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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
23 - 24 March 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/a17d97e3-6896-43de-a063-d2d0fb723484*

AGENDA

Section A Information and/or discussion

A.01 Summary Report of previous meetings.

A.02 New dossiers:

New active substances (admissible dossiers to be noted)

a) Swinglea glutinosa, ext.
b) Metarhizium brunneum Cb15-III (I)
c) NAS information sheet

Basic substances applications received (for information)

d) Mycosubtilin
e) Water extract tannins from Castanea sp and Schinopsis sp
f) Black soap
g) Sodium chloride (extension, for discussion)

Amendment of conditions of approval (no news)

Article 21 Reviews (no news)

A.03 Renewal of approval, general issues:

a) 6th renewal programme – allocation of RMS for active substances expiring from 2025 to the end of 2028

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

New active substances:

a) Napropamid-M (no news)
b) Asulam-sodium (short update)
c) Ethamethsulfuron-methyl

d) Chloropicrin

Renewal of approval

e) Blood meal

Basic substances

f) *Allium cepa* extract

g) Clayed charcoal

h) Vinegar (extension)

i) Comfrey steeping

Amendment of conditions of approval

A.05 Draft Review/Renewal Reports for discussion:

New active substances:

a) Dimethyl disulphide

b) Pydiflumetofen

Renewal of approval

c) Etoxazole (detailed discussion, tour de table)

d) Clopyralid

e) Famoxadone

f) Cyazofamid

g) Cypermethrin (detailed discussion, tour de table)

h) Indoxacarb

i) Pseudomonas chlororaphis MA 342

j) Bifenazate (detailed discussion, tour de table)

Basic substances

k) Lecithins (extension) – amended review report to take note

l) sucrose

m) fructose

Amendment of conditions of approval

A.06 Confirmatory Information:

1. Spiroxamine (amended review report to take note)
2. Azadirachtin (amendment review report to take note)
3. Fenpyrazamine
4. Triazole derived metabolites (TDMs)
   - Paclobutrazole (amended review report to take note)
   - Difenoconazole

5. Isofetamid
6. Terbuthylazine
7. Sulfoxaflor
8. Gamma-cyhalothrin
9. Pyrethrins
10. L-ascorbic acid
11. Benzovindiflupyr
12. Ipconazole

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

A.07 Guidance Documents:

1. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) - update
2. Guidance on emergency authorisations according to Article 53 (discussion)
3. Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance
4. Draft Guidance document on the risk assessment of metabolites produced by micro-organisms
5. 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)
6. 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
7. EFSA Guidance on the risk assessment of PPP a.s. and their transformation products that have stereoisomers
8. Additional data for review of EFSA Exposure Guidance Document– for information
9. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02 (no news)
10. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11) (no news)
11. Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004– rev 9) (no news)
12. Guidance document on Data Matching for applications for authorisation of PPPs according to Article 33/43 (no news)

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

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

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

1. Feedback about notification of additional phrases by MS (no news)
2. Report of 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.

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

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

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

A.16 Interpretation issues**:**

1. Nitrophenolates salts (Na/K) - update, new active substance vs. technical concentrate
2. Tall oil crude as co-formulant
3. 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
    c) In situ generation (update)

A.17 Epoxiconazole.

A.18 Safeners and Synergists.

A.19 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

A.20 News from Sustainable Use Directive (Directive 2009/128/EC).

A.21 News from Health and Food Audits and Analysis (SANTE, Directorate F).

A.22 Reports from Working groups, in particular:

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

A.23 Minor Uses.

A.24 Court cases.

A.25 Ombudsman cases.

A.26 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

A.27 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

A.28 Scientific publications and information submitted by stakeholders.

A.29 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 renewal of approval of the active substance metalaxyl-M, 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/11112/2019 Rev.3).

(SANTE/11110/2019 Rev. 2)

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 foramsulfuron, 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/11214/2016 Rev. 1).

(SANTE/11213/2016 Rev. 2)

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

Procedure: Examination procedure

B.04 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 NTE/11254/2018 Rev. 3).

(SANTE/11253/2018 Rev. 3)

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 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. 1).

(SANTE/11722/2018 Rev. 1)

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

Procedure: Examination procedure

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval the active substance Lavandulyl senecioate 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/10060/2020 Rev. 1).

(SANTE/10058/2020 Rev. 1)

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

Procedure: Examination procedure

B.07 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.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Saponaria officinalis* L. roots 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 (Draft Review Report SANTE/11515/2017– Rev. 2).

(SANTE/11514/2017 Rev. 0)

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

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 - Articles 23 and 13

Procedure: Examination procedure

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of L-cysteine 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/11056/2019 Rev. 2).

(SANTE/11054/2019 Rev. 3)

Legal Basis: Regulation (EC) 1107/2009 - Articles 23 and 13

Procedure: Examination procedure

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of propolis extract 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 (Draft Review Report SANTE/11782/2019 Rev.1).

(SANTE/11780/2019 Rev. 1)

Legal Basis: Regulation (EC) 1107/2009 - Articles 23 and 13

Procedure: Examination procedure

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation correcting Commission Implementing Regulation (EU) No 2019/706 renewing the approval of the active substance carvone, 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 (Amended Renewal Report SANTE/11718/2018 Rev. 1).

(SANTE/11310/2019 Rev. 0)

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

Procedure: Examination procedure

Section C **Draft(s) presented for discussion**

C.01 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.02 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. 0).

(SANTE/10154/2020 Rev. 0)

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

Procedure: Examination procedure

C.03 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.04 Exchange of views 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. 0).

(SANTE/11424/2019/ 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 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 - Article 23

Procedure: Examination procedure

C.06 Exchange of views 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

Procedure: Examination procedure

C.07 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 23

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation 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 - Article 23

Procedure: Examination procedure

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation 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 23

Procedure: Examination procedure