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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*
25 - 26 January 2021

CIRCABC Link: <https://circabc.europa.eu/w/browse/10dc1829-c3dd-4ed8-8207-901012c9b9da>

AGENDA

Section A **Information and/or discussion**

A.01 Summary Report of previous meetings.

A.02 New dossiers (for information):

- New active substances
 1. *Aspergillus flavus* strain MUCL54911
 2. *Trichoderma harzianum*
 3. Lysate of *Willaertia magna* C2
 4. OptiCHOS
 5. *Bacillus nakamurai* F727
- Basic substances applications received (for information)
 6. *Moringa oleifera* L. leaves & extract
 7. Extract of *Quassia amara*
- Amendment of conditions of approval
 8. *Clove oil*
- Article 21 Reviews

A.03 Renewal of approval and general issues.

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

- New active substances
 1. Pepino Mosaic Virus, EU strain, mild isolate Abp1
 2. Pepino Mosaic Virus, CH2 strain, mild isolate Abp2

- Renewal of approval
 3. *Pseudomonas chlororaphis* MA342
 4. *Bacillus thuringiensis* subsp. *Israelensis* (serotype H-14) strain AM65-52
 5. *Bacillus amyloliquefaciens* strain QST 713
- Basic substances
 6. Sodium hypochlorite
 7. Dimethyl sulphide
 8. Sunflower oil
- Amendment of conditions of approval

A.05 Draft Review/Renewal Reports for discussion:

- New active substances
 - a. Dimethyl disulphide
 - b. Chloropicrin
 - c. 1,3-dichloropropene
 - d. *Beauveria bassiana* 203
- Renewal of approval
 - e. *Metarhizium brunneum* strains BIPESCO 5/F 52
 - f. Captan
 - g. *Purpureocillium lilacinum* strain 251
 - h. Phosmet
 - i. *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857, *Bacillus thuringiensis* subsp. *aizawai* strain GC-91, *Bacillus thuringiensis* subsp. *kurstaki* strain SA-11, *Bacillus thuringiensis* subsp. *kurstaki* strain SA-12 (cross cutting issues)
 - j. *Pythium oligandrum* strain M1
 - k. Clopyralid
 - l. Flumioxazin
 - m. Famoxadone
 - n. Cypermethrin
- Basic substances
 - o. Vinegar (extension of use) (amended review report to be noted)
 - p. Clayed charcoal (amended review report to be noted)
 - q. Chitosan hydrochloride (extension of use) (amended review report to be noted)

- r. Whey (extension of use)
 - s. *Equisetum avense* (extension of use)
 - t. Willow bark and stem extract
 - u. Chitosan hydrochloride (extension of use and origin)
 - v. Calcium hydroxide (extension of use)
- Amendment of conditions of approval

A.06 Confirmatory Information:

1. Triazole derived metabolites (TDMs) - review reports updated to include the agreed TDM endpoints
 - prothioconazole (updated review report to take note)
 - penconazole (updated review report to take note)
 - metconazole (updated review report to take note)
 - triticonazole (updated review report to take note)
 - tebuconazole (updated review report to take note)
 - tetraconazole (updated review report to take note)
 - ipconazole (updated review report to take note)
 - mefentrifluconazole (updated review report to take note)
2. Pyrethrins (amended report to take note)
3. Tri-allate
4. Geraniol, Eugenol, Thymol, Clove oil, Orange oil
5. Propyzamide
6. Isopyrazam
7. Penthiopyrad
8. Meptyldinocap
9. *Bacillus pumilus* QST 2808
10. Mandestrobin
11. Fluxapyroxad
12. Flupyradifurone
13. Oxathiapiprolin
14. Terpenoid blend QRD 460
15. Metobromuron
16. Spiroxamine
17. **Pro memoria – Postponed to the next PAFF meeting** Penflufen

A.07 Guidance Documents:

1. Draft update of Guidance on emergency authorisations according to Article 53 (to take note)
2. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11) (to take note)
3. Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009 (SANCO/10363/2012) (to take note)
4. Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (to take note)
5. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
6. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009
7. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02
8. 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
9. Draft EFSA Administrative Guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure

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

Article 69

Article 71

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:

- update of uniform principles and Annex II

A.14 Safeners and Synergists.

