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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 stakeholders, 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. With the **new procedure** EFSA starts the process by launching a call for data and coordinates the activities of the RMS and Member States (MSs) 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 EC 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.

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**.
- **The report includes the active substances expected to be assessed under the new procedure or the combined.**

- **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 a Reasoned Opinion is expected generally within 4 weeks from the adoption of the Reasoned Opinion.

	Active Substance	RMS	Process	Start of data collection	Adoption of the RO (expected date)
1.	1,4-Dimethylnaphthalene	AT	New	15/03/2020	18/04/2021
2.	8-Hydroxyquinoline	ES	New	15/04/2020	03/05/2021
3.	Acetic acid	AT	STATEMENT	16/09/2019	*
4.	alpha-Cypermethrin	BE	New	to be defined	to be defined
5.	Aluminium ammonium sulfate	IE	STATEMENT	-	**
6.	Aluminium silicate (aka kaolin)	EL	COMBINED	15/12/2020	15/12/2021
7.	Aluminium sulphate	NL	STATEMENT	-	**
8.	Azadirachtin	DE	New	to be defined	to be defined
9.	Bacillus thuringiensis subsp. Aizawai (ABTS-1857 and GC-91)	NL	New***	to be defined	to be defined
10.	Bacillus thuringiensis subsp. Israelensis (serotype H-14), AM65-52	SE	New***	to be defined	to be defined
11.	Bacillus thuringiensis subsp. Kurstaki (ABTS 351, PB 54, SA 11, SA 12 and EG 2348)	DK	New***	to be defined	to be defined
12.	beta-Cyfluthrin	DE	New	15/09/2020	17/09/2021
13.	beta-Cypermethrin	BE	New	to be defined	to be defined
14.	Calcium carbonate	ES	COMBINED	10/01/2020	on-going
15.	Carbon dioxide	FR	COMBINED	21/02/2020	on-going
16.	Chlorates (incl. Mg, Na, K chlorates)	FR	New	to be defined	to be defined
17.	Chlorsulfuron	PL	STATEMENT	13/07/2018	*
18.	Clofentezine	ES	New	to be defined	to be defined
19.	Clopyralid	FI	New	to be defined	to be defined
20.	Cyflumetofen	ES	New	15/06/2020	17/06/2021
21.	Cyfluthrin	DE	New	15/09/2020	17/09/2021
22.	Cypermethrin	BE	New	to be defined	to be defined
23.	Cyproconazole	IE	New	15/12/2019	18/02/2021
24.	Dicamba	DK	New	to be defined	to be defined
25.	Didecyldimethylammonium chloride (DDAC)	NL	New	to be defined	to be defined
26.	Difenoconazole	ES	New	to be defined	to be defined
27.	Diflubenzuron	EL	STATEMENT		**
28.	Dimethoate	IT	STATEMENT		**
29.	Disodium phosphonate	FR	New	17/01/2020	15/02/2021
30.	Dithianon	EL	New	to be defined	to be defined
31.	Epoxiconazole	PL	STATEMENT		**
32.	Ethoprophos	IT	STATEMENT		**
33.	Ethylene	NL	COMBINED	to be defined	to be defined
34.	Etridiazole	NL	STATEMENT	14/02/2018	*
35.	Eugenol	ES	New	to be defined	to be defined
36.	Extract from tea tree	PL	COMBINED	to be defined	to be defined
37.	Fat distillation residues	CZ	STATEMENT		**

