SCIENTIFIC OPINION

Methodological guidance for the development of animal welfare mandates in the context of the Farm to Fork Strategy

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Abstract

This document provides methodological guidance developed by the EFSA Panel on Animal Health and Welfare to produce Scientific Opinions in response to mandates received from the European Commission in the context of the Farm to Fork Strategy. The mandates relate to the welfare of (i) animals during transport, (ii) calves, (iii) laying hens, (iv) broilers, (v) pigs, (vi) ducks, geese and quails, and (vii) dairy cows. This guidance was developed in order to define the methods and strategy to be applied for responding to the Terms of Reference (ToRs) of the mandates. The mandates each consist of a set of General ToRs which refer to the husbandry systems used in the production of each animal species or the current transport practices for free moving animals and animals transported in cages, and a set of specific ToRs for which difficulties in ensuring animal welfare have been identified and where specific scenarios are envisaged. Part I of the guidance includes a description of welfare consequences for the animals. Part II includes a new methodology for providing quantitative recommendations regarding animal welfare. The proposed methodology follows the assumption that the effect of an exposure variable (e.g. space allowance) on animal welfare can be quantified by comparing the expression of an animal-based measure (ABM) under 'unexposed conditions' (e.g. unlimited space) and under high exposure (e.g. restrictive conditions). The level of welfare as assessed through this ABM can be quantified for different levels of the exposure variable (e.g. at increasing space allowances) and quantitative recommendations can thus be provided. The final version of the methodological guidance was endorsed for public consultation, which took place between 14 February 2022 and 31 March 2022. The comments received are integrated in this document.

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Keywords: animal welfare assessment, Farm to Fork Strategy, husbandry systems, welfare consequences, animal-based measures

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1. Introduction

The purpose of this document is to present a methodological guidance to develop several Scientific Opinions on welfare and protection of animals in response to seven mandates received from the European Commission in the context of the Farm to Fork Strategy (F2F) revision.

The European Commission requested EFSA with seven mandates and EFSA will respond with 11 opinions because the original mandate on transport was split in five opinions.

The list of 11 Scientific Opinions to which this methodological guidance refers to is therefore:

1) Protection of animals during transport (free-moving animals – cattle)
2) Protection of animals during transport (free-moving animals – pigs)
3) Protection of animals during transport (free-moving animals – horses, donkeys and their crossings)
4) Protection of animals during transport (free-moving animals – sheep and goats)
5) Protection of animals during transport (animals transported in containers)
6) Protection of pigs
7) Protection of calves
8) Protection of domestic fowl kept for production of eggs (laying hens)
9) Protection of domestic fowl kept for meat production (broilers)
10) Protection of ducks, geese and quail
11) Protection of dairy cows

The opinions will be published between September 2022 and April 2023. Eight working groups are set up to develop the opinions, namely two working groups for all transport opinions and one per each of the other animal categories.

The development of this common methodology is executed by a working group called 'Welfare task force F2F' that involves EFSA staff (including an elicitation specialist), members of the different WGs and AHAW Panel members (including experts familiar with the guidance documents on uncertainty analysis in scientific risk assessments) (EFSA Scientific Comittee, 2018).

The methodological guidance was developed following the recommendations of the EFSA guidance protocol development (EFSA, 2020). It is developed as a 'generic' guidance that allows the different WGs to flexibly adapt it for the specific situations of their mandates (e.g. species-specific scenarios). The draft document has been launched for public consultation on 14 February 2022 until 31 March 2022 and the outcome of the public consultation can be found in Annex A.

1.1. Background and Terms of Reference as provided by the requestor

The mandates and their ToRs are reported in the next chapters.

In order to develop the methodology for the eleven F2F scientific opinions, a summary of the Terms of Reference (ToRs) is described here. In general, the ToRs of all mandates can be divided into two parts:

— Part I consists of general and descriptive ToRs (e.g. description of current husbandry systems and associated relevant welfare consequences; description of transport practices and associated relevant welfare consequences).
— Part II consists of specific ToRs and refers to specific scenarios (e.g. specific animal category, specific transport practices), for which the EC has found difficulties in ensuring animal welfare and for which a quantitative approach is envisaged. Specific ToRs are reported for each mandate.

1.1.1. Mandate on animal transport

The following groups and categories of farmed animals have to be considered.

- Group 1: free moving animals including equids, bovines, small ruminants and pigs;
- Group 2: animals in containers such as domestic birds (chickens for meat, end of lay hens, turkeys, ducks, geese, quails) and rabbits.

1.1.1.1. Part I transport – general ToRs

Describe based on existing literature reports and available data on the current practices regarding: (a) the preparation for transport, loading (including catching and crating of poultry and rabbits), journey, unloading and handling of animals at all stages of the journey, including at destination; (b) the means of transport by road and air, roll-on-roll-off vessels, livestock vessels; (c) the conditions

within the means of transport: space, microclimatic conditions, watering and feeding; (d) the journey duration and its circumstances as well as the resting of animals in the vehicle being stationary or at control posts; (e) the conditions for areas where animals are unloaded and/or grouped as part of the journey. Legally a journey is considered as short (< 8 h), long (> 8 h) and very long (> 24 h, long journeys that need unloading and/or feeding).

For each of the phases (i) describe the relevant welfare consequences for each category of animals during each step of the process; (ii) define qualitative or quantitative measures to assess the welfare consequences during transport (animal-based measures); (iii) identify the hazards leading to these welfare consequences and, (iv) provide recommendations to prevent and/or correct the hazards and to mitigate the welfare consequences (resource and management-based measures).

1.1.1.2. Part II transport – specific ToRs

For the following scenarios, the Commission has identified practical difficulties or insufficient information in ensuring the welfare of animals. For these, EFSA should propose detailed animal-based measures and preventive and corrective measures with, where possible, either qualitative (yes/no question) or quantitative (minimum/maximum) criteria (i.e., requirements to prevent and/or correct the hazards and to mitigate the welfare consequences):

1) "Export by livestock vessels" - Transport of adult cattle, weaned calves and sheep over long journeys involving the combination road/livestock vessels;
2) "Export by road" - Transport of adult cattle, weaned calves and sheep over long journeys by road involving the use of facilities where animals are unloaded and reloaded (control posts, livestock markets) or when animals are kept in stationary vehicles for hours (exit points) including in third countries;
3) "Roll-on-roll off" - Transport of adult cattle, calves and sheep over long journeys involving the combination road/roll-on-roll-off vessels;
4) "End-of-career animals" - Transport of end of career animals to slaughterhouses of dairy cows, breeding sows, and laying hens;
5) "Unweaned calves" - Transport of unweaned calves over long journeys; this scenario will particularly consider the risks regarding fitness for transport, watering, feeding and thermal comfort, inappropriate drinkers and liquid feed for unweaned calves;
6) "Horses" - Transport of horses on long journeys to slaughterhouses;
7) "Special health status animals" - Transport of ruminants and pigs where unloading them before the final destination might jeopardize their health status.

For all of these specific scenarios, the risks should be assessed regarding microclimatic conditions under the current practices associated with extremely high or low temperatures including the difficulty of measuring of temperature, humidity and gas concentration within animals' compartment.

1.1.2. Mandate on protection of pigs

1.1.2.1. Part I – general ToRs

For each specified category of animals (age, production, etc.) EFSA should (i) describe, based on existing literature and reports, the current husbandry systems and practices of keeping them, (ii) describe the relevant welfare consequences, (iii) define qualitative or quantitative measures to assess the welfare consequences (animal-based measures (ABMs)), (iv) identify the hazards leading to these welfare consequences and (v) provide recommendations to prevent and/or correct the hazards and to mitigate the welfare consequences (resource and management based measures).

1.1.2.2. Part II – specific ToRs

For the following specific scenarios, the Commission has identified practical difficulties or insufficient information in ensuring the welfare of animals. For these, EFSA should propose detailed animal-based measures and preventive and corrective measures with, where possible, either qualitative (yes/no question) or quantitative (minimum/maximum) criteria (i.e., requirements to prevent and/or correct the hazards and to mitigate the welfare consequences).

