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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*
12 DECEMBER 2018 - 13 DECEMBER 2018

CIRCABC Link: *https://circabc.europa.eu/w/browse/600fab43-5805-410c-9a18-27e79d9802f1*

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:
   a) Sodium hydrogen carbonate
3. Draft Review/Renewal Reports for discussion:
   a) Bacillus subtilis IAB/BS03
   b) Florpyroauxyfen benzyl
   c) Mefentrifluconazole

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play (no news)
2. Exchange of view on EFSA conclusions/EFSA scientific report:
   a) Bromoxynil/flumioxazin (article 4.7)
   b) Carvone
   c) Dimethoate
   d) Clodinafop
   e) Clopyralid
   f) Dichlorprop P

g) Alpha Cypermethrin
h) Cypermethrin
i) Beta cyfluthrin

3. Draft Review/Renewal Reports for discussion:
   a) Isoxaflutole
   b) Metalaxyl-M
   c) 1 MCP
   d) Mecoprop-P
   e) Spinosad
   f) Trinexapac-ethyl
   g) Fosetyl
   h) Etoxazole

A.04 Confirmatory Data:

1. General update, status and prioritisation
2. Metazachlor
3. Fluquiconazole
4. Ipconazole
5. Fluopyram
6. Bupirimate (amended review report to take note)
7. Spiroxamine
8. Trifloxystrobin
9. Dithianon

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)
   – chitosan hydrochloride extension
   – salix extension
   – sodium hydrogen carbonate extension
   – sunflower extension

– hydrogen peroxide extension

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) – final consultation before adoption
3. Data requirements and list of agreed test methods - Update of the revision of the Communications (short update)
4. Defining Specific Protection Goals for environmental risk assessment – update
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 – update on progress.

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

1. Feedback about notification of additional phrases by MS
2. Risk Mitigation – workplan
3. Pictogram 'bee hazardous'
4. Low-risk criteria (effects on lactation vs. reprotoxic; eye damage 1 /H318 vs. corrosive)
5. Labelling requirements as regards appropriate conditions of storage (question PT)

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 Plant Protection Products Application Management System (PPPAMS).

A.13 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009:

1. New notifications (to be noted)

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.

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 Report from Working Groups:

1. Working Group on Biopesticides
2. Working Group on Seed Treatments
3. Working Group on Co-formulants

A.20 OECD and EPPO:

1. First review of the new draft GD for Flammability testing of Plant Protection and Biocidal Products
2. Call for leads or co-leads for Joint EGBP and EGMU projects

A.21 Court cases.

A.22 Endocrine Disruptors.

A.23 Neonicotinoids.

A.24 Rapporteurship glyphosate.

A.25 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009:
    a) New case DewSmart (BE)
    b) New case Agrecol Liquid for Aphids (LT)
    c) Follow-up Frost Armour (FR)
    d) Follow-up Palm tree Protector INO128 (FR)
    e) Follow-up in situ generation (EL – July PAFF)
    f) New case sunflower oil (extension request for basic substance)

A.26 Classifications under Regulation (EC) No 1272/2008:

1. Status of harmonised classifications (summary table for info)
2. General update

A.27 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.28 PEST Committee.

A.29 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

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 Review Report SANTE/11966/2017 Rev. 2).

(SANTE/11965/2017 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 (EU) renewing the approval of the low-risk substance *Clonostachys rosea* strain J1446 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/11655/2017).

(SANTE/11654/2017)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1), 22 and 78(2)

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the approval of the active substance *Beauveria bassiana* strain IMI389521, 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/11650/2017).

(SANTE/11649/2017)

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 approval of the active substance *Beauveria bassiana* strain PPRI5339, 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/11265/2018).

(SANTE/11264/2018)

Legal Basis: Regulation (EC) 1107/2009 - Articles 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 non-approval of the active substance propanil, 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.

(SANTE/11242/2018 Rev.0)

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

Procedure: Examination procedure

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance mepanipyrim 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/11620/2017) (short update only).

(SANTE/11618/2017)

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 renewing the approval of the active substance methoxyfenozide, as a candidate for substitution, 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/10295/2018) (short update only).

(SANTE/10294/2018)

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

Procedure: Examination procedure

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2015/1108 of 8 July 2015 approving the basic substance Vinegar 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 SANCO/12896/2014– rev. 3).

(SANTE/11484/2018 Rev. 0)

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

Procedure: Examination procedure

B.10 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 abamectin, *Bacillus subtilis* (Cohn 1872) Strain QST 713, *Bacillus thuringiensis* subsp. Aizawai, *Bacillus thuringiensis* subsp. israeliensis, *Bacillus thuringiensis* subsp. kurstaki, *Beauveria bassiana*, benfluralin, clodinafop, clopyralid, *Cydia pomonella Granulovirus* (CpGV), cyprodinil, dichlorprop‑P, epoxiconazole, fenpyroximate, fluazinam, flutolanil, fosetyl, *Lecanicillium muscarium*, mepanipyrim, mepiquat, *Metarhizium anisopliae* var. Anisopliae, metconazole, metrafenone, *Phlebiopsis gigantea*, pirimicarb, *Pseudomonas chlororaphis* strain: MA 342, pyrimethanil, *Pythium oligandrum*, rimsulfuron, spinosad, *Streptomyces* K61, thiacloprid, tolclofos‑methyl, *Trichoderma asperellum*, *Trichoderma atroviride*, *Trichoderma gamsii*, *Trichoderma harzianum*, triclopyr, trinexapac, triticonazole, *Verticillium albo-atrum* and ziram

(SANTE/11151/2018 Rev. 1)

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

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 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of deltamethrin, diflufenican, epoxiconazole, fluoxastrobin, prothioconazole and tebuconazole for which the United Kingdom is rapporteur Member State

(SANTE/11150/2018 Rev. 1)

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

Procedure: Examination procedure

Section C Draft(s) presented for discussion

C.01 Exchange of views 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: Examination procedure

C.02 Exchange of views on a draft Commission Draft 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).

(SANTE/11947/2017)

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

Procedure: Examination procedure

C.03 Exchange of views on a draft Commission Draft Implementing Regulation (EU) 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).

(SANTE/10555/2018)

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

Procedure: Examination procedure

C.04 Exchange of views on a draft Commission Draft Implementing Regulation (EU) concerning the non-renewal of approval of the active substance phenmedipham, 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/10558/2018).

(SANTE/10557/2018)

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

Procedure: Examination procedure

C.05 Exchange of views on a draft Commission Draft 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 rev 0)

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

Procedure: Examination procedure

C.06 Exchange of views on a draft Commission Draft Implementing Regulation (EU) 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/11253/2018).

(SANTE/11254/2018)

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

Procedure: Examination procedure

C.07 Exchange of views on a draft Commission Draft Implementing Regulation (EU) as regards the approval periods of the active substances bifenthrin, 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) 1107/2009 - Article 17

Procedure: Examination procedure