European Food Safety Authority

**GMO UNIT**

EFSA/GMO/503

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# BILATERAL TECHNICAL MEETING BETWEEN MEMBERS OF THE EFSA PANEL ON GENETICALLY MODIFIED ORGANISMS AND AUSTRIAN DELEGATION

## AUSTRIAN SAFEGUARD CLAUSE ON GM MAIZE MON863

## Agreed meeting report of the meeting on 23 April 2009

***The below report does reflect the common understanding of EFSA and the Austrian delegation 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.***

**Participants**

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| Austrian delegation: | Andreas Heissenberger | Umweltbundesamt GmbH |
| | Veronika Kolar | Österreichische Agentur für Gesundheit und Ernährungssicherheit |
| | Kathrin Pascher | Universität Wien, Fakultätszentrum Biodiversität |
| | Eva Claudia Lang | Bundesministerium für Gesundheit |
| | Helmut Reiner | Pflanze-Lebensmittel-Qualität |
| | Armin Spök | Interuniversitäres Forschungszentrum für Technik, Arbeit und Kultur |
| | Walter Stepanek | Österreichische Agentur für Gesundheit und Ernährungssicherheit |
| | Markus Wögerbauer | Österreichische Agentur für Gesundheit und Ernährungssicherheit |
| EFSA GMO Panel: | Detlef Bartsch, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Joe Perry | |
| EFSA GMO Unit: | Jaime Aguilera, Per Bergman (Chair), Yann Devos, Yi Liu, Sylvie Mestdagh, Elisabeth Waigmann (co-Chair) | |
| European Commission: | Bernadette Murray (DG ENV) | |

*In the course of a one day bilateral technical meeting between EFSA GMO Panel experts and Austrian experts, issues related to safeguard clauses invoked by Austria for MON863, GT73 and Ms8/Rf3 were discussed. This meeting report focuses on issues related to MON863, but also includes topics of discussion common to all three safeguard clauses. The discussion on aspects related specifically to oilseed rapes GT73 and Ms8/Rf3 can be found in the EFSA meeting report published in connection with the respective safeguard clauses on the EFSA webpage.*

## 1. WELCOME

The Head of the EFSA GMO Unit chaired the meeting and welcomed the Austrian delegation, members of the GMO Panel of the European Food Safety Authority (EFSA) and an observer from the European Commission. The Chair announced that during the afternoon he will be replaced by the deputy Head of the GMO Unit.

The Chair clarified the aim of the bilateral meeting which is to listen to arguments of Austria and to obtain clarifications on scientific issues addressed in the Austrian reports supporting their national safeguard clauses on maize MON863 and oilseed rapes GT73 and Ms8/Rf3. The agenda of the meeting was agreed on by EFSA and Austria during communication prior to the meeting. The Chair briefly went through the agreed agenda of the meeting by pointing out how the meeting will be structured and how the Austrian delegation will be given the opportunity to present its argumentation. The Chair underlined the importance to adhere to the timing of this one day meeting as set in the agreed agenda.

It was clarified that the EFSA GMO Panel will issue a scientific opinion based on the evidence provided by Austria as part of the formal mandates from the European Commission to the EFSA, and the clarifying discussions in this meeting.

## 2. TOUR DE TABLE

Participants introduced themselves during a tour de table.

## 3. HISTORICAL, LEGAL AND PRACTICAL ASPECTS RELATED TO THE AUSTRIAN SAFEGUARD CLAUSES

The representative from the European Commission (EC, Directorate-General on Environment (DG ENV)) recalled the historical and legal background of the three Austrian safeguard clauses under discussion. She explained that the three Austrian national measures were subject to respective requests from the European Commission, directed to EFSA, to provide a scientific opinion based on the documents submitted by Austria. In order to reinforce the scientific co-operation with national institutions, and in order to ensure a more effective mode of collaboration on scientific issues, EFSA was also invited "*to contact Austrian experts to clarify all the requested information and potential sources of divergences before adopting the EFSA GMO Panel scientific opinion*".

It was recalled that the deadline to adopt a scientific opinion had been extended until 15th of June 2009.

