European Food Safety Authority

GMO UNIT

EFSA/GMO/538
Parma, 18 December 2009

STAKEHOLDER CONSULTATION WORKSHOP BETWEEN EXPERT OF THE EFSA WORKING GROUPS ON THE UPDATE OF THE ERA GUIDANCE DOCUMENT AND ENVIRONMENTAL INSTITUTIONS AND NON-GOVERNEMENTAL ORGANISATIONS

***M*eeting report of the meeting on 18 June 2009**
Berlin

The below report does reflect the common understanding of EFSA and the environmental institutions and non-governmental organisations attending the meeting. This report is not, and cannot be regarded as, representing the position, the views or the policy of the European Food Safety Authority or of any national or EU Institution, agency or body.

I. PARTICIPANTS

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

II. INTRODUCTION (CHAIR: D. BARTSCH)

The Chairman of the sub-environmental GMO working group on the update of the Environmental Risk Assessment (ERA) guidance document (sub-ERA GD WG), Detlef Bartsch, welcomed the applicants in Berlin. He briefly explained that the stakeholders consultation workshop was organised for 3 days: 1) the first day dedicated to the biotech companies, 2) the second day to the experts from Member States and finally 3) a third day to environmental institutions and environmental non-governmental organisations.

The Deputy Head of the EFSA GMO Unit, Elisabeth Waigmann, informed the participants that EFSA will prepare an EFSA meeting report that will be submitted to participants for comments and then published on EFSA website as an EFSA report.

The order of the agenda item was changed to comply with the time constraint of some speaker.

III. TOUR DE TABLE OF PARTICIPANTS

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

Address for correspondence:
European Food Safety Authority (EFSA)
Largo N. Palli 5/A, 43121 Parma - Italy
Telephone: +39 0521 036 111 - Fax: +39 0521 036 155 - http://www.efsa.europa.eu

IV. PRESENTATIONS AND DISCUSSIONS

Note: Please note that the slides presented by the EFSA GMO Panel members at the meeting were distributed in advance of the stakeholders' meetings and will be made publicly available on the EFSA website, together with this EFSA report of the meeting.

1) General update of the ERA guidance document (Speaker: D. Bartsch; Chair: J. Sweet)

The Chairman of the sub ERA GD WG, Detlef Bartsch, sets the scene providing the participants with some background information *(e.g.,* EC overall mandate, deadline, public consultation, ongoing activities of respective EFSA working groups) and, in particular, the state of play of the discussion within the EFSA sub ERA GD WG (e.g., new sections). The overall structure of the updated ERA Guidance Document was illustrated with section 9.4 concerning the interactions between the GM plants and target organisms. He stressed that all the information, including slides, disclosed during the meeting should not be considered as the final opinion of the EFSA experts but solely as work in progress. The draft updated Guidance Document is under development and therefore still need further discussions, changes and adjustments.

DISCUSSION:

Following feedback on the BiosafeNet seminar that took place in January 2009, some participants asked whether they could get access the related discussion. The EFSA experts explained that this workshop primarily examined statistical analysis and experimental design for field testing, particularly with respect to non-target organisms (NTOs) and mentioned that a scientific publication is under preparation to publish the outcome of the workshop.

Some participants sought for clarifications as regards the status of the final updated Guidance Document. As mentioned in the mandate from DGENV to EFSA, the updated Guidance Document will have "a regulatory status and will be adopted by the Member States". The representative from the European Commission (DGENV) mentioned that a final decision on the exact form of the updated ERA guidance document still needs to be made by the European Commission.

The EFSA experts explained that the objective of the current activities is to review and update, where needed, the EFSA guidance document to applicants for the environmental risk assessment (ERA) of GM plants, including data requirements to complete a comprehensive ERA.

