Minutes of the 3rd Meeting of the EFSA Scientific Network for Risk Assessment of GMOs[1]

held in Parma on 3-4 May, 2012

European Food Safety Authority[2] (EFSA), Parma, Italy

This report reflects the discussion and comments made at this meeting. This report has been subjected to verification by the intervening participants. 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.

TABLE OF CONTENTS

PARTICIPANTS

GMO Network: The GMO Network Member Organisations from 24 EU Member States and Norway (see http://www.efsa.europa.eu/en/gmo/gmonetworks.htm) appointed in 2010 through the EFSA

[1] Question No EFSA-Q-2012-00560
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Advisory Forum 44 experts as delegates to attend the GMO Network meetings. 41 Experts attended the 3rd meeting. As observers, 8 experts from Candidate Countries attended the meeting.

GMO Unit: Jaime Aguilera, Anna Christodoulidou, Antonio Fernandez Dumont, Ana Gomes (co-Chair), Andrea Germini, Karine L'heureux, Yi Liu, Sylvie Mestdagh, Claudia Paoletti (Acting DHoU, co-Chair), Irina Olaru, and Elisabeth Waigmann (Acting HoU, Chair).

European Commission: Kaja Kantorska (DG SANCO).

Invited experts: Michelle Epstein, Sirpa Kärenlampi, Harry Kuiper, Martinus Løvik, Joe Perry.

See the participants and apologies list in Appendix 1.

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1. WELCOME BY CHAIR

Elisabeth Waigmann, Acting Head of the EFSA GMO Unit, opened the meeting by welcoming the participants to this third meeting of the EFSA Scientific Network for risk assessment of GMOs (hereafter referred to as "GMO Network" or "Network"). She acknowledged the positive feedback expressed by the SCFCAH on the activities of the Network and encouraged attendants to actively participate in the meeting.

2. TOUR DE TABLE AND APOLOGIES FOR ABSENCE

All participants presented themselves, their affiliation and their role in GMO risk assessment, during a tour de table. Apologies for absence were received from 2 experts.

3. ADOPTION OF THE AGENDA

The draft agenda was prepared by EFSA taking into account previous input received from the Member States, recent outputs of the EFSA GMO Panel and other EFSA activities in the field of GMO risk assessment. The draft agenda, as published at the EFSA website http://www.efsa.europa.eu/en/events/event/120503.htm, was adopted.

4. DECLARATIONS OF INTEREST

Representatives of the organisational members of the GMO Network and their alternates were asked to fill in an Annual Declaration of Interest (ADoI) to declare any interest that might be considered prejudicial to their independence. In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the received ADoIs. Since representatives of the GMO Network are nominated by Member States, no conflicts of interests are expected for the nature of the activities of the GMO Network.

In accordance with the EFSA management board decision on the rules and procedures of EFSA Networks, the representatives of the organisational members of the GMO Network, their alternates, observers and staff of the European Commission were requested orally at the beginning of the meeting to declare any interests that might be prejudicial to their independence in relation to the items on the agenda. With regard to this meeting no other interests than those already declared in the ADoIs and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof, were declared by the experts.

5. MINUTES OF THE PREVIOUS NETWORK MEETING

The draft minutes of the 2nd meeting of the GMO Network (held on 9-10 June 2011) were presented to the Network after the meeting, and participants were given the possibility to verify that their views

expressed were correctly reflected. After amendments, the minutes were adopted and published on the EFSA website: http://www.efsa.europa.eu/en/events/event/110609.htm. The same procedure will be followed for the minutes of the 3rd meeting.

6. SCIENTIFIC INDEPENDENCE OF EFSA: INTRODUCTION TO EFSA'S NEW POLICY ON INDEPENDENCE

The Chair introduced the new EFSA Policy of Independence and Scientific Decision-Making Processes, and its implementing rules, which will enter into force in July 2012. The new Policy reflects the big efforts made by EFSA to safeguard its independence and transparency. The Policy sets new and better defined rules to identify potential conflicts of interest affecting EFSA managers, staff and external experts, and establishes the appropriate actions to be taken in case of conflict. The basic principles of the Policy also apply to Networks; however, it takes into account their specificities and singularities. Particularly, nominated institutions from the Member States will be contacted and given the opportunity to react in case a conflict of interest is identified for the appointed expert. Network members were encouraged to read the Policy and implementing rules.

A delegate from Bulgaria requested clarifications on what are considered as "small contributions to companies" by experts. EFSA explained that small contributions are those for which the financial contribution from the company to the expert does not exceed 25% of the budget managed by that expert during the last full budget year.

Upon request from a delegate from the United Kingdom, EFSA clarified that, although there is no fixed timeline foreseen for the revision of the Policy, it is a common procedure by EFSA to regularly review its policies. Hence, it would be expectable that the Policy will be reviewed about one year after entry into force.

A member of the EFSA GMO Panel asked what the experience is with respect to hearing experts. According to EFSA, around 100 hearing experts are invited to participate in EFSA meetings each year. Contributions from hearing experts are generally useful and of good quality, and some positive feedback has also been received from some of those experts. In general, EFSA considers that the possibility to invite hearing experts is a quite useful and successful tool. EFSA reminded that a hearing expert cannot be invited to more than 30% of the meetings of a given Working Group.

7. GMO RISK ASSESSMENT SYSTEM IN MS

The delegates of five MS presented to the Network how the GMO risk assessment system is established in their respective countries. After each presentation, the corresponding delegate answered to questions posed by other delegates:

The Netherlands: Two independent institutions (COGEM and RIKILT) perform the ENV and FF assessment of applications for GMOs, respectively. The assessment activities of these institutions are coordinated by a so-called food/feed portal, that checks for consistency of the assessments/comments and liaises with EFSA and with the three Dutch ministries responsible for GMO policy. Dutch voting at the SCFCAH on a given GMO is based on the scientific assessments received.

Answering to questions from different delegates and EFSA GMO Panel members, the Dutch delegate clarified that there is no internal communication channel open between COGEM and RIKILT, although ad-hoc contacts can happen if needed. COGEM experts are selected based on their expertise, and come from both industry and academia. A DoI policy is in place, and experts are prevented to discuss and vote on dossiers for which a conflict of interest is found. RIKILT experts are professional risk assessors, belonging to the staff of the institution.

Ireland: Two public institutions (FSAI and EPA) perform the FF and ENV assessment of applications for GMOs, respectively. FSAI has a body of external scientific advisors, that are subjected to a DoI policy. FSAI opinions on GMO dossiers are reported to the corresponding Departments involved in

GM food/feed policy. Those Departments determine the voting at the SCFCAH, which may or may not follow the opinion. FSAI is also responsible for the analysis of GM food and feed samples. EPA performs the assessment of cultivation dossiers. It counts with an external advisory committee, whose composition includes members from the biotech sector and NGOs. The Dept. of Environment Community and Local Government are responsible for national policy for GMO's and the environment.
To date Ireland has not received any applications for cultivation of GMOs.