## 4. INTRODUCTION TO THE TECHNICAL DISCUSSION

Having referred to the current situation on import and cultivation of GM crops in Europe and to related Austrian initiatives, the Austrian delegation clarified its position, and the arguments relating to

the use and safety of maize MON863 and oilseed rapes GT73 and Ms8/Rf3 were introduced. It was explained that the Austrian safeguard clauses are based on numerous uncertainties which trigger the application of the precautionary principle.

The Austrian delegation was of the opinion that each uncertainty should be better addressed in the current GM plant market authorisation dossiers. A state of the art risk assessment should be followed by applicants in the preparation of their dossiers. Uncertainties should be quantified and must be minimized by undertaking additional studies.

The Austrian delegation appreciated the possibility of an interactive exchange with the EFSA GMO Panel in order to identify diverging but also similar views.

## 5. PRESENTATION AND TECHNICAL DISCUSSION ON MOLECULAR CHARACTERISATION

An Austrian delegate initiated the session by giving a presentation on the main Austrian points with respect to the presence of the antibiotic resistance gene *npt*II in maize MON863. The therapeutic relevance of kanamycin and neomycin, the two antibiotics against which the gene product of *npt*II confers resistance, was highlighted. These two antibiotics were in 2005 classified by the World Health Organisation (WHO) as "*critically important*", as they fulfilled two proposed selection criteria: 1) sole therapy or one of few alternatives to treat serious human disease; and 2) antibacterial used to treat diseases caused by organisms that may be transmitted via non-human sources or diseases causes by organisms that may acquire resistance genes from non-human sources. Further in 2007, EMEA[1] stated that these two antibiotics are of importance for veterinary and human use and that minor use does not mean minor therapeutic relevance.

Next, the Austrian delegate presented updated information (not included in the safeguard clause according to which kanamycin and neomycin are of minor relevance in human therapeutic applications and veterinary medicine; Table on p. 33 in: Austrian Scientific Arguments – Import Ban Maize MON863[2]) about uses of kanamycin and neomycin in Austria. Several preparations containing these antibiotics are currently commercialised. Kanamycin is not licensed for human therapy in Austria. In animals, kanamycin is used for treatment of infections in a broad range of animals, cow mastitis being the main indication. Neomycin is licensed for both humans (topical uses) and animals.

With respect to the prevalence of resistance to these antibiotics in natural bacterial populations, the Austrian delegate presented recent studies[3] (not included in the safeguard clause data package; presentation transmitted to EFSA after the bilateral meeting) on reference pathogenic strains, which were referred to as being representative of the general situation in Austria. Results indicated that 0.74% of the infections caused by *Salmonella* were resistant to kanamycin, whereas about 2% of the infections caused by *Campylobacter* were resistant to neomycin. The Austrian delegate noted that these are very low levels of resistance, and hence, any additional inputs in aminoglycoside resistance due to the potential transfer of the *npt*II gene are undesirable.

With respect to the frequency of gene transfer from GM plants to bacteria, the Austrian delegate gave two examples of very rare events that have a substantial impact. First, the Austrian delegate talked about multidrug resistant (MDR) tuberculosis. Strains conferring tuberculosis are considered MDR

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[1] EMEA (2007) Presence of the antibiotic resistance marker gene nptII in GM plants for food and feed uses. EMEA/CVMP/56937/2007

[2] Austrian Scientific Arguments – Import Ban Maize MON863.pdf, 2008, http://registerofquestions.efsa.europa.eu; http://www.bmgfj.gv.at/cms/site/attachments/8/3/3/CH0817/CMS1216370866299/austrian_scientific_arguments_-_import_ban_maize_mon_863.pdf

