TECHNICAL REPORT OF EFSA

Table of Public Comments on the EFSA Draft Opinion[1] on Transparency in Risk Assessment – Scientific Aspects

Prepared by EFSA

(Question No EFSA-Q-2005-00298)

Issued on 24 April 2009

This technical report contains the comments received during the public consultation which was launched on 16 December 2009, and closed 15 February 2009 at 17:00 CET. At the deadline EFSA had received 103 submissions (among which 19 repetitive comments are included), from 16 interested parties (non-governmental organisations, industry organisations and national assessment bodies). All comments received are tabulated with reference to the contributor and the section of the draft opinion to which the comment referred. There were 3 comments received outside the electronic form which thus did not fulfil the EFSA submission criteria. However, those comments were still considered and have been manually inserted in the table below. Duplicate comments received from the same contributor appear only once. Comments submitted formally on behalf of an organization appear with the name of the organization. The line numbers mentioned in the comments refer to the draft opinion. A report on the outcome of the public consultation is published on the EFSA website: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902513151.htm.

[1] For citation purposes: Technical Report of EFSA on Table of Public Comments on the EFSA Draft Opinion on Transparency in Risk Assessment – Scientific Aspects. *EFSA Technical Report* (2009) 264, 1-17.

Contributor	Section	COMMENT
DBIB	General	The proposed rules in the pesticide risk assessments can greatly improve the confidence of the European citizens and the stakeholders versus the decisions taken by the authorities. Studying the pesticides assessment dossiers (DAR) we could not find a full implementation of these rules. We recommend that the Agency carefully checks that in the future the files fulfil the proposed guidance document.
DBIB	General	TERMS OF REFERENCE (Line 77): Also beekeepers are to be considered as stakeholders.
Norwegain Scientific Committee for food safety	General	The Norwegian Scientific Committee for Food Safety (VKM) welcomes the draft opinion from EFSA's Scientific Committee on Transparency in Risk Assessment – Scientific Aspects. Together with the Opinion from 2006 on the process-related issues VKM sees this document as very important guidance in securing transparency and thus also confidence in both the process and the results of scientific risk assessment. From our experience with risk assessment we find the draft opinion comprehensive and will endorse the intention behind it in our own guidelines. VKM would like to put special emphasis on the importance of transparency of the process of literature search and evaluation of the references as this element of the risk assessment may greatly influence the results. As the guidance document describes optimal risk assessment practices, VKM would also like to point out the importance of flexibility as different risk assessments would need different emphasis and weighing of relevant information. VKM will according to our plans implement the finalized opinion in our own guidelines. As an important step towards harmonization of RA-methodology VKM hope that other national and international RA-bodies will consider doing the same.
Bundesinstitut für Risikobewertung	General	The Bundesamt für Naturschutz in its capacity as an institution involved in the EFSA Focal Point work within BfR, makes the following general comments: Guidance is missing about involvement of stakeholders (see comment on Terms of Reference) and how to document the handling of minority opinions. A reference to the precautionary principle and how it relates to uncertainty is missing. Also, guidance is missing on how to document that the precautionary principle was followed and considered during risk assessment.
Austrian Agency for Health an Food Safety	General	This is a very comprehensive and very good opinion regarding scientific points of view of transparency. In some topics it seems to be very enthusiastic, but will lead to a better trust in risk assessments of the different national and international systems.

EPPO	General	The European and Mediterranean Plant Protection Organization is an intergovernmental organization responsible for European cooperation in plant health. It counts 50 member countries (including all European Union Member States). EPPO welcomes the opportunity to provide comments on the "Transparency in Risk Assessment- Scientific aspects, Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles". We fully support the approach described for ensuring transparency, nevertheless we have a few comments underlined below. In this document (lines 264 to 268) it is mentioned, that to achieve transparency, the risk assessment procedure by which an opinion is reached needs to be based on scientifically accepted standards of best practice. It is therefore important that existing European/international guidance documents on how to conduct risk assessment, for example those of the WHO, OIE, IPPC, OECD and Codex Alimentarius are taken into account. Pest Risk Analysis (PRA) is introduced in the International Plant Protection Convention (IPPC, article II), and defined in the International Standard for Phytosanitary Measures (ISPM) 5. as "the process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it". Two international 7Standards have been developed: ISPM no. 2 Framework for Pest Risk Analysis and I8SPM no. 11 Pest Risk Analysis for quarantine pests including analysis of e9nvironmental risks and living modified organisms and these are the reference standards for Pest Risk Analysis. EPPO would like to enquire as to why only the text of the International Plant Protection Convention is listed in the "list of guidance, guidelines and working documents developed or in use by EFSA" and not these two reference standards on Pest Risk Analysis. In a recent meeting of the Working Party of Chief Plant Health Officers of the EU (2008-12-04), it was recognised that at present most PRA documents follow the EPPO Standard PM 5/3(3) Decision-support scheme for quarantine pests, whose structure is directly based on ISPM no. 11. Furthermore, it was considered that "EFSA and EPPO contribute to a single set of general guidelines for creating PRA documents, based on their experience of assessment and/or of reviewing PRA documents in collaboration with other relevant organizations. In its comments on EFSA's Draft Strategic Plan 2009-2013, EPPO welcomed the intention of EFSA to increase cooperation with international bodies and considered that it was a very good basis for cooperation with EPPO. We take the opportunity of commenting on this document to stress that preparation of single guidelines for PRA is one of the aspects on which collaboration could be initiated.
CIAA	General	Before line 15: The guidance is very clear, understandable, and most of all sensible. The document highlights all of the principles that risk assessors should adhere to (regardless of where these risk assessors sit) and would suggest that risk assessors (including those in the private sector) embrace the principles of the EFSA document. One additional point to raise is consideration of the use of disease registries/surveillance data, both to provide relevant recent information pertinent to risk assessment and in the future to establish impact of risk assessments in appropriate areas. This is not covered in the document but these could provide useful ''alerts'' for unforeseen effects and could also provide evidence for efficacy of particular risk management actions taken. Understandably, the document is very focused on toxicological risk assessments, and this is reflected in the examples used. However further consideration of risk assessments for other areas, such as microbiological risk assessment, as appropriate. The principles will still hold for these other areas but there may some features or characteristics that are specific to these other areas, and it would therefore be useful if the examples used throughout the document could be expanded to include those from other areas.