Some participants queried the emphasis on resistance development (*e.g.* Bt resistance in insects and herbicide tolerance in weeds). The EFSA experts clarified that Bt resistance and herbicide-tolerant weeds will be addressed under different sections of the updated guidance document ('insectsBt' under the section on target pests and 'weeds' under the section on changes in agricultural practices). They also pointed out that a risk of resistance development identified in target organisms might also lead to changes in field management.

Some participants referred to recent publications and asked whether new findings (*e.g.* co-factors linked to the mode of action of Cry proteins) in GMOs field will be considered by the EFSA GMO Panel in its reviewing process. The EFSA GMO Panel representatives confirmed that they always consider recent literature in its risk assessment of GMOs applications.

Some participants were concerned that the updated new guidance document will not explicitly consider that some effects (e.g., interactions with eco-agricultural environments) can not be addressed sufficiently in a environmental risk assessment or some risks can not be appropriately managed. Some participant points out the extreme complexity of cropping systems and multiple interactions between cultivars, cropping practices and organisms. A such level of complexity make impossibility to conclude on absence of harm.

2) Non-target organisms (Speaker: J. Kiss, Chair: L. Roda)

The vice Chairman of the EFSA self-tasking working group on non-target organisms (EFSA NTO WG), Jozsef Kiss, gave a short state of play of the activities of the working group (*e.g.* drafting document, review by external referees, public consultation, deliverables). He went through the different steps of the NTO risk assessment starting with a clear problem formulation considered as paramount. He developed other important points like the selection of appropriate NTOs (= 'focal' species) via identification of relevant functional groups (considering agro-ecological, functions in farming) as well as the proposed approach for NTO testing, including the so-called 'extended compositional analysis'.

DISCUSSION:

Some participants sought for further clarifications to be given in the document, including clear requirements as well as standardised protocols, to the tiered-approach (Figure 4, Slide 17) as presented and currently proposed by the EFSA ENV sub-WG. The concept of substantial equivalence as used in the presented figure was especially criticised as not appropriate for NTOs or ecological testing.

The EFSA experts firstly clarified that the guidance document covers all GM plants and not only insect-resistant crops[1]. They stressed the importance to keep the risk assessment scheme flexible enough to cover all types of GM crops. However, they recognised the need for clarifications and explanations of the suggested tiered approach and in particular of the concept of extended compositional analysis. They also referred to the two different deliverables of the EFSA GMO Panel namely, (1) the restricted updated Guidance Document to applicants on ERA of GM plants and (2) a detailed scientific opinion including background and rationales for the ERA of NTOs in particular.

Some participants found the proposed ERA approach limitative and reductionist. Important key issues seem to have been overlooked such as the 3-D structure and conformation of a protein or its glycosilation modifying their interactions with other biotic and abiotic factors. In addition, the approach should be extended to a broader ecological testing of the whole GM plant in order to cover possible interactions (e.g. synergetic effects). The EFSA experts reminded that, pending clarifications, the proposed approach foresees a comprehensive range of molecular and food & feed safety assessment as well as lab-, semi-field and field tests that the applicants might be required to carry out to complete a comprehensive ERA. In this respect, the tiered approach still needs to be clearer on the ordering of the decision tree (Yes v. No). The EFSA experts recalled the importance of an appropriate exposure assessment as one of the first ERA step. Consequently the material to be tested (e.g., plant material as pollen) can be identified.

Some participants sought for recommendation on the duration of field trials. The EFSA experts mentioned that to assess e.g. long-term effects, it is not expected that the applicants will compulsory provide field data. A minimum of number of sites and duration of field testing will be proposed by EFSA and the specification of field trials will be left to the applicants. However, it is expected that applicants will provide a full data set, allowing risk assessors to undertake a comprehensive ERA. The data set will vary on a case-by-case basis depending on the combination of crop and trait.

Some participants asked whether the information provided by the applicant could be made publicly available. It was reminded that GMOs applications are covered by strict confidentiality rules set by the applicants and endorsed by the European Commission. EFSA confirmed that, upon request, non confidential parts of GMO applications might be disclosed to the public in accordance with Regulation (EC) 1049/2001 on public access to documents.

