TECHNICAL REPORT

Outcome of the public consultation on the guidance on risk assessment for animal welfare[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

EFSA requested the Animal Health and Welfare Panel to provide guidance on risk assessment for animal welfare. In order to ensure that the guidance is based on comprehensive, relevant and up-to-date information, a web-based consultation on the draft scientific output was launched in May 2011 for a two month period. The main objective of the consultation was to gather the widest range of views and comments from the scientific community, stakeholders and all interested parties. The consultation received 96 electronic submissions of comments. Relevant comments were incorporated into the draft scientific opinion when the working group considered their scientific basis to be valid. Some of the comments were based on the measures to be taken to improve welfare, meaning risk management, which is out of the remit of EFSA. In relation to the comments about the use of industry experts for the assessment of welfare, the independency of the experts involved in any of the EFSA activities should be guaranteed to prevent any possible bias of the scientific outputs. The document published for the public consultation was revised according to the comments received and the guidance on risk assessment for animal welfare was adopted by the AHAW Panel on 13th of December 2011[4]

KEY WORDS: risk assessment, animal welfare, guidance, public consultation

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[2] Correspondence: ahaw@efsa.europa.eu

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[4] Scientific Opinion on the Guidance on risk assessment for animal welfare, EFSA Journal 2012; 10(1):2513.

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SUMMARY

EFSA requested the Animal Health and Welfare (AHAW) Panel to develop guidance on risk assessment for animal welfare.

In order to ensure that the Guidance is based on comprehensive, relevant and up-to-date information, and in line with EFSA's policy on openness and transparency, a web-based consultation on the draft scientific output at stake was launched in May 2011 for a two months period.

The main objective of the consultation was to gather the widest range of views and comments from the scientific community, stakeholders and all interested parties to help finalise the scientific opinion on the Guidance on risk assessment for animal welfare. The web-consultation gave also the opportunity to inform the public about the draft guidance, the stage of development, and to receive feed back on the contents and its quality.

The total number of electronic submissions of comments was 96. Relevant comments to be considered in the scientific assessment (n=78) were incorporated into the draft guidance when the working group considered their scientific basis to be valid.

Some of the comments were based on the measures to be taken to improve welfare, meaning risk management, which is out of the remit of EFSA. In relation to the comments about the use of industry experts for the assessment of welfare, the independency of the experts involved in any of the EFSA activities should be guaranteed to prevent any possible bias of the scientific outputs.

The document published for the public consultation was revised according to the comments received and the guidance on risk assessment for animal welfare was adopted by the AHAW Panel on 13th of December 2011[5].

This Technical Report presents the main points of discussion, comments and actions taken by EFSA.

[5] Scientific Opinion on the Guidance on risk assessment for animal welfare, EFSA Journal 2012; 10(1):2513.

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BACKGROUND

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

An EFSA Scientific Colloquium on "Principles of Risk Assessment of Food Producing Animals" was held in Parma in December 2005[6] and a further EFSA workshop on "RA methodology in Animal Welfare" was held in Vienna in June 2007. One of the main conclusions from the colloquium was that "no specific standardized methodology exists in the field of the Animal Welfare Risk Assessment". While specific guidelines have been published on animal diseases or chemical substances by the World Organisation for Animal Health (OIE) and the Codex Alimentarius Commission (CAC) respectively, no specific international guidelines on RA for animal welfare are currently available.

The lack of specific guidelines and standardised working methodology on Risk Assessment applied to AW has been identified. Therefore, EFSA launched a self-mandate (EFSA-Q-2007-168) requesting the AHAW Panel to provide Guidance for the assessment of risks for animal welfare. The guidance is intended to be applicable to all types of factors that affect welfare (i.e. housing, transport, stunning and killing), to all types of husbandry systems and all animal categories. The background and terms of reference of the EFSA self-mandate are appended to this report (Appendix A).

The development of the Guidance was performed in two steps. As a first step, EFSA outsourced three Projects under the remit of Article 36 of Regulation 178/2002[7], to explore different approaches as a first attempt to provide guidelines on risk assessment for animal welfare at stunning and killing, during transport and during housing and management (Algers et al., 2009[8]; Dalla Villa et al., 2009[9]; Spoolder et al., 2010[10]). As a second step, a scientific ad hoc Working Group was established in September 2009 to develop a Scientific Opinion on the Guidance on Risk Assessment for Animal Welfare.

In line with EFSA's policy on openness and transparency, a web based consultation on the draft scientific output at stake was launched early May 2011 for a 2 month period in order to receive comments from the scientific community and all stakeholders. After completion of the public consultation, relevant comments were considered and addressed by the working group and included in the draft guidance.

The publication of this technical report about the public consultation is synchronous with the publication of the Scientific Opinion.

TERMS OF REFERENCE

- EFSA to launch a public consultation on the draft guidance.
- AHAW Panel to update the draft guidance considering the comments received.

[6] www.efsa.europa.eu/en/science/colloquium_series/no4_animal_diseases.html
[7] OJ L 31, 1.2.2002, p. 1.
[8] http://www.efsa.europa.eu/en/supporting/pub/11e.htm
[9] http://www.efsa.europa.eu/en/supporting/pub/21e.htm
[10] http://www.efsa.europa.eu/en/supporting/pub/87e.htm

THE CONSULTATION

In 2007, EFSA requested the Animal Health and Welfare (AHAW) Panel to develop a guidance on risk assessment for animal welfare.

In order to support the work of the AHAW Panel, an *ad hoc* Working Group was established in September 2009 to draft the guidance on risk assessment for animal welfare. The guidance[11] was adopted by the AHAW Panel at the Plenary meeting on 13 December 2011.

In line with EFSA's policy on openness and transparency, a web-based consultation on the draft scientific output at stake was launched early May 2011 for a two month period in order to receive comments from the scientific community, stakeholders and all interested parties.

This Technical Report presents the outcomes of the consultation on the draft guidance on risk assessment for animal welfare.

1. Public consultation

In line with EFSA's policy on openness and transparency, a web-based consultation on the draft scientific outputs was organised. The two-month public consultation was published on-line (www.efsa.europa.eu) with an invitation for submission of written comments by 1st July 2011[12]. The comments were sent exclusively by means of an on-line submission form, provided with the then-current version of the draft Guidance. The participants were requested to submit comments and to refer to the line and page numbers. Technical criteria for not considering the comments were also presented and are listed below:

- Comments submitted by e-mail or by post cannot be taken into account and that such a submission would not be considered if it is:
    - submitted after the deadline set out in the call
    - presented in any form other than that provided in the instructions and template
    - not related to the content of the document
    - containing complaints against institutions, personal accusations, irrelevant or offensive statements or material
    - related to policy or risk management aspects, which is out of the scope of EFSA's activity.

All comments were recorded (Appendix B) and assessed by the *ad hoc* working group of the AHAW Panel. The AHAW Panel considered all relevant comments in drafting the guidance on risk assessment for animal welfare.

1.1. Objectives

Main objectives of the consultation were to gather the widest range of views and comments from the scientific community, stakeholders and interested parties to help finalise the guidance on risk assessment for animal welfare. The web-consultation gave also the opportunity to inform the public about the draft Opinion, the stage of development, and to receive feed back on the contents and its quality.

[11] Scientific Opinion on the Guidance on risk assessment for animal welfare, EFSA Journal 2012; 10(1):2513.
[12] http://www.efsa.europa.eu/en/consultationsclosed/call/ahaw100702.htm

1.2. Comments

The total number of comments was 96. Comments were scrutinized for eligibility and when they were repeated comments, blank cells (i.e. wrong submission) or considered out of the scope of the consultation, they were deleted (n=18). No additional information, data or peer-reviewed references were provided. Relevant comments (n=78) were considered in the draft guidance when the working group considered their scientific basis to be valid (Appendix B).

1.3. Main issues commented

Only 78 relevant comments were considered eligible (Appendix B). The comments targeting common general topics of the draft guidance are summarized below:

- Consistent terminology: the consistency of the terminology used in the Guidance was revised (i.e. term magnitude avoided, definition of factor, etc.)
- Request for a detailed methodological approach: the objective of the Guidance is to give general principles and not to describe all possible methods for each welfare assessment.
- Risk Management: risk management (i.e. legislation) is out of EFSA remit. Eventual measures to be taken to improve welfare are part of the management and not of the risk assessment.
- Inclusion of Benefits: benefits should be the scope for a future EFSA work. The terminology was revised to avoid any misunderstanding.
- Involvement of industry experts and stakeholders: the use of industry experts and stakeholders for the development of any scientific opinion could introduce potential scientific bias and create an EFSA scientific independency problem (i.e. declaration of interest of industry experts). Stakeholder consultation meetings are held, whenever considered pertinent and possible.
- Welfare definition: the inclusion of a welfare definition is considered out of the scope of the Guidance focused on the risk assessment methodological approach.

The document published for the public consultation was revised and the guidance on risk assessment for animal welfare was completed.

CONCLUSIONS

A large number of organisations and participants were involved in the process of web-consultation because of their continuing interest in the topic (risk assessment methodology and/or animal welfare).

Comments related with the consistency of the terminology, editorial and typo errors were considered by the working group and amended accordingly.

Considering the comments requesting a detailed methodological approach, it was clarified that the objective of the guidance is to give general principles and not to describe all possible methods for each welfare assessment, which would be impossible. The guidance points at previous EFSA opinions on animal welfare that could serve as detailed examples.

Many contributions called for the need to include in the Guidance measures to be taken to improve welfare, such as, the definition of a severity threshold, definition of good farming practices, etc. These measures are part of the risk management, which is out of the EFSA remit.

