



Animal and Plant Health (ALPHA) Unit

ANIMAL HEALTH AND PLANT HEALTH UNIT

MINUTES OF THE 3rd MEETING OF THE WORKING GROUP ON AHAW Panel guidance documents (Self Mandate): Animal Welfare Guidance

M-2020-0033

Held on 22 September 2020 (Web-meeting): 14-16h

(Agreed on 01 October 2020)

Participants

- Working Group Members:¹
Dominique BICOUT (chair)
Virginie MICHEL
Antonio VELARDE
- Hearing Experts²:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
Yves VAN DER STEDE (Secretariat)

1. Welcome

The Chair welcomed the participants.

All working group members connected via Teams.

2. Adoption of agenda

The agenda was adopted without changes.

¹ Indicate first full name and then surname (John Smith) all throughout the document.

² As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

3. Declarations of Interest of Working Groups members

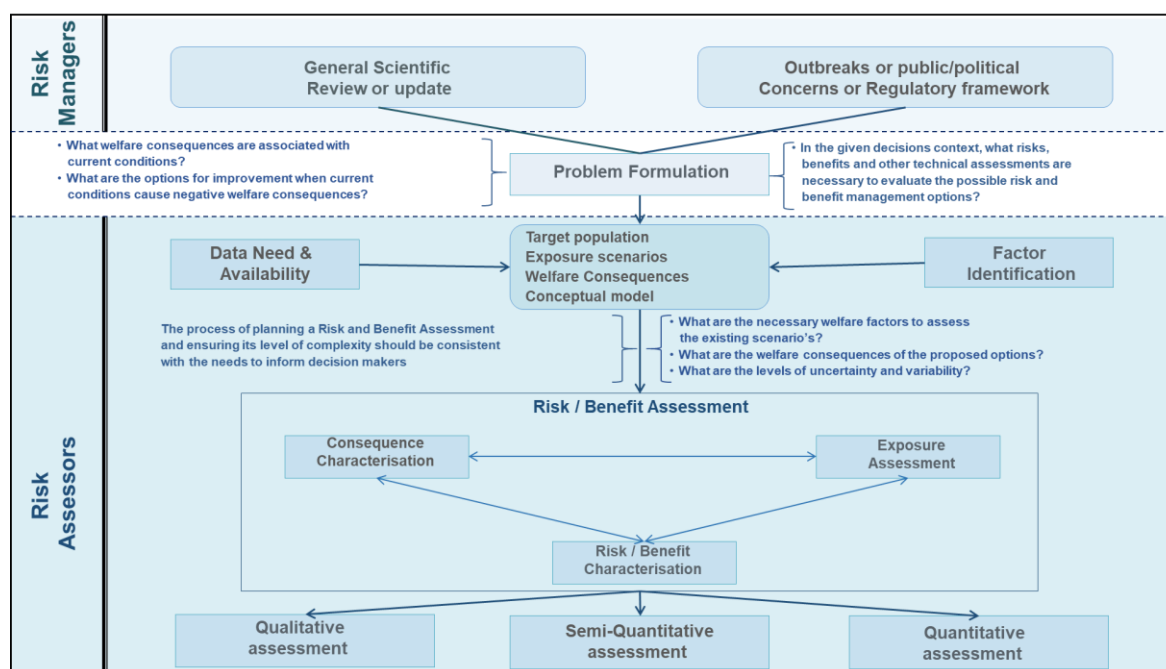
In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. No interests were declared orally by the members at the beginning of this meeting.

4. Discussion Agenda points : action points

In previous WG meeting (09 June 2020), eight action points were defined within the WG. In this WG meeting the state of play of each action point was discussed (Table 1). The working group only discussed the Guidance on Risk Assessment for Animal welfare (AW2012, <http://www.efsa.europa.eu/en/efsajournal/pub/2513>).

