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DRAFT Guidance Document

Guidance to define protection goals for environmental risk assessment in relation to biodiversity and ecosystem services[1]

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ABSTRACT

Maintaining a healthy environment and conserving biodiversity are major policy protection goals. Legal frameworks therefore require the protection of human, animal and plant health, and the environment. A challenge, however, is that protection goals outlined in legislation are often too general and broad to be directly applicable for environmental risk assessment (ERA) performed by the European Food Safety Authority (EFSA). Therefore, general and broadly formulated protection goals need to be translated into specific protection goals. This Guidance presents a framework, which accounts for biodiversity and ecosystem services, to make policy protection goals operational for use in EFSA's ERAs. The proposed approach follows three sequential steps: (1) the identification of relevant Ecosystem Services; (2) the identification of service providing units supporting/providing relevant Ecosystem Services; and (3) the specification of the degree/parameters of protection of the service providing units using interrelated dimensions. This last step involves the specification of the ecological entitiy and attribute to be protected, the spatial and temporal scale of protection, and the magnitude of acceptable effect. Considerations are proposed against which the selected options can be justified, in order to promote transparency and consistency when specifying the degree/parameters of protection. The proposed approach is considered adequate to provide a framework to derive specific protection goals in all different ERAs conducted by EFSA.

KEY WORDS

Protection goals, environmental risk assessment, plant protection products, genetically modified organisms, feed additives, invasive alien species.

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SUMMARY

Potential stressors assessed in any area of EFSA's remit, such as plant protection products, genetically modified organisms and feed additives are subject to a risk analysis and regulatory approval before being placed on the market in the European Union. In this process, the role of the European Food Safety Authority (EFSA) is to independently assess and provide scientific advice to risk managers on possible risks that plant protection products, genetically modified organisms and feed additives may pose to the environment. EFSA also assesses the environmental risks related to the entry and spread of invasive alien species that are harmful for plant health and the effects of their management.

At EFSA's 10th anniversary conference (EFSA, 2012), it became apparent that because of the different approaches laid down in the different legislative frameworks and established practices, EFSA's environmental risk assessment (ERA) schemes have evolved independently in the different areas within its remit (see EFSA, 2011), and that further harmonisation is possible on specific topics. EFSA therefore mandated (under mandate M-2013-0098) the Scientific Committee to harmonise EFSA's ERA schemes with regard to: (1) defining protection goals for ERA in relation to biodiversity and ecosystem services; (2) coverage of endangered species in environmental risk assessments at EFSA; and (3) temporal and spatial recovery of non-target organisms for ERAs. The Scientific Committee therefore prepared three separate scientific documents to address the abovementioned issues.

Maintaining a healthy environment and conserving biodiversity are major goals of environmental protection. Legal frameworks therefore require the protection of human, animal and plant health, and the environment. This necessitates the characterisation of protection. A challenge, however, is that protection goals outlined in legislation are often too general and vague to be directly applicable for ERA. Therefore, general and broadly formulated protection goals need to be translated into concise and concrete measurable endpoints, and scientifically testable hypotheses.

The overall aim of this guidance is to propose a common approach, using biodiversity and ecosystem services, to operationalise environmental protection goals for ERA in a harmonised manner in the different sectors of EFSA's responsibility.

The approach follows three sequential steps: (1) the identification of relevant ecosystem services; (2) the identification of service providing units supporting/providing relevant ecosystem services and (3) the specification of the degree/parameters of protection of the service providing units using interrelated dimensions. This last step involves the specification of the ecological entitiy and attribute to be protected, the spatial and temporal scale of protection and the magnitude of acceptable effect.

Considerations are proposed against which the selected options can be justified, in order to promote transparency and consistency when specifying the degree/parameters of protection. The proposed approach is considered adequate for a harmonised framework to derive specific protection goals across all different ERAs conducted by EFSA.

The general protection goals are defined in the legislation. The definition of specific protection goals should take place in dialogue between risk assessors and risk managers since it involves normative considerations, which cannot be set through natural sciences alone. This dialogue helps to define the framework in which risk assessors have to operate when performing ERAs. More precisely, in the context of defining specific protection goals, risk assessors may elaborate different options and describe the environmental consequences for each of them.

Risk managers *decide which* option(s) need to be set as specific protection goal(s). Risk managers base the granting of marketing authorisations on the work of the risk assessors, who do the assessment for each area within the remit of EFSA under the respective legislative frameworks and according to the EFSA Guidance.

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Background and Terms of reference as provided by EFSA

EFSA mandated the Scientific Committee (SC) to harmonise EFSA's ERA schemes with regard to the operationalisation of protection goals for use in ERAs. Policy protection goals are often vaguely and too broadly defined in legislation, and thus need to be specified further. A dedicated working group composed of experts from the relevant EFSA Panels is tasked to develop a scientific guidance in which a framework that accounts for biodiversity and ecosystem services (ES) is presented to make policy protection goals operational for use in EFSA's ERAs. This working group shall consider relevant ERA-related guidelines developed by EFSA Panels and other EU and MS agencies and scientific bodies (e.g. Scientific Committee for Environmental Health Risks, European Environmental Agency, European Medicines Agency, European Chemicals Agency, Joint Research Centre), international bodies (e.g. WHO/IPCS, OECD) and other international agencies (e.g. US Environmental Protection Agency).

Following the EFSA 10th Anniversary scientific conference (EFSA, 2012), wherein experts from various EFSA areas provided details and exchanged experiences on their current schemes for ERA, the SC explored the differences and similarities across EFSA areas when addressing protection goals. In response to the terms of reference, this guidance will therefore formulate "specific steps for achieving harmonisation of protection goals". Therefore the Terms of Reference are interpreted as having the goal to make protection goals operational as a first step towards their harmonization.

In consultation with the SC and following a public consultation, a common framework for making protection goals operational for use in EFSA's ERAs will be developed.

Interpretation of the terms of reference

In accordance with the various relevant legislations in place (EFSA, 2011)[4] EFSA performs ERA on the application of Plant Protection Products (PPPs), the deliberate release into the environment of genetically modified organisms (GMOs), the use of certain substances in food and feed (e.g. feed additives) and the introduction and spread of invasive alien species that are harmful to plant health (IAS)[5]. The purpose is to evaluate their potential adverse effects on the environment. In this document such agents are referred to as potential stressors. As defined in the glossary[6]:

[4] While an overview table is given in EFSA (2011), more detailed guidelines for ERA have been developed in a number of guidance documents from individual EFSA Scientific Panels (Panel on Plant Protection Products and Residues (PPR), 2009 and 2013; Panel on Plant Health (PLH), 2010 and 2011; Panel on Genetically Modified Organisms (GMO) 2010 and 2013, Panel of Feed Additives (FEEDAP), 2008 and Panel on Biological Hazards (BIOHAZ), 2010a,b). Moreover, it is envisaged that other Panels (e.g., the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)) will perform ERA on applications submitted to EFSA.

[5] Invasive alien species (IAS) are plants, animals, pathogens and other organisms that are non-native to an ecosystem, and which may cause economic or environmental harm or adversely affect human health (Convention on Biological Diversity, 2015; http://www.cbd.int/idb/2009/about/what/). The EFSA plant health panel assesses risks posed by invasive alien species that are harmful to plant health. Therefore, within the context of this opinion, the term IAS refers to invasive alien species that are harmful to plant health. Strictly, the term "invasive" refers to the tendency of a species to disperse and extend the spatial range, or colonize systems from which it was previously absent. An organism is "alien" if it does not naturally occur in a system or area.

[6] It is recognized that particular terms apparently have different meanings when used in the different areas of the EFSA's remit. In the context of the harmonization of the ERA procedures across the different areas, defining a common glossary is also important. The glossary of this guidance provides the definition of the terms as they are used in this document.

Potential stressor: is used herein as "environmental potential stressor" and meaning any physical, chemical, or biological entity resulting from the use of a regulated product or the introduction of an invasive alien plant species related to the food/feed chain that is assessed in any area of EFSA's remit and that can induce an adverse response. Potential stressors may adversely affect specific natural resources or entire ecosystems, including plants and animals, as well as the environment with which they interact (http://www.epa.gov/risk_assessment/basicinformation.htm).

The concept "**regulated products**" as used herein means "claims, materials, organisms, products, substances and processes" submitted to EFSA for evaluation in the context of market approvals/authorisation procedures[7] for which an ERA is required.

This guidance will support the EFSA Panels to accurately document the problem formulations for risk assessment, and thus contributes to more transparency, impartiality and openness as advocated by EFSA (see EFSA PROMETHEUS project[8] entailing an *a priori* development of the strategy for the assessment before initiating it, with strict methods for documenting processes and results).

In line with EFSA's responsibilities regarding regulated products related to the food and feed chain, the scope of this guidance covers the environmental risk assessment of products for use in, or threatening, plant and animal production, including their impact on the wider environment, as well as invasive alien species threatening crop and non-crop plant health.

The SC considers that harmonisation of ERA across sectors is only achievable in the problem formulation phase because of differences in sectorial legal requirements, pragmatic reasons of not being able to protect everything, everywhere, all the time and practical reasons of species availability, testability and conservation status.

In line with EFSA's remit to perform ERA for potential stressors related to the food/feed chain (including plant and animal production), this guidance focuses on their use in an agricultural context. However, it also considers the impact on the wider environment including natural/non-managed environments.

In an agricultural context typically a whole range of protection goals can be set and one has to prioritise what to achieve and what to protect. Therefore, trade-off decisions have to be made as one cannot protect everything, everywhere, at the same time. Biodiversity is a common and prominent legal PG for all ERAs performed by EFSA and it is noted that the agricultural context is a highly disturbed habitat with food production as one main goal[9]. It is also noted that it can form quite large proportions of the area of some Member States and therefore protection of biodiversity as another common good might strongly depend on the implementation of biodiversity goals in these areas (e.g. farmland birds as one prominent systematic group).
However, EFSA is not responsible for trade-off discussions, as this falls under the domain of risk management.

AIM OF THE GUIDANCE

This guidance addresses the same themes as described by EFSA in 2010 when developing the SPG for ERA of PPPs (EFSA PPR Panel 2010 and Nienstedt et al. 2012). The focus of the current guidance is to expand to a wider range of potential stressors, including GMOs, feed additives and invasive alien species, the principles developed for PPPs to derive SPGs.

[7] For an official list of the relevant legal acts identifying all the "products" subject to EFSA's scientific evaluation see: http://www.efsa.europa.eu/en/apdesk/docs/apdeskhow.pdf
[8] PROmoting METHods for Evidence Use in Science (EFSA-Q-2014-00896)
[9] This baseline is heavily impacting on biodiversity through necessary agricultural management practices such as tillage, ploughing, and harvesting. Greenhouse gas emissions are also stressors related to agricultural practices, which are not further discussed herein.

The aim of this guidance is to increase harmonisation and provide a common methodological framework for establishing specific protection goals (SPGs) in the different domains of EFSA's environmental work. Whilst it is fully recognised that there may be differences between the legal frameworks setting the assessments of PPPs, GMOs, invasive alien species and Feed Additives, they have a common feature. The protection goals in the sectorial legislation are very general and need translating to SPGs in order to facilitate the particular environmental risk assessments. This document proposes a common approach using biodiversity and ecosystem services to operationalise environmental protection goals. It is not the intention of this document to establish a common set of protection goals that can be applied to all relevant areas of EFSA's responsibility.

DATA AND METHODOLOGY

Data

This guidance does not focus on analysing experimental data.

Methodology

The methodology used for this guidance was to aggregate the information from the diverse EFSA areas, discuss draft answers to the ToR in working group meetings and extract from such discussions principles and proposals applicable to all potential stressors under the remit of EFSA for adoption by the SC. EFSA followed its specific Standard Operating Procedure (SOP) detailing the steps necessary for establishing, updating or closing the scientific working group (WG) that prepared this guidance for the SC. This SOP implements the Decision of the Executive Director on the selection of experts of the SC, Panels and Working Groups[10].

The following consultations took place on the prepared draft prior to adoption:

- Prior to the first operational meeting of the WG, the topics of the mandate were openly discussed with experts coming from a wide variety of stakeholders. The summaries and outcomes of the discussions from the 19th EFSA Scientific colloquium on "*Biodiversity as Protection Goal in Environmental Risk Assessment for EU agro-ecosystems*", are published on EFSA's website (EFSA, 2014b). The collection of views on how to make protection goals operational in ERA served as an information source for the WG. The broader context of this current mandate and the highlights of the colloquium have also been shortly communicated in Schoonjans and Luttik (2014).
- Letters of invitation to participate in this activity were sent to other EU bodies involved with risk assessment (ECHA, EEA, EMA, JRC, SCENIHR and SCHER), to WHO, OECD and US EPA. All invited bodies and the OECD have appointed a contact point or an observer to the WG meetings.
- Public consultations (including consultation of EU Institutions) were held online between mid-June-end August 2015. The report of this public consultation will be published together with this guidance.

[10] See http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

1. INTRODUCTION

1.1. General protection goals and areas of environmental concern as set in the sectorial legislation for EFSA areas

All the areas within EFSA's remit share the aim of assessing the safety of the potential stressor for the environment. However, the various sectorial legislations/international protocols, governing the work of EFSA in relation to the different potential stressors, provide different policy/general protection goals (GPGs) and areas of concern.

The different legislative framework makes it very difficult to achieve harmonisation of the procedures carried out to conduct the ERA and of the SPGs in the different areas. However, this guidance aims at proposing a harmonised procedure to derive SPGs and focuses on the problem formulation step of the ERA.

For PPPs, the overall goal of protection is human and animal health and the environment according to good agricultural practice (taking into account the intended use of PPPs in an agricultural context, contributing to crop production) (Regulation (EC) No 1107/2009 on plant protection products). Art.4 (3e) specifies that PPP "shall have *no unacceptable effects* on the environment, having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available: (i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation; (ii) its impact on non-target species, including on the ongoing behaviour of those species; (iii) its impact on biodiversity and the ecosystem". In 2010, the relationship between these effects and GPGs was reviewed, bearing in mind PGs outlined in other EU legislations (EFSA, 2010, Hommen et al. 2010).

For GMOs, the Directive 2001/18/EC (EC, 2001b) on the deliberate release of GMOs in the environment states that the overall goal of protection is human and animal health and the environment compared with the non-modified organism from which they derive under corresponding conditions of the release or use. Consideration is given to "direct", "indirect", "immediate", "delayed" and "cumulative" effects. According to the Directive, seven points require consideration in the case of "Genetically modified higher plants (GMHP)", as follows:

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats
2. Any selective advantage or disadvantage conferred to the GMHP
3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species
4. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable)
5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens
6. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s)

7. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

The relationship between these seven points and GPGs was discussed in EFSA GMO Panel (2010), EFSA GMO Panel (2013) and by Sanvido et al. (2012).

The sectorial legislation for PPPs and GMOs also specifies the types of potential adverse effects that have to be addressed (cumulative effects, direct or indirect, immediate or delayed).

For plant health the Council Directive 2000/29/EC (supported by a number of Control Directives and Emergency Measures) aims to protect crops, fruit, vegetables, flowers, ornamentals and forests from harmful pests and diseases (harmful organisms) by preventing their introduction into the EU or their spread within the EU. This aim helps to contribute to sustainable agricultural and horticultural production through plant health protection and to the protection of public and private green spaces, forests and the natural landscape.

In order to meet this aim, the EU Regulates the introduction of plants and plant products into the EU from countries outside the EU, the movement of plants and plant products within the EU and imposes eradication and containment measures in case of outbreaks[11]. These general principles are based upon provisions laid down in the International Plant Protection Convention (IPPC).

For Feed additives, the environmental compartments of concern are the terrestrial and aquatic compartments likely to be exposed (Regulation (EC) No 1831/2003, implemented by Regulation (EC) No 429/2008, see EC 2008a). The potential for additives to affect non-target species in the environment, including both aquatic and terrestrial species, or to reach groundwater at unacceptable levels, needs to be addressed. One more protection goal mentioned is that strains of micro-organisms intended for use as additives shall not contribute to the reservoir of antibiotic resistance genes already present in the gut flora of animals and in the environment.

1.2. Specification of protection goals and problem formulation as part of the environmental risk assessment

Most legal frameworks require the protection of human and animal health and the environment (including biodiversity) from harm. It follows that the first step in defining harm should be the characterisation of protection goals. In a second step, one must derive measurable entities on the basis of protection goals. Protection goals are often too broad to be directly applicable for risk assessment and regulatory decision making (US EPA, 1998; Evans et al., 2006; Raybould 2012). To be operational, it is important that these general and broadly formulated protection goals are translated into concise and concrete measurable endpoints and scientifically testable hypotheses (US EPA, 1998; Garcia-Alonso and Raybould, 2013; Herman et al., 2013). Such endpoints are required for regulatory decision-making because they specify what is to be protected. Furthermore, they allow quantifiable predictions of the probability and seriousness of harmful effects during ERA.

ERA of potential stressors such as PPPs, GMOs and feed additives is an important safeguard to ensure the desired level of protection of the environment and biodiversity. ERA evaluates the potential adverse effects on the environment of certain actions, and has become an important support to inform regulatory decision making.

ERA usually follows five steps, consisting of: (1) problem formulation as a critical first step; (2) effect assessment that examines potential hazards and the seriousness of potential harm; (3) exposure assessment that considers levels and the likelihood of exposure and thus how likely it is that harm occurs; (4) risk characterisation in which the magnitude and likelihood of harm are integrated to

[11] http://ec.europa.eu/food/plant/plant_health_biosafety/index_en.htm

estimate the level of risk and the remaining uncertainties; (5) the outcome of the risk characterisation, together with the risk mitigation measures, form the overall risk characterisation.

Problem formulation (PF) is given a central role in ERAs, as it enables a structured, logical approach to detecting potential risks and scientific uncertainties by summarising existing scientific knowledge and explicitly stating the assumptions and principles underlying the risk assessment. PF provides a foundation upon which the entire risk assessment depends. It aims at articulating the purpose of the assessment, defining the problem and determining a plan for analysing and characterising the risk (US EPA 1998; Suter 2006; Gray 2012). PF involves: the identification of characteristics of the potential stressor capable of causing adverse effects (hazards) and pathways of exposure through which the potential stressor may adversely affect human, animal and plant health or the environment; the definition of specific protection goals, which are explicit and unambiguous targets for protection extracted from legislation and public policy goals; and outlining specific risk hypotheses to guide the generation and evaluation of data in the subsequent risk assessment steps. This process also requires the development of a methodology – through a conceptual model and analysis plan – that will help to direct the risk characterisation and to produce information that will be relevant for regulatory decision-making (Raybould, 2006; Wolt et al., 2010; Gray, 2012).

As ERA is an iterative process, it is possible that the level of risk resulting from the overall risk characterisation determines the reformulation of the problem. Aspects that had not been taken into consideration previously (e.g. eventual conflict between specific protection goals) but were identified as relevant in a later stage should be taken into account by iteration.

The focus of this guidance is on the procedure to derive SPGs, which are necessary to delineate what is considered to be protected and at what temporal and spatial scale.

