Pesticide Action Network Europe

To: Ms. Sandra Gallina
Director-General
Directorate-General for Health and Food Safety (SANTE)
European Commission

Brussels, 21/11/2024

Subject: Request to ban residues of EU-banned and hazardous pesticides in EU imported food

Dear Ms. Sandra Gallina,

With this letter, PAN Europe wishes to follow up on our communication from April 2024[1] and express its profound concerns regarding the European Commission's ongoing practice of permitting residues of hazardous pesticides -banned within the EU- in imported food products. Specifically, we regret to see that no new proposal to delete all the Maximum Residue Limits (MRLs) for carbendazim, thiophanate-methyl, and cyproconazole has been included on the agenda for the upcoming Standing Committee of Plants, Animals Food and Feed (PAFF) meeting on Pesticide Residues (25-26 November), despite the objections from the European Parliament.

In light of this, we urge the Commission to take decisive action by proposing new draft regulations to eliminate these MRLs. Furthermore, **we reiterate our call for the Commission to end these unfair trade practices, which compromise the health of European consumers and citizens in third countries. Addressing these issues must be a cornerstone of the new EU Vision for Agriculture and Food**.

On 18 September 2024, the European Parliament overwhelmingly adopted two resolutions[2] opposing two Commission Regulations that, while aiming to lower most MRLs for carbendazim, thiophanate-methyl, and cyproconazole, retained certain MRLs for trade purposes. This is concerning since these three substances are no longer approved in the EU due to their significant health hazards. Their ban aims to protect not only farmers but also European citizens and consumers, particularly vulnerable groups, such as pregnant women, infants, and children.

[1] PAN Europe letter to Health Commissioner Kyriakides “Call for a ban on hazardous pesticides and their residues in European food products:thiacloprid and other reprotoxic pesticides” 9 April 2024
[2] Pesticides: No residues of EU-banned products in imported food | News | European Parliament

Carbendazim is classified as mutagenic category 1B and toxic for reproduction category 1B; it was banned in 2014, meaning MRLs should have been deleted nearly a decade ago. Additionally, it is a breakdown product of the next substance, thiophanate-methyl, which EFSA identified as an endocrine disruptor for humans. Lastly, cyproconazole is classified as toxic for reproduction 1B. In its objections, the European Parliament called upon the Commission to "*submit a new draft regulation to the committee lowering all MRLs for carbendazim and thiophanate-methyl [and cyproconazole] to the limit of determination or the default value of 0,01 mg/kg for all uses and to refuse any requests for import tolerances*"[3]. These two objections are in line with an earlier objection regarding the presence of thiacloprid residues in imported products from January 2024[4]. They signal a clear and repeated stand by the European Parliament against these double standards.

Under Article 5a, 3(c) of the Council Decision of 28 June 1999[5], the Commission cannot adopt the two objected Regulations. Consequently, the only path consistent with the requirement of the MRL Regulation 396/2005 to ensure a high level of protection for consumers is to lower all the MRLs for these substances, as requested by the European Parliament. We are, however, alarmed by the Commission's recent statement 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"*[6]. This seems to be confirmed by the fact that these three substances are not on the next SCoPAFF meeting agenda. This situation is unacceptable since the existing MRLs were found to pose a health risk for European consumers.

While the two objected Regulations aimed to partly address, even with delay, European consumers' protection, they fell short of the high standards required by Regulations 396/2005 and 1107/2009. Allowing certain MRLs for trade purposes based on import tolerance requests or Codex Maximum Residue Limits (CXLs) is not justified, as these pesticides were banned in the EU precisely due to health risks. Since the Pesticide Regulation 1107/2009 took effect in 2011, the EU has upheld a "negligible exposure" principle for substances meeting the 'cut-off criteria' for human health (i.e. no detectable residues or contact with humans)[7], except for mutagenic substances for which no exposure is tolerated[8]. EU citizens rightfully expect protection from these substances. Yet the Commission's Regulations were based on the view that EFSA can set safe thresholds for exposure to substances meeting the 'cut-off' criteria of Regulation 1107/2009, even for substances classified as mutagenic. PAN Europe strongly disagrees with this risk-based approach which, while creating an inconsistency between Regulation 396/2005 and Regulation 1107/2009, 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); therefore, tolerances for

[3] Objection to an implementing act: Maximum residue levels for carbendazim and thiophanate-methyl - 18 September 2024 (pt 4).
Objection to an implementing act: Maximum residue levels for cyproconazole - 18 September 2024 (pt 4).
[4] Objection to an implementing act: Maximum residue levels for thiacloprid - 17 January 2024
[5] EUR-Lex - 01999D0468-20060723 - EN - EUR-Lex
[6] 23 - 24 September 2024 - Summary report - SCoPAFF – Pesticide Residues
[7] Points 3.6.3 to 3.6.5 of Annex II of Regulation 1107/2009.
[8] Point 3.6.2 of Annex II of Regulation 1107/2009.

substances like carbendazim, thiophanate-methyl, and cyproconazole violate this standard. 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.

The Commission's decision to disregard the requirements of Regulation 1107/2009, relying instead on EFSA's opinion that a safe exposure threshold can be determined for certain mutagenic or other 'cut-off' substances, fails to provide adequate protection. Indeed, it 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 of combined substances. This is demonstrated by the case of carbendazim. For this substance, EFSA established an acceptable daily intake (ADI) of 0.02 mg/kg bw per day and an acute reference dose (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 100 -which is 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) appears to disagree with EFSA regarding carbendazim. Its WHO Core Assessment Group decided in 2023 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[10]. This only reinforces concerns about the soundness of EFSA's assessment.

Last, we would like to highlight the commitment of the EU Fark to Fork Strategy to eliminate double standards and drive the global transition towards a sustainable food system[11].

We trust that these pressing issues will receive your immediate attention and request a meeting to discuss this matter further. We look forward to hearing how your services plan to address these critical concerns.

Sincerely yours,

Angeliki Lysimachou
Head of Science and Policy
Pesticide Action Network (PAN) Europe

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[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

[10] FAO & WHO. 2024. Report 2023: Pesticide residues in food – Joint FAO/WHO Meeting on Pesticide Residues. Rome. https://doi.org/10.4060/cc9755en

[11] EUR-Lex - 52020DC0381 - EN - EUR-Lex