SCIENTIFIC OPINION

Guidance on Risk Assessment for Animal Welfare[1]

EFSA Panel on Animal Health and Welfare (AHAW)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

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BACKGROUND AS PROVIDED BY EFSA

EFSA provides independent information regarding risks associated with food and feed, plant health, environment, animal health, and animal welfare by using, whenever possible, a Risk Assessment (RA) approach. In addition, one of the tasks of the Authority is to promote and coordinate the development of uniform RA methodologies in the above-mentioned fields4.

The Animal Health and Welfare (AHAW) Panel of EFSA has adopted 32 Scientific Opinions on Animal Welfare (2003-2009) dealing with welfare related issues on fattening pigs, sows and boars, tail biting, fish, calves, dairy cows and seals. Several approaches have been followed for different scientific opinions on the Animal Welfare Risk Assessment.

An EFSA Scientific Colloquium on “Principles of Risk Assessment of Food Producing Animals” was held in Parma in December 2005[5] and a further EFSA workshop on “RA methodology in Animal Welfare” was held in Vienna in June 2007. One of the main conclusions from the colloquium was that “no specific standardized methodology exists in the field of the Animal Welfare Risk Assessment”. There was discussion about the beneficial effects of some factors for animal health and for animal welfare in general. However, at that time, only the assessment of risk was considered in detail. While specific guidelines have been published on animal diseases or chemical substances by the World Organisation for Animal Health (OIE) and the Codex Alimentarius Commission (CAC) respectively, no specific international guidelines on RA for animal welfare are currently available.

As a first step for the development of Risk Assessment Guidelines for Animal Welfare (AW), a contract was awarded to the “Italian Reference Centre for Animal Welfare” to set up the required basic information, and the report was delivered to EFSA in April 2007. The introductory part of the Report includes the definition of RA and a brief description of the existing models and reviews the definition of AW and the different approaches to its evaluation. In the following sections, this report defines the main issues to be considered in the guidelines and establishes the criteria for the selection and ranking of worldwide experts and centres. A complete list of key researchers and centres of excellence working in AW and, whenever possible, in RA related with AW is provided. Bibliographic references from the last 5 years, selected according to specific selection criteria, are also included. The identified animal welfare issues to be considered in the guidelines have been divided in the following main categories: slaughter, transport, housing and management.

The lack of specific guidelines and standardised working methodology on Risk-Benefit Assessment applied to AW has been identified. Therefore, and considering that the above mentioned Report with the basic information for the guidelines development is already available, EFSA would like to launch a self-mandate with the following terms.

TERMS OF REFERENCE AS PROVIDED BY EFSA

Terms of references of the self mandate addressed to:

I. To define a comprehensive harmonised methodology[1] to evaluate risks and benefits in animal welfare, taking into consideration the various procedures, management and housing systems and the different animal welfare issues, with reference to the methodologies followed in the previous EFSA Opinions on various species.

II. The defined methodology for assessing risks and benefits in animal welfare should take into account and adapt current risk assessment methodologies, for example those

[5] www.efsa.europa.eu/en/science/colloquium_series/no4_animal_diseases.html

for animal disease and food safety, and also the complex range of measurable welfare outcomes.

III. The guidance document should concisely define the generic approach for working groups addressing specific areas of assessment of risks and benefits in animal welfare.

[1]The methodology should include a terminology for the assessment of risks and benefits, defined strictly in terms of animal welfare.

ASSESSMENT

1. INTRODUCTION

The Animal Health and Welfare (AHAW) Panel of EFSA, during its XV Plenary Meeting (September 2005), recognised the lack of standardised guidelines and therefore the need to harmonise the risk assessment of animal welfare incorporated in the scientific opinions, and suggested that EFSA takes the appropriate steps to incorporate this approach in its work programme for 2006. In December 2005, an EFSA Scientific Colloquium "Principles of Risk Assessment of Food Producing Animals: Current and future approaches" was held in Parma to discuss the state of the art regarding RA of food producing animals (EFSA, 2006a).

One of the main conclusions of the Colloquium was that whilst some approaches exist for RA related to food microbiological (WHO, 1999) and animal health issues (OIE, 2004a, b), "no specific standardised methodology exists in the field of the Animal Welfare Risk Assessment". The colloquium recommended that EFSA should consider developing guidelines in this area and that it would be worthwhile to set up a working group to further investigate methodologies for risk assessment of animal welfare (EFSA, 2006a).

There is a very large scientific literature on the evaluation of the potential positive or negative effects of various factors on animal welfare. This started with animal health issues and, from 1980 onwards, began to consider in a scientific way the wider area of animal welfare (Fraser 2008, Broom 2011). It is important that an effective method should be developed which enables qualitative or quantitative comparisons of the positive and negative effects of various factors on animal welfare, in order to better estimate the net welfare impact of husbandry procedures, management methods and housing systems during an animal's lifetime.

The aim of this Guidance is to provide a harmonised methodology for the assessment of risks for animal welfare, together with suggestions about the assessment of benefits for animal welfare. The guidance is intended to be applicable to all types of factors that affect welfare (i.e., housing characteristics, transport conditions, stunning and killing conditions), to all types of husbandry systems and all animal categories.

The meaning of animal welfare and related terms, together with methods for its assessment, are discussed in previous EFSA reports, for example in Chapter 1 of "Effects of farming systems on dairy cow welfare and disease" (EFSA, 2009a). Since welfare refers to the state of an individual as regards its attempts to cope with its environment, effects on welfare include changes in health, mental functioning, positive and negative feelings, physiological and behavioural responses and injuries. As welfare is multidimensional, factors affecting welfare have the potential to affect one or several dimensions of animal welfare, either positively or negatively, and a range of welfare indicators is often required.

While specific guidelines have been published on import risk assessment for animal diseases or risk assessment of human diseases following exposure to food borne pathogens or to chemical substances present in foods by the World Organisation for Animal Health (OIE) and the Codex Alimentarius Commission (CAC) respectively, no specific international guidelines on risk assessment for animal welfare are currently available (see comparative terminology, Appendix A).

Since 2006, different approaches towards risk assessment for animal welfare were developed in connection with EFSA's scientific opinions (Smulders and Algers, 2009) and a series of scientific papers on those issues were published (Müller-Graf et al., 2008; Candiani et al., 2009). In addition to these published risk assessments, EFSA commissioned three projects under the framework of Article 36 in order to propose methodologies for animal welfare risk assessment. After a review of previous AHAW scientific opinions and the three "Article 36" projects reports, a list of methodological challenges that have to be considered in order to increase the reliability of the animal welfare risk assessment have been identified (see Section 2). The CAC and OIE frameworks have been used as a starting point to build a new framework that take into account the identified methodological challenges (see Section 3).

This Guidance may present more specific information on the various types of mathematical models and tools that have been used or that could be used for animal welfare assessment. However, a comprehensive review of the current scientific literature and subsequent evaluation of the strengths and limitations of models and tools in the context of animal welfare should form the basis for future work. Such issues are without doubt crucial and relevant, yet are beyond the scope of the current mandate.

In this Guidance, the term "risk assessment" refers to a formal, structured risk assessment. In many places in the text, where "risk assessment" is mentioned, the relevant assessment may necessitate the assessment of benefits as well as risks. It is recognised that competent literature review and the formulation of recommendations, such as those carried out by EFSA and its predecessors before 2006, involved assessment of risks and of benefits even when the formal methodology was not used.

The notion of risk assessment was considered by the Working Group to be relevant to animal welfare assessment. However, it was decided that the positive effect on welfare (benefit) could be handled within the framework of risk assessment if the analysis considers both factors having positive effects and factors having negative effects on animal welfare. Indeed, all animal welfare issues, including health issues, can be addressed by risk and benefit analysis because many of the factors considered have potential beneficial effects on the animals and on the likelihood of disease spread. Every EFSA report can consider the possibility of beneficial effects as well as the extent of risk. When this is done, the consideration of the benefit assessment can aid decision makers, who always have to consider possible benefits to animals and to humans as well as possible risks.

1.1 Methodological challenges

Since 2004, the AHAW Panel of EFSA has adopted several scientific opinions on the welfare of different animal species in various scenarios (i.e. housing and management, transport and slaughter). Under the remit of Article 36 of Regulation 178/2002 EFSA has also commissioned three reports which represent a first attempt to provide guidelines on risk assessment for animal welfare at stunning and killing, transport and housing and management. In the EFSA scientific opinions and reports, the approach to assessing the risk for animal welfare has continuously evolved (Appendix B). In this section the methodological challenges identified in the previous works on risk assessment for animal welfare are presented.

The broadness of risk questions and the lack of selection of welfare components of concern

The mandates requesting scientific assessment of animal welfare received by EFSA have included very broad questions (e.g. welfare of pigs, welfare of fish, or welfare of dairy cows) resulting in the necessity for a high number welfare components, animal subpopulations (including geographical areas), life stages and the husbandry systems to be considered (Ribó and Serratosa, 2009).

In particular the process of conducting an animal welfare risk assessment should include a formal identification of the baseline measures (Algers, 2009) and the welfare components of concern should be selected according to the objectives and defined consequences of the assessment in a previously defined scenario. In the absence of precise identification of the welfare components of concern in relation to the risk problem, the complexity of the risk assessment is increased and the numbers of risks assessed under each mandate are very high.

Benefit assessment

The improvement of animal welfare involves more than the simple elimination of major welfare risks. It is necessary also to identify and assess potential promoters of good welfare (Smulders, 2009;

Gavinelli and Ferrara, 2009; Broom, 2009). The current methodology can incorporate aspects that have a positive effect on animal welfare but this has seldom been carried out in a systematic way. It is desirable to integrate sets of factors that may have adverse effects according to one indicator of animal welfare and beneficial effects according to the same or another. This is being done in practice but a formal way of performing it needs to be developed further.

Scales in Animal Welfare data

Some animal welfare data are available only on a nominal scale particularly when it comes to the comparison between different consequences. Other data are ordinal but even when the defined indicators are metric, e.g. body temperature, body weight, duration of a behaviour, there can be disagreement about their interpretation. For some measures e.g. how much pain an animal is experiencing or how stressful is exposure to a particular factor, scoring, even by experts, can be variable. Moreover, as in all scientific evaluation, during a risk assessment exercise the greater the number of levels on an assessment scale, the more likely is disagreement between assessors. However, this depends on the way an 'agreement' is measured. For example, disagreement between scores 2 and 3 makes a very big difference on a scale from 1 to 3, but does not matter much if the scale is from 1 to 100. Therefore, with increasing numbers of levels, experts carrying out risk assessment tend to give a wider range of score values. There is, however, usually overall agreement with respect to the relative location on the scale. In fact, to some extent agreement could even increase with a more detailed scale, because it allows the assessors to pick a value that corresponds more exactly with their assessment. In general it is easier to achieve agreement about what constitutes a mild deviation from what is considered normal, and what constitutes a large deviation. Thus there is consensus for mild and severe but a stronger disagreement as to what indicators comprise moderate. For the practical purpose of modelling, this can be overcome by simply allowing assessors the option of scoring only mild and severe; anything that is not so classified is given a score of moderate. In this category therefore, there are recognisable changes or deviations but they are neither mild nor severe. This approach was followed to score the adverse effects in the scientific opinions to assess the welfare aspects of the stunning and killing of fish (EFSA, 2009b).

Availability and quality of the welfare data

Animal welfare risk assessment need to be science-based, well-documented, objective, repeatable and transparent. Due to the limited amount of quantitative data in some areas on the effects of hazards and other factors, on animal welfare and on some of the exposure rates, risk assessments in animal welfare may sometimes have to be qualitative and largely based on expert opinion (Ribó and Serratosa, 2009). In several of the earlier EFSA scientific opinions on animal welfare, the quality, (i.e. reliability and availability) of published data were not considered in the approach (Smulders, 2009). In addition the paucity of quantitative data, and of good data, in some cases generated high uncertainty. The risk assessment model should have inputs based on scientific evidence for factor identification, factor characterisation and exposure assessment as well as welfare measures. The review process should be well documented.

Loss of information in risk assessment reports and risk tables

In some EFSA scientific opinions on animal welfare, the hazard description and classification tables may not have been sufficiently detailed and hence are open to more than one interpretation (Smulders, 2009). To avoid misinterpretation of the hazards considered in the risk assessment, a clear description of each hazard should be included in the methodological approach.

Hazards whose magnitude of impact on welfare is high but where exposure is very low, can lead to risk estimates that may suggest to the decision-maker (risk manager) that they are of less importance. However, as an aim of animal welfare legislation is to avoid suffering, it is essential that such hazards are addressed by the decision-maker (Smulders, 2009). It is necessary, therefore, to assess the importance of both single hazards and multiple hazard scenarios.

Exposure assessment

Exposure assessment is defined as the estimation of the proportion (usually %) of the entire animal target population in a specified area (e.g. Europe or parts thereof) that is exposed to a certain factor. The scenario under scrutiny should be defined, determining which part of the considered time period (e.g. the entire life-cycle, lactation period) applies and the strength of the factor in quantitative terms (e.g. change in ambient temperature). Factors with the same factor description can be distinguished according to the strength of the factor (described in factor characterisation) with which an animal population is confronted.

It should be pointed out that only in rare cases were exposure data systematically collected. To reduce the uncertainty of estimation, it may not be sufficient to rely exclusively on expert information published in scientific reports, as experts from a certain geographical area might not be fully aware of the situation in a larger area such as the EU, particularly when the geographical area to be covered is large. Consequently, it is sometimes necessary to solicit more detailed local information, e.g. through 'consultation meetings' with independent field experts from the various sub-regions (Algers, 2009; Smulders, 2009).

Scientific profile of the selected experts

When empirical data are not available, expert knowledge can be used and in this case attention should be paid to the scientific profile of the experts involved. Scientists who work with issues relating to animal welfare may have a post-graduate career history in various subjects such as animal hygiene, applied animal behaviour, infectious diseases, pathology, or physiology. Their basic training may have been in subjects such as agriculture, biology, psychology, animal production or veterinary science. Hence, such experts may vary in their assessment of the importance of welfare indicators such as pain, malaise or frustration. Experiences from EFSA have emphasised that an optimal risk assessment requires experts from all the areas involved. In particular, there should be animal welfare scientists, including experts with veterinary expertise and experts in ethology. Criteria for the selection of experts, other than those listed as members of the working group, should be elaborated and stated for each assessment of risk in animal welfare and published together with the assessment (see also Algers et al., 2009 and Spoolder et al., 2010).

