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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*
23 - 24 March 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/a17d97e3-6896-43de-a063-d2d0fb723484*

SUMMARY REPORT

The invitation to the meeting was sent out on 9 March 2020. However, the physical meeting had to be cancelled due to measures taken to contain the COVID-19 outbreak. The Committee was consulted via written exchange of views as described in each section below.

Section A Information and/or discussion

For each agenda point which was not postponed and where applicable, the draft documents, comments received from Member States, and comments received from applicants were made available on CIRCA BC. On the basis of these documents, Member States were requested to send their positions on these agenda points by 14 April 2020 unless another deadline was indicated under the specific agenda point.

A.01 Summary Report of previous meetings.

The Commission informed that the summary reports of the previous meetings (December 2019, February 2020) had been published.

A.02 New dossiers:

POSTPONED.

A.03 Renewal of approval, general issues:

a) 6th renewal programme – allocation of RMS for active substances expiring from 2025 to the end of 2028

The Commission informed that active substances for which the approval expires between 31 March 2025 and 27 December 2028 (24 substances) would be included in this renewal programme.

The draft proposal of allocation of Rapporteur Member State had been first circulated by email on 27 January 2020. The Member States that had not yet reacted are asked to express if the proposal is acceptable in order to proceed with the preparation of the legal act.

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

POSTPONED.

A.05 Draft Review/Renewal Reports for discussion:

New active substances:

a. Dimethyl disulphide

POSTPONED

b. Pydiflumetofen

Written consultation initiated (see introductory paragraph above).

Renewal of approval

c. Etoxazole

Following the meeting of this Committee in December 2019, the Commission revised the draft review report from non-renewal (presented in 2018) to restricted renewal to ornamentals in permanent greenhouses. The restriction is needed due to the non-finalised consumer dietary risk assessment and high risk to non-target arthropods identified in the EFSA Conclusion.

Written consultation initiated (see introductory paragraph above). In particular, each Member State is requested to express whether they support the Commission's proposal or not. In case of objection, Member States are requested to give the reason of non-support.

d. Clopyralid

POSTPONED.

e. Famoxadone

Written consultation initiated (see introductory paragraph above).

f. Cyazofamid

Written consultation initiated (see introductory paragraph above).

g. Cypermethrin

Following the meeting of this Committee in October 2019, the EFSA Statement issued in September 2019 and the comments received from several Member States by December 2019, the Commission had revised the draft review report from 'renewal with a restriction of use to winter/autumn application combined with risk mitigation measures for exposure reduction' (presented at the meeting of this Committee in January 2019) to 'renewal as candidate for substitution setting restrictions in accordance with Article 6(i) of Regulation 1107/2009'. The draft specific conditions for the legal text had are been uploaded to CIRCA BC.

Written consultation initiated (see introductory paragraph above). In particular, each Member State is requested to express whether they support the Commission's proposal or not. In case of objection, Member States are requested to give the reason of non-support.

h. Indoxacarb

Written consultation initiated (see introductory paragraph above).

i. Pseudomonas chlororaphis MA 342

Written consultation initiated (see introductory paragraph above).

j. Bifenazate

The Commission had shared an overview of the discussions held so far at the earlier meetings of this Committee on CIRCA BC. This overview includes a summary of when and at which meeting the respective documents had been made available.

Written consultation initiated (see introductory paragraph above). In particular, each Member State is requested to express whether they support the Commission's proposal of July 2017. In case of objection, Member States are requested to give the reason of non-support.

Basic substances

k. Lecithins (extension) – amended review report to take note
l. sucrose
m. fructose

All POSTPONED.

Amendment of conditions of approval

No news to discuss.

A.06 Confirmatory Information:

All the following agenda items were POSTPONED, with exception of points 6 and 7:

1. Spiroxamine (amended review report to take note)
2. Azadirachtin (amendment review report to take note)
3. Fenpyrazamine
4. Triazole derived metabolites (TDMs)
   - Paclobutrazole (amended review report to take note)
   - Difenoconazole
5. Isofetamid
6. Terbuthylazine

   Written consultation initiated (see introductory paragraph above). In particular, Member States are asked to consider if they could support a restriction to biannual use at a maximum rate of 850 g/ha, in order to ensure that the levels of metabolites entering groundwater are reduced and to ensure no risk to consumers. Member States should consider the documents submitted by the applicant.

