Last update: 15 January 2019

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 presents the substances under the 'interim' procedure (see Annex, Fig. 1) or under the 'new' procedure (see Annex, Fig. 2).

The **interim procedure** was designed to perform the Article 12 reviews for active substances for which the information reported in the Pesticide Residues Overview File (PROFile) and the Evaluation Report (ER) submitted to EFSA need to be updated due to new authorisations or withdrawal of authorisations since the aforementioned documents were prepared. According to this procedure, the Rapporteur Member State (RMS) should contact the authorisation holders mainly in 2 different steps to ensure that the assessment is based on a complete and consistent data set: during the Completeness check and during the Clarification period. Only few active substances are left that are being assessed according to the interim procedure.

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 information in this document should allow stakeholders to timely prepare for providing the input to the process and to be ready with their data when the process is initiated. By publishing the information that an Article 12 review has been initiated, authorisation holders will get the signal that data supporting the MRL review process should soon be made available to the RMS upon request. According to this new procedure, the RMS may contact and involve the main authorisation holders in different steps: Identification of critical GAPs, Preparation of the ER and PROFile by the RMS, Clarification period after the completeness check. Nevertheless, Member States are encouraged to contact the authorisation holders at each step where Member States are involved (collecting GAP data or supporting data for the critical GAPs) as needed. It should be highlighted that in contrast to the interim procedure, the completeness check in the new procedure is not intended to collect additional GAPs and residue trials that have not been submitted previously. Thus, it is essential to inform the authorisation holders on the importance to provide the

complete GAP information and the supporting residue data at the beginning of the process.

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:

- Cells are highlighted in **green** if the step is completed. Dates reported in the cells that are not highlighted in green correspond to the steps not yet completed and the dates are **foreseen dates.**
- **The report includes the active substances under the interim or the new procedure.**
- **Completed** reviews finalised under the former process 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 (i.e. potassium phosphonates and disodium phosphonate await the outcome of the renewal of fosetyl aluminium).
- The publication of a Reasoned Opinion is expected generally within 2 weeks from the adoption of the Reasoned Opinion.

Active Substance	RMS (new RMS where applicable)	Process	Start of data collection* (expected date)	Adoption of the RO (expected date)
Chlorpyrifos	ES	Interim	26/11/2015	13/02/2017
Chlorpyrifos-methyl	ES	Interim	26/11/2015	13/02/2017
Cinidon-ethyl	UK	Interim	23/12/2014	22/06/2015
Deltamethrin	SE	Interim	22/12/2014	06/11/2015
Imazalil	NL	Interim	10/03/2016	09/08/2017
Triclopyr	IE	Interim	26/11/2015	13/02/2017
Triflumizole	NL	Interim	29/08/2016	09/03/2017
Bromuconazole	BE	Interim	08/08/2016	31/08/2017