- Specific Scenario 1: The welfare of gilts and dry pregnant sows after weaning in individual and group housing systems, during the first four weeks of pregnancy;

- Specific Scenario 2: The welfare of gilts and dry pregnant sows one week before farrowing in different housing systems offering different degrees of behavioural freedom;
- Specific Scenario 3: The welfare of sows and piglets from farrowing to weaning in different housing systems offering different degrees of behavioural freedom;
- Specific scenario 4: The welfare of weaners and rearing pigs, in particular with the risks associated with weaning, space allowance, including competition for space, types of flooring, including poor cleanliness and comfort, enrichment material, air quality, health status, diet, including competition for food and the practice of mutilations (tail docking, tooth clipping, castration);
- Specific Scenario 5: The assessment of ABMs collected in slaughterhouses to monitor the level of welfare on pig farms (such as tail damage, stomach ulcers, lung lesions).

1.1.3. Mandate on protection of calves

1.1.3.1. Part I − general ToRs

Same as for the mandate on pigs (see details in Section 1.1.2.1).

1.1.3.2. Part II − specific ToRs

For the following scenarios, the Commission has identified practical difficulties or insufficient information in ensuring the welfare of animals. For these, EFSA should propose detailed animal-based measures and preventive and corrective measures with, where possible, either qualitative (yes/no question) or quantitative (minimum/maximum) criteria (i.e., requirements to prevent and/or correct the hazards and to mitigate the welfare consequences).

- Specific scenario 1: The welfare of male dairy calves raised for producing "white" veal meat and the risks associated with individual housing, insufficient space and feed restriction (such as deprivation of iron and fibres);
- Specific scenario 2: The assessment of ABMs collected in slaughterhouses to monitor the level of on farm welfare of male dairy calves raised for producing "white" veal meat;
- Specific scenario 3: The welfare of dairy calves and the risks associated with limited cow-calf bond-

1.1.4. Mandate on protection of laying hens

1.1.4.1. Part I − general ToRs

Same as for the mandate on pigs (see details in Section 1.1.2.1).

1.1.4.2. Part II − specific ToRs

For the following scenarios, the Commission has identified practical difficulties or insufficient information in ensuring the welfare of animals. For these, EFSA should propose detailed animal-based measures and preventive and corrective measures with, where possible, either qualitative (yes/no question) or quantitative (minimum/maximum) criteria (i.e., requirements to prevent and/or correct the hazards and to mitigate the welfare consequences).

- Specific scenario 1: The welfare of laying hens and the risks associated with alternative systems (organic, free range and barn) compared to the cage system currently allowed;
- Specific scenario 2: Welfare of hens in furnished cages, and risks associated with rearing of animals non beak trimmed;
- Specific scenario 3: The assessment of ABMs collected in slaughterhouses to monitor the level of welfare on laying hen farms.

1.1.5. Mandate on protection of broilers

1.1.5.1. Part I − general ToRs

Same as for the mandate on pigs (see details in Section 1.1.2.1).

1.1.5.2. Part II − specific ToRs

For the following scenarios, the Commission has identified practical difficulties or insufficient information in ensuring the welfare of animals. For these, EFSA should propose detailed animal-based

measures and preventive and corrective measures with, where possible, either qualitative (yes/no question) or quantitative (minimum/maximum) criteria (i.e., requirements to prevent and/or correct the hazards and to mitigate the welfare consequences).

- Specific scenario 1: The welfare of fast-growing chickens in barns and the risks associated with air and floor temperature, access to feed and water, space allowance, air quality;
- Specific scenario 2: The assessment of ABMs collected in slaughterhouses (such as footpad dermatitis) to monitor the level of welfare on broiler farms;
- Specific scenario 3: The welfare of broiler breeders and the risks associated with housing in (individual) cages, the practice of routine mutilation (beak trimming, de-toeing, de-combing, de-clawing), the feed restriction;
- Specific scenario 4: The welfare of day-old chick until they reach the rearing or breeding farms: hatchery conditions, transport conditions.

1.1.6. Mandate on protection of ducks, geese and quails

1.1.6.1. Part I – general ToRs

EFSA is requested to provide a scientific opinion on the impact of caged-systems on the welfare of:

— domestic ducks (*Anas platyrhynchos*), muscovy ducks (*Cairina moschata*) and hybrids between domestic and muscovy ducks,
— geese (*Anser anser* f. *domesticus*, *Anser cygnoides* f. *domesticus*) and their crossbreeds,
— commonly farmed quail (family Phasianidae, e.g. species Common quail (*Coturnix coturnix*) and Japanese quail (*Coturnix japonica*), and family Odontophoridae),

related to the production of meat (including foie gras), to the production of eggs and to breeding.
The request refers to:

— The keeping of breeders;
— The keeping of ducklings/ chicks and pullets before they start laying eggs;
— The keeping of layers, including breeders, during the production of eggs;
— The keeping of animals for meat production.

The process of collecting feathers and downs, the process of force-feeding for fatty liver production, the transport and the killing of the animals are not part of this request.

For this purpose, the EFSA is asked, for each species (or group of species where comparable in view of their welfare) and category of animals as listed above, to describe the welfare of the animals and the associated risks by:

a) Describing the main husbandry systems with a focus on the accommodation currently used in the EU for keeping these animals;
b) Describing the relevant welfare consequences concerning restriction of movement, injuries, group stress and inability to perform comfort behaviour related to these husbandry systems. Relevance will not need to be based on a comprehensive risk assessment, but on EFSA's expert opinion regarding the severity, duration and occurrence of each welfare consequence.

1.1.6.2. Part II – specific ToRs

EFSA should provide recommendations on qualitative or quantitative criteria to prevent and correct the hazards and to mitigate the negative welfare consequences listed in point b for the concerned species in relation to:

- Specific scenario 1: space allowance (three-dimensional) per animal,
- Specific scenario 2: maximum size of the group,
- Specific scenario 3: floor quality,
- Specific scenario 4: availability, design and size of nesting facilities,
- Specific scenario 5: enrichment provided (including access to water to fulfil biological needs)

1.1.7. Mandate on protection of dairy cows

1.1.7.1. Part I – general ToRs

This request refers to cows which have had a calf and are kept for milk production and to pregnant heifers in the last third of gestation. These include dual purpose breeds used for milk production.

For this request, the EFSA will:

  a) Describe, based on existing literature and reports, the most prevalent housing systems and practices of keeping them in the EU, including tie-stalls, cubicle housing and systems with free lying area, combined or not with certain outdoor access with grazing.

  b) Describe the following welfare consequences for the housing systems and practices specified above:

  - inability to perform comfort behaviour,
  - restriction of movement,
  - locomotor disorders,
  - metabolic disorders,
  - mastitis.

  c) Define the most feasible animal-based measures to assess the welfare consequences above;
  d) Identify the highly relevant hazards, leading to the welfare consequences above mentioned
  e) provide recommendations to prevent and/or correct the hazards and to mitigate the welfare consequences (resource and management-based measures).

1.1.7.2. Part II – specific ToRs

Specific scenario 1: The recommendations to prevent and correct the hazards and to mitigate the negative welfare consequences listed in point b for the concerned species should be based on key risk factors that may increase the likelihood of welfare consequences to occur. In addition, EFSA should identify the specific relevant hazards, leading to the welfare consequences above-mentioned and which can be used to classify the level of risk for animal welfare based on data currently collected (e.g. milk production, herd size, housing system etc.).

2. Data and methodologies

2.1. Methodologies

This methodological guidance was developed following the steps detailed in the draft framework for protocol development for EFSA's scientific assessments (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1843).

The described ToRs and F2F mandates (see Section 1.1) are considered as a 'generic mandate' or a non-application scientific assessment and considered to be classified as Scientific Risk Assessment (E2.1) according to EFSA's Process Architecture.