3) Field trials (Speaker: J. Perry, Chair: G. Squire)

Joe Perry presented the grounds and state of play of the update of updated Guidance Document related to the statistical analysis and experimental design of field trials. He pointed out that a checklist will be provided to applicants and emphasized the importance of selecting the appropriate comparators.

DISCUSSION:

Some participants questioned the validity of the comparison with historical data as provided in the applications. The EFSA experts mentioned that the applicant should use appropriate data for their comparison, using e.g. both their field experiments and/or scientific publications. A discussion took place on the limits of concerns and who should define it. It was mentioned that the issue is under discussion in the WG but that a 50% difference would be a maximum level and that proposals for lower levels are under discussion. Moreover, the applicant will be requested to provide a power analysis for each field trial and an estimation of the effects they are expecting to detect.
Some participants considered the minimum requirements of 3 different sites for field trials as insufficient *e.g* in view to the high variability of geographical regions in Europe. In case of observed differences between years, they questioned how these differences would be handled. The importance of appropriate comparators and baselines (*e.g.* GM Bt and normal practices with/without insecticide) was also emphasized. Regarding the number of sites and years, the EFSA experts reported the outcomes of the BiosafeNet workshop. Three sites over two years were considered reasonable and constitute a minimum requirement. It will be the task of the applicants to justify the choice of comparators and sites and to explain any differences observed during the field experimentation (*e.g.* differences between sites over 1 year).

Some participants questioned the neutrality of the data provided by an applicant. The EFSA experts explained that the EFSA GMO Panel is an independent body in charge of reviewing the ERA carried out and the data provided by an applicant (and not the authorisation) in the light of i) the application, ii) the additional data requested to the applicant; iii) the Member States comments; iv) scientific literature. Moreover, the non CBI parts of the applications are available to the public upon request. On several occasions, the EFSA GMO Panel has requested additional information (including new field trials) from the applicant in the case where data from field trials were considered inadequate and with little statistical power.

4) Long-term effects (Speaker: G. Squire, Chair: J. Perry)

Geoff Squire briefly introduced some concepts underlying assessment of long-term effects of GM plants and presented the preliminary reflections of the EFSA sub ERA GD in this respect.

DISCUSSION

Some participants asked how the uncertainties linked to long-term and unanticipated effects will be dealt with. The EFSA experts made clear that uncertainties are inherent to every risk assessment. A major tool to address long-term and/or unanticipated effects is PMEM. In many cases it is likely that the applicants can not provide field trial data on long-term effects. However available baseline data (*e.g.*, carbon content of soil) could be used to predict possible long-term effects, since a change in soil carbon might be caused by agricultural management practices linked to specific GM crops (*e.g.* for GM HT crops). The publication of the BEETLE project[2] was mentioned. Some participants expressed their concern to have the issue of uncertainties rarely reflected in the EFSA scientific opinions.

[2] BEETLE report, 2009. Long-term effects of genetically modified (GM) crops on health and the environment (including biodiversity): prioritization of potential risks and delimitation of uncertainties. German Federal

Some participants questioned the baseline for long-term effects, the duration of the PMEM (only during the 10 year consent period and not necessarily longer), the limitation of PMEM to detect ecological effects and the impact on the authorisation if adverse effects were observed. The EFSA experts recalled that, while the baseline against which GM cropping should be compared is fluctuating over time, it is still possible to detect effects of GM cropping using suitable environmental indicators. However, the difficulty of the task was acknowledged. Reference was given to data published in the scientific literature on field trial performed over several years (*e.g.* Bt maize in Spain). The EFSA experts clarified that the PMEM (in particular case specific monitoring) is defined on the outcome of the ERA and that it shall be conducted in areas where the GM plants are released. Authorisation is given for a 10 year period but in case of adverse effects, the applicant shall immediately inform the risk managers (EC and MS) to invoke specific measures.

