European Food Safety Authority

GMO UNIT

EFSA/GMO/505

Parma, 24 May 2009

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

AUSTRIAN SAFEGUARD CLAUSES ON GM OILSEED RAPE MS8/RF3 AND GM OILSEED RAPE GT73

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

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 oilseed rapes Ms8/Rf3 and GT73, but also includes topics of discussion common to all three safeguard clauses. The discussion on aspects related specifically to maize MON863 can be found in the EFSA meeting report published in connection with the respective safeguard clause 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 arguments related 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 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. In the Austrian delegate's view, it focuses on novel proteins only and does not include whole food 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 oilseed rape 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. 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 and a comparative assessment of the allergenic properties of extracts from the GM and the wild type crop. The Austrian delegate subsequently showed and discussed two tables summarizing the information relevant to toxicity and allergenicity assessment provided in the dossiers of oilseed rape GT73 and Ms8/Rf3. He then commented in detail on the limitations and drawbacks of the types of evidence and test protocols used in toxicity assessment, including the history of safe use/consumption; amino acid sequence homology comparison; *in vitro* digestibility studies; acute toxicity studies; test protein analogues purified from microorganisms; risk characterization; and the absence of whole food studies. Comments specifically referring to allergenicity assessment include glycosylation; the role of the source organisms in allergenicity assessment; exposure route and sensitization scenarios considered; and the consideration of sensitization to allergies against oilseed rape. 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)[1].

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 offspring.

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, though this is not done on a routine basis during the risk assessment of GMOs.

[1] 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

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.

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 GMO Panel 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.

6. PRESENTATION AND TECHNICAL DISCUSSION ON ENVIRONMENTAL ISSUES

Several speakers of the Austrian delegation presented the environmental concerns supporting the invocation of the safeguard clauses at stake[2]:

1. A first speaker presented data and figures on the transportation routes of oilseed rape (OSR) onto the Austrian territory, including a map of OSR growing areas in Austria (174.593 tons in 2008 from 56.000 ha). OSR is processed particularly in two major oil mills in Austria. He explained that raw OSR material is usually transported from all around the country by trains, trucks and boats to oil mills, but that OSR might also be imported from many EU countries. Hence, the Danube is one of the main routes of transportation of commodities in Austria.

   Considering the information and data provided, the Austrian delegation is of the opinion that all possible points of entrance and transportation routes should therefore be considered in the context of consent for import & processing of GM crops – in particular of OSR: The speaker highlighted that seed spillage was already proven in Austria and consequently is considered a common phenomenon occurring in real transportation conditions. In addition to seed spillage, uncertainties were pointed out, namely that transport of OSR seeds in general cannot be completely controlled and that once GM OSR is present in the seed chain, it is more or less impossible to be removed.

2. A second Austrian speaker reported on the peculiarities of the Austrian situation in terms of OSR seed spillage, establishment of feral OSR populations and consequences thereof. Peculiarities of the Austrian agricultural system were summarised as: 1) a very small scale agriculture with an average field acreage of 1 ha; 2) high variety of landscape elements separating these small-scale fields; 3) numerous feral OSR plants and related Brassicaceae species are found in these particular

[2] http://www.bmgfj.gv.at/cms/site/attachments/6/0/0/CH0817/CMS1200574298070/scientific_arguments.pdf; http://www.bmgfj.gv.at/cms/site/attachments/3/0/9/CH0817/CMS1215778250501/importverbot_osr_ms8xrf3_-_internetfassung.pdf; http://registerofquestions.efsa.europa.eu

agrotopes between the fields; 4) Pannonian Region with additional species; and 5) the high faunistic and floristic biodiversity in Austrian agricultural areas. These characteristics were further shown in detail and quantified with appropriate figures which showed the high biodiversity in Austria. Reference was made to the Austrian research program BINATS, which aims at the collection and analysis of biodiversity data in representative agricultural regions of Austria, as well as to establish flora and fauna baselines for the environmental risk assessment of GM crops (project BINATS[3]; BIodiversity-NATure-Safety where 100 test areas were studied). 900 plant species of altogether 2.950 in Austria occurring vascular plant species were found in all 100 test areas demonstrating the high flora biodiversity in Austrian agricultural landscapes. In 71 test areas from all investigated 100 test areas, several feral or volunteer OSR plants were found. Feral OSR on road verges was detected in 8 test areas. From supporting figures, the speaker pointed out that more than twenty potential hybridisation partners of OSR (tribus Brassicaceae) are present in Austria, most of them are very frequent all over Austria. The two Austrian oil mills (Aschach, Bruck an der Leitha), mentioned here above, are located in areas where closely related hybridisation partners of OSR are highly present in Austria. Possible hybridisation with spilled OSR and consequences thereof should be carefully considered in the environmental risk assessment.

