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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*
11 - 12 December 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/9f03a75c-eaa8-4932-955c-b5b85324a43d?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. Potassium stearate
2. *Schinopsis lorentzii*, ext. bisulfited

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

1. Renewal process (Regulation (EU) 2020/1740)
   – approach on access to old studies (to endorse)
2. Alignment dossiers PPP / CLH (Regulations (EU) No 844/2012 and (EU) 2020/1740)
3. Availability of PPP products/ Information on delays / ZAPID workshop debrief
4. Possible procedures for applications to change status from normal approval to low risk

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

- New active substances / Amendment of conditions of approval
  1. Metalaxyl-M
- Renewal of approval
  2. Mecoprop-P
- Basic substances
  3. *Allium fistulosum*
  4. Eggshell powder
  5. Grape seed extract

A.05 Draft Review/Renewal Reports for discussion:

- Renewal of approval
  1. Metribuzin
  2. Metconazole
  3. Milbemectin
- Basic substances
  4. Caffeine
  5. Ozone / ozonated water

A.06 Guidance Documents, in particular:

1. Method for problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009 (to endorse)
2. Guidance document on semiochemical active substances and plant protection products (SANTE/12815/2014) – draft amendment
3. 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
4. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees)
5. EFSA Guidance Risk assessment for Birds and Mammals

A.07 Notifications under Regulation (EC) No 1107/2009 (for information):

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

A.08 Microorganism and low risk Active Substances, in particular:

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

A.09 Updates, clarifications & questions on specific active substances:

1. Common metabolites of pyrethroids / lambda-cyhalothrin (revised review reports to endorse)
2. Dimoxystrobin (revised review report to endorse)
3. beta-cyfluthrin (revised review report to endorse)
4. Copper compounds (updated toxicological reference values to endorse)
5. Sodium hydrogen carbonate
6. Prosulfocarb
7. Cyazofamid
8. *Trichoderma atroviride* strain SC1
9. TFA
10. Phenmedipham

A.10 General issues for information / discussion:

1. Scope of Regulation (EC) No 1107/2009:
   a) New cases
   b) Physical barriers (short update)
2. CHED-N - introduction of notification system for imports of PPPs

A.11 Amendments to Regulation (EU) No 547/2011.

A.12 Amendments to Regulations (EU) No 546/2011, (EU) No 283/2013 and (EU) No 284/2013.

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

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

A.14 Report from Working Groups, in particular:

1. Working Group Post Approval Issues

A.15 News and updates, in particular from:

1. European Food Safety Authority (EFSA)

A.16 Court cases, requests for internal review, Ombudsman cases.

A.17 Exchange of information from the Pesticide Residues section of the Committee, in particular:

1. possible impact on authorisations

A.18 Scientific publications and information submitted by stakeholders.

A.19 Date of next meeting(s).

A.20 AoB.

Section B <u>Draft(s) presented for an opinion</u>

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of the active substance asulam-sodium in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (Draft review report SANTE/10746/2018)

(SANTE/10745/2018)

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

Procedure: Examination procedure

B.02 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 benzovindiflupyr, bromuconazole, buprofezin, cyflufenamid, fluazinam, fluopyram, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metsulfuron-methyl, phosphane and pyraclostrobin

(PLAN/2023/2323)

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 Regulation (EU) defining data requirements for the approval of safeners and synergists and establishing a work programme for the gradual review of safeners and synergists on the market in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council

(PLAN/2023/2195)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 25(3) and 26

Procedure: Regulatory procedure with scrutiny

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance hydrolysed proteins as a low-risk active 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 Renewal Report PLAN/2023/1723 RR)

(PLAN/2023/1723)

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

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 urea as a low-risk active 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 Renewal Report PLAN/2023/2197 RR)

(PLAN/2023/2197)

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

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 metrafenone 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/2023/2534 RR)

(PLAN/2023/2534)

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

Procedure: Examination procedure

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance dimethomorph, 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 Renewal Report PLAN/2023/2347 RR)

(PLAN/2023/2347)

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

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 mepanipyrim, 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 Renewal Report SANTE/11620/2018)

(SANTE/11618/2018)

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 (EU) concerning the withdrawal of the approval of the active substance acibenzolar-S-methyl, 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 Renewal Report PLAN/2023/2650 RR)

(PLAN/2023/2650)

Legal Basis: Regulation (EC) No 1107/2009 - Article 21

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance trinexapac, as trinexapac-ethyl, 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 SANTE/11247/2018)

(SANTE/11246/2018)

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

Procedure: Examination procedure