Standing Committee on Plants, Animals, Food and Feed
Section Phytopharmaceuticals - Legislation
5 - 6 December 2019

CIRCABC Link: https://circabc.europa.eu/w/browse/464af872-3138-4681-b28a-2929453eaa28

AGENDA

Section A  Information and/or discussion

A.01 Summary Report of previous meetings.

A.02 New active substances:
   1. New admissible dossiers to be noted:
   2. Exchange of views on EFSA conclusions:
      a) Napropamid-M
      b) Pydiflumetofen
      c) 1,3-Dichloropropene
      d) Ethametsulfuron-methyl
   3. Draft Review/Renewal Reports for discussion:
      Pro memoriam / on hold until next PAFF meeting (January 2020): Lavandulyl senecionate

A.03 Renewal of approval:
   1. General topics:
      a) Access to original dossiers
      b) 6th renewal programme
   2. Exchange of views on EFSA conclusions/EFSA scientific reports:
      a) Phlebiopsis gigantea VRA 1835, VRA 1984 and FOC PG 410.3
      Pro memoriam / on hold until next PAFF meeting (January 2020): Mancozeb
   3. Draft Review/Renewal Reports for discussion:
      a) Flumioxazin
b) Clopyralid
c) Cyazofamid
d) Famoxadone
e) Etoxazole
f) Indoxacarb

Pro memoriam / on hold until next PAFF meeting (January 2020): Pyriproxyfen, Bromoxynil, Fenamiphos, Cypermethrin, Pseudomonas chlororaphis MA 342, Bifenthrate

A.04 Confirmatory Information:
   1. Spiroxamine
   2. Triazole derived metabolites (TDMs) (general appendix which will be added to each concerned review report to take note)
   3. Sulfoxaflor
   4. Isofetamid
   5. Terbuthylazine

Pro memoriam / on hold until next PAFF meeting (January 2020): Fenpyrazamine, Benzovindiflupyr, Ipconazole, Gamma-cyhalothrin, Geraniol, Eugenol, Thymol, Clove oil.

A.05 Article 21 Reviews.

A.06 Amendment of the conditions of approval:
   1. New admissible dossiers to be noted:
   2. Exchange of view on EFSA conclusions:
   3. Draft Review/Renewal Reports for discussion:
      a) Azadirachtin

A.07 Basic substances:
   1. New dossiers received (for information)
      a) Chitosan hydrochloride (extension)
      b) Ozone
   2. Exchange of views on EFSA Technical Reports
   3. Draft Review Reports for discussion:
      a) Sucrose
      b) Fructose
      c) Lecithins (extension)

Pro memoriam / on hold until next PAFF meeting (January 2020): Saponaria.
Guidance Documents:
1. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
2. Working Document on emergency authorisations according to Article 53 (discussion)
3. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02
4. Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance
8. Guidance document on Data Matching for applications for authorisation of PPPs according to Article 33/43

Defining Specific Protection Goals for environmental risk assessment.

Commission Regulation (EU) No 547/2011 and risk mitigation:
1. Feedback about notification of additional phrases by MS (no update)
2. Risk Mitigation / list of risk reduction measures: outline of Workshop on 17 January 2020

Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (no news).

Notifications under Article 36(3) of Regulation (EC) No 1107/2009 (no news).


Plant Protection Products Application Management System (PPPAMS).

News from European Food Safety Authority (EFSA).

Improving the efficiency of the process of a.s. approval.

News from Health and Food Audits and Analysis (SANTE, Directorate F).


Minor Uses:
1. Draft guidance document on minor uses according to Regulation (EC) No 1107/2009
A.20 Court cases.
A.21 Ombudsman cases.
A.23 Clarifications & questions related to specific active substance:
   1. Acibenzolar-S-methyl – updated review report (to take note)
   2. Chlorotalonil monitoring data
   3. Candidates for substitution
   4. Carvone: correcting act to the Implementing Regulation
   5. Maleic hydrazide labelling provisions
A.24 Interpretation issues:
   1. 2,4 D / 2,4 D EHE
   2. Nitrophenolates salts (Na/K ; CHAP)
   3. Scope of Regulation (EC) No 1107/2009:
      a) Scope Document rev.58 (previous border cases – confirmation)
      b) Ongoing cases:
         b.1. Irradiated pollen
         b.2. Ozone as soil fumigant and seed disinfection
         b.3. Water conditioner
         b.4. Eruca (Bacillus megaterium and B. mycoides)
         b.5. Wildfire fighting product
      c) Follow-up in situ generation (update)
   4. Data protection – access to old studies during the renewal process
   5. Article 32(1) v. article 44(3(a) and article 46 of Regulation 1107/2009
A.25 Classification under Regulation (EC) No 1272/2008:
   1. Status of notifications for harmonised classification (summary table for info)
A.27 Reports from Working Groups, in particular:
   1. Working Group on Biopesticides
   2. Working Group on Seed Treatments (no news)
   3. Post Approval Issues (no news)
A.28 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

A.29 OECD and EPPO activities, in particular:
   1. Expert Group on Drones

A.30 Scientific publications and information submitted by stakeholders:
   – FAO/WHO on report Foodborne Antimicrobial Resistance

A.31 Date of next meeting(s).

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) amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances.
   (SANTE/10722/2017)
   **Legal Basis:** Regulation (EC) 1107/2009 - Articles 19 and 78(2)
   **Procedure:** Examination procedure

   (SANTE/11936/2019 Rev. 2)
   **Legal Basis:** Regulation (EC) 1107/2009 - Articles 20(1) and 78(2)
   **Procedure:** Examination procedure

   (SANTE/11940/2019 Rev. 2)
   **Legal Basis:** Regulation (EC) 1107/2009 - Articles 20(1) and 78(2)
   **Procedure:** Examination procedure

(SANTE/11110/2019 Rev. 1)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

Section C Draft(s) presented for discussion


(SANTE/10257/2018)

Legal Basis: Regulation (EC) 1107/2009 - Articles 27(2) and 58(2)

Procedure: Regulatory procedure with scrutiny


(SANTE/11054/2019 Rev. 2)

Legal Basis: Regulation (EC) 1107/2009 - Article 23

Procedure: Examination procedure


(SANTE/12794/2019 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 23

Procedure: Examination procedure

(SANTE/11780/2019 Rev. 0)

Legal Basis: Regulation (EC) 1107/2009 - Article 23

Procedure: Examination procedure


(SANTE/11213/2016 Rev. 1)

Legal Basis: Regulation (EC) 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure