EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

SUMMARY RECORD OF THE

STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

HELD IN BRUSSELS ON 12 DECEMBER 2011

(SECTION GENETICALLY MODIFIED FOOD & FEED AND ENVIRONMENTAL RISK)

Chair: Dorothée André

All Member States were represented.

Adoption of the agenda

1. Ruling of the European Court of Justice on the regulatory status of genetically modified pollen in honey.

The Commission recalled briefly the consequences of the judgement on genetically modified (GM) pollen in honey as regards authorisation and labelling requirements. Regarding MON810 pollen, Monsanto will submit soon to EFSA an application. Concerning the safety of pollen from Ms8xRf3 and Gt73 oilseed rapes, the Commission sent a mandate to EFSA for which the outcome is expected for end of December, beginning of January. The Commission recalled that notifications under the Rapid Alert System for Food and Feed should be issued when there is a serious risk to health.

Regarding methods for detection and quantification of pollen, no harmonised methods are available yet. A representative of the Joint Research Centre (JRC) explained the difficulties they still encounter. The extraction of pollen from honey is possible but challenging as regard reproducibility. The quantification of GM pollen in total pollen is also challenging since no reference gene marker is specific for pollen. Argentinean experts have visited the JRC and approaches have been chaired and discussed in order to ensure harmonisation of methods also with third countries.

The Commission explained that analysis is ongoing in order to decide whether the status of pollen in honey should be further clarified.

A Member State stressed that a harmonised approach on this issue is key and Member States should wait for methods of extraction and detection to be harmonised before acting.

A second Member State explained that the impacts on trade and the honey industry are important and that a letter has recently been sent to the Commission calling for a solution to avoid unnecessary and unjustified burdens.

A third Member State stressed that the ruling should be applied without delay and that different samples of honey have been analysed.

2. Discussion on the impact of the implementation of Commission Regulation (EC) No 619/2011 on the feed and food chain.

The Commission indicated that Regulation (EU) No 619/2011 has been in force since July 2011, and that it was the intention of the Commission to prepare a report on the impact of its implementation on the feed and food chain. The Commission also outlined the impact assessment reports which had already been submitted by European Vegetable Oil and Proteinmeal Industry Federation (FEDIOL) and European Vegetable Protein Federation, which indicated that the annual import of 250,000 tonnes of non GM soya used in food processing, would potentially touch over 15 million tonnes given that it is incorporated in food at levels between 0.3% and 50%.

The Committee Members were invited to comment on their own experience. Six member States indicated that they would favour an extension of the current measure to food.

The Commission invited Member States to submit any data they had on the implementation of the measure before the end of the year.

3. Draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 356043 (DP-356Ø43-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. (Art. 7(3) and Atr. 19(3) of Regulation (EC) No 1829/2003) (Opinion of the Committee via the examination procedure)

The draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 356043 pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was presented and submitted to the Committee for an opinion.

Vote: no opinion (181 votes in favour, 94 votes against, 70 abstentions)

The following reasons were mentioned by Member States for not supporting the draft Decision:

- molecular characterization, compositional analysis and toxicological studies are not considered as satisfactory;

- no sufficient study and data for the comparative analysis between the GM soybean and its counterpart;

- the conclusion of the risk assessment is not considered as fully satisfactory;

- precautionary principle invoked;

- safety of glyphosate not 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;

- negative public opinion and perception to GMO;

- political reasons.

The Chair indicated that the Commission would be invited to submit a proposal to the Appeal Committee in accordance with Regulation (EU) No 182/2011.

4. Draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87701 (MON-877Ø1-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. (Art. 7(3) and Atr. 19(3) of Regulation (EC) No 1829/2003) (Opinion of the Committee via the examination procedure)

The draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87701 pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was presented and submitted to the Committee for an opinion.

Vote: no opinion (181 votes in favour, 84 votes against, 80 abstentions)

The following reasons were mentioned by Member States for not supporting the draft Decision:

- molecular characterization, compositional analysis, toxicological and allergenicity studies and nutritional assessment are not considered as satisfactory;

- no sufficient study and data for the comparative analysis between the GM soybean and its counterpart;

- the conclusion of the risk assessment is not considered as fully satisfactory;

- precautionary principle invoked;

- lack of experimental data;

- environmental monitoring plan not satisfactory;

- 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;

- negative public opinion and perception to GMO;

- political reasons.