Furthermore, some calculations to estimate general seed spillage in Austria were presented. Considering 1% of the spilled seeds being fertile, 134.454 OSR plants are likely to establish in the surrounding environment of transport routes taking into account the following figures: 1) 1kg OSR equals 50.000 seeds; 2) 134 billions of GM seeds in case of 1% GM OSR import in Austria, which equals to an OSR import of altogether 268.908 tons in Austria in 2008; and 3) 13,5 millions of lost GM seeds in assuming an accidental spillage of only 0,01% level.

The speaker also pointed out literature currently available confirming the persistence of oilseed rape in Europe (e.g., Pessel *et al.* (2001)[4], Crawley and Brown (2004)[5], Pivard *et al.* (2007)[6]). Specifically for Austrian receiving environments, Pascher *et al.* (2000, 2006)[7,8] found that most feral OSR populations were persistent and all feral sites contained more than one genotype. In conclusion, all these studies showed some persistence of feral OSR, but with some differences among the EU countries where research was carried out. Consequently, the Austrian delegation reiterates that the origin and persistence of feral OSR populations cannot be harmonized in different parts of Europe. Hence, a regional case specific evaluation is crucial. Feral OSR populations are frequently found throughout Austria.

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[3] 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

[4] Pessel FD, Lecomte J, Emeriau V, Krouti M, Messéan A, Gouyon PH (2001) Persistence of oilseed rape (*Brassica napus* L.) outside of cultivated fields. *Theoretical and Applied Genetics*, 102: 841-846

[5] Crawley MJ, Brown SL (2004) Spatially structured population dynamics in feral oilseed rape. *Proceedings of the Royal Society B-Biological Sciences*, 271: 1909-1916

[6] Pivard S, Adamczyk K, Lecomte J, Lavigne C, Bouvier A, Deville A, Gouyon PH, Huet S (2007) Where do the feral oilseed rape populations come from? A large-scale study of their possible origin in a farmland area. *Journal of Applied Ecology*, 45: 476-485

[7] Pascher K, Macalka-Kampfer S, Reiner H (2000) Vegetationsökologische und genetische Grundlagen für die Risikobeurteilung von Freisetzungen von transgenem Raps und Vorschläge für ein Monitoring. Studie im Auftrag des Bundeskanzleramtes, Sektion IX, Bundesministerium für soziale Sicherheit und Generationen, Forschungsberichte 7/00, pp.153 + pp.24 Anhang

[8] Pascher K, Narendja F, Rau D (2006) Feral Oilseed Rape – Investigations on its potential for hybridisation. Studie im Auftrag des Bundesministeriums für Gesundheit und Frauen, Forschungsberichte der Sektion IV, Band 3/2006, pp. 85

3. A third speaker addressed the Austrian concern of the possible spread of the male sterility (barstar-barnase) system from Ms8/Rf3 OSR plants to wild relatives, which might induce changes at the population level. It was explained that such a system has obviously direct influence on the reproduction system and population dynamics if transferred to wild relatives. This point becomes a major environmental safety concern in light of the broad range of wild OSR relatives in Austria as presented by the second Austrian speaker. In addition, due to the high rate of accidental spillage, the possible spread of the male sterile/restorer fertility cassette to wild populations should be better addressed by the applicant. Since it was already proven that accidental seeds spillage occurs and subsequently that stable feral OSR populations might establish, an adequate post-market environmental monitoring plan should be developed by applicants to cover possible consequences of seed spillage and of subsequent establishment of feral plants. In addition, the Austrian delegation questioned the fact that detailed information on the methodology, the reporting and the frequency of reporting of the post-market environmental monitoring activities is missing and should therefore be provided by the applicant.
4. This Austrian speaker also addressed the conditions of the post-market environmental monitoring plan (PMEM) for both GM OSR GT73 and Ms8/Rf3. Herbicide-tolerant OSR GT73 might indeed show a selective advantage in fitness as glyphosate is broadly used along railways tracks and road sides. This point should therefore be addressed in the PMEM plan. The Austrian delegation made clear that monitoring of OSR should be carried out by independent environmental scientists.

