SCIENTIFIC REPORT OF EFSA

Outcome of the public consultation on the draft Scientific Opinion of the Scientific Panel on Genetically Modified Organisms (GMO) on the assessment of potential impacts of genetically modified plants on non-target organisms[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

On 27 January 2010, the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) endorsed a draft scientific opinion on the assessment of potential impacts of genetically modified plants on non-target organisms with the aim of launching it for a two-month public consultation. This Scientific Report summarises the comments received through the public consultation and outlines how these were taken into account in the final scientific opinion.

EFSA received from 27 interested parties (individuals, non-governmental organisations, industry organisations, academia and national assessment bodies) 162 comments on the draft scientific opinion. All the public comments received that were within the remit of the EFSA GMO Panel were assessed and the scientific opinion on the assessment of potential impacts of genetically modified plants was revised taking these relevant comments into consideration. Against this background, the 65 comments submitted through the public consultation on the chapter dedicated to non-target organisms of the updated EFSA guidance document on the Environmental Risk Assessment of genetically modified plants were also considered by the EFSA GMO Panel when revising the draft scientific opinion.

The scientific opinion follows a weight-of-evidence, case-by-case approach as also described in the updated EFSA guidance document on the Environmental Risk Assessment of genetically modified plants. The EFSA GMO Panel addressed the general comments that were related to the conduct this approach, as well as more technical comments related to specific issues.

1 On request of EFSA, Question EFSA-Q-2010-00110, issued on 27 October 2010.

2 Correspondence: GMO@efsa.europa.eu

3 Acknowledgement: EFSA wishes to thank the members of the Working Group on Non-Target Organisms for the preparation of this EFSA scientific output: Salvatore Arpaia, Detlef Bartsch, Marc Delos, Achim Gathmann, Rosie Hails, Paul Henning Krogh, Jozsef Kiss, Barbara Manachini, Joe Perry, Jeremy Sweet, Claudia Zwahlen and EFSA's staff member Sylvie Mestdagh for the support provided to this EFSA scientific output.

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BACKGROUND

The European Food Safety Authority (EFSA) asked the Panel on Genetically Modified Organisms (GMO Panel) to establish a Working Group with the aim of (1) producing a scientific review of the current guidance of the GMO Panel for Environmental Risk Assessment (ERA), focusing on the potential impacts of GM plants on Non-Target Organisms (NTOs), (2) proposing criteria for NTOs selection, and (3) providing advise on standardized testing methodology.

On 27 January 2010, the EFSA GMO Panel endorsed a draft scientific opinion on the assessment of potential impacts of genetically modified (GM) plants on NTOs with the aim of launching it for a public consultation.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders on its work, EFSA engaged in public consultation on key issues. The work on the assessment of potential impacts of GM plants on NTOs is considered to be such an issue. Accordingly, the draft scientific opinion was released for public consultation on EFSA's homepage[4] for two months (from 5 March 2010 until 30 April 2010). Stakeholders were informed and invited to submit comments.

In parallel, the EFSA GMO Panel also updated specific topics (e.g. effects on NTOs, design of field trials, selection of receiving environments, long-term effects) of its 2006 guidance document for the ERA of GM plants (EFSA, 2006a). The updated ERA guidance document (EFSA, 2010a) contains in a condensed format the scientific opinion providing guidance to applicants on the assessment of potential impacts of GM plants on NTOs. However the scientific opinion further describes the data requirements and gives the scientific rationale as well as examples of methodologies in order to complete a comprehensive ERA for NTOs. Against this background, the draft ERA guidance document, including a dedicated chapter on NTOs, was also launched for a two-month public consultation.

This Scientific Report summarises the comments received through both public consultations and outlines how these were taken into account in the final scientific opinion as well as in the related NTOs chapter of the draft updated ERA guidance document.

EFSA has committed to publish the comments received during the public consultations as well as a short report on the outcome of the consultation on the draft scientific opinion. A similar Scientific Report is also produced as follow-up to the public consultation on the draft updated ERA guidance document.

COMMENTS RECEIVED

At the end of the public consultation period on the draft scientific opinion on NTOs, EFSA had received 162 comments from 27 interested parties (individuals, non-governmental organisations, industry organisations, academia and national assessment bodies). In addition, EFSA had received 65 comments submitted through the public consultation on the NTOs chapter of the draft updated ERA guidance document (EFSA, 2010a). All comments received were scrutinised by the GMO Unit and considered by the EFSA GMO Panel when revising the draft scientific opinion as well as the related NTOs chapter of the draft updated ERA guidance document. The comments related to the draft scientific opinion were subsequently compiled with reference to the contributor and the section of the draft scientific opinion to which the comment referred (see Appendix). Comments submitted formally on behalf of an organisation appear with the name of the organisation.

[4] http://www.efsa.europa.eu/en/consultationsclosed/call/gmo100305.htm

EFSA received many comments on Post-Market Environmental Monitoring (PMEM). However a revision of the PMEM requirements, as laid down in the EFSA scientific opinion of 2006 (EFSA, 2006b), did not fall under the current mandate.

SCREENING AND EVALUATION OF COMMENTS RECEIVED

1. General comments

In general, the comments were constructive and aimed to help improving the draft scientific opinion. There was a general agreement that the concepts of weight-of-evidence, case-by case and tiered approach still make the most appropriate way of assessing the potential impacts of GM plants on NTOs.

Some comments challenged however the interpretation of the scientific opinion and its recommendations since it was sensed that specific instructions on mandatory requirements should be clarified. In this context, a number of comments expressed the need for clearer guidance to applicants e.g. by giving more examples and by precising the type of data expected. In this respect, some commentators were of the opinion that the wording should be revised in order to distinguish strict compulsory requirements from recommendations.

There were also suggestions for editorial improvements and clarifications and few new references to scientific publications were provided.

2. Specific comments

Major and redundant technical comments related to the specifics addressed in the different sections of the scientific opinion are summarised as follows:

Environmental protection goals & Assessment endpoints:

A few comments questioned the issue of selecting specific protection goals from general protection goals set in EU legislation. Some other comments wondered how appropriate assessment endpoints can be identified from the selected specific protection goals.

Receiving environments:

Most of the comments received requested more clear guidance to applicants, in particular with respect to the specificities of the suggested geographical zoning concepts and the selection criteria for representative receiving environments. Some commentators also suggested additional zoning concepts to be considered by GMOs risk assessors.

Tiered approach:

The comments focused on the need for clear data requirements at each tier as well as concrete advice on trigger values in order to move from a lower tier up to a higher tier. Clarifications were also requested with respect to the mandatory requirement for tier 1b data (= *in planta* studies) that could not be carried out in all cases.

Assessment of unintended effects:

Major comments were received on the approach proposed to assess unintended effects (e.g. through initially called '*generic hypotheses*'), including an extended compositional analysis. The concept of extended compositional analysis was questioned as it would not provide sufficient data to rule out potential unintended effects due to the fact that no databases providing baselines for such compounds currently exist and to the lack of validated methods in order to conclude on the biological relevance of any differences.

Further details on the outcome of the public consultation on the draft updated ERA guidance document could be found in the respective Scientific Report of EFSA (EFSA, 2010b).

INCORPORATION OF THE COMMENTS IN THE SCIENTIFIC OPINION

The EFSA GMO Panel and, in particular, its Working Group on NTOs discussed the comments at several dedicated meetings. Many of the comments received were appropriate and of a high scientific value which aimed to enhance the scientific quality and clarity of the document. These comments were taken into account and the document was revised where appropriate. Following the changes inserted into the draft scientific opinion on NTOs, the draft updated ERA guidance document was revised accordingly for sake of consistency.

First of all, numerous comments that have been raised related to the need for clearer guidance to applicants, including clarifications on data requirements. In response to those comments, the wording used in the scientific opinion was checked for sake of clarity. In general, the rationales behind specific data requirements were clarified and supplemented in the scientific opinion considering the principle of proportionality as requested by some commentators.

The EFSA GMO Panel confirmed that the identification of aspects of the environment that need to be protected from harm according to protection goals set out in existing EU legislation, and that the translation of those aspects into concrete measurable phenomena are crucial steps in the problem formulation. Assessment endpoints will be defined on a case-by-case basis dependent upon the identified potential adverse effects and derived hypotheses. Through hypothesis, assessment endpoints are translated into quantitatively measurable endpoints.

Comments related to the different geographical zoning concepts were considered and additional zoning concepts as suggested by some commentators were added to the scientific opinion. With respect to comments on the selection of representative receiving environments, guidance is given through selection criteria (e.g. trait, GM plant and interaction of the GM plant with the environment). It was agreed not to be more prescriptive for the choice and number of receiving environments.

In response to comments related to the tiered approach, the scientific opinion clarified the need for GM trait-specific and GM event-specific data. In the document, the potential stressor for the environment is defined as the GM plant itself, its GM trait(s) and the products thereof. According to the legal framework for GMOs, potential direct and indirect effects of the GM plant on biodiversity need to be assessed. In this respect, *in planta* data from tritrophic studies (e.g. a parasitoid not directly feeding on GM plant parts) are expected in specific cases, in order to rule out possible indirect effects. Therefore the scientific opinion made clear that both tier 1a and tier 1b tests are justified and expected to complement each other in order to rule out trait-specific and plant-specific adverse effects and to perform a comprehensive ERA.

During the public consultation, many commentators questioned the proposed way to assess possible unintended effects through the so-called '*generic hypotheses*'. The scientific opinion was revised accordingly: the concept of '*generic hypotheses'* was dropped and emphasis was put on the weight of evidence approach based on existing data. Indeed, the scientific opinion was modified by listing a comprehensive set of existing data (e.g. data on molecular characterisation of the GM construct, data on the compositional analysis, data from field trials and field surveys, field data from outside EU) that could be used to rule out potential unintended effects. In accordance with some comments, the difficulty of performing an 'extended' compositional analysis due to the lack of validated methods was acknowledged. However, the extended compositional analysis still remains a tool for risk assessors, if focusing on some compounds and/or plant parts that are usually not tested under the standard compositional analysis. In addition, it was made clear that the extended compositional analysis is only one of the indicators of unintended effects of the GM plant on NTOs. Extended compositional analysis was considered to be useful for 'industrial' plants since for these types of plants little or no compositional analysis will have been conducted for food/feed purposes.

CONCLUSION

All comments received through the public consultations were scrutinised by the GMO Unit and considered by the EFSA GMO Panel when revising the draft scientific opinion on NTOs as well as the related NTOs chapter of the draft updated ERA guidance document.

As follow-up to the public consultations on both draft documents, EFSA organised a total of six technical meetings with stakeholders such as Member States competent authorities, applicants and environmental non-governmental organisations. The aim of these meetings was to further discuss and clarify scientific comments submitted by the stakeholders during the public consultations. The scientific discussions further informed the EFSA's GMO Panel and its respective Working Groups, and contributed to the finalisation of the scientific opinion on NTOs.

Further details on the outcome of the public consultation on the draft updated ERA guidance document could be found in the respective Scientific Report of EFSA (EFSA, 2010b).

The EFSA GMO Panel acknowledges the usefulness and quality of a large number of comments and would like to thank all stakeholders for their interest and input to its current and future work.

REFERENCES

EFSA, 2006a. Guidance document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed. The EFSA Journal 374, 1-115.

EFSA, 2006b. Opinion of the Scientific Panel on Genetically Modified Organisms on the Post Market Environmental Monitoring (PMEM) of genetically modified plants, The EFSA Journal 319, 1-27.

EFSA, 2010a. Scientific opinion on guidance on the Environmental Risk Assessment of genetically modified plants. The EFSA Journal 8, 1879.

EFSA, 2010b. Scientific report of EFSA on the outcome of the public consultation on the draft Scientific Opinion of the Scientific Panel on Genetically Modified Organisms (GMO) on the guidance on the environmental risk assessment of genetically modified plants. The EFSA Journal 8, 1877.

APPENDIX

The text below is from the EFSA website of the public consultation:

Public consultation on the draft scientific opinion on the assessment of potential impacts of genetically modified (GM) plants on non-target organisms (NTOs)

Deadline: 30 April 2010

EFSA's GMO Panel has published for public consultation a draft scientific opinion on the assessment of potential impacts of genetically modified (GM) plants on non-target organisms (NTOs).

The aim of the scientific opinion is to produce a scientific review of the current guidance of the GMO Panel for Environmental Risk Assessment (ERA), focusing on the potential impacts of GM plants on Non-Target Organisms (NTOs); to propose criteria for NTOs selection, and to provide advice on standardized testing methodology. This initiative was undertaken in response to a need and request from a wide range of stakeholders, including the European Commission, Member States and applicants. The GMO Panel considered the necessity for clear and objective protection goals, for which assessment and measurement endpoints should be developed; the need to initiate the scientific risk assessment by setting testable hypotheses; criteria for appropriate selection of test species and ecological functional groups; appropriate laboratory and field studies to collect relevant NTO data; and the use of statistical techniques that should be an integral part of experimental design. The GMO Panel considered the range of approaches and methodologies of ERA of NTOs as described in the current literature and proposed risk assessment approaches based on selection of functional groups and individual species within a tiered approach. The present scientific opinion provides guidance to risk assessors for assessing potential effects of GM plants on NTOs, together with rationale for data requirements in order to complete a comprehensive ERA for NTOs. In this respect, conclusions and guidance to applicants as outlined in the present opinion have been integrated into the draft updated Guidance Document of the EFSA GMO Panel for the ERA of GM plants (under public consultation in parallel to this document).

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and all stakeholders, EFSA has launched a public consultation on the draft opinion developed by the EFSA GMO Panel.

Interested parties are invited to submit written comments by 30 April 2010. Please use exclusively the electronic template provided with the documents to submit comments and refer to the line and page numbers. Please note that comments submitted by e-mail or by post cannot be taken into account and that a submission will not be considered if it is:

- submitted after the deadline set out in the call,
- presented in any form other than what is provided for in the instructions and template,
- not related to the contents of the document,
- contains complaints against institutions, personal accusations, irrelevant or offensive statements or material,
- is related to policy or risk management aspects, which is out of the scope of EFSA's activity.

After completion of the public consultation, a summary report of the comments will be prepared.

In addition, please note that:

- repeated comments received from the same contributor will appear in the report only once,
- comments submitted by individuals acting in a personal capacity will be published anonymously,

– comments submitted formally on behalf of an organisation will appear with the name of the organisation.

EFSA will assess all relevant comments from interested parties which are submitted in line with the above criteria. The comments will be evaluated by the relevant unit and taken into consideration where they enhance the scientific quality of the documents. Following this procedure, EFSA will publish the relevant comments received, as well as a short report on the outcome of the consultation.

Publication date: 5 March 2010

TABLE OF PUBLIC COMMENTS

European Food Safety Authority

Table of Member States and stakeholders comments received during the public consultation on the Scientific opinion of the EFSA GMO Panel on Non-Target Organisms

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
1	Finnish Environment Institute	FIN	Summary	Comments to the "Scientific Opinion on the assessment of potential impacts of genetically modified plants on non-target organisms", written by EFSA GMO Panel We appreciate that EFSA has stressed the importance of high quality field trials, especially because many of the field trials in already approved applications have been poorly designed (not enough repetitions, short time-scale etc.). We especially appreciate the fact that there are criteria for the experimental design of laboratory and field studies and their statistical analysis.
2	Finnish Environment Institute	FIN	Summary	Comments to the "Guidance on the Environmental risk assessment of genetically modified Plants" written by the EFSA Panel on Genetically Modified Organisms. Finnish Environment Institute, POBox 140, FIN-00251 Helsinki, Finland General comments: The document is comprehensive and represents a big step forward in the ERA of GM crops. EFSA updated e.g. the detailed requirements for the choice of appropriate comparators, types of receiving environments, the experimental design of laboratory and field studies (including statistical analysis). As a conclusive remark we would like to urge EFSA to implement this guidance more rigorously than before. However, the guidance should stress much more strongly that the applications should only contain relevant, high-level studies that clearly give answers to the tested hypotheses. This is unfortunately very often not the case. Many studies are short-term and the results have not always been statistically analyzed e.g. due to small sample size. Still these studies are used in the ERA (Environmental Risk Assessment) and as basis for the over-all conclusions of the ERA. Furthermore, the language is rather complex (there is no need to use too complex words either; the subject is complex enough!). The text would be improved by shortening. Also the requirements for testing various endpoints could be represented more clearly. There should be some examples of studies dealing with unintended effects included into the guidance. In addition, we are very unhappy for the insufficient commenting period provided us by EFSA. The original commenting period was foreseen to be 3 months minimum.
3	Federal Agency of Nature Conservation	DEU	Summary	We appreciate the draft document on the assessment of potential impact of GM plants on NTOs as a significant step forward in elaborating and specifying the requirements on envi-ronmental risk assessment laid down in the Directive 2001/18/EC. The considerations on how to implement receiving environments systematically in the ERA are a useful staring point for further elaboration. Moreover, we welcome the integration of aspects of both existing methodologies on NTO effect assessment, i.e. the so called ecological (Hilbeck et al. 2008) and the ecotoxicological (Romeis et al. 2008) approach. However, we identified a number of issues that needs revision. We strongly recommend that tiered testing should always be necessary for any specific GMO event or for any stacked event (see comments to p. 27) With regard to stacked events the guidance should be extended. It is the opinion of the BfN that NTO-testing for stacked events cannot rely mainly on information on the parental lines. NTO-testing for stacked events needs to include experiments (Tier1-3) with the relevant pro-tein combinations and the stacked whole-GMP. The existing document should be modified in a way that the selection of test organisms and of field sites for NTO-testing must reflect all representative receiving environments relevant for the market release (i.e. different selection procedures for each region). Consequently focal species need to be selected for each region in question. Although there may be over-lap between regions in the species selected for Tier1 this overlap will not be complete for all regions of concern. The statistical requirements for experiments, laid down in Chapter 1.8, should also apply for each of the regions identified. We do not understand the concept of pre-market and post-market (see p. experiments to assess possible risks of NTOs). In our view all necessary information on NTO effects must be available before the cultivation of a GMP can be granted. It is not acceptable to conduct safety-relevant experiments such as field test with larger plot size, after the approval of a GMO for cultivation has been granted. Also we reject the idea that an extended compositional analysis may provide sufficient in-formation to assess unintended environmental effects. Generic hypothesis also need NTO-testing. In accordance with the ecological test approach (Andow et al. 2006b; Hilbeck et al. 2008) NTO-testing should always include field experiments with the GMO in question.