Active Substance	RMS (new RMS where applicable)	Process	Start of data collection* (expected date)	Adoption of the RO (expected date)
Bitertanol	UK	Interim	14/07/2015	21/01/2016
Clethodim	NL	Interim	10/08/2017	07/02/2019
Carboxin	UK	Interim	31/10/2016	26/09/2017
Dazomet	BE	Interim	10/04/2017	12/12/2018
Fenbuconazole	UK (SI)	Interim	11/10/2016	26/07/2018
Fenbutatin oxide	BE	Interim	28/07/2017	27/11/2017
Fenoxycarb	NL	Interim	11/04/2017	21/12/2017
Fluazifop-P	FR	Interim	21/01/2015	04/09/2015
Flurochloridone	ES	Interim	20/06/2017	15/12/2017
Hexythiazox	FI	Interim	21/12/2016	12/12/2018
Myclobutanil	BE (AT)	Interim	23/06/2017	12/07/2018
Pencycuron	NL	Interim	21/11/2016	22/11/2018
Paclobutrazol	UK (AT)	Interim	16/12/2016	03/08/2017
Prochloraz	IE	Interim	23/05/2016	30/07/2018
Pyridaben	NL	Interim	03/10/2016	20/10/2017
Tebufenozide	DE	Interim	02/03/2017	05/02/2018
Tefluthrin	DE	Interim	19/02/2018	15/04/2019
Bromadiolone	SE	Interim	21/10/2016	26/04/2017
Zinc phosphide incl. phosphine	DE	Interim	16/03/2015	25/11/2015
Chloridazon (aka pyrazone)	DE	Interim	22/12/2014	28/08/2015
Fluazinam	AT	Interim	13/02/2015	10/09/2015
Fuberidazole	UK	Interim	21/01/2015	20/08/2015
Mepiquat	UK	Interim	21/01/2015	17/08/2015
Fenpyroximate	DE	Interim	17/02/2015	15/12/2015
Imidacloprid	DE	Interim	02/05/2016	12/12/2018
Tralkoxydim	UK	Interim	03/02/2015	28/08/2015
Aclonifen	DE	Interim	04/03/2015	17/11/2015
Aluminium phosphide	DE	Interim	16/03/2015	25/11/2015
Calcium phosphide	DE	Interim	16/03/2015	25/11/2015
Cymoxanil	AT	Interim	14/04/2015	04/12/2015
Magnesium phosphide	DE	Interim	16/03/2015	25/11/2015
Sulcotrione	DE	Interim	17/04/2015	04/11/2015
Triadimenol	UK	Interim	27/04/2015	18/12/2015
Bensulfuron	IT	Interim	29/03/2016	26/09/2016
Chlormequat (chloride)	UK (AT)	Interim	24/06/2015	24/02/2016
Copper compounds	FR	Interim	20/06/2016	01/03/2018
Dimethachlor	DE	Interim	28/04/2016	25/10/2016
Etofenprox	IT	Interim	08/06/2016	11/07/2017
Lufenuron	PT	Interim	29/03/2016	18/11/2016

Active Substance	RMS (new RMS where applicable)	Process	Start of data collection* (expected date)	Adoption of the RO (expected date)
Methomyl	UK	Interim	06/03/2015	22/10/2015
Penconazole	DE	Interim	19/05/2016	15/05/2017
Propaquizafop	IT (AT)	Interim	18/03/2016	13/10/2017
Quizalofop-P	FI	Interim	18/03/2016	13/10/2017
Sodium 5-nitroguaiacolate	EL	Interim	28/04/2015	04/12/2015
Sodium o-nitrophenolate	EL	Interim	28/04/2015	04/12/2015
Sodium p-nitrophenolate	EL	Interim	28/04/2015	04/12/2015
Tebufenpyrad	DE	Interim	03/07/2015	19/04/2016
Triflumuron	IT	Interim	29/08/2016	27/03/2017
2-Phenylphenol	ES	Interim	24/06/2016	11/01/2017
Penoxsulam	IT	Interim	08/08/2016	20/03/2017
Bispyribac	IT	Interim	21/07/2017	15/12/2017
Profoxydim	ES	Interim	29/09/2017	24/04/2018
Metam	BE	Interim	10/04/2017	12/12/2018
Fenpyrazamine	AT (LV)	Interim	25/01/2017	31/10/2017
Phosphane	DE (ES)	Interim	16/03/2015	25/11/2015
Mandipropamid	AT	Interim	10/08/2017	26/04/2018
Tembotrione	AT	Interim	25/09/2017	07/09/2018
alpha-Cypermethrin	BE	New	to be defined	to be defined
beta-Cyfluthrin	DE	New	to be defined	to be defined
Clopyralid	FI	New	to be defined	to be defined
Cyfluthrin	DE	New	to be defined	to be defined
Cypermethrin	BE	New	to be defined	to be defined
Dimethoate	IT	New	to be defined	to be defined
Ethoprophos	IT	New	to be defined	to be defined
Fosthiazate	DE	New	to be defined	to be defined
Glyphosate (incl trimesium aka sulfosate)	DE	New	05/10/2016	14/04/2018
Linuron	IT	New	to be defined	to be defined
Mancozeb	IT	New	to be defined	to be defined
Maneb	IT	New	to be defined	to be defined
MCPA	PL	New	to be defined	to be defined
MCPB	PL	New	to be defined	to be defined
Methiocarb (aka mercaptodimethur)	UK (DE)	New	to be defined	to be defined
Metiram (aka carbatene, aka zineb ethylene thiuram disulphide adduct)	IT	New	to be defined	to be defined
Metribuzin	EE	New	to be defined	to be defined
Phosmet	ES	New	to be defined	to be defined
Propineb	IT	New	to be defined	to be defined

