Call for expressions of interest to submit data for 10 non-approved active substances to review MRLs

Published:06/03/2024
Deadline for submission of interest:7/05/2024
Deadline for submission of data (after confirmation of interest): 08/07/2024

Background

In 2022, the European Commission (EC) submitted a request to the European Food Safety Authority (EFSA), in accordance with Article 43 of Regulation (EC) No 396/2005, to provide a targeted review of maximum residue levels (MRLs) for the following non-approved active substances: azocyclotin, bifenthrin, chlorfenapyr, cyhexatin, diazinon[1], dicofol, endosulfan, fenarimol, fenpropathrin and profenofos (mandate number M-2022-00116).

In 2023, EFSA published the related reasoned opinions, where it was concluded that, for all but one of the substances (chlorfenapyr), the existing toxicological reference values (TRVs) were no longer appropriate.

Following the discussions with Member States in the Standing Committee meeting on Plants, Animals, Food and Feed, section Phytopharmaceuticals – Pesticides residues – held between 18th and 19th of September and 20th and 21st of November 2023, it was concluded that an additional stakeholder consultation step was needed, in order to provide the applicants with the opportunity to submit additional existing data (complying with existing most recent data requirements) to support the TRVs evaluation.

Therefore, in February 2024, Commission requested EFSA (mandate number M-2023-00161) to carry out an additional stakeholder consultation step for the abovementioned reasoned opinions, in order to investigate whether additional data are available.

Overall objective

EFSA is launching **a call for expressing interest** to provide additional existing toxicological data not considered in the targeted reviews listed below and

[1] Diazinon is still approved for veterinary uses: MRLs for diazinon are set in Regulation (EU) 37/2010

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addressing the data gaps identified. It is noted that only studies finalised by the date of launch of this call of interest and complying with existing (most recent) data requirements, will be considered eligible for the assessment.

1. Azocyclotin and cyhexatin, EFSA Journal 2023;21(6):8038 https://www.efsa.europa.eu/en/efsajournal/pub/8038
2. Bifenthrin, EFSA Journal 2023;21(3):7864 https://www.efsa.europa.eu/en/efsajournal/pub/7864
3. Chlorfenapyr, EFSA Journal 2023;21(12):8444 https://www.efsa.europa.eu/en/efsajournal/pub/8444
4. Diazinon, EFSA Journal 2023;21:8426 https://www.efsa.europa.eu/en/efsajournal/pub/8426
5. Dicofol, EFSA Journal 2023;21:8425 https://www.efsa.europa.eu/en/efsajournal/pub/8425
6. Endosulfan, EFSA Journal 2023;21(7):8114 https://www.efsa.europa.eu/en/efsajournal/pub/8114
7. Fenarimol, EFSA Journal 2023;21(7):8113 https://www.efsa.europa.eu/en/efsajournal/pub/8113
8. Fenpropathrin, EFSA Journal 2023;21(6):8057 https://www.efsa.europa.eu/en/efsajournal/pub/8057
9. Profenofos, EFSA Journal 2023;21:8445 https://www.efsa.europa.eu/en/efsajournal/pub/8445

The data owner/data provider should inform EFSA on the availability of additional existing toxicological data by compiling the survey here provided:

https://ec.europa.eu/eusurvey/runner/interest_NA_activesubstances

The data owner/data provider that expressed interest in submitting data, will be invited by EFSA to submit the concerned data in a follow up step, after closure of this consultation.

Deadline for submission

Interest in providing data should exclusively be expressed via completion of the survey provided by EFSA. The survey must be submitted by **7 May 2024.**