The implementation of the problem formulation might depend on the sectorial legislation and therefore can differ among the scientific areas as reflected in the respective EFSA guidance documents.

An example of problem formulation for the ERA of PPP on honey bees, including defining the magnitude of acceptable effects, is elaborated in Appendix A (based on EFSA, 2013a).

1.3. Relationship between biodiversity and ecosystem services

Biodiversity is a common and important protection goal set in all ERA legal frameworks within the remit of EFSA. In addition, the European Parliament and European Commission have adopted an EU biodiversity strategy to 2020 (EC, 2011). The aim of this strategy is to halt the loss of biodiversity and ecosystem services. The strategy is in line with two commitments made by EU leaders in March 2010. The first is the 2020 headline target: "*Halting the loss of biodiversity and the degradation of ecosystem services in the EU by 2020, and restoring them in so far as feasible, while stepping up the EU contribution to averting global biodiversity loss*". The second one is the 2050 vision: "*By 2050, European Union biodiversity and the ecosystem services it provides – its natural capital – are protected, valued and appropriately restored for biodiversity's intrinsic value and for their essential contribution to human wellbeing and economic prosperity, and so that catastrophic changes caused by the loss of biodiversity are avoided*[12]."

All stakeholders and parties are encouraged to take responsiblility in their respective sectors to avoid biodiversity loss, also in the agricultural context. Furthermore, for Europe it has been considered that the delivery of both food production and biodiversity conservation should be reconciled at the field and landscape level (Firbank, 2005; Benton, 2007; Sutherland et al., 2009; Godfray et al., 2010). This

[12] http://ec.europa.eu/environment/nature/biodiversity/policy/index_en.htm

is a challenge because agriculture has considerable negative impacts on biodiversity of plant, invertebrates and vertebrate species (Chapin et al., 2000; Stoate et al., 2001; Hails 2002; Robinson & Sutherland, 2002; Tilman et al., 2002; Tscharntke et al., 2005).

Various definitions for biodiversity exist and highlight its different structural and functional components. The working definition for Biodiversity endorsed by the SC for the purposes of the present guidance is the one from the convention on biological diversity[13] which defines biodiversity as: "*the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems". It further states: "biological resources includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity*".

In particular, the maintenance of genetic diversity is increasingly seen as a vital component of environmental policy within the EU[14]. The proposed EU Biodiversity Strategy to 2020 (EC, 2011) stresses the need to support genetic diversity in agriculture and forestry and the fair and equitable sharing of benefits of genetic resources. Specifically, the European Council resolved to encourage the conservation and sustainable use of genetic resources for food, agriculture, aquaculture, fishing and forestry.

The ES concept is widely recognised as a useful framework for policy makers, as stated in Millennium Ecosystem Assessment (MEA, 2005), and in the Economics of Ecosystems and Biodiversity (TEEB) report (EC, 2008b). The MEA considered the current status and trends in services provided by terrestrial, marine and freshwater ecosystems, including cultivated systems. The concept is gaining prominence in European environmental policy making (e.g. Ecosystem Services Special Issue, *Science for Environmental Policy* news alert, Issue 20 May 2010[15]) and is being integrated in the latest developments of European policy (e.g. "Halting the loss of biodiversity by 2010 and beyond (EC, 2006a[16])").

In the agricultural context, there are examples where adopting an ecosystem services approach to ERA has proven useful in the definition of the elements of the environment that require protection. The use of the ecosystem services concept helped to translate GPG set-out in regulations into SPGs for ERA (Nienstedt et al., 2012; Sanvido et al., 2012; Gray, 2012; Garcia-Alonso & Raybould, 2013; Devos et al., 2014; Gilioli et al., 2014). This approach has been used also by EFSA in some areas within its remit, like PPPs (EFSA PPR Panel 2010, EFSA PPR Panel 2013, EFSA PPR Panel 2014), GMOs (EFSA GMO Panel, 2010), and invasive alien species (EFSA PLH Panel, 2011 and 2014). The process to derive SPGs starting from GPG using the ecosystem services approach is further detailed in section 2.

The working definition for ecosystem services endorsed by the SC for the purposes of the present guidance derives from the Millennium Ecosystem Assessment (MEA, 2005[17]) which defines the ecosystem services as: "*The benefits people obtain from ecosystems. These include provisioning services such as food and water; regulating services such as flood and disease control; cultural services such as spiritual, recreational, and cultural benefits; and supporting services such as nutrient cycling that maintain the conditions for life on Earth.*"

[13] http://www.cbd.int/convention/

[14] The inclusion of genetic resources in the definition of biodiversity is not implemented in all sectorial legislation (for example Regulation (EC) No 1107/2009 on plant protection products, Art. 3(29) defines the term "biodiversity" as "*... variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems;*"). However, it has been endorsed for the purposes of this guidance and should reflect what is being addressed in the ERA. Therefore, the SC recommends exploring how genetic diversity can be made operational, which requires a precise definition of genetic diversity, procedures for its measurement and estimates of the impact of its reduction.

[15] http://ec.europa.eu/environment/integration/research/newsalert/pdf/20si.pdf

[16] http://ec.europa.eu/environment/nature/info/pubs/docs/brochures/bio_brochure_en.pdf

[17] The relevant chapter of the MEA (2005) document can be found at: http://www.unep.org/maweb/documents/document.300.aspx.pdf

Biodiversity and ecosystem services are intertwined. The relationship between ecosystem services, biological functions and density, biomass and interactions of species within a community is actively being researched, and the field is rapidly evolving (Chapin et al., 2000; Cardinale et al., 2006, 2011 and 2012; Mace et al., 2012; Gilioli et al., 2014; Garbach et al., 2014; Harrison et al., 2014. An overview of the latest research of the links between biodiversity and ecosystem services is presented in Science for Environment Policy (2015). In this report the importance of biodiversity is highlighted, both for its inherent value and in providing resilience and stability in the supply of ecosystem services. Biodiversity has been described in the literature as: (a) a factor acting as a regulator of the ecosystem processes underpinning the provision of ecosystem services; and (b) an ecosystem service itself, expressing the intrinsic value of biodiversity.

Biodiversity is essential for ecosystem functioning, but the precise relationship between them is an area of considerable scientific debate (Loreau, et al., 2002; Naeem et al., 2009). Some species (i.e. keystone species and ecosystem engineers) contribute to ecosystem functioning in ways that are unique and hence their addition or loss from a community causes detectable changes in functioning. Most species, however, are at least partly substitutable for the ecosystem functioning and their loss can be compensated for by other species. The rivet hypothesis (Ehrlich and Ehrlich, 1981) assumes that communities are comprised of specialised species with limited capacity to compensate for each other, the loss of each additional species having an increasingly critical effect (cf. rivets in an airplane wing) (Lawton, 1994). The redundancy hypothesis (Walker, 1992), however, assumes a greater degree of functional redundancy in that more than one species plays a given role in a community and can therefore compensate if some species are lost. For example, if species sensitive to a particular stressor suffer a decrease in population density, they could be replaced by other resistant species having a similar function, thereby maintaining the delivery of the service. In communities with high functional redundancy, functional diversity (functional dissimilarity in the community) is more important than taxonomic diversity (species richness) in the delivery of ecosystem services (overview in Munns Jr et al., 2009). However, functional redundancy may be exhausted if too many species are lost (e.g. Schäfer et al., 2007) and taxonomic diversity within functional groups plays a crucial role in fluctuating environments by enabling ecosystems to cope with adverse effects originating from different stressors (i.e. insurance hypothesis, Yachi and Loreau, 1999). It should also be noted that species typically contribute to more than one service in an ecosystem, and that the degrees of functional redundancy may vary for different services.

Therefore, the protection of ESs contributes to the protection of biodiversity including its intrinsic value. This means that the ES framework provides ERA with the possibility of ensuring the conservation of a natural resource independently from any present or future use (McCauley, D.J. 2006). Aesthetic values, animal welfare and protection of species of conservation concern are also part of the ecosystem (cultural) services. In conclusion, as both the component of biodiversity underpinning ecosystem processes relevant for the delivery of services and the conservation aspect of biodiversity are considered, ESs can be used to identify SPGs for biodiversity.

2. DEFINING SPECIFIC PROTECTION GOALS IN RELATION TO BIODIVERSITY AND ECOSYSTEM SERVICES

This section aims at providing a framework which accounts for biodiversity and ESs, to make GPGs operational for use in ERAs conducted by EFSA. The three sequential steps below set out a suggested framework for deriving SPGs, starting with: (1) the identification of relevant ESs; followed by (2) the identification of service providing units (SPUs) supporting/providing relevant ESs; and (3) the specification of the degree/parameters of protection of the SPUs using interrelated dimensions.

Each step of this process needs to take into account the choices made for the previous steps. At the end of the process a reiteration might be needed in order to redefine previous choices.

2.1. Step 1 – Identifying relevant Ecosystem Services for ERA

The objective of this step is to identify and select the relevant ESs in the EU agricultural context that could be affected by the potential stressors under assessment. Depending on the scope and application of the ES concept, many classifications and interpretations exist (e.g. Daily 1997; De Groot et al., 2002; MEA 2005; Vandewalle et al., 2008). In general, four categories of ESs are distinguished: provisioning, regulating, cultural and supporting services. Supporting services underpin all other services. The descriptions of ESs show that a complete set of ESs covers, in principle, all species (including endangered species), all types of ecosystems, all environmental compartments in ecosystems and all types of habitats (including those of high conservation value). An ecosystem can provide multiple services at the same time and place, although human society, operating through for example land users and water managers, tends to optimise certain ESs in certain places. ESs are highly interconnected and interdependent and, therefore, the management or optimisation of one service may have negative consequences for others (Rodriquez et al., 2006).
Several classification schemes for ESs have been proposed, e.g. MEA (2005), CICES (http://cices.eu/) and TEEB (http://www.teebweb.org/). In this Guidance, a list of ecosystem services based on the MEA source has been used (Table 1) since it is widely recognised and adopted.

One criterion for the selection of an ES for ERA at EFSA is whether or not it is affected by the potential stressors. While it is difficult to quantify such relevance for each ES, it is suggested for transparency reasons to indicate which ESs are relevant or not. This will vary on a case-by-case basis, depending on the potential stressor or receiving environments. In general, the majority of ESs are potentially relevant in the agricultural context[18] for all assessed potential stressors.

Two types of ESs can be envisaged: (a) those underpinning plant or animal production; and (b) other services relevant for the society, normally competing with plant and animal production and requiring a trade-off decision by risk managers. It follows that ideally risk managers should inform risk assessors on which service(s) to focus on prior to conducting the ERA.

Biodiversity can be considered as the foundation for all ESs (Mace et al., 2012; Garbach et al., 2014). In its structural (genetic diversity, crop diversity, local abundance of species) and functional aspects (primary production, nutrient cycling, water regulation, provision of habitat and food), it includes several elements which are covered under different MEA categories. In principle, the broad scope of biodiversity as a protection goal determines that each of the four categories of ESs have elements that are either dependent on or influenced by biodiversity. For example:

- genetic resources under “Provisioning services” (e.g. genotypes of crop species and wild relatives of crops). They cover the genetic diversity component of biodiversity.
- pollination under “Regulating services” (e.g. several plants require specialised pollinators),
- soil formation and habitat provision under “Supporting services” (a wide array of species may play a role in soil formation; many plant species provide the obligatory food and habitat e.g. to symbionts),
- the intrinsic value of biodiversity and species of conservation concern can be considered a “Cultural service”.

[18] Note that the agricultural context comprises a mosaic of cropped and non-cropped areas, with semi-natural (e.g., hedge-rows, ditches) and natural habitats (e.g., streams, patches of forest)

2.2. Step 2 – Identifying relevant Service Providing Units for ERA

The objective of this second step is to select on a case-by-case basis the SPUs which could be affected by the potential stressor under assessment and that could serve as SPG.

The concept of SPU has been introduced by Luck et al. (2003) to explicitly link populations of species with the services they provide to humans and to stress that changes in population characteristics have implications for service provision. The SPU can be defined as the structural and functional components of biodiversity necessary to deliver a given ecosystem service at the level required by service beneficiaries (Luck et al., 2003; Vanderwalle et al., 2008). The concept of SPU is synonymous to "key driver" (EFSA PPR Panel 2010 and Nienstedt et al. 2012) but more commonly used in the literature on ESs. It will therefore be used in this guidance.

Table 1 provides examples of SPUs for each ES MEA categories[19]. It offers a non-exhaustive, non-binding list of common SPUs that can be *a priori* identified by the EFSA Panels concerned with ERA. Since it is impractical to list all species or taxa, in some cases the SPU refers to functional/taxonomic groups or landscape elements/habitats requiring protection. The SPU can be defined only up to a certain taxonomic and/or functional level. At the lower level, only very generic groups or functions can be identified, possibly linked to information requirements on some species mentioned in the legislation or for which standardised tests are available. An example of an SPU requiring consideration at the species level is the honeybee, which can be considered as a representative of potentially exposed pollinator.

Table 1: Ecosystem services categories according to MEA (2005) and examples of service providing units (SPU) providing them. Biodiversity forms the foundation for all ecosystem services (Garbach et al., 2014).

MEA category	***Ecosystem services***	***Examples: Service providing units (SPUs)***	
Provisioning services	Food	Crop species, cattle, pigs, poultry, small game and other consumable vertebrates, fungi, wild fruits (berries), roots, shoots, consumable fish, crayfish, molluscs, algae	BIODIVERSITY
	Fibre and fuel	Crop plants (fibres/biofuel), trees (wood/biofuel), emergent macrophytes (thatched roofs), aquatic primary producers and peat (biofuel)	
	Genetic resources	All species that potentially provide products to man e.g. crop species and their wild relatives	
	Biochemical/natural medicines/ pharmaceuticals	Organisms used for medicinal or personal care products	
	Ornamental resources	Ornamental species and landscape elements	
	Fresh water	Microorganisms, algae, fish.	
Regulating services	Pollination	Pollinators: arthropods such as bees, hoverflies, butterflies and other pollinator species	
	Seed/propagule dispersal	Insects, birds, mammals, fish and water	
	Pest/disease regulation	Beneficial arthropods (natural enemies such as ladybirds, ground beetles, true bugs, lacewings, spiders, parasitic wasps), vertebrate predators and fungal species	

[19] The list of ecosystem services is based on the list provided in the MEA (2005).

	Climate regulation	Several plant species (wild and domestic)
	Air quality regulation	Plants
	Water regulation	Plants, micro-organisms, soil fauna and beavers (dams)
	Erosion regulation	Rooted plants, soil fauna (ecosystem engineers)
	Natural hazard regulation	Rooted plants (shrubs and trees), flood plains
	Invasion resistance	Autochthonous species with a similar niche than invasive species
	Water purification/soil remediation/waste treatment/decomposition	Plants, fauna, macrofauna, bacteria and fungi
Supporting services	Primary production	Algae and vascular plants
	Secondary production	Invertebrates and vertebrates
	Photosynthesis	Algae and vascular plants
	Provision of habitat	Ecosystem engineers (e.g. beavers, earthworms, plants) and larger plants and animals that provide surfaces for periphytic organisms (e.g. shells of mussels), hedgerows
	Soil formation and retention	Soil fauna (mainly ecosystem engineers e.g. earthworms, ants) plants (e.g. organic matter and peat formation)
	Nutrient cycling	Microorganisms, macroorganisms (such as annelids, mites, springtails, polychaetes), primary producers, grazers, detritivores, consumers, predators
	Water cycling	Plants and terrestrial and aquatic ecosystems
Cultural services	Spiritual and religious values	All species
	Education and inspiration	All species
	Recreation and ecotourism	Fish (sport fishing), attractive plants and vegetation, vertebrates (bird watching, hunting) and attractive invertebrates
	Cultural heritage	Structures constructed and/or modified by man and their typical biota
	Aesthetic values	All species, in particular plants, vertebrates, attractive invertebrates and red list species
	Sense of place	Trees, patches of vegetation and ecosystems as landscape features, landscape elements/habitats
	Cultural diversity	Semi-natural habitats (e.g. heathlands, ponds) and appreciated agricultural landscapes (e.g. fields bordered by hedgerows)
	Species of conservation concern	Listed species, genetic diversity

Existing databases of faunal communities (for example, the generic information on the arthropod fauna in European maize fields contained in the arthropod database (Meissle et al., 2012; Romeis et al., 2014) associated with specific crops and relevant off-field habitats (like ponds, ditches, streams, hedgerows etc.) can assist in identifying valued species that may be at risk.

2.3. Step 3 – Specifying Protection Goals

For each SPU, the level/parameters of protection are to be specified, using the following five dimensions: the ecological entitiy and attribute to be protected, the spatial and temporal scale of protection, and the magnitude of acceptable effect. These dimensions have been proposed by the EFSA PPR Panel (2010) to structure and focus the procedure for making PGs operational, and have also been considered by the EFSA GMO Panel (2010), though the process of specification has not been described explicitly for all dimensions.

For each dimension specific options for selection are proposed as a collection coming from the different areas in EFSA concerned with ERA. The list is not exhaustive and other options can be envisaged. It is emphasised that not necessarily all options are equally applicable to all areas.

If different specific protection goals are set for different compartments, e.g. in-field and off-field[20], a check should be made to ensure that they are not in conflict with each other (EFSA PPR Panel 2014 and 2015). This may result in the need to adjust one of the protection goals to accommodate the other.

Since the interdependency among dimensions must be respected, the choice of an option for a certain dimension must consider the options chosen for the other dimensions. Therefore, the SPGs and the interrelationship between the chosen options should be presented to the risk manager in a concise and transparent manner (see section 2.4).

In order to promote transparency and consistency when specifying the degree/parameters of protection, some considerations are proposed against which the selected options can be justified.

This section will be focused on considerations based on the ecological characteristics of the SPU and the receiving environment. Pragmatic considerations (like available information, restrictions on what can be measured easily) are accounted for. Also, legal considerations are taken into account. These are mandatory Directives and Regulations under which these regulated products must be assessed, but in addition other official EU legislation on environmental PGs (like that establishing a protection status for natural habitats, wild fauna and flora, endangered species, wildlife and biological diversity) that may be helpful to guide the choice of SPGs (see, for example, Table 1 of EFSA GMO Panel, 2010).

Risk management considerations (e.g. for setting the magnitude of acceptable effects) might also play a role.

The degree of protection that is appropriate varies between SPUs, depending on the importance of the ESs they provide. It is important to emphasise that final decisions on the choice of SPGs involves normative considerations, which are outside the remit of EFSA, and therefore need to be made in consultation with risk managers.

