for birds and 12% for mammals for acute assessments, 63% and 59% respectively for reproductive assessments. The higher failure rates for the new mammal assessments are largely associated with the exposure scenario involving voles.

Failure rates in the future may vary depending on the profile of the substances involved. The List 3a substances (listed in Table 1) were chosen for these assessments because it was considered that they are more likely to reflect the profile of future substances than earlier Lists, which contained a higher proportion of acutely toxic substances. The proportion of List 3a substances with acute endpoints of 2000 mg/kg bw or higher was 64% for birds and 50% for mammals.

**Table 1.** List 3a substances considered for the assessments in this Appendix.

| | | | |
|---|---|---|---|
| Abamectin | Clomazone | Fenpyroximate | Pencycuron |
| Acetochlor | Copper compounds | Fluazifop-P | Propaquizafop |
| Amidosulfuron | Cyanamide | Fluazinam | Prosulfocarb |
| Benfluralin | Cycloxydim | Fludioxonil | Pyriproxyfen |
| Bifenox | Dicloran | Fluometuron | Quinoclamine |
| Bifenthrin | Diflubenzuron | Fluquinconazole | Tebufenozide |
| Bitertanol | Diflufenican | Flutolanil | Tetraconazole |
| Bromuconazole | Dimethipin | Fuberidazole | Thiobencarb |
| Buprofezin | Dithianon | Hexythiazox | Tralkoxydim |
| Butralin | Epoxiconazole | Imidacloprid | Triadimenol |
| Carbetamide | Etofenprox | Mepiquat | Triflumizole |
| Chloridazon | Fenazaquin | Metaldehyde | Triflumuron |
| Chloropicrin | Fenbuconazole | Metazachlor | Zeta-cypermethrin |
| Chlorthal-dimethyl | Fenoxaprop-P | Myclobutanil | |
| Clethodim | Fenpropidin | Napropamide | |
| Clofentezine | Fenpropimorph | Nicosulfuron | |

**Table 2.** Acute risk to birds: the proportion of 170 key uses of 55 List 3a substances with acute TERs below different levels. The grey shaded cells show the percentage of uses with TERs below the trigger value of 10, i.e. the failure rate.

| **BIRDS** | % List 3a uses below each level of TER | | |
|---|---|---|---|
| **Acute TER** | Previous procedure (EC, 2002) | New screening procedure | New Tier 1 procedure |
| 0.01 | 0% | 0% | 0% |
| 0.03 | 0% | 0% | 0% |
| 0.1 | 0% | 0% | 0% |
| 0.3 | 0% | 1% | 0% |
| 1 | 2% | 4% | 1% |
| 3 | 4% | 7% | 4% |
| 5 | 8% | 12% | 4% |
| **10** | **15%** | **24%** | **7%** |
| 30 | 28% | 42% | 18% |

**Table 3.** Acute risk to mammals: the proportion of 171 key uses of 55 List 3a substances with acute TERs below different levels. The grey shaded cells show the percentage of uses with TERs below the trigger value of 10, i.e. the failure rate.

| **MAMMALS** | % List 3a uses below each level of TER | | |
|---|---|---|---|
| **Acute TER** | Previous procedure (EC, 2002) | New screening procedure | New Tier 1 procedure |
| 0.01 | 0% | 0% | 0% |
| 0.03 | 0% | 0% | 0% |
| 0.1 | 1% | 1% | 0% |
| 0.3 | 1% | 1% | 1% |
| 1 | 4% | 5% | 5% |
| 3 | 7% | 9% | 7% |
| 5 | 8% | 16% | 10% |
| **10** | **12%** | **24%** | **14%** |
| 30 | 26% | 46% | 26% |

**Table 4.** Reproductive risk to birds: the proportion of 170 key uses of 55 List 3a substances with reproductive TERs below different levels. The grey shaded cells show the percentage of uses with TERs below the trigger value of 5, i.e. the failure rate. The new assessments with TWA=0.53 assume effects are caused by long-term exposure (the default), while those with TWA=1 assume effects are caused by short-term exposure (see text).

| **BIRDS** | % List 3a uses below each level of TER | | | | |
|---|---|---|---|---|---|
| **Reproductive TER** | Previous procedure (EC, 2002) | New screening procedure with TWA=0.53 | New Tier 1 procedure with TWA=0.53 | New screening procedure with TWA=1 | New Tier 1 procedure with TWA=1 |
| 0.01 | 0% | 0% | 0% | 1% | 0% |
| 0.03 | 1% | 1% | 0% | 3% | 1% |
| 0.1 | 5% | 5% | 2% | 9% | 4% |
| 0.3 | 12% | 12% | 6% | 22% | 6% |
| 1 | 27% | 29% | 13% | 44% | 24% |
| 3 | 50% | 54% | 29% | 65% | 38% |
| **5** | **63%** | **64%** | **35%** | **75%** | **46%** |
| 10 | 79% | 75% | 48% | 88% | 59% |
| 30 | 94% | 94% | 75% | 96% | 85% |

**Table 5.** Reproductive risk to mammals: the proportion of 173 key uses of 55 List 3a substances with reproductive TERs below different levels. The grey shaded cells show the percentage of uses with TERs below the trigger value of 5, i.e. the failure rate. The new assessments with TWA=0.53 assume effects are caused by long-term exposure (the default), while those with TWA=1 assume effects are caused by short-term exposure (see text).

| **Reproductive TER** | Previous procedure (EC, 2002) | New screening procedure with TWA=0.53 | New Tier 1 procedure with TWA=0.53 | New screening procedure with TWA=1 | New Tier 1 procedure with TWA=1 |
|---|---|---|---|---|---|
| 0.01 | 1% | 2% | 0% | 6% | 1% |
| 0.03 | 1% | 6% | 1% | 9% | 1% |
| 0.1 | 2% | 18% | 2% | 36% | 12% |
| 0.3 | 6% | 45% | 18% | 58% | 25% |
| 1 | 20% | 69% | 27% | 81% | 49% |
| 3 | 52% | 88% | 55% | 92% | 77% |
| **5** | **59%** | **92%** | **68%** | **93%** | **86%** |
| 10 | 73% | 94% | 87% | 97% | 92% |
| 30 | 92% | 99% | 93% | 99% | 94% |

## References

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[3] Available at: http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc19_en.pdf

# APPENDIX E

## IMPACT OF CROP INTERCEPTION ON RESIDUES ON PLANT FOOD ITEMS

The residue unit doses (RUDs) for vegetation are derived from trials in which the crops are directly oversprayed. However, there will, be situations where particular food items for birds and mammals will have lower concentrations than expected due to the compound being partly intercepted by the crop before it reaches the food item.

As already proposed in EC (2002), interception by the crop may be considered as a minimising factor for residues on plant food items when canopy-directed applications of insecticides and fungicides to orchards, vineyards, hops or bush fruit are performed and undergrowth vegetation (assumed to be grass) is present. Also vegetables growing on trellis might fall under this category and would be treated similar to vineyards. Only one deposition factor of 0.6 was given in EC (2002) that corresponded to the lowest interception of 40 % in these scenarios according to the FOCUS surface water report for Step 2 $PEC_{SW}$ calculations (FOCUS, 2001, Table 2.4.2.-1). Taking into account the generic nature of FOCUS interception factors, it is now proposed that crop and growth-stage specific values according to FOCUS (2001) may be used in the Tier 1 scenarios. No interception factor may be applied for herbicide applications in those crops, since these are typically directly made to the grass vegetation. Also, no interception factor is applied for hops before side shoot formation, i.e. at growth stages BBCH 10-19 (BBA, 2001), because it is cultivated like an arable crop at this early stage.

As regards arable crops, some of them are rarely, if ever, eaten by birds and mammals (e.g. potatoes) whilst other crops become less attractive and hence less likely to be consumed as they grow (e.g. sugar beet). Whilst these crops may not be eaten, it is possible that other plants on the field will be available as food. At certain stages the crop may intercept some of the applied product and hence the amount of pesticide deposited on the food item is less than the application rate. Since measured residues of such food items at the appropriate growth stage of the crop are not available, only estimates can be used. However, further considerations were deemed necessary whether the FOCUS figures intended to reflect deposition on the soil surface (2-dimensional) may also be used for estimating residues on potential undergrowth vegetation (3-dimensional structures above the soil surface). In fact, the data given in both the FOCUS groundwater report (FOCUS, 2000) as well as in the FOCUS surface water report (FOCUS, 2001) represent datasets originating from different sources, which comprise calculations based on the leaf area index (LAI) as well as experimental measurements of either soil deposition or plant interception (Ganzelmeier, 1997; van de Zande *et al*., 1999; Becker *et al*., 1999; Linders, 2000). Nevertheless, a remarkable agreement between results obtained according to different methods was pointed out in FOCUS (2001) as well as by Linders *et al*. (2000).

It was concluded that estimation of residues on undergrowth vegetation using FOCUS interception factors would become increasingly uncertain with decreasing soil cover of the crop and increasing height of weeds in relation to the crop. Thus, reliable predictions are only deemed possible where the

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix E. EFSA Journal 2009; 7(12):1438. [5 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

largest part of the soil surface is actually covered by the crop from a bird's eye view and undergrowth vegetation is clearly smaller than the crop plants. Weeds or grasses overgrowing the crop at those stages are deemed unlikely to occur in intensive agriculture, but would anyway not form a part of the diet of small to medium herbivores. Nevertheless, cases like desiccation of aboveground plant parts before harvesting subterranean crops might require specific consideration in that regard.

For identification of relevant BBCH crop stages that fulfil these criteria, it can be assumed that most arable crops will be sown or planted in a density to achieve maximum overall cover of soil at a growth stage where crop plants have occupied their foreseen standing room. This is done to maximise yields per hectare and to suppress emergence of weeds competing for water, nutrients and light. As soon as this certain growth stage is reached, small weeds growing in the field will normally no longer be directly and fully exposed to pesticide sprays. In Table 1, proposals are given for crop-specific BBCH growth stages that would correspond to such sufficient soil coverage.

Based on this assessment of growth stages, the corresponding crop interception values as used in the FOCUS surface water report (FOCUS, 2001) for Step 2 $PEC_{SW}$ calculations can be considered acceptable also in the context of bird and mammal risk assessment. These figures differ from the values listed in the FOCUS groundwater report (FOCUS, 2000) insofar as the more recent data by Linders *et al.* (2000) were additionally used in the framework of a conservative approach at an early stage of a tiered scheme. Table 2, giving deposition factors for bird and mammal plant food items according to BBCH growth stages, is thus based on Table 2.4.2.-1 of FOCUS (2001). The deposition factors provided for the different crops and growth stages are likely to reflect conservative estimates. In the context of a higher-tier assessment, the more detailed values of the FOCUS groundwater report (FOCUS, 2000) may therefore also be used in line with the explanations provided by FOCUS (2005).

**Table 1.** BBCH growth stages corresponding to high soil coverage by crop plants.

| Crop name (arable crops only) | Stage | Description | Rationale for selection (considering downward-directed treatments with boom sprayer) |
|---|---|---|---|
| Cereals | ≥ 30 | Stem elongation | Maximum of tillers reached at preceding stage BBCH 29 (subsequent growth mainly in vertical direction) |
| Maize | ≥ 30 | Stem elongation | 9 or more leaves unfolded at preceding stage BBCH 19 (subsequent growth mainly in vertical direction) |
| Oilseed rape | ≥ 30 | Stem elongation | 9 or more side shoots detectable at preceding stage BBCH 29 (subsequent growth mainly in vertical direction) |
| Faba bean (*Vicia faba*) | ≥ 51 | Inflorescence emergence | 9 or more visibly extended internodes at preceding stage BBCH 39** |
| Sunflower | ≥ 30 | Stem elongation | 9 or more leaves unfolded at preceding stage BBCH 19 (subsequent growth mainly in vertical direction) |
| Beet | ≥ 40 | Rosette growth (crop cover) | Leaves cover 90 % of ground at stage BBCH 39 |
| Potato | ≥ 40 | Tuber formation | Crop cover complete: about 90 % of plants meet between rows at preceding stage BBCH 39 |
| Strawberry* | ≥ 41 | Development of stolons and young plants | 9 or more leaves unfolded at preceding stage BBCH 19 |
| Cotton | ≥ 51 | Inflorescence emergence | Canopy closure: 90 % of plants meet between rows at preceding stage BBCH 39 |
| Bulb vegetables (e.g. onion) | ≥ 41 | Development of main harvestable vegetative plant parts | 9 or more leaves clearly visible at preceding stage BBCH 19 (subsequent growth mainly of harvestable subsoil parts, flowering stage typically not reached in commercial cropping) |
| Root and stem vegetables (e.g. carrot) | ≥ 41 | Development of main harvestable vegetative plant parts | 9 or more true leaves unfolded at preceding stage BBCH 19 (subsequent growth mainly of harvestable (subsoil) parts, followed by shoot elongation and flowering) |
| Leaf vegetables (forming heads) | ≥ 51 | Inflorescence emergence | Typical size, form and firmness of heads reached at preceding stage BBCH 49 |
| Leaf vegetables (not forming heads) | ≥ 51 | Inflorescence emergence | Typical leaf mass reached at preceding stage BBCH 49 |
| Other brassica vegetables | ≥ 51 | Inflorescence emergence | Typical size and form reached, head tightly closed at preceding stage BBCH 49 |
| Cucurbits | ≥ 51 | Inflorescence emergence | Side shoots developed in preceding stage BBCH 29/231 |
| Solanaceous fruit (e.g. tomato, pepper, egg plant) – if not grown on trellis | ≥ 51 | Inflorescence emergence | Side shoots developed in preceding stage BBCH 29/2NX |
| Pea – if not grown on trellis | ≥ 51 | Inflorescence emergence | 9 or more visibly extended internodes in preceding stage BBCH 39** |
| Bean – if not grown on trellis (*Phaseolus vulgaris*) | ≥ 51 | Inflorescence emergence | 9 or more side shoots visible in preceding stage BBCH 29 |

* The strawberry scenario is different from other arable fields, because the crop is typically grown in rows separated by broad bare soil strips, with either crop-directed treatments using 3-nozzle fork sprayer (fungicides, insecticides) or between-row treatments (herbicides).

** If plants are not grown on trellis, stem elongation of the main shoot will affect soil coverage of the crop plants.

**Table 2.** Deposition factors for bird and mammal plant food items according to BBCH growth stages (derived from FOCUS, 2001).

| Crop | Relevant principal BBCH growth stages | Interception according to FOCUS (2001) | Deposition factor |
|---|---|---|---|
| Bare soils | not applicable | - | - |
| Bulb vegetables | ≥ 4 | 0.4 | 0.6 |
| Bush and cane fruit<br>(not tabulated, surrogate value from vineyard) | ≥ 1<br>≥ 2<br>≥ 4 | 0.4<br>0.5<br>0.7 | 0.6<br>0.5<br>0.3 |
| Cereals | ≥ 3<br>≥ 4 | 0.5<br>0.7 | 0.5<br>0.3 |
| Cotton | ≥ 5 | 0.75 | 0.25 |
| Fruiting vegetables | ≥ 5 | 0.7 | 0.3 |
| Grassland | not applicable | - | - |
| Hop | ≥ 1<br>≥ 2<br>≥ 4 | 0.2<br>0.5<br>0.7 | not applicable**<br>0.5<br>0.3 |
| Leafy vegetables | ≥ 5 | 0.7 | 0.3 |
| Legume forage | ≥ 5 | 0.7 | 0.3 |
| Maize | ≥ 3<br>≥ 4 | 0.5<br>0.75 | 0.5<br>0.25 |
| Oilseed rape | ≥ 3<br>≥ 4 | 0.7<br>0.75 | 0.3<br>0.25 |
| Orchards | ≥ 1<br>≥ 2<br>≥ 4 | 0.2<br>0.4<br>0.7 | 0.8<br>0.6<br>0.3 |
| Ornamentals/nursery<br>(not tabulated, surrogate value from leafy vegetables) | ≥ 5 | 0.7 | 0.3 |
| Potatoes | ≥ 4 | 0.7 | 0.3 |
| Pulses | ≥ 5 | 0.7 | 0.3 |
| Root and stem vegetables | ≥ 4 | 0.7 | 0.3 |
| Strawberries* | ≥ 4 | 0.6<br>(value from FOCUS, 2000) | 0.4 |
| Sugar beet | ≥ 4 | 0.75 | 0.25 |
| Sunflower | ≥ 3<br>≥ 4 | 0.5<br>0.75 | 0.5<br>0.25 |
| Vineyard | ≥ 1<br>≥ 2<br>≥ 4 | 0.4<br>0.5<br>0.7 | 0.6<br>0.5<br>0.3 |

* The strawberry scenario is different from other arable fields, because the crop is typically grown in rows separated by broad bare soil strips, with either crop-directed treatments using 3-nozzle fork sprayer (fungicides, insecticides) or between-row treatments (herbicides).

** No consideration of interception for hops before side shoot formation, because it is cultivated like an arable crop at this early stage.

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# APPENDIX F

## RESIDUES OF PLANT PROTECTION PRODUCTS ON FOOD ITEMS FOR BIRDS AND MAMMALS

After the publication of the first Guidance Document for birds and mammals (EC, 2002) and the RIVM[1] fact sheet "Residues of plant protection products on food items" by Luttik (2001) several new studies have been carried out:

a) Baril *et al*. (2005) updated the database of Fletcher *et al.* (1994), to examine the validity of extrapolating residue unit dose values (RUD) across application rates, and to improve the categorization of crops using crop morphology and cultivation methods,

b) Several studies were carried out by the industry (ECPA) and the Central Science laboratory (CSL) to provide information for RUD values on insects,

c) The ECPA[2] provided databases for residues on cereals and grass and on non-grass weeds (see Appendices 17 and 18 of EFSA, 2008).

Baril *et al.* (2005) provided new RUD values for the following food items: small fruits from orchards (like apricot, cherry, date fig, kiwi or plum), large fruit from orchards (like apple, lemon, mandarin, nectarine, orange, pear or peach), berries (like black currant, blueberry, grape or raspberry), tomatoes, gourds and grains/ear. But their categories for cereals and grass could not be used for the assessment of the risk for wild birds and mammals. In the risk assessment proposed in this document only the first growth stages of the grasses and cereals are eaten (up to BBCH[3] stage 30, see BBA, 2001[4]) and not the later stages.

In the proposed risk assessment it is not assumed that birds and mammals will eat large leaves, nor that the birds and mammals will eat at all from the crop. It is assumed that the animals will eat monocotyledonous and dicotyledonous weeds or young crop plants (if palatable) and that these weeds will be always present. The category non-grass herbs of the Baril et al. database (2005) does not meet these criteria either.

Therefore, it was necessary to collect data for these food categories. These data were provided by the industry (see Appendix 17 of EFSA, 2008 for the leafy residue database of the ECPA with 307 entries for non-grass "weeds" like alfalfa, lettuce, oil seed rape spinach and broccoli and sugar beets (young

[1] National Institute for Public Health and the Environment
[2] European Crop Protection Association
[3] The abbreviation **BBCH** derives from **B**iologische **B**undesanstalt Bundessortenamt and **CH**emical industry.
[4] Available at: http://www.bba.de/veroeff/bbch/bbcheng.pdf

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix F. EFSA Journal 2009; 7(12):1438. [4 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

stages) and with 95 entries for grass and Appendix 18 of EFSA, 2008 for the cereal residue database of the ECPA with 1253 entries).

The residue data collected for the PSD[5] (UK) by CSL for arthropods was merged with the data collected by the ECPA and resulted in three different invertebrate categories: one for foliage dwelling invertebrates, one for ground dwelling invertebrates with interception (ground directed applications on top of crops for BBCH growth stage of 4 or greater) and one for ground dwelling invertebrates without interception (applications on bare soil, or ground directed applications up to BBCH growth stage 3, and ground directed applications in orchards/vines, e.g. herbicides).

CSL also carried out studies with over-sprayed aphids on plants. The results of these studies provided very high concentrations on the aphids. Although aphids are mentioned in the literature as food for several birds species, aphids are not a very important/relevant part of the diet for most of birds. For two of the insectivorous focal species in the crop scenarios (yellow wagtail and fan-tailed warbler), the "Handbuch der Vögel Mitteleuropas" does not mention aphids as food and for the willow warbler. The number of aphids compared to the total number of prey items can be as much as 15 %, but the proportion based on wet weight is low compared to the total weight of the food. Therefore, the aphid measurements have been omitted from the database, because it would, due to the numbers of measurements available, influence the outcome of the risk assessment.

Almost no data are available for RUDs on seeds (small seeds, weed seeds). As a result of this it is proposed still to use the RUD values that are mentioned in the first Guidance Document for birds and mammals (EC, 2002).

The resulting RUDs are presented in Table 1. Besides the mean, standard deviation and the number of values on which the RUD is based, also the 50$^{th}$ and 90$^{th}$ percentile of the RUD distributions are provided. This table only refers to food items that have been used for the screening step and/or for the first tier risk assessment.

In the screening step and first-tier risk assessment it is assumed that all seeds are small. For higher tier assessment the category large seeds can be introduced (in most cases lower residue values). It is not possible to define large and small seeds. This should be judged from a bird's or mammal's perspective. A linnet probably will not eat peas or maize, but these types of seeds could be part of the food of a partridge. Small mice like the wood mouse will rather eat large seeds than small ones.

[5] Pesticide Safety Directorate final Report (PS2323), available on the Defra website under (http://randd.defra.gov.uk). Please note that PSD joined the Health and Safety Executive on 1st April 2008.

**Table 1.** RUD table for different food items that are needed for calculating the exposure in the screening step and first-tier assessment.

| Crop/category of insects | Crop stage | mean | Standard deviation | 90th percentile[7] | n | Source |
|---|---|---|---|---|---|---|
| Grass+cereals | BBCH 10-30 | 54.2 | 55 | 102.3 | 132 | ECPA database[6] |
| Non-grass weeds | Whole season | 28.7 | 27.5 | 70.3 | 230 | ECPA database[6] |
| Small fruits from orchards[1] | Fruiting period | 3.3 | 2.6 | 6.5 | 33 | Baril *et al.* (2005) |
| Large fruit from orchards[2] | Fruiting period | 19.5 | 16.8 | 41.1 | 33 | Baril *et al.* (2005) |
| Berries[3] | Fruiting period | 8.3 | 7.2 | 16.7 | 9 | Baril *et al.* (2005) |
| Tomato | Fruiting period | 12.8 | 14.6 | 30.6 | 86 | Baril *et al.* (2005) |
| Gourds | Fruiting period | 34.3 | 54.7 | 61.5 | 19 | Baril *et al.* (2005) |
| Grains/ear | Fruiting period | 15 | 25.4 | 13.0 | 21 | Baril *et al.* (2005) |
| Seeds | Fruiting period | 40.2 | 50.6 | 87.0 | 108 | EC (2002) |
| Ground dwelling invertebrates without interception[4] | ground directed applications | 7.5 | 12.0 | 13.8 | 21 | ECPA |
| Ground dwelling invertebrates with interception[5] | applications directed to crop canopies | 3.5 | 3.8 | 9.7 | 28 | ECPA & CSL |
| Insects (foliar dwelling invertebrates[8]) | Whole season | 21.0 | 21.6 | 54.1 | 35 | ECPA & CSL (aphids) |

1 = e.g. apricot, cherry, date fig, kiwi and plum
2 = e.g. apple, lemon, mandarin, nectarine, orange, pear and peach
3 = e.g. black currant, blueberry, grape and raspberry
4 = applications on bare soil, or ground directed applications up to principle growth stage 3, ground directed applications in orchards/vines (e.g. herbicides)
5 = applications directed to crop canopies (orchards/vines), ground directed applications on top of crops with principle growth stage of 4 or greater
6 = See Appendices 17 and 18 of EFSA, 2008 for individual RUD values
7 = RUD values for 50th and 90th percentile for the Baril *et al.* (2005) data are derived from the original data collected by Baril *et al.*
8 = No data are available for canopy dwelling invertebrates in winter or before the leaves appear (interception would be less).

**Refinement of measured data for higher tier assessment**

For each of the relevant categories of food presented in Table 1 or for a food item introduced in higher tier assessment additional measured residue data can be provided for a particular compound. Recommendations for carrying out residue field studies can be found in sections 6.1.4.1, 6.1.4.2 and Appendix N. It should be noted that it has to be fully justified why new measured residue data will override the existing residue values presented in Table 1, as several studies were used to generate these generic RUDs. Therefore, it is unlikely that one study will be appropriate to replace the generic RUD value.

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# APPENDIX G

# CALCULATING EXPOSURE FOR THE DIETARY INTAKE APPROACH

## Estimated dietary intake

The estimated daily exposure, i.e. the uptake of a compound via a single food item is given by the following equation:

$$\mathrm{ETE} = \frac{\mathrm{FIR}}{\mathrm{bw}} \times \mathrm{C} \times \mathrm{PT} \quad [\mathrm{mg/kg\ bw/d}]$$

In which:

ETE = Estimated theoretical exposure
FIR = Food intake rate of indicator species [g fresh weight /d]
bw = Body weight [g]
C = Concentration of compound in fresh diet [mg/kg]
PT = Fraction of diet obtained in treated area (number between 0 and 1)

The concentration C will either be directly available (e.g. for treated seeds) or can be calculated using residue unit doses (RUD) for the relevant food items (see Appendix F).

If a mixed diet has to be considered, the ETE is calculated as the sum of ETEs for all food items. However, it is necessary to adjust the individual food intake rates for each food item [*i*] to account for its actual contribution to the daily energy expenditure (DEE) of the indicator species. This is described in more detail further below.

$$\mathrm{ETE} = \frac{1}{\mathrm{bw}} \times \sum_i \left(\mathrm{FIR}_{i,\,fresh} \times \mathrm{C}_i \times \mathrm{PT}\right) \quad [\mathrm{mg/kg\ bw/d}]$$

In which:

$\mathrm{FIR}_{i,fresh}$ = Food intake rate of food item [*i*] in mixed diet [g fresh weight/d]
$\mathrm{C}_i$ = Concentration of compound in food item [*i*] in fresh diet [mg/kg]

In case of multiple applications, it is necessary to apply a multiple application factor (MAF) to the concentration C. Further details are given in Appendix H.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix G. EFSA Journal 2009; 7(12):1438. [5 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

**Food intake rate (FIR)**

The estimates of food intake are based on means of daily energy expenditure for free-ranging animals, energy and moisture content and assimilation efficiencies. The FIR can be calculated as follows:

$$FIR = \left( \frac{DEE}{FE * \left(1 - \frac{MC}{100}\right) * \left(\frac{AE}{100}\right)} \right) \quad \text{[g fresh weight/d]}$$

In which:

DEE = Daily energy expenditure of the indicator species [kJ/d]
FE = Food energy [kJ/dry g]
MC = Moisture content [%]
AE = Assimilation efficiency [%]

**Daily energy expenditure (DEE)**

Data for the DEE are derived from a research project carried out for DEFRA[1] (Anonymous, 2007). Relationship between body weight (bw in g) and daily energy expenditure (DEE in kJ) can be described by the equation:

$$\log DEE = \log a + b \times \log bw$$

To obtain the specific equation for the relevant species group the respective log a and b from Table 2 have to be inserted.

**Table 2.** Species groups, log a and b, the standard errors for a and b (SE), the number of species in each group (N), and the proportion of variation explained by each equation ($r^2$).

| Species group | log a | SE log a | b | SE b | N | $r^2$ |
|---|---|---|---|---|---|---|
| Non passerines | 0.839 | 0.161 | 0.669 | 0.063 | 18 | 0.87 |
| Passerines(*) | 1.032 | 0.058 | 0.676 | 0.045 | 44 | 0.84 |
| Mammals(*) | 0.814 | 0.046 | 0.715 | 0.019 | 46 | 0.97 |

(*) = excluding desert passerines or desert and marine eutherians.

**Energy and moisture content of food items**

The energy and moisture content presented in Table 3 are from Smit (2005), see also Appendix L. These are the values used for calculating the FIR for the scenarios defined for the species of concern (indicator species and generic focal species) of Tier 1. For higher tier assessments it is sometimes necessary to include other food categories. Data energy and moisture content for these food items can be found in Smit (2005), Buxton *et al.* (1998) and Crocker *et al.* (2002).

[1] **Department for Environment, Food and Rural Affairs**

**Table 3.** Different food items, their energy content [kJ/g dry] and moisture content [%].

| Food items | kJ/g dry | Moisture [%] |
|---|---|---|
| Grasses and cereal shoots | 17.6 | 76.4 |
| Non-grass herbs | 17.8 | 88.1 |
| Cereal seeds | 18.4 | 14.7 |
| Weed seeds | 21.7 | 9.9 |
| Fruit | 14.8 | 83.9 |
| Arthropods (including caterpillars) | 22.7 | 68.8 |
| Soil invertebrates | 19.4 | 84.3 |
| Fish | 21.0 | 73.7 |
| Aquatic invertebrates | 20.9 | 76.3 |
| Aquatic vegetation | 15.0 | 81.4 |

**Assimilation efficiency**

Assimilation efficiencies for birds are from Bairlein (1998), the assimilation efficiencies for mammals are from Crocker *et al.* (2002) and Smit (2005). For higher tier assessments it is sometimes necessary to include other food categories. Data for some food items can also be found in these three references (see also Appendix L).

**Table 4.** Assimilation efficiency of different food items for mammals and different bird species.

| Assimilation efficiency of different food items | Mammal | Passerine | Duck & geese | Pigeon | Fowl |
|---|---|---|---|---|---|
| Grasses and cereal shoots | 0.47 | 0.76 | 0.41 | n.a. | 0.42 |
| Non-grass herbs | 0.76 | 0.76 | 0.41 | 0.53[b] | 0.42 |
| Cereal seeds | 0.84 | 0.80 | 0.83 | n.a. | 0.65 |
| Weed seeds | 0.84 | 0.80 | 0.83 | 0.76[a] | 0.65 |
| Fruit | 0.74 | 0.67 | n.a. | n.a. | 0.57 |
| Arthropods (including caterpillars) | 0.87 | 0.76 | 0.87 | n.a. | 0.70 |
| Soil invertebrates | 0.87 | 0.76 | 0.87 | n.a. | 0.70 |
| Fish | 0.87 | 0.76 | 0.87 | n.a. | 0.70 |
| Aquatic invertebrates | 0.87 | 0.76 | 0.87 | n.a. | 0.70 |
| Aquatic vegetation | 0.76 | 0.76 | 0.41 | n.a. | 0.42 |

[(a)] = No data available for pigeons, the value for seeds is the average of 3 data (83% for duck/geese + 65% for fowl + 80% for passerines).

(b) = No data available for pigeons, the value for the assimilation efficiency of herbage is the average of 6 data (36% for ostriches, 59% for cranes/coots/rails, 41% for ducks/geese, 42% for fowl, 61% for woodpeckers and 76% for passerines).

It should be noted that all of the above data on moisture content and calorific content have been used to determine food intake rates for indicator species as well as generic focal species.

