STANDING COMMITTEE
ON THE FOOD CHAIN AND ANIMAL HEALTH

SECTION *GM FOOD & FEED AND ENVIRONMENTAL RISK*
SECTION *PHYTOPHARMACEUTICALS*

SUMMARY RECORD OF THE 9TH MEETING – 3rd March 2006

SECTION PHYTOPHARMACEUTICALS

President: Mrs Patricia Brunko

24 Member States were present, Cyprus was absent and represented by Greece. Qualified majority: 232 votes and 13 Member States in favour.

At the start of the meeting the Commission explained the background of the proposals presented.

After the evaluation of the substances and because of the hazardous properties of the active substances the Commission, who has a responsibility for risk management, is of the opinion that in order to achieve the high level of protection of human and animal health and the environment chosen in the Community, the inclusion in Annex I to Directive 91/414/EEC should be restricted to the uses that have been actually assessed within the Community evaluation and for which the proposed uses were considered to comply with the conditions of Directive 91/414/EEC provided risk mitigation measures are applied. This means that other uses, which were not or only partially covered by the assessment performed for Annex I inclusion, must first be subject to a complete assessment at EU level, before their inclusion in Annex I of Directive 91/414/EEC can be considered. The Commission declared that for such uses, it is prepared, on the basis of such assessment, to consider as soon as possible an amendment of the inclusion conditions if the assessment confirms that they comply with the conditions of the Directive

The proposals provide for detailed risk mitigation measures, such as limitation of dose to be used, maximum number of applications, no air application or protective equipment for operators, and risk mitigation for birds, mammals, aquatic organism and non target arthropods.

For the active substances which are considered endocrine disruptors, there is an obligation to provide new studies as soon as OECD has finalised the test protocols. This would allow having a final picture of the endocrine disrupting properties of these substances.

The revisions at national level, taking into account the uniform principles and local conditions, must take place within 3 instead of 4 years for all plant protection products containing the substances. Moreover the inclusion in Annex I is restricted to 7 years in order to ensure that these substances are reviewed again when more experience on their use is available. Therefore the proposal also provides that authorisation holders have to report every year on any reported effect on operator health.

1. **Examination and possible opinion on a draft Commission Directive concerning the inclusion of azinphos-methyl in Annex I to Council Directive 91/414/EEC** (draft Directive SANCO/10324/2005 rev. 2, draft review report SANCO/7587/VI/97 rev. 2)

   The Committee took note of the review report outlined in document SANCO/7587/VI/97 rev. 2.

   Vote: No opinion (223 votes against, 4 MS in favour).

2. **Examination and possible opinion on a draft Commission Directive concerning the inclusion of carbendazim in Annex I to Council Directive 91/414/EEC** (draft Directive SANCO/10410/2004 rev 2, draft review report SANCO/5032/VI/98 rev.9)

   The Committee took note of the review report outlined in document SANCO/5032/VI/98 rev.9.

   Vote: No opinion (168 votes against, 9MS in favour).

3. **Examination and possible opinion on a draft Commission Directive concerning the inclusion of dinocap in Annex I to Council Directive 91/414/EEC** (draft Directive SANCO/10677/2005 rev 0, draft review report SANCO/4345/2000 rev. 1)

   The Committee took note of the review report outlined in document SANCO/4345/2000 rev. 1.

   Vote: No opinion (162 votes against, 9 MS in favour).

4. **Examination and possible opinion on a draft Commission Directive concerning the inclusion of fenarimol in Annex I to Council Directive 91/414/EEC** (draft Directive SANCO/10321/2005 rev 5, draft review report SANCO/6847/VI/1997 rev.4)

   The Committee took note of the review report outlined in document SANCO/6847/VI/1997 rev. 4.

   Vote: No opinion (156 votes against, 6 MS in favour).

5. **Examination and possible opinion on a draft Commission Directive concerning the inclusion of flusilazole in Annex I to Council Directive 91/414/EEC** (draft Directive SANCO/10439/2004 rev 5, draft review report SANCO/6850/VI/1997 rev. 71-3)

   The Committee took note of the review report outlined in document SANCO/6850/VI/1997 rev. 71-3.

   Vote: No opinion (193 votes against, 5 MS in favour).

6. **Examination and possible opinion on a draft Commission Directive concerning the inclusion of methamidophos in Annex I to Council Directive 91/414/EEC** (draft Directive SANCO/10230/2005 rev 3, draft review report SANCO/4341/2000 rev. 4)

   The Committee took note of the review report outlined in document SANCO/4341/2000 rev. 4.