The SC is of the opinion that in any assessment done by EFSA, the sources of uncertainty should wherever possible be systematically identified and their potential contribution to the outcome of the assessment analysed (EFSA SC, 2006). The degree of uncertainty reflects both the uncertainties in the choice of the dimensions (in the problem formulation phase) and the subsequent uncertainties in the later steps of the risk assessment. The SC is developing a Guidance Document on uncertainty analysis which will embrace the identification, characterisation and documentation of uncertainties in scientific assessments using qualitative, semi-quantitative and quantitative (deterministic and probabilistic) approaches. It is intended that the Guidance Document will provide a toolbox to help EFSA's

[20] A definition of the term in-field, off-field and the subdivision into in-crop and off-crop is provided in Alix et al. (editors) 2012 - ESCORT 3 Workshop - and in EFSA PPR Panel, 2014 and 2015.

Scientific Panels to address uncertainty in a systematic and harmonised way. The guidance document will focus on uncertainties related to the various steps of the risk assessment, i.e. hazard identification, hazard characterisation, exposure assessment and risk characterisation.

2.3.1. Ecological entity to be protected

The ecological entity to be protected refers to the level of biological organisation of the SPU (e.g. individuals, populations, etc).

The analysis of this dimension starts with the assessment of the ecology of the SPUs for each service.

The first step is to consider if the ecological entity should be best described as a structural (taxonomic) or functional unit. Most of them are described as structural ecosystem components or taxonomic groups (e.g. algae, aquatic plants, fish, birds, mammals). When deciding between structural or functional entities (see options in Table 2), the impact they have on the provision of the ES, should be evaluated. Whenever possible, this evaluation should also encompass the SPU potential to respond to multiple stressors and foreseeable changes.

The most appropriate option for the entity to be protected is also linked to the type of ecosystem service. For example, populations or functional groups are relevant primarily to services like seed dispersal or biological control, while communities or habitat to services like flood mitigation, water regulation and carbon storage (Luck et al., 2009).

Table 2: Options and **considerations** to justify the selection of relevant options for the ecological entity to be protected

Dimension	*Ecological entity to be protected*
Options	Individual, (meta)population, functional group, community, habitat, agro-ecosystem
Considerations to justify the selection of relevant options	Cultural value (e.g. conservation species, aesthetic species)
	Spatial characteristics of the SPU
	Geographical distribution of SPU
	Potential for recovery
	Functional redundancy
	Type of ecosystem service
	Legal considerations
	Pragmatic considerations

When choosing an option as presented in the table above, one should consider the following:

- When the aim is to maintain specific populations and biodiversity, structural endpoints need to be selected as the ecological entity. This is due to functional redundancy, and the fact that structural endpoints (like individuals, populations) might be more sensitive than functional endpoints (primary production, decomposition, nutrient cycling).

- When the aim is to ensure the provision of a certain ecosystem process that result from the interaction of a broad variety of species or group of species (e.g. litter breakdown, nutrient cycling), the most appropriate option is the functional group (e.g. microbes). Neverthless under particular conditions certain microbes might require protection at the population level (e.g. mycorrhizal fungi).

- For the majority of SPUs, the ecological entity to be protected is the (meta)population, where a metapopulation is defined as a "population of populations" of the same species connected through immigration and emigration (Hanski and Gyllenberg, 1993). The (meta)population option is therefore considered the default option to define the ecological entity

- There is also the possibility that the level of protection at the (meta)population level cannot be ensured everywhere (e.g. in in-field habitats). Under these circumstances, functional group can be selected as the most appropriate entity to be protected. However, this criterion is to be considered with caution since two SPUs might contribute to the same functions but be essential in the agricultural context, e.g. when differentiated in time. In some cases, one may have to protect habitats or the whole agro-ecosystem, to ensure the protection of specific organisms during their critical lifestages.

- When it concerns endangered species (protected by legislation), or species of aesthetic value (e.g. Lepidoptera), the selected ecological entity may be individuals or populations, depending on the impairment of the the endangered species. Note that for PPP protection goals, action must be taken to prevent lethality amongst vertebrates When there are specific vulnerable life stages of the species of concern (adult or larval, see Lepidoptera example in section 2.5), the option for the entity to be protected might depend on such life stage and could be either the individual or the (meta)population level.

- The individual is considered to be the most conservative option and protecting the individual will automatically protect the service provision also at the population and higher levels. The level of conservatism can be a scientific and/or societal choice. From a scientific point of view, the individual level of protection might be required in case of very small populations (i.e. where individual loss would represent a considerable loss in the gene pool). In most cases however, from a scientific point of view, protection on the population level is sufficient and methods are available to map the correspondent services to be protected. From a societal point of view, however, it can be decided that no individual should be affected. One example is that for PPPs the level of protection for birds, mammals and other vertebrates (e.g fish, reptiles, and amphibians) is set at the individual level in the acute ERA, as acute lethality of non target vertebrates is considered unacceptable.

As mentioned in Table 2, legal and pragmatic considerations can also influence the choice of the entity to be protected. For example, in the case of PPPs the information requirements (established in the Regulation (EU) No 283/2013, Regulation No 284/2013 and Regulation (EU) No 546/2011 on the Uniform Principles for evaluation agreed by risk managers), can indicate specific structural components (taxonomic groups) or functional endpoints as entity to be protected (e.g. soil microbial functional groups, nitrification).

2.3.2. Attribute to be protected

It is important to consider jointly the ecological entity and its most ecologically relevant attribute to be protected. The options and some considerations for the attribute are presented in Table 3.

When choosing the relevant attribute(s) for each ecological entity, the spatial and temporal scale of protection should be considered. In particular, it should be considered whether the effects are direct/short-term or indirect/long term. For example, survival of individuals affects populations and metapopulations through direct/short-term effects such as mortality, while growth, reproduction and behaviour of individuals affect populations and metapopulations through indirect sub-lethal (long-term) effects.

Table 3: Options and considerations to justify the selection of relevant options for the attribute to be protected

Dimension	*Attribute to be protected*
Options	Behaviour[21], survival, growth, reproduction, abundance, biomass, functional process, sustainability of agricultural systems[22], landscape structure, biodiversity
Considerations to justify the selection of relevant options	The ecological entity selected
	Life history traits of the SPU
	Chemical-physical properties of the environmental compartments
	Ethical considerations
	Legal considerations
	Pragmatic considerations

When choosing an option as presented in the table above, one should consider the following:

- If the ecological entity to be protected is the (meta)population of a given species, then in most cases the attribute to be protected will be abundance (e.g. numbers of individuals and their fitness), population biomass and reproductive performance (see EFSA PPR Panel, 2014).

- If the ecological entity to be protected is the community, species diversity is also a common attribute.

- When the SPU is microbes and/or algae, the entity "functional group" is mostly associated with the attribute "functional process" (e.g. primary productivity, nutrient cycling). However, in other cases, like for aquatic invertebrates providing water purification, nutrient cycling, pest and disease regulation services, the relevant attribute for the functional group entity is abundance and biomass.

- When the entity to be protected is "habitat", the "landscape structure" is the associated attribute. This attribute is important for species conservation, in particular when assessing the external population recovery. Such recovery depends for instance on the degree of connectedness or fragmentation of the populations, variations in land use, and types, spatial distribution and connectivity of habitats (see EFSA SC, 2016b).

- If functional processes are the focus it might be necessary to characterise the chemical physical properties of the environmental compartments (e.g. phosphorus concentration, oxygen concentration, pH, transparency).

- Albeit no default option to define the attribute can be envisaged, the following table (Table 4) indicates which attribute is usually associated with which ecological entity.

[21] For example, altered bee behaviour as a result of which they would no longer be in a position to find their beehive back, or upside down swimming of fish. Behaviour includes dispersal ability.

[22] Annex III of Directive 2009/128/EC on sustainable use of pesticides defines general principles of integrated pest management, based on crop rotation, use of adequate cultivation techniques, use of balanced fertilisation, liming and irrigation/drainage practices, preventing the spreading of harmful organisms by hygiene measures, protection and enhancement of important beneficial organisms, use, where appropriate, of resistant/tolerant cultivars and standard/certified seed and planting material.

Table 4 The attributes usually associated to each ecological entity

Ecological entity	*Attribute*
Individual	survival, growth, behaviour, reproduction
(meta)population	Abundance/biomass, Population growth,
Functional group	Process, abundance and biomass
Community	Species diversity
Habitat	Diversity, structure, abundance, biomass
Agro-ecosystem	Sustainability, landscape structure

In some cases, the attributes may be determined by legal considerations, e.g. lethality for individual vertebrates as an entity to be protected. In most cases, however, the selection of attributes is based on a combination of ecological needs and pragmatic considerations (such as available information and possibilities for extrapolation).

2.3.3. Temporal scale of protection

This dimension should describe, for each combination of ecological entity and attribute to be protected, the temporal scale(s) of protection (e.g. days, weeks, months, seasons, years, generations, and rotations) (see Table 5).

Table 5: Options and considerations to justify the selection of relevant options for the temporal scale of protection

Dimension	*Temporal scale of protection*
Options	Days, weeks, months, seasons, years, generations and rotations
Considerations to justify the selection of relevant options	Temporal scale during which the SPU operates
	Reproduction strategy of SPU in terms of generation time
	The potential and the time needed for recovery
	Time pattern of resistance and resilience
	Long-term and delayed effects
	Stability of the ecosystem service
	Spatial scale
	Type and quality of habitat
	Legal considerations
	Pragmatic considerations

When choosing an option as presented in the table above, one should consider the following.

- The temporal scale of "days" is usually used for attributes related to individuals and for short-term mortality.
- Days to months (depending on the magnitude of acceptable effects and the selected attribute) are used for the population entity.
- Seasons, generations and rotations are relevant for overall population dynamics (extinction, dispersal and colonization).
- A temporal scale of days to weeks is appropriate for avoidance behaviour (see EFSA PPR Panel, 2010).
- Regarding generations: Mortality caused by the potential stressor will not be the only source of mortality in the life-cycle of the organism at risk, and the complexity of estimating an overall effect on population dynamics is increased if the organism has several life-stages. These contributions to population dynamics are commonly measured by techniques such as

key factor analysis (Varley & Gradwell, 1960). These may require relatively large temporal scales, of the order of generations.

The following paragraphs expand on the considerations presented in the table.

The temporal scale of protection should consider the ecological characteristics of the structural components or functional groups covered by the SPU or the temporal scale of the effects/exposure e.g.

- The temporal scale during which the SPU ecological entity operates,
- Life history traits of the key taxonomic group in each SPU (for more details see opinions on endangered species and recovery EFSA SC, 2016b,c).
- The expected timing for direct and indirect effects following exposure. The temporal scale of protection is to be chosen considering the time pattern of resistance and resilience (see the example on invasive species in section 2.5) determining the rate of appearance of the effects: the faster the appearance of changes in affected ecosystems (low resistance) the shorter the time horizon. The temporal scale of protection is to be chosen also considering the assessment of long-term and delayed effects and the stability of the ecosystem service.
- The potential and time needed for recovery (see EFSA SC, 2016b).
- If the recovery option is adopted the focus should be on vulnerable species (i.e. species with longer generation time or low dispersal ability) (EFSA SC 2016b, EFSA PPR Panel 2015).

In order to define the temporal horizon, as part of the scenario assumptions, it is important to consider the reasonable length of time for the main issue of concern to be explored or managed (Henrichs et al., 2010).

Other considerations to consider are the associated spatial scale of protection and the type of habitat (e.g. in-crop, off-crop).

2.3.4. Spatial scale of protection

This dimension should define a quantifiable spatial scale of protection. A not exhaustive list of options and some considerations to justify their selection are presented in Table 6.

The spatial scale is directly linked to the temporal scale as different timings may be needed for different spatial scales. The spatial scale can be set at generic levels, or consider site-specific attributes. Several alternatives for mapping ecosystem services have been developed (Ungaro et al., 2014; Crossman et al., 2013). Most assessments for regulated products start with generic lower tiers, and therefore generic spatial descriptors are sufficient. Higher tiers may consider site-specific elements, for example using focal species or landscape modelling. Site-specific assessment covering representative or worst-case conditions can be used for generic assessment if proper justifications regarding the representativeness of the site-specific assessment are provided.

Table 6: Options and considerations to justify the selection of relevant options for the spatial scale of protection

Dimension	*Spatial scale of protection*
Options	In crop/field, edge of field/field margin, nearby off-crop, farm/holding/production unit, watershed, landscape, region, and continent
Considerations to justify the selection of relevant options	Ecological characteristics of the SPU among which occupancy[23], mobility and dispersal ability of relevant life stages
	Spatial scale of the effects, exposure and recovery.
	Direct or indirect effects
	Habitat and landscape characteristics, in particular its fragmentation
	Legal considerations
	Pragmatic considerations

The following paragraphs expand on the considerations presented in the table above.

The spatial scale of protection should consider the ecological characteristics (species mobility, species physiology and behaviour, population size, metapopulation structure -including genotypes - and sink–source dynamics, occupancy) of the structural components or functional groups covered by the SPU, determining the spatial scale at which the SPU ecological entity operates.

- It has to be noted that the sink–source dynamics depend directly on the landscape structure (see section 3.1.2 of EFSA PPR Panel 2015 and EFSA SC 2016b section 3 for examples of this aspect).

- Regarding mobility and dispersal ability of relevant life stages, it is very important to consider that these might determine the migration of unexposed organisms to exposed areas and/or of exposed organisms to unexposed areas or, in the case of invasive alien species threatening crop and non-crop plant health, the migration from the exposed to the non exposed area through seed/pollen. This aspect is linked to the potential for recolonisation and SPU recovery potential.

When conducting ERAs for potential stressors the selection of the spatial scale of protection cannot be separated from the spatial scales of exposure, effects and ecological recovery, which may be different (see EFSA SC, 2016b). When selecting the appropriate spatial scale at which recovery needs to be addressed (see EFSA SC 2016b) it is important to consider that landscape and habitat characteristics (composition, structure - in particular fragmentation - management etc), have implications for recovery and extinction (in case of endangered species). It is noted that there is an important interplay between homogeneity of agricultural practices and the potential for recovery and that external recovery might be particularly difficult for monocultural fields, with no other habitats in between (see section 2.3.5).

The spatial scale for direct and indirect effects on the same SPU may be different. For example, in the risk assessment of PPPs for non target arthropods (NTA, EFSA PPR Panel, 2015) it is considered that in-field impacts on non-target species can affect off-field populations. Even if the exposure of individuals in the off-field area is determined to be acceptable, the off-field population can be affected if the treated field acts as a sink. To ensure that effects in-field do not have unacceptable effects on

[23] Occupancy is the occurance of a species in a certain location or the percentage of investigated area where the species occur. An example is provided in the ERA of PPPs on NTA, where occupancy refers to populations of NTAs in the landscape level context (see EFSA PPR Panel 2015).

NTA biodiversity it is suggested to conduct a landscape level risk assessment in addition to the local scale assessment. Such a landscape level risk assessment could be done with population models. The local scale risk assessment is considered sufficient to address impacts on species with a very limited mobility. However for highly mobile species the overall population level impact may be underestimated. Therefore it is recommended to also address the risk to mobile species at larger spatial scales where treated fields occur.

A change of scale needs to be considered also when focusing the assessment of direct and indirect effects on different SPUs. For example direct effects of the PPP on non target organisms like arthropods might be assessed in the field and adjacent margins/hedges etc, while indirect effects on bird populations stemming from the decline of insects abundance might require an assessment at the landscape or regional scale. However, if the SPG refer to individuals (e.g. for protected species) then the scale of protection can be the field.

The definition of the spatial scale should consider the spatial scale of the potential stressor, but should not be limited to it. For example the impact on populations of birds may require a landscape assessment even if the exposure is limited to in crop and edge of field.

From the considerations expressed in the previous paragraphs it is evident that the protection of a service cannot always be limited to the area where the potential stressor is applied.

- The possibility of transport of the potential stressor to other areas should be considered.
- The assessment of the spatial scale introduces the needs to consider the possibility of multiple stressors[24]. A larger scale is more likely to be subjected to a higher variey of stressors.

The choice of the spatial scale, from local to continental, might be driven by legal considerations including the legal protection status (the protection of endangered species may require a local assessment).

The ecological concept of spatial scale encompasses both *extent* and *grain* (Wiens 1989). In an ecological risk assessment, *extent* would be the overall area covered by the assessment and would therefore refer to the area potentially impacted by introduction of a stressor.
Grain refers to the size of the individual units that are considered within the overall area covered by the assessment. For example, assessments of PPPs may make distinction between crop and off-crop, and field and off-field, and consider spillover of products into air or surface water, and impacts on aquatic biota. The grain of such assessments may go down to a scale of meters[25].

2.3.5. *Magnitude of acceptable effects*

This dimension identifies the level of change for the selected attribute that can be accepted for achieving the protection goal. When addressing the magnitude of effects, the nature and the level of

[24] For bees, EFSA has initiated work towards the development of Holistic Approaches to the Risk Assessment of Multiple Stressors in Bees, published on EFSA's website (EFSA, 2013b, 2014a). More recently, EFSA has embarked on a multi-annual work program on this complex issue (i.e. taking account of multiple stressors and aspects of the landscape). Ref: MUST-B: EU efforts towards the development of a holistic approach for the risk assessment on MUltiple STressors in Bees.

[25] See also: http://www.umass.edu/landeco/research/fragstats/documents/Conceptual%20Background/The%20Importance%20of%20Scale/The%20Importance%20of%20Scale.htm

change that would be considered biologically relevant should be assessed in the light of the Opinion on Statistical Significance and Biological relevance (EFSA SC, 2011)[26].

Table 7: Options and considerations to justify the selection of relevant options for the spatial scale of protection

Dimension	*Magnitude of acceptable effect*
Options	Negligible, small, medium, and large[27]
Considerations to justify the selection of relevant options	Options selected for the other dimensions
	Traits (ability to recolonize/ and escape stressor, life-cycle duration etc.)
	Potential for recovery
	Life stage of the SPU
	Level of endangerment and ecological relevance of the subpopulation (source/sink)
	Landscape structure
	Ecological characteristics of the receiving environment (among which functional redundancy)
	Duration and spatial scale of the exposure
	Spatial and temporal scale of the effects
	Population dynamics (spatial and temporal patterns)
	Direct/indirect effects
	Legal considerations
	Pragmatic considerations

The following paragraphs expand on the considerations as presented in Table 7.

The definition of the magnitude of acceptable effects needs to consider the following issues:

- The life cycle stage of the impacted species (e.g. early instars are often more sensitive to stressors).

- The traits of the impacted species, in particular the duration of the life cycle, the growth and reproduction rate, individual home range, habitat food preference, mobility and dispersal ability (determing the possibility/ability to recolonize and escape stressor in space and time and hence the potential for ecological recovery, see EFSA SC 2016b). The magnitude of acceptable effects should be smallest for organisms with a long life-cycle, a low growth and reproduction rate (see example on PPP ERA for aquatic organisms in section 2.5) and a poorly developed ability to recolonize and escape the stressor in space and time.

  At the landscape level, the protection goal could be to protect as much biodiversity as needed to guarantee the recovery of the agricultural environment as a whole (including the in-crop area, through recolonisation from the more biodiverse external areas) and the delivery of the relevant ecosystem services. Within this context the level of protection should be established at such a level that should not jeopardise the potential for recovery in the long term in a realistic time frame.

