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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 OCTOBER 2016 - 07 OCTOBER 2016

CIRCABC Link: <https://circabc.europa.eu/w/browse/ed11fa67-4b23-4905-a7e8-09ad6ecdaa5a>

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) *Paraffin oil [CAS 64742-55-8] Petroleum oils*

2. European Food Safety Authority (EFSA) conclusions:

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

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

4. Withdrawal of application for *Fusarium* sp. strain L13

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*
- vi. *Silthiofam*
- vii. *Propyzamide*

4. Draft Review Reports for discussion:

- i. *Famoxadone*
- ii. *Flumioxazin*
- iii. *Flupyr-sulfuron-methyl*
- iv. *Pymetrozine*
- v. *Fenamidone*
- vi. *Isoxaflutole*
- vii. *Foramsulfuron*
- viii. *Linuron*
- ix. *Iodosulfuron*
- x. *Imazamox*
- xi. *Maleic hydrazide*
- xii. *Picoxystrobin*
- xiii. *Cyazofamid*

5. List of studies relied upon in the renewal assessment

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. *Dicamba* (revised review report to be noted)
16. *Fluroxypyr*
17. Tall oil pitch
18. Tall oil crude
19. Straight chain lepidopteran pheromones (revised review report to be noted)

20. Methyl nonyl ketone (lack of data submission)
21. AOB

A.05 Article 21 Reviews:

- *Diflubenzuron* (Draft Review Report for discussion)
- *Thiametoxam* (Revised Review Report to be noted)
- *Clothianidin* (Revised Review Report to be noted)
- *Imidacloprid* (Revised Review Report to be noted)

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. Sea Salt
3. EFSA Technical Reports
 - i. *Urtica* spp.
 - ii. Hydrogen peroxide
4. Draft Review Reports for discussion
 - i. *Equisetum arvense* (Revised Review Report Rev. 6 for extension of use; to be noted)
 - ii. Sodium hydrogen carbonate (Revised Review Report for extension of use; to be noted)
 - iii. Clayed charcoal
 - iv. *Satureja montana* L.
 - v. *Origanum vulgare* L.

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. 13.9 to be noted)

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 to be noted)
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) (to be noted)
4. 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/3030/99 Rev. 5) (for discussion only).
5. 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 Notifications under Article 30 of Regulation (EC) No 1107/2009 (to be noted).

A.13 News from European Food Safety Authority (EFSA).

A.14 News from Directorate General for Health and Food Safety (DG SANTE) Directorate F (former FVO)

1. Workshop Formulation Laboratories .
2. Sustainable Use Directive (Directive 2009/128/EC)

A.15 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 the Netherland's proposal
8. DRAW Setac-Workshops

A.16 OECD

A.17 Bees:

1. Review of Neonicotinoids – state of play and next steps
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.18 Court cases.

A.19 Endocrine disruptors.

A.20 Minor Uses:

- State of play

A.21 Interpretation issues:

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

Article 81(2) – National lists of co-formulants

A.22 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 and amendment of the format of Draft Assessment Report (DAR) and Risk Assessment Report (RAR)

A.23 Glyphosate:

- State of the dossier
- Implementation of the ban of POE tallow amines in products containing glyphosate

A.24 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

A.25 Phosphonic acid (inorganic metabolite) - assessment of relevance (Germany).

- A.26** Proposal on amendment of criteria for the approval of low risk active substances (doc. SANTE/12376/2015).
- A.27** EFSA Opinion on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs.

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 concerning the non-renewal of the active substance diquat, 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/10396/2016 Rev. 1).

(B.02_SANTE_10395_2016 Rev. 1)

Legal Basis: Article 20(1) 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 approving the basic substance sunflower 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 Implementing Regulation (EU) No 540/2011. (Draft Review Report doc. SANTE/10875/2016 Rev. 1).

(B.03_SANTE_11052_2016)

Legal Basis: Article 13(2) and Article 23(5) 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. 4)

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

Procedure: Regulatory procedure with scrutiny

- 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

- 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 conditions of approval of the active substance sulfuryl fluoride (Draft Review Report doc.SANCO/10567/2010 Rev. 1).

(B.06_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.07** 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.07_SANTE_10314_2015 Rev. 0)

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 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acetamiprid, benzoic acid, flzasulfuron, mecoprop-P, mepanipyrim, mesosulfuron, propineb, propoxycarbazon, propyzamide, propiconazole, pseudomonas chlororaphis strain: MA 342, pyraclostrobin, quinoxyfen, thiacloprid, thiram, ziram, zoxamide.

(B.08_SANTE_11199_2016 Rev. 0)

Legal Basis: First paragraph of Article 17 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 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances fipronil and maneb.

(B.09_SANTE_11200_2016 Rev. 0)

Legal Basis: First paragraph of Article 17 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.