The members of the EFSA GMO Panel sought clarifications and discussed some points presented:

- An EFSA GMO Panel expert sought clarifications to some of the figures presented on the imported quantities of OSR in Austria as well as on controls and testing at the borders. An Austrian delegate explained that controls of seed lots are usually done, but are made publicly available only when an infringement to the law has been noted.
- The EFSA GMO Panel expert further asked whether any of the cross-compatible wild relatives of OSR are protected. An Austrian speaker responded that at least one of the more than twenty closely related species which is specific for Austria, *Conringia austriaca* is listed as a protected species (i.e., class 2: strongly endangered)[9].
- The EFSA GMO Panel expert discussed the possible selective advantage and increased fitness of feral OSR populations established from spilled seeds of herbicide-tolerant OSR in the presence of the complementary herbicide. According to the EFSA GMO Panel, the potential spread of the herbicide-tolerant trait into natural habitats will not lead to a selective advantage, since the herbicide is not applied there. The Austrian delegate reiterated the importance for applicants to assess the possible consequences of accidental seeds spillage not only in conjunction with natural environments.
- Furthermore another EFSA GMO Panel expert asked whether evidence has been collected on spilled OSR, whether GM OSR is present, and whether there is a change in fitness and invasiveness modifying the biodiversity. An Austrian expert provided an example of an aggressive invasion due to a singular hybridisation event; a cross between *Spartina maritima* and *Spartina alterniflora* gave rise to a sterile hybrid (*Spartina townsendii*) which emerged in South England. The spontaneously emerged fertile tetraploid form of this hybrid, *Spartina anglica*, combined the traits of the parents with an obvious hybrid vigour. However, no data on the presence of GM OSR among feral or spilled populations are available for Austria yet, as GM OSR is not imported into Austria due to the invoked safeguard clauses. An Austrian expert also stressed the detection of feral herbicide tolerant OSR along transport routes and harbours in Japan and Canada (multi-

[9] Niklfeld H (1999) Rote Listen gefährdeter Pflanzen Österreichs (Grüne Reihe des Bundesministeriums für Umwelt, Jugend und Familie, 10). Graz, 2. Auflage

resistant feral OSR, Knispel *et al.* (2008)[10]). Recently, two new Japanese studies (Aono *et al.* (2006)[11]; Kawata *et al.* (2009)[12]) have been published on herbicide-tolerant feral oilseed rape in the context of transport activities.

- The EFSA GMO Panel expert acknowledged the data referring to a general OSR exposure assessment submitted in support of the Austrian safeguard clauses, but would be pleased to receive further data on the hazard identification and characterization. Austria points also to the fact that European Union legislation instructs the EU Member States to protect special species and habitats (FFH Directive, NATURA 2000, etc.). The Member States all agreed on the ambition to protect national biodiversity.
- The EFSA GMO Panel expert asked whether Austria has some baseline data on the occurrence of natural male sterility in wild Brassicaceae (potentially crossable with OSR) populations in Austria in order to evaluate and compare the possible impact of an additional male sterility gene spread into the environment. Austria was not aware of such data available and stressed that a lack of an evidence of an effect is not an evidence of no effect; it was made clear that accidental spillage is a concern *per se* that is not sufficiently addressed in the GM plant market authorisation dossiers.
- On Austrian concerns regarding monitoring, the EFSA GMO Panel expert underlined that monitoring is mostly in the remit of risk managers. In this respect, exposure is of importance because it impacts the PMEM plan. The Austrian delegate stressed the importance of monitoring GM OSR (accidental) release considering the biology of the crop. 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 PMEM 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.

7. 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 Austrian safeguard measures on OSR GT73 and MS8/Rf3, 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.

[10] Knispel AL, McLachlan SM, Van Acker RC, Friesen LF (2008) Gene flow and multiple herbicide resistance in escaped canola populations. *Weed Science*, 56: 72-80

[11] Aono M, Wakiyama S, Nagatsu M, Nakajima N, Tamaoki M, Kubo A, Saji H (2006) Detection of feral transgenic oilseed rape with multiple-herbicide resistance in Japan. *Environmental Biosafety Research*, 5: 77-87

[12] Kawata M, Murakami K, Ishikawa T (2009) Dispersal and persistence of genetically modified oilseed rape around Japanese harbors. *Environmental Science and Pollution Research*, 16: 120-126

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.