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Table of Member States and stakeholders comments received during the public consultation on the Scientific opinion of the EFSA GMO Panel on Non-Target Organisms

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
4	Agroscope reckenholz-Tänikon Research Station ART	CHE	Summary	I agree with the EFSA GMO Panel, that more guidance on assessing the potential impacts of GM plants on non-target organisms would be helpful for risk assessors and evaluators of applications for GM crop cultivation. I have focused on the more detailed scientific opinion but would like to point out that my comments principally apply to the NTO section (3.4) in the revised guidance document. Unfortunately, I do not believe that the document in its current form is supporting its initial aim to provide clear and objective guidance. I strongly believe that the proposed approach will lead to an increase in the collection of irrelevant data that are not supporting the environmental risk assessment (ERA) process and cause confusion to risk assessors and evaluators. The latter has a number of unwanted consequences, namely it will reduce the confidence in any decision that has been made, it will increase risk (rather than safety) by directing the attention away from the risks that are most apparent, increase costs and waste resources by collecting and assessing irrelevant data, and further delay the decision-making process. I have the following general comments that will be specified in the comments to the individual sections of the document: i) The document provides very little practical guidance to risk assessors and evaluators and is rather a discussion document. ii) The compilation of the document was obviously driven by scientific curiosity rather than by the need to collect data that are meaningful for regulatory decision making. iii) The document contains numerous inconsistencies and contradicting statements. It is obvious that the document tries to combine very different approaches to ERA. iv) The document introduces the concept of problem formulation. Unfortunately this largely remains jargon and the concept is not applied to the benefit of the ERA. v) Consequently, numerous data are asked for that will confuse the risk assessors and evaluators since they are not related to a proper problem formulation and identified risk hypotheses. This will add uncertainty to the ERA rather than providing additional safety. vi) Trying to conduct ERA according to the draft document would substantially extend the amount of data that need to be collected. This will cause further delays in the decision-making process. vii) The document does not refer to any other regulatory system. It appears that experiences gained worldwide with the regulation of crops have not been considered.
5	Haut Conseil des biotechnologies	FRA	Summary	These are our general comments on the document. The Scientific Committee (SC) of the French High Council for biotechnologies (HCB) has acknowledged positive developments in the document, in particular in the area of statistics. The SC is critical, however, of the definition of the frame of reference. Conventional type agriculture, as a reference system, should be better defined. There are several types of conventional agriculture (different agricultural practices, different crop rotation systems, etc). Other types of reference systems could be considered. Organic agriculture, which is not mentioned in the document, could be a sensible frame of reference to consider with respect to the environment. “Measurement endpoints” are extremely important to guide the evaluation process, yet they are not clearly defined. EFSA should supervise this process more tightly rather than letting the applicant decide on measurement endpoints on its own. Biodiversity is only considered from a human point of view. Genetic diversity is not mentioned. The document would be more comprehensive with the addition of paragraphs from the general guidance document on environmental risk assessment, especially the paragraph on the choice of comparators and Appendice B on long-term effects. The specific issue of GM plants containing stacked transformation events could be more emphasised.
6	SRAGA	GBR	Summary	I am extremely concerned that the EFSA has been chosen to assess the impact of GM crops especially as you have already been shown to have a blatant bias towards the bio tech industry. However, I wish to express my opposition to the whole GM business as it has yet to prove that it does not have a detrimental effect on the flora and fauna. It will also contaminate organic crops and will prevent such crops from being organic. As an organic grower I resent that. Please consider the whole subject very seriously and give an HONEST and UNBIASED decision.

European Food Safety Authority

Table of Member States and stakeholders comments received during the public consultation on the Scientific opinion of the EFSA GMO Panel on Non-Target Organisms

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
7	In support of ANH, Avaaz, and ever growing numbers ,	GBR	Summary	I deplore the EU decision to allow GMO crops and that so much is contaminating our food, without even our knowledge, let alone consent. No one ever asked me what I think. This is quite unacceptable. I refute that it is "the way" forward" - nature has sustained life and always provided for all the needs of man and animal-kind. Natural breeding and husbandry are tried and tested. GMO will be found to be very bad science and will ultimately fail, because it works in opposition to nature. Nature always wins.
8	Fundação Casa Indigo	PRT	Summary	please stop all ogm, return to natural agriculture, no more chemicals.
9	Irish Doctors" Environmental Assoc	IRL	Background	I am writing this in the light of the statement in this section stating that the deliberate release of GMOs into the environment is only taken after a scientific assessment of the risks that they may present for human health
10	EuropaBio	BEL	Background	As already mentioned in the general comments to the ERA GD, we strive to have one clear guidance document. It is unclear why there are two separate documents. The ERA GD already refers to work by several subgroups. Including a summary of the NTO document in the ERA GD while maintaining a separate NTO document, creates complexity and confusion, requiring anyone interested to consult several documents to deduce fully the required information. The introduction of a tiered testing scheme and concept of ecological services are considered as scientifically sound and thus welcome. However, the document is contradictory, as higher tier studies are required even when a risk can be ruled out based on lower tier studies. This should be revised. Further, the ecological services concept is applied only concerning environmental protection relevant aspects (e.g. pollination). Important benefits as e.g. food supply or reduction of area needed for food supply are not considered as a relevant endpoint in the document. Finally, the document very often stops with general considerations, not providing clear thresholds. Experience with similarly elaborated EFSA guidance documents (Guidance document on birds and mammals for plant protection products assessment) shows, that such documents rather create more confusion than guidance. Most of the comments are complementary to the comments formulated under the different sections in the ERA DG also addressing impacts on NTOs.

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Table of Member States and stakeholders comments received during the public consultation on the Scientific opinion of the EFSA GMO Panel on Non-Target Organisms

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
11	NATIONAL COMMISSION ON BIOSAFETY	ESP	Background	Section 3.4. "Interactions of GM plant with non-target organisms" Although in both documents soil microorganisms are considered as potential non-target organisms, both fail to examine the potential effect that newly used herbicides my have on rhizomicrobial plant communities. The "Scientific Opinion" document seems to establish the basis for the development of the "Guidance" document; our comments would be centred on the latter, in the understanding that the observed loopholes should be taken into consideration in both documents. The possible GMO plant impact on microorganisms is dealt with in the "Guidance" document in section 3.2, regarding solely the potential transfer of genetic material from the genetically modified plants to the soil microorganisms. Henceforth, the document disregards the microorganisms as a functional group exposed directly or indirectly to the GM plant (section 3.4, "interactions of GM plant with non-target organisms"). Soil microorganism seems not to be singled out when considering the impacts on specific cultivation, management and harvesting techniques (section 3.5) however, the potential impact on biodiversity is mentioned. This seems to be directed more to the potential appearance of resistant weeds when considering herbicides as part of agricultural practice or when dealing with potential changes on tillage in the event of applying herbicides to which the GMO plants are tolerant. Finally, soil microorganisms may form part of potential biogeochemical processes and, as such, may have been considered in section 3.6. Moreover, consideration of soil microorganisms as such is also absent. Considering that: - a significant number of GMO plants are tolerant to herbicides not used before for that particular cultivar - some of these herbicides are post-emergency herbicides applied in a way that their uptake occurs in the aerial parts of the plant - these herbicides interact directly with the GMO plant and the substances resulting from that interaction are to be released by the root - herbicides are biocides by definition and therefore may have a bactericidal and/or fungicidal effect - communities of microorganisms present in the rhizospheres are known to have beneficial effects on plant growth, favouring the uptake of nutrients and combating plant pathogens, It seems that rhizobial microorganisms should have been given more attention, since changes in the rhizobial communities of microorganisms may have a negative effect on the mid/long term cultivation of a particular GMO over an extensive period. Therefore, it is our understanding that rhizobial microorganisms are non-target organisms in their own right and have to be considered as such, where appropriate, in both EFSA documents. We deem it is necessary to include of the following sentence on page 52, line 1796 of the "Guidance" document, just after the period in that line: "In this regard, special attention should be paid to the communities of beneficial rhizobial microorganisms". Additionally, "rhizobial microorganism non-plant symbionts" should be included as a functional group at the end of Table 4, page 54, section 3.4.1.2.
12	NATIONAL COMMISSION ON BIOS	ESP	Background	3.4. Interactions of GM plant with non-target organisms. About the effects derived from the interaction of GMO and non target organisms, the document places the biodiversity as the main factor susceptible to be measured. Even the guidance considers biodiversity under two perspectives, diversity and ecological functionality it is not clear how both can be interconnected through the adequate indicators. The guidance should state that results on reproduction, growth and development of non target organisms from ecotoxicological studies are not sufficient to evaluate effects on biodiversity. In the page 52 of this guidance it is said : "functional biodiversity is deemed important, since preserving the functional biodiversity may guarantee the quality of productions systems and ensure their sustainability, so applicants should consider whether GM plant is directly and /or indirectly potentially harmful to species guilds involved in ecosystem functions". Generally, non-target organisms are taken into consideration only for genetically modified insect resistant plants, but these organisms could also be harmed due to GMHT cultivation and management. In our opinion, all GM plant and its cultivation should be assessed including the flora that should be also taken into consideration as non target organisms due to its possible ecological function. Figure 6: It should be considered if boxes regarding risk management measures are correctly allocated: - Why risk management measures are taken if the answer to Questions 6 and 7 is negative?
13	NATIONAL COMMISSION ON BIOSAFETY	ESP	Background	The "Guidance on the environmental risk assessment of genetically modified plants" and the accompanying "Scientific Opinion on the assessment of potential impacts of genetically modified plants on non-target organisms" show a strong scientific foundation, but the current format is little operative. Both documents presents an exhaustive review about how to apply the scientific knowledge accumulated for years in laboratory and field studies on the evaluation of environmental effects of GM crops. However, the format in which it has been presented is not adequate for a guide, given its functional purpose. It should be taken into account that this guide will be used by applicants, evaluators and competent authorities. Thus, the final document should appear in a very clear, precise and concise way avoiding, as far as possible, the possibility of an open interpretation of the issues to be studied that could turn into different understanding by the different parts involved in the process of evaluation.

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Table of Member States and stakeholders comments received during the public consultation on the Scientific opinion of the EFSA GMO Panel on Non-Target Organisms

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
14	Agroscope Reckenholz-Tänikon Research Station ART	CHE	Background	Various countries in the world have a long history of commercial growing of GM crops. These countries have gained a lot of experience in the regulatory approval and safety assessment of those crops. It is apparent that the draft NTO guideline does not take into consideration such experience. It misses in particular reference to - a white paper on NTO risk assessment by USDA-Aphis and the US Environmental Protection Agency (US EPA) from 2007 http://www.epa.gov/pesticides/biopesticides/pips/non-target-arthropods.pdf - the risk analysis framework by the Office of the Gene Technology Regulator, Canberra, Australia http://www.health.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1
15	Netherlands Committee on Genetic Modification	NLD	Background	Two documents have been published for public consultation by the EFSA GMO Panel. Firstly the draft guidance document for the environmental risk assessment of genetically modified plants (referred to as the guidance document) and secondly the scientific opinion on the assessment of potential impacts of genetically modified plants on non-target organisms (further referred to as NTO document). Since the potential impact on NTOs is also part of the ERA of GM plants, it would be expected that both documents are consistent, taking into account that the specific NTO document might be more detailed. This is confirmed in the guidance document at lines 1772-1773 which states that 'Guidance to applicants as outlined in that (NTO document) opinion has been inserted in the present guidance document. However, comparing these two documents leads to the conclusion that there is at least one significant difference. Because of the limited time span for public consultation, a complete comparison between the two documents could not be made.
16	CropLife International	CAN	Background	The CropLife International (CLI) Environmental Risk Assessment (ERA) Project Team is composed of technical experts in ERA for genetically modified (GM) crops. Six member companies of CLI actively developing and marketing GM crops globally are represented on this team (BASF, Bayer CropSciences, Dow Agrosciences, DuPont/Pioneer, Monsanto, and Syngenta). As such, CLI's review of the draft Scientific Opinions from the EFSA Panel on Genetically Modified Organisms reflects significant experience in designing, conducting, and defending ERAs for the vast majority of the GM crop products that have been marketed globally for the past 14 years. We also note that these products have an impressive record of environmental safety and have delivered benefits to both the growers that use them and the environments in which they are planted. The members of CLI acknowledge the hard work done by the EFSA GMO Panel to produce these two scientific opinion documents. We also appreciate the opportunity to provide comments on these drafts prior to finalization. We hope that the GMO Panel will find our comments helpful for their task of producing valuable and relevant guidance to all potential future applicants. We chose to limit our comments to a high-level impression of both guidance documents. The purpose of ERA is to provide information for authorities (risk managers) to make decisions that will be appropriately protective of the environment and thereby consistent with achieving environmental protection and development goals. CLI believes that the EFSA GMO Panel shares this view. However, CLI also notes that decisions must be made in a timely manner or environmental protection and economic development will be thwarted. Both are foundational aspects of sustainable development. The standard for ERA is that decisions are always made using the available evidence (information), which is always limited. An appropriately constructed regulatory system also allows risk conclusions to be revisited based on new information deemed relevant to the ERA. In this way, the regulatory system accounts for the existing acceptable uncertainty at the time of the decision. Importantly, information used in the ERA must be relevant for the purposes of decision-making and sufficiently accurate to ensure that the uncertainty is acceptable. Because knowledge is always limiting, regulatory decisions must be made based on reasonable certainty (there is no absolute certainty).
17	In support of ANH, Avaaz, and ever growing numbers ,	GBR	Background	I deplore the EU decision to allow GMO crops and that so much is contaminating our food, without even our knowledge, let alone consent. No one ever asked me what I think. This is quite unacceptable. I refute that it is "the way" forward" - nature has sustained life and always provided for all the needs of man and animal-kind. Natural breeding and husbandry are tried and tested. GMO will be found to be very bad science and will ultimately fail, because it works in opposition to nature. Nature always wins.
18	Fundação Casa Indigo	PRT	Background	please stop all ogm, return to natural agriculture, no more chemicals.
19	Fundação Casa Indigo	PRT	Background	please stop all ogm, return to natural agriculture, no more chemicals.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
20	Fundação Casa Indigo	PRT	Background	please stop all ogm, return to natural agriculture, no more chemicals.
21	anh	NLD	Table of contents	I believe the GMO are not beneficial, either to targeted and non targeted organisms. To me it is a way towards destruction of nature and natural "as birthright" way of living. To this extent I don"t believe in the modification of species or that it is the way to take care of our planet, whatever the needs and reasons are for doing so. So I"m really against GMO and I really wish for it not to happen. I like to ask to WHO takes this harmful decisions, to re-consider why they are doing this, I can"t believe it"s for the wellness of anyone, and there is no power or wealth worth it! Not to destroy the planet and humanity, not to be done by the hands of no one, let us respect our home! OK technology, but this is really a wrong choice. Please let LOVE guide you, THANK YOU
22	N.A.A.C.	GBR	Table of contents	1.2 Environment protection goals: Table 2 points out that only 12.5% of all the estimated species across all kingdoms have been described. NAAC feel this underlines the need to follow the precautionary principle where there are any gaps or uncertainties about data. The importancs of the soil to all terestial life along with the lack of knowledge of the species or ecology of the soil means GM plant assessments must openly and transparently adopt the precautionary principle when assessing impacts on the soil.
23	Private Individual	FRA	Table of contents	There is no environmental protection when GM crops are used. Farmers have found their crops contaminated even though they have never grown GM crops on their land. There is too much risk with the use of GM crops. No long term independent studies have been done on the health issues which may arrive in the future. Studies done by the producing companies themselves cannot be regarded as reliable and research should be carried out by independent laboratories and the results assessed and published - not discounted as has been the case in the past. The development of super weeds, requiring more and more chemical use cannot also be passed aside. The use of weed control and pesticides is known to have increased with GM foods. Crop yields are known NOT to have increased with the use of GM crops The use of Terminator seeds by the agro companies such as Monsanto cannot be approved. People do NOT want GM crops in their countries. Why are they not listened to?
24	EuropaBio	BEL	Assessment	Again, we would like to highlight the fact that the creation of two separate documents leads to confusion.

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25	European Beekeeping Coordination	BEL	Assessment	Assessment, pp. 7-11 a. The central idea of this points and the global proposal of the whole document is that ERA could assess the environmental GMOs effects via the possible changing of the services provided by the biodiversity to human. This idea is open to criticism from various points of views. 1. It is very difficult, close to impossible to build a complete scientific model of biodiversity functioning based on current knowledge. Therefore, this impracticability raises the problem of the methods that could be carried out in order to assess possible effects on ecosystem services. We are aware on the fact that method used in the framework of the ecosystem approach will be further examined and developed but since this first step, the global purpose (assessing the ecosystem services) should be considered regarding the possible middles (developing methods). Otherwise, the entire frame developed in this document will have to be revised regarding the material feasibility of its implementation, and the work currently provided by EFSA and its stakeholders will be lost. 2. As recognized by many experts, such an ERA system is anthropocentric. Of course services provided to human are a central issue for the ERA, but such a point of view is too much restrictive. Consequently, it is likely to neglect some biodiversity components that play an indirect role in the services provided to human. These components will be less visible in the proposed ERA system; nevertheless they are needed by the whole system and long-term effects could be expected when they are disturbed. Naturally, a research effort could suffocate this problem, but there is a risk involved in the belief that human is going to discover all knowledge gaps in relation with nature and environment. 3. it seems really difficult to extrapolate effets from one country or region to another, and from one year to another (see note about p. 11). It must be cleared that society/mankind does accept that the broader ecosystem is no longer in the focus of ERA. This issue should be submitted to an open scientifical and political discussion.
26	CropLife International	CAN	Assessment	CLI believes that the Draft Guidance Document lacks sufficient information to guide an applicant in the process of defining assessment endpoints at the start of the ERA in problem formulation. The Draft Guidance Document communicates a protection goal of sustainable agriculture and makes reference to ecological concepts about biodiversity and ecosystem services. However, there is no clear linkage of the information in Section 3 to clearly defined, measurable, “explicit expression of the environmental value to be protected, operationally defined” (Suter, 2000). The task of defining and defending assessment endpoints is left to the applicant without sufficient guidance as to what properties of an agricultural system make it sustainable, and what elements, if impaired, would make it unsustainable (harm). Applicants are given much detail about elements of experimental design without context. CLI is concerned that the Draft Guidance Document is asking applicants to collect basic ecological data without clear endpoints or appropriate means to analyze it. As such, we feel vulnerable to the application process being an unguided and protracted discussion with the possibility of collecting data until a research objective is satisfied, a process that may be unhelpful for risk assessors or risk managers. Importantly, we feel that, at the end of this process, decision makers in the EU will still face challenges of making decisions with information of questionable relevance to an assessment of environmental safety. CLI would like to point to two publications where the issue of appropriate science for ERA has been described in detail (Johnson et al, 2006; Raybould, 2007). CLI believes that ERA for GM crops should be harmonized internationally as much as possible given international obligations to the WTO (SPS agreements) and Convention on Biological Diversity (CBD) (Cartagena Protocol on Biosafety). The principles of risk assessment, which should be the basis of harmonization, are well developed and described in documents from the OECD (1986 and 1993) and the Secretariat of the Convention on Biological Diversity (Cartagena Protocol on Biosafety, 2000). Furthermore, we feel that additional guidance as to the principles and process of ERA has been elaborated in several publications (for example see: Raybould, 2006; Raybould 2007; Nickson, 2008). The common elements within the documents cited here, and in the Draft Guidance Document, are that ERA should be case-by-case where the amount and nature of the information required depends on the specific case. In addition, ERAs should be scientifically sound, take into account expert advice, and be comparative and transparent. Consequently, guidance should be consistent with and supportive of the principles noted above. For guidance produced by an authority to add practical value, it should also have appropriate flexibility to allow for case-by-case assessment. Importantly, these principles are harmonized with both the WTO and CBD.
27	In support of ANH, Avaaz, and ever growing numbers ,	GBR	Assessment	I deplore the EU decision to allow GMO crops and that so much is contaminating our food, without even our knowledge, let alone consent. No one ever asked me what I think. This is quite unacceptable. I refute that it is "the way" forward" - nature has sustained life and always provided for all the needs of man and animal-kind. Natural breeding and husbandry are tried and tested. GMO will be found to be very bad science and will ultimately fail, because it works in opposition to nature. Nature always wins.

