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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*
22 - 23 March 2023

CIRCABC Link:
https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/6943ae5e-7c0e-4659-b9ae-486a92065ded?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. *Quassia amara*
2. *Plantago major* extract
3. sodium chloride – extension of use
4. chitosan hydrochloride – extension of use

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
  1. (3E)-dec-3-en-2-one
  2. *Aspergillus flavus* MUCL 54911
- Renewal of approval
  3. Clofentezine
  4. Benthiavalicarb
  5. Ethephon
- Basic substances
  6. *Onobrychis viciifolia* var. Perly - sainfoin dried pellets

A.05 Draft Review/Renewal Reports for discussion:

- New active substances / Amendment of conditions of approval
  a) Asulam-sodium
- Renewal of approval
  b) Aluminium silicate calcined
  c) Triflusulfuron-methyl
  d) Aluminium ammonium sulfate
  e) *Cydia pomonella* granulovirus (CpGV)
  f) Fat distilation residues
  g) Sulphur
  h) S-metolachlor
- Basic substances
  i) Sodium hypochlorite
  j) Chitosan hydrochloride (amended review report to endorse)

A.06 Confirmatory Information:

1. Pendimethalin
2. Flutianil
3. Dithianon

A.07 Guidance Documents:

1. Prioritisation of Guidance Documents (to endorse)
2. Scientific guidance on soil phototransformation products in groundwater – consideration, parameterisation and simulation in the exposure assessment of plant protection products (to endorse)
3. Data requirements and list of agreed test methods (Part B - microorganisms) (to endorse)
4. Data requirements and list of agreed test methods (Part A - chemicals) - Update of the Communications 2013/C 95/01 and 2013/C 95/02
5. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
6. EFSA guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil
7. EFSA Guidance on the use of the benchmark dose approach in risk assessment
8. EFSA Guidance Risk assessment for Birds and Mammals
9. Guidance on emergency authroisations according to Articile 53 of Regulation (EC) No 1107/2009 – under review

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. Clethodim
3. Common metabolites of pyrethroids
4. Common metabolite TFA
5. Copper compounds

A.12 Article 21:

1. Pirimicarb
2. Flupyradifurone

A.13 General issues for information / discussion:

1. Scope of Regulation (EC) No 1107/2009:
    a) New cases
    b) FAQ document Fertilising Products Regulation - products out of one single substance + plant biostimulant
    c) Phosphonates – update on status according to Fertilising Products Regulation
    d) 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. Residues on cut-flowers
7. TARIC codes

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

A.15 Coformulants and assessment of formulations.

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 Post Approval Issues
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. Setting of Toxicological Reference Values derived via an MRL application or MRL review process (outside an assessment for approval or renewal of an active substance) – <u>to endorse</u>

A.20 Scientific publications and information submitted by stakeholders.

A.21 Date of next meeting(s).

A.22 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) renewing the approval of the active substance *Bacillus amyloliquefaciens* strain QST713 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 SANTE/10294/2021 - Rev. 1).

(SANTE/10292/2021)

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

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 active substance *Bacillus thuringiensis aizawai* strain ABTS-1857 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/10282/2021 Rev. 1)

(SANTE/10280/2021)

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) renewing the approval of the active substance *Bacillus thuringiensis aizawai* strain GC-91 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/10286/2021 Rev. 1).

(SANTE/10284/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(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 active substance *Bacillus thuringiensis israelensis* strain AM65-52 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/10290/2021 Rev. 1).

(SANTE/10288/2021)

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

Procedure: Examination procedure

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain ABTS-351 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/2022/1636 RR Rev. 2).

(PLAN/2022/1636)

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

Procedure: Examination procedure

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain EG2348 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/2021/11143 RR Rev. 3).

(PLAN/2021/11143)

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

Procedure: Examination procedure

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain PB54 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/2021/11145 RR Rev. 2).

(PLAN/2021/11145)

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

Procedure: Examination procedure

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain SA-11 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/2021/10728 RR Rev. 3).

(PLAN/2021/10728)

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

Procedure: Examination procedure

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance *Bacillus thuringiensis kurstaki* strain SA-12 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/2021/10753 RR Rev. 3).

(PLAN/2021/10753)

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

Procedure: Examination procedure

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation withdrawing the approval of the active substance ipconazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Commission Implementing Regulation (EU) No 571/2014.

(PLAN/2022/2562)

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

Procedure: Examination procedure

B.11 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 oxamyl, 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/2022/1836 RR).

(PLAN/2022/1836)

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

Procedure: Examination procedure

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Commission Implementing Regulation (EU) 2021/1448 renewing the approval of the low-risk active substance calcium carbonate in order to include limestone as additional specification 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/2022/2635 RR).

(PLAN/2022/2635)

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

Procedure: Examination procedure

B.13 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 aclonifen, ametoctradin, beflubutamid, benthiavalicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, Helicoverpa armigera nucleopolyhedrovirus, hymexazol, indolylbutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-Metolachlor, Spodoptera littoralis nucleopolyhedrovirus, Trichoderma asperellum strain T34 and Trichoderma atroviride strain I-1237.

(PLAN/2023/474)

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

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 approval period of the active substance pyridalyl.

(PLAN/2023/473)

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-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 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/2022/2636 RR Rev. 1).

(PLAN/2022/2636)

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

Procedure: Examination procedure

C.03 Exchange of views 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 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/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

C.04 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/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.05 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 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/2022/976 RR).

(PLAN/2022/976)

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

Procedure: Examination procedure

C.06 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 Rev. 2).

(SANTE/11122/2021)

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

Procedure: Examination procedure