Answering to questions from different delegates, the Irish delegates clarified that the EPA advisory committee is composed by 14 members, including academic scientists, industry and NGOs. A DoI policy is in place. Governmental Departments are responsible for policy making and voting, but not for risk assessment.

Denmark: Two independent institutions (NFI and DCE) perform the FF and ENV assessment of applications for GMOs, respectively. DCE is in charge of the ERA of cultivation dossiers. In this case, a third institution (DAA, government-dependent) is also partially involved. Both NFI and DCE count with external experts. The assessments are submitted to the corresponding Competent Authorities for GM food/feed and GMO cultivation, that depend on different ministries, and are in charge of the voting at the SCFCAH. For cultivation dossiers, in addition to the assessment of DCE, the Competent Authority itself (EPA) produces its own opinion.

Answering to questions from different delegates and EFSA GMO Panel members, the Danish delegate clarified that Denmark has not been so far involved in the ERA for a cultivation dossier, so there is no experience on possible discrepancy between DCE and EPA assessments. DAA deals with agronomic assessment and has a minor role in the assessment, mainly by submitting comments.

Germany: BVL is the only German Competent Authority which has responsibilities in both risk assessment and risk management of GMOs. BVL sends comments to EFSA on applications for GM food/feed and performs the ERA of cultivation dossiers. Within the assessment procedure, BVL has to consult several institutions at the national level. The BVL consults the BfN and the RKI ("in consultation with"). Moreover, the BVL has to ask for opinions from the BfR (which also hosts the German EFSA Focal Point) and from the JKI. In the case of GM vertebrates or GM microorganisms that are applied to vertebrates, also the FLI has to be involved. In the context of an environmental risk assessment according to Directive 2001/18/EC, also the Central Committee on Biological Safety (ZKBS) is asked for an opinion. A DoI policy is in place for ZKBS experts.

Answering to questions from different delegates and EFSA GMO Panel members, the German delegate clarified that there is no involvement of the German Federal States ("Länders") in the assessment. It was noted that sometimes the positions of BVL and BfN towards a given dossier are not in agreement. In the case of differing scientific opinions, BVL has to deal in detail with the disagreements. Comments of BfN which - after exchange of arguments - eventually are not shared by BVL are not part of the German opinion. However, by virtue of an internal agreement, BVL sends the BfN comments to applications separately to EFSA for its information.

France: Two independent institutions (Anses and HCB) perform the assessment of applications for GMOs under regulation (EC) No 1829/2003: Anses performs the FF assessment while HCB performs an overall evaluation of GMOs, including FF, ENV, as well as economic, social and ethical issues. Both institutions have scientific committees composed of external experts (18 Anses and 39 HCB), selected through open calls for their expertise and competence. DoI policies are in place, and in case of conflict of interest, the concerned expert cannot participate in the discussions. The economic, ethical and social analysis is carried out by a separate committee in HCB, composed of 27 members representing stakeholders and civil society as well as qualified expertise in socio-economic issues. An extract of the Anses opinions is submitted to EFSA as MS comments through the Ministry of Economy, one of the French competent authorities under Regulation (EC) No 1829/2003. HCB comments on FF and ENV are sent to EFSA within the 3-month consultation period through the

Ministry of Agriculture, the other French competent authority under Regulation (EC) No 1829/2003. A final HCB opinion on FF, ENV and socio-economic and ethical issues is submitted to the Ministry of Agriculture prior to MS voting at SCFCAH. A governmental decision is taken between ministries (Economy, Agriculture, Environment, Foreign Affairs, etc.) based on both Anses and HCB opinions for all applications for placing on the market GMOs .

Answering questions from EFSA, the French delegate from Anses clarified that Anses opinions are ready within 3 months upon submission of an application. An extract of the opinion is submitted to EFSA as MS comment. Because ANSES opinions do not take into account additional information which may be requested to the applicant, it is explicitly stated that the opinions are on the initial dossiers. If necessary before MS voting at SCFCAH, Anses can be mandated to analyse additional information provided by the applicant. A new opinion based on the complete dossier is then published.

To finalise the session, EFSA posed an open question to the delegates of the MS which have not yet performed any initial ERA of cultivation dossiers, asking what would make it interesting to embark on such an ERA. Rather than finding the task unattractive, delegates expressed different reasons that hinder their participation in performing such an ERA as leading MS, such as lack of reception of applications for cultivation, staff shortages and structural reorganisations.

8. UPDATE ON RECENT AND CURRENT EFSA'S ACTIVITIES ON GMOS

The Head of the EFSA APDESK introduced to the Network the recently started Applications Desk. It is the primary EFSA platform for all issues related to applications for any kind of regulated products, including GM food and feed. It covers information to applicants and stakeholders, reception of applications, completeness checks (from an administrative perspective) and communications with applicants. The Applications Desk is currently in a developmental and staffing phase and is expected to be fully operational in the near future. Mid-term goals include a survey on the service and electronic applications. Delegates were invited to use the APDESK for any query related to applications. Answering to questions from delegates, the presentator explained that, because of the legal framework, it is not yet clear whether the future electronic applications will be submitted directly to EFSA or still to a MS. With respect to the survey, EFSA took note of a suggestion to include Sciencenet in the scope.

Following, the Acting Head of the EFSA GMO Unit gave an overview of the current activities of EFSA in the field of GMOs. In addition to the assessment of applications for GMO food and feed and GMO cultivation, which is a standing activity, several Guidance documents have been released during the two last years. Moreover, a number of mandates are in progress, including opinions on a series of new techniques for plant modification, a safeguard clause on GM maize cultivation, and several calls for procurement and grants to outsource diverse scientific activities in the field of GM plants and animals. Prompted by a delegate, EFSA clarified that the assessment of the new techniques for plant modification will be done one by one and not simultaneously.

