EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.g.3(2024)9273329

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
4 - 5 December 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/fdd89b7d-a724-404d-8b66-e398d3f91051?p=1*

AGENDA

Section A Information and/or discussion

A.01 Summary Report of previous meetings.

A.02 Applications and withdrawals, in particular basic substances:

1. Ginger extract – withdrawal of an application for an approval as basic substance

A.03 General issues on regulatory processes, in particular:

1. MS experiences and practices (updates and survey)
2. Delegated Regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008 – implications for DAR/RAR prepared in the context of renewal dossiers

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

- New active substances / Amendment of conditions of approval
  1. Bixlozone
- Renewal of approval
  2. Mecoprop-P
  3. Triclopyr
  4. Amidosulfuron
  5. Bensulfuron-methyl
  6. Pyrimethanil
  7. Pirimicarb
  8. Fludioxonil
  9. Penoxsulam

10. Gibberellic acid (GA3)
11. Gibberellins (GA4/7)
12. Paraffin oil

- Basic substances

A.05 Draft Review/Renewal Reports for discussion:

- New active substances / Amendment of conditions of approval
  1. Pydiflumetofen
  2. Clove oil
  3. 1-methylcyclopropene
  4. Elemental iron
- Renewal of approval
  5. Pelargonic acid
  6. Rape seed oil
  7. Sulfur
  8. Aluminium silicate calcinated
  9. Lenacil
  10. Fenoxaprop-P-ethyl
  11. 8-hydroxyquinoline (quinolin-8-ol)
  12. Milbemectin
- Basic substances

A.06 Confirmatory Information:

1. Difenoconazole
2. Thifensulfuron-methyl
3. Submission of confirmatory information related to the Guidance on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water

A.07 Guidance Documents, in particular:

1. Memorandum accompanying the compendium of conditions of use to reduce exposure and risk from plant protection products & national (draft) lists on pesticide application equipment or techniques
2. Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment
3. Technical guidance on the assessment of negligible exposure to an active substance, safener or synergist in a plant protection product under realistic conditions of use
4. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees)

5. FOCUS surface water scenarios – follow up
6. Statement of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on the design and conduct of groundwater monitoring studies supporting groundwater exposure assessments of pesticides

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

1. Article 44(4)
2. Article 36(3)
3. Article 53

A.09 Microorganism and low risk Active Substances.

A.10 Updates, clarifications & questions on specific active substances:

1. Sodium hydrogen carbonate (updated renewal report)
2. Copper compounds (updated renewal report to endorse)
3. Trifluoroacetic acid (TFA)
4. Talc
5. Ozone
6. Dimethenamid-P

A.11 Article 21:

1. Flupyradifurone
2. Tea tree oil
3. Acetamiprid

A.12 General issues for information / discussion:

1. Scope of Regulation (EC) No 1107/2009:
   a) Scope document rev.7
   b) SILTAC, K-PAK, STYX
   c) Cold Atmospheric Plasma
2. Basic substances – general issues
3. PFAS
4. Cut flowers
5. "New" impurities found in plant protection products
6. Update on mandate on the development of protocols for the assessment of emergency authorisations
7. Nano-forms of active substances used in plant protection products

A.13 Co-formulants and assessment of formulations, in particular:

1. Implementation of Regulation (EU) 2023/574
2. On-going actions

A.14 Implementation of Regulation (EU) 2023/564 (electronic record keeping).

A.15 Implementation of Regulation (EU) 2024/1487 (safeners and synergists).

A.16 Report from Working Groups, in particular:

1. Working Group Post Approval Issues (PAI)
2. Working Group on Biopesticides

A.17 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
6. Update on Horizon Europe Research projects / Research and Innovation Day (February 2025)

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:

A.20 Scientific publications and information submitted by stakeholders.

A.21 Rules of Procedure of the PAFF Committee:
- based on the Standard Rules of Procedure[1], and the basic Comitology Regulation (EU) No 182/2011[2]

A.22 Date of next meeting(s).

A.23 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) approving the basic substance *Vitis vinifera* L. seed extract (grape seed extract) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2024/800 RR)

(PLAN/2024/800)

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

Procedure: Examination procedure

---

1 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:206:0011:0013:EN:PDF

2 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0182&qid=1730898633391

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance mepiquat chloride in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2024/1843 RR)

(PLAN/2024/1843)

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

Procedure: Examination procedure

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the active substance *Pythium oligandrum* B301 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2024/2432 RR)

(PLAN/2024/2432)

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

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the low risk active substance *Betabaculovirus phoperculellae* in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report PLAN/2024/2073 RR)

(PLAN/2024/2073)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 13(2) and 22(1)

Procedure: Examination procedure

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the active substance *Bacillus subtilis* strain RTI477 as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2024/2050 RR)

(PLAN/2024/2050)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 13(2) and 22(1)

Procedure: Examination procedure

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the active substance *Bacillus velezensis* strain RTI301 as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2024/2192 RR)

(PLAN/2024/2192)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 13(2) and 22(1)

Procedure: Examination procedure

B.07 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 low-risk active substance aqueous extract from the germinated seeds of sweet *Lupinus albus* (Draft Review Report SANTE/11962/2020 Rev. 2)

(PLAN/2024/2075)

Legal Basis: Regulation (EC) No 1107/2009 - Article 21(3) in conjunction with 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 *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), *Bacillus amyloliquefaciens* subsp. *plantarum* D747, benalaxyl-M, cyprodinil, dichlorprop-P, formetanate, fosetyl, halosulfuron – methyl, imazamox, milbemectin, phenmedipham, pirimicarb, *Pseudomonas* sp. strain DSMZ 13134, pyrimethanil, pyriofenone, pyroxsulam, spinosad, sulphur, *Trichoderma harzianum* Rifai strains T-22 and ITEM 908, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T-25 and TV-1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, triticonazole and ziram

(PLAN/2024/2331)

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 Regulation (EU) amending Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products

(PLAN/2022/1649)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 65(1) and (3), Article 78(1)(m)

Procedure: Regulatory procedure with scrutiny

C.02 Exchange of views of the Committee on a draft Commission Regulation amending Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, 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

(PLAN/2023/1937)

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

Procedure: Regulatory procedure with scrutiny

C.03 Exchange of views of the Committee on a draft Commission Regulation amending Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, 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

(PLAN/2023/1936)

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

Procedure: Regulatory procedure with scrutiny

C.04 Exchange of views of the Committee on a draft Commission Regulation amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

(PLAN/2023/1934)

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

Procedure: Regulatory procedure with scrutiny

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Commission Implementing Regulation (EU) No 540/2011 to update the list of active substances approved or deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council

(PLAN/2024/2004)

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

Procedure: Examination procedure

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2015/408 as regards the deletion of gamma-cyhalothrin, ipconazole and oxamyl from the list of active substances to be considered as candidates for substitution

(PLAN/2024/2005)

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

Procedure: Examination procedure

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance flufenacet, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 and Commission Implementing Regulation (EU) 2015/408 (Draft Renewal Report PLAN/2024/2430 RR)

(PLAN/2024/2430)

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

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance flutolanil 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 PLAN/2024/2353 RR)

(PLAN/2024/2353)

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

Procedure: Examination procedure