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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*
16 - 17 July 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/8e3ac056-604d-4213-8685-2589166edf43*

AGENDA

Section A Information and/or discussion

A.01 Summary Report of previous meetings.

A.02 New dossiers:

- New active substances
  a) Swinglea glutinosa, ext. (admissible dossier to be noted)
  b) Metarhizium brunneum Cb15-III (I) (admissible dossier to be noted)
  c) Trichoderma atroviride 77B (admissible dossier to be noted)
  d) Benzobicyclon (admissible dossier to be noted)
  e) Fluoxapirolin (admissible dossier to be noted)
  f) Tolpyralate (withdrawal)
  g) NAS information sheet

- Basic substances applications received (for information)
  h) Yucca Schidigera

- Amendment of conditions of approval (no news)

- 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:

1. Topramezone
2. Bacillus amyloliquefaciens AH2

Renewal of approval:

3. Akanthomyces muscarius Ve6
4. Streptomyces K61

Basic substances:

5. Whey (extension)
6. Equisetum avense (extension)
7. Willow bark and stem extract

Amendment of conditions of approval:

8. Prosulfuron

A.05 Draft Review/Renewal Reports for discussion:

New active substances:

a) Dimethyl disulphide
b) Chloropicrin
c) 24-Epibrassinolide

Renewal of approval:

d) Clopyralid
e) Famoxadone
f) Cypermethrin
g) Bifenazate
h) Cyazofamid
i) Garlic extract

Basic substances:

j) Sucrose (extension of use) (amended review report to be noted)
k) Fructose (extension of use) (amended review report to be noted)
l) Vinegar (extension of use) (amended review report to be noted)
m) Sodium chloride (extension of use) (amended review report to be noted)
n) Comfrey steeping

o) Clayed charcoal

p) Capsicum annuum annuum, longum group, cayenne (extract)

Amendment of conditions of approval (no news).

A.06 Confirmatory Information:

1. Triazole derived metabolites (TDMs)
   - Bromuconzole (amended review report to be noted)
2. Triazine amine (relevant for metsulfuron-methyl, prosulfuron, thifensulfuron-methyl and iodosulfuron)
   - Metsulfuron-methyl (amended renewal report to be noted)
3. Isoxaben (amended review report to be noted)
4. Lamda-cyhalothrin (amended review report to be noted)
5. Gamma-cyhalothrin
6. Terbuthylazine
7. Ipconazole
8. Sulfoxaflor
9. Isofetamid
10. Pyrethrins
11. L-ascorbic acid
12. Benzovindiflupyr
13. Dithianon
14. Geraniol, Eugenol, Thymol, Clove oil, Orange oil
15. Acibenzolar-methyl
16. Amilsubron
17. Spirotetramat
18. Tebufenozide
19. L-ascorbic acid
20. Fluometuron

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. Brief procedural updates:
   a) Draft update of Guidance on emergency authorisations according to Article 53
   b) Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance

c) Draft Guidance document on the risk assessment of metabolites produced by micro-organisms

3. EFSA Guidance on the risk assessment of PPP a.s. and their transformation products that have stereoisomers
4. Additional data for review of EFSA Exposure Guidance Document– for information
5. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02
6. Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching)

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)

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 Transparency/confidentiality (Art. 38/39 GFL Regulation); Pre-submission phase (Art. 32a/32b/32c GFL Regulation);
2. Update on EFSA practical arrangements on PPP confidentiality in accordance with 7(3) and 16 of Regulation (EC) No 1107/2009.

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. Update on development on IUCLID as IT tool for notification and submission of application
2. Update on 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)

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

A.16 Clarifications & questions related to specific active substance

1. Chlorotalonil monitoring data
2. Potential resistance to azoles with demethylase inhibitor as mode of action
3. SDHI active substances
4. Copper compounds

A.17 General issues for information / discussion:

1. Nitrophenolates salts (Na/K) - update, new active substance vs. technical concentrate
2. Active Substances vs. Co-formulants (e.g. Tall oil crude, clove oil,… as co-formulant)
3. Scope of Regulation (EC) No 1107/2009:
    a) Scope Document rev.58 (previous border cases – confirmation; adaptation due to new legal status of plant biostimulants, overall review of table, publication on website)
    b) Ongoing cases: urea (NO)
    c) In situ generated active substances: update.
4. Better Training for Safer Food Training on the Risk Assessment of Microorganisms

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.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

A.26 OECD and EPPO activities, in particular:

- OECD Pesticides Working group annual meeting, 11-12 June 2020
- OECD Expert Group on Bio Pesticides annual meeting, 9-10 June 2020

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 Regulation (EU) modifying Annex III of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(SANTE/10257/2018 Rev. 2)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 27(2) and 78(2)

Procedure: Regulatory procedure with scrutiny

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiophanate-methyl, 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/11254/2018 Rev. 4)

(SANTE/11253/2018 Rev. 1)

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) concerning the non-renewal of approval of the active substance fenamiphos, 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/11402/2019 Rev. 2)

(SANTE/11400/2019 Rev. 2)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) 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 sodium hydrogen carbonate 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/11724/2018 Rev. 2)

(SANTE/11722/2018 Rev. 3)

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

Procedure: Examination procedure

B.05 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 bromoxynil, 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 Renewal Report SANTE/10156/2020 Rev. 1)

(SANTE/10154/2020 Rev. 1)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(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 ethametsulfuron-methyl, 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/10700/2020 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 concerning the non-renewal of 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/10326/2019 / Rev. 0)

(SANTE/10324/2020 Rev. 0)

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

Procedure: Examination procedure

B.08 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 benalaxyl, 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/10240/2020 rev. 1)

(SANTE/10238/2020 Rev. 1)

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

Procedure: Examination procedure

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance azadirachtin (Addendum to the Review Report SANTE/11848/2019 Rev. 0)

(SANTE/11846/2019 Rev. 0)

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

Procedure: Examination procedure

B.10 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 Article 23 of 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)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 13(2), 23(5) and 79(3)

Procedure: Examination procedure

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substances carbetamide, emamectin, flurochloridone, gamma-cyhalothrin, halosulfuron methyl, ipconazole and tembotrione in the list of candidates for substitution

(SANTE/11404/2019)

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

Procedure: Examination procedure

B.12 Exchange of views and possible opinion of the Committee on a draft Commission 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, blood meal, calcium carbonate, carbon dioxide, extract from tea tree, fat distillation residues, fatty acids C7 to C20, garlic extract, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, kieselgur (diatomaceous earth), Plant oils / rape seed oil, potassium hydrogen carbonate, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, Straight Chain Lepidopteran Pheromones, tebuconazole and urea

(SANTE/10880/2020)

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 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 concerning the placing of plant protection products on the market, 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

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of 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 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

C.03 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, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10300/2020 Rev. 1)

(SANTE/10298/2020 Rev. 1)

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

Procedure: Examination procedure

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the amendment of the conditions of approval of the active substance fenpyrazamine, 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/10690/2012 rev. 3)

(SANTE/10424/2020)

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

Procedure: Examination procedure

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of etoxazole as a candidate for substitution with restrictions in accordance with Article 23 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(SANTE/10318/2020)

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

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) No 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11236/2020)

(SANTE/11234/2020)

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

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of extracts from *Allium cepa* L. bulbs 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/10842/2020 Rev1)

(SANTE/10840/2020)

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

Procedure: Examination procedure

C.09 Exchange of views 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

Procedure: Examination procedure

C.10 Exchange of views 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, and zeta-cypermethrin.

(SANTE/11356/2020)

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

Procedure: Examination procedure