SUMMARY RECORD OF THE
STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

Held in Brussels on 10 October 2007

(Section Genetically Modified Food & Feed and Environmental Risk)

President: Michael Flueh and Dorothée André

All Member States were present, except Finland which was represented by the United Kingdom.

1. Information from the Commission on handling of the applications for renewals

A representative of the Commission presented the approach for the handling of applications for the renewal of the authorisations of the so-called "existing products".

As a follow-up of the approach followed by the European Food Safety Authority (EFSA), 3 types of applications may be distinguished:

- Applications for which another application related to the same Genetically Modified Organism (OGM) is already pending under Articles 5 and 7. EFSA will issue a single opinion covering both applications and the Commission is considering the possibility to propose a single decision covering all products.
- Applications for which a recent decision was taken by the Commission. Upon reception of the opinion of EFSA, the Commission will consider the most appropriate way to ensure the coherence between the existing decisions and the decision to be taken concerning the other products related to the same GMOs.
- Applications that are not corresponding to the two types above, the Commission will proceed in the same way than for applications for new GMOs.

It was clarified that the regulatory requirements for EFSA to consult Member States in the case of applications requiring an environmental assessment were identical for applications for renewals or for applications for new GMOs. EFSA informed the Member States that in order to ease their assessment it would indicate which information is new and which information was already considered by Member States and EFSA in the context of other applications.

For applications related to cultivation, EFSA has to ask a national competent authority to carry out the environmental risk assessment.

It was recalled that pending a decision, the existing products could continue to be placed on the market.

2. Update from the Commission on the Measures on LL601 rice

The Committee examined 3 types of information:

1. *United States Department of Agriculture (USDA) report on its investigation and possible revisions of Biotechnology framework published on Friday 5 October;*

   The Commission informed the Committee that USDA officials presented the main findings of the investigation to the Commission on Thursday 4 October 2007. This information that was still confidential has been published on the 5 October by US authorities. This was highly appreciated. Given the very recent publication of the reports, no in-depth analysis could be made by the Committee. It was noted that despite extensive investigations, the mechanism of contamination could not be established and no legal infringements could be determined. Nevertheless, the location and the timing of the contamination are circumscribed and all contaminated lots could be traced back. The launching of an in-depth review of the existing US Animal and Plant Health Inspection Service (APHIS) Biotechnology framework on the basis of the lessons learned from these incidents was welcomed.

2. *Overview of the controls carried out by Member States on import and products on the EC market;*

   An overview of the number of tests and number of positive results was made on the basis of information provided by the majority of Member States. It was underlined that limited trade was still ongoing, thus providing additional information on the functioning of the emergency measures. Results obtained were on the US harvest of 2006 that was made in a different context than 2007 (see point 3). Some Member states reported contaminated products that had still to be notified through the Rapid Alert System for Food and Feed (RASFF).

3. *Information from US rice operators on controls carried out on 2007 harvest;*

   It was recalled that US rice operators had put in place a "seed plan" in order to prevent seeds contaminated with rice LL601 or LL604 to be used in 2007. The Committee considered a new report summarising the results of the controls made by the US operators on the ongoing 2007 harvest. Out of the 366 tests reported, only 1 indicated the presence of LLRice. Additional information on the positive tests as well as the handling of the contaminated rice would be appreciated by the Committee. It was also indicated that it would be useful to have information on whether lots presented for import were from the 2006 or the 2007 harvest.

The Committee was also informed that preliminary contacts had been made with USDA in order to investigate whether US authorities could provide further assurances on the sampling and testing carried out prior export. This was welcomed by the Committee.

Prospects that, in the future, larger lots of rice (5000 t compared to 240 t at the present time) would be imported and the possible impact on control procedures was also discussed.

The Chairman indicated that the Commission would continue to carefully monitor the situation and have further contacts with US authorities in order to investigate which type of

official assurances on US exports could be provided. The situation will be re-assessed at the next meeting of the Committee.

3. Update from the Commission on the situation with BT63 rice

The Committee was informed that following Commissioner Kyprianou's recent visit to China the Chinese authorities made available control samples and a validated method for Bt63 in rice. As a next step the Joint Research Centre (JRC) will now verify the method and make samples and protocol available to the national laboratories.

4. Ongoing work of Codex Alimentarius on genetically modified organism

The outcome of the meeting of the Codex Task Force on Modern Biotechnology was presented to the Committee. Three draft guidelines related respectively to the assessment of food from genetically modified animals, food from plants modified for nutritional or health benefits and the assessment in situation of low-level presence were presented. These three drafts should be presented to the Codex Commission for adoption in July 2008.