   Vote: Unfavourable opinion (235 votes against, 5 MS in favour).

7. **Examination and possible opinion on a draft Commission Directive concerning the inclusion of procymidone in Annex I to Council Directive 91/414/EEC** (draft Directive SANCO/10440/2004 rev 1, draft review report SANCO/4064/2001 rev. 1)

   The Committee took note of the review report outlined in document SANCO/4064/2001 rev. 1.

   Vote: No opinion (176 votes against, 4 MS in favour).

8. **Examination and possible opinion on a draft Commission Directive concerning the inclusion of vinclozoline in Annex I to Council Directive 91/414/EEC** (draft Directive SANCO/10441/2005 rev 2, draft review report SANCO/5038/VI/98 rev 1.3)

   The Committee took note of the review report outlined in document SANCO/5038/VI/98 rev. 1.3.

   Vote: No opinion (205 votes against, 3 MS in favour).

The measures on which the Committee has not given a favourable opinion are subject to the procedure laid down in article 5 paragraph 4 of Council decision 1999/468/EC (submission to the Council).

SECTION GM FOOD & FEED AND ENVIRONMENTAL RISK

President: Mrs Dorothée André

9. **Bt10 maize: Review of Commission Decision 2005/317/EC of 18 April 2005 on emergency measures regarding the non-authorised genetically modified organism Bt10 in maize products according to Article 6 of the Decision**

   On 18 April 2005, the Commission adopted the Decision 2005/317/EC imposing that consignments of genetically modified corn-gluten feed and brewers grain from the USA can only be placed on the EU market if they are accompanied by an analytical report by an accredited laboratory which demonstrates that the product does not contain the unauthorised maize Bt10.

   In accordance with the Decision, the emergency measures provided for in this decision were reviewed during the previous meeting of the Standing Committee on 27 October 2005. During this meeting, it was agreed that the evolution of the situation would be re-discussed by the Committee beginning of 2006.

   The present review was based on the controls carried out by Member States as well as on information recently provided by Syngenta and the United States authorities.

   In the framework of the compulsory systematic testing of products intended to be exported to the EU, no positive tests were recorded by Syngenta since early November 2005. Information has also been provided on additional preventive actions taken by the company in order to divert Bt10 maize from the US export channels. The US authorities requested Syngenta to remove all seeds of Bt10 from the market.

   The controls in the Community were mainly carried out on feed, the type of product for which a contamination with Bt10 is more likely. Some Member States also carried out controls on food samples. No presence of Bt10 has been registered.

   This information was considered as the proof of the effectiveness of the emergency measures in handling the Bt10 contamination. The majority of the delegations were of the view that the data provided by the company need to remain constant in time and to be confirmed by third parties (and possibly by the US authorities). In this regard, it was suggested to investigate the possibility to send a mission of the FVO to the USA.

   The Chair of the meeting indicated that these elements will be analysed further before proceeding to the next review of the Decision.

Miscellaneous

Information from the Commission on:

- **Renewals of existing products according to Articles 8 and 20 of Regulation (EC) No 1829/2003 on GM food and feed**

On request of applicants, the Commission clarified the provisions regarding the date for submission of applications for renewal of authorisations for existing products falling under Article 8.1(a) and 20.1(a) of Regulation (EC) No 1829/2003.The Commission clarified that:

- Products that have been legally placed on the market under a different legislation may remain on the market if they have been notified according to Articles 8.1. and 20.1 of the Regulation;

- These products must subsequently be subject to a second, more complete notification within the deadlines laid down by Articles 8.4 and 20.4. To set these deadlines, the requirement not to submit the application within the period of 3 years after the date of application of the Regulation takes precedence over the requirement to submit the application within 9 years from the first placing on the market of the product concerned;

- If these rules are respected, the products in question may remain on the market until a decision on the basis of Regulation (EC) N^{o} 1829/2003 has been taken (see Articles 11.4 and 23.4), without regard of the date of expiry laid down in the authorisation that was granted under a different legislation.

Consequently, the Commission invites applicants that wish to apply for a renewal of authorisations for existing products falling under Article 8.1(a) and 20.1(a) of Regulation (EC) No 1829/2003 to submit the application on 18 April 2007, which is the earliest possible date three years after the date of application of the Regulation.

- **Applications submitted under Regulation (EC) No 1829/2003: State-of-play**

Thirty-three applications have been received by EFSA. Amongst those, the scope of 8 applications includes the placing on the market of a GMO for cultivation.

The Committee was also informed that the Decision authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 had been adopted by the Commission on the day of the meeting (3 March 2006).