Active Substance		RMS	Process	Start of data collection	Adoption of the RO (expected date)
38.	**Fatty acids C7 to C20**	EL	COMBINED	to be defined	to be defined
39.	**Fenoxaprop-P**	AT	New	to be defined	to be defined
40.	**Flufenoxuron**	FR	STATEMENT	12/04/2019	*
41.	**Fosthiazate**	DE	New	to be defined	to be defined
42.	**Gamma-cyhalothrin**	DE	New	to be defined	to be defined
43.	**Geraniol**	ES	New	to be defined	to be defined
44.	**Gibberellic acid**	SI	New***	To be defined	To be defined
45.	**Gibberellins**	SI	New***	To be defined	To be defined
46.	**Gliocladium catenulatum strain J1446**	HU	STATEMENT		**
47.	**Halosulfuron-methyl**	IT	New	to be defined	to be defined
48.	**Hydrolysed proteins**	ES	COMBINED	to be defined	to be defined
49.	**Imazaquin**	BE	STATEMENT	15/05/2020	*
50.	**Iron sulphate**	HU	COMBINED	to be defined	to be defined
51.	**Isopyrazam**	NO	New	15/02/2020	18/03/2021
52.	**Isoxaben**	SE	New	15/10/2020	15/10/2021
53.	**Lenacil**	BE	New	to be defined	to be defined
54.	**Lime sulphur**	CZ	STATEMENT	15/02/2019	*
55.	**Malathion**	CZ	New	to be defined	to be defined
56.	**Maltodextrin**	IE	STATEMENT	14/12/2018	*
57.	**Mancozeb**	IT	New	15/12/2020	15/12/2021
58.	**Maneb**	IT	New	15/12/2020	15/12/2021
59.	**MCPA**	PL	New	to be defined	to be defined
60.	**MCPB**	PL	New	to be defined	to be defined
61.	**Metarhizium anisopliae var. Anisopliae (BIPESCO 5/F52) (formerly Metharhizium anisopliae)**	NL	New***	To be defined	To be defined
62.	**Methiocarb (aka mercaptodimethur)**	DE	STATEMENT		**
63.	**Metiram (aka carbatene, aka zineb ethylene thiuram disulphide adduct)**	IT	New	15/11/2020	15/12/2021
64.	**Metobromuron**	FR	New	15/05/2020	16/05/2021
65.	**Metribuzin**	EE	New	to be defined	to be defined
66.	**Nicotine**	FR	New	to be defined	to be defined
67.	**Novaluron**	DE	New	15/11/2019	16/06/2021
68.	**Oxadiazon**	IT	STATEMENT		**
69.	**Penthiopyrad**	SE	New	15/02/2020	18/04/2021
70.	**Phosmet**	ES	New	to be defined	to be defined
71.	**Picloram**	PL	New	to be defined	to be defined
72.	**Pinoxaden**	AT	New	15/04/2020	17/03/2021
73.	**Plant oils / Citronella oil**	FR	COMBINED	to be defined	to be defined
74.	**Plant oils / Clove oil**	ES	COMBINED	to be defined	to be defined
75.	**Plant oils / Orange oil**	FR	STATEMENT	15/07/2019	*

Active Substance		RMS	Process	Start of data collection	Adoption of the RO (expected date)
76.	**Plant oils / Rape seed oil**	NL	COMBINED	30/09/2020	On-going
77.	**Plant oils / Spear mint oil**	SE	COMBINED	to be defined	to be defined
78.	**Potassium hydrogen carbonate**	NL	COMBINED	02/03/2020	On-going
79.	**Potassium phosphonates**	FR	New	17/01/2020	15/02/2021
80.	**Pyrethrins**	IT	New	to be defined	to be defined
81.	**Pyriproxyfen**	NL	New	to be defined	to be defined
82.	**Pythium oligandrum (M1)**	SE	New***	to be defined	to be defined
83.	**Quartz sand**	LV	COMBINED	to be defined	to be defined
84.	**Repellants: Fish Oil**	CZ	COMBINED	25/11/2020	25/11/2021
85.	**Repellants: Sheep fat**	CZ	COMBINED	30/11/2020	30/11/2021
86.	**Spirodiclofen**	AT	New	15/08/2020	15/08/2021
87.	**Straight chain Lepidoptera pheromones**	IT	New***	to be defined	to be defined
88.	**Sulfuryl fluoride**	AT	New	18/03/2019	18/12/2020
89.	**Tetraconazole**	FR	New	15/10/2020	15/10/2021
90.	**Thiram**	FR	New	15/10/2019	18/12/2020
91.	**Thymol**	ES	New	to be defined	to be defined
92.	**Tri-allate**	NL	New	to be defined	to be defined
93.	**Valifenalate**	HU	New	15/03/2020	17/03/2021
94.	**zeta-Cypermethrin**	AT	New	to be defined	to be defined
95.	**Ziram**	IT	New	15/11/2020	15/12/2021
96.	**Zoxamide**	LV	New	to be defined	to be defined

RMS: Rapporteur Member State; RO: Reasoned Opinion

* Following consideration of data submitted so far, in agreement with EC and RMS the Art.12 MRL Review is discontinued for this substance. The substance will be included in a statement

** In agreement with EC, the Art.12 MRL Review under the new process will be included in a statement

*** The GAP collection was started under the combined assessment but the MRL review could not be closed during the renewal.