# MINUTES OF THE 56TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 10-11 MARCH 2010 IN PARMA, ITALY

## (ADOPTED ON 28 APRIL 2010)


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**PARTICIPANTS**

*GMO Panel:*
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*GMO Unit*: Per Bergman, Christina Ehlert, Zoltán Diveki, Karine Lheureux, Yi Liu, Sylvie Mestdagh, Nancy Podevin, Ellen Van Haver, Elisabeth Waigmann.

*European Commission:*
Dorothée André, Sébastien Goux and Ioana Rodica Ispas (DG SANCO).

**APOLOGIES**

*GMO Panel*:
Gijs Kleter.

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## 1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from one Panel member as mentioned above.

## 2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

## 3. DECLARATION OF INTERESTS

EFSA secretariat screened the ADoI and SDoI filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.
With regard to this meeting no other interest than those already declared in the ADoI or in a previous SDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

## 4. ADOPTION OF THE MINUTES OF THE 55TH PLENARY MEETING HELD ON 27-28 JANUARY 2010

The minutes of the 55th Plenary meeting (27-28 January 2010) were adopted as proposed and will be published at: http://www.efsa.europa.eu/en/events/event/gmo100127.htm

## 5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

### 5.1. Scientific Opinion on application (EFSA-GMO-NL-2007-39) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MON89034 x MON88017 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto (EFSA-Q-2010-00054).

*Introduction*

Following the submission of an application (EFSA-GMO-NL-2007-39) under Regulation (EC) No 1829/2003 from Monsanto, the Panel on Genetically Modified Organisms was asked to deliver a scientific opinion on herbicide tolerant and insect resistant genetically modified (GM) maize MON89034 x MON88017 (Unique identifier MON-89Ø34-3 × MON-88Ø17-3) for food and feed uses, import and processing.

*Discussion*

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-NL-2007-39, additional information supplied by the applicant and scientific comments submitted by Member States. Further information from applications for placing the single events MON89034 and MON88017 on the market under EU regulatory procedures was taken into account where appropriate. The scope of application EFSA-GMO-NL-2007-39 is for food and feed uses, import and processing of maize MON89034 x MON88017 and all derived products, but excludes cultivation in the EU.

Maize MON89034 and MON88017 have been developed for protection respectively against specific lepidopteran (*Ostrinia nubilalis, Spodoptera* spp., *Agrotis ipsilon*) and coleopteran (*Diabrotica* spp.) pests and for tolerance to glyphosate herbicides. Lepidopteran resistance is achieved by expression of the Cry1A.105 and Cry2Ab2 proteins derived from *B. thuringiensis* subsp. *kurstaki* in maize MON89034 and coleopteran resistance by expression of Cry3Bb1 protein from B. *thuringiensis* subsp. *kumamotoensis*) in maize MON88017, while tolerance to glyphosate is conferred by expression of CP4 EPSPS protein from a transgene derived from *Agrobacterium tumefaciens (*renamed *Rhizobium radiobacter)* strain CP4 in maize MON88017.

*Conclusion*

The EFSA GMO Panel considers that the information available for maize MON89034 x MON88017 addresses the scientific comments raised by the Member States and that the maize MON89034 x MON88017 as described in this 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. The EFSA GMO Panel concludes that maize event MON89034 x MON88017 is unlikely to have any adverse effect on human and animal health and the environment, in the context of its intended uses.

*Adoption*

The opinion was adopted unanimously by the EFSA GMO Panel. The scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_ScientificDocuments.htm

**5.2. Scientific Opinion on application (EFSA-GMO-RX-MON863) for renewal of the authorisation for continued marketing of existing feed materials, feed additives and food additives produced from maize MON863, under Regulation (EC) No 1829/2003 from Monsanto (EFSA-Q-2007-163).**

*Introduction*

Following a request from the European Commission, the EFSA GMO Panel was asked to deliver a scientific opinion on an application submitted by Monsanto under Regulation (EC) No 1829/2003 (reference EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$) for renewal of the authorisation of existing feed materials, feed additives and food additives produced from genetically modified maize MON863.

