SCIENTIFIC OPINION

# Guidance on Risk Assessment for Animal Welfare[1]

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

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## ABSTRACT

The document provides methodological guidance to assess risks for animal welfare, considering the various husbandry systems, management procedures and the different animal welfare issues. The terminology for the risk assessment of animal welfare is described. Risk assessment should not be carried out unless the relevant welfare problem is clearly specified and formulated. The major components of the problem formulation are the description of the exposure scenario, the target population and the conceptual model linking the relevant factors of animal welfare concern. The formal risk assessment consists of exposure assessment, consequence characterisation, and risk characterisation. The systematic evaluation of the various aspects and components of the assessment procedure aims at ensuring its consistency. All assumptions used in problem formulation and risk assessment need to be clear. This also applies to uncertainty and variability in the various steps of the risk assessment. The choice between qualitative, semi-qualitative or quantitative approaches should be made based on the purpose or the type of questions to be answered, data, and resource availability for a specific risk assessment. Quantitative data should be used whenever possible. Positive effects on welfare (benefit) could be handled within the framework of risk assessment if the analysis considers factors as having both positive and negative effects on animal welfare. The last section details the main components of risk assessment documentation.



## KEY WORDS

Animal welfare risk assessment, problem formulation, exposure assessment, consequence characterisation, risk characterisation.

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[1] On request from EFSA, Question No EFSA-Q-2007-168, adopted on 13 December 2011.

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[4] The corporate authorship has been changed. The changes do not affect the overall conclusions of the opinion.

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## SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Animal Health and Animal Welfare (AHAW) for the development of Risk Assessment Guidelines for Animal Welfare.

The aim of this Guidance is to provide a harmonised methodology for the assessment of risks for farm 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), all types of husbandry systems and all animal categories.

The risks for animal welfare in EFSA scientific opinions have been considered since 2004 and the terminology used is explained in the Glossary. Risk assessment provides a science-based, transparent, and reproducible framework to address specific welfare problems within a limited time frame and with available scientific data. Benefit assessment should be possible with the same methodology. The definition of the target population, the exposure scenario and the conceptual model are the major components of the problem formulation. A conceptual model should be built in order to describe the exposure pathways and the different combination of events showing the relevant factors and their effects on the target population. Relevant factors related to, for example, genetic selection, housing and management, transport, stunning or killing, that are likely to improve or impair the welfare of the animals should be identified.

Risk assessment has three elements: exposure assessment, consequence characterisation and risk characterisation. Exposure assessment should provide a qualitative or quantitative evaluation of the strength, duration, frequency and patterns of exposure for the factors relevant to the exposure scenario(s) developed during the problem formulation.

Consequence characterisation involves assessing the magnitude (intensity and duration) of the negative and positive consequences for welfare and the probability of their occurrence at the individual level. Risk characterisation is the final step of risk assessment and is the qualitative or quantitative estimation of the probability of occurrence and magnitude of negative and positive welfare effects (known or potential) in a given population.

Uncertainty and variability in risk assessment, as well as all assumptions used in problem formulation and risk assessment, need to be clearly expressed. Quality of risk assessment includes the quality of the data input, the relevance of the assumptions and the quality of the final assessment in relation to uncertainty and variability.

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## BACKGROUND AS PROVIDED BY EFSA

The European Food Safety Authority (EFSA) provides independent information regarding risks associated with food and feed, plant health, environment, animal health, and animal welfare (AW) by using, whenever possible, a risk assessment (RA). In addition, one of the tasks of the Authority is to promote and coordinate the development of uniform RA methodologies in the above-mentioned fields.

The Animal Health and Welfare (AHAW) Panel of EFSA has adopted 36 Scientific Opinions on Animal Welfare between 2004 and 2010, dealing with welfare of calves, fattening pigs, sows and boars, tail biting, seals, fish and dairy cows (EFSA, 2006a; 2007a,b,c,d; 2008a; 2009). Different approaches have been followed for these scientific opinions.

An EFSA Scientific Colloquium on "Principles of Risk Assessment of Food Producing Animals" was held in Parma in 2005 (EFSA, 2006[5]) and, subsequently, an EFSA workshop on "Risk Assessment Methodology in Animal Welfare" was held in Vienna in 2007. One of the main conclusions was that no specific standardised methodology exists in the field of risk assessment for animal welfare. The beneficial effects of some factors for animal health and for animal welfare in general were also discussed; however, only the assessment of risks was considered in detail. While specific guidelines have been published on animal diseases or chemical substances by the World Organisation for Animal Health (OIE, 2004 a,b) and the Codex Alimentarius Commission (CAC, 2002) respectively, there are currently no specific international guidelines on risk assessment for animal welfare.

A report on basic information for the development of guidelines on risk assessment for animal welfare was produced by the "Italian Reference Centre for Animal Welfare" (EFSA, 2007). The report includes a definition of risk assessment, a description of existing models, reviews the definition of animal welfare and different approaches for its evaluation. The report lists the main issues to be considered in the guidelines. These issues have been divided in the following three categories: i) slaughter, ii) transport, and iii) housing and management.

A "Framework for EFSA AHAW Risk Assessment" was produced (EFSA, 2008[6]) but a requirement for specific guidelines and standardised working methodology for risk assessment, including the assessment of beneficial effects of some factors applied to animal welfare has been clearly identified. Against this background, EFSA launched a self-mandate in 2007 to develop guidance on risk assessment for animal welfare.

## TERMS OF REFERENCE AS PROVIDED BY EFSA

The original terms of references for the self-mandate were amended in 2009, and were to define a comprehensive and harmonised methodology 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 Scientific Opinions on various species.

The defined methodology for assessing risks and benefits in animal welfare should take into account and adapt current risk assessment methodologies, for example those for animal disease and food safety, and also the complex range of measurable welfare outcomes.

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

[5] http://www.efsa.europa.eu/en/supporting/pub/111e.htm

[6] http://www.efsa.europa.eu/fr/supporting/pub/233r.htm

## CLARIFICATION OF THE TERMS OF REFERENCE

While the original mandate exclusively focused on risk assessment (i.e. consideration of harmful factors), the 2009 terms of reference of the mandate included explicit consideration of benefit assessment. However, at its 55th plenary meeting[7], the AHAW Panel recognised that risk and benefit analysis in the context of animal welfare may require further conceptual and methodological refinement. The Panel recommended considering detailed aspects of benefit analysis for further work and possible future inclusion in its methodological framework. The Panel consequently proposed to concentrate on risk assessment aspects for the purpose of the Guidance. This was formally accepted by EFSA in April 2011.

[7] http://www.efsa.europa.eu/en/events/event/ahaw110224-m.pdf

## ASSESSMENT

## 1. Introduction

This Guidance provides a structured methodological framework based on existing EFSA practices as well as OIE and Codex Alimentarius risk assessment methodologies, for addressing risks to animal welfare related to any factors having the potential to affect the welfare of animals in any husbandry system.

The purpose of this Guidance is to provide a practical and generic procedure on how to conduct an assessment of the risks of poor animal welfare, and facilitate comparability of animal welfare risk assessments. The Guidance includes some suggestions concerning the assessment of benefits for animal welfare. The intention is to apply this Guidance in the working of the Animal Health and Welfare (AHAW) Panel of EFSA.

In this Guidance more explanatory text is given in some places to clarify the complex issues that are specifically related to animal welfare so that the reasons for taking certain actions are clear.

The main terms used in this guidance are defined in the Glossary.

## 2. Principles of animal welfare risk assessment

Risk assessment is one of the three components of risk analysis (Regulation (EC) 178/2002[8]). Risk assessment considers different types of factors within specific exposure scenarios (see the definitions in the Glossary) and it provides a scientific basis for appropriate risk analysis (i.e. the assessment, communication and management to reduce, eliminate or prevent the risks that can lead to poor welfare in animals).

Good communication between risk assessors, risk managers, and all interested parties, is essential to the risk analysis process.

At the inception of the assessment, risk assessors should consider the terms of reference and background information provided by those requesting the risk assessment. Risk assessors may request an initial planning stage to clarify the goals, scope, and focus of the risk assessment, and the major issues that will need to be addressed within the framework of a risk assessment (see Section 3.1, problem formulation).

Uncertainty and variability in risk assessment, as well as all assumptions used in problem formulation and risk assessment, need to be clearly expressed.

The choice between qualitative, semi-qualitative or quantitative approaches should be made according to the purpose or the type of questions to be answered, and the data and resources available for a specific risk assessment. Quantitative data should be used whenever possible without diminishing the utility of available qualitative information and expert knowledge.

### 2.1. Animal health risk assessment

The World Animal Health Organisation (OIE) has developed standards for risk analysis related to the importation of animals and animal products. The recommended steps of risk assessment are first and foremost designed to consider the risk of infectious agent introduction into an importing country.

[8] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, 1-24.

The Terrestrial Animal Health Code (OIE, 2011), which governs animal import risk assessment describes four steps: (i) Release assessment, (ii) Exposure assessment, (iii) Consequence assessment, and (iv) Risk estimation.

The OIE approach assumes that the hazard has already been identified. If the hazard has already been identified then further discussion should focus on how the hazard is released from its source(s), the pathways by which the population at risk becomes exposed, the consequence of the contact between the hazard and the susceptible hosts, and integration of the previous steps to estimate the risk associated with the specified hazard.

Hazard identification is a pre-risk assessment activity, to determine whether exposure to an agent (biological or infectious agent) might cause an adverse health effect (disease) in animals or in humans. It is a qualitative step where evidence in the literature is collated and presented in a logical and rational manner to justify the concern regarding the perceived risk of a particular hazard. This step entails examination of the evidence in the literature for disease causation.

Since the OIE guidance is only related to import risk analysis to prevent introduction of infectious diseases, it needs to be modified for use in relation to animal welfare and animal diseases in general.

## 2.2. Animal welfare risk assessment

Problem formulation, including factor identification, is a prerequisite for any risk assessment (see Figure 1). The next stage is formal animal welfare risk assessment which comprises three steps: (1) exposure assessment; (2) consequence characterisation; and (3) risk characterisation.

**Box 1.** *Examples of single input/single consequence, multiple input/single consequence, and multiple input/multiple consequence risk assessment approaches (SISC, MISC, MIMC)*

| **Single input** | | **Single consequence** |
|---|---|---|
| A microbial agent | → | One disease |
| Mycobacterium bovis | | Bovine tuberculosis |
| Listeria monocytogenes | | Listeriosis |

| **Multiple inputs** | | **Single consequence** |
|---|---|---|
| Various microbial agents | | |
| Milking hygiene factors | → | Mastitis |
| Housing system factors | | |
| Nutrition factors | | |
| Etc. | | |

| **Multiple inputs** | | **Multiple consequences** |
|---|---|---|
| Various microbial agents | | |
| Milking hygiene factors | | Mastitis |
| Housing system factors | → | Lameness |
| Nutrition factors | | Infertility |
| Chemical agents | | Injuries |
| Animal handling | | Abnormal behaviour |

Factor identification in animal welfare risk assessment is equivalent to hazard identification, which considers whether particular factors have the potential to improve or impair directly or indirectly the animal welfare in the target population.

Animal welfare risk assessment usually considers simultaneously several factors within an exposure scenario, where each factor could affect one or several of the four welfare principles (see the Glossary).

Some risk assessments consider one single hazard and one single consequence (SISC: single-input-single-consequence, see Box 1). However, for animal welfare risk assessment, the questions often make it necessary to consider multiple factors *vs.* single consequences (MISC: multiple-inputs-single-consequences) and multiple factors *vs.* multiple consequences (MIMC: multiple-inputs-multiple-consequences).

Animals can be exposed simultaneously or successively to one or more factors. Factors may contribute to the same consequence or a variety of consequences. Risk assessment for multiple factors may evaluate the risks one at a time, or may take into account possible interactions among factors (antagonisms, synergisms and feedback).

## 3. Operational guidance

The workflow to conduct a risk assessment is presented in Figure 1.