Due to the wide scope of the Scientific opinions, the methodologies developed here allow flexibility in the 'extent of planning', i.e. the degree of detail provided in the guidance for the methods that will be applied. It can be tailored to species-specific scenarios that accommodate the characteristics of the mandate (e.g. the requestor's needs – including the deadline, and the available resources). For this reason, it was agreed to develop the methodological guidance according to the 'low extent of protocol planning' modality. The low extent implies case-specific simplifications that allow a high level of flexibility since the scope of the opinions is broad and heterogeneous in relation to the specific species (pigs, laying hens, broilers, calves) as well as to the different topics to be assessed (different husbandry systems, different transport practices, welfare consequences, ABMs). Therefore, the following steps were taken (Box 1 in the EFSA guidance for protocol development; EFSA, 2020):

  - Step 1: Formulate the problem (the 'What')

    - Step 1.1. Translation of the mandate into assessment questions
    - Step 1.2. Definition of the sub-questions of each assessment question and their relationship
    - Step 1.3. Selection of the approach to be taken to tackle the sub-questions

  - Step 2. Plan the methods for conducting the assessment (the 'How')

○ Step 2.1. Definition of evidence needs and methods for answering each sub-question including uncertainty analysis

- Step 2.2. Definition of methods for integration of evidence across sub-questions and addressing remaining and overall uncertaintyThese steps are developed in the following sections.

3. Assessment

The ToRs of the mandates were first divided into those 'General ToRs' – referring to the husbandry systems or transport practices used in the production of each species – and referred to as 'Part I – general ToRs' in Sections 1.1.1.1, 1.1.2.1, 1.1.3.1, 1.1.4.1, 1.1.5.1, 1.1.6.1, 1.1.7.1 (respectively, for the mandates on transport, pigs, calves, laying hens, broilers, ducks geese and quail, and dairy cattle).

Those ToRs referring to specific scenarios (e.g. farrowing sows and piglets for swine, chicks and pullets before they become laying hens, or e.g. export by vessels) were categorised as 'specific ToRs' and referred to as 'Part II - Specific ToRs' in Sections 1.1.1.2, 1.1.2.2, 1.1.3.2, 1.1.4.2, 1.1.5.2, 1.1.6.2, 1.1.7.2 (respectively, for the mandates on transport, pigs, calves, laying hens, broilers, ducks geese and quail, and dairy cattle).

The methodology is therefore divided accordingly into a methodology for Part I - General ToRs – addressed in the following Section 3.1 and a methodology for Part II – Specific ToRs – addressed in the following Section 3.2.

For both methodologies, the decision was taken to implement the EFSA guidance on protocol development to the low extent.

3.1. Methodology for Part I – general Terms of Reference

3.1.1. Step 1: Formulate the problem (the 'What')

3.1.1.1. Step 1.1. Translation of the mandate into assessment questions

The general ToRs requested EFSA to answer the following five questions:

i) describe the current husbandry systems or transport practices,
ii) describe the relevant welfare consequences that may occur in these systems or due to the practices described under the above point,
iii) define ABMs to assess the identified highly relevant welfare consequences;

Feasible ABMs were considered those already routinely and currently collected or could be collected on-farm or at slaughter such as in a national program. A feasible ABM for use during transport should be able to be recorded quickly, without using any specialised equipment or laboratory test, at a low cost, and with no (or only minimal) interference with normal operation procedures. Llonch et al. (2015) divided feasibility into three categories: high (easy and quick recording without any special needs/tools), medium (extra time and/or space needed for recording), and low (not able to record under 'field conditions').

ABMs were qualitatively assessed on their 'sensitivity' and 'specificity' to the welfare consequence (WC).

For sensitivity, the following was considered: the presence of the ABM as its ability to identify animals suffering from the welfare consequence. An ABM that will be not be systematically present in all animals with the WC will be less sensitive. For specificity, the following was considered: the absence of the ABM as its ability to identify the animals, which are not suffering from the WC. An ABM that will be present in several WCs will tend to be less specific.

Lying behaviour is an example of a sensitive and specific ABM for identifying resting problems as resting problems are always associated with reduced lateral lying and if there are no resting problems, pigs will exhibit normal lateral lying behaviour. Teat lesions in lactating sows is an example of a non-sensitive and non-specific ABM for identifying resting problems in pigs as if resting problems are present, these may not always be associated with teat lesions and if resting problems are truly absent, lactating sows may still have teat lesions due to for example poor floor quality.

iv) identify hazards in housing or transport practices which may affect the welfare consequences, and.
v) provide recommendations to prevent and/or correct the hazards and mitigate the WCs.

3.1.1.2. Step 1.2 and Step 1.3. Definition of the sub-questions of each assessment question and their relationship & selection of the approach to be taken to tackle the sub-questions

To address the general ToRs of the mandates, EFSA will translate the assessment questions into more specific sub-questions. These are interrelated, meaning that the outcome of each sub-question is necessary to proceed to the next sub-question. The approach to develop the sub-questions is based on using both evidence from the scientific literature and expert opinion. The translation of the assessment questions into sub-questions is mapped in Table 1.

Table 1: Mapping of the translation of the mandate assessment questions into sub-questions

Assessment questions		Sub-questions	
i.	**Describe the current husbandry systems and transport practices**	*1. Identify and select all relevant husbandry systems or animal transport practices per species and animal category*	*2. Describe the husbandry systems and transport practices*
		Aim: Husbandry systems/transport practices to be considered in the assessment are identified and selected to be representative of the currently used systems in the EU. Approach: expert opinion via group discussion. Relationship with assessment question: This sub-question is necessary for the overall assessment question requiring the description of the husbandry systems/transport practices.	Aim: All the husbandry systems or animal transport practices per animal category identified and selected from Sub-question 1 are described narratively Approach: literature review, group discussion Relationship with assessment question: this corresponds to the assessment question and is necessary for the next assessment question
ii.	**Describe the relevant welfare consequences that may occur in these systems or due to the practices**	*3. Identify the welfare consequences common for all mandates and provide their definitions*	*4. Select the highly relevant welfare consequences for each husbandry systems or animal transport practices*
		Aim: To identify the welfare consequences that may impair the welfare of animals and to provide a definition for them. EFSA generates a list of welfare consequences common for all mandates. Approach: expert opinion via group discussion (see focus and full resulting list in Section 3.1.1.3) Relationship with assessment question: the list of all possible welfare consequences is necessary for the next assessment question asking to identify the highly relevant ones per each system	Aim: To select the highly relevant welfare consequences for each of the previously defined husbandry systems or animal transport practices per species and animal category Approach: expert opinion via Expert knowledge Elicitation (EKE) (see focus on this in Section 3.1.1.4) Relationship with assessment question: this corresponds to the assessment question, is related to Sub-question 1 in which relevant welfare consequences are identified only for current husbandry systems/transport practices
iii.	**Define qualitative or quantitative animal-based measures (ABMs) to assess these welfare consequences**	*5. Identify the feasible ABMs for the assessment of the highly relevant welfare consequences*	*6. Describe the feasible ABMs for the assessment of the highly relevant welfare consequences*
		Aim: Qualitative AMBs/Quantitative ABMs for the assessment of the welfare consequences previously identified as relevant are selected (distinguished the currently feasible ABMs from others). Approach: expert opinion via group discussion	Aim: The ABMs for the assessment of the welfare consequences previously identified as the highly relevant are described Approach: literature review

Assessment questions		Sub-questions	
		Relationship with assessment question: this corresponds to the assessment question and is related to sub- question 4 in which ABMs are identified only for the highly relevant welfare consequences	Relationship with assessment question: related to Sub-question 5
iv.	**Identify the hazards leading to these welfare consequences**	*7*. *Identify the hazards leading to the most highly welfare consequences*	*8*. *Describe the hazards leading to the highly relevant welfare consequences*
		Aim: The hazards leading to the highly relevant welfare consequences are identified Approach: expert opinion via group discussion. Relationship with assessment question: this corresponds to the assessment question and is related to sub- question 4 in which hazards are identified only for the highly relevant welfare consequences	Aim: The hazards are described Approach: literature review and group discussion Relationship with assessment question: related to Sub-question 7
v.	**Provide recommendations to prevent and/or correct the hazards and to mitigate the welfare consequences**	*9*. *Identify the measures to prevent and correct the hazards and mitigate the highly relevant welfare consequences*	*10*. *Describe the measures to prevent and correct the hazards and mitigate the highly relevant welfare consequences*
		Aim: Preventive and corrective measures for the hazards and mitigation measures for the highly relevant welfare consequences for the previously defined husbandry systems and transport practices per animal category are identified Approach: expert opinion via group discussion Relationship with assessment question: this corresponds to the assessment question and is related to Sub-question 4 in which preventive and corrective measures for the hazards and mitigation measures are identified only for the highly relevant welfare consequences	Aim: Preventive, corrective and mitigation measures are described Approach: literature review Relationship with assessment question: related to Sub-question 9

3.1.1.3. Focus on sub-question 3: identification of welfare consequences

The objective of this sub-question is to generate a draft list of known WCs that can impair the welfare of the animals along with their descriptions. The draft list consists of 33 WCs created via working group expert discussions and provides a common starting point for all animal species. Although some differences relating to species or context exist, it can be used consistently in all mandates (Table 2).

The description of each welfare consequence reported in the draft list refers to either one or more negative affective states (e.g. pain, fear, fatigue). These are the high-level states that derive from the occurrence of the welfare consequence and that can lead to animal suffering. A draft list and description of the negative affective states as derived from literature is reported in Table 3.

Table 2: List and description of 33 welfare consequences used for all animal species as produced via expert discussion

	Welfare consequence	Description
1	Bone lesions (incl. Fractures and dislocations)	The animal experiences negative affective states such as pain, discomfort and/or distress due to fractures or dislocations of the bones (excluding those fractures leading to locomotor disorders).
2	Cold stress	The animal experiences stress and/or negative affective states such as discomfort and/or distress when exposed to low effective temperature.
3	Eye disorders	The animal experiences negative affective states such as discomfort, pain and/or distress due irritation or lesion or lack of function of at least one eye.
4	Group stress	The animal experiences stress and/or negative affective states such as pain, fear and/or frustration resulting from a high incidence of aggressive and other types of negative social interactions, often due to hierarchy formation and competition for resources or mates.
5	Gastro-enteric disorders	The animal experiences negative affective states such as discomfort, pain and/or distress due to impaired function or lesion of the gastro-intestinal tract resulting from for example nutritional deficiency, infectious, parasitic, or toxigenic agents.
6	Handling stress	The animal experiences stress and/or negative affective states such as pain and/or fear resulting from human or mechanical handling (e.g. sorting and vaccination of newly hatched chicks, loading/unloading, catching and crating of animals to be transported, inversion).
7	Heat stress	The animal experiences stress and/or negative affective states such as discomfort and/or distress when exposed to high effective temperature.
8	Inability to avoid unwanted sexual behaviour	The animal experiences stress and/or negative affective states such as pain and/or fear resulting from inability to avoid forced mating.
9	Inability to perform exploratory or foraging behaviour	The animal experiences stress and/or negative affective states such as frustration and/or boredom resulting from the thwarting of the motivation to investigate the environment or to seek for food (i.e., extrinsically and intrinsically motivated exploration).
10	Inability to express maternal behaviour	The animal experiences stress and/or negative affective states such as frustration resulting from the thwarting of the motivation to care for offspring, including during the pre-partum/pre-laying phase.
11	Inability to perform sucking behaviour	The animal experiences stress and/or negative affective states such as frustration resulting from the thwarting of the motivation to suck from an udder.
12	Inability to chew and/or ruminate	The animal experiences stress and/or negative affective states such as frustration resulting from the thwarting of the motivation to ingest sufficient amounts of fibrous feed or the inhibition of rumination.
13	Inability to perform play behaviour	The animal experiences stress and/or negative affective states such as frustration resulting from the thwarting of the motivation to engage in social/locomotor or object play.
14	Inability to perform sexual behaviour	The animal experiences stress and/or negative affective states such as frustration resulting from the thwarting of the motivation to engage in sexual activities.

	Welfare consequence	Description
15	**Inability to perform comfort behaviour**	The animal experiences stress and/or negative affective states such as discomfort and/or frustration resulting from the thwarting of the motivation to maintain the function and integrity of the integument (e.g. cannot keep clean, scratch, dust bathe).
16	**Isolation stress**	The animal experiences stress and/or negative affective states such as frustration and/or fear resulting from the absence of or from limited social contact with conspecifics.
17	**Locomotory disorders (including lameness)**	The animal experiences negative affective states such as pain, discomfort and/or due to impaired locomotion induced by, e.g. bone, joint, skin or muscle damage.
18	**Mastitis**	The animal experiences negative affective states such as pain and/or discomfort due to the inflammation of at least one of the mammary glands.
19	**Metabolic disorders**	The animal experiences negative affective states such as inappetence, weakness, fatigue, discomfort, pain and/or distress due to disturbed metabolism (e.g. acidosis and ketosis), deficiencies in several nutrients (e.g. anaemia) or induced by ectoparasites affecting metabolism (anaemia due to red mites) or poisoning
20	**Motion stress**	The animal(s) experience motion sickness, stress and/or fatigue due to the forces exerted as a result of acceleration, braking, stopping, cornering, gear changing, vibrations and uneven road surfaces during transport.
21	**Muscle disorders**	The animal experiences negative affective states such as discomfort and/or pain due to a disorder or lack of function of the muscles (e.g. myopathy in broilers).
22	**Predation stress**	The animal experiences stress and/or negative affective states such as fear and/or pain resulting from being attacked or perceiving a high predation risk
23	**Prolonged hunger**	The animal experiences craving or urgent need for food or a specific nutrient, accompanied by a negative affective state, and eventually leading to a weakened condition, as metabolic requirements are not met.
24	**Prolonged thirst**	The animal experiences craving or urgent need for water, accompanied by an uneasy sensation (a negative affective state), and eventually leading to dehydration as metabolic requirements are not met.
25	**Restriction of movement**	The animal experiences stress and/or negative affective states such as pain, fear, discomfort and/or frustration due to the fact that it is unable to move freely, or is unable to walk comfortably (e.g. due to overcrowding, unsuitable floors, gates, barriers).
26	**Respiratory disorders**	The animal experiences negative affective states such as discomfort, pain, air hunger and/or distress due to impaired function or lesion of the lungs or airways.
27	**Resting problems**	The animal experiences stress and/or negative affective states such as discomfort, and/or frustration due to the inability to lie, rest comfortably or sleep (e.g. due to hard flooring, inability to perch or vibration during transport). This may eventually lead to fatigue.
28	**Reproductive disorders**	The animal experiences negative affective states such as pain and/or discomfort due to a disorder of the reproductive system resulting from physical injury or infection (including dystocia and metritis).
29	**Sensory under- and/or overstimulation**	The animal experiences stress and/or negative affective states such as fear, discomfort due to visual, auditory or olfactory under/overstimulation by the physical environment.
30	**Separation stress**	The animal experiences stress and/or negative affective states such as fear and/or frustration resulting from separation from conspecifics.
31	**Skin disorders (other than soft tissue lesions and integument damage)**	The animal experiences negative affective states such as pain, discomfort and/or distress due to e.g. infections (e.g. dermatophytosis/ringworm, pseudomonosis, staphylococcosis, viral diseases), ectoparasites (e.g. mange or red mites), inflammation of the skin or sunburn.

	Welfare consequence	Description
32	Soft tissue lesions and integument damage	The animal experiences negative affective states such as pain, discomfort and/or distress due to physical damage to the integument or underlying tissues, e.g. multiple scratches, open or scabbed wounds, bruises, ulcers, abscesses and feather or hair loss. This welfare consequence may result from negative social interactions such as aggression, tail-biting or feather pecking, from handling or from damaging environmental features, or from mutilation practices (e.g. beak trimming, de-toeing, de-horning, tail docking).
33	Umbilical disorders and hernias	The animal experiences negative affective states such as discomfort and/or pain due to inflammation of the navel or any type of hernias

Table 3: List and description of negative affective states

Negative affective state	Description
Boredom	Boredom is an unpleasant emotion including suboptimal arousal levels and a thwarted motivation to experience almost anything different or more arousing than the behaviours and sensations currently possible (adapted from Mason and Burn, 2011).
Discomfort	Discomfort can be physical or psychological and is characterised by an unpleasant feeling resulting in a natural response of avoidance or reduction of the source of the discomfort. Pain is one of the causes for discomfort, but not every discomfort can be attributed to pain. Discomfort in non-communicative patients is assessed and measured via behavioural expression, also used to describe pain and agitation, leading to discomfort being interpreted as pain in some conditions (Ashkenazy and DeKeyser Ganz, 2019).
Stress[1] and Distress	STRESS[1]: Stressors are events, internal or external to the body involving real or potential threats to the maintenance of homeostasis. When stressors are present, the body will show stress responses (biological defence to re-establish homeostasis – for example behavioural, physiological, immunological, cognitive and emotional). Stress is a state of the body when stress responses are present (Sapolsky, 2002). DISTRESS: Distress is a conscious, negatively valenced, intensified affective motivational state that occurs in response to a perception that current coping mechanisms (involving physiological stress responses) are at risk of failing to alleviate the aversiveness of the current situation in a sufficient and timely manner (McMillan, 2020).
Fatigue	Physiological state representing extreme tiredness and exhaustion of an animal (EFSA AHAW Panel, 2020).
Fear	The animal experiences an unpleasant emotional affective state induced by the perception of a danger or a potential danger that threaten the integrity of the animal (Boissy, 1995).
Frustration	Negatively valenced emotional state consecutive to the impossibility to obtain what is expected or needed. Frustration is very often triggered by restriction of natural behaviours thus resulting in thwarted motivation to perform these behaviours.
Pain	An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage (Raja et al. 2020).