A.15 Clarifications & questions related to specific active substance:

1. Flupyradifurone
2. Acetamiprid
3. Sulfoxaflor

A.16 General issues for information / discussion:

1. Brexit
2. Illegal plant protection product use
3. Nitrophenolates salts (Na/K) - update, new active substance vs. technical concentrate
4. Active Substances vs. Co-formulants (e.g. Tall oil crude, clove oil,... as co-formulant)
5. Scope of Regulation (EC) No 1107/2009:
 - a) Scope Document rev.60
 - b) New cases
 - c) In situ generated active substances
6. Basic substances – general issues

A.17 News from Sustainable Use Directive (Directive 2009/128/EC).

A.18 News from Health and Food Audits and Analysis (SANTE, Directorate F).

A.19 Report from Working Groups, in particular:

1. Working Group on Biopesticides
2. Working Group on Seed Treatments
3. Working Group on Post Approval Issues

A.20 Minor Uses.

A.21 Court cases.

A.22 Ombudsman cases.

A.23 Exchange of information from the Pesticide Residues section of the Committee, in particular:

- possible impact on authorisations.

A.24 OECD and EPPO activities.

A.25 Scientific publications and information submitted by stakeholders.

A.26 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) adopting a standard data format for the submission of applications for the approval of an active substance or amendment to the conditions of an approval as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

(SANTE/12162/2020)

Legal Basis: Regulation (EC) No 2019/1381 - Article 39f (2), Regulation (EC) 1107/2009 - Article 78(2)

Procedure: Examination procedure

- B.02** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance benfluralin, 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/10236/2020 Rev. 0).

(SANTE/10234/2020 Rev. 0)

Legal Basis: Regulation (EC) No 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 (EU) approving the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus* 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/11962/2020 Rev. 1)

(SANTE/11960/2020)

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 amending Implementing Regulations (EU) No 2017/375 and (EU) No 540/2011 as regards the conditions of approval of the active substance prosulfuron (Draft Addendum to the Renewal Report SANTE/12092/2020 Rev. 2).

(SANTE/12090/2020 Rev. 1)

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

Procedure: Examination procedure

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Commission Implementing Regulation (EU) 2017/1529 of 7 September 2017 approving the basic substance sodium chloride 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 amended Review Report SANTE/10383/2017).

(SANTE/12444/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Article 13(2) in conjunction with Article 23(5)

Procedure: Examination procedure

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Commission Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. Aizawai strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. Israeliensis (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, clopyralid, *Cydia pomonella Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, mepanipyrim, *Metarhizium anisopliae* (var. *anisopliae*) strain BIPESCO 5/F52, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, rimsulfuron, spinosad, *Streptomyces* K61 (formerly '*S. griseoviridis*'), *Trichoderma asperellum* (formerly '*T. harzianum*') strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly '*T. harzianum*') strain T11, *Trichoderma gamsii* (formerly '*T. viride*') strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram.

(SANTE/12510/2020)

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 Implementing Regulation amending Commission Implementing Regulations (EU) No 820/2011 and (EU) No 540/2011 as regards the conditions of approval of the active substance terbuthylazine (Draft Updated Review Report SANCO/11337/2011).

(SANTE/12148/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3) and 78(2)

Procedure: Examination procedure

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance *Streptomyces* strain K61 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/11958/2020).

(SANTE/11956/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20 (1) in conjunction with Article 13 (2)

Procedure: Examination procedure

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and (EU) 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 78(2)

Procedure: Examination procedure

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance cyazofamid, 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/ (Draft Review Report Rev. 2 SANTE/12060/2020).

(SANTE/12058/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1)

Procedure: Examination procedure

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) withdrawing the approval of the active substance alpha-cypermethrin 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.

(SANTE/12548/2020)

Legal Basis: Regulation (EC) No 1107/2009 - second alternative of Article 21(3)

Procedure: Examination procedure

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of fermented extract from leaves of *Symphytum officinale* L. (comfrey steeping) 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/10930/2020 Rev. 1).

(SANTE/10928/2020 Rev. 0)

Legal Basis: Regulation (EC) No 1107/2009 - Article 13(2) in conjunction with Article 23(5)

Procedure: Examination procedure

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of *Bacillus amyloliquefaciens* AH2 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/11938/2020).

(SANTE/11936/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 13(2) and 22(1)

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance abamectin, 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/ (Draft Review Report Rev. 0 SANTE/12068/2020).

(SANTE/12066/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1)

Procedure: Examination procedure

C.09 Exchange of views 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10730/2018 Rev. 2).

(SANTE/10729/2018 Rev. 2)

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

Procedure: Examination procedure

Pro memoria – TBT/SPS notification (to be) launched.