**Consideration of mixed diets**

If a mixed diet must be considered, the food intake rate for food items is not simply achieved by applying the respective fraction as a factor to the respective FIR for a "pure" diet. Instead, the FIR has to be adjusted to reflect the actual contribution of each food item to the daily energy expenditure (DEE) of the indicator species.

Considering the fractions ($PD_i$) of individual food items in a mixed diet together with data on their respective moisture (where relevant) and energy content, the specific energy content of the mixed diet is calculated (Step 1). This value is used to estimate the required amount of the mixed diet to satisfy the daily energy expenditure (DEE) of a bird or mammal (Step 2). In Step 3, individual food intake rates (FIR) for each food item are calculated using again the $PD_i$ values and the overall estimated theoretical exposure (ETE) is derived.

Based on a given diet composition, the specific available energy content (here related to 1 g for practical reasons) of the mixed diet is calculated, taking into account the respective specific energy contents of the food items (corrected for assimilation efficiency) according to their fractions in the diet. If the diet composition is given in terms of dry weight, the corresponding specific total diet energy content is thus calculated according to the following formula:

$$FE_{total,dry} = \sum_i \left( PD_{i,dry} \times FE_i \times \frac{AE_i}{100} \right)$$

In which:

| | |
|---|---|
| $FE_{total,dry}$ = | Food energy of total mixed diet [kJ/g dry weight] |
| $PD_{i,dry}$ = | Fraction of food item [*i*] in mixed diet [related to dry weight] |
| $FE_i$ = | Food energy of food item [*i*] in mixed diet [kJ/dry g] |
| $AE_i$ = | Assimilation efficiency of food item [*i*] in mixed diet [%] |

If the diet composition is given in terms of fresh weight, a respective additional correction factor has to be considered in the formula:

$$FE_{total,\,fresh} = \sum_i \left[ PD_{i,\,fresh} \times FE_i \times \left( 1 - \frac{MC_i}{100} \right) \times \frac{AE_i}{100} \right]$$

In which:

| | |
|---|---|
| $FIR_{total,fresh}$ = | Food intake rate of total mixed diet [kJ/g fresh weight] |
| $PD_{i,fresh}$ = | Fraction of food item [*i*] in mixed diet [related to fresh weight] |
| $MC_i$ = | Moisture content of food item [*i*] in mixed diet [%] |

Using the calculated specific energy content of the mixed diet, $FIR_{tota}$, the required amount of the mixed diet to reach the DEE of the indicator species can be determined.

$$FIR_{total,dry} = \frac{DEE}{FE_{total,dry}} \quad \text{or} \quad FIR_{total,\,fresh} = \frac{DEE}{FE_{total,\,fresh}}$$

To be compliant to the available residue data, the ETE equation makes use of fresh weight data. So, in case, $PD_i$ and $FIR_{total}$ are given in terms of fresh weight, the actual $FIR_i$ for one food item [*i*] in the

mixed diet is achieved by multiplying $FIR_{total}$ by the fraction for the respective food item and the ETE is calculated as follows.

$$ETE = \frac{1}{bw} \times \sum_i \left( PD_{i,fresh} \times FIR_{total,fresh} \times C_i \right)$$
$$= \frac{1}{bw} \times \sum_i \left( FIR_{i,fresh} \times C_i \right)$$

In which:

$FIR_{i,fresh}$ = Food intake rate of food item [$i$] in mixed diet [g fresh weight/d]
bw = Body weight of indicator species
$C_i$ = Concentration of active substance in food item [$i$] [mg/kg]

Whereas, when $PD_i$ and $FIR_{total}$ are given in terms of dry weight, recalculation of the actual $FIR_i$ values according to the moisture content of food items is required:

$$ETE = \frac{1}{bw} \times \sum_i \left( PD_{i,dry} \times FIR_{total,dry} \times \frac{1}{MC_i} \times C_i \right)$$
$$= \frac{1}{bw} \times \sum_i \left( FIR_{i,fresh} \times C_i \right)$$

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# APPENDIX H

# MULTIPLE APPLICATIONS AND RESIDUE DYNAMICS IN THE ENVIRONMENT

## Background and general assessment scheme

This Appendix outlines how to determine multiple application factors (MAFs) as well as time-weighted averages (TWAs). It is proposed to use multiple application factors if there is more than one application, and a moving time window approach in determining time weighted average concentrations. It is generally assumed in this document that residue dynamics follow first-order kinetics. All calculations are therefore based on the integrated form of respective basic equation:

$$C = C_0 \times e^{-kt}$$

With:

$C$ = actual concentration at time $t$

$C_0$ = initial concentration

$k$ = rate constant where $k = \ln 2/DT_{50}$

Multiple applications of a compound may cause a build-up of residue levels and must be taken into account in the exposure assessment for the estimated theoretical exposure (ETE) equation. As long as only peak concentrations are considered in the risk assessment, residue dynamics can be expressed by a multiple application factor (MAF). The MAF is a function of the number of applications, application interval, and decline of residues, typically expressed as a $DT_{50}$ assuming first order kinetics (single first order, SFO-$DT_{50}$). Equations are presented for calculation of a $MAF_m$ for average residue levels and of a $MAF_{90}$ for 90$^{th}$ percentile residue levels.

It is assumed that certain effects observed in reproductive toxicity testing with constant dietary exposure are not triggered by exposure to a single peak concentration but require a longer exposure period of more than one day. In contrast, residue unit dose (RUD) values for residue levels in food items reflect the height of the exposure peak directly after application. Using the assumption of residue dissipation via first order kinetics, it is possible to calculate time-weighted average factors (TWA) that translate residue decline following peak exposure into a constant exposure concentration over a chosen time interval. Care must be taken when estimating TWA exposure in cases where multiple applications occur in short sequence. Simple multiplication of $MAF_m$ and TWA would reflect a scenario where the averaging period starts after the final application peak. However, depending on number of applications, application intervals and active substance $DT_{50}$, also TWA intervals starting already before the last application might give the worst-case $MAF_m \times$ TWA factor. Therefore an assessment using a moving time window is necessary to identify the appropriate $MAF_m \times$ TWA factor for the risk assessment.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix H. EFSA Journal 2009; 7(12):1438. [11 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

## Multiple application factor for average residue levels ($MAF_m$)

In the calculation of the MAF, the build-up of residues on food items is expressed by the number of applications ($n$). A $MAF_m$ factor for use with average RUD data is calculated using the following equation.

$$MAF_m = \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

With:

$k$ = $\ln(2)/DT_{50}$ (rate constant)

$n$ = number of applications

$i$ = application interval (d)

By forming the limit value lim n → ∞ of the equation above, the term $e^{-nki}$ becomes zero and a "plateau" $MAF_m$ for an infinite number of applications can be calculated.

**Table 1.** $MAF_m$ for mean residue data for selected application intervals and $n$ = 1-8 applications (considering a default $DT_{50}$ of 10 d on foliage).

| **Application interval (d)** | **$MAF_m$ for mean residue data for *n* applications** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | ∞ |
| **7** | 1.0 | 1.6 | 2.0 | 2.2 | 2.4 | 2.5 | 2.5 | 2.5 | 2.6 |
| **10** | 1.0 | 1.5 | 1.8 | 1.9 | 1.9 | 2.0 | 2.0 | 2.0 | 2.0 |
| **14** | 1.0 | 1.4 | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 |

$MAF_m$ values for other application intervals can be either calculated using the above formula or the values for the next lower application interval should be used. For higher number of applications with one of the tabulated intervals, the limit value in the rightmost column should be used.

## Multiple application factor for 90$^{th}$ percentile residue levels ($MAF_{90}$)

In the calculation of $MAF_{90}$ values to be used in an exposure scenario with 90$^{th}$ percentile RUDs, it must be considered that not each single application event but the total residue after the last application should represent a 90$^{th}$ percentile. In principle, this can be achieved by modifying the $MAF_m$ for the mean RUD values with a correction term, which also considers the variance of the RUD dataset and a respective $MAF_{var}$. When assuming normally distributed residue data, an analytical solution is possible:

$$MAF_{90} = \frac{MAF_m \times RUD_m + f_{90} \times \sqrt{MAF_{var} \times \sigma^2}}{RUD_{90}}$$

With:

$$MAF_m = \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

$$MAF_{var} = \frac{1 - e^{-2nki}}{1 - e^{-2ki}}$$

$f_{90}$ = 1.28 (90th percentile for standard normal distribution)
$k$ = $\ln(2)/DT_{50}$ (rate constant)
$n$ = number of applications
$i$ = application interval (d)
$RUD_m$ = average RUD value
$RUD_{90}$ = 90th percentile RUD value
$\sigma^2$ = variance of RUD dataset

However, from a fundamental viewpoint, the assumption of normal distribution for RUD values could be challenged, because residue concentrations below zero cannot occur. It was previously generally assumed that RUDs would follow a log-normal distribution, but on closer analysis, the best fit seems to be achieved to a gamma distribution. The fit to log-normal distribution is only slightly, if at all, better than to normal distribution. Visual inspection of plotted normal and log-normal distribution curves versus. the underlying measured data did not suggest superiority of one approach over the other, particularly with regard to mean and 90th percentile values. However, both gamma and log-normal distribution share the disadvantage that more complex terms are required to describe variance and specific percentiles than for the normal distribution. This is demonstrated below for the log-normal distribution.

$$\sigma^2_{\text{lognorm}} = \ln\left(\frac{\sigma^2_{\text{norm}}}{\mu^2_{\text{norm}}} + 1\right)$$

$$f_{90,\text{lognorm}} = \exp(\mu_{\text{lognorm}} + \sigma_{\text{lognorm}} \times f_{90,\text{norm}})$$

With:
$\sigma^2_{\text{lognorm}}$ = variance of RUD dataset for lognormal distribution
$\sigma^2_{\text{norm}}$ = variance of RUD dataset for normal distribution
$\mu_{\text{lognorm}}$ = mean of RUD dataset for lognormal distribution
$\mu_{\text{norm}}$ = mean of RUD dataset for normal distribution
$f_{90,\text{lognorm}}$ = 90th percentile for lognormal distribution
$f_{90,\text{norm}}$ = 1.28 (90th percentile for standard normal distribution)

When both terms are inserted in the equation above, rearrangement of the variables to produce a generic analytical solution is no longer possible. The tabulated $MAF_{90}$ values for the acute risk assessment in the former Guidance Document (EC, 2002) were hence obtained from a Monte Carlo simulation based on log-transformed mean and standard deviation figures. As a consequence of this complex determination of the $MAF_{90}$, no option for refining these values using experimentally determined $DT_{50}$ values could be offered.

To provide a feasible solution, the two most relevant RUD data sets "grass + cereals" and "non-grass herbs" produced for this Guidance Document were analysed more closely. In addition, an adjusted version of the data set "grass + cereals" (elimination of one very large value as an outlier, resulting in a significantly better fit) was also considered. The differences between lognormal and normal 90th percentile RUDs, respectively, were in the range of 10 % or below in all cases, with higher values for the 90th percentile RUDs from the normal distribution. As already mentioned, visual inspection of distribution curves and plotted individual data points showed good agreement in the upper percentile range. Before that background, using approximate $MAF_{90}$ values based on the assumption of normally distributed RUD data is considered acceptable. As stated, analysis of the data was focussed on the three categories "grass + cereals" (n = 132), "grass + cereals (adjusted)" (n = 131) and "non-grass herbs" (n = 230) with the highest number of data points and greatest relevance for the standard risk assessment. The $MAF_{90}$ values obtained for the category "grass + cereals (adjusted)" turned out to be slightly higher than for "grass + cereals" and "non-grass herbs" as well as for all other data sets. Moreover, they match

remarkably well with the Monte-Carlo modelled figures from the preceding Guidance Document (EC, 2002) and should thus be used for standard as well as refined risk assessments.

$RUD_m$ = 50.5 (average RUD value from fitted normal distribution)

$RUD_{90}$ = 95.0 ($90^{th}$ percentile RUD value from fitted normal distribution)

$\sigma^2$ = 1206.9 (variance of RUD dataset from fitted normal distribution)

The following table gives the results of the calculation for the default $DT_{50}$ of 10 days. In the same way as for the $MAF_m$, a "plateau" $MAF_{90}$ for an infinite number of applications can be calculated by forming the limit value lim n → ∞ of the equation above (the terms $e^{-nki}$ and $e^{-nki}$ in the sub-equations for $MAF_m$ and $MAF_{var}$ both become zero).

**Table 2.** $MAF_{90}$ for $90^{th}$ percentile residue data for selected application intervals and $n$ = 1-8 applications (considering a default $DT_{50}$ of 10 d on foliage).

| **Application interval (d)** | **$MAF_m$ for mean residue data for *n* applications** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | ∞ |
| **7** | 1.0 | 1.4 | 1.6 | 1.8 | 1.9 | 1.9 | 1.9 | 1.9 | 2.0 |
| **10** | 1.0 | 1.3 | 1.5 | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 |
| **14** | 1.0 | 1.2 | 1.3 | 1.3 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 |

$MAF_{90}$ values for other application intervals can be either calculated using the formula above with the input parameters for "grass + cereals (adjusted)" or the values for the next lower application interval should be used. For higher number of applications with one of the tabulated intervals, the limit value in the rightmost column should be used.

Refinement of both $MAF_{90}$ and $MAF_m$ is possible if experimental values for the $DT_{50}$ are available. These may be inserted in the respective equations to obtain MAF values for specific risk assessments.

The MAF concept is a generic scheme intended to represent the effect of substance degradation in the ETE model. Thus, using distribution data for other food categories in a refined risk assessment is considered not meaningful. Fairly consistent results for $MAF_{90}$ were obtained for all analysed data sets, so the numerical worst case "grass and cereals (adjusted)" based on 131 independent measurements is deemed to provide a reliable basis for bird and mammal risk assessments.

## Time-weighted average factor (TWA) in connection with a single exposure peak

If no multiple applications have to be considered, a TWA factor is calculated using the following equation:

$$TWA = \frac{1 - e^{-ki}}{ki}$$

With:

$k$ = $\ln(2)/DT_{50}$ (rate constant)

$i$ = averaging interval

## Combination of $MAF_m$ and TWA for several applications

A $MAF_m \times TWA$ factor for the time period $i$ after the $n^{th}$ application can be described by a simple equation that is, however, only valid if the $n^{th}$ is the last application or if the averaging interval is shorter than the application interval between the $n^{th}$ and the $(n + 1)^{th}$ application:

$$MAF_m \times TWA = \frac{1 - e^{-nki}}{ki}$$

With:

$k$ = $\ln(2)/DT_{50}$ (rate constant)

$n$ = number of applications

$i$ = TWA interval

If the averaging interval covers several applications from the first to the $n^{th}$ application and ends directly before the $(n + 1)^{th}$ application (i.e. is a multiple of the application interval), the equation has to be expanded. Basically, $MAF_m \times TWA$ factors are calculated after each application event and are then averaged.

$$MAF_m \times TWA = \frac{1}{n} \times \sum_n \frac{1 - e^{-nki}}{ki}$$

However, if the TWA interval is no multiple of the application interval, which is most often the case, a weighted average of the individual $MAF_m \times TWA$ factors after each application must be calculated, considering their different contributions to the overall MAF × TWA factor. No generic equation is given for that. However, in practice, Excel-type spreadsheets or computer programs are available for such calculations. By varying the start of the time window in the spreadsheet or computer program, the highest $MAF_m \times TWA$ must be identified and used in the risk assessment.

## Use of $MAF_m$, TWA and $MAF_m \times TWA$

The following figures intended to illustrate the use of $MAF_m$, TWA and $MAF_m \times TWA$ in the exposure assessment for calculating an ETE. Please note that the time periods selected for those examples do not imply any statement on appropriate TWA intervals in an assessment of reproductive toxicity.

All calculations of $MAF_m$, TWA and $MAF_m \times TWA$ are based on the same concept as they apply the basic equation for first-order kinetics in its integrated form.

$$C = C_0 \times e^{-kt}$$

With:

$C$ = actual concentration at time $t$

$C_0$ = initial concentration

$k$ = rate constant where $k = \ln 2/DT_{50}$

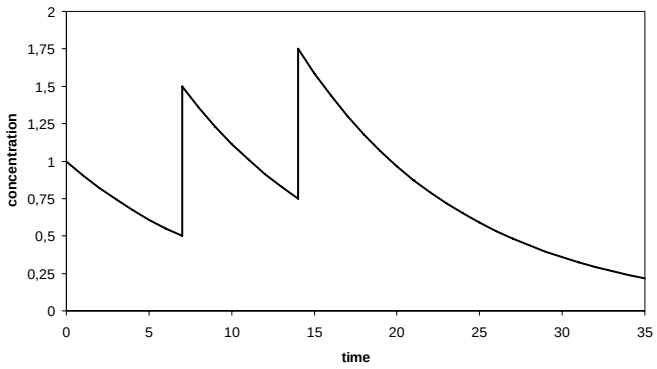


**Figure 1.** Time course of residues after three applications of a compound.

In the calculation of the MAF, the build-up of residues on food items is expressed by the number of applications (*n*). Their subsequent fate is described by a 1st-order kinetics model where the dissipation rate is dependent on the time interval after peak exposure but independent of the initial concentration. A $MAF_m$ factor for use with average RUD data can be easily calculated using the following equation.

$$MAF_m = \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

With:

$k$ = $\ln(2)/DT_{50}$ (rate constant)

$n$ = number of applications

$i$ = application interval (d)

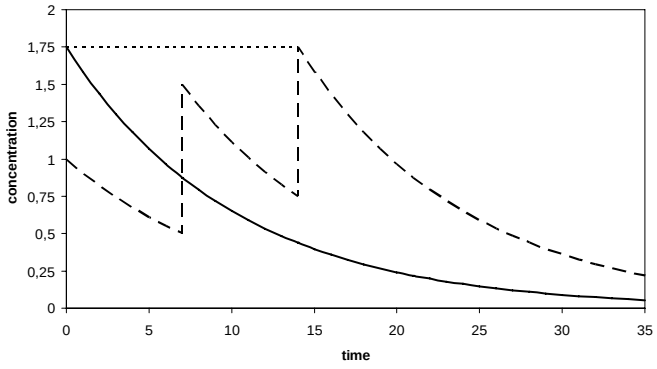


**Figure 2.** Expression of residue build-up by a $MAF_m$.

As mentioned before, it is assumed that certain effects observed in reproductive toxicity testing with constant dietary exposure are not triggered by exposure to a single peak concentration but require a longer exposure period of more than one day. In contrast, RUD values for residue levels in food items reflect the height of the exposure peak directly after application. Using the assumption of residue dissipation via first order kinetics, it is possible to calculate time-weighted average factors (TWA) that translate residue decline following peak exposure into a constant exposure concentration over a chosen time interval. As long as no multiple applications must be considered, such a TWA factor can be easily calculated using the following equation.

$$\mathrm{TWA} = \frac{1 - e^{-ki}}{ki}$$

With:

$k$ = $\ln(2)/DT_{50}$ (rate constant)

$i$ = averaging interval

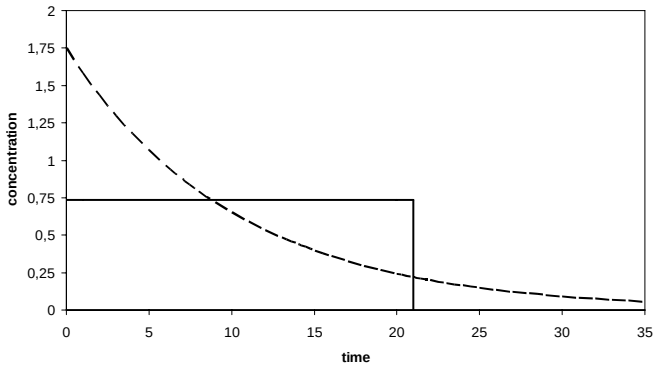


**Figure 3**. Translation of dissipation after peak exposure into constant TWA exposure.

Care must be taken when estimating TWA exposure in cases where multiple applications occur in short sequence. Simple multiplication of $MAF_m$ and TWA would reflect a scenario where the averaging period starts after the final application peak. However, depending on number of applications, application intervals and active substance $DT_{50}$, also TWA intervals starting already before the last application might give the worst-case $MAF_m \times$ TWA factor. Therefore an assessment using a moving time window is necessary to identify the appropriate $MAF_m \times$ TWA factor for the risk assessment. Thus, a time window comprising two or more application events must be used. If the averaging interval covers several applications from the first to the $n^{th}$ application and ends directly before the $(n + 1)^{th}$ application (i.e. is a multiple of the application interval), the equation has to be expanded. Basically, $MAF_m \times$ TWA factors are calculated after each application event and then averaged.

$$\mathrm{MAF_m} \times \mathrm{TWA} = \frac{1}{n} \times \sum_{n} \frac{1 - e^{-nki}}{ki}$$

However, if the TWA interval is no multiple of the application interval, which is most often the case, a weighted average of the individual $MAF_m \times$ TWA factors after each application must be calculated, considering their different contributions to the overall MAF × TWA factor. No generic equation is given for that. However, in practice, Excel-type spreadsheets or computer programs are available for such calculations. By varying the start of the time window in the spreadsheet or computer program, the highest $MAF_m \times$ TWA must be identified and used in the risk assessment.

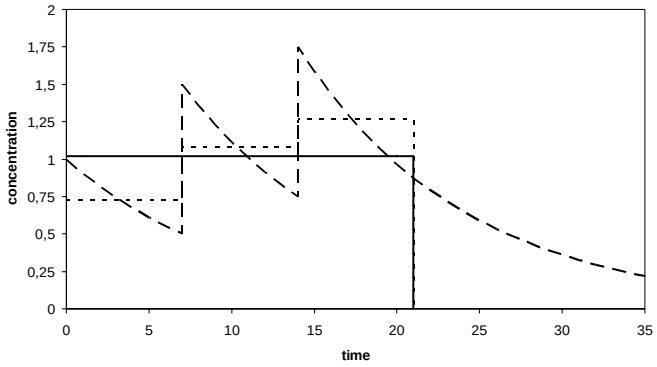


**Figure 4.** Combining $MAF_m$ and several TWA exposure concentrations into an overall $MAF_m \times$ TWA factor.

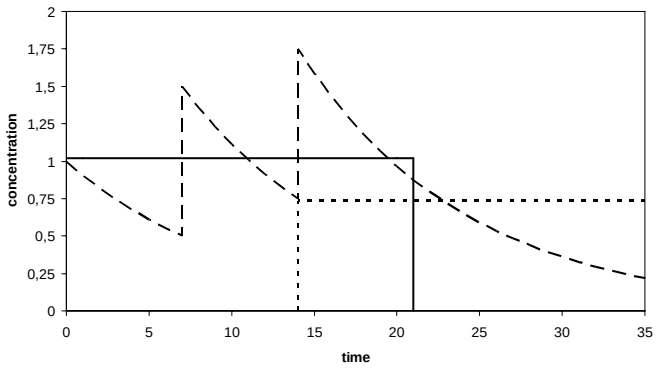


**Figure 5.** Appropriate selection of time window for $MAF_m \times$ TWA factor.

## Background for the selection of a pseudo-$DT_{50}$ of 10 d for describing residue dynamics in arthropod food items

To enable the calculation of daily dietary doses at the Tier-1 level for insectivorous and mixed diets of generic focal species, it is proposed to apply the same methodology to arthropod food items as for food items of plant origin, i.e. multiple application (MAF) and time-weighted average (TWA) factors based on a first-order pseudo-$DT_{50}$ of 10 d for residue decline. Residue decline over time will occur on arthropods and in certain circumstances accumulation will occur. Outlined below is the rationale behind the selection of the $DT_{50}$ and associated MAF and TWA factors. It should be noted that this approach does not imply that respective residue dynamics are most appropriately described by first-order degradation kinetics. Instead, the factors should be understood as generic descriptors for the possible extent of residue decline and accumulation, which can and should be refined by more appropriate data when these are available.

In order to check the appropriateness of using a first-order pseudo-$DT_{50}$ of 10 d for describing residue decline in arthropod food items, the time course of residues as reported in 90 datasets from field trials conducted by industry was analysed. These data comprise measured residues of insecticides, fungicides and herbicides on the three strata ground-dwelling, leaf-dwelling and flying insects during intervals of 0 to 7 days after spray application. For various reasons (insufficient sample mass, non-representative sample composition, etc.), nine datasets were excluded from quantitative assessment.

First inspection of the data revealed that in about 50 % of the cases, highest residues did not occur on the day of application, but up to 7 days later. This is probably due to the uptake of residues by arthropods from contaminated soil and plant surfaces and confirms, in principle, the more complex nature of residue dynamics on arthropod food items as compared to plant food items. Therefore, a twofold approach was followed for quantitative analysis of the data.

In one approach, average normalised residue concentrations per sampling date for all categories (n = 81), for ground and leaf dwellers (n = 70), for ground dwellers alone (n = 39) and for leaf dwellers alone (n = 31) were assessed according to the methodology of FOCUS degradation kinetics (FOCUS, 2006). Using a non-linear regression method, single first order (SFO) kinetics and the biphasic first-order multiple-compartment (FOMC) model were fitted to the data.

**Table 3:** Fitting of kinetical models to residues on arthropods

| Category | n | SFO | | | FOMC | | |
|---|---|---|---|---|---|---|---|
| | | $DT_{50}$ | $DT_{90}$ | $\chi^2$ (5 % err. lvl.) | $DT_{50}$ | $DT_{90}$ | $\chi^2$ (5 % err. lvl.) |
| All | 81 | 2.1 | 6.8 | 24.1 | 0.9 | 23.4 | 15.3 |
| Ground and leaf dwellers | 70 | 2.1 | 6.9 | 25.6 | 0.8 | 27.0 | 16.6 |
| Ground dwellers | 39 | 3.5 | 11.7 | 19.5 | 1.6 | 173.8 | 14.4 |
| Leaf dwellers | 31 | 2.6 | 8.5 | 23.0 | 1.1 | 94.5 | 14.8 |

As visible from the $\chi^2$ values, only poor fits were achieved for SFO kinetics, whereas the FOMC model yielded slightly better fits for all categories. Thus, assessment should be focused on FOMC $DT_{90}$ values, which can be used to derive conservative estimates for surrogate first-order $DT_{50}$ values (needed for MAF and TWA estimation) by division by (ln 10/ln 2) = 3.32. It is obvious from the data that exclusion of the category flying insects did not have a great impact on the results, whereas splitting the datasets between ground- and leaf-dwelling arthropods resulted in much higher $DT_{90}$ values than for the aggregated data. However, taking into account the knowledge on mechanisms that will drive residue decline in arthropod food items, these extremely high $DT_{90}$ values for the split datasets are considered not reliable. Hence, surrogate first-order $DT_{50}$ values according to this kinetical assessment will amount to about 7.0 to 8.1 d.

Following the second approach, a simple comparison was made between the highest residue levels in the 0-7 d interval ($c_{max}$) and the last measured value ($c_{final}$). Trials with only one measurement and trials where the maximum residue level occurred at the final sampling date were excluded. Using the quotient $c_{final}/c_{max}$ and the time interval $t$ between the two corresponding sampling dates, an estimate $DT_{50}$ can be calculated according to the following equation.

$$DT_{50} = -\frac{t \times \ln 2}{\ln \frac{c_{final}}{c_{max}}}$$

This type of calculation was performed for all categories using the average, the median and the 90$^{th}$ percentile of $c_{final}/c_{max}$ and $t$, respectively.

**Table 4:** $DT_{50}$ estimates based on the ratio of maximum and final measured residues on arthropods

| Category | average | | | median | | | 90th %-ile | | |
|---|---|---|---|---|---|---|---|---|---|
| | $c_{final}/c_{max}$ | t | $DT_{50}$ | $c_{final}/c_{max}$ | t | $DT_{50}$ | $c_{final}/c_{max}$ | t | $DT_{50}$ |
| All | 0.30 | 5.10 | 2.9 | 0.22 | 5 | 2.3 | 0.61 | 7 | 9.9 |
| Ground and leaf dwellers | 0.32 | 5.04 | 3.1 | 0.26 | 5 | 2.6 | 0.61 | 7 | 9.9 |
| Ground dwellers | 0.35 | 5.07 | 3.4 | 0.31 | 5.5 | 3.2 | 0.63 | 7 | 10.3 |
| Leaf dwellers | 0.28 | 5.00 | 2.7 | 0.20 | 4.5 | 1.9 | 0.61 | 7 | 9.9 |

No significant differences are visible between the four categories. The results for average and median parameters are well in line with the SFO-$DT_{50}$ according to the kinetical analysis of average RUDs, while the results for 90th percentile parameters are in the same range (numerically slightly above) as the relevant surrogate first-order $DT_{50}$ values derived from FOMC-$DT_{90}$ values.

Overall, it can be concluded that a first-order pseudo-$DT_{50}$ of 10 d constitutes an appropriate basis for estimating MAF and TWA factors for arthropod food items in the context of a Tier 1 exposure assessment for generic focal species.

## Consequences of using MAF and TWA for arthropod food items and important aspects to consider for refinements

Exposure calculations for insectivorous birds or mammals according to EC (2002) were based on the assumption that each treatment in a multi-application scenario could be considered an independent event with respect to residues on arthropod food items. No accumulation of residues (i.e. no MAF) and no residue decline (i.e. no TWA) were considered. This will result in a higher level of protection for single-application scenarios (potential overestimation of exposure due to non-consideration of residue decline) than for multiple-application scenarios (potential underestimation of exposure due to non-consideration of potential for accumulation of residues).

Consequently, inclusion of MAF and TWA in exposure calculations will have different impacts on the scenarios with single and multiple applications compared to previous assessments carried out under EC (2002). As regards calculated peak exposure levels, these will not change compared to previous assessments for single applications, but will be higher due to the use of a MAF factor for multiple applications. If time-weighted averaging is considered, the actual factor by which calculated exposure will be lower or higher as compared to EC (2002) will depend on the number of applications, the interval between applications and the relevant TWA interval. An overview for four typical scenarios is provided in Table 5.

It should be kept in mind that using the default pseudo-$DT_{50}$ of 10 d for Tier 1 calculations does not imply that respective residue dynamics are most appropriately described by first-order degradation kinetics. Instead, the factors should be understood as generic descriptors for the possible extent of residue accumulation and decline. If refinement is intended, attempts should be made to realistically describe the expected time course of residues under conditions of use (see Appendix N for further information on how to carry out a residue study).

