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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:

[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.

- Dates reported in the cells correspond to the starting and **foreseen dates to complete the assessment**.
- **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**" or as "**New/Statement**". For the substances under the process "Combined/New", 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 has been finalised. For the substances under the process "New/Statement", the MRL review was initiated but, following consideration of data submitted and in agreement with DG SANTE and RMS, the procedure was discontinued and it was agreed to cover the Art.12 MRL review by a statement.
- **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 on-going 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 the 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	Adoption of the RO (expected date)
1.	**alpha-Cypermethrin**	BE	New	16/04/2021	31/12/2022
2.	**Aluminium silicate (aka kaolin)**	EL	Combined	05/03/2021	30/09/2022
3.	**Azadirachtin**	DE	New	to be defined	to be defined
4.	**Bacillus thuringiensis subsp. Aizawai (ABTS-1857 and GC-91)**	NL	Combined/New	to be defined	to be defined
5.	**Bacillus thuringiensis subsp. Israelensis (serotype H-14), AM65-52**	SE	Combined/New	to be defined	to be defined
6.	**Bacillus thuringiensis subsp. Kurstaki (ABTS 351, PB 54, SA 11, SA 12 and EG 2348)**	DK	Combined/New	to be defined	to be defined
7.	**beta-Cypermethrin**	BE	New	12/05/2021	31/12/2022
8.	**Chlorsulfuron**	PL	New/Statement	not applicable	31/12/2022
9.	**Clofentezine**	ES	New	to be defined	to be defined
10.	**Clopyralid**	FI	New	to be defined	to be defined
11.	**Cypermethrin**	BE	New	15/04/2021	31/12/2022
12.	**Dicamba**	DK	New	to be defined	to be defined
13.	**Difenoconazole**	ES	New	17/09/2021	31/01/2023
14.	**Dithianon**	EL	New	15/03/2021	21/11/2022
15.	**Epoxiconazole**	PL	Statement	not applicable	31/12/2022
16.	**Ethylene**	NL	Combined	to be defined	to be defined
17.	**Etridiazole**	NL	New/Statement	not applicable	to be defined
18.	**Eugenol**	ES	Combined	to be defined	to be defined
19.	**Extract from tea tree**	PL	Combined	to be defined	to be defined
20.	**Fatty acids C7 to C20**	EL	New	to be defined	to be defined
21.	**Fenoxaprop-P**	AT	New	to be defined	to be defined
22.	**Fosthiazate**	DE	New	to be defined	to be defined
23.	**Gamma-cyhalothrin**	DE	New	to be defined	to be defined
24.	**Geraniol**	ES	Combined	to be defined	to be defined
25.	**Gibberellic acid**	SI	Combined/New	to be defined	to be defined
26.	**Gibberellin**	SI	Combined/New	to be defined	to be defined
27.	**Halosulfuron-methyl**	IT	New	to be defined	to be defined
28.	**Hydrolysed proteins**	ES	Combined	05/02/2021	15/10/2022
29.	**Iron sulphate**	HU	Combined	to be defined	to be defined
30.	**Lenacil**	BE	New	to be defined	to be defined
31.	**Malathion**	CZ	New	to be defined	to be defined
32.	**Mancozeb**	EL	New	15/12/2020	15/12/2022
33.	**Maneb**	IT	New	15/12/2020	15/12/2022
34.	**MCPA**	PL	New	to be defined	to be defined
35.	**MCPB**	PL	New	to be defined	to be defined
36.	**Metarhizium anisopliae var. Anisopliae (BIPESCO 5/F52) (formerly Metharhizium anisopliae)**	NL	Statement	to be defined	31/12/2022

	Active Substance	RMS	Process	Start of data collection	Adoption of the RO (expected date)
37.	**Metiram (aka carbatene, aka zineb ethylene thiuram disulphide adduct)**	IT	New	16/11/2020	15/12/2022
38.	**Metribuzin**	EE	New	to be defined	to be defined
39.	**Picloram**	PL	New	to be defined	to be defined
40.	**Plant oils / Citronella oil**	FR	Combined	to be defined	to be defined
41.	**Plant oils / Clove oil**	ES	Combined	13/06/2022	13/06/2023
42.	**Plant oils / Spear mint oil**	SE	Combined	to be defined	to be defined
43.	**Pyrethrins**	IT	New	to be defined	to be defined
44.	**Pyriproxyfen**	NL	New	16/08/2021	11/11/2022
45.	**Pythium oligandrum (M1)**	SE	Combined/New	to be defined	to be defined
46.	**Quartz sand**	LV	Combined	31/05/2021	31/08/2022
47.	**Straight chain Lepidoptera pheromones**	IT	Combined/New	to be defined	to be defined
48.	**Thymol**	ES	Combined	to be defined	to be defined
49.	**Topramezone**	FR	Statement	not applicable	31/12/2022
50.	**Tri-allate**	NL	New	to be defined	to be defined
51.	**zeta-Cypermethrin**	AT	New	12/05/2021	31/12/2022
52.	**Ziram**	IT	New	16/11/2020	15/12/2022
53.	**Zoxamide**	LV	New	15/09/2022	15/09/2023

RMS: Rapporteur Member State; RO: Reasoned Opinion.