European Food Safety Authority

GMO UNIT

Parme, 18 December 2009
EFSA/GMO/537

STAKEHOLDER CONSULTATION WORKSHOP BETWEEN EXPERT OF THE EFSA WORKING GROUPS ON THE UPDATE OF THE ERA GUIDANCE DOCUMENT AND MEMBER STATES

Meeting report of the meeting on 17 June 2009
Berlin

The below report does reflect the common understanding of EFSA and the delegations 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 the European Food Safety Authority or of any national or EU Institution, agency or body.

I. PARTICIPANTS

The list of participants is encloses (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 organized 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. Following a consultation period, the agreed meeting report will be made publicly available on the EFSA website.

III. TOUR DE TABLE OF PARTICIPANTS

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

IV. PRESENTATIONS AND DISCUSSIONS

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Note: Please note that the slides presented by the EFSA experts 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; Chairman: 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 GM plants and target organisms. He stressed that all the information, including slides, disclosed during the meeting should not be considered as final opinion of the EFSA experts but solely as work in progress. The draft updated Guidance Document is under development and therefore still needs further discussions, changes and adjustments.

DISCUSSION:

The Irish delegation sought clarifications with respect to the various rounds of update of the EFSA GMO Panel guidance document. The EFSA experts confirmed that the guidance document, initially adopted in 2004 and already updated in 2006, will be updated according to the most recent scientific and technical progress in the field of GMOs risk assessment. The German delegation supported the 'live' character of the EFSA guidance document which needs regular review in the light of the experience gained, technological progress and scientific developments. Making it legally binding will considerably reduce the flexibility in updating the updated Guidance Document to applicants. 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. Furthermore the need for flexibility of the updated Guidance Document to risk assessors was acknowledged by risk managers.

The EFSA experts confirmed that the deliverables of the EFSA WGs concerned will be: 1) detailed guidance to applicants on ERA of GM plants, and 2) a scientific opinion on the ERA of non-target organisms (NTOs) providing background and rationales of the NTOs ERA.

The Greek delegation urged the EFSA experts to consider potential effects of a GM insect-resistant crop on target pests in particular, the possible change in behaviour, the development of resistance and the subsequent management measures that might be enforced to delay and/or prevent a possible resistance development in target pests. Supporting the view of the Greek delegation, and in addition to the ERA requirements under chapter 9 of the EFSA guidance document, the Hungarian delegation emphasised the need to consider the constitutive expression of the inserted trait by the GM plant (e.g., dosage of GM proteins and comparison of protein dosage between GM and conventional crops) as part of the guidance document. The French delegation referred to the protein dosage in different plant parts as used by the US risk assessment bodies and therefore supported the Hungarian opinion. If resistance development is part of the ERA, the Dutch delegation wondered how to carry out an appropriate risk analysis in this respect. The EFSA experts confirmed that the first ERA step consists of an exposure assessment based, among other information, on data (e.g., field trials, national research projects, literature) available to the applicants. The next steps should then be on assessments of the consequences of the resistance development. To conclude it was reminded that the updated Guidance Document should be as generic and standard as possible to cover current and possible combinations crop-GM trait in the future.

2) Non-target organisms (Speaker: S. Arpaia, Chair: L. Roda)

The Chairman of the EFSA self-tasking working group on non-target organisms (EFSA NTO WG), Salvatore Arpaia, gave a short state of play of the activities of the working group (*e.g.* draft working

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:
Slide 17 (Figure 4) was considered by all participants as the core slide of this section and raised a general requirement for more explanation.

The German and Irish delegations were concerned with some newly proposed concepts and terminology (e.g. semi-field tests, stressor, sufficient information, substantial equivalence for NTO testing) and suggested to use the terminology of the existing legal document were ever possible. . The EFSA experts made clear that the updated Guidance Document will be supplemented with a scientific opinion including a glossary and some case-studies that will be developed to help the applicants. They re-emphasized the importance of a clear problem formulation and of the choice of appropriate comparators. In this respect, the applicants will be required to consider common agricultural practices implemented in various EU Member States.

Concerning the methodology, the Greek delegation was of the opinion that tests should be performed over the 3 different tiers to collect a comprehensive data set representative of real receiving environments. The EFSA experts referred to the two schools of thoughts as regards the NTO ERA approaches where 'tiers' are used differently but reiterated more on the need to consider relevant functional groups for EU representative receiving environments. The Austrian delegation was of the opinion that the applicants should systematically move from lower to higher tier test(s), including field tests, and also stated that the criteria for determining when data are considered to be sufficient and therefore would - according to the presented scheme – justify the ecological test to be completed, need to be defined very accurately in the guidance document. The EFSA experts referred to the step-by-step approach in which the applicant will formulate a clear problem hypothesis based on the available data set (*e.g.* field trials, research, literature, post-market environmental monitoring). This initial problem formulation will frame the subsequent tests and define the need to move from lower to higher tiers in accordance with trigger values set by the applicants.

