



PESTICIDE PEER REVIEW UNIT

Ref. MT/ss (2021) – OC-2021-24806769

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

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

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

Ref. Your letter dated 10 May 2021

Dear Ms Cingotti,

thank you for your letter sent on behalf of *HEAL*, *AML*P and *Générations Futures*, inquiring about the status of the peer-review of several pesticide active substances, namely on: **Cyprodinil**, **Fenbuconazole**, **Mepanipyrim**, **Spinosad**, **Ziram** and **Pyrimethanil**.

The new scientific criteria for the determination of endocrine disrupting properties, as laid down in Commission Regulation (EU) 2018/605¹, are applicable from 10 November 2018 onwards. The Regulation also foresees that the new criteria are also applicable to ongoing applications (i.e. for which a decision on approval or renewal of approval has been pending on 10 November 2018).

As you rightly pointed out in your letter, the peer review of these substances had started before the entry into force of the Regulation (EU) 2018/605, which sets out scientific criteria for the determination of endocrine disrupting properties. When this Regulation came into force, for the substances where the renewal peer review was already completed, the European Commission asked EFSA to complement the work carried out during the peer reviews by performing additional assessments, in line with the EFSA/ECHA (2018) Guidance for the identification of endocrine disruptors.

As outcome of that exercise, the need for additional data was identified and hence new data were requested to the applicants leading to 'clock stop' provisions to allow them to produce and submit to EFSA such data. This is why the scientific assessment of these substances is not fully finalised.

With regards to the substances you have identified, for two of them (Mepanipyrim; Spinosad) the peer review conclusions from the renewal were already issued before the new criteria entered into force and therefore EFSA was mandated to perform an additional endocrine assessment in line with the new scientific criteria. Fenbuconazole is no longer approved in the EU. For the three remaining substances (Cyprodinil, Ziram, Pyrimethanil) the peer review conclusions are not yet available, for the reasons briefly outlined above.

Cyprodinil:

The peer review for the substance cyprodinil was already in an advanced stage at the time of entry into force of the above-mentioned Regulation, while an assessment of the endocrine disrupting potential in line with the new criteria was not available. Therefore, as requested by the European

¹ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

Commission, EFSA performed an assessment in line with the EFSA/ECHA (2018) Guidance²: following an expert consultation held in May 2019, EFSA requested additional information from the applicant in June 2019 to complete the data package. For this reason, the substance is currently under 'clock stop', in accordance with the provisions of Article 13(3a) of Commission Regulation (EU) No 844/2012, as amended by Commission Regulation (EU) 2018/1659. The peer review will resume following submission of the additional information by the applicant (deadline for submission: 07/12/2021).

Fenbuconazole:

Fenbuconazole is no longer an approved active substance within the EU (expiry of approval: 30/04/2021). According to the European Commission Implementing Regulation (EU) 2018/155, Slovenia was appointed as rapporteur Member State for the renewal process, however no application was submitted for this active substance by the applicant by the legislative deadline of 30 April 2018 and, consequently, no renewal process was commenced. Accordingly, no documents are available on the EFSA website.

Mepanipyrim:

The EFSA Conclusion following the peer review of the renewal process on mepanipyrim was issued before the applicability of the new scientific criteria as laid down in Commission Regulation (EU) 2018/605. In January 2019 the European Commission mandated EFSA to update the assessment on the endocrine disrupting properties of the substance: following an expert consultation held in July 2019, EFSA requested additional information from the applicant in August 2019 to complete the data package and therefore the substance is currently under 'clock stop'. The peer review will resume following submission of the additional information by the applicant.

Spinosad:

The EFSA peer review conclusions on the active substance spinosad were issued before the applicability of the new scientific criteria as laid down in Commission Regulation (EU) 2018/605. In January 2019 the European Commission mandated EFSA to update the assessment on the endocrine disrupting properties of the substance, in accordance with the new scientific criteria: following an expert consultation held in July 2019, EFSA requested additional information from the applicant in August 2019 to complete the data package and therefore the substance is currently under 'clock stop'. The peer review will resume following submission of the additional information by the applicant

Ziram:

The peer review for the active substance ziram is not yet completed. Indeed, following the Pesticide Peer Review Experts' meetings held in April and June 2019, EFSA requested additional information from the applicant in July 2019 to complete the data package on the endocrine disruption potential in line with the new scientific criteria and therefore the substance is currently under 'clock stop'. The peer review will resume following submission of the additional information by the applicant

Pyrimethanil:

The peer review for the active substance pyrimethanil is not yet completed. Indeed, following the Pesticide Peer Review Experts' meetings held in November 2019, EFSA requested additional information from the applicant in December 2019 to complete the data package on the endocrine disruption potential in line with the new scientific criteria and therefore the substance is currently under 'clock stop'. The peer review will resume following submission of the additional information by the applicant.

