European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 76th Plenary meeting of the Scientific Panel on GMO

Held on 5–6 September 2012, Parma
(agreed on 17 October 2012[1])

Participants

- **Panel Members:**

Salvatore Arpaia, Andrew Nicholas Edmund Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Lieve Herman, Huw Jones, Jozsef Kiss, Gijs Kleter, Martinus Løvik, Antoine Messéan, Hanspeter Naegeli, Kaare Nielsen, Jaroslava Ovesná, Joe Perry, Nils Rostoks and Christoph Tebbe.

- **European Commission:**

Sabine Pelsser.

- **EFSA:**

GMO Unit: Anna Christodoulidou, Yann Devos, Zoltán Divéki, Antonio Fernández Dumont, Andrea Gennaro, Ana Gomes, Yi Liu, Sylvie Mestdagh, Irina Olaru, Claudia Paoletti and Elisabeth Waigmann.

Other EFSA Units/Directorates: None

- **Observers (in application of the guidelines for Observers[2]):**

None.

- **Others:**

Michael Meissle,[3] Jörg Romeis[4] (for item 9 of the agenda).

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Hilde-Gunn Hoen-Sorteberg Opsahl and Pagona Lagiou.

2. Adoption of agenda

The agenda was adopted without changes.

---

1 The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.
2 http://www.efsa.europa.eu/en/stakeholders/observers.htm
3 Member of Agroscope Reckenholz-Tänikon Research Station ART, Switzerland.
4 Member of Agroscope Reckenholz-Tänikon Research Station ART, Switzerland.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[3] and the Decision of the Executive Director implementing this Policy,[4] EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited to the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, as well as the Oral Declaration of Interest (ODoI) at the beginning of the meeting, please refer to Annex I.

4. Agreement of the minutes of the 75th Plenary meeting held on 4–5 July 2012, Parma

The minutes of the 75th Plenary meeting (4 and 5 July 2012) were adopted and will be published at: EFSA Event: 75th plenary meeting of GMO Panel .

5. Report on written procedures since 75th Plenary meeting

There have been no written adoptions since the 75th Plenary meeting.

6. Scientific outputs submitted for discussion and possible adoption

6.1 Scientific Opinion on application (EFSA-GMO-BE-2010-81) for the placing on the market of genetically modified herbicide-tolerant oilseed rape Ms8, Rf3 and Ms8 × Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from, oilseed rape Ms8, Rf3 and Ms8 × Rf3 (with the exception of processed oil) under Regulation (EC) No 1829/2003 from Bayer (EFSA-Q-2010-00947)

This scientific opinion is a risk assessment for the placing on the market of the genetically modified (GM) herbicide-tolerant oilseed rape (OSR) Ms8, Rf3 and Ms8 × Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from, these GM plants. OSR Ms8 (male sterile) and Rf3 (fertility restorer) are the parents of OSR Ms8 × Rf3, which is fertile, contains the *bar*, *barstar* and *barnase* genes, and is tolerant to glufosinate ammonium-containing herbicides. Integrity of the inserts present in the single events was demonstrated in the stack. Molecular characterisation did not reveal any safety issues. No biologically relevant differences were identified in the composition or agronomic and phenotypic characteristics of OSR Ms8 × Rf3 compared with its non-GM comparator, except for the newly expressed proteins. The safety assessment identified no concerns regarding the potential toxicity and allergenicity of OSR Ms8, Rf3 and Ms8 × Rf3. A broiler study confirmed that OSR Ms8 × Rf3 is as nutritious as its non-GM comparator. There are no indications of an increased likelihood of establishment and spread of feral OSR Ms8, Rf3 and Ms8 ×R f3 plants, or of hybridising wild relatives, unless exposed to glufosinate ammonium-containing herbicides. Considering the intended uses, potential interactions of feral OSR Ms8, Rf3 and Ms8 × Rf3 plants with the biotic and abiotic environment are not considered an issue. Environmental risks associated with a possible horizontal transfer into bacteria have not been identified. The monitoring plan and reporting intervals are in line with the intended uses. In conclusion, the EFSA GMO Panel considers that the information available for OSR Ms8, Rf3 and Ms8 × Rf3 addresses the scientific comments raised by Member States and that OSR Ms8, Rf3 and Ms8 × Rf3 are unlikely to have an adverse effect on human and animal health or on the environment, in the context of their intended uses.