Bundesinstitut für Risikobewertung	General	Once the EFSA Guidance Document is ready, EFSA should have it translated into the official languages of the EU.
Bundesinstitut für Risikobewertung	General	Lines 182-184: Some "Terms of reference" (e.g. appropriate stakeholder involvement, handling of minority opinions, consistent and harmonised documentation, criteria for “pivotal studies”) are not reflected in the document or in the summary.
Bundesinstitut für Risikobewertung	General	TERMS OF REFERENCE Line 182-183: According to the terms of reference the document should provide guidance on process-related considerations e.g. stakeholder involvement, handling, justification or explanation of minority opinions. A reference is missing that the Guidance Document on procedural aspects (EFSA 2006) is dealing with these aspects under chapter 2.6. Article 30 of Regulation (EC) 178/2002 foresees that EFSA should “… exercise vigilance in order to identify at an early stage any potential divergence between scientific opinions and to cooperate with Member states and national bodies with a view to resolve or clarify the contentious scientific issues.” EFSA’s efforts to co-operate and network should be made transparent and therefore detailed guidance given how to document meetings or other stakeholder involvement taking place prior or during the risk assessment. This should include information about the date, duration, agenda, presentations, attendees, and meaningful minutes of meetings and also explain in which way outcomes or discussions of meetings are considered in the risk assessment. The aspect of documentation of stakeholder meetings is not covered by either of the Guidance Documents including the recommendation (EFSA 2006, chapter 2.6.) Please refer to 299-300 for a comment on considerations about minority opinions.
Inter-Environnement Wallonie	General	Adding the proposed rules in the pesticide risk assessments can greatly improve the confidence of the European citizen in the decisions taken by the authorities. Currently these rules are not fully implemented in the pesticides assessment dossiers we have read. We recommend that the Agency carefully checks that further dossiers fulfil the current guidance document.
Austrian Agency for Health an Food Safety	General	Line 30: The term „high degree of transparency“ is open for interpretation, dependent from the people involve. Which are the criteria for a “high degree of transparency“
Austrian Agency for Health an Food Safety	General	Line 165: Background The effect of exposure alone is not always of importance (maybe in the case of oral exposure, but more to discuss in the case of inhalation). The dose or concentration at the place of action or in the target organ is of importance. Proposal for wording (as later in the paper done): "Comprehensive and reliable exposure-effect (dose-response) data are rarely available.
Copa-Cogeca working group Foodstuffs	Summary	Line 33-34 It should be made clear whereas “A transparent risk assessment should be understandable and as far as possible reproducible”, what “as far as possible” means, and what considerations must apply in order to maintain the high scientific profile of any EFSA Opinion. It could be useful to have a complete list of the studies (and of the underlying conditions) which can be evaluated without new, on-the-field risk assessments and other which, on the contrary, need it.

