Pesticide Action Network Europe

To: members of the PAFF committee - Section “Phytopharmaceuticals - Residues”

Brussels, 20/11/2024

Subject: Request to ban residues of EU-banned isopyrazam, carbendazim, thiophanate-methyl and cyproconazole - EU Standing committee on Plants, Animals, Food and Feed - 25-26 November 2024

Dear members of the PAFF committee,

On 25-26 November, you are invited to the EU Standing Committee on Plants, Animals, Food and Feed to discuss and/or potentially adopt opinions on several proposals of the European Commission. With this letter, PAN Europe urges you to **reject the Commission’s proposal to maintain MRLs of the ‘cut-off’ substance isopyrazam** (B. 02)[1]. We also call on you to request the Commission to present new draft Regulations to **delete all the Maximum Residues Limits (MRLs) of carbendazim, thiophanate-methyl et cyproconazole** in line with the Parliament’s objections[2]. Residues of any substances meeting the ‘cut-off’ criteria of the Pesticide Regulation 1107/2009 should not be allowed in imported food products.

1. Isopyrazam

Isopyrazam was banned in the EU in 2022 following its classification as ‘toxic for reproduction’ category 1B under Regulation 1272/2008. In accordance with point 3.6.4 of Annex II of Regulation 1107/2009, citizens shall not be exposed to such harmful substances unless the level of exposure is negligible, which means that the substance is only used in closed systems resulting in no contact with humans and no detectable residues in food i.e. below the default value of 0.01 mg/kg or the relevant level of quantification (LOQ). The Commission’s proposal to maintain/increase the existing level of certain MRLs of isopyrazam based on Codex Maximum Residue Limits (CXLs) or derived from import tolerance disregards these requirements of Regulation 1107/2009. Instead of lowering the MRLs to the LOQ, it relies on EFSA's risk-based

[1] f4242394-1223-44f3-802b-1897699af83d_en
[2] Pesticides: No residues of EU-banned products in imported food | News | European Parliament

opinion which assumes that a safe exposure threshold can be determined. While creating an inconsistency between Regulation 396/2005 and Regulation 1107/2009, this risk-based approach does not ensure the high level of consumer protection required by Regulation 396/2005. The latter permits import tolerances only when substances are banned for non-health-related reasons (Article 3(2)(g) of Regulation 396/2005). Moreover, CXL values should be disregarded if they provide a lower level of protection than EU standards, as per Article 5(3) of Regulation 178/2002.

Moreover, isopyrazam belongs to the succinate dehydrogenase inhibitor (SDHi) fungicides, which inhibit SDH activity in the mitochondria of non-target species, including humans. Combined exposure can lead to synergistic effects[3]. Recent evidence indicates these substances are non-genotoxic carcinogens and isopyrazam is no exception[4]. Therefore the assumption of the European Chemical Agency that the tumours developed in rodents following exposure to isopyrazam were non-human relevant could be equivocal. EFSA's opinion assuming that a safe exposure threshold can be determined for certain 'reprotoxic' and carcinogenic substances does not ensure that adverse effects will not occur at lower levels, possibly *via* non-investigated endpoints or as a result of cumulative and synergetic effects. EFSA opinion about isopyrazam relies on an Acceptable Daily Intake (ADI) of 0.03 mg/kg bw per day based on the Lowest Observed Adverse Effect (LOAEL) of 5.5 mg/kg bw/day from the 2-year rat study and applying an increased uncertainty factor of 200; as well as on an Acute Reference Dose (ARfD) of 0.2 mg/kg bw: based on the NOAEL of 20 mg/kg bw/day for decreased maternal body weight gain in rats in the first days of dosing with an uncertainty factor of 100 applied. These toxicological values were set in 2012 and have not been reviewed since by EFSA based on new scientific literature regardless of the classification of isopyrazam as 'toxic for reproduction' category 1B. As a result, EFSA's approach appears insufficiently protective for consumers.

PAN Europe urges you to reject the Commission's proposal to maintain certain MRLs of the 'cut-off' substance isopyrazam (B. 02).

