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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*

24 - 25 JANUARY 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/c8e50fd0-a860-4752-9ba3-5fabbbdf3e6a*

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) Bixlozone (F9600)
   b) BAS 684 H
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
3. Draft Review/Renewal Reports for discussion:
   a) Bacillus subtilis IAB/BS03
   b) Florpyroauxyfen benzyl
   c) Sodium hydrogen carbonate
   d) Asulam-sodium

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play (no news)
2. Exchange of view on EFSA conclusions/EFSA scientific reports:
   a) Bromoxynil/flumioxazin (article 4.7)
   b) Clodinafop
   c) Clopyralid
   d) Fenamiphos
3. Draft Review/Renewal Reports for discussion:
   a) Metalaxyl-M
   b) Fosetyl
   c) Etoxazole
   d) Alpha Cypermethrin
   e) Cypermethrin
   f) Beta cyfluthrin
   g) Methiocarb
   h) Dimethenamid-P
   i) Carvone

j) 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
3. Fluquiconazole (amended review report to take note)
4. Ipconazole (amended review report to take note)
5. Fluopyram (amended review report to take note)
6. Spiroxamine
7. Dithianon (short update)
8. Triazole derived metabolites (TDMs)

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:
3. Draft Review/Renewal Reports and Regulations for discussion:

A.07 Basic substances:

1. New dossiers received (for information)
   a) vinegar extension
   b) potassium metabisulfite
2. Exchange of views on EFSA Technical Reports
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. Data requirements and list of agreed test methods - Update of the revision of the Communications (no news)
4. Defining Specific Protection Goals for environmental risk assessment – (no news)
5. Draft guidance document on Consideration of Soil Photodegradates in FOCUS-PELMO 5.5.3 –discussion on next steps
6. Draft guidance document on the risk assessment of potential metabolites of concern produced by microbial plant protection products – (no news).
7. Draft guidance document on the approval and low-risk criterion criteria linked to "multiple antimicrobial resistance" (update on progress)
8. Working Document on emergency authorisations according to Article 53

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

1. Feedback about notification of additional phrases by Member States (no news)
2. Risk Mitigation – update on discussion of EU list of risk reduction measures

3. Pictogram 'bee hazardous' (follow-up from feedback received from Member States)
4. Low-risk criteria (effects on lactation vs. reprotoxic; eye damage 1 /H318 vs. corrosive) (follow-up from feedback received from Member States)
5. Labelling requirements as regards appropriate conditions of storage (question PT) (follow-up from feedback received from Member States)

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

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

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 Member States.

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 Rapporteurship glyphosate.

A.23 Interpretation issues:
1. Scope of Regulation (EC) No 1107/2009:
   a) New version of scoping document following up on feedback received from Member States on case DewSmart (BE), Agrecol Liquid for Aphids (LT)
   b) Follow-up in situ generation (update after Member States' reaction)
   c) New case sunflower oil (extension request for basic substance, update after Member States' reaction)

A.24 Classifications under Regulation (EC) No 1272/2008:
1. Status of harmonised classifications (summary table for info)
2. General update

A.25 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).
No news.

A.26 Report from working groups, in particular:
1. Working group on Biopesticides (no news)
2. Working group on Seed Treatments (no news)
3. Working Group on Co-formulants
4. Post Approval Issues (no news)

A.27 OECD and EPPO.
Risk Reduction Seminar (June 2019)

A.28 PEST Committee.

A.29 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.
No news.

A.30 Reference to significant impurities in List of Endpoints and Renewal Report (DE).

A.31 Scientific publications and information submitted by stakeholders.

A.32 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 Directive amending Directive 2009/128/EC of the European Parliament and of the Council as regards the establishment of harmonised risk indicators.
(SANTE/10821/2018)

Legal Basis: Directive 2009/128/EC - Article 15(1)

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 chlorpropham, 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/11966/2017 Rev. 3).

(SANTE/11965/2017 Rev2)

Legal Basis: Regulation (EC) No 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 non-renewal of approval of the active substance ethoprophos, 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/10803/2018 Rev. 2).

(SANTE/10802/2018 Rev1)

Legal Basis: Regulation (EC) No 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 approval of the active substance Flutianil 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/11948/2017 REV 5).

(SANTE/11947/2017 Rev1)

Legal Basis: Regulation (EC) No 1107/2009 - Article 13(2)

Procedure: Examination procedure

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the 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 1).

(SANTE/11227/2018)

Legal Basis: Regulation (EC) No 1107/2009 - Article 13(2) and 22

Procedure: Examination procedure

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance mefentrifluconazole 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/11612/2018).

(SANTE/11611/2018)

Legal Basis: Regulation (EC) No 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 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of 1-methylcyclopropene, mancozeb, methiocarb, methoxyfenozide, pirimicarb, pirimiphos-methyl and thiacloprid for which the United Kingdom is the rapporteur

Member State, and amending Commission Regulation (EU) No 1141/2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC, allocating, for the purposes of the renewal procedure, the evaluation of famoxadone for which the United Kingdom is the rapporteur Member State.

(SANTE/11615/2018 Rev1)

Legal Basis: Regulation (EC) No 1107/2009 - Article 19

Procedure: Examination procedure

B.08 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 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azimsulfuron, azoxystrobin, fluazifop p, fluquinconazole, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine.

(SANTE/10343/2018 Rev1)

Legal Basis: Regulation (EC) No 1107/2009 - Article 17

Procedure: Examination procedure

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the approval periods of the active substances bifenthrin, carboxin, FEN 560 (also called fenugreek or fenugreek seed powder), pepper dust extraction residue and sodium aluminium silicate amending the Annex to Implementing Regulation (EU) No 540/2011.

(SANTE/11390/2018)

Legal Basis: Regulation (EC) No 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) No 1107/2009 - Article 78(1)(c)

Procedure: Regulatory procedure with scrutiny

C.02 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 Review Report SANTE/11254/2018).

(SANTE/11253/2018)

Legal Basis: Regulation (EC) No 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 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 Review Report SANTE/11494/2018).

(SANTE/11493/2018)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1)

Procedure: Examination procedure

C.04 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.

(SANTE/10743/2018)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78

Procedure: Examination procedure

C.05 Exchange of views 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).

(SANTE/10657/2017)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21 (3) and 78(2)

Procedure: Examination procedure

C.06 Exchange of views 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 Commission Implementing Regulation (EU) No 540/2011 ((Draft Renewal Report SANTE/11653/2017).

(SANTE/11652/2017)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1)

Procedure: Examination procedure

C.07 Exchange of views 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).

(SANTE/11630/2018)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(2)

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 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 Review Report SANTE/10730/2018 Rev. 0) (short update only).

(SANTE/10729/2018)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(2)

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 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 Review Report SANTE/10556/2018).

Pro memoriam: no news – TBT notification ongoing.

(SANTE/10555/2018)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.10 Exchange of views of the Committee on a draft Commission Draft 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 Review Report SANTE/10186/2018) (short update only).

Pro memoriam: no news – TBT notification ongoing.

(SANTE/10185/2018)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure