EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

SUMMARY RECORD OF THE

STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

HELD IN BRUSSELS ON 22 SEPTEMBER 2011

(SECTION GENETICALLY MODIFIED FOOD & FEED AND ENVIRONMENTAL RISK)

Chair: Dorothée André (Items 1, 2, 5, 6)

Sébastien Goux (Items 3,4)

All Member States were represented.

Adoption of the agenda

1. Draft Commission 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

A Commission representative outlined the main reasons which lead the Commission to introduce new emergency measures on rice originating from China. In particular, the FVO mission carried out in April 2011 concluded that there is a high risk that rice products containing non authorised GMOs are exported to the EU. This is confirmed by the number of Rapid Alerts (already 30 in 2011) despite the current measures in place.

The two main features of the new measures are the following: in addition to the analytical report already provided for in the 2008 measure which has been maintained, the shipments must be accompanied by an official health certificate in order to avoid illegal exports from China that would not have been subject to official oversight by the Chinese authorities. With respect to the method of detection, a screening approach combining four different PCR methods will be imposed so as to ensure the detection of several events of non authorised GM rice.

Delegations expressed their support on the principle to reinforce the emergency measures. A discussion took place on various practical aspects regarding the implementation of the new measures, including on the application of the method of detection. The Commission took note of these comments and announced that a revised draft Decision would be submitted for vote at the next meeting of this Committee.

2. Ruling from the European Court of Justice (ECJ) regarding the legal status of pollen produced from GM maize MON810 and honey with pollen from GM maize MON810 – Discussion on implementation

A Commission representative presented the status of honey and pollen in honey prior to the ruling, a summary of the ECJ ruling and explained that the Commission is in the process of analysing the impact of the ruling and shaping its position.

The following points were raised during the discussion:

- Several Member States shared their concern about the possible negative impact of this ruling on honey produced in the EU as well as on honey imported from third countries.

- Several Member States enquired on the safety of pollen and honey containing pollen from MON810 maize. The Commission indicated that, in order to address these questions, EFSA will be requested to adopt as soon as possible a statement on the safety of these products.

- With respect to the legal status, the Commission recalled the particular status of MON810 maize i.e. only authorised for specific food uses (maize flour, maize gluten, maize semolina, maize starch, maize glucose and maize oil, and food additives) contrary to all recent authorisations (including the four authorisations for "stacked" maize where the genetic modification of MON810 is combined with one or several other modifications) which cover all food uses. The applicant (Monsanto) will have to submit an application in view of obtaining an authorisation for the food uses of MON810 maize which are not currently authorised in accordance with the GM Regulation (full scope authorisation).

- Member States requested the Commission to provide a comprehensive list of GMOs with incomplete scope of authorisation. The Commission provided this list orally and committed to provide this information also in writing. It is based on the authorised uses that are clearly indicated in the EU register on GM food and feed.

- Member States expressed their concerns as regards the implementation of the labelling provisions, in light of the ruling and proposed different implementation approaches to apply the labelling rules taking into account the requirements of Directive 2001/110/EC on honey and of Regulation (EC) No 1829/2003 on GM food and feed. It was also stressed that, to date, there is no harmonised method of sampling or validated method of analysis which would allow to verify that the labelling provisions were respected.

- Aspects related to coexistence and field trials will be further discussed in the framework of the Committee under Directive 2001/18/EC which will meet on 25 October and coexnet meeting on 11 November.

- Some delegations indicated that a modification of the legislation should be considered.

- Some Member States asked for guidance from the Commission for the issue of controls and measures to be taken for products illegally placed on the market.

- The Chair of the Committee concluded that the matter was highly complex and needed further reflection. She also indicated that the Commission would meet third countries and stakeholders on the 28th and 30th of October respectively. This point will be re-discussed at the next meeting of this Committee.