Please find in the Annex 1 a more detailed list of information for each substance, including the links to the relevant documents.

² ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311,135 pp. <https://doi.org/10.2903/j.efsa.2018.5311>. ECHA-18-G-01-EN.

We trust that the above information replies to your questions and may better clarify the status of the risk assessments of these six substances.

I'd like to use this opportunity to also address an aspect raised at the end of your letter about transparency and access to EFSA information. A topic to which EFSA attaches great importance and attention.

We appreciate the growing citizens' and civil society's demands to access all information relating to EFSA's scientific work and we do support the release of as much as possible information related to any of the dossiers under EFSA's scientific responsibility.

The **Transparency Regulation**³ (TR), introduced new EU rules that, as you point out, will allow citizens to follow every step of EFSA's work more closely and promptly, through tools and channels that provide an open window on the scientific assessment process. All documents produced and used in the risk assessment process, including all non-confidential data, will be easily accessible via the [Open EFSA portal](#).

The TR gives EFSA a new legal framework, allowing the Authority for greater transparency. And we are grateful to the European Parliament, to the European Commission and to the EU Member States for amending the regulation ruling our work.

However, it is important to be aware of the fact that **the provisions of the TR apply as of 27 March 2021** and cannot be implemented retroactively. This means that there will be a transitioning period during which the dossiers that started before 27 March 2021 will continue to be carried out under the previous rules and legal provisions.

This comprises several active substances, including the ones indicated in your letter, that fall under **Regulation (EU) 844/2012** on the renewal procedure of pesticide active substances.

As public regulatory body, EFSA is legally required to ensure its work is carried in respect to the applying laws. Therefore, in accordance with the provisions of Regulation (EU) 844/2012, EFSA is making publicly available: the application; the supplementary summary dossier (and/or its updates if available); as well as the draft renewal assessment report prepared by the Rapporteur Member State.

We appreciate your understanding and support in this transitional period.

Yours sincerely,



European Food Safety Authority
Digitally signed by: Manuela Tiramani
DN: CN = Manuela Tiramani email =
manuela.tiramani@efsa.europa.eu C
= IT O = EFSA OU = Pesticide Peer
Review Unit (PREV)
Date: 2021.05.31 17:28:53 +01'00'

Manuela Tiramani

cc: Tunde Molnar – Pesticide Peer Review unit

Victoria Villamar, Flavio Fergnani – Engagement and Cooperation unit

Encl: Annex 1

³ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC. OJ L 231, 6.9.2019, p. 1–28.

Annex 1

Active substance	Peer review before 10 Nov 2018 /Conclusion	ED assessment	Experts meeting	Outcome	Expected resumption of peer review	Relevant documents OpenEFSA
Cyprodinil	EFSA Conclusion 2005 EFSA Conclusion following the peer review of the renewal process not yet available. Peer review process still ongoing.	No mandate received. The peer review process on the renewal of approval was already in an advanced stage at the time of entry into force of the Regulation 2018/605. EFSA performed the ED assessment in line with the EFSA/ECHA (2018) Guidance during the peer review.	May 2019	Additional data requested 'Clock stop'	Deadline for submission of the additional information by the applicant: 07/12/2021	<ul style="list-style-type: none"> • application, supplementary summary dossier, cover letter of EFSA's request for additional information: available on the OpenEFSA portal, under the scientific evidences inventory under EFSA-Q-2015-00580 (pages 1-2)⁴ • draft renewal assessment report prepared by the rapporteur Member State
Fenbuconazole	EFSA Conclusion 2010 An EFSA Conclusion from the renewal process is not available. No renewal process is taking place ⁵ .	N/A No longer approved active substance within the EU (expiry of approval: 30/04/2021).	N/A	N/A	N/A	None related to the renewal.
Mepanipyrim	EFSA Conclusion following the peer review of the renewal process was issued on 12 May 2017 (EFSA Journal 2017:15(6):4852)	EC mandate received in January 2019 to update the ED assessment in accordance with the new scientific criteria and to deliver an	July 2019	Additional data requested 'Clock stop'	Deadline for submission of the additional information by the applicant: 09/02/2022	<ul style="list-style-type: none"> • The endocrine assessment performed by EFSA will be published at the end of the process as background document to the updated Conclusion. • EC mandate and the cover letter of EFSA's request for additional information are available on the OpenEFSA portal, under the

⁴ Under EFSA-Q-2015-00580: Request for an EFSA peer review (EFSA Conclusion) on the active substance cyprodinil according to Article 13 of Regulation (EU) No 844/2012

⁵ According to Commission Implementing Regulation (EU) 2018/155, Slovenia was appointed as rapporteur Member State for the renewal process, however no application was submitted for this active substance by the applicant by the legislative deadline of 30 April 2018 and, consequently, no renewal process was commenced.