The opinion was unanimously adopted by the Panel and will be published on the following EFSA website: http://www.efsa.europa.eu/en/publications.htm

6.2 Scientific Opinion on a request from the European Commission related to the prolongation of prohibition of the placing on the market of genetically modified oilseed rape events Ms8, Rf3 and Ms8 x Rf3 for import, processing and feed uses in Austria (EFSA-Q-2012-00714)

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) evaluated the documentation provided by Austria to support the prolongation of the safeguard clause measure prohibiting the placing on the market of the genetically modified oilseed rape events Ms8, Rf3 and Ms8 × Rf3 for import, processing and feed uses in Austria. The EFSA GMO Panel assessed whether the submitted documentation comprised new scientific information that would change or invalidate the conclusions of its previous risk assessments on oilseed rape Ms8, Rf3 and Ms8 × Rf3. The EFSA GMO Panel also considered the relevance of the concerns raised by Austria in the light of the most recent data published in the scientific literature. The authorised uses of oilseed rape Ms8, Rf3 and Ms8 × Rf3 exclude cultivation, but data on gene flow, persistence and invasiveness derived from cultivation were considered as a worst case, representing conditions in which exposure and potential impact are expected to be the highest, to assess possible environmental impacts resulting from seed import spills. In the documentation provided by Austria and in the scientific literature, the EFSA GMO Panel could not identify new scientific evidence that indicates that the import and processing of oilseed rape Ms8, Rf3 and Ms8 × Rf3 for feed uses in the EU pose a significant and imminent risk to the environment. In conclusion, the EFSA GMO Panel considers that, based on the documentation supplied by Austria and a review of recent scientific literature, there is no specific scientific evidence in terms of risk to the environment that would support the notification of a safeguard clause measure under Article 23 of Directive 2001/18/EC or its prolongation, or that would invalidate its previous risk assessments of oilseed rape Ms8, Rf3 and Ms8 × Rf3.

The opinion was unanimously adopted by the Panel and will be published on the following EFSA website: http://www.efsa.europa.eu/en/publications.htm

6.3 Scientific Opinion on a request from the European Commission related to the prolongation of prohibition of the placing on the market of genetically modified oilseed rape event GT73 for import, processing and feed uses in Austria (EFSA-Q-2012-00715)

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) evaluated the documentation provided by Austria to support the prolongation of the safeguard clause measure prohibiting the placing on the market of the genetically modified oilseed rape event GT73 for import, processing and feed uses in Austria. The EFSA GMO Panel assessed whether the submitted documentation comprised new scientific information that would change or invalidate the conclusions of its previous risk assessments on oilseed rape GT73. The EFSA GMO Panel also considered the relevance of the concerns raised by Austria in the light of the most recent data published in the scientific literature. The authorised uses of oilseed rape GT73 exclude cultivation, but data on gene flow, persistence and invasiveness derived from cultivation were considered as a worst case, representing conditions where exposure and potential impact are expected to be the highest, to assess possible environmental impacts resulting from seed import spills. In the documentation provided by Austria and in the scientific literature, the EFSA GMO Panel could not identify new scientific evidence that indicates that the import and processing of oilseed rape GT73 for feed uses in

the EU pose a significant and imminent risk to the environment. In conclusion, the EFSA GMO Panel considers that, based on the documentation supplied by Austria and a review of recent scientific literature, there is no specific scientific evidence in terms of risk to the environment that would support the notification of a safeguard clause measure under Article 23 of Directive 2001/18/EC or its prolongation or that would invalidate its previous risk assessments of oilseed rape GT73.

The opinion was unanimously adopted by the Panel and will be published on the following EFSA website: http://www.efsa.europa.eu/en/publications.htm

6.4 Scientific Opinion on a request from the European Commission related to the safeguard clause notified by Greece on genetically modified maize MON 810 according to Article 23 of Directive 2001/18/EC (EFSA-Q-2012-00612)

Following a request of the European Commission, the European Food Safety Authority's Panel on Genetically Modified Organisms (EFSA GMO Panel) evaluated the documentation submitted by Greece in support of its request for the prohibition of the placing on the market of the genetically modified maize MON 810 according to Article 23 of Directive 2001/18/EC. The EFSA GMO Panel notes that the majority of the publications referred to by Greece have already been addressed by the EFSA GMO Panel in previous scientific outputs on maize MON 810 or other related insect-resistant genetically modified maize transformation events. In the remaining evidence provided by Greece, the EFSA GMO Panel could not identify any new data subject to scientific scrutiny or scientific information that would invalidate its previous risk assessments of maize MON 810. With regard to issues related to management and monitoring of maize MON 810, the EFSA GMO Panel refers to its recent recommendations for management and monitoring measures of maize MON 810. In conclusion, the EFSA GMO Panel considers that, based on the documentation submitted by Greece, there is no specific scientific evidence, in terms of risk to human and animal health or the environment that would support the notification of a safeguard clause under Article 23 of Directive 2001/18/EC or that would invalidate the GMO Panel's previous risk assessments of maize MON 810.

