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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*
22 - 23 October 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/4420c3f7-f1c1-437f-b947-7020a0d43cbb*

AGENDA

Section A Information and/or discussion

A.01 Summary Report of previous meetings.

A.02 New dossiers

New active substances

a. Fluoxapiprolin (admissible dossier to be noted)
b. *Bacillus amiloliquefaciens* FZB42 (admissible dossier to be noted)
c. *Trichoderma harzianum* T78 (admissible dossier to be noted)

Basic substances applications received (for information)

d. Grape seed extract
e. Lemon essential oil
f. Eggshell powder
g. CO2 hop extract

Amendment of conditions of approval

h. Mecoprop-P

Article 21 Reviews (no news)

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. Captan

2. Abamectin
3. *Purpureocillium lilacinum* 251
4. *Bacillus thuringiensis subsp. kurstaki* strain SA-11
5. *Bacillus thuringiensis subsp. kurstaki* strain SA-12

Basic substances

6. Willow bark and stem extract
7. Sodium hypochlorite
8. Dimethyl sulphide
9. Chitosan hydrochloride
10. Calcium hydroxide

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. Aqueous extract from the germinated seeds of sweet Lupinus albus

Renewal of approval

e. Clopyralid
f. Famoxadone
g. Bifenazate
h. Cyazofamid
i. Flumioxazin
j. *Akanthomyces muscarius* Ve6
k. Clodinafop
l. *Streptomyces* K61

Basic substances

m. Vinegar (extension of use) (amended review report to be noted)
n. Clayed charcoal (amended review report to be noted)
o. Sodium chloride (extension of use)
p. Comfrey steeping
q. *Capsicum annuum annuum, longum group, cayenne* (extract)
r. Whey (extension)
s. *Equisetum avense* (extension)

Amendment of conditions of approval

t. Prosulfuron

A.06 Confirmatory Information:

1. Triazole derived metabolites (TDMs)
2. Gamma-cyhalothrin (amended report to take note)
3. L-ascorbic acid (amended report to take note)
4. Fluometuron (amended report to take note)
5. Terbuthylazine
6. Ipconazole
7. Tri-allate
8. Sulfoxaflor
9. Pyrethrins
10. Benzovindiflupyr
11. Dithianon
12. Geraniol, Eugenol, Thymol, Clove oil, Orange oil
13. Amilsubron
14. Tebufenozide
15. Isofetamid

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 update of Guidance on emergency authorisations according to Article 53 (to take note)
3. Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance (to take note)
4. Draft Guidance document on the risk assessment of metabolites produced by microorganisms (to take note)
5. 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)
6. EFSA Guidance on the risk assessment of PPP a.s. and their transformation products that have stereoisomers
7. Additional data for review of EFSA Exposure Guidance Document– for information
8. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02
9. Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching)

10. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009
11. 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
12. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11)

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

Article 44(4) (to take note)

Article 36(3) (to take note)

Article 53

A.11 Plant Protection Products Application Management System (PPPAMS).

A.12 News from European Food Safety Authority (EFSA), in particular;

1. Update on EFSA practical arrangements on PPP confidentiality in accordance with 7(3) and 16 of Regulation (EC) No 1107/2009.
2. Update on EFSA practical arrangements on Transparency/confidentiality (Art. 38/39 GFL Regulation); Pre-submission phase (Art. 32a/32b/32c GFL Regulation)
3. Update on development on IUCLID as IT tool for notification and on the Hypercare programme for first dossier submissions

A.13 Improving the efficiency of the process of a.s. approval / renewal.

A.14 New Transparency rules: General Food Law amendment and implementation

1. Data format for submissions of applications of approval/amendment of approval

A.15 Farm to Fork Strategy and REFIT evaluation – update and follow up actions, in particular

1. Microorganism Active Substances – update of data requirements
2. low risk plant protection products
3. comparative risk assessment

A.16 Clarifications & questions related to specific active substance

1. Potential resistance to azoles with demethylase inhibitor as mode of action
2. SDHI active substances
3. Residues in ornamental cut flowers
4. Flupyradifurone

A.17 General issues for information / discussion

1. Brexit preparedness
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.59
    b. New cases
    c. In situ generated active substances
6. BTSF – trainings

A.18 Safeners and Synergists.

