

#### **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*18 MAY 2016 - 19 MAY 2016

CIRCABC Link: https://circabc.europa.eu/w/browse/1a1a857a-2780-4288-8c55-8bf79e39eb5d

#### **AGENDA**

#### Section A <u>Information and/or discussion</u>

- **A.01** Summary Report of previous meetings.
- **A.02** New active substances:
  - 1. New admissible dossiers to be noted:
    - i. 1,3-Dichloropropene
    - ii. Mefentrifluconazole
  - iii. Sodium hydrogen carbonate
  - 2. European Food Safety Authority (EFSA) conclusions:
    - Cyclaniliprole
  - 3. Commission draft review report and Regulation concerning the (non-) approval of:
    - i. Reynoutria sacchalinensis extract
    - ii. Isofetamid
  - iii. Bacillus amyloliquefaciens strain MBI 600

#### **A.03** Renewal of approval:

- 1. Applications for renewal of approval of active substances submitted under Article 14 of Regulation (EU) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (SANCO/ 10148/2014 Rev. 6) (For information)
- 2. AIR III (Annex I Renewal Projects): State of play
- 3. AIR IV: State of play
- 4. EFSA conclusions:

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#### • Fenamidone

# 5. Draft Review Reports for discussion:

- i. Thiabendazole
- ii. *Cyhalofop-butyl*
- iii. Bentazone
- iv. Famoxadone
- v. Diquat
- vi. Ethofumesate (AIR3)
- vii. Metalaxyl-M
- viii. Flumioxazine
- ix. Flupyrsulfuron-methyl
- x. Pymetrozine
- 6. Metaldehyde: change of co-RMS (AT)

## **A.04** Confirmatory data:

- 1. Epoxiconazole (revised review report to be noted)
- 2. Bifenthrin
- 3. Dodine (revised review report to be noted)
- 4. Thiamethoxam
- 5. Clothianidin
- 6. Imidacloprid
- 7. Sulfuryl fluoride
- 8. Oxyfluorfen
- 9. Tetraconazole
- 10. Fluquinconazole
- 11. Metazachlor
- 12. Prochloraz (revised review report to be noted)
- 13. *1-NAD* (revised review report to be noted)
- 14. *I-NAA*
- 15. Buprofezin
- 16. Pyridaben (revised review report to be noted)
- 17. Malathion
- 18. Tri-allate
- 19. Diclofop
- 20. Cyflumetofen
- 21. Napropamide
- 22. Dicamba (revised review report to be noted)
- 23. Fluroxypyr
- 24. AOB

#### **A.05** Article 21 Reviews:

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## • Diflubenzuron

# **A.06** Amendment of the conditions of approval:

- 1. Abamectin
- 2. Fenazaguin
- 3. 8-Hydroxyquinoline
- 4. Acrinathrin

#### **A.07** Basic substances:

- 1. Pilot projects: state of play
- 2. New dossiers received
  - Mustard Powder
- 3. EFSA Technical Reports
  - i. Sunflower oil
- 4. Draft Review Reports for discussion

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

- 1. Draft Guidance Document on Semiochemical Active Substances used in Plant Protection Products (doc. SANTE/12815/2014 Rev. 4.6 to be noted)
- 2. 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)
- 3. 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)
- 4. 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)
- 5. Draft Guidance Document on Rules for Revision of Assessment Reports (doc. SANTE/10180/2013 Rev. 2 for discussion only)
- **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 Food and Veterinary Office (FVO).

# **A.16** Report from working groups:

- 1. Plant Protection Products (PPP) Application Management System (Authorisation database)
- 2. Article 68 Enforcement Working group
- 3. Post Approvals Issues group (PAI) (no news)
- 4. Unacceptable co-formulants
- 5. Biopesticides
- 6. Sustainable plant protection experts group NL proposal
- 7. 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. Follow-up of information received by an NGO as regards the emergency authorisations granted for neonicotinoids in accordance with Article 53 of Regulation (EC) No 1107/2009
- 4. Follow-up EFSA Conclusions on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam, clothianidin and imidacloprid considering all uses other than seed treatments and granules
- 5 AOB

#### **A.19** Court cases:

Cases C-442/14 and C-673/13: Opinions of the Advocate General.

#### **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
- 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 (no new meeting has taken place since March 2016).
- **A.26** Tefluthrin Article 56 submission by Syngenta (Germany).
- **A.27** Phosphonic acid (inorganic metabolite) assessment of relevance (Germany)
- **A.28** Straight Chain Lepidopteran Pheromones (SCLP): new specifications for a blend amended review report (SANCO/2633/2008 Rev. 11 to be noted).
- **A.29** Follow up to the workshop on harmonisation of risk assessment in section toxicology held in Vienna in June 2015.
- **A.30** Question from Denmark and Post Approval Issues (PAI) regarding the implementation of Acute Acceptable Operator Exposure Level (AAOEL).
- **A.31** Use of products containing 6-Benzyladine for sprouted seeds.

- **A.32** Discussion on amending the criteria for the approval of low risk active substances (doc. SANTE/12376/2015).
- 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.34** Dimethoate: notifications by France according to Art. 21 and 71 of Regulation (EU) 1107/2009.

## Section B Draft(s) presented for an opinion

Exchange of views and possible opinion of the Committee on a draft **B.01** Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P. ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin.

(B.01 SANTE 10046 2016 Rev. 0)

**Legal Basis:** Article 17 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 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.02 SANTE 00110 2015 Rev. 0)

**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 Regulation amending Commission Regulation (EU) No

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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.03\_SANTE\_10094\_2015 Rev. 2)

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

**Procedure:** Regulatory procedure with scrutiny

**B.04** 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.04\_SANTE\_10035\_2016 Rev. 0)

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

**Procedure:** Advisory procedure

**B.05** 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)

(B.05 SANTE 10206 2016)

**Legal Basis:** Article 20(1) 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 renewing the approval of the active substance glyphosate 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/10027/2016 Rev. 3)

(B.06 SANTE 10026 2016 Rev. 2)

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 approving the low-risk active substance *Saccharomyces cerevisiae* LAS02 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/12457/2015)

(B.07\_SANTE\_12458\_2015 Rev. 1)

Legal Basis: Articles 13(2) and 22(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 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.08\_SANTE\_12456\_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 concerning the approval of the active substance beta-cypermethrin, 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/12481/2015 Rev. 3)

(B.09 SANTE 12480 2015 Rev. 1)

**Legal Basis:** Article 13(2) 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 approving the low-risk active substance Trichoderma atroviride SC1 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/10389/2016 Rev. 1)

(B.10 SANTE 10387 2016 Rev. 1)

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

**Procedure:** Examination procedure

# Miscellaneous

M.01 New Scientific publications.

**M.02** AOB

M.03 Date of the next meeting.