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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
19 JULY 2018 - 20 JULY 2018

CIRCABC Link: <https://circabc.europa.eu/w/browse/8883e640-675b-4602-b7c2-acddf97d5125>

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) Metyltetraprole
 - b) *Trichoderma atroviride* AGR2
 - c) Isoflucypram
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
 - a) *Bacillus subtilis* IAB/BS03
 - b) Asulam-sodium

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play
 - a) AIR III
 - b) AIR IV
2. Exchange of view on EFSA conclusions:
 - a) Rimsulfuron
 - b) Tolclofos-methyl
 - c) Dimethenamid-P
 - d) Spinosad
3. Draft Review/Renewal Reports for discussion:
 - a) *Beauveria bassiana* PRI 5339

- b) Mecoprop-P
- c) Desmedipham (short update)
- d) Phenmedipham (short update)
- e) Ethoprophos
- f) Trinexapac-ethyl

A.04 Confirmatory Data:

- 1. Dithianon (short update only)
- 2. Iprovalicarb (review report to be noted)
- 3. Urea (review report to be noted)
- 4. Isofetamid (short update only)
- 5. Tea tree extract (short update only)
- 6. Bupirimate (short update only)

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:
- 4. SCLP new compounds belonging to the approved group:
 - a) Draft review report rev.14 to include (8Z)-tetradec-8-en-1-yl acetate (to be noted)

A.07 Basic substances:

- 1. Quassia amara L. wood extract
- 2. New dossiers received (only for information)
 - a) clayed charcoal (extension)
 - b) sodium hydrogen carbonate (extension)
 - c) *Salix* spp. (extension)
 - d) sunflower (extension)
- 3. Exchange of views on EFSA Technical Reports
- 4. Draft Review Reports for discussion:
 - a) Vinegar extension

A.08 Guidance Documents:

- 1. Draft revised Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (short update)

2. Draft revised Guidance Document on Zonal Evaluation, Mutual Recognition Withdrawal and Amendment of Authorisations under Regulation (EC) No 1107/2009 (short update)
3. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
4. 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 be noted)
5. Draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (SANTE/10407/2018 Rev.3) – final consultation before adoption
6. Defining Specific Protection Goals for environmental risk assessment – update on next steps

A.09 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted).

A.10 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
3. On-board fumigation of grain

A.11 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009:

1. New notifications (to be noted)
2. EFSA Technical Reports on the Art. 53(2) examination of emergency authorisations for neonicotinoid active substances

A.12 News from European Food Safety Authority (EFSA):

1. Guidance on preparing good quality dossiers and Assessment Reports
2. General update

A.13 News from Health and Food Audits and Analysis (SANTE, Directorate F, former FVO):

1. Legal basis for controls on the marketing and use of plant protection products under Regulations (EC) No 882/2004 and (EU) No 2017/625.
2. General update

A.14 News from Sustainable Use Directive (Directive 2009/128/EC).

A.15 Report from Working Groups:

1. Plant Protection Products Application Management System (PPPAMS)
2. Working group on Biopesticides
3. Working group on Seed Treatments

4. Working Group on Co-formulants

A.16 OECD:

1. Report of the WGP meeting (June 2018)
2. Report of the EGBP meeting (June 2018)

A.17 Court cases:

1. Judgements by the General Court for T-429/13, T-451/13 and T-584/13 (neonics and fipronil cases)

A.18 Endocrine Disruptors:

1. Draft Commission Notice - Implementation of Commission Regulation (EU) No 2018/605 under Regulation (EC) No 1107/2009: Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (ECHA, EFSA, 2018)
2. 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.19 Minor Uses.

A.20 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009:
 - a) New entries in working document: Lava meal (BE), Salvis freeze (BE), Straw pellets (BE), Moss control / fertilizers (DK), Uses against lichens on trees (AT), Biodegradable Mulch Film (FI)
 - b) New case Frost Armour (FR)
 - c) New case Palm tree Protector INO128 (FR)

A.21 Classifications under Regulation (EC) No 1272/2008 / REACH:

1. Status of harmonised classifications
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
3. Report on the alignment of the classification and peer-review processes

A.22 PEST Committee.

A.23 Neonicotinoids.

