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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*
8 - 9 December 2022

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/7c4a51b0-4792-4342-80e8-4d04318e0329?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*

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) No 2020/1740)
3. IUCLID
4. PPPAMS

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

- New active substances
  1. *Aspergillus flavus* strain MUCL54911
- Renewal of approval
  2. Clofentezine
  3. Benthiavalicarb
  4. Aluminium silicate calcined
  5. *Cydia pomonella* granulovirus (CpGV)
- Basic substances
- Amendment of conditions of approval

A.05 Draft Review/Renewal Reports for discussion:

- New active substances
  a) Asulam-sodium
  b) Isoflucypram
  c) Limestone
- Renewal of approval
  d) *Bacillus thuringiensis aizawai* strain ABTS-1857
  e) *Bacillus thuringiensis aizawai* strain GC-91
  f) *Bacillus thuringiensis israelensis* strain AM65-52
  g) *Bacillus thuringiensis kurstaki* strain ABTS-351
  h) *Bacillus thuringiensis kurstaki* strain EG2348
  i) *Bacillus thuringiensis kurstaki* strain PB54
  j) *Bacillus thuringiensis kurstaki* strain SA-11
  k) *Bacillus thuringiensis kurstaki* strain SA-12
  l) Pelargonic acid
  m) Oxamyl
  n) *Bacillus amyloliquefaciens* QST 713
  o) Triflusulfuron-methyl
  p) Quartz sand
  q) Dimoxystrobin
  r) Aluminium ammonium sulfate
- Basic substances
  s) Sodium hypochlorite
  t) Chitosan hydrochloride

A.06 Confirmatory Information:

1. Pendimethalin
2. Plant oils: Eugenol, Geraniol, Thymol, Clove oil and Orange oil
3. Thiabendazole
4. Flutianil
5. 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 A - chemicals) - Update of the Communications 2013/C 95/01 and 2013/C 95/02
4. Data requirements and list of agreed test methods (Part B - microorganisms)
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

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 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

A.12 Article 21:

1. Acibenzolar-methyl

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. Review of the Pollinator Initiative
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
3. Working Group Post Approval Issues

A.17 News and updates, in particular from:

1. European Food Safety Authority (EFSA), including MUST-B / APISRAM development
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
6. Update on Water Framework Directive, Groundwater Directive and Environmental Quality Standards Directive

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

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) as regards the content and format of the records of plant protection products 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

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

(SANTE/10226/2022)

Legal Basis: Regulation (EC) No 1107/2009 - Article 27(5)

Procedure: Examination procedure

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance benfluralin, 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10236/2020).

(SANTE/10234/2020)

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) approving the low-risk active substance *Trichoderma atroviride* strain AGR2 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2022/1837 RR).

(PLAN/2022/1837)

Legal Basis: Regulation (EC) No 1107/2009 - Article 13(1)

Procedure: Examination procedure

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) approving the low-risk active substance *Trichoderma atroviride* strain AT10 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report PLAN/2022/1616 RR).

(PLAN/2022/1616)

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

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 *Pseudomonas chlororaphis* strain MA 342 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/10884/2017).

(SANTE/10882/2017)

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

Procedure: Examination procedure

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of lemon essential oil (*Citrus limon* essential oil) 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

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 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) in conjunction with Article 22(1)

Procedure: Examination procedure

B.09 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 benfluralin, benzovindiflupyr, buprofezin, cyflufenamid, fluazinam, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metiram, metsulfuron-methyl, phosphane and pyraclostrobin.

(PLAN/2022/2431)

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

Procedure: Examination procedure

B.10 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 period of the active substance dimoxystrobin.

(PLAN/2022/2499)

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

Procedure: Examination procedure

B.11 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 period of the active substance oxamyl.

(PLAN/2022/2500)

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 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.02 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.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance abamectin 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/12068/2020).

(SANTE/12066/2020)

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) concerning the non-approval of silver-stabilised hydrogen peroxide 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.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of Napropamid-M 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 (Draft review report SANTE/10808/2019).

(SANTE/10806/2019)

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

Procedure: Examination procedure

C.06 Exchange of views 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 concerning the placing of plant protection products on the market, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Implementing Regulation (EU) No 571/2014

(PLAN/2022/2562 CIS)

Legal Basis: Regulation (EC) No 1107/2009 - Article 21(3)

Procedure: Examination procedure

C.07 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 the active substances.

(PLAN/2022/2580 CIS)

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

Procedure: Examination procedure