



EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE GENERAL

SANTE G

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## APPEAL COMMITTEE

### Genetically Modified Food and Feed and Plant Protection Products - Legislation

15 September 2016

### SUMMARY REPORT

#### 1. Adoption of the Agenda

The agenda was adopted without amendments.

#### 2. Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 (DAS-24236-5×DAS-21Ø23-5×MON-88913-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

The draft Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 was presented and submitted to the Committee for an opinion.

#### Vote taken: no opinion

Reasons for the negative vote or abstention:

- No agreed national position
- Absence of opinion of the national scientific committee
- Negative public opinion
- Political reasons
- Lack of long-term feeding study
- Risk assessment deemed not sufficient
- Interactions between single events not sufficiently assessed
- The Regulation on GM food and feed is not considered as the right legal basis to authorise products other than food and feed containing and consisting of GMOs

### *SE statement*

*The authorisation of products containing, consisting or produced from genetically modified cotton 281-24-236 x 3006-210-23 x MON 88913 is on the agenda of this meeting. The authorisation does not cover cultivation. Cotton 281-24-236 x 3006-210-23 x MON 88913 is tolerant to glyphosate- and glufosinate-ammonium-based herbicides.*

*The Swedish Board of Agriculture and the National Food Agency make the same conclusions as stated by the European Food Safety Authority i.e. this product is safe for human and animal health and for the environment. Sweden therefore votes in favour of granting the product authorisation according to the Commission proposal.*

*This does not preclude the Swedish vote on a possible future granting of authorisation for cultivation of seeds that are tolerant to glufosinate-ammonium.*

*Glufosinate-ammonium is classified as reprotoxic in category 1B, which means that it does not fulfil the requirements for authorisation according to the new Plant Protection Regulation No 1107/2009. Sweden is of the opinion that any potential use and cultivation of genetically modified organisms in Sweden should not have a negative effect on biodiversity and, as far as possible, not lead to an increased use of pesticides.*

According to the comitology rules, it is for the Commission to decide on the authorisation of this cotton.

### **3. Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision renewing the authorisation for the placing on the market of genetically modified maize MON 810 (MON-ØØ81Ø-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

The draft Decision renewing the authorisation for the placing on the market of genetically modified maize MON 810 products was presented and submitted to the Committee for an opinion.

#### **Vote taken: no opinion**

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Lack of long-term feeding and toxicity studies
- Risk assessment deemed not sufficient
- The Regulation on GM food and feed is not considered as the right legal basis to authorise products other than food and feed containing and consisting of GMOs

*IE statement*

*Ireland supports the authorisation of these cottonseed and maize products, however, this position does not prejudge or pre-empt any future decision on GMO authorisations, for food and feed or cultivation, or any future adoption of national opt out measures.*

According to the comitology rules, it is for the Commission to decide on the renewal of the authorisation of this maize.

**4. Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the active substance tricyclazole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market**

The Chair summarised the key background information concerning the regulatory history of tricyclazole in the European Union and the outcome of the scientific peer review following application for approval under Regulation (EC) No 1107/2009.

The PAFF Committee had not delivered an opinion in its meeting on 12 July 2016. Therefore, it was necessary to refer this draft to the appeal committee pursuant to Article 5(4) of the new Comitology Regulation (Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers).

The Commission introduced the draft, which was the same as that presented to the Standing Committee on 12 July 2016.

The Chair reiterated that the Commission has done its utmost to find a solution to the issues identified, but that the concerns identified were not new and that the applicant should have taken steps to address these fully in their dossier submitted for approval. Given the concerns and data gaps identified, the approval criteria for approval of active substances laid down in Regulation (EC) No 1107/2009 had not been satisfied.

The Chair asked whether any Member State had changed its position or whether Member States had any further comments.

Two Member States expressed their positions. One Member State fully supported the Commission proposal for non-approval and considered that the information available was not sufficient to demonstrate safety of tricyclazole and hence approval could not be supported. Another Member State expressed concerns about the lack of solutions for rice growers in the EU especially compared to those available in third countries.

The Commission concluded that there was no qualified majority for the draft, but noted that it was supported by a significant number of Member States.

**Vote taken: no opinion**