7. Sulfoxaflor

   Written consultation initiated (see introductory paragraph above). In particular, Member States are asked to comment on the EFSA Conclusion of 25 February 2020, especially as regards potential chronic risks in field margins

8. Gamma-cyhalothrin
9. Pyrethrins
10. L-ascorbic acid
11. Benzovindiflupyr
12. Ipconazole

Pro memoriam (on hold): Geraniol, Eugenol, Thymol, Clove oil.

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) – update***

POSTPONED.

2. ***Guidance on emergency authorisations according to Article 53 (discussion)***

Written consultation initiated (see introductory paragraph above). In particular, Member States are asked to consider the updated version of the document (version 5), especially the suggested new fields to be included in PPPAMS (as indicated in the document) and the changes introduced in section 4, and to provide any comments if applicable. The document will then be moved forward o stakeholder consultation.

3. ***Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance***

Written consultation initiated (see introductory paragraph above). A draft document with version dated 13 March (i.e. from after the last meeting of the Working Group Biopesticides) is available on CIRCA BC. Member States, in particular those Member States not represented in the Working Group, are invited to send final comments by 20 April 2020.

4. ***Draft Guidance document on the risk assessment of metabolites produced by micro-organisms***

Written consultation initiated (see introductory paragraph above). A draft document with version dated 7 March (i.e. from before the last meeting of the Working Ggroup Biopesticides) is available on CIRCA BC. Member States, in particular those Member States not represented in the Working Group, are invited to send final comments by 20 April 2020.

All the following agenda items were POSTPONED:

5. ***Review of Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 (SANCO/12638/2011)***

6. ***Draft 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***

7. ***EFSA Guidance on the risk assessment of PPP a.s. and their transformation products that have stereoisomers***

8. ***Additional data for review of EFSA Exposure Guidance Document– for information***

9. ***Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02 (no news)***

10. ***Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11) (no news)***

11. ***Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004– rev 9) (no news)***

12. ***Guidance document on Data Matching for applications for authorisation of PPPs according to Article 33/43 (no news)***

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

POSTPONED.

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

POSTPONED.

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

POSTPONED.

A.11 Plant Protection Products Application Management System (PPPAMS):

POSTPONED.

A.12 News from European Food Safety Authority (EFSA):

POSTPONED.

A.13 Improving the efficiency of the process of a.s. approval:

POSTPONED.

A.14 New Transparency rules: General Food Law amendment and implementation:

1. ***update on regulation for renewals of approval of active substances***
2. ***update on IT tools for notification and submission of applications***

The Commission provided an outline of a future Implementing Regulation on CIRCA BC. A written consultation was initiated (see introductory paragraph above).

A.15 Clarifications & questions related to specific active substance:

1. Acibenzolar-S-methyl – updated review report (to take note)
2. Chlorotalonil monitoring data
3. Candidates for substitution

All POSTPONED.

A.16 Interpretation issues:

POSTPONED.

A.17 Epoxiconazole.

The Commission informed Member States that the applicant had withdrawn the application for renewal of approval. As a consequence, the approval of the active substance will expire on 30 April 2020.

The Commission reminded Member States to revoke all authorisations of PPPs containing this active substance without delay in accordance with the foreseen procedures (e.g. Article 46).

A.18 Safeners and Synergists:

POSTPONED.

A.19 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005):

POSTPONED.

A.20 News from Sustainable Use Directive (Directive 2009/128/EC):

POSTPONED.

A.21 News from Health and Food Audits and Analysis (SANTE, Directorate F):

POSTPONED.

A.22 Report from Working Groups:

POSTPONED.

A.23 Minor Uses:

POSTPONED.

A.24 Court cases:

The Commission informed that a summary is available on CIRCA BC for information.

A.25 Ombudsman cases:

No news.

A.26 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

POSTPONED.