4.1. Figure 1: workflow to conduct a risk assessment in animal welfare

The flow chart in the guidance document (Figure 1) was discussed and transferred into a new figure taking into account the clarity needed for Risk & Benefit analysis in the risk assessment part. The benefit assessment was added into the figure (see Figure below) and a narrative text should be taken up (in caption of the figure). Further it was discussed how the conceptual model fits into the elements of 'target population', 'exposure assessment' and 'welfare consequences'. It was agreed to adopt the figure according that all interactions between these three elements constitute the conceptual model in the risk assessment. The figure was agreed within the working group.



³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

4.2. Revise Glossary on animal welfare risk assessment

The glossary (document Glossary_AW2020.0802 HS_CW_including AV_VM) that contained all feedback from the welfare experts of the AHAW panel was discussed thoroughly. The following terms were adopted: ABM, conceptual model, Exposure and exposure assessment, Exposure scenario, qualitative and quantitative risk and benefit assessment & characterisation, factors, welfare consequences, welfare criteria, welfare measures (ABM, resource based and management based) and corrective and preventive welfare measures. A new definition of welfare (Anses), adapted by the WG, was proposed. It was agreed that an attempt will be undertaken to list most encountered welfare consequences and ABM's in the guidance document. If these list would exist this would guide the risk assessors to use the same terminology for WC and ABM's. However, it was argued that it will be difficult to be exhaustive as possible with these lists.

4.3. Illustrative examples and figures

A list of example (qualitative and quantitative methods: e.g. pregnant cows, LAPS, slaughter of sheep in EU, EKE's in welfare) could not be discussed in this WG group meeting due to time constraints. This will be discussed in next WG meeting.

4.4. Other action points in guidance document

The following topics still should be addressed in the following working group: harmonise the glossary between AW and AH guidance documents (task nr. 4 as defined in WG of 9 June 2020) , Data collection section (task nr 6), improve the description of qualitative and quantitative assessment in welfare (task nr. 7), integrate uncertainty checklist in AW assessment (task nr.8).

5. Distribution of tasks

Table 1: State of play of action points (22 September 2020) to update guidance document (AW 2012):

Nr	Topic discussed	Description	Discussion. How to tackle it in the guidance document	Who?	By when?
1	Integrate the Concept of benefit assessment	Update the procedural guidelines for proper integration of modelling into Working Group operational procedures	Partly done: Figure 1. To be finetuned	Dominique & Antonio	1 Nov
2	Integrate concept of risk mitigation	Integrate possible measures for decreasing the risk and increasing the benefits; prevention, correction and mitigation options	Done in the glossary		
3	Terminology and glossary on risk and beneficial factors and animal welfare consequences	Update the terminology and glossary on all risk and beneficial factors and animal welfare consequences	Partly done - To be taken up in the next guidance document	Yves	15 Nov
4	Harmonizing terminology and glossary between AH and	Explore to which extend terminology and glossary can be harmonized (similarities & differences) between animal	To be finetuned in next guidance document	Dominique & Yves	15 Nov

	AW	health and animal welfare			
5	Problem formulation	Review the "problem formulation" to include both the "risk problem" and the "benefit formulation"	Done: see figure 1 and point 1		
6	Data collection section	Review the data collection section (systematic literature reviews, expert's opinion)	To be done in next guidance document	Antonio, Virginie	15 Nov
7	Qualitative and quantitative assessment	Improve the description of qualitative and quantitative assessment. Inputs from AMU. Include examples of both risk and benefit. Statistical methods, and interpretation of data.	To be done in next guidance document	Antonio, Virginie	15 Nov
8	Uncertainty checklist and guidance	Integrate in the guidance the checklist in relation to the assessment and handling of uncertainty and variability	To be done in next guidance document	Dominique	1 Nov
9	Illustrative examples and figures	Which type of example to integrate in the guidance documents	To be discussed in next WG	Yves – to send the example file to WG	1 Oct 2020

6. Workplan (next working group) and timelines

The next meeting dates and timelines were agreed:

