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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*

08 OCTOBER 2015 - 09 OCTOBER 2015

CIRCABC Link: *https://circabc.europa.eu/w/browse/adff7253-0311-4bd1-abac-942361ee5133Blank 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. *Aluminium potassium sulfate dodecahydrate*
   ii. *Beauveria bassiana IMI389521*
   iii. *Beauveria bassiana PPRI 5339*
   iv. *Chromobacterium subtsugae PRAA4-1 (MBI-203)*

2. EFSA conclusions

3. Commission draft Review Report and Regulation concerning the approval of:

   i. *Cyantraniliprole*
   ii. *3-decen-2-one*
   iii. *Tricyclazole*
   iv. *Benzovindiflupyr*
   v. *Beta-Cypermethrin*

A.03 Renewal of approval:

1. Applications for renewal of approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (doc. SANCO/10148/2014 Rev. 5) (For information)

2. State of play AIR (Annex I Renewal Project)

3. EFSA conclusions:

i. *Iprovalicarb*
ii. *Thifensulfuron*
iii. *Isoproturon*
iv. *Famoxadone*

4. Draft Review Reports for discussion:

i. *Flupyrsulfuron-methyl*
ii. *Thiabendazole*
iii. *Lambda-cyhalothrin*
iv. *Amitrole*
v. *Flumioxazin*
vi. *Pymetrozine*
vii. *Metsulfuron-methyl*
viii. *Pyraflufen-ethyl*
ix. *Cyhalofop-butyl*
x. *Metalaxyl-M*
xi. *Triasulfuron*
xii. *Bentazone*

5. Next stage of renewal programme:

- Proposed Rapporteurs and Co-rapporteurs for AIR-4

A.04 Confirmatory data:

i. *Imazalil* (confirmatory data and application to amend the ARfD) (amended review report to take note*)*
ii. *Fluazifop-p* (amended review report to take note)
iii. *Iron sulphate* (amended review report to take note)
iv. *Epoxiconazole*
v. *Bifenthrin*
vi. *Buprofezin*
vii. *Dodine*
viii. *Pyridaben*
ix. *Myclobutanil*
x. withdrawal of approval of *Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate*
xi. withdrawal of approval of *Z-13-hexadecen-11-yn-1-yl acetate*
xii. *Thiamethoxam*
xiii. *AOB*

A.05 Article 21 Reviews:

i. *Diflubenzuron*
ii. *Chlorpyrifos* – state of the dossier

A.06 Amendment of the conditions of approval.

A.07 Basic substances:

1. Pilot projects: state of play

2. New dossiers received:

i. *Capsicum spice*
ii. *Sunflower oil*
iii. *Satureja montana oil*
iv. *Millefolii herba*
v. *Talc*
vi. *Citrus pulp*

3. EFSA (European Food Safety Authority) Technical Reports

4. Draft Review Reports for discussion

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

i. Draft Technical Guidance Document on the interpretation of points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No 1107/2009), in particular regarding the assessment of negligible exposure to an active substance in a plant protection product under realistic conditions of use (doc. SANCO/12096/2014) (for discussion)
ii. Draft Guidance Document on the Interpretation of the Transitional Measures for the Data Requirements for Chemical Active Substances and Plant Protection Products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (doc. SANCO/11509/2013 Rev. 5) (to be noted)
iii. Draft Guidance Document on Semiochemical Active Substances used in Plant Protection Products (doc. SANTE/12815/2014 Rev. 4.1)

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 Sustainable Use Directive (Directive 2009/128/EC):

i. NAP (National Action Plans) Report
ii. State of play

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

A.14 Report from working groups:

i. Plant Protection Products (PPP) Application Management System (Authorisation database) – including presentation from Commission on data migration exercise
ii. Low risk : presentation working document for proposal to review criteria
iii. Zonal Workshop
iv. Post Approvals Issues group (PAI)
v. Biopesticides

A.15 OECD

A.16 Bees:

i. Review of Neonicotinoids – state of play and next steps
ii. EFSA Guidance Document on the risk assessment of plant protection products on bees –and implementation plan (doc. SANCO/10606/2014) "state of play"
iii. Uniform principles – Amendment to the Regulation (EU) No 546/2011 as regards the trigger values for bees to take into account the new scientific development
iv. EFSA Conclusions on the peer review of the pesticide risk assessment for bees for the active substances clothianidin, imidacloprid and thiametoxam considering all uses other than seed treatments and granules
v. Report - EU Conference "Field studies and Monitoring Activities carried out at National level on the effect of Pesticides on Bees and other Pollinators" (MAPoB) – 9-11 September 2015, Bonn

vi. Notification of 22 July 2015 by Germany of a measure taken under Article 71 of Regulation (EC) No 1107/2007 concerning the placing on the market and use of winter cereal seeds treated with the active substances clothianidin, imidacloprid or thiamethoxam in Germany

vii. AOB

A.17 Court cases:

Judgment of the General Court of 10/9/2015 - Case C-446/10 DOW v. Commission – Dismissal of the request to annul Commission Directive 2010/355/EU (second non-inclusion of trifluralin).

