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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*
3 - 4 December 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/cf613af9-6de2-400b-b4a6-3b99d2c3d9e2*

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. Didecyldimethylammonium chloride (DDAC)

Amendment of conditions of approval
e. Metalaxyl M

Article 21 Reviews
f. Ipconazole

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. *Bacillus thuringiensis* subsp. *aizawai strain ABTS-1857*
2. *Bacillus thuringiensis* subsp. *aizawai strain GC-91*
3. Phosmet
4. *Pseudomonas chlororaphis* MA342
5. *Pythium oligandrum* strain M1
6. *Beauveria bassiana* 2O3

Basic substances

7. Chitosan hydrochloride (extension of use and origin)
8. Calcium hydroxide (extension of use)
9. ***Pro memoria* – Postponed for next PAFF meeting (January 2021)**: Sodium hypochlorite, Dimethyl sulphide

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

Renewal of approval

d. Bifenazate
e. Cyazofamid
f. Clodinafop
g. *Streptomyces* K61
h. *Metarhizium brunneum* strains BIPESCO 5/F 52
i. Captan
j. Abamectin
k. *Purpureocillium lilacinum* strain 251
l. ***Pro memoria* – Postponed for next PAFF meeting (January 2021)**: Clopyralid, Famoxadone, *Bacillus thuringiensis* subsp. kurstaki strain SA-11, *Bacillus thuringiensis* subsp. kurstaki strain SA-12, Flumioxazin

Basic substances

m. Vinegar (extension of use) (amended review report to be noted)
n. Whey (extension of use)
o. *Equisetum avense* (extension of use)
p. Comfrey steeping
q. Willow bark and stem extract
r. Chitosan hydrochloride (extension of use)
s. ***Pro memoria* – Postponed for next PAFF meeting (January 2021)**: Clayed charcoal

Amendment of conditions of approval

A.06 Confirmatory Information:

1. Triazole derived metabolites (TDMs)
2. Pyrethrins (amended report to take note)
3. Benzovindiflupyr (amended report to take note)
4. Isofetamid (amended report to take note)
5. Gamma-cyhalothrin
6. Tri-allate
7. Sulfoxaflor
8. Dithianon

9. Amilsubron
10. Tebufenozide
11. Bentazone
12. Penflufen
13. Alpha-cypermethrin
14. Mesotrione
15. Thiabendazole
16. ***Pro memoria* – Postponed for next PAFF meeting (January 2021)**: Geraniol, Eugenol, Thymol, Clove oil, Orange oil

A.07 Guidance Documents:

1. Draft update of Guidance on emergency authorisations according to Article 53 (to take note)

2. EFSA Guidance on the risk assessment of PPP a.s. and their transformation products that have stereoisomers (to take note)

3. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11) (to take note)

4. 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)

5. Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching)

6. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

7. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009

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 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 development on IUCLID as IT tool for notification and on the Hypercare programme for first dossier submissions

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

A.13 New Transparency rules: General Food Law amendment and implementation.

A.14 Microorganism Active Substances – update data requirements.

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

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

A.16 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. 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 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 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) 1107/2009 - Article 20(1) in conjuction with Article 22(1)

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) 1107/2009 - Article 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) 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) 1107/2009 - Article 21(3) and 78 (2)

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11348/2020).

(SANTE/11346/2020)

Legal Basis: Regulation (EC) 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 (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 Rev. 2)

(SANTE/11048/2020 Rev. 1)

Legal Basis: Regulation (EC) 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 concerning the non-approval 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 Rev. 1).

(SANTE/11542/2020 Rev. 1)

Legal Basis: Regulation (EC) 1107/2009 - Article 13(2) in conjunction with Article 23(5)

Procedure: Examination procedure

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of the approval of the active substance *Akanthomyces muscarius* strain Ve6 (formerly *Lecanicillium muscarium* strain Ve6) 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 Renewal Report SANTE/11952/2020 Rev. 1).

(SANTE/11950/2020)

Legal Basis: Regulation (EC) 1107/2009 - Article 20(1) and Article 78(2)

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 extension of the approval periods of the active substances substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin.

(SANTE/12080/2020)

Legal Basis: Regulation (EC) 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) adopting a standard data format for the submission of applications for the approval or amendment of the approval of active substances 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 (EU) 2019/1381 - Article 39f (2), Regulation (EC) 1107/2009 - Article 78(2)

Procedure: Examination procedure

C.02 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) 1107/2009 - Article 13(2) and Article 22(1)

Procedure: Examination procedure

C.03 Exchange of views 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).

(SANTE/12090/2020)

Legal Basis: Regulation (EC) 1107/2009 - Article 13(2)(c)

Procedure: Examination procedure

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation amending 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) 1107/2009 - Article 21(3) and Article 78(2)

Procedure: Examination procedure

C.05 Exchange of views 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) 1107/2009 - Article 13(2) in conjunction with Article 23(5)

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 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) 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 (EU) concerning the approval of 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) 1107/2009 - Article 13 (2) in conjunction of Article 22 (1)

Procedure: Examination procedure

***Pro memoria* – Postponed for next PAFF meeting (January 2021)**: Cypermethrin.