Active Substance	RMS (new RMS where applicable)	Process	Start of data collection* (expected date)	Adoption of the RO (expected date)
Quinoxyfen	UK	New	to be defined	to be defined
Thiram	BE (FR)	New	to be defined	to be defined
Ziram	BE (IT)	New	to be defined	to be defined
Zoxamide	LV	New	to be defined	to be defined
Buprofezin	UK (IT)	New	to be defined	to be defined
Chlorates (incl. Mg, Na, K chlorates)	FR	New	to be defined	to be defined
Napropamide	DK (SI)	New	16/06/2017	11/07/2018
Bupirimate	NL	New	17/07/2017	10/05/2019
Acequinocyl	DE	New	14/08/2018	26/11/2019
Cyproconazole	IE	New	to be defined	to be defined
Ametoctradin	NL (DE)	New	15/05/2018	26/08/2019
Dithianon	EL	New	to be defined	to be defined
Chlorsulfuron	EL (PL)	New	13/07/2018	09/08/2019
Chromafenozide	HU	New	16/04/2018	02/12/2018
Flufenoxuron	FR	New	15/04/2019	
Fluometuron	EL	New	15/09/2017	12/12/2018
Fluquinconazole	IE (CZ)	New	16/08/2017	17/08/2018
Cycloxydim	AT (NL)	New	15/05/2018	12/07/2019
Isoxaben	SE	New	to be defined	to be defined
Oxyfluorfen	ES	New	15/08/2019	
Quinmerac	UK (EE)	New	15/06/2019	
Sintofen (aka Cintofen)	FR (CZ)	New	16/08/2017	13/08/2018
tau-Fluvalinate	DK	New	17/07/2017	22/10/2018
Terbuthylazine	UK (ES)	New	16/11/2017	04/07/2019
Aluminium sulphate	NL	New	to be defined	to be defined
Azadirachtin	DE	New	to be defined	to be defined
Clofentezine	ES	New	to be defined	to be defined
Dicamba	DK	New	to be defined	to be defined
Difenoconazole	ES	New	to be defined	to be defined
Diflubenzuron	EL	New	to be defined	to be defined
Fenoxaprop-P	AT	New	to be defined	to be defined
Imazaquin	BE	New	to be defined	to be defined
Lenacil	BE	New	to be defined	to be defined
Oxadiazon	IT	New	to be defined	to be defined
Picloram	PL	New	to be defined	to be defined
Pyriproxyfen	NL	New	to be defined	to be defined
Epoxiconazole	DE (UK)	New	to be defined	to be defined
2,5-Dichlorobenzoic acid methylester	DE (FR)	New	16/05/2017	08/06/2018