Because their experience and for the purpose of data gathering, the use of industry experts and stakeholders for the development of any scientific opinion was suggested in several comments. However, the use of such experts could introduce potential scientific bias and create an EFSA scientific independency problem (i.e. potential conflict of interest of industry experts). Whenever considered pertinent and possible, stakeholder consultation meetings are held to give the possibility to provide comments and submit additional data.

It should be highlighted that some of the comments received during the public consultation were not anymore applicable because the changes suffered by the Guidance from the version submitted for public consultation until the final version adopted and published.

The document published for the public consultation was revised and the guidance on risk assessment for animal welfare was completed.

APPENDICES

A. SELF-MANDATE SUBMITTED BY EFSA

Background as provided by EFSA

The European Food Safety Authority (EFSA) provides independent information regarding risks associated with food and feed, plant health, environment, animal health, and animal welfare (AW) by using, whenever possible, a risk assessment (RA). In addition, one of the tasks of the Authority is to promote and coordinate the development of uniform RA methodologies in the above-mentioned fields. The Animal Health and Welfare (AHAW) Panel of EFSA has adopted 36 Scientific Opinions on Animal Welfare between 2004 and 2010, dealing with welfare of calves, fattening pigs, sows and boars, tail biting, seals, fish and dairy cows. Different approaches have been followed for these scientific opinions.

An EFSA Scientific Colloquium on "Principles of Risk Assessment of Food Producing Animals"[13] was held in Parma in 2005 and, subsequently, an EFSA workshop on "Risk Assessment Methodology in Animal Welfare" was held in Vienna in 2007. One of the main conclusions was that no specific standardised methodology exists in the field of risk assessment for animal welfare. The beneficial effects of some factors for animal health and for animal welfare in general were also discussed; however, only the assessment of risks was considered in detail. While specific guidelines have been published on animal diseases or chemical substances by the World Organisation for Animal Health (OIE) and the Codex Alimentarius Commission (CAC) respectively, there are currently no specific international guidelines on risk assessment for animal welfare.

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

A "Framework for EFSA AHAW Risk Assessment" was produced (EFSA, 2008[14]) but a requirement for specific guidelines and standardised working methodology for risk assessment, including the assessment of beneficial effects of some factors applied to animal welfare has been clearly identified. Against this background, EFSA launched a self-mandate in 2007 to develop guidance on risk assessment for animal welfare.

Terms of reference as provided by EFSA

The original terms of references for the self-mandate were amended in 2009, and were to define a comprehensive and harmonised methodology to evaluate risks and benefits in animal welfare, taking into consideration the various procedures, management and housing systems and the different animal welfare issues, with reference to the methodologies followed in the previous EFSA Scientific Opinions on various species.

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

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

[13] http://www.efsa.europa.eu/en/supporting/pub/111e.htm
[14] http://www.efsa.europa.eu/fr/supporting/pub/233r.htm

Clarification of the Terms of Reference

While the original mandate exclusively focused on risk assessment (i.e. consideration of harmful factors), the 2009 terms of reference of the mandate included explicit consideration of benefit assessment. However, at its 55th plenary meeting[15], the AHAW Panel recognised that risk and benefit analysis in the context of animal welfare may require further conceptual and methodological refinement. The Panel recommended considering detailed aspects of benefit analysis for further work and possible future inclusion in its methodological framework. The Panel consequently proposed to concentrate on risk assessment aspects for the purpose of the Guidance. This was formally accepted by EFSA in April 2011.

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

B. WEB CONSULTATION COMMENTS

ORGANISATION	CHAPTER_TEXT	COMMENT_TEXT	COMMENTS_DEAL
Protection Mondiale des Animaux de Ferme	3. Concluding remarks: When and how to use risk analysis?	1112 : On parle de « modèles conceptuels » sans en avoir aucun exemple ? 1177 : pas de résumé des clefs d''analyse (comme celles présentées en ligne 1067), ni demandes d''études plus approfondies ?	1112. The conceptual model is described in section 3.1 Problem formulation.1177. The requested "keys for analysis" were considered part of the interpretation of the results and not of the risk assessment process, and thus not included in the final version.
Protection Mondiale des Animaux de Ferme	2.4.3 Expert knowledge elicitation	1067 : « clefs » de gestion ou de réduction des risques très utiles et pertinents	N/A
Protection Mondiale des Animaux de Ferme	2.4.3 Expert knowledge elicitation	983 : analyse très fine et complète	N/A
Protection Mondiale des Animaux de Ferme	2.4.1 Data input in the risk assessment model	911 : les critères différents ne sont pas listés ? Ni analysés ? Ni critiqués ? 912 : les méthodes pour mesurer la répétabilité ne sont pas listées ? Ni analysées ? Ni critiquées ?	It is out of the scope of the Guidance to review all data collection and validation methods. Only general principles are given and it is believed that no specific methodology is needed to validate animal welfare data.
Protection Mondiale des Animaux de Ferme	2.4.1 Data input in the risk assessment model	860 : il s''agit de la figure 3 (et non pas de la figure 6 comme écrit).	To be corrected.
Protection Mondiale des Animaux de Ferme	2.3.3 Risk characterization: integration of welfare consequences	822 : l''exemple d''intégration donné ici ne fait pas état d''une possible pondération lors de l''agrégation des mesures. La note d''absence de blessures a t''elle le même poids que celle du confort de repos? 841 : Les notions de « both total score » et « combination » ne sont pas explicitées ici. Il n''y a pas d'explication sur les différentes méthodes qui ont d''ores et déjà été utilisées, comment elles ont fait leurs preuves etc. La question de la pondération lors de l''agrégation revient à nouveau ici.	These examples were considered confusing and not included in the final version. Box 3 gives the generic approach on the assessment of poor welfare.
Protection Mondiale des Animaux de Ferme	2.3.2.2 Assessing the welfare consequences	745 : il est indiqué qu''on ne peut pas, dans tous les cas, combiner la force et la durée des effets dans une mesure de magnitude appropriée. On est pourtant là dans un des nœuds du problème de l''évaluation du bien-être animal ! (une souffrance courte et aigue vaut-elle mieux qu''une souffrance moindre mais à long terme ?). Un besoin d''études supplémentaires se fait ressentir ici.	The term magnitude, which includes both intensity and duration of the welfare effect, has been used in the final version.
Protection Mondiale des Animaux de Ferme	2.3.2.2 Assessing the welfare consequences	732 : la notion de réaction en cascade, introduite ici, est pourtant peu développée. Elle paraît pourtant être quasi omniprésente dans le cas des indicateurs sur le bien-être animal ? (le bien-être animal pouvant influer sur l''état physiologique et immunologique de l''animal, qui peuvent conduire ensuite à d''autres effets sur le bien-être animal !).	The possibility of different intensities of the consequences depending on the strength of the factor, i.e. high temperature lead to sweating; very high temperature lead to dehydration has been considered in section 3.3.

Protection Mondiale des Animaux de Ferme	2.2 Problem formulation	477 : Le tableau donne l''exemple d''effets négatifs et positifs, mais semble placer au même niveau des effets potentiels (comme le risque de parasitisme) et des effets avérés et permanents (comme les comportements d''exploration). La question de la pondération des facteurs apparaît ici, sous la forme d''une pondération selon la fréquence et la potentialité des risques. On peut aussi voir une question de pondération en fonction de la catégorie de l''effet (le risque de parasitisme peut être géré par le management ; l''expression des comportements exploratoires est définie par une structure d''élevage, par les ressources disponibles) mais aussi de la complexité des facteurs de variation de l''effet (le parasitisme peut varier selon un grand nombre de facteurs, les comportements exploratoires varient selon moins de facteurs différents).	In the problem formulation (3.1) the possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated, but no no ranking or ponderation of these effects has been done. The outcomes of the risk assessment will consider the ranking and ponderation, whenever relevant.
Protection Mondiale des Animaux de Ferme	1.2 Risk assessment - definitions	310 : La définition de « facteur » ne prend pas en compte les facteurs de type génétique. Pourtant, la sélection génétique peut avoir un impact important sur le bien-être des animaux d''élevage (exemple de la sélection des truies reproductrices ou des poulets de chair à croissance rapide ; et l''EFSA concluait pour ce dernier que la souche génétique était la source principale des problèmes de bien-être rencontrés en élevage).	The definition of factor aims to include all possible aspects independently if they are explicitly mentioned or not. i.e. management aspects would include food, water, genetic selection, etc...(see Glossary)
Protection Mondiale des Animaux de Ferme	1. Introduction	Ce guide est très intéressant par la prise de conscience de la complexité des risques qui y est faite. Il est cependant assez frustrant de ne pas avoir de « méthodes » à proprement dit, ni même de critiques des méthodes existantes (si l''on part du principe qu''il est difficile, même pour l''EFSA, de définir une méthode parfaite, on peut pour autant faire la liste des existantes, comparer leurs utilisations, les résultats et les différentes critiques des unes et des autres). On parle de « modèles conceptuels » (ligne 1112) sans en avoir aucun exemple L''analyse très fine et complète des dires d''experts (ligne 983) est particulièrement utile. On comprend ici son utilité, ses risques et on a ensuite les « clefs » qui nous permettent de réduire ou de gérer les risques (encadré de ligne 1067 à 1090). On pouvait attendre ce type d''analyse pour les autres étapes de la construction d''une évaluation du bien-être animal. Il n''y a, d''une manière générale, pas d''approche sur la pondération des différentes mesures ou indicateurs lors de leur agrégation. C''est pourtant l''un des grands risques de mauvaises conclusions ! L''EFSA ne fait ici ni recommandations, ni demande d''études plus approfondies sur tel ou tel sujet, alors que c''est dans son habitude dans les anciens rapports. Il n''y a pas de propositions de solutions données à l''évaluation des risques. Sans parler de faire la liste exhaustive de l''existant (quasi impossible !) on s''attendrait à trouver une liste des catégories : solutions de management / structure / pratiques d''élevage / etc. ainsi qu''à une critique des solutions proposées, comme sa facilité de mise en place par exemple.	Because the variability on methodologies and approaches for risk assessment and animal welfare situations, the objective of the Guidance is not to describe all methods and approaches for each welfare assessment (probably impossible) but gives a general approach of what has to be done in any case and give the principles to the users to implement the best methodology in any welfare assessment. In relation to the need of recommendations for further research on this issue, it is necessary to wait the implementation and use of the first version of the Guidance and feedbacks and critics from the users. At this point further recommendations and further research could be suggested. The question about the solutions is answered itself. Management options are not part of the risk assessment and thus out of the scope of the Guidance.