[3] http://www.bmgfj.gv.at/cms/site/attachments/4/6/2/CH0954/CMS1237532383420/jb_salmonellen_2008.pdf; Much P *et al.* Überwachung ausgewählter Zoonosen und Antibiotikaresistenzen in Österreich, Vet-AURES 2007

when they are resistant to isoniazid and rifampicin, a combined resistance that has a probability of occurrence of $10^{-16}$ per cell. If in addition, bacteria are also resistant to amikacin and ciprofloxacin (probability of $10^{-38}$ per cell), they are considered extensively multidrug resistant (XMR). Even though the likelihood of occurrence is low, treatments of diseases caused by MDR bacteria in USA cost in 2007 $240000 per patient, while treatments of diseases caused by XDR bacteria cost $483000 per patient from 1997 to 2007. In a second example, the Austrian delegate spoke about rapid clonal spread of resistant bacteria, presenting data of MRD infections by *S. pyogenes* in Portugal, Brazil and Finland, were it was found that 88% of the resistant bacteria causing infections came from one single clone. The Austrian delegate concluded that kanamycin and neomycin are relevant antimicrobials in animal and human therapy of infectious diseases in Austria (and worldwide); background resistance levels to kanamycin and neomycin are usually low in Austria; Directive 2001/18/EC contains a legal requirement to phase out ARM genes; rare events may not be easily detectable by current methodology but may rapidly overtake whole bacterial populations under suitable environmental conditions. Hence, rare events must not be confused with the absence of important environmental effects. The Austrian delegate concluded his presentation by stating that currently only about 1% of the bacterial strains present in the soil can be cultured. Considering the range of possible hosts and diverse methods of transfer, there is a lack of knowledge on gene transfer. Hence, and in view of the dramatic crisis caused by increasing antibiotic resistance occurring nowadays, the application of the precautionary principle is necessary.

An expert from the EFSA GMO Panel thanked the Austrian delegation for the presentation and the updated data on the use of aminoglycosides and bacterial resistance in Austria. With respect to the WHO classification of antibiotics, it was pointed out that in a more recent report (2007) these antibiotics were downscaled from "*critically important*" to "*highly important*" because they no longer were considered to comply with criterion 1. On the subject of MDR tuberculosis, it was commented that this infection is caused by *Mycobacterium tuberculosis*, a species in which resistance to aminoglycosides is caused by a mutation and not by the presence of an acquired *npt*II gene. The EFSA GMO Panel expert agreed that >99% of the existing bacteria are not culturable, but recent metagenomic studies (allowing the examination of total bacterial populations) showed that kanamycin/neomycin resistance genes were found in all samples analysed. Moreover, recently the first long-term (10 years) study on the prevalence of an antibiotic resistance gene in GM and non-GM fields was published by Demanèche *et al.* (2008)[4]. No difference was found in the frequency of the antibiotic resistance gene in bacterial populations sampled in the fields of GM and non-GM crops. However, much higher prevalence was found in pristine fields than in the crop fields. Although the gene in question conferred resistance to ampicillin and not aminoglycosides, the results of the study are also relevant in the context of the *npt*II gene in GT plants. Finally, also the EFSA GMO Panel expert agreed that alternatives to the use of *npt*II as marker gene for GM plant technology exist and are welcomed and appreciated.

An EFSA GMO Panel expert noted that the percentages of resistance to kanamycin and neomycin in bacterial infections in Austria should not be considered low. 1% of resistance in human foodborne pathogenic bacteria could be considered high.

The Austrian expert acknowledged the metagenomic studies pointing out however, that no conclusions on the functionality of the antibiotic resistance genes can be drawn, since those studies do not include analyses of RNA levels. In addition, other reports are available showing lower levels of *npt*II presence in bacteria. On the other hand, transfer of the whole *npt*II gene from a GM plant to bacteria is just one possible input for augmenting antibiotic resistance. The transfer of only a part of the antibiotic resistance gene may be sufficient to confer resistance in bacteria, if that part has suffered a mutation

[4] Demanèche S, Sanguin H, Poté J, Navarro E, Bernillon D, Mavingui P, Wildi W, Vogel TM, Simonet P (2008) Antibiotic-resistant soil bacteria in transgenic plant fields. *Proceedings of the National Academy of Sciences of the United States of America*, 105: 3957-3962

(in the plant or in the bacteria), as suggested by some studies.

