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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*

18 February 2020

(subsection of PAFF Committee meeting of 17-18/02/2020, section Phytopharmaceuticals-Pesticide residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/99b3dad7-56fb-47e9-bde4-7b4d4654f2ac*

SUMMARY REPORT

B.01 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 abamectin, Bacillus subtilis (Cohn 1872) strain QST 713, Bacillus thuringiensis subsp. Aizawai strains ABTS-1857 and GC-91, Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52, Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, Beauveria bassiana strains ATCC 74040 and GHA, clodinafop, clopyralid, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, epoxiconazole, fenpyroximate, fosetyl, Lecanicillium muscarium (formerly "Verticillium lecanii") strain Ve6, mepanipyrim, Metarhizium anisopliae (var. anisopliae) strain BIPESCO 5/F52, metconazole, metrafenone, Phlebiopsis gigantea strains FOC PG 410.3, VRA 1835 and VRA 1984, pirimicarb, Pseudomonas chlororaphis strain MA342, pyrimethanil, Pythium oligandrum M1, rimsulfuron, spinosad, Streptomyces K61 (formerly "S. griseoviridis"), Trichoderma asperellum (formerly "T. harzianum") strains ICC012, T25 and TV1, Trichoderma atroviride (formerly "T. harzianum") strains IMI 206040 and T11, Trichoderma gamsii (formerly "T. viride") strain ICC080, Trichoderma harzianum strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram.

The Commission presented the draft Regulation, which extends the approval of 35 active substances due to delays in the assessment procedures, either at the level of Rapporteur Member States or during the peer-review, which are beyond the control of the applicants. Some of these extensions are also due to the ongoing assessment of endocrine disruption properties according to the new criteria, which were applied also to ongoing regulatory procedures without transition period. The Commission is obliged to enact these extensions in accordance with Article 17 of Regulation (EC) No 1107/2009.

Three Member States indicated they would vote against the draft Regulation because they do not agree with an extension for epoxiconazole. One of them indicated that it is

also not supporting the extension of fenpyroximate, clodinafop, rimsulfuron, and mepanipyrim.

Another Member State declared it would abstain because of epoxiconazole, mepanipyrim, and clodinafop.

The Commission amended the draft Regulation by removing epoxiconazole from the text. Therefore, the revised draft Regulation presented for a vote concerned only 34 active substances.

The Rapporteur Member State (RMS) was surprised by the exclusion of epoxiconazole, as the evaluation of epoxiconazole is still ongoing. It stressed that it is not possible to conclude the peer review before the expiry of the approval of the active substance. The RMS asked for a discussion on this issue at the next meeting of the Committee, section Phytopharmaceuticals-Legislation. The Commission confirmed that this issue would be discussed at the next meeting.

Another Member State agreed with the RMS and noted that it was not impressed at all by the revised draft presented by the Commission, as only few Member States were against extending the approval of the active substance that had been deleted. The Commission clarified that the original draft Regulation presented would not have been supported by a qualified majority.

The vote was taken on the revised draft (34 active substances): favourable opinion with qualified majority.

Poland made the following protocol declaration:

Taking into account the fact that amended draft Regulation extends the approval period for 34 other active substances (except of epoxiconazole) in the spirit of compromise Poland supports amended draft regulation as we do not want to "sacrifice" other active substances. However in the opinion of Poland, the decision-making process for each active substance, should be based on evidence, scientific knowledge and expert evaluation. In our view it is not possible to conduct reliable and comprehensive assessment without necessary amount of time and from our perspective administrative extensions of approval period is very useful tool to provide RMS with it. Otherwise, the decision taken before finalizing the peer-review process would be in our view premature and not scientifically justified.

As a new RMS for epoxiconazole we do not see the possibility to finish the peer-review process by the expiration of approval period and we would like to come back to this discussion at the next PAFF meeting, section Phytopharmaceuticals - Legislation.

Vote taken: Favourable opinion.