**Table 5:** Modification of calculated exposure as compared to EC (2002), due to consideration of MAF and TWA, for a default $DT_{50}$ of 10 d.

| TWA-inter-val | 1 applic. | 2 applic., interval 14 d | | 3 applic., interval 10 d | | 5 applic., interval 7 d | |
|---|---|---|---|---|---|---|---|
| | TWA only | $MAF_{90}$ | $MAF_m \times TWA$ (start of interval) | $MAF_{90}$ | $MAF_m \times TWA$ (start of interval) | MAF90 | $MAF_m \times TWA$ (start of interval) |
| 2 | 0.934 | 1.234 | 1.288 (d 14) | 1.467 | 1.634 (d 20) | 1.852 | 2.214 (d 28) |
| 3 | 0.903 | | 1.245 (d 14) | | 1.580 (d 20) | | 2.141 (d 28) |
| 10 | 0.721 | | 0.995 (d 14) | | 1.262 (d 20) | | 1.878 (d 21) |
| 21 | 0.527 | | 0.791 (d 0) | | 1.157 (d 10) | | 1.741 (d 14) |
| 28 | 0.441 | | 0.761 (d 0) | | 1.029 (d 10) | | 1.626 (d 7) |
| 60 | 0.237 | | 0.467 (d 0) | | 0.695 (d 0) | | 1.140 (d 0) |
| 90 | 0.160 | | 0.319 (d 0) | | 0.479 (d 0) | | 0.796 (d 0) |

For example, if a multi-application scenario is appropriately reflected in a test, then both the $MAF_{90}$ (highest peak measured) and $MAF_m \times TWA$ (area under residue versus. time curve) could be replaced with 'real' data. Another option could be to justify with data that multiple applications can be treated as single individual events, due to fast and quantitative decline of residue levels after each application. In case of broad-spectrum insecticides, the lethal effect on in-field arthropods might contribute to such fast decline.

However, any argumentation must account for aspects like the potential of residue increase in arthropod after application due to uptake from contaminated surfaces. Thus, refinement should not aim at simply replacing the default pseudo-$DT_{50}$ of 10 d by a different value, but should always include a detailed justification for the appropriateness of this value as discussed above in the explanation for the default pseudo-$DT_{50}$.

## References

FOCUS (Forum for the Co-ordination of pesticide fate models and their use), 2006. Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.

EC (European Commission – DG Health and Consumer Protection), 2002. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000 – final 25 September 2002, pp 74.[1]

[1] Available at: http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc19_en.pdf

# APPENDIX J

# PHASE-SPECIFIC APPROACH FOR REPRODUCTIVE RISK ASSESSMENT

This Appendix provides detailed information regarding the phase-specific approach for reproductive risk assessment for birds and mammals. The phase-specific approach was proposed by EFSA (2008) for use in first-tier assessments, but a Joint Working Group of representatives from DG Health and Consumers and nominated Member States (assisted by technical experts from EFSA) decided that it should instead be introduced as an option for use at higher tiers (EC, 2009). A detailed account of the reasons for developing a new approach is provided in Appendix 16 to the PPR Panel Opinion (EFSA, 2008).

### TOXICITY

Outlined in section 2.2 and 2.3 of the Guidance Document is information regarding the toxicity studies that are considered along with issues such as determining the appropriate endpoint, how to deal with data from more than one study or on more than one species, etc.

### EXPOSURE

The reproductive risk to both birds and mammals is assessed using the same process as outlined for the first tier reproductive risk assessment. Details regarding the indicator species and generic focal species and the relevant 'shortcut values' can be found in the Guidance Document.

### Use of a time-weighted average approach

The use of a 21-day time window in EC (2002) and in the first tier reproductive assessment (section 4 of this Guidance Document) is arbitrary. In the phase-specific methodology a different approach is proposed, that aims towards a more refined assignment of exposure periods. However, because the exposure periods are generally uncertain, each assessment is done twice, once assuming short-term effects and once assuming long-term effects. Guidance on how to use the results of these parallel assessments is provided later in this Appendix.

For birds it is proposed to run two parallel assessments, one assumes that the effects observed in the toxicity study are the result of short-term exposure (1-3 days depending on endpoint), whilst the other assessment assumes that the effects are the result of long-term exposure (21 days, again chosen arbitrarily). When better information is available to determine what time window is relevant, the assessment should be modified accordingly. As regards the mammalian assessment, use is made of whether an acute reference dose (ARfD) is required for the substance. If one is deemed to be necessary, then it is initially assumed that the reproductive effects may be the result of short-term exposure (1 day); if however an ARfD is not considered necessary, it is assumed that reproductive effects are the result of long-term exposure (up to 90 days, see below).

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix J. EFSA Journal 2009; 7(12):1438. [16 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

## PHASE-SPECIFIC ASSESSMENT FOR BIRDS

### Selection of the toxicity endpoints for the phase-specific approach

According to Bennett et al. (2005) a phase-specific approach makes greater use of information on specific reproductive and other toxicological endpoints. This information is used as a potential indication of the types of effects that could occur during the reproductive cycle. Bennett et al. (2005) divided the breeding cycle of birds into five phases, namely:

Phase 1 = pair formation and establishing site selection;

Phase 2 = copulation and egg laying ranging from 5 days pre-laying through to the end of the egg-laying period;

Phase 3 = incubation and hatching;

Phase 4 = juvenile growth and survival until fledging; and

Phase 5 = post-fledging

It is strongly recommended that Bennett et al. (2005) and the accompanying papers be consulted for a fuller explanation behind the phase specific approach and the selection of endpoints.

Some of the phases are further divided to reflect possible effects from extrinsic (pesticide exposure from the environment occurring coincidentally with the phase) and intrinsic (pesticide residues contained in the egg affecting a later stage of the breeding cycle) exposure. For precocial species (i.e. those species that are able to fend for themselves soon after hatching, e.g. ducks) phase 4 refers to the period when chicks are dependent on parents for brooding and protection and phase 5 refers to the older, more independent chicks. Full details regarding these five phases and their further breakdown into extrinsic and intrinsic exposure are provided in Bennett et al. (2005).

Further details regarding the selection of toxicity endpoints are provided below. It should be noted that if more than one study has been presented then it is necessary to extract all the following endpoints from all studies submitted. Section 2.3 of the Guidance Document should be consulted as to how to incorporate data from more than one study in to the risk assessment.

### Phase one

For phase one, i.e. pair formation and establishing site selection, it is assumed that pair formation and breeding site selection is essential for successful mating. This could be adversely affected by the behaviour of adults, for example, if their exposure is such that they are prevented from defending a territory. Unfortunately this effect is not measured directly in any of the available toxicity studies. A review of $LD_{50}$ studies shows that severe signs of toxicity likely to lead to deficits interfering with a bird's normal activities tend to be recorded at dosing levels greater than 1/10 of the $LD_{50}$ (Callaghan and Mineau, 2000; Appendix 11 of EFSA, 2008). On the basis of this work, it is proposed that 1/10 of the $LD_{50}$ be used. If the $LD_{50}$ is a limit dose and hence the endpoint is a 'greater' than value it is proposed to use the methodology outlined in section 2.1.2 of the Guidance Document to determine an $LD_{50}$.

It should be noted that for pesticides where the mode of action and/or results from mammalian studies indicate a potential for the $LD_{50}$ measured by a short term dietary study to be lower than the $LD_{50}$ based on an acute oral study then it may be more appropriate to use information from an avian dietary study. Bennett et al. (2005) recommend the use of bodyweight and food consumption endpoints from the avian reproduction study. EFSA (2008, Appendix 16) considered this approach to be too precautionary in the majority of cases because of the prolonged exposure period in the test – typically ten weeks. A shorter dietary dosing test with sub-adult birds has been proposed by an OECD committee (OECD 1986) but this protocol has never been formally accepted.

### Phase two

For phase two, i.e. copulation and egg-laying, it is assumed that adult behavioural effects that lead to reduced clutch size or abandonment of a nesting attempt could impact upon the success of copulation and

hence fertility, egg-laying or, possibly, eggshell quality. Unfortunately not all of these parameters are measured in the standard study and therefore it is proposed to use the lower of either:

- The NOAEL for the number of eggs laid per hen or
- The NOAEL for mean eggshell thickness.

Based on the work of Mineau et al. (1994a), it was determined that the number of eggs laid has a strong component of 'parental' toxicity and clusters with measures of weight loss or food intake in the currently-designed avian reproduction study. The number of eggs laid per hen was a measurement that was found to have the lowest NOAEL in a sample of studies analysed for the York workshop (see Mineau (2005) for further consideration of this issue).

**Phase three**

Phase three deals with the incubation of the clutch and hatching of young. Changes in the behaviour of the adult may adversely affect nest care and incubation ability and hence the same endpoint (i.e. 1/10 of the $LD_{50}$ from the acute oral study) used above in phase one is used again here. There may also be an impact on the fertility of the adult and hence the hatchability of eggs; this is indicated by the proportion of fertile eggs per eggs set per hen. (This endpoint may not be presented in the study; if this is the case then the most relevant endpoint is 'percent viable embryos over number of eggs set'). As regards toxicity to the embryo itself, the concern here is direct toxicity to the embryo and an indication of this can be obtained from the NOAEL for the proportion of hatching per fertile eggs set per hen. (This endpoint may not be presented in the study; if this is the case then the most relevant endpoint is 'percent hatching of viable embryos'.)

The endpoints required for phase 3 are:

- NOAEL for the proportion of fertile eggs per eggs set per hen; this endpoint may not be presented in the study, if this is the case then the most relevant endpoint is viability or 'percent viable embryos and number of eggs set'.
- NOAEL for the proportion of hatching per fertile eggs per hen; this endpoint may not be presented in the study, if this is the case, then the most relevant endpoint is hatchability or 'percent hatching of viable embryos' and
- 1/10 of the $LD_{50}$ for adult birds.

**Phase four**

Phase four deals with the growth and survival of the juvenile. There may be an adverse effect from exposure of the embryo in the egg (an intrinsic effect), so the NOAEL for the proportion of 14-day old juveniles per number of hatchlings is used. As regards extrinsic impacts on juvenile survival, Bennett et al. (2005) proposed to use an endpoint from the dietary ($LC_{50}$) study. However this study is problematic and difficult to interpret, for example it is difficult to determine a daily dose if food avoidance has occurred (see Mineau et al., 1994b). Therefore, it is proposed to use 1/10 of the adult $LD_{50}$ to assess the ability of juveniles to grow and develop. This is based on the assumption that for precocial young at least, there is no systematic difference between the relative sensitivity of young and adult (Hudson et al., 1972). There may be differences on a substance by substance basis but no systematic correction factor is possible. It should be noted that this may not be the case for altricial young (i.e. species where the young are tended by their parents, e.g. passerines) where, for cholinesterase-inhibiting chemicals at least, young are known to be more sensitive (Wolfe and Kendall, 1998). However, it is not known whether this difference applies to pesticides with other modes of action. In the absence of any further information, it is proposed that the $1/10LD_{50}$ toxicity endpoint should be matched to a specific chick exposure scenario. For further details on this issue see Appendix 5 of EFSA (2008).

**Phase five**

Finally, phase five assesses post-fledging survival therefore 1/10 of the LD50 adjusted for chick food intake rate is required as well as the NOAEL for 14-day old juvenile weights per hen from the reproduction study.

**Summary of toxicity endpoints required for the phase-specific approach**

The measured endpoints used in this approach fall into the three general categories (i.e., parental toxicity, developmental toxicity, and eggshell effects) as described by Mineau et al. (1994a) and Mineau (2005). In total, seven endpoints are required to carry out a phase-specific risk assessment in birds:

- 1/10 of the measured adult $LD_{50}$. If this value is a limit value (e.g. > 2000 mg/kg) see section 2.1.2 (phases 1, 3, 4 and 5)
- NOAEL for the number of eggs laid per hen (phase 2)
- NOAEL for mean eggshell thickness (phase 2)
- NOAEL for the proportion of fertile eggs per eggs set per hen; this endpoint may not be presented in the study, if this is the case then the most relevant endpoint is 'percent viable embryos and number of eggs set' (phase 3)
- NOAEL for the proportion of hatching per fertile eggs per hen; this endpoint may not be presented in the study, if this is the case, then the most relevant endpoint is 'percent hatching of viable embryos' (phase 3)
- NOAEL for the proportion of 14-day old juveniles per number of hatchlings (phase 4)
- NOAEL for 14-day juvenile weights per hen (phase 5)

If there is more than one study available, then endpoints should be extracted from all available studies. It should be noted that it may be possible to merge the studies (see section 2.3 of the Guidance Document for further details).

**Selection of exposure scenarios and associated risk assessment**

In order to address uncertainty about the appropriate exposure scenario for the phase-specific approach, two exposure scenarios are assessed, namely:

1. A scenario where the residue on treated food is assumed to be based on a 1- to 3-day period.
2. A scenario where the residue on treated food is assumed to be based on a 21-day period.

For the first scenario, it is assumed that a short exposure *could* lead to reproductive effects, whereas in the second scenario it is assumed that prolonged or long-term exposure *could* lead to reproductive effects. Each of the phase-specific endpoints outlined above is compared to a 21-day time-weighted average. It should be noted that this time window is used for all phases and that it is **arbitrary** and does not imply any biological relevance. This step is simply to try to determine, by comparing the two scenarios, what the potential effect on the risk assessment could be if the effects were the result of prolonged exposure.

**Determination of the daily dietary dose (DDD) estimates based on the assumption that reproductive effects are due to short-term exposure**

If the resulting TER produced as a result of the screening step breaches the Annex VI trigger of 5, then further refinement is required. In the first instance, it is assumed that the timing of application may overlap with breeding such that applications always occur on the first day of each phase. Therefore, each of the phase-specific toxicity endpoints outlined above should be compared to an exposure estimate that is pertinent to the endpoint (e.g. either single day maximum estimates or a biologically-appropriate time-weighted average). The DDD should initially be for a **generic focal species** (see Annex I of the Guidance Document, and the shortcut values for the mean RUD). Where more than one generic focal species is highlighted, the one that is relevant in terms of time of application or growth stage should be selected. Where there is more than one generic focal species in terms of timing, then it is proposed that risk assessment should be carried out with **all** relevant generic focal species and then refined as necessary.

**Daily dietary dose**

Once an appropriate generic focal species has been selected, then DDD based on 1-, 2-, and 3-day exposure should be determined. In order to calculate the DDD, it is necessary to select the appropriate generic focal species and the corresponding shortcut value based on mean RUD, then multiply this figure by the application rate in kg a.s./ha and if appropriate a time-weighted average or TWA figure (see below for further details). This then gives the DDD that can be compared to the appropriate toxicity endpoint.

The one-day DDD uses the initial exposure estimate. In order to calculate the 2 and 3-day DDD it is necessary to apply a TWA factor to the initial exposure estimate. For 2 days, the factor is 0.93 and 0.9 for 3 days. It is proposed that these values be used for both arthropods and vegetation (see Appendix H of the Guidance Document for details).

As regards the chick scenario it is proposed that a chick shortcut value of 3.8 and 22.7 should be used. These values are based on residues on ground and foliar dwelling arthropods (i.e. mean RUD of 3.5 and 21 respectively, see Appendix F of the Guidance Document) and food intake rate of chicks (see Appendix R of the Guidance Document). In the first instance both scenarios should be assessed. If either or both of the scenarios fail then refinement should include consideration of the dietary composition of chicks of relevant species. The following equation should be used:

$$DDD = application\ rate \times shortcut\ value \times TWA \times MAF_m$$

These DDD should then be compared to the appropriate toxicity endpoint relevant for the exposure period; this is summarised below in Table 1.

**Table 1** Summary of the relevant DDD that need to be generated for each phase.

| Phase | Breeding phase | Type of effect | Test endpoint used as surrogate | DDD[1] |
|---|---|---|---|---|
| 1 | Pair formation/ breeding site selection[2] | Extrinsic adult | 1/10 of $LD_{50}$ | 1-day maximum DDD for relevant generic focal species. |
| 2 | Copulation and egg laying (5 days pre-laying through end of laying) | Extrinsic adult | NOAEL for the number of eggs laid per hen | 1-day maximum DDD for relevant generic focal species. |
| | | Extrinsic adult | NOAEL for mean eggshell thickness | 1-day maximum DDD for relevant generic focal species. |
| 3 | Incubation and hatching | Extrinsic adult | 1/10 of $LD_{50}$ | 1-day maximum DDD for relevant generic focal species. |
| | | Extrinsic adult | NOAEL for proportion of viable eggs per eggs set per hen | 1-day maximum DDD for relevant generic focal species. |
| | | Intrinsic juvenile | NOAEL for proportion hatchling per viable eggs per hen | Ovum development 3-day time-weighted average (TWA). |
| 4 | Juvenile growth and survival until fledging[2] | Extrinsic adult | 1/10 of $LD_{50}$ | 2-day TWA DDD[3]. |
| | | Extrinsic juvenile | 1/10 of $LD_{50}$ | 1-day DDD based on chick shortcut value of 3.8 and 22.7 |
| | | Intrinsic juvenile | NOAEL for proportion of 14-day-old juveniles per number of hatchlings per hen | Ovum development 3-day TWA DDD[4]. |
| 5 | Post-fledging survival[2] | Extrinsic juvenile | 1/10 of $LD_{50}$ | 1-day DDD based on chick shortcut value of 3.8 and 22.7 |
| | | Intrinsic juvenile | NOAEL for 14-day-old juvenile weights per hen | Ovum development 3-day TWA DDD[4]. |

1. DDD is based on the application rate in kg a.s./ha, multiplied by the 'shortcut value' based on mean RUD (see Annex I of the Guidance Document) and any appropriate TWA factor. If multiple applications are made then multiple application factors (MAF) as outlined in table 2 are used.
2. The types of behavioural effects on territorial defence and pairing can occur very rapidly after exposure, so the toxicity endpoint should be compared with the maximum exposure concentration estimated for any single day. If pesticide application occurs during this phase, the exposure based on the short-term is appropriate. This will also be the case for extrinsically-affected juvenile survival and post-fledging survival.
3. Nestlings that are still in the process of yolk absorption are capable of withstanding temporary abandonment by the adult. Bennett et al. (2005) proposed that a 2-day time-weighted average (TWA) be used to reflect the fact that a nesting attempt may not necessarily fail if the parents are temporarily prevented from caring for the young by a fast-disappearing substance.

4. The endpoint for embryo toxicity is compared to the TWA for an exposure period equivalent to length of time for an ovum to develop in the species or range of species of concern. This assumes that the primary in ovo exposure is from material deposited in the yolk during the formation of an ovum or by maternal transfer from feathers to the eggshell and subsequent absorption into the egg. Based on the rapid follicular development period in small passerines, it is proposed to use a 3-day window for calculating the TWA.
(Further details regarding the rationale behind the selection of time windows are provided in Bennett et al., 2005.)

**Determination of daily dietary dose based on the assumption that reproductive effects are due to long-term exposure**

Having determined appropriate toxicity endpoints for each phase and then compared them to DDD based on the assumption that the effects seen were due to *short-term* exposure, it is now necessary to repeat the exercise, however this time it is assumed that the effects seen were the result of **long-term exposure**. It should be noted that this step is only necessary if the TER from the above assessment are less than 5.

Each of the phase-specific endpoints outlined above is compared to a 21-day time-weighted average. This time-window is used for all phases. The selection of this time window is **arbitrary** and does not imply any biological relevance, this step is simply to try to determine, along with the above assessment, what the potential effect on the risk assessment could be if the effects were the result of prolonged exposure.

In order to determine the exposure estimates, or DDD, the same procedure regarding selection of generic focal species should be followed. In calculating the 21-day time weighted average DDD it is assumed that the $DT_{50}$ for pesticides on vegetation is 10 days (see EC, 2002). As regards arthropods, there is no standard default value based on measured values as there is for vegetation; however it is considered that in the first instance it is possible to use the same data as for vegetation and hence a $DT_{50}$ of 10 days is proposed (see Appendix H of the Guidance Document for further details). Using these assumptions the 21-day TWA factor is 0.53. For single applications, this factor, along with the application rate, should be combined with the shortcut value based on mean RUD. For multiple applications, the relevant MAF from the Guidance Document should be used.

The following equation should be used:

$$DDD = application\ rate \times shortcut\ value \times TWA \times MAF_m$$

Presented in Table 2 is a summary of the relevant toxicity endpoints as well as the DDD that need to be generated for each phase.

**Table 2** Summary of the relevant DDD that need to be generated for each phase.

| Phase | Breeding phase | Type of effect | Test endpoint used as surrogate | DDD[1] |
|---|---|---|---|---|
| 1 | Pair formation/ breeding site selection | Extrinsic adult | 1/10 of $LD_{50}$ | 21-day TWA DDD[2, 3] |
| 2 | Copulation and egg laying (5 days pre-laying through end of laying)[4] | Extrinsic adult | NOAEL for the number of eggs laid per hen | 21-day TWA DDD[2] |
| | | Extrinsic adult | NOAEL for mean eggshell thickness | 21-day TWA DDD[2] |
| 3 | Incubation and hatching | Extrinsic adult | 1/10 of $LD_{50}$ | 21-day TWA DDD[2] |
| | | Extrinsic adult | NOAEL for proportion of viable eggs per eggs set per hen | 21-day TWA DDD[2] |
| | | Intrinsic juvenile | NOAEL for proportion hatchling per viable eggs per hen | 21-day TWA DDD[2] |
| 4 | Juvenile growth and survival until fledging[3] | Extrinsic adult | 1/10 of $LD_{50}$ | 21-day TWA DDD[2] |
| | | Extrinsic juvenile | 1/10 of $LD_{50}$ | 21-day TWA DDD[2] based on chick shortcut value of 3.8 and 22.7 |
| | | Intrinsic juvenile | NOAEL for proportion of 14-day-old juveniles per number of hatchlings per hen | 21-day TWA DDD[2] |
| 5 | Post-fledging survival[3] | Extrinsic juvenile | 1/10 of $LD_{50}$ | 21-day TWA DDD[2] based on chick shortcut value of 3.8 and 22.7 |
| | | Intrinsic juvenile | NOAEL for 14-day-old juvenile weights per hen | 21-day TWA DDD[2] |

1. DDD is based on the application rate in kg a.s./ha, multiplied by the 'shortcut value' based on mean RUD (see Annex I) and any appropriate TWA factor. If multiple applications are made then multiple application factors (MAF) as outlined in table 2 are used.
2. The selection of a 21-day time window is arbitrary and arbitrary and does not imply any biological relevance, this step is simply to try to determine, along with the above assessment what the potential effect on the risk assessment could be if the effects were the result of prolonged exposure. The use of the output of this risk assessment should be considered alongside the output from the assessment assuming that effects are the result of short-term exposure.
3. Although derived from an acute study, using 1/10 $LD_{50}$ is considered to make the long-term assessment sufficiently conservative overall (see section 3.5 of Guidance Document). Using parental endpoints from the reproduction study would be likely to over-estimate risk as they are measured over longer time scales of constant exposure than is ecologically relevant.
4. The types of behavioural effects on territorial defence and pairing can occur very rapidly after exposure, so the toxicity endpoint should be compared with the maximum exposure concentration estimated for any single day. If pesticide application occurs during this phase, the exposure based on the short-term is appropriate. This will also be the case for extrinsically-affected juvenile survival and post-fledging survival.

### Interpretation and use of the TER for the phase-specific approach

Following the above procedure, it is possible that there could be two TER per toxicity endpoint – one assuming that the effects are the result of short-term exposure and the other assuming that the effects are the result of long-term exposure. Outlined in Table 3 below is guidance on how to interpret and hence use the outputs from the above assessment.

**Table 3** Summary table on how to interpret the outcome from the phase-specific risk assessment

| Scenario | Assessment outcomes | | |
|---|---|---|---|
| 1 to 3-day DDD (i.e. effects are based on short-term exposure) | TER≥5 | TER<5 | TER<5 |
| 21-day DDD scenarios (i.e. effects are based on long-term exposure.) | TER≥5 | TER≥5 | TER<5 |
| ***Next Steps*** | No further refinement required | Further refinement is required. The outcome of the risk assessment indicates that one possible refinement step is to try to determine if the effects are the result of short-term exposure. | Further refinement is required, however, the outcome of the risk assessment indicates that little will be gained by additional effects data and hence trying to determine if the effects are the result of short-term exposure, it is recommended that refinements should concentrate on effects, and the potential consequences of effects. |

**Further refinement of the phase-specific approach for birds**

If the substance and associated use under consideration has 'passed' the assessment assuming that the effects are the result of long-term exposure, but 'failed' when it is assumed that exposure is the result of short-term exposure, then it may be possible to carry out further toxicity studies to determine if effects are due to short or long-term exposure (see below for further details). It should be noted that due to animal welfare reasons, refining the risk by using modified toxicity studies should not be the first option; refinements to the exposure estimates should be considered first, as well as the potential consequences of effects before additional toxicity studies are contemplated.

Refine the residue element of the initial DDD – in the above assessment default residue information has been used; and it has also been assumed that the $DT_{50}$ on vegetation and arthropods is 10 days. It is feasible that initial residues as well as the speed of residue decline may differ from these initial default assumptions; therefore, it is possible to refine the residue element of the DDD calculation.

If a more realistic indication of the initial residues for the substance and use under consideration is required then residue studies should be carried out as outlined in the Guidance Document. Once substance specific residue data have been obtained, it will be necessary to re-run the scheme.

Refine ecological parameters – In the above assessment a generic focal species has been used; in using this it is assumed that the bird obtains all of its food from the treated areas and that its diet is realistically worst case. It is possible to refine these ecological elements of the exposure estimate by first determining the appropriate focal species (FS) for the crop under consideration (see section 6.1.3 of Guidance Document). It should be noted that the focal species selected should represent species breeding in and around the crop of concern, and hence should be worst case in terms of food intake, use of crop and breeding behaviour. It should further be noted that the FS selected may not be the same as used to refine the acute risk assessment.

Having selected a suitable FS, it is possible to determine the composition of diet obtained from the treated area (PD); the methodology for doing this is outlined in section 6.1.6 of the Guidance Document. It is also possible to determine the proportion of food that the bird or mammal obtains from the treated crop (PT), and details of how to do this are presented in section 6.1.5 of the Guidance Document. Section 6 of the Guidance Document provides details on how to combine the refinement steps as well as issues to consider when combining them.

Assess the broods at risk – the above phase-specific approach assumes that every phase of every reproductive attempt is maximally exposed. In reality, only a proportion of birds will be exposed and

furthermore, for those which are exposed, the peak exposure may not occur during the most sensitive reproductive phase.

In order to assess the number of broods at risk, it is essential to identify a suitable focal species. Once a suitable focal species has been identified, information on the possible start dates and durations for each phase of reproduction is required. Information is also required on the proportion of the population of the focal species that visit treated fields, i.e. consumers, as well as a scale of interest to the risk manager (i.e. local, national, international population scale). This information can then be combined with information on the timing of pesticide applications. Once this information is available, the exposure can be assessed and then compared to the relevant toxicological endpoint for each reproductive phase. The final output should be an estimate of the proportion of broods at risk, i.e. the proportion of reproductive attempts where exposure in one or more phases exceeds the relevant toxicological endpoint (including the appropriate uncertainty factor). Examples of this approach were provided by Shore et al. (2005) and Roelofs et al. (2005). User-friendly population models able to integrate timing of application with breeding cycle information for a number of generic species are currently being developed and tested by the US EPA (Rick Bennett, pers. comm.). It is expected that they will be available shortly, making this approach potentially attractive.

Field trials – Theoretically it is possible to carry out a field study to assess the potential effects on reproduction, however from a practical point of view, this refinement step is not really practical. It has long been suggested (OECD 1996) that residue levels in eggs should be measured in the current protocol in order to allow a comparison with residue levels in eggs taken from focal species in the field. This may provide some possibility for refinement where the effects are the result of intrinsic exposure, i.e. material transferred into the egg influencing embryo development and survival. (Further details are presented in Section 6.4 of the Guidance Document)

Population modelling – if despite the above refinements, there is still concern regarding the risk to birds, then one option would be to assess the risk at the population level. Unfortunately there are no population models that can be readily used or adapted for use in pesticide risk assessment. This should not, however, preclude their use, possible examples of population models are presented in Topping et al. (2005), Sibly et al. (2005), Roelofs et al. (2005) and Wang and Grimm (2007).

Refine the risk assessment via the use of modified toxicity studies – As stated above, it may be possible to refine the risk assessment by carrying out a modified toxicity study. Due to animal welfare reasons, this should not be first option and it is recommended that the exposure refinements as well as an assessment of the consequences of effects should be considered first.

## PHASE-SPECIFIC ASSESSMENT FOR MAMMALS

Provided below is a detailed explanation of the proposed risk assessment process for mammals. This scheme is based on EFSA (2006) and Bennett et al. (2005) and it is recommended that these documents are consulted to provide further explanation behind the following scheme.

In the following section the text is laid out with information on how to select toxicity endpoints, how to determine the daily dietary dose, and then how to refine the risk assessment.

### Selection of the toxicity endpoints for the phase-specific approach

According to the PPR opinion (EFSA, 2006a) a phase-specific approach makes greater use of information on specific reproductive and other toxicological endpoints. This information is used as a potential indication of the types of effects that could occur during the reproductive cycle. The PPR divided the breeding cycle of mammals into four phases, namely:

Phase 1 – establishing a breeding site, pairing and mating

Phase 2 – pregnancy

Phase 3 – pup growth and survival until weaning

Phase 4 – post-weaning survival until maturity

Full details regarding these four phases are provided in EFSA (2006a) as well as Bennett et al. (2005). Further details regarding the toxicity endpoints required are provided below. Details regarding the studies and determination of endpoints is presented in section 2.2 of the Guidance Document.

### Phase one

For phase one, i.e. establishing a breeding site, pairing and mating, it is assumed that pair formation and breeding site selection is essential for successful mating. This could be adversely affected by the behaviour of adults leading to territory abandonment or delayed or abnormal mating, or systemic effect leading to reduced fertility. In order to try to assess this risk, it is proposed that effects on body weight, indices of mating, indices of fertility and systemic toxicity are required and information on these endpoints is obtained from either a single dose (e.g. modified $LD_{50}$ type or acute neurotoxicity study if performed), 28 (if available) or 90-day toxicity test and two-generation tests.

An evaluation of the single dose toxicity study can be found at B.6.2.1 of the draft assessment report (DAR), the acute neurotoxicity study (if performed) can be found at B.6.7.1 of the DAR, whilst the two-generation study can be found at B.6.6.1. It should be noted that the 28-day study, if performed, can be found at B.6.3.1 of the DAR along with the 90-day study.

It is proposed that the four studies listed above should be examined for the following toxicological endpoints – body weight, indices of mating, indices of fertility and systemic toxicity. In the first instance the lowest overall NOAEL should be selected.

### Phase two

For phase two, i.e. pregnancy, effects on pup and litter parameters developmental abnormalities and maternal effects are of concern. According to the PPR opinion, in order to try to assess the effects on pup and litter parameters, the two-generation study should be consulted and NOAEL for the indices of gestation, litter size, pup and litter weight, indices of viability and pre- and post-implantation loss should be obtained. The two-generation reproduction study can be found in Section B.6.6.1 of the DAR. The lowest NOAEL from this study(ies) should be obtained for the above parameters.

As regards abnormalities, it is proposed that the pre-natal developmental toxicity test and/or the two-generation reproduction study are consulted. The NOAEL for the embryo/foetal toxicity including teratological effects should be obtained. The pre-natal development toxicity test - this should be in Section B.6.6.2 of the DAR

As regards the maternal effects, the prenatal development toxicity test should be consulted and the NOAEL for the number aborting and the number delivering early should be obtained.