- The level of endangerment needs to be considered as well, in particular with reference to endangered species. In a parallel opinion of the SC (EFSA SC, 2016a), it is described that the level of endangerment can be spatial-scale dependent and that global, European, National and Regional "red lists" exist. Endangered species are species listed therein as threatened (i.e.

[26] According to EFSA SC (2011) a ***biologically relevant*** effect can be defined as an effect considered by expert judgement as important and meaningful for human, animal, plant or environmental health. It therefore implies *a change that may alter how decisions for a specific problem are taken*.
[27] The nomenclature for the magnitude of effects and the scientific justification for this choice need to be defined on a case by case basis. An example of the definition of negligible, small, medium and large effects of PPPs on bees, based on expert judgement, can be found in EFSA 2013a.

vulnerable, endangered, or critically endangered, or variants thereof) or rare based on Rabinowitz's (1981) classification.

- Properties relevant to define vulnerability of non-target organisms are species traits and characteristics that determine 1) susceptibility to exposure (e.g. related to habitat preference and the ability to avoid exposure), 2) (toxicological) sensitivity, 3) internal and external recovery processes (e.g. related to generation time, growth rate, number of offspring, dispersal ability, refugia and connectivity of suitable patches of habitat in landscape).

- In the case of endangered species, when defining the magnitude of acceptable effects it is proposed to make a distinction between ecologically critical subpopulations, which are essential for a species' survival in a particular region, and subpopulations which are not (e.g. the source and sink population). The underlying rationale is that critical subpopulations should be provided with a higher level of protection than non-critical subpopulations (see EFSA SC, 2016a).

- Besides these structural components of the receiving environment, also its ecological characteristics (complexity and stability of the ecosystem; food web structure; functional redundancy implying the possibility of accepting structural effects on ecosystems provided ecological functions are maintained; weather parameters like temperature, influencing, for example, individual growth; soil and stream properties; water quality in terms of loads of nutrients and oxygen consuming substances etc.) can play a role in determining the magnitude of acceptable effects. Biological interactions such as interspecific competition and predation have to be considered since interspecific competition may increase time for recovery considerably. Similarly, predation may also reduce capacity for population recovery (EFSA PPR Panel 2015).

- The ecological characteristics of the receiving environment can influence the life cycle characteristics of the SPU. For example, the life cycle characteristics of arthropods may be different depending on the temperature of the environment. In cooler climates they may have only one generation per year while under warmer climates two or more. Such differences can significantly change the recovery capacity.

- The magnitude of each effect needs to be evaluated with respect to its spatial and temporal scales.

- Another important factor to consider when defining the magnitude of effects is whether the effect under assessment is direct or indirect (e.g. propagated through disturbed predator-prey or competitive relationships). SPGs have to be defined for both types of effect. An example of evaluation of the magnitude for indirect effects is provided in section 2.5 relative to the assessment of the EFSA GMO Panel on potential adverse effects resulting from the exposure of non-target Lepidoptera to maize 1507 pollen (EFSA GMO Panel 2011 and 2012b). If there is not enough scientific information on indirect effects, it is suggested that risk assessors report this in their uncertainty analysis.

- Another aspect to be considered is the duration of the exposure and the spatial scale over which the exposure occurs (see EFSA PPR Panel, 2010).

- Successive exposure may result in culmination of low-dose effects (for a PPP case, see Liess et al. 2013). For example, populations exposed over several generations to repeated pulses of low concentrations of a pesticide and challenged with interspecific competition with a less sensitive species continuously declined and did not recover. Hence, a repeated toxicant pulse may result in a multigenerational culmination of low-dose effects.

- Also population dynamics (spatial and temporal patterns) should be taken into account.

The definition of the magnitude of acceptable effects needs to consider also the legal framework. For example, regulation (EC) No 546/2011 on the uniform principles for evaluation and authorisation of plant protection products, describes in section 2.5.2.4 that *"Where there is a possibility of beneficial arthropods other than honeybees being exposed, no authorisation shall be granted if more than 30 % of the test organisms*[28] *are affected in lethal or sublethal laboratory tests…"*.

A dialogue with risk managers is needed for setting the magnitude of acceptable effects. As an example, for PPPs different alternatives for risk management options can be considered: a) accepting only negligible effects on the SPUs or b) accepting some effects if ecological recovery takes place within an acceptable time-period (see EFSA PPR, 2013; EFSA SC, 2016b).

The definition of the magnitude of effect causing environmental harm can also consider exposure and effect assessment goals, based on realistic worst case scenarios, agreed between risk managers and risk assessors. Such a scenario is, for example, applied in the risk assessment of plant protection products for non-target terrestrial plants (see also section 2.5). It is based on a realistic worst case exposure level (e.g. the 90th percentile of expected concentrations at the downwind edges of the field) and on the 5th percentile of the species sensitivity distribution. The operational protection goals can then be described in the following way: 95% of the non target terrestrial plants will not be exposed above their ER_{10}[29] in 90% of the cases at the edge of the field[30].

Another example is that GMOs are assessed and authorised at the EU level. The ERA must allow for and cover all the likely receiving environments within the EU and take due cognisance of the fact that these may differ in factors such as climate, soil structure, ecology, management systems. If the ERA takes appropriate consideration of such differences then there is no reason why the ERA of a GMO should differ between Member States. For GMOs the European Commission as risk manager drafts a Decision based on the ERA from EFSA. Part of this drafting involves setting the level of protection for a SPG. Member States can comment on this level, but the level, once set, is uniform across the EU and does not vary between Member States. As an example, consider the GMO case in section 2.6.2 where the risk is to non-target Lepidoptera exposed to pollen from Bt maize plants. In that case, the protection level, after allowing for exposure factors, is set at 1% mortality. However, this setting of uniform protection goals across the EU may differ for other potential stressors.

The definition of the magnitude of acceptable effects should take multiple stressors into account (e.g. multiple PPP applications according to typical PPP 'spray schedules', see EFSA PPR Panel 2015). This will possibly imply a lower level of acceptable effects for individual PPPs.

[28] The recommendation of 30% effects which is listed in the legal requirements dates back to a SETAC workshop held in 1994 (ESCORT1 – Barret et al. 1994)

[29] Effective application rate (g a.s./ha) of a pesticidal active substance resulting in a 10 % change of an endpoint. Where ER10 values are proposed for use in risk assessment, they are considered as a better representation for negligible effects than no observed effect rate (NOER) values.

[30] It should be noted that this scenario choices are relevant in determining the conservativeness of the protection goal. For example, the 95th percentile concentration of the pesticide in water bodies at the edge of the treated field will result in a greater exposure estimate and hence in a more strict protection goal than the 95th percentile of pesticide concentrations in all water bodies in Europe which would include also water bodies which are far away from agricultural land.

2.4. Interdependency of the five dimensions

As mentioned in the beginning of section 2.3, the dimensions are interrelated, meaning that choosing one option under one dimension directly influences the option chosen under another dimension.

Before choosing the option for each of the five dimensions, it is important to realise the interdependencies between them and the effects of scaling within them.

In order to clarify this concept, the following examples of interdependency are proposed:

- As an example of interdependency between ecological entity and magnitude, what may be a large magnitude of *effect* for individuals may not greatly affect a population.
- As another example, inferences concerning the *attribute* of behaviour, abundance or functional process rely on whether the *entity* is an individual expressing that attribute, a population or a functional group. Behaviour can be linked to an individual, abundance to a population, functional group to a process.
- Vertebrates may require protection at the individual level (entity) regarding survival (attribute) but at the population level (other entity) regarding non-lethal effects (other attribute).

Furthermore, the dimensions of *ecological entity*, *magnitude of* effect, *temporal scale* and *spatial scale* have ordered categorical levels, and so correlations might be expected between them.

Regarding scaling, particularly for highly mobile or migrating taxa, it is clear to see that an adverse effect over the longest *temporal scale* of generations may be difficult to detect at small *spatial scales* such as an individual field and therefore needs to be assessed at larger scales such as the landscape level.

Often, it will be necessary to assess a potentially adverse effect at more than one scale, since local biological interactions may decouple systems by the introduction of temporal and spatial lags in system dynamics or by creating webs of indirect effects, whereas at larger scales other processes such as agricultural management may dominate or dissipate these biological effects.

The dimension concept outlined here is followed, either implicitly or explicitly, by environmental risk assessors from a wide range of disciplines. However, as indicated by the above examples, care and flexibility is needed in the application of the concept.

This is clearly described in EFSA (2010) in relation to the ERA of PPPs: "a magnitude of effect that is acceptable over a short time scale may not be acceptable if it continues over a long time scale, or small effects on population density could be allowed at a local scale for a medium period of time, as long as on a regional scale the population is not affected". An example is provided in Appendix B in relation to the ERA of PPP on aquatic species. No demonstrable adverse effects on biodiversity, population densities or biomass/growth are acceptable in surface waters that fall under the domain of the Water Framework Directive[31] and Natura 2000. On the other hand, small to large effects, if lasting not longer than 8 weeks, may locally be allowed in edge-of-field surface waters if not leading to unacceptable effects further downstream (EFSA PPR, 2013a).

[31] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. OJ L 327/1, 22.12.2000, pp. 1–72.

It should be noted that the first four dimensions (entity, attribute, temporal and spatial scale) can be considered together, setting a list of relevant combinations used for the discussion on the magnitude of acceptable effects.

Additional recommendations can be found in several scientific papers including Faber and van Wensem, 2012; Galic et al., 2012; Landers and Nahlink, 2013.

The interrelated nature of the five dimensions is highlighted by the fact that they often share common considerations. An example is constituted by landscape structure (including land use) and habitat heterogeneity. These play a pivotal role in modulating local and regional biodiversity and strongly affect the sink-source population dynamics (see EFSA PPR Panel 2015). Important aspects are:

- proportion of off-field areas;
- quality of off-field structures/refuges;
- fragmentation of habitats;
- disruption level between in- and off-field areas, margins and the other landscape components (e.g. tillage, PPPs, irrigation flooding).

It is evident that some of these aspects related to landscape structure and habitat heterogeneity play a role in the definition of the spatial scale. In addition, they have an impact on the organisms' possibility to recolonize, thus influencing the temporal scale of protection and the magntitude of acceptable effects, as explained below.

In an agricultural context characterised by a complex and structured landscape with organic farming management or with a large proportion of semi-natural off-field habitats the acceptable magnitude of effect might be higher than in a conventional managed agricultural context with large crop fields. A complex and structured landscape can support populations by providing diversified refuge areas, consisting of meadows, woods and freshwater bodies. In this landscape, many species would be able to maintain functioning spatially structured populations even with heavy in-crop losses caused by the stressor. The off-field areas will support a high biodiversity and act as a donor for recolonisation. This agricultural context is more likely to provide a stable ecosystem service.

On the other hand, in a simply structured agricultural context (e.g large monocultures and little semi-natural off-field habitats), recolonisation from unaffected off-field populations will take much longer and local extinction of rare species becomes more likely. In this case it is particularly important that the definition of the acceptable effects ensure that no long-term effects emerge as a consequence of, for example, source–sink dynamics between off-field and in-field areas. This kind of landscape may not provide enough habitat diversity to maintain the overall population structure. In this case, even relatively minor disturbances due to agricultural practices may bring many populations to extinction (see EFSA PPR Panel, 2015).

Finally, given the interrelated nature of the five dimensions of the SPGs, it is suggested that risk assessors at EFSA present them to the risk managers in a concise and transparent manner, using visual aids like the example in Figure 1.

dimension	**options**							
Entity	Individual	**(Meta)pop**	Funct. group	Community	Habitat	**Agro-ecosystem**		
Attribute	Behaviour	Survival	Growth	Reproduction	**Abundance**	Biomass	Occupancy	**Process**
Temporal scale	Not applicable	Days	**Weeks**	Months	**Seasons**	Years	Generation	Rotations
Spatial scale	In crop/field	**Edge of field/field margin**	**Nearby off-crop**	Farm/holding/ prod. unit	Watershed	Landscape	Region	Continent
Magnitude	**Negligible**	**Small**	Medium	Large				

Figure 1: Example of the derivation of SPGs. For each SPG, a set of choices for each dimension must be defined (adapted from Nienstedt et al. 2012). In this picture two SPGs are represented, one composed of bold blue choices for each dimension and the other one of bold red choices. The represented options for the dimension "attribute" are not complete in this picture.

2.5. Examples of how Service Providing Units and their five dimensions can be used to define specific protection goals in the problem formulation

The following examples (in text or tabular format) can give guidance on how the above steps 1 to 3 (identification of the relevant ecosystem services, identification of the SPU and specification of the five dimensions) can be implemented during the problem formulation phase in the different environmental areas of EFSA's remit.

2.5.1. Invasive species

Ecological entity and attributes

In the Scientific Opinion on the ERA of the apple snail *Pomacea* sp. (EFSA PLH Panel, 2014), the EFSA PLH panel defined the entity as shallow fresh water areas containing macrophytes, such as wetlands, shallow lakes, river deltas and the littoral zone of deeper lakes and rivers**.** This choice was made on the basis of expert knowledge on the kind of natural habitats likely to be invaded by the snail and on the basis of the likely impacts of the snail on ecosystem structure and functioning, and the services provided by those systems. More in particular, although the above-mentioned areas are ecologically diverse, they all share a homogeneous environment in which the macrophytes offer retention and processing of nutrients and toxic substances, physical structure, habitat, refuge, food or substrate and an environment for spawning of invertebrates, fish and amphibians. In addition, these environments share a homogeneity in the type of ecosystem services they provide, which justifies grouping them into a single SPU. Three attributes ("traits" in the idiom of the PLH panel) were identified: attributes related to the macrophytes, attributes related to water quality, and attributes related to biodiversity.

Spatial and temporal scales

Most of the work by the PLH panel concerns cultivated plants threatened by invasive alien species, but not exclusively. In the case of ecological risk assessment, the assessment is very broad, and not limited to particular systems or to systems spatially associated to crop areas. For instance, the opinion on the oriental chestnut gall wasp, *Dryocosmus kuriphilus,* addressed risks to both cultivated and wild chestnuts, throughout the EU territory (EFSA PLH Panel, 2010a; http://dx.doi.org/10.2903/j.efsa.2010.1619).

In the apple snail opinion (EFSA PLH Panel, 2014), first a detailed temperature-driven process-based population dynamics model for the apple snail was used to map areas of potential establishment of the organism across Europe, thus delineating the spatial extent of the assessment.

Temporal, spatial and biomass scales and the influence of resistance, resilience and management were addressed. The influence and the time variability of resistance, resilience and management led to the consideration of two different scenarios for this case, a short-term assessment for a high impact 5 years after establishment (main influence: resistance of the ecosystem) and a long-term assessment, 30 years after establishment (main influence: resilience, determining some recovery of functioning). This temporal frame is dependent on the expected trends in the time evolution of the environmental impact of the IAS. The identification of the most suitable time horizon has to take into consideration:

- The rate of population growth of the IAS in invaded locations, and the speed at which the ecosystem response: the faster the population increase of the pest and the response of the ecosystem, the shorter the time horizon.
- The rate of appearance of the impact, depending on the resistance of the ecosystem.

Furthermore, in its assessment of the apple snail (EFSA PLH Panel, 2014), the PLH Panel accounted for resilience in the ecosystem due to changes in species composition, following invasion. A re-arrangement of feeding relationships in the food web of the affected ecosystem was considered to result in a partial recovery of ecosystem functioning and associated flows of ecosystem services over time.

Magnitude of effects

For plant health, there are no details or specific inclusions in the GPGs provided in the legal framework about adverse effect categories or specific thresholds for defining environmental harm. Any change in the structural and functional attributes of the invaded ecosystem would be considered potentially adverse. A possible way to assess the effects of invasion of the alien organism on ecosystem traits and ecosystem services is by using a structured semi-quantitative assessment scheme with ordinal ratings described in the PLH ERA guidance document (EFSA PLH Panel, 2011). Experts were asked to estimate the magnitude of effects by assigning a percentage to the expected reduction in each ecosystem service or a biodiversity component of between 0 and 100 %.

2.5.2. Genetically Modified Organisms

The GMO Panel does not structure its Guidances through explicit choices for the five dimensions in a single section, using the highly structured procedure outlined in section 2.3, above. However, its guidance documents (EFSA GMO Panel 2010 and 2013) require each of the dimensions to be considered in different sections of the risk assessment; these are then integrated during risk characterization. Indeed, there is already considerable implicit harmonization of the five dimensions concept within the GMO and PPP panels' Guidance documents and Opinions, as illustrated in the following examples. In this section, the current approach of the GMO Panel is first exemplified in detail for Lepidoptera, and then for biodiversity associated with and impacted by herbicide-tolerant soybean crops. Thirdly, the choices of dimensions for the protection goals for Lepidoptera are revisited and an attempt made to express them in the concise form of Figure 1.

Lepidoptera

The following table (Table 8) summarises the assessment of the EFSA GMO Panel on potential adverse effects resulting from the exposure of non-target Lepidoptera to maize 1507 pollen (EFSA GMO Panel 2011 and 2012).

Table 8 Assessment of the EFSA GMO Panel on potential adverse effects resulting from the exposure of non-target Lepidoptera to maize 1507 pollen (EFSA GMO Panel 2011 and 2012).