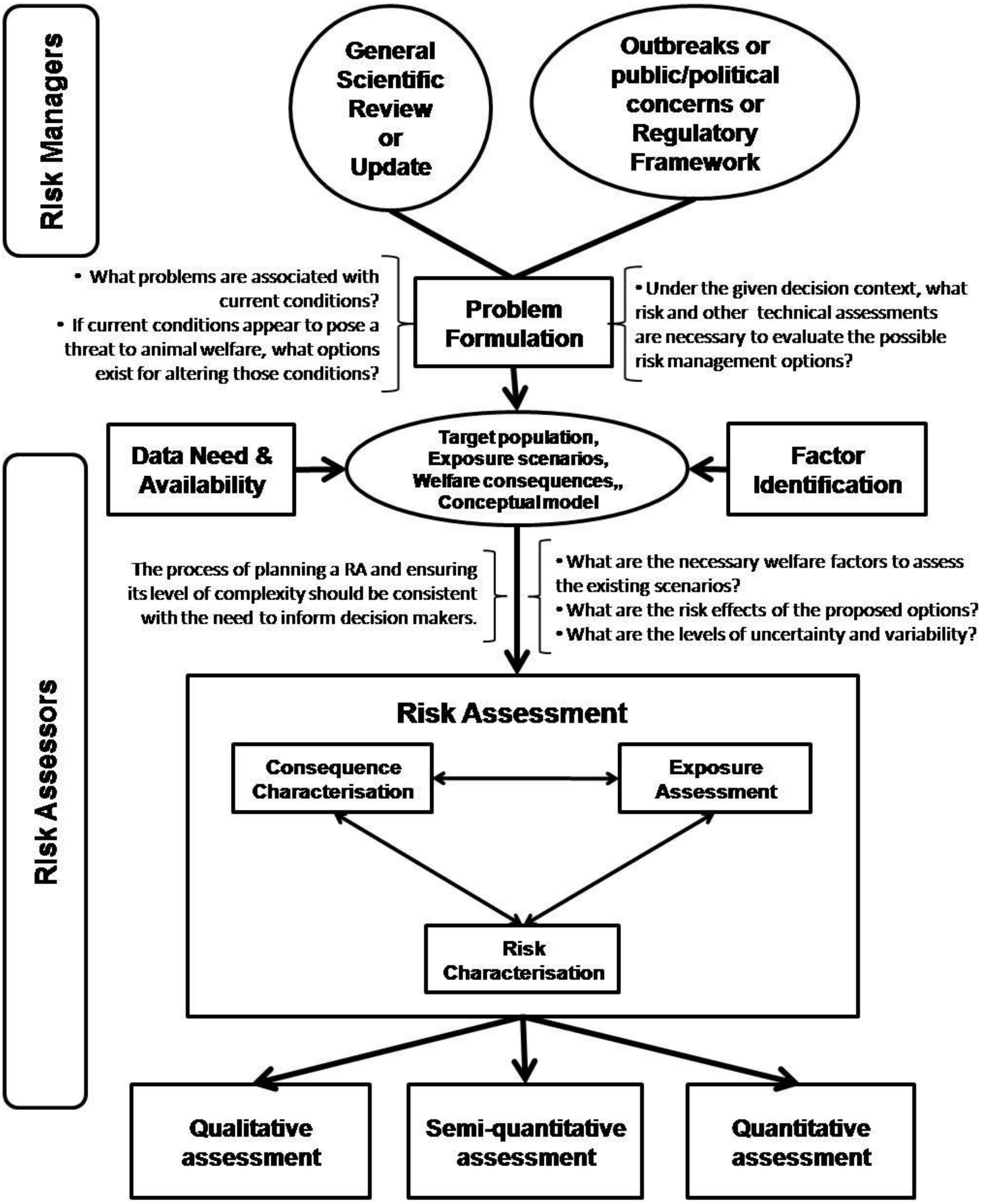


**Figure 1:** Workflow to conduct a risk assessment

### 3.1. Problem formulation

Problem formulation precedes the formal risk assessment and defines the original question that needs addressing. It establishes the purpose, breadth, and focus of the animal welfare risk assessment. Problem formulation comprises the following steps.

1. Clarify the risk question(s)
2. Identify the target population
3. Identify factors of animal welfare concern
4. Identify exposure scenarios
5. Identify the known animal welfare consequences and their measurement
6. Build a conceptual model, including identification of the relevant methodology and the data needs

**Risk question(s):** During problem formulation, the aim of the exchanges between the risk managers and the risk assessors is to achieve precise and clear formulation of the risk questions (see Box 2).

The questions may arise within the management context of enforcing a new policy or procedure or defining requirements for the application of alternative policies or procedures.

**Box 2. A risk question can typically be:**

- A factor-based question: for example, how does a potential management option compare with an existing option regarding the risk for the welfare of the animals?
  *Examples*: *welfare consequences of changing transport duration; consequences for welfare of reducing ante-mortem inspection procedures; consequences for welfare when rearing laying hens in large cages.*
- A consequence-based question: for example, what is the welfare consequence of changing an existing management system to an alternative system?
  *Examples: how to transport animals in order to minimise heat stress; identifying the risks when animals are killed by Method A vs Method B; the best way to minimize the risk of injuries during pre-slaughter*.

**Target population:** The population considered in the risk assessment is a subset of the animal population, and is defined by a set of common characteristics (e.g. geographical area, and intrinsic attributes such as age, breed, sex, etc.) in relation to the risk question(s).

As an example, depending on the risk question, the target population could be dairy cows in general or dairy cows farmed in a particular system (dairy cows kept in cubicle houses; dairy cows kept in tie stalls; dairy cows kept in straw yards; and dairy cows kept at pasture) in a particular region.

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; and the mode of transport (e.g. truck, boat, aeroplane).

**Factor identification**: Factors are defined as any aspect of the environment of the animals in relation to housing and management, animal genetic selection, transport and slaughter, which may have the potential to impair or improve their welfare. A hazard is a factor with the potential to cause poor welfare.

Identification of factors should be based on the scientific literature. In this step, in accordance with the risk question(s), as well as the target population and exposure scenario, the aim is to list all the relevant factors that have the potential to influence the animals' welfare.

Factor selection commences with the preparation of a list of the needs of the animals under consideration which is compiled using the scientific literature on the biological functioning and strengths of preferences of the animals (EFSA, 2008; p.30). It is then necessary to draw up a clear description of the selected factors related to their known welfare consequences (see the EFSA report on the welfare of dairy cows (EFSA, 2009)).

Factors may have both negative and positive effects, and there may be more than one effect. A scientific literature review should then be undertaken to collate all the available studies identifying the associations between factors and animal welfare effects. Such an analysis highlights the factors likely to influence animal welfare. These are then discussed and prioritised within the target population and the risk questions.

Data describing the magnitude and estimating the probability of occurrence of welfare consequences are extracted from published studies.

**Exposure scenarios**: An exposure scenario is a sequence or combination of events in relation to the risk question that includes, in general, all information on housing, nutrition, genetic selection, transport, farming and management procedures, slaughter procedures and husbandry to which animals of the target population are subjected.

Relevant combination(s) of the identified factors and their exposure levels are defined at this stage. It may be necessary to describe a reference scenario for comparison with the scenario under investigation (e.g. barren *versus* enriched cages for laying hens).

The list of factors may be revised after consideration of the different exposure scenarios.

**Animal welfare consequences and their measurement**: At this stage, risk assessors propose what animal welfare consequences are important for the risk question and how they can be measured. Welfare consequences are **changes in** welfare that result from the effect of a factor or factors (see Figure 2). During this step it should be decided whether or not the assessment will simultaneously include negative (risk) and positive (benefits) consequences. The assessment of the eventual positive consequences is appropriate when: (i) a particular factor or a group of factors could have positive and negative consequences for the same scenario of exposure; or (ii) an exposure scenario can include groups of factors that have both positive and negative consequences.

Animal-based measures (indicators) are necessary to assess the welfare consequences, and their interpretation and assessment will depend on their magnitude (Figure 2). Those animal-based measures of welfare consequences that can be used by a farmer, veterinarian or other trained inspector (welfare measures) are of particular value and these are the subject of a series of EFSA Opinions, such as for dairy cows (EFSA, 2012a), and pigs (EFSA, 2012b).

**Conceptual model, including identification of the relevant methodology and the data needs**: A conceptual model in problem formulation is a written description and visualisation of a model of known or supposed relationships between factors and animal welfare. It considers logically how the changes made to the scenario under consideration will affect animal welfare. Subsequently, the model shows how the risk 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.

Problem formulation is not just a literature review and a description of all the available information about a risk issue. It should also determine the type of risk assessment to be used - qualitative, semi-quantitative or quantitative (see the Glossary). Both of these approaches can be valid: the criteria for selection include time availability, data availability, data quality, as well as resource availability to collect and analyse the data in order to build the model. The framework for risk assessment presented in Figure 1 is used in every case.

### 3.2. Exposure assessment

The assessment of the exposure scenario should include a list of the relevant factors, the level, duration and variability of exposure to those factors for the target population, as well as their interrelations.

The steps are: (i) exposure description, (ii) identification of data required, (iii) data collection, and (iv) interpretation and summarisation of data.

**i. Exposure description**: The exposure to the identified factors is broadly described as:

- **Factor present/absent all the time**. 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; presence of an endemic pathogen, etc) might be sufficiently reflected by constant duration in some scenarios, since they are present or not for the entire time being considered (on-farm, in transport or at slaughter).

- **Factor present/absent during a certain period**. For example, shouting at animals, hitting them, using handling tools such as electric goads, etc.

- **Factor at different levels all the time or during a certain period**. For example, temperature may increase by 5, 10 or 20 ºC, or an increase of 5 ºC degrees that may last for 1, 2 or 5 days.

Factors can be expressed as a categorical, ordinal or continuous variable. A **categorical variable** (or nominal variable) is one that has two or more categories, but there is no intrinsic ordering of the categories. An **ordinal variable** is similar to a categorical variable but the difference between the two is that there is a clear ordering of the categories. For example, the consideration of an exposure factor, such as the speed of air movement resulting from ventilation, with three categories (low, medium and high). A **continuous variable** is one that theoretically can assume an infinite number of values between any two points on the scale. For example, the consideration of an exposure factor, such as a toxic chemical substance, with an infinite number of values for ingested doses. The level of a factor is relevant only for ordinal and continuous variables.

