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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*
24 - 25 May 2023

CIRCABC Link: <https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/7e7381fd-d3cb-41ea-b5bf-8799966a1b90?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.
- A.03** General issues on regulatory processes, in particular:
1. Financial assistance to Member States in the context of PPP and BPR between 2023-2027
 2. Renewal process (Regulation (EU) 2020/1740)
 3. IUCLID
- A.04** Exchange of views on EFSA conclusions/EFSA scientific reports:
- New active substances / Amendment of conditions of approval
 - Renewal of approval
 1. Metiram
 2. Flutolanil
 - Basic substances
 3. Magnesium hydroxide
 4. Caffeine
- A.05** Draft Review/Renewal Reports for discussion:
- New active substances / Amendment of conditions of approval
 - a) (3E)-dec-3-en-2-one
 - b) Asulam-sodium
 - Renewal of approval

- c) Bentiavalicarb
- d) Clofentezine
- e) Aluminium silicate calcined
- f) Aluminium ammonium sulfate
- g) Sulphur
- h) Ethephon
- i) Metrafenone
- Basic substances
 - j) *Onobrychis viciifolia* var. Perly - sainfoin dried pellets
 - k) Chitosan (amended Review Report to endorse)

A.06 Confirmatory Information:

1. Flutianil (amended Review Report to endorse)
2. Pendimethalin
3. Dithianon

A.07 Guidance Documents:

1. Prioritisation of Guidance Documents (to endorse)
2. Data requirements and list of agreed test methods (Part A - chemicals) – Revised versions of Communications 2013/C 95/01 and 2013/C 95/02 (to endorse)
3. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
4. EFSA Guidance on the use of the benchmark dose approach in risk assessment
5. EFSA Guidance Risk assessment for Birds and Mammals
6. Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water
7. Explanatory notes on data requirements on micro-organisms
8. Superseded Guidance documents SANCO/12116/2012 (on contaminating micro-organisms) and SANCO/10754/2005 (on taxonomic level of micro-organisms)

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, in particular:

1. Implementation of low risk criteria for active substances of natural origin

A.10 Safeners and Synergists.

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

1. Sodium hydrogen carbonate
2. Common metabolites of pyrethroids
3. Common metabolite TFA
4. Common metabolites 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid and 3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxylic acid (formed by bixafen, fluxapyroxad, isopyrazam, sedaxane, benzovindiflupyr and pydiflumetofen)
5. Prosulfocarb

A.12 Article 21:

1. Acibenzolar-methyl
2. Pirimicarb
3. Flupyradifurone

A.13 General issues for information / discussion:

1. Scope of Regulation (EC) No 1107/2009:
 - a) New cases
 - b) Phosphonates – update on status according to Fertilising Products Regulation
 - c) Physical barriers
2. Basic substances – general issues
3. Potential follow-ups on incidents with phosphine products
4. Work plan for the development of test methods focusing on wild pollinators
5. ECI ‘Save Bees and Farmers’
6. ECI ‘Save Cruelty Free Cosmetics’
7. Phytodrone
8. REACH Restriction PFAS

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

A.15 Co-formulants and assessment of formulations, in particular:

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

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, in particular:

- i. Method for problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009
 3. Working Group on comparative assessment
 4. Working Group on Negligible Exposure
- 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:
1. possible impact on authorisations
 2. Toxicological Reference Values (TRV) derived via Regulation (EC) No 396/2005 for fosetyl-Al, potassium phosphonates, and disodium phosphonate (to endorse)
- 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-renewal of the approval of the active substance dimoxystrobin, 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 Review Report PLAN/2022/2636 RR).

(PLAN/2022/2636)

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

Procedure: Examination procedure

- B.02** 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 quartz sand 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/2022/2457 RR)

(PLAN/2022/2457)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1) in conjunction with Article 22(1)

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 extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, calcium carbide, cymoxanil, dodemorph, ethylene, extract from tea tree, fat distillation residues, fatty acids C7-C20, flonicamid (IKI-220), gibberellic acid, gibberellins, halosulfuron – methyl, hydrolysed proteins, iron sulphate, magnesium phosphide, maltodextrin, metamitron, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, pyrethrins, quartz sand, sulcotrione, tebuconazole and urea.

(PLAN/2023/997)

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

Procedure: Examination procedure

- B.04** 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 period of the active substances *Bacillus pumilus* QST 2808 and penflufen.

(PLAN/2023/998)

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 captan 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/12270/2020).

(SANTE/12268/2020)

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) concerning the non-approval of *Yucca Schidigera* 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 (Draft review report SANTE/10236/2022).

(SANTE/10234/2022)

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) renewing the approval of the active substance rape seed oil 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/2022/976 RR).

(PLAN/2022/976)

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

Procedure: Examination procedure

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance pelargonic acid 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/11124/2021).

(SANTE/11122/2021)

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

Procedure: Examination procedure

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance *Cydia pomonella* granulovirus (CpGV) 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 PLAN/2023/240 RR).

(PLAN/2023/240)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1) in conjunction with Article 22(1)

Procedure: Examination procedure

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance triflurosulfuron-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 (Draft review report PLAN/2022/2157 RR).

(PLAN/2022/2157)

Legal Basis: Regulation (EC) No 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 non-renewal of the approval of the active substance S-metolachlor 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 PLAN/2023/641/RR).

(PLAN/2023/641)

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

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the approval of sodium hypochlorite 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/2021/10408).

(SANTE/2021/10406)

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

Procedure: Examination procedure

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the low-risk active substance fat distillation residues in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft review report PLAN/2023/637).

(PLAN/2023/637)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1) in conjunction with Article 22(1)

Procedure: Examination procedure

C.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of hydrogen peroxide silver-stabilised 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.11 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of etoxazole which approval expires 31 January 2028.

(PLAN/2023/1102)

Legal Basis: Regulation (EC) No 1107/2009 - Article 19

Procedure: Examination procedure