Item	***Choice***	***Considerations guiding choice / Relative weight given to importance of criterion***
SPU	Lepidoptera	
Ecosystem services	Provisioning service: genetic resources/biodiversity	Many lepidopteran species are iconic sentinels of biodiversity / *ES type is a major criterion*
	Regulating service: Pollination, pest regulation (i.e. herbivory of weeds)	Adult lepidoptera provide some pollination service; some larval lepidopteran species are herbivores of certain weeds /

		ES type is a minor criterion
	Cultural services: recreation and ecotourism, aesthetic values	Lepidopteran species, especially diurnal butterflies, are subjects of conservation concern / *ES type is a major criterion*
Legal considerations	1) No adverse effect on the environment (Directive 2001/18/EC on release of GMOs is the legal basis for ERA); 2) Guidance towards choice of SPGs is aided by consideration of the need to maintain semi-natural habitats and populations of species of wild flora and fauna at favourable statuses (as set out in Directive 92/43/EEC on conservation of habitats, wild fauna and flora, and see Table 1 of EFSA GMO Panel, 2010).	*Mandatory for risk assessment* *Necessary for adequate risk assessment*
Specific protection goal	No unacceptable loss of biodiversity; No adverse effect on pollination functions of Lepidoptera; No adverse effect on sustainability of populations of individual species of Lepidoptera	All considerations are based on regulation requiring an analysis compared to conventional farming
Dimension	**Choice**	**Considerations guiding choice /** ***Relative weight given to importance of criterion***
Ecological entity	Individuals of lepidopteran species	Some Member States consider that Lepidoptera require protection at an individual level for aesthetic and legal reasons.
	Populations and metapopulations of particular species of Lepidoptera	Some MSs consider overall effect on populations and metapopulations is guiding criterion, especially if the potential stressor operates on larval rather than adult population.
Attribute	Pollination efficiency	*/ Minor, since Lepidoptera are less efficient than some other taxa such as* Apis.
	Survival, abundance	These attributes affect populations and metapopulations, through direct effects such as mortality / *Major*
	Distribution, reproduction, behaviour	These attributes affect populations and metapopulations, through indirect sub-lethal effects. / *Major*
	Biodiversity	Must be included because of the choice of the specific provisioning and cultural services. Of especial importance if biodiversity is measured in terms of indices depending upon species number, which if sufficiently large, may aid the maintainenance of community diversity.
Temporal scale	Days, weeks, seasons, generations (relevant for population and metapopulation dynamics and to account for alternative sources of mortality using key factor analysis), rotations	Scales chosen on the basis of type and period of operation of the potential stressor, life-history stage of Lepidoptera affected and the expected timing for direct and indirect effects following exposure. Effects at all of the scales listed must be accounted for to achieve protection that allows for (meta)population extinction, dispersal and colonization dynamics. Days most relevant for short-term mortality; weeks most relevant for Bt maize flowering periods; seasons, generations and rotations all relevant for overall population dynamics in context of agricultural systems

		Larger scales also necessary to account for alternative sources of mortality using key factor analysis
Spatial scale	Fragmentation of habitats and of the populations In crop (relevant for in-crop host-plants); off-crop, in-field (i.e. field margins, in which host-plants may be at greatest densities); off-crop, off-field (areas adjacent to fields which may contain host-plants and to which Bt maize pollen may be transported from a source field); landscape structure (in which there may be protected areas); region (areas over which agricultural systems may be similar)	Scales chosen on the basis of type and extent of exposure to the potential stressor, mobility of life-history stage of Lepidoptera affected and the expected extent of direct and indirect effects following exposure. Effects at all of the scales listed must be accounted for to achieve protection that allows for (meta)population extinction, dispersal and colonization dynamics. Spatial scales correlate in degree with those chosen for temporal scales (see above). Larger scales also necessary to reflect agricultural context and to account for alternative sources of mortality using key factor analysis.
Magnitude of effects	Relevant decrease in the attributes, and in particular to include sub-lethal effects and effects known to impact attributes such as behaviour.	See choices for above dimensions. EC risk managers have set a uniform protection level for the whole of the EU at 1% mortality. However, this setting may be changed in the future by risk managers, and may certainly differ for other potential stressors. Ideally, this should be extended to account for alternative sources of population change through key factor analysis or similar techniques, although in practice paucity of data has not yet allowed this. Also, sensitivity analysis may be required to study resilience of system and potential for recovery of populations, including worst-case exposure scenarios for hypothetical extremely sensitive Lepidoptera.

Biodiversity impacted by soybean herbicide tolerant systems

More examples, extracted, for each dimension, from the opinions of the EFSA GMO Panel on GM plants and animals (EFSA GMO Panel 2010 and 2013) and the opinion on the placing on the market of a herbicide tolerant genetically modified soybean (EFSA GMO Panel, 2012a) are described below.

<u>Ecological entity and its attributes</u>

The laboratory environment is recommended as an appropriate area to identify impacts of GM products and metabolites on *individuals* through dose-response relationships. Persistence and invasiveness are measured through the fitness of *individuals*. Later, *population* or *metapopulation* models are used to explore the conditions under which GM plants may invade and establish and/or under which the mortality of individual non-target arthropods may affect population abundance. These include any changes to *habitat*. Assessment of the *sustainability of production systems*, including specific cultivation, management and harvesting techniques is mandatory under Directive 2001/18/EC. Any or all of the attributes listed may be relevant for assessment; because of the legislative need to consider both direct and indirect effects, any sub-lethal effects must be accounted for.

A recent example, related to the *placing on the market of a herbicide tolerant genetically modified soybean,* may be found in EFSA GMO Panel (2012). Here, the indirect effects on the entities *weed populations and sustainable agricultural systems* were assessed using the attribute "biodiversity" of species of the plant community and weed resistance to herbicides (a form of *functional process*).

Temporal and spatial scales

The need to characterize risk at a range of *temporal and spatial scales* is stressed: "detailed quantitative modelling may be required to scale up effects at the field level both temporally and spatially" (and see especially sections 2.3, 3.4 and 3.5 of EFSA GMO Panel, 2010).

In the soybean example, the comparison was between GM herbicide-tolerant management systems for a soybean and conventional equivalent soybean systems, using scenario analyses over the temporal scale of *crop rotations*, involving rotations, herbicide usage and tillage applied at the *farm spatial scale*.

Both the guidance documents for ERA of GM plants (EFSA GMO Panel, 2010, section 2.3.4) and GM animals (EFSA GMO Panel, 2013, section 3.6.1) describe the temporal scale of long-term effects both in terms of absolute time and in generations, and the effects as covering both immediate and delayed effects over individual years and rotations. In the soybean example, mentioned above, 2-, 3- and 4-year rotations were considered within scenario analyses. In the Lepidoptera example, the phenology of the six-week flowering time of maize and its coincidence with the neonate life stage of the lepidopteran larvae at risk is a crucial consideration within the exposure assessment of the ERA.

Magnitude of effects

For GMOs, defining the magnitude of effect causing environmental harm is done on a case-by-case basis during RA as the legal framework does not define criteria for characterising adverse effects and determining the magnitude which causes environmental harm.

The *magnitude* of effect is addressed specifically by expressing, "for each measurement endpoint, the level of environmental protection to be preserved through the setting of 'limits of concern'" (section 2.2.1 of EFSA GMO Panel, 2010).

In the soybean example*, in order to assess the magnitude of effects,* the relative risks compared with appropriate baselines were categorized as considerably lower, lower, similar, higher and considerably higher.

Selection of dimensions for the specific protection goal for Lepidoptera

In this section an attempt is made to follow the processes outlined in previous sections to choose a single option for each of the dimensions, for the example of the specific protection goal for Lepidoptera. Scientifically, bearing in mind the large number of interdependent components, both within and between the five dimensions discussed in Table 8 above, the choice tends towards higher scales. For the entity, there is undoubtedly a conflict, implied in Table 8, between the views of risk managers in some individual Member States that consider that Lepidoptera require protection at an individual level and the European Commission which, as risk manager, has set a uniform protection level, at the landscape or regional scale. The tentative choices below (fig. 2) are therefore made both on scientific grounds and to be consistent with the overall European Commission approach. As already noted in Table 8, the relationship between mortality at the neonate larval stage and its effect on population abundance over the whole life-cycle requires key factor or similar analysis, and there is currently insufficient data to quantify this for the great majority of non-pest species. In the presence of this uncertainty the magnitude chosen for mortality (1%) is almost certainly conservative, in order to demonstrate confidence that any effect on the attribute of abundance would be negligible.

dimension	options							
entity	Individual	**(Meta)pop**	Funct. group	Community	Habitat	Agro-ecosystem		
attribute	Behaviour	Survival	Growth	Reproduction	**Abundance**	Biomass	Occupancy	Process
temporal scale	Not applicable	Days	Weeks	Months	Seasons	Years	Generation	**Rotation**
spatial scale	In crop/field	Edge of field/field margin	Nearby off-crop	Farm/holding/ prod. unit	Watershed	**Landscape**	Region	Continent
magnitude	Negligible	**Small**	Medium	Large				

Figure 2 Specific protection goal (bold blue choices) for butterflies (Lepidoptera)

2.5.3. *Plant Protection Products*

Non target terrestrial plants

Ecological entity and attributes

In the EFSA PPR (2014) opinion on non target terrestrial plants (NTTP) it is stated that for NTTPs in the off-field area, it is possible to define a SPG that integrates structural (genetic diversity, local abundance of species) as well as functional aspects of biodiversity (primary production, nutrient cycling, water regulation, provision of habitat and food). Owing to ecological redundancy, structural endpoints are generally more sensitive to PPP application than functional endpoints. Thus, effects at the population level of NTTP species should drive the risk assessment to make sure that a suitable level of protection for off-field NTTPs is ensured.

The protection goal for higher terrestrial plants aims to protect both plant species abundance (e.g. numbers and/or cover of individuals for single species) and plant diversity in an agricultural area. It is assumed that the biodiversity is maintained when the plant populations will not be affected, even for a short period, by the use of PPPs.

Spatial scale

One of the aims of the assessment is to maintain the biodiversity in the off-field situation. At this moment it is not known where (at how many meters distance from the field) the assessment should be based to maintain the biodiversity and therefore the edge of the field is chosen (when the biodiversity is maintained just outside the field the biodiversity is also maintained in the agricultural context).

Magnitude of effects

The SPG is thereafter defined as follows:

- Negligible effects on reproduction at the edge of the field.
- Negligible to small effects on biomass at the edge of the field (maintenance of plant species diversity may be hampered by direct impairment of reproduction (sexual and vegetative) as well as by indirect effects owing to competitive interactions in the field resulting from effects on growth, which is not covered by the reproductive endpoint).

The SPG is further made operational with the following assumptions:

- For exposure the 90^{th} percentile of expected concentrations at the downwind edges of the field,
- Of the available toxicity data (often 6 or more) the 5^{th} percentile of the species sensitivity distribution will be used

There are no available standard toxicity tests that directly provide a measurement for biodiversity, but in the EFSA PPR (2014) opinion it is assumed that for maintaining the biodiversity two other endpoints are available: an endpoint that provides information whether after an application of a PPP the species is still able to reproduce and an endpoint that gives information about the biomass of plant species after treatment. When no effects are expected for either reproduction or biomass it is assumed in the opinion that than also the biodiversity will be maintained. For the reproductive endpoint the $ER_{repro}10$ and for biomass the ERveg10 is proposed (Those are the effect rates where 10% effect is seen. These values can be calculated from the dose response relationship observed in the toxicity test and they are considered as a better representation for negligible effects than the no observed effect rate (NOER) values.)

The operational protection goals (see also figure 3 below) can then be described in the following way: 95 % of the non target terrestrial plants will not be exposed above their ER_{10} under consideration of realistic worst case off-field scenarios (e.g. 90^{th} percentile of the calculated exposure distribution in the defined down wind edge of field scenario).

dimension	options							
entity	Individual	**Population**	Funct. group	Community	Habitat	Agro-ecosystem		
attribute	Behaviour	Survival	Growth	Reproduction	Abundance	**Biomass**	Occupancy	Process
temporal scale	**Not Applicable**	**Days**	**Weeks**	Months	Seasons	Years	Generation	Rotations
spatial scale	In crop/field	**Edge of field/field margin**	Nearby off-crop	Farm/holding/ prod. unit	Watershed	Landscape	Region	Continent
magnitude	**Negligible**	**Small**	Medium	Large				

Figure 3 Specific protection goals (one in red, the other in yellow highlight) for Higher Plants. The purpose of the protection goals is to maintain the biodiversity in the agricultural area. Because no measurement is available for biodiversity two attributes are proposed to maintain it.

Honeybees

The following example (Table 9), focusing on honeybees as providers of food and pollination services, is extracted from EFSA PPR Panel, 2010. A more detailed description of how the problem formulation has been conducted can be found in the Appendix A. The protection goal for honey bees was further elaborated in EFSA PPR Panel (2012) and EFSA (2013a).

Table 9 Honeybees example extracted from EFSA PPR Panel (2010).

SPU	Ecosystem service	Legal requirement	Specific protection goal	Ecological entity	Attribute	Spatial scale	Temporal scale	Magnitude of effects
Honeybees	Food	No unacceptable acute or chronic effects on colony survival and development, taking into account honey bee larvae and honey bee behaviour	No significant effect on colony survival and development and on production of honey, pollen, etc.	Colonies per apiary	Survival and function	Edge of the field and other non-crop areas	No to days	Negligible to small effect
Non-target arthropods (terrestrial) including honeybees	Pollination	No unacceptable lethal and sublethal effects; No effects on on-going behaviour	No to small effect on biodiversity, abundance and behaviour	Populations	Abundance and foraging behaviour	In crop to off crop	No to days during the crop flowering period; days to weeks in edge of field areas (depends on period of foraging)	Negligible to small effects (depends on life cycle of species)
		No unacceptable acute or chronic effects on colony survival and development, taking into account honeybee larvae and honeybee behaviour	No significant effect on survival and foraging behaviour on bees foraging in flowering crop	Forager populations			No to days during the crop flowering period; weeks to months in off crop areas (depends on period of bee foraging)	Negligible to medium effects on forager population within the colonies, no significant impact on foraging behaviour

For the survival of honeybees it is necessary to protect all categories of bees in a colony because they all act together. Therefore, it was proposed to consider the colony as an ecological entity placed between the "individual" and "population". For the ecosystem service pollination it was suggested to define in addition foragers as the relevant ecological entity.

The attributes to protect were taken from the PPP legislation which lists acute and chronic effects on the survival and development of the colonies and effects on larvae and honey bee behaviour. Abundance, biomass and reproduction were suggested as additional attributes because they are important parameters for the development and long-term survival of colonies.

It was necessary to quantify the magnitude of effects and duration of effects in order to make the protection goals operational in the risk assessment context. Different options of magnitude of effects ranging from negligible effects to large effects were elaborated and discussed with risk managers from the EU Commission and Member States. The risk managers chose the most protective option which was negligible effects.

Negligible effects were defined as an effect on colony size not larger than 7 % (magnitude of acceptable effects) compared to control colonies without exposure to the pesticide. In addition, the average daily mortality of foragers should not be larger than a factor of 1.5 in 6 days, a factor of 2 in 3 days or a factor of 3 in 2 days (magnitude and temporal scale of acceptable effects, EFSA 2013a). These increases in forager mortality would lead to an effect on colony size of 7%. For effect on larvae and sublethal effects (HGP gland development) a no effect level was chosen because it was not possible to make a quantitative link between larvae mortality and sublethal effects.

The SPG is defined, through a dialogue between risk assessors and risk managers, in such a way that the exposure to the PPP under evaluation, and considering all relevant exposure routes, does not exceed a level that could lead to effects on colony size greater than 7% in 90% of the colonies at the edge of the treated fields. Whether effects are likely to be observed in the remaining 10% of the colonies at the edge of the field depends on the margin of safety identified in the risk assessment for the specific compounds (e.g. if a compound is of low toxicity to bees and the risk assessment shows a large margin of safety then there will be no effects even if the exposure exceeds the 90th percentile, but if the risk assessment indicates a narrow margin of safety then it is likely that effects are observed when the exposure exceeds the 90th percentile).

The operational protection goals can then be described according to the following figure 4:

dimension	**options**							
entity	Individual	Colony	Population	Funct. group	Community	Habitat	Agro-ecosystem	
attribute	Behaviour	Survival	Growth	Development	Reproduction	Biomass	Occupancy	Process
temporal scale	Not applicable	Days	Weeks	Months	Seasons	Years	Generation	Rotations
spatial scale	In crop/field	Edge of field/field margin	Nearby off-crop	Farm/holding/ prod. unit	Watershed	Landscape	Region	Continent
magnitude	Negligible	Small	Medium	Large				

Figure 4 Specific protection goals (yellow highlight) for honeybees.

Aquatic organisms

Ecological entity

Table 10: The aquatic SPUs and their ecological entity to be protected as proposed in EFSA PPR Panel (2010a and 2013a) and the current standard aquatic test species related to these SPUs (Commission Regulation (EU) 283/2013)

SPU	*Ecological entity to be protected*	**Tier 1 taxa mentioned in data requirements (Commission Regulation (EU) 283/2013)**
Aquatic algae	Populations	Green algae, e.g. *Pseudokirchneriella subcapitata*
		Other taxonomic groups, e.g. the diatom *Navicula pelliculosa*
Aquatic vascular plants	Populations	Monocots, e.g. *Lemna gibba/minor, Glyceria maxima*
		Dicots, e.g. *Myriophyllum*
Aquatic invertebrates	Populations	Crustaceans: *Daphnia magna/pulex*, *Americamysis bahia*
		Insects: *Chironomus riparius*
		Oligochaets*: Lumbriculus* spp.
Aquatic vertebrates	Individuals (in acute risk assessment to avoid visible mortality) – populations (in chronic risk assessment)	Fish, e.g. *Oncorhynchus mykiss*
Aquatic microbes	Functional groups	No standard test species

Attributes, magnitude and scale

Table 11: Overview of proposed SPGs for the ecological threshold option (EFSA PPR, 2013a)

Organism group	***Ecological entity***	***Attribute***	***Magnitude***	***Time***
Algae	Population	Abundance/biomass	Negligible effect	Not applicable
Aquatic plants	Population	Survival/growth		
		Abundance/biomass		
Aquatic invertebrates	Population	Abundance/biomass		
Vertebrates	Individual	Survival		
	Population	Abundance/biomass		
Aquatic microbes	Functional group	Processes (e.g. litter break down)	RA will not be developed since tier 1 data requirements are not defined	

Table 12: Overview of proposed SPGs for the ecological recovery option (EFSA PPR, 2013a)

Organism group	***Ecological entity***	***Attribute***	***Effect allowable on most sensitive/vulnerable population***[c]	
			Magnitude	**Duration**
Algae	Population	Abundance/biomass	Small effect[a]	Months
			Medium effect[a]	Weeks
			Large effect[a]	Days
Aquatic plants[b]	Population	Survival/growth	Small effect[a]	Months
		Abundance/biomass	Medium effect[a]	Weeks
Aquatic invertebrates[b]	Population	Abundance/biomass	Small effect[a]	Months
			Medium effect[a]	Weeks
			Large effect[a]	Days
Vertebrates	No recovery option			
Aquatic microbes	Functional group	Processes	RA will not be developed since Tier 1 data Requirements are not defined	

(a) None of the direct effects should lead to unacceptable indirect effects.
(b) The recovery option will often not be applicable in case organisms with a long life cycle could be affected and short-term (days) large effects generally will be acceptable only for short-cyclic organisms that have a high reproduction capacity.
(c) In the EFSA Aquatic Guidance Document the allowable effect on the most sensitive/vulnerable population in the surrogate reference tier (mesocosm tests) is operationalised by using Effect classes in the derivarion of Regulatory Acceptable Concentrations (see EFSA PPR, 2013a).

As indicated in the PPR guidance for aquatic organisms (EFSA PPR Panel, 2013) when the attribute is established at the (meta)population level, a key element for setting the temporal scale is the risk management option for accepting only negligible population-level effects, or for accepting some population effects if ecological recovery takes place within an acceptable time-period. For the ecological recovery option the temporal scale should be set at the acceptable time for recovery.

Some of the temporal scale options relate to case specific management systems.

A more complete description of the process of defining SPGs for water organisms in the ERA for PPPs can be found in the appendix B.

2.5.4. Feed additives

Ecological entity

In assessing the safety to the environment of additives in animal feeds, the aim is to protect the (meta)populations of each species potentially exposed to the additives following excretion from the target (farm) animal and spreading of manure (in the case of terrestrial farm animals) on the field.