1.2 Risk assessment - definitions

Risk assessment is a process that evaluates the likelihood that positive or negative animal welfare effects will occur following exposure to a particular scenario. For the purpose of this opinion, the scenario includes information about the animals related to their housing, nutrition, genetic selection, transport, farm procedures, slaughter procedures and husbandry in general.

A scenario is a description of a real or hypothetical animal population, of specified genetic origin, and its environment at a particular stage or particular stages of life or during certain management procedures.

The animal population considered in a risk assessment is sometimes referred to as the target population (see section 2.2.1).

In relation to food safety (CAC framework), risk assessment considers a specific form of disease related to the consumption of certain food products, e.g. severe listeriosis in human cases and consumption of ready-to-eat foods. In the OIE framework, the risk that a specific animal disease will spread, as a result of the importation of animals or animal products, i.e.

introduction and establishment in Europe of an animal exotic disease through the importation of meat products might be assessed. In the general animal welfare area, however, the question is always broader. Animal welfare risk assessment or benefit assessment deals with different components of welfare and both their positive and negative aspects and so the notions of both risk and benefit are appropriate when considering the impact of some exposure scenarios.

Risk is a function of the probability of negative welfare effects and the magnitude of those effects, consequent to exposure to a particular scenario.

Benefit is a function of the probability of positive welfares effect and the magnitude of those effects, consequent to exposure to a particular scenario.

In the context of food safety risk assessment, a hazard is defined as ‘a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect’ (CAC, 2002). This definition could be adapted to animal welfare issues by including other types of agent and exposure pathways (non-food pathways). In contrast to the food safety context, in animal welfare it has hitherto been extremely rare to the exposure to a single hazard or factor. The welfare of organisms depends on many factors linked to the environment where they live and to their biological role and position. The question is mainly about the consequence of exposure to a set of factors associated with the defined scenario. A factor could contribute to a positive or to a negative effect. So instead of the concept of hazards, the concept of factor is proposed, including all types of hazards as well as all the factors that have the potential to improve animal welfare.

Factors are any aspect of housing and management, transport, stunning and killing including any of a group of specific chemical, physical or microbial agents and other environmental factors that directly or indirectly influence, either positively or negatively, animal welfare.

Unlike a risk assessment in the context of food safety or in the import of animals or animal products, for animal welfare many potential ‘adverse’ or ‘positive’ effects have to be considered. Welfare is multidimensional reflecting animal health, physiology, behaviour. etc… and therefore welfare factors have the potential to affect one or several dimensions of animal welfare, either positively or negatively.

1.3 Instruments measuring animal welfare

Animal welfare needs to be measured in a scientific way. For this purpose it is crucial to identify meaningful indicators or measures of animal welfare. Some of these are more useful for research studies and other more practical can be used by a veterinary or inspector to check animal welfare in situ, for example on a farm or at an abattoir. To distinguish the later, the term welfare outcome indicator is sometimes used by the regulator.

There is a widespread consensus that the assessment of animal welfare has to include the biological functioning of the animal including its health, its feelings and its ability to show normal patterns of behaviour (Manteca et al., 2009). The Welfare Quality project built on and extended the five freedoms to four principles: good housing, good feeding, good health and appropriate behaviour, each comprising two to four criteria making a total of 12 (Table 1). These 12 criteria for animal welfare can be assessed by a wide variety of indicators, a few of which are exemplified in Table 1. The most accurate welfare indicators are direct and measure actual consequences as they are animal-based. Examples of animal-based welfare indicators include foot lesions, skin damage and stereotypic behaviour. Other indicators are indirect and non-animal-based as they refer to inputs to the animal that are resource-based or management-based. These non-animal-based indicators may be good predictors of potential and actual effects on welfare, or they may be poor predictors. The value and use of these indicators is discussed in EFSA reports on the use of welfare indicators to address the recommendations of various EFSA reports on animal welfare.

Table 1. The principles and criteria proposed by 'Welfare Quality' together with examples of indicators useful for assessing farm animal welfare (modified after Botreau et al., 2009)

> A **welfare indicator** is an observation, a record or a measurement used to obtain information on an animal's welfare. It may be direct (animal-based) or indirect (non-animal-based).

In order to measure welfare accurately, it is critical that the measurement tools are able to capture the multi-dimensional nature of animal welfare. Four general categories of animal-based indicators may be distinguished: health indicators, animal performance indicators, physiological indicators and behavioural indicators. The relationship between the indicator and the welfare criteria under consideration should be described and well-documented. The following indicator properties should be taken into account:

- Accuracy: is the variable measurable in a precise way?
- Validity: Sensitivity and specificity of the indicator
- practicality: the right balance between reliability and efforts needed to obtain the data

2. PROPOSED RISK ASSESSMENT IN ANIMAL WELFARE

The production of scientific reports reviewing available scientific information on animal welfare matters is a prerequisite of formal assessment of risk. A review of observational or experimental studies has the potential to contribute significantly to the knowledge regarding the factors that affect welfare and to help to identify strategies to mitigate the associated risk. This knowledge is crucial for building science-based recommendations that are effective and

Welfare principles (Domains of criteria)	Welfare criteria	Example of Measures (animal based and resource-based*)
Good feeding	Absence of prolonged hunger Absence of prolonged thirst	Body condition score Water provision*
Good housing	Comfort around resting Thermal comfort Ease of movement	Bursitis, Time needed to lie down Shivering, panting, huddling Space allowance, access to outdoor*
Good health	Absence of injuries Absence of disease Absence of pain induced by management procedures	Lameness, wounds on the body Mortality, coughing, prolapse tail docked, pain vocalisations
Appropriate behaviour	Expression of social behaviours Expression of other behaviours Good human-animal relationship Positive emotional state	Agonistic and cohesive behaviour Functional grooming behaviour, rooting behaviour Fear of humans, avoidance distance Qualitative behaviour assessment (reference to be added)

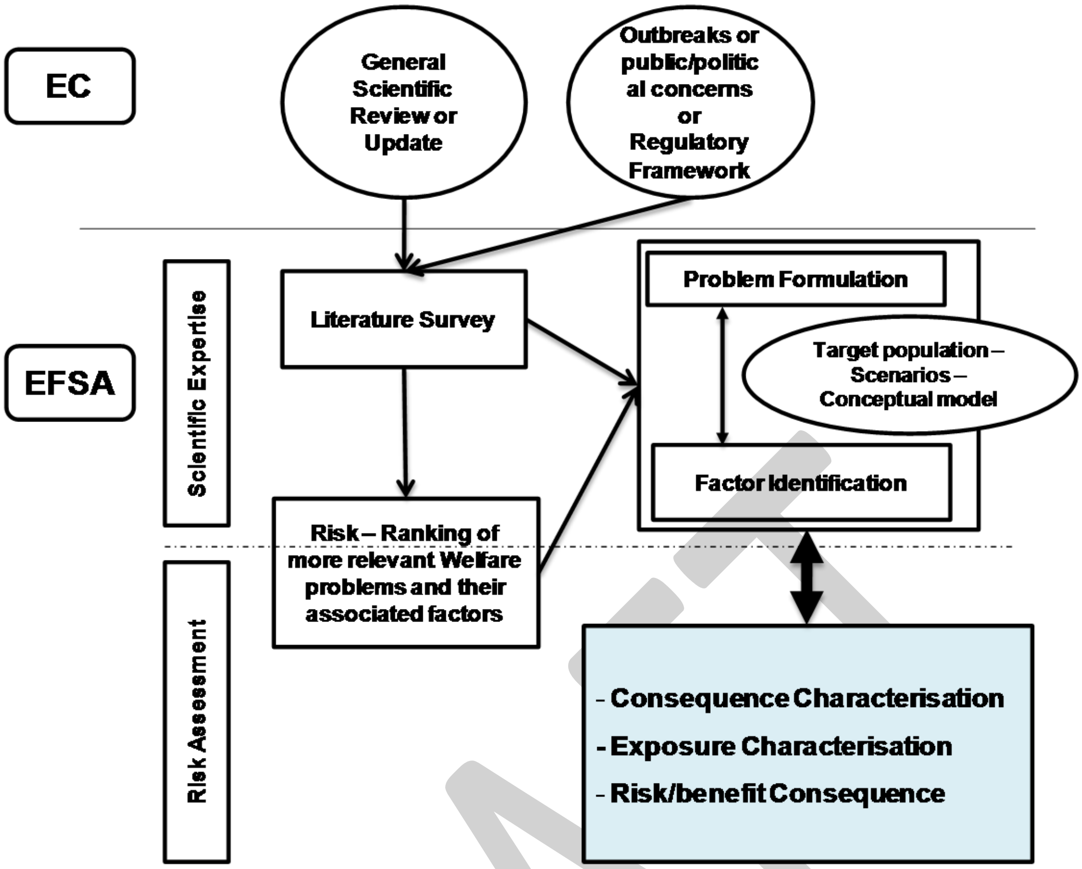
have reproducible results. Depending on the resources available and the timeline for assessing the effect of factors on welfare, investigators should choose different approaches to conducting epidemiological or experimental studies. Often, there is not enough resources available or sufficient time to carry out a comprehensive empirical approach (experimental or epidemiological studies such as cohort studies) to understand and delineate the pathway by which factors might cause positive or negative effects on the animals. which might be needed to complement the observational and experimental studies with simulation approaches. This complementary approach could be based on risk assessment procedures. Conducting an observational study from which the relationship between factor and some welfare components is assessed is not a risk assessment procedure, but contributes to risk assessment by providing relevant input information.

2.1 When a risk assessment approach is needed?

The goal of risk assessment in relation to animal welfare is to provide support to decision makers and to propose a choice of solutions and measures. Indeed, risk assessment should not be carried out unless the decision-makers' question is clearly specified and formulated. Risk assessment should be conducted before the decisions are made and there will often be limitations in the knowledge and data available. The idea of risk assessment is to systematise and describe all the available knowledge and lack of knowledge relevant to a specific welfare problem to the Risk Manager who has the possibility to choose between options in a given situation. It provides a science-based, valid, and reproducible framework to address specific welfare problems within a limited time and with currently available scientific data.

There should always, however, be questions about whether the extra work involved in a comprehensive risk assessment is justified in terms of the cost of scientists' time. It is important to know if conclusions drawn from literature surveys (see Figure 1) are more appropriate than risk assessment, because they have the ability to capture rapidly, the relevant factors. As shown in Figure 1, a literature survey is a pre-requisite for risk assessment or risk-ranking. In the latter, after providing a list of welfare problems for a particular animal population and their associated determinants, it is possible to rank them. A risk-ranking procedure could be conducted in order to prioritise animal welfare problems on the basis of the risk they pose to animal welfare. One of the recurrent problems of risk-ranking and prioritisation analysis is to combine the different indicators and aggregate them in order to get a ranking of all animal welfare issues or alternatives. Multi-criteria analysis is an older concept, but its framework fits the methodology of animal welfare prioritisation analysis.

Figure 1. Workflow to conduct a formal risk assessment after the scientific review and the narrative assessment.



After identification of the more relevant welfare problem and their associated determinants (Risk-Ranking) or directly after a literature survey the conduction of a formal risk assessment can be decided.

Risk assessment models require assumptions and simplifications and could result in limited validity. However, they have the advantage of offering more insight through comparison of welfare associated with different scenarios, alternatives, measures and assumptions. The problem when performing comprehensive risk assessment is that they demand considerable effort and resources. It is crucial, before making the decision to use or not to use risk assessment to consider the available resources and question whether or not the decision problem really needs it. If a risk analysis is expected to do little to aid decision makers in government and other users in industry and animal protection or consumer organisations, it would be better if it was not done. If the added value of the risk analysis to a report or opinion is expected to be substantial, then it would be better to do it. Automatic reliance on a risk analysis approach could waste time and resources.

In order to decide to conduct or not to conduct a formal risk assessment a clear formulation of the welfare problem is needed.

The use of risk assessment should not be automatic. The decision to conduct formal risk assessment should be made after the literature survey and the analysis of the available resources.

2.2 Problem formulation

Problem formulation should precede the risk assessment and be conducted with a minimum of interaction with the decision maker to ensure that the chosen terms of reference and welfare concerns are not limited by the risk assessor's intended approach. However, the decision maker can help to identify the context of the questions.
The risk assessor has to understand the specific objectives of the question in order to decide on appropriate methods. Questions that may arise could include:

- Is there a potential management option that will be compared with existing or alternative options regarding the risk for the welfare of the animals?

- Are existing alternatives different in term of their impact on particular components of the animals' welfare, e.g. absence of injuries?

Such questions may arise within the management context of enforcing a new procedure or defining gradual requirements for application of alternative procedures. The task of the risk assessor is to choose the relevant welfare components of greatest concern to the decision maker. In some instances specific welfare components that appear particularly relevant in the problem can be identified in advance with the assessor without loss of independence of the assessment.

Problem formulation is not only made to help clarify the question, it is considered a systematic planning step to identify the goals, scope, and focus of the risk assessment, and the major issues that will need to be addressed for the particular assessment. Once the purpose of the assessment is stated, the reasons for conducting the risk assessment are taken into account during the development of the conceptual model. The conceptual model describes qualitatively the possible interactions of a particular factor or a group of factors affecting welfare and a defined (target) population within a defined exposure scenario. An initial specific scientific review is conducted in order to identify the relevant factors (Figure 1). The exposure scenario(s) and the relevant welfare criteria are defined, including the target population, the characterisation of exposure to the welfare factors, endpoints (welfare components to be assessed), and key assessment variables.

The ultimate goal of problem specification is to guide the development of the risk assessment, its scope and scale.