Some participants commented on the complexity of assessing agro-ecosystems (*e.g.* lack of causality and predictability), the dynamic of a natural systems and the difficulty of detecting long-term effects in general. The EFSA experts re-iterated that in comparing the biological properties of the GM plant with already existing plants (comparators) and associated farming practices, the ERA should consider the possibility of long-term effects arising above the background variation in suitable environmental indicators.

5) Farming practices (Speaker: J. Sweet, Chair: C. Chueca)

Jeremy Sweet built on the requirement under Directive 2001/18/EC as regards potential effects due to changes in agricultural practices and briefly presented the preliminary reflections of the EFSA sub ERA GD WG in this respect. He referred to the ongoing discussion with respect to the interplay between Directive 2001/18/EC (regulating deliberate release of GMOs) and Directive 91/414/EEC (regulating placing on the market of plant protection products (PPP)) and recognised the complexity of the situation in this respect.

DISCUSSION:

Some participants were concerned by the changing of management practices induced with i) the introduction of GM HT crops, ii) the possibility of multiple herbicide use and iii) whether there is a compulsory requirement for mitigation measures. The EFSA experts explained that the management of the GM HT crop will be decided at the Member States' level and is therefore the Member State that will propose the most appropriate measures. It was also mentioned that there is currently little experience in Europe of cultivation of GM HT crops with combined herbicide traits.

6) Receiving environments (Speaker: J. Kiss, Chair: D. Bartsch)

Jozsef Kiss briefly introduced some notions in terms of receiving environments (*e.g.*, zoning systems, criteria for selection of appropriate receiving environments for field tests) and presented the preliminary reflections of the EFSA sub ERA GD and EFSA NTO WGs in this respect.

DISCUSSION:

Some participants questioned the absence of more references to existing geographical regions (e.g. Zones of comparable climate in the EPPO region (European and Mediterranean Plant Protection Organisation). FOCUS-Concept: Forum for the coordination of pesticide fate models and their use. Indicative map of European biogeographical regions (NATURA 2000), Ecological land classification of Europe (Hornsman et al. 2008), DMEER: Digital map of European Ecological regions). They argued that applicants might be requested to initially consider 12 existing geographical regions and then to select 5 among the 12 and explain the selection of these 5 regions considering the crop and trait combination of the GM plant. Such an approach would provide clear guidance to the applicants

---

Office of Consumer Protection and Food Safety, BLaU Umweltstudien and Genius GmbH, http://ec.europa.eu/environment/biotechnology/pdf/beetle_report.pdf

and would be in line with the requirements currently in place for crop variety development. The EFSA experts questioned this approach and re iterated that the WGs will prepare two documents, one of them providing more explanation and setting the rationales for specific new guidance (including the description of existing geographical regions as in Nature 2000 or Seamless). It was mentioned that different crop/trait combinations will – if regarded necessary - trigger field experiments in different zones. In such a case the applicant will be requested to justify the selection of each specific region for establishing field trials. Then, field trials over 2 years in 3 different sites would be the basic requirements, keeping in mind that such requirements might be extended in the case of new crop/trait combinations for which there is little experience (*e.g.* drought resistant plants for cultivation with tendency of feralization). Some participants were of the opinion that 3 sites are not sufficient to cover the variability of geographical regions all over Europe.

V. GENERAL DISCUSSION (CHAIR: D. BARTSCH)

The chairman of the sub ERA DG WG thanked the participants for their valuable contributions and confirmed that the outcome of the stakeholder discussion will be taken into consideration in future discussions of the EFSA ERA WG and EFSA NTO WG. The Deputy Head of the GMO unit reiterates that a draft EFSA report of the meeting will be submitted to participants for comments, then published on the EFSA website as an EFSA report.

