



EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

D(2009) 410802

**SUMMARY REPORT OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND
ANIMAL HEALTH – PLANT PROTECTION PRODUCTS –**

PESTICIDES LEGISLATION

11 MAY 2009

President: M. Flüh

27 Member States were present.

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

1. **Examination and possible opinion on a draft Commission proposal concerning Chlorthal-dimethyl (SANCO/1335/2008 Rev. 0) (DRR SANCO/1336/2008 Rev. 0) - *Vote postponed.***
2. **Examination and possible opinion on a draft Commission proposal concerning Methomyl (SANCO/5448/2009 Rev. 0) (DRR SANCO/5449/2009 Rev. 0) - *Vote postponed.***
3. **Examination and possible opinion on a draft Commission Decision recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of BAS 650 F in Annex I to Council Directive 91/414/EEC (SANCO/5339/2009 Rev. 0)**
Vote: Favourable opinion by unanimity.
4. **Examination and possible opinion on a draft Commission Decision allowing Member States to extend provisional authorisations granted for the new active substances novaluron, spiroadiclofen, spiromesifen, ascorbic acid, aminopyralid, proquinazid, mandipropamid, benalaxyl-M or acequinocyl (SANCO/5321/2009 Rev. 1)**
Vote: Favourable opinion by qualified majority (1MS obtained, 26 MS in favour).
5. **Format of Notifications under Article 8(4) of the Directive – revised version to include information on MRLs according to Art 18(4) to Reg. (EC) No 396/2005**
The Committee took note of the new format.
6. **Amended review report of Bifenox**
The Committee took note of the doc SANCO 3776/08 revised.

7. Notifications under Article 8(4) of the Directive

The following notifications have been received:

- a. Diuron (DK)
 - b. Naphtylacetic acid (AT)
 - c. 6-Benzyladenine (AT)
 - d. Calcium Polysulfide (AT)
 - e. Ethephon (AT)
 - f. Imazamox (AT)
 - g. Quassia (AT)
 - h. Streptomycin (AT). Commission recalls that uses of antibiotics in general must be minimised in order to avoid antimicrobial resistance. Their agricultural application has been phased out and any uses under Article 8(4) should be exceptional. Quantities actually used or resistance observed are to be reported to the Commission.
 - i. Imazamox (BG)
 - j. Thiamethoxam- Metalaxil-M- Fludioxinil-2 (BG)
 - k. Chlorpyrifos-methyl (DE)
 - l. Linuron (DE)
 - m. Methamidophos (DE)
 - n. Streptomycin (DE)
 - o. 1,3-Dichloropropene (ES)
 - p. Thiametoxam (ES)
 - q. Thiram (NL)
 - r. Trifluralin (FI) – 2 notifications
 - s. 1,3-Dichloropropene (IT)
 - t. Endosulfan (IT)
 - u. Benzoic acid (NL)
 - v. Clothianidin (PL)
 - w. Dichlorvos – ammonium acetate – trimethyl HCl- putrescine (PT)
 - x. Hydrolysed protein (PT)
 - y. Imazamox (PT)
 - z. Imidacloprid (PT)
 - aa. Fluazifop-P-butyl (PT)
8. **Guidance document on confirmatory data procedures under Council Directive 91/414/EEC - *Point postponed.***
9. **Any other business**

- a. Nicotine in wild mushrooms.

The Committee agreed to the "Guidelines as regards measures to be taken as regards the presence of nicotine in wild mushrooms" (see Annex to this report).

10. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Council directive 91/414/EEC

The Committee took note of the doc SANCO/10597/2003 Rev. 8.1.

ANNEX

Guidelines as regards measures to be taken as regards the presence of nicotine in wild mushrooms

agreed by the Standing Committee of the Food Chain and Animal Health (SCoFCAH) on 11 May 2009

Background

The Commission has been informed by food business operators that dried wild mushrooms (mainly *Boletus edulis* hereafter called ceps, but also truffles and cantarelles) may contain levels of nicotine higher than 0.01 mg/kg¹ (default level as set by Article 18.1.b to Regulation (EC) No 396/2005). According to the information received, almost all wild mushrooms are affected, irrespective of their origin, although most of them originate from China. The data received show that 99% of the 2008 production does not comply with the default limit of 0.01 mg/kg as set in the Regulation (EC) No 396/2005. Residue levels found can be up to 9.9 mg/kg on the dried product.

Food business operators have been investigating the reason(s) for this unexpected presence of nicotine in dried mushrooms, but so far no clear causal link could be established. The nicotine residues found could be of various origins but could also result from the combination of various factors, including pesticide use, cross-contamination and natural presence.

A monitoring and testing programme will be launched by food business operators at the start of the forthcoming 2009 harvest season. Member States should also monitor the levels of nicotine in mushrooms as from the next harvest season, with a view to collecting monitoring data and to have a clear understanding of the natural levels and unavoidable background presence that can be expected from various EU regions.

However, pending the submission of this data, urgent measures are needed to allow the placing on the market of dried mushrooms from the 2008 season, provided that they are safe.

Therefore, with a view to setting a temporary MRL under Reg. (EC) No 396/2005, the Commission asked EFSA on 27 April 2009 to deliver an opinion in relation to the risks for human health due to the presence of nicotine in wild mushrooms at concentrations up to 0.5 mg/kg.

In reply to this request, the EFSA issued on 7 May 2009 a statement, concluding that a level of 0.5 mg/kg is not safe, because it would lead to an exceedance of the acute reference dose (ARfD). The EFSA proposed alternative MRLs to be set on a temporary basis both for fresh (0.036 mg/kg) and for dried (1.17 mg/kg) wild mushrooms.

The EFSA also highlighted that the evaluation performed was affected by a number of uncertainties and limitations on the data available (consumption of wild mushrooms in Europe, and in particular on dried ones, contamination levels, actual unit to unit variability in fresh mushrooms).

¹ Recalculated on the fresh mushroom, to which the default level applies. According to the available information the concentration factor as a consequence of drying is a factor of about 9.

As regards dried ceps, the Commission notes that one of the uncertainties highlighted by EFSA refers to the poor data as regards children consumption of ceps. It would be therefore more appropriate to restrict the evaluation of a safe level of nicotine in ceps to the consumption data available for the adult population. Moreover, the Commission considers that, on a temporary basis and pending the submission of more detailed and reliable data, the 95th percentile of the consumption² should be used to estimate the acute exposure to nicotine in dried ceps. As a consequence, for dried ceps, an acceptable level of 2.3 mg/kg could be derived.

Guidelines

The SCoFCAH had an exchange of views on the available information and on the results of the risk assessment carried out by EFSA on the presence of nicotine in wild mushrooms.

Based on the statement from EFSA³, the SCoFCAH has considered that the current default MRL for nicotine in mushrooms is not a health standard and that it is appropriate to take the following proportionate risk management measures on a temporary basis, ensuring a high level of consumer protection in the European Union:

- 1) Fresh wild mushrooms with a level of nicotine higher than 0.04 mg/kg and dried wild mushrooms other than ceps with a level of nicotine higher than 1.2 mg/kg should not be placed on the market and be withdrawn from the market and safely disposed of.
- 2) Dried ceps with a level of nicotine higher than 2.3 mg/kg should not be placed on the market and be withdrawn from the market and safely disposed of.
- 3) Member States should put in place a monitoring programme for the 2009 season with a view to having a clear understanding of the natural levels and unavoidable background presence of nicotine in different wild mushroom species that can be expected from various origins. Member States should without any delay, communicate to the Commission and to EFSA the results of the monitoring programmes with a view to setting an MRL for nicotine in fresh and dried mushrooms under the provisions of Reg. (EC) No 396/2005.

The management measures referred to in points 1 and 2 are to be applied on a temporary basis, awaiting the setting of a MRL for nicotine in fresh and dried mushrooms foreseen by the end of 2009, taking into account the results of the monitoring programme, referred to in point 3.

² Expressed as grams/kg body weight/day and calculated for the consuming days only (table 4-2 of the EFSA statement).

³ Statement of EFSA on the risks for public health due to the presence of nicotine in wild mushrooms, issued on 7 May 2009.

Available at:

http://www.efsa.europa.eu/cs/BlobServer/Statement/Statement_nicotine_mushrooms_ej286_en.pdf?ssbinary=true