European Food Safety Authority

GMO UNIT

Parma, 16 July 2010
EFSA/GMO/SM/KL/EW632

EFSA TECHNICAL MEETING WITH MEMBER STATES ON THE UPDATED GUIDANCE DOCUMENT FOR THE ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS

(Berlin, 17 June 2010)

FOLLOW-UP TO PUBLIC CONSULTATION

TECHNICAL REPORT

The below report reflects the common understanding of the European Food Safety Authority (EFSA) and the delegates of attending Member States of the meeting. This report is not, and cannot be regarded as representing the position, the views or the policy of EFSA or of any national or EU Institution, agency or body.

I. PARTICIPANTS

The list of participants is enclosed, together with apologies received (see Annex).

II. INTRODUCTION (CHAIR: E. WAIGMANN)

The Chair of the meeting, the Deputy Head of the EFSA GMO Unit Elisabeth Waigmann, welcomed the representatives from Member States (MS) in Berlin and thanked the German Federal Office for Consumer Protection and Food Safety (BVL) for hosting this EFSA technical meeting. She announced that the meeting is webcasted live and will be visible to web viewers. The current revision of the 2006 EFSA Guidance Document for the Environmental Risk Assessment (ERA GD) of Genetically Modified Plants follows a formal request from the European Commission (EC) to update specific topics (e.g. effects on non-target organisms, design of field trials, selection of receiving environments, long-term effects). Since 2008, the EFSA GMO Panel Working Groups (WG) on ERA GD and Non-Target Organisms (NTO) have elaborated a draft updated ERA GD supplemented by a scientific opinion on the ERA of NTO which provides more background information and examples to risk assessors. Both documents were submitted to the public for a two-month consultation. All comments received from both public consultations were made publicly available on the EFSA website and are currently under evaluation by the ERA GD WG and the NTO WG.

The Chair reminded that this meeting is organised by EFSA to further facilitate close collaboration between the EFSA GMO experts and MS experts, in line with EFSA's policy of collaboration with MS and the mandate of the EC. The objective of the meeting is further discussion and clarification of scientific comments submitted by the MS during the public consultations. The Chair recalled that, according to the mandate received from the EC, it is an objective that the ERA GD would become a legally binding document once it has been finalized by EFSA.

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The Chair informed the participants that EFSA will prepare an EFSA meeting report that will be submitted to participants for comments. Following a consultation period, the meeting report will be made publicly available on the EFSA website. Short meeting minutes of the technical meeting will also be made available on the EFSA webpage shortly after the meeting.

III. TOUR DE TABLE OF PARTICIPANTS

The participants introduced themselves during a tour de table (see the Annex).

IV. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

V. PRESENTATIONS AND DISCUSSIONS

Note: Please note that the slides presented by EFSA experts were distributed on the day of the meeting.

1) Introduction

The Chairman of the ERA GD WG, Detlef Bartsch, remarked that the discussion during the meeting should not be considered as the final opinion of the EFSA GMO Panel as both the ERA GD document and the scientific opinion on NTO are still under development. He provided the participants with background information (e.g. EC overall mandate, deadline, stakeholder meetings in June 2009, interim report to EC, public consultation) and summarized the state-of-play of the discussion on the ERA GD. The main topics that had received most of the public comments were highlighted (e.g. strategies of ERA, NTOs, receiving environments). He clarified that a revision of Post-Market Environmental Monitoring (PMEM) requirements, as laid down in the EFSA scientific opinion of 2006, does not fall under the mandate of the EC.

Most of the comments gathered from the public consultation came from Member States (254 out of 494 comments). This demonstrated the need for the meeting in order to give an opportunity to MS experts to clarify and further discuss their comments. The deadline to finalize the updated ERA GD is early November 2010.

2) Strategies for ERA of GM plants (1) (Speaker: J. Sweet)

The Vice-Chair of the ERA GD WG, Jeremy Sweet, briefly described the overall structure of the updated ERA GD as well as the differences with the current GD (e.g. plant-to-plant gene flow has been merged with the chapter on fitness and invasiveness where the consequences of gene flow are addressed). Applicants are requested to follow a more systematic approach, starting with the problem formulation (including hazard identification) followed by exposure and hazard characterisation. Some considerations, such as the choice of comparators, selection of receiving environments, statistical design of field trials and systematic assessment of long-term effects, are further developed in the updated ERA GD.

Discussion

Many of the attending Member States (AT, BE, DE, DK, FI, FR, NL, SL, SP, UK) welcomed in general EFSA's work in updating the ERA GD and acknowledged the efforts and progress made over the last two years. The updated ERA GD was considered a major step forward in the context of ERA of GM plants.

The British delegate welcomed Figure 1 of the document providing an overall structure of the document and asked how data requirements set in Annex IIIB of Directive 2001/18/EC fit with this approach. The EFSA delegate explained that the ERA GD relies on data requirements laid down in Directive 2001/18/EC and that step 1 (i.e. problem formulation) consists in an overview of potential differences between the GM plant and its non-GM counterpart. The Belgian delegate would have welcomed a public consultation over a longer period of time since due to time constraints it was only possible to comment on the chapter related to NTOs. The Swedish delegate proposed to use exactly the same wording in the ERA GD as in Directive 2001/18/EC (e.g. step 3 "exposure characterisation" is referred to as "*evaluation of the likelihood of the occurrence of each identified potential adverse effect"* in Directive 2001/18/EC). The German delegate commented on (1)

the adequacy of the term 'step-by-step' in the ERA GD compared to its meaning in Directive 2001/18/EC; (2) the selection of appropriate baselines and most appropriate comparator(s); (3) how to address uncertainties and (4) a reference to the precautionary principle. The German delegate also sought for clarifications on a possible forthcoming revision of chapter 3.5 on PMEM.

The EFSA GMO experts acknowledged the differences in terminology, referring to the 10-years old Directive 2001/18/EC, and considered that some flexibility to use improved wordings should be allowed. The Chair of the ERA GD WG repeated that an update of the PMEM chapter was not part of the EC mandate to the EFSA. The Chair of the meeting commented that the standard duration for an EFSA public consultation had already been extended from 6 to 8 weeks and that, due to the legal deadline set by the requestor, this time period could not be further extended. The EC representative explained that, once finalized by the EFSA GMO Panel, the ERA GD will be discussed with the MS in the context of the regulatory committee and additional comments might be provided by the MS at that stage. The Dutch delegate pointed out that, due to time constraints, they commented on three major issues: (1) how to assess indirect effects, as they might overlap socio-economic issues (which the Netherlands considers outside of the scope of the updated ERA GD); (2) clear data requirements are lacking, increasing the need for more guidance; and (3) lack of clarity concerning the compulsory or voluntary nature of data requirements. The Slovenian delegate asked for streamlining and simplifying the terminology throughout the document (e.g. different approaches are mentioned throughout the document such as 'step-by-step', 'stage' or 'step-wise' approach).

The EFSA GMO experts underlined the difficulty of reviewing and updating the approach for the GMO risk assessment bearing in mind the most recent scientific developments in this area and the need to cover the diversity of traits and crops, including those of possible future GM crops. The indirect effects due to the use of herbicides associated with the cultivation of GM plants is to be considered in the context of the interplay between the respective legislations on GMOs and Plant Protection Products (PPP) which is in the hands of risk managers.

The Austrian delegate would also welcome adjustments in terminology used (e.g. the 'step-by-step' approach) and considered that, in view of the high number of comments with respect to PMEM, the chapter at stake would also deserve improvements, as was done for the rest of the ERA GD. The EFSA and the EFSA GMO experts expressed their willingness to technically support the EC in this respect, if needed. The Spanish delegate would welcome more guidance and proposed a tick-box scheme in an annex to the ERA GD. The French delegate raised comments on the approach including the terminology ('step-by-step' basis), the need to consider genetic diversity and socio-economic aspects. The German delegate commented on the choice of baseline and appropriate comparators to protect the environment. The Lithuanian delegate made comments on terminology, better definition of assessment endpoints and unintended effects. The Polish delegate questioned how the precautionary principle and long-term effects were considered in the document.

