



EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2019)6809169

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
21 - 22 October 2019

CIRCABC Link: <https://circabc.europa.eu/w/browse/878ad6f8-bcc2-40e9-8494-47b1d8665808>

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) Limestone
 - b) *Bacillus subtilis* strain FMCH002
 - c) *Bacillus licheniformis* strain FMCH001
 - d) *Chromobacterium subtsugae* PRAA4-1 (withdrawal)
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
 - a) Napropamid-M
 - b) Pydiflumetofen
3. Draft Review/Renewal Reports for discussion:
 - a) Lavandulyl senecionate
 - b) 1,3-Dichloropropene

A.03 Renewal of approval:

1. General topics:
 - a) Access to original dossiers
 - b) 6th renewal programme
2. Exchange of view on EFSA conclusions/EFSA scientific reports:
 - a) Mancozeb
 - b) *Phlebiopsis gigantea* VRA 1835, VRA 1984 and FOC PG 410.3

3. Draft Review/Renewal Reports for discussion:

- a) Bromoxynil
- b) Flumioxazin
- c) Fenamiphos
- d) Cypermethrin
- e) Beta cyfluthrin
- f) *Pseudomonas chlororaphis* MA 342
- g) Bifenazate
- h) Clopyralid
- i) Cyazofamid
- j) Famoxadone
- k) Etoxazole
- l) Fosethyl
- m) Pyriproxyfen

A.04 Confirmatory information:

1. Fluopicolide (review report to take note)
2. Spiroxamine
3. Dithianon
4. Triazole derived metabolites (TDMs)
5. Sulfoxaflor
6. Fenpyrazamine
7. Isofetamid
8. Benzovindiflupyr
9. Geraniol (no news)
10. Eugenol (no news)
11. Thymol (no news)
12. Clove oil (no news)
13. Gamma-cyhalothrin
14. Ipconazole
15. Terbutylazine

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 for discussion:
 - a) Azadirachtin

A.07 Basic substances:

1. New dossiers received (for information):
 - a) *Equisetum arvense* extension
 - b) E235 natamycin
 - c) Tribasic
 - d) Sodium hypochlorite
 - e) *Urtica spp.* extension
2. Exchange of views on EFSA Technical Reports:
3. Draft Review Reports for discussion:
 - a) Milk
 - b) Propolis extract
 - c) Saponaria
 - d) sucrose
 - e) fructose

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. Working Document on emergency authorisations according to Article 53 (discussion)
3. Data requirements and list of agreed test methods - Communications 2013/C 95/01 and 2013/C 95/02 (update)
4. Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance (final discussion)
5. Draft Guidance document on the risk assessment of metabolites produced by micro-organisms (state of play)
6. Guidance on the impact of water treatment processes on the nature of residues in drinking water (state of play)
7. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11)
8. Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004– rev 9)
9. Guidance document on Data Matching for applications for authorisation of PPPs according to Article 33/43

A.09 Defining specific protection goals for environmental risk assessment.

- A.10** Commission Regulation (EU) No 547/2011 and risk mitigation:
1. Feedback about notification of additional phrases by Member States
 2. Risk Mitigation / list of risk reduction measures
- A.11** Notifications under Article 44(4) of Regulation (EC) No 1107/2009:
1. New notifications (to be noted)
- A.12** 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.13** Authorisations granted under Article 53 of Regulation (EC) No 1107/2009:
1. New notifications (to be noted)
- A.14** Plant Protection Products Application Management System (PPPAMS).
- A.15** News from the European Food Safety Authority (EFSA).
1. Presentation of Isomer Guidance Document
 2. Presentation of new GAP table
- A.16** Improving the efficiency of the process of a.s. approval.
- A.17** News from Health and Food Audits and Analysis (SANTE, Directorate F).
- A.18** News from Sustainable Use Directive (Directive 2009/128/EC).
- A.19** Minor Uses:
1. Draft guidance document on minor uses according to Regulation (EC) No 1107/2009
- A.20** Court cases.
- A.21** Ombudsman cases.
- A.22** New Transparency rules: General Food Law amendment and implementation.
- A.23** Clarifications & questions related to specific active substance:
1. Chlorotalonil monitoring data
 2. Candidates for substitution
 3. Carvone: correcting act to the Implementing Regulation
 4. Maleic hydrazide labelling provisions
- A.24** Interpretation issues:
1. 2,4 D / 2,4 D EHE

