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Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Legislation*

21 - 22 March 2019

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AGENDA

Section A Information and/or discussion

A.01 Summary Report of previous meetings.

A.02 New active substances:

1. New admissible dossiers to be noted:
 - a) Inpyrfluxam (S-2399)
 - b) *Trichoderma atroviride* AT10
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
 - a) 1,3 Dichlorpropene
 - b) Napropamide-M
3. Draft Review/Renewal Reports for discussion:
 - a) Florpyroauxyfen benzyl
 - b) Lavandulyl senecionate

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play
2. Exchange of view on EFSA conclusions/EFSA scientific reports
3. Draft Review/Renewal Reports for discussion:
 - a) Bromoxynil
 - b) Flumioxazin
 - c) Clodinafop
 - d) Fenamiphos
 - e) Metalaxyl-M
 - f) Fosetyl
 - g) Etoxazole
 - h) Alpha Cypermethrin
 - i) Cypermethrin
 - j) Beta cyfluthrin
 - k) *Verticillium albo-atrum*
 - l) *Pseudomonas chloroaphis* MA 342
 - m) Bifenazate

- n) Clopyralid
- o) Thiacloprid
- p) Assessment of ED potential in accordance with Commission Regulation (EU) No 2018/605, according to Commission Regulation (EU) No 2018/1659 amending Commission Implementing Regulation (EU) No 844/2012

A.04 Confirmatory Information:

- 1. General update (no news)
- 2. Metazachlor (amended review report to take note)
- 3. Ipconazole (short update)
- 4. Spiroxamine
- 5. Dithianon (short update)
- 6. Triazole derived metabolites (TDMs) (short update)
- 7. Geraniol
- 8. Eugenol
- 9. Thymol

A.05 Article 21 Reviews.

A.06 Amendment of the conditions of approval:

- 1. New admissible dossiers to be noted:
- 2. Exchange of view on EFSA conclusions:
 - a) Azadirachtin
- 3. Draft Review/Renewal Reports for discussion:

A.07 Basic substances:

- 1. New dossiers received (for information)
 - a) chitosan hydrochloride (extension in olive trees, amenity grassland, ornamentals, post harvest fruits, grapes as an elicitor to enhance resistance against pathogens)potassium metabisulfite
 - b) Dimethyl Sulfide (against truffle beetle in *Tuber melanosporum*, *Tuber* spp)
 - c) Disodium citrate perhydrate (fungicide in apricot, apple, pear and potatoes)
 - d) Sodium hydrogen carbonate (extension in citrus fruits as a post harvest application against *Penicillium*)
- 2. Exchange of views on EFSA Technical Reports
 - a) Propolis extract
- 3. Draft Review Reports for discussion:
 - a) *Castanea* and *Schinopsis* tannins
 - b) *Vitis vinefera* tannins

A.08 Guidance Documents

- 1. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
- 2. Draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (SANTE/10407/2018 Rev.3) – (to take note)
- 3. Draft revised Guidance Document on generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013 (to take note)

4. Updated list of endpoints to include a new field in the Identity Section (to take note)
5. Draft guidance document on Consideration of Soil Photodegradates in FOCUS-PELMO 5.5.3 –discussion on next steps
6. Working Document on emergency authorisations according to Article 53 (discussion)
7. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02
8. Defining Specific Protection Goals for environmental risk assessment
9. Guidance Documents for biopesticides and low risk pesticides – update on progress
10. EFSA's Administrative guidance on submission of dossiers and assessment reports and associated updates to relevant existing documents (to take note):
 - Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008 Agreed by Member States' Competent Authorities in the SCoPAFF: Phytopharmaceutical legislation section. SANCO/12592/2012 –rev. 1.2, 6 October 2017 (Volume 1, Volume 2 and Volume 3).
 - Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation). SANCO/2012/11251 rev. 4, 12 December 2014
 - Guidance document on preparing lists of test and study reports according to article 60 of Regulation (EC) No 1107/2009. SANCO/12580/2012 - rev. 3.1, 17 May 2013
 - Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013. SANCO/10181/2013– rev. 3, 12 December 2014
- including updated Document N3

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

1. Feedback about notification of additional phrases by MS (no news)
2. Risk Mitigation / list of risk reduction measures

A.10 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted).

A.11 Notifications under Article 36(3) of Regulation (EC) No 1107/2009.

1. New notifications (to be noted)
2. Differences in application of article 36(3) amongst Member States

A.12 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009.

1. New notifications (to be noted)
2. Antimicrobials notified 2017/2018 (update)
3. Draft Commission Implementing Decisions under Art 53(3)

A.13 Plant Protection Products Application Management System (PPPAMS)

1. Updated EPPO codes

- A.14** News from European Food Safety Authority (EFSA).
1. General update
- A.15** Improving the efficiency of the process of a.s. approval – update on on-going activities including feedback of MS
- A.16** News from Health and Food Audits and Analysis (SANTE, Directorate F, former FVO).
- A.17** News from Sustainable Use Directive (Directive 2009/128/EC).
- A.18** Minor Uses.
- A.19** Progress Report on Low Risk Active Substances.
- A.20** Court cases.
- A.21** Endocrine Disruptors.
- A.22** Interpretation issues:
1. Scope of Regulation (EC) No 1107/2009:
a) Follow-up in situ generation (update)
b) New case Herbie – soil fumigation
c) New case : pellets of sugarcane – biofumigation
- A.23** Classifications under Regulation (EC) No 1272/2008:
1. Status of harmonised classifications (summary table for info)
2. General update
- A.24** Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).
- A.25** Report from working groups, in particular:
1. Working Group on Biopesticides
2. Working Group on Seed Treatments
3. Post Approval Issues
- A.26** OECD and EPPO
a) General update
b) Recommendation of the Council on Countering the Illegal Trade of Pesticides
- A.27** Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.
- A.28** Lists of tests and studies relied upon for active substance assessments.
- A.29** Propiconazole – revised Renewal Report including the agreed toxicological reference values (for taking note).

A.30 Scientific publications and information submitted by stakeholders.

A.31 Date of next meeting(s).

Section B **Draft(s) presented for an opinion**

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the low risk active substance ABE-IT 56 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/11228/2018 rev 2).

(SANTE/11227/2018 Rev. 1)

Legal Basis: Regulation (EC) 1107/2009 - Articles 13(2) and 22

Procedure: Examination procedure

B.02 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 chlorothalonil, 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 Renewal Report SANTE/10186/2018 rev. 1).

(SANTE/10185/2018 Rev. 1)

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 1-methylcyclopropene, 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 Renewal Report SANTE/11631/2018 REV 2)

(SANTE/11630/2018 Rev. 3)

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 renewing the approval of the active substance isoxaflutole, 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 Renewal Report SANTE/11653/2017 Rev 2)

(SANTE/11652/2017 Rev. 0)

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

Procedure: Examination procedure

- B.05** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation 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 (Draft Renewal Report SANTE/ / 2018 REV0)

(SANTE/11716/2018 REV0)

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

Procedure: Examination procedure

- B.06** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the low-risk active substance *Bacillus subtilis* strain IAB/BS03, 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/10318/2019 rev 1).

((SANTE/10316/2019 rev. 1))

Legal Basis: Regulation (EC) 1107/2009 - Articles 13(2) and 22

Procedure: Examination procedure

- B.07** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance dimethenamid-P, 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 Renewal Report SANTE/11149/2018-rev1)

(SANTE/11148/2018 Rev. 2)

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

Procedure: Examination procedure

- B.08** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 22/2013 and (EU) No 540/2011 as regards the conditions of approval of the active substance cyflumetofen (Draft Review Report SANCO/12618/2012 Rev. 2)

(SANTE/10657/2017 Rev 2)

Legal Basis: Regulation (EC) 1107/2009 - Article 21 (3) and 78(2)

Procedure: Examination procedure

- B.09** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, isoxaflutole, metalaxyl-m, methiocarb, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole, amending the Annex to Implementing Regulation (EU) No 540/2011

(SANTE/10102/2019)

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

Procedure: Examination procedure

Section C Draft(s) presented for discussion

- C.01** Exchange of views of the Committee on a draft Commission Regulation amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards bees principles for evaluation and authorisation of plant protection products.

(SANTE/10094/2015)

Legal Basis: Regulation (EC) 1107/2009 - Article 78(1)(c)

Procedure: Regulatory procedure with scrutiny

- C.02** Exchange of views of the Committee on a draft Commission Regulation (EU) modifying Annex III of Regulation (EC) 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(SANTE/10257/2018)

Legal Basis: Regulation (EC) 1107/2009 - Articles 27(2) and 58(2)

Procedure: Regulatory procedure with scrutiny

- C.03** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance indoxacarb, 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 Renewal Report SANTE/10730/2018).

(SANTE/10729/2018)

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

Procedure: Examination procedure

- C.04** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance methiocarb, 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 Renewal Report SANTE/11710/2018)

(SANTE/11708/2018)

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

Procedure: Examination procedure

- C.05** Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member State

(SANTE/11469/2018)

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

Procedure: Examination procedure

- C.06** Exchange of views 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 Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11254/2018).

(SANTE/11253/2018)

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

Procedure: Examination procedure

Pro memoriam: no news – TBT notification process ongoing.

- C.07** Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance dimethoate, 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/11494/2018).

(SANTE/11493/2018)

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

Procedure: Examination procedure

Pro memoriam: no news – TBT notification process ongoing.

- C.08** Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of the active substance tolclofos-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 Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11272/2018)

(SANTE/11271/2018)

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

Procedure: Examination procedure

Pro memoriam: no news – TBT notification process ongoing.

- C.09** Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance desmedipham, 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/10556/2018).

(SANTE/10555/2018)

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

Procedure: Examination procedure

Pro memoriam: no news – TBT notification process ongoing.