To questions from the Dutch delegation, the EFSA experts confirmed that examples of protocols for classical ecotoxicological tests will be given to applicants (e.g. sub-lethal effects, reproduction effects) as well as further guidance regarding specific compounds that should be considered in the extended compositional analysis. The Hungarian delegation was concerned by the large compositional variability between commercial varieties criticized the generic approach of the guidance document and would welcome more specific guidance.

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

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

DISCUSSION:
Considering the high natural variability between years among crops production systems , the Czech delegation recognised the difficulty in assessing long-term effects. In this respect, the Greek delegation referred to the post-market environmental monitoring (PMEM) as valuable tool to detect possible long-term effects. The EFSA experts also consider modelling as potential suitable alternative: models could be combined with PMEM activities and data from long-term field experimentations on agricultural systems. Reference was made by EFSA experts to various modelling approaches around the Farm Scale Evaluation trials in UK and recommended a cautionary approach to the use of models in GM risk assessment. Indeed the French and German delegations raised the point of availability of validated models to detect such effects, specifically due to the GM crop per se, among hundreds of effects due to the broad range and high natural

variability of ecological (including biotic and abiotic) factors. Taking the French experience of PMEM activities with Bt maize, the EFSA experts recognised the difficulty to distinguishing effects due to the GM plant from effects due to cultivation management practices (e.g., herbicides use, ploughing) due to the broad range and variability of baselines. The guidance document should be clear on this point.

The EFSA experts pointed out that the risk assessment of potential long-term (including cumulative) effect is regarded as an important requirement set under Directive 2001/18/EC. In this respect, the EFSA experts would not advice compulsory long-term field experimentations but would recommend a comprehensive PMEM. The Greek and Austrian delegations were of the opinion that scientifically valuable data cannot be collected from monitoring activities the way they are currently performed, i.e. mainly focussing on farmers questionnaires which could not be considered as a scientific method for environmental monitoring, which requires expert knowledge, and were in favour of field experimentation. The Polish delegation suggested taking advantage of commercial GM fields in some EU Member States as a valid source of information from EU representative receiving environments.

The Austrian delegation reminded that PMEM is not part of the Environmental Risk Assessment, but that data acquired by a scientific sound monitoring would be very valuable for the risk assessment. Members of the EFSA WG agreed and made reference to its guidance for monitoring activities[1] and reminded that the EFSA GMO Panel only comments the scientific quality of the monitoring plan provided by the applicants. Monitoring is outside EFSA remit and falls in the hands of risk managers. The European Commission currently works on a template form for reporting monitoring activities.

4) Receiving environments (Speaker: J. Kiss, Chair: A. De Schrijver)

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:

The German delegation was concerned by the current zoning concept and would not support a possible restriction of the GM crop approval to those zones where the GM crop under consideration had been tested in the field. In its assessment of environmental risk , the EFSA GMO Panel considers the whole EU area as potential receiving environmen(s) bearing in mind that the commercialisation approval of a GM crop applies in all EU Member States. The EFSA experts reminded that this is the task of the applicants to identify representative receiving environments in which to carry out field trials. In this context, the identification of zones should be seen as a tool to gather data representative of environments where the GM crop is likely to be grown. Selection criteria for identification of possible receiving environments will be developed by the EFSA experts and will be mainly based on the combination crop and GM trait.

In response to some delegations' concern, the EFSA experts reinsured the participants that the concept of zoning will be clarified in the guidance document in order to avoid misinterpretations and misuses. Against this background, the Greek delegation was in favour of field tests in a large selection of Northern and Southern EU MS to cover a broad range of environmental, biotic and abiotic (e.g., soil, climate), conditions.

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

[1] 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, http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/gmo_op_ej319_pmem_en,0.pdf

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:

The EFSA experts explained that potential consequences of herbicides use (e.g., development of herbicide-tolerant weeds) are considered by the risk assessors in their environmental risk assessment.

In this context, the Dutch and Irish delegations recognised the regional character of herbicides management practices and hence wondered how the EFSA GMO Panel plans to consider these local and specific differences in a EU-wide context. The registration of the PPP at the national level should allow some fine tuning for commercialisation criteria of herbicides, including recommendations for use (e.g., dosage), set at the Member State level. In addition, the EFSA experts informed the participants that the approach suggested by the EFSA GMO Panel had already been presented to the European Commission and Member States and the discussion on this approach is still in progress. The EFSA experts are of the opinion that the issue shall be addressed under Directive 91/414/EEC since the possible risks are mostly likely linked to the use of herbicides rather than the GM plant itself. In addition, the ongoing revision of Directive 91/414/EEC is likely to change the interplay between both Directives by considering some impacts on biodiversity.

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

Joe Perry presented the grounds and state of play of the update of 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:

The EFSA experts recommended that field trials (including NTO testing) should be carried out on a minimum of 3 sites over a minimum of 2 years. Each of the data sets collected at the three sites needs to stand alone and be supported by adequatepower analysis. The Greek delegation believed that the requirement for 2-years field trials will not permit detection of possible long-term effects. The EFSA experts reminded that requests for longer-duration field trials would have to be justified.