9. RISK ASSESSMENT OF GM ANIMALS

1. Introduction to the GM animals GD

EFSA started the session by presenting to the Network the Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects, developed by the EFSA GMO and AHAW Panels, and published in 2012. The presentation was focused only on risk assessment issues. For this, the Guidance considers the previously published guidelines of the *Codex Alimentarius* Commission and the comments received through a public consultation. The scope covers only animals whose genetic modifications are heritable. The basic principle for the assessment is the comparative approach, with the underlying assumption that there is a history of safe consumption of traditionally bred (non-GM) animals. Health and welfare of the animals are considered indicators of safety, as occur with traditionally-bred animals. The assessment is conducted through different steps: molecular characterisation, comparative analysis, toxicological analysis, allergenicity assessment,

nutritional assessment, and conclusions. For the comparative assessment, the principles applied in animal experimental designs are contemplated. In addition to ad-hoc experimental data, previous existing data on health, veterinary, and treatment records, physiology, reproduction or behaviour may also be considered. In this respect, EFSA has launched a call for data collection and methodology support for the analysis. In addition, compositional analysis is also contemplated. Depending on the outcome of the molecular characterisation and the comparative analysis, a toxicological assessment may be needed, although it is emphasised that this will not be the case for most of the situations. There are also limitations in the animal feeding trials for testing the whole food or feed derived from animals. The allergenicity assessment of the newly expressed protein can be performed on the weight of evidence approach. However, this approach does not apply to the whole food testing, as foods of animal origin are in general a source of allergens. In those cases, the same management measures taken for the traditionally bred animal products are recommended. The need for nutritional assessment will be determined on a case-by- case basis, and taking into account the legal limitations with respect to animal-derived feeds for farmed animals. An exposure assessment is also required for the nutritional evaluation. In the conclusions of the risk assessment, applicants should demonstrate whether the consumption of GM animal-derived foods/feed is i) as safe as the consumption of the comparator(s), and ii) not nutritionally disadvantageous. Assumptions and uncertainties should be indicated clearly.

Discussion

The Dutch delegate asked how animal welfare was considered in the risk assessment. EFSA explained that animal welfare is measured by phenotypic characteristics such as behaviour. Welfare records exist for farmed animals. Welfare is related to health, and both parameters are relevant for the risk assessment, as they are linked to safety.

Answering a question from the Finnish delegate, EFSA clarified that both raw and processed animal material are considered in the assessment.

The Belgian delegate indicated that, unlike for GM pants, no guidance is given on collection of compositional data from different places and growing seasons. She also asked whether studies with human volunteers would be in agreement with the declaration of Helsinki on ethical principles for research involving humans. EFSA explained that, contrary to plants, it is difficult to provide common guidance on how to collect the materials, as they will differ from animal to animal. However, the statistical analysis of the expression data will also apply for GM animals. With respect to human volunteer studies, they were considered only for the nutritional assessment and not for safety testing. Nevertheless, they were removed from the draft Guidance after some concerns received in the public consultation. A member of the GMO Panel recognised that the issue is sensitive, and confirmed that they should not be related to safety issues but to nutritional testing. Such studies are useful, and, although not requested in the Guidance, existing data can be accepted. The Latvian delegate indicated that studies with human volunteers are normally performed for testing human drugs, so they could be also done for GM food.

The German delegate asked how the differences in health indicators are considered in the assessment, since the comparative assessment is written in similar terms as in the Guidance for GM plants. She also asked if, in addition to toxicological assessment, pathogenicity is also considered. EFSA indicated that the health indicators should always be considered in comparison with the conventional counterpart. A general health assessment of the animals belongs to the veterinarian practice and is independent of the comparative approach. A member of the EFSA GMO Panel stressed that the chapter on choice of comparator emphasises the importance of considering animal husbandry. With respect to pathogenicity, another member of the GMO Panel indicated that the zoonotic potential of the GM animal is indeed considered in the Guidance.

2. Current developments on GM animals

The Dutch delegate presented the history of GM animal development in the EU, and the current advances on GM animals as presented in the First International Workshop on the Food and Environmental Safety Assessment of Genetically Modified Animals (Buenos Aires, 2011). The first GM animal developed in Europe (1990) was a bull which harboured a gene for lactoferrin production, so its female offspring would produce lactoferrin in their milk. It was unsuccessful because of the lack of knowledge about regulation of animal gene expression at that moment; however, this aspect has advanced a lot in the past number of years. Even so, with the exception of the GloFish, there are no reports of GM animals in the market yet. China, Argentina, Brazil, Canada, The USA and Australia are the most active countries in GM animal development. Most of the engineered traits are intended to the production of pharmaceutical products in the milk (of cattle, sheep or goat). Other traits include: Increased production (growth of salmon, wool of sheep), improved nutrition (cow and pig), disease resistance (chicken, cow and pig), low environmental impact (pig), disease vector control (mosquitoes) and production of new substances (goat, sheep). There are also GM animals developed as models for research and for ornamental purposes.

GM animal development is at its 2nd phase, it is likely to stay and the number of traits will increase. There is large consensus on regulatory and safety aspects of GM animals, mainly based on the *Codex Alimentarius* Commission and the Cartagena protocol. However, there is no clear guidance on the safety assessment of GM animals with non-heritable traits, which are likely to be the subject of most applications in the future. This is because animal genetic modification is usually coupled with cloning, as they are complementary techniques, and the resulting animals are often mosaic.

Asked by a member of the EFSA GMO Panel, the Dutch delegate explained that GM animals as models for the study of human diseases, even if they are not intended for food/feed applications, might end up in the food/feed chain. This would pose additional risks, because the GM animals are morphologically undistinguishable from the rest.

Another Dutch delegate asked if there have been improvements over the years in the health of the offspring of GM animals. She also asked how non-heritable traits were achieved. It was explained that it is the GM animal itself which is unhealthy. However, because so much basic research has been done, the situation is much better nowadays. Non-heritable traits can be introduced by using viral vectors, by using the combination of genetic modification and cloning, or by means or a DNA vaccine.

3. General discussion

With respect to the GM salmon subject to a market application in the USA, the Irish delegate expressed his concern about how the ERA and PMEM should be done. A member of the EFSA GMO Panel shared this concern, and indicated that, given the limitations and the lack of documentation on PMEM, little guidance can be provided. The UK delegate wanted to know whether the dossier on the GM salmon submitted to the USA would match the expectations of the Guidance. EFSA explained that this a dossier was used as a case study during the development of the Guidance, and that it was found not to be detailed enough to enable the assessment, particularly in terms of compositional analysis. A member of the EFSA GMO Panel confirmed that the GM salmon dossier is not detailed enough to enable the ERA according to the Guidance which is in preparation by EFSA, as the possible ecological impact of the environmental release is not covered in depth.

The Hungarian delegate was concerned about the safety of using retroviral vectors to construct GM animals for organ transplantation purposes. The Dutch delegate clarified that these animals are not in the scope of the EFSA GM animals GD; however, the possibility that these animals end up in the food/feed chain would be of concern. In this respect, a member of the EFSA GMO Panel considered the possibility of including mosaic individuals in the scope of a revised version of the Guidance. The Dutch delegate indicated that, during the development of the GD, there were lengthy discussions on whether heritable and non-heritable traits can be covered by the same document. The WG concluded that, given the large differences among mosaic individuals, it would be impossible to represent all

cases in one single document. Answering a question from a German delegate, the Dutch delegate clarified that animal cloning leads to different mosaic individuals, because each of the resulting embryos carry a different set of GM cells.

