

Parma, 18 December 2008

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

AUSTRIAN SAFEGUARD CLAUSE ON GM MAIZE MON810 AND MAIZE T25

EFSA Meeting report of the meeting of 02 December 2008

The below report does reflect EFSA's understanding 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

Austrian delegation of 7 experts led by	Eva Lang (Bundesministerium für Gesundheit, Familie und Jugend)
EFSA GMO Panel:	Detlef Bartsch, Niels Hendriksen, Jozsef Kiss, Gijs Kleter, Harry Kuiper, Joe Perry, Joachim Schiemann, Jeremy Sweet
EFSA ENV WG:	Sue Hartley, Gerd Neemann, Marco Nuti
EFSA GMO Unit:	Per Bergman (Chair), Yann Devos, Elisabeth Waigmann
European Commission:	Helen Clayton, Yannis Karamitsios

1. Welcome

The Chair of the meeting welcomed the Austrian delegation, members of the EFSA GMO Panel and its WG, as well as observers from the European Commission.

2. Tour de table

Participants introduced themselves during a tour de table.

3. Historical, legal and practical aspects relating to the Austrian safeguard clause

A representative from the European Commission presented the historical and legal background of the Austrian safeguard clause, and its request, directed at the European Food Safety Authority (EFSA), to provide a scientific opinion on the documents submitted by Austria. According to the mandate of the European Commission, EFSA was requested “to assess whether the information submitted by Austria comprises information affecting the environmental risk assessment of existing information on the basis of new scientific knowledge such that detailed grounds exist to consider that the above authorised GMOs, for the uses laid down in the corresponding consent, constitute a risk to the environment”. In order to reinforce 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”.

The Chair explained the aim of the bilateral meeting which was for EFSA to listen to arguments of Austria and to obtain clarifications on scientific issues addressed in the Austrian data package submitted in support of the safeguard clause. It was clarified that the opinion of the GMO Panel cannot be expressed during the meeting, as the GMO Panel has not met to discuss the safeguard clause opinion yet. It was further clarified that the GMO Panel of EFSA will issue a scientific opinion based on the information provided by Austria as part of its formal mandate to EFSA. GMO Panel members noted that some of the issues addressed in the Austrian safeguard clause submission are not in the remit of the GMO Panel, and will thus not be commented during the meeting.

The Austrian delegation regretted not having received feedback on Austria’s scientific arguments from the GMO panel. It was reiterated that the views and opinions of the GMO Panel cannot be expressed before the GMO Panel has met to discuss the safeguard clause opinion.

4. Technical aspects relating to the Austrian safeguard clause

The Austrian delegation introduced the Austrian position and arguments relating to the use and safety of maize MON810 and maize T25, and explained that the Austrian safeguard clause is based on the precautionary principle.

While not being part of the initial data package submitted to the European Commission and forwarded to EFSA, and while not being included in the mandate of EFSA to estimate potential risk for the environment, the Austrian delegation presented in support of its invoked safeguard clause the following new information, focusing on food and feed issues. In addition, the submitted information relating to environmental issues was discussed.

Food and feed issues

Acknowledging that environmental issues are the core of the invoked safeguard clause, the Austrian delegation argued that two new studies ^[1,2] relating to the food and feed risk assessment of maize MON810 would be presented and that both studies have implications for the risk assessment and safety of maize MON810.

One member of the Austrian delegation, who is co-author of the study presented the content of the study by Velimirov et al. (2008), entitled “*Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice*”^[3]. This study is composed of three individual studies: a life-time study, a multi-generation study (MGS) and a reproductive assessment through continuous breeding study (RACB). Thereby, maize NK603xMON810

^[1]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, http://bmgfj.cms.apa.at/cms/site/attachments/3/2/9/CH0810/CMS1226492832306/forschungsbericht_3-2008_letztfassung.pdf

^[2]Finamore A, Roselli M, Britti S, Monastra G, Ambra R, Turrini A, Mengheri E (online first; 2008) Intestinal and peripheral immune response to MON810 maize ingestion in weaning and old mice. *Journal of Agricultural and Food Chemistry*, DOI: 10.1021/jf802059w

^[3] While preparing this EFSA meeting report, the GMO Panel has adopted and published its deliberations of this study as a part of the 46th plenary meeting minutes (http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/gmo_statement_austrianstudy_en.pdf?ssbinary=true)

was compared with a near-isogenic counterpart and, for the life-time study and the MGS study, also with a commercial maize variety (produced in Austria, 2005). According to the authors, the life-time study and the MGS study showed no statistically significant differences in survival and reproductive traits between mice fed maize kernels of NK603xMON810 and controls, respectively. Differences in reproductive parameters between mice fed GM maize and controls were identified in the RACB study, with significantly fewer pups born in the GM group in the 3rd and 4th delivery and fewer pups weaned in the 4th litter, as compared with the control group. Therefore, the main focus of the presentation was on data pertaining to the RACB study.

