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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
12 DECEMBER 2017 - 13 DECEMBER 2017

CIRCABC Link: *https://circabc.europa.eu/w/browse/dc726a32-02ef-4a22-8050-d228c60601a3*

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:
   a. Limestone
   b. (3E)-3-decen-2-one
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions
3. Commission Draft Review Report and Regulation concerning the (non-) approval of:
   a. Flutianil
   b. *Reynoutria sachalinensis* extract

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play
2. Exchange of view on EFSA conclusions:
   a. Etoxazole
   b. Methoxyfenozide
3. Draft Review/Renewal Reports and Regulations for discussion:
   a. Propineb
   b. Pseudomonas chlororaphis strain MA342
   c. Oxasulfuron
   d. Thiram
   e. Diquat
   f. Mecoprop-P
   g. Carfentrazone-ethyl
   h. Propyzamide
   i. Silthiofam

j. Pymetrozine (short update only)
k. Isoxaflutole (short update only)
l. Clonostachys rosea J1446
m. Forchlorfenuron
n. Mepanipyrim
o. Tribenuron
p. Pethoxamide
q. Flurtamone
r. Propiconazole

A.04 Confirmatory Data:

1. Bifenthrin
2. Cyflumetofen (follow-up discussion only)
3. Malathion
4. Dithianon
5. Tri-allate
6. Terbuthylazine
7. Iprovalicarb (to be noted)
8. Metazachlor
9. Pyretrins
10. Picloram (to be noted)
11. Chlorsulfuron
12. Triazine amine (common metabolite)
13. Pseudomonas sp. Strain DSMZ 13134 (draft review report)
14. Pyroxsulam (draft review report)
15. Chlorantraniliprole (draft review report)
16. Halauxifen-methyl (draft review report)
17. Thiencarbazone-methyl (draft review report)
18. Kieselgur (draft review report)
19. Mandipropamid (draft review report)
20. Bupimirate (draft review report)
21. Azimsulfuron (draft review report)
22. Tau-fluvalinate (draft review report)
23. Disodium phosponate (draft review report)
24. AOB

A.05 Article 21 Reviews (no news).

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 and Regulations for discussion:
   a. Fenazaquin

A.07 Basic substances:

1. Pilot projects: state of play
2. New dossiers received (only for information)
   a. Extract from rhododendron
3. Exchange of views on EFSA Technical Reports
4. Draft Review Reports for discussion:
   a. *Saponaria officinalis* root extract

A.08 Exchange of views on Guidance Documents:

1. Guidance document on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report (SANCO/6895/2009 Rev. 2, for discussion)
2. Proposed Mandate to revised the Guidance Document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 (SANCO/12638/2011, rev. 2)
3. Guidance document on the Evaluation Efficiency of Residue Analytical Methods (SANTE/10632/2017, for information)
4. Guidance document on the establishment of the residue definition for dietary risk assessment (SANTE/11644/2017, possible follow-up discussion)
5. Commission Communications on the data requirements for active substance and plant protection product dossiers (for discussion)

A.09 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted).

A.10 Notifications under Article 36(3) of Regulation (EC) No 1107/2009.

1. New notifications (to be noted)
2. Differences in application of article 36(3) amongst Member States

A.11 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009 (to be noted).

A.12 News from European Food Safety Authority (EFSA).

A.13 News from the Directorate General for Health and Food Safety (SANTE) Directorate F, Health and Food Audits and Analysis (former FVO).

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)
2. Post Approvals Issues group (PAI)
   a. Terms of Reference of the Working Group on Post Approval Issues from the Standing Committee on Animals, Plants, Food and Feed: section Pesticide Legislation (SANTE/11102/2017 to be noted)
   b. Update on the November meeting
3. Sustainable plant protection experts group Dutch proposal (no meeting)
4. Working group on Biopesticides
5. Working group on Seed Treatments (short update)
6. Working Group on Co-formulants
7. Working Group on Low-risk criteria

A.15 OECD (no news).