1: The term stress does not describe a negative affective state in itself, but it is mentioned and defined in the table as it is a prerequisite of distress.

3.1.1.4. Focus on Sub-question 4: selection of highly relevant welfare consequences

As explained above (Sub-question 4), the mandates request the identification of the highly relevant welfare consequences for each of the defined husbandry systems or animal transport practices per animal category. This identification of the highly relevant WCs is executed via expert opinion. Hereto, the opinion of the WG experts is elicited through an exercise of individual classification of welfare consequences in terms of relevance followed by group discussion to identify the highly relevant ones by consensus.

The starting point is the list of 33 specific WCs identified under Sub-question 3 (for details see Section 3.1.1.3). The exercise is carried out separately for each of the husbandry systems or animal transport stages per species or animal category resulting from Sub-question 1.

The exercise consists in selecting the highly relevant WCs out of these 33 per each of these combinations.

For each combination, WG experts classify, based on an estimate of their magnitude, the 33 WCs into four categories of relevance: (i) non-applicable, (ii) slightly relevant, (iii) moderately relevant and (iv) highly relevant. The magnitude of a WC is defined as the product of three parameters (severity, duration and frequency of occurrence) (EFSA AHAW Panel, 2012). Duration refers to the time an animal spends within a certain production stage (combination animal category and husbandry system) while the occurrence refers to the prevalence of animals experiencing the welfare consequence in that production stage. Owing to the lack of published data on these three parameters, the experts express their qualitative expert opinion on the magnitude of WCs.

Expert opinion is elicited in 3 phases:

1) First phase: the experts go individually through the list of welfare consequences and identify those that would fall in the 'non-applicable' or 'slightly relevant' categories. Their individual judgements are then be collated, and those WCs unanimously identified as belonging to these two categories are removed and not considered for further assessment. Those WCs for which there is no consensus whether they are considered 'non-applicable' or 'slightly relevant' remain for further assessment and require an open group discussion to find a consensus.

2) Second phase: the experts go individually through the list of remaining welfare consequences and identify those that would fall in the category of 'highly relevant' in order to only identify the highly relevant WCS that are kept for further assessment (Sub-question 5 Section 3.1.1.2). Similarly, as during the first phase in case discrepant opinions emerge, consensus is sought through group discussion.

3) Third phase: the experts are asked to rank individually all the remaining WCs in the list that are not already identified as highly relevant (and thus kept) or non-applicable or slightly relevant (and thus removed) from the highest to the least relevant. Their individual rankings are then discussed again in an open group discussion with the aim to assign the remaining WCs into the category 'highly relevant' or in the category 'moderately relevant'.The general ToRs of the scientific opinions only report, for each of the defined husbandry systems or animal transport practices per animal species or category, those WCs that are selected to be highly relevant from this exercise.

3.1.2. Step 2. Plan the methods for conducting the assessment (the 'How')

3.1.2.1. Step 2.1. Definition of evidence needs and methods for answering each sub-question including uncertainty analysis

Tables 4 and 5 present the specific assessment of each of the sub-questions listed above along with the evidence needs and methods used for answering each of them depending on whether they are based on expert opinion (Table 4) or data extracted from literature reviews (Table 5).

Table 4: Methodology for sub-questions for Part I – General ToRs that will be addressed using expert opinion using the LOW extent of planning (according to Table 3 of https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1843)

	Sub-question					
	Identification of relevant husbandry systems or animal transport practices per animal categories (Sub-question 1)	**Identification of welfare consequences (Sub-question 3)**	**Selection of highly relevant welfare consequences (Sub-question 4)**	**Identification of ABMs for relevant WC (Sub-question 5)**	**Identification of hazards for relevant WC (Sub-question 7)**	**Identification of preventive and corrective measures (Sub-question 9)**
Formulation of sub-question	For the on-farm welfare mandates: to generate a list of husbandry systems per animal category. For transport mandate: to generate a list of main animal transport practices per animal category.	To generate a list of all welfare consequences that can impair the welfare of animals along with their definition.	For the on-farm welfare mandates: to identify the highly relevant WCs considering the severity, duration and frequency of occurrence for each of the previously defined husbandry systems per animal category. For transport mandate: to identify the highly relevant WCs considering the severity, duration and frequency of occurrence for each of the previously defined animal transport practices per animal category.	To generate a list of ABMs for the highly relevant WC. For the on-farm welfare mandates: Only those ABMs that are feasible on-farm and at the slaughterhouse will be taken up. For transport mandate: Feasible ABMs in transport will be included.	For all mandates: to generate a list of hazards leading to each identified welfare consequence.	For all mandates: to generate a list of measures to prevent or correct the identified hazards or WCs.
Definition of the approach	For all mandates: A group discussion within the WG and hearing experts selected for each of the specific species and agreed in the Welfare Task Force. The Welfare Task Force is the steering group	A group discussion within the WG and hearing experts selected for each of the mandates and agreed in the Welfare Task Force.	Individual classification of WCs in terms of relevance and group discussion to identify the highly relevant ones by consensus.	A group discussion within the WG and hearing experts selected for each of the mandates and agreed in the Welfare Task Force.	A group discussion within the WG and hearing experts selected for each of the mandates and agreed in the Welfare Task Force.	A group discussion within the WG and hearing experts selected for each of the mandates and agreed in the Welfare Task Force.

	Sub-question					
	Identification of relevant husbandry systems or animal transport practices per animal categories (Sub-question 1)	**Identification of welfare consequences (Sub-question 3)**	**Selection of highly relevant welfare consequences (Sub-question 4)**	**Identification of ABMs for relevant WC (Sub-question 5)**	**Identification of hazards for relevant WC (Sub-question 7)**	**Identification of preventive and corrective measures (Sub-question 9)**
	consisting of EFSA staff (including internal/external elicitation specialist) and members of the selected WGs and AHAW Panel members (including specialists on uncertainty assessment).					
Identification of experts	Expert profile: Researchers with field experience and specialised in animal husbandry systems, transport practices, welfare consequences, animal-based and resource-based measures. Diplomates in animal welfare, behaviour and other veterinary science topics;	See expert profile Sub-question 1.	See expert profile Sub-question 1.	See expert profile Sub-question 1.	See expert profile Sub-question 1.	See expert profile Sub-question 1.
Preparation of the evidence dossier	No specific evidence dossier needed for common ToRs. Consulted experts provide the evidence.	No evidence dossier is needed, and judgement is based on the expertise of the consulted experts.	No evidence dossier is needed, and judgement is based on the expertise of the consulted experts.	No evidence dossier is needed, and judgement is based on the expertise of the consulted experts.	No evidence dossier is needed, and judgement is based on the expertise of the consulted experts.	No evidence dossier is needed, and judgement is based on the expertise of the consulted experts.