Simultaneous consideration of negative and positive effects in the risk assessment

During this step it should be decided whether or not the assessment will include simultaneously negative (risk) and positive effects (benefits). The past EFSA experience is mainly risk assessment. However, in relation to animal welfare, the assessment of the eventual positive effects is appropriate i.e.:

- A particular factor or a group of factors could have positive and negative effects for the same scenario of exposure
- An exposure scenario can include two groups of factors, some with positive effects and others with negative effects.

Examples where the assessment of the positive effects on animal welfare might be appropriate

Factors	Negative effects	Positive effects
Unloading of animals at control posts during transport	- Mixing of animals from different origins may lead to fighting, stress, disease spread. - Immuno-depressed animals: increased susceptibility to cross contamination. - Stress of loading unloading practices.	- The animals have more space allowance - Resting could be better if adequate space is provided on vehicles - Drink/Feed could be easier
Use of straw in pigs	- Increase of temperature leading to heat stress (mainly in warm conditions) - Ammonia accumulation - Salmonella, Campylobacter spread.	- Exploration, foraging, rooting and chewing behaviours stimulated. - Less slippery floor. - Adequate bedding (physical comfort of the floor) - Increase thermal comfort (except in warm conditions) - Decreased pen manipulation - Nesting material for pre-parturient sows. - Decreased tail biting
Beak trimming in broiler breeders	- Distress and pain - Deprives bird of sensory feedback - Neuromas may become a source of chronic pain	- Incidence and severity of injurious behaviour could be reduced
De-toeing and de-spurring in broiler breeders	- Distress and pain greater neuromas may become a source of chronic pain	- Reduces damage to males resulting from fighting.
Non-caged versus caged system for laying hens kept indoors	- Could be increased risk of faecal oral transmissions of pathogens sometimes more injurious behaviour	- Larger total available space - Improved opportunity for natural behaviour - Decreased risk of osteoporosis and cage layer fatigue
Free range layer hens	- Parasitism increase if not well-managed	- Exploration, foraging, behaviour stimulation.

Problem specification is conducted to guide the risk assessment model development and includes the following steps:

- Clarify the risk question(s) and the motivating factors for conducting the risk assessment
- Factor identification (based on scientific review)
- Define the target population
- Define the exposure scenarios
- Define the welfare components to be assessed
- Build a conceptual model
- Identify the relevant methodology and the needed data

2.2.1 Target population and scenarios

The target population:

The exposure to a specific factor can be different according i.e. to the different farming systems. In this context the target populations could be: dairy cows kept in cubicle houses; dairy cows kept in tie stalls; dairy cows kept in straw yards; and dairy cows kept at pasture (EFSA, 2009a). The way in which these systems are implemented varies slightly among countries in Europe, depending on geographical factors such as climate and soil type, availability of resources, traditions, and market circumstances. In addition, they can also vary substantially between farmers within countries and regions.

In the case of the transport of animals, the target population can be defined by: the species of animals being transported, animal categories within each species, the mean of transport, the duration of the transport and the thermal environment during the transport (Dalla Villa et al., 2009).

The definition of target population may include:

1. Condition: housing, management, transport, slaughter, etc.
2. Species
3. Characteristics of the particular genetic line (e.g. genotype)
4. Health and physiological state (e.g. disease or pregnancy)
5. Age group and sex
6. Season
7. Geographic area (EU, Member State, Region)

Some examples of the target population have been included for clarification:

Example 1

Transport of fattening lambs from farm to slaughterhouse (short journey) in summer in the south of Spain. Truck with mechanical ventilation

Target population: Fattening lambs, short journey, slaughterhouse, ventilated truck.

Change of scenario: increase of density of animals (number of animals/m^2) + increase of journey duration (i.e. change of slaughterhouse).

Welfare determinants (adverse effects):

- Increased animal density only (thermal comfort, thirst and death)
- Increase in journey duration only (hunger, thirst, thermal comfort)
- Increase in both density and journey duration (hunger, thirst, thermal comfort, dehydration and death).

Example 2

Dairy Cows Housing System
Target population: Dairy Cows with rubber floor and deep sand bedding in cubicles
Change of scenario: concrete floor, slippery floor, lack of space in cubicles, no bedding in cubicles.
Welfare determinants (adverse effects):
- Concrete floor (locomotor disorders, skin lesions and joint lesions, reduced lying time in cubicles)
- Slippery floor (locomotor disorders, joint lesions, difficulty in standing up and lying Change Factors down)
- Lack of space in cubicles (reduced lying time, joint lesions, locomotor disorders, difficulty in standing up and lying down)
- No bedding in cubicles (reduced lying time).

Example 3
Scenario: Stunning and killing of Salmon by electricity –dry system
Target population: Fattening Salmon, adequate stunning and killing method: good water quality, adequate pumping design and water flow, adequate verification of unconsciousness, system to avoid entering tail first.
Change of scenario: inadequate stunning and killing method: poor water quality and low oxygen levels, poor pumping design, slow water flow, unavoidable entry tail first, salmon conscious when experiencing electricity and exsanguination, or a mis-cut, or evisceration or asphyxia.
Welfare determinants (adverse effects):
- Poor water quality [low pH, insufficient DO, high water temperature] at lairage (stress)
- Low water oxygen levels when crowding due to poor supervision (stress, escape behaviour)
- Poor pipe design when pumping (trauma, injuries, pain)
- Salmon held in pipe due to slow water flow (stress, exhaustion)
- Fish enter tail first (escape behaviour, pain stress)
- Experiencing electricity while conscious – low voltage system <50V (escape behaviour, pain distress, exhaustion)
- Experiencing electricity while conscious – medium voltage system 50-110V (escape behaviour, pain distress, exhaustion)
- Experiencing electricity while conscious – high voltage system >110V (pain, trauma, distress)
- Exsanguinations, mis-cut, evisceration, if conscious (pain, trauma, stress)
- Asphyxia if conscious (distress, pain)

2.2.2 Conceptual model

A **conceptual model** in problem formulation is a written description and visual model of predicted relationships between factors and animal welfare.

A conceptual model is built in order to describe the exposure pathways or the different combination of events showing the implication of the relevant factors and their interactions with the considered target population. It considers how logically the changes made on the reference scenario will affect animal welfare and subsequently shows how the risk specific questions will be addressed, the relevant information needed, the method that will be used to analyse the data and the assumptions inherent in the analysis. An explanatory assessment could be performed at this stage to evaluate data gaps and prioritise resources for risk assessment.

2.3 Risk Assessment

The proper risk assessment phase consists of the technical evaluation of data concerning the potential exposure and associated welfare effects, based on the conceptual model developed during the problem formulation. This phase has three elements: exposure characterisation, characterisation of the animal welfare effects or consequence characterisation, and the integration of the welfare consequences or risk characterisation.

2.3.1 Exposure Characterisation

The scenario of exposure involves generally more than one factor. Characterisation of the exposure involves an evaluation of the relationships between several factors: environmental factors, animal factors and physical, chemical or microbial agents. The analysis should provide a qualitative or quantitative evaluation of the strength, duration, frequency, and patterns of exposure to the factors relevant to the scenario(s) developed during the problem formulation.

The strength and duration of exposure to the factors considered according to the objective of the assessment are defined. For example, if temperature increases by 5, 10 or 20 C (i.e. the factor has different strength levels) or the increase in 5 degrees may last for 1, 2 or 5 days (i.e. the factor has different durations). The objective of the assessment specifies whether duration is relevant for all factors or in all scenarios considered in the assessment (i.e. on farm, during transport, at slaughter). For example, a factor that is due to inadequate facilities (e.g. slippery floor of the stables/pens; steep loading ramps; too narrow corridors in slaughter plants; etc) might be sufficiently reflected by constant duration in some scenarios, i.e. they are either present or not for the entire length of the process considered (on farm, transport, or slaughter). Other factors have in theory a variable duration, which might be irrelevant for the assessment, e.g. shouting at the animals, hitting them, using handling tools such as the electric goads, etc). Therefore, factor identification necessitates implicitly that the assessors have to define the specific intensity and duration of the factor as relevant in an assessment (i.e. the scale of the factor relative to the scale of the assessment).
The frequency of the exposure profiles (defined by the strength and duration) needs to be assessed. This frequency could be assessed empirically based on observational studies or by using simulation models. For example, if the scenario includes poor house-ventilation, the analysis could consider the sequence of events that causes the dysfunction of ventilation. Event tree analysis, or fault tree analysis could be used to assess the probability of ventilation system failure or, when empirical data are available, assess directly the frequency of farms with poor ventilation systems.

In the situation where the changes in the scenario involve factors that could have an indirect effect on animal welfare, in addition to their direct effect, the characterisation of the frequency could be more complicated. As an example, a feeding distribution system could promote the multiplication of a microbial pathogen such as Salmonella. The implementation of such a feeding distribution system could be associated with a certain increase of the animal exposure to Salmonella. The exposure profile to Salmonella depends on the pathogen characterisation, pathogen occurrence and the characteristic of the feed.

In this scenario, the inter-relation between the factors Salmonella and the feeding distribution system has to be considered.

Another example may be that the indirect effects are positive. For example the implementation of a feeding distribution system may give the farmer more free time so that inspection and general care of the animals is better.

Exposure characterisation is the qualitative or quantitative evaluation of the strength, duration, frequency, and patterns of exposure to the welfare determinants (and their inter-relationships) relevant to the scenario(s) developed during the problem formulation.

2.3.2 Consequence Characterisation

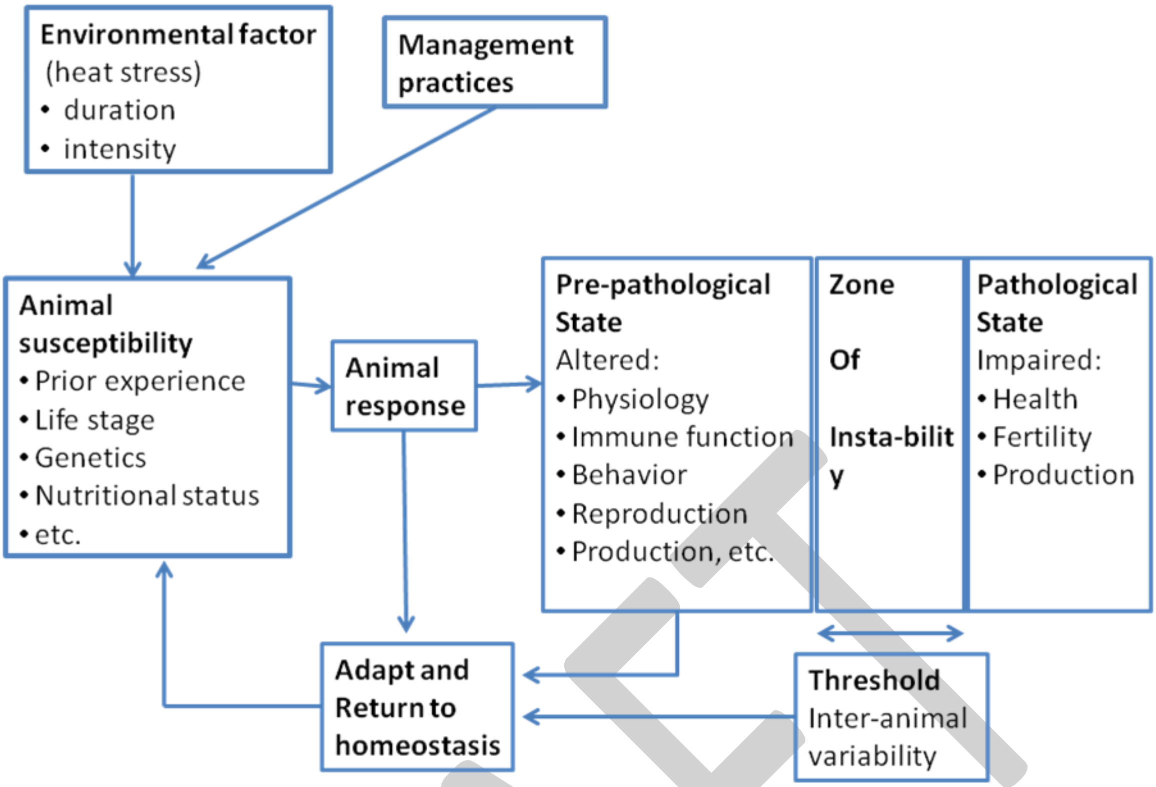
2.3.2.1 The animals' response triad

Animals' responses are a result of the interaction of three different types of factors: environmental factors, animal factors, and management factors. To illustrate the animal's response triad, we use the example of animal heat stress.

Environmental factors: Predicting animal stress has typically relied upon the environment, for example on measurements of environmental temperature. The temperature humidity index (THI) combines the effects of dry bulb temperature and relative humidity, and provides reasonable information about the environment, especially for housed animals. However in the case of beef cattle and other animals typically held in open-air pens, the effects of wind speed and solar radiation are significant contributors to heat stress and also need to be included. Recently, several indices that combine four weather variables (dry-bulb temperature, humidity, wind speed, and solar radiation) into a single value were developed (Black-Globe Humidity Index, Adjusted THI, Estimated Respiration Rate, etc.). The goal of a single value index has been to accumulate and summarise the total impact the environmental conditions have on animals. The correlations between the index value and individual animal welfare measurements have an R^2 between 0.4 – 0.7, indicating that a large portion of the variation is not explained by the model.

Animal factor or animal susceptibility: If we look at one animal response to high temperature etc., say respiration rate (breaths per minute) in relation to environmental variables, say dry-bulb temperature, it is apparent that some of the errors in prediction are due to differences between animals. It is also apparent that, while there are fluctuations in the respiration rate, there are distinct differences in the responses of individual animals to the same environmental conditions, with some animals more vulnerable or susceptible than others. The difference between susceptibility and vulnerability is that the animal's state (defined by genetics, age, nutritional status, acclimatisation to heat) defines its susceptibility. Then, that animal becomes vulnerable when it is exposed to a particular factor (stressor). Figure 2 provides a depiction of the adaptability of an individual animal to different factors and also illustrates both the genetic and the dynamic components of individual responses.

Figure 2. Diagram illustrating variation in animal response to a single factor (specifically heat stress).