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	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
28	Fundação Casa Indigo	PRT	Assessment	please stop all ogm, return to natural agriculture, no more chemicals.
29	Greenpeace European Unit	BEL	1. Problem formulation	1. Problem formulation It needs to be recognised that there are unknowns making problem formation difficult. Unknowns might include unexpected pathways to non target organisms, or unexpected toxicity to a non target organism. Indeed, this underlines Greenpeace's general view that, whilst this document represents an improved consideration of the risk assessment for NTOs, it does not address our fundamental concerns that, because of the risks to the environment and the unknowns in the system, the precautionary principle should be invoked, and GM crops not released to the environment.
30	Agroscope Reckenholz-Tänikon Research Station ART	CHE	1. Problem formulation	The document introduces the concept of Problem Formulation and in the following repeatedly refers to this important stage of the ERA. While I welcome the fact that the issue of problem formulation has entered the European regulation in respect to GMOs, it is not applied to direct the ERA. Numerous data are requested independent from the outcome of the problem formulation and the specific case that is assessed. I provide several examples in my comments to later sections of the draft document below. It is not clear what happens in the problem formulation stage and which information (including the source of information such as: published literature, earlier risk assessments, data from crop characterization) has to be considered. It should also be made clear that some of the risk hypotheses identified in the problem formulation stage might be addressed using existing information. A key point of problem formulation is that it identifies the stressor of concern that is subsequently addressed in the ERA. In the case of an insecticidal GM plant it may simply be the expressed insecticidal protein (such as a single Cry protein in the case of a Bt crop). The draft document consistently regards the GM plant as a whole as "the stressor of concern". This concept has far-reaching implications and leads, for example to the formulation of "generic hypotheses" (see comment to section 1.7.3), the request for in planta tests in the laboratory (see comments to section 1.7.3.1 and 1.7.5.1), and to the requirement to conduct field experiments independent from the results derived at earlier tiers of the assessment (see comments to section 1.7.5.2).
31	Federal Office of Consumer Protect	DEU	1. Problem formulation	General critique: The crucial element of the problem formulation step is the hazard identification. Hazard identification is described as the identification of characteristics of the GM plant capable of causing potential adverse effects to the environment (hazards), of the nature of these effects, and of pathways of exposure through which the GM plant may adversely affect the environment (see Chapter 2.2.1 of the draft EFSA „Guidance document for the environmental risk assessment of genetically modified plants"). Therefore, the characteristics of the GM plant in question which have been changed by the genetic modification relative to its non-GM comparator(s) should be the starting point of the assessment of potential impacts on NTOs. This fundamental principle is not adequately represented in this chapter of the draft NTO opinion which first elaborates on protection goals and then jumps to receiving environments and assessment endpoints. Before defining assessment endpoints for potential impacts of a GM plant on NTOs, it is essential to consider on a case-by-case basis the characteristics of the GM plant in question which have been changed by the genetic modification relative to its non-GM comparator(s). The assessment of the potential impacts of a GM plant on NTOs does not start de novo, but has to take into account the results of the molecular, compositional and agronomic characterisation of the GM plant. A description of the link between these results and the assessment of potential effects of the GM plant on NTOs is missing. Furthermore, it should be made clear that the ERA can be completed and the further steps shown in Figure 1 are not necessary to be performed if no characteristics of the GM plant capable of causing potential adverse effects to the environment are identified in the problem formulation step.
32	DBIB-EPBA	DEU	1.1 Introduction	It is stated:"1.1. Introduction Through the identification and formulation of the problem, a broadly-stated problem should be transformed into a manageable analysis that will be relevant for regulatory decision-making. In this respect, the most important questions to be solved (= testable hypotheses) are to be identified by applicants" knowing about the actual hot topics in risks in Plant protection--Guttation and dusts from sowing machines-- I doubt if applicants are the adequat representatives to formulate & identify those problem due to the constrains that cope here being an applicant.

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33	EuropaBio	BEL	1.1 Introduction	General We welcome the introduction of the "problem formulation" concept into the document. However, it appears that EFSA does not understand this as the applicants do since a lot of data are requested independently from the outcome of the problem formulation. For example, where data establishing that the risk to NTOs is low in laboratory studies, EFSA argues that field studies are still requested. It appears that when EFSAI describes "the stressors" the outcome of the comparative safety assessment is ignored and even when the only difference between the GM plant and the conventional plant is the introduced trait, the whole plant is considered as an stressor. We believe that this needs to be reviewed. Page 7 The use of the terms 'manageable analysis' and 'testable hypotheses' are interesting. Are either of these possible in the case of a generic hypothesis given the statistical requirements that will be imposed?
34	Federal Agency of Nature Conservation	DEU	1.1 Introduction	p. 7: In the problem formulation only those questions that are deemed to be most important and merit a detailed risk characterisation are considered. This could lead to an exclusion of questions relevant to the ERA. It would be preferable, if every conceivable question is men-tioned and the applicant should give a well-founded explanation on why he has limited his risk characterisation to only some.
35	DBIB-EPBA	DEU	1.2 Environmental protection goals	1.2. Environmental protection goals To scientifically assess these potential interactions, it is thus necessary to test hypotheses and identify clear assessment endpoints in the context of protection goals for biodiversity and ecosystem services Why separate protectioon goals for biodiversity from ecosystem services?

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
36	EuropaBio	BEL	1.2 Environmental protection goals	Page 8, §1 It is mentioned: "To scientifically assess these potential interactions, it is thus necessary to test hypotheses and identify clear assessment endpoints in the context of protection goals for biodiversity and ecosystem services." What are these 'clear assessment endpoints', in line with the EU protection goals, in the case of a generic hypothesis? Precise guidance on what clear assessment endpoints are would be highly appreciated Page 8, § 2 The paragraph starts with: "Specifically when considering NTOs, the receiving environment consists of: the managed terrestrial ecosystem (e.g. agro-ecosystem) including the GM cultivated fields, orchards and plantations,…" Why are 'orchards and plantations' specifically mentioned here, why are they not included in other non-GM cultivations? Page 8, §3 This paragraph refers to the Fauna-Flora-Habitat Directive 92/43/EEC: This Directive describes the protection and conservation aims for natural and semi-natural habitats, … Why in this paragraph is the emphas of an insecticidal GM plant it may simply be the expressed insecticidal protein (such as a single Cry protein in the case of a Bt crop). The draft document consistently regards the GM plant as a whole as "the stressor of concern". This concept has far-reaching implications and leads, for example to the formulation of "generic hypotheses" (see comment to section 1.7.3), the request for in planta tests in the laboratory (see comments to section 1.7.3.1 and 1.7.5.1), and to the requirement to conduct field experiments independent from the results derived at earlier tiers of the assessment (see comments to section 1.7.5.2). s a risk involved in the belief that human is going to discover all knowledge gaps in relation with nature and environment. 3. it seems really difficult to extrapolate effets from one country or region to another, and from one year to another (see note about p. 11). It must be cleared that society/mankind does accept that the broader ecosystem is no longer in the focus of ERA. This issue should be submitted to an open scientifical and political discussion. han providing additional safety. vi) Trying to conduct ERA according to the draft document would substantially extend the amount of data that need to be collected. This will cause further delays in the decision-making process. vii) The document does not refer to any other regulatory system. It appears that experiences gained worldwide with the regulation of crops have not been considered. term cultivation of a particular GMO over an extensive period. Therefore, it is our understanding that rhizobial microorganisms are non-target organisms in their own right and have to be considered as such, where appropriate, in both EFSA documents. We deem it is necessary to include of the following sentence on page 52, line 1796 of the "Guidance" document, just after the period in that line: "In this regard, special attention should be paid to the communities of beneficial rhizobial microorganisms". Additionally, "rhizobial microorganism non-plant symbionts" should be included as a functional group at the end of Table 4, page 54, section 3.4.1.2. nder stress. However, stress, especially poor nutritional status and pathogens, will be a realistic scenario and the imp
37	NA	GBR	1.2 Environmental protection goals	1.2 Environmental Protection Goals All assessments must adopt the precautionary principle (Convention on Biodiveristy). This is generally important and especially important where there are knowledge gaps or uncertainty about data. SOIL ECOLOGY - ESSENTIALLY IMPORTANT The importance of the soil to all terrestrail life, along with the lack of knowledge of the species or ecology of the solil, means that GM plant risk assessments must openly and transparently adopt the precautionary pricniple when assessing impacts on the soil. Thank you.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
38	Federal Agency of Nature Conserva	DEU	1.2 Environmental protection goals	p.8, 3rd para: Although we agree with the listed EU protection goals, we consider it important to refer also to special or more detailed protection goals of the member states. We also sug-gest to state page 11 (last para) that species and habitats which have to be considered are not restricted to the ones listed under EU law. p.8, 4th para: The preservation of the functional biodiversity in agro-ecosystems is an impor-tant environmental protection goal. In this context it should also be mentioned that the func-tions of ecosystems are also protected by conservation of ecosystem structures. Table 1: The conservation of biodiversity is indeed a very important protection goal. However, the areas of its protection are not restricted to species of conservation or cultural value; red list species; protected habitats and landscapes as mentioned in table 1. According to the CBD the term biodiversity covers the three levels: genetic, species and ecosystem diversity. It is necessary to refer to all three levels of biodiversity in this table and the whole ERA GD. p.11, 2nd para: The intention to use a broad definition of biodiversity as starting point for the NTO risk as-sessment is welcomed. However, according to CBD the term biodiversity does not only cover (NTO) species richness and ecological functions in various ecosystems as defined here (and may be related to the term “species diversity”) but also genetic and ecosystem diversity.
39	Agroscope Reckenholz-Tänikon Research Station ART	CHE	1.2 Environmental protection goals	Table 1 lists “areas of protection” as the objectives of environmental policy. The “areas of protection” clearly consider species that are valued either because of the ecological function they provide or because they are rare or protected. Unfortunately, no guidance is given on how to derive assessment endpoints to be considered in the ERA (see section 1.4). The document provides conflicting statements about the species/guilds that need to be protected. In contrast to Table 1, the “area of protection” is expanded to the “wider biodiversity in itself” (p. 8, 3rd par.; p. 11, 2nd par.). On p. 22 (2nd par.) the species to be protected even expands to herbivores that are not targeted by an insecticidal trait.
40	European Beekeeping Coordination	BEL	1.2 Environmental protection goals	Assessment, p. 11: It is understood from the paragraph starting as follows: “Ecosystem services are distinct […]” that ecosystem services should be assessed globally; if one species providing a service is disturbed, a GMO could be authorized if the overall level of the service is maintained by other species providing the same service. Considerations about the species guild (p. 23: predation, pollination) go in the same direction. Such a proposal raises the problem of the possible extrapolation of the replacing species: the overall provision of a service can be maintained under particular weather/geographical/local biodiversity conditions, whilst in another place or under other meteorological conditions, the replacing species can fail in efficiently substitute the disturbed species. Moreover it is really dangerous to define a threshold of “acceptable disturbance” of a service: what are the exact effects on the entire system of a pollination decreasing of 10%? Nobody can evaluate that. That is why, we request the EFSA to maintain an ERA analytical system at the side of the ecosystem assessment system: for pollinators for instance, one could assess the effects on relevant focal species (Dipters, Hymenopters…) and the effects on more sensitive species (for instance, small bees that have a light weight, bees that are dependant of the concerned crop, e.g. bees with a long tong for pulses…)
41	European Beekeeping Coordination	BEL	1.2 Environmental protection goals	b. p. 8, last paragraph: “The close interaction between cultivation and soil processes…”: horizontal transfers of modified genes are proved; this phenomenon does not concern soil organisms only. For instance, micro-organisms of bees gut include modified genes when the bee are fed with genetically modified pollen (see i.a. Ho MW 2000: Horizontal Gene Transfer - The Hidden Hazards of Genetic Engineering, http://www.i-sis.org.uk/horizontal.shtml). A similar phenomenon has been shown in other species (Douville M et al, 2009: Occurrence of the transgenic corn cry1Ab gene in freshwater mussels (Elliptio complanata) near corn ¿elds: Evidence of exposure by bacterial ingestion, Ecotoxicology and Environmental Safety 72 (2009) 17–25. These phenomena should be considered and possible effects should be assessed.
42	World Family	GBR	1.2 Environmental protection goals	Re: 1.2 Environmental Protection Goals Only 12.5% of all estimated species across the kingdoms have been described and of those that have been described even their functions may not have been studied. This underlines the great importance for GM plant risk assessments to adopt the precautionary principle where there are knowledge gaps or uncertainty about data. Because the soil is vital to all terrestrial life and because lack of knowledge of species and of the ecology of the soil, it is vital that GM plant risk assessments openly and transparently adopt the precautionary principle when assessing the impacts on the soil.

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43	Haut Conseil des biotechnologies	FRA	1.2 Environmental protection goals	p.11: To be exhaustive, this part should mention not only ecological services (anthropocentric), but also ecological functions. p.11: "In this context, biodiversity is interpreted broadly and covers both species richness and agro-eco-functions providing ecosystem services." Genetic diversity is an essential component of biodiversity that is important to consider for the estimation of long-term population viability. Could "genetic diversity" be explicitly mentioned along with "species richness"? Table 2 p.11: When and how were these estimations determined?
44	GM Freeze	USA	1.2 Environmental protection goals	Section1.2 Environmental Protection Goals Table 2 in section1.2 presents data on the total numbers of species described and estimated to exist by the Convention on Biodiversity. It reveals that around 12.5% of all the estimated species across all kingdoms have been described. In most cases the function of these species may not even have been studied. GM Freeze believes that this underlines the need for GM plant risk assessments to adopt a precautionary principle where there are knowledge gaps or uncertainty about data. The importance of the soil to all terrestrial life along with the lack of knowledge of the species or ecology of the soil means that GM plant risk assessments must openly and transparently adopt the precautionary principle when assessing impacts on the soil.
45	Förbundet Sveriges Småbrukare	SWE	1.2 Environmental protection goals	Section 1.2 Environmental protection goals Table 2 in section 1.2 presents data on the total numbers of species described and estimated to exist by the Convention on Biodiversity. It reveals that around 12.5% of all the estimated species across all kingdoms have been described. In most cases the function of these species may not even have been studied. Förbundet Sveriges Småbrukare believes that this underlines the need for GM plant risk assessments to adopt the precautionary principle where there are knowledge gaps or uncertainty about data. The importance of the soil to all terrestrial life, along with the lack of knowledge of the species or ecology of the soil, means that GM plant risk assessments must openly and transparently adopt the precautionary principle when assessing impacts on the soil.
46	Soil Association	GBR	1.2 Environmental protection goals	There is a critical need for GM plant risk assessments to adopt the precautionary principle where there are knowledge gaps or uncertainty about the data. This need is underlined by the data presented in Table 2 on the total numbers of species described and estimated to exist by the Convention on Biodiversity. Only 12.5% of all the estimated species have been described and in many cases the function of these species may not even have been studied. The soil is clearly critical to all terrestrial lie and given lack of knowledge of the species or ecology of the soil, the GM plant risk assessment must adopt the precautionary principle when assessing the impacts on the soil.

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47	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	1.2 Environmental protection goals	The legal basis for the environmental risk assessment of genetically modified plants is Directive 2001/18/EC. The regulations listed in Table 1 serve different purposes, and they have different protection goals. Some of them apply only to specific protected areas. These regulations and their protection goals can be taken as examples of environmental protection goals in the EU. They can be helpful to put the ERA of GMO into the context of other environmental risk assessments in the EU, but they can not be directly applied to the ERA of GMO. There are at least two important types of GM plants for which there is a considerable relation and partly a potential overlap between the ERA that has to be carried out in the authorisation procedure for the GM plants and the risk assessment that is carried out in the procedures for the registration of pesticides: Insect resistant (Bt) GM plants and herbicide tolerant GM plants. Harmonised approaches between pesticide and GMO authorisation should be developed, and it is therefore important to have comparable protection goals. Authorisation of pesticides is only possible if no unacceptable effects to non-target species and biodiversity are expected. The relevant guidance documents refer very much to the protection of local populations, especially adjacent to the fields where the pesticide is used. For this assessment endpoint it is possible to define measurement endpoints like for example toxicity data from field tests or monitoring studies, and subsequently these data can be linked to laboratory test results. Short-lasting effects where recovery is expected in the season of use are generally acceptable. There is a common understanding that for species like birds or fish a higher protection level is required. Specifically tailored protection goals for the in-crop area are under discussion. There must be a clear relationship to the risk from the use of pesticides. However, the protection of individuals and an improving biodiversity are typical protection goals in the area of nature conservation. Most of the cited directives in Table 1 belong to this area. There exist special nature conservation areas and regulations for red list species to be followed by farmers using pesticides. These issues are not relevant for a predictive environmental risk assessment before placing a plant protection product on the market. With respect to acceptability of effects the protection of crops and a sufficient and a healthy food production must be taken into account according to the relevant regulations 91/414/EEC and 1107/2009/EC.
48	Federal Agency of Nature Conservation	DEU	1.3 Receiving environments	We fully appreciate that EFSA listed relevant concepts to define the receiving environments which have to be kept in mind during the GMO risk assessment. As stated by EFSA the receiving environment which has to be tested will also depend on the experimental endpoint in question. I.e. test environments for the compositional analysis will most likely differ from studies aiming at biodiversity. In this context it should be also made clear that the applicant must cover all receiving envi-ronments for which the applicant seeks permission. It is not logical that, as in the past, ap-plicants only provided data for few regions where cultivation is most likely but the permission included all other regions of the EU. In this regard the present EFSA opinion is not precise enough and should give stronger guidance (e.g. setting a minimum number of environments which have to be considered). It is a fallacy to assume that the strongest NTO-effects al-ways will occur in the main growing areas. From the viewpoint of agriculture 'less produc-tive' areas (e.g. richly structured landscapes) may be of equal or greater concern.
49	Greenpeace European Unit	BEL	1.3 Receiving environments	1.3 Receiving environments Geographical zones (Section 1.3.4) are a vital part of a risk assessment. We are pleased EFSA is taking this into account.
50	World Family	GBR	1.3 Receiving environments	Re: 1.3 Receiving environments As part of the risk assessment all applicants must provide reliable data on non-target species in all the habitats and bio-geographical zones in which the GM plant concerned is likely to be grown. In addition it is vital that all potential habitats and species in these zones be investigated as part of the assessment. If applicants wish to exclude any habitat or species they must back this request by data supporting such a decision.
51	Netherlands Committee on Genetic Modification	NLD	1.3 Receiving environments	One of the characterizing components of a receiving environment is a 'geographical zone' (1.3.2). Examples are given concerning the elements of a geographical zone. However, the geographical zones itself are not defined. In par. 1.3.4 examples are given of zoning concepts for geographical regions. COGEM is of the opinion that more guidance is needed on this subject and that the EFSA should take a position on which zoning concept should be used in an ERA. COGEM is of the opinion that a limitation to three zones (as in 'Plant protection product' regulation) does not cover European environments and their biogeographical variations adequately. COGEM suggests the use of the formal biogeographic/phytogeographic zoning concept which is based on climatologic gradients in Europe and leads to four regions: Atlantic, Central European, Illyrian and Mediterranean provinces. In addition, the word 'biogeographical' would better describe zones as meant by EFSA than 'geographical'. The applicant has to submit a description of the range of relevant biotic and abiotic interactions likely to occur in the receiving environment (par 1.3.5). This request involves vast amounts of data and literature and is formulated vaguely. Moreover, it is unclear how most of this information can be used in the environmental risk analysis. Also, since in most cases information on the baseline will not be present, the information supplied by the applicant will not be useful for the ERA. Therefore, COGEM stresses the importance of clear and precise requests for information, limited to data directly applicable in the ERA.

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	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
52	GM Freeze	USA	1.3 Receiving environments	Section 1.3. Receiving environments GM Freeze believes that that applicants should have to provide reliable data on non-target species in all the bio-geographical zones and habitats that the GM plant is likely to be grown in and to ensure that all potential habitats and species likely to be exposed to the GM plant are investigated as part of the risk assessment. Exclusion of any habitat or species by the applicants must be backed by data in support of such a decision. It should be made clear by EFSA that any data gaps will mean that applications will fail.
53	Förbundet Sveriges Småbrukare	SWE	1.3 Receiving environments	Section 1.3. Receiving environments Förbundet Sveriges Småbrukare believes that that applicants should have to provide reliable data on non-target species in all the bio-geographical zones and habitats in which the GM plant is likely to be grown and to ensure that all potential habitats and species likely to be exposed to the GM plant are investigated as part of the risk assessment. Exclusion of any habitat or species by the applicants must be backed by data in support of such a decision. It should be made clear by EFSA that any data gaps will mean that applications will fail.
54	Soil Association	GBR	1.3 Receiving environments	It must be compulsory in the EFSA guidelines that applicants have to provide reliable data on non-target species in all the habitats and bio-geographical zones where the GM plant is likely to be grown. All the potential habitats and species that are likely to be exposed to the GM plant must be investigated as part of the risk assessment. If any are excluded, this must be backed up by data supplied by the applicant to support such a decision.
55	EuropaBio	BEL	1.3.2 Receiving environments - Principles	Page 13 § 1 If even the differentiation between irrigated and non-irrigated maize is deemed to cause significant differences in the risk assessment, the number of different scenarios and interactions to be considered becomes very high. The document should provide guidance on "worst case scenarios" which help to reduce the scenarios to a workable amount. Page 14, §1 The paragraph starts with "Applicants should take into account interactions of the GM plant with any other GM plants that have been deliberately released or placed on the market in the same receiving environments…" How are we supposed to address these interactions? More information on what is expected and why this is of concern should be provided, with examples. The requirement to consider also likely / predicted trends brings a very speculative element into the risk assessment. This is somehow contradictory to the permanent requirement to highlight any uncertainties. It is not clear who should define the required baselines and how this should be done. Further, it looks like there will be a suite of different baselines depending on each specific case, thus providing no orientation for the applicant whether any effects might be acceptable. Page 14, §2 The paragraph starts with "Relevant baseline(s) of the receiving environment(s), including farming and production systems, indigenous biota and their interactions, should be determined …." It is not clear whether EFSA is asking for a baseline based on published literature or if applicants are required to do field surveys or should data from the conventional comparator be enough? Baselines like this have not been established. At this point in time the risk assessment can not be based on these data, as they do not exist.
56	Federal Agency of Nature Conservation	DEU	1.3.2 Receiving environments - Principles	p.11, first enumeration and figure 2: Please change "GM plant" in "whole GM plant" in order to indicate that unintended and unexpected effects caused by the genetic modification have also to be considered when assessing GM plant - environment interactions. p.11, 2nd enumeration and figure 2: Please substitute the term "Geographical Zones" by "Biogeographical Zones" here and in the whole document. Geographical zones are defined by longitude and altitude and are primary described by abiotic factors. The term "Bio-geographical Zones" indicates that flora, fauna and habitat structure which are important part of the receiving environment are included when defining these zones. p. 12 last para, middle item in list: We suggest referring to biogeographical instead of geo-graphical zones (flora and fauna were already included in this item).

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
57	Agroscope Reckenholz-Tänikon Research Station ART	CHE	1.3.2 Receiving environments - Principles	P. 14 (1st par.) says that "…applicants should consider likely and/or predicted trends and changes to receiving environments, including uptake of new technologies, and how these might interact with the GM plants." In my view it is impossible to consider possible future technologies and trends in an ERA. The baselines of comparison can only consider technologies that are currently applied. The concept proposed is also in conflict with the concept of familiarity that has been adopted in the EFSA guidance document. According to this concept the environmental impact of a GM crop is compared to the conventional crop which has a history of safe use, but not with potential future crops/traits.
58	Haut Conseil des biotechnologies	FRA	1.3.2 Receiving environments - Principles	p.13: "Management systems" Timescales should be considered in management systems, with particular attention to the long-term evolution of management systems, as mentioned in Appendice B of the ERA document.
59	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	1.3.2 Receiving environments - Principles	Page 12: Replace "variety" by "species". Authorisations for GM plants according to Directive 2001/18/EC are issued for a GMO belonging to a certain species, not for a certain variety. Page 14: Delete "deliberately released or". The reference to "deliberate releases" and "placing on the market" could be understood as if experimental releases of GM plants according to Part B of Directive 2001/18/EC were meant by "deliberately released". Due to the confinement and the spatial and temporal limitation of experimental releases according to Part B of Directive 2001/18/EC, it is neither necessary nor practicable to consider them as part of the receiving environment in the ERA for placing on the market of a GM plant. Better "Relevant baseline(s) […] should be taken into account" than "Relevant baseline(s) […] should be determined". In the majority of cases (cultivation of GM plants of a species that is already cultivated in the EC) sufficient information characterizing the receiving environments in the EU will be available. It will therefore not be necessary to determine the baseline(s) of the receiving environments experimentally.
60	EuropaBio	BEL	1.3.3 Potential cultivation areas of GM plants in the EU receiving environments	Page 14, §3 Correct text as follows: "However, applicants should also consider selecting sites, where the exposure and impacts are expected to be the highest, and where it is anticipated that if effects exist they will be detected." 'achieve meaningful results'? What is meant by meaningful results? It seems that EFSA suggests that a meaningful result is a negative result. Page 15 The first sentence on page 15 is "The case-by-case approach would cover the heterogeneity of zones outside the field." Are applicants expected to carry out field trials on 'assemblages outside the field'? Or is it expected that the applicants will consider assemblages outside the field when selecting field sites?

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
61	Federal Agency of Nature Conservation	DEU	1.3.4 Geographical zoning concepts	pp. 14-15: A clear recommendation for the most suitable regionalization concept for the ERA of GMOs should be given based on the pros and cons of the already existing concepts. From our point of view a modified Natura-2000 concept would be most appropriate to identify the relevant regions for NTO risk assessment. Relevant criteria for the choice of a suitable regionalization concept are: First, a balance between a manageable number of regions in a regulatory context and the ecological uniformity of a single geographical unit must be achieved. Second, the distribution of non-target organisms needs to be considered. A suitable regionalization concept should reflect the specific characteristics of the animal and plant communities of the different EU environments. Therefore, such a classification should be done by an ecoregion approach, meaning that different ecoregions support different communities of organisms which may have different functions in terms of ecosystem services. One problem with this approach is that information on the distribution of NTO-invertebrates in Europe is not available in suffi-cient detail. Hence, it is proposed to use the information about site conditions like climatic, vegetation and soil parameters, which strongly influence the assemblage of NTO (inverte-brate) communities. p. 15, a): Plant protection product registration-based zoning: For the purpose of ERA of GMOs we consider this concept, which supports three regions only, as much too rough. p. 15, b): The Natura 2000 concept is based on the 'European biogeographical regions' (ETC/BD 2006). This concept meets many of the requirements for the ERA of GMO. The classification is based on parameters that also determine the distribution of invertebrate communities (i.e., the natural vegetation; Bohn et al. 2002/2003) and nine biogeographical regions represented within the member states of the EU-27 seem a manageable number for regulatory purposes. In order to tailor the Natura 2000 concept to ERA of GMPs the area in the EU where GMPs are likely to be grown should be considered. The overlap between the biogeographical regions and the intended area of cultivation for a novel GMP form the differ-ent cases, each of which should undergo a specific ERA process. This approach also allows integration of specific information on agricultural management. Bohn, U., & Neuhäusl, R. (2000/2003): Karte der natürlichen Vegetation Europas / Map of the Natural Vegetation of Europe. Maßstab / Scale 1 : 2.500.000. Landwirtschaftsverlag, Münster, Germany ETC/BD (European Topic Centre on Biological Diversity) (2006): The indicative Map of European Biogeographical Regions: Methodology and development. Paris, France. p. 15, c): Please add references for the SEAMLESS project. p. 15, d): LANMAP: A concept differentiating up to 350 landscape types seems to be too detailed for practical consideration in the ERA of GMPs. p. 17: An indication is missing, how many different environments have at least to be consid-ered within the ERA for NTOs. p. 17 first para, first enumeration: It has to be expected, that GM plant – NTO interactions generally do occur where GM plants are grown. The relevance of these interactions and their potential change can not be estimated until they are investigated. Hence, this criterion seems not be suitable to select the relevant regions.
62	Agroscope Reckenholz-Tänikon Research Station ART	CHE	1.3.4 Geographical zoning concepts	The document describes different zoning concepts for the EU but fails to describe how these concepts apply to the agricultural environments in which current and future GM crops will likely be grown. Furthermore, it does not specify which of the described concepts should be applied for the ERA of GM plants. It does not become clear, for example, why the plant protection product registration-based zoning should not be applied to Bt or HT GM plants. The document does not provide criteria that can be used to select the appropriate zones for the ERA of a specific GM plant. Clear guidance is needed to allow risk assessors to identify zones in which for example field tests with a certain crop and trait combination would have to be conducted to be representative of different agricultural situations and to be acceptable by EFSA.
63	Haut Conseil des biotechnologies	FRA	1.3.4 Geographical zoning concepts	p.15: Other zoning types exist for protected areas (Natura 2000) – at the international scale: biosphere reserves (UNESCO programme), and in France: national parks and their peripheral zones, natural regional parks, etc. The definition of zones depends on parameters used in the different specialised softwares. Other types of markers could be considered. Beyond the definition of these zones, it is important to assess whether a particular GM plant will go beyond the geographical area of its conventional counterpart, in which case biodiversity should be monitored beyond the initial zones.
64	EuropaBio	BEL	1.3.5 Conclusion and guidance to applicants	Page 17, Table 3 -Replace in step 2, Plant x Trait by GM plant x cultivation practices (we are not assessing the plant x trait interaction but rather the GM plant interacting with the agricultural practice) -Replace in step 3, Plant x Trait x NTO by GM plant x NTO -Replace in step 4, Plant x Trait x NTO x Region/zone by GM plant x NTO x Region/zone
65	Greenpeace European Unit	BEL	1.3.5 Conclusion and guidance to applicants	1.3.5 Conclusion and guidance to applicants The schematic steps shown in Table 3 are clear, but what is not clear (and this applies to the assessment procedure as a whole), is who is going to make the decisions regarding what organisms and what tests are adequate. Who will decide whether the correct "focal NTO guilds from all relevant functional groups in the production system" have been identified? Or whether the "consequences of gene flow for potential secondary exposure" have been adequately considered? And with which criteria? Unless these are pre-ordained, there is a danger that companies do report research only on their selection which may omit very important elements. In this sense, there is a real danger that the risk assessment, although appearing very detailed and comprehensive on paper, could simply result in a "greenwash" tick box exercise.

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	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
66	European Beekeeping Coordination	BEL	1.3.5 Conclusion and guidance to applicants	1.3.5. Conclusion and guidance to applicants (p. 16) 3d paragraph, last sentence:When appropriate, the presence of cross compatible wild/weedy relatives nearby etc…: the possibility that GM plants form fera population shold always be considered. The assessment should never be based on a supposed "normal" situation including possible (and fulfilled) conditions of authrorisation, e. g. complete absence of weed in the crop (even with "herbicide resistant" GMOs: some weeds can become "herbicide-resistant", too – cfr Amaranthus palmeri resistance to glyphosate).
67	dbyd	GBR	1.3.5 Conclusion and guidance to applicants	lllllllllllllllllllllll
68	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	1.3.5 Conclusion and guidance to applicants	Page 17: Delete "and genetic background". The potential genetic background has to be taken into account in the risk assessment for a GMO, but it is not part of the receiving environment. It is part of the characteristics of the GM plant.
69	EuropaBio	BEL	1.4 Assessment endpoints	Page 18, §1 The paragraph says that "To allow regulatory decision-making, assessment endpoints should be defined by applicants as far as possible using measurable criteria relevant …" In practice this is going to be very difficult to define therefore detailed guidance would be appreciated. The industry is not aware of a great body of literature that describes the perturbations that many species or assemblages are able to withstand in terms of population dynamics. Moreover, as we are in the context of an agricultural field, where the crop is harvested and maybe in rotation, it seems a moot point as the habitat is transient by its nature. It seems that these measurable endpoints must relate to outside the field? How can we possibly measure the non-measurable? EFSA acknowledges (p.11) that in a particular assemblage, the abundance of any species naturally fluctuates. We are talking about population dynamics. If such changes really occur we would need to be testing for a long time (10 years???) to be able to witness them (or for these changes to be measurable). Further work is required before this is applicable and implementable. Page 18, §1 The paragraph also mentions that "These endpoints are operationally defined by an ecological entity (e.g. a natural enemy species, a pollinator species, a species of conservation concern, a soil function)…" But, some of these species may not be found in the corn field so would we need to go outside?
70	Federal Agency of Nature Conservation	DEU	1.4 Assessment endpoints	p. 18 2nd para,: Species assemblage in conventional as well as organic or integrated produc-tion systems should be considered. Please add "integrated and organic" in the 1st sentence. It should be acknowledge here that the protection of biodiversity goes beyond the protection of ecological functions in agro-ecosystems.
71	Greenpeace European Unit	BEL	1.4 Assessment endpoints	1.4 Assessment endpoints The idea that measurable assessment endpoints are needed for both species and ecosystem function is welcome (although Greenpeace would question whether field testing would be necessary). But who will approve these endpoints? Surely such a concept requires a company getting approval (from EFSA?) for an experimental design before embarking on the work. Else, the company may complain they have done all the required work, feel they have fulfilled the criteria and expect a positive opinion from EFSA. At this point, EFSA may feel pressure to give a positive opinion, even though the work may not adequately address the hypotheses.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
72	Agroscope Reckenholz-Tänikon Research Station ART	CHE	1.4 Assessment endpoints	Unfortunately, no guidance is given on how to derive assessment endpoints to be considered in the ERA. I don't believe that the assessment endpoints should be defined by the applicants but should be agreed upon by both the applicant and the risk evaluators to ensure that the data that are provided in the application are relevant for decision-making.
73	Haut Conseil des biotechnologies	FRA	1.4 Assessment endpoints	p.18: "From a practical point of view the species assemblage in a conventional production system should be considered, specifically describing the functional groups active in these agro-ecosystems." Organic production systems should be considered here as it may use variety mixtures. Organic production systems could be mentioned as a reference system for GM production along with conventional production systems throughout the document.
74	EuropaBio	BEL	1.5 Limits for concern	Page 18, §3 The paragraph states that "Hence, once assessment endpoints have been set, the 'environmental' quality to be preserved is to be defined (limits/threshold for concern, trigger values, decision criteria)," How can we possibly define this? It is not clear how and on what basis the limits of concern should be defined, especially as "the required level of biodiversity ….. is often subjective ….., rather than a basic and definitive biological measure".
75	Federal Agency of Nature Conservation	DEU	1.5 Limits for concern	The document mixes the detection of environmental damage and the acceptance of envi-ronmental adverse effects by laying a strong focus on effects, which differ from the compara-tor. In view of the aim of a sustainable agriculture many negative effects of conventional far-ming are deemed nowadays no more acceptable. The detection of damage und the evalua-tion of their social acceptance should be clearly separated. The definition of measurable changes as harm and the interpretation are not clear. The document does not distinguish between the direct and indirect (by indicators) determination of damages. It has to be clearly differentiated between the direct determination of damages and the indirect determination of damages by indicators. If this is not the case, the impres-sion arises that damages can/need only be determined directly. In order to assess the significance of adverse effects the environmental value of the affected conservation resources must be considered. It is not clear which population size and recov-ery potential of a species are the basis of the assessment. This is of great importance as these two factors could differ quite significantly in the member states. It should be stated in the document that it is important not to discount any potential adverse effect on the basis that it seems unlikely to occur or difficult to obtain sufficient data.
76	Agroscope Reckenholz-Tänikon Research Station ART	CHE	1.5 Limits for concern	I acknowledge that it is very difficult to provide a definition about what constitutes environmental damage. The document provides the following definition (p. 18): "'Damage or harm" means a measurable adverse change." Thus every negative effect is defined as damage as long as it is measurable. The latter, however, depends largely on sample size, replication and statistics and is not meaningful from an environmental or ecological point of view. The definition furthermore neglects the fact that damage occurs if a state represents a change that is valued negatively compared to an initial state. A more precise definition would be to include the necessity for a value judgement such as in the following definition: "Damage is a measurable loss or change that has adverse and significant impact upon conservation and sustainable use of biodiversity". No guidance is given on how the given definition of damage can be made operational. A key issue appears to be the selection of a baseline against which a potential GM plant effect can be compared. Again, it is not clear who is going to define this baseline (p. 19, 1st par.) and how this can be done. I believe that what is regarded as an unacceptable damage to the environment needs to be defined by the decision-maker, and not the applicant. On p. 19 (1st par.) it is discussed at length that: "Since agro-ecosystems are heavily human-modified environments, it is logical to expect biodiversity levels to depend upon how that agro-ecosystem is managed. They will therefore vary from region to region, from Member State to Member State, and from season to season, depending upon many parameters (e.g. nature of the particular environment, farming system, weed pressure, soil type and climatic conditions). Agro-ecosystems comprise crop areas, field margins and other semi-natural habitats that may be utilized by NTOs in several ways. It is therefore important that the ERA takes into account the possible threats to biodiversity within the agro-ecosystems and in the surrounding habitats, particularly considering the possible implications for protected areas and natural habitats that might be in proximity of cropping areas." I fully agree with this statement. This is exactly why guidance is needed on how to derive the appropriate baseline against which potential GM plant effects can be compared.