Attribute

In accordance with Directive 2001/79/EC (EC, 2001a), the goal of the FEEDAP ERA is that the use of feed additives in animal nutrition should not cause a negative effect to the environment. This is achieved by satisfying that the Predicted Environmental Concentration (PEC) of each compound does not exceed the Predicted No Effect Concentration (PNEC) in each compartment of concern. These are soil, groundwater, surface water, freshwater sediment, and marine sediment (under sea cages). As it is not practically feasible to experimentally determine PNEC for all species that might be exposed, the PNEC is calculated from toxicity endpoints in surrogate species, using standardised testing protocols, and application of an appropriate safety factor, which depends on the amount of data available. In these toxicity tests, the attributes are usually survival, growth, reproduction, or nitrogen transformation (of soil microorganisms).

Magnitude of effects

No feed additives are designed or used with the purpose to affect free-living organisms and the goal is that they should not have any additional effect on the environment, beyond those caused by farming practices themselves. This can however only be extrapolated from measured effects on surrogate test organisms, which are selected because of their sensitivities and key roles in their respective habitats.

Temporal scale

The FEEDAP risk assessment assumes that exposure to the environment occurs throughout the production cycle of the relevant farm animal, and that in many cases there will be a succession of farm animal cohorts throughout the year.

Spatial scale

A distinction needs to be made between feed additives used in terrestrial animals and feed additives used in aquatic animals.

For feed additives used in terrestrial animals, feed additives and/or their metabolites are spread in manure on arable land. They will leach into the soil, which is the first compartment to be protected. It is assumed that the first 5 - 20 cm soil in the field will be mostly impacted and this is thus the spatial scale.

From the soil, the additive/metabolite may drain into ground water and surface waters which are also compartments of concern in the ERA for this Panel. For the ground water, there is no spatial scale per se. For the surface water it will usually be the local stream (not the ditch, but the natural stream closest to the treated field).

For feed additives used in aquatic animals and additives used in sea cages it has been modelled that their impact on the water column will be minimal in comparison with the sediments beneath the cages. Therefore, the area under the cages is constituting the spatial scale for protection.

For aquatic animals and additives used in land based aquaculture operations (e.g. ponds, tanks and recirculation systems) the spatial scale will usually be the nearest natural water that receives the outflow from the farm.

3. CHALLENGES

The Scientific Committee identified the following challenge arising from the development of a framework for the identification of Specific Protection Goals accounting for biodiversity and the ecosystem services approach.

The challenge is the investigation of the relationship between biodiversity and the provision of ecosystem services and therefore how addressing carefully chosen ecosystem services and defined specific protection goals help in achieving the general legislative goal of protecting and maintaining biodiversity.

Because of the complex interaction between species it is extremely difficult to determine the ‘number’ of species that a system can afford to loose without jeopardising ecosystem functioning and ecosystem service provisioning. Some species loss can be compensated for, but, if the erosion process continues, a ‘tipping point’ is reached and the ecosystem reaches an alternative stable state or definitively collapses (e.g. Lever et al., 2014).This relationship will differ among services, landscapes, agricultural systems, etc.

Qualitative approaches are used in the absence of sufficient quantitative data regarding these issues. However qualitative approaches do not contribute much to the development of ERA schemes or to decide whether a specific protection goal has been met.

A quantitative relationship between biodiversity (e.g species richness or genetic diversity) and the provision of ecosystem services is required. This is very challenging because of several factors:

- Biodiversity is a multidimensional concept, identified at various hierarchical levels (landscapes, communities, species, individuals, genes);

- The information related to various measures of biodiversity has been gathered for particular purposes (e.g. environmental quality monitoring, conservation reporting);

- The nature of the relationship between ecosystem services and biodiversity varies according to the service considered (TEEB 2010, Chapter 2).

There is no modelling approach currently available to explore how the abundance (density), type and location of the SPU influences the provisioning of ecosystem services and to quantify the actual delivery of ecosystem services. In the recent EFSA opinion on the environmental impact of apple snail invasion in the EU (EFSA PLH Panel, 2014), expert judgement was utilised to assess the impacts of invasive species on the traits, ecosystem service provisioning and biodiversity of a given SPU.

4. CONCLUSIONS

Generic Protection Goals as provided in the sectorial legislative frameworks are expressed very broadly and require further interpretation to make them operational for the purposes of efficient ERA. However the ERA approaches followed in the scientific areas within EFSA's remit are often different and depend on the sectorial legislation as reflected in the respective EFSA guidance documents.

The SC is of the opinion that biodiversity and the ecosystem services concept can be used as an overarching methodology to define Specific Protection Goals for the purpose of ERA because: (1) it provides a coherent framework applicable to all types of ecosystems, habitats (including habitats of high conservation value), environmental compartments, species (including endangered species); (2) it covers structural and functional components of biodiversity underpinning the provision of ESs as well as its conservation value; (3) it can be applied at a range of spatial and temporal scales; 4) it addresses recovery. Additionally, protection goals fixed by legislation to protect particular species or geographic areas could be accommodated within the Ecosystem Services concept by including these under cultural ecosystem services.

It is evident from their environmental risk assessment outputs, that different EFSA Panels have developed their own approaches and consequently seem to focus on different protection goals or specific protection goals and different service providing units. It appears as if the potential stressor affects the choice of specific protection goals that are being addressed in the ERA. This apparent inconsistency is a major challenge and needs to be overcome if greater harmonisation is to be achieved. The same holds true for the definition of the five dimensions for each specific protection goal.The advantage of making generic protection goals operational in a harmonised manner is to achieve a consistent approach regardless of the potential stressor. This reduces the potential for providing conflicting advice to risk managers who may be responsible for the management of multiple stressors under multiple authorisations or different pieces of legislation.

The level of protection for a given valued entity remains, from a scientific point of view, the same across different risk assessments, regardless of the type of stressor. On scientific grounds alone, protection goals for the risk assessments should be uniform and may be harmonised across the different domains of EFSA's responsibility. However risk managers' definitions of the entity and level of protection (whether on the European Union or national level) may vary for different stressors as a result of, for example, existing legislation, political trade-offs, socio-economic arguments, and societal perceptions.

The Scientific Committee proposes three successive steps in the problem formulation phase to identify efficient specific protection goals for biodiversity (and the ecosystem in general) by using the ecosystem services approach: 1) to identify relevant ecosystem services that may be affected by the potential stressor, 2) to identify service providing units that deliver those ecosystem services and 3) to specify the level and parameters of required protection using five interrelated dimensions. In order to increase the transparency, scientific consistency and completeness of the assessment, considerations have been proposed to guide and justify the choices for each dimension. These three overall steps should be used to harmonise the approach to identify practical or operational specific protection goals in all relevant areas of EFSA's environmental responsibilities.

While biodiversity underpins the provision of ecosystem services, in this document it is also considered as a relevant potential attribute of the ecological entity that delivers a particular ecosystem service. The Scientific Committee considers that the importance of biodiversity is therefore recognised and accommodated within the three step approach described in this document.

The procedure described in this scientific guidance for identifying SPGs do not depend on the type of potential stressor, the scope of the application of the regulated product or the availability of data. They therefore should be implemented in any future environmental assessment. This guidance document is designed to support the EFSA Panels in order to consistently inform the problem formulation for their respective ERAs. This will also contribute to the increased transparency and greater harmonisation of EFSA's environmental risk assessments.

Besides providing a framework for making general protection goals for biodiversity (and the ecosystem in general) operational the ecosystem services concept also facilitates communication to the full range of stakeholders, risk assessors and risk managers involved in ERA. However, the goal of using one common language to define what requires protection, where and for how long, regardless of the type of potential stressor, requires the necessary agreement on the underlying concepts and definitions of protection goals between risk assessors and risk managers. The need of this discussion arises from the fact that there are a lot of value judgements to be made that cannot be derived scientifically.

Such dialogue would assist risk assessors in their tasks to operationalise protection goals during the problem formulation phase of the ERA and to deliver opinions suited to the policy requirements of risk managers. However it should be clear in the dialogue between risk assessors and managers that the ultimate aim is the fulfillment of the general protection goals as defined by the respective regulation, e.g. biodiversity (and the ecosystem in general), and not the single ecosystem services per se. Therefore it is necessary to make clear to risk managers whether or to which degree the combination of the selected SPG options achieve the general PG. In the framework proposed by this guidance, such dialogue is needed in particular when determining:

- which ecosystem services are relevant and to be focused on in the agricultural context. In such dialogues potential trade-offs between, for example, food provision and genetic resources in a wide sense, recreation or ecotourism could be considered;
- the magnitude of effects that would be regarded as acceptable;
- how to use the relevant ecosystem services to build specific protection goals, by submitting to the risk managers the various possible specific protection goals at the problem formulation phase in order to agree on the focus of the assessment before initiating it. The best moment for this dialogue is when a new guidance document is to be developed.

The need for communication between risk assessors, risk managers and other stakeholders is clearly identified at several places in this document. The challenge for risk assessors is to encourage risk managers to frame clear questions that will aid the risk assessors to derive relevant specific protection goals. This should take place in all EFSA's risk assessment domains.

In order to facilitate the implementation of the framework proposed in this document, it is recommended to risk managers to clarify the policy generic protection goals. Such clarification would help both decision makers and risk assessors to decide what are the important potential changes to the environment and the biodiversity therein.

GLOSSARY

Adverse (environmental) effect: Any effect that causes harm to the normal functioning of plants or animals. Establishing what an adverse effect is and which effect is regarded as environmental harm is a complex process of also analysing and implementing policy objectives taking into account broader societal and relevant stakeholder values. It requires that risk managers define what is important to protect and the magnitude of the effect that is to be regarded as harmful or unacceptable.

Agricultural context: Land used for crops, pasture, and livestock; the adjacent uncultivated land that supports other vegetation and wildlife; and the associated atmosphere, the underlying soils, groundwater, and drainage networks (Kattwinkel et al. 2012).

Alien species: According to the EU Directive on Invasive Alien Species an 'alien species' means any live specimen of a species, subspecies or lower taxon of animals, plants, fungi or micro- organisms introduced outside its natural range; it includes any part, gametes, seeds, eggs or propagules of such species, as well as any hybrids, varieties or breeds that might survive and subsequently reproduce, (see also invasive alien species).

Analysis plan: Step of the ERA problem formulation phase describing how the formulated risk hypotheses can be tested.

Biodiversity: The variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

Case-by-case: Approach by which the required information may vary depending on the type of the potential stressor concerned, its intended use or impact and potential receiving environments, taking into account, *inter alia*, related stressors already in the environment (generalised from the GMO-specific definition in EC, 2001b).

Community: An association of interacting populations, usually defined by the nature of their interactions, by their combined ecological functions or by the place in which they live (adapted from Ricklefs and Miller, 1999).

Conceptual model: Step of the ERA problem formulation phase describing and modelling scenarios and pathways on how the use of a regulated product may cause harm to a specific protection goal (Sanvido et al. 2012; Wolt et al. 2010; Raybould 2010). It guides the formulation of testable risk hypothesis.

Cultural service: Non-material benefit obtained from ecosystems (Harrington et al., 2010).

Delayed effect: Effect that occurs sometime after exposure (Rand and Petrocelli, 1984).

Direct effect: An effect that is mediated solely by the interaction between the specified receptor/target and the environmental stressor, i.e. when the receptor/target is exposed directly to the stressor and as a result the receptor/target exhibits a response or an ecological effect.

Ecological habitat of a species: Place where an organism normally lives, often characterized by a dominant plant form (e.g. forest habitat) or physical characteristic (stream habitat) (Ricklefs, 1990).

Ecological recovery: The return of the perturbed ecological endpoint (e.g. species composition, population density) to its normal operating range.

Ecosystem: A dynamic complex of plant, animal and microorganism communities and their nonliving environment interacting as a functional unit (MEA, 2003).

Ecosystem function: See ecosystem process.

Ecosystem process: Actions or events that result in the flow of energy and the cycling of matter (Ellis and Duffy, 2008). Examples of ecosystem processes include decomposition, production, water and nutrient cycling (MEA, 2003).

Ecosystem service: The benefit people obtain from ecosystems. Ecosystem services include provisioning services such as food and water; regulating services such as flood and disease control; cultural services such as spiritual, recreational, and cultural benefits; and supporting services such as nutrient cycling that maintain the conditions for life on Earth.

Ecosystem structure: Attributes related to the instantaneous physical state of an ecosystem. There are several characteristics to describe ecosystem structure. For example, species population density, species richness or evenness, and standing crop biomass

Effect: In general, an effect is something that inevitably follows an antecedent (cause or agent). A biological effect is the biological result of exposure to a causal agent.

Environment: Natural environment, encompassing all living and non-living entities occurring naturally on earth or some region thereof (Johnson et al., 1997).

Environmental harm: Measurable adverse change in a natural resource or measurable impairment of a natural resource service which may occur directly or indirectly (EC, 2004).

Environmental risk assessment (ERA): The evaluation of the probability and seriousness of harmful (or adverse) effects to human health and the environment, whether direct or indirect, immediate or delayed, following exposure to a potential stressor.

Feed additive: According to Commission Regulation (EC) No 1831/2003 feed additives are substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions: favourably affect the characteristics of feed or animal products, favourably affect the colour of ornamental fish and birds, satisfy the nutritional needs of animals, favourably affect animal production, performance or welfare and, and have a coccidiostat or histomonostatic effect (Article 5(3)).

Fitness (population fitness): The relative ability to survive and reproduce of a given genotype or phenotype conferred by adaptive morphological, physiological or behavioural traits.

Focal species: A representative subset of species, selected for testing purposes. Focal species are usually selected based on their ecological relevance, their likely exposure to the potential stressor under field conditions, their susceptibility to the potential stressor, and their testability (Hilbeck et al., 2013, Romeis et al., 2013). Ideally, focal species should have equal or greater sensitivity to the potential stressor than do the species they represent in the ERA and thus knowledge of the effects on these species provides reliable predictions about effects on many other species (Raybould et al., 2011).

Food web: A representation of the various paths of energy flow through populations in the community (Ricklefs, 1990).

Functional group: A collection of organisms with similar functional trait attributes and that are likely to be similar in their response to environmental changes and effects on ecosystem functioning (Hooper et al. 2002).

Functional redundancy: A characteristic of species within an ecosystem where certain species contribute in equivalent ways to an ecosystem function such that one species may substitute for another. Note that species that are redundant for one ecosystem function may not be redundant for others

Functional trait: A measurable property (e.g. mobility, feeding behavior, trophic level, and place in the food web) of an organism, which has demonstrable links to the organism's function (Lavorel et al., 1997; Harrington et al., 2010).

Genetic diversity: Genetic variation between and within species. This can be characterised by the proportion of polymorphic loci (different genes whose product performs the same function within the organism), or by the heterozygous individuals in a population (Frankham and Briscoe, 2002).

Genetically modified organism (GMO): An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination (EC, 2001b).

Hazard (harmful characteristics): The characteristics of a potential stressor that can cause harm to or adverse effects on human health and/or the environment.

In-crop area: Surface covered by the crop plants including the space between the crop rows.

Indirect effect: An indirect effect involves effects being transmitted to the specified receptor through an indirect route involving one or more other, intermediary, receptors. A predatory non-target organism for example could be affected indirectly by a stressor in several ways, including effects of the stressor reducing the abundance of its prey species, its intra-specific or inter-specific competitors, its pathogens or its parasites.

In-field area: The in-crop area and its boundaries that are managed by the farmer in the context of the crop management.

Invasive alien species: Invasive alien species (IAS) are plants, animals, pathogens and other organisms that are non-native to an ecosystem, and which may cause economic or environmental harm or adversely affect human health. The EFSA plant health panel assesses risks posed by invasive alien species that are harmful to plant health. Therefore, within the context of this opinion, the term IAS refers to invasive alien species that are harmful to plant health. Strictly, the term "invasive" refers to the tendency of a species to disperse and extend its spatial range, or colonize systems from which it was previously absent. An organism is "alien" if it does not naturally occur in a system or area.

Landscape: An area comprising a system of interest (e.g. agricultural system) at a relatively large scale resulting in heterogeneity in space such as fields or habitat patches.

Life-history trait: Also referred as a demographic trait. A trait that influences the population growth rate and ultimately drives population densities and age distributions (Rubach et al., 2011).

Limit of concern: The minimum ecological effect that is deemed biologically relevant and that are deemed of sufficient magnitude to cause harm. These limits of concern are set for each specific protection goal in the problem formulation.

Measurement endpoint: Measurable quality related to the valued characteristics chosen as the assessment (Suter et al., 1993). Within the context of ERAs that fall under the remit of EFSA this concerns a quantifiable response to a potential stressor that is related to the specific protection goal.

Metapopulation: Population of populations of the same species connected through immigration and emigration (Hanski and Gilpin, 1991).

Modelling: An attempt to describe the behaviour of a natural system or to predict the likelihood of an event occurring within a system; it may utilise mathematical formulas and computer simulations.

Non-target arthropod (NTA): An arthropod species that is not intended to be affected by the potential stressor under consideration.

Non-target organism (NTO): An organism that is not intended to be affected by the potential stressor under consideration.

Off-crop area: Area where the product is not intentionally applied.

Off-field area: Area outside the managed "in-field area".

Pest: The concept of pest organisms is anthropocentric and thus a pest is defined as any organism that is perceived by humans to interfere with their activities. Ecologically there are no such organisms as pests. Organisms in several phyla are considered to be pests: e.g. arthropods, nematodes, molluscs, vertebrates. In particular, any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products are called plant pests (IPPC, 2014).

Plant Protection Product (PPP): A substance (or device) used to protect (crop) plants from damage by killing or reducing pest organisms or by mitigating its effects.

Population: A group of individuals of the same species.

Potential stressor: used as "environmental potential stressor" and meaning any physical, chemical, or biological entity resulting from the use of a regulated product or the introduction of an invasive alien plant species related to the food/feed chain that is assessed in any area of EFSA's remit and that can induce an adverse response in a receptor (Romeis et al. 2011). Potential stressors may adversely affect specific natural resources or entire ecosystems, including plants and animals, as well as the environment with which they interact (http://www.epa.gov/risk_assessment/basicinformation.htm).

Problem formulation: Phase of environmental risk assessment which includes a preliminary description of exposure and environmental effects, scientific data and data needs, key factors to be considered, and the scope and objectives of the assessment. This phase produces the risk hypotheses, conceptual model and analysis plan, around which the rest of the assessment develops (Raybould 2006; Wolt et al. 2010).

Protection goals: The objectives of environmental policies, typically defined in law or regulations. (Romeis et al. 2011).

Provisioning services: Products obtained from ecosystems (Harrington et al., 2010).

Recovery option: Specific protection goal option accepting some population-level effects of the potential stressor if ecological recovery takes place within an acceptable time-period.

Regulated products: Claims, materials, organisms, products, substances and processes submitted to EFSA for evaluation in the context of market approvals/authorisation procedures for which an ERA is required.

Regulating services: Benefits obtained from regulation of ecosystem processes (Harrington et al., 2010).

Risk: The combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences occur.

Risk hypotheses: A tentative explanation of how the proposed actions, such as the cultivation of GMO crops, may cause harm. (Romeis et al. 2011)

Service providing unit (SPU): The systematic and functional components of biodiversity necessary to deliver a given ecosystem service at the level required by service beneficiaries (Luck et al., 2003; Vanderwalle et al., 2008).