Management factors or Practices: Management schemes may be intended to be applied uniformly to all animals in a group with little regard for individual animal susceptibility. Some of the management options are different feeding strategies (different rations, different feeding times), the management of the animals' water resources (space allowances at the water troughs, the temperature of the water), environment modifications (shade, sprinkling animals, wetting the ground), and timing of animal handling. The impact of these different management strategies can range from a small decrease in the consequences of heat stress to almost eliminating the heat stress. While different management options reduce heat stress, there are disadvantages (perhaps economic or logistic) to each strategy. For example, while providing shade decreases heat stress and in some cases increases animal productivity, shade structures are very costly, require regular maintenance, and can result in persistent wet areas that may also have consequences for welfare e.g. foot or hoof health. Each management strategy has a unique set of challenges; however, most would be more beneficial and economical if applied only when needed. If susceptible animals can be identified and separated from the larger group, then management strategies can be applied to different groups of animals as environmental conditions dictate.

An **animal's response** to a particular exposure scenario is the result of the interaction between three different components: the environmental conditions that exist, the management protocols used, and the susceptibility of the animals in question. For risk assessment, it is crucial to define clearly the relevant scenarios in regard to all types of factors that have a potential to modify the welfare consequence.

2.3.2.2 Assessing the welfare consequences

Consequence characterisation is a qualitative or a quantitative evaluation of the relationship between specified exposures to a factor and the consequences of those exposures. The intensity and duration of the consequences (which, combined, correspond to the magnitude) and their likelihood to occur at the individual level are assessed.

The consequence assessment should consider 4 steps:

- *Step 1. Relation between strength of factor and consequence intensity*
- *Step 2. Duration of application of the factor*
- *Step 3. Duration of the consequence*
- *Step 4. Interaction between factors*

Uncertainty about the consequences including their magnitude and likelihood is an integral part of consequence characterisation

The magnitude of welfare consequences (the response) can only be quantified through sets of animal-based welfare indicators.
As explained in section 1.3, a **welfare indicator** is an observation, a record or a measurement used to obtain information on an animal's welfare. It may be direct (animal-based) or indirect (non-animal-based).

Here discontinuous response measures, in this case a set of indicators, are modelled to represent a gradual change in the factor or scenario.

Step 1. Relation between strength of factor and consequence intensity

In welfare assessments there is a factor scenario (e.g., low vs. high magnitude; or factor off vs. on), and the response is the resulting welfare consequence. For several welfare consequences no unique measure exists that functionally describes the change in consequence as factors become greater. Therefore, **cascading indicators** (grey boxes, referring to the left axis) are introduced to express successive levels of intensity of a welfare consequence. These levels of consequence then can be modelled by their correspondence to the causative factor intensity. Hence, the particular set of indicators together may be used to construct a relationship between factor level and response level.

Certain indicators in the set may reflect the consequence level resulting from a particular factor level (i.e. dose), while others are observable over several factor levels. These multi-level indicators may change their fate gradually indicating increasing consequence level together with increasing factor level (e.g. "sweating" to '"more sweating" if the environment becomes warmer). Alternatively, they may even be constant although the factor level continues to increase (e.g. '"death" from heat remains "death" at higher heat intensity).

Often, but not necessarily, the indicators add to each other along the cascade instead of replacing one other. In such cases, the indicator reflecting of the most intense consequence could be considered as corresponding to the respective intensity of the factor.

Step 2. Duration of application of the factor

Although the strength of one factor might be assumed constant, the consequence of duration of its application might differ according to the objective of the assessment. For example, a 5 C temperature increase for 1 day might have different consequences from the same increase lasting over 10 days.

The intensity and duration of the consequences are defined by factor strength and factor duration. However there is no meaningful universal solution. The relative contribution of intensity and duration to magnitude are case specific. In most but not all cases it is possible to combine strength and duration into a measure of magnitude appropriate to the consequences of the assessment.

Back to the example of temperature increase, the magnitude of thermal load of a 5 C increase for 1 day will have the consequence of mild thermal distress, indicated by panting and sweating. However, if the thermal load is an increase of 5 C for 10 days, then the animal may not only show indicators 1 and 2 (panting and sweating), but eventually will become dehydrated i.e. the new indicator. It should be noted that model "dehydration" will not always be expressed by the multiplicative result "panting" times the duration of the factor (i.e. panting x 10 ≠ dehydration) although consequence intensity was increased from the level indicated by "panting" to the level indicated by "dehydration". As a general rule, the resulting intensity of the consequence to a five times factor magnitude (e.g. by prolonged time, or increased intensity) will often not be measured simply as five times the original indicator (sweating), but rather by a qualitatively completely different one (dehydration).

Step 3. Duration of the consequence

In reality the responses to different factors of different magnitude will rarely occur on the same time scale. To cope with this, it is frequently necessary to measure the *duration of the consequence* by an appropriate indicator, in addition to the intensity.
This is illustrated by an example of bad handling of an animal where the animal is shocked with the electric goad at different electric currents (i.e. in this example the increase in intensity of the factor alters factor magnitude). As a consequence of a mild shock, the animal will respond with acute fear indicated by a vocalisation. The fear will slowly decline over some minutes /hours as the animal recovers. As a consequence of a high shock from the goad the animal will show a more intense acute fear response and a vocalisation, but may also be injured as measured by a wound. The immediate fear will reduce rather quickly, , but the injury and the memory of the experience and perhaps drastic change in behaviour such as avoidance of humans will take some days or weeks to heal or recover and the behaviour effect could be permanent. The duration of the consequence of the severe shock with the electric goad is therefore longer than the duration of the consequence of the mild shock. Generally, the area under the curve on the respective plane of intensity and duration of the consequence is accepted to represent the magnitude of the consequence (Broom 2001; Figure 5, compare hatched area of the two graphs). As before, the indicator representing the greatest magnitude of consequence in response to a given factor magnitude could be selected for modelling.

Step 4. Interaction between factors

Interactions between factors should also be considered. This is illustrated by two examples, a relatively qualitative example from the broiler welfare (EFSA, 2010b) and a quantitative example involving heat stress in beef cattle.
It is well known that wet litter increases the risk of hock burns (a type of contact dermatitis) and leg weakness involving pain when walking, means that a bird will stand less and sit more,

therefore having its hocks in contact with the litter. So, even if hock burns are not a direct consequence of leg weakness, in combination with wet litter, leg weakness is a factor increasing the risk of hock burns. In this example, a new factor could be created to represent the interaction of these two factors for the purpose of risk assessment.
Hot weather can have negative impacts on feedlot cattle by reducing animal performance and compromising animal well-being. However the impact of this factor (defined by change in ambient temperature and duration of change) can vary widely, ranging from little or no effect to death of vulnerable animals during an extreme heat event.

2.3.3 **Risk characterisation:** integration of welfare consequences

Risk characterisation is the process of determining the qualitative or quantitative estimation, including attendant uncertainties, of the probability of occurrence and intensity of negative and positive welfare effects (known or potential) in a given population. It consists on integrating the results from Exposure characterisation and the Consequence characterisation.

The welfare aspect could cover one or several welfare criteria, among others, the ones described in Table 1. In some cases it is sufficient to describe the impact of different factors simply in terms of their effect on one single specific criteria of welfare state (e.g. hunger, thermal stress). Thus the risk assessment is considering separately the different affected welfare criteria without combining them. Nevertheless there are occasions when it is necessary to provide an overall assessment of welfare or welfare change. Several systems may be used for the overall assessment of animal welfare (Botreau et al., 2007a, b). They are mainly based on the aggregation of several indicators used to assess the different states or changes of the welfare criteria, using different possible rules to assemble the information provided by the different indicators. However, some interpretation of welfare considers the welfare as the sum of states along a number of dimensions and in order to have a high degree of welfare one must score high on all dimensions.

One possible approach to the final integrating step of the positive and negative effects is shown. The impact levels for intensity of those consequences relevant to the objectives of the assessment (c.a.o.a.) are given numerical scores (i.e. A=+1, B=0, C=-1, D=-2, E=-3) so that the intensity of the consequences can be scored for each criterion. This is illustrated by two examples in Table 2.

Table 2. Examples of a qualitative integration of positive and negative effects in the risk characterisation.

Cow housing	**Scenario 1**	**Scenario2**
Comfort around resting	0	-2
Ease of movement	-1	-2
Absence of injuries	-1	-3
Absence of disease	-1	-2
Human/animal relationship	+1	0
Total score	-2	-9
Horse transport	**Scenario 1**	**Scenario 2**
Comfort around resting	0	-2

Heat stress	-3	0
Absence of injury	0	-2
Absence of disease	0	-1
Absence of fear	+1	-2
Total score	-2	-7

In the Cow Housing examples, the welfare criteria are of the same order, but differ in strength. In this case it is appropriate to sum the scores.

In the Horse Transport examples, the welfare criteria differ. In Scenario 1 most aspects of transport have been satisfactory but the horses experienced severe heat stress. In Scenario 2 many aspects of the journey caused moderate welfare problems but there was no thermal stress. Here the total scores of -2 and -7 respectively for Scenario 1 and Scenario 2 presented in isolation would fail to convey sufficient information and seriously underestimate the threat to horses in Scenario 1.

It could be concluded that, for the purpose of risk assessment, it is possible to measure the impact of defined factors and scenarios in terms of one or more of the independent and exhaustive 12 welfare criteria, as assessed from the cascade of relevant indicators. Final judgement as to the overall impact on welfare of a particular scenario requires value judgements of the relative importance of the different criteria (e.g. pain vs. thirst vs. fear) but this is not within the scope of the risk assessment.

It is prudent that the results of every risk assessment should include both total score and the scores for each of the considered welfare components and when a combination is needed several methods should be used, justified and their advantage and disadvantages discussed in the risk assessment report.

2.4 Assessing the quality of the risk assessment

Quality assessment of a risk assessment procedure is the systematic evaluation of the various aspects and component of the assessment procedure to maximize the probability that minimum standards of quality are being attained.

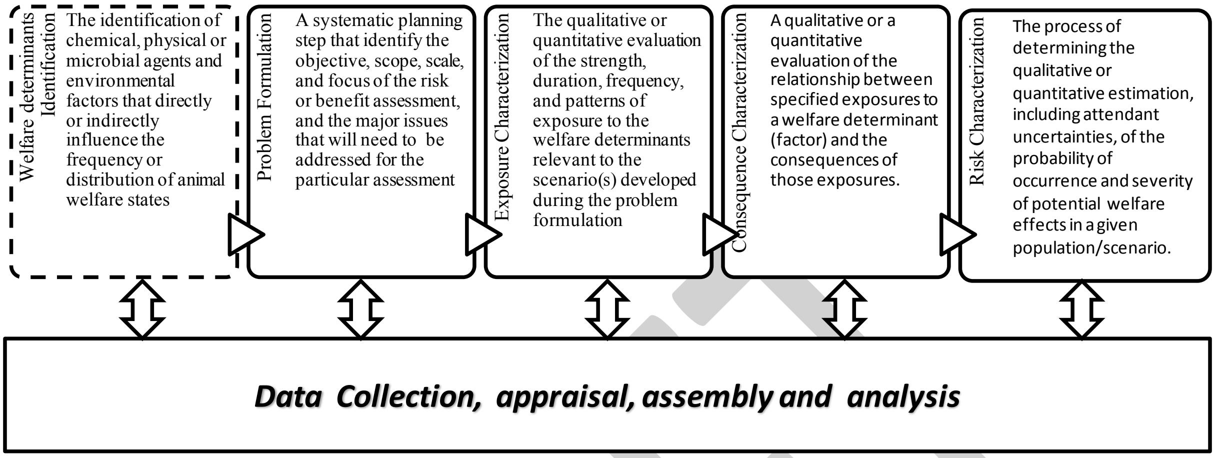
Two principles included in quality assessment (QA) are: "Fit for purpose" - the assessment product should be suitable for the intended purpose; and "Right first time" - mistakes should be eliminated. QA includes the quality of data and their assemblies, the relevance of the assumptions, the quality of the final assessment results and its interpretation, the management and the verification that all tasks incorporated in the different steps of the risk assessment are conducted in a technically and scientific correct manner. These will ensure the reproducibility of the whole procedure and increase the credibility of the risk assessment results and facilitate their use by welfare managers as a decision support tool.

2.4.1 Data input in the risk assessment model

The method for identifying, selecting, appraising and synthesising the input data for the risk model should be thoroughly considered and clearly documented (Figure 6).

In general data needed for risk welfare assessment are sparse. The assessors should primarily collect data relevant to the assessment objectives, and assess the quality of the available data sources. Ideally, risk assessors should have access to the raw data to make possible inferences on probability distributions if needed.

Figure 3. Process of identification, selection, appraisal and synthesis of the input data for the risk model



The risk assessments for animal welfare involve a diversity of data sources to build the model. It is then logical to make an inventory of what is known in the scientific literature on a specific welfare problem (narrative assessment see Figure 1).

Systematic review (SR) could be utilized to collect, appraise and synthesise the relevant data. A systematic review is an overview of existing evidence pertinent to a clearly formulated question, which uses pre-specified and standardised methods to identify and critically appraise relevant research, and to collect, report and analyse data from the studies that are included in the review (for details on the Systematic Review method, see EFSA, 2010c). In view of the above, it is recommended to consider SR at the stage when the conceptual model is built and the required input information is identified.

In risk assessment for animal welfare, a first question generated by the model is factor identification and selection, i.e. “which factors have the potential to positively or negatively change the welfare of the animals under consideration?” For this type of question, the available evidence proving a relation between a change in determined factors and the welfare baseline conditions of the animals exposed to those factors should be extensively researched, critically appraised and synthesised. Another question generated by the conceptual model for animal welfare is the identification of determinants that describe the status of the independent variables, thereby measuring changes in the system. These indicators have to be robust, i.e. they prove accuracy, reliability and repeatability and can be validated by scientific evidence. The question to answer systematically in order to feed back the model with unbiased data is, in this case, “what elements reflect a welfare change in an accurate, reliable, reproducible way?” Other questions generated by the risk assessment process seek to assess the duration and likelihood of the adverse effect, and exposure assessment.