New cases:

- T-296/15 IQV v. Commission (metalaxyl)
- T-310/15 European union copper task force v. Commission (copper compounds)

Two actions for annulment against the Commission Implementing Regulation (EU) 2015/408 establishing a list of candidates for substitution.

A.18 Endocrine disruptors:

- Impact assessment

A.19 Minor Uses:

- State of play

A.20 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009

   i. clayed charcoal

2. Questions and answers

A.21 Classifications under Regulation (EC) No 1272/2008:

1. Status of harmonised classifications
2. Implementation of the criteria in Annex II point 3.6.2 to 3.6.5 of Regulation (EC) No 1107/2009

A.22 Glyphosate:

- State of the dossier

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

A.24 Changes of toxicological endpoints and consequent review of authorisations.

A.25 Metam - new information submitted.

A.26 New greenhouse operator exposure model.

A.27 Follow-up activities EFSA Exposure Guidance (Acute Acceptable Operator Exposure Level (AAOEL) (mandate).

A.28 Straight Chain Lepidopteran Pheromones (SCLP): new compound amended Review Report (doc. SANCO/2633/2008 Rev. 8) (take note)

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 approving the active substance flumetralin, as a candidate for substitution, 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/10672/2015 Rev. 2).

(B.01_SANTE_10671_2015 Rev. 2)

Legal Basis: Article 13(2), Article 24 and Article 78(2) 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 renewing the approval of the active substance prosulfuron, as a candidate for substitution, 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/10681/2015 Rev. 1).

(B.02_ SANTE_10680_2015 Rev. 1)

Legal Basis: Article 20(1) and Article 24 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 active substance rescalure, 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/11644/2015 Rev. 1).

(B.03_SANTE_11643_2015)

Legal Basis: Article 13(2) and Article 78(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 Implementing Regulation approving the active substance mandestrobin, 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/11647/2015 Rev. 1).

(B.04_Doc. SANTE_11646_2015 Rev. 1)

Legal Basis: Article 13(2) 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 approving the active substance flupyradifurone, 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/11649/2015 Rev. 1).

(B.05_Doc. SANTE_11648_2015 Rev. 1)

Legal Basis: Article 13(2) and Article 78(2) 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 esfenvalerate, as a candidate for substitution, 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/10362/2015 Rev. 1).

(B.06_Doc. SANTE_10361_2015 Rev. 1)

Legal Basis: Article 20(1) and Article 24 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 active substance 2,4-D, 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/11961/2014 Rev. 3).

(B.07_Doc. SANTE_11022_2015 Rev. 2)

Legal Basis: Article 13(2) and Article 78(2) of Regulation (EC) No 1107/2009
Procedure: Regulatory procedure with scrutiny

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of Artemisia absinthium 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/10313/2015 Rev. 0).

(B.08_Doc. SANTE_10312_2015 Rev. 1)

Legal Basis: Articles 13(2) and 23(5) 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 non-approval of Tanacetum vulgaris, 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/10369/2015 Rev. 1).

(B.09_Doc. SANTE_10368_2015 Rev. 1)

Legal Basis: Articles 13(2) and 23(5) 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 Arctium lappa, 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/10663/2015 Rev. 0).

(B.10_Doc. SANTE_10662_2015 Rev. 1)

Legal Basis: Articles 13(2) and 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 approving the basic substance sodium hydrogen carbonate, 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/10667/2015 Rev. 1).

(B.11_Doc. SANTE_10666_2015 Rev. 1)

Legal Basis: Articles 13(2) and 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 amending Commission Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest.

(B.12_Doc. SANTE_11365_2015 Rev. 1)

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

B.13 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 haloxyfop-P (Draft Review Report doc. SANTE/12648/2010 Rev. 2).

(B.13_SANTE_10223_2015 Rev. 2)

Legal Basis: Article 13(2) and Article 78(2) of Regulation (EC) No 1107/2009
Procedure: Examination procedure

Miscellaneous

M.01 News from Food and Veterinary Office (FVO)

M.02 New scientific publications.

M.03 AOB

M.04 Date of the next meeting.