Sink population: A local sub-population within a spatially-structured population that does not produce enough offspring to maintain itself through future generations without immigrants from other populations.

Source population: A local sub-population within a spatially-structured population that produces an excess of offspring above those needed to maintain itself through future generations. The excess offspring provide a source of immigrants to other sub-populations.

Species sensitivity distribution: models of the variation in sensitivity of species to a particular stressor (Posthuma et al. 2002). They are generated by fitting a statistical or empirical distribution function to the proportion of species affected as a function of stressor concentration or dose. Traditionally, SSDs are created using data from single-stressor laboratory toxicity tests, such as median lethal concentrations (LC50s).

Specific Protection Goal (SPG): An explicit expression of the environmental value to be protected, operationally defined as an ecological entity and its attributes (Suter et al., 1993).

Supporting services: Services necessary for the production of all other ecosystem services (Harrington et al., 2010).

Threshold option: Specific protection goal option accepting no to negligible population-level effects of exposure to a potential stressor.

Trait: A well-defined, measurable, phenotypic or ecological character of an organism, generally measured at the individual level, but often applied as the mean state of a species (McGill et al., 2006).

Time horizon: Fixed point of time at which certain processes will be evaluated.

Uncertainty: Uncertainty is the inability to determine the true state of affairs of a system (Haimes, 2015) and it may arise in different stages of risk assessment due to lack of knowledge and to natural variability (EFSA SC, 2016c).

Voltinism: A trait of a species pertaining to its number of broods or generation per year or per season.

Vulnerable species: A vulnerable species is a species with a relatively high sensitivity for a specific stressor, high exposure and a poor potential for population recovery. It should be noted that this definition of vulnerability is limited to the direct effects of toxic stressors. Vulnerability to indirect effects, e.g. propagated through disturbed predator-prey or competitive relationships, cannot be characterized by the triad of exposure, sensitivity and recovery. Vulnerability to indirect effects is related to dependability, i.e. whether a species depends, either directly or indirectly, on a species that is affected by the stressor at hand. Other pathways for indirect effects are related to behavioural change resulting e.g. in decreased predator avoidance or decreased competitive strength due to toxicant stress. Additionally, direct and indirect long-term effects need to be taken into account (Van Straalen, 1994).

ABBREVIATIONS

BIOHAZ Panel	EFSA Panel on Biological Hazards
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Environment Agency
EFSA	European Food Safety Authority
ERA	Environmental Risk Assessment
EU	European Union
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed
GMO	Genetically Modified Organisms
GMO Panel	EFSA Panel on genetically modified organisms
GPG	General Protection Goal
IAS	Invasive Alien Species
JRC	Joint Research Centre
MEA	Millennium Ecosystem Assessment
NTA	Non Target Arthropod
NTO	Non Target Organisms
OECD	Organisation for Economic and Co-operation Development
PEC	Predicted Environmental Concentration
PEC_{max}	Maximum predicted environmental concentration
PEC_{twa}	Time-weighted average exposure concentrations
PG	Protection Goals
PLH Panel	EFSA Panel on Plant health
PNEC	Predicted no effect concentration
PPP	Plant Protection Product
PPR Panel	EFSA Panel on Plant Protection Products and their Residues
RA	Risk Assessment
RAC	Regulatory Acceptable Concentrations

REACH	Registration, Evaluation, Authorization and Restrictions of Chemicals
SC	Scientific Committee
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
SCoFCAH	Standing Committee on the Food Chain and Animal Health
SPG	Specific Protection Goal
SSD	Species Sensitivity Distribution
ToR	Terms of Reference
UK	United Kingdom
US	United States
WFD	Water Framework Directive
WG	Working Group
WHO	World health Organisation

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Appendix A: Example of problem formulation based on the ecosystem services approach for the ERA of PPPs on Honey bees

To communicate how ERA is conducted, the following questions need to be addressed during problem formulation:

WHAT IS TO BE PROTECTED/RISK ASSESSED? SPGs

A. Identify the relevant ecosystem services and Service Providing Units
B. Define the ecological entity, attributes, and the spatial-temporal scale of protection
C. Define what an adverse effect is and the magnitude of the acceptable effects

WHAT IS TO BE MEASURED? Measurement endpoints

D. Identify characteristics of potential stressor that can cause harm and develop conceptual models on how the potential stressor of concern can adversely affect the SPGs
E. Identify exposure pathways
F. Derive risk hypotheses to be tested
G. Define relevant measurement endpoints (e.g. mortality).

HOW TO MEASURE? Analysis plan

H. Decide how the hypotheses should be tested
I. Select representative test species and testing approaches

Information from the PPP sectorial legislation

Regulation (EC) No 546/2011 on the uniform principles for evaluation and authorisation of plant protection products describes, in section 2.5.2.3, that *"Where there is a possibility of **honeybees** being exposed, no authorisation shall be granted if the **hazard quotients** for oral or contact exposure of honeybees are **greater than 50**, unless it is clearly established through an appropriate risk assessment that under field conditions there are no **unacceptable effects** on honeybee **larvae**, honeybee **behaviour**, or **colony** survival and **development** after use of the plant protection product in accordance with the proposed conditions of use".* The Regulation also describes in section 2.5.2.4 that *"Where there is a possibility of beneficial arthropods other than honeybees being exposed, no authorisation shall be granted if more than **30 % of the test organisms** are **affected** in lethal or sublethal laboratory tests conducted at the maximum proposed application rate, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on those organisms after use of the plant protection product in accordance with the proposed conditions of use. Any claims for selectivity and proposals for use in integrated pest management systems shall be substantiated by appropriate data."*

Specific Protection Goals

In order to develop a guidance document on PPP risk assessment for bees SPGs were agreed with risk managers (EFSA, 2013a), following the ecosystem service approach as outlined in the PPR Scientific opinion (EFSA PPR Panel, 2010; see also Nienstedt et al., 2012).

EFSA PPR Panel (2012) defined "pollination", "bio diversity" and "provisioning of food" (honey and other beehive products for honeybees only) as the ecosystem services to be protected.

SPGs have been proposed for wild bees (i.e. bumble bees and solitary bees). However, data on mortality rates are scarce and it is not so far possible to give clear definitions for the magnitude of effects based on background mortality and thresholds of effects on populations. Differences in biology and ecology make bumble bees and solitary bees potentially more vulnerable to PPP impacts than honeybees (Thompson and Hunt, 1999; EFSA PPR Panel, 2012a) requiring an extrapolation factor.

Define dimensions

In order to ensure the protection of the identified ecosystem services, attributes for honeybees are defined as follows (EFSA PPR Panel, 2012):

- survival and development of colonies
- effects on larvae
- bee behaviour
- abundance/biomass
- reproduction

A systematic review followed by a meta-analysis on bee species sensitivity to PPPs (including *Apis mellifera* in comparison with other bee species) showed that a factor 10 was appropriate for accounting the higher vulnerability of bumble bees and solitary bees with respect to honeybees (Arena and Sgolastra, 2014).

Define acceptable effects[32]

The risk assessment scheme and associated trigger values enable an assessment that, if met, would protect a certain percentage of sites where honeybee colonies are located on the edge of treated fields.

In order to decide the appropriate levels of protection (to make choice on the magnitude, temporal scale (duration) and spatial scale of acceptable effects, and the related exposure percentile), risk managers need to be consulted.

For honeybee colonies, effects of PPP exposure on colony size located at the edge-of-field (spatial scale) should always be negligible. Negligible effects were defined as an effect on colony size not larger than 7% (magnitude of acceptable effects). In addition, compared to control bee hives bordering fields not exposed to PPPs average daily mortality of foragers should not be larger than a factor 1.5 in 6 days, a factor of 2 in 3 days or a factor of 3 in 2 days (magnitude and temporal scale of acceptable effects, EFSA 2013a). Note that daily mortality of foragers can be estimated by comparing the reduction in abundance of foragers reaching the bee hives located at edge-of-field localities of treated and control fields.

The overall level of protection also considers exposure assessment goals, which was set at the 90th percentile of colonies placed at the edge of treated fields. This means that, to meet the SPG, the *exposure in the field should not exceed a level that could lead to effects greater than 7 % in 90 % of the colonies at the edge of the treated fields*. Whether effects are likely to be observed in the remaining 10 % of the colonies at the edge of the field depends on the margin of safety identified in the risk assessment for the specific compounds (e.g. if a compound is of low toxicity to bees and the risk assessment shows a large margin of safety then there will be no effects even if the exposure exceeds the 90th percentile, but if the risk assessment indicates a narrow margin of safety then it is likely that effects are observed when the exposure exceeds the 90th percentile).

Identify exposure routes

To assess risk of PPPs on bees, the following routes of exposures are considered (for both the active substance and its metabolites):

- Exposure via contact either from spray deposits or dust particles when bees are either foraging the treated crop, weeds in the field, plants in field margin and the adjacent crop;

[32] the effect percentages may change in future if the beehave model is used (depends on the outcome of the model evaluation).

- Exposure via consumption of pollen and/or nectar from the treated crop, weeds in the field, plant in field margin, the adjacent crop or succeeding crop/permanent crop the following year;
- Exposure via consumption of water (i.e. guttation fluid, surface water and puddles).

Although not all routes are relevant for all PPPs uses, still they need to be considered. Risk mitigation measures may be required and uncertainty needs to be included.

What to measure

To measure magnitude of effects on the ecosystem services (pollination and yield of hive products), colony size (i.e. number of individual bees) and number of foragers which are correlates of colony strength/activity, were proposed (EFSA PPR Panel, 2012).

APPENDIX B: DEFINITION OF SPGS FOR WATER ORGANISMS IN THE ERA FOR PPPS

Identification of Ecosystem Services provided by water organisms potentially affected by PPPs

For this task the list of ecosystem services (ES) as mentioned by MEA (2005) was used as a starting point. A distinction was made between the overall importance of ES for smaller edge-of-field surface waters (ponds, ditches, streams) in agricultural landscapes and large surface waters (falling under the domain of the Water Framework Directive and Nature 2000). The ES potentially impacted by PPPs were identified, as well as the main SPUs (representative taxonomic or functional groups) performing the ES in surface waters (see Table 1).

Table 1: Ecosystem services to be considered, and their importance (+ small; ++ intermediate; +++ large) for aquatic ecosystems (including e.g. rivers, streams, lakes, ditches, estuaries, transitional waters and wetlands) and the potential impact of PPPs on them. The ecosystem services are largely based on the Millennium Ecosystem Assessment Report, but some categories are added/adapted.

Millennium Ecosystem Assessment category	**Ecosystem service**	**Smaller edge-of-field surface waters (agricultural landscapes)**	**Larger surface waters (WFD and Natura 2000)**	**Potentially impacted by PPPs**	**SPUs**
Provisioning services (products obtained)	Food	+	++ to +++	**Yes**	**Consumable fish, crayfish, and Mollusca**
	Fibre and fuel	+	+	**Yes**	**Emergent macrophytes (thatched roofs)** **Harvestable algae, macrophytes and peat (biofuel)**
	Energy (hydroelectric)	+	++ to +++	**No, but indirectly yes (fouling organisms)**	**Water power, cooling water**
	Transport	+	++ to +++	**No, but indirectly yes (fouling organisms)**	**Infrastructure waterways (boat traffic etc.)**
	Genetic resources/biodiversity	+	+++	**Yes**	**Potentially all species taxonomically related to harvestable species**
	Biochemical/natural medicines	+	+	**?**	
	Ornamental resources	+	+	**marginal**	**Garden pond species**
	Fresh water	+++	+++	**Yes**	**Overall water quality (e.g. drinking water)**
Regulatory services (beneficial regulations)	Pollination	+	+	**Yes**	**(semi-)aquatic insects that pollinate vascular plants (including aquatic macrophytes)**
	Seed/propagule dispersal	++	++	**Marginal, via indirect impact on fish and birds**	**Water, fish, birds**
	Pest & disease regulation (e.g. mosquito control and control of aquatic species that act as host for parasites and diseases such blue tongue disease)	+	+	**Yes**	**Fish and invertebrate predators**
	Climate regulation	+	++	**marginal**	
	Air quality regulation	**?**	**?**	**marginal**	
	Water regulation (quantitative aspects)	+++	+++	**Yes**	**Macrophytes;** **Beaver dams**
	Erosion regulation	++	++	**Yes**	**Rooted macrophytes**
	Natural hazard regulation (other than water regulation)	**?**	**?**	**?**	
	Invasion resistance	+	++	**Yes**	**Native aquatic organisms (plants, invertebrates, fish) with a similar niche than invasive species**

	Water purification/waste treatment	+++	+++	**Yes**	**Bacteria, fungi, microfauna, macroinvertebrate filterers, plants**
Cultural services	Spiritual and religious values	**?**	**?**	**?**	
	Education and inspiration	+++	+++	**Yes**	**All taxa**
	Recreation and ecotourism	++	+++	**Yes**	**Fish (sport fishing), aquatic vegetation, water fowl (bird watching and hunting), aquatic vertebrates (otters, beavers), aquatic amphibian and reptiles, larger invertebrates (e.g. crayfish, dragonflies)**
	Cultural heritage	+++	+++	**Yes**	**Preservation/conservation of surface waters constructed and/or modified by man and their typical biota (e.g. canals, clay and peat excavations)**
	Aesthetic values	+++	+++	**Yes**	**All taxa, and red list species in particular**
	Sense of place	+	++	**no**	**Aquatic ecosystems as landscape features**
Supporting services (to produce other ES)	Primary production	+++	+++	**Yes**	**Algae and vascular plants**
	Herbivory	+++	+++	**Yes**	**Grazers of algae (e.g. zooplankton and snails) and consumers of macrophytes (e.g. insects and waterfowl)**
	Top down food web control	++	+++	**Yes**	**Predatory fish and in fishless ponds predatory insects**
	Provision of habitat	+++	+++	**Yes**	**Macrophytes, larger animals that provide surfaces for periphytic organisms (e.g. shells of mussels)**
	Soil formation and retention	+	++	**Yes**	**Fen and peat formation by plants**
	Nutrient cycling	+++	+++	**Yes**	**Microorganisms, plants, invertebrate grazers and consumers, fish**
	Water cycling	+++	+++	**Yes**	**Emergent , floating macrophytes (evaporation) and submerged macrophytes (drainage)**

Identification of important SPUs that need to be addressed in ERA for PPPs in surface water

On basis of Table 1 the main SPU groups (representative taxonomic groups) were identified and compared with the Tier 1 taxa mentioned in data requirements (Table 2). For all main SPUs, except aquatic microbes, Tier 1 taxa are available.

Table 2: Important taxonomic groups responsible for the ES performed in surface water and related Tier 1 taxa mentioned in the data requirements for effect assessment of PPPs.

SPU group	**Tier 1 taxa mentioned in data requirements (Commission Regulation (EU) 283/2013)**
Aquatic algae	Green algae, e.g. *Pseudokirchneriella subcapitata* Other taxonomic groups, e.g. the diatom *Navicula pelliculosa*
Aquatic vascular plants	Monocots, e.g. *Lemna gibba/minor, Glyceria maxima* Dicots, e.g. *Myriophyllum*
Aquatic invertebrates	Crustaceans: *Daphnia magna*/*pulex*, *Americamysis bahia* Insects: *Chironomus riparius* Oligochaets*:* *Lumbriculus* spp.
Aquatic vertebrates	Fish, e.g. *Oncorhynchus mykiss*
Aquatic microbes	No standard test species

For each SPU an overall summary table was constructed addressing the important ES, general protection goals (legal requirements), specific protection goal (SPG) options, higher tier effect assessment approaches that can be used to place the SPG and lower tiers in perspective, as well as possible consequences of exposure assessment. As an example, such summary tables are presented below for aquatic algae (Table 3), aquatic macrophytes (Table 4) and aquatic invertebrates (Table 5).

Table 3: Overall summary table for the SPU group aquatic algae and information of importance for the derivation of specific protection goals in the aquatic ERA for PPPs.

Important Ecosystem Services	***Legal requirement***	***Proposed specific protection goal***	***Ecological Entity***	***Attribute***	***Scale of acceptable effect***		
					Magnitude of acceptable effect	***Spatial Scale***	***Temporal scale***
Genetic resources Education and inspiration Aesthetic values Primary production Nutrient cycling	No unacceptable lethal and sublethal effects (on algae).	No PPP-related decline in biodiversity of aquatic algae in the watershed/ landscape No to short-term effects on population densities and community composition of aquatic algae in surface waters	Population to community level	Diversity and abundance in numbers and/or biomass (as affected by impacts on growth)	No to large (site and species dependent) Most algae have a short life-cycle and a high growth rate and are efficiently dispersed by water and wind	Edge-of-field to watershed. No effects on biodiversity and population densities in surface waters that fall under the domain of WFD and Natura 2000. Small to large effects may locally be allowed in edge-of-field surface waters if not leading to unacceptable effects further downstream.	Assessment in edge-of-field surface waters may be based on population recovery. The total period of the effect due to (repeated) application of the PPP should not be longer than weeks to months

Table 4: Overall summary table for the SPU group aquatic macrophytes and information of importance for the derivation of specific protection goals in the aquatic ERA for PPPs.

Important Ecosystem Services	***Legal requirement***	***Proposed specific protection goal***	***Ecological Entity***	***Attribute***	***Scale of acceptable impact***		
					Magnitude of acceptable impact	***Spatial Scale***	***Temporal scale***
Genetic resources Water regulation and purification Education and inspiration Recreation and ecotourism Aesthetic values Primary production Provision of habitat Nutrient cycling	No unacceptable lethal and sublethal effects (on macrophytes).	No PPP-related decline in biodiversity of aquatic macrophytes in the watershed/ landscape No to short-term effects on population densities and community composition of aquatic macrophytes in surface waters	Population to community level	Diversity, abundance in shoot (root) numbers and/or biomass (as affected by impacts on growth)	No to medium (site and species dependent) Macrophytes considerably differ in species traits, including growth rate and their ability to disperse.	Edge-of-field to watershed. No effects on biodiversity and biomass/ growth of species in surface waters that fall under the domain of WFD and Natura 2000. Small to medium effects may locally be allowed in edge-of-field surface waters if not leading to unacceptable effects further downstreams.	Assessment in edge-of-field surface waters may be based on recovery of growth/biomas. The total period of the effect due to (repeated) application of the PPP should not be longer than weeks to months

Table 5: Overall summary table for the SPU group aquatic invertebrates and information of importance for the derivation of specific protection goals in the aquatic ERA for PPPs.