EFSA noted that it would be difficult for the GMO Panel to assess the presented report and its conclusions, as raw data have not been included in the report. The member of the Austrian delegation presenting the study confirmed that various statistical models are under consideration for reanalysing the available dataset prior to submission for publication in a peer-reviewed journal and that therefore raw data cannot be provided to the GMO Panel at this time point.

Another member of the Austrian delegation remarked that even though results are preliminary, the outcomes of the study are important and warrant the need for further studies.

An Austrian delegate presented the content of the study performed by Finamore et al. (2008) entitled "*Intestinal and peripheral immune response to MON810 maize ingestion in weaning and old mice*" in which phenotyping of lymphoid cell populations isolated from the gut, spleen and blood, together with an analysis of various cytokines in blood serum from mice of different age groups has been done for mice fed maize MON810.

GMO Panel members questioned how the two above tested study approaches should be considered in the frame of routine food and feed safety testing of whole GM foods and feeds. So far, the RACB-based approach has only been used within the American National Toxicology (NTP) program for testing chemicals such as pesticides and plasticisers, and has not been standardised as an OECD protocol. With regard to the study by Finamore et al., it was discussed that this type of immunological study is generally not performed on whole foods and feeds. Reference was made to the feed additives field where additional studies may include examination of immunotoxicity if there are reasons for concern^[4].

Environmental issues

An Austrian delegate argued that data provided by the applicant in the frame of the environmental risk assessment of maize MON810 are insufficient to appropriately assess potential risks to **non-target organisms (NTOs)**. Due to the absence of agreed criteria for performing environmental risk assessments and of a systematic approach for selecting certain organisms for NTO testing, the Austrian delegation claimed that no conclusions can be drawn on the safety of maize MON810. According to the Austrian delegation, uncertainties remain about the safe use of maize MON810 & T25.

GMO Panel members noted that approaches to environmental risk assessment, especially those related to NTO testing, have been discussed at the EFSA Scientific Colloquium held in Tabiano on 20-21 June 2007^[5]. EFSA informed that the scientific debates at the colloquium served as a basis for a recently established EFSA working group on NTO testing aiming at providing a harmonized guidance for risk assessment on the subject.

^[4] Commission Regulation (EC) No 429/2008, 3.2.2.6. p. 28

^[5] EFSA (2007) Environmental Risk Assessment of Genetically Modified Plants – Challenges and Approaches. Scientific Colloquium Series of the European Food Safety Authority N°8, June 2007, http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/sci_coll_8_summary_report.pdf

With regard to the **specificity of the Cry1Ab protein**, GMO Panel members argued that the Bt-toxin has been tested on an array of NTOs. In line with the EFSA Guidance Document, NTO testing focuses on representative model species that might be exposed directly or indirectly to maize MON810. The selection of key species is generally based on different criteria. Subsequently, results obtained on key species are used to make extrapolations to other species.

GMO Panel members noted that new scientific data have been published and that data have emerged from the **monitoring of maize MON810**, for example, in Spain where Bt-maize has been cultivated for a considerable period. It was explained that the most recent scientific literature will be referred to in the GMO Panel opinion on the Austrian safeguard clause. As regards monitoring, the Austrian delegate expressed doubts that the use of farmer questionnaires in the context of general surveillance will be sufficient to detect unintended effects relating to the use of maize MON810.

An Austrian delegate briefly explained that Austria attaches importance to perform agriculture in a sustainable way, and therefore aims to protect **biodiversity** and ecosystem services from harm. In addition, it was specified that regional particularities of the Austrian landscape, farmland biodiversity (including fauna, flora, natural resources, ecological services and functions) and agricultural practices have been poorly addressed. Thereby, reference was made to the biodiversity monitoring study of Traxler et al. (2005)^[6] to illustrate that Austria is a biodiversity hotspot for butterflies. An important proportion of Austrian butterflies was claimed to be of conservational importance, and should be preserved from potential harm assigned to the use of maize MON810. In this respect, GMO Panel members mentioned that several studies on Bt-maize pollen/anther consumption effects on lepidopteran larvae have been performed including one of the most sensitive lepidopteran species, *Plutella xylostella*, and that no adverse effects had been observed on larvae of this species. In response to a question from GMO Panel members asking about which butterfly species caused the most concern regarding possible cultivation of MON810 in Austria, the Austrian delegation informed that, in this respect, further research is currently being conducted in Austria in order to collect and analyse biodiversity data in representative agricultural regions of Austria, as well as to establish floristic and faunistic baselines for the environmental risk assessment of GM crops (project BINATS; Biodiversity-NATure-Safety)^[7]. This study is not finished yet, so no data were presented at the meeting.