German Animal Breeders Federation (ADT e.V.)	6. Glossary and abbreviations	Line 1757-1759: The definition of conceptual model given here is a different one than given in chapter 2.2.2 (line 566/567)! Please choose for one. Line 1775: The definition of Exposure characterisation in line 624-626 contains additionally the words "(and their inter-relationships). Line 1816: In the definition of consequence characterisation in line 1763 the impression is given that welfare determinant and factor are synonyms. From the text, this is not so clear. If it were really meant to be synonym, I would propose to replace the definition for welfare determinant given here by the definition of factor given in line 310-312.	Definitions will be revised and amended in order to be consistent in the entire document. The term determinant will be replaced in all cases by factor to be consistent.
German Animal Breeders Federation (ADT e.V.)	5.3 C Case studies: consequence assessment and quantitative risk assessment	Line 1628/1629: Why are the "steps" mentioned here not in line with the wording in chapter 2? Is "factor selection" the same as "factor identification" and "factor exposure assessment" the same as "exposure characterisation" (cf. Figure 1)?? And what about the risk/benefit consequence? Line 1625: Which category 2 are you referring to? Line 1653: Why is ketosis not included? Line 1657 ff.: Which experts were asked? The figures seem to be very subjective? Line 1665: Why did the experts opt for a difference of 20 between male and female? Line 1671: I can't believe that a study from 1990 which is related to Swedish cattle only has been used to evaluate such a complex issue. Is there no more recent research or studies for more widespread breeds? More research is needed, basic and applied, to understand and address the problem. Line 1676: Maybe you should explain that SRB stands for Swedish Red and White cattle, not everyone might know (either in the text or in the glossary and abbreviations chapter). Line 1679 ff.: Where do these figures originate? Line 1699: Where are these probabilities taken from? What about heifers and second and more lactation cows? Line 1718: Why is this associated with – 5 welfare units for the disposal of an unwanted male calf? Line 1740: it should read "using sexed semen in first lactating SRB cows is preferable", because all figures seem to have been taken from studies related to SRB. For other breeds, the probability of dystocia would be different, leading to a different final result, too. Line 1741/1742: could you explain how you derived the percentages?	The examples given in Appendix C (Appendix B in the final version) have been amended in order to be consistent with the nomenclature and risk assessment steps defined in the Guidance. The origin of the data used for this assessment has been clarified. It should be clarified that the example was used to illustrate how an animal welfare assessment could be done in quantitative way independently of the data used and the results obtained in the study.
German Animal Breeders Federation (ADT e.V.)	4. References	Line 1285: The citation seems wrong. The article of Ribo and Serratosa is found on pages 305 to 338 and not from 239 – 274. The title is also missing "International context and impact of EFSA activities in animal welfare in the European Union".	References will be revised and amended accordingly.

German Animal Breeders Federation (ADT e.V.)	2.4.3 Expert knowledge elicitation	There are some very important remarks about unconscious heuristic bias in this chapter. In addition, there is no Value freedom (Wertfreiheit) for scientists and this has to be taken into account when interpreting research results. Line 985: If traditional scientific research is not possible, what speaks against including experts from the animal breeding sector in the expert groups? There are also some scientists working in the industry, which have practical experience. That could be a useful completion of the more academic experience of the "normal" scientists in EFSA panels.	Benefits are not considered in the Guidance but they will probably be the scope of a future EFSA work. In relation to the inclusion of industry experts, consultation with the breeding sector and the industry is usually performed. However, the possible bias introduced in the science-based Scientific Opinions from experts linked with the industry because potential conflicts of interests should be considered. To avoid any possible bias, experts linked and/or working with the industry are usually not allowed to take part on EFSA WGs. An expert declaration of interest (DoI) is submitted to EFSA and must be approved before inviting any expert to an EFSA meeting.
German Animal Breeders Federation (ADT e.V.)	2.2.2 Conceptual model	We would welcome the participation of practitioners in developing the conceptual model (and/or in formulating the problem, see line 430 ff.). This is a decisive step - if impractical (although theoretically workable) alternatives are assessed, the implementation is endangered. Practicalities of the recommendations should be taken into account. It should be considered when and to what extent the "field experience" of animal keepers is useful in that step.	Usually the formulation of the problem and the conceptual model comes from a previous situation and concern infield, which involves practitioners and farmers. What it is intended in the section, however, is not to define who formulates it, but the correctness of the risk question in order to be able to answer appropriately and get the adequate corrective measures.
German Animal Breeders Federation (ADT e.V.)	2.2.1 Target population and scenarios	Line 550: I would assume that DO stands for dissolved oxygen. Maybe explain it in the glossary and abbreviations chapter.	Target population examples have been removed in the final version.
German Animal Breeders Federation (ADT e.V.)	2.2 Problem formulation	Line 442/443: On a more positive note, the risk assessor could also identify the welfare component (factor) with the greatest potential to improve animal welfare. Line 446 (box with examples): Another positive effect of not unloading animals at control posts is that the length of the rest period could be abridged resulting in an overall shorter transport time. Line 465: If "simultaneous consideration of negative and positive effects" is a step on its own, it should appear in the figure, too! (Problem formulation is also named a "step", see line 449).	442: the final objective is the improvement of AW. In this case, there is an intermediate step to allow managers to find management alternatives to improve AW. 446 and 465: Examples have been removed in the final version. The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated In the problem formulation (3.1).

German Animal Breeders Federation (ADT e.V.)	2.1 When a risk assessment approach is needed?	Figure 1: The figure is quite illustrative, but could be better explained in the accompanying text. We would prefer a subsection for every term and we recommend using the same terms in the picture and the text. For example: if there is a subsection for "Risk assessment", why is there no paragraph on "Scientific expertise" (which is shown in the figure as being on the same level)? The lower grey box in the figure lists three elements of risk assessment, but in the text, they appear in a different order (the figure starts with consequence, but the text with exposure characterisation). Moreover, in the figure the term "Risk/benefit consequence" is used, while the text has a chapter on "Risk characterisation" – is it meant to be the same? Lastly, we are missing the quality assessment of the risk assessment procedure in the figure.	According to these and other received comments Figure 1 has been revised and amended accordingly. Quality assessment is considered not to be part of the risk assessment procedure which is the objective of the Guidance.
German Animal Breeders Federation (ADT e.V.)	1.3 Instruments measuring animal welfare	Line 351: As it is rightly stated that the relationship between the indicator and the welfare criteria should be well-documented, we propose that an example for an animal performance indicator be given. If in table 1, third column, the term measure is used as a synonym for indicator we would prefer to use "indicator" directly. Otherwise, the difference between measure and indicator should be explained more clearly.	351: Table 1 has been removed in the final version and terms welfare criteria, welfare measure and welfare indicator clarified (see Glossary).
German Animal Breeders Federation (ADT e.V.)	1.2 Risk assessment - definitions	Line 295: It should read "positive welfare effects and"	Typo mistake N/A in the final version..
German Animal Breeders Federation (ADT e.V.)	1. Introduction	In general, the word "risk assessment" is not the best term, because most observers will perceive it as something negative or something to be avoided. A more neutral term like e. g. animal welfare assessment would be better. We would also like to see the EU follow an approach that is embedded in the international framework. The EU should try to integrate previous considerations of the subject in other countries (e. g. Australia: http://www.daff.gov.au/__data/assets/pdf_file/0004/1046497/37-michael-paton.pdf). Risk assessment is also addressed by OIE or Codex Alimentarius. The final approach should be coherent. There is a need for global approaches for global risks. How will communication to the public and stakeholder dialogue fit in? (P. Testori Coggi highlighted the importance of a framework for RA at international level which will increase its utility for all involved (assessors, managers and society), identified the need for clarity and consistency in RA, including the need for transparent terminology and description of uncertainties in the RA process (see the Summary Report of the 2nd Int. RA Conference from January 26-28, 2011 in Brussels; page 1, http://ec.europa.eu/health/risk_assessment/docs/ev_20110126_mi_en.pdf)). Line 144: Mathematical modelling has its own snares, going beyond the approach described in the guidance document. In any case, a clear and understandable description of the model is needed and why it has been preferred to others. Other aspects have been treated by Prof. Barnett in his talk "The impact of disease outbreaks: some dangers of modelling" at the conference on Crisis Management in the Food Chain on May 19/20, 2001 in Brussels. Line 160: More impetus than in the past should be given to the description of inherent conflicts (a certain factor (as defined on page 9) may have a negative impact on one dimension and at the same time a positive on another (see also line 190-192 as well as lines 465 ff., which we fully support).	The word risk assessment is internationally recognised and known, and EFSA is recognised as a risk assessment organisation. Therefore, use only the word assessment would mislead the real objective of the Guidance. Whenever considered relevant, other approaches, such as the OIE guidelines, have been considered in order not to reinvent the wheel. In relation to the communication strategy, following the EFSA policy on transparency all EFSA documents are published in the EFSA web. Same will happen with the Guidance once adopted. In relation to the Model and because the variability on methodologies and approaches for risk assessment and animal welfare situations, the objective of the Guidance is not to describe all possible models for each welfare assessment (probably impossible) but to give a general approach of what has to be done in any case and give the principles to the users to implement the best model in any welfare assessment.