The EFSA GMO experts mentioned that, in most crop related cases, current agricultural practices should be considered as appropriate baseline. Consequently, a decision on the relevant baseline should be taken by risk assessors based on the acceptable level of risk as set by risk managers. For example, in the NTO risk assessment, an appropriate baseline should be the current agricultural practices taking into account the development of integrated pest management techniques.

3) Strategies for ERA of GM plants (2): Problem formulation & further steps (Speaker: J. Sweet)

The Vice-Chair of the ERA GD WG, Jeremy Sweet, reported that most of the comments referred to the step 1 (i.e. problem formulation) as starting point of the ERA of GM plants. The EFSA GMO experts said that problem formulation is an intellectual exercise in order to define the most important questions for RA. Problem formulation should consider data from all available sources (e.g. field data from outside EU, agronomic & phenotypic studies, molecular characterisation, compositional data) and subsequently identify potential knowledge gaps in order to carry out a comprehensive ERA. The problem formulation therefore aims at identifying differences between the GMO and its non-GM counterpart and at identifying knowledge gaps. Problem formulation starts with the identification of relevant specific protection goals (i.e. what aspects of the environment should be protected) based on a wide range of legal texts laying down general

concepts of biodiversity protection. The updated ERA GD places more emphasis on problem formulation as a first and critical step of the ERA. Applicants are expected to provide a comprehensive reasoning, based on initial assessment of all available data on the GMO under study. The EFSA GMO experts also acknowledged the difficulty of quantifying environmental impacts in the ERA which is the goal of the hazard and exposure characterisation. A synthesis of all the available data allows a conclusion of the ERA on the identified risks and any relevant management measures.

Discussion

The Swedish delegate sought clarifications whether an 'audit' of management measures proposed by applicants should become obligatory and asked why the level of statistical significance is higher in the ERA GD than for usual biological studies. The British delegate commented on hazard characterisation and in particular, on the lack of baselines data to test interactions. An extensive set of information is required under the problem formulation although at that stage, there is no real specific hypothesis to be tested. The UK expert inquired whether this information could serve to set the baseline(s) for the following steps of the ERA. The German delegate commented on the first step of problem formulation which is paramount for framing the rest of the ERA and indicated that more guidance on how to perform the problem formulation is expected. In addition, the German delegate wondered whether the problem formulation only relies on applicants or could be done with the help of MS. With respect to protection goals, the German delegate asked that national protection goals are also considered. More guidance on appropriate controls and appropriate baselines should be provided to applicants.

The EFSA GMO experts indicated that when a dossier is submitted, data on molecular characterisation and compositional analysis are already available and could be used to identify and, where appropriate, rule out potential unintended effects. However other type of data such as data on compounds, that are related to environmental interactions and not usually studied under the standard compositional analysis, could be considered. In conclusion, problem formulation should be seen as an important component of the ERA. The EFSA GMO experts acknowledged the difficulty of assessing unintended environmental effects and consider that field data from outside EU can provide useful information on the likelihood of unintended effects. This is the reason why applicants will be asked to consider all available data in the problem formulation, in order to identify knowledge gaps and to better design subsequent field trials. More guidance is given to applicants with respect to statistical considerations of field trials. Applicants will be invited to set limits of concern and to provide a power analysis of each experiment or test when designing their trials (e.g. size of plot, number of replications).

The Dutch delegate invited risk assessors to focus on data needed for risk assessment and decision-making (e.g. difference between 'need to know' and 'nice to know' information) and mentioned that the ERA GD fails to provide a clear definition of 'baselines'. The German delegate called for 'hard' scientific data gathered during cultivation of a GM crop, and considered that observations (e.g. gathered within PMEM) might not be suitable for statistical analysis. As regards direct and indirect effects, the respective part of the text should be clarified and attributed to one or the other type of effects.

The EFSA GMO experts acknowledged that certain information and data (e.g. gathered from PMEM activities) should be considered with care.

4) Persistence & invasiveness (Speaker: D. Bartsch)

The Chair of the ERA GD WG, Detlef Bartsch, gave an overview of the major comments received on this specific section: Figure 3 describing the different stages of information collection in the ERA and the need for data requirements for each stage, the need for event vs. trait-specific data, definition of environmental damage, the requirement for field trials and field derived information, or the use of models (including worst-case scenario).

