EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Plant Protection Products - Legislation*
06 DECEMBER 2016 - 07 DECEMBER 2016

CIRCABC Link: *https://circabc.europa.eu/w/browse/a86e6f46-217c-49d0-9dfb-feeedba73a46*

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:

No new dossiers

2. Exchange of view on new European Food Safety Authority (EFSA) conclusions (no specific conclusion identified)

3. Commission Draft Review Report and Regulation concerning the (non-) approval of:

i. *Beta-cypermethrin*
ii. *Pseudozyma flocculosa* ATTC 64874
iii. *Bacillus amyloliquefaciens* FZB24
iv. Cyclaniliprole
v. *Beauveria bassiana* strain 147
vi. *Beauveria bassiana* NPP111B005
vii. Orthosulfamuron
viii. Flutianil

A.03 Renewal of approval:

1. AIR III (Annex I Renewal Projects): State of play
2. AIR IV: State of play
3. Exchange of view on the following EFSA conclusions:

i. 2,4-DB
ii. *Silthiofam*
iii. *Propyzamide*
iv. *Carfentrazone-ethyl*

4. Draft Review Reports for discussion:

i. Flupyrsulfuron-methyl
ii. Pymetrozine
iii. Fenamidone
iv. Isoxaflutole
v. Imazamox
vi. Maleic hydrazide
vii. Picoxystrobin
viii. Flazasulfuron
ix. *Coniothyrium minitans* strain CON/M/91-08
x. *Mesosulfuron-methyl*
xi. *Mesotrione*
xii. *Pendimethalin*

A.04 Confirmatory Data:

1. Bifenthrin
2. Thiamethoxam
3. Clothianidin
4. Imidacloprid
5. Oxyfluorfen
6. Tetraconazole
7. Fluquinconazole
8. Metazachlor
9. Buprofezin
10. Malathion
11. Tri-allate
12. Diclofop
13. Cyflumetofen
14. Napropamide
15. Fluroxypyr
16. Tall oil pitch
17. Tall oil crude
18. 8-hydroxyquinoline (to be noted)
19. Methyl nonyl ketone (lack of data submission)
20. TDM (Triazole Derivative Metabolites)
21. AOB

A.05 Article 21 Reviews:

- *Diflubenzuron* (Draft Review Report and draft Implementing Regulation for discussion)

- *Thiametoxam*, other uses than seed treatments and granules (Revised Review Report to be noted)
- *Clothianidin*, other uses than seed treatments and granules (Revised Review Report to be noted)
- *Imidacloprid*, other uses than seed treatments and granules (Revised Review Report to be noted)

A.06 Amendment of the conditions of approval:

1. *Fenazaquin*
2. *8-Hydroxyquinoline*

A.07 Basic substances:

1. Pilot projects: state of play

2. New dossiers received:

   i. Beer
   ii. *Saponaria officinalis*

3. Exchange of view on EFSA Technical Reports (no specific report identified)

4. Draft Review Reports for discussion:

   i. Clayed charcoal
   ii. *Urtica spp.*
   iii. Hydrogen peroxide

A.08 Exchange of views and possible taking note of the following Guidance Documents:

1. Draft Guidance Document on the assessment of exposure of operators, workers, residents and bystanders in risk assessments for plant protection products (Doc. SANTE/10832/2015) (to be noted)
2. Draft Guidance Document on Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414), (Doc. SANCO/3030/1999 Rev. 5) (for discussion only).
3. Draft template for the data matching check (Doc. SANTE/11449/2016) (to be noted)

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 (to be noted).

A.11 Notifications 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 Consumers (SANTE) Directorate F, (former FVO):

1. Follow up workshop Formulation laboratories
2. Sustainable Use Directive (Directive 2009/128/EC)
3. Article 68 Enforcement Working group

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)
2. Post Approvals Issues group (PAI)
3. Sustainable plant protection experts group Dutch proposal
4. DRAW Setac-Workshops

A.15 OECD

A.16 Bees:

1. Review of Neonicotinoids – state of play and next steps (no news)
2. Review of Fipronil – state of play and next steps
3. Commission Communications amending Commission Communications (2013/C 95/01-95/02) as regards the effects on bees
4. Review of the Uniform Principles for Decision Making as laid down in Commission Regulation (EU) No 546/2011
5. Draft Commission Notice concerning time-frame for the use of EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera, Bombus* spp. and solitary bees).
6. AOB

A.17 Court cases:

- Case T-746/15 - Biofa AG v European Commission - Order of the General Court of 9/11/2016 – Action for the annulment of Regulation (EU) 2015/2069 approving the basic substance sodium hydrogen carbonate dismissed.
- Cases C-442/14 and C-673/13 - Judgements announced for 23/11/2016

A.18 Endocrine disruptors.

A.19 Update concerning Minor Uses.

A.20 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009
2. Questions and answers

A.21 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

A.22 Glyphosate:

- State of the dossier

A.23 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

A.24 Phosphonic acid (inorganic metabolite) - assessment of relevance (Germany).

A.25 Proposal on amendment of criteria for the approval of low risk active substances (SANTE/12376/2015).

A.26 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

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 renewing the approval of the 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 Implementing Regulation (EU) No 540/2011. (Draft Review Report doc. SANTE/12012/2015 Rev. 5).

(B.01_SANTE_12011_2015 Rev. 2)

Legal Basis: Article 20(1) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.02 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 sulfuryl fluoride (Draft Review Report SANCO/10567/2010 Rev. 1).

(B.02_SANTE_12459_2015 Rev. 2)

Legal Basis: Article 6(f), Article 6(i) and Article 78(2) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance thiabendazole 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 doc. SANTE/10315/2015 Rev. 2).

(B.03_SANTE_10314_2015 Rev. 0)

Legal Basis: Article 20(1) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance linuron, 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report doc. SANTE/10944/2016 Rev. 1)

(B.04_SANTE_10943_2016 Rev. 1)

Legal Basis: Article 20(1) and Article 78(2) of Regulation (EC) No 1107/2009
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 686/2012 as regards the co-rapporteur Member State for the active substance metaldehyde.

(B.05_SANTE_11478_2016 Rev. 1)

Legal Basis: Article 19 of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.06 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 several active substances listed in Part B in Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme).

(B.06_SANTE_11479_2016 Rev. 1)

Legal Basis: First paragraph Article 17 of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation modifying the conditions of 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 Addendum to the Review Report doc. SANTE/11617/2016)

(B.07_SANTE_11619_2016)

Legal Basis: Article 13(2)(c) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance oxathiapiprolin, 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 doc. SANTE/11169/2016 Rev. 1)

(B.08_SANTE_11168_2016 Rev. 0)

Legal Basis: Article 13 (2) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance iodosulfuron-methyl-sodium (approved as iodosulfuron) 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 doc. SANTE/11167/2016 Rev. 2)

(B.09_SANTE_11166_2016 Rev. 0))

Legal Basis: Article 20(1) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Satureja montana* L. 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 doc. SANTE/11411/2016 Rev. 0)

(B.10_SANTE_11410_2016 Rev. 0)

Legal Basis: Article 23(5) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Origanum vulgare* L. 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 doc. SANTE/11413/2016 Rev. 0)

(B.11_SANTE_11412_2016 Rev. 0)

Legal Basis: Article 23(5) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation confirming the conditions of approval of the active substance acrinathrin, as set out in Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11357/2011 Rev. 6)

(B.12_SANTE_11038_2016 Rev. 1)

Legal Basis: Article 13(2)(c) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

Miscellaneous

M.01 New Scientific publications and information submitted by stakeholders.

M.02 AOB

M.03 Date of next meeting.