



EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

Brussels,
SANCO D (2011)

STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

Section *PHYTOPHARMACEUTICALS – PLANT PROTECTION PRODUCTS – LEGISLATION – 22-23 NOVEMBER 2010*

Summary Report

President: M. Flüh

25 Member States were present. Portugal was absent and represented by Spain, Malta was absent and represented by Italy.

Qualified majority: 255 votes and 14 Member States in favour.

A. Points for vote

- 1. Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC to include bromuconazole as active substance.** (Doc. SANCO/12613/2010 Rev. 1) (draft review report doc. SANCO/12620/2010 Rev. 1).

The Committee took note of the review report outlined in document SANCO/12620/2010 Rev. 1.

Vote: Qualified Majority by 324 votes in favour, 21 votes against.

- 2. Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC to include cycloxydim as active substance and amending Decision 2008/934/EC.** (Doc. SANCO/12738/2010 Rev. 3) (draft review report doc. SANCO/12492/2010 Rev. 2).

The Committee took note of the review report outlined in document SANCO/12492/2010 Rev. 2.

Vote: Unanimous favourable opinion.

- 3. Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC to include tau-fluvalinate as active substance and amending Decision 2008/934/EC.** (Doc. SANCO/12739/2010 Rev. 0) (draft review report doc. SANCO/12254/2010 Rev. 0).

Vote postponed.

4. **Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC to include buprofezin as active substance.** (Doc. SANCO/12740/2010 Rev. 1) (draft review report doc. SANCO/12256/2010 Rev. 3).

The Committee took note of the review report outlined in document SANCO/12256/2010 Rev. 3.

Vote: Qualified Majority by 338 in favour, 7 votes against.

5. **Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC to include hymexazol as active substance and amending Decision 2008/934/EC.** (Doc. SANCO/13041/2010 Rev. 2) (draft review report doc. SANCO/13057/2010 Rev. 1).

The Committee took note of the review report outlined in document SANCO/13057/2010 Rev. 1.

Vote: Qualified Majority by 275 votes in favour, 70 votes abstained.

6. **Examination and possible opinion on a draft Commission Decision concerning the non-inclusion of guazatine in Annex I to Council Directive 91/414/EEC.** (Doc. SANCO/12798/2010 Rev. 0) (doc. draft review report SANCO/12799/2010 Rev. 0).

Vote postponed.

7. **Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC to include dodine as active substance and amending Decision 2008/934/EC.** (Doc. SANCO/12741/2010 Rev.1) (draft review report doc. SANCO/12248/2010 Rev. 2).

The Committee took note of the review report outlined in document SANCO/12248/2010 Rev. 2.

Vote: Qualified Majority by 321 votes in favour, 14 votes against, 10 votes abstained.

8. **Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC to include myclobutanil as active substance and amending Decision 2008/934/EC.** (Doc. SANCO/13044/2010 Rev. 2) (draft review report doc. SANCO/13039/2010 Rev. 0).

The Committee took note of the review report outlined in document SANCO/13039/2010 Rev. 0.

Vote: Qualified Majority by 331 votes in favour, 14 votes against.

9. **Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC to include 6-benzyladenine as active substance and amending Decision 2008/941/EC.** (Doc. SANCO/13045/2010 Rev. 2) (draft review report doc. SANCO/12667/2010 Rev. 3).

The Committee took note of the review report outlined in document SANCO/12667/2010 Rev. 3.

Vote: Unanimous favourable opinion.

- 10. Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC to renew the inclusion of carbendazim as active substance.** (Doc. SANCO/12553/2010 Rev. 3; Draft Review Report doc. SANCO/13063/2010 rev 2).

Vote: No opinion (156 votes in favour, 160 votes against, 29 votes abstained).

- 11. Examination and possible opinion on a draft Commission Regulation implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances.** (Doc. SANCO/11484/2010 Rev. 1).

Vote: Unanimous favourable opinion.

- 12. Examination and possible opinion on a draft Commission Regulation implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products.** (Doc. SANCO/11485/2010 Rev. 3).

Vote: Unanimous favourable opinion.

- 13. Examination and possible opinion on a draft Commission Regulation implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the uniform principles.** (Doc. SANCO/11483/2010 Rev. 1).

Vote: Unanimous favourable opinion.

- 14. Examination and possible opinion on a draft Commission regulation laying down the requirements on labelling of plant protection products.**(SANCO/12644/2010)

Vote postponed.

- 15. Notifications under Article 8(4) of the Directive.**

- Mesotrione – FR
- Diclobenil – IE
- Endosulfan - RO
- 1,3 Dichloropropene - ES

The Committee took note of the notifications submitted by France, Ireland, Romania and Spain.

The Commission recalls that under the provisions of article 8(4) Member States are obliged to inform the Commission and the other Member States immediately after they have granted such derogation.

In addition, the Commission pointed out that if an MRL set under Reg. (EC) No 396/2005 cannot be met and a national MRL is set, nevertheless, a consumer risk assessment has to be carried out and forwarded to the Commission, the European Food Safety Authority and Member States.

Member States are reminded that they shall put in place the necessary risk mitigation measures to ensure acceptable uses for human and animal health and the environment.

16. Pyrimethanil- revised review report – (point to note)

The Committee took note of the revised review report outlined in document SANCO/10019/2006 final Revision of 23 November 2010.

17. Draft guidance document on zonal evaluation and mutual recognition under Regulation 1107/2009. (point to note)

Taking note postponed

18. Draft guidance document on renewal, withdrawal and amendment of authorization under Regulation (EC) No 1107/2009. (point to note)

Taking note postponed.

B. Any other business

• **Glyphosate**

The Commission has been made aware of the publication of an article in the scientific press regarding potential reprotoxicological effects generated by glyphosate and glyphosate containing products. Such effects were observed after injection of embryos of chickens and frogs.

The matter had been put on the agenda of the Standing Committee on the Food Chain and Animal Health on 29 September 2010 and the Commission invited Germany, the Rapporteur Member State which evaluated glyphosate prior to its EU wide approval in 2001, to provide its views on the above studies, the validity of their methodology, and, importantly, their relevance to the normal evaluation and application of glyphosate as a pesticide.

The German authorities came to the conclusion that the above studies had been performed under highly artificial conditions, extremely different from what can be expected in agricultural circumstances, and that it is hardly possible to predict adverse effect on mammals on this basis. They pointed out that there is a comprehensive and reliable toxicological database for glyphosate and the effects observed have not been revealed in mammalian studies, nor evidenced epidemiologically in humans. Germany therefore concludes that the findings of the studies do not put into question the current EU risk assessment for the substance and the products used in the EU that contain this substance with regard to human health.

That conclusion, reported in the Standing Committee meeting on 28 October 2010 and reconfirmed on 23 November 2010, is shared by the other Member States.

As a consequence, the Commission does not consider there is currently a solid basis to ban or impose specific restrictions on the use of glyphosate in the EU.