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	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
77	European Beekeeping Coordination	BEL	1.5 Limits for concern	1.5. Limit for concerns (p. 18) a. The statement of the second sentence "This would mean that damage should be measurable" seems to be illusive. Experts in damage measurement, i.e. Reinsurance Companies, do not insure damages resulted from GMOs because they estimate that these damages are not measurable (see for instance http://ec.europa.eu/agriculture/analysis/external/liability_gmo/ex_sum_en.pdf). b. Next to last paragraph: " The magnitude should describe to what extend the environmental quality…": it is needed to underlined that the definition of the threshold for which a disturbance in environment should be considered, is the concern of the public authorities' competence ; it is not the part of the applicant. c. Last paragraph: "The issue of selecting an appropriate or acceptable baseline level…": it needs to be said that the biodiversity threshold for which the essential ecosystem services are no longer fulfilled are already overstepped in many regions. In such cases, the considered threshold should be the theoretical sufficient threshold (required level of biodiversity) and not the current disturbed threshold.
78	World Family	GBR	1.5 Limits for concern	Re: 1.5 Limits of Concern Policies in the UK aim at reversing the decline in species in agro-ecosystems and habitats. Therefore any negative impact on any non-target species would be wholly unacceptable.
79	Haut Conseil des biotechnologies	FRA	1.5 Limits for concern	p.18: "In this scientific opinion, environmental damage is defined as a measurable adverse change in a natural resource (e.g. a protected species, ecosystem service or other environmental entity of conservational relevance), or as a measurable impairment of a natural resource service which may occur directly or indirectly " The influence of genetically modified crops on the maintenance of cultivated and wildlife genetic diversity could be emphasised here. p.18: "The issue of selecting an 'appropriate' or 'acceptable' baseline level of biodiversity for any agro-ecosystem is widely debated. Logically, an 'acceptable' level of biodiversity needs to be defined in terms of a 'minimum' biodiversity level for the efficient and sustainable functioning of the particular agro-ecosystem (i.e., providing essential 'ecosystem services', including biological control of pests and diseases, nutrient fixing and cycling, decomposing plant materials, maintenance of soil quality and fertility and structural stability)" This text is unclear, especially regarding the minimum biodiversity level for the efficient and sustainable function of a particular agro-ecosystem. Biodiversity seems to be considered from an anthropocentric point of view. An agro-ecosystem also includes wildlife biodiversity. Genetic diversity should be more explicitly taken into account.
80	FAS/USEU	USA	1.5 Limits for concern	• We agree with the text "the issue of selecting an 'appropriate' or 'acceptable' baseline level of biodiversity for any agroecosystem is widely debated." It is unclear how a researcher will establish the "minimum acceptable level", and the process may be open to bias. • "Damage" or "harm" is defined as a measurable adverse change. This raises two issues: 1) Consider that the paper might benefit from a more complete description of how one would determine whether a change is adverse. This section seems mostly to focus on measurements of differences with respect to comparators. But to assess risks, one must first know how to identify hazards. Perhaps a citation to the literature or reference to another section would help. 2) Large changes could have an adverse effect while very small, but measurable, changes of the same type may be insignificant. Would the small, but measurable, changes be considered "harm" under the definition?
81	GM Freeze	USA	1.5 Limits for concern	Section 1.5 Limits of Concern UK biodiversity policies are aimed at reversing declines in species in agro-ecosystems and associated habitats and therefore any impact on a non-target species, other than an improvement, would be unacceptable.

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	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
82	Förbundet Sveriges Småbrukare	SWE	1.5 Limits for concern	Section 1.5 Limits of Concern Swedish biodiversity policies are aimed at reversing declines in species in agro-ecosystems and associated habitats and therefore any impact on a non-target species, other than an improvement, would be unacceptable.
83	Soil Association	GBR	1.5 Limits for concern	Policies in the UK are aimed at reversing declines in species in agro-ecosystems and associated habitats and therefore any negative impact on a non-target species would be unacceptable.
84	Federal Agency of Nature Conservation	DEU	1.6 Conceptual model	p. 19, 3rd para; When citing relevant conceptual models and analysis plans reference to the ERA GMO Guideline project (Hilbeck & Andow et al. 2004, Hilbeck et al. 2006, Andow et al. 2008) should be given here. Hilbeck A. and D.A. Andow. 2004. Environmental Risk Assessment of Genetically Modified Organisms, Volume 1, A case study of Bt maize in Kenya. CABI Publishing, Wallingford, UK. 281 Andow, D.A., A. Hilbeck. Nguyen V.T. 2008. Environmental Risk Assessment of Genetically Modified Organisms, Volume 4, Challenges and Opportunities with Bt Cotton in Vietnam. CABI Publishing, Wallingford, UK., 360 pages Hilbeck A., D.A. Andow and Fontes, E.M.G., 2006. Environmental Risk Assessment of Ge-netically Modified Organisms, Volume 2, Challenges and Opportunities with Bt Cotton in Brazil. CABI Publishing, Wallingford, UK., 373 pages p. 19, last para; cases where application does not include cultivation: We disagree that the release of GMO during transport, storage, and processing is considered as negligible expo-sure to NTOs. This argument will only hold for effects on the agro-ecosystem but not for effects on the wider environment including aquatic ecosystems. Exposure paths via waste material (also sewage water) need to be reflected in NTO-testing. If feral GMO-populations may occur, further NTO tests may be required, depending on the fitness change in the GMO.
85	Greenpeace European Unit	BEL	1.6 Conceptual model	1.6 Conceptual model The very concept of a “conceptual model” is flawed because “all relevant exposure scenarios of how harm to the assessment endpoint may arise from the GM plant in a way that allows for a characterisation of …risks” cannot be known. There is no provision in the assessment for (as yet) unknown exposure routes (e.g. the recent concerns over Bt crop residues entering aquatic systems). This is why Greenpeace recommends the precautionary principle should be invoked.
86	Fundação Casa Indigo	PRT	1.6 Conceptual model	1.8 Conceptual model: please stop all ogm, return to natural agriculture, no more chemicals.
87	Irish Doctors" Environmental Association	IRL	1.6.1 Exposure profiles	It is very difficult to quantify exposure of non target organisms to genetically engineerd plantsand it may not be possible to adequately assess their impact on ecosystems over the stated 2 years. In view of the complexity of ecosystems and their multiple interactions, many of which are not understood and in some cases not even known about, a substantially longer time frame would be necessary to assure the safety of genetically engineered plants.
88	Haut Conseil des biotechnologies	FRA	1.6.1 Exposure profiles	p.19: “A GM plant introduces additional potential stressors into the environment: the transgene in an organismal context, its products and the GM plant itself.” The use of herbicides in conjunction with the production of herbicide-tolerant GM crops could also be counted among the potential stressors introduced by GM plants into the environment. p.20: “In cases where the application includes cultivation in the EU, the level of environmental exposure is estimated on a case-by-case basis depending upon the biological and ecological characteristics of the GM plant and its transgene(s), the expected scale and frequency of GM plant use, the receiving environment(s) where the GM plant is likely to be cultivated, and upon the regional interactions among these elements” The case-by-case assessment approach should be complemented by an analysis of interactions between GM plants in the receiving environment.

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	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
89	Federal Agency of Nature Conservation	DEU	1.7 Analysis plan	Chapter 1.7-Part 5 p. 35 Table 6: Field trials also allow studying acute and direct impacts of GM plants and its products at population level. Please add this information. p. 36, comparators and baselines for field experiments: The common or alternative pest con-trol measures will strongly depend on several factors such as the region and the pest pres-sure. For this reason it seems appropriate to reflect several scenarios in NTO field experi-ments. For insect resistant plants one of the comparators should always be 'no insecticide use'. This can serve as a useful baseline and also provides information on the absolute ef-fect of the GMO treatment in comparison to other means of pest control. When using the "current agricultural practice" in conventional crops as baseline/comparator for NTO field trails organic and integrated managed fields should also be included in the comparison, be-cause adverse effect of intensively managed fields are well known and may be questioned to be acceptable. In addition depending on the case the normal agricultural practise may be not to use any insecticide
90	Federal Agency of Nature Conservation	DEU	1.7 Analysis plan	Chapter 1.7-Part 4 p. 30. Compositional analysis: An extended compositional analysis may give indications on potential alterations in GM plant - NTO interactions and may help to focus NTO studies. However, the complex interactions between plant compounds involved in plant defence mechanisms and NTOs are complex and not well enough understood in order to conclude on possible effects only based on compositional data. In some cases those compounds are only produced when plants come in contact with pest organisms or stressors. Plant com-pounds involved in plant defence mechanisms may be gaseous. There are further consider-able practical implications. For instance, sampling time point(s), kind and number of tissues samples for the analysis of secondary plant metabolites can be quite different from those for food/feed risk assessment, i.e. at harvest. This applies especially to cases, in which plant components are only expressed in specific tissues and at special developmental stages or even induced by biotic stress. p. 31, laboratory studies, 1st para: In planta experimental protocols should in every case require a quantitative assessment of expression of the novel proteins. Only with this infor-mation it is possible to ensure that the experimental exposure level equals the situation in the field. p. 32, 1st list, 4th indent: Expression of the novel proteins should be quantified. In our opin-ion a mere check of expression is not sufficient because expression levels between locations and years may vary considerably. E.g. for Bt-proteins differences in expression between locations/regions/years may vary within a factor of 5. Because the safety margin for experi-ments with plant material is 1 the above differences are important to compare and analyse different experiments. p. 32, 2nd list, 2nd indent: We suggest that also the uptake of the novel proteins by the test organisms (e.g. Bt) should be demonstrated (if possible quantified). p. 33 2nd box: With regard to studies on Apis we suggest to include the publication of Bar-bendreier et al. (2005; Apidologie 36 (5) pp. 585-94) which tests effects on the development of hypopharyngeal glands. p.33, last para: Römbke et al. (2010) evaluated soil ecotoxicological methods developed for the testing of pesticides and chemicals whether they are suitable for risk assessment of GMPs as well. The authors compiled existing standardized test method that can be used for the testing of GMPs with some modifications. In addition, methods that are not suitable for the effect assessment of GMPs were indentified. Recommendations on how to accommo-date test methods to relevant GM plant exposure pathways are given. Please cite this refer-ence here. Römbke, J., S. Jänsch, M. Meier, A. Hilbeck, H. Teichmann and B Tappeser, 2010. General recommendations for soil ecotoxicological tests suitable for the environmental risk ssess-ment of genetically modified plants. Integrated Environmental Assessment and Management - Volume 6, number 2, pp. 287-300 General comment on laboratory studies and conditions tested: So far the document does not foresee tests to analyse the impact of the GMO on NTOs under stress. However, stress, especially poor nutritional status and pathogens, will be a realistic scenario and the impact of GMO/novel proteins as a additional stressors should be assessed in the ERA. The guidance should make suggestions when and how these issues could be experimentally clarified. p. 34, first para: Please cite Römbke et al. (2010) here again. p. 34, 2nd para: Design of in planta Tier 1b tests: In order to differentiate between effects cause by the trangene products and pleiotropic and/or positional effects additional test vari-ant(s) consisting of non-GM plant material spiked with definite concentration(s) of isolated transgene products may be advisable.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
91	Federal Agency of Nature Conservation	DEU	1.7 Analysis plan	Chapter 1.7-Part 2 p. 25, 4th para: First sentence: We fully agree, that long-term effects on NTOs population and functional guilds are a substantial element of ERA. Hence, reproduction parameters should be considered as appropriate endpoints. In addition, testing over multiple generations is ad-vised, if a long-term exposure over multiple generations is likely. Please substitute “could” by “should”. p. 25, 4th para: The term “hazard” is used here in a context, where the term “effects” or “ad-verse effect” is correct. Ecotoxicological tests do not measure hazards but solely effects. (If an effect is an hazard depends on several criteria, amongst others the exposure and the probability, that the measured effect may occur) p. 25, 4th para: Please add acute effect concentration (EC50), sub-acute and chronic effect concentration ECx (x may be 10 or 20) (see p. 29). p. 26, last para: Laboratory tests give valuable input for the risk assessment for NTOs. How-ever, the risk assessment should not be completed solely based on data from Tier 1 labora-tory tests. Test results and/or the exposure in the environment could be either variable or difficult to quantify. It may experimentally difficult to mimic a worst-case szenario with a real-istic exposure path in a laboratory setting. Because of multiple interactions between both abiotic and biotic factors in the receiving environment laboratory tests can only be one as-pect of the assessment of GMO effects in the environment. See also pros and cons of labo-ratory and field trials described in subchapter 1.7.4. This means that even if no effects can be observed in laboratory tests, semi-field test (Tier 2) and field tests (Tier 3) are needed to test for unexpected, indirect, long-term, and cumulative effects (see Annex II Directive 2001/18/EC) (Hilbeck et al 2008). p. 27, last para: The chosen wording may be ambiguous and should be amended. Tier 1 tests should be always of crucial importance, irrespective of other ‘similar’ traits. The focus of European GMO regulation is, on a case-by-case basis, on every single transformation (event). Tier1a experiments are carried out with isolated/synthetic proteins and may be thus submitted with different GMO-applications, Tier 1b tests are always necessary and must relate to the specific GMO-event for which approval is sought. The idea that no test must be submitted because a similar trait-GMO has already been approved (e.g. different Cry1Ab maize events) should clearly be rejected. Moreover, purified metabolites used in Tier 1a tests should preferably be extracted from GM plants. p. 28 Figure 4, Tier0: We propose to delete the wording “significantly” in both questions or to provide a clear definition on how this term should be interpreted. In our opinion the decision tree should be followed, if exposure is likely or the connected hazard is very high. The statement should furthermore refer to NTO-species and not be restricted to the focal spe-cies. Moreover, in order to answer question of significant exposure a quantitative exposure char-acterisation is needed, which is intended primary in Step 3. However, hazard characterisa-tion and NTO testing is scheduled in Step 2 in the document. According to the diagram showing the six steps of GMO ERA in the EU (see Directive 2001/18/EC and Figure 1 of this draft NTO ERA GD) hazard and exposure characterisation are placed at the same level. It should be clearly stated, that hazard and exposure characterisation should be performed in parallel and interlinked in order to inform and tailor each other.
92	Federal Agency of Nature Conservation	DEU	1.7 Analysis plan	Chapter 1.7-Part 1 pp. 21 ff: The proposed species selection procedure seems to be based on the methodology developed with the GMO ERA Guideline Project (Hilbeck & Andow et al. 2004, Hilbeck et al. 2006, Andow et al. 2008) and developed further by Hilbeck et al. 2008. It is requested to cite these references accordingly. Hilbeck A. and D.A. Andow. 2004. Environmental Risk Assessment of Genetically Modified Organisms, Volume 1, A case study of Bt maize in Kenya. CABI Publishing, Wallingford, UK. 281 Andow, D.A., A. Hilbeck. Nguyen V.T. 2008. Environmental Risk Assessment of Genetically Modified Organisms, Volume 4, Challenges and Opportunities with Bt Cotton in Vietnam. CABI Publishing, Wallingford, UK., 360 pages Hilbeck A., D.A. Andow and Fontes, E.M.G., 2006. Environmental Risk Assessment of Ge-netically Modified Organisms, Volume 2, Challenges and Opportunities with Bt Cotton in Brazil. CABI Publishing, Wallingford, UK., 373 pages Hilbeck, A., Jänsch, S., Meier, M. and Römbke, J., 2008. Analysis and validation of present ecotoxicological test methods and strategies for the risk assessment of genetically modified plants. BfN – Skripten 236, 287 pages. p. 22, 3rd para: It is not described, how the different receiving environments in the EU MS are considered in the species selection procedure. We propose to assess the interaction between GM plants and NTOs for relevant receiving environments within the EU territory as separate cases (see Hilbeck et al. 2008). Further-more clearer recommendations for the selection of relevant receiving environments for NTO ERA should be provided and linked to the species selection. Hilbeck, A., Jänsch, S., Meier, M. and Römbke, J., 2008. Analysis and validation of present ecotoxicological test methods and strategies for the risk assessment of genetically modified plants. BfN – Skripten 236, 287 pages. p. 23 step 4: For practical reasons EFSA recommends to focus the selection on a restricted number of focal test species. For the actual guidance it would be necessary to provide a rough or minimum estimate on the number of species tested. In our view a comparison to pesticide testing may be useful. In order to obtain an approval between 7 to 35 terrestrial tests have to be performed with an active ingredient of a pesticide and its formulations as well, In cases of concern the number, complexity, effort, and ecological relevance of tests increase. As an example an applicant provided 23 standard tests with soil organisms and 17 tests with bees and nontarget arthropods for an pyrethroid insecticide in order to get ap-proval in the EU. In addition, 54 more data sets from specific regions, performed with non-standard species, were presented (Römbke et al. 2010). Römbke, J., S. Jänsch, M. Meier, A. Hilbeck, H. Teichmann and B Tappeser, 2010. General recommendations for soil ecotoxicological tests suitable for the environmental risk ssess-ment of genetically modified plants. Integrated Environmental Assessment and Management - Volume 6, number 2, pp. 287-300 p. 23, 1st para, 1st enumeration: Species exposure to GM plant residues and products as well as indirect exposure via the food web should be added. p. 24, Figure 3: The figure seems to be adopted from Hilbeck et al. 2008. If yes please refer to this reference here.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
93	Haut Conseil des biotechnologies	FRA	1.7 Analysis plan	p.20: "Reasonable scenarios should be placed in the context of an analysis plan by describing and selecting (1) the various measures to be used in the assessment and subsequent risk characterisation; and through the description of (2) methods and criteria of measurement." Please define "reasonable scenarios". The definition of "reasonable scenarios" should not be left to the sole applicants.
94	AgroParisTech	FRA	1.7 Analysis plan	Dear Madam, dear Sir, We have carried out a meta-analysis on impacts of Bt maize cultivation on NTO in this publication: Ricroch A., J. B. Bergé, M. Kuntz (2009). Is the German Suspension Of MON810 Maize Cultivation Scientifically Justified? Transgenic research. 23 June 2009. 12 pages DOI:10.1007/s11248-009-9297-5. Volume 19, Issue 1 (2010), 1-12. http://www.springerlink.com/content/r6052757667ng364/fulltext.pdf The risk management option is often based on confusion between a potential hazard and a proven risk in the scientific procedure of risk assessment. Laboratory studies are necessary to set up diagnostic tests and to detect toxicological impacts. In the tiered approach (stepwise), if early tests in the laboratory yield uncertain results, further well-designed laboratory studies could ensure that results are relevant to in natura observations. Subsequently, if effects are seen in laboratory assays, in natura studies should be implemented. If no effect is seen under laboratory worst-case exposure conditions, then effects are unlikely to be detected in the field. In our survey we showed taht majority of laboratory studies and all the field studies reviewed did not reveal any unexpected adverse or long-lasting effect. One important lesson is that even if negative effects were observed in the laboratory (e.g. under worst-case conditions) no similar quantitative or qualitative adverse were necessarily detected in the field'' (http://ec.europa.eu/environment/biotechnology/pdf/beetle_report.pdf). We demonstrated that many publications have shown that the differences are more significant between two non-Bt varieties than between isogenic Bt and non-Bt varieties at the farm scale. Sincerely, Dr A. Ricroch

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
95	EuropaBio	BEL	1.7.1 Species selection	Page 21, §3 The paragraph mentions that "The concept of using surrogates is widely applied in regulatory toxicity testing, in monitoring effects of environmental pollutants and in conservation biology to indicate the extent of anthropogenic influences, to monitor population changes of other species and to locate areas of high biodiversity." This is not necessarily applicable to a crop-field setting. Page 21, §3 Species selection would normally prioritize the functional role of these taxa and thus focuses on the ecosystem services role of certain functional groups, so that conclusions from the risk assessment address important processes and are broadly applicable. To select species on a "case by case" studies certainly makes sense on a higher tier level. However, most (if not all) other toxicological and ecotoxicological assessments start with the selection of standard surrogate organisms. It should be considered how far this concept can be applied also for GM plants. Interestingly, testability is only one of several selection criteria – and not the first one. We wonder how to do studies with organisms which are not "testable". Page 22, §2 "1. Identification of functional groups: As a first step in species selection, ……., in the environment(s) where the GM plant is likely to be grown." This should be limited to the field and it margins, otherwise where does the assessment stop? Last sentence: To include species of aesthetic and cultural value is seen critical, as there is no clear guidance what are these species. This should be deleted. Page 23 "3. ranking of species" Reverse the order of ranking, put last criteria ('Known susceptibility of the species to products expressed in the GM plant') first. Page 23, §4 "4. Final selection of focal species" -For field trials, estimation of ecosystem functions and services could complement or replace data on focal species. Comment: This is contradictory with the above statement that suggests that focal species selection criteria can be applied to the field too. Considering threatened species might lead to the need to test endangered species. This should not be a matter of ecological testing, but rather a matter of risk assessment. The concept of focal species led to many debates and uncertainties in the plant protection risk assessment. Thus "focal species" should be defined as clearly as possible.
96	Agroscope Reckenholz-Tänikon Research Station ART	CHE	1.7.1 Species selection	In the document the terms "assessment" and "testing" are confused. Throughout section 1.7.1 it remains unclear whether species selection refers to species that need to be considered in the risk assessment (i.e., for which a risk should be 'assessed') or species that should be tested for example in a laboratory experiment. For example, section 1.7.1 (p. 20) says that "…focal species shall be selected,…, for consideration in the risk assessment…". This is incorrect! The risk assessment has to consider all organisms in the environment (with a particular consideration of the "areas of protection"). Since not all organisms can be tested for potential adverse effects of the GM plant, species have to be selected for experimental studies that are taxonomically or functionally representative of others. The idea of problem formulation is not applied to species selection despite the statement on p. 21 (1st par.) that "NTO testing should start with a clear problem formulation to enable the development of decision trees for species selection." The proposed selection procedure misses an important fact which should play a major role during the problem formulation stage. That is the current knowledge on the stressor that needs to be addressed in the ERA, such as an insecticidal protein in case of an insect-protected GM plant. For example: if one has to assess the NTO effects of a GM plant that expresses a narrow-spectrum insecticidal protein targeting pest Coleoptera, NTOs belonging to the order of Coleoptera are most likely to be affected by the GM plant. Consequently, the NTO testing would place a particular focus on representatives of this order of insects. I also criticise that practical aspects about the availability and amenability of species to testing come in as the last criterion in the species selection process (p. 23, Fig. 3). There is no guidance given as what has to be done with species that were selected but can not be tested (for example, because they can not be reared in the laboratory). No consideration is given to the fact that very different criteria might be used to select species for toxicity tests to be conducted in the laboratory or experiments to be conducted in the open field. The review of two very contrasting species selection approaches in section 1.7.1.1 should be deleted.

