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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***

**21 - 22 October 2021**

**CIRCABC Link:** <https://circabc.europa.eu/w/browse/2a9b1df7-3908-4d5c-aa5e-698241855545>

<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. *Bacillus amyloliquefaciens* AT-332
  2. *Metarhizium brunneum* BNL102
  3. Polypeptide, ASFBIOF01-02
  4. L-Carvone
- Basic substances applications
- Amendment of conditions of approval
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**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
  3. *Bacillus thuringiensis subsp. kurstaki* strain ABTS-351
- Basic substances
  4. Calcium propionate
  5. Black soap
  6. Hydrogen peroxide silver stabilised

7. Lemon essential oil
8. Ozone
- Amendment of conditions of approval
9. 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) *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV)
- Renewal of approval
  - c) *Metarhizium brunneum* strain M43 (subcultures BIPESCO 5/F 52)
  - d) Captan
  - e) *Bacillus amyloliquefaciens* strain QST 713
  - f) *Pseudomonas chlororaphis* strain MA342
  - g) *Bacillus thuringiensis* (horizontal discussion)
  - h) *Pythium oligandrum* strain M1
  - i) Straight Chain Lepidopteran Pheromones
  - j) Carbon Dioxide
  - k) Bifenazate
  - l) Pelargonic acid
- Basic substances
  - m) Caffeine
- Amendment of conditions of approval

**A.06** Confirmatory Information:

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

**A.07** Guidance Documents:

1. Guidance document on the assessment of the relevance of metabolites in groundwater (SANCO/221/2000 Rev 11) (to take note)

2. Updated (errata) Guidance document on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (to take note)
3. Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004 rev. 9) (to take note)
4. Guidance document on rules for revision of assessment reports (SANCO/10180/2013– rev. 2 May 2021) (to take note)
5. Guidance document on data matching for applications for authorisation of plant protection products according to article 33/43 (SANTE/2016/11449 rev. 1) (to take note)
6. Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No. 1107/2009 (SANCO/10473/2003 – rev. 5) (to take note)
7. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
8. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009
9. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02
10. 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)
11. EFSA guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil

**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. Calcium hydroxide
2. Clethodim
3. Dimethomorph
4. Napropamid-M

**A.16** Article 21:

1. Tebufenozide
2. Isopyrazam
3. Pirimicarb
4. Ipconazole

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

1. Brexit
2. COVID-caused delays
3. Illegal plant protection product use
4. Scope of Regulation (EC) No 1107/2009:
  - a) Scope delineation with biocidal products
  - b) New cases: chabazite
5. Basic substances – general issues
6. MS updated survey on timing of regulatory procedures
7. Mono- and polymers as co-formulants
8. Microplastics / REACH: Ongoing regulatory activities regarding restrictions of use under REACH
9. BTSF-training on ED
10. Art. 68 submissions

**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
  - residue definition for risk assessment (to take note)
- A.26** OECD and EPPO activities.
- A.27** Scientific publications and information submitted by stakeholders.
- A.28** 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) 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 (EU) concerning renewing the approval of the active substance 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 Review Report SANTE 11527/2018).

(SANTE/10590/2021)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 20(1) in conjunction with Article 24 (1)

**Procedure:** Examination procedure

- B.03** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the new active substance *Purpureocillium lilacinum* strain PL11 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10418/2021).  
(SANTE/10416/2021)

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

**Procedure:** Examination procedure

- B.04** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance *Purpureocillium lilacinum* strain 251 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/12462/2020).  
(SANTE/12460/2020)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 20(1) in conjunction with Article 22(1)

**Procedure:** Examination procedure

- B.05** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance flumioxazin, 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 and to Commission Implementing Regulation (EU) 2015/408 (Draft Review Report SANCO/12512/2014).  
(SANCO/12510/2014)

**Legal Basis:** Regulation (EC) No 1107/2009 - Article 20(1) in conjunction with Article 78(2)

**Procedure:** Examination procedure

- B.06** 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 indoxacarb, 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/10730/2018).  
(SANTE/10729/2018)

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

**Procedure:** Examination procedure

- B.07** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, mepiquat, metiram, oxamyl, and pyraclostrobin.

(SANTE/11120/2021)

**Legal Basis:** Regulation (EC) No 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) amending Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, to specify criteria for the approval of microbial active substances.

(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 Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, 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.

(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 Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, 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.

(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 Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

(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 - Article 21(3) and Article 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 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

- C.08** Exchange of views 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

- C.09** Exchange of views 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



- C.10** Exchange of views 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

- C.11** 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**