The opinion was unanimously adopted by the Panel and will be published on the following EFSA website: http://www.efsa.europa.eu/en/publications.htm

6.5 Scientific Opinion on application (EFSA-GMO-NL-2010-78) for authorisation of genetically modified soybean MON 87705 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-Q-2010-00165)

This scientific opinion is a risk assessment of the genetically modified, herbicide-tolerant, increased oleic acid soybean MON 87705 for food and feed uses, import and processing. MON 87705 contains the soybean *FAD2-1A/FATB1-A* gene fragments down-regulating endogenous FAD2 and FATB enzymes and the CP4 *epsps* gene cassette conferring tolerance to glyphosate-containing herbicides. Bioinformatic analyses and genetic stability studies did not raise safety issues. The levels of the CP4 EPSPS protein in soybean MON 87705 have been sufficiently analysed. MON 87705 differs from the conventional counterpart in the fatty acid profile (proportion of (C18:1) oleic acid increased and proportions of (C18:2) linoleic acid and (C16:0) palmitic acid decreased) in seeds and the presence of the CP4 EPSPS protein. Scientific risk assessment of soybean MON 87705 was carried out in the context of the intended use as specified by the applicant, namely its use for food and feed as any conventional soybean except for the oil derived from soybean MON 87705,

which is to be used in margarine, salad dressing, mayonnaise and home-use liquid vegetable oil, excluding the use of soybean MON 87705 oil for commercial frying. The safety assessment identified no concerns regarding potential toxicity and allergenicity of the CP4 EPSPS protein. The altered fatty acid profile did not raise concerns regarding toxicity. The overall allergenicity of the whole plant was not changed by the genetic modification. The estimated changes in intake levels of these fatty acids do not raise nutritional concerns in the context of the intended use as specified by the applicant. A feeding study on broiler chickens confirmed that defatted meal of soybean MON 87705 is as nutritious as meals produced from its conventional counterpart and non-GM reference varieties. There are no indications of an increased likelihood of establishment and spread of feral soybean plants. Considering its intended uses, environmental risks associated with an unlikely, but theoretically possible, horizontal gene transfer from soybean MON 87705 to bacteria have not been identified. Potential biotic and abiotic interactions of soybean MON 87705 were not considered to be an issue owing to the low level of exposure. The monitoring plan is in line with the intended uses of soybean MON 87705. The EFSA GMO Panel considers that the information available for soybean MON 87705 addresses the scientific comments raised by the Member States and states that soybean MON 87705, as described in the application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses as proposed by the applicant.

The opinion was unanimously adopted by written procedure on 28 September 2012 and will be published on the following EFSA website: http://www.efsa.europa.eu/en/scdocs.htm.

6.6 Scientific Opinion on a request from the European Commission for the assessment of the scientific elements put forward by Luxembourg to support the prohibition for the placing on the market of GM potato EH92-527-1 for cultivation purposes in Luxembourg (EFSA-Q-2012-00614)

Luxembourg notified to the European Commission its scientific arguments justifying the implementation of a national safeguard measure prohibiting the placing on the market of GM potato EH92-527-1 for cultivation purposes in Luxembourg, after which the European Commission asked the European Food Safety Authority (EFSA) to assess the scientific information supporting the prohibition. Having considered the information package provided by Luxembourg and all relevant scientific publications, the EFSA Panel on Genetically Modified Organisms (GMO Panel) concluded that (i) no new data specific to the safety of the *npt*II gene have been provided; (ii) although bacterial DNA release and development of competence are expected to occur more efficiently in biofilms, the link between resistance in biofilms and cultivation/processing of GM potato EH92-527-1 was not established by Luxembourg, and the main barriers limiting the transformation frequency of bacterial cells with transgenic plant DNA remain; (iii) the risk posed by the formation of mosaic structures of aminoglycoside phosphotransferase genes could not be assessed without data documenting the existence of such structures among the existing gene variants, and such data were not provided; and (iv) the knowledge gaps and uncertainties highlighted in the Luxembourgeois document and the therapeutic relevance of kanamycin and neomycin have already been considered in the previous EFSA opinion on antibiotic resistance marker genes, and no new information on the safety of *npt*II gene as present in the GM potato EH92-527-1 has been identified in the scientific literature that would cause the GMO Panel to change its previous conclusions. Therefore, the EFSA GMO Panel concludes that no grounds exist to date that would lead to reconsideration of its opinion on GM potato EH92-527-1.