European Food Safety Authority

Table of Member States and stakeholders comments received during the public consultation on the Scientific opinion of the EFSA GMO Panel on Non-Target Organisms

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
97	European Beekeeping Coordination	BEL	1.7.1 Species selection	1.7.1.1: NTO species selection approach. a. We agree of course with the idea that honeybees should be considered as both a key-species and a surrogate for pollinator taxa. Others pollinator species should be considered as key-species too, based on their particular sensitivity or to their particular dependence on the considered crops. b. The GMOs dissemination by pollinators should be considered in the assessment. The usual foraging radius is 3 km for honeybees, 6 km for some wild bees (Xylocopa: see Pasquet RS et al., 2008 : Long-distance pollen flow assessment through evaluation of pollinator foraging range suggests transgene escape distances, PNAS 105, 13456 – 13461). More generally, the possibility that some GM individuals could be disseminated into their environment, with sometimes an evolutional advantage, should be taken into account and the effects taken into account in the framework of the assessment. c. Honeybees should be considered from their ecological point of view, and from their economic point of view too (loss of colonies and loss of harvesting): the possible economical loss should be assessed as well as the pollination capacity.
98	World Family	GBR	1.7.1 Species selection	Re: 1.7.1.2 Guidance for selection of test species ("focal species") Applicants should never be permitted to select focal species on the grounds of ease of study or because data already exists. They should be obliged to study those species that could genuinely be affected by the presence of GM plants or their management. Applicants must be able to justify their choice of "focal species" with reference to their functions and populations in the agro-ecosystem and associated habitats – for instance hedges, field margins, streams and ponds.
99	Haut Conseil des biotechnologies	FRA	1.7.1 Species selection	p.21: "There are several criteria suggested for species selection to conduct ERA for GM plants by various authors." In addition to the chosen criteria, the Scientific Committee of the High Council for biotechnologies suggests to consider those species known to interact with the target organisms of insect-resistant GM plants. Figure 4 p.28: Please elaborate on the notion of "acceptable risk" in the text describing the figure.
100	GM Freeze	USA	1.7.1 Species selection	1.7.1.2 Guidance for selection of test species ('focal species') The applicant must be able to back up their choice of "focal species" by reference to its functions and population in the agro-ecosystem and associated habitat (eg streams, ponds, hedges and field margins), evidence of exposure to the GM plant(s) or to crop management changes. Applicants could easily select focal species on the basis that they are easier to study or that data already exists rather than species which could genuinely be affected by the presence of GM plants or their management. The choice of "focal species" must also be based on judgement as to how significant losses in groups or species might be. This reinforces the comment made above. It require applicant to demonstrate an understanding of what changes in population might be considered to be ecologically significant. This can vary greatly between species and groups – depending in some part on the ability of populations to recover in subsequent breeding cycles. Long term studies of farmland wildlife in England (Ewald JA & NJ Aebischer (1999). "Pesticide use, avian food resources and bird densities in Sussex", JNCC Report No 296, p71) found that differences in weed abundance was ecologically significant at -13% (P <0.001). For many field experiments including the UK's Farm Scale Evaluations the sensitivity was far less than this and therefore significant ecological change can easily be missed. Ecologically significant differences may be different between different groups or levels in the food chain. Adopting a "one size fits all approach" to designing field experiments and monitoring may again miss important difference which could have long-term significance.
101	Förbundet Sveriges Småbrukare	SWE	1.7.1 Species selection	1.7.1.2 Guidance for selection of test species ("focal species") Förbundet Sverges Småbrukare believes that applicants must be able to back up their choice of "focal species" by reference to its functions and populations in the agro-ecosystem and associated habitat (eg, streams, ponds, hedges and field margins), evidence of exposure to the GM plant(s) or to crop management changes. Applicants should not be permitted to select focal species on the basis that they are easier to study or that data already exists rather than species which could genuinely be affected by the presence of GM plants or their management.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
102	Soil Association	GBR	1.7.1 Species selection	Applicant's choice of focal species must ensure that those species that could be genuinely affected by the presence of GM plants or their management are included. This selection process should be supported with reference to the species functions and populations in the agro-ecosystem and associated habitat (e.g. streams, ponds, hedges and field margins), evidence of exposure to the GM plant(s) or to crop management changes.
103	EuropaBio	BEL	1.7.2 Definition of measurement endpoints	Page 25, §2 This paragraph starts with "The abundance and species richness of certain groups of NTOs at a relevant life-stage within a landscape or region are typical measurement endpoints." It seems to be in contradiction with the previous sections on ecosystem function. Furthermore, the reference to landscape and regional level suggest that several trials may be required to cover this adequately. This is highly unrealistic and onerous.
104	Greenpeace European Unit	BEL	1.7.2 Definition of measurement endpoints	1.7.2 Definition of measurement endpoints Long- term effects: It is welcome that EFSA recognises long-term effects as an important part of the assessment. However, it is vital that, should any GM crop be authorised for cultivation, a rigorous post-market monitoring plan is produced. Those in the past have been exceptionally weak, relying on farmers to report any effects. This simply is not adequate. In addition, it is not clear how the results of any monitoring are to be assessed by EFSA. Perhaps EFSA might consider detailed requirements for a post-market environmental monitoring.
105	Agroscope Reckenholz-Tänikon Research Station ART	CHE	1.7.2 Definition of measurement endpoints	There is no guidance provided on how measurement endpoints shall be selected. The document simply refers to the "case-by-case" approach and to problem formulation. Criteria need to be provided that allow the selection of appropriate measurement endpoints for a specific test. Again, I wonder where the knowledge about the mode of action of an insecticidal protein would come in. The known mode of action and activity against the sensitive targets of an insecticidal protein should be of importance. In the case of Bt Cry proteins for example, sensitive insects (like Lepidoptera larvae in the case of Cry1Ab) are killed relatively quickly after ingestion of the protein. Consequently one would also look for toxic effects to NTOs. In the case of an insecticidal protein that is known to have no effect on the survival of sensitive insect but reduces the fecundity, fecundity should also be an appropriate measurement endpoint for NTO studies. The document lists a number of possible measurement endpoints on p. 25. While these are all possible (and often investigated in scientific studies) criteria to establish the relevance of the measurement endpoints in respect to the previously defined assessment endpoints need to be established. Furthermore, the document does not recognize that trigger values and thresholds shall be defined and agreed upon by risk assessors and evaluators for each of those measurement endpoints for each test organism. Long-term effects on NTOs are mentioned several times in the document (e.g., p. 25, 3rd par.). Unfortunately, it remains unclear what "long-term" means in the context of the document. The term is not defined and it is thus unclear how long-term effects can be considered in the ERA. In respect to laboratory studies, it is stated on p. 25 that "…reproduction parameters and testing over multiple generations could be considered as appropriate endpoints." There is no guidance as when such tests would have to be conducted, whether they need to be conducted in any case, for any GM plant, for any selected NTO, etc.
106	DBIB-EPBA	DEU	1.7.3 Testable hypotheses & Tiered approach	1.7.3. Testable hypotheses & Tiered approach Tier 1 testing is of crucial importance for the ERA if no or little data on similar GM traits are available. Moreover, based on the experience with Cry toxins, tier 1 tests generally seem to represent useful predictors for results at higher tier tests (Duan et al., 2009) provided that designs include all ecologically relevant ways of exposure Practice (Guttation&sowing dusts for example) makes very clear how difficult it is to "inlude all relevant ways of exposure. What measures to be taken if it can be shown that applicants did not "see" al relevant ways of exposure in their designs?

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
107	EuropaBio	BEL	1.7.3 Testable hypotheses & Tiered approach	Page 30, §5 "2. Compositional analysis" The whole paragraph is very confusing, and we don't see what the point is. Disagreement with this approach for 'extended compositional analysis': the role of secondary plant compounds and their metabolites and their interactions with arthropod assemblages is little understood. So it is unlikely this would provide information that would be useful for the risk assessment. This is research driven by scientific curiosity rather than a tool for generating information that would allow risk assessors to make decisions regarding environmental safety. Page 31 Under 3. Ecotoxological tests: Same comment as above, unclear why this is mentioned here. Previously it was stated that the ecotoxicology approach was not useful for assessing unintended effects to which we disagree.
108	EuropaBio	BEL	1.7.3 Testable hypotheses & Tiered approach	Page 26 About generic hypotheses: disagreement that it is possible to test for generic hypotheses. Page 27, §2 Both the general GMO and NTO documents contain the following sentence, "In justified cases where testing on a lower tier is not appropriate (e.g. test organisms cannot be reared in the laboratory), applicants can perform tests at the next tier." [Line 1929, page 57 general GM O doc; page 27 in NTO doc] This statement is contradictory to earlier statements regarding the selection of appropriate test species. In the NTO document (page 21) the surrogate species approach of Romeis et al., 2008 is highlighted. The inherent difficulties of maintaining and testing certain species in the laboratory are acknowledged by EFSA and as such ,the use of surrogate species that represent functional groups is advocated. Steps 1 and 2 of the outlined test species selection guidance include the identification of functional groups and the selection of species from said groups. Furthermore, Step 4 of this selection guidance states that ' practical criteria' should be considered in the final species selection and highlights effective testing in the laboratory as an example. In addition, though threatened and endangered species are listed as one for special consideration for effects from GMOS, the EFSA NTO document does acknowledge that legal constraints may prohibit the testing of such species. Though not directly stated, the implication here to the reader is that surrogate species would be appropriate. Page 29, §1 "Unintended impacts of GM plants on species richness and ecological functions should be considered in the ERA." Is this not a never ending requirement given the natural fluctuations in species composition and should this not be better addressed in general surveillance? Page 29, §4 "The evidence to confirm this hypothesis can come from numerous sources including data already collected for other parts of the risk assessment. Applicants can choose to test a generic hypothesis by collating appropriate information from these data sources to provide a weight of evidence approach." It is not clear how the statistical requirements outlined later in the document can be met when looking across groups and functions as proposed here. The conclusion of this paragraph is that GM plants which produce no toxic substances have to be tested very broadly as no clear effects can be seen in ecotox testing. This sounds like there is higher scrutiny applied to plants not producing Bt toxin than those that do. Page 29, §10 "1. Field-generated data related to NTO guilds and their functionality: Since unintended effects are to a large extent event specific,…." How can unintended effects be event specific when there is no identified route of exposure or risk hypothesis defined? Surely if they are event specific they can be assessed by specific hypothesis testing. When a comparative safety assessment has been conducted and the result is that the only difference of biological relevance is the trait, then the only stressor is the trait. So unintended effects should not then be event specific or at least a different genetic background of the same crop should not result in different unintended effects. Page 30, §2 "Field surveys: These may provide appropriate data from trials that do not involve hypothesis tests, but are scientifically designed. " Will these field surveys be required for generating a baseline? The applicant needs a more clear definition of what type of field trials EFSA refers to. It is unclear what exactly are "field surveys", "field trials", "semi-field trials", "agronomic field trials" Page 30, §4 "Agronomic field trials" This seems to be a re-iteration of part of the field trials section earlier
109	Greenpeace European Unit	BEL	1.7.3 Testable hypotheses & Tiered approach	1.7.3.2 Extended compositional analysis, whilst welcome, should in no way be an excuse not to conduct toxicity testing on NTOs of focal species. This is an important point that Greenpeace has made orally at EFSA's presentation of the risk assessment.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
110	Greenpeace European Unit	BEL	1.7.3 Testable hypotheses & Tiered approach	1.7.3 Although the framework is detailed, the criteria upon which the data requirements proceed to the next tier are not. For example, in Fig. 4 Tier Zero: Who decides whether the "NTO focal species are significantly exposed"? Who decides on the "case-by-case basis" decisions? How (and who?) will decide whether the rationale for not proceeding further up the tiers is acceptable? This is vital as, all too often, paltry and often irrelevant tests (e.g. acute exposure of honey bees to the inactivated toxin) have been deemed to be evidence of no expected effects to any non-target organisms. Although the intention of EFSA is that this has to be rigorous, it is still open to "greenwashing" by companies.
111	European Beekeeping Coordination	BEL	1.7.3 Testable hypotheses & Tiered approach	1.7.3.2, about the semi field and field trials: When effects appear at very long term or with a delay (for instance: resistance to the insecticide produced by the modified gene, horizontal transfers, etc.), they cannot be covered by field or tunnel trials. For this reason the global authorisation process should allow the ban of a GMO as soon as sufficient arguments showing its danger or risk appear in the post-market monitoring (see point 2.6). Otherwise, the GMO will be ban only if it is enterely proved that it has unacceptable effects, such a complete scientific prove cannot be provided by field testing and the GMO will remain on the market even if unacceptable effects appear in the long term.
112	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	1.7.3 Testable hypotheses & Tiered approach	Page 30: Change "Data from the molecular characterisation and compositional analysis can indicate whether there are general differences between the GM plant and its conventional counterpart. However, these data only provide limited information on potential alterations in GM plant-NTO interactions." to "Data from the molecular characterisation and compositional analysis can indicate whether there are unintended differences between the GM plant and its conventional counterpart and can thus provide information on potential alterations in GM plant-NTO interactions". Molecular characterisation and compositional analysis can detect very specific (not "general") differences between the GM plant and its conventional counterpart. Both methods provide valuable information about the occurrence of unintended differences between the GM plant and its conventional counterpart which may have an effect on GM plant-NTO interactions. Change "Such an extended analysis can help to identify the likelihood of occurrence of unintended effects of GM plants on NTO guilds and their functionality" to "Such an extended analysis can help to identify the likelihood of occurrence of unintended effects in GM plants that could affect NTO guilds and their functionality". In line 16 of the paragraph on "Compositional analysis", replace "unintended" by "unexpected". In line 17 of the paragraph on "Compositional analysis", insert "for these compounds" after "analysed". Page 31: In line 2 of the paragraph on "Ecotoxicological tests", replace "unintended" by "unexpected".