Active Substance	RMS (new RMS where applicable)	Process	Start of data collection* (expected date)	Adoption of the RO (expected date)
Aluminium ammonium sulfate	PT (IE)	New	to be defined	to be defined
Aluminium silicate (aka kaolin)	HU (EL)	New	to be defined	to be defined
Denathonium benzoate	PT (IT)	New	16/05/2017	12/03/2018
Diclofop	FR (PT)	New	15/03/2018	04/06/2019
Pyrethrins	IT	New	to be defined	to be defined
Sodium aluminium silicate	HU	New	to be defined	to be defined
Didecyldimethylammonium chloride (DDAC)	NL	New	to be defined	to be defined
Etridiazole	NL	New	14/02/2018	**
Fenazaquin	EL (DE)	New	14/02/2018	05/07/2019
Nicotine	UK (FR)	New	to be defined	to be defined
Tetraconazole	IT (FR)	New	to be defined	to be defined
Tri-allate	UK (NL)	New	to be defined	to be defined
zeta-Cypermethrin	BE (AT)	New	to be defined	to be defined
Cyflufenamid	UK (DE)	New	16/06/2017	04/09/2018
Fluopicolide	UK (AT)	New	15/09/2017	15/04/2019
Malathion	UK (CZ)	New	to be defined	to be defined
Flubendiamide	EL	New	17/09/2018	09/09/2019
Spirodiclofen	NL (AT)	New	to be defined	to be defined
Sulfuryl fluoride	UK (AT)	New	15/03/2019	
Triazoxide	UK (DE)	New	16/11/2017	02/12/2018
8-Hydroxyquinoline	ES	New	to be defined	to be defined
Fluxapyroxad	UK (FR)	New	15/06/2018	17/06/2019
Isopyrazam	UK (NO)	New	to be defined	to be defined
Hymexazol	FI (AT)	New	16/04/2018	17/05/2019
Bixafen	UK (CZ)	New	15/10/2018	07/10/2019
Halosulfuron-methyl	IT	New	to be defined	to be defined
Potassium phosphonates	FR	New	to be defined	to be defined
Spiromesifen	UK (IT)	New	12/10/2017	18/12/2018
Cyflumetofen	NL (ES)	New	to be defined	to be defined
Fluopyram	DE (AT)	New	13/10/2017	14/06/2019
Sedaxane	FR	New	15/11/2017	02/12/2018
Emamectin	NL	New	15/12/2017	15/04/2019
Disodium phosphonate	FR	New	to be defined	to be defined
Metamitron	UK (DK)	New	17/09/2018	07/10/2019
Novaluron	UK (DE)	New	15/11/2019	
Penflufen	UK (PL)	New	15/01/2018	27/05/2019
Benalaxyl-M	PT	New	15/09/2017	15/04/2019
Pyroxsulam	UK (DK)	New	15/09/2019	

Active Substance	RMS (new RMS where applicable)	Process	Start of data collection* (expected date)	Adoption of the RO (expected date)
Proquinazid	UK (SE)	New	15/06/2018	19/07/2019
Chlorantraniliprole	IE	New	15/12/2017	17/06/2019
Penthiopyrad	UK	New	to be defined	to be defined
Spinetoram	UK (HR)	New	15/10/2018	
Pyridalyl	NL	New	14/08/2018	10/06/2019
Valifenalate	HU	New	to be defined	to be defined
Thiencarbazone	UK (FR)	New	19/11/2018	09/09/2019
1,4-Dimethylnaphthalene	NL (AT)	New	to be defined	to be defined
Amisulbrom	UK (EL)	New	15/01/2019	
Pyriofenone	UK (LV)	New	15/01/2018	27/05/2019
Ipconazole	UK (BE)	New	11/12/2018	
Metobromuron	FR	New	to be defined	to be defined
Aminopyralid	UK (FI)	New	15/06/2019	
Metaflumizone	UK (SE)	New	22/11/2018	09/09/2019
Spirotetramat	AT	New	12/07/2018	19/07/2019
Gamma-cyhalothrin	UK (DE)	New	to be defined	to be defined
Meptyldinocap	UK (ES)	New	15/01/2019	
pinoxaden	UK (AT)	New	to be defined	to be defined
Gliocladium catenulatum strain J1446	HU			
Straight chain Lepidoptera pheromones	AT (IT)			
6-Benzyladenine	UK (SE)	New	15/04/2019	
Lime sulphur	ES (CZ)	New	15/02/2019	
Bacillus thuringiensis subsp. Aizawai (ABTS-1857 and GC-91)	IT (NL)			
Bacillus thuringiensis subsp. Israelensis (serotype H-14), AM65-52	IT (SE)			
Bacillus thuringiensis subsp. Kurstaki (ABTS 351, PB 54, SA 11, SA 12 and EG 2348)	DK			
Bacillus thuringiensis subsp. Tenebrionis (NB 176 (TM 14 1))	IT			
Metarhizium anisopliae var. Anisopliae (BIPESCO 5/F52) (formerly Metharhizium anisopliae)	NL			
Pythium oligandrum (M1)	SE			
1,4-Diaminobutane (aka Putrescine)	AT (ES)	New	15/03/2019	