The Polish delegation supported the EFSA proposal and reminded the 2/3-year field trials carried out for registration of conventional varieties. In addition, the Polish delegation is convinced that molecular characterisation data on a GM event could also contribute to information in respect to possible risks. The EFSA experts recalled the requirement for the applicant to characterise the genomic construct of a GM plant although this information alone is not considered sufficient to conclude on the environmental safety of a GM plant. The French delegation wondered about the practicability and feasibility for applicants in implementing such prescriptive guidelines which aim at reducing the gap in data quality between typical applications to date and those of publications (*e.g.,* high power analysis not always feasible due to low NTO abundance).

V. GENERAL DISCUSSION (CHAIR: D. BARTSCH)

The Chairman of the EFSA ERA WG, Detlef Bartsch, thanked the participants for the fruitful discussion and informs that the outcome of the stakeholders' consultations will be taken into consideration in future discussions of the EFSA sub ERA GD and NTO WGs. The Deputy Head of the GMO unit thanked the participants and reminded them that a draft meeting report will be submitted to comments from participants and then published on EFSA website as an EFSA report.

The Polish delegation would have appreciated some discussion on the genomic analysis that is likely to be of high scientific quality and a cost-effective tool for GMOs risk assessment. The Austrian delegation welcomed the progress made by EFSA and stressed the need to provide applicants with clear updated Guidance Document, especially with regard to the definition of criteria for terminating the ecotoxicological

investigations at a certain tier. The German delegation made the following two points: (1) the case-by-case RA principle (≈ flexible guidance) remains for every application although some risk managers are likely to prefer a cook-book; (2) the need to put in place a mechanism allowing a rapid update of the revised guidance document once it has the legally binding status by the European Commission. The Greek delegation welcomed the progress made and highlighted the importance of PMEM by national research institutes and universities.

The Deputy Head of the EFSA GMO Unit, Elisabeth Waigmann, thanked the participants and reminded them that an EFSA draft meeting report will be prepared and sent for comments.

ANNEX – LIST OF PARTICIPANTS

	Panel Members	Date	Presence
1	Salvatore Arpaia	17 June 2009	Present
2	Detlef Bartsch	17 June 2009	Present
3	Jozsef Kiss	17 June 2009	Present
4	Joe Perry	17 June 2009	Present
5	Joachim Schiemann	17 June 2009	Apologies
6	Jeremy Sweet	17 June 2009	Present
	Ad hoc experts		
7	Cristina Chueca	17 June 2009	Present
8	Marc Delos	17 June 2009	Present
9	Achim Gathmann	17 June 2009	Apologies
10	Rosie Hails	17 June 2009	Apologies
11	Paul Henning Krogh	17 June 2009	Present
12	Andreas Lang	17 June 2009	Apologies
13	Barbara Manachini	17 June 2009	Apologies
14	Antoine Messéan	17 June 2009	Apologies
15	Lucia Roda	17 June 2009	Present
16	Geoff Squire	17 June 2009	Present
17	Adinda de Schrijver	17 June 2009	Present
18	Angela Sessitsch	17 June 2009	Apologies
19	Claudia Zwahlen	17 June 2009	Apologies
	Member State representatives	Date	Presence
20	Mereth Aasmo Finne / Norway	17 June 2009	Present
21	Martin Batič / Slovenia	17 June 2009	Present
22	Denis Bourguet / France	17 June 2009	Present
23	Hans-Jőrg Buhk / Germany	17 June 2009	Present
24	Steffan Eklőf / Sweden	17 June 2009	Apologies
25	Nikolaus Emmanouil / Greece	17 June 2009	Present
26	Rosario Graça / Portugal	17 June 2009	Present
27	Igor Ferencik / Slovak Republic	17 June 2009	Apologies
28	Oxana Habustova / Czech Republic	17 June 2009	Present
29	Andreas Heissenberger / Austria	17 June 2009	Present
30	Gösta Kjellsson / Denmark	17 June 2009	Present
31	Tuuli Levandi / Estonia	17 June 2009	Apologies
32	Volker Matzeit / Germany	17 June 2009	Present
33	Tom McLoughlin / Ireland	17 June 2009	Present
34	Felix Ortega / Spain	17 June 2009	Apologies
35	Odeta Pivoriené / Lithuania	17 June 2009	Present
36	Matti Sarvas / Finland	17 June 2009	Present
37	Frantisek Sehnal / Czech Republic	17 June 2009	Present
38	Andras Szekacs / Hungary	17 June 2009	Present
39	Darina Todorova / Bulgaria	17 June 2009	Apologies
40	Tomasz Twardowski / Poland	17 June 2009	Present
41	Andre Varnava-Tello / Cyprus	17 June 2009	Apologies
42	Frank van der Wilk / The Netherlands	17 June 2009	Present
43	Andre Varnava-Tello / Cyprus	17 June 2009	Apologies
44	Stuart Wainwright / United Kingdom	17 June 2009	Present
	European Commission		
45	Helen Clayton	17 June 2009	Present
46	Bernadette Murray	17 June 2009	Apologies
47	Ioana Rodica Ispas	17 June 2009	Apologies

E F S A			
48	Karine Lheureux	18 June 2009	Present
49	Sylvie Mestdagh	18 June 2009	Present
50	Elisabeth Waigmann	18 June 2009	Present