The EFSA GMO Panel expert agreed upon the lack of RNA data in metagenomic studies. However, the functionality of the antibiotic resistance genes is demonstrated in these studies. Moreover, the genetic determinants were sequenced and, based on the deduced amino acid sequence, their resistance mechanism could be identified. It was also mentioned that possible mutations of *npt*II in the plant are assessed in the dossiers supporting each transgenic event since the complete sequence introduced into the plants has to be provided.

An EFSA GMO Panel expert stressed that the evolution of antibiotic resistance in bacteria is not questioned but probabilities and frequencies encountered in this evolutionary process are not applicable to the potential gene transfer from plants to bacteria, which would be a totally different process. Transfer of genes from plants to bacteria would occur, if at all, differently and with a very low frequency compared to that between bacteria. The EFSA GMO Panel expert further noted that there is a fundamental difference between an event that has never been found and one found in low frequencies. Gene transfer from plants to bacteria has never been observed. The only statistical frequency estimate possible for a probability of a phenomenon that has never been demonstrated is 0. Hence, the probability of occurrence must be considered either to be 0 or to be below the reciprocal of the number of events tested. The EFSA GMO Panel expert stressed that a statement that the probability is *below* that reciprocal value is very different from a statement that the probability is *equal* to it.

A member of the Austrian delegation replied that such gene transfer has been observed in artificial conditions in the laboratory, and that no methods for studying this phenomenon in the field are available.

An EFSA GMO Panel expert highlighted that those laboratory studies should be considered cautiously, because in these studies conditions are optimized to force the occurrence of the gene transfer. Sequence homology is a condition always required for the transfer to occur.

The Chair concluded the discussion on *npt*II gene in maize MON863.

## 6. PRESENTATION AND TECHNICAL DISCUSSION ON FOOD/FEED ISSUES

A presentation with the title "*Assessment of toxic and allergenic properties in rape Ms8xRf3, GT73, and maize MON863*" was given by one of the Austrian delegates. His presentation listed a number of criticisms related to the toxicity and allergenicity assessment conducted by the applicant. According to the Austrian criticisms, the toxicity and allergenicity risk assessment approach would not allow for a robust assessment as required by Directive 2001/18/EC, because, in the Austrian delegate's view, it focuses on novel proteins only and does not include whole food allergenicity studies. The comparative approach alone would not be sufficient, especially because, in the delegate's view, statistically significant differences are not interpreted as indicators for possible pleiotropic effects and because maize allergens are not included in the compositional analysis. With respect to the assessment of the novel protein, the delegate stated that, in his view, the assessment is based on indirect approaches only. An acute toxicity study does not reflect real-world exposure. The Austrian delegation then presented a summary of suggestions including: the need for more detailed guidance on procedures and limitations of *in vitro* studies; homology studies; and on the type of evidence that would allow claiming a history of safe use/consumption. The indirect evidence should be complemented by repeated dose toxicity studies of the protein and a comparative assessment of the allergenic properties of the extracts from the GM and the wild type crop. The Austrian delegate subsequently showed and discussed two tables summarizing the information relevant to toxicological and allergenicity assessment provided in the maize MON863 dossier. He then commented in detail on the limitations and drawbacks of the following types of evidence approaches and test protocols used in the toxicity testing, including the history of safe use/consumption; amino acid sequence homology

comparisons; *in vitro* digestibility studies; acute animal toxicity studies; test protein analogues purified from microorganisms; and risk characterization. Comments specifically referring to allergenicity assessment include *in vitro* digestibility studies; amino acid sequence homology comparisons; glycosylation; exposure route and sensitization scenarios considered; and the absence of whole plant testing. The delegate thereby frequently referred to statements of the European Commission supporting his view (e.g., the need for whole plant testing, source of test protein, history of safe use/consumption) published by the WTO (2006)[5].