An Austrian delegate gave a presentation focussing on the process of **vertical gene flow** and its agro-ecological consequences. In this respect, it was argued that uncertainties and particularities of the Austrian agricultural landscape are insufficiently addressed. Uncertainties relating to pollen flow, pollen viability, wind characteristics, long-distance pollen flow and cross-pollination hot spots were briefly presented. Based on available vertical gene

^[6]Traxler A, Minarz E, Höttinger H, Pennerstorfer J, Schmatzberger A, Banko G, Placer K, Hadrbolec M, Gaugitsch H (2005) Biodiversitäts-hotspots der Agrarlandschaft als Eckpfeiler für Risikoabschätzung und Monitoring von GVO. Bundesministerium für Gesundheit und Frauen, Forschungsberichte der Sektion IV, Band 5/2005, https://www.dafne.at/prod/dafne_plus_common/attachment_download/67681236fc348e82565fbedc17d0343b/1356_BioDiv_Hotspots.pdf

^[7]Pascher K, Moser D, Dullinger S, Sachslehner L, Höttinger H, Traxler A, Sauberer N, Frank T, Grabherr G (2008) Monitoring design to evaluate biodiversity in Austrian agricultural regions. In: Breckling B, Reuter H, Verhoeven R (Eds.) Implications of GM-crop cultivation at large spatial scales. Theorie in der Ökologie 14. Frankfurt, Peter Lang, pp. 146-150, <http://www.gmls.eu/beitraege/Pascher.pdf>

flow studies and a study performed in Austria ^[8], the Austrian delegate concluded that low levels of gene flow are unavoidable at the landscape level. According to the Austrian delegation, the impact of regional characteristics on pollen flow and consequent cross-pollination levels is not clear so far, requiring further investigations, especially in Austria where maize fields are quite small (on average 1.8ha).

With regard to **seed-mediated gene flow**, the Austrian delegate mentioned that the occurrence of maize volunteers is not uncommon in Austria, and that feral maize plants have been reported at ruderal sites in Austria. Acknowledging that these plants can be controlled by herbicide applications, the Austrian delegate explained that the application of herbicides would alter current Austrian agricultural practices. The fact that maize fields are small, organic farming is common and agricultural equipments are shared amongst farmers, should be considered in the risk assessment of maize MON810 and T25.

GMO Panel members noted that a safeguard clause should be based on precise data indicating risks of the specific GM crop under consideration. To the question of the GMO Panel, the Austrian delegation confirmed that there has not been any GM maize (including MON810 or T25) field releases in Austria from which data would have been available supporting the safeguard clauses. However, the Austrian delegation argued that sufficient studies with non-GM maize have been performed under Austrian conditions to support their claim of a lack of data and of remaining uncertainties.

The Austrian argumentation was expressed in line with the information provided in the written submission for the safeguard clause. No new evidence on environmental risks was presented at the meeting.

5. Closing of the meeting

The Austrian delegation acknowledged the fruitful scientific discussion between the Austrian delegation and experts of the GMO Panel. However, uncertainties about the safety of both maize events remain, whilst particularities of the Austrian landscape have been not sufficiently considered. Therefore in the view of the Austrian delegation, so far cultivation of maize MON810 and T25 would pose considerable risks for the receiving environment in Austria.

The Chair closed the meeting after thanking the EFSA GMO panel and WG members present, the Austrian delegation and observers from the European Commission.

^[8] Leonhardt C., Hartmann J., Girsch L., Angerer N., Nagl H., Zimmermann H., Rieple E., Berg W., Stueger H.P., Kaiser B., Moder K. (2008) Untersuchungen zur Fremdbefruchtungsrate in Maiskulturen unter Berücksichtigung der Umwelten in den Hauptanbaugebieten Österreichs. Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH und Universität für Bodenkultur Wien, ISBN: 978-3-200-01213-4. http://www.ages.at/uploads/media/Endbericht_Vers02_Fo-Proj_100194_03.pdf