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Health and Food Safety Directorate General

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**Standing Committee on Plants, Animals, Food and Feed**  
**Section *Phytopharmaceuticals - Legislation***  
**16 - 17 July 2019**

**CIRCABC Link:** <https://circabc.europa.eu/w/browse/c46bc996-9f82-4f11-831d-13b6d80994db>

<b>AGENDA</b>
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**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) Fluindapyr
  - b) *Bacillus subtilis* strain RTI477
  - c) *Bacillus velezensis* strain RTI301
  - d) *Phthorimaea operculella* granulovirus (PhopGV)
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
  - a) Napropamid-M (update)
3. Draft Review/Renewal Reports for discussion:
  - a) Lavandulyl senecionate
  - b) 1,3-Dichloropropene

**A.03** Renewal of approval:

1. Annex I Renewal Projects: State of play
2. Exchange of view on EFSA conclusions/EFSA scientific reports:
  - a) Pyriproxyfen
3. Draft Review/Renewal Reports for discussion:
  - a) Bromoxynil
  - b) Flumioxazin
  - c) Clodinafop

- d) Fenamiphos
- e) Cypermethrin
- f) Beta cyfluthrin
- g) *Pseudomonas chlororaphis* MA 342
- h) Bifenazate
- i) Clopyralid
- j) Cyazofamid
- k) Famoxadone
- l) Foramsulfuron
- m) Etoxazole
- n) Fosethyl
- o) Assessment of ED potential in accordance with Commission Regulation (EU) No 2018/605, according to Commission Regulation (EU) No 2018/1659 amending Commission Implementing Regulation (EU) No 844/2012

**A.04** Confirmatory Information:

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

**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:
  - a) Azadirachtin

3. Draft Review/Renewal Reports for discussion:

**A.07** Basic substances:

1. New dossiers received (for information)
  - a) Lecithin (extension)
2. Exchange of views on EFSA Technical Reports
  - a) Propolis extract
3. Draft Review Reports for discussion:
  - a) Milk

**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 - Update of the Communications 2013/C 95/01 and 2013/C 95/02
4. Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance (state of play)
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 MS (no news)
2. Risk Mitigation / list of risk reduction measures (proposed way forward)

**A.11** Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (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** New authorisations granted under Article 53 of Regulation (EC) No 1107/2009:
1. New notifications (to be noted)
  2. 1,3-Dichloropropene
- A.14** Plant Protection Products Application Management System (PPPAMS).
- A.15** News from European Food Safety Authority (EFSA).
- A.16** Improving the efficiency of the process of a.s. approval:
- Update on on-going activities including feedback of MS
  - Transparency of decision-making
- A.17** News from Health and Food Audits and Analysis (SANTE, Directorate F, former FVO).
- A.18** News from Sustainable Use Directive (Directive 2009/128/EC).
- A.19** Minor Uses:
- Draft guidance document on minor uses according to Regulation (EC) No 1107/2009
- A.20** Progress Report on Low Risk Active Substances (update).
- A.21** Court cases.
- A.22** Ombudsman cases.
- A.23** New Transparency rules: General Food Law amendment.
- A.24** Endocrine Disruptors.
- A.25** Clarifications & questions related to specific active substance:
- a) Maleic hydrazide
  - b) Chlorotalonil monitoring data
  - c) Candidates for substitution
- A.26** Interpretation issues:
1. 2,4 D / 2,4 D EHE
  2. Scope of Regulation (EC) No 1107/2009:
    - a) Follow-up in situ generation (update)
    - b) CVAS Disinfectant product based on propan-2-ol
- A.27** Classification under Regulation (EC) No 1272/2008:
1. Status of notifications for harmonised classification (summary table for info)

2. General update
- A.28** Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).
- A.29** Report from Working Groups, in particular:
1. Working Group on Biopesticides
  2. Working Group on Seed Treatments
  3. Post Approval Issues
- A.30** OECD and EPPO:
- a) General update
  - b) Debriefing of OECD June Meetings
- A.31** Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.
- A.32** Scientific publications and information submitted by stakeholders.
- A.33** 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 approving the low-risk active substance *Bacillus subtilis* strain IAB/BS03, 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/10318/2019 rev 1).

(SANTE/10316/2019 Rev. 1)

**Legal Basis:** Regulation (EC) 1107/2009 - Articles 13(2) and 22

**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 Decision concerning the renewal of the approval of the active substance *Verticillium albo-atrum* WCS850 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/10198/2019)

(SANTE/10196/2019)

**Legal Basis:** Regulation (EC) 1107/2009 - Articles 13(2) and 78(2)

**Procedure:** Examination procedure

**B.04** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance alpha-cypermethrin, 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 Renewal Report SANTE/11525/2018)

(SANTE/11524/2018)

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

**Procedure:** Examination procedure

**B.05** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance methiocarb, 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/11710/2018)

(SANTE/11708/2018)

**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 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-p, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanate-methyl, triflusulfuron and tritosulfuron, amending the Annex to Implementing Regulation (EU) No 540/2011

(SANTE/10104/2019)

**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 Regulation amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards bees 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

**B.08** 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.09** 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

## **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)

(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.0).

(SANTE/11110/2019 Rev. 0)

**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 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).

(SANTE/10448/2019)

**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 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)

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

**Procedure:** Examination procedure

- C.06** 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)

**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 *Vitis vinefera* 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11448/2019 Rev.0).

(SANTE/11446/2019 Rev. 0)

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

**Procedure:** Examination procedure