



EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE GENERAL

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SUMMARY REPORT OF THE APPEAL COMMITTEE

Genetically Modified Food and Feed

Regulatory Committee 2001/18/EC

27 MARCH 2017

Chair: Ladislav Miko

1. **Adoption of the Agenda**

The Chair explained the interpretation regime for the Appeal Committee. The agenda was adopted without amendments.

2. **Exchange of views and possible opinion of the Committee on a Draft Commission Implementing Regulation renewing the authorisation for the placing on the market for cultivation of genetically modified maize MON 810 (MON-00810-6) seeds pursuant to Directive 2001/18/EC.**

SANTE/10702/2016

The Chair introduced the draft Commission Implementing Regulation renewing the authorisation for the placing on the market for cultivation of genetically modified maize MON 810 (MON-00810-6) seeds, which was the same as that presented to the Standing Committee on 27 January 2017.

No questions were raised by Member States and the draft was put up for vote.

Vote taken: no opinion

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk of harm to the national agri-food industry
- Uncertainties in risk assessment
- Safety concerns for the environment
- Precautionary principle
- Lack of comprehensive data on long-term potential impact of GMOs

The chair informed the members of the Committee that, in accordance with Regulation (EU) No 182/2011, it is now for the Commission to decide on this authorisation.

3. Exchange of views and possible opinion of the Committee on a Draft Commission Implementing Decision concerning the placing on the market for cultivation of genetically modified maize Bt11 (SYN-BT011-1) seeds pursuant to Directive 2001/18/EC.

SANTE/10704/2016

The Chair introduced the draft Commission Implementing Decision concerning the placing on the market for cultivation of genetically modified maize Bt11 (SYN-BT011-1) seeds, which was the same as that presented to the Standing Committee on 27 January 2017.

No questions were raised by Member States and the draft was put up for vote.

Vote taken: no opinion

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk of harm to the national agri-food industry
- Uncertainties in risk assessment
- Safety concerns for the environment
- Potential risks for the environment and health due to tolerance of maize Bt11 to glufosinate ammonium
- Precautionary principle
- Lack of comprehensive data on long-term potential impact of GMOs

Written Statement from Sweden:

"The granting of authorisation of cultivation of seeds of the genetically modified maize Bt11 (SYN-BT011-1) is on the agenda for this meeting. Maize Bt11 is tolerant to glyphosate- and glufosinate-ammonium-based herbicides.

Sweden votes against the authorisation of cultivation of the genetically modified maize Bt11 with reference to the serious effects of glufosinate-ammonium on health and environment should the substance be released in to the environment.

Glufosinate-ammonium is classified as a substance toxic for reproduction in category 1B which means that it does not fulfil the approval criteria for active substances according to the Regulation (EC) No 1107/2009. In our view, 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.

The Swedish government is of the view that an holistic approach to the use of the substance is important. The political assessment is that glufosinate-ammonium is such a toxic pesticide that a NO-vote is warranted in order to contribute to an Union strategy for a non-toxic environment in the European Union."

The chair informed the members of the Committee that, in accordance with Regulation (EU) No 182/2011, it is now for the Commission to decide on this authorisation.

4. Exchange of views and possible opinion of the Committee on a Draft Commission Implementing Decision concerning the placing on the market for cultivation of genetically modified maize 1507 (DAS-01507-1) seeds pursuant to Directive 2001/18/EC.

SANTE/10703/2016

The Chair introduced the draft Commission Implementing Decision concerning the placing on the market for cultivation of genetically modified maize 1507 (DAS-01507-1) seeds, which was the same as that presented to the Standing Committee on 27 January 2017.

No questions were raised by Member States and the draft was put up for vote.

Vote taken: no opinion

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk of harm to the national agri-food industry
- Uncertainties in risk assessment
- Safety concerns for the environment
- Potential risks for the environment and health due to tolerance of maize Bt11 to glufosinate ammonium
- Precautionary principle
- Lack of comprehensive data on long-term potential impact of GMOs

Written Statement from Sweden:

"The granting of authorisation of cultivation of seeds of the genetically modified maize Bt11 (SYN-BT011-1) is on the agenda for this meeting. Maize Bt11 is tolerant to glyphosate- and glufosinate-ammonium-based herbicides.

Sweden votes against the authorisation of cultivation of the genetically modified maize Bt11 with reference to the serious effects of glufosinate-ammonium on health and environment should the substance be released in to the environment.

Glufosinate-ammonium is classified as a substance toxic for reproduction in category 1B which means that it does not fulfil the approval criteria for active substances according to the Regulation (EC) No 1107/2009. In our view, 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.

The Swedish government is of the view that an holistic approach to the use of the substance is important. The political assessment is that glufosinate-ammonium is such a toxic pesticide that a NO-vote is warranted in order to contribute to an Union strategy for a non-toxic environment in the European Union."

The chair informed the members of the Committee that, in accordance with Regulation (EU) No 182/2011, it is now for the Commission to decide on this authorisation.

- 5. 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 maize Bt11 x 59122 x MIR604 x 1507 x GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604,1507 and GA21 pursuant to Regulation (EC) 1829/2003**

SANTE/11494/2016

The Chair introduced the draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21, which was the same as that presented to the Standing Committee on 27 January 2017.

No questions were raised by Member States and the draft was put up for vote.

Vote taken: no opinion

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk of harm to the national agri-food industry
- National GM-free strategy
- EFSA minority opinion
- Risk assessment deemed not sufficient
- Lack of long-term feeding studies
- Precautionary principle
- Lack of comprehensive data on long-term potential impact of GMOs

Written Statement from Sweden:

"The authorisation of placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 x 59122 x MIR604 x 1507 x GA21 is on the agenda for this meeting. The authorisation does not include cultivation. Maize Bt11 x 59122 x MIR604 x 1507 x GA21 is tolerant to glyphosate- and glufosinate-ammonium-based herbicides.

The Swedish Board of Agriculture and the National Food Agency make the same conclusion as stated by EFSA i.e. this product is safe for human and animal health as well as 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 of cultivation of seeds that are tolerant to glufosinate-ammonium.

Glufosinate-ammonium is classified as a substance toxic for reproduction in category 1B which means that it does not fulfil the approval criteria for active substances according to the Regulation (EC) No 1107/2009.

In our view, 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."