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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***  
**5 - 6 December 2019**

**CIRCABC Link:** <https://circabc.europa.eu/w/browse/464af872-3138-4681-b28a-2929453eaa28>

<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:
2. Exchange of views on EFSA conclusions:
  - a) Napropamid-M
  - b) Pydiflumetofen
  - c) 1,3-Dichloropropene
  - d) Ethamethsulfuron-methyl
3. Draft Review/Renewal Reports for discussion:

*Pro memoriam / on hold until next PAFF meeting (January 2020): Lavandulyl senecionate*

**A.03** Renewal of approval:

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

*Pro memoriam / on hold until next PAFF meeting (January 2020): Mancozeb*

3. Draft Review/Renewal Reports for discussion:
  - a) Flumioxazin

- b) Clopyralid
- c) Cyazofamid
- d) Famoxadone
- e) Etoxazole
- f) Indoxacarb

*Pro memoriam / on hold until next PAFF meeting (January 2020): Pyriproxyfen, Bromoxynil, Fenamiphos, Cypermethrin, Pseudomonas chlororaphis MA 342, Bifenazate*

**A.04** Confirmatory Information:

- 1. Spiroxamine
- 2. Triazole derived metabolites (TDMs) (general appendix which will be added to each concerned review report to take note)
- 3. Sulfoxaflor
- 4. Isofetamid
- 5. Terbutylazine

*Pro memoriam / on hold until next PAFF meeting (January 2020): Fenpyrazamine, Benzovindiflupyr, Ipconazole, Gamma-cyhalothrin, Geraniol, Eugenol, Thymol, Clove oil.*

**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) Chitosan hydrochloride (extension)
  - b) Ozone
- 2. Exchange of views on EFSA Technical Reports
- 3. Draft Review Reports for discussion:
  - a) sucrose
  - b) fructose
  - c) Lecithins (extension)

*Pro memoriam / on hold until next PAFF meeting (January 2020): Saponaria.*

**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
5. Draft Guidance document on the risk assessment of metabolites produced by micro-organisms
6. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11)
7. Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004– rev 9)
8. 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 update)
2. Risk Mitigation / list of risk reduction measures: outline of Workshop on 17 January 2020

**A.11** Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (no news).

**A.12** Notifications under Article 36(3) of Regulation (EC) No 1107/2009 (no news).

**A.13** Authorisations granted under Article 53 of Regulation (EC) No 1107/2009 (no news).

**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.

**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. Acibenzolar-S-methyl – updated review report (to take note)
  2. Chlorotalonil monitoring data
  3. Candidates for substitution
  4. Carvone: correcting act to the Implementing Regulation
  5. Maleic hydrazide labelling provisions
- A.24** Interpretation issues:
1. 2,4 D / 2,4 D EHE
  2. Nitrophenolates salts (Na/K ; CHAP)
  3. Scope of Regulation (EC) No 1107/2009:
    - a) Scope Document rev.58 (previous border cases – confirmation)
    - b) Ongoing cases:
      - b.1. Irradiated pollen
      - b.2. Ozone as soil fumigant and seed disinfection
      - b.3. Water conditioner
      - b.4. Eruca (*Bacillus megaterium* and *B. mycooides*)
      - b.5. Wildfire fighting product
    - c) 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** Reports from Working Groups, in particular:
1. Working Group on Biopesticides
  2. Working Group on Seed Treatments (no news)
  3. Post Approval Issues (no news)

- 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. Expert Group on Drones
- A.30** Scientific publications and information submitted by stakeholders:
- FAO/WHO on report Foodborne Antimicrobial Resistance
- 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 (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
- B.02** Exchange of views and possible opinion 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. 1).  
(SANTE/11936/2019 Rev. 2)  
**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 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. 2).  
(SANTE/11940/2019 Rev. 2)  
**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 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

### **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) No 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 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.2).

(SANTE/11054/2019 Rev. 2)

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

**Procedure:** Examination procedure

**C.03** Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of Milk 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/12816/2019 Rev.2).

(SANTE/12794/2019 Rev. 0)

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

**Procedure:** Examination procedure

**C.04** Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of propolis 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/11782/2019 Rev.0).

(SANTE/11780/2019 Rev. 0)

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

**Procedure:** Examination procedure

**C.05** 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