COPA-COGECA	3. Concluding remarks: When and how to use risk analysis?	Line 1170 This effort requires significant input from the stakeholders associated with the need for decisions to be informed by the risk assessment. COPA-COGECA response – we welcome this interaction.	Whenever possible, EFSA always try to involve and consult stakeholders.
COPA-COGECA	2.3.3 Risk characterization: integration of welfare consequences	Line 820 COPA-COGECA response - Whether or not scores can be given and make sense is related to the reliability of the data involved, and their repeatability, and to the proper adjustment for disturbing factors. Simply adding up factors is dangerous. Proof of the background of the judgments must be provided. Reality checks of the results are important.	These examples were considered confusing and therefore not included in the final version. Box 3 gives the generic approach on the assessment of poor welfare.
COPA-COGECA	2.2 Problem formulation	Line 430 – 438 COPA-COGECA response - Problem formulation should precede the risk assessment and be conducted with an interaction with both the decision maker and the farming industry representative in order to ensure that the chosen terms of reference and welfare concerns are not limited by the risk assessors' intended approach. This transparent interaction can help to identify the right context of the questions. Farmers can be identified as 'field experts' (see line 250). Practical experience can reinforce the pure and scientific modelling approach;	Usually, the formulation of the problem and the conceptual model comes from a previous situation and concern infield, which involves the farming industry. What it is intended in the section, however, is not to define who formulates it, but the correctness of the risk question in order to be able to answer appropriately and get the adequate corrective measures.
COPA-COGECA	1.1 Methodological challenges	Line 262 ...an optimal risk assessment requires experts from all the areas involved COPA-COGECA response - It has become commonplace to see research-based proposals focused mainly on behavioural aspects of animals. Welfare based scientific opinions must be developed in a broader scope, taking into account not only behavioural aspects but also physiology, genetics, genomics, animal health, as well as the cost and benefits for the environment and the practical consequences on the whole veterinary and food chain. Line 321 Animal welfare needs to be measured in a scientific way COPA-COGECA response - Most research is problem-driven or concern-driven. As a consequence, much of the scientific literature is about problems – not about their possible solutions, and certainly not about actual implementation of such solutions and the beneficial outcome of this. Improvements and applications of good practice cannot realistically be included when they form only a minor part of the scientific literature. The complete system cannot realistically be taken into account when the majority of the scientific literature zooms in on particular details and is not particularly strong in relating to the balance and total outcome of systems.	262. In the EFSA scientific opinions on animal welfare not only behavioural aspects are considered. See also the definition of factor in the Glossary which includes, among others, physical, chemical and microbiological agents. 321 the comment is pertinent but it should be considered that risk management is out of the scope of EFSA and of this Guidance.

COPA-COGECA	1. Introduction	Line 155-158 The notion of risk assessment was considered by the Working Group to be relevant to animal welfare assessment. However, it was decided that the positive effect on welfare (benefit) could be handled within the framework of risk assessment if the analysis considers both factors having positive effects and factors having negative effects on animal welfare. COPA-COGECA response - Risk assessment methodologies may have several difficulties of implementation in the area of animal welfare: openness and transparency of the entire process is needed. Changing and evolving technologies, globalised interactions between science, technology, and economy, can play an crucial role in guaranteeing a robust and unbiased risk assessment. There is a problem of weighting the various factors. Functional weighting as part of the whole system is important because of inherent conflicts such as (1) weighting, in outdoor systems, the risk of a disease outbreak against the animal's benefit of free ranging, or (2) what happens when a particular treatment takes place or not. Because of the complexity of farming systems this cannot be captured responsibly in through a risk assessment analysis. There are too many factors that, added up, can give a biased outcome, as rightfully indicated in the Risk Assessment guide. This means that Risk and Benefit Assessment is not a good tool to capture farm production systems, let alone animal breeding programmes. The balance of production systems and breeding programmes requires fine-tuned management. Animal breeding systems apply fact-based weighting to a wide range of factors, with continuous further refinement. We propose to move towards sectorial responsibility where e.g. management systems on the farm can be used to monitor and continuously improve overall farming practice, farm animal health and welfare.	Because the risk of getting biased conclusions when adding too many factors, the importance of a proper problem formulation and an adequate target population definition is crucial, as described in section 3.1. The correctness of the risk question will make easier to answer it appropriately and get the adequate corrective measures. It should be pointed out that the objective of the Guidance is to give general principles on how to perform risk assessment in animal welfare. Any aspect related to the subsequent management measures are out of scope of the Guidance.
Eurogroup for Animals	2.2.1 Target population and scenarios	Welfare determinants Page 15 dehydration should be mentioned as a welfare determinant in lines 521 and 522 too. At the moment it is only included in line 523.	Target population examples have been removed in the final version.
Eurogroup for Animals	2.2.1 Target population and scenarios	Target population (p. 15, paragraph 2.2.1. (starting with line 489)) The definition of "target population" (lines 504 to 511) should also include the intended use in a very precise way. In the introductory sentence (line 504) to the list of aspects to be included in the definition the word "may" should be replaced by "should".	It has been discussed whether the scenario should be included in the target population definition or not. They are considered separately and the section amended accordingly (section 3.1 in the final version).

Eurogroup for Animals	1.2 Risk assessment - definitions	Factors influencing animal welfare In lines 118 and 119, the draft states "the guidance is intended to be applicable to all types of factors that affect welfare (i.e., housing characteristics, transport conditions, stunning and killing conditions) (…)". We believe that some of the factors which affect welfare are missing here, such as: management, genetic selection, provision and quality of food (or nutrition) and provision of water. Either i.e. should be replaced by e.g., or a full list of the factors should be included. This would be consistent with the section 1.2. on risk assessment definitions, in lines 269 to 273, which states that "For the purpose of this opinion, the scenario includes information about the animals related to their housing, nutrition, genetic selection, transport, farm procedures, slaughter procedures and husbandry in general". Equally on page 9, lines 310-312, no reference is made to nutrition or genetic selection as factors which can directly or indirectly influence animal welfare. In lines 1107-1110 genetic selection is not stated as being part of the scenario. There is a reference to "breeding practices", which might be understood as genetic selection, but might also not be. We strongly believe that genetic selection is a factor that can strongly influence animal welfare and this should be stated as such in a consistent way through the whole document.	The definition of factor aims to include all possible aspects independently if they are explicitly mentioned or not. i.e. management aspects would include food, water, genetic selection, etc... (see Glossary)
Eurogroup for Animals	2.2 Problem formulation	Examples for the assessment of positive effects In the table on page 14, we believe that some of the examples are not relevant, as they refer to practices which are primarily detrimental to the welfare of animals and it doesn't look appropriate to use them as examples of practices where positive effects on animal welfare need to be evaluated. These practices are used primarily to compensate the negative impacts (the risks) caused by bad management or inadequate breeds, and they would not be used if there was no bad management in the first place. This is the case for beak trimming, de-toeing and de-spurring in broiler breeders. The example of the cage system for laying hens is also inappropriate as it has been recognized as a rearing system which has negative impact on the welfare of laying hens.	Examples have been removed in the final version. The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated in the problem formulation (section 3.1).

Eurogroup for Animals	1.1 Methodological challenges	Risk and benefit The terminology for Risks and Benefits is unclear, and this lack of clarity may be damaging. In this context, 'Risk' is appropriately used to mean a potential negative effect on welfare (or, in quantitative terms, the probability of such an effect). Unfortunately there is no single word available that means the opposite, a potential positive effect. Presumably for this reason, the document therefore redefines 'Benefit' to have this meaning (see definitions in line 292-6 and the Glossary). In common use, of course, Benefit means an actual positive effect, not a potential one. Formalisation of this terminology may perpetuate misperceptions about the welfare impact of different procedures. Discussions of genetic engineering, for example, have often listed associated risks and benefits, giving the impression that the former are avoidable but the latter are concrete. The lack of clarity is made worse by inconsistency in the document. In some places (both before and after the definition in line 295) 'benefit' is used with its everyday meaning: line 156 refers to "the positive effect on welfare (benefit)," line 163 to "possible benefits to animals" and line 466 to "positive effects (benefits)." In other places no clear distinction is made between definite and possible effects. The Box on page 14 has lists of Negative effects and Positive effects; some in each are phrased as definite and some as possible. We accept that there is no easy solution to this terminology problem. To refer to 'potential benefits' and 'Risk-Potential Benefit Assessment' consistently, for example, would be difficult. We strongly suggest, though, that the problem needs to be addressed: First, by discussing it explicitly at the outset (and wherever else appropriate, for example in any abstract or summary), explaining that in this context 'Benefit' is defined as having this specialist meaning; Second, by consistency in the rest of the document. This can be achieved by using a synonym such as 'advantage' for the everyday meaning of an actual positive effect on welfare, and 'benefit' only in its specialised, redefined meaning of a potential advantage for welfare.	This point originated several discussions at different levels. It was concluded that benefits will not be considered at this stage and will probably be the scope of a future EFSA work. The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated in the problem formulation (section 3.1)..