Active Substance	RMS (new RMS where applicable)	Process	Start of data collection* (expected date)	Adoption of the RO (expected date)
Acetic acid	DE (AT)	New	15/09/2019	
Ammonium acetate	PT			
Blood meal	BE (AT)			
Calcium carbonate	ES			
Carbon dioxide	UK (FR)			
Ethylene	UK (NL)	New	15/05/2019	
Extract from tea tree	LV (PL)			
Fat destilation residues	CZ			
Fatty acids C7 to C20	IE (EL)			
Garlic extract	PL (IE)			
Gibberellic acid	HU (SI)			
Gibberellin	HU (SI)			
Hydrolysed proteins	EL (ES)			
Iron sulphate	UK (HU)			
Kieselguhr (aka diatomaceous earth)	EL (AT)			
Limestone	AT (CZ)			
Pepper	UK (BE)			
Plant oils / Citronella oil	UK (FR)			
Plant oils / Clove oil	UK (ES)			
Plant oils / Rape seed oil	ES (NL)			
Plant oils / Spear mint oil	SE	New	15/07/2019	
Potassium hydrogen carbonate	IE (NL)			
Quartz sand	AT (LV)			
Repellants: Fish Oil	EL (CZ)			
Repellants: Sheep fat	EL (CZ)			
Sea-algae extract	IT (BE)			
Trimethylamine hydrochloride	BE (BG)	New	15/05/2019	
Maltodextrin	UK (IE)	New	14/12/2018	
Eugenol	UK (ES)			
Thymol	UK (ES)			
Geraniol	UK (ES)			
Plant oils / Orange oil	FR	New	15/07/2019	
Bacillus pumilus QST 2808	NL	New	15/02/2019	
Pseudomonas sp. strain DSMZ 13134	NL	New	15/08/2019	
Streptomyces lydicus strain WYEC 108	NL	New	15/11/2019	

RMS: Rapporteur Member State; RO: Reasoned Opinion

* start of data collection for interim process: start of GAP and trials collection (2 months + 1 month + 3 weeks)
* start of data collection for new process: start of activities (1 months + 6 weeks + 1 month)
** in view of the fact that the substance is no longer supported for renewal and following consideration of the data submitted so far, in agreement with EC and the RMS, the Art 12 MRL review is discontinued for this substance. For transparency, the substance will be included in a statement after the expiry of the approval.

New RMS (where applicable) refers to MS to carry out the Article 12 MRL review following Regulation (EU) No 686/2012 as last amended by Regulation (EU) 2018/155. RMS before amendment is also given for information. However, the **new RMS** is considered only in cases where the start of activities was as of December 2017 onwards.