**ii. Identification of data required**: The level, duration and variability of the exposure have to be described. Description of variability may require quantitative or qualitative methods as appropriate. Whenever possible, exposure is better assessed based on observational and experimental studies. In the risk assessment the data may pertain to one type or several types of farming system, or to one or several regions.

**iii. Data collection**: the data can be obtained from published papers in scientific journals or scientific reports and extracted directly or indirectly from databases collected and stored by governments or non-governmental organisations.

After the identification of data sources, protocols and methodology are needed in order to extract properly the data required for the risk assessment question.

In order to facilitate data validation and data quality assessment, the methodology used for data collection, including the definition of metadata standards for outcome values, needs to be described at this stage. Metadata may include sampling frame, characteristics of diagnostic tests or animal-based measures.

**iv. Interpretation and summarisation of data**: Data are analysed with the appropriate statistical methods and interpreted by the working group experts in the light of the available metadata. The quality of the exposure assessment depends upon the validity of the data used. At this stage it is therefore necessary to assess quantitatively or qualitatively all elements of uncertainty relating to the exposure data.

If the data are absent or inadequate, it may be necessary to use expert elicitation. More details about expert elicitation are provided in Appendix B

If the risk assessment is considering a combination of factors, the analysis of available data must examine and assess the possible factor associations. An association exists if exposure to one factor affects the characteristics of exposure (e.g. level, duration, variability) to a second factor.

### 3.3. Consequence characterisation

Consequence characterisation provides a qualitative or quantitative description of the intensity and duration of the animal welfare consequence(s) that may result from the exposure to a factor or exposure scenario (see the case studies in Appendix A). It starts with the description of welfare consequences for which the welfare criteria (see the Glossary) provide a general guide. A list of measures is selected in order to describe the consequences. The interpretation of the scores for each measure will provide an assessment of the intensity for each specific welfare consequence (see Figure 2). The magnitude is the mean intensity times the duration of the measured welfare.

If one factor is characterised by various levels and duration, then the welfare consequence assessment has to be repeated for all the relevant combinations by level and by duration.

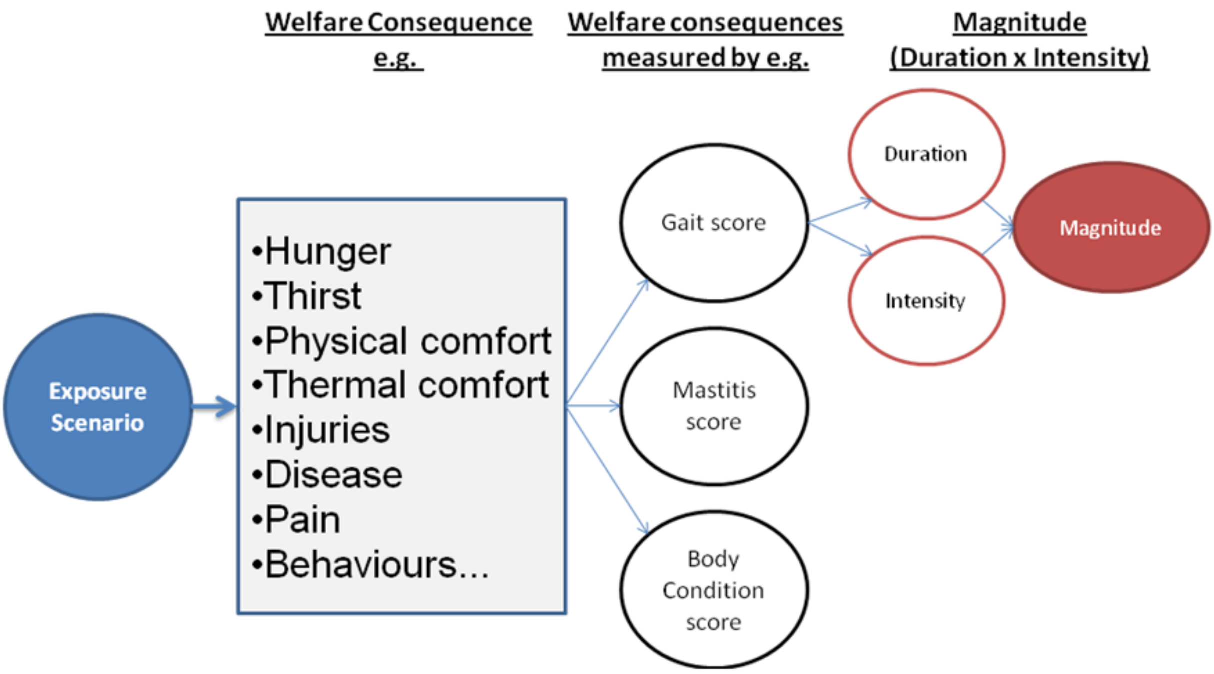


**Figure 2:** Consequence characterisation flowchart

The following steps should be considered:

**Description of the welfare consequence**: The consequence of exposure to a factor at a certain level and duration is identified. For several factors the nature of the consequence may differ as the factor level and duration of exposure changes. A cascade of potential consequences may be defined (e.g.

'sweating' to 'dehydration' if the environment becomes warmer). In some cases the consequence remains constant (e.g. 'death' from heat remains 'death' at higher heat levels). When the consequences are additive along the cascade instead of replacing one other, the indicator reflecting the most intense consequence should be considered as corresponding to the respective level of the factor.

**Duration of the consequence**: The duration of the consequence should be considered. This is illustrated by an example of bad handling of an animal when the animal is shocked with an electric goad at different electric currents. As a consequence of a mild shock, the animal may respond with acute fear indicated by vocalisation. However, the fear reaction will slowly decline over some minutes or hours as the animal recovers. As a consequence of a brutal shock from the goad, the animal may show a more intense acute fear response and vocalisation but, in addition to this more intense fear response the animal may also be injured as measured by a skin wound. The injury could take some days or weeks to heal, the memory of the experience and perhaps drastic change in behaviour such as avoidance of humans, could also take some days or weeks to heal or recover and the behaviour effect could even be permanent. The duration of the consequence of the brutal shock with the electric goad is therefore longer than the duration of the consequence of the mild shock. The measurement representing the greatest intensity of consequence in response to a given factor level should be selected for modelling

**Intensity assessment**: The intensity of the expected consequences is assessed whenever possible using evaluation from the scientific literature. If this is not adequate or available, the expert elicitation approach (see Appendix B) can be used to assign a welfare intensity score based on perceived pain and distress associated with the expected welfare consequence.

**Interaction between factors**: An interaction exists between two factors if one or several animal welfare consequences related to a factor is (are) modified when the animal is exposed to the other factor. For example, it is well known that wet litter increases the risk of hock burn (a type of contact dermatitis) and that leg weakness involves pain when walking (EFSA, 2010). This means that a bird will stand less and sit more, thus having its hocks in contact with the litter. Therefore, even if hock burns are not a direct consequence of leg weakness, in combination with wet litter, leg weakness is a factor that increases the risk of hock burn. Depending on the quantity and quality of the available experimental or field data, statistical tools may be used quantitatively to assess the interactions.

**Probability assessment**: The probabilities of the occurrence of the identified consequences are assessed based on the existing scientific information. Ideally, at this stage available data are collected and statistically analysed to assess the probabilities.

The accuracy and validity of a given consequence characterisation and the resulting modelling are dependent on the existence of adequate scientific data. It is necessary to describe, at each step of consequence characterisation, the data used and how knowledge and data gaps are to be handled. If data are absent or inadequate, it may be necessary to use expert elicitation (see Appendix B).