A.24 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

- A.25** Information concerning Brexit:
1. Re-allocation of ongoing assessments
- A.26** Draft Commission Notice concerning a list of potentially low-risk substances (update).
- A.27** Data requirements and list of agreed test methods:
1. Update of the revision of the Communications (short update)
- A.28** Commission Regulation (EU) No 547/2011:
1. Feedback about notification of additional phrases by MS
 2. Steering Committee, workplan and expert groups to follow-up on MAgPIE project.
- A.29** Confirmatory data pending and overlapping with ongoing renewal – Clofentezine and Difeconazole (RMS ES).
- 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.

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 approving the active substance fenpicoxamid 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/10319/2018 Rev. 2).

(SANTE/10318/2018)

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

Procedure: Examination procedure

- 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 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)

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 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)

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 approval of the basic substance Onion oil 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/10615/2018 Rev. 1).

(SANTE/1614/2018)

Legal Basis: Regulation (EC) 1107/2009 - Article 23(5) in conjunction with Article 13(2)

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 pethoxamid 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/11637/2017 Rev 0.2).

(SANTE/11636/2017)

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 regards the extension of the approval periods of the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, carboxin, clethodim, cycloxydim, dazomet, diclofop, dithianon, dodine, fenazaquin, fluometuron, flutriafol, hexythiazox, hymexazol, indolylbutyric acid, isoxaben, lime sulphur, metaldehyde, paclobutrazol, pencycuron, sintofen, tau-fluvalinate and tebufenozide amending the Annex to Implementing Regulation (EU) No 540/2011.

(SANTE/10018/2018)

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

Procedure: Examination procedure

B.07 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 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, clomazone, cypermethrin, daminozide, deltamethrin, dimethenamid-p, diuron, fludioxonil, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, prosulfocarb, thiophanate-methyl and tribenuron amending the Annex to Implementing Regulation (EU) No 540/2011.

(SANTE/10635/2018)

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

Procedure: Examination procedure

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of Landes pine tar as a basic substance 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/10109/2018 Rev. 1).

(SANTE/10108/2018)

Legal Basis: Regulation (EC) 1107/2009 - Article 23(5) in conjunction with Article 13(2)

Procedure: Examination procedure

Section C **Draft(s) presented for discussion**

C.01 Exchange of views of the Committee on the Commission Draft Review Report and 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11948/2017) (short update only).

(SANTE/11947/2017)

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

Procedure: Examination procedure

C.02 Exchange of views of the Committee on the Commission Draft Review Report and Regulation concerning the non-renewal of approval of quinoxifen 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 (SANTE/10213/2018 rev 1)(short update only).

(SANTE/10213/2018)

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

Procedure: Examination procedure

C.03 Exchange of views of the Committee on the Commission Draft Review Report and Regulation renewing the approval of 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 rev 5) (short update only).

(SANTE/11618/2017)

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

Procedure: Examination procedure

C.04 Exchange of views of the Committee on the Commission Draft Review Report and Regulation concerning the non-renewal of approval of 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (SANTE/10183/2018 rev 1) (short update only).

(SANTE/10183/2018)

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

Procedure: Examination procedure

C.05 Exchange of views of the Committee on the Commission Draft Review Report and Regulation renewing the approval of 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 rev 1) (short update only).

(SANTE/10294/2018)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(01) and 78(2)

Procedure: Examination procedure

C.06 Exchange of views of the Committee on the Commission Draft Review Report and 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).

(SANTE/10471/2018)

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

Procedure: Examination procedure

C.07 Exchange of views of the Committee on the Commission Draft 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 - Article 24 in conjunction with Article 20(1)

Procedure: Examination procedure

C.08 Exchange of views of the Committee on the Commission Draft 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)

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

Procedure: Examination procedure

C.09 Exchange of views of the Committee on the 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 Rev. 0) (short update only).

(SANTE/10185/2018)

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

Procedure: Examination procedure

C.10 Exchange of views of the Committee on the Commission Draft 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) 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.11 Exchange of views of the Committee on the Commission Draft 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

C.12 Exchange of views of the Committee on the Commission Draft 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.13 Exchange of views of the Committee on the Commission Draft Implementing Regulation (EU) amending Implementing Regulation (EU) No 686/2012 as regards the rapporteur Member State and co-rapporteur Member State for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin.

(SANTE/10421/2018)

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

Procedure: Examination procedure

C.14 Exchange of views of the Committee on the Commission Draft Directive (EU) amending Directive 2009/128/EC to establish harmonised risk indicators.

(SANTE/10821/2018)

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

Procedure: Regulatory procedure with scrutiny

Section M **Miscellaneous**