Discussion

The Swedish delegate asked that the principle of proportionality should be considered (e.g. data requirements in the ERA to be proportionate to risks and scale of release) throughout the ERA. The British delegate inquired whether case-studies will be developed by the EFSA GMO Panel in support of Figure 3.

The EFSA GMO experts acknowledged the comment on proportionality for data requirements, at the same time recognising the difficulty to apply this principle to the whole document. The EFSA GMO experts welcomed the proposal for case-studies but pointed out the difficulty to develop case-studies within the limited time available. The NTO WG is considering developing a roadmap as Annex to the NTO scientific opinion.

The Dutch delegate mentioned that the genetic background is important for the expression level, however it is impossible to assess every genetic background during the ERA. Therefore feedback from the information collected in the field during cultivation (e.g. PMEM data) is important. The German delegate asked to adapt the wording of Figure 3 in order to include the trait as well as the event.

The EFSA GMO experts reminded that the transgene, genetic background and interactions between the transgene and the recipient genetic background should be systematically considered by the applicant in step 1 of the ERA.

5) Non-target organisms (Speaker: S. Arpaia)

As already mentioned in the introductory talk, the Chair of the NTO WG, Salvatore Arpaia, recalled that the ERA GD will be supplemented by a scientific opinion on the ERA of NTO providing more background information and examples to risk assessors. The draft NTO scientific opinion was submitted in parallel to the draft ERA GD document for public consultation. A total of 149 comments from 27 stakeholders (including five MS) was received on the draft NTO opinion in addition to the 65 comments received on the NTO chapter of the ERA GD. Some comments overlap with comments on the NTO chapter of the ERA GD. He reminded that the EFSA task to update the methodology for risk assessing impacts of a GM plant on NTOs does not start from scratch but relies on extensive sets of available information, such as scientific literature on existing GMO and ERA approaches. He briefly summarised the key comments from the consultation regarding: (1) the request for more guidance to applicants, (2) the assessment of unintended effects based on a weight of evidence approach and (3) the role of the so-called 'extended' compositional analysis. Against this background, he explained that a comprehensive set of existing data (e.g. data on molecular characterisation of the GM construct and on the compositional analysis, *in planta* data) could be used to rule out potential unintended effects. He also acknowledged the difficulty of performing an 'extended' compositional analysis due to the lack of validated methods but clarified the approach by focusing on some compounds and/or plant parts that are usually not tested under the standard compositional analysis. He pointed out the different steps for the selection of focal species and emphasised the importance of the first step of selecting relevant functional groups exposed to the GM plant in the representative receiving environments. He finally commented on the concept of the tiered approach and, in this respect, the need for GM trait-specific and GM event-specific data.

Discussion

The Swedish delegate welcomed the sequential steps proposed for the selection of focal non-target (NT) species, and suggested to consider additional NT focal species when the NT focal species initially selected were negatively affected by the GM plant. The EFSA GMO experts shared the view of the Swedish delegate and will consider this suggestion. Furthermore, the Swedish delegate was of the opinion that semi-field trials should not be required on a routine basis but only when there is a likelihood of risk identified at lower tiers. The EFSA GMO experts answered that, according to the tiered approach, semi-field trials should be carried out subject to adverse effects detected in tier 1 tests. However, in some cases (e.g. greenhouse test with honeybees), it might be more practical to test the possible effects of the GM plant under more realistic conditions (e.g. through semi-field trials). Following the case-by-case approach, it is for applicants to consider whether to move straight to higher tier tests and to provide justifications for such a decision.

The Belgian delegate welcomed the EFSA work on NTOs and specially appreciated the efforts put to describe the rationales for specific data requirements. However more guidance to applicants is expected for the following aspects: which type of data is expected from the applicants? How binding is the guidance e.g. is a tier 1a and/or tier 1b test required for each selected focal NT species? According to the Belgian delegate, a clear message, on the type of data that are needed and therefore required in a GMO application for

performing a comprehensive ERA, should be provided to applicants. The Belgian delegate proposed to clarify and streamline the process by avoiding creation of new concepts (e.g. tier 0) and to instead rely on existing concepts internationally endorsed. The Belgian delegate reflected on the use of an 'extended' compositional analysis and in particular, how and which key compounds should be analysed bearing in mind that no databases providing baselines for such compounds currently exist. It was considered difficult to compare the 'extended' composition of a GM plant to that of its non-GM counterpart and to conclude on the biological relevance of any differences. The Belgian delegate sought for clarifications on the mandatory requirement for *in planta* studies which should be properly designed. It might not be possible to carry out *in planta* tests for each selected focal species.

