



EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2018)2627092

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
24 MAY 2018 - 25 MAY 2018

CIRCABC Link: <https://circabc.europa.eu/w/browse/99e8a049-5c0d-47e9-a710-ffc730c6c9b6>

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:
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
 - a *Beauveria bassiana* PRI 5339
 - b *Bacillus subtilis* IAB/BS03
 - c Asulam-sodium
3. Commission Draft Review Report and Regulation concerning the (non-) approval of:
 - a Flutianil
 - b *Metschnikowia fructicola* NRRL Y-27328

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play
2. Exchange of view on EFSA conclusions:
 - a Trinexapac
3. Draft Review/Renewal Reports and Regulations for discussion:
 - a Chlorpropham
 - b Quinoxifen (short update only)
 - c Mecoprop-P (short update only)
 - d Copper compounds
 - e Mepanipyrim (short update only)

- f Tribenuron
- g Flurtamone (short update only)
- h Propiconazole (short update only)
- i Etoxazole (short update only)
- j Pethoxamid (short update only)
- k Methoxyfenozide
- l Desmedipham
- m Phenmedipham
- n Chlorothalonil
- o Indoxacarb

A.04 Confirmatory Data:

1. Dithianon (tour de table of voting intentions)
2. Terbutylazine (short update only)
3. Iprovalicarb (review report to be noted)
4. Ipconazole (review report)
5. Urea (review report)
6. Cyflumetofen (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:
5. Draft review report rev.14 to include (8Z)-tetradec-8-en-1-yl acetate

A.07 Basic substances:

1. Pilot projects: state of play
2. New dossiers received (only for information)
 - a clayed charcoal (extension)
3. Exchange of views on EFSA Technical Reports
4. Draft Review Reports for discussion:
 - a Landes pine tar (short update only)
 - b Lecithin extension (to be noted)
 - c Onion oil

A.08 Exchange of views on 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. Draft Mandate for a Technical Guideline on the Structure of the Biological Assessment Dossier (to be noted)
4. Draft revised template to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009 (SANCO/12544/2014 rev. 1, to be noted)
5. EFSA Guidance of Dermal Absorption (SANTE/ 10591/2018, to be noted)
6. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (short update)

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 (to be noted).

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

A.13 News from the Directorate General for Health and Food Safety (SANTE) Directorate F, Health and Food Audits and Analysis (former FVO).

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)
2. Working group on Biopesticides
3. Working group on Seed Treatments (no update)
4. Working Group on Co-formulants

A.15 OECD:

1. Coordination for the WGP

A.16 Court cases:

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

A.17 Endocrine Disruptors:

1. Implementation of the new ED Criteria renewal active substances:
 - date of application;
 - amending Implementing Regulation 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties
2. Draft EFSA/ECHA guidance document:
 - risk manager consultation and future guidance adoption under Article 77 of Regulation (EC) No 1107/2009

A.18 Minor Uses.

A.19 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009:
 - a Lava meal (BE)
 - b Salvis freeze (BE)
 - c Straw pellets (BE)
 - d Moss control / fertilizers (DK)
 - e Uses against lichens on trees (AT)
 - f Biodegradable Mulch Film (FI)

A.20 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.21 Glyphosate.

A.22 PEST Committee.

A.23 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

A.24 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

A.25 Information concerning Brexit.

A.26 Draft Commission Notice concerning a list of potentially low-risk substances (state of play).

- A.27** Scientific publications and information submitted by stakeholders.
- A.28** Confirmatory data pending and renewal ongoing – Clofentezine and Difeconazole (RMS ES).
- A.29** Commission Regulation (EU) No 547/2011: notification of additional phrases by Member States and follow-up of MAgPIE project.
- A.30** 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 low-risk active substance *Pasteuria nishizawae* Pn1, 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/10160/2018 rev. 0.1).

(SANTE/10159/2018)

Legal Basis: Regulation (EC) No 1107/2009 - Article 22(1) in conjunction with 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 oxasulfuron 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/10886/2017 Rev.1).

(SANTE/10885/2017 Rev.2)

Legal Basis: Regulation (EC) No 1107/2009 - Article 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 renewing the approval of the active substance *Ampelomyces quisqualis* strain AQ10, as a low risk active 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE-10210-2018 Rev.1)

(SANTE/10209/2018)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1) and Article 22(1)

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 diquat, 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/10396/2016 Rev.2).

(SANTE/10395/2016 Rev.2)

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

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 trifloxystrobin, 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/10107/2018 Rev.2)

(SANTE/10106/2018)

Legal Basis: Regulation (EC) No 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 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.1).

(SANTE/10318/2018 Rev.1)

Legal Basis: Regulation (EC) No 1107/2009 - Article 13(3)

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 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/11635/2017 Rev.0.1).

(SANTE/11636/2017)

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

Procedure: Examination procedure

B.08 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 fenamidone, 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/11004/2016 Rev.2).

(SANTE/11003/2016 Rev.1)

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

Procedure: Examination procedure

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance carfentrazone-ethyl 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/10144/2017 Rev.6).

(SANTE/10143/2017 Rev.2)

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

Procedure: Examination procedure

B.10 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 pymetrozine, 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/00103/2015 Rev.4).

(SANTE/00102/2015 Rev.3)

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

Procedure: Examination procedure

B.11 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 thiram, 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/11020/2017 Rev.3).

(SANTE/11019/2017 Rev.4)

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

Procedure: Examination procedure

- B.12** 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 fenbuconazole, metosulam, pyridaben, quinmerac, triflumuron and zinc phosphide amending the Annex to Implementing Regulation (EU) No 540/2011.

(SANTE/10017/2018 Rev.1)

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

Procedure: Examination procedure

- B.13** 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 alpha-cypermethrin, *Ampelomyces quisqualis* strain: AQ 10, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, carfentrazone ethyl, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diquat, ethephon, ethoprophos, etoxazole, famoxadone, fenamidone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, *Gliocladium catenulatum* strain: J1446, isoxaflutole, metalaxyl-m, methiocarb, methoxyfenozide, metribuzin, milbemectin, oxasulfuron, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, pymetrozine, s-metolachlor and trifloxystrobin amending the Annex to Implementing Regulation (EU) No 540/2011.

(SANTE/10292/2018 Rev.1)

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

Procedure: Examination procedure

- B.14** Exchange of views and possible opinion of the Committee on a draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009.

(SANTE/10407/2018 Rev.2)

Legal Basis: Regulation (EC) No 1107/2009 - Article 77

Procedure: Advisory procedure