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
113	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	1.7.3 Testable hypotheses & Tiered approach	In this chapter, the term "unintended effects" is used for two different kinds of effects: a) unintended effects of the genetic modification on the metabolism of the GM plant; b) unintended (or unexpected) effects of the GM plant on NTOs. The latter kind of effects can be caused either by new proteins or metabolites due to expression of the transgene(s) in the GM plant (= "intended effects" in the bottom row of Table 5) or by unintended effects of the genetic modification on the metabolism and composition of the GM plants (= "unintended effects" in the bottom row of Table 5). To understand the reasoning regarding "specific hypothesis-driven investigation" and "generic hypothesis-driven investigation", it is essential to avoid confusion between the two kinds of effects. Since the term "unintended effects" is commonly used for meaning "a)" in GM plant risk assessment, it is suggested to replace "unintended" by a different word, for example "unexpected", if the kind of effects described under b) is meant. In the sentence "On the other hand, GM plants may have an altered composition, […]", insert "intentionally" before "altered composition". Between the first and the second paragraph in 1.7.3., insert an additional paragraph: "In all of those five cases, the metabolism and the composition of the GM plants may in addition be unintentionally altered as a consequence of the genetic modification in a way that could affect NTO-plant relationships ("unintended effects")." Change "e.g. possible impacts of a GM plant on ecosystem services" to "e.g. possible impacts of unintended metabolic changes in a GM plant on ecosystem services". Table 5: It should be clarified in which cases (i.e. based on which information) a protein would be classified as having "non-toxic properties" (no specific hypothesis driven investigation required) or as having an "unknown toxicity" (specific hypothesis-driven investigation required). If a function of a protein is known (for example an enzyme like EPSPS), are the tests that have to be carried out for the food/feed safety assessment of a protein sufficient to consider a protein as having "non-toxic properties" in this sense? In the last two columns, second row, of Table 5 insert "intentionally" before "altered". Page 27: No reasons are given why tier 1b ("in planta") tests are necessary if tier 1a tests showed no effects on NTOs. It should be kept in mind that chapter 1.7.3.1. is about the detection of possible effects on NTOs of known proteins or other substances that are newly expressed in a GM plant or known modifications of the metabolism of the GM plant, not about the detection of possible effects on NTOs of unanticipated changes in the metabolism of a GM plant (which is treated in chapter 1.7.3.2.). Page 28, Figure 4: When this decision tree will be applied to a concrete application, it will be scientifically impossible to answer "no" to many of the questions with a certainty of 100%. Therefore, in practice, "no" should be interpreted as "highly unlikely" or "extremely unlikely". This should be explained in the document. Page 29: In the heading and the first two paragraphs of chapter 1.7.3.2., replace "unintended" by "unexpected". In the sentence "Since unintended effects are to a large extent event specific, […]", replace "unintended effects" by "unexpected effects on NTOs that are caused by unintended metabolic changes in GM plants".
114	EuropaBio	BEL	1.7.4 Design of protocols – Laboratory and field trials	Page 31, §1□ "Once specific measurement endpoints are chosen and given a priority, appropriate methods and criteria of measurement should be selected and described in the analysis plan." How will specific endpoints be chosen for generic hypothesis testing for unintended effects? 1.7.5.1 Laboratory studies Numbering needs to be corrected to: 1.7.4.1. 1.7.5.2 Field trials Numbering needs to be corrected to: 1.7.4.2. Page 33 Exotic or out-dated test guidelines should not be recommended. Thus it is proposed to concentrate on OECD methods or IOBC / EPPO methods where there is sufficient experience from PPP registration testing. Studies on Aphidius ervi, Cotesia sp. and Heilx aspersa are not really validated and should not be recommended as not validated. Page 34 The aim of field trials is not to confirm observed effects in lower tier experiments, but rather to conclude whether considered worst case assumptions in lower tiers were over-protective and effects can not been seen under real conditions. If field trials are seen as an element to "discover …. Effects not anticipated in lower tier tests", the concept of a tiered approach is obsolete.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
115	European Beekeeping Coordination	BEL	1.7.4 Design of protocols – Laboratory and field trials	Field trials p. 32 We entirely agree with the EFSA concerns "they exhibit the highest experimental complexity … large natural variability" and EFSA observations about the lack of the control in field tests (p. 35). For these reasons field tests cannot be considered as the determining step of the whole assessment. Lab tests and data provided by the scientific literature should be considered and compared to the ones provided by the tunnel or field tests.
116	World Family	GBR	1.7.4 Design of protocols – Laboratory and field trials	Re: 1.7.5.2 Field trials Applicants must be required to identify all exposure routes so that the right species are tested in the following stage of eco-toxicological testing. It is not necessary to release GMOs into the environment in order to be able to identify exposure routes and pathways. This can be done through knowledge and studies of the behaviour of species in conventional crops. Additionally testing needs to examine the impact of GMOs on the reproductive potential and longevity over a number of generations.
117	GM Freeze	USA	1.7.4 Design of protocols – Laboratory and field trials	1.7.5.2. Field trials EFSA recognise that field work is important in identifying possible exposure routes for non-target organisms. This is a vital area and one in which previous risk assessments have fallen down, leading to potentially damaging exposures taking place, for instance exposure of non-target species to pollen blown or washed off fields or predators via their herbivore prey or the long distance transfer of seeds or pollen by wild species. Applicants must be required to identify all exposure routes in order to test the right species in the following stage of ecotoxicological testing. Identifying exposure routes or pathways can be done without releasing GMOs into the environment based on the behaviour of species in conventional crops. We also recommend that testing should examine impacts on reproductive potential and longevity over a number of generations as well as the standard toxicological testing.
118	Förbundet Sveriges Småbrukare	SWE	1.7.4 Design of protocols – Laboratory and field trials	1.7.5.2. Field trials EFSA recognises that field work is important in identifying possible exposure routes for non-target organisms. This is a vital area and one in which previous risk assessments have fallen down, leading to potentially damaging exposures taking place (eg, exposure of non-target species to pollen blown or washed off fields, or carried by predators via their herbivore prey, or the long distance transfer of seeds or pollen by wild species). Applicants must be required to identify all exposure routes in order to test the right species in the following stage of ecotoxicological testing. Identifying exposure routes or pathways can be done without releasing GMOs into the environment based on the behaviour of species in conventional crops. We also recommend that testing should examine impacts on reproductive potential and longevity over a number of generations as well as the standard toxicological testing.
119	Soil Association	GBR	1.7.4 Design of protocols – Laboratory and field trials	Identifying exposure routes or pathways can be done without releasing GMOs into the environment based on the behaviour of species in conventional crops. Testing should examine the impacts on reproductive potential and longevity over a number of generations in addition to the standard toxicological testing.

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	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
120	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	1.7.4 Design of protocols – Laboratory and field trials	Page 31 ("Laboratory studies"): OECD-test guidelines proposed for GMOs have been in use for pesticide authorisation over the last 20 years and even with these test methods it is sometimes difficult to reach harmonised conclusions about the endpoints to be used for risk assessment. More guidance would be helpful, specifically on how to adapt those guidelines to generate broadly acceptable toxicity data for use in GMO ERA. No reasons are given why "in planta" tests are compulsory. A disadvantage of "in planta" test is that the exposure levels in an "in planta" test are limited by the level of expression of the transgene(s) in the GM plant. This will limit the sensitivity of in planta tests compared to tier 1a tests in which the test organisms can be exposed to different and higher doses of the expression product(s) of the transgene(s). Page 34 ("Field trials"): It should be made clear what the consequences would be if effects that were observed in lower tier experiments would not be confirmed in field trials (for example because the exposure in the field is below a certain threshold). If this could lead to the dismissal of effects that were observed in lower tier experiments, the words "or dismiss" should be inserted after "confirm". In the sentence "To discover potential unintended effects not anticipated in lower tear tests; […]", replace "unintended effects" by "unexpected effects on NTOs". Page 35, Table 6: In the table, under "Laboratory studies", change "Organisms tested under optimised conditions" to "Organisms tested under optimised and/or standardised conditions". One important difference between laboratory studies and field trials is that laboratory studies can be carried out under standardised conditions which means that they can be replicated within a laboratory and/or compared to studies that were carried out in other laboratories.
121	EuropaBio	BEL	1.8 General statistical principles	Page 37 General comments to this chapter: It was proposed to conduct the equivalence test in addition to the difference test between the same pair of treatments. Suppose a prospective power analysis has been conducted and enough number of replications is determined to provide the difference test with sufficient power. In this case, when the difference test is actually conducted, we know the test is adequately empowered to detect a biologically meaningful difference ("effect size"). Therefore, we see no reason to conduct an equivalence test in addition to the difference test. It was also proposed to use the "effect size", the same one used for the power analysis, as the equivalence interval for equivalence test. Doing this, we will likely find inconsistent or contradictory results from the two types of tests. For example, if the observed difference is less than the effect size, then the difference is likely not "significant" by the difference test; however, the same difference may be concluded as "lack of equivalence" by the equivalence test. This is because in the equivalence test, it is not the point estimate of the difference that needs to be within the equivalence interval, but the entire interval estimate of the difference (90% confidence interval for the difference in the TOST procedure) that needs to be completely within the equivalence interval. The fact that 90% confidence interval is contained within the two equivalence limits (two-sided test) is equivalent to the fact that statistically significant differences are identified between the observed difference and the effect size on both side. It is not reasonable to require the observed difference to be statistically significantly different from the effect size, because the later is interpreted as the biologically meaningful difference for the former. Therefore, we see no reason to require the observed difference between two treatments to be statistically different from the effect size. If equivalence test is to be required, we suggest that the equivalence interval should be wider than the effect size, and the interpretation for the equivalence limits is not "effect size" or "biologically meaningful difference, but "maximum allowable difference that poses no concern". Page 37, §3 "The use of meta-analysis is recommended,…." While meta-analysis has several merits, it is difficult to anticipate how this can be include at a stage which should be early in the introduction process and where only few studies may be available. It is suggested that meta-analysis is recommended, particularly to quantify studies that may not have sufficient power. It is important to provide basic quality criteria on the acceptability a study before inclusion in a meta-analysis. A good meta-analysis of badly designed studies will still result in bad statistics. Later on (power analysis section) it is mentioned that field trials should yield a standalone analysis and the power analysis should relate to a single site. Since it are the single site analyses that are required to be adequately powered, not the meta-analysis, the property of statistical power for the "meta-analysis" is unknown. Page 37, §4 "The (sets of) limits of concern represent the minimum relevant ecological effects (in positive and negative directions) that are deemed biologically significant." What is considered biologically relevant under field conditions?

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
122	Federal Agency of Nature Conservation	DEU	1.8 General statistical principles	p. 37: We fully agree that statistical differences may not be biologically relevant and vice versa. The idea of EFSA for a compulsory power analysis and testing of type II errors is highly appreciated. Also the idea to use meta-analyses is welcomed. For the latter it is im-portant though, also to recognize the limits of such analysis. Details in methodology or ex-perimental settings (e.g. environment) may strongly influence the experimental outcome so that meta-analyses may not be suitable to decide in the case of contradicting results. Also, meta-analyses require large data sets which are usually not available for the pre-market as-sessment of a GMO event but may rather apply for the re-assessment of a GMO after the permission has expired. The pretence to specify a minimum effect size for each variable is consequent, but may not be feasible in practice. At this point we want to come back to the statistical and biological differences. The decision on biological relevancy which may differ from case-to-case (e.g. region or protection status of species) should be transparent and separate from the statisti-cal analysis. The aspired statistical power for an experiment may differ with the variable/protection goal in question. For this reason we do not advise to recommend one fixed value. For laboratory experiment a statistical power of 80% should be realistic and sample sizes should be large enough to achieve this power. For field experiments a power of 80% should be recom-mended. From our viewpoint a statistical power of 60% or lower as propagated by some authors (e.g. Duan et al. 2006, Ecol Entomol, 31, pp. 521-531) should be rejected. For field experiments the EFSA opinion states that power analysis is only required for those NTO species of prime importance and those expected to be the most abundant. This ap-proach should be challenged for the consequence would be that only reliable data for these species can be generated. The original question, however, may be different. If statistical power for some species/guilds cannot be achieved this should be clearly documented. Lower statistical power will need to be reflected in the assessment of uncertainty during the overall risk assessment.
123	Greenpeace European Unit	BEL	1.8 General statistical principles	1.8 Meta-analysis. The use of meta-analysis is often problematic because of differences in experimental design. The problem being that you can artificially get so much variation that any adverse effect is lost in this inflated variability. How will EFSA ensure that this is not the case? Biological relevance. It is welcomed that EFSA gives some clarity to the issue of statistical difference and biological relevance. However, the statement “statistically significant differences may point to biological changes caused by the genetic modification, but these may or may not be relevant on safety grounds” gives cause for concern. A central tenet of the substantial equivalence is that there are no changes apart from those intended by the insert. If, indeed differences are the result of the genetic modification, then they are not substantially equivalent and must undergo further tests, especially for food safety, or rejected. It is not acceptable to claim substantial equivalence and then evaluate whether the changes brought on by the genetic modification raise safety concerns or not.
124	Agroscope Reckenholz-Tänikon Research Station ART	CHE	1.8 General statistical principles	The guidance of the statistics section has many gaps und leaves a number of open questions. The use of meta-analyses is recommended “particularly to quantify studies that may not all have the power to be individually significant” (p. 37, 3rd par.). While we agree that meta analyses can be useful to combine data from various studies (Wolfenbarger et al., 2008: PLoS ONE 3(5):e2118; Naranjo, 2009: CAB Reviews: Perspect Agric, Vet Sci, Nutrit Nat Resour 4:No.011) it remains unclear how they can be used for a regulatory risk assessment which is based on a restricted number of field experiments conducted typically during very few years. Section 1.8.2 (p. 38) on the specification of the effect size has several weaknesses: (a) “…risk characterization cannot be done without relating effects to potential harm. Therefore it is essential to specify for each effect variable a minimum effect size which is considered to potentially have a relevant impact on the environment(s).” This definition of “harm” or “damage” differs from that on p. 18 where it is simply a “measurable adverse change”. The question remains who is going to define what a harmful effect on a particular assessment endpoint or on a measurement endpoint in a particular NTO laboratory study is. (b) “The applicant should state explicitly how the chosen effect size(s) relates to the limits of concern through the minimum relevant ecological effect that is deemed biologically significant. Usually, these quantities will be identical; the applicant should justify cases where this is not so. The applicant should state explicitly the limits of concern that were used for each equivalence test.“ It is not the applicant who should define what the limit of concern is but the regulatory authority needs to set these limits and provide clear guidance on this.
125	European Beekeeping Coordination	BEL	1.8 General statistical principles	1.8. General statistical principles I needs to be emphasized the importance of the statistical validation of the trials presented. All the credibility of the assessment should be based on this validation. Currently a great part of European citizen or NGOs challenge the assessment of GMOs and pesticides based on this point of the assessment. For the same reason it is highly important to define the range of uncertainties (point 1.9). The statistical significance threshold (how many trials are necessary to reveal an given effect) should be defined by the public authorities and not by the applicant.
126	Haut Conseil des biotechnologies	FRA	1.8 General statistical principles	See the comments of the Scientific Committee of the High Council for biotechnologies on the corresponding chapter in the ERA guidance document.

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127	Greenpeace European Unit	BEL	1.8.2 Specification of the effect size and the limits of concern	1.8.2 Biological relevance. An addition issue here is the comparator. Often, the GM crop is compared to historical ranges across many varieties (i.e. the broadest possible population) rather than a sister line to gauge biological relevance. It is not simply an effect of samples size. Comparing to a population range is not acceptable.
128	Finnish Environment Institute	FIN	1.8.4 Experimental design	1.8.4., page 39. Experimental design: What is the scientific rationale for stating that the requirements for minimum replication and time-scale do not apply for the field trials providing data to assess potential persistence and invasiveness? This is contradictory to present ecological understanding. What other methods or experiments are suggested to assess potential persistence and invasiveness?
129	Federal Agency of Nature Conservation	DEU	1.8.4 Experimental design	Experimental design: Guidance for the minimum number of replicates and sites (three sites over two years) do not reflect the requirements for conducting NTO-field tests but seem to follow the recommendation for the production of material for the compositional analysis. From our experience it will not be possible to test genotype x environment interaction repre-sentative for the full biogeographical range of Europe with only three sites. We recommend applying these criteria for each of the regions which were identified in the selection process (representative EU environments). Also, it is not comprehensible that the guidance foresees a relaxation of these weak criteria in the case of the necessary data for the assessment of possible unexpected effects or for field trials providing data to assess potential persistence and invasiveness. Especially the latter may be of special importance for the assessment of ecological risks associated with GMOs. We also do not agree that additional replication over years should be allowed to compensate for the omission of the already small number (3) of different sites. According to Directive 2001/18/EG the release of GMO into the environment should follow a stepwise approach. This implies that, in the case of GMO cultivation, the applicant should carry out sufficient field tests (Part B experiments) to obtain the necessary data for the GMO market release. Therefore a much higher number of field experiments should be available to answer the questions relating to NTO safety. The guidance on page 40 (first para) also opens the option for the applicant to omit field data from Europe. While this may be an option for applications aiming at import and processing only, the submission of representative, scientifically sound field experiments from the representative EU regions are necessary when cultivation is envisaged. Criteria for the representativeness will depend on the parameters in question (e.g. herbivores, predators, pollinators in and outside the field). We strongly disagree that using the same plots and experimental design for the com-parative assessment will yield sufficient data to analyse the ecology of a GMO or to analyse possible non-target effects. As has been argued before, the criteria for representativeness will differ between agricultural and ecological questions. Moreover, the small plot size usu-ally used in compositional studies will not yield biologically relevant results for relatively mo-bile organisms such as many beneficials or other non-target arthropods (see also the need for statistical power). The distinction of the EFSA document between pre- and post-market commercialization must be rejected. The role of the ERA is to ensure that the cultivation of the GMO will not cause adverse effects for the environment. Although a certain uncertainty will always remain scientifically sound data must be available to conclude on the ERA. Di-rective 2001/18/EG does not foresee to clarify ERA issues (such as effects on NTOs) with post-market research.
130	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	1.8.5 Analysis and reporting	Page 41: As this guidance document shall apply to GM plants with all kinds of traits, it is not clear why the protocols for field trials should include details on insecticide and herbicide use but not on the use of other plant protection products. Either change this point to "iv) insecticide use (in case of insect resistant GM plants) and herbicide use (in case of herbicide resistant GM plants)" or replace "insecticide and herbicide use" by "use of plant protection products".
131	World Family	GBR	1.8.6 Statistical analysis of field trials	Re: 1.8.6 Statistical analysis of field trials Because small differences can be cumulative and can become ecologically significant over several growing seasons, EFSA should include detailed guidance showing how cumulative effects should be assessed and pointing out the limitations of the methods available. For example meta analysis can suffer from bias if applicants select studies showing favourable over unfavourable results or if inappropriate studies are included because so few appropriate one are available.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
132	GM Freeze	USA	1.8.6 Statistical analysis of field trials	1.8.6. Statistical analysis of field trials Field trials are generally designed to detect big differences between crops or management techniques. Smaller differences can be cumulative and become ecologically significant over several growing seasons. The EFSA guidance makes only passing reference to cumulative effects. Smaller differences may not be detected or could be assumed to be standard error. We recommend that the EFSA guidance should include detailed guidance on how cumulative effects should be assessed and the limitations of the methods available. For instance meta analysis (combining the results of several unconnected studies) can suffer from bias caused by applicants selecting studies which show favourable rather than unfavourable results or the selection of inappropriate studies to included because there are so few appropriate ones available.
133	Förbundet Sveriges Småbrukare	SWE	1.8.6 Statistical analysis of field trials	1.8.6. Statistical analysis of field trials Field trials are generally designed to detect big differences between crops or management techniques. Smaller differences can be cumulative and become ecologically significant over several growing seasons. The EFSA guidance makes only passing reference to cumulative effects. Smaller differences may not be detected or could be assumed to be standard error. We recommend that the EFSA guidance should include detailed guidance on how cumulative effects should be assessed and the limitations of the methods available. For instance meta analysis (combining the results of several unconnected studies) can suffer from bias caused by applicants selecting studies which show favourable rather than unfavourable results or the selection of inappropriate studies to be included because there are so few appropriate ones available.
134	Soil Association	GBR	1.8.6 Statistical analysis of field trials	The EFSA guidance should include detailed guidance on how cumulative effects should be assessed and the limitations of methods available. One example is meta analysis that combines the results of several unconnected studies. These can suffer from bias by applicants if the studies selected show favourable rather than unfavourable results, or the selection of inappropriate studies occurs because there are so few appropriate ones available.
135	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	1.8.6 Statistical analysis of field trials	Page 41: It should be made clear that requirements in this paragraph only apply to field trials in a strict sense but not, for example, to the field surveys and the agronomic field trials mentioned on page 30.
136	Irish Doctors" Environmental Association	IRL	1.9 Uncertainties	There is a great deal of uncertainty, particularly as extensive safety testing of genetically engineered foods is not required in the EU if the new plant is deemed to be 'substantially equivalent' to the parental plant. This term has no clear definition and no scientific meaning. The concept itself does not make sense, for if a genetically engineered plant is the same as its original counterpart, there would be no need to develop it in the first place. The regulation of GM food is currently based on a series of 'extremely insufficient' guidelines and little research has been conducted on unintended compositional changes from genetic engineering . In addition, issues of chronic toxicity, carcinogenesis and teratogenesis of genetically engineered foods are seriously under-investigated . The WHO states that 'feasibility and methods for post-marketing monitoring of GM food products, for the continued surveillance of the safety of GM food products are under discussion' . It is clear that sufficient uncertainty exists in relation to the safety of genetically engineered food and that the precautionary principle must be invoked in the case of genetically engineered food and that a moratorium must be initiated until the scientific data has been presented.
137	Greenpeace European Unit	BEL	1.9 Uncertainties	1.9 Uncertainties Further clarification on the issue of uncertainties is welcomed, although Risbey & Kandlikar (2007) does not appear to be in the reference list. It is imperative that both the companies applying to market GM crops and EFSA give a clear account of the uncertainties. This can point the way to further studies, or guide risk managers.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
138	GM Freeze	USA	1.9 Uncertainties	1.9 Uncertainties Section 1.9 contains significant comments regarding the lack of data, inadequacy of date and interpretation of data on non-target species: ERA has to take into account uncertainty at various levels (see Section 1.9.). Uncertainties may arise from limitations in the data (e.g. limited exposure data), gaps in the effect database, the limitation of the test systems and measurement endpoints selected, inadequacy of study designs and the uncertainties in extrapolating between species (EFSA, 2009a). Scientific uncertainty may also arise from differing interpretations of existing data or lack of some relevant data. Uncertainty may relate to qualitative or quantitative elements of the analysis. The level of knowledge or data for a baseline is reflected by the level of uncertainty, which should be discussed by the applicant. The applicant should in addition assess the degree of uncertainty within the ERA in comparison with the current uncertainties displayed in the scientific literature. However, it then goes on to say: Scientific knowledge and experience gained from growing GM plants encompassed in Post-Market Environmental Monitoring (PMEM) may also inform the risk assessment process and provide opportunities to continually update ERA in the light of new knowledge. GM Freeze believes that the precautionary principle should be applied at the risk assessment stage. If “gaps” or “uncertainties” have been identified the applicant should be asked to investigate these further as part of the risk assessment. The role of Post Market Environmental Marketing (PMEM) should be to identify any unanticipated events arising from the releases of a GM plant ansd not to fill data gaps. Baseline data of the highest quality is necessary to enable PMEM to be effective in detecting unexpected changes which could be attributable to GM plants. GM Freeze recommends that EFSA amend to section on PMEM to make it clear to applicants that if possible adverse impacts are identified during the risk assessment these should be further investigated as part of the risk assessment and not by PMEM.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
139	AgroParisTech	FRA	2. Risk characterisation	Dear Madam, dear Sir, We carried out a meta-analysis on impacts of Bt maize cultivation on NTO in this publication: Ricroch A., J. B. Bergé, M. Kuntz (2009). Is the German Suspension Of MON810 Maize Cultivation Scientifically Justified? Transgenic research. 23 June 2009. 12 pages DOI:10.1007/s11248-009-9297-5. Volume 19, Issue 1 (2010), 1-12. http://www.springerlink.com/content/r6052757667ng364/fulltext.pdf We carried out an extensive survey of the scientific literature regarding possible effects under natural field conditions on nontarget animals. Publications from 1996 to 2008 (376 publications) and recent meta-analyses do not allow to conclude on consistent effects either. The vast majority of the 41 articles published in 2008 and 2009 indicate no impact on these organisms and only two articles indicate a minor effect, which is either inconsistent during the planting season or represents an indirect effect. The lower abundance of some insects concerns mainly specialized enemies of the target pest (an expected consequence of its control by Bt maize). On the contrary, Bt maize have generally a lower impact than insecticide treatment. To encourage evidence-based risk analyses, we have constructed a systematic compilation of publicationsdealing with Cry proteins from B. thuringiensis or maize (see Supplementary electronic material in this publication).. Sincerely,
140	Irish Doctors" Environmental Association	IRL	2.2 Hazard characterisation	As is evident from the paucity of published data, evaluation of scientific is difficult in the case of the impact of genetically engineered food on non target organisms, i.e. humans. Although the WHO clearly states the criteria by which the safety of genetically engineered foods is assessed , nevertheless, there is no standardized independent scientific protocol by which the data provided by the applicant company can be examined. The data supplied by the manufacturers varies widely in terms of the numbers and types of animals studied, and the duration of the feeding trials. Significantly, the data which describes the safety testing undertaken on genetically engineered foods is not published in scientific journals. It is clear from the paucity of scientific studies that the safety of genetically engineered food has not been established. Furthermore, there are no mechanisms by which any adverse health impacts might be monitored. If human beings developed similar problems to the rats in the early experiments, it could take years to appear and it would be extremely unlikely that genetically modified food would be suspected. Although it is frequently cited that the health of people in the US is evidence that people are not suffering adverse impacts from genetically engineered food, a lesson gleaned from the BSE experience tells us that it is unwise for policymakers to assert that there is no risk without evidence .
141	Finnish Environment Institute	FIN	2.2 Hazard characterisation	Chapter 2.2 Objectives of the different steps of the environmental risk assessment, Chapter 2.2.1 Step 1: Problem formulation (including hazard identification) Line 371 and line 409: The guidance should give examples how different environmental strategies deal with the complex issue of unacceptable and acceptable magnitude of harm.