Another member of the Austrian delegation presented a thorough description of the dairy cattle study (Grant *et al.*, 2003)[6], poultry study (Taylor *et al.*, 2003)[7], swine study (Hyun *et al.*, 2005)[8], and cattle study (van der Pol *et al.*, 2005)[9]. The Austrian delegate was of the opinion that the duration of the tests was generally too short, that insufficient compositional parameters (including mycotoxins and identity of GM crops) were provided for the diets, and that there are difficulties to compare USA studies to European studies. In addition, crops used as dietary reference substances displayed a broad genetic variation; this and the potential relevance of non-significant effects would not allow for the authors' conclusions on the nutritional equivalence of the feed containing GM crops. The Austrian delegate also questioned the usefulness of studies where antibiotics as growth promoter and meat and bone meal were included into the animal diets, whilst these have been banned in the European Union. An immunological study by an Italian team (Finamore *et al.*, 2008)[10] should be considered, as well as reproductive studies (long-term effects). The importance of Multiple Generation Studies was underscored. In the Austrian delegate's view, the "*Additives and products or substances used in animal feed (FEEDAP) Guidance*" should be followed to conduct animal tests. Toxicological studies should be performed according to OECD Guidance. In addition, long-term reproduction studies should be done to assess possible consequences in the offspring.

An EFSA GMO Panel expert asked why the scientific underpinning of the Austrian safeguard clauses focused on what the Austrians considered to be shortcomings of the article by Hammond *et al.* (2006)[11] and some other cited studies because these studies had been published after the scientific EFSA opinion on maize MON863 was published in 2004. He also asked if there was any evidence of hazards or risks identified in the scientific underpinning provided by Austria. Members of the Austrian

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[5] WTO (2006) European Communities: Measures affecting the approval and marketing of biotech products (DS291, DS292 and DS293) Report of the Panel; ANNEX I4. (Comments by the European Communities on the replies by the scientific experts to the questions posed by the Panel. 28 JANUARY 2005, WT/DS291/R/Add.7, WT/DS292/R/Add.7, WT/DS293/R/Add.7); 29th September 2006, http://www.wto.org/english/tratop_e/dispu_e/291r_i4_e.pdf

[6] Grant RJ, Fanning KC, Kleinschmit D, Stanisiewski EP, Hartnell GF (2003) Influence of glyphosate-tolerant (event nk603) and corn rootworm protected (event MON863) corn silage and grain on feed consumption and milk production in Holstein cattle. *Journal of Dairy Science*, 86: 1707-1715

[7] Taylor ML, Hyun Y, Hartnell GF, Riordan SG, Nemeth MA, Karunanandaa K, George B, Astwood JD (2003) Comparison of broiler performance when fed diets containing grain from YieldGard Rootworm (MON863), YieldGard Plus (MON810 x MON863), nontransgenic control, or commercial reference corn hybrids. *Poultry Science*, 82: 1948-1956

[8] Hyun Y, Bressner GE, Fischer RL, Miller PS, Ellis M, Peterson BA, Stanisiewski EP, Hartnell GF (2005) Performance of growing-finishing pigs fed diets containing YieldGard Rootworm corn (MON 863), a nontransgenic genetically similar corn, or conventional corn hybrids. *Journal of Animal Science*, 83: 1581-1590

[9] Van der Pol KJV, Erickson GE, Robbins ND, Berger LL, Wilson CB, Klopfenstein TJ, Stanisiewski EP, Hartnell GF (2005) Effects of grazing residues or feeding corn from a corn rootworm-protected hybrid (MON 863) compared with reference hybrids on animal performance and carcass characteristics. *Journal of Animal Science*, 83: 2826-2834

[10] Finamore A, Roselli M, Britti S, Monastra G, Ambra R, Turrini A, Mengheri E (2008) Intestinal and peripheral immune response to MON810 maize ingestion in weaning and old mice. *Journal of Agricultural and Food Chemistry*, 56: 11533-11539

[11] Hammond B, Lemen J, Dudek R, Ward D, Jiang C, Nemeth M, Burns J (2006) Results of a 90-day safety assurance study with rats fed grain from corn rootworm-protected corn. *Food and Chemical Toxiology*, 44: 147-160

delegation clarified that the original report of the 90-days rat feeding studies with maize MON863 by Burns (2002)[12], which was provided in the dossier and later summarized in public literature by Hammond *et al.* (2006), was the focus. Moreover, Austrian experts reported to have checked all references available in order to provide scientific arguments for their safeguard clause on maize MON863. An Austrian delegate stated that when invoking an import ban it is in their view correct to point out the flaws of studies that should in fact prove the safety of a product: Experts from the ARC Seibersdorf, Austria, (now AIT) reanalysed (original data and test design) the Burns-study[12] already in 2005 and in the Austrians' view, this study does not prove safety of the product. Together with insufficient data presented, this was considered a major reason to invoke a national safeguard clause on maize MON863.