**Phase three**

As regards phase three, this deals with pup growth and survival until weaning. In order to try to assess the risk re-adult behavioural effects leading to abnormal litter care, it is proposed that information on systemic toxicity and effects on adult body weight should be considered. This information may be obtained from single dose, 28 (if available) or 90-day toxicity test and two-generation tests and hence the lowest NOAEL for systemic toxicity and effects on body weight should be obtained.

As regards effects on post-natal litter and pup parameters, it is proposed that the two-generation test should be considered and the NOAEL for indices of post-natal growth, indices of lactation and data on physical landmarks be obtained.

**Phase four**

Phase four deals with the post-weaning survival until maturity. In order to try to assess the risk, it is proposed that information on juvenile survival, growth and development be obtained from either the single dose studies or the two-generation reproduction study. The use of the single dose studies may be useful if there are no effects at the top concentration tested in the two generation study. It should be noted that if this approach is followed then the endpoint will be based on survival or overt signs of toxicity. Other studies might also provide useful information but are not always available for many substances, e.g. acute neurotoxicity study or developmental neurotoxicity study. It is proposed that in the first instance the lowest overall NOAEL should be selected.

**Note** – it is possible that there may be more than one study to address a specific endpoint, if this is the case, see the refinement section at the end of this Appendix for further details.

**Conclusion**

In conclusion the endpoints presented in Table 4 are required to carry out a phase-specific risk assessment.

**Table 4.** Source of information for the different mammalian reproductive phases.

| Phase | Source of information |
|---|---|
| One<br>(Establishing a breeding site, pairing and mating) | Data from single dose studies and the 90-day study and if available the 28-day study as well as the two-generation study should also be consulted for information on body weight change/behavioural effects and systemic toxicity[1]. As regards indices of mating and fertility the two-generation study should be consulted. In the first instance the lowest NOAEL should be used.<br>There should be one endpoint for this phase. |
| Two<br>(Pregnancy) | For effects on pup and litter parameters, the two-generation reproduction study should be consulted and the NOAEL regarding the indices of gestation, litter size, pup and litter weight[2], indices of viability, pre- and post-implantation loss should be selected. (NB some information on these endpoints may be obtained from developmental studies.)<br>For developmental abnormalities, the prenatal development toxicity test and/or the two-generation reproduction study should be consulted for embryo/foetal toxicity including teratological effects and lowest NOAEL should be selected.<br>For maternal toxicity, the prenatal development toxicity test should be consulted for the number aborting and number delivering early and the lowest NOAEL selected.<br>There should be a total of three NOAEL for this phase. |
| Three<br>**(**pup growth and survival until weaning) | This phase deals with the potential effects on parents bringing up young as well as on the young themselves.<br>In order to try to assess the risk re-adult behavioural effects leading to abnormal litter care (e.g. reducing feeding of young etc which would not be seen in laboratory studies, e.g. due to readily available food supply), information on systemic toxicity and effects on adult body weight should be considered and the lowest overall NOAEL be obtained from either the single dose, 28 (if available) or 90-day toxicity test and two-generation tests. The results of the 2-generation study would generally take precedence over the effects seen in the 28 or 90 day study.<br>As regards effects on the young themselves, i.e. post-natal litter and pup parameters, the 2-generation study should be consulted for endpoints for indices of post-natal growth[3], indices of lactation and data on physical landmarks and the lowest overall NOAEL obtained.<br>There should be two NOAEL for this phase. |
| Four<br>(Post-weaning survival and maturity) | The single dose studies and the two-generation study should be assessed to determine in the first instance the lowest NOAEL for survival and general toxicity up to sexual maturity.<br>There should be one NOAEL for this phase**.** |

1. Effects derived from absorption of the substance that causes modification of an organ or an apparatus (biochemical, physiological and/or morphological). Examples include behavioural or physiological impairment (e.g. reduced locomotive activity, altered reflexes)
2. Any effects in foetal body weight should be evaluated in the context of all pertinent data including other developmental effects as well as maternal toxicity.
3. For example body weight gain, ear and eye opening, tooth eruption, hair growth and effects on sexual maturation such as age and body weight at vaginal opening or balano-preputial separation.
4. NB Please note for points 2 and 3 above a slight, e.g. 1 day, delay in obtaining a particular endpoint or developmental milestone can be ignored, however longer delays could be considered as adverse. This is based on a frequency of measuring and hence is a pragmatic approach. Please note that a 1 d delay may be of importance for certain substances and it should be checked that it is not treatment related before discounting it.

### Determination of daily dietary doses

In order to carry out a risk assessment it is necessary to have information on the toxicity of the substance and then compare this to the likely exposure levels. In trying to determine likely exposure levels, it is proposed to use the mammalian toxicity assessment and in particular whether an 'acute reference dose' (ARfD) has been determined.

An ARfD is determined for those substances that are considered to cause effects following short-term exposure. It is usual that an ARfD is based on just oral routes of exposure and hence normally only reflects this route of exposure. It should also be noted that the ARfD is dose dependant, i.e. if an extremely high dose of any substance were tested, then it would it could be possible to set an ARfD, however it is being used in this context to highlight those substances likely to cause effects with long-term consequences following short-term exposure and hence are most concern. It should be further noted that for solid formulations the ARfD may not be totally appropriate due to concerns regarding the concentrations tested in relation to the potential DDD, in these circumstances it is proposed that the assessor should determine if the product is classified in terms of acute oral toxicity; if it is then it can be assumed, in the first instance, that effects with long-term consequences may be the result of short-term exposure. For further information on ARfD see Solecki et al. (2005)[1].

Where an ARfD has been determined it can be concluded that effects in the reproduction repeat dose or developmental studies *may* have been the result of single or short-term exposures. In these cases, it is proposed that estimated theoretical exposure estimate or DDD are based, in the first instance, on a short time window.

It should be noted that it is **not** proposed to use the ARfD itself, but merely use it as an indicator as to whether the effects seen are the result of short or long-term exposure.

If, as a result of the mammalian toxicology assessment, no ARfD is considered necessary then it can be assumed that any effects seen are the result of long-term or continuous exposure. If this is the case it is proposed that the following time windows can be used:

- If the endpoint from a two-generation study is being used and an ARfD is not considered necessary, then it is assumed that the effects are the result of the 60 day pre-mating period, therefore a 60-day TWA is proposed.
- If the 90-day study is being used and an ARfD is not considered necessary, then it is assumed that the effects are the result of 90 days exposure, therefore, a 90-day TWA is proposed.
- If the 28-day study is being used and an ARfD is not considered necessary, then it is assumed that the effects are the result of 28 days exposure, therefore a 28-day TWA is proposed.
- If the prenatal study has been used and an ARfD is not considered necessary, this it is assumed that the effects are the result of 10 days exposure as the animals are dosed generally from day 6 to 16, therefore a 10-day TWA is proposed.
- If an endpoint from a single-dose study is providing the lowest NOAEL, it is proposed that a 1-day DDD is used.

It should be noted that shorter time windows should be used if there is any indication in these studies of adverse effects occurring during the study, for example if in the 90-day study there were effects at 20 days, then a 20-day TWA should be used.

It is accepted that in certain circumstances the lowest NOAEL may come from the longest study, and hence when combined with a TWA calculated over a long period, will result in a high TER; whereas the next highest NOAEL may come from a shorter study, and hence when combined with a TWA calculated over a short time period may produce a lower TER. Whilst this is possible it is considered that this is unlikely to be a serious issue due to the influence of dose spacing and arbitrary selection of doses in the above studies.

Outlined in Table 5 is a summary of the relevant DDD that need to be generated for each phase. The rationale behind the time-windows proposed for those substances where an ARfD is not considered necessary is outlined above. The rationale for those where there is an ARfD is provided in EFSA (2006), however, it can be summed up that there is the potential for the effects to be the result of a one off or a short-term exposure and hence a 1-day DDD is used.

[1] Solecki R., Davies L., Dellarco V., Dewhurst I., van Raaij M., and Tritscher A. (2005) Guidance on setting of acute reference dose (ARfD) for pesticides. Food and Chemical toxicology 43 (2005) 1569 – 1593.

**Table 5.** Summary of relevant DDD that need to be generated for each phase.

| Phase | Breeding phase | Endpoint | DDD – assuming ARfD is necessary | DDD – assuming ARfD is not considered necessary |
|---|---|---|---|---|
| 1 | Establish breeding site, pairing and mating | NOAEL to reflect body weight change/behaviour effects.<br>NOAEL for systemic toxicity[1] | 1-day DDD[4]<br><br>1-day DDD | TWA will depend on the study used, but could range from 1 day to 90 day – see above for details |
| | | NOAEL for mating<br>NOAEL for fertility | 1-day DDD<br>1-day DDD | |
| 2 | Pregnancy | NOAEL for gestation, litter size, pup and litter weight[2], indices of viability, pre- and post-implantation loss | 1-day DDD | |
| | | NOAEL for embryo/foetal toxicity including teratological effects | 1-day DDD | |
| | | NOAEL for number aborting<br>NOAEL for number delivering early | 1-day DDD<br><br>1-day DDD | |
| 3 | Pup growth and survival until weaning | NOAEL for systemic toxicity/body weight change/behaviour effects | 1-day DDD | |
| | | NOAEL for indices of lactation/post-natal growth/for physical landmarks[3] | 1-day DDD<br>1-day DDD<br>1-day DDD | |
| 4 | Post-weaning survival until maturity | NOAEL for survival or general toxicity up to 4 weeks of age. | 1-day DDD | |

1. Effects derived from absorption of the substance that causes modification of an organ or an apparatus (biochemical, physiological and/or morphological). Examples include behavioural or physiological impairment (e.g. reduced locomotor activity, altered reflexes)
2. Any effects in foetal body weight should be evaluated in the context of all pertinent data including other developmental effects as well as maternal toxicity.
3. For example body weight gain, ear and eye opening, tooth eruption, hair growth and on sexual maturation such as age and body weight at vaginal opening or balano-preputial separation.
   (Please note that for points 2 and 3 above a slight, e.g. 1 day, delay in obtaining a particular endpoint or developmental milestone can be ignored, however longer delay of greater than 1 day could be considered as adverse. This is based on a frequency of measuring and hence is a pragmatic approach. Please note that a 1 day delay may be of importance for certain substances and it should be checked that it is not treatment related before discounting it.)
4. 1-day DDD is the initial exposure estimate.

The DDD should be based, in the first instance, on a **generic focal species** and the shortcut value based on the mean RUD should be used. Where more than one generic focal species is highlighted, the one that is relevant in terms of time of application or growth stage should be selected. Where there is more than one generic focal species in terms of timing etc, then it is proposed that risk assessment should be carried out with all relevant generic focal species and then refined as necessary.

In determining the above DDD it is necessary to use the shortcut value based on the mean RUD (see Annex I of the Guidance Document and shortcut values based on the mean RUD), the application rate in kg a.s./ha and the appropriate TWA value. For the one-day DDD the initial exposure estimate should be used, and hence no TWA factor should be applied. In order to calculate the 10, 28, 60 and 90 days DDD outline above it is necessary to apply a TWA factor to the initial exposure. For 10 days, the factor is 0.72, for 28 days, the factor is 0.44; for 60 days the factor is 0.24 and for 90 days the factor is 0.16. It is

proposed that these TWA factors and related MAF factors are applicable to both arthropods and vegetation (see Appendix H of the Guidance Document for further details). (Please note that it is possible that, depending upon the effects seen and the studies used to derive the endpoints, other TWA factors may be required. If this is the case, please see Appendix H of the Guidance Document for details.)

The following equation should be used:

$$DDD = application\ rate \times shortcut\ value \times TWA \times MAF_m$$

In order to calculate the TER it is necessary to combine the information on the toxicity at each phase with the potential exposure at each phase. If the substance under consideration has an ARfD then DDD based on the information in column 4 in the Table 5 should be used; however if an ARfD is not considered necessary then the information in Column 5 should be used.

**Calculation of TER for phase-specific approach using generic focal species for the average scenario**

Having determined the various NOAEL as well as the various exposure estimates as outlined above, they should be compared to obtain TER. Each TER should be compared to the Annex VI trigger value of 5. If the $TER_{repro}$ is greater than 5 then it can be assumed that the risk to this particular stage is 'acceptable', however if the TER is less than 5, then further work is required.

**Further refinement of the phase-specific approach for mammals**

Outlined below is a selection of possible refinement steps, these can be used individually or combined together. Before considering any of the following refinement steps it is important to read section 6 of the Guidance Document on refinement options, and in particular ensure that the likely level of protection that will result from the refined risk assessment is the level wanted by the risk manager.

Re-examination of the mammalian toxicity dataset – In the above assessment the lowest relevant NOAEL has been selected for each phase. It may be valid to re-examine the mammalian toxicity dataset and confirm that the NOAEL used is also the lowest biologically relevant NOAEL (see section 2.2.1 of Guidance Document). It is not proposed for this step to use the geometric mean approach due to difficulties regarding the determination of an appropriate time window for the time-weighted average calculation.

Re-assessment of the exposure period relevant to the toxicity endpoints – If the substance under consideration has an ARfD, it has initially been assumed that all the effects seen were the result of a single- or short-term exposure. However, this may not have been the case and hence there is scope to refine the toxicity endpoint. Therefore, it may be worthwhile revisiting the toxicity endpoints to determine if they are totally appropriate. If this refinement step is chosen, it is recommended to discuss with a mammalian toxicologist.

Refine the residue element of the initial DDD – It is possible to refine the residue element of the DDD calculation. To do this, data are required on either the initial residue values or/and the residue decline. Details regarding refining the risk using specific residue data are provided in section 6.1.4 of the Guidance Document.

Refine ecological parameters – Focal species (FS), composition of diet obtained from treated area (PD) and proportion of an animal's daily diet obtained in habitat treated with pesticide (PT). – It is possible to refine the DDD by using more relevant data on the ecological components of the risk assessment, i.e. FS, PT and PD (see sections 6.1.3, 6.1.5 and 6.1.6 of the Guidance Document).

Assess the litters at risk – The above phase-specific approach assumes that every phase of every reproductive attempt is maximally exposed. In reality, only a proportion of mammals will be exposed and furthermore, for those that are exposed, the peak exposure may not occur during the most sensitive reproductive phase. Assessing the risk by comparing the exposure to the relevant reproductive phase is the primary advantage of the phase-specific approach. However, concerns regarding the availability of data (e.g. time of application of the pesticide, time of breeding phases for focal species etc) exist. Despite these concerns, refining the risk to breeding mammals is still considered a viable alternative if the data are available.

In order to assess the number of litters at risk, it is essential to identify a suitable focal species (see section 6.1.3 of the Guidance Document). Once a suitable focal species has been identified, information on the possible starting dates and durations for each phase of reproduction is required.

Field trials – Effects on reproduction for small mammals may be studied by using capture-mark-release-recapture techniques to monitor population density and age structure (see section 6.4 of the Guidance Document).

Population modelling – If, despite the above refinements, there is still concern regarding the risk to mammals, then one option would be to assess the risk at the population level. Unfortunately, there are no population models that can be readily used or adapted for use in pesticide risk assessment. Existing possible examples of population models are presented in Topping et al. (2005), Sibly et al. (2005), Roelofs et al. (2005) and Wang and Grimm (2007). It should be noted that the models included in these references are not endorsed but are provided as an indication of the types of studies that are available. Due to the complexity of this issue, it is envisaged that each assessment would be on a case-by-case basis.

## REFERENCES

See reference list in Guidance Document.

# APPENDIX K

# BACKGROUND INFORMATION ON THE ASSESSMENT OF UPTAKE VIA DRINKING WATER

## Relevant crops for the leaf scenario and calculation of $PEC_{pool}$

The leaf scenario, i.e. the uptake of contaminated water collected in leaf whorls, reflects specific concerns that were raised by incidents reported in Germany. Cole crops were treated with highly acute pesticides during a long dry period and irrigated shortly thereafter. Birds were attracted by the water collected in the leaf whorls of the crop plants, which resulted in a great number of observed mortalities due to the action of the pesticide dissolved in the water (Schietinger and Hoffmann, 1984; Hommes et al., 1990).

With regard to the risk to birds, the leaf scenario clearly reflects a worst-case situation. It is relevant for spray applications only. Formation of pools that would serve as drinking water supply for birds requires a certain plant morphology. Leaves must point upwards and at the same time must be closely pressed against other leaves or the stem at their basis to form cavities that could hold water over a considerable amount of time. Also, these structures must be accessible to birds, i.e. they must be able to sit on the plant for drinking. Considering these criteria, the following crop categories are proposed to be relevant for an assessment according to the leaf scenario:

- Leaf vegetables (forming heads) at principal growth stage 4 until harvest (classification according to BBCH[1]).
- Other leaf vegetables (e.g. cauliflower) at principal growth stage 4 or later, with a morphology that facilitates collection of rain/irrigation water in reservoirs that are large enough and easily accessible to attract birds and sufficiently stable over some hours.

The leaf scenario is not deemed relevant for small mammals as no concurrent poisoning of mammals was reported for the sites with bird incidents.

Based on measurements conducted at the sites of incidents, it was concluded that the worst-case concentration in water would correspond to the concentration in the spray solution (i.e. the product already diluted in the required amount of water), diluted by a factor of 5.

[1] Biologische **B**undesanstalt, **B**undessortenamt und **CH**emische Industrie

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix K. EFSA Journal 2009; 7(12):1438. [6 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

$$PEC_{pool} = \frac{C_{spray}}{5}$$

With:

$PEC_{pool}$ = Predicted environmental concentration in the pool of the leaf whorl

### Calculation of $PEC_{puddle}$ for the puddle scenario

The puddle scenario accounts for the uptake of contaminated water collected in puddles on soil. To obtain an estimate for pesticide concentrations in puddles formed on a field after rainfall ($PEC_{puddle}$), it may be assumed that this concentration would be the same as the concentration in runoff water as calculated for the assessment of surface water exposure. The FOCUS[2] surface water model employs the PRZM[3] for estimating these runoff contributions to $PEC_{sw}$, which could thus in principle be used for estimating $PEC_{puddle}$ under appropriate worst case conditions.

However, runoff entries in surface water as calculated in FOCUS Step 3 reflect the effect of all precipitation events after pesticide application in the modelled time period, whereas puddles on the field are deemed to be related to one precipitation event only. Also, many input parameters are required to run the model. Nevertheless, closer inspection of the intended scenario reveals the potential for using a simplified model. In first instance, concentrations in runoff water are identical to concentrations in the pore water diluted by rainfall. While the subsequent calculation of actual runoff entries in surface water bodies requires complex calculations of water outflow from the field, this is not necessary for estimating $PEC_{puddle}$. Thus, a simplified model without water outflow routines can be proposed to calculate $PEC_{puddle}$ as a function of application rate and the organic carbon adsorption coefficient ($K_{OC}$) of a substance. As long as the full application rate is considered, this approach assumes application to bare soil without degradation and thus reflects a worst case for crop-directed applications. Where appropriate, crop interception may be considered in the same way as for calculation of $PEC_{soil}$, $PEC_{gw}$ and $PEC_{sw}$, in order to increase realism.

The standard assumptions for $PEC_{soil}$ calculations from the Fate section are applied, i.e. a field soil layer with a depth of 5 cm and a density of 1.5 kg/L. For pesticides incorporated into the soil, a soil layer of 5 cm or deeper (reflecting actual incorporation depth) is relevant. Depending on the distribution coefficient $K_d$ of the substance, a part of it is sorbed to the soil matrix and the remaining part is dissolved in the pore water. Only the latter part is of interest for further considerations.

$$X_{pw} = \frac{V_{pw}}{V_{pw} + V_s \times d \times K_d}$$

With:

$X_{pw}$ = fraction of substance in pore water

$V_{pw}$ = volume of pore water

$V_s$ = volume of soil – here per field area: 0.05 $m^3/m^2$ (at 5 cm depth)

[2] Forum for the Co-ordination of pesticide fate models and their use
[3] Pesticide Root Zone Model

d = soil density – 1.5 kg/L (default)

$K_{d\,=}$ distribution coefficient of the substance

To achieve $V_{pw}$ after rainfall, the amount of precipitation per m² is added to the pore water volume before rainfall. A realistic estimate for the latter considers a moisture level of 50 % of field capacity with field capacity 0.4 $m^3/m^3$. Multiplication of the figures for 50 % field capacity and soil depth yields 0.01 $m^3/m^2$ as pore water volume before rainfall.

The amount of precipitation must be fixed at a level high enough to ensure production of runoff water, but all precipitation above this threshold will lead to dilution of concentrations in runoff water. In FOCUS surface water, the pesticide application timer (PAT) is used for setting the application date due to the requirement that at least 10 mm of precipitation be received within ten days following application (FOCUS, 2001). Therefore, a value of 10 mm = 10 $L/m^2$ is assumed in this model. So, with a $K_d$ of 1, the fraction in pore water would be:

$$X_{pw} = \frac{0.02}{(0.02 + 0.05 \times 1 \times 1.5)} = 0.21$$

The pesticide concentration in the pore water is then calculated as follows:

$$C_{pw} = \frac{X_{pw} \times AR/10}{V_{pw}}$$

With:

AR = application rate in g/ha; divisor of 10 to achieve rate in $mg/m^2$

For $K_d = 1$ and an application rate of 1 kg/ha (100 $mg/m^2$), the concentration, taking into account a divisor of 1000 for recalculation from $m^3$ to L, would thus amount to:

$$C_{pw} = \frac{0.21 \times 100}{0.02 \times 1000} = 1.05 mg/L$$

As stated above, only a part of this diluted pore water will leave the field as runoff, while the concentration of the water remaining in puddles on the field will not change; only the actual volume of water in puddles would be affected. So, it can be concluded that $PEC_{puddle} = C_{pw}$.

For use in the context of the bird and mammal risk assessment, the $K_d$ parameter is replaced by the more likely available $K_{OC}$ (ie. $K_d$ normalised to the organic carbon content $frac_{OC}$ of the soil, $K_{OC} = K_d / frac_{OC}$). This requires introducing a standard factor for $frac_{OC}$ in the calculation where 2 % is proposed as a typical value for field soils. The equations can then be combined and rearranged to give $PEC_{puddle}$ in mg/L as a function of application rate and $K_{OC}$, taking into account a divisor of 1000 for recalculation from $m^3$ to L.

$$PEC_{puddle} = \frac{AR/10}{1000(w + Koc \times s)}$$

With:

AR = application rate [g/ha]; divisor of 10 to achieve rate in mg/m$^2$

$w$ = $V_{pw}$ = 0.02 (pore water term)

$s$ = $V_s \times d \times frac_{OC}$ = 0.0015 (soil term)

When multiple spray applications are considered, a multiple application factor (MAF) based on the $DT_{50}$ in soil (single first order kinetics, geometric mean as used for $PEC_{gw}$ and $PEC_{sw}$) may be applied to achieve the effective application rate $AR_{eff}$.

$$AR_{eff} = AR \times MAF_m = AR \times \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

With:

$k$ = $\ln(2)/DT_{50}$ (rate constant)

$n$ = number of applications

$i$ = application interval (d)

**Drinking water rates (DWR) for indicator bird species (potential use in refined RA)**

New data on water demand and water balance of birds have recently been made available as drinking water rates (DWR) by Defra4 (2007). Conceptually, these are based on the work of Nagy and Peterson (1988) who provided allometric equations for total water fluxes for birds as well as for mammals. Drinking water rates can be calculated from these values by subtracting the water amounts contained in food items and metabolic water formed during food digestion. For calculation of the latter, data on the daily energy expenditure (DEE) of animals as well as on food water content and metabolic water production are required, which can be either found in Appendices G and L or in the report by Defra (2007). DWRs for selected generic focal species representing different dietary guilds are presented in Table 1 and Table 2 below, together with further information on how they were derived. In principle, such values may also be used for assessing the risk from combined dietary and drinking water uptake of a pesticide for a focal species. However, it should be noted that no robust and reliable model for assessing such combined exposure can currently be proposed.

[4] **Department for Environment, Food and Rural Affairs**

**Table 1.** Drinking water rates (DWR) for selected generic focal bird species after Defra (2007).

| Generic FS | BW | Food type | FIR (fresh mat.) | Moist. | Food water | Water flux | | Metabolic water | DWR | DWR/ BW |
|---|---|---|---|---|---|---|---|---|---|---|
| | (g) | | (g/d) | (%) | (mL) | Equation | Flux (mL/d) | (mL) | (mL/d) | |
| Granivorous bird 'finch' | 15.3 | Cereal seeds | 5.4 | 14.7 | 0.8 | Passerine[1] | 9.8 | 2.0[3] | 7.0 | 0.46 |
| Insectivorous bird 'warbler' | 9.5 | Arthropods | 9.2 | 68.8 | 6.3 | Passerine[1] | 6.1 | 1.4[4] | -1.6 | -0.17 |
| Large herbivorous bird 'goose' | 3108 | Grasses, cereal shoots | 782.9 | 76.4 | 598.1 | All birds[2] | 490.5 | 68.7[5] | -176.3 | -0.06 |
| Medium herbivorous bird 'partridge' | 390 | Non-grass herbs | 214.2 | 88.1 | 188.7 | All birds[2] | 110.5 | 10.4[5] | -88.6 | -0.23 |

[1] log WF = log a + b × log BW; with log a = -0.195, b = 1.003
[2] log WF = log a + b × log BW; with log a = 0.183, b = 0.718
[3] factor for seeds from bird studies: 0.0294 mL/kJ
[4] factor for insects from bird studies: 0.0257 mL/kJ
[5] mean factor: 0.0278 mL/kJ

**Table 2.** Drinking water rates (DWR) for selected generic focal mammal species after Nagy and Peterson (1998) and Defra (2007).

| Generic FS | BW | Food type | FIR (fresh mat.) | Moist. | Food water | Water flux | | Metabolic water | DWR | DWR/ BW |
|---|---|---|---|---|---|---|---|---|---|---|
| | (g) | | (g/d) | (%) | (mL) | Equation | Flux (mL/d) | (mL) | (mL/d) | |
| Granivorous mammal 'mouse' | 21.7 | Cereal seeds | 4.5 | 14.7 | 0.7 | Non-desert species[1] | 7.4 | 1.6[2] | 5.1 | 0.24 |
| Insectivorous mammal 'shrew' | 9.7 | Arthropods | 5.3 | 68.8 | 3.6 | Non-desert species[1] | 4.1 | 0.9[2] | -0.4 | -0.04 |
| Small herbivorous mammal 'vole' | 25.0 | Grasses, cereal shoots | 34.1 | 76.4 | 26,0 | Non-desert species[1] | 8.3 | 1.8[2] | -19,5 | -0.78 |
| Medium herbivorous mammal 'rabbit' | 1543 | Non-grass herbs | 791.6 | 88.1 | 697.4 | Non-desert species[1] | 169.9 | 34.5[2] | -562,0 | -0.36 |

[1] log WF = log a + b × log BW; with log a = -0.110, b = 0.734
[2] mean factor: 0.0278 mL/kJ

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# APPENDIX L

# ENERGY, MOISTURE CONTENT AND ASSIMILATION EFFICIENCY OF BIRD AND MAMMAL FOOD

This Appendix contains the document

**"Energy, moisture content and assimilation efficiency of bird and mammal food"**

by C.E. Smit.[1]

[1] In: Factsheets for the (eco)toxicological risk assessment strategy of the National Institute for Public Health and the Environment, Part V, eds. J.W.A. Scheepmaker, C.E. Smit, M.T.M. van Raaij, RIVM report 601516013/2005, Bilthoven, The Netherlands.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix L. EFSA Journal 2009; 7(12):1438. [18 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

**"Energy, moisture content and assimilation efficiency of bird and mammal food".**

**Author: C.E. Smit**

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## 1. Introduction

The risk assessment for birds and mammals as performed within the framework of EU Directive 91/414/EC is based on a comparison of the estimated daily uptake of a pesticide with the toxic dose for that compound. The principles of the risk assessment are laid down in a guidance document (EC, 2002). The main exposure route is assumed to be ingestion of food items containing spray residues. Additional exposure may take place by secondary poisoning via eating of contaminated earthworms or fish.

For the exposure via sprayed food, the daily pesticide uptake for a given species is determined by the daily intake of a specific food type (Food Intake Rate, FIR), the concentration of the pesticide in that food, the fraction of the diet that is contaminated, the fraction of a specific food type in the total diet and the potential to avoid contaminated food. The FIR is equal to the daily energy expenditure divided by the energy content of the food with a correction for assimilation efficiency expressed per day. For the standard risk assessment, four typical bird and mammal species are distinguished, in combination with four different food types. In order to establish the FIR for these four indicator species, data on DEE, energy and moisture content and assimilation efficiency have been collected at the Central Science Laboratory in York, United Kingdom (Crocker *et al.*, 2002).

For caloric values, the CSL dataset contains about 2000 data, which are grouped into 15 different food categories. A summary of the data as presented in the CSL report is given in Table 1.

**Table 1.** Energy and moisture content of several food sources (Crocker *et al.*, 2002).

| Group | Energy content [kJ/g DW] | Moisture content [%] |
|---|---|---|
| Dicot. crop leaves | 11.2 | 88.6 |
| Grasses and cereal shoots | 18.0 | 76.4 |
| Non-grass herbs | 18.0 | 82.1 |
| Tree leaves | 20.7 | 51.4 |
| Orchard topfruit | 11.6 | 83.7 |
| Cereal seeds | 16.7 | 13.3 |
| Weed seeds | 21.0 | 11.9 |
| Small mammals | 21.7 | 68.6 |
| Bird and mammal carrion | 22.6 | 68.8 |
| Arthropods | 21.9 | 70.5 |
| Caterpillars | 21.7 | 79.4 |
| Soil invertebrates (earthworms and slugs) | 19.3 | 84.6 |
| Fish | 20.7 | 71.1 |
| Aquatic invertebrates | 19.6 | 77.3 |
| Aquatic vegetation | 15.0 | 81.4 |

For assimilation efficiency of *birds*, the average data as presented by Bairlein (1998) are used by CSL. For assimilation efficiency of *mammals*, the dataset contains 91 individual records. Resulting values are given in Tables 2 and 3 below.