The welfare consequences may be positive or negative. Where they are wholly positive, or when the consequence is a reduction in negative effects, a benefit assessment may be conducted.

### 3.4. Risk characterisation

Risk characterisation is the process of determining the qualitative or quantitative estimation, including attendant uncertainties, of the probability of occurrence and magnitude of welfare consequences in a given population. It consists of integrating the results from exposure assessment and consequence characterisation.

The structure and endpoints of risk characterisation will differ from assessment to assessment depending on the risk question being asked. This section presents examples of general types of risk assessment results that may be useful for the risk managers. Specific endpoints (see the Glossary) may need to be established at the problem formulation stage.

**Occurrence of welfare consequences factor by factor**: Theoretically, for each factor the probability of occurrence of a welfare consequence is derived by multiplying the probability of exposure by the probability of the occurrence if exposed (see Box 3). This can be conducted at the level of either the individual or the group, or both.

If a factor is associated with two or more welfare consequences (e.g. lameness and mastitis), the consequences due to this factor will be characterised by two or more probabilities (e.g. one for the occurrence of lameness and the other for the occurrence of mastitis).

**Occurrence of welfare consequences scenario by scenario:** For each exposure scenario the occurrence of all the expected welfare consequences are assessed (see Box 3).

If several factors are contributing to the same welfare consequences, say lameness, the expected probability of lameness will be derived according to the probability calculation rules (see the Glossary) taking into account all the possible combinations of exposure of individuals or a group of animals to the considered factors and the possible interaction between the factors.

The endpoints of the risk characterisation in this case describe the impact of the different factors in terms of their effect on one single welfare consequence. Thus, the risk assessment is carried out considering the different welfare consequences separately.

When different exposure scenarios are compared (e.g. different farming systems), first the probability of the different welfare consequences can be compared one by one without any combination. Secondly, the magnitude of different consequences can be calculated and compared. At this stage it may be possible to consider the total outcomes of the various negative consequences.

**Use of magnitude of welfare consequences:** since the different welfare consequences differ in their intensity and duration, the probability of the occurrence of the welfare consequences associated with each factor or each scenario is multiplied by its magnitude (multiplication of the mean intensity of the consequence by the consequence duration). This operation provides a common metric for the welfare consequences.

The endpoint of the assessment of the risk of poor welfare is described as in Box 3.

**Box 3. Endpoints for the assessment of the risk of poor welfare**

For a given factor in a given exposure scenario:

Risk (associated to a **Factor** F)
=
(Magnitude of consequence $M_C$)
**X**
(Probability of welfare consequence ($P_C$) given exposure to factor F)
**X**
(Probability of exposure to factor ($P_E$) within the considered scenario)

Or, for an exposure scenario:

Risk (associated to an Exposure **Scenario** S)
=
(Magnitude of consequence $M_C$s)
**X**
(Probability of welfare consequence ($P_C$s) given exposure to a set of factors $\mathcal{F}$)
**X**
(Probability of exposure to a set of factors $\mathcal{F}$ ($P_E$s) within the considered scenario)

Calculations have to be made for all the considered consequences and the principle for these calculations applies to all type of risk assessment. However the calculations are only performed in quantitative and semi-quantitative risk assessments, using probability estimates or scores respectively.

An indication of uncertainty should accompany each estimate of probability or score.

The whole procedure described for risk assessment is likely to be appropriate for the assessment of benefits.

## 4. Risk assessment documentation

Data needed for risk assessment are often incomplete or only partially relevant in one way or another. Experts involved in risk assessment are asked to review and assess the quality of available data and they play a critical role in the interpretation and characterisation of these data.

Risk assessment documentation should include the following.

- The rationale for the specific questions to be answered
- Terms of reference
- Description of the target population
- The rationale for the scenarios of exposure
- Data or references to data sources, including the criteria used to include or exclude the available data
- The analytical model used, including the theoretical and field data as appropriate

- Discussion and comparison of alternative methodological approaches, and justification for choices made regarding the approach used

- Description of how knowledge and data gaps are handled, including expert elicitation protocols (see Appendix B)

- Discussion of risk assessment model verification, including model specification and checking for errors

- Assessment of results from sensitivity and uncertainty analysis

- Discussion of risk assessment validation (i.e. how the model meets its intended requirements in terms of the methods employed and the results obtained)

The principle of transparency requires that risk assessment should be completely and scientifically documented and communicated to the risk manager, and to interested independent parties so that other risk assessors can critically review and repeat the assessment.

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# APPENDICES

## A. APPENDIX A: CASE STUDIES

### 1. CONSEQUENCE ASSESSMENT CASE STUDY, CUBICLE HOUSING FOR DAIRY COWS

The consequences of scenarios as defined by a number of factors and interactions between factors on animals of the target population, in this example lactating dairy cows, need to be assessed in terms of the objectives. In this case study the factors have already been determined (see section 3). The factor levels which relate to different dairy cow housing and the consequences can be assessed in terms of welfare measures: the animal's comfort around resting, ease of movement, incidence of injuries, occurrence of disease, expression of pain, and limitations in social behaviour.

<u>Example Step 1:</u>

In this example, the scenarios of "Cow housing" are established as combination of the following factors (with factor levels):

- Access to outdoor loafing area or pasture (yes; no)
- Physical condition of the floor surface (e.g. rubberised, concrete).
- Quality of bedding (sand; inadequate; none)
- Quality of floor management (well managed; poorly cleaned; adequate, depth of slurry, frequency of scraping)
- Design of cubicles (adequate; inadequate; inadequate with dangerous passageways)

The co-occurrence of factor strength and consequence intensity is modelled on a semi-quantitative scale (A to E), where B is set as the baseline state where the animal shows physiological and behavioural patterns in a usual form accepted as standard for the average husbandry system. A defines a state where there is evidence of welfare quality beyond the average (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 (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). In the interests of consistency between assessors, all intensities assessed as intermediate between mild and severe are placed at level D.

Consequence intensity may be defined in terms of increasing intensity of specific welfare measures (e.g. skin and joint lesions) and/or increasing numbers of measures within the overall cascade (e.g. skin and joint lesions *plus* locomotion scoring *plus* mastitis incidence).

**Table A1.** Relationship between strength of factor scenario and consequence intensity for dairy cow housing.

| Scenarios of “cow housing” shown by related factor levels | Welfare measures (examples) | Consequence categorisation | Consequence level |
|---|---|---|---|
| - Access to pasture<br>- No floors | Social behaviour expressed<br>Time of lying at pasture<br>Condition of skin and coat<br>Incidence of locomotor disorders | Optimum social behaviour;<br>Great comfort around resting;<br>Great physical comfort | A |
| - No access to pasture<br>- Rubberised floors<br>- Deep sand bedding<br>- Floor well managed<br>- Adequate cubicle design | Incidence of locomotor disorders | Physiological and behavioural balance | B |
| - No access to pasture<br>- Concrete floors<br>- Inadequate bedding<br>- Floor well-managed<br>- Adequate cubicle design | Lying time in cubicles<br>Incidence of skin lesions<br>Incidence of locomotor disorders | Discomfort at rest<br>Pain and injury | C |
| - No access to pasture<br>- Concrete floors<br>- No bedding<br>- Floor poorly cleaned<br>- Inadequate cubicle design | Prevalence of skin and joint lesions<br>Incidence of locomotor disorders<br>Level of mastitis | Discomfort at rest<br>Impaired movement (e.g. changing position)<br>Pain and injury<br>Infectious disease | D |
| - No access to pasture<br>- Concrete floors<br>- No bedding<br>- Inadequate cubicles design with slippery passageways | >40% with skin and joint lesions<br>>50% with locomotion disturbance<br>>50% showing difficulty in standing up and lying down<br>> 100 mastitis cases/100 cows/year | Marked discomfort at rest and in movement<br>Severe pain and injury<br>Life threatening infectious disease | E |

<u>Example Step 2. Duration of the factor</u>

In this case study the time of application of the factor is not considered as the cows are assumed to spend their time in the respective “cow housing”, hence exposure to the factors and their strength is set constant within each of the scenarios.