In response to these comments, the EFSA GMO experts committed to check the wording currently used in the NTO opinion for sake of clarity. Following the respective comments received from the public, the use of extended compositional analysis will be reconsidered bearing in mind the lack of historical data in this field. It was considered 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.

It was recalled that, 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. Many focal NT species which do not feed (or feed to a limited extent) on GM plant parts (e.g. parasitoids, some predators) are likely to be selected for further testing; tritrophic studies with NT species indirectly exposed to the GM plant through their prey or host are required on a case-by-case basis. Therefore tier 1a and tier 1b tests are both 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. Indeed the potential stressor for the environment is defined as the GM plant itself, its GM trait(s) and the products thereof.

The German delegate welcomed the EFSA work on NTOs and appreciated the reference to existing ERA methodologies. Nevertheless, the concept of extended compositional analysis was questioned as it would not provide sufficient data to rule out potential unintended effects. However *in planta* tests are considered of importance as tier 1a tests carried out with a bacteria-produced toxin might not detect effects that are due to the whole GM plant, nor give indications on possible interactions between plant compounds. For stacked events, the ERA should not only rely on comparative data from parental lines but other comparators should also be studied. The German delegate called for a selection of focal species exposed to the GM plant and representative of the receiving environments where the GM plant is likely to be grown. Clarifications on the concept of 'pre-market' and 'post-market' studies as introduced in the ERA GD are needed considering that all relevant data needed for a reliable ERA should be provided before the GM plant is marketed.

The EFSA GMO experts agreed with the German viewpoint that representative receiving environments should be tested and reminded the MS that the ERA GD will not be prescriptive for the choice and number of receiving environments. However the ERA GD will provide criteria to help the applicants in selecting appropriate receiving environments.

The Finnish delegate welcomed the sequential process for selecting focal NT species as laid down in the NTO opinion and ERA GD. The Spanish delegate looked forward to the roadmap and further examples to illustrate the guidance to applicants. In addition, the Spanish delegate proposed to include 'soil microbial communities' to the list of examples of functional groups. The Chair of the EFSA NTO WG fully agreed with the Spanish comment and referred to an example in the NTO opinion where possible changes to the agro-ecosystem are assessed with respect to the function of a whole soil microbe community. The Danish delegate expressed concerns on PMEM as the farmer questionnaire is not considered suitable for detection of possible adverse effects from GMOs cultivation. The EFSA GMO experts reminded that revision of the PMEM guidance does not fall under the mandate of the EC. Furthermore, the representative of the European Commission clarified that the European Commission is currently examining further options in terms of PMEM of GMOs, in close collaboration with MS and EFSA. The Dutch delegate wondered about the need

for testing generic hypotheses and, in this context, which species should be tested. The EFSA GMO experts agreed that the context should be revised and referred to the weight of evidence approach based on existing data. In choosing different focal species, the receiving environments, where these focal species are likely to be exposed to the GM plant, should be considered. The EFSA GMO experts explained that in some cases, the indicator is not a single species but rather a specific function of the ecosystem ensured by a particular animal guild.

The Austrian delegate acknowledged the requirement of whole plant studies and welcomed the definition of 'stressor' being the whole GM plant. However the Austrian delegate required more emphasis on the selection of protection goals. Similarly to other MS delegates, the British delegate did not agree with the concept of using extended compositional analysis for testing generic hypotheses.

The EFSA GMO experts concluded by mentioning that many diverging comments were submitted by different stakeholders and that this divergence will complicate EFSA's task of considering and integrating those comments. The EFSA GMO experts will further develop the rationales behind specific data requirements considering the principle of proportionality.

