



EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Plant Protection Products - Legislation*
11 July 2016 - 12 July 2016

CIRCABC Link:

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:

- i. *ABE IT45*
- ii. *Pydiflumetofen*
- iii. *Pasteuria nishizawae Pn1*
- ~~iii~~.iv. *Ferric pyrophosphate*

2. European Food Safety Authority (EFSA) conclusions:

3. Commission draft review report and Regulation concerning the (non-) approval of:

- ~~ii~~. *Reynoutria sacchalinensis extract*
- i. *Beta-cypermethrin*

A.03 Renewal of approval:

1. AIR III (Annex I Renewal Projects): State of play
2. AIR IV: State of play
3. EFSA conclusions:

- i. *Flurtamone*
- ii. *2,4-DB*
- iii. *Coniothyrium minitans* Strain CON/M/91-08
- iv. *Mesotrione*
- v. *Pendimethalin*

~~i.~~ Linuron

4. Draft Review Reports for discussion:

- i. *Cyhalofop-butyl*
- ii. *Bentazone*
- iii. *Famoxadone*
- iv. *Diquat*
- ~~v.~~ *Metaxyl M*
- ~~vi.~~ *Flumioxazin*
- ~~vii.~~ *Flupyr-sulfuron-methyl*
- ~~viii.~~ *Pymetrozine*
- ~~ix.~~ *Fenamidone*
- ~~x.~~ *Isoxaflutole*
- x. *Foramsulfuron*
- xi. Linuron
- xii. Iodosulfuron
- ~~xi.~~ xiii. Imazamox

A.04 Confirmatory data:

- ~~1.~~ *Epoxiconazole (revised review report to be noted)*
2. *Bifenthrin*
3. *Thiamethoxam (revised review report)*
4. *Clothianidin (revised review report)*
5. *Imidacloprid (revised review report)*
6. *Sulfuryl fluoride (no news)*
7. *Oxyfluorfen*
8. *Tetraconazole*
9. *Fluquinconazole*
10. *Metazachlor*
- ~~11.~~ *Prochloraz (revised review report to be noted)*
- ~~12.~~ *I-NAD (revised review report to be noted)*
- ~~13.~~ *I-NAA*
14. *Buprofezin*
15. *Malathion*
16. *Tri-allate*
17. *Diclofop*
18. *Cyflumetofen*
19. *Napropamide*
20. *Dicamba (revised review report to be noted)*
21. *Fluroxypyr*
22. Tall oil pitch
23. Tall oil crude
24. Straight chain lepidopteran pheromones
25. Methyl nonyl ketone (lack of data submission)
26. AOB

A.05 Article 21 Reviews:

- *Diflubenzuron*

A.06 Amendment of the conditions of approval:

1. *Abamectin*
2. *Fenazaquin*
3. *8-Hydroxyquinoline*
4. *Acrinathrin*

A.07 Basic substances:

1. Pilot projects: state of play
2. New dossiers received
 - i. Salt
 - ii. Extension for whey
- ~~ii.~~ iii. Fatty acids C7-C18 and C18 unsaturated potassium salts with CAS number 67701-09-01
3. EFSA Technical Reports
 - i. Talc
 - ii. *Satureja montana* L.
 - iii. *Origanum vulgare* L.
4. Draft Review Reports for discussion
 - i. Sunflower oil
 - ii. *Equisetum arvense* (revised review report for extension of use)

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

1. Draft Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (doc. SANCO/13170/2010 Rev. 13.4 for discussion only)
2. Draft Guidance Document on zonal evaluation and mutual recognition, withdrawal and amendment of authorization under Regulation (EC) No 1107/2009 (doc. SANCO/13169/2010 Rev. 10 for discussion only)
3. Draft Guidance Document on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (Doc. SANTE/10832/2015) (amendment of implementation schedule - discussion and possible note taking)
4. Draft Guidance Document on Rules for Revision of Assessment Reports (doc. SANTE/10180/2013 Rev. 2 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 Notifications under Article 30 of Regulation (EC) No 1107/2009 (to be noted).

A.13 Sustainable Use Directive (Directive 2009/128/EC):

1. NAP (National Action Plans) Report
2. State of play

A.14 News from European Food Safety Authority (EFSA).