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

The duration of the consequences is not considered in the example, since applied welfare measures reflect a momentary situation, for example:

- If standing up and lying down is difficult in cubicles now it will be for the total duration of time spent in the cubicle house.

- Incidence of locomotor disorders is measured momentary knowing that early treatment will last 3-4 weeks (Whay et al., 1997).

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

Example Step 4. Interaction between factors (examples for dairy cow housing)

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

One factor will only cause a welfare change in the presence of another. For example: the intensity of systemic (*E. coli*) mastitis associated with high exposure to dirty floors is greatly increased in early lactation.

When the consequence of exposure to two similar factors (e.g. harmful) is greater than the sum of the consequences of the two factors present in isolation. For example: Injurious and badly maintained walkways plus inadequate foot care (claw trimming, early diagnosis and treatment of lameness).

## 2. EXAMPLE FOR QUANTITATIVE RISK ASSESSMENT

**Risk Assessment to evaluate the effect of using sexed semen relative to regular semen on the welfare of first lactation dairy cows.**

This example was developed to illustrate each step of the risk assessment process conducted to address a real life welfare problem in dairy cattle. The example follows the steps outlined in this guideline: (1) Problem formulation that includes clarification of the risk question, identification of the target population, description of the exposure scenarios, identification of factors affecting the welfare and identification of welfare outcomes (consequences) and the measurements used to assess them; (2) exposure assessment that includes defining the exposure to different factors, acquisition of necessary data and use of the data to characterize factor exposures; (3) consequence characterization that includes description of welfare consequences, definition of duration, intensity and magnitude for each welfare consequence and the likelihood assessment for welfare consequences when exposed to a factor; and (4) risk characterization assessing the welfare burden (combined effect of all welfare consequences considered) for each scenario.

### 1. Problem formulation

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. The type of parturition is greatly dependent on the sex of the calf, with higher frequency of dystocia for male calves relative to female calves (.25 vs. .05). A second major welfare problem is associated with the bull calves born in a herd. Past selection for “dairy type” led to decreased economic value of bull calves. Some are transported long distances to veal farms when two weeks old but many are killed on the farm at birth.

The current reproductive management program in dairy herds consists of artificial insemination (AI) of cows using regular semen from bulls most likely chosen for their superior genetic merit for milk production with little attention to their genetic merit for ease of calving.

Sexing of semen is a technology now available for the dairy farmer. *The risk question* to be evaluated is: what is the impact of using of sexed semen relative to regular semen on the welfare status of the animals in a dairy herd?

The *target population* consists of first lactation dairy cows.

In this risk assessment example the *exposure scenarios* that are compared are two management strategies, use of regular semen versus sexed semen. It is hypothesised 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.

The most important risk factor, as stated above, is the sex of the calf, other factors known affect parturition type that should be considered are age at first calving and season of calving.

The *welfare consequences* considered in this risk assessment example are: dystocia (DYST), calf born dead (STLB), retained placenta (RTPL), metritis (METR), cystic ovaries (CYST) and anestrous (SLHT). Culling (CULL), representing the termination status for each record (subsequent calving and death or culled from the herd) was also considered a welfare consequence as it affects length of productive life (longevity).

*Conceptual model* is described as follows: In the "regular semen" scenario, a heifer is inseminated with regular semen, get pregnant and carry a male or female calf (50:50 ratio) to parturition. The parturition is either normal or complicated (requires veterinary assistance = dystocia). The major factor determining the type of parturition is the sex of the calf (i.e., its size). A cow with a difficult first calving is much more likely to develop subsequent health problems, such as retained placenta, metritis, cystic ovaries or anestrus and be culled from the herd relative to a cow with a normal parturition. In the "sexed semen" scenario, a heifer is inseminated with sexed semen, get pregnant and carry a female calf (100:0 ratio) to parturition. The parturition is either normal or dystocia and it is followed by the same possible sequence of welfare consequences. Data is needed to quantify the probabilities of normal parturition or dystocia given the sex of the calf and the probabilities of subsequent welfare consequences considered, given the type of parturition.

## 2. Exposure assessment

Multiple logistic regression techniques and path analysis have been used to unravel the complex web of causal relationships between diseases (Oltenacu et al., 1990). The average incidence rate of difficult calving at first calving (DYST) in the target population was 0.15, but 5 times greater (0.25) if the calf born was male then if it was female (0.05). A path diagram describing the associations between difficult calving (DYST) and subsequent diseases (welfare consequences) expressed as odds ratios relative to cows with normal parturition for first lactation dairy cows are shown in the Figure A1.

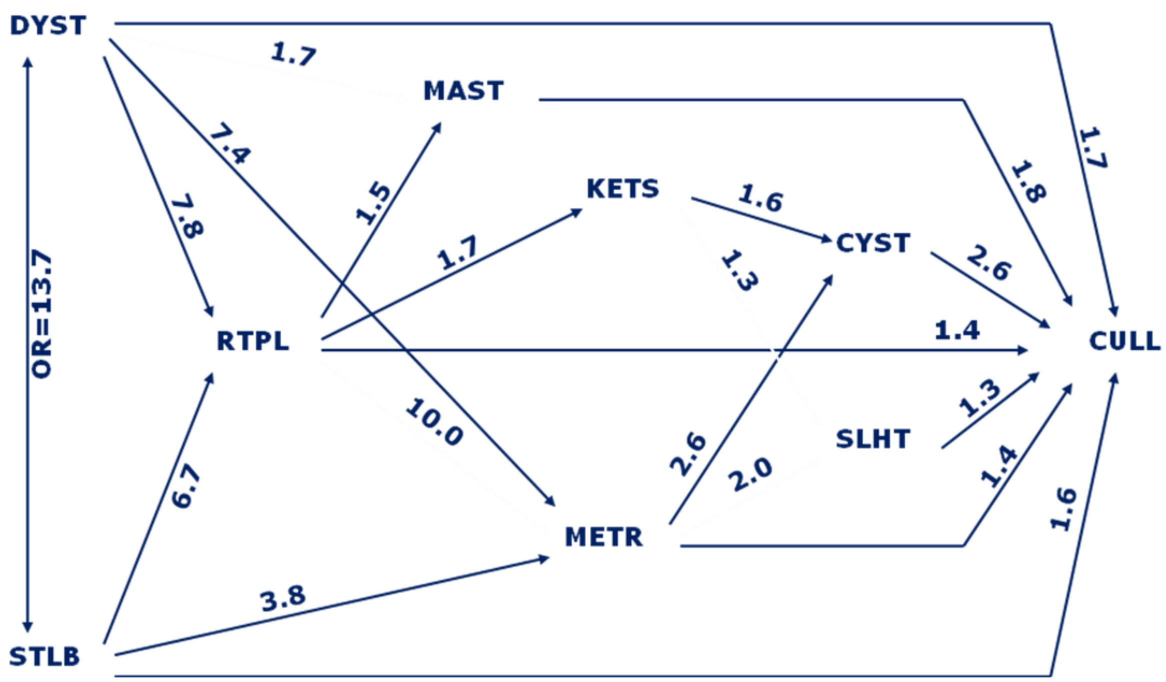


**Figure A1:** Path analysis model describing association between calving status and subsequent diseases in first lactation cows.