Bundesinstitut für Risikobewertung	Summary	Line 39: "Also when" should be inserted at the beginning of the sentence "When circumstances … crisis situations". Line 90: It should read "opinion" (singular). Line 118: The word "international" should be deleted because these are opinions that are "issued by bodies/committees other than EFSA", i.e. not just international bodies.
Confederazione Nazionale Coldiretti	Summary	Line 39: Due to time-resources constrictions, data provided from firms requesting authorization for food use purposes should be very pertinent to scientific protocols/guidelines. In case EFSA objectively supposes not to have all the information necessary to proceed, and that there is a clear lack of respect of the principles of the protocols, it could be useful to update procedures followed in the past, not being merely limited to the request of new data. It could be evaluated a more stiff disciplinary approach, (ie penalty on time of response by EFSA, lack of the temporal preference against other requests of authorization). This praxis should be able to reward these firms which seriously have a commitment towards transparency.
Copa-Cogeca working group Foodstuffs	Summary	Line 39: Due to time-resources constrictions, data provided from firms requesting authorization for food use purposes should be very pertinent to scientific protocols/guidelines. In case EFSA objectively supposes not to have all the information necessary to proceed, and that there is a clear lack of respect of the principles of the protocols, it could be useful to update procedures followed in the past, not being merely limited to the request of new data. It could be evaluated a more stiff disciplinary approach, (ie penalty on time of response by EFSA, lack of the temporal preference against other requests of authorization). This praxis should be able to reward these firms which seriously have a commitment towards transparency.
Inter-Environnement Wallonie	Summary	Line 75: Assessment When a calculation includes various steps, all these steps should be explained. When the calculations are spread out over 50 pages, it is really hard to understand the global meaning.
Confederazione Nazionale Coldiretti	Summary	Confidential data, lines 65 onwards: to give the highest visibility and publicity to toxicological studies accordingly to emergent aspects of European legislation on risk assessment. Data confidentiality in such cases should be accurately balanced to protect public health.
Copa-Cogeca working group Foodstuffs	Summary	Confidential data, lines 65 onwards: to give the highest visibility and publicity to toxicological studies accordingly to emergent aspects of European legislation on risk assessment. Data confidentiality in such cases should be accurately balanced to protect public health.

Inter-Environnement Wallonie	Summary	Inclusion and exclusion of data (line 59): Validity criteria should be explained as general rules before including/excluding particular studies, in order to avoid giving the reader the feeling that some criteria are tailor-made to exclude "disturbing" results. Validity criteria should be defined in the guidelines; if not, they must be presented for each category of trials, at the top of the considered chapter/point. The criteria should include: • Appropriate endpoints • Statistical validity (i.a. sufficient sampling regarding the results variance) • Appropriate limits of detection/quantification • Exposure assessment/ measurement • Appropriate sampling – samples collection methods should be explained. • Appropriate test design regarding the assessed endpoints Conclusions should be statistically validated as well (meaning of an average regarding the variance?).
Inter-Environnement Wallonie	Summary	Line 47: Data of a same category should be expressed in the same units. We've found in a single dossier application rates expressed in gr/ha, in lb/acre, in gr/1000 seed or in gr/kg seed; such an incoherence makes comparisons difficult. A single unit must be chosen, and all data expressed in another unit should be converted.
Austrian Agency for Health an Food Safety	Summary	Line 33: Need of transparency The term "understandable" is open for interpretation. It is dependent from the reader of the contents of the risk assessment. On the in hand the risk assessors of other institutions are the readers, on the other hand the stakeholder. The scientific knowledge and experience with risk assessments may be different between these two groups.
Confederazione Nazionale Coldiretti	Summary	Need for transparency, line 33-34: It should be made clear whereas "A transparent risk assessment should be understandable and as far as possible reproducible", what "as far as possible" means, and what considerations must apply in order to maintain the high scientific profile of any EFSA Opinion. It could be useful to have indication of the studies (and of the underlying conditions) which can be evaluated without new, on-the-field risk assessments and other which, on the contrary, need it.
DBIB	Summary	Line 47: Data of a same category should be expressed in the same units. We've found in a single dossier application rates expressed in gr/ha, in lb/acre, in gr/1000 seed or in gr/kg seed; such an incoherence makes comparisons difficult. A single unit must be chosen, and all data expressed in another unit should be converted. The description of the observations and the experimental conditions under which the data were generated must be critically evaluated to determine their relevance to the assessment. Not always the used test guidelines cope with the intrinsic mode of action of the substance, making an assessment non-valid.
Austrian Agency for Health an Food Safety	Summary	Line 55 – 58 This seems to be necessary, but does not reflect usual practices in any way. The practicability seems to be questionable. If a new question is raised, the risk assessor tries to look for information starting with an overall overview about the topic and then to concrete more in deep