3. EFSA Guidance on selection of comparators for the risk assessment of GM plants – Presentation by EFSA

The presentation provided an overview of the Guidance on selection of comparators for the risk assessment of GM plants. The specific issues addressed in this document are the following:

- Selection of comparator for GM plants containing single events;

- Selection of comparator for GM plant containing stacked events;

- Role of negative segregants;

- Selection of comparators for GM plants containing stacked events obtained by techniques other than conventional breeding;

- Design of field trials for the cases analysed

- Selection of comparators in cases where the current comparative approach may not be suitable (e.g. where major compositional changes are targeted).

4. EFSA Updated Guidance for risk assessment of food and feed from GM plants – Presentation by EFSA

The presentation provided an overview of the Guidance for risk assessment of food and feed from GM plants. Compared to the previous guidance, the following modifications have been made:

- An introductory paragraph to explain why information and a summary are required for each section

- The required information is more detailed, especially with respect to:
    - Requirements for the risk assessment of GM plants containing stacked events
    - Assessment of protein expression
    - Toxicological assessment: reference to internationally agreed protocols

- Opinions adopted by the GMO panel on the following matters have been integrated:
    - Criteria for selection of appropriate comparator(s) under different scenarios (Opinion adopted in 2011)
    - Design of field trials for compositional, agronomic and phenotypic traits (Opinion adopted in 2010)
    - Statistical analysis of field trial data: difference/equivalence tests (Opinion adopted in 2010)
    - Animal feeding studies: when considered necessary (Opinion adopted in 2008)
    - Allergenicity assessment: newly expressed proteins and whole GM food/feed (Opinion adopted in 2010)

This document is thus providing an up-to-date and consolidated EFSA guidance for the preparation of applications for authorisation of food and feed from GM plants. The discussion on the draft Regulation on applications for GM food and feed will resume within the Committee in the coming months.

5. EFSA opinion on application for the placing on the market of insect resistant genetically modified soybean MON 87701 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto – Presentation by EFSA

EFSA presented the opinion on MON 87701 which was adopted in July 2011. One Member State asked for more clarifications on answers provided by EFSA in annex G of its opinion. EFSA will evaluate this information and will directly reply to the Member State.

A more general question was also raised on the acceptability of non-required studies which are submitted by applicants. It was concluded that this matter would be further clarified in the context of the draft Regulation on applications for GM food and feed which will be presented and discussed within the Committee in the coming months.

6. Development of national rules and private schemes regarding GM-free labelling – Information from the Member States on current developments

The delegation of France presented the draft legislation that was notified under Directive 98/34/EC. The draft is making the distinction between products from plant origin and animal origin. Apiarian products are also covered. Specific rules apply to each type of product. The draft has been modified following the comments received in the framework of the notification procedure. The legislation is due to be adopted by the end of the year after the review of the "Conseil d'Etat".

The delegation of Germany reported on the current implementation of the German law which applies since 2008. The delegation of Austria reported on the current implementation of the soft law. Four other delegations indicated that guidelines had been developed on the matter.

Several delegations indicated that they were not in favour of the development of "GM free labelling" since they consider that positive labelling (labelling indicating the GM origin of the product) remains the most appropriate way to inform consumer.

Several delegations (either being in favour or opposed to GM-free labelling) indicated that they would appreciate an initiative of the Commission to harmonise such labelling.

A Commission representative indicated that in the absence of EU legislation establishing harmonisation rules on GM-free labelling, such rules could be adopted by Member States subject to notification under Directive 98/34/EC. The analysis of the Commission of such notification is done in particular in light of Directive 2001/13/EC which provides general rules on food labelling. The guiding principle of this analysis is that the draft national legislation must not mislead the consumer. It was also stressed that such national rules should include a clause of mutual recognition.

The Chair of the meeting indicated that such labelling was included in the evaluation of Regulation (EC) No 1829/2003 on GM food and feed of which the results are due to be published by the end of October. The Commission will also announce at this occasion the actions which will be taken following this evaluation.