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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 <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 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 <u>Draft(s) presented for discussion</u>

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 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 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**