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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*
24 - 25 March 2021

CIRCABC Link: <https://circabc.europa.eu/w/browse/31cd0ad8-be68-445e-8e9b-aa3b3a1564c4>

AGENDA

Section A **Information and/or discussion**

A.01 Summary Report of previous meetings.

A.02 New dossiers (for information):

New active substances

- Indaziflam
- Pretilachlor

Basic substances applications received

- Magnesium hydroxide
- Chitosan hydrochloride (extension of use)
- Sodium chloride (extension of use)

Amendment of conditions of approval

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

Renewal of approval

- a) Calcium carbonate
- b) *Bacillus thuringiensis ssp. kurstaki* strain PB 54
- c) *Bacillus thuringiensis ssp. kurstaki* strain EG2348

Basic substances

- d) Sunflower oil
- e) Caffeine

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) *Purpureocillium lilacinum* strain PL11

Renewal of approval

- e) *Metarhizium brunneum* strains BIPESCO 5/F 52
- f) Captan
- g) *Purpureocillium lilacinum* strain 251
- h) Flumioxazin
- i) Cypermethrin
- j) *Bacillus amyloliquefaciens* strain QST 713
- k) *Pseudomonas chlororaphis* strain MA342
- l) *Pythium oligrandum* strain M1
- m) *Bacillus thuringiensis subsp. kurstaki* strain SA-11
- n) *Bacillus thuringiensis subsp. kurstaki* strain SA-12
- o) *Bacillus thuringiensis subsp. israelensis* (serotype H-14) strain AM65-52
- p) *Bacillus thuringiensis subsp. aizawai* strain ABTS-1857
- q) *Bacillus thuringiensis subsp. aizawai* strain GC-91

Basic substances

- r) Whey (extension of use) (amended review report to take note)
- s) Calcium hydroxide (extension of use) (amended review report to take note)
- t) *Equisetum arvense* (extension of use)
- u) Chitosan hydrochloride (extension of use and origin)
- v) Sodium hypochlorite
- w) Dimethyl sulphide

Amendment of conditions of approval

A.06 Confirmatory Information:

1. Meptyldinocap (amended review report to take note)
2. *Bacillus pumilus* QST 2808 (amended review report to take note)
3. Metobromuron (amended review report to take note)
4. Mandestrobin (amended review report to take note)
5. Fluxapyroxad (amended review report to take note)
6. Flupyradifurone (amended review report to take note)
7. Oxathiapiprolin (amended review report to take note)
8. Terpenoid blend QRD 460 (amended review report to take note)
9. Tri-allate
10. Isopyrazam
11. Spiroxamine
12. Dithianon
13. Penflufen
14. Gamma cyhalothrin

A.07 Guidance Documents:

1. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
2. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009
3. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02
4. 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
5. 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
6. Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (follow up discussion)
7. Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004 Rev. 9) (for information)

A.08 Defining Specific Protection Goals for environmental risk assessment, in particular:

- Terms of Reference (to take note)

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 on data requirements
- update on uniform principles and Annex II
- Commission Communications in the framework of the implementation of the data requirements

A.14 Safeners and Synergists.

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

1. Pirimicarb

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. Scope of Regulation (EC) No 1107/2009:
 - a) Scope delineation with biocidal products
 - b) Scope Document rev. 60
 - c) New cases
5. Basic substances – general issues
6. Development of resistance in *Aspergillus fumigatus* to azoles used as medicines from use of azole fungicides
7. Use of groundwater monitoring data in EU regulatory pesticide risk assessment
8. Co-formulants
9. Trifluoroacetic acid (TFA)

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** Information on the proposal for a Regulation of the European Parliament and of the Council on statistics on agricultural input and output and repealing Regulations (EC) No 1165/2008, (EC) No 543/2009, (EC) No 1185/2009 and Council Directive 96/16/EC.
- A.20** Report from Working Groups, in particular:
1. Working Group on Biopesticides
 2. Working Group on Seed Treatments
 3. Working Group Post Approval Issues
- A.21** Minor Uses.
- A.22** Court cases.
- A.23** Ombudsman cases.
- A.24** Exchange of information from the Pesticide Residues section of the Committee, in particular:
- possible impact on authorisations
- A.25** OECD and EPPO activities.
- A.26** Scientific publications and information submitted by stakeholders.
- A.27** 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 amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 as regards the conditions of approval of the active substance terbuthylazine (Draft Updated Review Report SANCO/11337/2011, Rev. 3 dated March 2021).

(SANTE/12148/2020 Rev 2.)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3) 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-approval of fermented extract from leaves of *Symphytum officinale* L. (comfrey) 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
- B.03** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the low risk active substance *Streptomyces* strain K61 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 Rev. 0).
(SANTE/11956/2020 Rev. 0)
Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1) 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 on the approval of the new active substances *Pepino Mosaic Virus*, EU strain, mild isolate Abp1 and *Pepino Mosaic Virus*, CH2 strain, mild isolate Abp2 as low risk 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, and amending Commission Implementing Regulation (EU) No 540/2011 (SANTE/10078/2021 Rev. 1).
(SANTE/10076/2021 Rev. 1)
Legal Basis: Regulation (EC) No 1107/2009 - Article 13 (2) in conjunction of Article 22 (1)
Procedure: Examination procedure
- B.05** Exchange of views and possible opinion 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 540/2011 (Draft Review Report Rev. 3 SANTE/12060/2020).
(SANTE/12058/2020 Rev. 1)
Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1)
Procedure: Examination procedure

B.06 Exchange of views and possible opinion 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) and Article 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 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, bentiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cyazofamid, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils / rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea.

(SANTE/10122/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 17

Procedure: Examination procedure

B.08 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 approval periods of the active substances *Adoxophyes orana granulovirus* strain BV-0001 and flutriafol.

(SANTE/10272/2021)

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 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 - Article 20(1) and Article 78(2)

Procedure: Examination procedure

- C.02** 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 - Article 21(3) and Article 78(2)

Procedure: Examination procedure

- C.03** 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 - Article 13(2) and Article 22(1)

Procedure: Examination procedure

- C.04** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of *Salix spp* stem extract (willow stem infusion) 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/12638/2020 – Rev. 0)

(SANTE/12636/2020 Rev. 0)

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

Procedure: Examination procedure

C.05 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.06 Exchange of views 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 Rev. 3).

(SANTE/12602/2020 Rev. 0)

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

Procedure: Examination procedure

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance clopyralid, 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/10206/2021).

(SANTE/10204/2021)

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

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance famoxadone, 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/12986/2019 Rev. 1).

(SANTE/12984/2019 Rev. 0)

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

Procedure: Examination procedure

C.09 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 Rev. 0).

(SANTE/12066/2020 Rev. 0)

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) correcting Implementing Regulation (EU) 2015/408 as regards the deletion of the active substance propoxycarbazone from the list of candidates for substitution.

(SANTE/10304/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 78(2) and 80(7)

Procedure: Examination procedure

C.11 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 notification (to be) launched