In addition to sex of the calf, age at first calving and season of calving were accounted for statistically (included in the statistical model). Other factors, such as nutrition, etc., that may affect the type of parturition but were not included in the model were assumed to be identical for the two scenarios evaluated.

### 3. Consequence characterization

At this stage, the intensity, duration and resulting magnitude of each welfare consequence and its likelihood to occur in an individual is assessed. In this example we have essentially one factor (sex of the calf) and multiple consequences.

The expert elicitation approach was used to assign a "qualitative" welfare score (its magnitude) based on perceived pain and suffering associated with each welfare consequence using a score of 0 to 10 welfare units (wu) (from none 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 scale, a score to describe the welfare problems associated with the sex of the calf born was also assigned, with 0 wu if the calf is female and 10 wu if it is male.

### 4. Risk characterization

In this final stage the probability of occurrence and the magnitude of welfare consequences. In this example the welfare consequences are assessed for each scenario.

A tree diagram (Figure A2) was constructed describing the possible sequence of welfare consequences a cow with a difficult calving (DYST=yes) or normal (DYST=no) calving can experience. The disease sequence (yes or no) considered was:

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

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

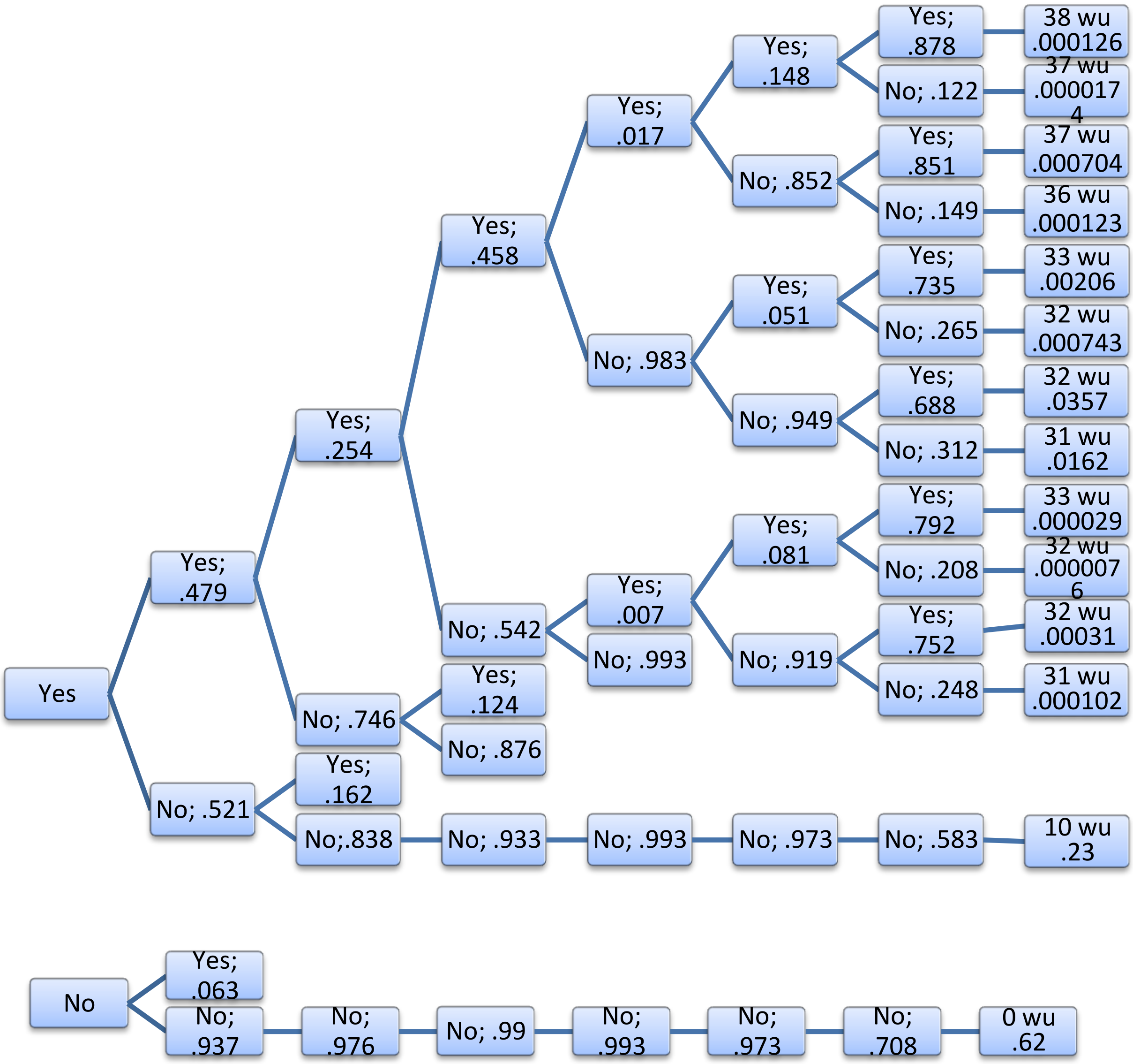


**Figure A2:** Tree diagram describing the sequence of disease events, conditional probabilities and probabilities for each branch. The welfare scores for each branch were calculated considering only the disease events. For the scenario "sexed semen" it represents all welfare consequences because in this scenario all calves born are female and there are no welfare consequences for them. For the scenario "regular semen", 5 wu are added to each branch representing the welfare cost of unwanted male calves (remember, the sex ratio is 50:50).

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 the cumulative welfare score, have been calculated. 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 (increasing from 0 representing no pain or suffering, to major pain and suffering).

For example, the probability of a first lactation cow with calving difficult parturition (DYST=yes) not to develop STLB or RTPL or METR or CYST or SLHT and also not to be culled from the herd is (see Figure A1):

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

It is assumed that the experts consulted for this assessment concluded that the pain and suffering associated with these diseases is additive. Therefore, the welfare score for a cow that experience this particular sequence of welfare events is equal to:

(10)+(0)+(0)+(0)+(0)+(0)+(0) = 10

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 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 15 wu.

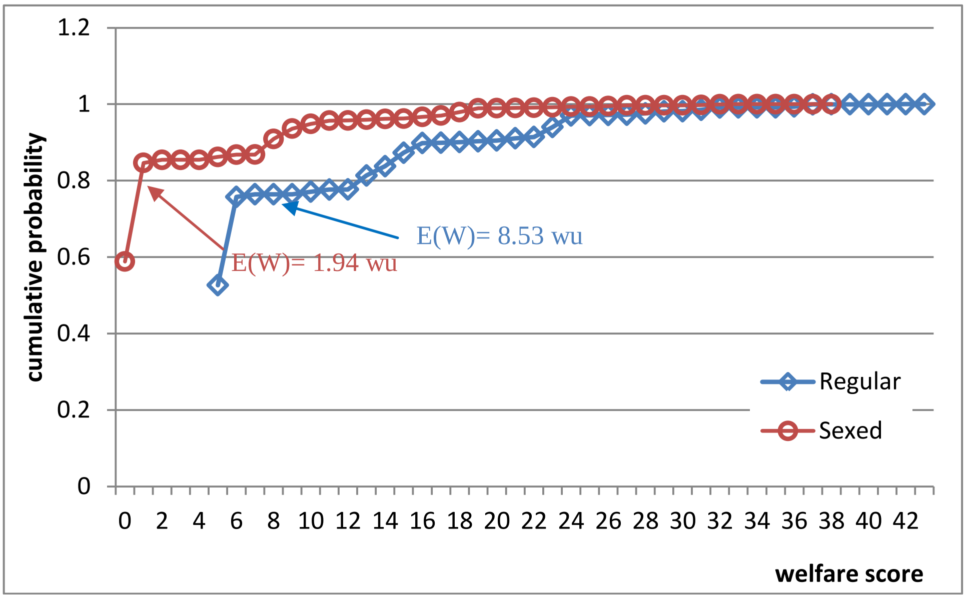


**Figure A3:** Cumulative probability of all possible welfare outcomes for first lactation cows when using regular or sexed semen.

