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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
18 - 19 May 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/f8942369-3a8a-4eef-a521-e50fadb4f1d0*

AGENDA

Section A Information and/or discussion

A.01 Summary Report of previous meetings.

A.02 New dossiers:

– New active substances
  a. Swinglea glutinosa, ext. (admissible dossier to be noted)
  b. Metarhizium brunneum Cb15-III (I) (admissible dossier to be noted)
  c. Trichoderma atroviride 77B (admissible dossier to be noted)
  d. Tolpyralate (withdrawal)
  e. NAS information sheet

– Basic substances applications received (for information)
  f. Sodium chloride (extension of use, for discussion)
  g. Mycosubtilin
  h. Water extract tannins from *Castanea* sp and *Schinopsis* sp
  i. Black soap
  j. Pepper dust
  k. Calcium propionate

– Amendment of conditions of approval (no news)

– Article 21 Reviews (no news)

A.03 Renewal of approval and general issues:

1. Withdrawals (for information)
   a) Haloxyfop-P
   b) Ca-Phosphide

2. Potential resistance to azoles with demethylase inhibitor as mode of action and epidemiological data

A.04 Exchange of views on EFSA conclusions/EFSA scientific reports:

– New active substances:

a) Chloropicrin

– Renewal of approval:

b) Blood meal

– Basic substances:

c) Capsicum annuum annuum, longum group, cayenne, ext

– Amendment of conditions of approval (no news).

A.05 Draft Review/Renewal Reports for discussion:

– New active substances:
  a. Dimethyl disulphide
  b. Ethamethsulfuron-methyl

– Renewal of approval:
  c. Etoxazole (detailed discussion, tour de table)
  d. Clopyralid
  e. Famoxadone
  f. Cypermethrin (detailed discussion, tour de table)
  g. Indoxacarb
  h. Bifenazate (detailed discussion, tour de table)
  i. Kieselgur
  Pro memoriam (no news): Cyazofamid; Pseudomonas chlororaphis MA 342

– Basic substances:
  j. Lecithins (extension of use) – amended review report to take note
  k. Sucrose (extension of use)
  l. Fructose (extension of use)
  m. Comfrey steeping
  n. Clayed charcoal
  o. *Allium cepa* (extract)
  p. Vinegar (extension of use)

– Amendment of conditions of approval (no news).

A.06 Confirmatory Information:

1. Spiroxamine (amended review report to take note)
2. Azadirachtin (amended review report to take note)
3. Triazole derived metabolites (TDMs)
   – Paclobutrazole (amended review report to take note)
   – Difenoconazole (amended review report to take note)
   – Bromuconzole
4. Terbuthylazine

5. Ipconazole
6. Triazine amine (relevant for metsulfuron-methyl, prosulfuron, thifensulfuron-methyl and iodosulfuron)
7. Sulfoxaflor
8. Gamma-cyhalothrin
9. Lamda-cyhalothrin
10. Pyrethrins
11. L-ascorbic acid
12. Benzovindiflupyr
13. Isoxaben

Pro memoriam (on hold): Geraniol, Eugenol, Thymol, Clove oil, Isofetamid

A.07 Guidance Documents:

1. 1 EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

2. Brief procedural updates:

    a. Draft update of Guidance on emergency authorisations according to Article 53

    b. Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance

    c. Draft Guidance document on the risk assessment of metabolites produced by micro-organisms

3. Review of Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 (SANCO/12638/2011)

4. Draft Guidance Document for the Generation and Evaluation of Data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No 1107/2009

5. EFSA Guidance on the risk assessment of PPP a.s. and their transformation products that have stereoisomers

6. Additional data for review of EFSA Exposure Guidance Document– for information

7. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02 (no news)

A.08 Defining Specific Protection Goals for environmental risk assessment, in particular:

- Report on the Workshop on 3-4 February 2020 and way forward

A.09 Commission Regulation (EU) No 547/2011 and risk mitigation, in particular:

- Report on the Workshop on 17 January 2020 and way forward

A.10 Notifications under Regulation (EC) No 1107/2009:

- Article 44(4) (to take note)
- Article 36(3) (to take note)
- Article 53 (for information and discussion)

A.11 Plant Protection Products Application Management System (PPPAMS).

A.12 News from European Food Safety Authority (EFSA).

A.13 Improving the efficiency of the process of a.s. approval / renewal.

A.14 New Transparency rules: General Food Law amendment and implementation:

1. update on regulation for renewals of approval of active substances
2. update on IT tools for notification and submission of applications
3. update on Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009 (SANCO/10363/2012)

A.15 Clarifications & questions related to specific active substance:

1. Acibenzolar-S-methyl – updated review report (to take note)
2. Chlorotalonil monitoring data

A.16 General issues for information / discussion:

1. BREXIT
2. COVID-19
3. 2,4 D / 2,4 D EHE
4. Nitrophenolates salts (Na/K) - update, new active substance vs. technical concentrate
5. Active Substances vs. Co-formulants, e.g. Tall oil crude, clove oil,… as co-formulant
6. Scope of Regulation (EC) No 1107/2009:
   a) Scope Document rev.58 (previous border cases – confirmation; adaptation due to new legal status of plant biostimulants)
   b) Ongoing cases

A.17 Safeners and Synergists.

A.18 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

A.19 News from Sustainable Use Directive (Directive 2009/128/EC).

A.20 News from Health and Food Audits and Analysis (SANTE, Directorate F).

A.21 Report from working groups, in particular:

1. Working group on Biopesticides
2. Working group on Seed Treatments
3. Working group Post Approval Issues

A.22 Minor Uses.

A.23 Court cases.

A.24 Ombudsman cases.

A.25 Exchange of information from the Pesticide Residues section of the Committee, in particular:

- possible impact on authorisations
- mandates to EFSA on the joint review of MRLs for fosetyl and phosphonates, on toxicology and MRLs for propoxur, on MRLs for spinosad and on MRLs for methoxyfenozide.

A.26 OECD and EPPO activities, in particular:

- Report of the OECD Risk Reduction Seminar on Evolving Digital and Mechanical Technologies
- WG on Drones
- Invitation Expert Group on the Electronic Exchange of Pesticide Data (EGEEPD)
- Guidance Document on the Exchange and Use of International Efficacy and Crop Safety Data for Minor Uses
- Preparation of OECD WG on Pesticides (Virtual meeting)

A.27 Scientific publications and information submitted by stakeholders.

A.28 Date of next meeting(s).

Section B <u>Draft(s) presented for an opinion</u>

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) modifying Annex III of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(SANTE/10257/2018 Rev. 4)

Legal Basis: Regulation (EC) 1107/2009 - Articles 27(2) and 78(2)

Procedure: Regulatory procedure with scrutiny

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiophanate-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11254/2018 Rev. 4).

(SANTE/11253/2018 Rev. 3)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance pyriproxifen, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540 (Draft Review Report SANTE/11426/2019/ Rev. 1).

(SANTE/11424/2019 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 20(1)

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance beta-cyfluthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12798/2019 Rev 1).

(SANTE/12796/2019)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance fenamiphos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11402/2019 Rev. 1).

(SANTE/11400/2019 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 20(1) and 78(2)

Procedure: Examination procedure

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the low risk active substance ferric pyrophosphate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10230/2020 Rev. 0).

(SANTE/10228/2020 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 13(2) in conjunction with Article 22(1)

Procedure: Examination procedure

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance sodium hydrogen carbonate as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11724/2018 Rev. 2).

(SANTE/11722/2018 Rev. 3)

Legal Basis: Regulation (EC) 1107/2009 - Article 22(1) in conjunction with Article 13(2)

Procedure: Examination procedure

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval the active substances *Phlebiopsis gigantea* VRA 1835, VRA 1984 and FOC PG 410.3 as low-risk substances in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12900/2019 Rev. 1).

(SANTE/12898/2019 Rev. 1)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 22(1)

Procedure: Examination procedure

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of Milk as a basic substance, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12816/2019 Rev.3).

(SANTE/12794/2019 Rev. 1)

Legal Basis: Regulation (EC) 1107/2009 - Article 13(2) in conjuction with Article 23(5)

Procedure: Examination procedure

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substances carbetamide, emamectin, flurochloridone, gamma-cyhalothrin, halosulfuron methyl, ipconazole and tembotrione in the list of candidates for substitution.

(SANTE/11404/2019)

Legal Basis: Regulation (EC) 1107/2009 - Articles 78(2) and 80(7)

Procedure: Examination procedure

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and s-metolachlor.

(SANTE/10420/2020)

Legal Basis: Regulation (EC) 1107/2009 - Article 17

Procedure: Examination procedure

Section C <u>Draft(s) presented for discussion</u>

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances.

(SANTE/10692/2020)

Legal Basis: Regulation (EC) 1107/2009 - Article 19

Procedure: Examination procedure

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance azadirachtin (Amended Review Report SANCO/10311/2011 Rev. 1).

(SANTE/11846/2019 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 13(2)(c)

Procedure: Examination procedure

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance bromoxynil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/10156/2020 Rev. 1).

(SANTE/10154/2020 Rev. 1)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance mancozeb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10326/2019 / Rev. 0).

(SANTE/10324/2020 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance benfluralin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10236/2020 Rev. 0).

(SANTE/10234/2020 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of the active substance pydiflumetofen, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10236/2020 Rev. 0).

(SANTE/10234/2020 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 13

Procedure: Examination procedure

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the amendment of the conditions of approval of the active substance fenpyrazamine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10690/2012 Rev. 3).

(SANTE/10424/2020)

Legal Basis: Regulation (EC) 1107/2009 - Article 21

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance benalaxyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10240/2020 Rev. 0).

(SANTE/10238/2020 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 20(1)

Procedure: Examination procedure

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of carbon dioxide as a basic substance in accordance with Article 23 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

(SANTE/10790/2020)

Legal Basis: Regulation (EC) 1107/2009 - Articles 13(2), 23(5) and 79(3)

Procedure: Examination procedure