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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***  
**1-2 December 2021**

**CIRCABC Link:** <https://circabc.europa.eu/w/browse/40db7ac9-bfa3-427b-a70a-ce1a486bc24b>

<b>AGENDA</b>
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**Section A**     **Information and/or discussion**

**A.01** Summary Report of previous meetings.

**A.02** New dossiers (for information):

- New active substances
  1. *Cryptophlebia peltastica* nucleopolyhedrovirus, strain SouthAfrica
  2. Bacteriophage of Potato Soft Rot Enterobacteriaceae (BPSRE)
  3. *Trichoderma afroharzianum* Th2RI99
- Basic substances applications
  4. Ginger extract
- Amendment of conditions of approval

**A.03** Renewal of approval and general issues.

**A.04** Exchange of views on EFSA conclusions/EFSA scientific reports:

- New active substances
- Renewal of approval
  1. Clofentezine
  2. Bentiavalicarb
- Basic substances
  3. Calcium propionate
  4. Black soap
  5. Lemon essential oil
  6. Yucca Schidigera extract

- Amendment of conditions of approval
- 7. Paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3)

**A.05** Draft Review/Renewal Reports for discussion:

- New active substances
  - a) Dimethyl disulphide
  - b) Asulam-sodium
- Renewal of approval
  - c) Captan
  - d) *Bacillus amyloliquefaciens* strain QST 713
  - e) *Pseudomonas chlororaphis* strain MA342
  - f) *Bacillus thuringiensis* (horizontal discussion)
  - g) *Pythium oligandrum* strain M1
  - h) Straight Chain Lepidopteran Pheromones
  - i) Pelargonic acid
- Basic substances
  - j) Hydrogen peroxide silver stabilised
  - k) Ozone
- Amendment of conditions of approval

**A.06** Confirmatory Information:

1. Flutianil (amended review report to take note)
2. Potassium phosphonate
3. Pyrethrins
4. 1-decanol
5. Acibenzolar-methyl
6. Pyridaril
7. Acequinocyl

**A.07** Guidance Documents:

1. Updated (errata) Guidance document on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (to take note)
2. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
3. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009
4. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02

5. Draft technical guidance on points 3.6.3. to 3.6.5 of Annex II to Regulation (EC) No 1107/2009, in particular regarding the demonstration of negligible exposure to an active substance in a plant protection product under realistic conditions of use (update)
6. EFSA guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil
7. EFSA Guidance on aneugenicity assessment

**A.08** Defining Specific Protection Goals for environmental risk assessment.

**A.09** Commission Regulation (EU) No 547/2011 and risk mitigation.

**A.10** Notifications under Regulation (EC) No 1107/2009 (for information):

- Article 44(4)
- Article 36(3)
- Article 53

**A.11** News from European Food Safety Authority (EFSA).

**A.12** Improving the efficiency of the process of a.s. approval / renewal.

**A.13** Microorganism Active Substances, in particular:

- Commission Communications in the framework of the implementation of the data requirements

**A.14** Safeners and Synergists.

**A.15** Updates, clarifications & questions on specific active substances:

1. Clethodim
2. Dimethomorph
3. Napropamid-M
4. Sodium hydrogen carbonate

**A.16** Article 21:

1. Tebufenozide (amended review report to take note)

**A.17** General issues for information / discussion:

1. Illegal plant protection product use (Seminar/Training February 2022)
2. Scope of Regulation (EC) No 1107/2009:
  - a) Scope delineation with biocidal products
  - b) Scope Document rev. 67
3. Basic substances – general issues

4. MS updated survey on timing of regulatory procedures
5. Mono- and polymers as co-formulants
6. Microplastics / REACH: Ongoing regulatory activities regarding restrictions of use under REACH
7. Synergistic effects of pesticides on pollinators
8. Trifluoroacetic acid (TFA)
9. MS-proposal PPP TARIC Code
10. PPPAMS – update

**A.18** News from Sustainable Use Directive (Directive 2009/128/EC).

**A.19** News from Health and Food Audits and Analysis (SANTE, Directorate F).

**A.20** Implementation Art. 67 Regulation (EC) No 1107/2009.

**A.21** Report from Working groups, in particular:

1. Working group on Biopesticides
2. Working group on Seed Treatments (Risk Assessment)
3. Working group Post Approval Issues

**A.22** Minor Uses.

**A.23** Court cases.

**A.24** Ombudsman cases.

**A.25** Exchange of information from the Pesticide Residues section of the Committee, in particular possible impact on authorisations.

