EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Food and feed safety, innovation
Director

Brussels,
SANTE/E4/5.1.2.e Woo/df (2020) 2328728

To be translated into Dutch

Dear Ms 5.1.2.e Woo,

Subject: Your letter dated 9 March 2020 on Parkinson's disease and resistance to medicinal azoles

Thank you for your letter dated 9 March 2020, in which you outline concerns about the impact of plant protection products on human health, specifically their potential link to the development of Parkinson's disease and the development of resistance to medicinal azoles, and in which you call for a review of the approvals of azole fungicides.

Your letter will be made available to all Member States ahead of the next Standing Committee on Plants, Animals, Food and Feed (section phytopharmaceuticals) in order to allow a discussion with Member States on the issues raised.

Let me first stress that the protection of human health and the environment is the fundamental objective of the EU legislation on pesticides. All available information must be taken into account in the risk assessment for active substances that are to be used in plant protection products including monitoring and epidemiological data (where available) and peer-reviewed literature. Regulation 283/2013 sets out the data requirements for active substances[1], which include the need for providing studies or information on the postnatal manifestation of effects such as developmental neurotoxicity.

Scientific knowledge and understanding about the links between exposure to pesticides and adverse impacts on human health is continually evolving. In 2013, the literature review[2] carried out for European Food Safety Authority on epidemiological studies linking exposure to pesticides and human health, reported a potential association between exposure to some pesticides and increased risk of Parkinson's disease. As a follow up,

[1] OJ L 93, 3.4.2013, p. 1.

[2] Ntzani EE, Chondrogiorgi M, Ntritsos G, Evangelou E, Tzoulaki I, 2013. Literature review on epidemiological studies linking exposure to pesticides and health effects. EFSA supporting publication 2013:EN-497, 159 pp.

Ms 5.1.2.e Woo
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EFSA published an opinion[3] in 2017 and organised a scientific conference[4] on the use of epidemiological findings in regulatory pesticide risk assessment.

Such developments could be discussed at the Standing Committee, if that is found appropriate, and might also lead to amendments in the data requirements or in the associated Communications 2013/C 95/01 and 2013/C 95/02, for which the Commission has initiated an update to take into account advances in regulatory scientific knowledge and regulatory areas like e.g. the updates of data requirements for biocides.

As regards azole fungicides used in agriculture and their potential role in the development of resistance of fungal pathogens to medicinal azoles, your concerns are well known and have also been raised in the context of the use of azoles in biocidal products. In fact the European Centre for Diseases Prevention and Control (ECDC) published a report[5] on this topic in 2013, raising the need for better epidemiological surveillance and investigations on the environmental origin of the azoles, as they may come from different sources.

The use of azole fungicides in agriculture has already declined in a number of Member States over the past several years, while it has increased in some (including in the Netherlands, in particular in the period 2015-2017[6]). A further decline may be seen over the coming years since the approvals of several azole substances will expire over the next two years because they are no longer supported by applicants[7], in addition to other azole active substances removed from the market some time ago (e.g. carbendazim, fluzilazole, propiconazole).

All active substances which are supported by applicants are subject to a reassessment before they can be renewed; the reassessments for the majority of the remaining azoles will occur in the next 1-2 years. Those evaluations can already take into consideration possible risk of development of azole cross-resistance if there is evidence of such a concern. All Member States contribute to the peer review of these assessments and the findings of the review by the CTGB of authorisations granted for PPP containing azole substances used in flower cultivation that you refer to in your letter can be taken into account in those evaluations. In addition, during the regulatory decision-making at the Standing Committee, the need for specific conditions or restrictions of use can also be considered, including setting environmental monitoring. This approach is also being followed for the assessment of substances under the Biocidal Products Regulation.

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3 EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2017. Scientific Opinion on the investigation into experimental toxicological properties of plant protection products having a potential link to Parkinson's disease and childhood leukaemia. EFSA Journal 2017; 15(3):4691, 325 pp. doi:10.2903/j.efsa.2017.4691

4 https://www.efsa.europa.eu/en/events/event/171121-0

5 European Centre for Disease Prevention and Control. Risk assessment on the impact of environmental usage of triazoles on the development and spread of resistance to medical triazoles in Aspergillusspecies. Stockholm: ECDC; 2013.

6 Based on data from Eurostat on sales of substances in the group 'Fungicides based on imidazoles and triazoles'
https://appsso.eurostat.ec.europa.eu/nui/show.do?query=BOOKMARK_DS-382683_QID_249DC084_UID_-3F171EB0&layout=TIME,C,X,0;GEO,L,Y,0;PESTICID,L,Z,0;UNIT,L,Z,1;INDICATORS,C,Z,2;&zSelection=DS-382683PESTICID,F04;DS-382683UNIT,KG;DS-382683INDICATORS,OBS_FLAG;&rankName1=UNIT_1_2_-1_2&rankName2=PESTICID_1_2_-1_2&rankName3=INDICATORS_1_2_-1_2&rankName4=TIME_1_0_0_0&rankName5=GEO_1_2_0_1&sortC=ASC_-1_FIRST&rStp=&cStp=&rDCh=&cDCh=&rDM=true&cDM=true&footnes=false&empty=false&wai=false&time_mode=NONE&time_most_recent=false&lang=EN&cfo=%23%23%23%2C%23%23%23.%23%23%23

7 Expiry dates: Epoxiconazole – 30 April 2020; triflumizole – 30 June 2020; fenbuconzole – 30 April 2021; myclobutanil – 31 May 2021; etridiazole - 31 May 2021; fluquinconazole – 31 December 2021.

If evidence emerges about concerns from the particular use of specific substances, including from reviews carried out nationally such as the one in the Netherlands that you refer to in your letter, the Commission can at any time consider the need to review existing approvals (in accordance with Article 21 of Regulation (EC) No 1107/2009). I would therefore like to invite you to inform the Commission about the outcome of this review conducted by CTGB in particular in relation to particular active substances. Member States may in exceptional cases also apply the provisions of Article 50 of the Regulation (EC) 1107/2009 when evaluating an application for authorisation of a plant protection product not containing a candidate for substitution, if a non-chemical control or prevention method exists for the same use and it is in general use in that Member State. Lastly, if an urgent need for action is clearly identified, the provisions of Article 69 to 71 of the Regulation may be invoked to restrict or prohibit the use and/or sale of substances or products.

Article 55 of Regulation (EC) 1107/2009 provides that authorised plant protection products shall be used applying principles laid down in the Sustainable Use Directive 2009/128/EC[8] (SUD). In particular, plant protection products should be used according to Integrated Pest Management (Article 14 of SUD), i.e. priority shall be given to non-chemical methods, where possible. In line with these principles, the Commission is fostering low risk and biological pesticide usage to reduce the dependency from chemical pesticides, including azole-based fungicides. Furthermore, EU Framework Research programmes have funded more than 40 projects with focus on non-chemical substitutes to plant protection products or less risky crop protection practices.

Finally, I wish to recall that the European Green Deal aims at a more sustainable EU economy and provides for a series of actions in several policy areas, including the Farm to Fork Strategy to be adopted[9]. This Strategy will aim at making food systems more sustainable and will set ambitious targets for the reduction of the risks and use associated with chemical pesticides.

Yours sincerely,

5.1.2.e Woo

Cc.: Ms 5.1.2.e Woo (EFSA)
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[8] OJ L 309, 24.11.2009, p.71

[9] https://ec.europa.eu/food/farm2fork_en