An EFSA GMO Panel expert made five points on certain statistical issues raised in the supporting Austrian documents: 1) multiple significant differences are always taken into consideration by the EFSA GMO Panel, but the EFSA GMO Panel accounts for the fact that some are expected to arise solely because of natural variation; the difference between statistical and biological relevance is addressed during the risk characterization phase; thus, argumentation provided by the Austrians constitutes no new information; 2) he agreed with the Austrian position that within experiments related to compositional analysis replication is important. He stressed that it is of primary importance to ensure sufficient replication to allow for accurate comparison of the GM with its non-GM comparator, he agreed with the Austrian position that replication of the GM and its comparator is important, but stressed it is important in absolute terms not in the percentage of the total experimental units that are allocated to the GM and comparator, rather than to reference varieties. 3) Regarding the publication by Hammond *et al.* (2006): 20 animals per test group is considered adequate according to international standards as advised by expert colleagues in the animal testing field; it should be noted that the EFSA GMO Panel does assess the absence of adverse effects of a GM food/feed by a comparative approach to ensure that the GM product is as safe as the comparable non-GM product. 4) Regarding the use of reference varieties used for the proposed equivalence test for compositional testing, this approach is considered a step forward from the previous guidance that was restricted solely to the comparison of GM to its near isogenic-control. 5) The Austrian comments submitted during public consultation on the updated EFSA guidance document were supportive of equivalence tests.

Austria acknowledged it is satisfied by the outcome of the EFSA Statistics Report that was available for public consultation on the EFSA website, which improves risk assessment by giving guidance on experimental design. Austria agreed that multiple significant differences are expected in various studies. However, it was maintained that the validity of any analysis depends completely on the validity of the study itself. It was stressed that the Austrian delegation disagrees with the study design of Burns (2002)[12], which is considered as not state of the art by the Austrian delegation..

Also, further comparative analyses need to be applied, if differences are detected. In addition, many OECD Consensus Documents state that food allergens should be analyzed, but this is not done on a routine basis during the risk assessment of GMOs.

The EFSA GMO Panel expert acknowledged that food allergens are addressed in OECD consensus documents, but mentioned that the respective tables listing recommended key parameters for analysis do not list allergens as such. Intrinsic allergenicity is usually evaluated if the crop under consideration is an important allergen (such as soybean). The EFSA GMO Panel is aware of the situation, and will address the issue in the context of a self-tasking activity.

The EFSA GMO Panel expert asked whether Austrian experts agree that a nutritional study is not a toxicity study. The answer from the Austrian delegation was positive.

[12] Burns JM (2002) 13-week dietary subchronic comparison study with MON 863 in rats preceded by a 1-week baseline food consumption determination with PMI certified rodent diet #5002. Monsanto Report, http://www.monsanto.com/monsanto/content/products/technicalandsafety/fullratstudy.pdf

An EFSA GMO Panel expert further inquired why Austria requests feeding studies with whole food as well as with purified protein on a mandatory basis, while Codex Alimentarius and EFSA guidance documents specify that those studies should be requested on a case-by-case basis. The Austrian delegation explained that Austria so far has only banned three GMOs after 2004, which is a minority of the number of approved GMOs. According to the Austrian delegation, the safeguard clauses are based on a case-by-case scenario and only if scientific reasons exist. Such scientific reasons are mostly based on lack of data, for example, on compositional and comparative assessment, allergenicity or toxicology. Due to these lacking data the safety of the product is not proven. If statistically significant differences – for example on compositional and comparative assessment – occur, further investigations have to be carried out. As the scope for this product is particularly feed use, the inclusion of feeding studies was particularly stressed.