The opinion was unanimously adopted by the Panel and will be published on the following EFSA website: http://www.efsa.europa.eu/en/publications.htm

6.7 Scientific Opinion on a request from the European Commission for the assessment of the scientific elements put forward by Hungary to support the prohibition for the placing on the market of GM potato EH92-527-1 for cultivation purposes in Hungary (EFSA-Q-2012-00615)

This item of the agenda was not discussed owing to lack of time.

7. New mandates

7.1 Applications under Regulation (EC) No 1829/2003

Application for authorisation of genetically modified soybean SYHT0H2 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2012-111) (EFSA-Q-2012-00753)

7.2 Annual post-market environmental monitoring reports of GM plants

7.3 Other requests and mandates

8. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission

8.1 Scientific Committee and other Scientific Panels

Several Panel members indicated their involvement in various working groups of the Scientific Committee.

8.2 Working Groups

Interpretation of equivalence test results

A Panel member gave a presentation on the outcome types of the equivalence test. Several issues were addressed during the presentation, including the analysis of non-equivalent endpoint values, the use of an adequate comparator and the variability associated with the genetic background. Further discussion is needed.

New Techniques Working Group – nomination of Chair

The Chair of the GMO Panel nominated Kaare Nielsen as the Chair of the New techniques WG.

8.3 EFSA

8.4 European Commission

Update on the Regulation (EU) on applications for authorisation of GM food and feed
The representative of the European Commission informed the EFSA GMO Panel that the draft regulation has been notified to SPS/TBT for comments (deadline beginning of October). It is expected that the vote in the Standing Committee will take place before the end of the year.

9. Update on internal mandate activities, generic mandates and guidance for GMO risk assessment

The EFSA GMO Panel was informed about the final deliverables of the EFSA project, entitled "Establishing a database of bio-ecological information of non-target arthropod species to support the environmental risk assessment of genetically modified crops in the EU".[5] The objectives of the project were two-fold. The first objective was to establish a database that contains relevant information on non-target arthropod species found in maize, oilseed rape, potato, sugar/fodder beet, soybean, cotton and rice, and in field margins in Europe. The second objective was to explore how the information contained in the database can inform the environmental risk assessment of GM crops, be it in terms of problem formulation, species selection, environmental risk assessment studies or post-market environmental monitoring. Based on an extensive systematic literature search, data on taxonomy, geography, abundance, habitat, and ecological function were retrieved from over 1 000 publications. Species attributes and abundance data have been stored in a SQL-queryable database, which provides ecological information on 3 030 arthropod species and 14 762 abundance records from 31 European countries. The project started in December 2010 and was finalised in August 2012. The final deliverables (both the database and report) are publicly available on EFSA's website at External Scientific Report: European Arthropod Database for ERA of GM crops.

10. Any other business

Item postponed to the next meeting owing to lack of time.

11. Questions from and answers to Observers (in application of the guidelines for Observers[2])

As there were no observers attending the meeting, this item is not applicable.

[5] For further details, please see Meissle M, Álvarez-Alfageme F, Malone LA, Romeis J, 2012. Establishing a database of bio-ecological information on non-target arthropod species to support the environmental risk assessment of genetically modified crops in the EU. Supporting Publications 2012:EN-334, European Food Safety Authority (EFSA), Parma, Italy [170 pp.], http://www.efsa.europa.eu/en/supporting/pub/334e.htm.

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOI

CONFLICT OF INTEREST: In his SDoI, Christoph Tebbe declared the following interest: the applicant company for the Amflora potato, BASF, had previously commissioned a study on potato by the expert's institute and in which the expert participated. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of interest. This results in the inadmissibility for the expert to be present when agenda items 6.6 and 6.7 are discussed, voted on or in anyway processed by that scientific group concerned.