Important Ecosystem Services	***Legal requirement***	***Proposed specific protection goal***	***Ecological Entity***	***Attribute***	***Scale of acceptable impact***		
					Magnitude of acceptable impact	***Spatial Scale***	***Temporal scale***
Genetic resources Water purification Education and inspiration Aesthetic values Herbivory and other food web control Nutrient cycling	No unacceptable lethal and sublethal effects (on aquatic invertebrates) No unacceptable effects on ongoing behaviour (of aquatic invertebrates)	No PPP-related decline in biodiversity of aquatic invertebrates in the watershed/ landscape No to short-term effects on population densities and community composition of aquatic invertebrates in surface waters	Sub- population to community level	Diversity and abundance (as affected by impacts on survival and reproduction) For some larger taxa behaviour may also be relevant	Species and site dependent. Magnitude of acceptable effects should be smallest for organisms with a long life-cycle, a low growth and reproduction rate and a poorly developed ability to recolonise/ disperse	Edge-of-field to watershed. No effects on biodiversity and population densities in surface waters that fall under the domain of WFD and Natura 2000. Small to median level effects may locally be allowed in edge-of-field surface waters if not leading to unacceptable effects further downstream.	Assessment in edge-of-field surface waters may be based on population recovery. The total period of the effect due to (repeated) application of the PPP should not be longer than weeks to months

Specific protection goal options for aquatic SPUs in edge-of-field surface water as discussed with risk managers

Currently edge-of-field surface waters (ponds, ditches and streams) are the focus of prospective ERA for PPPs. For key driver groups in edge-of-field surface waters that need to be protected at the population level and higher two options were presented to risk managers:

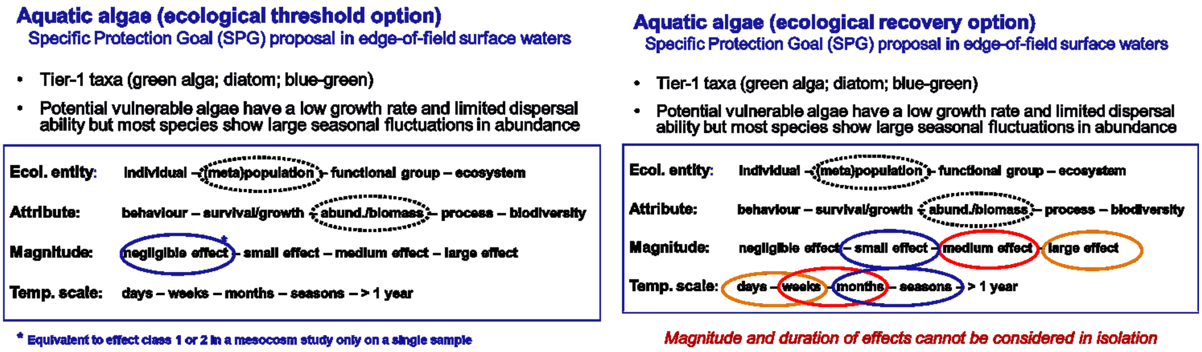
1. Accepting only negligible[33] population-level effects (**ecological threshold option, ETO**). The reasoning for this approach is based on the consideration that by not accepting population-level effects on representative sensitive populations in edge-of-field surface waters, these populations will be protected and propagation of effects to the community-, ecosystem- and landscape-level will not occur.

2. Accepting some population effects if ecological recovery takes place within an acceptable time-period (**ecological recovery option, ERO**). The short-term direct toxic effect, however, should not lead to longer-term indirect effects due to shifts in food web interactions. In addition, if recovery of populations of short-cyclic water organisms is predicted, it also has to be ensured that species with contrasting life cycle traits (i.e. longer generation time) are able to completely recover in the time available between the exposure events. The selection of option 1 (ETO), above, for the RA of individual PPPs is more likely to avoid stress caused by the multiple use of different PPPs. Although, a RA that considers recovery of sensitive populations may be a reasonable option for surface waters adjacent to crops with a limited PPP input, it is more uncertain if option 2, SPG (ERO) can be achieved when assessing risks for individual PPPs for their use in crop protection programmes characterised by intensive PPP use (simultaneous or repeated use of different PPPs).

The procedure described by EFSA (2010) to develop Specific Protection Goals (SPGs) for edge-of-field surface waters on the basis of five dimensions (ecological entity, attribute, magnitude, duration, spatial scale) was used in the communication between risk assessors (PPR Aquatic WG of EFSA) and risk managers. The spatial scale was fixed at 'edge of field'.

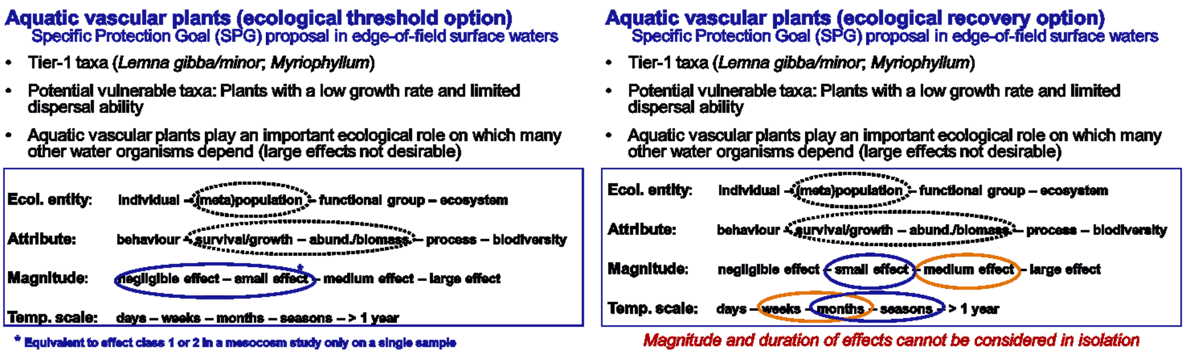
In an attempt to define SPG the following proposals (addressing both the ETO and ERO option) for aquatic algae (Figure 1), aquatic macrophytes (Figure 2) and aquatic invertebrates (Figure 3) were shared with risk managers. In these proposals the available Tier-1 taxa (current data requirements) as well as vulnerable representatives of the taxonomic group are described. In the ERA also the vulnerable taxa inhabiting edge-of-field surface waters should be sufficiently protected. Properties relevant to define vulnerability of non-target organisms to PPPs are species traits and characteristics that determine 1) susceptibility to exposure (e.g. related to habitat preference and the ability to avoid exposure), 2) toxicological sensitivity, 3) internal and external recovery processes (e.g. related to generation time, number of offspring, dispersal ability, refugia and connectivity of suitable patches of habitat in landscape).

Figure 1: SPG proposal for aquatic algae differentiated for the ecological threshold option and the ecological recovery option that was discussed with risk managers.



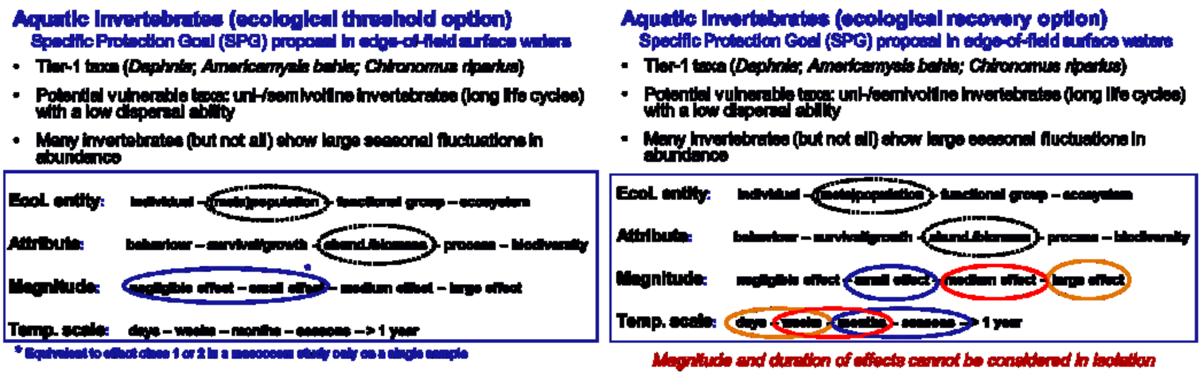
Risk managers agreed that for algae in edge-of-field surface waters both the ecological threshold option (ETO) and the ecological recovery option (ERO) should be used when developing ERA schemes for PPPs. Risk managers overall agreed with the proposal for the ETO option and ERO option, but felt unsecure about the combination of magnitude and duration of acceptable effects. Appropriate micro-/mesocosm tests were considered as an adequate higher-tier effect assessment approach for algae also useful to calibrate the lower tiers (addressing both the ETO option). The ERO option was considered a higher-tier option that can be addressed in micro-/mesocosm studies.

Figure 2: SPG proposal for aquatic macrophytes differentiated for the ecological threshold option and the ecological recovery option that was discussed with risk managers.



Risk managers agreed that for aquatic macrophytes in edge-of-field surface waters both the ecological threshold option (ETO) and the ecological recovery option (ERO) should be used when developing ERA schemes for PPPs. Risk managers overall agreed with the proposal for the ETO option and ERO option, but felt unsecure about the combination of magnitude and duration of acceptable effects. Appropriate micro-/mesocosm tests were considered as an adequate higher-tier effect assessment approach for aquatic macrophytes also useful to calibrate the lower tiers (addressing the ETO option). The ERO option was considered a higher-tier assessment that can be addressed in micro-/mesocosm studies, possibly in combination with population models.

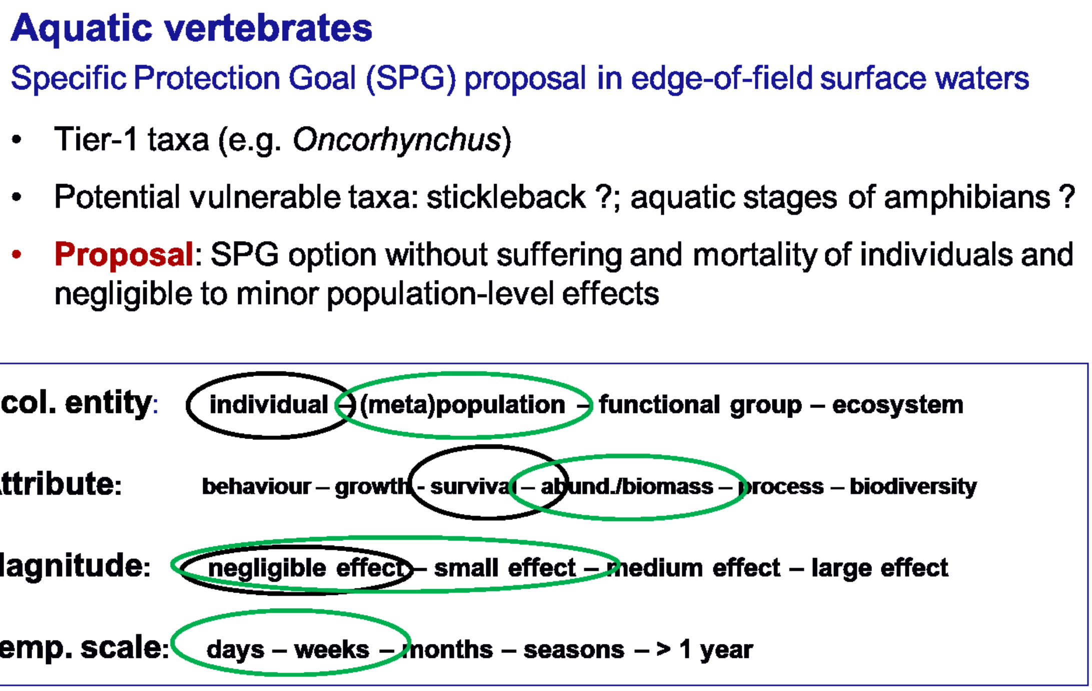
Figure 3: SPG proposal for aquatic invertebrates differentiated for the ecological threshold option and the ecological recovery option that was discussed with risk managers.



Risk managers agreed that for aquatic invertebrates in edge-of-field surface waters both the ecological threshold option (ETO) and the ecological recovery option (ERO) should be used when developing ERA schemes for PPPs. Risk managers overall agreed with the proposal for the ETO option and ERO option, but felt unsecure about the combination of magnitude and duration of acceptable effects. Appropriate micro-/mesocosm tests were considered as an adequate higher-tier effect assessment approach for aquatic invertebrates also useful to calibrate the lower tiers (addressing the ETO option). The ERO option was considered a higher-tier assessment that can be addressed in micro-/mesocosm studies, possibly in combination with population models.

Based on the EFSA guidance documents for birds and mammals it was anticipated that the SPG for aquatic vertebrates should be more strict than that for aquatic invertebrates and aquatic plants. The proposal offered to risk managers was more or less restricted to the ETO option (to avoid suffering and mortality of individuals) (see Figure 4).

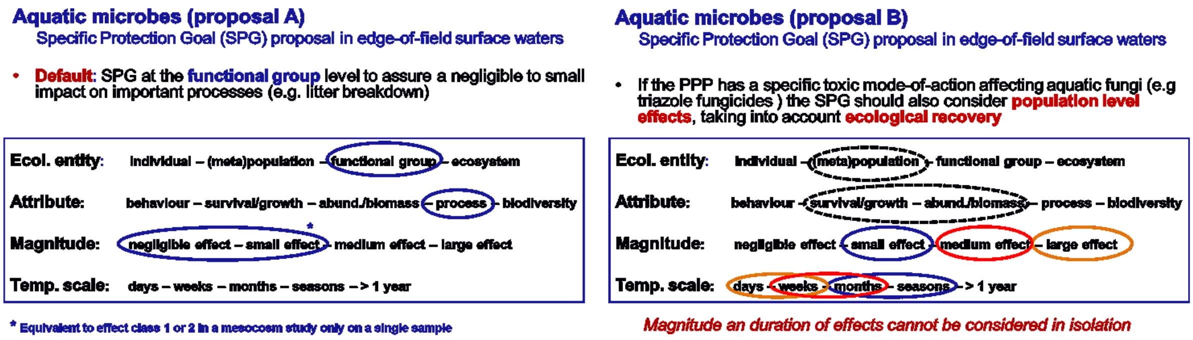
Figure 4: SPG proposal for aquatic vertebrates that was discussed with risk managers.



Risk managers agreed that for aquatic vertebrates in edge-of-field surface waters the ecological threshold option (ETO) should be used when developing ERA schemes for PPPs. Currently the Species Sensitivity Distribution approach based on laboratory toxicity tests predominantly is used as an higher-tier approach. Both risk assessors and risk managers were unsecure about the appropriate higher-tier test that can be used to calibrate the lower tier effect assessments, sine controlled micro-/mesocosm tests with fish populations are difficult to conduct. Perhaps tailor-made population models can be used for this.

SPG proposals for microbes were also developed, although currently no Tier-1 data requirements for the aquatic ERA of PPPs are described in legislation (Figure 5).

Figure 5: SPG proposal for aquatic microbes that was discussed with risk managers.



Risk managers had diverging opinions, but most of them felt that in the aquatic ERA schemes for edge-of-field surface waters aquatic microbes should not be addressed because of the lacking tier-1 requirements.

Proposed Specific Protection Goals in the EFSA Aquatic Guidance Document

Below, SPGs are described for the different aquatic key driver groups in edge-of-field surface waters and that are used in the EFSA Aquatic Guidance Document. These SPGs are adopted after two consultations with risk managers and are based on the Ecological Threshold Option (Table 6) and the Ecological Recovery Option (Table 7). Note that the Ecological Threshold Option in principle can be addressed in all effect assessment tiers, while the Ecological Recovery Option can only be addressed in higher tiers, e.g. on basis of experimental model ecosystems or mechanistic population models.

Table 6: Overview of specific protection goals for water organisms in edge-of-field surface water and the ecological threshold option as adopted in the EFSA Aquatic Guidance Document

Organism group	Ecological entity	Attribute	Magnitude	Time
Algae	Population	Abundance/biomass	Negligible effect	Not applicable
Aquatic macrophytes	Population	Survival/growth Abundance/biomass		
Aquatic invertebrates	Population	Abundance/biomass		
Vertebrates	Individual	Survival		
	Population	Abundance/biomass		
Aquatic microbes	Functional group	Processes (e.g. litter break down)	RA will not be developed since tier 1 data requirements are not defined	

Table 7: Overview of specific protection goals for water organisms in edge-of-field surface water and the ecological recovery option as adopted in the EFSA Aquatic Guidance Document

Organism group	Ecological entity	Attribute	Effect allowable on most sensitive/vulnerable population	
			Magnitude	**Duration**
Algae	Population	Abundance/biomass	Small effect[a] Medium effect[a] Large effect[a]	Months Weeks Days
Aquatic plants[b]	Population	Survival/growth Abundance/biomass	Small effect[a] Medium effect[a]	Months Weeks
Aquatic invertebrates[b]	Population	Abundance/biomass	Small effect[a] Medium effect[a] Large effect[a]	Months Weeks Days
Vertebrates	No recovery option			
Aquatic microbes	Functional group	Processes	RA will not be developed since Tier 1 data Requirements are not defined	

(a): None of the direct effects should lead to unacceptable indirect effects.
(b): The recovery option will often not be applicable in case organisms with a long life cycle could be affected and short-term (days) large effects generally will be acceptable only for short-cyclic organisms that have a high reproduction capacity. Consequently, strict criteria for (not) allowing the recovery option are given in the further guidance below.

In the EFSA Aquatic Guidance Document a more or less precautionary approach is adopted when evaluating the effects of individual plant protection products on basis of the Ecological Recovery Option in higher-tier aquatic micro-/mesocosm tests. Important requirement are that the aquatic micro-/mesocosm tests should also provide information for vulnerable taxa of the key driver groups potentially at risk. The maximum duration of an allowable effect on the most sensitive (vulnerable) population in the micro-/mesocosm tests is set at 8 weeks (Effect class 3A). Furthermore, the Regulatory Acceptable Concentration (RAC) on basis of the Ecological Recovery Option is derived by applying an Assessment Factor of 3 to 4 to the Effect class 3A concentration for the most sensitive (vulnerable) population in the test system. If in the micro-/mesocosm test systems vulnerable populations are insufficiently present the Ecological Recovery option will not be used to derive a RAC. In that case it will be checked if a RAC derivation on basis of the Ecological Threshold Option is possible (see Decision scheme on page 124 of Aquatic Guidance Document).

Concluding remarks with respect to biodiversity as protection goal

In the EFSA aquatic guidance document it is assumed that protecting water organisms at the individual (aquatic vertebrates) or population level (aquatic algae, macrophytes, invertebrates) in edge-of-field surface waters will also protect aquatic biodiversity in agricultural landscapes, certainly when adopting the Ecological Threshold Option. It is a research question to date whether the aquatic prospective ERA sufficiently protects aquatic biodiversity, particularly in agricultural landscapes that are characterised by intensive and multiple PPP use and a limited amount of refuge areas. A way forward to evaluate this is the development and use of mechanistic effect models and ecological scenarios in the ERA for PPPs. Another aspect that needs attention when protecting biodiversity in agricultural landscapes is that ERA of PPP exposure is based on both exposure and effect assessment. To date, limited experience in landscape level assessment of aquatic exposure and of aquatic effects is available. Particularly the appropriate linking of the spatio-temporal variation in exposure concentrations to effect estimates will be a challenge.