		by more focused searching. Shall really everything be documented, described and published? The search part may be longer than the scientific opinion itself.
Bundesinstitut für Risikobewertung	1. Introduction	Lines 223-224: The roles of EFSA and Member States are not accurately depicted in the draft opinion. Undertaking risk assessments and communicating their outcome is not just an EFSA task. Public agencies in the Member States, e.g. BfR, do this too. Furthermore, the task of risk assessment is also incumbent on food and feed business operators: food and feed business operators bear responsibility for the safety of their own products. Hence, they are legally bound to undertake an objective assessment of the risks of their products and, beyond this, to react accordingly. In this context they must take into account not only the EFSA risk assessments but also the risk assessments and findings of other institutions, e.g. on the national level. In addition, companies have to carry out, where appropriate, risk analyses in accordance with the HACCP concept for their production processes, for which there is no equivalent on the level of EFSA and the Member States.
Bundesinstitut für Risikobewertung	1. Introduction	222-225: Member states comment also on technical dossiers for applications of GMO. Their role in the approval process is not adequately described here. Please adapt.
DBIB	2. Need for transparency	Line 272: The toxicity testing methods, e.g. OECD/EU guidelines often do not allow to find effects of newer classes of PPP on honeybees.
Bundesinstitut für Risikobewertung	2. Need for transparency	Line 263: The following should be added: To achieve this, the results of risk assessments should have a harmonised format and structure in order to help avoid misinterpretations caused by differences in structure and accuracy of detail in the texts. A possibly harmonised structure will facilitate the comparison of risk assessments on the same or similar topics and identify any deviations. Furthermore, risk assessments should be as comprehensible and precise as possible (BfR Guidance Document for Health Assessments , paragraphs 9 - 12). Imprecise formulations like "Health risks cannot be ruled out" should be avoided. Line 271: The statutory framework in food and feed legislation does not regulate just the "authorisation of substances" as it says in the draft but rather the authorisation of products or the authorisation of substances for use in specific products. (Unlike for example the statutory provisions in REACH.) In order to determine the risk from products, it is necessary to evaluate the information provided with the substances/products. The conditions of product distribution, e.g. advertising of a pr30oduct for children or claims to prevent specific diseases, can have a major impact on risk and risk assessment. Attention should be drawn to these aspects in the Guidance Document.
U.S. Office of Management and Budget	3. General measures to provide transparency	In the discussion of transparency, there is one area that is not mentioned at all and that is transparency regarding the level of external independent expert review and public comment. It would be helpful if the EFSA assessments provided mention of the level of external review any assessments may have had. In the US, we typically have public comment as well as external peer review as in general, we find that public comment is not a substitute for the knowledge gained from having an independent external peer review. A transparent discussion of both the public comment process and external review process that each document has undergone would be helpful. For discussion of expert review, the following OMB bulletin on peer review may be helpful: http://www.whitehouse.gov/omb/assets/omb/fedreg/2005/011405_peer.pdf

FAVV	3.1 Scope and objectives	This paragraph gives a list of elements that need to be addressed in a risk assessment report or opinion. It would be useful to add to this list 'the questions that need to be answered on the basis of the performed risk assessment'.
Bundesinstitut für Risikobewertung	3.1 Scope and objectives	Line 299-300: According to the document "Any minority opinion within the Panel conducting should be attributed to their authors with their supporting arguments (EFSA 2006)." Please add that the opinions should include the handling, justification and discussions about minority and majority opinions.
Bundesinstitut für Risikobewertung	3.1. Scope and objectives	The **Bundesamt für Naturschutz** in its capacity as an institution involved in the EFSA Focal Point work within BfR, proposes the following amendments: Line 299-300: According to the document "Any minority opinion within the Panel conducting should be attributed to their authors with their supporting arguments (EFSA 2006)." Please add that the opinions should include the handling, justification and discussions about minority and majority opinions.
Bundesinstitut für Risikobewertung	3.2. Data and data sources	A statement is missing whether the amount of data is judged to be sufficient to address certain questions and with respect to the scope of the application.
DBIB	3.2 Data and data sources	Line 308 "Peer reviewed scientific papers": existing peer-reviewed literature must always be summarized for each point of the risk assessment.
NATUREPARIF	3.2 Data and data sources	For each author of each study included in the risk assessment report, the discipline, the issue on which he/she is a specialist and the number of publications in international peer-reviewed journals should be given.
NATUREPARIF	3.2 Data and data sources	The financing source of each study, as well as the employer of each of the authors and their contact information should be included in the list of studies considered in the risk assessment report.
Inter-Environnement Wallonie	3.2 Data and data souces	Line 308: "Peer reviewed scientific papers": existing peer-reviewed literature must always be summarized for each point of the risk assessment.
Bundesinstitut für Risikobewertung	3.2 Data and data sources	Lines 311-312: The second half of the sentence after the comma should be deleted as the quality of data and their possible exclusion are dealt with in Section 3.3. In Section 3.3 the following bullet should be inserted after Line 351: "Compliance with relevant guidelines and/or regulations, when data are submitted by applicants supporting authorisation requests". Line 313: It should be clarified if and in which cases and how expert opinions can replace missing data. Line 317: Particularly in authorisation procedures it should be borne in mind that the risk assessor is dependent on knowledge from an external