EFFAB, EPB, AVEC, AEH, PVSG	3. Concluding remarks: When and how to use risk analysis?	Any analysis to include both risks and benefits: yes Quantification of expected or recorded benefits associated with each factor examined: not acceptable. The expertise to undertake proper weighting is not available so far. This would make quantifications based on incomplete or unreliable data unacceptable. "Welfare scientists from a wide range of areas" should be: "Scientists from a wide range of areas and inclusion of three to five industry specialists". Practical experience of the available scientists is also important. General conclusion: Risk and benefit assessments should only be used in animal welfare as part of an integrated animal production approach where the inputs are complete and accurate.	Benefits are not considered in the Guidance but they will probably be the scope of a future EFSA work. In relation with inclusion of industry experts, consultation with the breeding sector and the industry is usually performed. However, the possible bias introduced in the science-based Scientific Opinions from experts linked with the industry because potential conflicts of interests should be considered. To avoid any possible bias, experts linked and/or working with the industry are usually not allowed to take part on EFSA WGs. An expert declaration of interest (DoI) is submitted to EFSA and must be approved before inviting any expert to an EFSA meeting.
EFFAB, EPB, AVEC, AEH, PVSG	2.4.3 Expert knowledge elicitation	Comment The remarks about expert input hold also for scientists. The text is written from a peculiar perspective with little respect for the value of the expert, and little self criticism of the scientist on his own bias. For instance, scientific recommendations tend to advice more research (and funding for it) in their own area – with little thinking out of the box.	EFSA scientific opinions always include recommendations for further research when data gaps are identified, from previous conclusions and recommendations.,
EFFAB, EPB, AVEC, AEH, PVSG	2.4.2 Uncertainty and variability	In general, when information is lacking, or not reliable enough, it is dangerous to undertake a risk assessment Line 965-966: Comment The management of variability and uncertainty needs to be managed by specialists with sufficient mathematic, programming, quantitative analysis skills, so that they can use the correct method for each type of research that is being undertaken. A meta analysis of data must be undertaken under the guidance of statisticians and mathematicians.	The comment although pertinent is not totally right. It is not the uncertainty which indicates to perform or not the risk assessment. Is the uncertainty of the risk assessment outcomes which indicates how accurate the conclusions will be and therefore the reliability of the decisions taken from these conclusions.
EFFAB, EPB, AVEC, AEH, PVSG	2.4.1 Data input in the risk assessment model	Lines 859-865 Comment So far no professional explanation has been given on how scoring would take place. Input from people from practice will be crucial to make a reality check. As scientists need to focus on small separate areas, their skills and expertise in combining interrelating factors is small. Therefore, it is not advisable that they undertake collation of data. For that, in-depth analyses by skilled management programme or breeding programme specialists is required. In these areas expertise is available to handle difficult data sets in scientifically responsible ways.	It is out of the scope of the Guidance to review all data collection and validation methods. Only general principles are given and it is believed that no specific methodology is needed to validate animal welfare data.

EFFAB, EPB, AVEC, AEH, PVSG	2.3.1 Exposure Characterization	Line 706-707, ´The magnitude of welfare consequences (the response) can only be quantified through sets of animal-based welfare indicators´ Question This is a strong statement. It is not an axioma. Line 774-776, ´Generally, the area under the curve on the respective plane of intensity and duration of the consequences is accepted to represent the magnitude of the consequence Line 820 Comment Whether or not scores can be given and make sense is related to the reliability of the data involved, and their repeatability, and to the proper adjustment for contributing factors. Simply adding up factors is dangerous. Proof of the background of the judgments must be provided. Reality checks of the results are important.	707: The term measure is used instead of indicator. 776: type error N/A in the final version.820: These examples were considered confusing and therefore not included in the final version. Box 3 gives the generic approach on the assessment of poor welfare.
EFFAB, EPB, AVEC, AEH, PVSG	2.1 When a risk assessment approach is needed?	Line 381-382, ´there will often be limitations in the knowledge and data available´. Comment: In such a case a risk assessment should be avoided. Lines 411-412, Line 419 Comment: We agree Simultaneous consideration of negative and positive effects in the risk assessment Example 476-477 ´Beak trimming in broiler breeders´ ´Incidence and severity of injurious behaviour could be reduced´ Comment: This should be ´Incidence of behaviour causing injuries, and severity of injuries will be reduced´.	The section has been shortened. Section 2 and Figure 1 illustrate the previous steps before the risk assessment process. Examples of negatives and positive effects have been removed in the final version. The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated in the problem formulation (section 3.1).
EFFAB, EPB, AVEC, AEH, PVSG	2. Proposed risk assessment in animal welfare	Lines 360-371 Comment: The scientists agree that the scientific literature often does not provide enough reliable information to base a judgment on. Adding simulation studies cannot overcome this. We suggest that practical data are being taken into account; they are more valuable than simulations in these cases, as they relate to reality. It is a widely accepted fact that simulation studies can easily deviate further away from reality.	The section has been shortened. Section 2 and Figure 1 illustrate the previous steps before the risk assessment process.

EFFAB, EPB, AVEC, AEH, PVSG	1.3 Instruments measuring animal welfare	Comment: Ideally welfare is to be assessed as part of general assessments. Line 321, `Animal welfare needs to be measured in a scientific way´ Comment: Most research is problem-driven or concern-driven. As a consequence, much of the scientific literature is about problems – not about their possible solutions, and certainly not about actual implementation of such solutions and the beneficial outcome of this. Improvements and applications of good practice cannot realistically be included when they form only a minor part of the scientific literature. The complete system cannot realistically be taken into account when the majority of the scientific literature zooms in on particular details and is not particularly strong in relating to the balance and total outcome of systems. Line 329, ´Welfare Quality´ Comment: It is fruitful to mention Welfare Quality as an example. But other research and achievements must also been taken into account. Line 338, ´or they may be poor predictors´ Comment: This holds for both animal and non-animal based indicators. Presented in this way, it is biased. Line 342-343, ´Table 1´ Comment: The behavioural criteria seem to be vulnerable to subjectivity: automated data would be preferable. More examples of possibilities to improve welfare would be welcome, so that a balance of positive-negative would come into reach.	321. The comment is pertinent but it should be considered that risk management is out of the scope of EFSA and the objective of the Guidance is risk assessment on animal welfare. 329: Welfare Quality is the biggest project about welfare indicators. EFSA welcomes to receive additional references. 338. it is generally accepted that animal-based should provide more information that outcome-based. Table 1 has been removed in the final version.
EFFAB, EPB, AVEC, AEH, PVSG	1.2 Risk assessment - definitions	Compare with line 119. Line 288, ´risk assessment or benefit assessment´… Comment See line 156-158, suggestion of risk assessment to include both risks and benefits. In lines 288-290 risk assessment seems to exclude benefit assessment. Remark: the precautionary principle (attached or will be sent separately) requires, in addition to weighting pros and cons, also the appropriate weighting of consequences.	Benefits will not be considered at this stage and will probably be the scope of a future EFSA work. Terminology has been revised to avoid misunderstandings (see Glossary).

EFFAB, EPB, AVEC, AEH, PVSG	1.1 Methodological challenges	Line 182-183, ´In the absence of precise identification of the welfare components of concern in relation to the risk problem, the complexity of the risk assessment is increased and the numbers of risks assessed under each mandate are very high´ Our comment This confirms what we have indicated re Lines 84, 97, 107 and Lines 156-158. Conclusion: in these cases, a Risk Assessment is not an appropriate method in scientific EFSA opinions. Availability and quality of the welfare data Line 217, ´Due to the limited amount of quantitative data in some areas´ Line 219, ´largely based on expert opinion´ Line 219-220, ´quality … of published data were not considered in the approach´ Line 222, ´the paucity of quantitative data, and of good data, in some cases generated high uncertainty´ Comment It is crucial that the quality of (published) data and the quality of scientific articles is taken into account in any approach. Expert opinion as the main basis for a scientific opinion has proven to be insufficient. Therefore, expert and scientific panels should be extended with practical people (representing the farming industry) to deliver input on farming systems and other practical issues during the process, e.g. 3 industry experts in a group of 12-15 scientists. They should not form the majority, and are there to enable reality checks of the scientists at work. Scientists with experience in working with industry data can also give important realistic input. Calls for data e.g. from public bodies or industry, are an important means to acquire quantitative data. However, it must be understood that not all data can be delivered unconditionally (confidentiality and intellectual property; agreements of anonym data to e.g. protect farmers, data owned by other parties). In cases where the scientific or expert panel need additional information concerning data that was previously delivered we recommend that the panel requests such additional information from the data provider rather than dismissing the data due to incompleteness.	This section was related to the constraints found when performing risk assessments in animal welfare in EFSA. As it was considered not to be pertinent in a Guidance document, the section has not been included in the final version. In relation with inclusion of industry experts, consultation with the breeding sector and the industry is usually performed. However, the possible bias introduced in the science-based Scientific Opinions from experts linked with the industry because potential conflicts of interests should be considered. To avoid any possible bias, experts linked and/or working with the industry are usually not allowed to take part on EFSA WGs. An expert declaration of interest (DoI) is submitted to EFSA and must be approved before inviting any expert to an EFSA meeting.

EFFAB, EPB, AVEC, AEH, PVSG	1.1 Methodological challenges (cont.)	Line 233, ´animal welfare legislation´ Comment There is a movement towards agreements and practical solutions, rather than legislation. This is a promising development. Line 245, ´only in rare cases were exposure data systematically collected´ (See remark line 84, italic) Line 262, ´an optimal risk assessment requires experts from all the areas involved´ Comment It is crucial to involve experts from all relevant areas. In addition to animal behaviour, and animal health, these areas include: animal husbandry, animal nutrition, animal reproduction, animal physiology, animal genetics, animal genomics, animal breeding programmes, farming systems, slaughterhouse procedures, animal transport, management systems and management guides, data development and data integration, extension and training, certification schemes (practical rather than university scientists). There should be ample experience with, and close links to, practice. For instance, ¨the Poultry Veterinary Study Group/PVSG" (http://pvsgeu.org/admin/constitu.htm) has a large number of practical veterinarians working on a daily basis in poultry production in a wide range of EU member States. Their opinions can only be of significant value.	233: legislation is out of EFSA scope. 262: this comment about the experts has been answered in the previous one (see above).

