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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*
27 - 28 January 2022

CIRCABC Link: <https://circabc.europa.eu/w/browse/9956349c-78a7-4da9-8b5e-6dd26fb3e8c1>

AGENDA

Section A Information and/or discussion

A.01 Summary Report of previous meetings.

A.02 New dossiers (for information)

New active substances

1. 8-Methyl-2-Decanol Propionate
2. *Pseudomonas putida* strain B2017

Basic substances applications

3. Extension of use of chitosan hydrochloride
4. Extension of use of sodium chloride

Amendment of conditions of approval

A.03 General issues on approval and renewal of approval processes, in particular

- Update of Annex to Regulation (EU) No 540/2011 – deletion of no longer approved active substances

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

New active substances

Renewal of approval

1. Clofentezine
2. Bentiavalicarb
3. Fish oil
4. Sheep fat

Basic substances

5. Calcium propionate
6. Black soap
7. Lemon essential oil
8. Yucca Schidigera extract

Amendment of conditions of approval

A.05 Draft Review/Renewal Reports for discussion

New active substances

- a. Dimethyl disulphide
- b. Asulam-sodium

Renewal of approval

- c. Captan
- d. *Bacillus amyloliquefaciens* strain QST 713
- e. *Pseudomonas chlororaphis* strain MA342
- f. *Bacillus thuringiensis* (horizontal discussion)
- g. *Pythium oligandrum* strain M1
- h. Pelargonic acid
- i. Straight Chain Lepidopteran Pheromones

Basic substances

- j. Hydrogen peroxide silver stabilised
- k. Ozone
- l. Vinegar (amended review report to take note)

Amendment of conditions of approval

- m. Paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3)

A.06 Confirmatory Information:

1. Potassium phosphonates (amended review report to take note)
2. Pyridaril (amended review report to take note)
3. 1-decanol
4. Acibenzolar-methyl

5. Acequinocyl
6. Pendimethalin
7. Propyzamide
8. Penthopyrad

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 Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009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 (update)
5. EFSA guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil
6. EFSA Guidance on aneugenicity assessment

A.08 Notifications under Regulation (EC) No 1107/2009 (for information)

Article 44(4)

Article 36(3)

Article 53

A.09 Microorganism Active Substances, in particular:

- Commission Communications in the framework of the implementation of the data requirements

A.10 Safeners and Synergists.

A.11 Updates, clarifications & questions on specific active substances

1. Sodium hydrogen carbonate
2. Flupyradifurone and acetamiprid

A.12 Article 21

1. Ipconazole

A.13 General issues for information / discussion

1. Illegal plant protection product use (Seminar/Training February 2022)
2. Scope of Regulation (EC) No 1107/2009:
 - a Nitrophenolates
 - b Scope Document – new cases: Procrop/Nuvagrain, Nitrogen-based atmosphere
3. Basic substances – general issues
4. MS updated survey on timing of regulatory procedures
5. Mono- and polymers as co-formulants
6. Trifluoroacetic acid (TFA)
7. MS-proposal PPP TARIC Code
8. PPPAMS – update
9. Incidents with phosphine products
10. Art. 68 reporting
11. Labelling of PPP imported in bulk
12. Development of azole resistant *Aspergillus* from use of azole fungicides – update

A.14 Implementation Art 67 Regulation (EC) No 1107/2009.

A.15 Report from working groups, in particular:

1. Working group on Biopesticides
2. Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009
3. Working group on Seed Treatments (Risk Assessment)
4. Working group Post Approval Issues

A.16 News and updates, in particular from

1. European Food Safety Authority (EFSA)
2. Sustainable Use Directive (Directive 2009/128/EC)
3. Health and Food Audits and Analysis (SANTE, Directorate F)
4. Minor Use Facility (MUCF)
5. OECD, FAO and EPPO activities

A.17 Court cases.

A.18 Ombudsman cases.

A.19 Exchange of information from the Pesticide Residues section of the Committee, in particular possible impact on authorisations.

A.20 Scientific publications and information submitted by stakeholders.

A.21 Date of next meeting(s).

A.22 AoB

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) amending Annex II to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are micro-organisms.

(SANTE/10686/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 78(1)(a)

Procedure: Regulatory procedure with scrutiny

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms.

(SANTE/12040/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Article 78(1)(b)

Procedure: Regulatory procedure with scrutiny

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms.

(SANTE/12042/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Article 78(1)(b)

Procedure: Regulatory procedure with scrutiny

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms.

(SANTE/10716/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 29(6) and Article 78(1) (c)

Procedure: Regulatory procedure with scrutiny

- B.05** Exchange of views and possible opinion 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/10298/2021).
(SANTE/10296/2021)
Legal Basis: Regulation (EC) No 1107/2009 - Article 13 (2)
Procedure: Examination procedure
- B.06** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of the active substance 1,3-dichloropropene, 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/10814/2019).
(SANTE/10812/2019)
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 (EU) concerning the non-approval of the active substance chloropicrin, 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/11096/2020).
(SANTE/11094/2020)
Legal Basis: Regulation (EC) No 1107/2009 - Article 13 (2)
Procedure: Examination procedure
- B.08** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and 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 79(3)
Procedure: Examination procedure
- B.09** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the basic substance chitosan 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/10594/2021).
(SANTE/ 10592/2021)

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

Procedure: Examination procedure

- B.10** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the low-risk active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 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/11266/2021).

(SANTE/ 11264/2021)

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

Procedure: Examination procedure

- B.11** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance carbon dioxide 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/10824/2021).

(SANTE/10822/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20 and Article 22, Regulation (EC) No 844/2012 - Article 14

Procedure: Examination procedure

- B.12** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) withdrawing the approval of the active substance isopyrazam 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.

(SANTE/10308/221)

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

Procedure: Examination procedure

- B.13** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of approval of the active substance *Metarhizium brunneum* strain Ma 43 as a low-risk active 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/10278/2021).

(SANTE/10276/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1) and Article 22 (2)

Procedure: Examination procedure

- B.14** 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 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, *Cydia pomonella* Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, *Metarhizium anisopliae* (var. anisopliae) strain BIPESCO 5/F52, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, rimsulfuron, spinosad, *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/11388/2021)

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

Procedure: Examination procedure

- B.15** 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 flubendiamide, L-ascorbic acid, spinetoram and spirotetramat.

(SANTE/11448/2021)

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) renewing the approval of the active substance bifenthrin 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/11300/2021).

(SANTE/ 11298/2021)

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

Procedure: Examination procedure

C.02 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 penflufen and repealing Implementing Regulation (EU) 2018/185 (Draft Review Report SANTE/10028/2017).

(SANTE/10574/2021)

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

Procedure: Examination procedure

Pro memoria – TBT notification (to be) launched