Although systematic scientific reviews represent the best approach to address questions generated by the risk assessment process in a transparent, reproducible, evidence-based way, they may have some limitations. They are most effective when limited to addressing questions that are sufficiently well-structured to be answered in a primary study. A useful framework for assessing the suitability of questions to systematic review is provided in EFSA (2010c). In addition, systematic reviews may be time and resource intensive and therefore it may not be worthwhile or practically feasible to submit all suitable questions generated by the risk assessment model to systematic review. The EFSA Guidance on the use of SR in risk assessment (EFSA, 2010c) illustrates some aspects that may serve as a check-list for each model input quantity to assess whether a SR is needed.

The method used for reviewing the literature should be clearly documented. This implies illustrating the search strategies used (i.e. combination of search terms and Boolean operators); the sources of literature searched (e.g. bibliographic databases, scientific journals tables of contents, specialised websites, etc); the criteria (if any) applied to select the studies for inclusion in the reviews; the method used (if any) for assessing the reliability (quality) of the studies; and the approach to synthesising the findings of the included studies. The reliability of the studies used to input the risk model should also be considered. Some aspects related to reliability are discussed here below.

Appraising the collected data:

The strength and limitations of the data identified and used to identify and select the relevant factors, to characterise the consequence and to assess the exposure should be clearly presented. These analyses require risk assessors to synthesize and draw inferences from different data sources generally not specifically collected for use in risk assessment.

Once suitable data are collected, they should be evaluated using different criteria such as representativeness of the geographical and temporal properties of the candidate study. For example, if the literature search selected 5 studies quantifying the relation between a management factor with the occurrence of lameness in dairy cows and if one of the studies provided a significantly different odds-ratio estimate from the rest (based on statistical criteria), but had been conducted in a production system very different from that pertaining to the question under consideration, this data set could be excluded. In contrast, if all studies originated from the same country, same year, etc., but are have different management systems, the differences may be due to variability among the systems the assessors might decide to incorporate all of the studies in the model.

A systematic planning process can be applied to any type of data-generation. It includes two types of criteria: the first type of criteria considers the preliminary aspects of scoping and defining the assessment effort, the second type of criteria is related to the establishment of performance criteria or acceptance criteria that will help ensure the quality of the model outputs and conclusions. *Performance criteria* are used to judge the adequacy of information that is newly collected or generated on the assessment project, while *acceptance criteria* are used to judge the adequacy of existing information that is drawn from sources that are outside the current assessment. Generally, performance criteria are used when data quality is under the assessment project's control, while acceptance criteria focus on whether data generated outside of the project are acceptable for their intended use on the project.

The performance and acceptance criteria should be linked to some appropriate *data quality parameters* that measure features of data quality such as:

- Precision (i.e., variability in data under given similar conditions),
- Bias (i.e., systematic error),
- Accuracy,

- Representativeness,
- Completeness, and
- Comparability.

Although the level of rigour with which the data quality analysis is done and documented within the risk and assessment project can vary widely depending on the particular type of the assessment, this analysis represents an important improvement in implementing quality assurance. In the end, it is an expert opinion to use and interpret available data and their usefulness and validity under different scenarios. Data can thus vary with the epidemiological and environmental situation and e.g. the outcome of an infection and associated impact on welfare can well vary with the management and the epidemiological situation including e.g. the use of antibiotics and vaccines.

2.4.2 Uncertainty and variability

Evaluation of data may also include uncertainty and variability assessment. One of the more challenging aspects within scientific assessment is the characterisation of variability and uncertainty associated with the input data and in the case of risk assessment among elements in the model of the risk generating system. It is very common to find when specifying the risk problem that not all of the information is available to complete the scientific assessment. The reasons for this might be that the not all the factual information required is known, or there may be lack of information on the specific farming system issues or on the prevalence, management and outcome of certain infections or the science is not yet at the stage to provide all the answers. Sometimes the biological information is available (i.e. published) but uncertain. “Uncertainty” is the quality of being unknown, for example because inadequate data exist or because the biological phenomena involved are not well understood. Variability between observations can be another problem with animal welfare data, for example animals can be exposed at different levels of factors, and the interaction between factors and the animal could vary widely from one animal to another.
It is important that the unknowns, uncertainties and variability about any of the data are documented clearly. This will ensure that the risk managers know:

- When there is actually enough information to act.
- Where more resources need to be placed to gather more necessary data.

2.4.3 Expert Elicitation

Expert elicitation is a multi-disciplinary process that can help characterising uncertainty and filling data gaps where traditional scientific research is not possible or data are not yet accessible or available. It is a systematic process for formalising and quantifying expert judgments where there is a lack of good scientific data and hence uncertainty about the probability of different events, relationships, or model parameters.

The goal of using expert knowledge is to characterise each expert’s judgements (usually expressed as probabilities) about relationships, quantities, events, or measures of interest. The process uses expert knowledge, synthesised with experience and judgment, to produce probabilities about their confidence in that knowledge. Experts derive judgments from the available body of evidence, including a wide range of data and information ranging from direct empirical evidence to theoretical insights. Even when direct empirical data are available on the subject of interest, such measurements would not capture the full range of uncertainty. Experts use their scientific judgment to interpret available empirical data and theory. It should

also be noted that the results are not limited to the quantitative estimates. These results also include the rationale of the experts regarding what available evidence was used to support their judgments and how these different pieces of evidence were weighed.
The reasons for using expert knowledge during risk assessment of animal welfare include:

- Empirical data are not available or are not practically obtainable, or the analyses are not practical to perform.
- Uncertainties are large and significant.
- More than one conceptual model can explain, and be consistent with, the available data.
- To provide quantitative limits on subjective judgments. Interpretations of qualitative terms (e.g., "likely" and "rare") are difficult. EE can provide numbers with truthful uncertainty limits that are more valuable for subsequent analyses;
- To promote discussion and if possible consensus among experts regarding a complex decision.

The successful use of expert knowledge depends on the well-orchestrated interplay of the right subject matter experts, using the right information, or the information available, in conjunction with analysts providing the correct method to judge event likelihoods and making the correct inferences.
Different tools and techniques can be used, such as paired comparison, ranking and rating, direct numerical estimation, and indirect numerical estimation techniques applied to error estimation, with a particular emphasis on aggregating the estimates from multiple experts.

The use of expert opinions in risk assessment can present difficulties: possible dissension and competition between experts, difficulty in combining heteroclite fields of expertise, incomprehension of the other fields of expertise, incomprehension of the probabilities and inconsistency of the elicited estimates of probability, unconscious heuristic bias, subjectivity, unequal influence of various experts, socio-political pressures etc. Unlike rigorous but long mathematical algorithms, the heuristic ones are used to arrive quickly at a solution or a rough and satisfactory estimate, tending towards that which is optimal without reaching it. However, these heuristics can also strongly bias the expert judgments if the experts are not warned to avoid them or to limit them. There are several types of heuristic in cognitive psychology, but four types particularly common: 1) the affect, 2) anchoring and adjustment, 3) the availability and 4) the representation (O' Hagan et al., 2006; Tversky and Kahneman, 1974).

1) The heuristics of the effect indicate the process by which the expert judgments are influenced or determined by emotions. Their judgment can be biased positively or negatively according to their perception of the event and their personal attitude when they are faced with the considered event and its implications. Conflict of interests is another of the many possible effects of heuristics, and it implies, usually, the impact of risk assessment on the management decision. Example: An expert could underestimate the probability of a disease caused by the exposure to a contaminant if she feared that a high estimate involves closing-down of factories or if it were remunerated by owners of these factories. On the other hand, it could tend to over-estimate this probability if it was feared that they be accused by his/her peers or groups fighting against the impacts of the considered contaminant.
2) The heuristics of anchoring and adjustment, as its name indicates, is a phenomenon which encourages the people to be anchored to their first experiment and opinion about the specific event (e.g., their first study describing and quantifying the relationship between the exposure

to one factor and the animal welfare consequences) while not adjusting their opinion enough to the new relevant information or external information (e.g. other studies undertaken by other researchers) to the event in question.

3) The heuristics of availability is a mental short cut taking into account only the most recent facts or over-estimating their importance because of their 'availability' in the expert memory, since one can reach them more quickly and more easily. Presented differently, the heuristics of availability eliminates the older facts and information. Examples: 1) The media can bring back facts concerning a disease and give the impression that the probability of contracting this disease is higher than it should actually be. 2) The studies with more dramatic outcomes will tend to be remembered more strongly than other studies with negative (non-significant results). 3) The studies published more recently will be more accessible to the expert 'smemory. 4) Lastly, the heuristics of representation could also have been called the heuristics of association since it consists in estimating the probability of an event while being based on the probability of another event which is associated or similar to it. Example: To extrapolate data from an event to the general population is an example of use of the heuristics of representation. In research, it is often about bias consisting in an exaggerated over-generalisation to the general population the results observed in a particular population or in some particular circumstances.

In order to prevent and limit the heuristic bias the use of expert opinion should take into account the following points:

Before the work

- Expert calibration: familiarizing the expert with the elicitation process.
- A brief review of basic probability concepts.

During the work:

- Use only questions from within the area of expertise
- Use known measurements.
- Divide or break down the elicitation into tasks that are as 'small' and distinct as possible.
- Check for coherency - help the expert to be coherent.
- Use specific wording and test different type of question framing (e.g. positive vs negative formulation).
- Give the possibility to the expert to challenge the main hypothesis, to propose specific alternatives and to discuss estimates, giving evidence both for and against the main hypothesis.
- When it is relevant consider the assessment of competing hypotheses separately and compared by a ratio.
- Offer process feedback about the expert assessments, for example, offer different representations of probability (e.g. graphical), give summaries of the assessments made and allow expert to reconsider estimates.

After the work:

- Depending on the time frame, duplicate the elicitation procedure with the same experts at a later date to check their consistency.

3. Concluding remarks: When and how to use risk analysis?

Risk assessment is performed to support decisions on how to manage any risks and to decide on what systems for keeping and managing animals should be used. Since many of the factors affecting welfare lead to benefits, a similar analysis of benefits is desirable but this has not yet been carried out by EFSA. The process of benefit assessment can be essentially the same as risk assessment. The result will be a quantification of expected or recorded benefits associated with each factor examined. The process therefore begins with a clear formulation of the problem (Figure 1) and to include in the working group, welfare scientists with expertise that covers all the different key areas to be assessed. This is logically necessary to inform the specification of the welfare consequence categories to be addressed, the target scenario and population. It is useful to clearly separate the risk assessment from the subsequent risk management and within the EU food safety system this is a basic principle for the risk assessment done by EFSA including by AHAW. The balancing of different kinds of risk with one another is similar to what has to be done to balance risks and benefits. Risks are scored or ranked and systems can then be compared. In the same way, scores or ranks for risk and for benefit could be compared.

After familiarisation with the target population and the characteristics of the scenario (including e.g. housing, nutrition, and farm managing and feeding procedures, disease situation and disease management, breeding practices, slaughter procedures including transport) the identification of the initial events (determinants) can start, and other analyses can be undertaken, including consequence characterisation and exposure assessment. During the problem formulation, the development of a conceptual model helps to indicate events whose probabilities need to be determined and select the data needed to accomplish the risk assessment tasks. Data collection and analyses are not included in Figure 1.

<u>Problem formulation step:</u>

- What is the question and is it as specific as it should be?
- Is there sufficient scientific information for a qualitative or quantitative risk assessment? e.g. on :
    - Information about the needs of the animals in relation to the question in order to establish the list of factors.
    - Information about the procedures or questions that are the subject of the question to be considered
    - Information about relevant welfare indicators at a qualitative or quantitative level.
    - At what level is the risk assessment possible?
- Is the time taken to conduct a risk assessment justified by the added value likely to accrue as a result?
- What is the best way for conducting this risk assessment, should a modelling process be applied?
- Which people are needed in order to produce an adequate report and to conduct the risk assessment? (Decide on criteria for the selection of experts. Set up the full group)
- Conduct initial literature survey for report and decisions about methodology details.
    - Compile a list of welfare determinants that might result in poorer welfare.
    - Compile a list of welfare determinants that might result in better welfare.
    - Decide which components or aspects of welfare those need to be addressed.
    - Compile a list of relevant welfare indicators in regard to welfare aspects considered.
    - Consider sets of scenarios that have to be considered.
    - Decide on the type of risk assessment.

The sequence is the same for benefit assessment but, at the end, the comparison of values for risk and values for benefit is necessary.

Once initial estimates of scenario consequences and exposure frequencies are obtained, a preliminary characterisation of welfare changes may determine that some input parameters need additional refinement. Sensitivity analysis and interpretation of results by welfare experts help to determine the need for additional analysis. Risk assessment steps are not conducted in a single pass. Scenarios can be sophisticated externally, but resources are finite, so it is important to sort out clearly insignificant contributors and avoid spending effort in modelling them. The rule for discarding scenarios or part of their elements is to be based on positive or negative significance, which should be defined by the decision objective (management decision). Thus, having decided to implement a risk analysis, before conducting that analysis it is necessary to review not only the conclusions but also the quality, reliability and relevance of the conclusions. This poses a further set of questions and procedures:

- Review risk assessment outputs to identify procedural anomalies and errors.
- Consider risk assessment outputs in relation to identifying scientific/logical errors.
- Remedy errors.
- Consider method of presentation of the results of the risk assessment, taking account of report/opinion structure.
- Identify important gaps in knowledge revealed by risk assessment and report and make recommendations for further research.
- Consider strengths and weaknesses of report and risk assessment in order to be able to respond objectively to comments on the conclusions and recommendations that result from the work.

Due to the complex nature of animal welfare and its measure, there is a need for comprehensiveness in the risk assessment model that requires a significant effort at the scientific expertise stage (Figure 1) in the development of the scenario set. This effort requires significant input from the stakeholders associated with the need for decisions to be informed by the risk assessment. In return, the stakeholders are entitled to expect high standards of project quality assurance. The general approach and specific methodologies presented in this guidance are expected to promote comprehensiveness, to support peer review of the assessment model, and to facilitate communication of the modelling results to end users and outsiders.