		private source and that said source has an interest in a positive risk assessment. It is possible that the relevant findings for risk assessment may not be published or presented either intentionally or unintentionally. There is a risk here concerning the impartial distance between the assessor and the stakeholders and he should be aware of this. This should be mentioned in the Guidance Document. Line 325: "Key search terms and strategies" should be replaced by "search frame (e.g. online data bases) and search string".
NATUREPARIF	3.2 Data and data sources	The relevant studies in other languages than English (e.g., French) should be included in the risk assessment report and their results considered in the assessment.
NATUREPARIF	3.2 Data and data sources	The literature produced by all the stakeholders should be included in the risk assessment report.
NATUREPARIF	3.2 Data and data sources	Line 308: ALL the peer-reviewed scientific literature dealing with the aspects included in the risk assessment report should be included in the risk assessment report, and not only, for example, the studies proposed by the producer or published in particular journals. Each paper can contain essential information for the result of the risk assessment.
FAVV	3.2 Data and data sources	It would be interesting to include in a risk assessment report the statistical characteristics of the input data (e.g. mean, mode, standard deviation, confidence interval, minimum, maximum).
Austrian Agency for Health an Food Safety	3.2 Data and data sources	Line 308-314 The handling with not peer-reviewed scientific papers is missing. Some information available is not published in peer-reviewed scientific papers, but necessary and useful for a scientific risk assessment. Therefore this information should be taken into account, too. Especially in “quick and dirty” risk assessments, eg. in urgent situations, one has to use the most appropriate and fast available information without checking in detail the fact of “peer-reviewed scientific paper”. However it has to be checked in every case, how valid the data and information are!
Austrian Agency for Health an Food Safety	3.2 Data and data sources	Line 48 - 49 (and 305 - 306, 539 - 540): The formulation is a little bit unclear, because normally risk assessors do not create data, they use them. Proposal for wording: "...and/or environmental conditions under which the data - which have been taken into consideration for risk assessment - were generated."
Bundesinstitut für Risikobewertung	3.3. Inclusion and exclusion of data	Line 351: See Line 313 [Original comment 33: The point "Methodology for identifying experts and elicitation of expert opinion" should be added].
Bundesinstitut für Risikobewertung	3.3. Inclusion and exclusion of data	A general remark and some guidance are missing here and elsewhere, how considerations leading to the inclusion or exclusion of data are documented. This is important because the document is about transparency in risk assessment rather than about risk assessment itself.

DBIB	3.3. Inclusion and exclusion of data	Line 341 sq: The following aspects should be considered: a point should be added: • effectiveness of the treated sample exposure
Bundesinstitut für Risikobewertung	3.3 Inclusion and exclusion of data	The **Bundesamt für Naturschutz** in its capacity as an institution involved in the EFSA Focal Point work within BfR, proposes the following amendments: 346-347: Please add “material and test organism used” in brackets and “and with respect to the scope of the application” after the brackets. 348-349: Please add “representativeness of data” in brackets. Please add another bullet point: “study description (e.g. all relevant details given)”
Bundesinstitut für Risikobewertung	3.3 Inclusion and exclusion of data	346-347: Please add “material and test organism used” in brackets and “and with respect to the scope of the application” after the brackets. 348-349: Please add “representativeness of data” in brackets. Please add another bullet point: “study description (e.g. all relevant details given)”
Inter-Environnement Wallonie	3. 3 Inclusion and exclusion of data	Line 341: The following aspects should be considered: a point should be added: • effectiveness of the treated sample exposure.
NATUREPARIF	3.3 Inclusion and exclusion of data	Line 332: The criteria of validation, based on which the inclusion / exclusion of data is decided, should be listed and their use for each study and/or result should be explained. These criteria should be scientifically robust. A minimum set of criteria should be established by the EFSA and applied coherently to all risk assessments. ADDITIONAL criteria should be developed by the authors of risk assessment reports, for aspects of the risk assessment for which criteria are not yet developed by the EFSA.
DBIB	3.3 Inclusion and exclusion of data	Inclusion and exclusion of data (also line 59 in the summary) Validity criteria should be explained as general rules before including/excluding particular studies, in order to avoid giving the reader the feeling that some criteria are tailor-made to exclude “disturbing” results. Validity criteria should be defined in the guidelines; if not, they must be presented for each category of trials, at the top of the considered chapter/point. The criteria should include: • Appropriate endpoints •Statistical validity (i.a. sufficient sampling regarding the results variance) • Appropriate limits of detection/quantification • Exposure assessment/ measurement •Appropriate sampling – samples collection methods should be explained. • Appropriate test design regarding the assessed endpoints Conclusions should be statistically validated as well (meaning of an average regarding the variance?).

JKI, Institute for Biosafety of Genetically Modified Plants	3.3 Inclusion and exclusion of data	Line number 340: delete (e.g. pour quality) because the aspects of quality are given in this chapter.
EMEA	3.3 Inclusion and exclusion of data	Line 343: modify as follow: study design and power (e.g. robust statistical design, potential bias)
Copa-Cogeca working group Foodstuffs	3.4 Confidential data	Line 358 onwards: Data confidentiality should be made transparent in the overall criteria which determine it, in order to better protect both industry and consumers. It could be useful to this extent, methods (es, check list) to assess and identify the causes which can make confidential the use and diffusion of data, and made public. If certain data are not to be published, at least the specific reasons which made them not public should be illustrated, with precise and detailed explications.
NATUREPARIF	3.4 Confidential data	Line 352: The nature of confidential data, the reasons for keeping them confidential and who asked for confidentiality should be present in the report.
Confederazione Nazionale Coldiretti	3.4 Confidential data	Confidential Data (358 onwards): Data confidentiality should be made transparent in the overall criteria which determine it, in order to better protect both industry and consumers. It could be useful to this extent, methods (es, check list) to assess and identify the causes which can make confidential the use and diffusion of data, and made public. If certain data are not to be published, at least the specific reasons which made them not public should be illustrated, with precise and detailed explications.
NATUREPARIF	3.5 Assumptions	Line 367: The sensitivity of the results to the assumptions should be quantitatively assessed (sensitivity analysis).
Confederazione Nazionale Coldiretti	3.5 Assumptions	Line 367: Coherently with the EFSA commitment, default assumptions should be clearly outlined, considering moreover problems which can arise from such choice and the risk deriving from conditions of “unknowns- unknown”, and uncertainty over uncertainty. In such conditions, expectations of the wider society could be reasonably taken into account, with an increased space for public consultations to lead EFSA decisions.
FAVV	3.5 Assumptions	It would be useful to include in this paragraph, as a specific example, the problem of left censored data. Every risk assessment should clearly indicate how these data points are treated and what the influence of this assumption on the result of the risk assessment and the conclusions is.
Austrian Agency for Health an Food Safety	3.5 Assumptions	Line 377 The term “fully explained” is open for interpretation, dependent from the people involved. Which are the criteria for „fully explained“