EFSA asked the audience on the scope of the guidance (road map) on GMOs which is being developed under the Cartagena protocol. The Dutch and German delegates pointed out that, although current experience is limited to GM mosquitoes, the road map contemplates coverage of all GMOs.

10. BREAKOUT SESSIONS

a. FF: ALLERGENICITY ASSESSMENT OF GM FOOD AND FEED

1. EFSA GD on allergenicity of GM plants and microorganisms

EFSA presented its recent work on allergenicity assessment of GM food and feed. The 2011 EFSA GMO Panel Guidance for the risk assessment of food and feed derived from GM plants includes a section on assessment of allergenicity, which is based in the 2010 Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed. The assessment of allergenicity (which is not an intrinsic property of a protein) is made through an accumulative body of evidence, and follows two approaches: assessment of the newly expressed proteins, and assessment of the whole GM plant. The first approach considers bioinformatic analyses of the amino acid sequence of the protein, in vitro digestibility tests, and, on a case-by-case basis, specific serum screening. The second approach is followed when recipient is known to be allergenic, and is based on the comparative approach. The body of evidence is obtained from analytical methodologies e.g. proteomics, the results of the compositional analysis and existing available information on occupational allergy. Potential adjuvant activity of the newly expressed protein should also be considered.

In March 2012, EFSA and the CA of Austria and Norway organised the workshop “Key allergens and compositional analysis in the allergenicity assessment of genetically modified plants”, covering issues of endogenous allergenicity. In the workshop, the usefulness of different available methodologies was discussed. In general, it was considered that profiling technologies like mass spectrometry are very valuable, whereas the use of human sera had several limitations. The inclusion of allergens in the compositional analysis of GM pants is also being considered by the OECD, that will continue discussions.

Discussion

The presentation triggered several questions from the audience. The Hungarian delegate was concerned about how to identify newly allergenic proteins and about the limitations of *in vitro* protein degradation systems. EFSA agreed on such limitations, but stated that a definitive test to prove allergenicity does not exist. To test the allergenic potential of new proteins, bioinformatic analysis is a useful tool.

The Danish delegate questioned why the potential allergenicity of enzymes should be considered in GM food assessment, as the currently marketed food enzymes are not tested for this possibility, not even under the new EU legislations on the safety of food enzymes. According to EFSA, as all enzymes are proteins, they constitute potential allergens and this should be assessed.

With respect to the lack of existing baseline data for plant allergenicity pointed out by the German delegate, EFSA considered that data for commercial varieties could be included as a reference in applications, as currently occurs with the compositional analysis. However, the lack of existing baseline data is well recognised. A member of the GMO Panel indicated that, although the EFSA Guidance values the testing of endogenous allergenicity, the limited availability to human sera is a fundamental issue yet to be solved.

Another member of the GMO Panel highlighted a discrepancy between EFSA and the OECD on the extent of the quantification of allergenicity. The basis for an agreement on this should be the fundamental fact that the allergenicity risk assessment is not quantitative.. With this respect, the UK delegate considered that quantification of the allergenic potential may be meaningful for cases in which we know that such potential is really big.

2. Criteria for the allergenicity assessment of GMOs

Presentation by Michelle Epstein

Dr. Michelle Epstein, invited speaker from the Medical University of Vienna, gave a presentation on the usefulness of animal models to study allergenicity. Her research group used a genetically modified pea carrying a bean alpha-amylase inhibitor (AAI) to study the molecular basis of allergenicity. They used mice as animal models, and performed different experiments with the mice fed with GM peas and their isogenic controls. Concretely, they tested whether i) differences in glycosylation patterns between GM pea AAI and native bean AAI enhance allergenicity of the former, ii) GM pea feeding induces allergy to the novel transgenic protein, iii) GM peas worsen allergies to other allergens, iv) human-severe combined immunodeficiency (SCID) mice chimera are a good model for GMO allergenicity testing. Their results showed that i) changes in glycosylation are not specifically linked to transgenic AAI in mice, ii) Both GM, isogenic and control peas induce allergy in mice, iii) GM pea feeding does not specifically worsen allergic responses to egg allergen, iv) Both healthy and SCID mice develop allergic asthma upon feeding with GM peas and conventional beans. As a general conclusion, Dr. Epstein highlighted that these results contradicted earlier studies indicating that AAI peas are not allergenic and that careful consideration must be taken when using mice as a model for testing allergenicity of certain GMOs. The study has been performed in the frame of the EC-founded GMSAFOOD project[3] on post-market monitoring of GM food. This project aims to build a public repository for existing datasets on the safety of GM food and feed in humans, livestock, and experimental animals and to use a bioinformatics machine learning approach to analyse these disparate datasets for early detection of biomarkers and the identification of risks of GM food and feed.

Discussion

A delegate from Ireland was interested in the validity of other animals (rabbit, rat) as models. Dr. Epstein casted doubt about the validity of any small animal as model to study allergenicity. There are also some inter-laboratory differences between the results of equivalent experiments, meaning that more that one study is necessary for reliable conclusions. The German delegate was interested in the criteria followed to choose the mouse strain for the experiments. The strain used was BALB/c. It was found that females are more prone to allergy than males. For other studies using milk other strains were found better.

Answering to a question from a member of the GMO Panel, Dr. Epstein clarified that the induction of asthma was used as a method to study the validity of the mouse model, but not as an indicator of food allergy.

Presentation by Martinus Løvik

Dr. Martinus Løvik, invited speaker from the Norwegian Institute of Public Health, presented to the audience the report of the Norwegian Scientific Committee for Food Safety (VKM) titled “Cry proteins: risk assessment in relation to allergy adjuvant activity”, that was published in April 2012. The report was triggered after some concerns expressed regarding the potential adjuvant effect of the Cry proteins on immune responses to food proteins, increasing the risk of food allergy caused by Bt-crops. The report acknowledges the lack of understanding of the mechanisms of adjuvanticity and of a validated method to test such effect. Differences also exist among the animal models tested. The

[3] http://www.GMSAFOODproject.eu

current existing data are limited to the Cry1Ab and Cry1Ac proteins. Cry1Ac showed an adjuvant effect to immunoglobulin responses against co-administered hepatitis virus and bovine serum albumin, pneumococcal antigen and amoeba lysate. Cry1Ab showed an adjuvant effect to peanut sensitisation, although there are some contradictory results. It must be taken into account that adjuvant effects are only of concern if related to allergy, and that further data are needed to properly characterise the potential adjuvant effect. There are limitations in the available experimental models. The exposure to Cry proteins is highly variable and difficult to quantify. It is also not clear what is the best dose estimation (micrograms per kilogram of body weight or micrograms per individual). In addition, Cry proteins are normally degraded by cooking and in simulated in vitro digestions. The conclusion of the report is that, because of the existing lack of knowledge and amount of uncertainties, it is not possible to quantify the risk of increase of food allergy potentially caused by consumption of Bt-crops. However this risk is considered to be very small, compared to the risk of eating the corresponding non-modified plants. It is also reasonable to expect that there will be no adverse health effects in animals caused by a putative allergy adjuvant effect from Cry proteins.