**Table 2.** Assimilation efficiency [%] of different food types for birds (Crocker *et al.*, 2002; taken from Bairlein, 1998)

| Bird order | Representatives | Food type | | | | | | n | n |
|---|---|---|---|---|---|---|---|---|---|
| | | animals | fruits | herbage | seeds | sugars | artificial | species | cases |
| Struthioniformes | Ostriches | | | 36 | | | | 2 | 6 |
| Gruiformes | Cranes, coots, rails | 34 | 45 | 59 | | | 69 | 1 | 5 |
| Ralliformes | Coots, rails | | | | | | | 1 | 1 |
| Charadriiformes | Gulls, waders | 69 | | | | | 74 | 7 | 19 |
| Lariformes | Gulls, terns | 79 | | | | | | 1 | 3 |
| Alciformes | Auks | 76 | | | | | | 1 | 2 |
| Sphenisiciformes | Penguins | 75 | | | | | | 7 | 26 |
| Procellariformes | Petrels | 87 | | | | | | 2 | 3 |
| Pelecaniformes | Pelicans, gannets, cormorants | 80 | 76 | | | | | 4 | 8 |
| Columbiformes | Pigeons | | | | | | 76 | 4 | 36 |
| Psittaciiformes | Parrots | | | | | 96 | | 1 | 4 |
| Strigiformes | Owls | 77 | | | | | | 6 | 45 |
| Falconiformes | Eagles, falcons | 84 | | | | | | 4 | 12 |
| Accipitriformes | Hawks | 82 | | | | | | 11 | 22 |
| Ciconiiformes | Herons, storks | 80 | | | | | | 4 | 8 |
| Anseriformes | Ducks, geese | 87 | | 41 | 83 | | 74 | 22 | 98 |
| Galliformes | Fowl | 70 | 57 | 42 | 65 | | 67 | 18 | 184 |
| Opisthocomiformes | Hoatzin (S. America) | | | | | | 74 | 1 | 2 |
| Trochiliformes | Hummingbirds | | | | | 98 | | 7 | 16 |
| Coliiformes | Mousebirds (Africa) | | 56 | | | | 73 | 4 | 14 |
| Piciformes | Woodpeckers | 64 | | 61 | | | 80 | 1 | 14 |
| Passerriformes | Passerines | 76 | 67 | 76 | 80 | 09 | 72 | 67 | 441 |

**Table 3.** Assimilation efficiency [%] of different food types for mammals (Crocker *et al.*, 2002).

| Mammal species | Food type | mean | SD | n |
|---|---|---|---|---|
| shrews and bats | insects | 88 | 5.9 | 8 |
| Carnivores | vertebrates | 85 | 5.8 | 16 |
| Squirrels | nuts | 85 | 7.5 | 10 |
| small mammals | seeds and nuts | 83 | 8.5 | 11 |
| small mammals | grasses | 46 | 10.7 | 15 |
| small mammals | crops, forbs, mixed vegetation | 74 | 12.3 | 17 |
| Lagomorphs | general vegetation | 74 | 13.5 | 4 |
| white tailed deer | tree tissue | 32 | 8.4 | 7 |
| Ruminants | hay and browse | 80 | 2.8 | 3 |

About 10 years ago, a similar dataset has been established at the RIVM to be used in a food chain model for birds and mammals. The data were published in an RIVM report (Jongbloed *et al.*, 1994) and referred to by Traas *et al.* (1996). The purpose of the current project was to combine both datasets to obtain a more complete database which in the future can be used to refine the existing exposure scenarios and to establish scenarios for new indicator species.

## 2. Methods

### 2.1 Caloric values, moisture and ash content

#### 2.1.1 Data arrangement

A first comparison the two datasets with respect to caloric value and moisture content indicated that there was little overlap in literature sources. This can be explained by the

fact that these data are often published as part of a different type of research, and are thus not found with a keyword based literature search.

Both datasets were available as Excel-spreadsheets in which data for different organism groups were ordered, but not to the same taxonomic level. After combining both files, data were therefore first sorted by scientific species names. Obvious duplicates with the same literature reference were removed. For suspected duplicates, those values that were (nearly) the same but originated from different sources, the original reference was retrieved where possible and the numbers were checked. It appeared that a number of references in both the CSL and the RIVM file were review papers and in addition, various data originated from different papers by the same author(s). Duplicate values could therefore often be attributed to citations or self-citations.

After removal of duplicates, taxonomic position of the species was checked and/or completed using the Integrated Taxonomic Information System on-line database, http://www.itis.usda.gov, an internet database containing authoritative taxonomic information on plants, animals, fungi and microbes. Data were then ordered into the following main groups: fungi, annelids, molluscs, fish, arthropods, seeds, tree and plant tissue, fruit, birds, mammals, fodder and other. Additional information on life form or habitat was also obtained from the internet.

### 2.1.2 Data treatment and statistical methods

The CSL dataset contained information on caloric content on a dry weight basis (kJ/g DW) and % moisture, the RIVM dataset has additional values for caloric content on the basis of fresh weight (kJ/g FW) and ash-free dry weight (kJ/g AFDW), and for % ash content. After re-arranging the dataset, missing variables were calculated from the other parameters where possible, if kJ/g DW and % ash were available, kJ/g AFDW was calculated, kJ/g FW was calculated from kJ/g DW and % moisture and so on.

Data within each main group were subdivided on the basis of taxonomic level, habitat and/or life stage or because it is anticipated that birds or mammals forage on a specific type of food. Statistical analyses were performed with GraphPad Prism 4.0. Significant differences in caloric content between sub-groups were identified using the dry weight data, because this parameter had the highest number of observations and the smallest variation within subgroups. In case of a comparison between two sub-groups, an unpaired two-sided t-test was used; three or more groups were compared using one-way ANOVA with Tukey's multiple comparison of means. Non-parametric variants were used in case data were not normally distributed and/or variances were not homogeneous. P was 0.05 in all cases.

## 2.2 Assimilation efficiency

### 2.2.1 Birds

For assimilation efficiency of *birds*, Dr. Franz Bairlein of the Institute of Avian Research in Wilhelmshaven, Germany, kindly supplied the underlying data on which the CSL overview was based. It appeared that this dataset, with over 1200 entries, completely covers the RIVM data. This means that for birds, the values as presented in the CSL report (see Table 2) remain unchanged.

### 2.2.2 Mammals

For assimilation efficiency of *mammals*, the CSL and RIVM database relied partly on different literature sources. A comparable strategy as presented above was followed, except that food was not classified to the species level but only sorted by category. The following food types were distinguished: fodder, vertebrates, insects, nuts and seeds, grasses, non-grass herbs/crops and mixed plants, and tree tissue. The different food sources were compared taking all mammals together. Where possible, differences between mammal groups for one type of food were analysed.

## 3. Results

### 3.1 Caloric values, moisture and ash content

For each of the main groups, the average, standard deviation, minimum and maximum and number of observations for the respective parameters are given in the summary tables below. The Coefficient of Variation (CV) is the standard deviation expressed as percentage of the mean (= [SD/mean] x 100 %). The results of the statistical analysis of the kJ/g DW data are given in separate tables.

### 3.1.1 Annelids

The annelids were divided into terrestrial and aquatic species. No further division in life stage or habitat (freshwater or marine) was made because too few data were available. Terrestrial and aquatic annelids did not significantly differ in caloric content (two-sided t-test, $P > 0.05$).

**Table 4.** Caloric values, moisture and ash content of annelids.

| Parameter | Subgroup | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **kJ/g FW** | all values | 3.1 | 1.5 | 49 | 0.6 | 9.4 | 31 |
| | terrestrial | 3.2 | 0.3 | 8 | 2.7 | 3.5 | 8 |
| | aquatic | 3.1 | 1.8 | 57 | 0.6 | 9.4 | 23 |
| **kJ/g DW** | all values | 18.7 | 4.7 | 25 | 8.9 | 31.5 | 48 |
| | terrestrial | 18.7 | 3.0 | 16 | 13.0 | 22.2 | 16 |
| | aquatic | 18.6 | 5.4 | 29 | 8.9 | 31.5 | 32 |
| **kJ/g AFDW** | all values | 21.6 | 2.8 | 13 | 19.7 | 23.6 | 2 |
| | terrestrial | 23.6 | - | - | - | - | 1 |
| | aquatic | 19.7 | - | - | - | - | 1 |
| **% H2O** | all values | 82.8 | 5.9 | 7 | 62.0 | 97.6 | 31 |
| | terrestrial | 83.3 | 1.4 | 2 | 80.0 | 85.0 | 10 |
| | aquatic | 82.5 | 7.2 | 9 | 62.0 | 97.6 | 21 |
| **% ash** | all values | 0.8 | - | - | - | - | 1 |
| | terrestrial | 0.8 | - | - | - | - | 1 |
| | aquatic | - | - | - | - | - | |

### 3.1.2 Molluscs

A sub-division was made between terrestrial gastropods and aquatic gastropods, bivalves and cephalopods. Only few data were available for the latter group and they were not included in the statistical analysis. There was a significant difference in caloric content between terrestrial and aquatic gastropods and between aquatic gastropods and bivalves. Bivalves and terrestrial gastropods did not significantly differ, and terrestrial gastropods were not significantly different from terrestrial annelids (see above).

**Table 5.** Caloric values, moisture and ash content of molluscs.

| Parameter | Subgroup | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **kJ/g FW** | all values | 2.2 | 1.5 | 69 | 0.6 | 6.9 | 68 |
| | terrestrial gastropods | - | - | - | - | - | - |
| | aquatic gastropods | 2.1 | 1.6 | 73 | 0.8 | 6.9 | 34 |
| | bivalves | 1.9 | 1.1 | 61 | 0.6 | 4.9 | 29 |
| | cephalopods | 4.7 | 0.8 | 17 | 3.6 | 5.6 | 5 |
| **kJ/g DW** | all values | 18.2 | 3.6 | 20 | 3.8 | 27.7 | 95 |
| | terrestrial gastropods | 20.0 | 1.3 | 7 | 17.2 | 21.9 | 9 |
| | aquatic gastropods | 16.8 | 4.2 | 25 | 3.8 | 27.7 | 49 |
| | bivalves | 19.3 | 2.0 | 10 | 14.3 | 25.5 | 35 |
| | cephalopods | 23.8 | 0.4 | 2 | 23.5 | 24.0 | 2 |
| **kJ/g AFDW** | all values | 25.2 | 7.5 | 30 | 14.6 | 54.6 | 24 |
| | terrestrial gastropods | 22.5 | 2.6 | 12 | 19.8 | 25.0 | 3 |
| | aquatic gastropods | 26.8 | 7.9 | 30 | 20.7 | 54.6 | 18 |
| | bivalves | 18.6 | 3.5 | 19 | 14.6 | 21.3 | 3 |
| | cephalopods | - | - | - | - | - | - |
| **% $H_2O$** | all values | 86.8 | 10.7 | 12 | 42.8 | 96.9 | 77 |
| | terrestrial gastropods | 85.7 | 3.2 | 4 | 80.2 | 90.6 | 17 |
| | aquatic gastropods | 84.5 | 14.5 | 17 | 42.8 | 96.0 | 34 |
| | bivalves | 91.7 | 5.5 | 6 | 75.6 | 96.9 | 24 |
| | cephalopods | 78.9 | 4.0 | 5 | 76.0 | 81.7 | 2 |
| **% ash** | all values | 35.0 | 19.5 | 56 | 1.0 | 74.6 | 21 |
| | terrestrial | 22.8 | - | - | - | - | 1 |
| | aquatic | 37.3 | 20.0 | 54 | 1.0 | 74.6 | 18 |
| | bivalves | 19.8 | 10.7 | 54 | 12.2 | 27.3 | 2 |
| | cephalopods | - | - | - | - | - | - |

**Table 6.** Comparison of mean caloric content (kJ/g DW) for molluscs.

| | all values | terrestrial gastropods | aquatic gastropods | bivalves | cephalopods |
|---|---|---|---|---|---|
| all values | | | | | |
| terrestrial gastropods | | | * | n.s. | |
| aquatic gastropods | | * | | ** | |
| Bivalves | | n.s. | ** | | |
| cephalopods | | | | | |

| | |
|---|---|
| ** | significant, one-way ANOVA with Tukey's, P < 0.01 |
| * | significant, one-way ANOVA with Tukey's, P < 0.05 |
| n.s. | not significant, one-way ANOVA |
| | not tested |

### 3.1.3 Arthropods

The arthropods were divided into aquatic and terrestrial species and for each group a subdivision was made between larvae or sub-adults on the one hand, and adults, mixed or non-specified life-stages on the other hand. The aquatic species were also divided into marine and freshwater species. It should be noted that for most of the freshwater species only the larval stage is truly aquatic. The adults often have a wet habitat, but do not actually live in the water. Caloric values are presented in Table 7, moisture and ash-content in Table 8.

**Table 7.** Caloric values of arthropods.

| Parameter | Subgroup | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **kJ/g FW** | all values | 5.6 | 2.8 | 50 | 0.9 | 22.5 | 166 |
| | aquatic and terrestrial, larvae | 6.3 | 3.2 | 51 | 1.9 | 14.7 | 28 |
| | aquatic and terrestrial, adults | 5.4 | 2.7 | 50 | 0.9 | 22.5 | 138 |
| | aquatic, freshwater and marine | 4.9 | 2.6 | 52 | 0.9 | 22.5 | 113 |
| | aquatic, freshwater | 5.1 | 2.7 | 53 | 0.9 | 22.5 | 98 |
| | aquatic, freshwater, larvae | 3.6 | 0.8 | 22 | 2.9 | 4.7 | 4 |
| | aquatic, freshwater, adults | 5.1 | 2.7 | 53 | 0.9 | 22.5 | 94 |
| | aquatic, marine, adults | 4.0 | 1.3 | 32 | 1.6 | 5.5 | 14 |
| | terrestrial | 7.0 | 2.7 | 39 | 1.9 | 14.7 | 53 |
| | terrestrial, larvae | 6.8 | 3.2 | 47 | 1.9 | 14.7 | 23 |
| | terrestrial, adults | 7.1 | 2.4 | 34 | 3.1 | 14.0 | 30 |
| **kJ/g DW** | all values | 21.7 | 3.8 | 17 | 7.4 | 31.0 | 582 |
| | aquatic and terrestrial, larvae | 22.4 | 3.2 | 14 | 10.3 | 31.0 | 185 |
| | aquatic and terrestrial, adults | 21.4 | 4.0 | 19 | 7.4 | 30.9 | 397 |
| | aquatic, freshwater and marine | 20.1 | 4.3 | 21 | 7.4 | 29.2 | 232 |
| | aquatic, freshwater | 20.9 | 3.5 | 17 | 9.0 | 29.2 | 202 |
| | aquatic, freshwater, larvae | 20.9 | 3.7 | 18 | 10.3 | 29.2 | 49 |
| | aquatic, freshwater, adults | 20.9 | 3.5 | 17 | 9.0 | 28.0 | 153 |
| | aquatic, marine, adults | 15.3 | 5.5 | 36 | 7.4 | 25.2 | 29 |
| | terrestrial | 22.7 | 3.0 | 13 | 10.3 | 31.0 | 350 |
| | terrestrial, larvae | 23.0 | 2.8 | 12 | 11.8 | 31.0 | 135 |
| | terrestrial, adults | 22.6 | 3.2 | 14 | 10.3 | 30.9 | 215 |
| **kJ/g AFDW** | all values | 23.7 | 2.5 | 10 | 16.0 | 31.6 | 257 |
| | aquatic and terrestrial, larvae | 23.5 | 2.1 | 9 | 18.3 | 29.8 | 80 |
| | aquatic and terrestrial, adults | 23.7 | 2.6 | 11 | 16.0 | 31.6 | 177 |
| | aquatic, freshwater and marine | 22.9 | 2.6 | 12 | 16.0 | 31.1 | 118 |
| | aquatic, freshwater | 23.0 | 2.7 | 12 | 16.0 | 31.1 | 110 |
| | aquatic, freshwater, larvae | 23.3 | 2.4 | 10 | 19.1 | 29.8 | 34 |
| | aquatic, freshwater, adults | 22.8 | 2.8 | 12 | 16.0 | 31.1 | 76 |
| | aquatic, marine, adults | 21.6 | 1.9 | 9 | 19.1 | 24.4 | 8 |
| | terrestrial | 24.4 | 2.1 | 9 | 18.3 | 31.6 | 139 |
| | terrestrial, larvae | 23.7 | 1.9 | 8 | 18.3 | 29.2 | 46 |
| | terrestrial, adults | 24.7 | 2.1 | 9 | 19.2 | 31.6 | 93 |

The relatively low dry weight based value for marine arthropods (15.3 kJ/g DW) is caused by the inclusion of crabs in this dataset, which all had a lower energy content as compared to the other groups (mainly shrimps). The most probable explanation for this is that the exoskeleton was included in the analysis. The dataset for ash free dry weight energy content only contained shrimps and the resulting mean value is comparable with that of the other arthropod groups.

**Table 8.** Moisture and ash content of arthropods.

| Parameter | Subgroup | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **% $H_2O$** | all values | 71.5 | 9.4 | 13 | 38.1 | 96.0 | 265 |
| | aquatic and terrestrial, larvae | 72.7 | 10.0 | 14 | 46.6 | 92.0 | 57 |
| | aquatic and terrestrial, adults | 71.1 | 9.2 | 13 | 38.1 | 96.0 | 206 |
| | aquatic, freshwater and marine | 75.9 | 8.8 | 12 | 38.1 | 96.0 | 99 |
| | aquatic, freshwater | 76.3 | 8.0 | 10 | 61.0 | 96.0 | 83 |
| | aquatic, freshwater, larvae | 79.9 | 8.3 | 10 | 74.0 | 85.8 | 2 |
| | aquatic, freshwater, adults | 76.2 | 8.0 | 11 | 61.0 | 96.0 | 81 |
| | aquatic, marine, adults | 74.0 | 12.7 | 17 | 38.1 | 89.8 | 15 |
| | terrestrial | 68.8 | 8.7 | 13 | 44.2 | 92.0 | 166 |
| | terrestrial, larvae | 72.4 | 10.1 | 14 | 46.6 | 92.0 | 54 |
| | terrestrial, adults | 67.0 | 7.4 | 11 | 44.2 | 82.8 | 110 |
| **% ash** | all values | 7.6 | 9.4 | 124 | 0.0 | 56.0 | 219 |
| | aquatic and terrestrial, larvae | 8.8 | 10.1 | 114 | 0.0 | 48.0 | 65 |
| | aquatic and terrestrial, adults | 7.1 | 9.1 | 129 | 0.1 | 56.0 | 154 |
| | aquatic, freshwater and marine | 11.9 | 11.1 | 93 | 0.0 | 56.0 | 96 |
| | aquatic, freshwater | 11.1 | 10.4 | 94 | 0.0 | 48.0 | 88 |
| | aquatic, freshwater, larvae | 13.7 | 12.8 | 93 | 0.0 | 48.0 | 31 |
| | aquatic, freshwater, adults | 9.6 | 8.5 | 89 | 0.8 | 31.7 | 57 |
| | aquatic, marine, adults | 21.0 | 15.0 | 71 | 7.0 | 56.0 | 8 |
| | terrestrial | 4.2 | 6.1 | 145 | 0.1 | 55.0 | 123 |
| | terrestrial, larvae | 4.4 | 2.2 | 50 | 0.5 | 8.9 | 34 |
| | terrestrial, adults | 4.2 | 7.1 | 169 | 0.1 | 55.0 | 89 |

There was no significant difference in caloric content of adults and larvae within the terrestrial and freshwater groups, the marine group contained only one value for the larval stage. There was a significant difference between the caloric content of marine and freshwater adults, the same was found for the grouped means of freshwater and terrestrial arthropods (Table 9).

**Table 9.** Comparison of mean caloric content (kJ/g DW) for arthropods.

| | aq. + terr. all | aq. + terr. larvae | aq. + terr. adults | freshwater, all | freshwater, larvae | freshwater, adults | marine, adults | terrestrial, all | terrestrial, larvae | terrestrial, adults |
|---|---|---|---|---|---|---|---|---|---|---|
| aquatic + terrestrial, all | | | | | | | | | | |
| aquatic + terrestrial, larvae | | | n.s. | | | | | | | |
| aquatic + terrestrial, adults | | n.s. | | | | | | | | |
| Freshwater, all | | | | | | | | *** | | |
| Freshwater, larvae | | | | | | n.s. | | | | |
| Freshwater, adults | | | | | n.s. | | *** | | | |
| marine, adults | | | | | | *** | | | | |
| terrestrial, all | | | | *** | | | | | | |
| terrestrial, larvae | | | | | | | | | | n.s. |
| terrestrial, adults | | | | | | | | | n.s. | |

*** significant, t-test, P < 0.001
n.s. not significant, t-test, P > 0.05
not tested

### 3.1.4 Tree and plant tissue

Tree and plant tissue data were divided on the basis of life form (trees or plants) and taxonomy (*Poaceae* and other plants) and for plants, a subdivision was made on the basis of the plant parts analysed. Caloric content of various plant parts was not significantly

different, as was the case for the difference between cereals and other grasses. Caloric content is given in Table 10, moisture and ash content of tree and plant tissue is given in Table 11.

**Table 10.** Caloric values of tree and plant tissue.

| Parameter | Subgroup | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **kJ/g FW** | tree tissue | 9.9 | 0.8 | 8 | 9.0 | 11.1 | 5 |
| | conifer needles | 9.5 | 0.0 | 0 | 9.5 | 9.6 | 2 |
| | crop leaves (incl. pods) | 1.1 | 0.6 | 53 | 0.5 | 2.3 | 20 |
| | cereals and grasses | 3.9 | 1.7 | 43 | 2.3 | 6.1 | 6 |
| | cereals | 2.4 | 0.1 | 4 | 2.3 | 2.4 | 2 |
| | other grasses | 4. | 1.6 | 34 | 2.5 | 6.1 | 4 |
| | plants, all values | 1.9 | 1.1 | 56 | 0.8 | 3.5 | 8 |
| | plants, leaves | - | - | - | - | - | - |
| | plants, roots | 1.9 | 1.0 | 55 | 0.8 | 3.0 | 4 |
| | plants, stems and branches | - | - | - | - | - | - |
| | plants, miscellaneous | 2.6 | 1.1 | 41 | 1.2 | 3.5 | 4 |
| **kJ/g DW** | tree tissue | 20.2 | 0.9 | 4 | 18.9 | 21.9 | 16 |
| | conifer needles | 21.2 | 0.8 | 4 | 20.0 | 22.3 | 13 |
| | crop leaves (incl. pods) | 11.4 | 3.0 | 26 | 6.3 | 16.7 | 21 |
| | cereals and grasses | 17.6 | 1.5 | 8 | 12.7 | 20.9 | 68 |
| | cereals | 16.9 | 2.1 | 13 | 12.7 | 19.6 | 11 |
| | other grasses | 17.8 | 1.3 | 7 | 13.5 | 20.9 | 57 |
| | plants, all values | 17.8 | 1.9 | 11 | 11.7 | 23.2 | 146 |
| | plants, leaves | 17.8 | 1.6 | 9 | 14.0 | 20.0 | 24 |
| | plants, roots | 17.1 | 1.5 | 9 | 13.0 | 19.8 | 15 |
| | plants, stems and branches | 17.4 | 1.1 | 6 | 16.1 | 19.4 | 10 |
| | plants, miscellaneous | 18.0 | 2.1 | 12 | 11.7 | 23.2 | 98 |
| **kJ/g AFDW** | tree tissue | - | - | - | - | - | - |
| | conifer needles | 56.2 | 1.1 | 2 | 21.4 | 43.3 | 5 |
| | crop leaves (incl. pods) | - | - | - | - | - | - |
| | cereals and grasses | 19.1 | 0.9 | 5 | 17.6 | 20.3 | 10 |
| | cereals | - | - | - | - | - | - |
| | other grasses | 19.1 | 0.9 | 5 | 17.6 | 20.3 | 10 |
| | plants, all values | 20.1 | 1.1 | 6 | 18.1 | 23.6 | 26 |
| | plants, leaves | 20.1 | 0.8 | 4 | 19.3 | 21.4 | 7 |
| | plants, roots | 19.4 | - | - | - | - | 1 |
| | plants, stems and branches | - | - | - | - | - | - |
| | plants, miscellaneous | 20.1 | 1.3 | 6 | 18.1 | 23.6 | 17 |

**Table 11.** Moisture and ash content of tree and plant tissue.

| Parameter | Subgroup | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **% $H_2O$** | tree tissue | 49.5 | 4.4 | 9 | 42.7 | 54.7 | 5 |
| | conifer needles | 56.2 | 1.1 | 2 | 55.4 | 56.9 | 2 |
| | crop leaves (incl. pods) | 88.5 | 4.6 | 5 | 79.7 | 95.3 | 31 |
| | cereals and grasses | 76.4 | 5.7 | 7 | 68.5 | 87.6 | 11 |
| | cereals | 82.2 | 5.3 | 6 | 77.0 | 87.6 | 3 |
| | other grasses | 74.2 | 4.3 | 6 | 68.5 | 81.5 | 8 |
| | plants, all values | 88.1 | 5.4 | 6 | 80.0 | 95.0 | 8 |
| | plants, leaves | - | - | - | - | - | - |
| | plants, roots | 88.4 | 5.8 | 7 | 81.9 | 95.0 | 4 |
| | plants, stems and branches | - | - | - | - | - | - |
| | plants, miscellaneous | 84.7 | 4.4 | 5 | 80.0 | 90.0 | 4 |
| **% ash** | tree tissue | - | - | - | - | - | - |
| | conifer needles | 18.2 | 26.7 | 147 | 2.3 | 49.0 | 3 |
| | crop leaves (incl. pods) | - | - | - | - | - | - |
| | cereals and grasses | 4.2 | 1.6 | 38 | 1.6 | 6.1 | 9 |
| | cereals | - | - | - | - | - | - |
| | other grasses | 4.2 | 1.6 | 38 | 1.6 | 6.1 | 9 |
| | plants, all values | 7.2 | 4.0 | 57 | 0.5 | 18.0 | 21 |
| | plants, leaves | 8.8 | 0.6 | | 8.2 | 10.0 | 7 |
| | plants, roots | 1.4 | - | - | - | - | 1 |
| | plants, stems and branches | - | - | - | - | - | - |
| | plants, miscellaneous | 7.1 | 4.7 | 67 | 0.5 | 18.0 | 12 |

Pooled means for plants and for cereals and other grasses were not significantly different from each other. There was also no significant difference between tree tissue and conifer needles. Other groups differed significantly (Table 12).

**Table 12.** Comparison of mean caloric content (kJ/g DW) for tree and plant tissue.

| | tree tissue | conifer needles | crop leaves | cereals/grasses | cereals | other grasses | plants | plants, leaves | plants, roots | plants, stems | plants, misc. |
|---|---|---|---|---|---|---|---|---|---|---|---|
| tree tissue | | n.s. | *** | *** | | | | | | | |
| conifer needles | n.s. | | *** | *** | | | | | | | |
| crop leaves | *** | *** | | *** | | | | | | | |
| cereals/grasses | *** | *** | *** | | | | | | | | |
| cereals | | | | | | n.s. | | | | | |
| other grasses | | | | | n.s. | | | | | | |
| plants, all values | *** | *** | *** | n.s. | | | | | | | |
| plants, leaves | | | | | | | | | n.s. | n.s. | n.s. |
| plants, roots | | | | | | | | n.s. | | n.s. | n.s. |
| plants, stems and branches | | | | | | | | n.s. | n.s. | | n.s. |
| plants, miscellaneous | | | | | | | | n.s. | n.s. | n.s. | |

| | |
|---|---|
| *** | significant, one-way ANOVA with Tukey's test or Kruskal-Wallis with Dunn's test, P < 0.001 |
| n.s. | not significant, one-way ANOVA with Tukey's test or Kruskal-Wallis with Dunn's test, P > 0.05 |
| n.s. | not significant, Mann-Whitney test, P > 0.05 |
| | not tested |

### 3.1.5 Seeds

For seeds, a similar division was made as for tree and plant tissue, and a distinction was made between kernels and whole seeds. Non-specified values were added to the dataset

for whole seeds. Caloric content is given in Table 13, moisture and ash content in Table 14.