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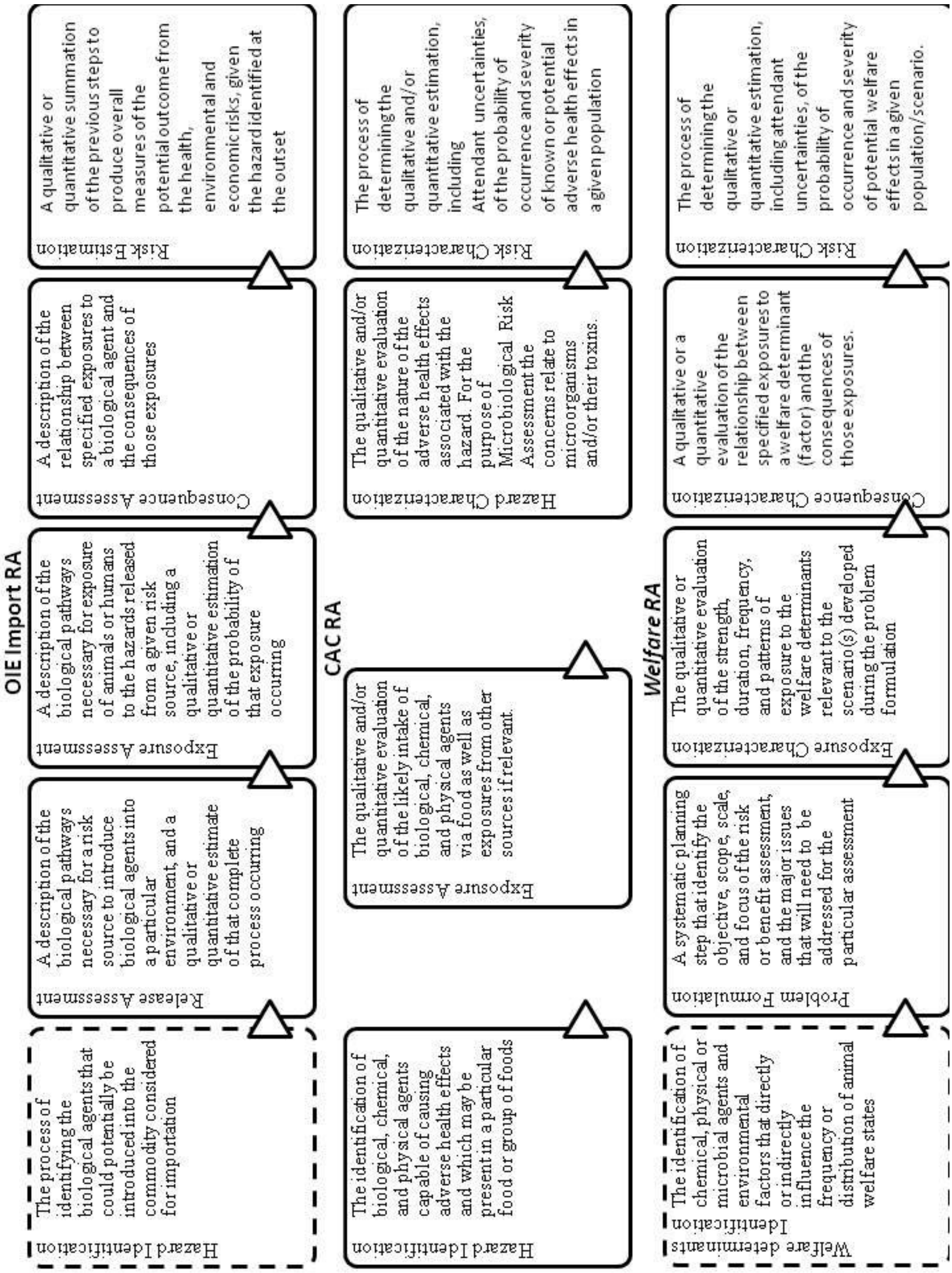
APPENDICES

A COMPARATIVE TERMINOLOGY BETWEEN THE OIE IMPORT, CAC AND ANIMAL WELFARE RA



B PREVIOUS WORK ON RISK ASSESSMENT IN ANIMAL WELFARE

EFSA Scientific Opinions on Risk Assessment in Animal Welfare

The work done by the AHAW Panel of EFSA in providing scientific advice on the welfare of animals has been reviewed by Ribó and Serratosa (2009). This includes description of how the risk assessment methodological approach in animal welfare has evolved starting from the scientific reports of the former Scientific Veterinary Committee (SVC) and the Scientific Committee on Animal Health and Welfare (SCAHAW). Other information about this work, and about general aspects of risk assessment in animal welfare, has been reviewed by Smulders and Algers (2009).

Since 2004, the AHAW Panel of EFSA has adopted 36 scientific opinions on animal welfare dealing, among others, with laboratory animals, stunning and killing methods, animal transport, the welfare of calves, the welfare risks of the import of captive birds, the welfare of pigs, fish welfare, welfare aspects of fish stunning and killing, dairy cow welfare, feather collection from live geese, and other topics (www.efsa.europa.eu).

The approach followed by EFSA has evolved steadily in relation to the usage of risk assessment and risk/benefit assessment. All reports since 1990 have considered risks to welfare. However, the earliest scientific opinions on animal welfare adopted by the SVC and SCAHAW did not use a formal RA approach. In the first EFSA scientific opinions (EFSA, 2004a, 2004b) RA was discussed but formally limited to the listing of hazards which may lead to poor welfare, some qualitative or quantitative evaluation of their impact and the definition of risk pathways. Developments in this methodology included the estimation of the magnitude of the adverse effects, a function of their intensity and duration (Broom, 2001). A formal, semi-quantitative RA, including hazard identification and characterisation, exposure assessment and risk estimation was conducted in the scientific opinion on the welfare of calves (EFSA, 2006b). In subsequent reports, this was associated with the hazards and the probability of their occurrence in the animal population and hence allowed a more reliable calculation of the risk estimates. This model was used in reports on welfare assessments for captive birds, pigs, fish and seals. The methodology for the current risk assessment model was extended using a much greater volume of scientific data in the dairy cow welfare report. Table 1 shows the animal welfare scientific opinions adopted by EFSA since 2003 and the evolution of the use of the formal RA methodology.

Table 1. Evolution of the formal RA approach amongst the AHAW Opinions (2003-2009) (adapted from Ribó and Serratosa, 2009)

AHAW Opinion on Animal welfare	Year	Formal RA	HI	Qual - RA	Semi-Qt RA
Welfare of animals during transport	2004	-	-	-	-
Welfare aspects of various systems of keeping laying hens	2004	-	x	x	-
Impact of the current housing and husbandry systems on the health and welfare of farmed domestic rabbits	2005	-	x	x	-
Welfare of weaners and rearing pigs: effects of different space allowances and floor types	2005	-	x	x	-

Biology and welfare of animals used for experimental and other scientific purposes	2005	-	x	x	-
Welfare aspects of the main systems of stunning and killing applied to commercially farmed deer, goats, rabbits, ostriches, ducks, geese and quail	2006	-	x	x	-
The risks of poor welfare in intensive calf farming systems	2006	x	x	-	X
Animal health and welfare risks associated with the import of wild birds other than poultry into the European Union	2006	x	x	-	X
Welfare of pigs (sows and boars, fattening pigs and tail-biting) (3 scientific opinions)	2007	x	x	-	X
Stunning and killing methods for seals	2007	x	x	x	-
Welfare of fish (salmon, trout, eel, sea bass-sea bream, carp) (5 scientific opinions)	2008	x	x	-	X
Stunning and killing methods of fish (salmon, trout, eel, sea bass-sea bream, carp, turbot and tuna) (7 scientific opinions)	2009	x	x	-	X
Welfare assessment of dairy cow welfare (leg and locomotion, udder, metabolic and reproductive and behaviour) (5 SOs)	2009	x	x	-	X
Broilers (Genetic selection, Housing and Management of broiler breeders)	2010	x	x	-	X
Harvesting feathers from live geese	2010	x	x	x	-

HI =hazards identified and list produced; Qual RA: qualitative RA; Semi-Qt RA: semi-quantitative RA;

The formal risk assessments applied have been analysed and their limitations are summarised in Table 2. All the analysed RA methods were based on existing risk assessment methodologies published in Codex Alimentarius RA guidelines on food safety (CAC, 2002). The method gradually improved by solving several constraints inherently related to animal welfare RA. The term "formal RA" is used to exclude the less systematic assessment of the effects of risks that is inherent in a good quality scientific review of any aspect of animal welfare, including animal health. In contrast to risk questions formulated in the areas of food safety or import of disease, the risk questions in the mandates for risk assessment of animal welfare and formulated for the Article 36 projects have been very broad: e.g. risk question for the mandate on farmed fattening pigs should consider "animal health and welfare aspects of different housing and husbandry systems for farmed fattening pigs" inter alia the following specific issues:

- The effects of stocking density, including the group size and methods of grouping the animals, in different farming systems on the health and welfare
- The animal health and welfare implications of space requirements.
- The impact of stall design and different flooring types on the health and welfare of fattening pigs taking into account different climatic conditions"

The questions resulted in 255 risk assessments (EFSA, 2007a) in fattening pigs. In the dairy cow risk assessment the mandate resulted in 555 risks assessed (EFSA, 2009a).

Table 2. Limitations of formal RA in AW approaches used by EFSA[6]

EFSA Opinion	Main limitations of the RA approach
The risks of poor welfare in intensive calf farming systems (EFSA, 2006b)	• Interaction between hazards not considered • Does not allow for variation in severity or exposure (inherent to classification) • Descriptors in classification tables not transparent (open for interpretation) • Quality (reliability) and availability of (published) data not considered. • Uncertainty Analysis in HC (based on quality of published or expert data); in EA mere indication of presence-or-absence of uncertainty • Duration of adverse effects were not separately scored but considered in the HC (severity score) • As a consequence of HC and EA scores being discrete the Risk Estimate (HC x EA) scale is discontinuous (remedied by designing a Risk outcome matrix)
Animal health and welfare risks associated with the import of wild birds other than poultry into the European Union (EFSA, 2006c)	• Description of hazards and the adverse effects not detailed and not transparent (open for interpretation) • Interaction between hazards not considered • Only severity of the adverse effects considered (no duration, no likelihood) • Uncertainty not addressed.
Welfare of pigs (sows and boars, fattening pigs and tail-biting) (3 scientific opinions) (EFSA, 2007a, b, c)	• Interaction between hazards not considered • Descriptors in classification tables not transparent (open for interpretation) • Formula for magnitude assumes linearity of the severity scores • In EA the intensity could only be expressed by the presence-or-absence of the factor (with few exceptions, e.g. concentration of ammonia in the range 25-49 ppm); partly remedied through introducing specific exposure scenarios describing defined combinations of EA intensities and durations.
Stunning and killing methods for seals (EFSA, 2007d)	• Interaction between hazards not considered • Fully applying the improved RA model was not considered (possibly for reasons of lack of data) allowing little if any quantification • Very restricted availability of published quality data and of experts, which generated high uncertainties • The terms with which severity (named "intensity") was described in HC are not transparent (open for interpretation); it was merely stated that they were based on pain and distress recognition • The descriptors for the EA classification were not defined • The criteria by which uncertainty should be classified were lacking
Animal welfare aspects of husbandry systems for farmed Atlantic salmon (EFSA, 2008)	• Largely qualitative exercise, probably related to the lack of data • Interaction between factors make RA difficult • Different life stages with very different conditions make a "total" description of fish welfare difficult • A problem in scoring the "duration of adverse effect" arises when the animal dies as a consequence of a particular hazard. and it was decided to score the duration of the effect over the "potential life time" of the

[6] The limitations of the RA method applied in Opinions 2006b, 2007a and b, and 2008 have been analysed by Algers et al., 2009 and summarised here.

EFSA Opinion	Main limitations of the RA approach
	animal, but indicating if a hazard was so severe that it could lead to instant death
Stunning and killing methods of fish (salmon, trout, eel, sea bass-sea bream, carp, turbot and tuna) (7 scientific opinions) (2009b)	• Qualitative exercise, probably related to the lack of data • Interaction and cumulative effects between hazards not considered • A problem in scoring the "duration of adverse effect" arises when the animal dies as a consequence of a particular hazard. and it was decided to score the duration of the effect over the "potential life time" of the animal, but indicating if a hazard was so severe that it could lead to instant death
Welfare assessment of dairy cow welfare (leg and locomotion, udder, metabolic/reproductive and behaviour) (5 SOs) (2009a)	• Difficult Hazard Identification resulting in very broad and unspecific hazards considering the broad framework of the risk assessment (i.e. leg and locomotion problems in EU dairy cows) • Interaction between hazards not considered • Difficult scoring of the duration and intensity of exposure to the hazard in the exposure assessment, due to the large target population considered (EU Dairy Cows population).

Guidelines on risk assessment for animal welfare commissioned by EFSA

Under the remit of Article 36 of Regulation 178/2002, EFSA has commissioned three scientific reports on the use of risk assessment methodology for animal welfare (Table 3). The three reports represent a first attempt to provide guidelines on risk assessment for animal welfare in three different scenarios: stunning and killing, transport and housing and management.

In addition to addressing the method for risk assessment for animal welfare, the Article 36 reports provide a bibliographic review of the various stunning and killing procedures used in farm, slaughter, experimental and wild animals (cattle, pigs, broilers, turkeys, deer, salmon and rats) (Algers et al., 2009); the most important transport means (road, sea and air) and phases (preparation for transport, loading and unloading, space allowance, feeding and watering, vehicle design, journey plan, and driving quality) for the main species transported in Europe (pigs, cattle, sheep and goats, horses, poultry, rabbits and fish) (Dalla Villa et al., 2009); and the housing and management conditions in various housing systems for cattle, pigs, sheep, goats, laying hens, broilers, broiler breeders, ducks, geese and turkeys (Spoolder et al., 2010).