A.19 News from Sustainable Use Directive (Directive 2009/128/EC).

A.20 News from Health and Food Audits and Analysis (SANTE, Directorate F).

A.21 Report from working groups, in particular:

1. Working group on Biopesticides
2. Working group on Seed Treatments
3. Working group Post Approval Issues
    a. Updated Terms of Reference rev.3 (to take note)

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
- mandate to EFSA on MRLs for abamectin

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 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012.

(SANTE/13040/2019 rev.0)

Legal Basis: Regulation (EC) No 1107/2009 - Article 19, Regulation (EC) No 178/2002 - Article 39f

Procedure: Examination procedure

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EC) No 540/2011 as regards the extension of the approval periods of the active substances 1-decanol, 1,4-Dimethylnaphthalene, 6-Benzyladenine, acequinocyl, *Adoxophyes orana granulovirus*, aluminium sulfate, amisulbrom, *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), azadirachtin, *Bacillus pumilus* QST 2808, benalaxyl-M, bixafen, bupirimate, *Candida oleophila* strain O, chlorantraniliprole, disodium phosphonate, dithianon, dodine, emamectin, flubendiamide, fluometuron, fluxapyroxad, flutriafol, hexythiazox, imazamox, ipconazole, isoxaben, L-ascorbic acid, lime sulphur, orange oil, *Paecilomyces fumosoroseus* strain Fe9901, pencycuron, pendimethalin, penflufen, penthiopyrad, potassium phosphonates, prosulfuron, *Pseudomonas sp*. Strain DSMZ 13134, pyridalyl, pyriofenone, pyroxsulam, quinmerac, S-abscisic acid, sedaxane, sintofen, Sodium silver thiosulphate, spinetoram, spiromesifen, spirotetramat, *Streptomyces lydicus* WYEC 108, tau-Fluvalinate, tebufenozide, tembotrione, thiencarbazone, valifenalate, zinc phosphide.

(SANTE/11726/2020 Rev. 0)

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

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 mancozeb, 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/10326/2020 / Rev. 1).

(SANTE/10324/2020 Rev.1)

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

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance etoxazole 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/2020/10320 Rev 2).

(SANTE/10318/2020)

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

Procedure: Examination procedure

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of carbon dioxide 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.

(SANTE/10790/2020 Rev. 1)

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

Procedure: Examination procedure

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the active substance topramezone, 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/11472/2020 Rev. 0)

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

Procedure: Examination procedure

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance blood meal 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/11236/2020).

(SANTE/11234/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1) and Article 22(1)

Procedure: Examination procedure

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance extracts from *Allium cepa* L. bulbs 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/10842/2020 Rev1).

(SANTE/10840/2020)

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

Procedure: Examination procedure

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance Kieselgur (Diatomaceous earth) 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/10898/2020).

(SANTE/10896/2020)

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

Procedure: Examination procedure

B.10 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 calcium phosphide, denathonium benzoate, haloxyfop-P, imidacloprid, pencycuron and zeta-cypermethrin.

(SANTE/11356/2020)

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

Procedure: Examination procedure

Section C <u>Draft(s) presented for discussion</u>

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 (EU) concerning the non- approval of the active substance pydiflumetofen 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/10300/2020 rev. 1).

(SANTE/10298/2020 rev. 1)

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

Procedure: Examination procedure

C.03 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 - Article 20(1) and Article 78(2)

Procedure: Examination procedure

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11527/2018 Rev 1).

(SANTE/11526/2018 Rev0)

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

Procedure: Examination procedure

C.05 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.06 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of of extracts from *Capsicum annuum* L. var. *annuum*, longum group (cayenne extract) 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/11544/2020).

(SANTE/11542/2020)

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 on the approval of the active substance 24-epibrassinolide as 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/11348/2020).

(SANTE/11346/2020)

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

Procedure: Examination procedure

C.08 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 fenpyrazamine (Draft Review Report SANTE/10690/2012 rev. 3).

(SANTE/10424/2020)

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

Procedure: Examination procedure

Pro memoria – no news - TBT notification process ongoing

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance Garlic extract 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/11050/2020).

(SANTE/11048/2020)

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

Procedure: Examination procedure