6) Receiving environments (Speaker: J. Kiss)

The Vice-Chair of the EFSA NTO WG, Jozsef Kiss, gave an overview of the major public comments on this section: (1) specificity of the suggested zoning concepts, (2) selection criteria for zoning and (3) request for case-studies. The main objective of the ERA review is to provide more guidance to applicants. In this respect, suggestions made by some stakeholders (e.g. additional zoning) will be considered to be added to the ERA GD.

Discussion

The Hungarian delegate favoured the term '*biogeographical'* instead of '*geographical'* zone as it concerns biodiversity. The Austrian delegate asked for further elaboration of the ERA GD, e.g. more guidance to applicants. An overview of the pros and cons of each zoning concept should be inserted. The German delegate supported the comments made by Hungary and Austria and made special reference to the Natura 2000 biogeographical concept which seems to be the most appropriate and helpful for applicants when combining this concept with the main cultivation areas of the crops to be assessed.

The EFSA GMO experts will consider these comments. Guidance in terms of selection of representative receiving environments is given through selection criteria but will not be more prescriptive.

7) Impacts of the specific cultivation, management and harvesting techniques (Speaker: A. Messéan)

The GMO Panel member, Antoine Messéan, gave a short overview of the comments received and explained that in the current update of the ERA GD, more focus was put on the cultivation practices in the EU. The choice of baselines is difficult considering the broad range of evolving agricultural production and management systems. The ERA carried out in third countries is likely to provide useful data that can be of use for the ERA of the same GM plants in the EU. It was reminded that the balance of overall risk/benefit falls out of EFSA remit. More guidance was requested as regards (1) the selection of receiving environments and assessment endpoints; (2) the conduct of scenario analysis (based on comparison between GM based and non-GM based management systems) and (3) the interplay between the GMO and PPP regulatory frameworks. With respect to the latter point, the EFSA GMO Panel decided to address the point from a scientific and ERA point of view leaving the final decision up to risk managers.

Discussion

The Dutch delegate mentioned that change in agricultural practices due to the cultivation of GM plants might induce environmental impacts but that the environment is dynamic. The Netherlands considers that this aspect opens questions with regard to the baseline or comparator which are inadequately addressed in the updated ERA GD and also refers to their general comments. Reference to the high variability of baselines and on how baselines should be defined was reiterated. The German delegate reiterated the comment that the

choice of baseline(s) (e.g. what kind of management system?) should be better described by the applicants. In this respect further guidance should be given to applicants.

The EFSA GMO experts acknowledged the variability of the management systems and the complexity to define an appropriate comparator. It was reminded that in the current ERA GD, the applicants are required to consider major trends in agronomic practices and to apply worst-case scenarios where appropriate.

8) Any other issue related to ERA

The Swedish delegate mentioned that the probability of horizontal gene transfer (HGT) from plant to microorganism should not be categorized as "rare event" as there is a limited number of experiments performed under natural conditions to confirm that statement. This viewpoint was shared by the German delegate. The Swedish delegate suggested to insert three elements into the chapter on HGT: (1) the probability for HGT and spontaneous mutations; (2) the ways of dispersal including the transmission for pathogenic strains; (3) the intended uses of the GM plant. The Swedish delegate asked to remove the requirements for PMEM from the chapter on HGT. The German delegate wondered how uncertainties linked to HGT are addressed in the updated ERA GD in order to be of use for decision-makers. The German delegate proposed to consider possible HGT from plant cells in the context of grafting.

The EFSA GMO experts referred to the recently published EFSA scientific opinion on antibiotic resistance genes used as marker genes in which the likelihood of HGT is considered and estimated to be very low. It was mentioned that for the time being there are few methods if any to detect such phenomena in the environment. A clear rationale is expected from applicants on a case-by-case basis. The key concern is not the HGT per se but the consequences of it.

9) Closing remarks

The Chair of the ERA GD WG, Detlef Bartsch, thanked the MS delegates for their helpful comments. He reminded that the GD should guide applicants in their ERA without being too prescriptive. In this respect, he suggested that some flexibility should be maintained in order to accommodate new types of GM plants currently under development.