2. Carbendazim, thiophanate-methyl and cyproconazole

PAN Europe would like to draw your attention to a subject which worryingly is not on the agenda for the upcoming SCoPAFF meeting: the MRLs of carbendazim, thiophanate-methyl and cyproconazole following the European Parliament's adoption of two Regulations retained some MRLs for trade purposes for these three 'cut-off" substances. In its objections, the European Parliament called upon the Commission to withdraw its Regulations and propose the lowering of all MRLs for these three EU-banned substances. Carbendazim is classified as mutagenic category 1B and toxic for reproduction category 1B. Additionally, it is a breakdown product of

[3] Wu S, Lei L, et al 2018. Single and mixture toxicity of strobilurin and SDHI fungicides to Xenopus tropicalis embryos. *Ecotoxicol Environ Saf.* 30;153:8-15 https://doi.org/10.1016/j.ecoenv.2018.01.045

[4] Hospital CD, Tete A, et al 2023. SDHi fungicides: An example of mitotoxic pesticides targeting the succinate dehydrogenase complex *Environment International* 180: 198219 https://doi.org/10.1016/j.envint.2023.108219

thiophanate-methyl which EFSA identified as an endocrine disruptor for humans. Lastly, cyproconazole is classified as toxic for reproduction 1B.

These two Parliament's objections are in line with an earlier objection to the presence of thiacloprid residues in imported products from January 2024[5]. They signal a clear and repeated call by the European Parliament against these practices, which echo the Farm to Fork's commitment to eliminate double standards and drive the global transition towards a sustainable food system[6]. In accordance with Article 5a 3(c) of the Council Decision of 28 June 1999[7], the Commission cannot adopt its two objected Regulations. Since the existing MRLs were found to lead to harmful effects on consumers, the only way to comply with the requirement of Regulation 396/2005 to ensure a high level of protection for consumers is to lower all the MRLs for these substances, as asked by the European Parliament. We are nonetheless very concerned by the Commission's recent declaration that *"as a consequence of the European Parliament's objections, the Commission now cannot adopt the draft Regulations which means that the existing MRLs continue to apply"*[8]. This seems to be confirmed by the fact that these three substances are not on the agenda for the next SCoPAFF meeting. We therefore ask you to call on the Commission to submit proposals for a regulation lowering all MRLs for these three substances.

In particular, we would like to express our concerns about carbendazim, a mutagenic substance banned in the EU in 2014 for which no exposure level is permitted under Regulation 1107/2009. For this substance, EFSA established an ADI of 0.02 mg/kg bw per day and an ARfD of 0.02 mg/kg bw. These are based on a developmental toxicity study in rats, performed more than 30 years ago (NOAEL of 10 mg/kg), applying an uncertainty factor of 500 instead of the standard 100 -normally applied for approved substances. While EFSA claims this approach is "conservative", scientific literature reveals that carbendazim may have an impact on the gut microbiome and inflammation even at concentrations of 0.02 mg/kg of body weight[9], which is an endpoint that hasn't been taken into consideration by EFSA. This suggests a much lower ADI even by applying an extra uncertainty factor of 5. Moreover, it is important to note that the Joint Meeting on Pesticide Residues (JMPR) disagrees with EFSA regarding carbendazim. Its WHO Core Assessment Group decided to withdraw the existing ADI and ARfD, which were established almost 30 years ago following two insufficient attempts to re-evaluate carbendazim due to insufficient data for toxicological assessment. This only reinforces concerns about the soundness of EFSA's assessment.

PAN Europe urges you to request the Commission to lower all the MRLs of carbendazim, thiophanate-methyl and cyproconazole to the relevant LOQ.

[5] Objection to an implementing act: Maximum residue levels for thiacloprid - 17 January 2024
[6] EUR-Lex - 52020DC0381 - EN - EUR-Lex
[7] EUR-Lex - 01999D0468-20060723 - EN - EUR-Lex
[8] 23 - 24 September 2024 - Summary report - SCoPAFF – Pesticide Residues
[9] C. Jin *et al*, Insights into a Possible Mechanism Underlying the Connection of Carbendazim-Induced Lipid Metabolism Disorder and Gut Microbiota Dysbiosis in Mice, Toxicological Sciences, Volume 166, Issue 2, December 2018, Pages 382–393, https://doi.org/10.1093/toxsci/kfy205

More broadly, we ask you to engage in discussions with the Commission to ensure that the lowering of all MRLs becomes the standard procedure once a substance that is hazardous to human health is banned. Allowing residues of such substances in food not only poses a potential health risk to European consumers but also implicitly endorses their agricultural use in third countries. This practice exposes farmers, agricultural local communities, and their families to known health risks. Such an unethical double standard must be urgently addressed and eliminated.

Sincerely yours,

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