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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*
14 - 15 July 2022

CIRCABC Link: <https://circabc.europa.eu/w/browse/b4fe15da-969e-48c2-bbc1-b95867359841>

AGENDA

Section A **Information and/or discussion**

- A.01** Summary Report of previous meetings.
- A.02** New applications, in particular basic substances:
1. Chitosan hydrochloride extension of use
- A.03** General issues on approval and renewal of approval processes, in particular:
- financial assistance to Member States in the context of PPP and BPR between 2023-2027
 - renewal of active substances: allocation of Rapporteur Member States for active substances which expire between 31 January 2029 and 1 October 2035
- A.04** Exchange of views on EFSA conclusions/EFSA scientific reports:
- New active substances
 1. *Aspergillus flavus* strain MUCL54911
 2. *Trichoderma atroviride* strain AGR2
 3. *Trichoderma atroviride* strain AT10
 4. Limestone
 5. Isoflucypram
 - Renewal of approval
 6. Oxamyl
 7. Triflurosulfuron-methyl
 8. Aluminium ammonium sulfate
 9. Clofentezine (no news)
 10. Bentiavalicarb (no news)

- Basic substances
- Amendment of conditions of approval

A.05 Draft Review/Renewal Reports for discussion:

- New active substances
 - a) Asulam-sodium (no news)
 - b) napropamid-M
- Renewal of approval
 - c) Captan
 - d) *Pseudomonas chlororaphis* strain MA 342
 - e) *Bacillus thuringiensis aizawai* strain ABTS-1857
 - f) *Bacillus thuringiensis aizawai* strain GC-91
 - g) *Bacillus thuringiensis israelensis* strain AM65-52
 - h) *Bacillus thuringiensis kurstaki* strain ABTS-351
 - i) *Bacillus thuringiensis kurstaki* strain EG2348
 - j) *Bacillus thuringiensis kurstaki* strain PB54
 - k) *Bacillus thuringiensis kurstaki* strain SA-11
 - l) *Bacillus thuringiensis kurstaki* strain SA-12
 - m) Pelargonic acid
 - n) rape seed oil
- Basic substances
 - o) Extension of use of sodium chloride (amended review report to endorse)

A.06 Confirmatory Information:

1. Propyzamide (amended review report to endorse)
2. Pendimethalin
3. Plant oils

A.07 Guidance Documents:

1. EFSA Scientific Committee (2017) Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971 (to endorse)
2. EFSA (2017) Guidance on Uncertainty Analysis in Scientific Assessments. EFSA Journal 2018;16(1):512 (to endorse)
3. EFSA Scientific Committee (2017) Guidance on the assessment of the biological relevance of data in scientific assessments. EFSA Journal 2017;15(8):4970 (to endorse)

4. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
5. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009
6. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02
7. EFSA guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil
8. Scientific guidance on soil phototransformation products in groundwater – consideration, parameterisation and simulation in the exposure assessment of plant protection products

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
3. Acetamiprid

A.12 Article 21:

1. Ipconazole
2. Pirimicarb

A.13 General issues for information / discussion:

1. Scope of Regulation (EC) No 1107/2009:
 - a) Scope Document rev.70
 - b) new cases: in particular Crop-coat, Styx, Herbicides on roofing felts
 - c) Heptamaloxyloglucan
 - d) FAQ document Fertilising Products Regulation - products out of one single substance + plant biostimulant
2. Basic substances – general issues

3. MS updated survey on timing of regulatory procedures
4. PPPAMS – update
5. Incidents with phosphine products
6. Work plan for the development of test methods focusing on wild pollinators
7. Report from workshop on crop protection measures and pollinator protection (7 April 2022)
8. Long term toxicity effects of formulations
9. Residues on cut-flowers
10. Pheromones

A.14 Amendment Regulation (EU) No 547/2011.

A.15 Co-formulants, in particular:

1. draft procedures for listing additional unacceptable co-formulants
2. unacceptable co-formulants (mono/polymers and unacceptable concentrations)

A.16 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
5. Working Group on PPP Formulation Analysis

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA)
2. Sustainable Use Directive (Directive 2009/128/EC) / Proposal Regulation on the sustainable use of plant protection products
3. Health and Food Audits and Analysis (SANTE, Directorate F)
4. Minor Use Facility (MUCF)
5. OECD, FAO and EPPO activities

A.18 Court cases, requests for internal review, Ombudsman cases.

A.19 Exchange of information from the Pesticide Residues section of the Committee, in particular:

- possible impact on authorisations
- Bifenazate: acute health risk identified for peaches

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 Implementing Regulation (EU) concerning the non-approval of calcium propionate 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/11490/2021).

(SANTE/11488/2021)

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

Procedure: Examination procedure

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of black soap E470a 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 PLAN/2022/679 RR).

(PLAN/2022/679 - CIS)

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 (EU) renewing the approval of the low-risk active substance fish oil 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 Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10076/2022).

(SANTE/10074/2022)

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

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance sheep fat 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 Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE10072/2022).

(SANTE/10070/2022)

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

Procedure: Examination procedure

- B.05** 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 penflufen and repealing Implementing Regulation (EU) 2018/185 (Draft Updated Review Report SANTE/10028/2017).

(SANTE/10574/2021)

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

Procedure: Examination procedure

- B.06** 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 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, triallate, triflusulfuron and tritosulfuron.

(PLAN/2022/1367 - CIS)

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) as regards the content and format of the records of plant protection products to be kept by professional users pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

(SANTE/10938/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 67(4)

Procedure: Examination procedure

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of hydrogen peroxide silver-stabilised a 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/11406/2021).

(SANTE/11404/2021)

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

Procedure: Examination procedure

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of *Yucca Schidigera* extract a 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-2022-10236).

(SANTE/10234/2022)

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

Procedure: Examination procedure

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of lemon essential oil a 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/10240/2022)

(SANTE/10238/2022)

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

Procedure: Examination procedure

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Pythium oligandrum* strain M1 as 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 Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10332/2021 Rev. 3).

(SANTE/10330/2021)

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

Procedure: Examination procedure