Bundesinstitut für Risikobewertung	3.5 Assumption	The **Bundesamt für Naturschutz** in its capacity as an institution involved in the EFSA Focal Point work within BfR, proposes the following amendments: Line 377-381: It says here that uncertainty regarding assumptions can be evaluated by repeating the assessment with alternative assumptions. Since the document shall provide guidance it should be clearer with those assumptions that could have reasonably been chosen (line 378). A shortened paragraph is proposed to replace lines 377-381: “Transparency requires that all assumptions should be documented and fully explained. Where alternative assumptions could reasonably have been chosen, this is a form of uncertainty and should be documented and evaluated by repeating the assessment with the alternative assumptions and then examining their impact on the assessment outcome.”
Bundesinstitut für Risikobewertung	3.5 Assumption	Line 377-381: It says here that uncertainty regarding assumptions can be evaluated by repeating the assessment with alternative assumptions. Since the document shall provide guidance it should be clearer with those assumptions that could have reasonably been chosen (line 378). A shortened paragraph is proposed to replace lines 377-381: “Transparency requires that all assumptions should be documented and fully explained. Where alternative assumptions could reasonably have been chosen, this is a form of uncertainty and should be documented and evaluated by repeating the assessment with the alternative assumptions and then examining their impact on the assessment outcome.”
Copa-Cogeca working group Foodstuffs	3.5 Assumption	Line 367 onwards: Coherently with the EFSA commitment, default assumptions should be clearly outlined, considering moreover problems which can arise from such choice and the risk deriving from conditions of “unknowns- unknown”, and uncertainty over uncertainty. In such conditions, expectations of the wider society could be reasonably taken into account, with an increased space for public consultations to lead EFSA decisions.
Bundesinstitut für Risikobewertung	3.6 Assessment	Line 392: The following should be added: "All model parameters should be described in detail (definition, numerical representation, unit, assumption, variability, uncertainty, reference). The model code should be made available on request for peer review." Line 401: The following should be added: The terminology in risk assessments should be standardised as far as possible for recipients and target groups in order to avoid any misunderstandings. In its Guidance Document for Health Assessments (paragraphs 14-22) BfR submitted corresponding wording proposals for the characterisation of the frequency (from "frequently" up to "no known cases up to now"), severity (from "severe" down to "minimal"), probability of occurrence (from "definite" down to "practically ruled out") and proof (from "generally recognised proof" down to "concern"), the use of which should be suggested in EFSA guidance documents.
DBIB	3.6 Assessment	Assessment (also line 75) When a calculation includes various steps, all these steps should be explained. When the calculations are spread out over 50 pages, it is really hard to understand the global meaning.
Confederazione Nazionale Coldiretti	3.6 Assessment	Line 382 and onwards A strict assessment not only of the risks, but even of the benefits could be regarded as an element to improve transparency in the risk

		assessment.
FAVV	3.6 Assessment	Concerning the understandability, it should be specified more precisely who should be able to understand. For example: Line 389: who is meant with 'others'? Line 403: who is meant with 'general readers'? Is it a scientist, a citizen? Line 404: who is meant with 'others with appropriate expertise'? Is it a modeller, a statistician, a scientist?
Austrian Agency for Health an Food Safety	3.6 Assessment	Line 402-403 The term "general reader" is open for interpretation. Is the general reader another risk assessor, a stakeholder or the consumer? The degree of clarification of calculation and mathematical models is dependent from the "general reader" or a clarification maybe impossible because of missing knowledge of this reader.
Austrian Agency for Health an Food Safety	3.6 Assessment	Line 78 – 80 "every element … should be communicated … understood by others" Shall in reality every mathematical step be written down in the opinion and then transfered in "understandable" terms. This seems very enthusiastic, because in some cases a group of experts is working out opinions, were some are specialists on one topic and others on other special points. Even these experts have troubles to understand each other and then it should be made understandable to "external" people. It is dependent from the reader of the risk assessment. On the in hand the risk assessors of other institutions are the readers, on the other hand the stakeholders and in addition consumers may be interested in the risk assessment. The scientific knowledge and experience with risk assessments may be different between these groups.
Bundesinstitut für Risikobewertung	3.7 Variability	UBA comments: The Federal Environment Agency (Umweltbundesamt), in its capacity as an institution involved in the EFSA Focal Point work within BfR, proposes the following amendments: The proposal is made for that EFSA factors that aim to compensate quantitatively for the variability between man and experimental animals and within the human population on the basis of scientific data, to be explicitly described in the Guidance Document as "EF = extrapolation factors". In this way their designation would correspond exactly to the function they have.
Austrian Agency for Health an Food Safety	3.7 Variability	Line 88 – 89 It is very important to highlight this point, because sometimes statistic mathematical interpretations may lead to incorrect scientific outcomes in regard to biological processes.
FAVV	3.7 Variability	In this paragraph a list of sources of natural variability is given, however this list does not contain food production conditions. It would be more complete to include a point 'food production conditions (e.g. use of additives, conditions for pesticide use)' to this list.