**A.26** OECD, FAO and EPPO activities.

**A.27** Scientific publications and information submitted by stakeholders.

**A.28** Date of next meeting(s).

**A.29** AoB.

## **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) concerning the non-renewal of approval of the active substance phosmet, 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/12604/2020).

(SANTE/12602/2020)

**Legal Basis:** Regulation (EC) No 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 approving the active substance *Beauveria bassiana* strain 203 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/10296/2021).

(SANTE/10298/2021)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 13(2)

**Procedure:** Examination procedure

**B.03** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of the active substance 1,3-dichloropropene, 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/10814/2019).

(SANTE/10812/2019)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 13(2)

**Procedure:** Examination procedure

**B.04** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of the active substance chloropicrin, 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/11096/2020).

(SANTE/11094/2020)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 13(2)

**Procedure:** Examination procedure

**B.05** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the low-risk active substance *Bacillus amyloliquefaciens* strain IT-45, 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/10762/2021).

(SANTE/10760/2021)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 13(2) in conjunction with Article 22(1)

**Procedure:** Examination procedure

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

**C.01** Exchange of views of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are micro-organisms.

(SANTE/10686/2021)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 78(1)(a)

**Procedure:** Regulatory procedure with scrutiny

**C.02** Exchange of views of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms.

(SANTE/12040/2020)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 78(1)(b)

**Procedure:** Regulatory procedure with scrutiny

**C.03** Exchange of views of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms.

(SANTE/12042/2020)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 78(1)(b)

**Procedure:** Regulatory procedure with scrutiny

**C.04** Exchange of views of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms.

(SANTE/10716/2021)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 29(6) and Article 78(1)(c)

**Procedure:** Regulatory procedure with scrutiny

**C.05** Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor (Draft Updated Review Report SANCO/10665/2015).

(SANTE/10724/2020)

**Legal Basis:** Regulation (EC) No 1107/2009 - Articles 21(3) and 79(3)

**Procedure:** Examination procedure

**C.06** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) approving the basic substance chitosan 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/10594/2021).

(SANTE/10592/2021)

**Legal Basis:** Regulation (EC) No 1107/2009 - Articles 23(5), 13(2) and 79(3)

**Procedure:** Examination procedure

**C.07** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) approving the active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 as a low-risk 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11266/2021).

(SANTE/11264/2021)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 13(2) in conjunction with Article 22(1) and Article 79(3)

**Procedure:** Examination procedure

**C.08** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance carbon dioxide 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/10824/2021).

(SANTE/10822/2021)

**Legal Basis:** Regulation (EC) No 1107/2009 - Articles 20 and 22, Regulation (EU) No 844/2012 - Article 14

**Procedure:** Examination procedure

- C.09** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) approving the bifenazate 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/11300/2021, Rev. 1)  
(SANTE/11298/2021)  
**Legal Basis:** Regulation (EC) No 1107/2009 - Article 20(1)  
**Procedure:** Examination procedure
- C.10** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of approval of the active substance *Metarhizium brunneum* strain M43 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/10278/2021).  
(SANTE/10276/2021)  
**Legal Basis:** Regulation (EC) No 1107/2009 - Articles 20(1) and 22(2)  
**Procedure:** Examination procedure
- C.11** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) withdrawing the approval of the active substance isopyrazam 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/10308/2021)  
**Legal Basis:** Regulation (EC) No 1107/2009 - Articles 21(3) and 78 (2)  
**Procedure:** Examination procedure
- C.12** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance penflufen and repealing Implementing Regulation (EU) 2018/185 (Draft Review Report SANTE/10028/2017).  
(SANTE/10574/2021)  
**Legal Basis:** Regulation (EC) No 1107/2009 - Articles 21(3) and 78 (2)  
**Procedure:** Examination procedure

**Pro memoria – TBT notification (to be) launched**