



Brussels, 2 May 20

Guilhem de Sèze
Head of Risk assessment production department
European Food Safety Authority
Parma
Italy

Concerns: EFSA's scientific assessment of pesticides in greenhouses

Dear Guilhem de Sèze,

Regulation (EU) 1107/2009 on pesticides mentions that greenhouses are systems that prevent the release of pesticides into the environment (art.3(27)). As EFSA is aware, PAN Europe has initiated a legal procedure before the General Court of the EU on the reply from the European Commission to our Request for Internal review on the reapproval of abamectin.

PAN Europe would like to receive a series of clarifications on the work from EFSA regarding the use of pesticides in greenhouses, and abamectin in particular. Our investigations in the risk assessment of abamectin have led to many questions remaining unanswered.

In its Peer review from 2020 on abamectin, the EFSA has not run a risk assessment based on a representative use of 1 x 2.7 g a.s./ha on tomatoes and strawberries. Why not? Was this application rate part of the application rate from the representative uses submitted in the initial applicants' dossier? If yes, why are all application rates and representative uses not systematically risk assessed by EFSA?

The EFSA received in January 2022 a mandate by the European Commission (EFSA-Q-2022-00166) requesting the EFSA to produce a new peer review on Abamectin using an application rate of 1 x 2.7 g a.s./ha. Among the documents publicly available, PAN Europe has not found any exposure data provided by the applicants, on the basis of this application rate. In the same way, PAN Europe has not found any efficacy data for this substance, based on the 1 x 2.7 g a.s./ha. Both information are needed in the frame of the regulatory process. In the Technical assistance provided to the Commission on our Request for Internal Review, the EFSA mentions that Spain informed EFSA that it had assessed the efficacy at such a low application rate. We ask the EFSA to share with us any document in its possession related to exposure or efficacy at the above-mentioned application rate. We also ask you to share with us all exchanges you had with the European Commission, Spain and the Abamectin applicant, with regards to this application rate. We would like to further ask if it is a general practice, for EFSA to not verify itself if the announced application rate is efficient? In case the initial application rate from the dossier included 2.7 g/ha, why has EFSA not assessed the efficacy at this application rate in the

Pesticide Action Network Europe – Rue de la Pacification 67 – 1000 Brussels – Belgium

2020 peer review?

In its updated Renewal Assessment Report (RAR), the Rapporteur Member State (RMS), Austria, concluded a high risk for non-target arthropods. In the new Peer review 2022, the EFSA did not follow Austria's view as you consider that non-target arthropods are not exposed to pesticides in high-tech greenhouses (negligible exposure). Could the EFSA provide us with a document defining precisely what a high-tech greenhouse is? What are the technical specificities to define a greenhouse as "high-tech"? What is the level of leakage? Why are you considering the toxicity to aquatic organisms and not non-target arthropods or soil organisms? How does the EFSA justify that leakage could reach water bodies, but not soil for instance? Could you please provide us with a scientific document demonstrating that arthropod's exposure is negligible in greenhouses?

According to EFSA's 2014 guidance: 'For contamination of surface water, non-permanent greenhouses are considered as walk-in tunnels, therefore it is assumed that there will be emissions. The GD scenario appendix D, explains that for spray drift and drainage it is evaluated if toxicity exposure ratios < trigger values in a step-wise approach.' What are these trigger values?

In appendix D it is also mentioned that (Box on Example rose in average year in the Netherlands) "The yearly average water supply to the crop is 18m³/day (max = 45m³/day). The yearly average amount of drainage (= excess water supply) is 5 m³/day (max = 11m³/day). So, a dose of 1kg (applied on one day) would result in 0.2kg/m³ (200mg/L). for comparison: 5% drift in open field would result in 17µg/L (a factor of 10000 lower)." Do you confirm our understanding that drainage from greenhouses is expected to be higher from open fields by default?

In case of permanent greenhouses, what type of risks are considered to be addressed when the use of a pesticide is restricted to "permanent" structures? What exposures are considered negligible? If greenhouses are soil-less is it considered there will be no emissions to groundwater? How about air-emissions? Are these expected to be controlled via certified filtering of the ventilation during application?

What is the basis for the differentiation between high-tech and low-tech greenhouses? Could you please share with us any technical documents enabling to make a difference between one or the other?

Article 3(27) from Regulation (EU) defines a greenhouse as a closed system. The EFSA works outside this legal definition by differentiating high-tech and low-tech greenhouses but in no case 'closed systems'. When the European Commission restricts the re-approval of a pesticide to greenhouses, it even clarifies 'permanent greenhouses' (e.g. Regulation (EU) 2023/515 renewing the approval of abamectin) and specifies that it is a space where the release of pesticides is prevented. The EFSA seemingly does not understand a permanent greenhouse as a space preventing the release of pesticides into the environment as, for instance in the Peer review for Abamectin 2020, you claim 'a high risk was identified for walk-in tunnels uses for birds and mammals, aquatic invertebrates (for the metabolite 8-carboxy-6-hydroxy avermectin B1a in permanent greenhouses as well)', meaning that bird, mammals and aquatic invertebrates can be exposed even in the case a pesticide is used in a permanent greenhouse. How does EFSA explain that it uses similar denominations (permanent greenhouses) as the European Commission but that it gives a completely reverted definition: the Commission's is not leaking while EFSA's is leaking?

Do you confirm that, in your publications, a 'permanent greenhouse' is, what you call in your 2014 guidance document on greenhouses, a 'high tech' greenhouse?

Pesticide Action Network Europe – Rue de la Pacification 67 – 1000 Brussels – Belgium

www.pan-europe.info – info@pan-europe.info - +32 2 318 62 55

PAN Europe is of the opinion that EFSA and risk managers should use the same language, and that EFSA's work must be underpinned by solid scientific, technical and legal grounds. As in past letters, some questions raised were left unanswered in your replies, we have underlined the questions, for the sake of clarity. We thank you in advance for providing us precise and detailed answers to all questions.

Best regards,

Martin Dermine Executive Director