**Table 13.** Caloric values of tree and plant seeds.

| Parameter | Subgroup | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **kJ/g FW** | all seeds | 18.8 | 6.3 | 33 | 2.4 | 31.8 | 57 |
| | kernels | 22.3 | 6.4 | 29 | 6.9 | 31.8 | 20 |
| | whole/not specified | 16.9 | 5.3 | 32 | 2.4 | 31.0 | 37 |
| | cereals | 13.2 | 3.7 | 28 | 2.4 | 17.1 | 14 |
| | grasses (incl. sedges) | 16.8 | 0.6 | 3 | 16.4 | 17.2 | 2 |
| | grasses, kernels | | | | | | |
| | grasses, whole/not specified | 16.4 | 17.2 | 105 | 16.8 | 0.6 | 2 |
| | non-grass plants | 18.6 | 5.8 | 31 | 12.4 | 29.4 | 6 |
| | non-grass plants, kernels | | | | | | |
| | non-grass plants, whole/not specified | 18.6 | 5.8 | 31 | 12.4 | 29.4 | 6 |
| | non-conifer trees | 20.5 | 6.2 | 30 | 6.9 | 31.8 | 30 |
| | non-conifer trees, kernels | 21.5 | 7.2 | 33 | 6.9 | 31.8 | 15 |
| | non-conifer trees, whole/not specified | 19.6 | 5.0 | 26 | 12.1 | 31.0 | 15 |
| | conifers | 24.8 | 2.2 | 9 | 22.8 | 28.4 | 5 |
| | conifers, kernels | 24.8 | 2.2 | 9 | 22.8 | 28.4 | 5 |
| | conifers, whole/not specified | | | | | | |
| **kJ/g DW** | all seeds | 21.6 | 4.1 | 19 | 9.5 | 33.6 | 292 |
| | kernels | 24.8 | 4.8 | 19 | 15.0 | 33.6 | 66 |
| | whole/not specified | 20.7 | 3.5 | 17 | 9.5 | 32.8 | 226 |
| | cereals, whole/not specified | 17.6 | 1.8 | 10 | 12.8 | 19.7 | 41 |
| | grasses (incl. sedges) | 19.1 | 1.0 | 5 | 16.8 | 21.8 | 42 |
| | grasses, kernels | 19.7 | 1.0 | 5 | 18.5 | 21.2 | 6 |
| | grasses, whole/not specified | 19.0 | 1.0 | 5 | 16.8 | 21.8 | 36 |
| | non-grass plants | 21.7 | 3.3 | 15 | 9.5 | 31.4 | 109 |
| | non-grass plants, kernels | 23.3 | 3.4 | 14 | 19.0 | 30.8 | 11 |
| | non-grass plants, whole/not specified | 21.5 | 3.2 | 15 | 9.5 | 31.4 | 98 |
| | non-conifer trees | 22.9 | 4.5 | 19 | 15.0 | 33.6 | 67 |
| | non-conifer trees, kernels | 24.1 | 5.0 | 21 | 15.0 | 33.6 | 31 |
| | non-conifer trees, whole/not specified | 21.9 | 3.7 | 17 | 15.9 | 32.8 | 36 |
| | conifers | 27.2 | 3.1 | 11 | 18.6 | 32.4 | 33 |
| | conifers, kernels | 28.4 | 3.1 | 11 | 18.6 | 32.4 | 5 |
| | conifers, whole/not specified | 25.7 | 2.4 | 9 | 19.7 | 29.8 | 15 |
| **kJ/g AFDW** | all seeds | 25.6 | 4.8 | 19 | 17.4 | 34.0 | 51 |
| | kernels | 28.1 | 4.3 | 15 | 18.7 | 34.0 | 25 |
| | whole/not specified | 23.2 | 3.9 | 17 | 17.4 | 33.6 | 26 |
| | cereals | 19.4 | 1.3 | 7 | 18.4 | 20.3 | 2 |
| | grasses (incl. sedges) | | | | | | |
| | grasses, kernels | | | | | | |
| | grasses, whole/not specified | 11.6 | 1.8 | 16 | 10.3 | 12.9 | 2 |
| | non-grass plants | 22.7 | 2.8 | 12 | 20.7 | 24.7 | 2 |
| | non-grass plants, kernels | | | | | | |
| | non-grass plants, whole/not specified | | | | | | |
| | non-conifer trees | 23.9 | 4.3 | 18 | 17.4 | 34.0 | 28 |
| | non-conifer trees, kernels | 25.3 | 4.5 | 18 | 18.7 | 34.0 | 11 |
| | non-conifer trees, whole/not specified | 23.0 | 4.0 | 17 | 17.4 | 33.6 | 17 |
| | conifers | 29.6 | 2.7 | 9 | 23.6 | 33.3 | 18 |
| | conifers, kernels | 30.7 | 2.1 | 7 | 26.1 | 33.3 | 13 |
| | conifers, whole/not specified | 26.7 | 2.1 | 8 | 23.6 | 28.8 | 5 |

**Table 14.** Moisture and ash content of seeds.

| Parameter | Subgroup | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **% $H_2O$** | all seeds | 14.6 | 12.0 | 82 | 2.8 | 87.6 | 70 |
| | kernels | 15.5 | 11.7 | 76 | 5.0 | 54.0 | 21 |
| | whole/not specified | 14.3 | 12.2 | 85 | 2.8 | 87.6 | 49 |
| | cereals | 17.7 | 18.1 | 102 | 5.8 | 87.6 | 17 |
| | grasses (incl. sedges) | 11.6 | 1.8 | 16 | 10.3 | 12.9 | 2 |
| | grasses, kernels | | | | | | |
| | grasses, whole/not specified | | | | | | |
| | non-grass plants | 9.9 | 2.8 | 29 | 6.0 | 13.0 | 7 |
| | non-grass plants, kernels | | | | | | |
| | non-grass plants, whole/not specified | 9.6 | 2.9 | 31 | 6.0 | 13.0 | 6 |
| | non-conifer trees | 15.0 | 11.0 | 74 | 2.8 | 54.0 | 34 |
| | non-conifer trees, kernels | 16.8 | 13.6 | 81 | 5.0 | 54.0 | 15 |
| | non-conifer trees, whole/not specified | 13.5 | 8.6 | 64 | 2.8 | 34.6 | 19 |
| | conifers | 12.2 | 4.5 | 37 | 6.9 | 19.0 | 5 |
| | conifers, kernels | 12.2 | 4.5 | 37 | 6.9 | 19.0 | 5 |
| | conifers, whole/not specified | | | | | | |
| **% ash** | all seeds | 4.2 | 2.8 | 68 | 0.4 | 19.4 | 47 |
| | kernels | 4.2 | 1.4 | 34 | 1.6 | 6.9 | 24 |
| | whole/not specified | 4.1 | 3.8 | 93 | 0.4 | 19.4 | 23 |
| | cereals | 1.0 | 0.8 | 82 | 0.4 | 1.5 | 2 |
| | grasses (incl. sedges) | | | | | | |
| | grasses, kernels | | | | | | |
| | grasses, whole/not specified | | | | | | |
| | non-grass plants | | | | | | |
| | non-grass plants, kernels | | | | | | |
| | non-grass plants, whole/not specified | | | | | | |
| | non-conifer trees | 3.9 | 1.8 | 46 | 1.6 | 7.1 | 25 |
| | non-conifer trees, kernels | 3.9 | 1.7 | 44 | 1.6 | 6.9 | 11 |
| | non-conifer trees, whole/not specified | 3.9 | 1.9 | 49 | 1.6 | 7.1 | 14 |
| | conifers | 4.0 | 1.5 | 37 | 0.9 | 6.1 | 18 |
| | conifers, kernels | 4.5 | 1.1 | 26 | 2.3 | 6.1 | 13 |
| | conifers, whole/not specified | 2.8 | 1.6 | 59 | 0.9 | 4.9 | 5 |

It was first tested whether kernels and whole seeds were different, this was the case when all seeds were combined, for conifers and trees, but not for grasses and non-grass plants (t-test). Thereafter, differences in caloric content of kernels and whole seeds between groups were tested (one-way ANOVA). Results are summarised in Table 15.

**Table 15.** Comparison of mean caloric content (kJ/g DW) for seeds.

| | all seeds | kernels | whole/not spec. | cereals, whole | grasses | grasses, kernels | grasses, whole | non-grass plants | non-grass plants, kernels | non-grass plants, whole | non-conifer trees | non-conifer trees, kernels | non-conifer trees, whole | conifers | conifers, kernels | conifers, whole |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| all seeds | | | | | | | | | | | | | | | | |
| kernels | | | *** | | | | | | | | | | | | | |
| whole/not specified | | *** | | | | | | | | | | | | | | |
| cereals (only whole/not spec.) | | | | | n.s. | | n.s. | *** | | *** | *** | | *** | *** | | *** |
| grasses | | | | n.s. | | | | *** | | | *** | | | *** | | |
| grasses, kernels | | | | | | | n.s. | | n.s. | | | n.s. | | | *** | |
| grasses, whole | | | | n.s. | | n.s. | | | | *** | | | *** | | | *** |
| non-grass plants | | | | *** | *** | | | | | | n.s. | | | *** | | |
| non-grass plants, kernels | | | | | | n.s. | | | | n.s. | | n.s. | | | ** | |
| non-grass plants, whole | | | | *** | | | *** | | n.s. | | | | *** | | | *** |
| non-conifer trees | | | | *** | *** | | | n.s. | | | | | | *** | | |
| non-conifer trees, kernels | | | | | | n.s. | | | n.s. | | | | n.s. | | ** | |
| non-conifer trees, whole | | | | *** | | | *** | | | *** | | n.s. | | | | *** |
| conifers | | | | *** | *** | | | *** | | | *** | | | | | |
| conifers, kernels | | | | | | *** | | | ** | | | ** | | | | ** |
| conifers, whole | | | | *** | | | *** | | | *** | | | *** | | ** | |

| | |
|---|---|
| *** | significant, one-way ANOVA with Tukey's test or Kruskal-Wallis with Dunn's test, P < 0.001 |
| n.s. | not significant, one-way ANOVA with Tukey's test or Kruskal-Wallis with Dunn's test, P > 0.05 |
| *** | significant, Mann Whitney test, P < 0.001 |
| ** | significant, t-test, P < 0.01 |
| n.s. | not significant, t-test or Mann Whitney test, P > 0.05 |
| | not tested |

### 3.1.6 Vertebrates

A summary of vertebrate food sources fish, birds and mammals (including meat) is given in Table 16. Dry weight caloric content of birds and mammals and of mammals and fish did not significantly differ; the difference between fish and birds was significant (Kruskal-Wallis with Dunn's test, P < 0.001).

**Table 16.** Caloric values of vertebrate food and fodder.

| Parameter | Subgroup | mean | SD | Cv [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **kJ/g FW** | fish | 6.1 | 2.1 | 35 | 2.9 | 11.2 | 66 |
| | birds | 7.7 | 2.4 | 31 | 3.5 | 17.7 | 57 |
| | mammals | 7.1 | 1.8 | 25 | 3.2 | 11.5 | 64 |
| **kJ/g DW** | fish | 21.0 | 3.7 | 18 | 12.0 | 30.5 | 60 |
| | birds | 24.2 | 5.2 | 21 | 16.8 | 38.6 | 141 |
| | mammals | 22.2 | 2.9 | 13 | 16.5 | 28.3 | 109 |
| **kJ/g AFDW** | fish | - | - | - | - | - | - |
| | birds | 27.2 | 5.4 | 20 | 19.1 | 38.8 | 68 |
| | mammals | 25.8 | 2.9 | 11 | 20.9 | 30.9 | 39 |
| **% $H_2O$** | fish | 73.7 | 5.4 | 7 | 62.3 | 81.8 | 43 |
| | birds | 67.2 | 7.7 | 11 | 44.0 | 84.6 | 54 |
| | mammals | 69.6 | 5.7 | 8 | 58.8 | 84.5 | 66 |
| **% ash** | fish | - | - | - | - | - | |
| | birds | 8.5 | 5.0 | 59 | 0.3 | 16.2 | 64 |
| | mammals | 9.0 | 4.0 | 44 | 1.2 | 13.4 | 23 |

### 3.1.7 Fruit and fodder

The last group contains data of fruit and of commercial fodder. The data for fodder are mainly for bird fodder (22) with only two for mammal fodder (2). Data are summarised in Table 17.

**Table 17.** Caloric values of fodder.

| Parameter | Subgroup | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| **kJ/g FW** | fruit | 2.2 | 1.3 | 57 | 1.0 | 5.8 | 19 |
| | fodder | 15.7 | 3.9 | 25 | 11.8 | 22.8 | 7 |
| **kJ/g DW** | fruit | 14.8 | 4.9 | 33 | 7.2 | 22.2 | 24 |
| | fodder | 15.1 | 2.5 | 17 | 12.6 | 19.7 | 21 |
| **kJ/g AFDW** | fruit | - | - | - | - | - | - |
| | fodder | 20.3 | 1.2 | | 19.4 | 21.1 | 2 |
| **% $H_2O$** | fruit | 83.9 | 4.1 | 5 | 74.0 | 88.0 | 19 |
| | fodder | 8.0 | 1.7 | 22 | 6.0 | 9.3 | 3 |
| **% ash** | fruit | - | - | - | - | - | - |
| | fodder | - | - | - | - | - | - |

## 3.2 Assimilation efficiency of mammals

In Table 18, summary statistics are given for the different food types. Assimilation efficiency of grasses and tree-tissue are significantly lower as compared to other food types (one-way ANOVA with Dunnett's test, $P < 0.005$). For tree tissue, this may be caused by deer having lower efficiencies than other ruminants. The number of data for the latter group, however, is too small to draw conclusions on this. For mammals eating seeds and nuts, there was no difference between squirrels and mice. The same goes for the assimilation efficiency of non-grass herbs/crops and mixed plants by either small mammals or hares and rabbits.

**Table 18.** Assimilation efficiency [%] of different food types for mammals.

| Mammal species | Food type | mean | SD | CV [%] | min | max | n |
|---|---|---|---|---|---|---|---|
| mouse, rabbit, squirrel, badger | fodder | 85.5 | 10.2 | 12.0 | 71.2 | 95.0 | 6 |
| shrew, bat | insects | 87.4 | 6.3 | 7.2 | 78.0 | 94.9 | 8 |
| shrew, otter, bobcat, fox, weasel | vertebrates | 80.8 | 7.3 | 9.1 | 62.7 | 91.0 | 21 |
| mouse, vole, squirrel | seeds and nuts | | | | | | |
| | all mammals | 84.3 | 7.6 | 9.1 | 65.2 | 94.0 | 23 |
| | squirrels | 85.2 | 7.5 | 8.8 | 72.0 | 94.0 | 10 |
| | mice | 83.6 | 8.0 | 9.6 | 65.2 | 91.0 | 13 |
| vole, lemming | grasses | 46.8 | 12.8 | 27.3 | 19.0 | 79.0 | 35 |
| mouse, vole, hare | non-grass herbs[1] | | | | | | |
| | all mammals | 75.5 | 11.0 | 14.5 | 50.7 | 91.4 | 26 |
| | lagomorphs | 74.3 | 13.5 | 18.2 | 60.0 | 91.3 | 4 |
| | small mammals | 75.7 | 10.8 | 14.3 | 50.7 | 91.4 | 22 |
| deer, ruminants | tree tissue | | | | | | |
| | all mammals | 42.1 | 21.9 | 52.1 | 24.0 | 80.6 | 9 |
| | deer | 31.7 | 8.4 | 26.4 | 24.0 | 45.9 | 7 |
| | other ruminants | 78.5 | - | - | 76.4 | 80.6 | 2 |

1: including crops and mixed vegetation

# 4. Discussion and conclusions

## 4.1 Caloric values, moisture and ash content

From the above presented tables it appears that variation in energy content within subgroups is reduced when values are expressed on the basis of dry weight or ash free dry weight. As for the latter far less data are available, dry weight data are preferred. For most groups, the greater variation in caloric content expressed on a fresh weight basis cannot be explained by a variation in moisture content. The variation in moisture content is remarkably low, with CV almost always < 15 %. Only for seeds, a large variation in moisture content is found, indicating that the usually applied drying period of 24 hours at 80 or 105 °C may not be sufficient for this type of material. It is suggested by Cummins and Wuycheck (1971) that freeze drying followed by desiccation over $P_2O_5$ should be used for material with a high lipid content.
From the statistical comparison, it appeared that for a number of subgroups data can be pooled, and that for other groups a subdivision should be applied.

Based on the division in food sources as made by Crocker *et al.* (2002), which is presented in Table 1, the values as proposed on the basis of the combined dataset are given in Table 19.

**Table 19.** Energy and moisture content of several food sources (combined dataset).

| Group | Energy content [kJ/g DW] | Moisture content [%] |
|---|---|---|
| Dicot. crops | 11.4 | 88.5 |
| Grasses and cereal shoots | 17.6 | 76.4 |
| Non-grass herbs | 17.8 | 88.1 |
| Tree and conifer tissue | 20.7 | 52.9 |
| Fruit | 14.8 | 83.9 |
| Grass and cereal seeds | 18.4 | 14.7 |
| Weed seeds | 21.7 | 9.9 |
| Tree seeds | 22.9 | 15.0 |
| Conifer seeds | 27.2 | 12.2 |
| Terrestrial vertebrates | 23.2 | 68.4 |
| Fish | 21.0 | 73.7 |
| Bivalves | 19.3 | 91.7 |
| Freshwater arthropods | 20.9 | 76.3 |
| Terrestrial arthropods | 22.7 | 68.8 |
| Soil invertebrates (earthworms and slugs) | 19.4 | 84.3 |
| Aquatic vegetation[1] | 15.0 | 81.4 |

1: value taken from Crocker *et al.* (2002), no new data available

## 4.2 Assimilation efficiency

### 4.2.1 Mammals

Relatively few data on assimilation efficiency by mammals are available. Especially for insects and tree tissue, the dataset is limited. For the latter group, this is not considered problematic, as the intake of contaminated tree tissue is not assumed to be a major exposure route. Contaminated insects, however, are considered to represent a major uptake route. The present dataset consists of only eight values, seven of which are for shrews, and of those seven, four values are obtained with the sawfly as prey species. To obtain a more reliable estimate, more data on other insect species and arthropods in general should become available. The assimilation efficiencies as proposed on the basis of the combined dataset are given in Table 20.

**Table 20.** Assimilation efficiency [%] of different food types for mammals

| Mammal species | Food type | mean | SD | n |
|---|---|---|---|---|
| small and medium mammals | fodder | 85.5 | 10.2 | 6 |
| shrews and bats | insects | 87.4 | 6.3 | 8 |
| carnivores | vertebrates | 80.8 | 7.3 | 21 |
| small mammals | seeds and nuts | 84.3 | 7.6 | 23 |
| small mammals | grasses | 46.8 | 12.8 | 35 |
| small and medium mammals | non-grass herbs[1] | 75.5 | 11.0 | 26 |
| deer, ruminants | tree tissue | 42.1 | 21.9 | 9 |

1: including crops and mixed vegetation

### 4.2.2 Birds

As already stated in section 2.2.1, the values for birds as presented by Crocker *et al.* (2002) and summarised in Table 2, remain unchanged.

## References

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Traas, TP, Luttik, R, Jongbloed, RH., 1996. A probabilistic model for deriving soil quality criteria based on secondary poisoning of top predators. *Ecotox Environ Saf*, 34: 264-78.

# APPENDIX M

## HOW TO DETERMINE A FOCAL SPECIES

If an active substance, and its associated product and use, fails Tier 1, it is possible to further refine the exposure element of risk via the use of a **'focal species'**. A 'focal species' is a real species that actually occurs in the crop when the pesticide is being used. The aim of using a 'focal species' is to add realism to the risk assessment insofar as the assessment is based on a real species that uses the crop. It is essential that the species actually occurs in the crop at a time when the pesticide is being applied. It is also essential that this species is considered to be representative of all other species from the feeding guild highlighted at the screening level and at Tier 1 that may occur in the crop at that time. As a 'focal species' needs to cover all species present in the crop, it is possible that there may be more than one 'focal species' per crop representing more than one feeding guild.

Determining a focal species

In order to determine a suitable 'focal species' it is necessary to carry out field work and presented below is a brief outline of the key issues to consider:

**Selection of field sites**: As for any field work it is necessary to select appropriate fields, in order to ascertain what species occur in the crop of concern. The crop studied should be the same as the one used in the risk assessment at the screening level and at Tier 1, it should also be at the same growth stage. It is also necessary to have a range of fields that are representative of where the pesticide is used or is intended to be used. This may be across relevant geographical and climatic regions or zone, within a Member State (MS) if the pesticide is to be used in one MS, or if the pesticide is used across a range of MS, then it may be appropriate to have a selection of fields across MS. The key point is that the focal species selected should be appropriate for the risk assessment.

Experience has shown that the fields surveyed should be separated by at least 250 m so as to avoid any potential double counting. Cropping details of the fields studied as well as their surrounding habitats (e.g. what crops were being grown, presence of woodlands, hedgerows etc) should be included in the final report.

If data are only available from either one MS or a small selection of sites and the Notifier wishes to extrapolate to another, then it is necessary to justify its use. Justification can be based on a comparison of the agricultural landscape including size of fields, presences of hedgerows, field boundaries as well as climatic conditions. Likewise, if a Notifier wishes to extrapolate from one crop to a closely related crop, justification is required.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix M. EFSA Journal 2009; 7(12):1438. [3 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

**Survey techniques**: Basically there are two techniques for birds – namely the transect method and the field survey method. These are described in more detail below:

**The 'transect method':** All bird species are recorded in the field by walking slowly along a defined longitudinal line transect, allowing for a clear view between the rows of crop plants. Birds are recorded only within the ,in-crop transect band' as individual birds visually or acoustically registered (see Figure 1 for details).

**'In-crop transect band':** birds are recorded within a wide band, for example 50 m either side of the observer where the crop field was at least 100 m wide. For narrower fields the band considered could be narrowed and contain only the in-crop area (i.e. width of the crop field).

**'Outside transect area/band:** no birds are recorded beyond the in-crop transect band. Depending on the width of the field the 'outside transect band' may include in-crop and off-crop habitat.

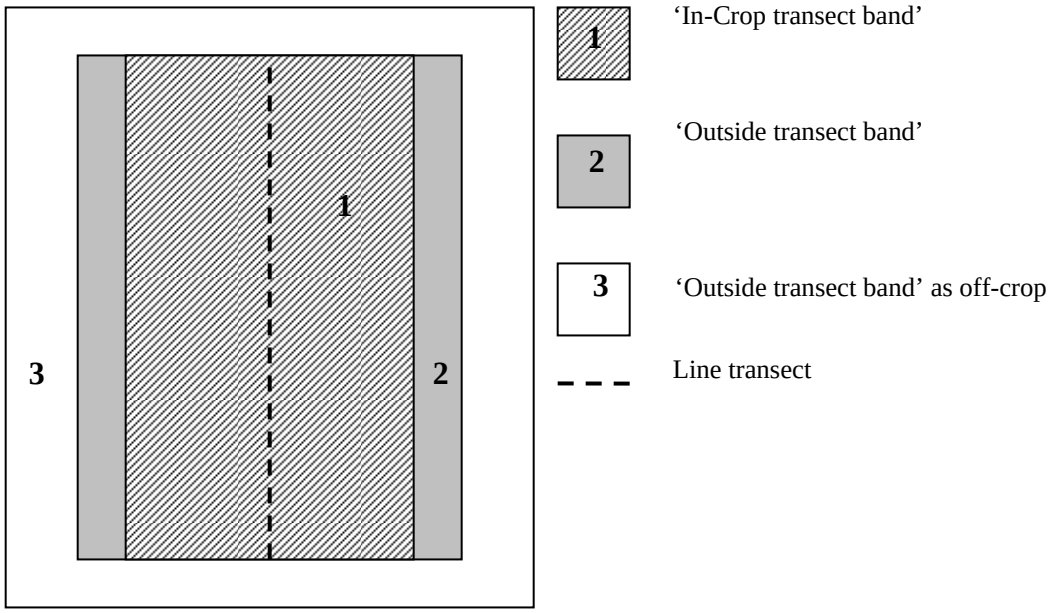


**Figure 1**. *Graduation of different areas within defined crop fields as applied by this focal species studies*

**The 'point count method':** With this method the observers survey the part of a field from a single location to avoid disturbing the birds. Both methods, i.e. field survey and transect methods, are complimentary to obtain unbiased census. It should be noted that this technique may be more appropriate for fields in the winter, freshly drilled fields or bare soil. This method is further described in Crocker and Irving (1999) or Bibby *et al.* (2000).

**Analysing the data**: the survey data may be analysed in a variety of ways, however in trying to determine 'focal species' the following information is considered to be most relevant:

**FOfield or frequency of observation in the field** – denotes the number of fields in which a defined species was recorded as percentage of the total number of fields regardless of the number of individuals observed. This approach serves as a measure for the spatial frequency of occurrence, or the proportion of fields a species is present on. A FOfield of 100% for one species indicates that this species was observed in all fields during at least one survey.

**FOsurvey or frequency of observation per survey** – denotes the number of surveys in which a defined species was recorded given as percentage of the total number of surveys. This approach gives an approximation for the temporal evenness of occurrence throughout the complete study period. This gives an indication of how widespread a species is and is considered to be an indication of 'prevalence'. A FOsurvey of 100% means the species was recorded during each survey in every field with at least one individual.

**Selection of Focal Species:** The above gives an indication of what potential focal species may occur in the crop. Those species with a frequency of occurrence >20% might be considered to be of high priority especially if they have high dominance. However before deciding which species 'covers' all other species present on the field, it is necessary to consider issues such as feeding strata, food intake rate, body weight of potential focal species and diet to ensure that species with the highest potential exposure are considered. It should be noted that a focal species is not automatically the species that was most frequently seen in FOfield and/or FOsurvey.

The above is illustrated by an example where a swallow was recorded as being both prevalent and abundant in a certain crop at a certain time of year. But whilst is has a high intake to body weight ratio, and consumes small invertebrates it is not consuming invertebrates with residues on and hence is not protective of other species that may occur in the crop at the same time. Similarly, wood pigeons are potential focal species in sugar beet in the summer (see Crocker and Irving, 1999); however on the basis of its low food intake rate it is clear that the wood pigeon is not protective of other species, e.g. the skylark.

## References

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Bibby, C. J., N. D. Burgess, D. A. Hill and S. H. Mustoe, 2000. Bird census techniques. 2nd ed. Academic Press, London. Buckland, S.T., D.R. Anderson, K. P. Burnham, & J. L. Laake (1993): Distance Sampling: Estimating abundance of biological populations. Chapman & Hall, London.

[1] Available at: http://www.pesticides.gov.uk/uploadedfiles/Surveys_short1.pdf

# APPENDIX N

# RECOMMENDATIONS ON ARTHROPOD RESIDUE FIELD STUDIES TO REFINE FOOD RESIDUES IN HIGHER TIERED BIRD AND MAMMAL RISK ASSESSMENTS[1]

## STUDY CONDUCTION AND INTERPRETATION

### Introduction

The aim of this document is to provide guidance on how to carry out an arthropod residue field study and considerations on how to interpret the results of a study for a higher tiered risk assessment. This guidance given in this document should not be seen as fixed as it may be more appropriate to design a specific study to address a specific issue highlighted during the initial risk assessment. In situations where there have been deviations from the recommendations made here a full justification and explanation should be given to explain why and how a study was conducted in a specific way and why the data can be used to refine the exposure different from Tier 2 scenarios in the Guidance Document (GD).

### Laboratory versus field studies

As in many other areas of ecotoxicology it might be helpful to start with simpler laboratory studies, followed by semi-field approaches, before scheduling a field study as the highest tiered approach. However, it should be emphasised that it might be very difficult to simulate the processes relevant for residue levels in arthropods under laboratory conditions, especially if the time courses of residues are to be examined. Furthermore, laboratory studies are limited to a single species whereas field studies investigate the whole arthropod community, which together represents the potential food of insectivorous birds and mammals. The figures below show how the residue curves can differ for a compound which is non-toxic to arthropods. Results demonstrate the residue decline after over-spraying a single species in the laboratory compared to the data obtained from a field experiment, considering the whole arthropod community in the respective crop (NB: the curves shown below are hypothetical (generic) curves derived from a number of real studies; those studies normal contain protected data owned by specific companies). Due to food web interactions and environmental conditions

[1] Acknowledgement: EFSA wishes to thank Christian Wolf and Katja Schneider, RIFCon GmbH, Germany, for the elaboration of this Appendix.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix N. EFSA Journal 2009; 7(12):1438. [8 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

the residue pattern obtained from the whole arthropod community in the field shows a higher maximum (accumulation) and a slower decline. However, in field studies where single species of arthropods were artificially exposed to applications, e.g. in cages, exposure conditions are normally not comparable to those experienced by free-living arthropods under natural circumstances. Absolute residue levels (peak values) in single species tests tend to be lower (no accumulation in a food web) and residue decline can be faster (no consideration of inter-species interaction, different feeding strategies and metabolic processes). Thus a single species test is less representative compared to data obtained from the whole fauna and therefore, field studies should be preferred to laboratory and semi-field studies.

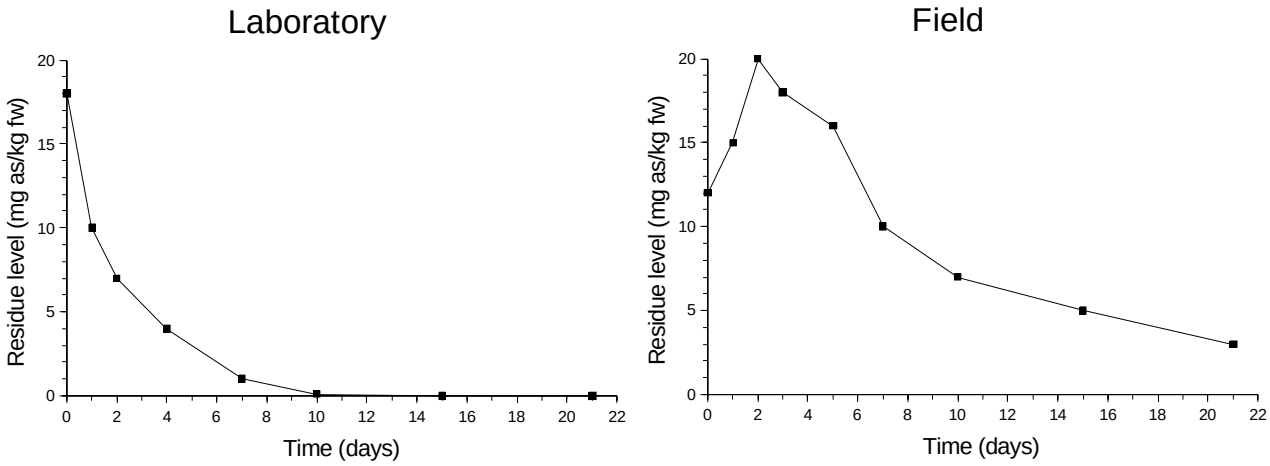


**Figure 1.** Hypothetical (generic) residue levels plotted as a function of time for a compound which is non-toxic to arthropods, (based on real studies). Due to confidentially and data protection rules claimed with studies conducted by applicants no specific reference can be given.

**General remarks on the use of field residue data in refined exposure assessments**

Concerns are often raised over whether data from field studies where sample size is often limited can be used to replace worst case Tier 2 data. In principle, field data obtained under practical use conditions add a further level of realism to a risk evaluation. Furthermore, the replacement of RUDs for maximum residue levels is reasonable if data are more focussed on a particular application regimen, crop stage or geographical area. Also, as noted above, data from field studies may be suitable to describe residue declines over time under natural conditions, which are very difficult to obtain from laboratory studies. Both the definition of Tier 3 maximum residue values and as well data of residue decline under natural conditions could be derived from the same field study.

**Number of study sites and site selection**

When planning a residue field study it is clear that the number of study sites and the number of replicates within the study sites are the decisive factors for the significance of the data, i.e. the more test sites and replicates the more reliable the data. But this is often limited by several factors including the availability of suitable study sites and cooperative farmers, analytical capacities and available resources, so normally a study will be conducted at one test site.

Each test site will represent an individual residue value/time course, i.e. an individual study. Nevertheless, within each site it is desirable to have at least three replicates available to have information on intra-site variability of the residue values. The minimum size of each replicate within the test site should be approximately 1 ha, otherwise effects of immigration and emigration may have an unrealistically high impact on the residue dynamics within the monitored arthropod community (i.e. sampling should be avoided in the border structures of a crop, e.g. the outer tree rows from an orchard).

The abundance of arthropods is one of the most important factors for the selection of suitable study sites. Since an orchard plot which has been intensively farmed for several decades, surrounded by other high production commercial orchards, may contain a very small arthropod community and will therefore be unsuitable for an arthropod residue study even if it is a typical site where several pesticides are used throughout the season. Conversely, a small orchard out of production, surrounded by a diverse woodland habitat may hold an enormous amount of arthropods but exchange with the surrounding source habitat may lead to an unrepresentatively fast dilution of individuals with a residue loading- so this is not a suitable situation for residue decline studies. Therefore it is absolutely critical to describe the orchard use history (e.g. planting or age, prior crop, treatments before study start, pesticides used) and also the surrounding landscape in detail (e.g. kind of crop or vegetation of the bordering areas, current aerial photos) to justify the selection of the study site and also to facilitate the discussion of observed residue decline patterns.

To ensure the maximum abundance of arthropods, no insecticides should be used during the study year and up to the termination of the study. Fungicides, which will not affect arthropod communities, can be used according to the usual application schedule. To prevent major habitat changes, no herbicides should be used during the trial unless it is necessary to assure a proper application of the test substance or the survival of the crop itself. Hence a balance between commercial practice and detrimental effects for the arthropod community should be achieved for the study site.

**Application of the test item**

The application(s) should be performed according to the recommendations of the product label and to good agricultural practice. Special attention should be given to the adjustment of the volume of the spray liquid towards the dimension of the crop, especially in orchards (tree size, tree spacing, row spacing etc.). All exact data and details of the application technique should be described in the study report. The water volume used for spray applications in the study should be justified and represent a typical commercial application.