24 November 2020 (PM): TEAMS meeting (whole day with both subgroups: Animal welfare and Animal Health).

Upcoming meetings:

Tuesday 19 January 2021 (whole day)

Tuesday 23 February 2021 (whole day)

ANIMAL HEALTH AND PLANT HEALTH UNIT

MINUTES OF THE 2nd MEETING OF THE WORKING GROUP ON AHAW Panel guidance documents (Self Mandate): Animal Health Guidance

M-2020-0033

Held on 11 June 2020 2020 (Web-meeting): 14-17h

(Agreed on 18 June 2020)

Participants

- Working Group Members:⁵
Dominique BICOUT (chair)
Julio ALVARES
Arvo VILTROP
- Hearing Experts⁶:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
Yves VAN DER STEDE (Secretariat)

7. Welcome

The Chair welcomed the participants.

All working group members connected via Teams.

8. Adoption of agenda

The agenda was adopted without changes.

9. Declarations of Interest of Working Groups members

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10. Discussion: Action points

The working group only discussed the Guidance on Conducting Scientific Assessments in Animal Health using Modelling (AH2009) <http://www.efsa.europa.eu/en/efsajournal/pub/1419>

The table (Table 1) below represents the specific topics that needs update and how these will be tackled in the guidance document.

Table 1: Overview of topics discussed to update guidance document (AH2009):

Nr	Topic	How?	Discussion. How to tackle it in the guidance document	Who?
1	Integration of Modelling	Update the procedural guidelines for proper integration of modelling into Working Group operational procedures	The starting point of the guidance document is that it is clear that the request (mandate) requires a model.	Dominique to review the chart on page 16
2	Data limitations	Improve the section on data limitations and to link to the EFSA guidance on uncertainty	Data helps to define the model; depending on the data you have your parameters may be quiet noisy or not.	<u>Under Figure 1:</u> Julio: to add some lines on data limitations (and that this may influence the outcome of the model).
3	Uncertainty checklist and guidance	Integrate in the guidance the checklist in relation to the assessment and handling of uncertainty and variability		Dominique: Account the uncertainty associated to the model? How do you assess the uncertainty associated to the model from one model to another.
4	Terminology and glossary	Update Section 2.2: wiki based glossary to harmonise with glossary in Appendix B Update the terminology and glossary on the use of mathematical and statistical models	A terminology and glossary in wiki allow it to update fast and easy once it is online. Two options were discussed 1) the glossary only related to the guidance document 2) the glossary should contain all terms related to AH modelling. Option 1 was agreed during the WG meeting.	Yves will ask Simon More and EFSA Staff about the wiki-glossary (been done, useful?) YVES will provide the list of terminology and glossary to be checked by AMU.

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

			<p>The glossary and terminology should be aligned with the one of the welfare guidance document in case there is common glossary and terminology.</p> <p>Terminology in appendix A should also be checked by AMU and AHAW.</p>	
5	Model transparency	Update the section on model transparency	Model transparency should be explained more in function of communication and reproducibility of the output.	Yves to add part where transparency is highlighted in the guidance document (e.g. good practices on to make of Transparency of the modelling- sharing scripts Appendix: scripts Foresee also for part in Appendix A)
6	Workflow	Update the workflow presented on page 16		Dominique to review the chart on page 16 (see topic 1)
7	Illustrative examples and figures	<p>Align the document with practical examples</p> <p>Examples: ASF → relation with the model, ...</p>	<p>3 Example were agreed in the WG meeting where the application of the guidance could apply:</p> <ol style="list-style-type: none"> 1) RVF opinion: mint risk model (made of combination of knowledge (decision tool modeling). 2) RVF, LSD spread model 3) IFN-gamma on bTB 	Yves: check with kind of models have been used by AHAW as described in current guidance between 2002 & 2009 and between 2009 and 2019.
8	Editorial	Editing the manuscript (deleting some parts, updating other parts and rearranging some)		Arvo: Comments of Arvo needs to be implemented in the document. Dominique: integrate Arvo's comments