2. Nitrophenolates salts
 3. Scope of Regulation (EC) No 1107/2009:
 - a) Scope Document rev.56 (previous border cases – confirmation)
 - b) Kaolin as sunscreen
 - c) New cases:
 - c.1. Fescues seeds infected with endophytic fungus (FR)
 - c.2. Banana latex removers
 - c.3. Potassium permanganate sachets
 - c.4. Cis-jasmone
 - c.5. Irradiated pollen
 - c.6. Ozone
 - d) Follow-up in situ generation (update)
 4. Data protection – access to old studies during the renewal process
 5. Article 32(1) v. article 44(3(a) and article 46 of Regulation 1107/2009.
- A.25** Classification under Regulation (EC) No 1272/2008:
1. Status of notifications for harmonised classification (summary table for info)
- A.26** Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).
- A.27** Report from working groups, in particular:
1. Working group on biopesticides
 - update on on-going revision of data requirements for microorganisms
 2. Working group on seed treatments
 3. Post approval issues
 - updated Terms of Reference (to take note)
- A.28** Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.
- A.29** OECD and EPPO activities, in particular:
1. Report of last WG Pesticides + Seminar on Digital and Mechanical Technologies (+ Expert group on drones)
 2. Expert group on biopesticides: call for comments
- A.30** Scientific publications and information submitted by stakeholders.
- A.31** 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 Implementing Regulation concerning the non-renewal of approval of the active substance thiacloprid, 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 Renewal Report SANTE/10450/2019 Rev. 1).

(SANTE/10448/2019 Rev. 2)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 78(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 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 Renewal Report SANTE/11254/2018 Rev. 3).

(SANTE/11253/2018 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 concerning the non-approval of *Vitis vinifera* cane tannins 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 (Draft Review Report SANTE/11448/2019 Rev. 1)

(SANTE/11446/2019 Rev. 1)

Legal Basis: Regulation (EC) 1107/2009 - Article 23

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the non-repetition of emergency authorisations by Romania for the placing on the market of plant protection product MODESTO 480 FS, containing the active substance clothianidin, and plant protection product NUPRID AL 600 FS, containing the active substance imidacloprid, for use on *Brassica napus* to combat the pests *Phyllotreta* spp. and/or *Psylliodes* spp. in accordance with Article 53 (1) of Regulation (EC) No 1107/2009.

(SANTE/10382/2019)

Legal Basis: Regulation (EC) 1107/2009 - Article 53(3)(a)

Procedure: Examination procedure

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the non-repetition of emergency authorisations by Lithuania for the placing on the market of plant protection product “CRUISER OSR” containing the active substance thiamethoxam for use on spring rape to combat the plant pests *Phyllotreta* spp. and/or *Psylloides* spp. in accordance with Article 53(1) of Regulation (EC) No 1107/2009.

(SANTE/10388/2019)

Legal Basis: Regulation (EC) 1107/2009 - Article 53(3)(a)

Procedure: Examination procedure

B.06 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 benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin.

(SANTE/11598/2019)

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

Procedure: Examination procedure

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

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) modifying Annex III of Regulation (EC) 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

(SANTE/10257/2018)

Legal Basis: Regulation (EC) 1107/2009 - Articles 27(2) and 58(2)

Procedure: Regulatory procedure with scrutiny

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances.

(SANTE/10722/2017)

Legal Basis: Regulation (EC) 1107/2009 - Articles 19 and 78(2)

Procedure: Examination procedure

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance metalaxyl-M, 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/11112/2019 Rev. 2).

(SANTE/11110/2019 Rev. 1)

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

Procedure: Examination procedure

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance chlorpyrifos, 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 Renewal Report SANTE/11938/2019 Rev. 0).

(SANTE/11936/2019 Rev. 1)

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

Procedure: Examination procedure

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance chlorpyrifos-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 Renewal Report SANTE/11942/2019 Rev. 1).

(SANTE/11940/2019 Rev. 1)

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

Procedure: Examination procedure

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of L-cysteine 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11056/2019 Rev.0).

(SANTE/11054/2019 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 23

Procedure: Examination procedure

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Castanea* and *Schinopsis* tannins 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11444/2019 Rev. 0).

(SANTE/11442/2019 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 23

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance foramsulfuron, 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/11214/2016 Rev. 1).

(SANTE/11213/2016 Rev. 1)

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

Procedure: Examination procedure