EFFAB, EPB, AVEC, AEH, PVSG	1. Introduction	Line 97, ´lack of standardized guidelines and therefore the need to harmonise the risk assessment of animal welfare´ Line 107, ´worthwhile to set up a working group´ Line 97, 107 Our advice is that the scientific opinions as they are to date should not be used to base a Risk Assessment on. They are much a paper exercise, not sufficiently imbedded in practice nor equipped to include recent developments. A balanced assessment needs a different approach. (See our various suggestions) Line 155-158, ´ The notion of risk assessment was considered by the Working Group to be relevant to animal welfare assessment. However, it was decided that the positive effect on welfare (benefit) could be handled within the framework of risk assessment if the analysis considers both factors having positive effects and factors having negative effects on animal welfare´ Our advice: ´could be handled´ to be replaced by ´should be handled´ or ´must be handled´ Remark: In a Risk and Benefit Assessment, there is a big danger of weighting the various factors in an artificial way. Functional weighting as part of the whole system is important because of inherent conflicts such as among many other examples (1) weighting, in outdoor systems, the risk of a disease outbreak against the animal's benefit of free ranging, or (2) what happens when a particular treatment takes place or not. Because of the complexity of farming systems this cannot be captured responsibly in a Risk Analysis by a group of part-time employed researchers. There are too many factors that, added up, will not give a reliable outcome, as rightfully indicated in the Risk Assessment guide. This means that Risk and Benefit Assessment is not a good tool to capture farm production systems, let alone animal breeding programmes. The balance of production systems and breeding programmes requires fine-tuned management. Animal breeding systems apply fact-based weighting to a wide range of factors, with continuous further refinement. This is an ongoing process of improvement. We propose to move towards corporate and sector responsibility [instead of using Risk and Benefit Assessments] where e.g. management systems on the farm can be used to monitor and continuously improve overall farming practice, farm animal health and welfare.	107: it is not said that EFSA opinions are the basis of the risk assessment. It is said that in previous EFSA opinions a risk assessment approach was tentatively performed without any harmonisation and guidelines. 156: The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated in the problem formulation (section 3.1)..The importance of a proper problem formulation and an adequate target population and scenarios definition is crucial, as described in section 3.1. The correctness of the risk question will make easier to answer it appropriately and get the adequate corrective measures. It should be pointed out that the objective of the Guidance is to give general principles on how to perform risk assessment in animal welfare. Any aspect related to the subsequent management measures are out of scope of the Guidance.

EFFAB, EPB, AVEC, AEH, PVSG	Terms of Reference as provided by EFSA	Line 84, ´with reference to the methodologies followed in the previous EFSA opinions on various species. The Risk Assessments undertaken for fish and broiler chickens must be excluded from this. It has been agreed that the fish assessment, being the first one, was not complete enough. Therefore, it should not be published as a Risk Assessment report. The broiler opinions – scientific part – did not manage to include important practical data that were provided, and were thus heavily based on outdated and biased literature. That was not a sound basis for a Risk Assessment. Instead, renewed efforts to further investigate how to involve the developments in the last 25 years should have been undertaken. Currently the published ´final broiler opinions´ rely heavily on the Risk Analysis process, representing almost 25% of the documents. This is disproportionate to its value, as the process of the Risk Analysis employed in the broiler opinions was a matter of concern, and also because the outcomes present a one-sided picture: many issues identified as a risk have been successfully taken up and solved by the breeding organisations for over 25 years, and this fact – that the risk factor was addressed – was not mentioned. Reports should not be based on risks of decades ago that have been addressed already. Our advice: when data are not sound, or when the scientific opinion does not include a balanced overview of the situation, the EFSA panel should refrain from a Risk Assessment as then the risk of the Risk Assessment itself is too high. Line 92, ´strictly in terms of animal welfare´. We propose that animal welfare is to be considered as an inherent part of farming systems: the adequate animal for adequate production with adequate management under balanced conditions that are environmentally responsible, efficient and cost-effective. This is in line with the advice of the Advisory Council of the Welfare Quality project (report attached or will be sent separately), which advises for welfare indicators to be part of running and existing schemes and management programs, rather than stand alones.	84: previous EFSA opinions on animal were very useful to realise about the main constraints and methodological challenges on risk assessment for animal welfare. The objective of the Guidance is to give general principles on how to perform risk assessment in animal welfare without focusing in any precise approach or previous opinion. 92: animal welfare has to be considered as an inherent part of the farming systems in order to implement all necessary management measures, which are out of scope of the Guidance and the remit of EFSA. The risk assessment, whenever relevant, comes before that phase.

EFFAB, EPB, AVEC, AEH, PVSG	Table of Contents	Submission on behalf of AVEC – Association of Poultry Processors and Poultry Trade in the EU countries AEH – Association of European Hatcheries EFFAB – European Forum of Farm Animal Breeders EPB – European Poultry Breeders PVSG – the Poultry Veterinary Study Group General remarks * There is a movement towards stakeholder agreements, and sector and corporate responsibility. This should continue. * We propose that any Risk and Benefit Assessment or any welfare opinion should include the whole area of animal welfare, as part of balanced animal production systems. We note that currently the examples in the report are still mainly coming from the behavioural area. * We propose that animal welfare is to be considered as an inherent part of farming systems: the adequate animal for adequate production with adequate management under balanced conditions that are environmentally responsible, efficient and cost-effective. * We propose to remove the Risk Assessment chapters that have proven to be too crude (fish) or biased (broiler) from the reports that have been delivered so far. * We suggest that all EFSA panels, working groups and projects as a general rule embedded in the TOR have representation from the farming industry to deliver input on farming systems and other practical issues during the process, e.g. 3 industry experts in a group of 12-15 scientists. General conclusion: Risk and benefit assessments should only be used in animal welfare as part of an integrated animal production approach where the inputs are complete and accurate.	All these general remarks have been answered in their respective sections.
Friedrich-Loeffler-Institut	5.3 C Case studies: consequence assessment and quantitative risk assessment	p. 44 ff: case study: Is this example from a reference or has it been created for the report? The calculations are not clear. p. 78 fig.1: Fig is not self-explaining, some descriptions are missing. What do bubbles stand for?	Example given in Appendix A (in the final version) has been amended in order to be consistent with the nomenclature and risk assessment steps defined in the Guidance. It should be clarified that the examples were used to illustrate how an animal welfare assessment could be done in quantitative way independently of the data used and the results obtained in the study.
Friedrich-Loeffler-Institut	5.2 B Previous work on risk assessment in animal welfare	p. 36 L.1316: change title to "Previous work on risk assessment in animal welfare done by EFSA"	This section related to the previous EFSA work on risk assessment was considered not to be pertinent in the Guidance and therefore it has not been included in the final version.
Friedrich-Loeffler-Institut	3. Concluding remarks: When and how to use risk analysis?	p. 28 L.1091 ff: Is "risk assessment" = "risk analysis"? The chapter contains some information not presented in chapter 2. However, this chapter is the best chapter in the report, much clearer than 1 or 2	This section was considered not to be pertinent in a Guidance document and therefore it has not been included in the final version.
Friedrich-Loeffler-Institut	2.4.3 Expert knowledge elicitation	p. 26 L.983 ff: How should different expert opinions be dealt with (calculate mean? call a meeting to find consensus?)? p. 27 L.1035: affect instead of effect p. 27 L.1018-1020: reference missing p. 27 L.1041 ff: Mix of she /it /he	Section has been revised and moved as Appendix B of the final version

Friedrich-Loeffler-Institut	2.3.3 Risk characterization: integration of welfare consequences	p. 23 L.839: Why is value judgement of the relative importance of criteria not within the scope of risk assessment? p. 23 L.849: What are the minimum standards of quality? p. 23 L.860: Figure 6 = figure 3	The section has been revised and amended accordingly (section 3.4 in the final version). The integration examples were considered confusing and therefore not included in the final version. Box 3 gives the generic approach on the assessment of poor welfare..
Friedrich-Loeffler-Institut	2.3.2.2 Assessing the welfare consequences	p. 20 L.719: What grey boxes? p. 21 L.780 ff: How should interactions be dealt with in analysis? Please be more concrete. p. 22 L.788: The creation of a new factor to represent an interaction is what happens in most statistical models. Is it different in risk factor assessment mathematics?	The section has been revised and amended accordingly (section 3.3 in the final version). Interaction between factors has been considered.
Friedrich-Loeffler-Institut	2.3.2.1 Animal's response triad	p. 18 L.643-645: reference missing; welfare definition missing	Section deleted in the final version.
Friedrich-Loeffler-Institut	2.2 Problem formulation	p. 13 L.444: and some other places: Are "welfare components" the same as "welfare criteria" (p. 10)? p. 13 L.463: In animal welfare science it is usually impossible to divide influences in risks and benefits. Therefore the "factor" approach introduced earlier is most suitable. As the outcome animal welfare always depends on positive AND negative influences, models focussing on one of the two only will be non-reliable.	444. Terms such as welfare criteria, welfare measure and welfare indicator have been clarified (see Glossary). 463: this is why the possible simultaneous consideration of positive and negative effects is considered in this section..
Friedrich-Loeffler-Institut	2.1 When a risk assessment approach is needed?	p. 12 L. fig. 1: Figure does not agree with text. Text lines 379/380 and 423/424 state that "problem formulation" should be first, but in the graph it's 3rd level. In addition, the two two-way- arrows are wrong, as they would mean, "Factor identification" could influence "problem formulation". Why is "General Scientific review" a task of the EC?	Figure 1 has been reviewed and amended accordingly..
Friedrich-Loeffler-Institut	2. Proposed risk assessment in animal welfare	p. 10 L.342: Should be in L 365	Pdf conversion problem.
Friedrich-Loeffler-Institut	1. Introduction	p. 5 L.119: "all types of husbandry systems and all animal categories": does that also include zoo animals? p. 5 L.121/122: + p.7 L 193 + p. 9L 320 ff: It is mandatory for a report concerning animal welfare to define the term, as several considerations depend on the definition, such as scales or instruments used to measure animal welfare. In addition, animal welfare (or sub-definitions of it) will be the outcome of risk assessment modelling, which makes it crucial to define it clearly. p. 6 L.144: Present more specific information than what? p. 6 L.144 ff: The current report only includes work done by EFSA. It would be of much higher quality, if other work done in the field of welfare risk assessment would have been considered. Why are the addressed issues beyond the scope of the current mandate even though they are crucial?	The Introduction has been shortened a lot in the last version. Although the related text is not anymore present some of this questions could be answered. 119: general principles of the Guidance should be applicable to any type of animal. 122-190-320: welfare definition included in the Glossary. 144: This section was related to the constraints found when performing risk assessments in animal welfare in EFSA. As it was considered not to be pertinent in a Guidance document, the section has not been included in the final version. It should be pointed out that not many relevant works on the methodology on risk assessment for animal welfare are available.
Friedrich-Loeffler-Institut	Background as provided by EFSA	p. 3 L.50: footnote missing? p. 3 L.66: reference for report missing	Amended

