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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, ameninity 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 014
      - 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 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 <u>Draft(s) presented for discussion</u>

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.