Table 3. Guidelines on RA for AW commissioned by EFSA under the remit of Article 36 of Regulation 178/2002

Article 36 Scientific Report	Reference	Web link
Animal Welfare Risk Assessment Guidelines on Stunning and Killing	Algers et al., 2009	http://www.efsa.europa.eu/en/supporting/pub/11e.htm
Animal Welfare Risk Assessment Guidelines on Transport	Dalla Villa et al., 2009	http://www.efsa.europa.eu/en/supporting/pub/21e.htm
Animal Welfare Risk Assessment Guidelines on Housing and Management	Spoolder et al., 2010	http://www.efsa.europa.eu/en/supporting/pub/87e.htm

For each of the scenarios reviewed and described, the three reports illustrate the most common hazards to animal welfare. The Article 36 reports did not deal with benefit assessment aspects, as it was not the purpose of the EFSA calls. In Algers et al. (2009) benefit effects were mentioned and to some extent discussed, although they were not included in the assessments.

The risk assessment for animal welfare method illustrated in the three reports has been analysed and considered to develop this Guidance (Table 3). Considerable experience and knowledge has been gained across the three projects, which has allowed the method to gradually improve from the first experience (Stunning and Killing, Algers et al., 2009) to the latest (Housing and Management, Spoolder et al., 2010).

Method for performing hazard identification in the Article 36 scientific reports

In the reports on Stunning and Killing and Transport, the identification of the hazards relevant to the various scenarios under consideration was performed by reviewing the available literature, without specifying the method of review, i.e. the search process and the information sources searched. In the Transport report a literature review was carried out for each species to identify the main hazards in every transport phase: preparation for transport, loading and unloading, space allowance, feeding and watering, vehicle design, journey plan, and driving quality. The term hazard, rather than factor was used in this case as the Article 36 Projects referred to risk assessment only without considering benefits.

Different scenarios were described considering the species, the animal categories within each species, means of transport, duration of the transport and thermal environment during the transport. The hazards were grouped according to three different target populations: mammals, which are loaded moving on their own feet; rabbits and poultry, which are transported in cages; and fish, which have different needs and peculiarities. Furthermore, hazards during animal transport were categorized in two groups: 1) hazards related to facilities (design of the vehicle, the cages drinking and feeding devices, etc), 2) hazards related to management (handling during loading and unloading, management of the stationary vehicle, stocking density etc). The adverse effects of each hazard were classified according to the outputs of the Welfare Quality project (Welfare Quality®, 2009).
The Housing and Management report (Spoolder et al., 2010) illustrates a framework for identifying the relevant hazards in a more comprehensive and systematic way, based on the use of the 12 Welfare Quality® criteria for welfare and including two different approaches: the "Criteria to Hazard" approach, which starts with listing possible adverse effects and then identifying the hazards causing the adverse effects; and the "Hazard to Criteria" method, which starts with identifying the hazards and then lists the adverse effects that are caused by the hazard. The 12 animal welfare assessment criteria are either used as framework to start the identification of adverse effects in a structured way or as a last check to see if all areas of animal welfare are covered when hazard lists are composed. Although it is acknowledged that the framework proposed in the Housing and Management report may prove to be very useful for producing comprehensive lists of hazards, as the other Article 36 projects, this report does not report the method applied for searching the literature and indentifying the hazards relevant to the scenarios under assessment. A third general approach is also discussed which consists of producing a more generic list of hazards independent from the animal species. This list would include all possible types of hazards relating to the scenario under assessment and is expressed in general terms so that it could be applied to any species and situation. The advantages and disadvantages of the three hazard identification methods are illustrated (Spoolder et al., 2010).

In some cases (e.g. Stunning/Killing report) the description of the hazards has been generic. While, in this case, this approach is appropriate it may hamper the reproducibility of the exercise and the use of the lists of hazards for other, more broadly based risk assessments.

When identifying the hazards, the assessor defines also their strength and duration (i.e. the magnitude) according to the objective of the assessment (section 3.4). In the Stunning/Killing report different hazards' strength and durations are not addressed and strength is only expressed by the presence-or-absence of the hazard. In the Transport report hazards' strength is described by assigning different adverse effects (with different severity levels) to the same hazard depending on its strength, and duration is not addressed as transport is by its nature a very limited process in time. In the Housing report it is not clear how hazard strength is tackled whereas duration is clearly described considering two aspects: duration of the exposure, i.e. "how long the hazard would last", and frequency of the exposure, i.e. "how often the hazard would be encountered". This approach to estimating hazard duration and frequency seems to be the most comprehensive.

Data input in the Article 36 scientific reports

All reviews undertaken to input the risks assessment with relevant and reliable data, independently of the type of review performed (i.e. systematic or narrative review – section 3.2) should be clearly documented, to ensure transparency and reproducibility. This implies illustrating the search strategies used (i.e. combination of search terms and Boolean operators); the sources of literature searched (e.g. bibliographic databases, scientific journals tables of contents, specialised websites, etc); the criteria (if any) applied to select the studies for inclusion in the reviews; the method used for assessing the reliability (if any) of the studies; and the approach to synthesising the findings of the included studies.
Although the Housing report provides a structured framework for producing comprehensive lists of relevant hazards, none of the three Article 36 reports documents the literature review process undertaken to produce such lists (and the hazards identified are not cross-referenced with the supporting bibliographic references). In addition, the three reports seem not to perform any reliability (i.e. inherent quality) assessment of the studies reviewed, leaving it implicit that the reviews relied on scientific, peer-reviewed literature.

The way to collect input data (e.g. perform exposure assessment) has not been thoroughly documented in the three reports and when expert opinion is used, the method for eliciting expert knowledge is not illustrated. However, the main objective of the projects was to develop methodology and not to perform a RA. In all three projects, the importance of a systematic procedure for collecting input data was stressed. Most important, however, is that the methodology for such a formal and systematic procedure was not elaborated and described.

Method for dealing with interacting or associated hazards in the Article 36 scientific reports

Interactions between hazards occur when one or several adverse effects of a certain hazard depend on the exposure to other hazards; associations exist if the different aspects of a certain hazard (severity, duration, frequency, etc.) depend on the aspects of other hazards. Both associations and interactions can occur between two or more hazards. Moreover, hazards can be both associated and interact at the same time.

The question of how to deal with hazard interactions and associations in animal welfare risk assessment in not considered in the Stunning/Killing report; only partially considered in the

Transport report (by clearly defining the different scenarios); and only thoroughly discussed in the Housing report. In particular in the third Article 36 project the existing approaches for dealing with interacting/associated hazards are presented and discussed: estimating the risk associated to each hazard separately; estimating the risk due to a specific hazard at different levels of an associated or interacting hazard (e.g. genotype/housing interaction can be described considering the influence of housing on different breeds separately); or fully describing the interaction, specifying the adverse effect of each of the interacting hazards separately and also the extra adverse effect (positive or negative) due to each interaction.

The Housing report also describes possible developments of the method for dealing with interactions and associations between hazards in animal welfare risk assessment. The problem could be addressed qualitatively, using matrices visualisations of interactions; or quantitatively, using regression (for interacting hazards measured on a continuous scale, where the dependent variable is described by a formula that uses the independent variables and corresponding coefficients) or ontological analysis, which is a basic hierarchical system for visualising (in the form of pathways) relationships between different welfare hazards and consequences, based on principles and practices in information systems and philosophy.

Although the issue of interacting/associated hazards is thoroughly discussed in the Housing report, no particular method is applied and interactions between hazards are not considered in the lists of identified hazards.

Description of adverse effects and their magnitude in the Article 36 scientific reports

With regard to description of the adverse effects, in the Stunning/Killing report the authors acknowledge that adverse effects consist of several different components (not all occurring at slaughter: pain, fear, anxiety, frustration, behavioural disruption, malaise, thirst, hunger, discomfort) and that ideally one RA should be performed for each component. In practice they find a compromise by reaching a consensus within the project team on: the type of adverse effects caused by each hazard (i.e. which welfare components are affected among fear, pain, frustration, etc); and which of those welfare components are the most prominent. However, in the risk tables the most prominent welfare components (defined as "adverse effect types") are not clearly highlighted; the adverse effect description is not always clear (open to interpretation); and the same adverse effects description is repeated for all phases of pre-slaughter handling.

In the Transport and Housing reports the approach to adverse effects description is based on the Welfare Quality approach (4 welfare principles and 12 welfare criteria). Each hazard is linked to a welfare criterion and 2 elements are illustrated: adverse effect type (criterion, e.g. Injuries); and adverse effect description, corresponding to indicators of welfare (e.g. bruising, wounds). It must be noted that adverse effect types are not always clearly described (e.g. "difficult movement") and are thus open to interpretation, making it difficult to reproduce the exercise.

The same lack of details in the description of the adverse effects has been observed for duration and likelihood of the adverse effects.

In all three reports the severity of adverse effects is scored according to a definition worked out before starting the risk assessment and on the basis of physiological and behavioural responses of the animals (e.g., in the Stunning/Killing report, pain, fear, anxiety, frustration, behavioural disruption, malaise, thirst, hunger, discomfort). This approach often implies linearity and continuity of adverse effect and means that for instance severe pain (severity level 3) is equal to a three times greater reduction in overall welfare than mild pain (severity level 1), when set against a baseline value of no pain (level 0). In reality, the association between pain and overall reduction in welfare might not be linear and continuous. However, as reliable data to support a specific type of relationship usually are lacking, the most suitable way to deal with it for the moment is to discuss it at the beginning of the study before the RA and define the scores and the relationships (Spoolder et al., 2010).

Uncertainty in the Article 36 scientific reports

In all three reports uncertainty is estimated qualitatively using a 1-3 scale (high, medium or low), which gives an indication of the type of information available, whether there are different studies with differing conclusions, but also whether the scientific information has been published or not. Expert knowledge/experience is not considered in the definition of uncertainty. In addition, uncertainty refers to whole adverse effect characterisation, with no difference between uncertainty on the intensity, duration or likelihood of the adverse effect. Moreover, when uncertainty is indicated as low or medium, the supporting evidence is not always indicated.

C CASE STUDIES: CONSEQUENCE ASSESSMENT AND QUANTITATIVE RISK ASSESSMENT

Consequence assessment case study, cubicle housing for dairy cows

The impact of scenarios defined by a number of factors and interactions between factors on a specified target population (in this example lactating dairy cows) needs to be defined in terms of the objectives and defined consequences of the assessment. In this case study the major consequences of factor level relating to dairy cow housing can be assessed in terms of measurable welfare indicators relating to the following welfare criteria: Comfort around resting, Ease of movement, Absence of injuries, Absence of disease, Absence of pain, Social behaviour

<u>Example Step 1:</u>
As a general rule it is proposed that the impact of factor strength on consequence intensity be measured on a semi-quantitative 5-point scale (A to E), where B defines a baseline state where the animal is in a state of physiological and behavioural equilibrium. A defines a state where there is positive evidence of very high quality welfare (e.g. play, excellent condition of skin and coat). C, D and E define impact levels equating to states of mild, moderate and severe harm within each of the selected criteria, e.g. injuries associated with lameness. There tends to be general agreement among welfare assessors when assessing the intensity of a consequence as mild (C) or severe (E) (section 2.2). In the interests of consistency between assessors, all intensities assessed as intermediate between mild and severe are placed at level D.

Factors that may be included within the scenario "Cow housing" include:
Physical condition of the floor surface (e.g. abrasive, broken, slippery concrete, installation of "comfort" surfaces.
Quality of floor management (depth of slurry, frequency of scraping)
Physical dimensions of cubicles
Quality of bedding
Design and dimensions of passageways
Access to outdoor loafing area or pasture

Table 1. Relation between strength of factor scenario and consequence intensity for dairy cow housing.

Factor levels of factor "cow housing"	Welfare indicators (examples)	Consequence categorisation	Consequence level
access to pasture	Play, mutual grooming Prolonged lying at pasture Excellent condition of skin and coat Excellent locomotion	Social behaviour Comfort around resting Physical comfort	A
Rubberised floors Deep sand bedding in cubicles	No change in indicators of welfare Very low incidence of locomotor disorders	Physiological and behavioural equilibrium	B
Concrete floors, well managed Adequate cubicle design Inadequate bedding	Reduced lying time in cubicles Low incidence of skin lesions Low incidence of locomotor disorders	Discomfort at rest Pain and injury	C

Concrete floors, poor cleaning Inadequate cubicle design No bedding in cubicles	Moderate prevalence of skin and joint lesions Moderate prevalence of locomotor disorders Untreated severely lame cows Evidence of environmental mastitis	Discomfort at rest Impaired movement (e.g. changing position) Pain and injury Infectious disease	D
Cubicles inadequate in number and design, no bedding, slippery, dangerous passageways, bad stockmanship	>40% with skin and joint lesions >50% with locomotion disturbance >50% showing difficulty in standing up and lying down > 100 mastitis cases/100 cows/year	Marked discomfort at rest and in movement Severe pain and injury Life threatening infectious disease	E

<u>Example Step 2. Time of application of the factor</u>

In this case study the time of application of the factor is the length of time the cows spend within the cubicle house under constant exposure to the factors and at the strength defined within the scenario.

<u>Example Step 3. Duration of the consequence</u>

The duration of the consequences is specific to the welfare indicator, for example

Difficulty in standing up and lying down in cubicles will last for the total duration of time spent in the cubicle house.

Mild locomotor disorders, diagnosed and treated early will last 3-4 weeks (Whay et al., 1997)

Environmental (E coli) mastitis will proceed to cure or death within less than 10 days

<u>Example Step 4. Interaction between factors (examples for dairy cow housing)</u>

The interaction between factors needs to be taken into account when:

One factor will only cause a welfare change in the presence of another.

Example: the risk of systemic (E coli) mastitis associated with high exposure to dirty floors is greatly increased in early lactation.

When the impact of two factors with similar (e.g. harmful) consequences is greater than the sum of the two factors present in isolation.

Example: Injurious and badly maintained walkways PLUS inadequate foot care (claw trimming, early diagnosis and treatment of lameness).

Quantitative Risk Assessment

As stated in the report, when welfare in general or a component of health, such as the occurrence of a disease is evaluated, the negative (risks) as well as positive (benefits) effects of factors should be considered.

