EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

Brussels,
SANTE/E4/NT/ai(2022)3931519

Dear Dr Dermine,

Subject: Your letter of 15 April 2022 providing references on new scientific publications related to neonicotinoids

Thank you for your above-mentioned letter to Commissioner Kyriakides, who asked me to respond on her behalf. In your email you request in particular to urgently mandate the European Food Safety Authority (EFSA) to provide an opinion on a reduction of MRLs for all neonicotinoids and neonicotinoid-like insecticides that have the same mode of action and comparable water-solubility properties (including sulfoxaflor and flupyradifurone) and to launch a procedure under Article 21 Regulation (EC) No 1107/2009, in order to review the scientific literature and assess if, based on this information, neonicotinoids and neonicotinoid-like substances meet the criteria for approval, in light of the obligation to implement the precautionary principle.

First, I would like to recall that only one neonicotinoid remains approved in the EU – acetamiprid. As you are aware, following a mandate from the Commission, EFSA recently published a statement[1] on acetamiprid in the preparation of which a number of scientific papers investigating hazards and/or exposure to humans and the environment to acetamiprid have been considered. The statement evaluates the likelihood of those studies indicating new or higher hazards and exposure to humans and the environment compared to previous EU assessments. Currently, the Standing Committee on Plants, Animals, Food and Feed – section phytopharmaceuticals legislation is discussing the need for possible follow up actions with respect to the approval of acetamiprid. We will make your above-mentioned letter available to the Member States so that it will be taken into account in this discussion.

As you are aware, the approval of sulfoxaflor has recently been restricted to indoor uses only and in the light of the expiry of the current approval on 18 August 2025, a new procedure to review the approval will start on 18 August 2022, during which all relevant scientific publications will be considered. As regards flupyradifurone, I would like to refer to my letter of 12 May 2022 to your organisation (reference ARES (2022)3626521).

Please be informed that existing maximum residue levels (MRLs) for acetamiprid and imidacloprid and/or applications for amending such MRLs were reviewed by EFSA in

[1] EFSA (European Food Safety Authority), 2022. Statement on the active substance acetamiprid. EFSA Journal 2022; 20(1):7031. https://doi.org/10.2903/j.efsa.2022.7031

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recent years[2] and relevant amendments of the MRLs were discussed in the Standing Committee on Plants, Animals, Food and Feed – section phytopharmaceuticals, pesticides residues. Furthermore, the Commission intends to present in the near future to this Committee draft Regulations to lower the MRLs for clothianidin and thiamethoxam. We will make your letter available to the Member States at the earliest occasion so that the information provided therein will be taken into account in this discussion.

I would also like to inform you that work is on-going at international level on case studies for an integrated approach to testing and assessment (IATA) on developmental neurotoxicity (DNT) risk assessment[3] that should improve DNT hazard identification and characterisation of active substances, including acetamiprid. Results are not yet available but are expected soon.

Yours sincerely,

Klaus Berend
Head of Unit

[2] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6830; https://www.efsa.europa.eu/en/efsajournal/pub/5262; https://www.efsa.europa.eu/en/efsajournal/pub/5570

[3] EFSA (European Food Safety Authority), 2021. Development of Integrated Approaches to Testing and Assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment. EFSA Journal 2021; 19(6): 6599. https://doi.org/10.2903/j.efsa.2021.6599