	Sub-question					
	Identification of relevant husbandry systems or animal transport practices per animal categories (Sub-question 1)	**Identification of welfare consequences (Sub-question 3)**	**Selection of highly relevant welfare consequences (Sub-question 4)**	**Identification of ABMs for relevant WC (Sub-question 5)**	**Identification of hazards for relevant WC (Sub-question 7)**	**Identification of preventive and corrective measures (Sub-question 9)**
Methods of synthesis of individual expert estimates and their uncertainty	Only the agreed final list of defined husbandry systems or animal transport practices per animal category is kept. No uncertainty analysis is performed at this point other than the identification of sources of uncertainty affecting the assessment.	Only the agreed list of all identified welfare consequences is kept. No uncertainty analysis is performed at this point other than the identification of sources of uncertainty affecting the assessment.	Use of plots summarising individual classifications and variations of classification among the group. Classification of WCs into four categories (highly relevant – the target, moderately relevant, slightly relevant and non-applicable).	Only the agreed list of ABMs is kept. No uncertainty analysis is performed at this point other than the identification of sources of uncertainty affecting the assessment.	Only the agreed list of hazards kept. No uncertainty analysis is performed at this point other than the identification of sources of uncertainty affecting the assessment.	Only the agreed list of measures is kept. No uncertainty analysis is performed at this point other than the identification of sources of uncertainty affecting the assessment.

Table 5: Methodology for sub-questions for Part I – General ToRs that will be addressed using evidence from the scientific literature

	Sub-question			
	Description of current practices and housing systems (Sub-question 2)	**Description of ABMs for relevant WC (Sub-question 6)**	**Description of hazards per relevant WC (Sub-question 8)**	**Description of preventive and corrective measures (Sub-question 10)**
Formulation of sub-question	For the on-farm welfare mandates: to provide a description of housing systems (divided when appropriate into different animal categories, e.g. sows, weaners, boars, etc.) and management routines most commonly found associated with the respective housing systems. For transport mandate: to provide a description of transport practices per species and transport stages divided when appropriate into different categories (e.g. vehicle, vessel) and management routines (e.g. duration of transport)	For all mandates: To describe the ABMs for the highly relevant WC.	For all mandates: To describe all hazards leading to the identified highly relevant welfare consequences.	For all mandates: To describe preventive and corrective measures to prevent the identified hazards
Eligibility criteria for study selection	For the on-farm welfare mandates: literature describing current practices and housing systems in the European Union for the husbandry systems identified in Sub-question 1. For transport mandate: literature describing current transport practices from the EU and beyond EU for the scenarios identified in Sub-question 1.	For all mandates: literature describing ABMs for the highly relevant welfare consequences	For all mandates: literature describing hazards and their relationship with the highly relevant welfare consequences.	For all mandates: literature describing preventive and corrective measures for the identified hazards or WCs
Search strategy	For all mandates: Previous EFSA scientific outputs complemented with recent studies published in peer-reviewed and grey literature describing housing systems and transport practices. The screening is performed by one reviewer.	For all mandates: Previous EFSA scientific outputs complemented with recent studies published in peer-reviewed and grey literature describing the ABM related to the highly relevant WC. The screening is performed by one reviewer.	For all mandates: Previous EFSA scientific outputs complemented with recent studies published in peer-reviewed and grey literature describing the hazards related to the highly relevant WC. The screening is performed by one reviewer.	For all mandates: Previous EFSA scientific outputs complemented with recent studies published in peer-reviewed and grey literature describing preventive and corrective measures. The screening is performed by one reviewer.

	Sub-question			
	Description of current practices and housing systems (Sub-question 2)	**Description of ABMs for relevant WC (Sub-question 6)**	**Description of hazards per relevant WC (Sub-question 8)**	**Description of preventive and corrective measures (Sub-question 10)**
Methods for study inclusion/ exclusion	Publications that are not considered relevant nor providing any additional value to address the question will be removed	Same as in Sub-question 2	Same as in Sub-question 2	Same as in Sub-question 2
Methods for extracting data from included studies	Qualitative information related to the main characteristics of the housing systems and current management and transport practices will be extracted by one expert (one reviewer).	Information on the use of the ABM to assess the welfare consequence, including, when possible, qualitative information on sensitivity, specificity and feasibility of the ABM.	Qualitative information on the relevant hazards related with the selected welfare consequences will be extracted by one reviewer.	Qualitative information on the preventive and corrective measures for the identified hazards will be extracted by one reviewer.
Methods for appraising evidence	Relevance of the evidence will be assessed qualitatively after reading of abstracts and, if a paper is selected, the full text document is taken into account for the assessment, if the application of a correct methodology used to describe WCs (using ABMs) and hazards related to WCs is reported.	Same as in Sub-question 2	Same as in Sub-question 2	Same as in Sub-question 2
Preliminary identification and prioritisation of sources of uncertainty	Main sources of uncertainty will be identified based on the appraisal of the scientific literature and the working group experts' knowledge on the housing systems, or transport practices, ABMs and hazards. For the selection of housing systems, WCs, ABMs and hazards there is still a risk of missing important issues. This is excluded as much as possible by selecting wide range of Welfare experts in working groups and task force welfare, but a full quantification of the uncertainty is not being carried out at this stage (only identification of sources of uncertainty).	Same as in Sub-question 2	Same as in Sub-question 2	Same as in Sub-question 2

	Sub-question			
	Description of current practices and housing systems (Sub-question 2)	**Description of ABMs for relevant WC (Sub-question 6)**	**Description of hazards per relevant WC (Sub-question 8)**	**Description of preventive and corrective measures (Sub-question 10)**
Methods for synthesising the evidence	Evidence is synthesised qualitatively through a narrative text	Same as in Sub-question 2	Same as in Sub-question 2	Same as in Sub-question 2
Methods for analysing uncertainties individually and combined	Not applicable	Not applicable	Not applicable	Not applicable

3.2. Methodology for part II – specific ToRs

3.2.1. Step 1: Formulate the problem (the 'What')

3.2.1.1. Step 1.1. Translation of the mandate into assessment questions

For these specific ToRs, EFSA is requested to provide scientific information regarding risks and benefits of possible alternative housing/husbandry systems (other than cages) or requirements for existing systems or transport practices (e.g. space allowance for calves or e.g. export by vessels). In addition, if possible, it should propose detailed animal-based measures (ABMs) of the welfare consequences and preventive and corrective measures with, where possible, either qualitative (categorical description) or quantitative (continuous or discrete description) criteria (i.e. requirements to prevent and/or correct the hazards and to mitigate the welfare consequences).

Each specific scenario can include one or more sub-questions. For instance, one scenario requires to assess 'The welfare of weaners and rearing pigs, in particular with the risks associated with a., weaning, b., space allowance, including competition for space, c., types of flooring, including poor cleanliness and comfort, d., enrichment material, e., air quality, f., health status, g., diet, including competition for food, and h., the practice of mutilations (tail docking, tooth clipping, castration)'. In this example, the question includes eight sub-questions to be dealt with separately (points a–h in Section 3.2.1.2), and leading up to general conclusions if possible.

Quantitative assessment is carried out where a clear and unconfounded question can be identified and where sufficient quantitative data can be sourced from literature to address this question. However, in cases where insufficient quantitative data exist, or where the inter-relationship of many different factors makes it impossible to set up an acceptable model, which can address an unconfounded question, a qualitative approach is adopted. For example, due to the framing of the specific scenarios for transport, making them very broad, combined with the complex nature of transport practices with many interacting hazards, quantitative models were not considered possible.

3.2.1.2. Step 1.2. Definition of the sub-questions of each assessment question and their relationship

Per each sub-question, the following queries are answered in order to provide the context of the sub-question. These elements are included in a specific scenario factsheet and are needed to prepare the questions for the expert knowledge elicitation (EKE) method (see next Section 3.2.1.3). The following **example** from the mandate on the protection of pigs illustrates this process:

a) Exact wording of the specific scenario:
   'The welfare of sows and piglets from farrowing to weaning in different housing systems offering different degrees of behavioural freedom'.
b) Interpretation of the scenario to give a specific question which was agreed with the Commission: 'How does the amount of space offered to sows and piglets in different farrowing systems affect their welfare?'
c) Selection of the animal category considered:
   Farrowing and lactating sows, suckling piglets.
d) Selection of the housing/husbandry system to be considered:
   Crates, indoor pens.
e) Selection of the exposure variable (hazard):
   Space allowance.
f) Identification of the highly relevant welfare consequence at stake for the EKE influenced by the exposure variable:
   Sows: Restriction of movement, Piglets: soft tissue lesions, bone lesions.
g) Definition of the ABM at stake for the EKE with clear relationship between exposure and ABM:
   Sows: Proportion of time sows spent in locomotor activity, Piglets: pre-weaning mortality.