A.15 News from SANTE Directorate F (former FVO).

A.16 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)
2. Article 68 Enforcement Working group
3. Post Approvals Issues group (PAI)
4. Unacceptable co-formulants
5. Biopesticides
6. Seed treatment
7. Sustainable plant protection experts group NL proposal
8. DRAW Setac-Workshops

A.17 OECD

A.18 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. AOB

A.19 Court cases :

A.20 Endocrine disruptors:

- ~~1. Impact assessment~~
- ~~2. Next steps: draft criteria~~

A.21 Minor Uses:

- State of play

A.22 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009
 - ~~+~~ 01. CO2
2. Questions and answers

A.23 Classifications under Regulation (EC) No 1272/2008:

1. Status of harmonised classifications
2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States and amendment of the format of Draft Assessment report (DAR) and Risk Assessment Report (RAR)

A.24 Glyphosate:

- State of the dossier

A.25 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations

[A.26](#) [ECPA letter on genotoxicity assessments for active substances](#)

[A.2627](#) Tefluthrin - Article 56 submission by Syngenta (Germany).

[A.2728](#) Phosphonic acid (inorganic metabolite) - assessment of relevance (Germany)

[A.3029](#) Question from Denmark and Post Approval Issues (PAI) regarding the implementation of Acute Acceptable Operator Exposure Level (AAOEL).

~~A.32~~

~~A.33 Information about a Commission Proposal for a Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 adopted by the Commission on 17.3.2016 (COM(2016) 157 final)~~

~~A.3430~~ Dimethoate: notifications by France according to Art. 21 and 71 of Regulation (EU) 1107/2009.

~~A.3531~~ ECPA letter on protection goals (NTP)

~~A36A.32~~ Acrinathrin – implementation of approval restrictions

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 concerning the approval of the active substance cyantraniliprole, 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/00111/2015 Rev. 1)

(B.01_SANTE_00110_2015 Rev. 0)

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

Procedure: Examination procedure

[For the second time in part B of the Agenda]

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the active substance isofetamid, 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/10401/2016 Rev. 1)

(B.02_SANTE_10400_2016 Rev. 1)

Legal Basis: Article 13(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 concerning the approval of the active substance *Bacillus amyloliquefaciens* strain MBI 600, 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/10008/2016 Rev. 2)

(B.03_SANTE_10007_2016 Rev. 2)

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

Procedure: Examination procedure

- B.04** Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending 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.

(B.04_SANTE_10094_2015 Rev. 24)

Legal Basis: Article 78(1)(c) of Regulation (EC) No 1107/2009

Procedure: Regulatory procedure with scrutiny

[For the second time in part B of the Agenda]

- B.05** Exchange of views and possible opinion of the Committee on a 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).

(B.05_SANTE_10035_2016 Rev. 0)

Legal Basis: Article 77 of Regulation (EC) No 1107/2009

Procedure: Advisory procedure

[For the second time in part B of the Agenda]

- B.06** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance thifensulfuron methyl 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/10150/2016 Rev. 1)

[For the second time in part B of the Agenda]

(B.06_SANTE_10206_2016)

Legal Basis: Article 20(1) 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 renewing the approval of the active substance picolinafen 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/12455/2015)

(B.07_SANTE_12456_2015 Rev. 2)

Legal Basis: Article 20(1) 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 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.08_SANTE_10314_2015 Rev. 1)

Legal Basis: Article 20(1) 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 ethofumesate 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/10120/2016 rev. 2)

(B.09_SANTE_10119_2016 Rev. 2)

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 Regulation amending Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, as regards the criteria for the approval of low risk active substances (SANTE/12376/2015)

Legal Basis: Article 22(3) and 78(1)(a) of Regulation (EC) No 1107/2009

Procedure: Regulatory procedure with scrutiny

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (Draft Review report Doc. 6511/VI/99 and Addendum SANTE-11051-2016 rev. 0).

(B.11 SANTE_10903_2016 Rev. 1)

Legal Basis: Article 21(3) 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 concerning the non-approval of the active substance tricyclazole, 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 (Review Report (SANTE/11866/2015 rev.0).

(B.12 SANTE_11865_2015 Rev. 2)

Legal Basis: Article 13(2) 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 the next meeting.

