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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
23 OCTOBER 2018 - 24 OCTOBER 2018

CIRCABC Link: *https://circabc.europa.eu/w/browse/d4213216-e1cc-420f-b513-bc4ac32d94a9*

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) Elemental Iron
   b) Bixlozone (F9600)
   c) Spodoptera exigua multicapsid nucleopolyhedorvirus (SeMNPV)
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
   a) Propanil (withdrawal of application following EFSA conclusion)
   b) Mefentrifluconazole
3. Draft Review/Renewal Reports for discussion:
   a) ABE IT 156
   b) Bacillus subtilis IAB/BS03

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play
2. Exchange of view on EFSA conclusions/EFSA scientific report:
   a) Bromoxynil/flumioxazin (article 4.7)
3. Draft Review/Renewal Reports for discussion:
   a) Rimsulfuron
   b) Mecoprop-P
   c) Spinosad

d) Thiophanate-methyl
e) Trinexapac-ethyl
f) Fosetyl

A.04 Confirmatory Data:

1. General update, status and prioritisation
2. Isofetamid (short update only)
3. Metazachlor
4. Fluquiconazole
5. Ipconazole
6. Fluopyram
7. Sulfoxamid
8. Bupirimate (amended review report to take note)
9. Sulfoxaflor

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. *Quassia amara* L. wood extract (withdrawal)
2. New dossiers received (for information)
   a) caffein
   b) L cysteine
   c) oleoresins capsicum
   d) *Allium* cepa extract
   e) sucrose (extension)
3. Exchange of views on EFSA Technical Reports
4. Draft Review Reports for discussion:
   a) Vinegar extension
   b) *Castanea* and *Schinopsis* tannins
   c) *Vitis vinefera* tannins

A.08 Guidance Documents:

1. General update and stakeholder consultation via Advisory Group on the Food Chain and Animal and Plant Health
2. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
3. Draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (SANTE/10407/2018 Rev.3) – final consultation before adoption
4. Data requirements and list of agreed test methods - Update of the revision of the Communications (short update)
5. Defining Specific Protection Goals for environmental risk assessment – update
6. Corrigendum of cover page for noting the Guidance Document on Dermal Absorption
7. Update of cover page for noting the Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil
8. Draft guidance document on Consideration of Soil Photodegradates in FOCUS-PELMO 5.5.3 – update and discussion on next steps

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'

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)
2. Update on emergency authorisations for neonicotinoid active substances

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. Declassification of Guidance document on secondary metabolites.

A.21 Court cases.

A.22 Endocrine Disruptors:

1. Member States views on the draft Commission Regulation amending points 3.6.5. and 3.8.2. of Annex II to Regulation (EC) 1107/2009 taking into account current scientific and technical knowledge (SANTE/12011/2016, as discussed under point B.02 at the meeting the 21 December 2016).

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)

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

1. Status of harmonised classifications (summary table for info)
2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States – Amending Implementation Regulation 844/2012 in view of the harmonised classification of active substances + Report on the alignment of the classification and peer-review processes (short 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).

A.28 PEST Committee.

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

A.30 Information concerning Brexit:

1. Re-allocation of ongoing assessments.
2. 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 diflufenican, epoxiconazole, fluoxastrobin and tebuconazole for which the United Kingdom is rapporteur Member State.

A.31 Reference to significant impurities in List of Endpoints and Renewal Report (DE).

A.32 Human Biomonitoring in Europe (presentation Directorate General RTD).

A.33 Scientific publications and information submitted by stakeholders.

A.34 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 Implementing Regulation (EU) amending Commission Implementing Regulation (EU) No 844/2012 in view of the implementation of Commission Regulation (EU) 2018/605 setting out scientific criteria for the determination of endocrine disrupting properties.

(SANTE/11120/2017)

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

Procedure: Examination procedure

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance copper compounds, 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/10506/2018).

(SANTE/10505/2018)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 24

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 flurtamone, 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/11585/2016 Rev. 2).

(SANTE/11584/2016 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 propiconazole, 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/11932/2017 Rev. 1).

(SANTE/11931/2017 Rev. 1)

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 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.06 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 etoxazole, 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/10184/2018 rev 2).

(SANTE/10183/2018 Rev. 1)

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

Procedure: Examination procedure

B.07 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 quinoxyfen, 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/10214/2018 rev 1).

(SANTE/10213/2018 Rev. 1)

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 tribenuron, 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/11859/2017 Rev 3).

(SANTE/11858/2017 Rev. 2)

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 concerning the approval of the active substance *Metschnikowia fructicola* strain NRRL Y-27328 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/10472/2018 – rev 2).

(SANTE/10471/2018 Rev. 1)

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

Procedure: Examination procedure

B.10 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 amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, pethoxamid, picloram, propiconazole, pyraclostrobin, pyriproxyfen and tritosulfuron amending the Annex to Implementing Regulation (EU) No 540/2011

(SANTE/10798/2018 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 as regards the extension of the approval periods of the active substances bispyribac and triazoxide amending the Annex to Implementing Regulation (EU) No 540/2011

(SANTE/10342/2018 Rev. 1)

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

Procedure: Examination procedure

Section C Draft(s) presented for discussion

C.01 Exchange of views 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

C.02 Exchange of views on 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 uniform 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.03 Exchange of views 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).

(SANTE/11947/2017)

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

Procedure: Examination procedure

C.04 Exchange of views on a draft Commission 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.05 Exchange of views on a draft Commission 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.06 Exchange of views 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 Review Report SANTE/10803/2018).

(SANTE/10802/2018)

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

Procedure: Examination procedure

C.07 Exchange of views 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

C.08 Exchange of views 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

C.09 Exchange of views 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10186/2018) (short update only).

(SANTE/10185/2018)

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

Procedure: Examination procedure

C.10 Exchange of views 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) (short update only).

(SANTE/10729/2018)

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

Procedure: Examination procedure

C.11 Exchange of views on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance cyflumetofen.

(SANTE/10657/2017)

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

Procedure: Examination procedure

C.12 Exchange of views on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11272/2018).

(SANTE/11271/2018)

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

Procedure: Examination procedure

C.13 Exchange of views 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

C.14 Exchange of views 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

C.15 Exchange of views 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