EMEA	3.7 Variability	Line 435: to be modified: “however the relevance of statistical differences interpreted in the absence of an understanding of the biological process has always to be assessed with caution” it could be misunderstood. The relevance of an observed statistical difference may not necessarily be dependent on an understanding of a biological process, but rather on statistical issue such as multiplicity of testing.
NATUREPARIF	3.8 Uncertainties	The report should explain why the method of risk assessment chosen is adequate for the nature of the substance assessed. In some cases, substances issued from new types of substances could be inappropriately assessed using risk assessment methods created for “old” types of substances.
NATUREPARIF	3.8 Uncertainties	Line 465: The source of uncertainty should be explicitly provided: the entry data, the model, the risk assessment method, the availability of peer-reviewed scientific literature on the subject, the scenarios, the assumptions, etc.
NATUREPARIF	3.8 Uncertainties	Line 465: Uncertainties should not only be listed, but also assessed (see, for example, the procedure adopted by IPCC reports, for climate change, based on levels of confidence).
FAVV	3.8 Uncertainties	Line 445 Mentions that opinions should indicate the relative importance of the uncertainties that are encountered. Since in a lot of risk assessments limited information concerning the uncertainties is available, it would be useful to include in the sentence ‘when possible’. In the same line it is indicated that the influence of the different uncertainties on the assessment outcome should be described. It would be useful to indicate what the level of detail should be.
Bundesinstitut für Risikobewertung	3.8 Uncertainties	In future, factors that aim to express that the experimental data used in the assessment come with narrative scientific uncertainties that have to be qualified more closely, are not quantifiable but which challenge the safety of the risk assessment should be described only as "SF = safety factors". Reference: Re: Ritter, Leonard, Totman,Céline, Krishnan,Kannan, Carrier, Richard, Vézina, Anne, Morisset, Veronique (2007). Deriving uncertainty factors for threshold chemical contaminants in drinking water. Journal of Toxicology and Environmental Health, Part B, 10:527-557
Bundesinstitut für Risikobewertung	3.8 Uncertainty	The **Bundesamt für Naturschutz** in its capacity as an institution involved in the EFSA Focal Point work within BfR, proposes the following amendments: Line 439-441: Please add “amount of data” to the list
Bundesinstitut für Risikobewertung	3.8 Uncertainty	Line 439-441: Please add “amount of data” to the list

Bundesinstitut für Risikobewertung	3.8 Uncertainty	Line 458: It is recommended that the three quoted scientific opinions be examined as we were unable to identify any explicit use of the "tiered approach" in the assessments of the AHAW panel.
Bundesinstitut für Risikobewertung	3.8 Uncertainty	Lines 194 and 442: Even when a need for additional studies is established in risk assessment, the unclear level of knowledge about the safety issue should be described as far as possible on the basis of the scientific knowledge currently available. Any actual indications that give cause for concern should be presented. In this way an impartial science-based decision should be possible in the period up to the submission of the research results and a so-called definitive risk assessment. Even so-called definitive risk assessments are subject to review and, where appropriate, amendment. Attention should be drawn to this aspect in the Guidance Document.
EMEA	3.8 Uncertainty	Line 457-460: Some of the acronyms such as PPR, CONTAM, AHAW panels are not explained in the glossary. I suggest to include these acronyms and more generally to put in the glossary all the other panels that appear in the part related to guidance guidelines and working documents.
NATUREPARIF	3.9 Conclusion of a scientific opinion	Line 465 Each of the demands for quality, developed in the present document, should be taken into account in risk assessment reports. EFSA should establish some quantified target for which the quality of a risk assessment report is considered unsatisfactory. Let's say, if 2 or more of the conditions listed in the document are not respected, a risk assessment report is considered of low quality and returned to its authors for additional information.
U.S. Office of Management and Budget	4.1 Opinions issued by other bodies/committees other than EFSA	2) Section 4 mentions the importance of considering opinions issued by other bodies and committees. We agree this consideration is very important. We also think it is very important to transparently present a summary of these opinions in the risk assessment with discussion of why there may be similarities and/or differences. This discussion should likely help strengthen the EFSA assessment as if it is different it will clearly explain why and thus help inform risk managers and if it is the same, it will help to strengthen the support for the EFSA decision. From the draft guidance it is unclear if EFSA is recommending only consideration of other opinions or is also suggesting that a discussion of the other opinions be transparently included.
Bundesinstitut für Risikobewertung	4.1 Opinions expressed by international bodies/committees	Lines 475-507: The EFSA document distinguishes between EFSA risk assessments/risk assessments on the international level on the one hand and risk assessments on the national level on the other. The risk assessments on the national level are presented as less important. This valuation is not justified. The breakdown in sections 4.1 and 4.2 should, therefore, be deleted.
U.S. Office of Management and Budget	4.1 Opinions expressed by international bodies/committees	3) In the US, in 2007, OMB and OSTP released an updated memo on the principles for risk analysis. This memo is available at: http://www.whitehouse.gov/omb/assets/omb/memoranda/fy2007/m07-24.pdf. This memorandum is very similar to the draft guidance EFSA has released as it stresses many of the same important points: transparency, use of best available data etc. It may be helpful for EFSA to mention this document as it provides international support for the guidance document and shows that it is consistent with other international opinions.

Austrian Agency for Health an Food Safety	4.2 Opinions expressed by national bodies/committees	The term “risk management elements” is open for interpretation. It should be clarified, what is meant. On national level the risk managers, who formulate in most of the cases a request, wants to have proposals for risk management and sometimes, like in Austria, this is laid down by law. The risk managers need these proposals, even if it is in their responsibility to choose the most appropriate risk management tool. A well conducted risk assessment with well described proposals including assessments of possible effects of these proposals, if they are implemented, helps very much the risk managers to decide.
Austrian Agency for Health an Food Safety	4.2 Opinions expressed by national bodies/committees	Line 110 – 115 Should these lines be understood in that way, that all institutions should take into account the EFSA transparency paper as reference guideline for their own systems. This seems very enthusiastic and maybe difficult in practical because of different systems on national or institutional level. What are the real criteria to accept another opinion or not? In addition, if EFSA itself or its panels may not fulfil all criteria. Should then the individual national or international systems maybe not take into accounts EFSA´s opinion?
Bundesinstitut für Risikobewertung	4.3 Diverging opinions	The **Bundesamt für Naturschutz** in its capacity as an institution involved in the EFSA Focal Point work within BfR, proposes the following amendments: Line 516: Please add: “This joint document along with the efforts to resolve the diverging views shall be made public.” Article 30 of Regulation (EC) No 178/2002 foresees the publication of the joint document. Efforts to resolve the diverging views shall be documented as well so that the discussion process can be followed.
Bundesinstitut für Risikobewertung	4.3 Diverging opinions	Line 516: Please add: “This joint document along with the efforts to resolve the diverging views shall be made public.” Article 30 of Regulation (EC) No 178/2002 foresees the publication of the joint document. Efforts to resolve the diverging views shall be documented as well so that the discussion process can be followed.
Bundesinstitut für Risikobewertung	4.3 Diverging opinions	Lines 517- 613: In order to avoid duplications and to increase the readability of the Guidance Document, the section "Conclusions and Recommendations" should be deleted as the preceding summary contains, in principle, the same text (Lines 15-125).
Copa-Cogeca working group Foodstuffs	4.3 Diverging opinions	Line 508 and following: In order to copy properly with divergent opinions at any level, It should be given maximum transparency on agreements and meetings which EFSA has with actors at closed doors (i.e., on risks assessment protocols), and on the negotiation about the meaning of methodologies, studies, criteria. Other stakeholders and the broader public should be adequately and timely informed.
Confederazione Nazionale Coldiretti	4.3 Diverging opinions	Line 508 and following: In order to copy properly with divergent opinions at any level, it should be given maximum transparency on agreements and meetings which EFSA has with actors at closed doors (i.e., on risks assessment protocols), and on the negotiation about the meaning of methodologies, studies, criteria. Other stakeholders and the broader public should be adequately and timely informed.

Copa-Cogeca working group Foodstuffs	Conclusions and recommendations	"4) eventual benefits balancing the risk" A strict assessment not only of the risks, but even of the benefits (to make more acceptable the risk in itself) could be regarded as an element to improve transparency in the risk assessment.
FAVV	Conclusions and recommendations	Line 524 and 571: please indicate who should understand.
JKI, Institute for Biosafety of Genetically Modified Plants	Conclusions and recommendations	Line number 555: delete (e.g. pour quality); insert (see 3.3)
CIAA	Conclusions and recommendations	Line 521 without however undermining the strict application of confidentiality rules as stated in the later text. Lines 553 – 555 It is not clear how the exclusion of data could be made public in an opinion. The uninformed reader of the opinion might misunderstand the exclusion of data.
Bundesinstitut für Risikobewertung	Conclusions and recommendations	The **Bundesamt für Naturschutz** in its capacity as an institution involved in the EFSA Focal Point work within BfR, proposes the following amendments: Line 523: Please add "including stakeholder involvement and documentation". Line 553-555: Same comment as for lines 62-64
Bundesinstitut für Risikobewertung	Conclusions and recommendations	Line 523: Please add "including stakeholder involvement and documentation". Line 553-555: Same comment as for lines 62-64