A.16 Court cases:

1. Case C325/16 – preliminary ruling from the Spanish Tribunal Supremo – re-registration deadlines
2. Case T-719/417 – annulment of Commission Implementing Regulation (EU) No 2017/11496 concerning the non-renewal of the approval of the active substance flupyrsulfuron-methyl

A.17[3.] Endocrine Disruptors – state of play.

A.18 Minor Uses.

A.19 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009:
   a. Plant strengtheners (request by Lithuania)

A.20 Classifications under Regulation (EC) No 1272/2008 / REACH:

1. Status of harmonised classifications
2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States – Amending Implementation Regulation 844/2012 in view of the harmonised classification of active substances
3. Follow-up of the merging of CLH and xAR templates (discussion only)

A.21 Glyphosate – State of the Dossier.

A.22 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

A.23 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

A.24 Mandate for a Working Group (WG) to set up a procedure to assess new variants of approved active substances (to be noted).

A.25 Initial information concerning Brexit.

A.26 EU Pollinators Initiative (DG ENV).

A.27 Possible update of the "guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) N° 1107/2009" (proposal DE/FR).

A.28 Scientific publications and information submitted by stakeholders.

A.29 Date of next meeting.

A.30 Confirmatory data pending and renewal ongoing – Clofentezine and Difeconazole (RMS ES).

A.31 Data requirement on peer reviewed literature (Art 8.5).

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on draft Commission Implementing Regulation renewing the approval of the active substance acetamiprid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and 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/10502/2017 Rev 3).

(SANTE/10501/2017 Rev3)

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 renewing the approval of the active substance laminarin, as a low risk 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, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft review Report SANTE/11558/2017/Rev.2).

(SANTE/11557/2017 Rev2)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 13(2) and 22(1)

Procedure: Examination procedure

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances.

(SANTE/11749/2017 Rev1)

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

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing approval of active substance bentazone 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/12012/2015 Rev 6).

(SANTE/12011/2015 Rev5)

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 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance penflufen (Draft Review Report: SANTE/10028/2017 Rev. 1.4).

(SANTE/10029/2017 Rev1)

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

Procedure: Examination procedure

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of honey from rhododendron 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 Doc. SANTE/10450/2017– rev. 0).

(SANTE/10449/2017)

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 approving the basic substance Talc E553B 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/11639/2017).

(SANTE/11638/2017)

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 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid (Draft Addendum to the Review Report SANCO/10590/2013 Rev. 5).

(SANTE/12105/2016 Rev5)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3), 49(2) and 78(2)

Procedure: Examination procedure

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (Draft Addendum to the Review Report SANCO/10589/2013 Rev. 5).

(SANTE/12106/2016 Rev5)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3), 49(2) and 78(2)

Procedure: Examination procedure

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (Draft Addendum to the Review Report SANCO/10591/2013 rev 5).

(SANTE/10834/2016 Rev8)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3), 49(2) and 78(2)

Procedure: Examination procedure

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011as regards the extension of the approval periods of the active substances chlorpyrifos, chlorpyrifos-methyl, clothianidin, copper compounds, dimoxystrobin, mancozeb, mecoprop-p, metiram, oxamyl, pethoxamid, propiconazole, propineb, propyzamide, pyraclostrobin and zoxamide.

(SANTE/11622/2017 Rev1)

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

Procedure: Examination procedure

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances FEN 560 (also called fenugreek or fenugreek seed powder) and sulfuryl fluoride.

(SANTE/11623/2017 Rev1)

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

Procedure: Examination procedure

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Regulation correcting Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

(SANTE/11240/2017 Rev1)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 29(6) and 84(d)

Procedure: Regulatory procedure with scrutiny

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.

(SANTE/11992/2017)

Legal Basis: Regulation 1107/2009 - in particular Article 78(1)(a) and the second paragraph of point 3.6.5 of Annex II

Procedure: Regulatory procedure with scrutiny