Discussion

The delegate from Hungary asked whether there are studies combining different Cry proteins, or combining Cry proteins and mitogens. Dr. Løvik answered that there are no literature data on experiments with such combinations. The potential effects of Cry proteins on mitogens are merely speculative and unpredictable.

Answering to another question from the UK delegate, Dr. Løvik recognised that, in case that the Cry-proteins really had adjuvant effects, it would be expectable that consumers reported symptoms to their medical advisor/hospitals. However, this issue was not considered in the VKM report, as allergic symptoms are normally looked at in predisposed individuals. In addition, it might be difficult to establish a post-market monitoring covering such consumer reports, due to the very large amount of data that would be needed.

The delegate from Germany asked if adjuvants share any common structural properties that can be looked at to predict adjuvant activity through bioinformatic analysis, as it is the case for allergens. Dr Løvik clarified that so far no such structural characteristics have been identified. This issue needs to be further investigated.

b. ENV: MSs ACTIVITIES RELATED TO ERA ON CULTIVATION DOSSIERS

1. ERA of HT crops

The delegate from the UK gave a presentation which highlighted two areas in the ERA where a divergence in approach was possible. One was in the data required for hazard identification (in particular to deal with the potential for unintended effects to occur) and the other was in assessing the potential for adverse effects associated with altered crop management practices. In the case of the latter, this could be sub-divided into two issues: i) the scope of this part of the ERA and ii) the challenge in assessing the potential impacts on biodiversity resulting from altered weed control practices.

With respect to hazard identification, the UK noted the weight of evidence based approach to identifying unintended effects recommended by the EFSA GMO Panel ERA Guidance Document of 2010, which was based on four datasets: i) molecular data, ii) compositional data, iii) agronomic and phenotypic characteristics, and iv) data on GM crop-environment interactions (e.g. *in planta* data). The UK argued for a flexible, case by case approach taking into account existing knowledge rather than an overly prescriptive set of requirements. The UK noted that for some GM HT maize, much information and data to underpin the ERA is already available e.g. on the biology and agronomy of the species, on other GM crops containing HT traits, in addition to event-specific data such as the molecular characterisation. The UK considered the data from the Farm Scale Evaluations (FSE)

adequate to address unanticipated impacts on NTOs. The UK differentiates between two types of unintended effects i.e. those that are unintended but can be predicted and those that can be classified as unknown. The UK's position is that ERAs cannot deal with the latter and pursuing this class of unintended effects is an open-ended activity. UK sought the views of the group on its ERA approach.

The UK delegate reported on the difficulty in assessing the indirect effects on farmland biodiversity associated with the adoption of altered herbicide regimes, due to the different weed control systems which vary spatially and temporally. Farmers adapt their weed management practices depending on parameters such as weather conditions, crop development stage, emergence of specific weeds, crop rotations, etc., and the need to consider all these parameters makes the assessment very complex. To approach to this problem, the UK looks at the potential for harm to occur, i.e. taking the biodiversity value of the crop into account. Data from the FSE and other studies demonstrate that, in general, maize has a low value for biodiversity, so any differences between GM and non-GM based maize systems will have a low impact in absolute terms. This differs from crops such as oilseed rape where the biodiversity value is significantly higher. The UK introduced three different options for dealing with the uncertainty about the use and relative impacts of herbicide regimes (with GM and non-GM maize) on biodiversity over a ten year authorisation period. These were i) requiring more trial data –for this, there is a need to understand the type and level of change to particular parameters, as well as the relevance of the results, given the dynamic nature of farming systems. Moreover, the UK questioned whether these data should be provided before or after authorisation. ii) Mitigating against the hazard (e.g. by introducing management methods that would increase biodiversity). In case of HT maize, the UK highlighted that no evidence of harm has been demonstrated and that it is even feasible that such a maize could improve the biodiversity (as was found by FSE), and iii) collecting more data post-authorisation to determine whether farmers are producing 'cleaner crops' using the GM HT system and acting on the results. In the case of HT GM maize, as the potential for harm is generally low (given the biodiversity of maize), the UK favoured the third option.

The UK delegate concluded that there is an interplay between the risk assessment of the pesticides and of the GM crop and agreed that when making such assessments, efforts should not be duplicated. In addition, she questioned the need to ask for further data, given the low likelihood of harm posed by the GM crop and the proportionality principle for data requirements.

Discussion

After the presentation, the delegates from Belgium and The Netherlands started the discussion. According to their views, direct effects of the herbicide associated to a GM HT crop on weed biodiversity in the field, seeds in the seed bank, and development of herbicide resistance in weeds, are important issues; but should be assessed under the Regulation on plant protection products (PPP), and not under Directive 2001/18/EC, in order to avoid duplication of assessments. On the other hand, the German delegate was of the opinion that this should be addressed under the GMO risk assessment. She also wondered about the consequences of the possible phasing out of some active substances (e.g., glufosinate-ammonium) on the authorisation of the respective HT crops. This concern is not considered by GMO risk assessors.

In response to questions from the delegate from Italy, the presentator clarified that possible adverse effects of the HT maize on soil arthropods were considered by the FSE trials (e.g. detritovores – the numbers of which were affected by the availability of weed biomass); and that the impact of (no-tillage practices on biodiversity was not considered during the ERA as this is not a common practice in UK.

2. ERA of Bt crops

The Spanish delegate presented how the ERA of GMOs -and in particular, insect resistant crops- is performed in Spain. The CA for the ERA is the Ministry of Agriculture, Food and the Environment, assisted by various national and regional agencies and committees. Spain has a huge experience in the

evaluation of dossiers under Part B and Part C of Directive 2001/18/EC. Spain also carried out the initial ERA of four applications for cultivation under Regulation 1829/2003 (e.g. NK603, RX-MON810).