11. Distribution of tasks

See Table 1

12. Workplan (next working group) and timelines

The next meeting dates and timelines were agreed:

22 September 2020 (AM + PM): TEAMS meeting (whole day with both subgroups: Animal welfare and Animal Health)

24 November 2020 (PM): TEAMS meeting (whole day with both subgroups: Animal welfare and Animal Health)

ANIMAL HEALTH AND PLANT HEALTH UNIT

MINUTES OF THE 2nd MEETING OF THE WORKING GROUP ON AHAW Panel guidance documents (Self Mandate): Animal Welfare Guidance

M-2020-0033

Held on 9 June 2020 2020 (Web-meeting): 14-17h

(Agreed on 18 June 2020)

Participants

- Working Group Members:⁹
 - Dominique BICOUT (chair)
 - Virginie MICHEL
 - Anonio VELARDE
- Hearing Experts¹⁰:
 - Not applicable
- European Commission and/or Member States representatives:
 - Not applicable
- EFSA:
 - Yves VAN DER STEDE (Secretariat)

13. Welcome

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All working group members connected via Teams.

14. Adoption of agenda

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16. Discussion: Action points

The working group only discussed the Guidance on Risk Assessment for Animal welfare (AW2012, <http://www.efsa.europa.eu/en/efsajournal/pub/2513>). The table (Table 1) below represents the specific topics that needs update and how these will be tackled in the guidance document.

Table 1: Overview of topics discussed to update guidance document (AW2012):

	Topic	How?	Discussion. How to tackle it in the guidance document	Who?
1	Integrate the Concept of benefit assessment	New title could be "Guidance on risk and benefit assessment for animal welfare". Subdivide the document into two parts: <ul style="list-style-type: none"> Guidance on risk assessment (update) Guidance on benefit assessment (how to perform it → inputs from an extended group might needed) 	Structure the document: negative factors and positive factors (welfare consequences) should be taken up. In the problem formulation it should be made clear what kind of questions we may receive for RA in welfare (WC approach and factor approach). This should be made clear from the beginning and integrated in Figure 1. Make a problem framing: make the question as clear as possible: at the end of RA we have beneficial and bad effects (WC approach or factor approach): see comment in word file. Include in Figure 1.	Antonio to change Figure 1 and be updated by Dominique. Dominique: Provide new Figure 1 aligned with protocol development. (ppt, visio, etc).
2	Integrate Concept of risk mitigation	Integrate possible measures for decreasing the risk and increasing the benefits; prevention, correction and mitigation options	Include in Figure 1: see topic 1	
3	Terminology and glossary on risk and beneficial factors and animal welfare consequences	Update the terminology and glossary on all risk and beneficial factors and animal welfare consequences	<u>Terms to be discussed or revised are listed below.</u> It was agreed that these terms will be discussed first. This list can be discussed and commented over Summer. In function of this feedback an extra WG meeting can be planned in July 2020 (if needed). <ul style="list-style-type: none"> ABM: take from opinion on use of ABM and list of ABMs* Benefit: same wording as risk Conceptual model Consequence characterisation: to compare with AH Delete or discuss Endpoint Expert elicitation Welfare consequence and list 	Yves to prepare list of terms for discussion with AW expert of Panel in Teams → by 20 June 2020. *for ABMs and for WCs it was considered to make a list of WCs and then a list of ABMs (see Figure 2). In addition a list of factors and factor origin could be