Friedrich-Loeffler-Institut	Table of Contents	p. 1 ff : Inconsistent use of terminology (e.g. risk assessment vs. risk analysis, welfare criteria vs. welfare components). No clear guidance on how an outcome parameter for risk assessment should be defined (can impact quality of risk assessment!). Many references missing. Layout, especially of figures needs to be improved. Criteria for lay outing term definitions in boxed are not clear. p. 5 ff: Chapter 1 is misleading, as some contents promised are not addressed in chapter 2. Who is the audience of the report? p. 1 L.8: title should read "Guidance on Risk-Benefit-Assessment for Animal Welfare", because the report includes benefits as well p. 2 L.13: A summary of the report would be helpful. (Chapter 3 almost seems to be one, but does not really match information from other chapters)	Consistency of the terminology, layout of the references and contents checked. Abstract and summary included in the final version.
FLI Federal Research Institute for Animal Health	2.1 When a risk assessment approach is needed?	400-401. In Figure 1 the "General Scientific Review or Update" really is done on the EC-level? The arrows from both bubbles on the EC-level should be directed to the "Problem Formulation" on the EFSA-Level, not to the "literature survey", or to both. The bidirectional arrow between "Problem Formulation" and "Factor Identification" implies, that the factor identification changes the problem formulation - is that right? 443 in this line and also later the term "components" is used. This should be defined, is there a difference to the term "criteria"? 470-473. The simultaneous consideration of negative and positive effects in the risk assessment needs a new wording, as described before. in this Opinion the risk assessment includes both the positive and the negative aspects. The term used are "risk" and "benefit", this leads to misunderstandings. It would be better to use "hazard" and "benefit" in the risk assessment. Nevertheless the using of both terms implies the possibility of aggregation of positive and negative effects in both tirets given in line 470-473. From animal welfare point of view this clearly should be avoided. 476-477. In the example "Unloading of animals..." a positive effect is stated as "the animals have more space allowance". Compared to what? To the transport environment or to that in origin husbandry system? Compared to the transport loading density the positive effect is only relative and not more than a reduced negative impact. This should not be counted as a real positive effect from animal welfare point of view. A possible Example "Not unloading of animals..." would not lead to a simple conversion of the negative and positive effects. This example indicates clearly to distinguish two groups of factors as "positive" and "negative" and not to summarize as given in lines 814-845.	Figure 1 reviewed and amended accordingly. Terminology reviewed and consistency checked. 473: Examples of negatives and positive effects have been removed in the final version. The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated in the problem formulation (section 3.1).

FLI Federal Research Institute for Animal Health	1.1 Methodological challenges	150-152. It should be clear, that the assessment of risk and the assessment of benefits may include different procedures. 186-192. It should be clear stated, that animal welfare benefits in the environment of risk assessment should be distinguished from reduced hazard impacts, which may lead to (relative) welfare benefits in given scenarios. From animals welfare point of view this will bear the danger of misinterpretation of results. 292-318. in the EFSA opinions in the past the term "hazard" is often used, whereby the term "factor" is very rare. In this opinion now the term "factor" is used instead of the term "hazard" to imply a term without judgement. This seems to be done with the background of including animal welfare benefits into the risk assessment. This may lead to misunderstanding, because an animal welfare benefit is in the very mostly cases not to "allocate" with animal welfare hazard. 292. The term "risk" should be replaced by the term "hazard", because from animal welfare point of view the opposite of the benefit is the hazard, not the risk. 310-312. The definition of "factors" implied a possible simple aggregation of positive and negative influences on animal welfare. Especially in the environment of animal transport or animal slaughter the "positive influences" are only reduced negative effects (f. e. reduced loading density) and within relative. They should not be counted as positive effect. With this background the term "factor" should be deleted in the risk assessment in animal welfare, because negative or positive effects do not have the same effect, either with "-" or "+". In the risk assessment in animal welfare a clear terminology should be used, either with the terms "hazard" or "benefit". Additionally it should be clear, that a "benefit" do not mean "avoidance of hazard".	152, 192: Benefits are not considered in the Guidance but they will probably be the scope of a future EFSA work. 292: using the term factor allows considering both positive and negative effects, instead of hazard which only considers negative effects. 292: risk is a probability and hazard is the negative effect of a factor, therefore the word hazard can not replace risk. 310: Examples of negatives and positive effects have been removed in the final version. The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated in the problem formulation (section 3.1).
FLI Federal Research Institute for Animal Health	Background as provided by EFSA	The Opinion reflects the EFSA-Activity in this field very well. But it is only the EFSA activity and not the activity of the "scientific world" in the environment of Animal Welfare. In General the targeted group of the Opinion should be better defined	This is the background of the EFSA internal mandate written at EFSA level.
FLI Federal Research Institute for Animal Health	Table of Contents	The Headline should be as following: Guidance on Risk and Benefit Assessment for Animal Welfare	Benefits will not be considered at this stage and will probably be the scope of a future EFSA work. Terminology will be revised to avoid misunderstandings.
PORCAT	2.2 Problem formulation	Line 476 (table) In this table, even if it's only to include different examples, it could be appropriate to include castration in pigs as one of the factors. In the table are included the main factors that actually are discussed (unloading of animals during transport, use of straw, beak trimming...) and castration in pigs is at present being discussed in different stakeholders.	Examples of negatives and positive effects have been removed in the final version. The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated in the problem formulation (section 3.1).

PORCAT	1.1 Methodological challenges	Lines 261-263....an optimal risk assessment requires experts from all the areas involved. In particular, there should be animal welfare scientists, including experts with veterinary expertise and experts in ethology. Different types of breeds are used actually, especially in some species (like pigs), and it has very important consequences on animal welfare risk. Is very important to consider the specific characteristics of each type of breed. So it could be better to write these lines like this: "...an optimal risk assessment requires experts from all the areas involved. In particular, there should be animal welfare scientists, including experts with veterinary expertise, experts in ethology and experts in genetics".	This section was related to the constraints found when performing risk assessments in animal welfare in EFSA. As it was considered not to be pertinent in a Guidance document, the section has not been included in the final version.
Ministry of Economic Affairs, Agriculture and Innovation	2.1 When a risk assessment approach is needed?	p.12. Figure 1, above l. 404: Somehow it should be expressed, that a risk assessment should be followed by an impact assessment, to formulate and/or rank several policy options, not just with regard to welfare, but also with regard to other values, like economy, environment, food safety, public opinion. This step is essential for the risk manager to take decisions, or recommend routes of response. p. 14, table with examples above l. 477: Several positive effects should be better formulated: at present they are often formulated as the reverse of negative effects, like e.g. decreased tail biting, decreased risk of osteoporosis etc. Suggestions for adequate formulations are to use: species specific behaviour, such as grazing in cattle, rooting and wallowing in pigs, scratching and dust bathing in poultry, play behaviour...etc.. p.15: Ad Examples, from l. 514 and further: When formulating a change of scenario, the actual /initial state should first be formulated as well. p. 19, Figure 2 above l. 662: It addresses 'environmental factors' and 'management practices' in a negative sense only. We miss "positive factor(s)" in the figure. May be the figure would be different if positive factor(s) would influence the animal /animal response. We wonder how the figure would look like if positive factor(s) /benefits would be included and whether that would give insights in ´benefit assessment´.	404: the impact assessment is the subsequent step of the risk assessment. However, as it is a management issue it is out of the scope of the Guidance and of EFSA. 477: Examples of negatives and positive effects have been removed in the final version. The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated in the problem formulation (section 3.1). 514: the section has been shortened and examples removed (see section 3.1). 662: Section and Figure 2 revised and amended.
Ministry of Economic Affairs, Agriculture and Innovation	2.2.1 Target population and scenarios	p.22, table 2 from line 820: We miss the description of the actual /initial /baseline state. Furthermore, we miss the reference to /explanation of the scores and scales A - E and 1 to minus 3. These are probably taken from the Case study on p. 44/45? The scales proposed - (which provide for the possibility of easy compensation between positive and negative scores) - do not provide a good possibility to identify unacceptable situations. E.g. even if '-3' on 'Heat stress' is absolutely unacceptable, than a few 'plusses' elsewhere will bring the overall score back to an acceptable level. The proposed integration methodology should not allow this to happen. p. 28, above line 1091: Suggestion to add an extra paragraph: "2.5 Presentation of Outcomes'' There is no specific indication in the report on how the outcomes are to be presented to the risk manager and other interested parties. The presentation should be transparent, unambiguous, easily interpretable, etc. Can EFSA describe how this should be done?	820: these examples were considered confusing and not included in the final version. Box 3 gives the generic approach on the assessment of poor welfare. 1091: It is out of the scope of the Guidance to review all possible presentation methods (widely known).