*Discussion*

The scope of this application covers the continued marketing of existing feed materials, feed additives and food additives produced from maize MON863 which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. After the date of entry into force of Regulation (EC) No 1829/2003 these products were notified to the European Commission according to Articles 8(1)(b) and 20(1)(b) of this Regulation and subsequently included in the Community Register of genetically modified food and feed[1]. The scope of this application excludes import of viable plant material and cultivation.

Maize MON863 expresses a variant *Bacillus thuringiensis cry3Bb1* gene which confers protection against coleopteran pests, principally corn rootworms (*Diabrotica* spp.). In addition, a selectable marker gene *npt*II encoding neomycin phosphotransferase II has been introduced.

The EFSA GMO Panel has previously issued opinions[2] related to a Notification (reference C/DE/02/09) for the placing on the market of maize MON863 for import and processing under Part C of Directive 2001/18/EC and to a request under Article 4 of the Novel Food Regulation (EC) No 258/97 for the placing on the market of foods and food ingredients derived from maize MON863. In these opinions the Panel concluded that MON863 will not have an adverse effect on human and animal health or the environment in the context of its intended use. In addition, several applications related to stacked events including maize MON863 have been evaluated and the GMO Panel concluded that these stacked events are unlikely to have an adverse effect on human and animal health and on the environment, in the context of their intended uses.

The scope of this application excludes import of viable plant material, which is covered by the previous opinions, and cultivation. Therefore, there is no requirement for scientific information on environmental safety assessment of accidental release or cultivation of maize MON863. A post-market environmental monitoring plan for maize MON863 is not required.

*Conclusion*

The EFSA GMO Panel has evaluated the new information provided by the applicant and the scientific literature and concluded that there was no new information that would require changes of its previous scientific opinions on maize MON863 (EFSA, 2004a,b). Therefore, the EFSA GMO Panel reiterates its previous conclusions that GM maize MON863 and its products which are the

[1] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=12

[2] http://www.efsa.europa.eu/EFSA/efsa_locale1178620753812_117862077233.htm & http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620772383.htm

subject of this application are unlikely to have an adverse effect on human and animal health or the environment in the context of its intended uses (EFSA, 2004a,b).

*Adoption*

The opinion was adopted unanimously by the EFSA GMO Panel. The scientific opinion will be published on the following EFSA website: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_ScientificDocuments.htm

## 6. DISCUSSION OF OPINIONS

The EFSA GMO Panel discussed the risk assessment approach for GM plants containing higher stacked transformation events and their possible segregants. It was concluded that applicants need to take into account the potential impact of any reduction in the number of events involved and they should provide scientific argumentation for the absence of specific data on the stacked events with a lower combination of events. Therefore, the applicants are requested to provide a risk assessment including information/scientific rationale on the safety of all segregants. Questions will be sent to the respective applicants for the following applications currently under assessment by the Panel: EFSA-GMO-CZ-2008-62 (MON89034 x 1507 x MON88017 x 59122 maize); EFSA-GMO-NL-2009-65 (MON89034 x 1507 x NK603 maize); EFSA-GMO-DE-2009-66 (Bt11 x MIR162 x MIR604 x GA21 maize), and EFSA-GMO-DE-2009-67 (Bt11 x MIR162 x GA21 maize).

## 7. UPDATE ON APPLICATIONS RECEIVED UNDER REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

None

## 8. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES

### 8.1. Applications under Regulation (EC) No 1829/2003

Two new applications have been received:

- Application for authorisation of genetically modified GHB614xLLCotton25 cotton for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2010-77).
- Application for authorisation of genetically modified MON 87705 soybean submitted under Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2010-78).

Competent Authorities of the Member States within the meaning of Directive 2001/18/EC as foreseen by Articles 6 (4) and 18 (4) of Regulation (EC) No 1829/2003 will be consulted by EFSA once the above mentioned applications are valid. On its own initiative EFSA has broadened this consultation also to the Member States' National Competent Authorities under Regulation (EC) No 1829/2003 and other national risk assessment bodies. The comments will be considered during the scientific evaluation by the EFSA GMO Panel of the risk assessment performed by the applicant. The summary of these applications, as well as the information on their current status can be found on Register of Questions under the respective question numbers: http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf.