A Commission representative drew the attention of the Committee on a recent circular letter aiming to receive comments from Codex Members on the ongoing work on labelling of genetically modified food. The Commission will draft an answer on the basis of the contribution received from Member States.

5. Opinion on a Draft Commission Decision authorising the placing on the market of food and feed containing, consisting of, or produced from the genetically modified potato line EH92-527-1 (BPS-25271-9) under Regulation (EC) No 1829/2003 of the European Parliament and of the Council

A draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified potato line EH92-527-1 (BPS-25271-9) pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was submitted to the Committee for an opinion.

It was first underlined that this Decision covering the presence of the GM potato in the food and feed chain was complementary to a Decision to be adopted under Directive 2001/18/EC authorising the cultivation and the handling of the same genetically modified potato for the production of industrial starch. Once authorised, this potato is planned to be cultivated in a restricted number of Member States.

The restrictions of the draft decisions were, during the discussions, put in perspective to the general rules of the legislation on GMO and to other Decisions that were recently adopted. In particular, in accordance with the labelling provisions of Regulation (EC) No 1829/2003, operators who wish to place on the market non-genetically modified food or feed, should take appropriate measures to ensure that the adventitious or technically unavoidable presence of GMOs is below 0.9%. It was underlined that if the conditions set out in the Decision to be adopted under Directive 2001/18/EC were followed, the risk of adventitious presence was limited. Similar restrictions were adopted in recent Decisions of the Commission on the withdrawal of genetically modified products from the market.

As a general principle, products which by their nature are likely to be used as food or feed should be assessed for use in the same way as their conventional counterpart. The restrictions of the present authorisation to AP below 0.9% were considered as exceptional but in line with the intended and unintended uses of the potato and reflected that, in the same way that conventional starch potato that are not intended to be used as food, adventitious presence cannot be totally excluded.

The title of the draft decision was amended in order to better reflect its scope. Recital 9 was amended in order to clarify that it is only when all the measures provided in Directive 2001/18/EC to prevent the presence of the potato had been applied, that this presence could be considered as adventitious or technically unavoidable.

Vote: no opinion (123 votes in favour, 133 against, 89 abstentions)

The following considerations were mentioned as reasons for not supporting the draft decision:
- some Member States considered that the EFSA opinion was not fully satisfactory. In particular, the presence of the *nptII* gene was, although a specific recent opinion of EFSA confirming its favourable opinion on the use of this gene as marker of selection, considered as not desirable.
- other reasons such as the opposition to tolerate the adventitious presence in some products, the negative public opinion with respect to GMO, the fact that internal national consultations were not concluded or the unclear national political situation

One delegation provided a written declaration (see hereunder).

Written declaration from the delegation of Belgium
"Tenant compte de la situation politique actuelle en Belgique et en attente de la formation d'un nouveau gouvernement fédéral, la Belgique s'abstient pour le vote de ces 4 dossiers."

6. Opinion on a Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xNK603 (MON-ØØ863-5xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

7. Opinion on a Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xMON810 (MON-ØØ863-5xMON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

8. Opinion on a Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xMON810xNK603 (MON-ØØ863-5xMON-ØØ81Ø-6xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

Three draft Commission Decisions authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize stacks pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was submitted to the Committee for an opinion.

The Committee expressed the same vote for the three draft decisions.

Vote: no opinion (149 votes in favour, 119 against, 77 abstentions)

The following considerations were mentioned as reasons for not supporting the draft decision:
- some Member States considered that the EFSA opinion was not fully satisfactory. In particular, the presence of the *nptII* gene was, although a specific recent opinion of EFSA confirming its favourable opinion on the use of this gene as marker of selection, considered as not desirable.
- other reasons such as opposition to authorise products other than food and feed containing and consisting GMOs under the Regulation on GM food and feed, the technical limitations to apply the labelling rules for this type of GMOs, the negative public opinion with respect to GMO, the fact that internal national consultations were not concluded or the unclear national political situation

One delegation provided a written declaration (see hereunder).

The Chairman indicated that the Commission would be invited to submit a proposal to the Council in accordance with the Regulatory procedure.

Written declaration from the delegation of Belgium
"Tenant compte de la situation politique actuelle en Belgique et en attente de la formation d'un nouveau gouvernement fédéral, la Belgique s'abstient pour le vote de ces 4 dossiers."