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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
19 - 20 May 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/8aa708bc-2a69-47d1-81f4-6c112a65d068*

AGENDA

Section A Information and/or discussion

A.01 Summary Report of previous meetings.

A.02 New dossiers (for information):

- New active substances
  a) Choline Hydrogen Phosphonate
  b) *Metharhizium pingshaense* CF62
  c) *Metharhizium pingshaense* CF69
  d) *Metharhizium pingshaense* CF78
  e) *Pythium oligandrum* strain B301
- Basic substances applications
  f) *Psidium guajava* L. leaf extract
  g) Sainfoin (*Onobrychis viciifolia* var. Perly) dried pellets
  h) Organic polyphenolic botanical compost
  i) *Ocium gratissimum* extract
  j) Chabazite
  k) *Allium fistulosum* extract
  l) *Urtica* spp (extension of use)
- Amendment of conditions of approval
  m) Maleic Hydrazide

A.03 Renewal of approval and general issues.

A.04 Exchange of views on EFSA conclusions/EFSA scientific reports:

- New active substances
  a) *Bacillus amyloliquefaciens* IT-45
- Renewal of approval
  b) *Bacillus thuringiensis ssp. kurstaki* strain PB 54
  c) *Bacillus thuringiensis ssp. kurstaki* strain EG2348
  d) Potassium hydrogen carbonate
- Basic substances
  e) Sunflower oil
  f) Caffeine
  g) *Urtica* spp (extension of use)
- Amendment of conditions of approval

A.05 Draft Review/Renewal Reports for discussion:

- New active substances
  a) Dimethyl disulphide
  b) Chloropicrin
  c) 1,3-dichloropropene
  d) *Purpureocillium lilacinum* strain PL11
- Renewal of approval
  e) *Metarhizium brunneum* strains BIPESCO 5/F 52
  f) Captan
  g) *Purpureocillium lilacinum* strain 251
  h) *Bacillus amyloliquefaciens* strain QST 713
  i) *Bacillus amyloliquefaciens* AH2
  j) *Pseudomonas chlororaphis* strain MA342
  k) *Bacillus thuringiensis subsp. kurstaki* strain SA-11
  l) *Bacillus thuringiensis subsp. kurstaki* strain SA-12
  m) *Bacillus thuringiensis subsp. Israelensis* (serotype H-14) strain AM65-52
  n) *Bacillus thuringiensis subsp. aizawai* strain ABTS-1857
  o) *Bacillus thuringiensis subsp. aizawai* strain GC-91
  p) Rimsulfuron
- Basic substances
  q) *Equisetum arvense* (extension of use)
  r) Chitosan

s) Sodium hypochlorite

- Amendment of conditions of approval

A.06 Confirmatory Information:

1. Gamma cyhalothrin (amended review report to take note)
2. Flupyradifurone
3. Spiroxamine
4. Dithianon
5. Pyriofenone

A.07 Guidance Documents:

1. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
2. Draft Guidance document on treatment of seeds and placing on the market of treated seeds under Regulation (EC) No 1107/2009
3. Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02
4. Draft technical guidance on points 3.6.3. to 3.6.5 of Annex II to Regulation (EC) No 1107/2009, in particular regarding the demonstration of negligible exposure to an active substance in a plant protection product under realistic conditions of use
5. Draft GD on time dependent sorption of pesticides in soil (aged sorption for groundwater leaching) (follow up discussion)
6. Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004 Rev.9) (for information)
7. Guidance document on rules for revision of assessment reports (SANCO/10180/2013 – Rev. 2 May 2021) (for information)
8. Guidance document on the assessment of the relevance of metabolites in groundwater (SANCO/221/2000 Rev. 11)
9. Guidance document on data matching for applications for authorisation of plant protection products according to Article 33/43 (for information)
10. Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No 1107/2009 (for information)

A.08 Defining Specific Protection Goals for environmental risk assessment, in particular:

– Terms of Reference (to take note)

A.09 Commission Regulation (EU) No 547/2011 and risk mitigation.

A.10 Notifications under Regulation (EC) No 1107/2009 (for information):

– Article 44(4)

– Article 36(3)

- Article 53
- Article 69
- Article 71

A.11 News from European Food Safety Authority (EFSA).

A.12 Improving the efficiency of the process of a.s. approval / renewal.

A.13 Microorganism Active Substances, in particular:

- update on data requirements
- update on uniform principles and Annex II
- Commission Communications in the framework of the implementation of the data requirements

A.14 Safeners and Synergists.

A.15 Updates, clarifications & questions on specific active substances:

1. Copper compounds
2. Tebufenozide (Art 21 procedure)
3. Calcium hydroxide

A.16 General issues for information / discussion:

1. Brexit
2. Illegal plant protection product use
3. Nitrophenolates salts (Na/K) - new active substance vs. technical concentrate (pro-memoriam)
4. Scope of Regulation (EC) No 1107/2009:
   a) Scope delineation with biocidal products
   b) Scope Document rev. 62
   c) New cases
5. Basic substances – general issues
6. Development of resistance in *Aspergillus fumigatus* to azoles used as medicines from use of azole fungicides
7. Use of groundwater monitoring data in EU regulatory pesticide risk assessment
8. Trifluoroacetic acid (TFA)
9. MS updated survey on timing of regulatory procedures

A.17 News from Sustainable Use Directive (Directive 2009/128/EC).