Ministry of Economic Affairs, Agriculture and Innovation	1.1 Methodological challenges	p. 7: l. 217: Suggestion to add after "... transparent": "There is an urgent need to support Risk Assessment with quantitative data regarding welfare of animal husbandry in Europe". l. 222: Suggestion to add after "... uncertainty": "However there should by a gradual shift form expert opinion to quantitative data." l. 225: Suggestion to add at the end of the sentence: "..., including the formalisation of the use of expert opinions.' (Rationale: the importance of quantitative data and objectivity) p. 8: l. 266: Suggestion to add after the end of the sentence: "Alternatively, or in addition, an anonymous Delphi-procedure could be used to base the discussion more on arguments and referenced data rather than on authority of individuals."	This section was related to the constraints found when performing risk assessments in animal welfare in EFSA. As it was considered not to be pertinent in a Guidance document, the section has not been included in the final version.
Humane Society International/Humane Society of the United States	3. Concluding remarks: When and how to use risk analysis?	The risk assessment work of the EFSA AHAW panel can impact the work of the HSUS/HSI. Our major campaign work focuses on the elimination of intensive confinement systems for farmed animals, so naturally the science surrounding these issues is important to us. Given that lines 1092-3, section 3, state that "[risk assessment is performed to support decisions on how to manage any risks and to decide on what systems for keeping and managing animals should be used", we have a stake in the outcome of future risk assessments. We would like to point out that some "risks" inherent to a system are not actually "risks" as much as "guaranteed negative consequences for welfare". The word "risk" implies that there is a probability of either a positive or negative outcome. But, for example, the "risk" of behavioural deprivation in battery cages and gestation crates is always 100%. On the other hand, some risks to welfare are truly risks and can be reduced or even eliminated with good management, for example the occurrence and severity of certain diseases and parasites. It would be helpful if the risk analysis method could differentiate these two broad categories. If all welfare problems are treated as risks, and are treated equally, they may leave uninformed readers with an inaccurate impression of certain housing systems, depending on the factors chosen for analysis. Another way to overcome this difficulty is to put more emphasis on the benefits of certain housing systems, which the Guidance on risk assessment for animal welfare does propose. We applaud this approach (see further comments on Lines 1093-7 below). Lines 1093-7 state that "since many of the factors affecting welfare lead to benefits, a similar analysis of benefits is desirable but this has not yet been carried out by EFSA. The process of benefit assessment can be essentially the same as risk assessment. The result will be a quantification of expected or recorded benefits associated with each factor examined." We feel that the assessment of welfare benefits is a particularly important part of this generally useful exercise, and hope that the EFSA will encourage more of this in future welfare assessments. Some housing systems have both increased risks, but also increased benefits. If the risks can be managed, then the higher welfare potential can be reached in these systems and it would be helpful if the risk assessments could acknowledge this possibility. The final outcome of an assessment that included the welfare benefits would thus be a much larger push in the direction of more welfare-friendly systems.	Benefits are not considered in the Guidance stage but will probably be the scope of an EFSA future work. However, as factors may have an adverse effect and a positive effect on the animal and these could be also considered in the risk assessment, this issue is illustrated in the problem formulation section (see 3.1).

Humane Society International/Humane Society of the United States	2.3.1 Exposure Characterization	On line 609, it would be helpful if you could please define, explain or provide a reference for "Event tree analysis, or fault tree analysis".	The section has been revised and these words are not used in the final version.
Humane Society International/Humane Society of the United States	2. Proposed risk assessment in animal welfare	In lines 370-1, section 2, page 11, there seems to be an incomplete sentence: " which might be needed to complement the observational and experimental studies with simulation approaches".	Typo error. Section revised and amended accordingly.
Humane Society International/Humane Society of the United States	1.3 Instruments measuring animal welfare	Line 321, section 1.3; page 9 states, "Animal welfare needs to be measured in a scientific way". We agree completely. However, we also understand that not all factors and positive and negative effects associated with the factors that affect welfare have been identified. Further, some factors may be difficult or impossible to measure. For example, we don't have a solid understanding of how important freedom is to an animal, how long mothers miss their newly weaned young or whether boredom is a factor that should be considered in barren environments. Even though it may not be possible to include factors such as these in a formal risk assessment, their consideration may still be appropriate in making determinations about how to manage or house animals. We would like to see the EFSA AHAW Panel allow some room for the possibility of additional factors, simply by emphasizing that some remain to be identified or cannot be incorporated into the risk assessment at this time.	The objective of the Guidance is to give general principles on how to perform risk assessment in animal welfare. The consideration of other factors which can not be included in the risk assessment, although may be relevant, are out of the scope of the Guidance.
Humane Society International/Humane Society of the United States	1.1 Methodological challenges	SCIENTIFIC PROFILE OF THE SELECTED EXPERTS Lines 254-8 state that "[w]hen empirical data are not available, expert knowledge can be used and in this case attention should be paid to the scientific profile of the experts involved. Scientists who work with issues relating to animal welfare may have a post-graduate career history in various subjects such as animal hygiene, applied animal behaviour, infectious diseases, pathology, or physiology. Their basic training may have been in subjects such as agriculture, biology, psychology, animal production or veterinary science." We acknowledge and respect the many experts and their opinions that have been utilized in the risk assessment process to date. We are concerned, however, that because animal welfare issues can be controversial and divisive, experts often have strong subjective opinions. This is especially true in the United States. It is worrying that the group(s) performing the risk assessment could choose experts who agree with their own particular opinions. Section 2.4.3 "Expert Elicitation" addressed this concern, but does not completely negate it. Therefore it would be helpful if the EFSA AHAW panel could expand the overall discussion of the scope of intended use of the risk assessment tool. If the risk assessment tool is meant for use by others outside of the AHAW group, more guidance on the process of selecting a balanced pool of experts would be beneficial. If the risk assessment tool is meant for use by EFSA AHAW only, or within the EU only, that should be clearly stated.	The possible bias introduced in the risk assessments because potential conflicts of interest from experts with different profiles (i.e. industry, breeding organisations) are always considered in EFSA when setting up the expert working group. To identify any possible conflict interest, each expert has to submit a declaration of interest (DoI) to EFSA. The DoI must be approved before inviting any expert to an EFSA meeting.
Farm Animal Welfare Committee	2.4.3 Expert knowledge elicitation	In section 2.4.3, the report highlights correctly the role of expert elicitation. However, the focus is upon scientific experts. Despite the application of science-based language to the subject, animal welfare concerns are focused on our moral obligation to animals so it is essential that ethical expertise is also included at the heart of expert judgments.	Ethical aspects are by law (EFSA founding Regulation 178/2002) out of the EFSA remit.
Farm Animal Welfare Committee	6. Glossary and abbreviations	Despite the need to include positive effects, as presently drafted there are some fundamental difficulties with including positive alongside negative welfare. For example, in the glossary the "risk" only includes negative welfare effects whereas "risk assessment" also includes positive ones, this terminology is cumbersome and confusing.	Terminology and Glossary checked, and amended accordingly.

Farm Animal Welfare Committee	2.3 Risk Assessment	The report identifies interventions / husbandry changes that can have positive as well as negative welfare effects i.e. better or worse. However, the report should be more explicit about negative vs. positive experiences. FAWC now uses an animal's quality of life (e.g. life worth living and good life) to deal with this issue: "A significant difference between the two proposed standards (of a life worth living and a good life) is the provision of opportunities in the higher standard for an animal's comfort, pleasure, interest and confidence. .. An opportunity that would be considered to contribute to a good life would be a resource that an animal does not need for biological fitness but is valued (i.e. used) by the animal. Such an opportunity could also cause harm and this would need to be minimised so as not to outweigh the benefits of the opportunity."	The objective of the Guidance is to give general principles on how to perform risk assessment in animal welfare. The possibility to consider simultaneously positive and negative effects in the risk assessment is illustrated in the problem formulation (section 3.1).
Farm Animal Welfare Committee	1.3 Instruments measuring animal welfare	The document would benefit from a clear definition of welfare at the start as there are inconsistencies in the approach within the report. For example, the "welfare effect" is defined in the glossary as a change in biological functioning ... as well as health and behaviour, whereas section 1.3 states that welfare includes "its health, its feelings and its ability to show normal patterns of behaviour". The exclusion of feelings or reference to mental state in the glossary is a serious omission; mental experiences of farm animals have been accepted in the UK as being highly relevant to their welfare ever since the Brambell Report of 1965. Since the EFSA report aims to consider welfare assessment it would be more appropriate to include an explicit definition of welfare in the main body of the text alongside the existing definitions of risk, benefits, factors and welfare indicators. FAWC 2009 has stated that : "welfare principally concerns both physical and mental health, which is largely determined by the skills of the stockman, the system of husbandry and the suitability of the genotype for the environment." Another possible definition could be that adopted by the OIE in 2008.	Welfare definition included in the Glossary.
Farm Animal Welfare Committee	3. Concluding remarks: When and how to use risk analysis?	FAWC welcomes efforts to standardise risk assessment in animal welfare, however, further work is needed to include some important concepts of animal welfare. For example, in its report "Farm Animal Welfare in Great Britain: Past, Present and Future" (2009), FAWC advocates the concept of a "life not worth living" to point out that some welfare effects are so serious that the animal would, literally, be better off dead. The concept of a severity threshold is not reflected in this document. This one-life scale integrates the Five Freedoms. [The one-life scale is proving a popular concept; the FAWC report in which it is described has been downloaded over 44,000 times from FAWC's website in 14 months.]	The objective of the Guidance is to give general principles on how to perform risk assessment in animal welfare. The suggested set up of a severity threshold is a management issue, and therefore, out of the scope of the Guidance.