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142	Netherlands Committee on Genetic Modification	NLD	2.2 Hazard characterisation	The NTO document states that hazard assessment should consider possible effects at different ecological scales (e.g. organizational level, population level) (NTO document, page 43, par. 2.2). In this document it is also emphasized that 'both lethal and sub-lethal effects are relevant in the assessment of a possible hazard for a given NTO species (NTO document. page 24, par. 1.7.2). The relative fitness is considered an appropriate measurement endpoint for NTO testing (NTO document, pg.25). In the ERA document these measurement endpoints for NTOs are not defined. The hazard identification on page 61 only mentions that 'Once specific measurement endpoints are chosen, appropriate methods and criteria of measurements should be selected and described' (lines 2041 - 2042). This leaves the interpretation of these endpoints to the applicant. COGEM points out that sub-lethal effects are not covered in any of the current market applications. COGEM is of the opinion that sub-lethal effects can have a severe adverse effect on a population and should thus be assessed in the ERA of GM plants. In 2008, COGEM issued a report in which experimental protocols to investigate the impact of GM crops on non-target arthropods are discussed in detail. Population growth measurements are suggested in this report as an alternative to simple mortality tests because they combine lethal and sub-lethal effects. This report is cited in the NTO document, but not mentioned in the guidance document. COGEM is of the opinion that this report by Charleston & Dicke presents useful and concrete guidance on the assessment of NTO effects of GM plants. Report: Charleston D.S. & Dicke M. (2008) Designing experimental protocols to investigate the impact of GM crops on non-target arthropods
143	Haut Conseil des biotechnologies	FRA	2.2 Hazard characterisation	p.43: "Hazard assessment should consider possible effects at different ecological scales (e.g. organismal level, population levels)." Please clarify that impacts on genetic diversity are included in this definition.
144	FAS/USEU	USA	2.2 Hazard characterisation	The section on hazard identification is very brief and could be improved by expansion. There is one vague example of hazard characterization with a Cry protein, but characterizations with other types of GM plants will likely be more challenging. How will this be done for those plants not known to produce a toxin?

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	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
145	Finnish Environment Institute	FIN	2.3 Exposure characterisation	Chapter 2.2 Objectives of the different steps of the environmental risk assessment, Chapter 2.2.1 Step 1: Problem formulation (including hazard identification) Line 371 and line 409: The guidance should give examples how different environmental strategies deal with the complex issue of unacceptable and acceptable magnitude of harm. Chapter 2.3.1 Choice of comparators: We appreciate the different aspects raised in choosing relevant comparators. However, the guidance should more strongly request the applicant to consider more than one comparator when the comparator is not the negative segregant. In addition, we are very pleased with the demand for three test material in case of insect-resistant and herbicide-tolerant GM plants. Unfortunately, we have seldom seen such data included in the applications. We strongly urge EFSA in the future to demand such tests in the ERA. Chapter 2.3.2 Receiving environments The receiving environment is described as the environment into which the GM plant(s) will be released and into which the transgene(s) may spread. We think that this description should include "into which the GM plant(s) (itself) may spread". Theoretically, transgene spread includes the spread via seed and other propagules, however we think that a more common use of transgene spread refers to spread only via pollen. It is clear that spread of GM plant or transgene(s) is to be assessed taking into consideration assessment endpoints. However, proper knowledge on spreading behavior is essential in e.g. evaluating the possibility of long-term effects on the dynamics of population of species in the receiving environment. E.g. oilseed rape is known to spread into the environment very efficiently. Moreover, the guidance should clearly emphasize (see also 3.1) that knowledge of spread and persistence can only be obtained through long-term experiments. Most importantly, the described 3-step approach should be revised to contain in step 1 and step 2, in addition to "intended use(s)" and "present/potential cultivation areas", possible exposure areas or possible areas where spread may occur (field margins, non-managed areas, roadsides, semi-natural and/or natural areas etc.). Chapter 2.3.3 General statistical principles Line 697-699: We are very impressed by the profound knowledge and coverage of the section. However, we do not fully understand why this section does not apply to 1) data obtained from surveys or observational data and 2) field trials described in the food / feed Guidance document. What is the scientific basis for this exclusion? Line 976: Inadequacy in study design is listed as one of the sources of uncertainty. We agree that this theoretically is of course the case. However, we think that the guidance should clearly and constantly point out that inadequacy in study design is not acceptable. These types of studies should not be included at all in the applications! Chapter 2.3.5 ERA of GM plants containing stacked transformation events Line 1134-1141: We think that stacked GM crops shall be treated as new events. Therefore, applicants should provide experimental data and not rely on results obtained from single events.
146	Federal Agency of Nature Conservation	DEU	2.3 Exposure characterisation	Again it should be clearly stated here, that hazard and exposure characterisation should be performed in parallel and interlinked in order to inform and tailor each other. (see comments on p. 28 Figure 4). Moreover, the exposure analysis needs to be carried out in general terms and not limited to focal species. In fact, the exposure analysis will be needed to identify the focal species for a given case (environment). p. 44 threshold levels: It may be difficult to quantify a given threshold level. We suggest to refer to different scenarios here. This would provide the risk manager with the necessary information for her/his decision.
147	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	2.4 The result of risk characterisation	Page 44: In the sentence “Hence applicants should conclude on risk for intended and unintended effects on NTOs taking into account focal species as well as the overall functionality of the agro-ecosystem.”, replace “unintended effects on NTOs” by “unexpected effects on NTOs”.
148	Federal Agency of Nature Conservation	DEU	2.5 Risk management strategies	Proof needs to be given that the proposed management strategies will have the desired results and a monitoring of the effectiveness of risk management measures need to be established. The given example in para 2 of p. 45 seems not suitable because the proof of effectiveness has not been given yet.

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	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
149	European Beekeeping Coordination	BEL	2.5 Risk management strategies	2.5 Risk management strategies The feasibility of the application of the proposed risk management measures should be analysed, based on a realistic approach of actual field conditions. For instance, it seems impossible to prevent any seed dissemination or to ensure the complete burying of all the seeds during the sowing.
150	Haut Conseil des biotechnologies	FRA	2.5 Risk management strategies	p.45: "These strategies should be designed to reduce the risk to a level considered acceptable (criteria defining this acceptability should be explicitly discussed)." Please elaborate on the notion of "risk acceptability": acceptable for what, for whom?
151	Conseil & Savoir Ltd	FRA	2.5 Risk management strategies	The real dimension of germs as genes resources, which might use for building GM-crops here is the full scope of micro-organisms which were estimated on our planet (see: Scientific American, 2001, November, p.28-37): • Bacteria & archaea – Total species: 1, 000, 000; Named species: 4,000 (0.40% of total) • Viruses – Total species: 400,000; Named species: 1,550 (0.39% of total) • Fungi – Total species: 1,500,000; Named species: 72,000 (4.80% of total). • Protozoa – Total species: 200,000; Named species: 40,000 (20% of total) • Nematodes & worms – Total species: 400,000; Named species: 25,000 (6.25% of total). And for the reason of the booming limitless insertion of genes from named micro-organisms in food & feed crops, the EU Commission should consider my following scientific inquiries: A. Who has defined the health-risk limit of microbial genes insertion in GM-crops? B. Who will remove non-efficient and health-risk microbial genes from GM-crops? C. Who has investigated the long-term consumption of GM-crops influence on children's immune-endocrine-nerve and reproductive systems development? D. Who has defined the worth of human immune-endocrine-nerve-reproductive systems? E. Who will compensate the cost of health damage if some of these "cheap" GM-crops will turn out to be hazardous, especially for children, pregnant women and elderly people? Thus, I am against microbial genes but welcome plant orgin genes use with so called "molecular breeding" for creation abiotic & biotic stress ressist plants.
152	Irish Doctors" Environmental Association	IRL	2.6 Post-market environmental monitoring	I am unclear who will undertake the "general surveillance", how adverse impacts are identified as such (including "unanticapated" events), who these impacts are reproted to and what actions should be taken should such adverse impacts be noted.
153	Greenpeace European Unit	BEL	2.6 Post-market environmental monitoring	2.6 Post-market environmental monitoring The recognition that the post-market environmental monitoring could be improved is welcome. We hope that EFSA pays particular attention to this, and recommends it as a precautionary approach for all NTOs, rather than stating that the risk assessment does not indicate a need. Case-specific monitoring would be vital for detecting any long term impacts, should any insect-resistant GM crops be cultivated.

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Table of Member States and stakeholders comments received during the public consultation on the Scientific opinion of the EFSA GMO Panel on Non-Target Organisms

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
154	European Beekeeping Coordination	BEL	2.6 Post-market environmental monitoring	2.6: Post-market environmental monitoring: Due to the lacks of reliability of field tests (see point 1.7.5.2), it should be kept in mind that post-market monitoring is conducted through field tests from which it is impossible to build up an absolute evidence of any effect. For this reason serious and convergent suspicions scientifically supported should be considered as sufficient to ban the considered GMO. Otherwise the GMO will remain on the market even if serious effects are shown during the monitoring (we are facing such problems in matter of pesticides).
155	Federal Agency for Nature Conservation	DEU	2.6 Post-market environmental monitoring	There are only few remarks on the monitoring issue although non-target organisms are crucial monitoring items in many cases. The discussed aspects like geographical zoning, species selection, analysis design, statistical power an defining hazard or damage are relevant for the post-market monitoring as well as for the ERA. Therefore it is important to elaborate this issue in more detail. We agree with EFSA, that case-specific monitoring is linked to the outcome of the ERA. But scientific evidence of a potential relevant adverse effect may be weak in some cases because of uncertainties, so that case-specific monitoring may be never-theless necessary. Therefore it has to be decided individually for each potential ad-verse effect identified in the ERA, wether a case-specific monitoring has to be estab-lished or not, including effects, where a risk is estimated negligible. This aspect should be clarified in the Opinion. We agree, that if EFSAs own definitions for case-specific monitoring and general sur-veillance are applied, the two instruments may lack of power in some cases. This would lead to a gap in security resulting from limitations of the ERA, which do not consider effects resulting from large-scale cultivation, as above mentioned, as well as interactive and cumulative effects, e.g. synergistic effects together with other GMOs. It is not clear, how the suggested implementation of an ex-post assessment, which by the way is not further explained, could be helpful in this case. With regard to the pre-cautionary principle it is essential to consider the above mentioned effects within the two mandatory instruments, which means, that the EFSAs definitions should be ex-tended, as e.g. described by ACRE (2004). ACRE (2004): Guidance on Best Practice in the Design of Post-market monitoring Plans in Submissions to the Advisory Committee on Releases to the Environment. ACRE Guidance Note 16. http://webarchive.nationalarchives.gov.uk/20080727101330/http://www.defra.gov.uk/environment/acre/postmarket/acre_postmarketmonitor-guidance.pdf
156	Irish Doctors" Environmental Association	IRL	Conclusions and Guidance	I am very concerned that it is the applicants who are charged with identifying the risks and developing management strategies should an adverse impact develop. We need independent assessments and strategies of any proposals. This may not always be possible; it is often not possible to quantify impacts in a reductionist manner as is frequently the case in this consultation document. In this situation, we should desist from releasing such organisms into ur environment. Our ecosystem is all we have; the organisms in it have survived evolution and are suited to the living conditions they find themselves in. It is foolhardy to introduce organisms that may have adverse consequences that we have not even thought of.
157	Federal Agency of Nature Conservation	DEU	Conclusions and Guidance	pp. 45-46 Generally see our comments on the summary. P. 45 1st sentence of conclusions: We sug-gest not referring to focal species but to all species of concern as well as on biodiversity. We also suggest replacing the wording 'relevant' by 'available'. The listed protection goals (last sentence on p. 45) should also refer to species diversity and estimated effects on organism groups. Risk management may be also appropriate when uncertainty is too high. We advise to include this and to refer to the precautionary principle in the last sentence.
158	Agroscope Reckenholz-Tänikon Research Station ART	CHE	Conclusions and Guidance	The self-tasking working group should test the draft guidance document, by producing an example (or better several examples) of a model GM crop and lay out which data they would require. This would serve as a self-test to see whether the approach that is proposed works and to help risk assessors and evaluators to work with these guidelines.

	ORGANISATION	COUNTRY	CHAPTER_TEXT	COMMENT_TEXT
159	CropLife International	CAN	Conclusions and Guidance	In conclusion, CLI appreciates the hard work done by the GMO Panel and the opportunity to provide feedback on these draft Scientific Opinions. Nevertheless, given CLI's extensive experience in developing and defending applications around the world, we feel that this Draft Guidance Document falls short in many aspects. It provides no meaningful guidance as to how harm would be defined in the EU, and it is inconsistent with useful guidance produced by functioning regulatory systems around the world. CLI feels that EFSA's approach contains too much detail on experimental design, statistical analysis, and other issues without explanation how this is needed in a particular ERA. The emphasis seems to be placed on assessing changes with great precision, which is appropriate for basic research, but typically inappropriate for ERA. As such, EFSA's approach to ERA is not harmonized with functioning regulatory systems around the world. In particular, we are concerned that the emphasis on pursuing questions of basic research will result in inefficient and protracted review processes, delays in bringing potentially environmentally superior tools to growers in Europe; and at the same time, increase the burden on European regulators who will be required to review large amounts of data collected without a clear link to answering critical questions associated with assessing environmental risk. References: Cartagena Protocol on Biosafety (2000) Cartagena Protocol on Biosafety to the Convention on Biological Diversity, text and annexes. Montreal: Secretariat of the Convention on Biological Diversity. Montreal, Canada. 30 pps. Johnson et al, (2006) How does scientific risk assessment of GM crops fit with the wider risk analysis? Trends Plant Sci. 12(1): 1-5. Nickson, TE (2008) Planning environmental risk assessment for genetically modified crops: problem formulation for stress-tolerant crops. Plant Physiology 147: 494-502. OECD (1986) Recombinant DNA safety considerations: safety considerations for industrial, agricultural and environmental applications of organisms derived by recombinant DNA techniques. Organization for Economic Cooperation and Development, Paris. OECD (1993) Safety considerations for biotechnology: scale-up of crop plants. Organization for Economic Cooperation and Development, Paris. Raybould, AJ (2006) Problem formulation and hypothesis testing for environmental risk assessments of genetically modified crops. Environ. Biosafety Res. 5: 119-125. Raybould, AJ (2007) Ecological versus ecotoxicological methods for assessing the environmental risks of transgenic crops. Plant Sci. 173: 589-602 Suter II, GW (2000) Generic assessment endpoints are needed for ecological risk assessment. Risk Analysis 20(2): 173-178.
160	Federal Office of Consumer Protection and Food Safety (BVL)	DEU	Conclusions and Guidance	In the sentence "Applicants should conclude on the risk of intended and unintended effects on NTOs taking into account focal species considering all relevant ecosystem services", replace "unintended" by "unexpected".
161	Finnish Environment Institute	FIN	Appendix: NTO Table	Appendix 1, page 55. The NTO table for assessment of potential impacts of GM-plants looks like an excellent way forward and would be a practical and productive way to guide the risk assessors.
162	Agroscope Reckenholz-Tänikon Research Station ART	CHE	Appendix: NTO Table	The purpose of the Appendix remains unclear.