A.18 News from Health and Food Audits and Analysis (SANTE, Directorate F).

A.19 Implementation Art 67 Regulation (EC) No 1107/2009.

A.20 Report from Working Groups, in particular:

1. Working Group on Biopesticides
2. Working Group on Seed Treatments
3. Working Group Post Approval Issues

A.21 Minor Uses.

A.22 Court cases.

A.23 Ombudsman cases.

A.24 Exchange of information from the Pesticide Residues section of the Committee, in particular:

- possible impact on authorisations
- residue definition for risk assessment

A.25 OECD and EPPO activities.

A.26 Scientific publications and information submitted by stakeholders.

A.27 Date of next meeting(s).

Section B <u>Draft(s) presented for an opinion</u>

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance clopyralid, 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 Rev. 1 SANTE/10206/2021).

(SANTE/10204/2021 Rev. 0)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1)

Procedure: Examination procedure

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation correcting Implementing Regulations (EU) No 540/2011 and (EU) No 563/2014 as regards the CAS number of the basic substance chitosan hydrochloride (Draft Review Report SANCO/12388/2013 – Rev. 4).

(SANTE/10596/2021 Rev. 0)

Legal Basis: Regulation (EC) No 1107/2009 - Article 13(2) in conjunction with Article 23(5)

Procedure: Examination procedure

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2015/408 as regards the deletion of propoxycarbazone from the list of active substances to be considered as candidates for substitution.

(SANTE/10304/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 78(2)

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of dimethyl sulphide 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 SANTE/10366/2021).

(SANTE/10364/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 23(5) in conjunction with Article 13(2)

Procedure: Examination procedure

Section C **Draft(s) presented for discussion**

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12068/2020 Rev. 0).

(SANTE/12066/2020 Rev. 0)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1)

Procedure: Examination procedure

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and (EU) No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor (Draft Updated Review Report SANCO/10665/2015).

(SANTE/10724/2020)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3) and 78(2)

Procedure: Examination procedure

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-approval of *Salix spp* stem extract (willow stem infusion) 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 SANTE/12638/2020 – Rev. 0).

(SANTE/12636/2020 Rev. 0)

Legal Basis: Regulation (EC) No 1107/2009 - Article 13(2) in conjunction with Article 23(5)

Procedure: Examination procedure

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation approving the active substance *Beauveria bassiana* strain 203 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 SANTE/10296/2021).

(SANTE/10298/2021)

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

Procedure: Examination procedure

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance phosmet, 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 SANTE/12604/2020 Rev. 3).

(SANTE/12602/2020 Rev. 0)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance famoxadone, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12986/2019 Rev. 2).

(SANTE/12984/2019 Rev. 1)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of approval of the active substance flumioxazin, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12512/2014 Rev. 3).

(SANTE/12510/2014 Rev. 0)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning renewing the approval of the active substance cypermethrin 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 SANTE 2018-11527 Rev. 6).

(SANTE/10590/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 24

Procedure: Examination procedure

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulations (EU) No 540/2011 and (EU) 2015/2085 as regards the conditions of approval of the active substance mandestrobin (Draft Review Report SANTE/11647/2015 Rev. 3)

(SANTE/10564/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3) and 78(2)

Procedure: Examination procedure

C.10 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulations (EU) No 540/2011 and (EU) 589/2012 as regards the conditions of approval of the active substance fluxapyroxad (Draft Review Report SANCO/10692/2012 Rev. 2)

(SANTE/10566/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3) and 78(2)

Procedure: Examination procedure

C.11 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulations (EU) No 540/2011 and (EU) 2015/1192 as regards the conditions of approval of the active substance terpenoid blend QRD 460 (Draft Review Report SANTE/00134/2015 Rev.5)

(SANTE/10568/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3) and 78(2)

Procedure: Examination procedure

C.12 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulations (EU) No 540/2011 and (EU) 2018/185 as regards the conditions of approval of the active substance penflufen (SANTE/10028/2017 Rev.1)

(SANTE/10574/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 21(3) and 78(2)

Procedure: Examination procedure

C.13 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance *Pythium oligrandum* strain M1, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10332/2021 Rev. 0).

(SANTE/10330/2021 Rev. 0)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

C.14 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance calcium carbonate as a low risk active 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10430/2021 Rev. 0).

(SANTE/10428/2021)

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

Procedure: Examination procedure

C.15 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances acrinathrin and prochloraz.

(SANTE/10578/2021)

Legal Basis: Regulation (EC) No 1107/2009 - Article 17

Procedure: Examination procedure

C.16 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance indoxacarb, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10730/2018 Rev. 2).

(SANTE/10729/2018 Rev. 2)

Legal Basis: Regulation (EC) No 1107/2009 - Articles 20(1) and 78(2)

Procedure: Examination procedure

Pro memoria – TBT notification (to be) launched