The EFSA GMO Panel expert referred to the EFSA report on animal feeding studies (EFSA, 2008), and explained that the EFSA approach is based on comparative analysis. The Austrian delegation agreed with the approach, adding that the main issues of their criticisms are related to potential toxicity and allergenicity of the GMOs.

An EFSA GMO Panel member mentioned the study[13] entitled "*Biological effects of transgenic maize NK603 x MON 810 fed in long term reproduction studies in mice*" and in particular the multi-generation study (MGS). Austria explained that the study is not part of the data package supporting the safeguard clause and therefore not relevant to today's discussion.

## 7. PRESENTATION AND TECHNICAL DISCUSSION ON ENVIRONMENTAL ISSUES

In their presentation, the Austrian delegation questioned the conditions of the post-market environmental monitoring plan for maize MON863. Austria recognised that the main reason for invoking a safeguard clause on maize MON863 in Austria was insufficient toxicology and allergenicity assessment of that GM maize. However, Directive 2001/18/EC foresees monitoring as well as, where appropriate, management measures for this GM maize. According to the Austrian delegation, none of these regulatory requirements were properly fulfilled for maize MON863.

The members of the EFSA GMO Panel then asked the Austrian delegation for clarifications and discussion on several points:

- One EFSA GMO Panel expert asked for clarifications on the Austrian view with respect to the degradation of the Cry protein (Cry3Bb1 in maize MON863) in the animal or human gastro-intestinal tract mentioning that the risk of exposure is considered negligible. In response, the Austrian delegate reiterated that all possible routes of exposure must be examined in the course of the environmental risk assessment, including the exposure through manures and faeces. The EFSA GMO Panel expert acknowledged the importance of the fate and degradation of Bt proteins in the gastro-intestinal tract of humans and animals as well as in soil referring to a large volume of scientific literature available on the matter. The Austrian delegate agreed that the environmental risk by Cry3Bb1 protein (in faeces of animals fed by this maize grains and/or via accidental spillage along transportation and processing routes) might be negligible, but should be documented.
- On Austrian concerns regarding monitoring, the EFSA GMO Panel expert underlined that monitoring is mostly in the remit of risk managers. In this respect, the environmental exposure is of importance because it will condition the extent of the post-market environmental monitoring

[13] Velimirov A, Binter C, Zentek J (2008) Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice. Bundesministerium für Gesundheit, Familie und Jugend, Forschungsberichte der Sektion IV, Band 3/2008, ISBN 978-3-902611-24-6

plan. The Austrian delegation agreed with the EFSA GMO Panel that monitoring is not part of the risk assessment, but might be seen as a major source of information feeding into the environmental risk assessment. The Austrian delegation questioned the monitoring methodology, including the different parties involved in the post-market environmental activities. In this respect, it was commonly agreed in the meeting that appropriate national/regional monitoring networks should be integrated in a cooperative manner into the applicants monitoring activities. A stronger cooperation between applicants and Member States should be urged and initiated from both sides in order to ensure a comprehensive data collection. The EFSA GMO Panel expert referred to the existing alert system (used by applicants) which includes screening available literature in the frame of general surveillance. In addition to the data collection, the evaluation of the data was also tackled and it was acknowledged that additional independent institutions in charge of data collection and analysis from monitoring activities would be welcome for sake of harmonisation.

## 8. CONCLUSIONS

The Austrian delegation acknowledged the fruitful scientific discussion between the Austrian delegation and members of the EFSA GMO Panel, and the opportunity to present its scientific arguments, which justify from the Austrian point of view the safeguard measure on maize MON863, in detail. The Austrian delegation appreciated that EFSA and its GMO Panel dedicating this meeting to the Austrian safeguard clauses.

The EFSA GMO Panel experts also thanked for the fruitful scientific discussion.

The Chair closed the meeting, thanking the Austrian delegation, the experts of the EFSA GMO Panel, and the observer from the European Commission. The Chair also informed the participants that a meeting report will be prepared by EFSA staff and sent for comments prior to publication.