Annex

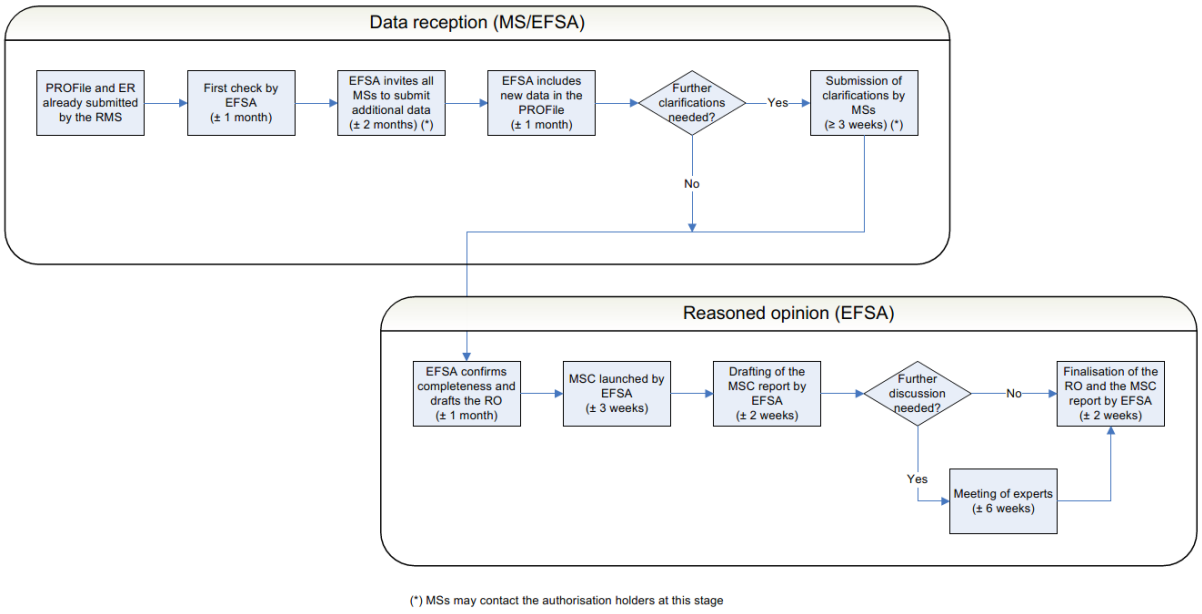

Fig. 1 Interim procedure

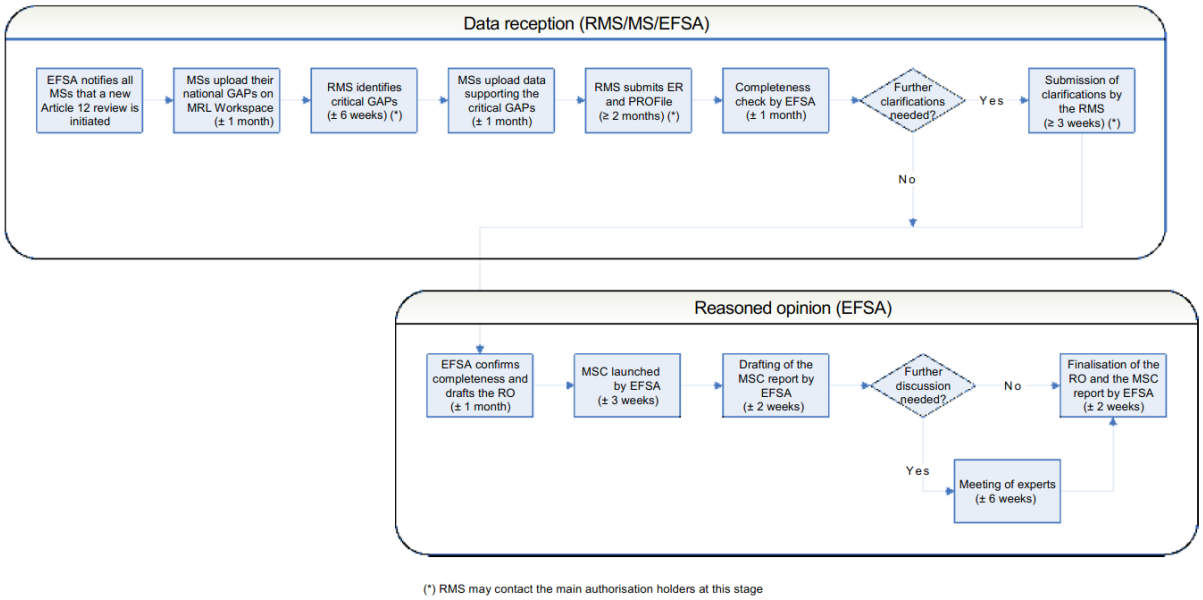

Fig. 2: New procedure (used as from May 2017)