The Chair indicated that the Commission would be invited to submit a proposal to the Appeal Committee in accordance with Regulation (EU) No 182/2011.

5. Draft Commission Implementing Decision amending Commission Decisions 2007/305/EC, 2005/306/EC and 2005/307/EC to prolong the transitional period of time needed to ensure the withdrawal from the market of respectively Ms1xRf1 (ACS-BNØØ4-7xACS-BNØØ1-4) hybrid oilseed rape, Ms1xRf2 (ACS-BNØØ4-7xACS-BNØØ2-5) hybrid oilseed Rape and Topas 19/2 (ACS-BNØØ7-1) oilseed rape, as well as their derived products (Opinion of the Committee via the examination procedure)

A draft implementing Decision to amend Commission Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC concerning the withdrawal from the market of several GM oil seed rape events [Ms1xRf1, Ms1xRf2, and Topas 19/2) was presented to the Committee. The Commission's representative indicated that the Decision to extend was based on test results from stakeholders, which show that while the measures undertaken by the authorisation holder (Bayer CropScience AG) have allowed the removal of practically all the GM material from the market, minute traces (<0.1%) may still be present in food or feed chain at the end of the transitional period foreseen in the original withdrawal Decisions adopted in 2007. The presence of remaining traces after the transitional period of 5 years can be explained by the biology of oilseed rape which can remain dormant for long periods as well as by the farm practices employed to harvest the seed. The Commission highlighted that while the draft Decision provides for the extension of the current phasing out period for another five years, the tolerance level will be reduced from 0.9% to 0.1% and it will also require the authorisation holder to continue to implement the measures in the original Decisions to ensure that all remaining traces are removed from the food and feed chain.

Vote: Qualified majority opinion (287 votes in favour, 27 against, 31 abstentions)

The following reasons were mentioned by Member States for not supporting the draft Decision:

- Concerns on an additional 5 year phasing out period and the ability of authorisation holders to phase out GM events.

- Proposal sent too late to finalise a position.

- Negative political and public sentiment.

6. AOB

6.1. ECJ ruling on the French safeguard clause on MON810 maize

The Commission made a presentation on the ruling of the Court of 8 September 2011 C-58/10 to C-68/10 Monsanto SA against the French Ministry of Agriculture and Fisheries. The Commission highlighted in particular the following elements of the ruling:

The Court confirms the exclusive application of Regulation (EC) N° 1829/2003 to products notified as existing product in the sense of Article 20 of the Regulation- only the safeguard clause referred to in Article 34 of this Regulation is applicable to these products. It clearly states that the safeguard clause referred to in Article 23 of Directive 2001/18/EC is not applicable (point 62 of the judgement).

The Court explains the functioning of the safeguard clause referred to in Article 34 of the Regulation: in order to use it, a Member State has to respect the substantial conditions set out in Article 34 and the procedural conditions set out in Article 54 of Regulation (EC) N° 178/2002 (point 69). As regards the procedural conditions, the Court recalled the Member State first to inform the Commission "officially" of the need to take emergency measure and secondly, where the Commission has not acted, to inform "immediately the other Member States and the Commission of the measures adopted" (points 70 to 74). On the substantial conditions, the Court considers that, to invoke Article 34, a Member State has to establish, in addition to urgency, the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health and the environment (point 81).

The Court notes that the assessment and management of a serious and evident risk ultimately comes under the sole responsibility of the Commission and the Council, subject to review by the EU Courts (point 79). However, the national Courts have jurisdiction to assess the lawfulness of safeguard clauses as long as no decision has been adopted in that regard at EU level (point 79).

6.2. Evaluations of Directive 2001/18/EC and Regulation (EC) No 1829/2003

The Commission asked the Member States for further comments on the results of the evaluations of Directive 2001/18/EC and Regulation (EC) No 1829/2003. No feedback was given.

6.3. Draft Commission Implementing Decision repealing Commission Decision 2008/289/EC and introducing new emergency measures regarding unauthorised genetically modified organisms in rice products originating from People's Republic of China. (Art. 53(1) of Regulation (EC) No 178/2002)

The Joint Research Centre outlined the proposed training for Member States (December 2011) and the Chinese laboratories (February 2012) regarding the screening method in the Decision.

6.4. Appeal committee

The Commission explained that according to the new Comitology Rules the two draft measures for which no opinion was reached today will be presented for an opinion at the Appeal Committee meeting.