**Test organisms**

Attention should focus on organisms likely to be consumed by the potential focal species. Therefore it is necessary to have information about the prey selection of the bird (and/or mammal) community inhabiting the study site from a study on 'portion of diet' (PD). If this information is available the division of sampled arthropods into classes, e.g. 'beetles', 'caterpillars', 'spiders' etc, can be useful. It is important that the fresh weight of the total of each of these groups should be recorded. Without this information it is not possible to reconstitute in the correct proportions the total residue for a bird which may feed on all these groups. The specific residue level and decline information could then be used to estimate a more refined exposure level based on dietary information for a suitable focal species. However, detailed information about the composition of the diet are rarely available and often

the amount of sample matrix necessary for a proper residue analysis limiting the ability to divide arthropods into specific classes. If no information on dietary preferences of focal wildlife species are available it is recommended to collect sub samples of arthropods of the different foraging strata in a crop, e.g. foliage dwellers and ground dwellers, to have more information on residue levels of specific food groups. Since an insectivorous bird collecting arthropods from the tree canopy may receive a different exposure level in an orchard when compared to a nocturnal shrew collecting ground dwelling arthropods in predominantly dense vegetation cover.

The division of arthropods into 'large' and 'small' classes is unnecessary, because the ecology of specific arthropod groups and the feeding ecology of the bird and mammal species concerned are the most significant factors.

**Methodological considerations for sample methods in field studies**

A main point always to be taken into consideration is the loss or increase of residues in the sample matrix based on methodological shortcomings. Desiccation of the sample matrix should be avoided by fast handling times and storage of the samples as soon as possible in a deep freezer or on dry ice. Another problem which can severely influence residue levels of the sample is cross contamination with other (non-arthropod) materials like soil particles or plant material. This will be discussed in more detail in the section on specific sample techniques below. Nevertheless it should be noted that so far no real comparative assessment of different sampling techniques with respect to their influence on the resulting residue levels is available. Only for suction sampling techniques (i.e. D-VAC sampling) it was proved that the residue data will be significantly biased by cross contamination from dust particles (SETAC, 2007)[2]. Accurate recording of the composition of each sample, e.g. the number of individuals in each of the various taxonomic groups present, is very important to explain specific data points. For example, if a sample consists of one large beetle and a few tiny spiders only, the residue level analysed very much describes the residue loadings only of the single large beetle.

**Ground dwelling arthropods**

The most practical method to collect ground dwelling arthropods is the use of pitfall traps. They have of course the disadvantage of collecting only active and moving individuals, but, on the other hand, pitfall traps are the only method to selectively collect only arthropods. Other methods, like suction sampling (e.g. with a D-Vac) have the huge disadvantage of severe cross contamination with soil-, plant- and other dust-particles potentially carrying often high residue loadings. Pitfall traps should be used without a preservation liquid (which would dissolve/wash off residues from arthropods) and should be emptied once at least every 24 hours. If the sample container of a pitfall trap is contaminated with water or soil material, e.g. during rainfall events samples should be discarded.

Arthropods should be killed with an ether-soaked paper after being recovered from the traps. Following the determination of suitable sub-fractions (if intended, see above) and weighing, the sample should be stored on dry ice or in a deep freezer. The number of pitfall traps used per sample site should be adjusted to the matrix mass necessary for residue determination in the analytical part of the study.

[2] S. Moreno, J. Pascual, A. Drexler & J.-D. Ludwigs (2007). Unsuitability of a suction sampling method for the collection of arthropods for residue analysis of plant protection products. SETAC Poster 2007.

**Foliage dwelling arthropods**

Methods to collect foliage dwelling arthropods are most relevant in high crops like orchards, vineyards, hops. Field crops with sufficient plant material and arthropods inhabiting the plant layer may also be sampled successfully (e.g. in potatoes, cereals, some vegetables). In principle, the two most established methods for sampling foliage-dwelling arthropods are beating and inventory spray.

With **beating**, the leaves/plants/branches are beaten with a stick and the arthropods dropping down are captured in a large funnel. The disadvantage of this method is that some species (like flying ones) may escape instead of falling into the funnel. Other materials such as leaves, petals, bark, dust etc. will also fall into the sample container of the funnel. Thus, some sorting between arthropods and undesired material is necessary after the sampling event. This may prolong the handling time before the sample is stored in a freezer and the problem of desiccation of the arthropods arises (see above). The problem can, at least partly, be overcome by direct freezing of the samples and sorting under frozen conditions. Beating is however, only able to sample the parts of the plant readily accessible by hand. For example, it is not possible to sample the upper parts of fruit trees.

A more sophisticated method for sampling foliage dwelling arthropods is inventory spraying. Using this method, a number of plants are treated with a fast acting knock-down insecticide. The most common knock-down insecticides in current use are pyrethroids. Formerly, compounds such as Dichlorvos were also often used. Depending on the knock-down insecticide used this method has also a certain selectivity and not every arthropod inhabiting the respective plant foliage will fall down on the collection sheet. It is important to apply the knock down insecticide very gently and when there is no wind, to avoid disrupting the un-sampled parts of the study. After spraying the arthropods which have fallen from the leaf layer will be collected from sheets placed underneath the plants or trees. Dense cotton sheets acting like a sponge for the pesticide and the knock down substance when dripping from the treated foliage and avoid puddles in which arthropods can fall (resulting in changes of the residue loadings like with pitfall traps when preserve liquids are used), hence they are an optimal underlay. However, care must be taken when collecting the arthropods from the cotton sheet, because claws of beetles might get entangled and legs get pulled off – both resulting in an underestimation of residue levels. The best way is to collect the individual arthropods selectively from the sheets using tweezers or a small suction device, in order to avoid contamination with other material like leaves or pieces of bark. For some small-bodied arthropods such as aphids individual sampling with tweezers or a suction device is inappropriate and too slow resulting in desiccation; these can be carefully collected using a soft brush. Those samples should be kept and analysed separately if possible. The number of plants/trees used for one inventory spray sampling event should be also adjusted to the amount of sample matrix needed for residue determination. The plants should be randomly spread throughout each sample site and each plant/tree should be sampled only once during the study. The method requires some waiting time between inventory spray and collection of the arthropods until the spray liquid has dried. It is important to ensure that as much individuals as possible are knocked down and dropped on the collection device. The waiting time must be kept reasonably short (1-2 hours) and meanwhile, the arthropods should not be exposed to direct sunshine on the collection device to minimise the effect of desiccation. Subsequent sorting, partition into sub-samples and weighing must also be done immediately after the collection in order to transfer the samples as soon as possible into a freezer or on dry ice.

Sampling methods which differ from the two methods mentioned above may be used in some circumstances and for certain crops. However, for all these methods, clear descriptions are necessary to allow any possible influence of the methodology on residue levels to be assessed (e.g. cross contamination).

**Knock down samples during application**

It can be assumed for insecticides (and other pesticides with insecticidal side effects like some fungicides) the highest initial residue loading occurs on those arthropods which are killed during or immediately after application of the product. These individuals are normally missed during the sample events for foliage dwelling arthropods (because they are already dead and have fallen on the ground) and will not be found in pitfall traps (because they can no longer move). It is unclear to what extent those arthropods are used as food items by birds and mammals. At least some reports can be found in the scientific literature describing the uptake of dead and/or moribund arthropods by birds[3]. Thus, in principle this scenario should not be overlooked and a respective sample of those arthropods affected directly from the product application should be obtained whenever possible. In high crops (e.g. orchards) this can be easily achieved with a method similar to the inventory spray method used to collect foliage dwelling arthropods. The sampling devices (e.g. sheets) should be placed before the application and arthropods can be collected in a suitable time after the spraying, normally when the spray liquid has dried. Note that these collecting sheets should be covered at the time of spraying itself and the covers removed immediately afterwards to prevent the specimens being contaminated with further residues of the test item.

**Number of samples and sample intervals**

The number of samples analysed in parallel depends on the study site (size, structure, abundance of arthropods) and available capacities within the respective analytical facility. In order to get some information on intra-site variability of the residue levels at least three samples from each strata/sample method should be planned for each sampling date ($n \geq 3$). Nevertheless, unexpected low masses of arthropods may force the pooling of samples to obtain sufficient matrix for residue analysis.

The general sampling scheme should be adjusted to the properties of the test substance and should be performed in such a way that the aims of the study can be achieved. In general, at least for spray applications, more sampling events should take place within the first three to six days after application, in order to obtain the maximum residue levels after application. If more than one application is being investigated then a sampling should also take place on the day before the next application. Some samples should also be obtained before the first application to adjust the sampling effort required for each method intended and to obtain reference matrix for the analytical laboratory.

[3] J. Schabacker, B. Giessing (2006). Pesticide Kills, Easy Prey for Insectivores? Poster on SETAC-Europe 16th Annual Meeting, The Hague, The Netherlands.

**Table 1.** Example for a sampling schedule for a field study with two spray applications:

| DAT (Day After Treatment) | | Number of samples | | | | |
|---|---|---|---|---|---|---|
| | | Plot | | | | |
| First application | Second application | 1 | 2 | 3 | 4 | 5 |
| -1 | | 1 | 1 | 1 | 1 | 1 |
| 0 (before application) | | 1 | 1 | 1 | 1 | 1 |
| +1 | | 1 | 1 | 1 | 1 | 1 |
| +2 | | 1 | 1 | 1 | 1 | 1 |
| +3 | | 1 | 1 | 1 | 1 | 1 |
| +4 | | - | - | - | - | - |
| +5 | | 1 | 1 | 1 | 1 | 1 |
| +6 | -1 | - | - | - | - | - |
| +7 | 0 (before application) | 1 | 1 | 1 | 1 | 1 |
| +8 | +1 | 1 | 1 | 1 | 1 | 1 |
| +9 | +2 | 1 | 1 | 1 | 1 | 1 |
| +10 | +3 | 1 | 1 | 1 | 1 | 1 |
| +11 | +4 | - | - | - | - | - |
| +12 | +5 | 1 | 1 | 1 | 1 | 1 |
| +13 | +6 | - | - | - | - | - |
| +14 | +7 | 1 | 1 | 1 | 1 | 1 |
| +15 | +8 | - | - | - | - | - |
| +16 | +9 | 1 | 1 | 1 | 1 | 1 |
| +17 | +10 | - | - | - | - | - |
| +18 | +11 | 1 | 1 | 1 | 1 | 1 |
| +19 | +12 | - | - | - | - | - |
| +20 | +13 | - | - | - | - | - |
| +21 | +14 | 1 | 1 | 1 | 1 | 1 |
| +22 | +15 | - | - | - | - | - |
| +23 | +16 | - | - | - | - | - |
| +24 | +17 | - | - | - | - | - |
| +25 | +18 | - | - | - | - | - |
| +26 | +19 | - | - | - | - | - |
| +27 | +20 | - | - | - | - | - |
| +28 | +21 | 1 | 1 | 1 | 1 | 1 |
| Sum | | 16 | 16 | 16 | 16 | 16 |

**Reporting and data interpretation**

As every arthropod residue field study for the submission to a regulatory authority should be performed according to GLP the respective report must be comprehensible and should describe clearly the aim, all methods, deviations, encountered problems and results of the study. As the main results are normally initial residue values and / or time course of residues these data should be explicitly expressed in the study, if possible, including data on their variance. It should be considered that, regarding initial (maximum) residue values, the maximum is often found some time later - not immediately after application of the test substance (especially for substances non-toxic to arthropods may accumulate within the first few days after application). For a proper elucidation of the time courses of residues it is important to use an appropriate model to describe the residue decline. Normally it is not a first order kinetic, because several processes are interfering (e.g. a rapid decline of surface

residues by abrasion / renewal of the wax layer of the cuticula of individuals with direct contamination during the application vs. systemic uptake via food and residue decline via metabolisation and excretion, which is often much slower as well as immigration and emigration and population turnover). Thus, often a time weighted average approach (TWA), summarising the area under the curve is the most suitable method to describe longer-term residue patterns for arthropods. Nevertheless, for what ever method is chosen as most appropriate, clear evidence should be provided that this particular way of providing data for a refined exposure calculation is representing a realistic but sufficiently conservative approach to be suitable for a risk assessment.

# APPENDIX P

## HOW TO ESTIMATE PT[1]

PT is defined as the proportion of an animal's daily diet obtained in habitat treated with pesticide. As a worst-case (first tier assessment) it is assumed that individuals find all their food in the treated area and that PT = 1. In reality, birds and mammals in the agricultural landscape may visit a variety of habitats within a single day, and not all of them may be treated with plant protection products. Therefore, in higher tier risk assessment it is recommended that more realistic estimates of PT be obtained for relevant species and crop scenarios.

It has not been possible so far to make direct measurements of the amount of treated food ingested by individual birds and mammals in the farming landscape. However, by radio-tracking, it is possible to make indirect estimates of PT. Radio-tracking can deliver data on how much time an individual spends in different habitats. Assuming a) that the amount of time spent by an animals in a given crop is directly proportional to the food eaten there, and b) that the crop has been recently treated with pesticide, then it may be followed that a bird, which spends e.g. 50 % of its day in a given crop is likely to have 50 % of its daily food intake contaminated with pesticide.

When considering how to use radio-tracking data to estimate PT, the risk assessor should be aware of some methodological and analytical questions:

1. Using radio-tracking contact time as an estimate of foraging time.
2. Selection of which individuals to radio-track and which to include in the estimate of PT.
3. How long to follow individuals?
4. How to use PT in deterministic worst-case calculations?

### 1. Radio-tracking contact time as an estimate of foraging time.

PT is intended to be a measure of exposure to pesticides through the consumption of contaminated food. Radio-tracking data are more likely to be a good estimate of PT if they distinguish between time spent in crop where the animal is active and potentially foraging and time spent where the animal is inactive or engaged in non-foraging activity (e.g. singing, nest building, burrowing). For example, a blackbird may spend a large part of its day in a hedgerow but be relatively inactive there, using it principally as a refuge and only leaving it for short periods when searching intensively within a crop for food items. Ideally, PT should be expressed as the amount of (potential) foraging time in the crop expressed as a proportion of the total time spent (potentially) foraging in the day.

[1] Acknowledgement: EFSA wishes to thank Joe Crocker and Magnus Wang for the elaboration of this Appendix.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix P. EFSA Journal 2009; 7(12):1438. [7 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

## 2. Selection of which animals to radio-track and which to include in the estimate of PT

This is essentially a question for the risk manager. Pesticide risk assessments usually concern a particular pesticide used on a particular crop and the possible dangers presented to a particular wildlife species.

In choosing which individuals to radio-track one might:

a) Focus on the crop and radio-track only those individuals that were caught in the target crop.

b) Focus on the species and radio-track individuals captured in local farmland habitats where they are most abundant.

In estimating PT from radio-tracking data, one might:

c) Include only those individuals that foraged in the target crop ("consumers only" group).

d) Include all individuals with sufficient radio-tracking data.

PT estimated from group (a) (crop caught individuals) is likely to be higher (more conservative) than that from group (b) where individuals may visit a variety of habitats. For example the woodpigeon is a very common bird on UK arable land and may often be seen on fields of wheat in summer. But it is much more frequently seen on oilseed rape. Estimating cereal PT for woodpigeons by including only those caught on cereal fields will focus the risk to that sub-group of woodpigeons that use cereals but may be a rather unrepresentative sample of the broader woodpigeon population on arable land. On the other hand, estimating PT from the radio-tracking data obtained from all individuals in the general locality may give a better description of the exposure for a typical woodpigeon on arable land, (if the pattern of agriculture in the locality is also representative of the general pattern) but by including animals whose normal home range may not actually include the target crop, the risk assessment will be less conservative.

Having decided to focus on the particular group around the target crop (a) or the more general population in the locality (b), one needs to determine whether the interest is primarily in the exposure of those birds that actually foraged in the target crop (i.e. group (c) excluding individuals where PT = 0) or whether birds that ignored or avoided the crop (i.e. group (d) including individuals where PT = 0) should be included as well. For birds or mammals that were actually caught in the crop (a) it could be argued that PT must necessarily be greater than zero, and that all radio-tracked individuals are therefore legitimate subjects. However, some animals may have been caught in crop margins as they moved along the (non-crop) hedgerow and the crop itself may have played no significant part in their foraging routine.

In general it would seem reasonable that for focal species caught in the crop, PT can be estimated from all individuals (whether they used the crop or not) whereas for the population caught in the general locality, PT should be estimated from only those individuals shown by radio-tracking to have used the crop (PT > 0). The inclusion or exclusion of individuals with PT = 0 is a trivial calculation so it may be advisable to compare the risk for both groups (c and d), regardless of whether the animals were caught in the target crop or outside it.

In addition to the different sampling bias on PT from focusing on wildlife species caught in particular target crops or species in a variety of farmland habitat, there may be practical issues to consider. Restricting the sample to those caught in the target crop has the advantage that it gives a focused sample but it may increase the effort required to capture a large enough sample size and each crop will need a new radio-tracking sample. For wildlife caught in the general locality, some individuals may visit a variety of crops and may legitimately be used to estimate PT for each of those crops.

## 3. How long to follow individuals

In acute pesticide risk assessments, possible dangers to wildlife are assessed over a presumed exposure of 1 day. Therefore the most appropriate time course for collecting radio-tracking data is a set of continuous observations covering all the hours in a single day that the species may be potentially foraging. Observations of less than one day can exaggerate extremes in animals' choices of foraging habitats. For example, in an extreme case where an animal was observed for only a second then PT is likely to be either 0 or 1 and is unlikely to be an intermediate value because 1 second is not enough time for an individual to visit more than 1 habitat. Similarly, as crop maturity changes and food sources vary, individuals followed for days or weeks will tend to show some drift in habitat use with time: some habitat averaging will occur and PT will be less likely to be 0 or 1. Therefore the ideal radio-tracking record will last all of a single day.

However, the behaviour of some species in some seasons may make it particularly difficult to obtain a continuous record of behaviour lasting a day. Linnets for example can make rapid flight of more than a kilometre staying only briefly at new sites and making it difficult for radio-trackers to keep track of their movements. Another reason why continuous observation for a single day may not be available for analysis is that the experimenter chose to sample individuals' behaviour. For example the radio-tracking data collected by CSL and reported in Finch *et al.* (2006) aimed to collect observations for 1 hour in 2 of a typical day's behaviour. This made it easier for the data to be collected by a single observer and enabled more than 1 individual bird or mammal to be tracked during the course of a day. However, it will push estimates of PT closer to 0 or 1.

The degree to which an observation time of less than a full day will exaggerate the extreme value of PT will depend on the length of typical observation time in relation to the frequency with the subject moves between habitats. For example if a blue tit moved between cropland and woodland every few minutes and this was a constant feature of its behaviour throughout the day, then an observation time of an hour or so may be more than sufficient to estimate its PT. But if the individual spent the morning in a crop and the afternoon in woodland then a single hour's observation would most likely give a PT of 0 or 1, when the true value is 0.5. For radio-tracking reports covering less than a full day's observations it is recommended that the experimenter should:

- Show that the general sampling regime is unlikely to introduce biases into the estimation of PT e.g. will not lead to greater sampling of the animal when it is in the crop, and does not favour particular times of day when the animal is engaged in particular behaviours.
- Show that the shorter observation time is unlikely to have a significant bias on estimates of PT; or estimate the likely bias that shorter observation may have on the estimation of PT and correct it; or at least indicate whether the bias will have conservative or non-conservative effects on the risk assessment and allow the risk manager to decide if this is acceptable.

## 4. How to use PT in deterministic worst-case calculations

Having obtained estimates of PT for all individuals in the sample, the default value of 1 in the first tier need to be replaced. If the PT of 1 was replaced by a median or mean then this would suggest, in the absence of other safety factors, that the estimation of risk would be protective for only half the target population. The risk manager needs to decide what proportion of the population should be protected. In other words the risk manager should decide whether a reasonable worst-case is represented by a specific percentile of the population at risk.

How to estimate relevant percentiles and confidence bounds.

The simplest (non-parametric) way of estimating any centile is to rank the individuals in increasing order of PT and to choose the value of PT corresponding to e.g. the $90^{th}$ centile individual. Where there is no precise identity between an individual and the percentile of interest, an interpolate between values of neighbouring individuals in the sequence can be made. A problem of this approach is that, with small sample sizes (which is the case for many radio-tracking scenarios), the value of any given

centile may be very variable between samples. A better (parametric) estimate of the 90$^{th}$ percentile may be obtained by assuming that the data represent a random sample from a parent distribution with known mathematical properties. For many real-world measurements, statisticians assume that a sample comes from a normal distribution with parameters μ and σ estimated by the mean and standard deviation of the sample. However, the normal distribution (with infinite upper and lower bounds) does not often provide a good fit for proportional data (limited between 0 and 1). Therefore, the Beta distribution is considered as the most appropriate one for describing PT.

For the calculation of confidence intervals, bootstrap methods are commonly applied (Efron and Tibshirani, 1993; Manly, 2001, Davison and Hinkley, 2003). They can be categorised as *parametric* or *non-parametric* bootstraps. Non-parametric bootstraps repeatedly resample from the same dataset and the results of such a procedure will be critically dependent on how representative the underlying dataset is. Small datasets are less likely to be representative and the confidence limits obtained by non-parametric bootstraps are likely to be underestimated. Therefore parametric bootstrapping may be preferable for small radio-tracking datasets. For the analysis of PT data the following approach is proposed[2]:

1) From a field study *n* PT values are obtained, where *n* is the number of birds observed during one tracking session.
2) A beta distribution is fitted (distribution A) to all *n* PT values.
3) A random sample of sample size *n* is taken from distribution A.
4) Again, a beta distribution (B) is fitted to the new random sample.
5) From distribution B the 90$^{th}$ centile (or other estimate) of PT is calculated and recorded.
6) Steps 3 to 5 are repeated many times (e.g. 1000 times), each time a random sample of size *n* is taken from distribution A, a new beta distribution is fitted and the 90$^{th}$ centile is recorded.
7) Finally, the upper 95$^{th}$ (or other) one-sided confidence bound is calculated by ordering all 1000 estimates of the 90$^{th}$ centile from low to high and picking the value of the **95**$^{th}$ place (or other) in the sequence.

### Example protocol

Detailed protocols of how to fit radio-transmitters and appropriate field practice for radio-tracking birds are given in Appendixes 1 and 2 of Crocker *et al.* 1998, and RifCon (2006). Examples of how the data may be analysed can be found in Appendices 1-3 of Finch *et al.*, 2006, RifCon 2006, and Crocker *et al.*, 1998. The following summarises the essential points.

### Telemetry

There are two purposes of the radio-tracking technique: (i) To locate a bird in order to observe its behaviour ('radio surveillance', Kenward, 2001) and (ii) to follow the bird continuously over a defined period (see below) in order to determine its exact location and any behavioural changes ('continuous monitoring', Kenward, 2001).

During the tracking session birds should be tracked continuously, i.e. a bird should be followed non-stop by car or by walking. Every change in behaviour (according to the categories in Table 1) and

[2] This is a simplified explanation that omits important assumptions about the most appropriate distribution to fit (e.g. Beta, Binomial, Uniform, or some mixture of distributions), what method of fitting to use, and how to decide what is a good fit. For fitting a beta distribution to specific data different statistical method are available (e.g. maximum likelihood estimation, method of moments). These methods can give quite different results depending on the mature of the underlying data. Therefore the goodness of fit should be checked either graphically by comparing plots of the data and fit as cumulative distribution functions and/or by calculating appropriate goodness of fit statistics (e.g. chi Square, Kolmogorov-Smirov, Anderson-Darling) (See appendix 3 of Finch *et al.* (2006), Frey *et al.*, 1999, Efron & Tibshirani 1993, Skylar & Smith 2003).

location (habitat and position) should be accurately recorded to the minute. If the tracking session lasts a whole day, an exchange of observers may take place every few hours to ensure full attention of the persons tracking the birds. When monitoring bird activity, the sampling regime should be designed to capture activity throughout the day, and trackers should follow the sampling regime irrespective of "bird's compliance", i.e. sampling sessions should not be cut short because the bird has moved away or extended because the birds is easy to monitor (see Crocker *et al.*, 1998, Appendix 1).

With the use of unidirectional Yagi-antennas it is possible to determine the location of the tracked bird. The signal strength also allows an estimation of the distance to the bird. In order to describe the behaviour of the tracked bird as accurately as possible and to verify its location the tracker always endeavours (if the bird is not hidden by vegetation) to observe the bird by visual contact and with optical devices (scope, binoculars). Moreover, during visual contact it is possible to connect the signal quality of the radio tag to the observed behaviour of the bird. Hence, it may sometimes be possible to deduce the behaviour of the bird from the signal quality. Use of colour rings enables the observer to identify each bird with certainty. To ensure that the observer does not affect the behaviour of the bird, an appropriate 'safe distance' has to be maintained. Different species in different habitats may call for different safety distances. The idea is to follow the bird's habitual movements rather than chase it about the landscape.

As a general rule, the aim should be to obtain data from at least 20 individuals for any given scenario in order to get an appropriate sample size. For acute risk assessments the data should reflect a single typical day in the life of a focal species under conditions when the target crop might be treated with a given pesticide. For long-term assessments observation of more than one day may be considered.

**Calculation of PT in a specific crop**

The calculation of PT assumes a correlation between the time spent by a bird in a particular habitat and the amount of food it ingested in that habitat. In other words, it is assumed that the amount of food taken by a bird in a certain time span will be the same in any habitat or crop within its home range. The 'proportion of time foraging' is thus assumed to be equivalent to the 'proportion of diet obtained'.

At each telemetry session the proportion of diet obtained by an individual bird in a specific crop (PT) is calculated as the proportion of time the bird spent 'potentially foraging' in that crop. **'Potential foraging time'** is thus the sum of the time intervals during which a bird showed any of the behaviour categories, 'foraging', or 'active unknown'. All instances when the animal is known to be performing definitely non-foraging activities (e.g. singing, nest building) or when it is considered to be inactive are excluded from the calculation of PT. For each tracking session the 'time potentially foraging' within the crop of concern is compared with the total 'time potentially foraging' in any habitat (see below).

To provide further behavioural details, e.g. to assess whether a bird is active but not foraging (see text below for details on behaviour categories), all recorded visual observations of radio-tracked birds are included in the evaluation.

During some of the telemetry sessions it may not always be possible to determine a bird's location throughout the whole tracking session (i.e. whether it is in a specific crop or not). In such cases, the habitat should be recorded as 'unknown'. In most cases, the corresponding time periods during which the habitat is unknown are rather short and may therefore be excluded from the data analysis. This approach is justified when assuming that there is an equal likelihood of determining a bird's position in all habitat types in an agrarian landscape.

**Table 1.** Definition of behaviour categories (used for calculation of PT)

| | | |
|---|---|---|
| *Potentially foraging All instances when the bird was foraging for sure, or might have been foraging.* | Foraging | Bird is foraging (e.g. fluctuating radio-tracking signal, supported by visual sightings of bird searching for food) |
| | Active: unknown | Bird is active (e.g. fluctuating radio-tracking signal strength) but more definite information cannot be obtained |
| *Not Foraging All instances where bird was inactive or clearly engaged in non-foraging activity* | Breeding | Bird is engaged in behaviours that are part of reproduction (e.g. singing of males, song flight), copulation, mate guarding, territory defence, incubating (if nest site is known) etc., thus foraging can be excluded |
| | Active: other non-foraging | Bird is carrying out activities other than foraging and reproduction (e.g. seen preening, bathing, drinking, sunbathing) |
| | Inactive | Bird classified as inactive (not moving) by radio-tracking signal and/or by visual contact (thus, foraging can be excluded) |

**Example of PT calculation**

Total time a bird is present in all known habitats including the 'crop in focus' during an individual tracking session:

| **Behavioural category** | **Duration [h]** | **Sum** |
|---|---|---|
| Foraging | 1.5 | potentially foraging: 9 h |
| Active: unknown | 7.5 | |
| Breeding | 2 | time when foraging behaviour can be excluded: 7 h |
| Active: other non-foraging | 1 | |
| Inactive | 4 | |
| **Total time in all known habitats** | **16** | |

This results in a 'potential foraging time' for the 'crop in focus' of **4 h.**

The individual PT is then calculated as:

$$\frac{Potentially\ foraging\ time\ in\ the\ crop\ in\ focus}{Potentially\ foraging\ time\ in\ all\ known\ habitats} = \frac{4\ h}{9\ h} = 0.44$$

**Example justification for using < 1 day of observation data**[3]

It was noted earlier that where individuals had been observed for less than a continuous full day, then it should be shown that this does not significantly affect the estimate of PT, or the bias arising should be quantified. For the data obtained by example Finch *et al.* (2006) for a variety of arable and orchard scenarios typically tracked radio-tagged birds for 1 hour in 2 throughout the day. In the case of 17 yellowhammers monitored on cereal fields in summer this amounted to an average of 9.1 hours radio-tracking observation. The shortest observation time lasted 5.6 hours. It might be expected that PT estimated from very short observation times would be significantly different from PT estimated from longer observation times.

Based on the first 1 to 9 hours radio-tracking data for each bird the 90$^{th}$ centile PT and its 95$^{th}$ centile upper bound as calculated by the method described above. It may be seen that the 90$^{th}$ centile PT changes noticeably over the first couple of hours of monitoring but then stabilises to a fairly constant value. Similarly the upper 95$^{th}$ confidence bound appears stable even when observation times are short. With the shortest yellowhammer observation time lasting 5.6 hours, it would seem that the sampling protocol does not, in this scenario, seriously affect the estimation of 90$^{th}$ centile PT and its upper confidence bound.

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[3] Where possible it is preferable to collect a full day's observations. But if less than this is available the data may still be useful in estimating PT provided they meet the criteria detailed in section 3a and 3b.

# APPENDIX Q

# HOW TO DETERMINE BIRD AND MAMMAL DIETS

## 1. Introduction

At Tier 1, a worst case diet is used along with an indicator species to produce a screening step. If a pesticide fails Tier 1, then, in a higher tier it is possible to refine the risk assessment by using a more realistic scenario in terms of bird or mammal occurring in a treated crop, along with a more realistic diet. The diet used at higher tiers is based on publicly available data. Therefore if a compound fails Tier 1, it may be possible to refine the exposure component via revising the diet in two ways.

Firstly, it may be possible to revisit the publicly available data, providing that the studies on the diet of focal species are conducted in an appropriate landscape (crop of agricultural mosaic) and to a methodology considered to be equivalent to that outlined below. Alternatively, the diet of focal species can be determined via field work as outlined below.

## 2. How to determine a bird diet

An analysis of the diet of a bird can help to estimate the exposure of a bird to a plant protection product after application. Different food sources of birds may contain different residue levels. For example, when seeds are dressed with a fungicide and sown in a field they may contain higher residue levels than the arthropods living in that field. The risk for seed eating birds may then be greater than that for omnivores. Therefore, for a realistic estimation of the actual exposure to birds the respective proportion of these food items in the diet of a bird species must be examined.

Several methods for measuring the composition of the diet of birds are used. Direct monitoring of the birds' food selection is often hindered by vegetation or the observation distance. Therefore, alternative methods have to be considered. Video recordings at bird nests can offer an insight in the nestlings' diet. However, the diet of nestlings may differ considerably from the diet of the adults. Another method is the application of neck collars to chicks in order to prevent food items to be swallowed. This method restricts the view to the analysis of the nestlings' diet and is therefore not an ideal method for determining the diet of adult birds.