### 8.2. Applications under Regulation (EC) No 1831/2003

Two new applications have been received:

- RONOZYME RumiStar (alpha-amylase) for dairy cows (EFSA-Q-2010-00151).
- Optiphos (6-phytase) for chickens for fattening, turkeys for fattening, other birds for fattening, chickens reared for laying, laying hens, turkeys reared for breeding, other laying birds, piglets (weaned), pigs for fattening, sows (EFSA-Q-2010-00153).

The summary of the applications as well as the information on their current status can be found through the following webpage leading to the EFSA's Register of Questions: http://registerofquestions.efsa.europa.eu/roqFrontend.

### 8.3. Other mandates

EFSA received a request from the European Commission (DG Environment) on 4 December 2009 under Article 18 of Directive 2001/18/EC and in conjunction with Articles 29(1) and 22(5)(c) of Regulation (EC) No 178/2002 to deliver a scientific opinion on the revised molecular characterisation for Rf3 oilseed rape received from the Competent Authority of Belgium under Article 20(3) of Directive 2001/18/EC. EFSA is requested to consider "whether the new information received in respect of oilseed rape Rf3, Ms8Rf3[3] could have consequences for the risks of the GMO to human health or the environment within the scope of Directive 2001/18/EC. In particular, EFSA is requested to take account of the objections raised by the competent authority of Austria in this context."

The first draft of the opinion was presented to the EFSA GMO Panel. The opinion will be further discussed at its next working group on Molecular Characterisation. The adoption of the opinion is foreseen by written procedure to meet the deadline for this mandate of 22 April 2010, which expires before the next plenary meeting of the GMO Panel.

## 9. UPDATE ON SELF-MANDATE ACTIVITIES AND GUIDANCE FOR GMO RISK ASSESSMENT

**Self-mandate on the choice of comparators.** The Chair of the working group presented to the EFSA GMO Panel the outline of the working group's document. The working group will hold its next meeting on 15 April 2010. It is planned that a draft opinion will be presented at the GMO Panel plenary meeting of 28-29 April 2010.

**Self-mandate for updating the Guidance for risk assessment of GM microorganisms.** The working group met on 2-4 March 2010 and will hold its next meeting on 14-16 July.

**Environmental risk assessment of GM animals.** The working group on the environmental risk assessment of GM fish will hold its first meeting on 30 April 2010.

**Human health safety assessment of GM animals**. The working group will reconvene to discuss a revised draft guidance document. Animal welfare issues will be included as far as they relate to safety aspects.

[3] Hybrid oilseed rape Ms8 x Rf3 has been produced by conventional crossing between the GM parental lines Ms8 and Rf3.

**Self mandate Allergenicity assessment of GM foods**. The EFSA GMO Panel was informed about the comments that were received during the public consultation held from 1 December 2009 until 14 February 2010.

## 10. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The two opinions on the Environmental risk assessment of GM plants and on the Assessment of potential impacts of GM plants on non-target organisms, which were adopted by the GMO Panel at their plenary meeting of 27-28 January 2010, have been presented to the Scientific Committee at their plenary meeting of 2 February 2010. The GMO Panel was also informed about the kick-off meeting of the Scientific Committee working group on 90-day feeding trials that took place 10 February 2010. The minutes of the 41st plenary meeting of the Scientific Committee are available at: http://www.efsa.europa.eu/en/events/event/scaf100102.htm.

The EFSA GMO Panel was informed about the tri-partite meeting of 3 March 2010 between the European Commission, EFSA and EuropaBio. In addition, EFSA informed the Panel about its participation to the Standing Committee on the Food Chain and Animal Health of 9-10 February 2010 to present the opinions on NK603 maize and MON 88017 x MON 810 maize, as well as the revised statistical approach as embedded in the draft EC guidelines.

## 11. FEEDBACK FROM THE COMMISSION

Dorothée André, Head of the DG SANCO Unit E.1. (Biotechnology and plant health), presented to the EFSA GMO Panel the activities of the Unit.

## 12. DATE AND PLACE OF FUTURE MEETINGS

Proposals for plenary meeting dates for 2011 were presented to the EFSA GMO Panel.

## 13. ANY OTHER BUSINESS

The EFSA GMO Panel was briefed about the EFSA Workshop on the "Application of systematic review methodology to food and feed safety assessments in support of decision making", which took place 23-25 February 2010 in Parma.