Some participants asked the EFSA GMO Panel how possible uncertainties should be dealt. The EFSA experts clarified that the risk assessment needs to be substantiated and contextualised. If risks are identified and characterised during the environmental risk assessment, recommendation would be given to risk managers who would then decide for the condition of authorisation of the GM product. It depends on the acceptability of identified harm and the level of this harm; the EFSA GMO Panel will try to elaborate on this. The EFSA experts y also reiterated that before the EFSA GMO Panel concludes on risks it regularly does request additional information from the applicant in order to complete their evaluation.

Some participants asked if there was EFSA guidance on GM animals. It was confirmed that EFSA received an official mandate from the European commission to develop guidance for the risk assessment of GM animals and that various activities are ongoing (*e.g.* call for tender on ERA of GM fish and GM insects, WG food feed aspects).

Some participants asked if EFSA had collaboration with the European Environmental Agency. It was mentioned that EFSA has currently no direct collaboration with EEA. However, EFSA is in close collaboration with the Member States via the Member State consultation on all applications and the networking with some Member States in the context of applications including cultivation in their scope.

Some discussions took place on the availability of research material in the context of patent and GMOs. The views was expressed by all participants that it would be beneficial for independent research.

ANNEX – LIST OF PARTICIPANTS

Panel Members		Date	Presence
1	Salvatore Arpaia	18 June 2009	Apologies
2	Detlef Bartsch	18 June 2009	Present
3	Jozsef Kiss	18 June 2009	Present
4	Joe Perry	18 June 2009	Present
5	Joachim Schiemann	18 June 2009	Apologies
6	Jeremy Sweet	18 June 2009	Present
Ad hoc experts			
7	Cristina Chueca	18 June 2009	Present
8	Marc Delos	18 June 2009	Present
9	Achim Gathmann	18 June 2009	Apologies
10	Rosie Hails	18 June 2009	Apologies
11	Paul Henning Krogh	18 June 2009	Present
12	Andreas Lang	18 June 2009	Apologies
13	Barbara Manachini	18 June 2009	Apologies
14	Antoine Messéan	18 June 2009	Apologies
15	Lucia Roda	18 June 2009	Present
16	Geoff Squire	18 June 2009	Present
17	Adinda de Schrijver	18 June 2009	Apologies
18	Angela Sessitsch	18 June 2009	Apologies
19	Claudia Zwahlen	18 June 2009	Apologies
Environmental Institutes and Organizations			
20	Christof Potthof / Gen-ethisches Netzwerk e.V.	18 June 2009	Present
21	Frédéric Jacquemart / France Nature Environnement	18 June 2009	Present
22	Janet Cotter / Greenpeace	18June 2009	Present
23	Heike Moldenhauer / Friends of the Earth	18 June 2009	Present
24	Marina Gebhard / Federation of German Consumer Organisations	18 June 2009	Apologies
25	Christian Schlatter / ENCA	18 June 2009	Apologies
27	Anna Hope / English Nature	18 June 2009	Apologies
28	Beatrix Tappeser / Federal Agency for Nature Conservation	18 June 2009	Present
29	Michael Eckerstorfer / Landnutzung & Biologische Sicherheit Landuse & Biosafety Austria	18 June 2009	Apologies
30	Gebhard Marina / Federation of German Consumer Organisation	18 June 2009	Apologies
31	Ruth Veale / Bureau Européen des Unions de Consommateurs (BEUC)	18 June 2009	Invited
32	Bernard Chevalier / Bureau Européen des Unions de Consommateurs (BEUC)	18 June 2009	Invited
33	John Hontelez / European Environmental Bureau (BEUC)	18 June 2009	Invited
34	Hans Muilerman / European Environmental Bureau (BEUC)	18 June 2009	Invited
European Commission			
35	Helen Clayton	18 June 2009	Present
36	Bernadette Murray	18 June 2009	Apologies
37	Ioana Rodica Ispas	18 June 2009	Apologies
E F S A			

38	Karine Lheureux	18 June 2009	Present
39	Sylvie Mestdagh	18 June 2009	Present
40	Elisabeth Waigmann	18 June 2009	Present