The updated ERA GD contains new elements. A major improvement was to include the concept of problem formulation as sound basis for a comprehensive and reliable ERA of GM plants. By endorsing the principle of a comparative analysis of the GM plant and its non-GM counterpart, more focus should be put on the definition and selection of baselines (including appropriate comparators).

Following the comments on the concept of extended compositional analysis, it was reminded that this concept is an additional tool for the assessment of possible unintended effects. In addition, he mentioned the view of the EFSA GMO experts that *in planta* data allow risk assessors to rule out potential unintended effects already at an early ERA stage. Reference to trait-specific and/or plant-specific data will be considered where needed in the draft document. Finally, it was reiterated that updating the guidance on PMEM was not part of the EC mandate.

To conclude, the ERA of GM plants should not be considered as pure research but data requirements should be proportionate to the GM plant and its intended uses. Closely linked to proportionality, the 'acceptability' of risk is in the hands of risk managers to the initial limits of concern set by applicants.

It was made clear that the outcome of the discussion will be considered by the EFSA GMO Panel and its respective working groups for the finalization of the ERA GD and of the NTO opinion.

The Chair of the meeting, Elisabeth Waigmann, thanked all the participants for the comments submitted during the public consultation and for the fruitful and constructive discussions during this meeting.

ANNEX – LIST OF PARTICIPANTS

Panel Members		Date	Presence
1	Salvatore Arpaia	17 June 2010	Present
2	Detlef Bartsch	17 June 2010	Present
3	Jozsef Kiss	17 June 2010	Present
4	Joe Perry	17 June 2010	Apologies
5	Antoine Messéan	17 June 2010	Present
6	Jeremy Sweet	17 June 2010	Present
Ad hoc experts			
7	Cristina Chueca	17 June 2010	Present
8	Marc Delos	17 June 2010	Present
9	Achim Gathmann	17 June 2010	Apologies
10	Rosie Hails	17 June 2010	Apologies
11	Paul Henning Krogh	17 June 2010	Present
12	Barbara Manachini	17 June 2010	Present
13	Lucia Roda	17 June 2010	Present
14	Geoff Squire	17 June 2010	Present
15	Angela Sessitsch	17 June 2010	Apologies
16	Claudia Zwahlen	17 June 2010	Apologies
Member State representatives		Date	Presence
17	Mereth Aasmo Finne / Norway	17 June 2010	Apologies
18	Martin Batič / Slovenia	17 June 2010	Present
19	Patrick Saindrenan/ France	17 June 2010	Present
20	Beatrix Tappeser/ Germany	17 June 2010	Present
21	Elisabeth Lundqvist/ Sweden	17 June 2010	Present
22	Nikolaus Emmanouil / Greece	17 June 2010	Apologies
23	Maria Rosario Graça / Portugal	17 June 2010	Present
24	Jan Turna / Slovak Republic	17 June 2010	Apologies
25	Josef Kubicek / Czech Republic	17 June 2010	Present
26	Andreas Heissenberger / Austria	17 June 2010	Present
27	Gösta Kjellsson / Denmark	17 June 2010	Present
28	Tuuli Levandi / Estonia	17 June 2010	Apologies
29	Bernie Murray/ Ireland	17 June 2010	Present
30	Felix Ortego / Spain	17 June 2010	Present
31	Odeta Pivoriené / Lithuania	17 June 2010	Present
32	Matti Sarvas / Finland	17 June 2010	Present
33	Katalin Rodics / Hungary	17 June 2010	Present
34	Dimitar Djilianov / Bulgaria	17 June 2010	Apologies
35	Zbigniew Dabrawski/ Poland	17 June 2010	Present
36	Andre Varnava-Tello / Cyprus	17 June 2010	Apologies
37	Marco Gielkens / The Netherlands	17 June 2010	Present
38	Adinda De Schrijver / Belgium	17 June 2010	Present
39	Diana Bellin / Italy	17 June 2010	Present
40	Louise Ball / United Kingdom	17 June 2010	Present
European Commission			
41	Alice Stengel	17 June 2010	Present
E F S A			
42	Karine Lheureux	17 June 2010	Present
43	Sylvie Mestdagh	17 June 2010	Present
44	Elisabeth Waigmann	17 June 2010	Present