To compare the benefits and risks of several management methods, or housing systems, etc., to animal welfare an effective strategy need to be developed which enables qualitative and/or quantitative comparison of animal welfare risks and benefits in order to estimate the net welfare impact of the factors considered. This example belongs to category 2, reducing an existing or expected harm (Beneficence).

The steps defined in this guideline to conduct a risk/benefit assessment are: (1) factor selection; (2) consequence characterization; (3) factor exposure assessment; and (4) characterization of welfare change.

Factor selection: In this example a risk/benefit assessment is performed to compare two management strategies, use of regular semen versus sexed semen (**scenarios**). We hypothesize that sexed semen technology could have a positive impact on welfare of dairy cows by reducing the frequency of dystocia and the number of unwanted dairy bull calves. Several other factors may affect parturition type. The effect of some, such as herd environment, age at first calving and season of calving were accounted for statistically (included in the statistical model). Factors not included in the model are assumed to be identical for the two scenarios evaluated.

Consequence characterization: Calving is a critical time for dairy cows and many health problems tend to occur together as a sequence of events around parturition time. A major welfare problem is difficult calving (dystocia) in first lactation dairy cows and subsequent health problems associated with difficult calving. Sex of the calf is an important determinant of parturition problems, with higher frequency of dystocia for male calves relative to female calves. One consequence of selection for "dairy type" is a decreased economic value of bull calves which, in some circumstances, creates welfare problems associated with disposal of unwanted bull calves. Some are transported long distances to veal farms when two weeks old but many are killed at birth.

In this risk assessment example the following production diseases are considered: dystocia (DYST), calf born dead (STLB), retained placenta (RTPL), metritis (METR), cystic ovaries (CYST) and anestrous (SLHT). The occurrence of a disease implies clinical diagnosis and treatment by the field veterinarian. EXIT described the termination status for each record (subsequent calving and death or culled from the herd).

Expert elicitation approach can be used to assign a "qualitative" welfare score based on perceived pain and suffering associated with these disease events using a score of 0 to -10 welfare units (wu) (from minor to major pain and suffering). Let us assume that for this example the expert elicitation approach resulted in the following scores:

DYST=-10 wu; STLB=-8 wu; RTPL=-8 wu; METR=-5 wu; CYST=-5 wu; SLHT=-1 wu; EXIT=-1 wu; no disease=0 wu;

Using the same approach, a score to describe the welfare problems associated with the sex of the calf was obtained using a scale from 0 to -20, with 0 wu if the calf is female and -20 wu if it is male.

Factor exposure assessment: In the target population the breeding of cows is done with AI using standard semen. Multiple logistic regression techniques and path analysis have been used to unravel the complex web of causal relationships among diseases (Oltenacu et al., 1990). The magnitude of direct and indirect causal relationships among clinical diseases and between diseases and culling were estimated in a large epidemiological study (Oltenacu et al., 1990). These estimates were used to quantify the increased risk of developing a respective disease relative to a first lactation cow with a normal calving. The target population is the one providing the estimated probabilities, first lactation SRB cows, or one that can be assumed to be very similar so the estimated parameters will still hold.

The incidence rates of difficult calving (dystocia) and normal calving were estimated to be 0 .15 and 0.85, respectively. There is a 20% difference in incidence of dystocia as a function of the sex of the calf (i.e., .05 for female calves and .25 for male calves).

Characterization of welfare change: We can construct a tree diagram (Figure 1) describing the possible sequence of disease events a cow with a difficult calving (DYST=yes) or normal calving (DYST=no) can go through. The disease sequence (yes or no) considered was:

STLB→RTPL→METR→CYST→SLHT→EXIT   with appropriate probabilities.

For each branch representing a possible sequence of disease events a cow can go through following parturition, we calculated its probability (product of brunch probabilities) as well as cumulative welfare score. The cumulative probability of all possible outcomes is, of course, equal to 1, and for each brunch the product of its probability with the cumulative welfare score represents expected welfare, E(W), for that outcome.

For example, the probability of a first lactation SRB cow with veterinary assisted calving (DYST=yes) not to develop STLB or RTPL or METR or CYST or SLHT and also not to be be culled from the herd is (see figure 1):

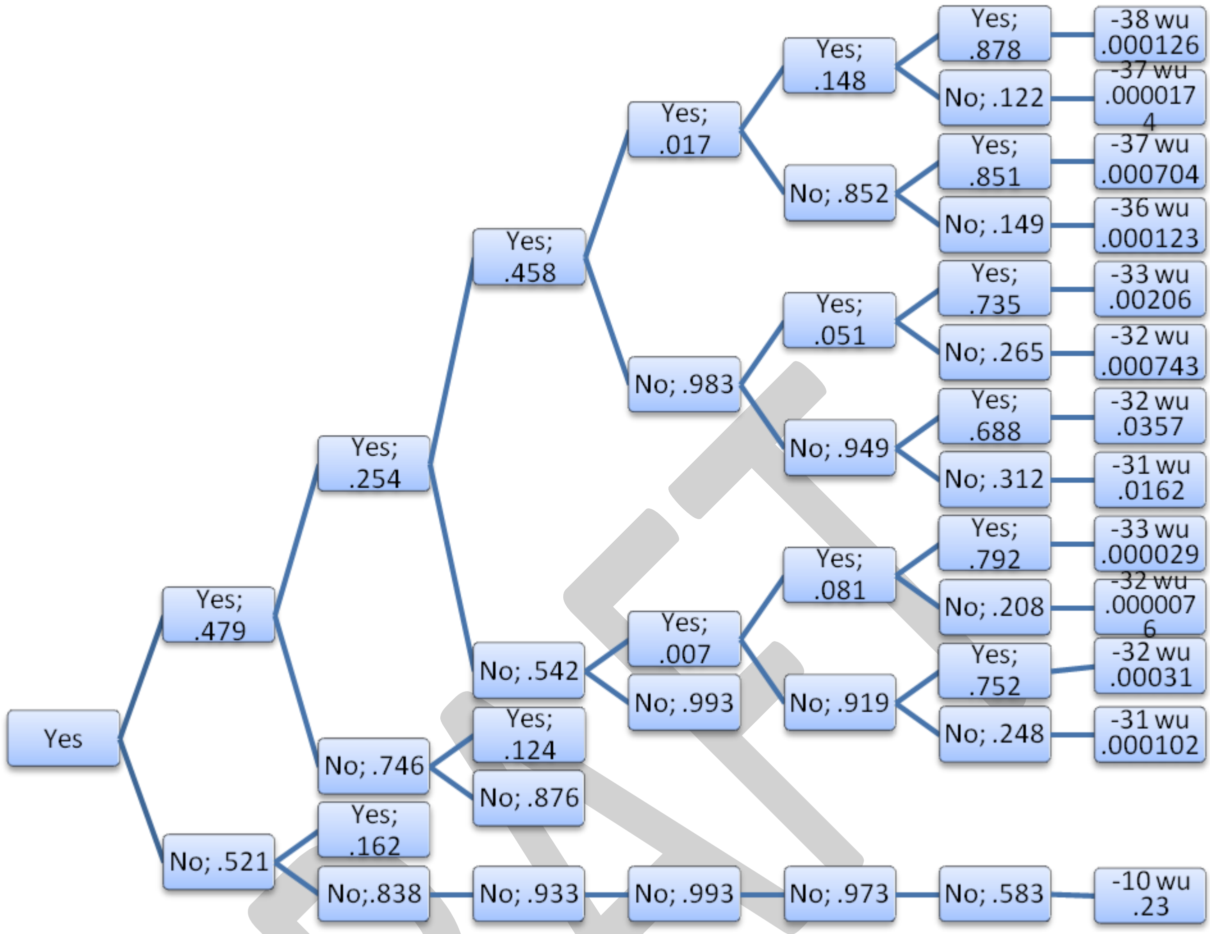
$$(.521)*(.838)*(.933)*(.993)*(.973)*(.583) = .23$$

Let us assume that the experts consulted for this assessment concluded that the pain and suffering associated with these diseases is additive. Therefore, the welfare score for this particular cow is equal to:

Dystocia	Stillbirth; probability	Rt.Placenta; probability	Metritis; probability	Cysts; probability	Anestrous; probability	Exit; probability	Welfare score

$$(-10)+(0)+(0)+(0)+(0)+(0)+(0) = -10$$

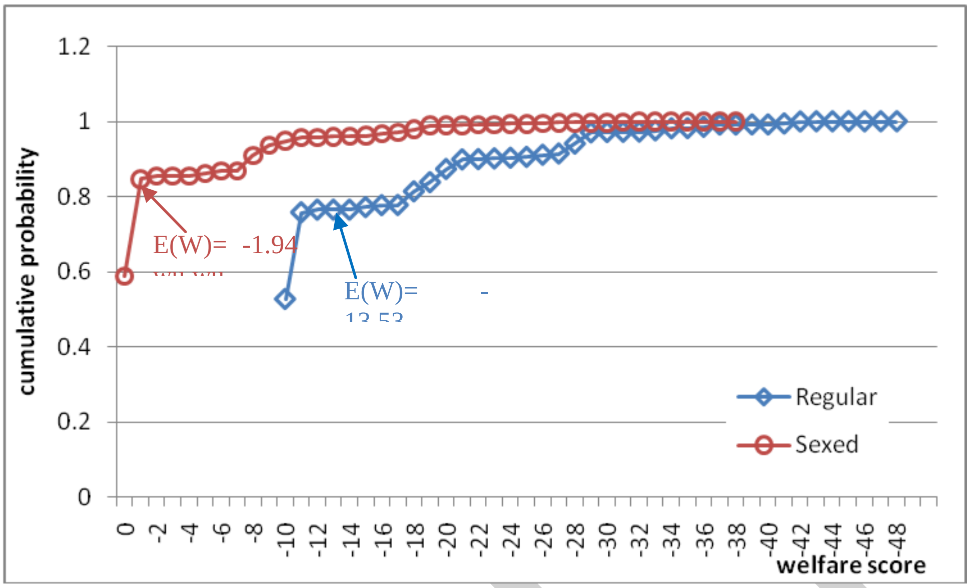
Figure 1. Tree diagram describing the sequence of disease events and conditional probabilities, the welfare score and probability for each branch.



If this cow was serviced with standard semen, the probability of dystocia is .05 if the calf is female or .25 if the calf is male and, with 50:50 sex ratio, the probability of this sequence of disease events is (.15)*(.23) = .0345 and the welfare score is (-10 wu) associated with dystocia plus -5 wu associated with disposal of unwanted male calf, for a total of -20 wu.

We calculated the probabilities of all possible outcomes for the two management strategies (scenarios) considered in this example (using standard semen vs. sexed semen) and plotted the cumulative probabilities of outcomes against the welfare score for each strategy in Figure 2. We also calculated the expected welfare, E(W), for each scenario by multiplying the probability of each outcome with its welfare score and summing over all outcomes. With E(W) of -1.94 wu for sexed semen and -13.53 wu for standard semen, there is a decrease in expected welfare score (welfare benefit resulting from reduced pain and suffering) of 11.59 wu.

Figure 2. Cumulative probability of all possible welfare outcomes for SRB first lactation cows when using regular or sexed semen.



With standard semen, a cow will have a welfare score of -10 wu, -11 to -20 wu, -21 to -30 wu or <-30 wu with probability of .52, .36, .10 and .02, respectively. With sexed semen, a cow will have a welfare score of 0 wu, -1 to -10 wu, -11 to -20 wu, or <-20 wu with probability of .59, .36, .04 and .01, respectively.

It is clear from this example that, with respect to welfare, using sexed semen is preferable because it improves the welfare of the target population. The major benefit (86%) is associated with elimination of unwanted male calves. Additional benefits (16%) come from lower frequency of diseases.

Glossary and abbreviations

AHAW
Animal Health and Welfare

Benefit
Function of the probability of positive welfare effect and the magnitude of that effect, consequential to the exposure to a particular scenario.

CAC
Codex Alimentarius Commission

Conceptual model
In a problem formulation is a written description and visual representation of predicted relationships between welfare determinants and the considered animal welfare aspects.

Consequence characterisation
Qualitative or a quantitative evaluation of the relationship between specified exposures to a welfare determinant (factor), and the consequences of those exposures. The intensity and duration of the consequences (which, combined, correspond to the magnitude) and their likelihood to occur at the individual level are assessed.

EFSA
European Food Safety Authority

Expert elicitation
Multi-disciplinary process that can inform decision making by characterizing uncertainty and filling data gaps where traditional scientific research is not possible or data are not yet accessible or available.

Exposure characterization
Qualitative or quantitative evaluation of the strength, duration, frequency, and patterns of exposure to the welfare determinants relevant to the scenario(s) developed during the problem formulation.

Hazard (in the context of the food safety risk assessment)
Biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

OIE
Office International des Epizooties (World Organization for Animal Health)

Quality Assessment (QA)
Systematic evaluation of the various aspects and component of the assessment procedure, to maximize the probability that minimum standards of quality are being attained.

Risk
Function of the probability of negative welfare effect and the magnitude of that effect, consequential to the exposure to a particular scenario.

Risk Assessment
Process that evaluates the likelihood that positive or negative animal welfare effects which occur following the exposure to a particular scenario.

Risk characterization
Process of determining the qualitative or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of negative or positive welfare effects (known or potential) in a given population. It consists on integrating the results from Exposure characterization and the Consequence characterization.

SCAHAW
Scientific Committee on Animal Health and Welfare

Scenario
Description of an animal population and their environment at a particular stage(s) of their live or during particular management procedures. It includes information about housing, nutrition, breeding practices, transport, farm procedures, slaughter procedures and husbandry in general.

SVC
Scientific Veterinary Committee

Welfare determinants
Any of a group of specific chemical, physical or microbial agents and environmental factors that directly or indirectly influences, either positively or negatively, the frequency or distribution of animal welfare states.

Welfare effect
Change in biological functioning of organisms, such as growth and reproduction, as well as health and behaviour.

Welfare indicator
Characteristic of an animal or its environment which is subject to direct or indirect measurement and can be used to describe one or more aspects of the welfare of an animal.