¹¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

			<p>of welfare consequence*</p> <ul style="list-style-type: none"> • What are FACTORS? List of factors and factor origin • Add poor/negative welfare • Delete 'Need' • Qualitative risk assessment: tailor for Welfare • Quantitative risk assessment: tailor for Welfare • Semi-quantitative risk assessment: tailor for Welfare • Uncertainty: integrate definition with current guidance documents on uncertainty • Welfare: needs to undifferentiated from the factors (reference: welfare domains, welfare quality). • Welfare measure: to reconsider in function of welfare discussion <p><u>Terms to be added are listed below.:</u></p> <ul style="list-style-type: none"> • <u>Exposure</u> in Welfare is missing • <u>Welfare criteria</u> and link with • <u>Negative welfare consequence and positive welfare consequence;</u> • Welfare preventive measures; • Welfare corrective measures; • Hazard origin • Prevalence/likelihood in context of welfare (prevalence of factor & prevalence of WC) • For a given factor in a given scenario: Risk == magnitude of WC x prevalence of WC x Exposure to factor • For an exposure scenario (you may have many WCs): Needs to be clearer explained in Box3. 	added to this Figure/list.
4	Harmonizing terminology and glossary between AH and AW	Explore to which extend terminology and glossary can be harmonized (similarities & differences) between animal health and animal welfare	Based on Topic 3: harmonise with AH but some terms need to tailored to AW	Yves (see topic 3)
5	Problem formulation	Review the "problem formulation" to include both the "risk problem" and the "benefit formulation"	Include in Figure 1	See Topic 1
6	Data collection section	Review the data collection section (systematic literature reviews, expert's opinion)	Align with the protocol assessment : guidance on data collection in function of the scenario we have for Welfare (Figure 1); Consider the factors, WC, ABMs for the systematic literature review given the scenario at stake and foresee	See Topic 1

			synonyms for these three terms.	
7	Qualitative and quantitative assessment	Improve the description of qualitative and quantitative assessment. Inputs from AMU. Include examples of both risk and benefit. Statistical methods, and interpretation of data.	Needs to be tailored for welfare	Dominique
8	Uncertainty checklist and guidance	Integrate in the guidance the checklist in relation to the assessment and handling of uncertainty and variability	Needs to be tailored for welfare (with AMU)	Dominique
9	Illustrative examples and figures	<p>Update figures and examples according to the new topics and assessment procedures. Some of the figures are currently focus on health (e.g., Box 1 page 7)</p> <p>Review and include examples:</p> <ul style="list-style-type: none"> • Animal welfare consequences and their measurement (e.g. level, duration and intensity). • Animal based measures to assess the welfare consequences • Multiple interactions between welfare factors and welfare consequences <p>Examples: LAPS, ...</p>	<p><u>Agreed Examples to be put in document:</u></p> <p>-Pregnant opinion or tail biting: example of WC approach (scenario)</p> <p>-LAPS: example of factor approach/scenario (comparing three stunning methods)</p> <p>- Example General opinion: Slaughter or sheep: (Welfare of sheep → what are the different scenario's, production systems, etc; for each scenario RF identified and associated with the WC)</p> <p>-Example of Qualitative assessment</p> <p>-Example of (semi)-Quantitative assessment including EKE</p>	Yves to prepare in guidance document the structure on how to integrate these examples.
10	Communication on risks, benefits and animal welfare	Integrate a part on communication on risks, benefits and animal welfare. Inputs from the Communication Unit from EFSA	Guidance of communication should be used and tailored to the scenario's at stake for welfare.	Antonio
11	Risk characterization section	Risk characterization section and Box 3 need to be revised: consider combining distributions of intensities, of durations and the probability of occurrence (prevalence) rather than multiplying the mean. Add uncertainty analysis. Consider adding a Box 4 (similar to Box 3) for modelling in qualitative assessment (see ANSES document)	Endpoint == magnitude (combination of intensity/severity and duration); Conclusion is based on the magnitude for each WC (used to rank the WCs); the combination of different WCs needs to be clearer explained in Box3; Consider this point with point 7 and 8 (mainly quantitative assessment)	Dominique

17. Distribution of tasks

See Table 1

18. Workplan (next working group) and timelines

The next meeting dates and timelines were agreed:

22 September 2020 (AM + PM): TEAMS meeting (whole day with both subgroups: Animal welfare and Animal Health)

24 November 2020 (PM): TEAMS meeting (whole day with both subgroups: Animal welfare and Animal Health)