Next update: 27 March 2024

Overview of the MRL review progress under Article 12 of Regulation (EC) No 396/2005

The current document presents the status of the Maximum Residues Levels (MRL) reviews (ongoing and upcoming) under Article 12 of Regulation (EC) No 396/2005. In order to improve the communication with the interested parties, EFSA is publishing the detailed work programme (progress report) to allow stakeholders to better prepare and support the MRL review. The document will be updated on a **quarterly** basis and published on the EFSA website.

This document focusses on the substances under the 'new' procedure agreed with Commission and Member States at the Pesticide Steering Network (PSN) meeting in June 2014 and modified at the **Pesticide Steering Network meeting in November 2019** (see Art.12 MRL work instructions). All substances that were assessed under the 'interim' procedure have been finalised and are not included in this report. With the **new procedure** EFSA starts the process by launching a call for data and coordinates the activities of the RMS, Member States (MSs) and the UK[1] in collecting authorised good agricultural practices (GAPs) and residue trials.

The Article 12 MRL review in parallel with renewal peer review (**combined** assessment) procedure considers substances for which the Art.12 review has not been conducted and that are currently temporarily included in Annex IV or for which the Annex IV inclusion is pending. In order to optimise resources (for both EFSA and MSs), in agreement with DG SANTE and MSs (presented at September 2019 PAFF) EFSA is launching the GAP collection of all authorised uses in parallel to the peer review for the renewal. Once all GAPs have been collected, it can be evaluated if the data submitted to support the representative use(s) cover all authorised uses and import tolerances and thus the EFSA Conclusion could also address the Art.12 question number. This will avoid re-visiting the substance for the MRL review based on the same data package as assessed during the peer review. In case the GAP collection results in authorised GAPs that cannot be assessed based on the data submitted for renewal of a given active substance, the MRL review will not continue and will stay on hold until the renewal process is concluded. This proposal is therefore not creating unnecessary additional work for the RMS, as the only step is the GAP collection and there is no need to prepare an evaluation report.

Furthermore, for some active substances, it is agreed with the RMS and DG SANTE that a full MRL review procedure is not any longer considered necessary and the MRL review can be covered by a **statement**.

Finally, it is underlined that the work plan published as part of the June 2014 Pesticides Steering Network (PSN) minutes (Appendix B.2 and B.3 to the Minutes of the 1st meeting on the MRLs procedures) should be considered superseded by this document.

When looking at the progress report, the following information should also be taken into account:

- Dates reported in the cells correspond to the starting and **foreseen dates to complete the assessment**.

[1] The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and in particular with the Protocol on IE/NI, the EU requirements on data reporting are also applicable to NI.

- **The report includes** the **active substances** expected to be assessed under the **new procedure, the combined assessment or closed by a statement.** It is noted that for some active substances the process is reported as "**Combined/New**". Specifically, for these substances the GAP collection was started under the combined assessment but the MRL review could not be closed during the renewal and will resume when renewal procedure is finalised.
- **Completed** reviews finalised under the former and the interim processes as well as finalised statements comprising of active substances that do not require a review of the existing MRLs under Art 12 of Regulation (EC) No 396/2005 are not included in this report; the finalised Reasoned Opinions for these old reviews as well as the statements can be retrieved from the EFSA website.
- Re-prioritisation of some substances is possible and will be decided in collaboration with DG SANTE and Member States taking into account ongoing or upcoming assessments under other procedures (i.e. renewal, confirmatory data following the approval).
- EFSA may need to await the outcome of another assessment before proceeding with the MRL review for a certain active substance (renewal of approval, confirmatory data for the approval). Therefore, for certain substances no starting date is indicated, and it is mentioned 'to be defined' in the below overview table.
- The publication of an output is expected generally within 4 weeks from its adoption.
- Details on the different steps of the process are available in the Art.12 MRL work instructions.

Active Substance		RMS	Process	Start of data collection	Approval of the RO (expected date)	Comment
1.	**Azadirachtin**	DE	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that has not started yet. The approval of this a.s. will expire on 31/08/2024.
2.	***Bacillus thuringiensis* subsp. *Aizawai* (ABTS-1857 and GC-91)**	NL	Combined/New	to be defined	to be defined	The approval of this a.s. has been renewed and it will expire on 30/06/2038. The MRL review is pending the submission of further data regarding the density decline of Bt concentration after application, and for storage stability data (Commission implementing Regulation (EU) 2023/998).
3.	***Bacillus thuringiensis* subsp. *Israelensis* (serotype H-14), AM65-52**	SE	Combined/New	to be defined	to be defined	The approval of this a.s. has been renewed and it will expire on 30/06/2038. The MRL review is pending the submission of further data regarding the density decline of Bt concentration after application, and for storage stability data (Commission implementing Regulation (EU) 2023/998).
4.	***Bacillus thuringiensis* subsp. *Kurstaki* (ABTS 351, PB 54, SA 11, SA 12 and EG 2348)**	DK	Combined/New	to be defined	to be defined	The approval of this a.s. has been renewed and it will expire on 30/06/2038. The MRL review is pending the submission of further data regarding the density decline of Bt concentration after application, and for storage stability data (Commission implementing Regulation (EU) 2023/998).
5.	**Clofentezine**	ES	New	15/09/2024	15/09/2025	The approval of this a.s. was not renewed (it expired on 11/11/2023). The MRL review will focus only on import tolerances and Codex MRLs.
6.	**Clopyralid**	FI	New	15/09/2024	15/09/2025	The approval of this a.s. will expire on 30/09/2036. The launch of the Art.12 MRL review initially planned for 16/08/2023 has been postponed due to the re-registration of uses still ongoing in several MSs.
7.	**Dicamba**	DK	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that is currently on clock-stop (clock-stop was expected until 17/04/2022). The approval of this a.s. will expire on 31/03/2027.