To facilitate the assessment one specific ABM will be defined as reference. Similar ABMs should be converted to the reference, if possible. ABMs with strong relationship to the exposure are preferred as well as validated ones for the selected welfare consequence. If the welfare consequence cannot be sufficiently described by one ABM, additional ABMs will be defined. The ABMs should cover independent aspects of the welfare consequence. If more ABM are applicable, ABMs that are feasible for surveillance at the farms are preferred.

h) Identification of other influencing factors to be considered as strata or within an appropriate context. Pigs: nesting material.
i) Interpretation of the exposure variable within the context: The amount of m^2 available to the sow in these systems

The definition of an appropriate context is necessary to reduce the complexity of the assessment (eliminate further influencing factors, e.g. farming practice) and focus on the assessment on the selected exposure variable. The context should be close to the current practice in the selected husbandry systems. Important dependencies will be included by stratification (e.g. by the age of the animals).

3.2.1.3. Step 1.3. Selection of the approach: a model for welfare risk assessment

In order to provide quantitative criteria, it was decided to set up a risk assessment model, which describes the relation between influencing factors and animal welfare. Such a model enables the evaluation of a specific scenario in order to provide qualitative/quantitative recommendations for the mandates. Necessary parameters are extracted from literature and evaluated by a structured EKE as weight of evidence approach.

The underlying assumptions of the model are:

1) The ABM considered is a valid and sensitive indicator of the welfare of the animals related to the exposure variable.
2) Since there is no gold standard for animal welfare, it is assumed that the expression of the ABM (i.e. the extent to which a certain behaviour is shown or the occurrence of a certain health disorder) under unexposed conditions (e.g. unlimited space, full cow-calf contact) reflects the natural situation an animal population may experience, which is considered the optimum in terms of animal welfare. The ABM observed under these conditions could be seen as not influenced by exposure to the hazard and work as a control measurement to describe the influence of the exposure.The level of welfare as assessed through this ABM can thus be quantified in relation to optimal welfare, for different degrees of the exposure variable (e.g. 'what proportion of play behaviour is shown by a calf at different space allowances below unrestricted space?'). Therefore, quantitative recommendations on the exposure variables, as required by the mandates, can be drawn by associating different levels of ABMs expression to different levels of exposure variables that are assessed.

The idea of the assessment model is the interpolation of the ABM between a highly exposed population of animals and a non-exposed population. The assessment relates to the European average situation. For the definition of the highly exposed population extremes exposures are considered, which are still allowed by law (e.g. minimal allowed space). For the non-exposed population farming practices are considered, where the conditions are virtually without exposure, e.g. outdoor farming on wide pasture with virtual no restriction of the space for the animal. If possible, the variation of the ABM within the non-exposed population is estimated. This variation between animals may be used to interpret the strength of the exposure effect on the average animal.

The proposed method/model aims to provide qualitative/quantitative recommendations for specific scenarios in the mandates. Within a simple interpolation framework, the model involves four parameters to describe the relationship between the exposure variable (hazard) and the ABM considered. A structured EKE exercise within the working group can be executed in order to retrieve the four parameters.

The four parameters are:

1) The median ABM in a population of animals subjected to optimal conditions, namely a population not exposed to the hazard (e.g. with no space restriction = situation of reference);
2) The variation of the ABM in the population of animals not exposed to the hazard (e.g. with no restriction of space);
3) The greatest degree of exposure to the hazard resulting in no change in the median value of the ABM compared to the value observed in the unexposed population of animals;
4) The median value of the ABM in a population of animals under a high exposure to the hazard (e.g. with substantial restriction of space).

In order to construct the relationship between exposure and ABM, a regression model can be envisioned according to the complexity. In case of a qualitative assessment the exposure can

be described categorical (e.g. different exposure scenarios as crated/non-crated), and the ABM can be estimated on an ordinal scale (e.g. by scoring). A linear relationship and an ordinal relationship require two questions (ABMs for high and low exposure and eventually 'in-between' exposure), while categorical relationship requires one question per category.

The risk assessment model is graphically represented in Figure 1. The model interpolates the ABM between low and high values of the exposure variable (hazard) by a linear trend (red line). The 'Range of exposure allowing ABM expression' (blue range) represents the ABM expression with no significant effect to the average animal and is defined by the hazards (exposure values), which results in ABM values comparable with the variation (80% confidence interval) within a non-exposed population (green distribution in Figure 1).
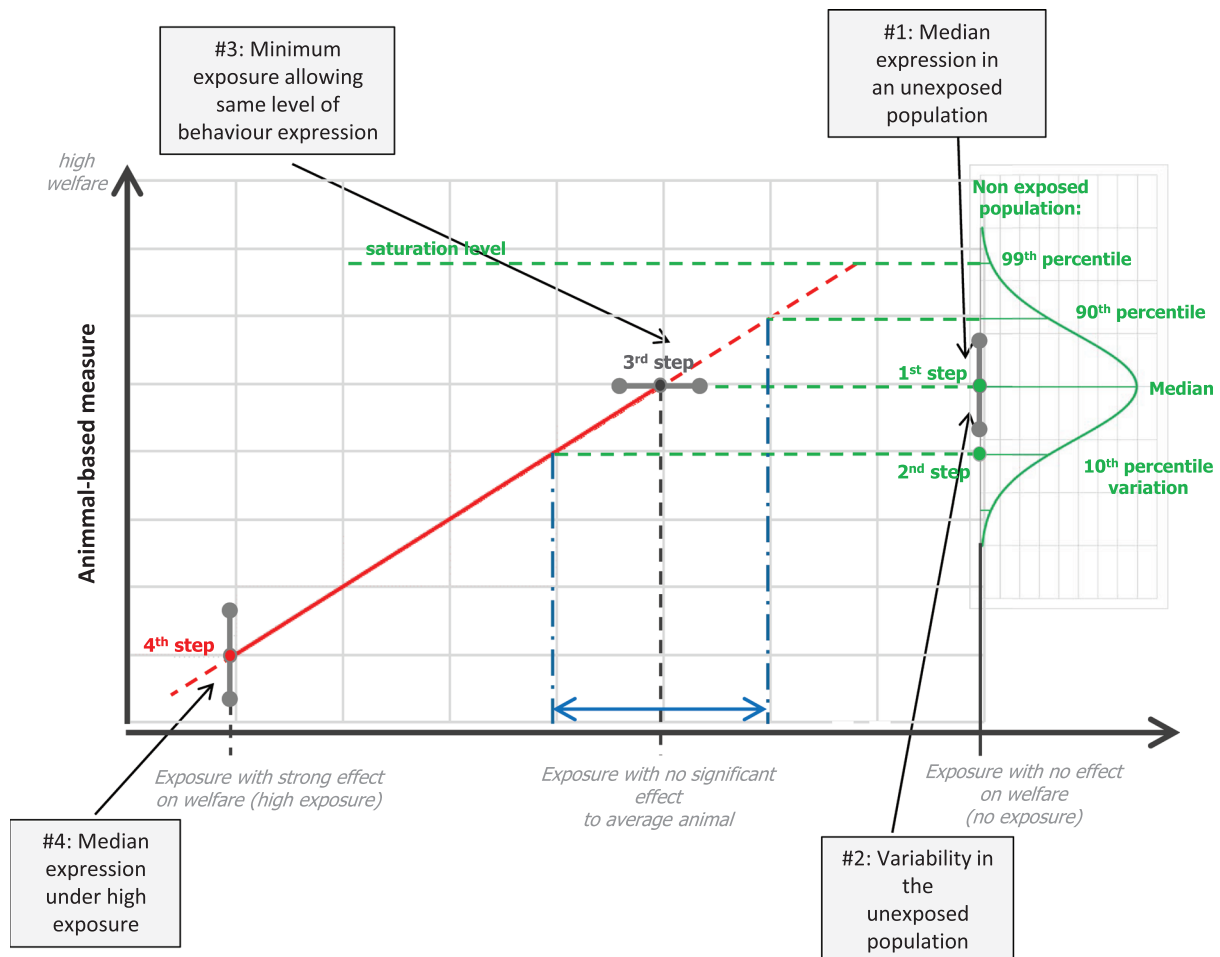

Figure 1: Graphical representation of the risk assessment model used in F2F welfare mandates to express the relationship between exposure and ABMs. This is an illustration of one case where a linear relationship was assumed

The EKE follows a four-step approach that allow to retrieve the four different parameters listed above.