The presentator highlighted Spain's concerns and the weaknesses of the ERA of typical GM crops. General weaknesses are i) the low quality of some of the applications and/or the limited datasets provided, ii) the approach of assessing the single events before the stacked events (time consuming), and iii) the lack of data from field trials representative of different relevant EU receiving environments. For insect resistant crops, Spain is of the opinion that a full range of pests should be considered by the applicant, rather than only the European corn borer and the Mediterranean corn borer. This opinion is generally further supported by MS commenting on applications. For HT crops, Spain believes that the possible evolution of weed resistance due to a particular herbicide use is an indirect effect. In case of stacked transformation events, Spain would expect more data from field studies carried out with the stacked events themselves. With respect to case-specific monitoring (CSM), regionally important Lepidopteran pests other than the European corn borer and the Mediterranean corn borer should also be considered. Furthermore, outbreaks of secondary pests should also be considered under CSM. Talking about general surveillance (GS), the presentator questioned the usefulness of the farmer questionnaires for collecting data on unanticipated effects of the GM crop on biodiversity (fauna/flora). Existing surveillance networks might also not be the best tools for GS of GM crops as they are not specific enough.

The Spanish delegate summarised the ERA of the application for marketing renewal of maize MON810 for all uses, including cultivation. Spain raised the difficulty to receive from the applicant a complete data set. Spain concluded its ERA with a favourable advise subject to the following recommendations: i) the insect resistance management (IRM) plan should be continued, ii) other regionally important Lepidopteran pests to be considered in the IRM plan, and iii) preliminary agreements between the applicant and relevant stakeholders/operators for a proper PMEM plan should be established.

Discussion

A discussion started on the usefulness of GS to detect unanticipated effects. EFSA recalled that there is an ongoing debate on PMEM, and in particular, on GS. Recently, the European Commission organised a workshop with relevant stakeholders to discuss the implementation and the limitations of GS. Concerning the PMEM of maize MON 810, Spain recommends that the IRM is continued, whereas the monitoring of NTO (including soil organisms), which was part of the initial 1998 authorisation, is no longer considered necessary.

The German delegate shared the Spanish concern about the completeness of the dataset provided for a stacked transformation event, as well as the poor quality of the data (e.g. low tier studies on NTO with bacterial protein only). Conversely, the Dutch delegate did not support the need for a full dataset on a stacked event unless interactions between the single events are expected. Furthermore, in The Netherlands, the emergence of secondary pests is not considered an environmental harm but rather an agronomic effect that could be handled by common pest management practices.

As regards the issue of interactions between each individual event, a member of the EFSA GMO Panel mentioned that the absence of interactions at the DNA and/or protein level does not rule out possible interactions at the biotic/environmental level. For example, the weed management systems (e.g. herbicide use) associated to an HT maize event stacked with a Lepidoptera-resistant maize event will have an impact on the host-plant density within the field and hence the level of exposure of sensitive non-target Lepidoptera to Bt maize pollen deposited on their host-plants/weeds[4]. Against this

[4] For further details, please consult http://www.efsa.europa.eu/en/efsajournal/pub/2429.htm

background, the GMO Panel is waiting for further data on the stacked GM maize for a comprehensive ERA on NT Lepidoptera.

3. ERA of HT x Bt crops

The Belgian delegate gave a presentation which was structured according to the following questions: i) why to carry out the initial ERA of GMO applications for cultivation? ii) How is the ERA conducted? iii) What are the challenges? iv) Are there specific issues for crops combining IR and HT traits?

i) Belgium volunteered for the evaluation of ERAs in order to keep and to strengthen its scientific expertise in ERA. In particular, Belgium is involved in the evaluation of the ERA of applications for GMO cultivation 30, 54, 71 and 90 currently in the pipeline.

ii) The SBB (Biosafety and Biotechnology Unit) plays a major role in the evaluation of the ERA of GMO applications and works in close collaboration with external experts. The SBB performs a first evaluation of the ERA, identifies its weaker points and poses specific scientific questions to the experts in order to make optimal use of their expertise. Belgium starts with the ERA and concludes with the PMEM, with the exception of the evaluation of the possible evolution of resistance in target pests and the IRM plan, that is considered in parallel. Belgium mostly focuses its evaluation on new studies, that are studies that have not been evaluated before in the context of a food/feed application on the same event. To conduct the ERA, a full set of data is compiled, including a regular search for peer-reviewed publications which were not provided in the initial application. In addition, Belgium screens the comments from MS in order to identify relevant concerns for the ERA.

iii) A challenge experienced by Belgium is how to consider and reflect in its initial ERA evaluation certain concerns expressed by other MS. It is generally difficult to figure out the protection goals of a specific MS, and hence the desired assessment endpoints (e.g. weed biodiversity). In addition, there are some hurdles in the current evaluation procedure, such as the time consuming mechanism of questions and answers, and the pre-requisite for assessing the single events before a stacked event. For the latter issue, and considering that the initial ERA evaluation of applications on single and stacked events is performed by different MS, Belgium experienced that it is better to wait for the EFSA opinions on the single events (and lower stacks), before commencing the evaluation of the stack. This avoids duplication of the work done by other leading countries. Another challenge mentioned for the evaluation of the ERAs of stacked events was the extremely long timeframes for the ERA evaluations. The presentator noted that requesting separate applications for the single events has an impact on the workload. When applications last for years it is also a challenge to ensure the continuity of the ERA evaluation by the same experts.

iv) In case of applications for GM crops combining IR and HT traits, which ERA is under evaluation by Belgium and are finalised or almost finalised, no scientific questions were identified so far different from those identified for crops containing IR or HT traits only.

Discussion

The audience briefly discussed the high variability of protection goals across the EU and the difficulty to define and consider all appropriate assessment endpoints for all MS, even though the ERA is EU-wide. The Belgian delegate noted that MS do not generally state clearly what they consider being an environmental harm in their comments on an application. Further expertise would be needed to address all points raised by the various MS.

The Dutch delegate considered that is not the task of the leading MS to cover all national protection goals within the EU MS, but this is the task of EFSA. She also stated that the data requirements for the ERA of GMOs have increased over the past years, have become quite detailed, and the context of agriculture seems to have been lost. The ERA of GM crops should be put more into the context of agriculture and agro-ecosystems in general (e.g. impacts of weed control systems such as herbicide use, impact on biodiversity).

With respect to the pre-requisite of assessing the single events prior to the assessment of the stacked event, the Belgian delegate asked for a scientific rationale for this approach. Some reasons were put forward supporting a stepwise approach: i) the initial ERA of the single and stacked events are not always carried out by the same leading MS, ii) the ERA of the stack should focus on possible interactions between the single events, and iii) the European Commission requires that the scientific opinion on the stacked event covers all sub-combinations (in cases when maize seed lots containing all sub-combinations would enter the EU). Finally, EFSA raised the question of the feasibility to conclude on the safety of the single events by extrapolating from the ERA of the highest stacked combination. This needs further discussion.

11. RISK ASSESSMENT OF GM MICROORGANISMS

1. Introduction to the EFSA GMM GD

EFSA introduced to the Network the Guidance on the risk assessment of GMMs and their products intended for food and feed use, published in 2011. The Guidance was an update of the former document from 2006, triggered by a self-task from the GMO Panel after the experience gained from assessing applications, and the input received from different parties. There are several types of food/feed products that can be obtained involving GMMs. The Guidance fully covers the assessment of products consisting, containing or made from GMMs, that fall under Regulation (EC) No 1829/2003. For products falling under other legislations (e.g. feed additives, food enzymes), the Guidance covers the assessment of the GMM and the safety aspects that the genetic modification of the production strain could exert in the final product. For safety issues of such products themselves, cross-references to other existing guidance or guidelines are provided.

According to their nature, GMMs are divided in four different categories. This categorisation marks the strategy to be followed in the risk assessment, the criteria to be applied, and the extent of the scientific information to be provided in applications. This information can be divided in three main blocks: i) information necessary for a full characterisation of the GMM, with emphasis in the molecular characterisation of the genetic modification and its potential effects in terms of toxicity, pathogenicity and antibiotic resistance of the GMM, among other factors; ii) information on the production and purification process, paying special attention to the validity and effectiveness of the methods used to kill or remove the production strain, and to the possible presence of GMMs and their recombinant genes in the final product; iii) information on the safety of the product itself (composition, toxicity, allergenicity, nutritional properties, potential environmental impact). For this, the comparative approach is used, and guidance is provided for the selection of adequate comparators for the GMM itself and/or for the product thereof. With respect to environmental considerations, the criteria to be applied depend on the category of the assessed product, with the deepest scrutiny for products consisting of or containing GMMs. In this case, it will be necessary to consider the ability of the GMM to proliferate in the receiving environments, its potential adverse effects in the ecosystem, and the consequences of a potential horizontal gene transfer of the recombinant genes to indigenous organisms.

2. Input from MSs towards a future update

The Danish delegate started the discussion by asking whether classical strain mutagenesis was covered in the guidance. This aspect is indeed not covered, given that, according to the GM food legislation, mutagenesis is not considered as genetic modification. However, as the RA of the product covers its potential toxicity and pathogenicity, possible effects of mutagenesis, if applied in addition to genetic modification, are expected to be detected.

Triggered by the delegate from Finland, some discussion took place on the quality standards of the laboratories that produce data for the applications. The GMM Guidance stipulates that Good Laboratory Practice principles should be followed. Applicants normally use them and the submitted data is usually accompanied by quality assurance documents.

The Irish delegate stated that some operators are reluctant to apply for market permits of GMMs carrying antibiotic resistance (AR) genes as selectable markers, and asked how this issue was addressed in the GMM Guidance. EFSA clarified that in this case, there is a need to check whether the GMM and the AR gene are no longer present in the final product. In cases when the AR gene has been removed from the production strain, this will need to be demonstrated experimentally. This also applies for all the AR genes that could have been used in previous genetic modifications of the strain.

Sampling was another point of discussion. The Finnish delegate asked how reliable sampling could be assessed. EFSA recognised the difficulty of this issue. Unlike for seeds, there are no sampling standards (like ISO) currently in place for industrial fermentations. To take into account the possible heterogeneity of a product, the Guidance proposes to analyse a minimum of 3 analytical samples, each obtained by pooling at least 10 sub-samples from the same batch. Alternative sampling strategies are accepted, as soon as their reliability is documented. However, this will be difficult to assess.

Answering to a Dutch delegate, EFSA clarified that, as microbial strains obtained through self-cloning are still considered GMMs as defined in Directive 2001/18/EC, its assessment will follow the same principles as that of any other GMM. Nevertheless, the RA is done on a case-by-case basis so, the experts can always consider the particularities of self-cloned GMMs.

Another delegate from the Netherlands noted that it is not possible, for products obtained at industrial scale, to ensure absolute absence of viable production cells or genes. EFSA agreed on this issue, as the sampling and detection methods have their limits. Independently of the requirement by the Guidance to provide the limits of detection of the applied methods, the Dutch delegate suggested that the possibility of remaining GMMs or recombinant genes in the product should be taken into account in the risk assessment. Indeed, this is considered by EFSA when making the assessment, although not covered by the Guidance. EFSA took this proposal as a good input for a future update of the document. The delegate from Latvia pointed out that another -possibly unavoidable- way of environmental release of GMMs is at the fermentation phase, where GMMs can accidentally escape from the production facility. EFSA clarified that this aspect is considered in the contained use of GMMs, which is covered by other legislation. Therefore, contained use is out of the scope of the GMM GD.

As a concluding remark, EFSA mentioned the toxicological assessment as another difficult point for products that contain GMMs, such as wine, beer and yogurt. How to conduct such assessment remains an open question, as animal studies may not be applicable for those cases. Another added difficulty is that adequate comparators for certain products may not exist. Further discussion is needed with the view of a possible future update of the Guidance.

12. EXPERIENCES AFTER 2.5 YEARS OF EFSA NETWORK OF RISK ASSESSMENT OF GMOS AND FUTURE PROSPECTS

1. Progress on comments to applications

EFSA reviewed the main achievements made so far by the Network from its establishment in 2010. Discussions in Network meetings have been of a high level, and the Network has received positive comments from the EC Standing Committee on Food Chain and Animal Health (SCFCAH). Several issues recurrently expressed by MS in their comments to applications have been discussed. Such discussions have been very useful to EFSA for the preparation of recent guidance documents. Furthermore, EFSA noted that the comments from MS to recent applications are in line with those guidance and with the outcome of past discussions within the Network. EFSA acknowledged that some MS also indicated in their comments when the provided data are sufficient for the risk assessment. EFSA also endeavours to explain the rationale of answers to relevant MS comments and communicate them to risk managers.

2. Future scientific activities of the Network

EFSA reminded the audience of the Terms of Reference of the Network, that may be adjusted to upcoming needs. The mandate of the Network finalises in 2012 and both the nomination of national institutions and appointed experts will need to be renewed. EFSA encouraged a proactive involvement from the members in the agenda of the Network and their further active participation in meetings. The dedicated EFSA Extranet space for discussions within the Network is open for the members to be used. EFSA asked the participants for their opinions on the functioning of the networks and their proposals for future activities of the Network.

The possibility of splitting the Network in two (one dedicated to FF aspects and the other to ENV) was put on the table. Several delegates (from Belgium, UK, Denmark, The Netherlands, Czech Republic, Slovenia, Hungary, Poland, and Ireland) expressed their views. Comments were raised on the quality of the discussions and the complexity of the issues addressed, which needed input from different expertise. Therefore, there was a general agreement that the current model of one Network is the best; however, more breakout sessions could be organised. Some delegates were also of the opinion that the agenda should cover less topics but let more time for discussion on each agenda point. Particularly, during the current meeting, the breakout session on ENV was not long enough and fruitful discussions had to be shortened. There was also an agreement on the current format of the meetings (2 half-days, PM and AM, respectively), although it was proposed to start the first day earlier, if permitted by the arrival schedule of the participants. Inviting external speakers was also appreciated.