Active substance	Peer review before 10 Nov 2018 /Conclusion	ED assessment	Experts meeting	Outcome	Expected resumption of peer review	Relevant documents OpenEFSa
		updated Conclusion.				<p>Scientific evidences inventory for EFSA-Q-2019-00024⁶.</p> <ul style="list-style-type: none"> The background documents to the EFSA Conclusion finalized on 12 May 2017 (i.e. the Peer Review Report and the final renewal assessment report prepared by the rapporteur Member State), the application and summary dossier are available on the OpenEFSa portal, under the Scientific evidences inventory for EFSA-Q-2014-00834⁷.
Spinosad	EFSA Conclusion following the peer review of the renewal process was issued on 28 March 2018 (EFSA Journal 2018;16(5):5252)	EC mandate received in January 2019 to update the ED assessment in accordance with the new scientific criteria and to deliver an updated Conclusion.	July 2019	Additional data requested 'Clock stop'	Deadline for submission of the additional information by the applicant: 09/02/2022	<ul style="list-style-type: none"> The endocrine assessment performed by EFSA will be published at the end of the process as background document to the updated Conclusion. The EC mandate and the cover letter of EFSA's request for additional information are available on the OpenEFSa portal, under the Scientific evidences inventory for EFSA-Q-2019-00026⁸. The background documents to the EFSA Conclusion finalized on 28 March 2018 (i.e. the Peer Review Report and the final renewal assessment report prepared by the rapporteur Member State), the application and summary dossier are available on the OpenEFSa portal, under the Scientific evidences inventory for EFSA-Q-2015-00632⁹.
Ziram	EFSA Conclusion following the peer review of the renewal process not yet available.	No mandate received. ED assessment was performed by the RMS in line with the	April and June 2019	Additional data requested 'Clock stop'	Deadline for submission of the additional information by the applicant: 10/01/2022	<ul style="list-style-type: none"> The background documents (i.e. Peer Review Report and final renewal assessment report including the ED assessment) will be published together with the EFSA Conclusion at the end of the peer review.

⁶ Under EFSA-Q-2019-00024: Request to EFSA to update the assessments concerning the endocrine disrupting properties in line with Commission Regulation (EU) 2018/605 for mepanipyrim.

⁷ Under EFSA-Q-2014-00834: Request for an EFSA peer review (EFSA Conclusion) on the active substance mepanipyrim according to Article 13 of Regulation (EU) No 844/2012.

⁸ Under EFSA-Q-2019-00026: Request to EFSA to update the assessments concerning the endocrine disrupting properties in line with Commission Regulation (EU) 2018/605 for Spinosad.

⁹ Under EFSA-Q-2015-00632: Request for an EFSA peer review (EFSA Conclusion) on the active substance spinosad according to Article 13 of Regulation (EU) No 844/2012.

Active substance	Peer review before 10 Nov 2018 /Conclusion	ED assessment	Experts meeting	Outcome	Expected resumption of peer review	Relevant documents OpenEFSA
	Peer review process still ongoing.	EFSA/ECHA (2018) Guidance and considered during the peer review.				<ul style="list-style-type: none"> the cover letter of EFSA's request for additional information, the application and summary dossier are available on the OpenEFSA portal, under the Scientific evidences inventory for EFSA-Q-2018-00109¹⁰ (pages 1-3) draft renewal assessment report prepared by the rapporteur Member State
Pyrimethanil	EFSA Conclusion 2006 EFSA Conclusion following the peer review of the renewal process not yet available. Peer review process still ongoing.	No mandate received. ED assessment was performed by the RMS in line with the EFSA/ECHA (2018) Guidance and considered during the peer review.	November 2019	Additional data requested 'Clock stop'	Deadline for submission of the additional information by the applicant: 16/06/2022	<ul style="list-style-type: none"> the cover letters of EFSA's request for additional information and the summary dossier are available on the OpenEFSA portal, under the Scientific evidences inventory for EFSA-Q-2018-00827¹¹ draft renewal assessment report prepared by the rapporteur Member State

¹⁰ Under EFSA-Q-2018-00109: Request for an updated EFSA peer review (EFSA Conclusion) on the active substance ziram according to Article 13 of Regulation (EU) No 844/2012

¹¹ Under EFSA-Q-2018-00827: Request for an updated EFSA peer review (EFSA Conclusion) on the active substance pyrimethanil according to Article 13 of Regulation (EU) No 844/2012.