The first question (step 1) asks for the median ABMs under the assumption of 'absence of exposure' (e.g. What is the average proportion of time over all days from birth to weaning, that a sow is performing locomotor behaviour in pens of unlimited space for a median sow (median of the distribution)? The answer estimates the median ABM in the non-exposed population (step 1, median of distribution).

The second question assesses the variation of the ABM, e.g. the locomotor behaviour, within the non-exposed population (green distribution, Figure 1). It is asking for the ABM values limiting the 10% of the sows with lowest, respectively, highest expression of the ABM, e.g. the proportion of time sows are performing locomotor behaviour in pens of unlimited space (10th and 90th percentile of the green distribution, Figure 1).

In a third question the experts are asked to estimate the highest level of the exposure variable (e.g. lowest space allowance) at which the value of the ABM does not significantly differ from the median ABM

value of the non-exposed population (question 1) (e.g. What is the minimal space allowance with no reduction in performance of time spent in locomotor behaviour, compared to the unrestricted situation?). It is assumed, that from this level a further reduction of the exposure (e.g. more space allowance) would significantly change the ABM (e.g. the locomotor behaviour) of the average animal.

In the fourth and final question, the experts are asked about the expression of the ABM at high exposure to the hazard (e.g. what is the average proportion of time over all days from birth to weaning, that a sow is showing locomotor behaviour in pens of low space (e.g. like in a crate for a median sow?).

The answers to the questions above allow a quantitative estimation of the impact that increased exposure (e.g. space allowance) has on the selected ABM (e.g. locomotor behaviour). The uncertainty of the ABM in the unexposed population is estimated via step 1 (uncertainty around the median value of ABM in the unexposed population) and step 2 (variation of the ABM in the unexposed population). The uncertainty around each point is estimated via elicitation, with the final uncertainty distribution being determined through model fitting. The answers to the questions also allow to express the level of locomotor behaviour as a proportion of what would be expressed in an unrestricted environment (in which welfare is not challenged by limitations in space allowance).

3.2.2. Step 2. Plan the methods for conducting the assessment (the 'How')

3.2.2.1. Step 2.1. Definition of evidence needs and methods for answering each sub-question including uncertainty analysis (Table 6)

Table 6: Methodology for sub-questions for specific ToRs (Part II – Specific ToRs) that will be addressed using expert opinion using the LOW extent of planning (according Table 3 of https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1843)

Sub-question	Identification of relevant steps
Formulation of sub-question	Generate a list of questions for each species and exposure variables, which can be categorical or continuous, WCs and the ABMs that should be assessed in a quantitative way by EKE.
Definition of the approach	A structured EKE within the WG and hearing experts selected for each of the specific species and agreed in the Welfare Task Force. The Welfare Task Force is the steering group consisting of EFSA staff (including internal/ external elicitation specialist) and members of the selected WGs and AHAW panel members (including specialists on uncertainty assessment).
Identification of experts	Expert profile: Welfare expert for each specific animal species of animals: researchers specialised in animal husbandry systems, WCs and animal-based and resource-based measures.
Preparation of the evidence dossier	For each specific scenario an evidence dossier is compiled (e.g. space allowance in sows). An evidence dossier should consist of all definitions to specify the scenario: the animal category, the different housing systems, the hazard selected for the scenario, the WCs, the ABMs, the identified exposure variable for the model; the assessment model and the EKE questions (see above) in order to retrieve the relationship between ABMs and exposure variable, and a summary from literature in relation to hazards/ABMs/other influencing factors/limitations.
Methods of synthesis of individual expert estimates and their uncertainty	Behavioural aggregation (group consensus) is applied regarding the description of uncertainty around the EKE parameters of the questions (steps 1 to 4, Figure 1). In case of limited evidence on the variation of the ABM in non-exposed populations (question 2) the corresponding EKE parameter is assessed in a simplified way (e.g. as CV), assuming that the uncertainty in the estimation of the full distribution is described by the uncertainty of its location (median parameter).

3.2.2.2. Step 2.2. Definition of methods for integration of evidence within or across sub-questions

As explained in Section 3.2.2.1, per each sub-question requiring the provision of quantitative criteria, a welfare consequence, measured by a 'reference ABM' (chosen to be best ABM reflecting the welfare consequence under assessment), is selected to describe the relationship between the exposure variable (hazard) and the welfare consequence.

However, one welfare consequence may be assessed by more than one ABM and, similarly, one exposure variable may lead to more than one welfare consequence. For instance, in broilers, the welfare consequence 'restriction of movement' may be assessed using the ABMs presence of locomotor behaviour and foot pad dermatitis. An example of one exposure variable leading to different welfare consequences is limited space allowance (as the exposure) resulting in restriction of movement, inability to perform play behaviour, and potentially resting problems in calves.

Therefore, an approach was developed for an overview of the evidence obtained via structured EKE and the available evidence in the scientific literature within a sub-question. The findings from the EKE performed for the 'reference/selected ABM' are integrated with the findings from literature about other ABMs for the selected welfare consequence or, similarly, other and different welfare consequences that can be expressed at different levels of the exposure variable. This information is provided in a tabular format, for an overview of the welfare effects at each increase/decrease in the degree of exposure. For instance, for different space allowances (i.e. exposure variable), data from literature on resting behaviour and respiratory problems depending on space allowance were compiled and combined with EKE outcomes.

A similar approach can be used to integrate the evidence across sub-questions within the same specific scenario.

4.   Conclusions

This document outlines the methodologies that can be implemented by the AHAW Panel to develop the Scientific Opinions on welfare and protection of animals in response to mandates received from the European Commission in the context of the F2F. It is developed in order to define as much as possible the strategy to be applied for collecting data, appraising the relevant evidence, and analysing and integrating the evidence in order to draw conclusions in the Scientific Opinions.

For addressing the general ToRs (Part I) of the Scientific Opinions a 'low extent of planning' is selected as methodological approach because it allows the working group to leave a high level of flexibility in the methods to be used (mainly expert opinion and literature review/search). The flexibility is required as the scope of the opinions is broad and heterogeneous in relation to the specific species (e.g. followed by pigs, laying hens, broilers, calves, etc.) as well as to the different topics to be assessed (different husbandry systems, different transport practices, WCs, ABMs, etc.). Therefore, these methodologies might/will be implemented and adapted for any animal species and husbandry system/transport practice that may be requested in future mandates. This means that, in the future, new WCs may need to be defined and described or existing WC-definitions may be updated as well as the need for inclusion of positive welfare. Future assessments might also include positive welfare indicators and not only negative WCs and negative affective states considering that animals should be provided with opportunities for positive experiences with a given assumption that one should not inflict pain or suffering on an animal. Additionally, in the future, the cumulative effects on animal welfare of different hazards and subsequently different WCs should be considered.

Related to the methodology for part II (Section 3.2.1.3), a new model is proposed for the housing mandates, and may serve as a guidance for risk assessment in animal welfare and, more precisely, when quantitative recommendations are required. The model starts from the concept of how an important ABM (a measure of animal welfare) is expressed under 'unexposed' (hazard) circumstances. It is followed by the ABM under 'highly exposed' circumstances. A structured EKE exercise is used to elicit the necessary parameters of the model to allow an interpolation between the extremes (EFSA, 2014). Thus, the model provides an agreed estimation of the relationship between an exposure variable (hazard) and the expression of an ABM in an animal (e.g. how the amount of locomotor behaviour increases at increasing space allowances).

An additional method is provided to integrate the evidence from EKE with the evidence from literature explaining the relation between ABMs and the exposure (hazard).

Based on this relationship, the WG can describe different scientifically based options, taking into account the related uncertainties, to risk managers as a basis for integration with other considerations (e.g. economical, societal) and for subsequent risk management decisions.

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Abbreviations

ABM	animal-based measure
AHAW	Animal Health and Welfare
EKE	Expert knowledge Elicitation
F2F	Farm to Fork
ToR	Term of Reference
WC	welfare consequence

Annex A – Outcome of the public consultation on the draft scientific opinion on Methodological guidance for the development of animal welfare mandates in the context of the Farm To Fork Strategy

Annex A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7403