The investigation of faeces or stomach contents obtained via gastric lavage (stomach flushing) of adult birds is not subject to these constraints. For these approaches it is essential to be able to identify food items on the basis of diminutive remains found in faeces or stomach flushing samples. A considerable difficulty is the differential digestibility of different food types. Few remains may be found either because few items were eaten or because food items were almost completely digested. Calibration trials with captive birds can help to overcome this difficulty. Also, in some cases it may be possible to apply correction factors taken from the literature.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix Q. EFSA Journal 2009; 7(12):1438. [4 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

If radio-tracking is applied simultaneously to the collection of diet samples, the source (e.g. a specific crop) of the food items found in the sample can be identified.

## 2.1 Test procedure

### 2.1.1 Bird trapping and sample collecting

In order to obtain an estimate of the diet of a focal species, it is necessary to trap birds using accepted methods (e.g. mist nets, whoosh nets, perch traps, spring traps), when they have access to the crop of concern. The study should also be done at the appropriate time of year. Nets and/or traps should be placed within or at least in close proximity to the target crop. The sites should be representative of where the pesticide is used or is intended to be used. This may be across relevant geographical and climatic regions, within a MS if the pesticide is to be used in one MS, within a zone, or if the pesticide is used across a range of MS, then it may be appropriate to have a selection of fields across MS.

Once caught, it is possible to obtain a diet sample of a bird by obtaining faecal (after Brensing, 1977) and/or stomach flushing samples (modified after Ralph *et al*., 1985). Generally faecal sampling is favoured over stomach flushing as it is not intrusive and tends to give more reliable results (see e.g. Jenni *et al*., 1990). Therefore, it is recommended that stomach flushing should only be used if no faeces can be obtained.

#### 2.1.1.1 Faeces sampling

For collecting faeces, birds can be kept in a clean bird bag or held over a polythene sheet during handling (Sutherland, 2004). Droppings can often also be collected in the field, e.g. where birds perch, roost and at nests. Faeces samples should be stored separately and can be preserved with sodium chloride.

It is important to keep samples separate and not to pool them. Separation of the samples serves two purposes, to account for individual variability and to apply correction factors to the food contents in order to take account of digestibility (see 2.4.1). Since these correction factors are derived from individual samples, proper application requires separate storage and analysis of each sample.

#### 2.1.1.2 Stomach sampling

A vaseline coated narrow plastic tube is inserted into the stomach and lukewarm water is pumped in the stomach through a syringe until the contents of the oesophagus and stomach are voided (Sutherland, 2004). The obtained sample is transferred in a sample container and preserved with alcohol. As for faeces sampling it is important not to pool the samples.

## 2.2 Collection of reference material

For an accurate determination of the diet of a bird a “reference collection” is useful as it facilitates the identification of the taxa of the food items. Additionally, the collection of reference material or food items, (such as invertebrates, seeds, or plants) from the study area can help to estimate the original size of food items. As a rule, un-digestible fractions of one food item are not obtained as a whole but rather as food fragments (“remains”). In order to minimize the uncertainty of the size estimation of food items a regression analysis of the dimension (size) of the potential food items and parts of these food items likely to be found within the samples can be conducted. Reference material, i.e. potential food items can be collected within the crop and the assumed home range of the birds.

## 2.3 Sample analysis

Food items are investigated via microscopic analysis (reflected light microscopy and transmission light microscopy; see e.g. Flinks and Pfeiffer, 1988). Insect remains can often be assigned at least to the family. The remains of other invertebrates can mostly be assigned at least to the class. For the

determination of the green plant material, structures of the cuticle, particularly stomata, are considered. Seeds can be identified by analysing husk remains.

The size of characteristic parts of invertebrates or plants (e.g. chitin fragments of arthropods, setae of earthworms, fragments of seeds (pericarp), plant material, i.e. area of leaves and stems) can be measured with a measuring ocular. The obtained sizes can be compared to the specimens from a reference library.

In order to quantify the number of food items (e.g. number of arthropods), within each sample food fragments found in the sample are counted and the minimum number of individuals required to account for the number of assigned remains is calculated (see e.g. Jenny *et al.*, 1990). For example, two right mandibles and one left mandible of a beetle species can be attributed to (at least) two individuals. In plant material, the number of fruits and seeds can be obtained by measuring the area of the fragments and dividing this figure by the area of a reference fruit or seed. From remains of leaves the area is measured and recorded.

The quality of the results obtained by the analysis of faeces or stomach flushing samples depends significantly on the ability of the processor to identify the remains accurately. Trials using captive birds fed with a variety of different food items can help to quantify the recovery rate (see also 2.4.1).

## 2.4 Data evaluation

### 2.4.1 Conversion of the number of food items in the faeces samples or stomach flushes to the number of food items actually ingested

For estimating how many food items were ingested by a bird, based on the number of food items found in the faeces or stomach, correction factors (or correlation coefficients) can be applied. For each type of food a specific correction factor has to be used, because during the digestion process some food items may almost completely disappear while others remain almost intact. For example earthworms or other soil invertebrates are usually digested efficiently. In contrast, cuticle parts of many arthropods remain often unaffected and can easily be identified in the faeces. Correction factors for some food types and bird species can be derived from the literature (e.g. Jenni *et al.*, 1990; Green, 1984). For example it has been shown that the number of Araneida (spiders) ingested is about 3.9 times higher than the number found in the birds' faeces (100/25.5, Jenni *et al.*, 1990).

Alternatively bird species specific feeding trials can be carried out in captivity to identify traces found in faeces and stomach flushing samples when known food items are consumed. These data can be used to establish food item specific correction factors which compensate for differential digestion (Jordan, 2005). Feeding trials also offer the opportunity to account for the uncertainty and variability of correction factors.

### 2.4.2 Calculation of dry weight from length of food items ingested

In order to convert the calculated numerical proportions into mass proportions length-weight regressions derived from the literature (e.g. Collins, 1992; Henschel *et al.*, 1996, Klotz *et al.*, 2002; Rogers *et al.*, 1976; Sample *et al.*, 1993) can be applied, which are available for different invertebrate taxa and plant seeds. Hence, the approximate dry weight of food items can be calculated from their estimated length.

### 2.4.3 Quantification of percentiles of the diet of farmland birds

Since the quantification of the diet of birds involves several measurement errors and also natural variability (e.g. body size of food items) the mean or median may include biases. Therefore, a percentile could be used instead of the arithmetic mean for deterministic assessments. A probabilistic approach for estimating the diet of birds offers the advantage that the different levels of variability and uncertainty can be included. A probabilistic approach uses distributions instead of constant parameter

values, from which parameter values are sampled many times in order to calculate the distribution of food groups for which RUDs are available (using a Monte Carlo method). This approach also allows an estimation of percentiles.

### 3. How to determine a mammal's diet

The method of faeces analysis outlined above in section 2.1.1.1 can also be used for mammals. It is also possible to analyse stomach contents for mammals caught in snap-taps (mice, voles etc.) or shoot by hunters (hares, rabbits etc.) However, stomach flushing is not appropriate for mammals.

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# APPENDIX R

## NESTLING SCENARIOS FOR LONG-TERM ASSESSMENTS[1]

In the phased approach to the long-term risk assessment in birds, it was suggested (Shore et al., 2005) to turn to the $LC_{50}$ study and use the $LC_{05}$ as an indication of a dietary dose that could be tolerated by young birds. Unfortunately, the $LC_{50}$ test has been plagued with problems (Mineau et al., 1994) and, furthermore, will no longer be required at an early tier in EU registration procedures. Therefore, it was agreed that an alternate strategy utilising the $LD_{50}$ would be developed.

In order to estimate the ability of nestlings to survive a pesticide application, an approach parallel to that used for the acute assessment in adult birds has been developed. The approach uses information on the measured energetic needs of young birds, coupled to a feeding model and calculates a TER.

### 1. Toxicity

The sensitivity of altricial nestlings to pesticides is known to be higher than that of adults in the case of organophosphorous insecticides (Wolfe and Kendall, 1998). This is in part because the cholinesterase system of altricial birds is not fully developed at birth. It is possible that altricial chicks are more sensitive to other classes of compounds as well but, unfortunately, no information is available on which to base a correction factor.

In the case of precocial chicks, available information does not suggest that a correction factor is required. The relationship between chick toxicity and adult toxicity follows roughly a 1:1 relationship (Fig. 1). Therefore, we propose at this stage to use adult $LD_{50}$ values to reflect chick toxicity. More research is needed to characterize the toxicity of different pesticides to altricial chicks.

[1] Acknowledgement: EFSA wishes to thank Pierre Mineau, Science and Technology Branch, Environment Canada, for the elaboration of this Appendix.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix R. EFSA Journal 2009; 7(12):1438. [4 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

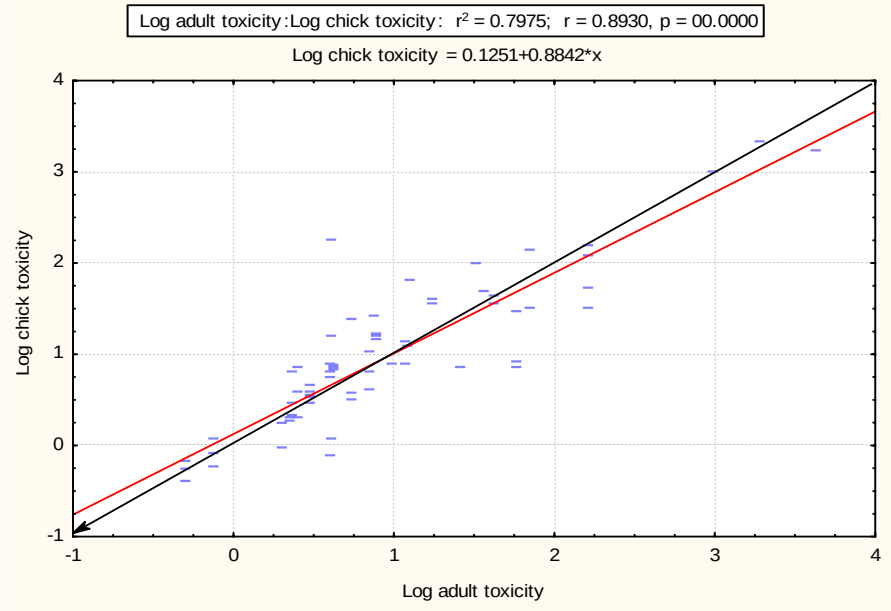


**Figure 1.** Log-log plot of chick $LD_{50}$ (aged 1.5 - 60 days; median and mode age of 7 days) for bobwhite, mallard and japanese quail against the geometric mean $LD_{50}$ in the adult. Exact values only. N = 69. Data source: Environment Canada database.

## 2. Exposure

Comparisons provided in Kendeigh *et al.* (1977) suggest that gross energy intakes expressed as a proportion of body weight are higher in altricial nestlings than in precocial ones. Therefore, in order to be protective of all bird species, a generic exposure scenario used in the assessment of reproductive effects should be based on the energetic needs of a precocial species.

***Correction factor for digestive inefficiency and thermoregulatory status of very young altricial nestlings.***

Based on the work of Kendeigh *et al.* (1977) in house sparrows, young birds aged 1-4 days have a food assimilation efficiency approximately 15% lower than that of adults. Based on the information provided for that species, correction factors of 0.83, 0.87, 0.87, and 0.93 are applied to ages 1-4 days respectively.

It has been shown by Williams and Prints (1987) that laboratory studies of energy use in altricial nestlings conducted under thermo neutral conditions underestimate field energy use because they do not usually take into account the thermoregulatory costs of 'outdoor living`. Information from that work was used to correct the maintenance portion of the daily energy needs of the nestlings. Correction factors were estimated from Figure 4 of Williams and Prints (1987) (Table 1). The discrepancy between the two measures increases with age which corresponds to the decrease in adult brooding behaviour over time.

***Body Mass***

Nestling weights of different species are dependant on egg size (and therefore clutch size and reproductive strategy) and on growth rate. The latter varies with age and is also subject to a number of ecological constraints. Based on examples gleaned from the literature (Kendeigh for house sparrows, Williams and colleagues in savannah sparrows), it is probably safe to use

a hatching weight of 11% of female adult body mass for scenarios involving freshly hatched altricial passerines. Maximum exposure (see table 1 below) in nestling savannah sparrows occurred when the birds were 2 days of age (48-72 hours post hatch), approximately 25% of adult female body weight. This percentage should be applied to the indicator species or generic focal species of concern unless more reliable data are available to estimate the weight of nestlings at 2 days of age.

***Choice of scenario***

Few if any of the generic focal species (Appendix A1) have been studied from the point of view of nestling energetics. It is therefore proposed that the exposure scenario for an altricial chick be based on the combined work of Williams and Prints (1987) on the savannah sparrow, and that of Kendeigh *et al.* (1977) in the house sparrow. Calculations suggest that an altricial chick is at its most vulnerable a few days after birth when its FIR/bw peaks (Table 1). We therefore propose that, until such time as better information becomes available, the max. FIR/bw value of 1.08 calculated in the savannah sparrow for the 48-72 hour period after hatch (25% of adult female bodyweight) should be used to model peak vulnerability to pesticide exposure in altricial insectivores.

**Table 1.** Energy budget of a nestling savannah sparrow based on Williams and Prints (1987) and Kendeigh *et al.* (1977).

| Age(d) | BW[1] (g) | Energy for growth (kj/d) | Energy for maintenance (kj/d) | Correction for thermo-regulation[2] | DEE (kj/d) | Food energy (kj/g dry wt) | Moisture (%) | Assimilation efficiency (%)[3] | FIR (g/day) | FIR /bw |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 to 1 | 1.79 | 4.96 | 1.67 | 1.3 | 7.13 | 21.9 | 70.5 | 63 | 1.75 | 0.98 |
| 1 to 2 | 2.81 | 8.53 | 2.19 | 1.35 | 11.49 | 21.9 | 70.5 | 66 | 2.69 | 0.96 |
| 2 to 3 | 4.24 | 13.19 | 4.54 | 1.4 | 19.55 | 21.9 | 70.5 | 66 | 4.58 | 1.08 |
| 3 to 4 | 6.04 | 17.56 | 6.55 | 1.45 | 27.06 | 21.9 | 70.5 | 71 | 5.90 | 0.98 |
| 4 to 5 | 8.05 | 19.15 | 10.36 | 1.5 | 34.69 | 21.9 | 70.5 | 76 | 7.07 | 0.88 |
| 5 to 6 | 10.02 | 16.84 | 15.33 | 1.55 | 40.60 | 21.9 | 70.5 | 76 | 8.27 | 0.83 |
| 6 to 7 | 11.70 | 12.24 | 20.37 | 1.6 | 44.83 | 21.9 | 70.5 | 76 | 9.13 | 0.78 |
| 7 to 8 | 12.98 | 7.73 | 24.59 | 1.65 | 48.30 | 21.9 | 70.5 | 76 | 9.84 | 0.76 |

[1] based on growth equation (g)
[2] estimated from Fig. 4 in Williams and Prints (1987)
[3] corrected for inefficiency in young house sparrow after table 5.6 in Kendeigh

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# APPENDIX S

## BIOACCUMULATION OF CHEMICALS IN TERRESTRIAL VERTEBRATES

This Appendix is predominantly based on Appendix III of EC (2002), thus containing the paper of Pablos et al. "Proposal to establish an initial risk assessment of terrestrial vertebrates for the estimation of pesticides with biomagnification potential". However, the example calculations were adapted to new values.

Suggested citation: European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix S. EFSA Journal 2009; 7(12):1438. [9 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

# PROPOSAL TO ESTABLISH AN INITIAL RISK ASSESSMENT OF TERRESTRIAL VERTEBRATES FOR THE ESTIMATION OF PESTICIDES WITH BIOMAGNIFICATION POTENTIAL

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The current model assesses the potential for consumption of sprayed items and bioaccumulation of pesticides. Other hazards, such as biomagnification are not taken into account in this evaluation, but are important aspects for the protection of top predators. If the substance is persistent and likely to bioaccumulate (on the aquatic and/or terrestrial compartment), it would be necessary to apply an additional biomagnification model. For this assessment, it is necessary to calculate for each trophic level, the percentage of the total intake that is retained by the organism. These data can be obtained from the studies of both, metabolism on mammals and bioaccumulation on fish. Therefore an initial biomagnification assessment can be easily done with the available information.

This proposal presents a simplified model to assess the potential for biomagnification through the food chain.

## BIOACCUMULATION OF CHEMICALS IN TERRESTRIAL VERTEBRATES

The bioaccumulation of pesticides in terrestrial vertebrates is estimated from the food-organism bioaccumulation factor (BAF):

$$BAF = \frac{C_{Organism}}{C_{food}}$$

where C organism and C food represent the steady-state concentrations of the chemical in the organism and the food respectively.

The BAF can be directly obtained from experimental assays or estimated from a combination of default values and the available data on the toxicokinetics of the pesticide in mammals.

The following equation is proposed for the estimation of the BAF:

$$BAF_{organisms,\,food} = \frac{\alpha F}{k_2}$$

This is a modification of the typical equation

$$ssBCF = \frac{k_1}{k_2}$$

where the uptake rate is represented by the product of the assimilation efficiency (α) and the feeding rate (F) while $k_2$ represents the depuration rate.

The assimilation efficiency (α) represents the ratio between the amount of chemical existing in the

food and the amount of chemical absorbed by the organisms. This information is generally available in the toxicokinetic studies on mammals.

The feeding rate (F) represents the food intake rate related to body weight (FIR/bw). Appendix 12 and 13 of the Guidance Document offer estimated values for several bird and mammal species. The following table covers predators and top-predators.

**Table 1:** Food intake rate (FIR) and Food intake rate related to body weight (FIR/bw) for predatory birds and mammals (table of former guidance document updated with information from Appendices 12 and 13.

| Indicator species | Example | Body weight (g) | DEE[1] (kJ/d) | Food characteristics | | | Assimi-lation efficiency (%) | FIR (g fresh weight /d) | FIR/bw |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Food type | Energy (kJ/g dry weight) | Moisture (%) | | | |
| Predatory bird | Peregrine falcon | 1000 | 701 | Birds | 22.6 | 68.8 | 84 | 118 | 0.118 |
| Predatory bird | Golden eagle | 5000 | 2059 | Birds & mammals | 22.6 | 68.8 | 84 | 348 | 0.070 |
| Predatory mammal | Fox | 8000 | 4024 | Birds & mammals | 22.6 | 68.8 | 85 | 671 | 0.084 |
| Predatory mammal | Linx | 20000 | 7749 | Birds & mammals | 22.6 | 68.8 | 85 | 1293 | 0.065 |
| Predatory mammal | Wolf | 40000 | 12720 | Birds & mammals | 22.6 | 68.8 | 85 | 2122 | 0.053 |

[1] = Daily energy expenditure calculations for predatory birds based on values for non passerines and for predatory mammals on values for mammals, excluding desert and marine eutherians.

The depuration rate ($k_2$) is obtained from the metabolism studies in mammals, using the elimination half-life $T_{1/2}$ in the following equation:

$$k_2 = \frac{\ln(2)}{T_{1/2}}$$

For a first tier assessment the estimation could consider a steady state concentration (ss), estimated as:

$$ssPEC_{organisms} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{food}$$

where PEC food is estimated from the application rate and the RUD (90$^{th}$ percentiles).

For the refinement, the dissipation of the pesticide in the environment can be incorporated, assuming first order kinetics, by a slightly modified equation frequently used for oral exposures (i.e. Fisk et al.,

1998):

$$PEC_{organisms} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{food}\,(1 - e^{-(\frac{\ln(2)}{DT_{50}}t}})$$

## A SIMPLIFIED SCHEME FOR FOOD-CHAIN RELATIONSHIPS

Ecosystems are constructed by a set of assembled food chains producing very complex structures. For the inclusion of biomagnification in the environmental risk assessment of pesticides, these structures must be simplified to workable schemes.

Tables 2 and 3 describe the different links of the food-chain considered in the proposal for birds and mammals respectively.

**Table 2.** Characteristics of selected birds.

| Diet/nutrition | Food composition | Body size |
|---|---|---|
| Insectivore | 100 % contaminated insects<br>100 % contaminated soil-dwelling invertebrates | Medium & small |
| Herbivore | 100 % contaminated plants | Medium & large |
| Omnivore | 33 % contaminated invertebrates, 33% contaminated seeds, 33 % contaminated plants | Small |
| Carnivore | 100 % contaminated birds and mammals | Medium |
| Carnivore/piscivore | 50 % contaminated birds and mammals<br>50 % contaminated fish | Large & medium |
| Piscivore | 100 % contaminated fish | Medium & large |
| Aquatic herbivore/insectivore | 50 % contaminated aquatic invertebrates<br>50 % contaminated aquatic plants | Medium |

**Table 3.** Characteristics of selected mammals

| Diet/nutrition | Food composition | Body size |
|---|---|---|
| Insectivore | 100 % contaminated insects | Small |
| Herbivore | 100 % contaminated plants | Small & medium |
| Omnivore | 33 % contaminated invertebrates, 33% contaminated seeds, 33 % contaminated plants | Medium |
| Carnivore | 100 % contaminated mammals | Medium |
| Piscivore | 100 % contaminated fish | Medium |

**ESTIMATION OF PEC FOR THE DIFFERENT FOOD CHAIN LEVELS.**

The simplified proposal can be easily quantified using the equations described previously. For steady state conditions, each trophic level is considered to feed exclusively on contaminated food, corresponding to the previous trophic level.

The initial assessment, to quantify the concentration in the food items for intermediate consumers (birds and mammals) considers the consumption of sprayed food items, fish from contaminated waters and earthworms from contaminated soils.

The steady state concentration for the intermediate consumers is therefore calculated by:

$$PEC_{\text{int}ermediate\cdot consumers} = \frac{\alpha F}{k_2} \times (ETE) = (\frac{\alpha F \times T_{1/2} \times application \cdot rate \times RUD}{\ln(2)})$$

In the case of omnivores the estimation assumes that the feeding of the animal is distributed proportionally between leaves, grass and insects; therefore, the estimation is:

$$PEC_{\text{int}ermediate\cdot consumers\cdot(omnivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times (application \cdot rate \times R_p)$$

The $R_p$ is the averaged coefficient assuming the different proportions of the animal diet. This $R_p$ is estimated as:

$$R_p = \frac{\left(\frac{\sum_i^n RUD_i}{P_i}\right)}{n})$$

The steady state concentration for predators is estimated assuming that contaminated intermediate consumers constitute 100% of their diet; the equations are different depending on the predators are piscivores, insectivores or carnivores. PECs can be estimated as:

$$PEC_{predators\cdot(piscivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{sw} \times BCF$$

$$PEC_{predators\cdot(insectivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{soil} \times BAF_{soil-earthworms}$$

$$PEC_{predators\cdot(carnivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{\text{int}ermediate\cdot consumers\,(omnivores)}$$

$$PEC_{predators\cdot(carnivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times application \cdot rate \times R_p)$$

The same values for α and $k_2$ than those used for intermediary consumers can be used for the preliminary assessment. Only those insectivore species feeding on soil dwelling organisms are considered in this assessment as those feeding on foliar insects have been already covered as intermediate consumers. Earthworms are suggested as model since QSARs for soil bioaccumulation are available. Other soil-dwelling organisms can also be considered.

Similarly, the steady state concentration for top predators is estimated assuming that contaminated predators constitute 100% of their diet:

$$PEC_{toppredators} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{mammals\cdot\&\cdot birds}$$

Depending on the relevant compartment, the equations are:

$$PEC_{toppredators} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{predatores\,(piscivores)} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{sw} \times BCF$$

$$PEC_{toppredators} = \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times PEC_{predatores\,(carnivores)}$$

$$= \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times \frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times \left[\frac{\left(\frac{\alpha F}{\ln(2)}\right)}{T_{1/2}} \times application \cdot rate \times R_p\right]$$

For episodic or intermittent exposures, the steady state calculations are not appropriate and the equations must be substituted by the kinetic equations. These equations can be modelled as combinations of two additive components, the chemical remaining from previous exposures and the newly absorbed chemical. Selecting Δt PEC values much lower than the $T_{1/2}$, the elimination component for the newly absorbed chemical becomes negligible, and the concentration in the organisms at time t, assuming first order dissipation kinetics, is represented by:

$$PEC_{organisms,t} = PEC_{organisms,(t-1)}(e^{-k2\Delta t}) + \left[(\alpha F)PEC_{food,t}\Delta t\right]$$

Finally, the following scheme (Figure 1) summarises the links assumed in this proposal.

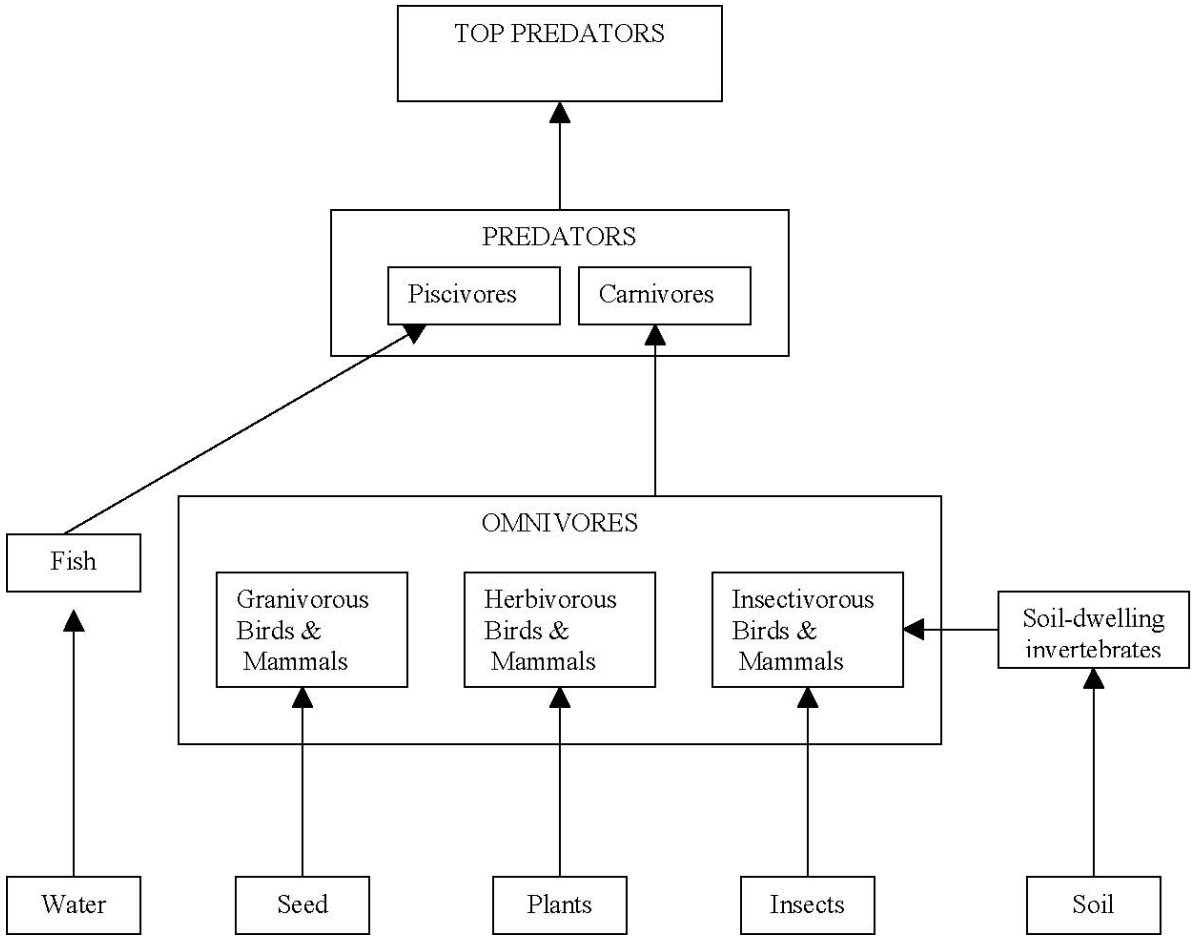


**Figure 1.**

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## Worked example - Bioaccumulation issues

This example describes the risk to birds and mammals arising from bioaccumulation potential of a fictitious substance. It is assumed that the standard tier 1 assessment has been completed.

### Key endpoints

| | |
|---|---|
| long-term NOEL mammals | 50 mg/kg bw/d |
| long-term NOEL birds | 20 mg/kg bw/d |
| BCF (fish) | 640 |
| Adsorption, distribution, | Rate and extent of excretion: >95 % after 7 days |
| Excretion and metabolism in mammals | Potential for bioaccumulation: none |
| $K_{OW}$ | 20000 (log $K_{OW}$ = 4.3) |
| $K_{OC}$ | 6200 |
| $PEC_{soil}$ | 1.4 mg/kg |
| $PEC_{sw}$ | 0.001 mg/l |

### Initial trigger

It is noted that log $K_{OW}$ is greater than 3 thus making necessary the considerations outlined in chapter 4.3.

### Food chain from earthworms to earthworm-eating birds and mammals

Measured residues in earthworms are not available, nor experimentally determined bioconcentration factor for worms. Therefore the model calculation is applied.

- $PEC_{soil}$ = 1.4 mg/kg
- The BCF for worms is estimated as BCF = $(0.84 + 0.01K_{OW}) / (f_{OC} \times K_{OC})$

with

$K_{OW}$ = 20000,

$K_{OC}$ = 3200,

and $f_{OC}$ = 0.02 (default value):

the resulting BCF is 1.6

- The estimated concentration in worm ($PEC_{worm}$) is $PEC_{soil} \times$ BCF, i.e. $1.4 \times 1.6 = 2.2$ mg/kg.
- The daily dose for mammals is $2.2 \times 1.28 = 2.82$ mg/kg bw/d, and for birds it is $2.2 \times 1.05 = 2.31$ mg/kg bw/d.

The long-term TER-values are 50/2.82 = 17.7 for mammals and 20/2.4 = 8.66 for birds, and therefore the risk is acceptable.

**Food chain from fish to fish-eating birds and mammals**

- A model calculation is applied using the PEC for surface water and the experimentally determined BCF for fish. $PEC_{sw}$ = 0.001 mg/l.
- The estimated concentration in fish ($PEC_{fish}$) is $PEC_{sw}$ × BCF, i.e. 0.001 × 640 = 0.64 mg/kg.
- The daily dose for mammals is 0.64 × 0.137 = 0.088 mg/kg bw/d, and for birds it is 0.64 × 0.205 = 0.131 mg/kg bw/d.

The long-term TER-values are 50/0.088=568 for mammals and 20/0.205=98 for birds, and therefore the risk is acceptable.

**Biomagnification in terrestrial food chains**

As the evaluation of the toxicokinetic studies in the toxicology section concluded that the potential for bioaccumulation is low it can be assumed that there is no biomagnification along the food chain.