Active Substance		RMS	Process	Start of data collection	Approval of the RO (expected date)	Comment
8.	**Difenoconazole**	ES	New	17/09/2021	30/06/2024	The expected date for approval of the Art.12 reasoned opinion might be delayed pending the peer review of the confirmatory data which is ongoing in parallel (Risk Assessment DL: 31/05/2024).
9.	**Ethylene**	NL	Combined	to be defined	to be defined	The MRL review will be launched in parallel with peer review for renewal that has not started yet. The approval of this a.s. will expire on 30/11/2026.
10.	**Eugenol**	ES	Combined	03/07/2023	31/12/2024	The expected date for approval of the Art.12 reasoned opinion might be delayed since the a.s. eugenol, geraniol, thymol and clove oil are expected to be discussed together in the framework of the peer review. The approval of this a.s. will expire on 30/04/2026.
11.	**Fatty acids C7 to C20**	EL	New	to be defined	to be defined	The MRL review is pending the finalisation of the peer review for renewal for all fatty acids. The approval of these active substances will expire on 15/12/2024.
12.	**Fenoxaprop-P**	AT	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that is currently ongoing (Risk Assessment DL: 28/06/2024). The approval of this a.s. will expire on 15/08/2025.
13.	**Fosthiazate**	DE	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that has not started yet. The approval of this a.s. will expire on 31/01/2027.
14.	**Gamma-cyhalothrin**	DE	New	15/01/2023/	05/04/2024	-
15.	**Geraniol**	ES	Combined	14/08/2023	31/12/2024	The expected date for approval of the Art.12 reasoned opinion might be delayed since the a.s. eugenol, geraniol, thymol and clove oil are expected to be discussed together in the framework of the peer review. The approval of this a.s. will expire on 30/04/2026.
16.	**Gibberellic acid**	SI	Combined/New	to be defined	to be defined	The MRL review is pending the peer review for renewal that is currently ongoing (Risk Assessment DL: 31/12/2024). The approval of this a.s. will expire on 15/07/2025.

Active Substance		RMS	Process	Start of data collection	Approval of the RO (expected date)	Comment
17.	**Gibberellin**	SI	Combined/New	to be defined	to be defined	The MRL review is pending the peer review for renewal that is currently ongoing (Risk Assessment DL: 31/12/2024). The approval of this a.s. will expire on 15/07/2025.
18.	**Halosulfuron-methyl**	IT	New	to be defined	to be defined	The MRL review is pending the peer review on confirmatory data. The approval of this a.s. will expire on 31/03/2025.
19.	**Iron sulphate**	HU	Combined	to be defined	to be defined	The MRL review will be launched in parallel with peer review for renewal that has not started yet. The approval of this a.s. will expire on 30/11/2026.
20.	**Lenacil**	BE	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that is currently ongoing (Risk Assessment DL: 30/09/2024). The approval of this a.s. will expire on 15/08/2025.
21.	**Malathion**	CZ	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that has not started yet. The approval of this a.s. will expire on 31/07/2026.
22.	**MCPA**	PL	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that is currently ongoing (Risk Assessment DL: 30/06/2025). The approval of this a.s. will expire on 15/08/2026.
23.	**MCPB**	PL	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that is currently ongoing (Risk Assessment DL: 30/06/2025). The approval of this a.s. will expire on 15/08/2026.
24.	***Melaleuca alternifolia*, essential oil (tea tree oil)**	PL	Combined	6/12/2022	31/05/2024	Confirmation that the MRL review will be covered by the peer review for the renewal is still pending.
25.	**Metribuzin**	EE	New	to be defined	to be defined	The MRL review is pending the decision from risk managers as regards the renewal of approval. The approval of this a.s. will expire on 15/02/2025.
26.	**Picloram**	PL	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that is currently on clock-stop (clock-stop expected until 01/03/2026). The approval of this a.s. will expire on 15/02/2028.

Active Substance		RMS	Process	Start of data collection	Approval of the RO (expected date)	Comment
27.	**Plant oils / Clove oil**	ES	Combined	13/06/2022	31/12/2024	The expected date for approval of the Art.12 reasoned opinion might be delayed since the a.s. eugenol, geraniol, thymol and clove oil are expected to be discussed together in the framework of the peer review. The approval of this a.s. will expire on 31/01/2026.
28.	**Plant oils / Spear mint oil**	SE	Combined	to be defined	to be defined	The MRL review will be launched in parallel with peer review for renewal that has not started yet. The approval of this a.s. will expire on 31/01/2026.
29.	**Pyrethrins**	IT	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that is currently on clock-stop (clock-stop expected until 31/05/2026). The approval of this a.s. will expire on 15/06/2026.
30.	**Thymol**	ES	Combined	05/07/2023	31/12/2024	The expected date for approval of the Art.12 reasoned opinion might be delayed since the a.s. eugenol, geraniol, thymol and clove oil are expected to be discussed together in the framework of the peer review. The approval of this a.s. will expire on 30/04/2026.
31.	**Tri-allate**	NL	New	to be defined	to be defined	The MRL review is pending the peer review for renewal that has not started yet. The approval of this a.s. will expire on 31/03/2027.

RMS: Rapporteur Member State; RO: Reasoned Opinion; a.s.: active substance; DL: deadline.