

BRUSSELS, 10 MAY 2021

To: Manuela Taramani, Head of Pesticides Peer Review Unit, European Food Safety Agency (EFSA)

Re: Peer-review status of several pesticide active substances, including endocrine disruption assessment

Dear Mrs Taramani,

On behalf of the Health and Environment Alliance (HEAL), Alerte des Médecins sur les Pesticides (AMLP) and Générations Futures, we are contacting you to inquire about the peer-review status of several pesticide active substances currently under assessment, and for which publicly available information is unclear.

Those substances – **Cyprodinil, Fenbuconazole, Mepanipyrim, Spinosad, Ziram, Pyrimethanil** – are potentially of concern for endocrine disruption, in particular for thyroid disruption. According to a 2013 EFSA report, those substances affect thyroid signaling [1], and they are also among the substances regularly found in food according to several French ANSES studies [2].

We understand that for pesticide active substances, of which the assessment started before the 2018 entry into force of the scientific criteria for the identification of endocrine disruptors (thereafter ED criteria), EFSA has requested additional information from applicants and that this information is being assessed as part of the peer-review process. We therefore assume that this is the situation those six substances fall in.

According to Regulation 844/2012 on the renewal procedure of pesticide active substances, the application (Article 5), supplementary summary dossier (Article 8.4) as well as the draft renewal assessment report and updated supplementary dossier following the assessment by the Rapporteur Member State (Article 12.2 and 12.4) shall be made available to the public by EFSA upon receipt. This is key to ensure transparency in the procedure.

At the time of writing however, no information is publicly available in relation to the assessment of the potential for endocrine disruption of these six substances, which prevents adequate scrutiny on how such assessment is being carried out.

The assessments of these substances started long before the entry into force of the ED criteria and should be well advanced at the time of writing – as illustrated by the upcoming expiry of the approvals for some of them, or multiple administrative extensions thereof. This is also confirmed by a recent analysis of the six renewal assessment reports of these substances by AMLP and Générations Futures [3].

Therefore, we would like to request more information about the case status of the six substances mentioned above. More specifically:

- **Cyprodinil:** the current approval expiry appears to be 30th April 2022. We understand that EFSA requested additional information from the applicant in 2019 and that the peer-review process was due to be finalized in January 2021. However, the latter process does not appear to be finalized at the time of writing and no information relating to the assessment of potential endocrine disruption is publicly available.

- **Fenbuconazole:** the current approval was due to expire on 30th April 2021 and we have not found indications of the granting of an administrative extension. This would suggest that this substance is no longer authorized in the EU. We have not found any recent information about a public consultation and the peer-review. Therefore, we would like to understand whether an assessment is currently ongoing, whether it has stopped, or whether an earlier application might potentially have been withdrawn.
- **Mepanipyrim:** the current approval is due to expire on 30th April 2022. For this substance, we understand that data gaps on endocrine disruption were already identified early in the process in 2017 and that further data requests were sent to the applicant in 2019, with a deadline early in 2021. It is however unclear whether the deadline for data provision has been met, what information (if any) has been submitted and at which stage the overall assessment currently is.
- **Spinosad:** the current approval is due to expire on 30th April 2022. As is the case for Mepanipyrim, we understand that additional data have been requested in 2019 with deadline early 2021. The same unclarities about the state of the peer-review process exist.
- **Ziram:** the current approval is due to expire on 30th April 2022. We understand that requests for additional data were sent to the applicant following the adoption of the ED criteria. The status of the data provision and the peer-review is however unclear.
- **Pyrimethanil:** the current approval is due to expire on 30th April 2022. As in the above case, we understand that additional data have been requested from applicants following the adoption of the ED criteria and some of these studies are available from the EFSA register of questions. It remains unclear how much data is still yet to be provided, by when and the overall status of the peer-review process.

With the recent entry into force of the Transparency Regulation, we expect that all such information relating to EFSA's exchanges with applicants about potential data gaps in the renewal dossiers, the studies in the initial dossiers and further information received throughout the process, as well as status of the peer-review should be made available for the public to see on the EFSA website and easy to find.

We look forward to your responses on the status of the assessments of those six substances. We would also be grateful for your indications about ways for civil society organisations and interested stakeholders to access up-to-date and accurate information about the status of the application and renewal processes of pesticide active substances.

Yours sincerely,



Natacha Cingotti
Programme Lead, Health and Chemicals
Health and Environment Alliance (HEAL)

On behalf of Alerte des Médecins sur les Pesticides and Générations Futures

References

[1] EFSA, Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile¹, in EFSA Journal 2013;11(7):3293. 2013

[2] ANSES, Etude de l'alimentation totale (EAT) et Etude de l'alimentation totale infantile (EATi)

[3] AMLP, Générations Futures, Perturbateurs Endocriniens, il est temps d'agir, March 2021, https://alerte-medecins-pesticides.fr/wp-content/uploads/2021/04/2021-04-09-22h55_RAPPORT-THYROIDE.pdf

The Health and Environment Alliance (HEAL) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health.

HEAL's over 70 member organisations include international, European, national and local groups of health professionals, not-for-profit health insurers, patients, citizens, women, youth, and environmental experts representing over 200 million people across the 53 countries of the WHO European Region.

As an alliance, HEAL brings independent and expert evidence from the health community to EU and global decision-making processes to inspire disease prevention and to promote a toxic-free, low-carbon, fair and healthy future.

HEAL's EU Transparency Register Number: 00723343929-96