A.27 OECD and EPPO activities, in particular:

The Commission informed that as regards the OECD working group on Drones, an e-mail was sent to all Member States on 3 March regarding an expert group data call-in. Member States were invited to send the requested information by 14 April to 2020.

A.28 Scientific publications and information submitted by stakeholders.

POSTPONED.

A.29 Date of next meeting(s).

The next meeting, subject to confirmation, is scheduled for 18 - 19 May 2020.

Section B <u>Drafts presented for an opinion</u>

On the basis of the documents provided under the points of this section, Member States were requested to send their preliminary positions and/or comments on these agenda points by 19 March 2020.

After this preliminary consultation, the vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 was launched for some of the points, as detailed below.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) modifying Annex III of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

Based on the outcome of the written exchange of views (see introductory paragraph above) the vote on the draft Regulation was postponed.

Member States were invited to send any additional comment by 14 April 2020.

Vote postponed.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance metalaxyl-M, 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/11112/2019 Rev.3).

Based on the outcome of the written exchange of views (see introductory paragraph), the Commission presented an amended version of the draft Regulation and launched the vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance foramsulfuron, 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/11214/2016 Rev. 1).

Based on the outcome of the written exchange of views (see introductory paragraph), the Commission launched the vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiophanate-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 NTE/11254/2018 Rev. 3).

Based on the outcome of the written exchange of views (see introductory paragraph), the Commission launched the vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

No vote: the written procedure was terminated without result on request of one Member State.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance sodium hydrogen carbonate as a low-risk 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11724/2018 Rev. 1).

Based on the outcome of the written exchange of views (see introductory paragraph above) The vote on the draft Regulation was postponed.

Member States were invited to send any additional comment by 14 April 2020.

Vote postponed.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval the active substance Lavandulyl senecioate as a low-risk 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10060/2020 Rev. 1).

Based on the outcome of the written exchange of views (see introductory paragraph), the Commission launched the vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval the active substances *Phlebiopsis gigantea* VRA 1835, VRA 1984 and FOC PG 410.3 as low-risk substances 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/12900/2019 Rev. 1).

The vote on the draft Regulation was postponed because internal procedures were not yet finished.

Member States were invited to send any additional comment by 14 April 2020.

Vote postponed.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Saponaria officinalis* L. roots 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/11515/2017– Rev. 2).

Based on the outcome of the written exchange of views (see introductory paragraph), the Commission launched the vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of Milk 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/12816/2019 Rev. 3).

Based on the outcome of the written exchange of views (see introductory paragraph above) the vote on the draft Regulation was postponed.

Member States were invited to send any additional comment by 14 April 2020.

Vote postponed.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of L-cysteine 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/11056/2019 Rev. 2).

Based on the outcome of the written exchange of views (see introductory paragraph), the Commission launched the vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of propolis extract 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/11782/2019 Rev.1).

Based on the outcome of the written exchange of views (see introductory paragraph), the Commission launched the vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation correcting Commission Implementing Regulation (EU) No 2019/706 renewing the approval of the active substance carvone, 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 (Amended Renewal Report SANTE/11718/2018 Rev. 1).

Based on the outcome of the written exchange of views (see introductory paragraph), the Commission launched the vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

For each agenda item in this section, the documents, comments received from Member States, and comments received from applicants were made available on CIRCA BC. On the basis of these documents, Member States were requested to send their positions on these agenda points by 14 April 2020.

C.01 Exchange of views 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 azadirachtin (Amended Review Report SANCO/10311/2011 Rev. 1).

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance bromoxynil, 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 Renewal Report SANTE/10156/2020 Rev. 0).

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance mancozeb, 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/10326/2019 / Rev. 0).

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance pyriproxifen, 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/(Draft Review Report SANTE/11426/2019 / Rev.0).

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance beta-cyfluthrin, 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/12798/2019 Rev. 1).

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the approval of the low risk active substance ferric pyrophosphate, 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-2020-10230 Rev. 0).

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance benalaxyl, 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/10240/2020 Rev. 0).

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance benfluralin, 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/10236/2020 Rev. 0).

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance fenamiphos, 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/11402/2019 Rev. 1).