The Belgian delegate raised the need to better define the remit of the Network, as there are overlaps with other fora for MS (e.g. MEACB), the European Commission (e.g. Working Group on PMEM) and EFSA (e.g. MS consultations on a GD). EFSA, though recognising that several Network delegates are also attending the SCFCAH, tries to keep the Network agenda purely focused on scientific issues and away of discussions of political or other nature.

A member of the GMO Panel, after commenting on the success of the meetings, acknowledged that there are still some differences in opinions, and proposed to identify the controversial issues and organise targeted sessions between regular meetings, a viewpoint that was shared by an Italian delegate. A delegate from Austria suggested, for this purpose, to organise online discussion meetings on an ad-hoc basis, as the Extranet space for discussions may not be efficient enough.

13. ANY OTHER BUSINESS

EFSA gave notice to the Network on the following initiatives in which MS could be interested, asking delegates to spread these through their possibly interested contacts: i) next EFSA public consultation on GM animals ERA, ii) NEPT and SNE positions at EFSA open for MS experts to work at EFSA, iii) EFSA expert database, open for MS experts to work with the GMO Panel, iv) possible future calls for ERA on cultivation files to be performed by volunteer MS, and v) call for participation in open procurements and grants.

At the instances from the UK delegate, EFSA announced that the first meeting of the EFSA GMO Panel on its new mandate will take place on 4-5 July, 2012. The names of the Panel members will be made public by the end of June.

CLOSING OF THE MEETING

The Chair thanked all participants for their attendance and constructive discussion and closed the meeting.

APPENDIX 1 - LIST OF PARTICIPANTS

Appointed experts of EU Member States and other EU countries

	LAST NAME	NAME	COUNTRY CODE	AREA OF EXPERTISE
1	Arar	Chantal	FR	**FF**
2	Ball	Louise	UK	**ERA**
3	Bardocz	Zsuzsanna	HU	**ERA**
4	Batic	Martin	SI	**ERA**
5	Cattivelli	Luigi	IT	**ERA**
6	Cuadrado	Carmen	ES	**FF**
7	Dabrowski	Zbigniew	PL	**ERA**
8	De Schrijver	Adinda	BE	**ERA**
9	Djilianov	Dimitar	BG	**ERA**
10	Falk	Anders	SE	**FF**
11	Finne	Merethe Aasmo	NO	**ERA**
12	Georgieva	Tzveta	BG	**FF**
13	Glandorf	Boet	NL	**ERA**
14	Golstein	Catherine	FR	**ERA**
15	Heissenberger	Andreas	AT	**ERA**
16	Jenes	Barnabas	HU	**FF**
17	Jurgelevicius	Vaclovas	LT	**FF**
18	Karavangeli	Margarita	GR	**FF**
19	Kjellsson	Gösta	DK	**ERA**
20	Lawrie	Sandy	UK	**FF**
21	Mäe	Andres	EE	**ERA**
22	Mcloughlin	Thomas	IE	**ERA**
23	Mikalsen	Arne	NO	**FF**
24	Muiznieks	Indrikis	LV	**FF**
25	Navratilova	Miloslava	CZ	**ERA**
26	Nyman	Marie	SE	**ERA**
27	O"Mahony	Patrick	IE	**FF**
28	Onori	Roberta	IT	**FF**
29	Ortego	Félix	ES	**ERA**
30	Ovesna	Jaroslava	CZ	**FF**
31	Pedersen	Jan W.	DK	**FF**
32	Peltonen	Kimmo	FI	**FF**
33	Pivoriene	Odeta	LT	**ERA**
34	Scheepers	Andrea	DE	**FF**
35	Sowa	Slawomir	PL	**FF**
36	Tappeser	Beatrix	DE	**ERA**
37	Törmäkangas	Kirsi	FI	**ERA**
38	Van Leeuwe - Kok	Esther	NL	**FF**
39	Woegerbauer	Markus	AT	**FF**
40	Zammit	Flavia	MT	**FF**
41	Zupancic	Alenka	SI	**FF**

Apologies: Philip Herman (BE)

Observers from of Candidate Countries

1	Misja	Edi	AL	
2	Vidovic	Miroslav	BA	
3	Milos	Sanja	HR	
4	Popovska	Suzana	MK	

5	Bucan	Ervin	ME	
6	Kojic	Vanja	RS	
7	Krasniqi	Naser	XK	
8	Sari	Ali Osman	TR	
Observers from the European Commission				
1	Kantorska	Kaja	DGSANCO	

Invited Experts			
1	Epstein	Michelle	Invited speaker *(Medical University of Vienna, Austria*)
2	Kärenlampi	Sirpa	GMO Panel
3	Kleter	Gijs	GMO Panel
4	Kuiper	Harry	GMO Panel
5	Løvik	Martinus	Invited speaker *(Norwegian Institute of Public Health, Norway*)
6	Perry	Joe	GMO Panel
EFSA			
1	Aguilera	Jaime	GMO Unit
2	Christodoulidou	Anna	GMO Unit
3	Devos	Yann	GMO Unit
4	Fernandez Dumont	Antonio	GMO Unit
5	Gennaro	Andrea	GMO Unit
6	Germini	Andrea	GMO Unit
7	Gomes	Ana	GMO Unit
8	Lheureux	Karine	APDESK Unit
9	Liu	Yi	GMO Unit
10	Mestdagh	Sylvie	GMO Unit
11	Olaru	Irina	GMO Unit
12	Paoletti	Claudia	GMO Unit
13	Waigmann	Elisabeth	GMO Unit

LIST OF ABBREVIATIONS USED

Bt : *Bacillus thuringiensis*
EC : European Commission
EFSA : European Food Safety Authority
ENV : Environment
ERA : Environmental Risk Assessment
ERA GD : Environmental Risk Assessment Guidance Document on GM plants for Applicants
EU : European Union
FF : Food and Feed
GM : Genetically Modified
GMM : Genetically Modified Microorganism
GMO : Genetically Modified Organism
HT : Herbicide-Tolerant
MEACB : Meeting of European Advisory Committees on Biosafety
NTO : Non-Target Organism
NEPT : National Expert in Professional Training
MC : Molecular Characterisation
MS : Member States
OECD : Organisation for Economic Co-operation and Development
RA : Risk Assessment
RM : Risk Management
SNE : Seconded National Expert