The probabilities of all possible outcomes for the two management strategies (scenarios) considered in this example (using standard semen *vs.* sexed semen) were calculated and the cumulative probabilities of outcomes against the welfare score for each strategy were plotted in Figure A3. The expected welfare score E(W) was calculated 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 8.53 wu for standard semen, there is a decrease in expected welfare score (welfare improvement resulting from reduced pain and suffering) of 6.59 wu.

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 (76%) is associated with elimination of unwanted male calves. Additional benefits (24%) come from lower frequency of diseases.

## B. APPENDIX B: EXPERT ELICITATION

Expert elicitation (EE) is a multi-disciplinary process that can help to characterise uncertainty and fill 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) concerning 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:

- Scientific evidence is not available or 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 uncertainty limits that are more robust 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 experts within the appropriate disciplines, using the right information, or whatever information is 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 opinion in risk assessment can present difficulties, due to 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 heuristics in cognitive psychology, but four types are particularly common: 1) the effect, 2) anchoring and adjustment, 3) the availability and 4) the representation (Tversky and Kahneman, 1974; O' Hagan et al., 2006).

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 usually implies the impact of risk assessment on the management decision. For example, experts could underestimate the probability of a disease caused by the exposure to a contaminant if they feared that a high estimate might involve closing-down of factories or if they were remunerated by the owners of these factories. On the other hand, they could tend to over-estimate this probability if it was feared that they would be accused by their 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’s memory, since one can reach them more quickly and more easily. Presented differently, the heuristics of availability eliminate the older facts and information. For example: i) The media can reproduce facts concerning a disease and give the impression that the probability of contracting this disease is higher than it should actually be; ii) The studies with more dramatic outcomes will tend to be remembered more strongly than other studies with negative (non-significant) results; and iii) The studies published more recently will be more accessible to the expert‘s memory.

4) Lastly, the heuristics of representation could also have been called the heuristics of association since they consists of estimating the probability of an event while being based on the probability of another event that is associated or similar to it. For 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 of an exaggerated over-generalisation to the general population of 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: familiarising 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 so that all experts define and use the same words in the same way.
- 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 the experts 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.

## GLOSSARY AND ABBREVIATIONS

The following definitions are included to establish a common understanding of the terms used in this document.

**AHAW:** EFSA Scientific Panel on Animal Health and Animal Welfare

**Animal-based measure**: a response of an animal or an effect on an animal. It can be taken directly from the animal or indirectly and includes the use of animal records. The measure may, for example, be intended to: (i) assess the degree of impaired functioning associated with injury, disease, and malnutrition; (ii) provide information on animals' needs and affective states such as hunger, pain and fear, often by measuring the strength of animals' preferences, motivations and aversions; or (iii) assess the physiological, behavioural and immunological changes or effects that animals show in response to various challenges.

**Benefit:** is a function of the probability of positive welfare consequences and the magnitude of those consequences, following exposure to a particular factor or exposure scenario, in a given population.

**CAC:** Codex Alimentarius Commission

**Conceptual model:** a written description and visual representation of predicted relationships between factors that affect welfare and the animal welfare aspects that are being considered in a problem formulation.

**Consequence characterisation**: the qualitative or the quantitative evaluation of the nature of animal welfare effects associated with a given factor in a given exposure scenario.

**EFSA:** European Food Safety Authority

**Endpoint:** the impact of a factor in terms of its welfare consequence.

**Expert elicitation:** A multi-disciplinary survey of expert opinion that can inform decision making by characterising uncertainty and filling data gaps where traditional scientific research is not possible or data are not yet accessible or available (see Appendix B).

**Expert opinion (judgement):** The views on particular issues of those who have experience on farming procedures, such as veterinarians in practice or practising farmers, particularly for welfare consequences.

**Exposure assessment**: The qualitative or quantitative evaluation of the level, duration, and variability of exposure to the identified factors.

**Exposure scenario**: A sequence or combination of events in relation to the risk question that includes all information on housing, nutrition, genetic selection, transport, farming and management procedures.

**Factor**: Any aspect of the environment of the animal in relation to housing and management, animal genetic selection, transport and slaughter, which may have the potential to impair or improve their welfare.

**Hazard:** A factor with the potential to cause poor welfare.

**Magnitude:** A function of the intensity and duration of a positive or negative consequence on welfare.

**Need:** A requirement, which is a consequence of the biology of the animal, to obtain a particular resource or respond to a particular environmental or bodily stimulus.

**OIE:** Office International des Epizooties (World Organisation for Animal Health).

**Qualitative risk assessment**: A risk assessment that provides categorical or ordinal expressions of risk and indication of the attendant uncertainties.

**Quantitative risk assessment**: A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties.

**Risk**: A function of the probability of negative welfare consequences and the magnitude of those consequences, following exposure to a particular factor or exposure scenario, in a given population.

**Risk analysis**: A process consisting of the three components: risk assessment, risk management and risk communication.

**Risk assessment**: A scientifically-based process consisting of the following steps: (i) exposure assessment; (ii) consequence characterisation; and (iii) risk characterisation.

**Risk characterisation**: the qualitative or quantitative estimation, including attendant uncertainties, of the probability of occurrence and magnitude of known or potential adverse animal welfare effects in a target population based on factor identification, consequence characterisation and exposure assessment.

**Semi-quantitative risk assessment**: A risk assessment based on data which, while forming an adequate basis for numerical risk estimates, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties, permits risk ranking or separation into descriptive categories of risk.

**Target population**: A population considered in a risk assessment, where a population is a group of animals defined by a set of common characteristics (e.g. geographical area, and intrinsic attributes such as age, breed, sex, etc.).

**Uncertainty:** Uncertainty is the expression of lack of knowledge that can be reduced by additional data or information.

**Variability:** The heterogeneity of the subjects modelled, including both stochastic variability (randomness) and inter-individual variability. Variability cannot be reduced by additional data or information.

**Welfare**: The welfare of an individual is its state as regards its attempts to cope with its environment. The welfare of an animal is good if , as indicated by scientific evidence, it is healthy, comfortable, well-nourished, safe, able to express key aspects of behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane slaughter/killing. Animal welfare refers to the state of the animal, whereas the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, management, and humane treatment.

**Welfare consequence:** the change in welfare that results from the effect of a factor or factors.

**Welfare criteria:** represents a specific area of welfare concerns that has to be addressed to satisfy good animal welfare (Welfare Quality, 2009).

**Welfare measure:** a category of observation, recording or evaluation used to assess an animal's welfare.

**Welfare measurement:** The actual numerical or other score obtained when a welfare measure is used.

**Welfare principles:** collection of criteria associated with one of the following four areas: feeding, housing, health and behaviour (Welfare Quality, 2009).