EU PESTICIDE RENEWAL MONITOR

September 2019

In the European Union, all active ingredients undergo periodic reevaluation, as laid out in Regulation (EC) No. 1107/2009[1]. The reevaluation process typically follows the scheme indicated in the figure below.

This document provides an overview of active ingredients that are currently undergoing or are scheduled for the periodic active ingredient renewal in the European Union and it is prepared based on publicly available information. It lists active ingredients that expired or are expected to expire, status of August 2019. Please note that the renewal process relates to the approval of active ingredients used in the EU market. It is lengthy and unpredictable. Only final, published Regulations are definitive. Renewal is a separate process to the EU MRL and Import Tolerance setting, change or removal, which typically happens after non-renewal has been finalized, and is governed by specific legislation.

For additional information on the registration status and expiry dates for active ingredients that are not listed in this document, please refer to the EU pesticide database.

For information on specific active ingredients, please consult the EFSA website (then click on the "Pesticide Dossier" tab) or contact the companies which are supporting the active ingredient through the renewal process by contacting croplife@croplife.org.

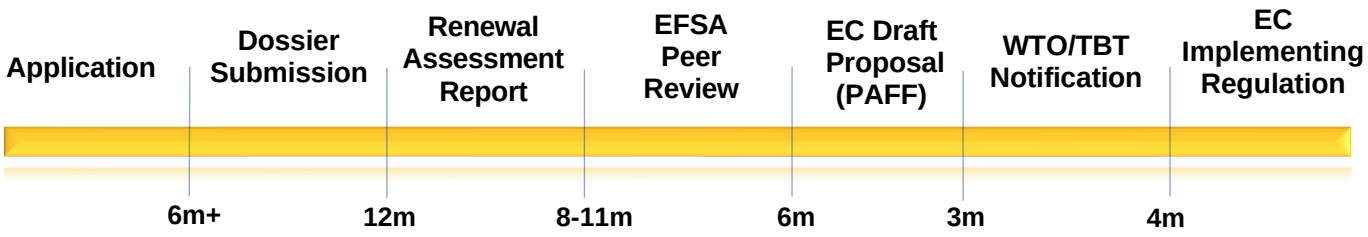

Figure 1: Schematic overview of the EU reevaluation process, timelines are indicative as outlined in Regulation (EC) No. 1107/2009. Steps can take longer than indicated.

Disclaimer: The EU Pesticide Renewal Monitor is intended for information purposes only. Users are invited to verify the information obtained from the EU Pesticide Renewal Monitor with knowledgeable third parties prior to engaging in any business activities, such as the sale or shipments of any products. Users acknowledge that CropLife International and BCI are not responsible for the accuracy, reliability, and currency of the information and that the information provided may not be one hundred percent (100%) accurate, up-to-date, and free of omissions. CropLife International and BCI shall not be held liable for any losses or damages arising from any errors, omissions, or misrepresentations from the use of the information contained in the EU Pesticide Renewal Monitor.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&from=EN

APPLICATION FOR RENEWAL - EXPIRED (July 2018 – August 2019)

Chemical companies must submit an application for renewal of approval of their active ingredient to EU authorities. If they do not, the active ingredient will automatically expire in the EU on a set date. Active ingredients below **have already expired** due to **no submission of application for renewal** or **withdrawal of application for renewal**. This list includes substances that have expired since July 2018.

Glufosinate	31/07/2018
Methyl nonyl ketone	31/08/2018
Chloridazon (aka pyrazone)	31/12/2018
Imazaquin	31/12/2018
Oxadiazon	31/12/2018
Quinoclamine	31/12/2018
Propanil	20/02/2019
Fuberidazole	28/02/2019
Fenpropimorph	30/04/2019
Tralkoxydim	30/04/2019
Trichoderma polysporum strain IMI 206039	30/04/2019
Bacillus thuringiensis subsp. Tenebrionis strain NB 176 (TM 14 1)	30/04/2019
Sea-algae extract	31/08/2019
Ammonium acetate	31/08/2019
Limestone	31/08/2019
Methomyl	31/08/2019
Pepper	31/08/2019
Putrescine	31/08/2019
Sodium hypochlorite	31/08/2019
Triadimenol	31/08/2019
Trimethylamine hydrochloride	31/08/2019
Sodium aluminium silicate	31/08/2019

APPLICATION FOR RENEWAL - EXPECTED TO EXPIRE (September 2019 – July 2020)

Applications for **renewal of approval were not submitted** or **applications have been withdrawn** for the active ingredients below. The expiration date is outlined. Please note that the expiration of active ingredients in the EU is not notified to the World Trade Organization (WTO).

Quizalofop-P	30/11/2019
Teflubenzuron	30/11/2019
Difenacoum	30/12/2019
Chlorsulfuron	31/12/2019
Cyromazine	31/12/2019
Lufenuron	31/12/2019
Phlebiopsis gigantea multiple strains	30/04/2020
Trichoderma atroviride	30/04/2020
Triflumizole	30/06/2020
Spirodiclofen	31/07/2020

UP NEXT FOR REVIEW (September 2019 – July 2020)

Under the EU pesticide review program, the active ingredients listed below have **upcoming deadlines** for the **submission of the application for renewal.** The list shows all active ingredients that are scheduled to go through the periodic renewal process. This does not imply that these active ingredients will have issues with renewal in the EU.

Flumetralim	11/12/2019
Esfenvalerate	15/12/2019
Glyphosate	15/12/2019
Fenpyrazamine	31/12/2019
Fluxapyroxad	31/12/2019
Adoxophyes orana GV strain BV-0001	31/01/2020
Benzovindiflupyr	02/03/2020
Isopyrazam	31/03/2020
Lambda-Cyhalothrin	31/03/2020
Metsulfuron methyl	31/03/2020
Phosphane	31/03/2020
Cyflumetofen	31/05/2020
Helicoverpa armigera nucleopolyhedrovirus (HearNPV)	31/05/2020
Spodoptera littoralis nucleopolyhedrovirus	31/05/2020
Trichoderma asperellum (strain T34)	31/05/2020
Trichoderma atroviride strain I-1237	31/05/2020
Zucchini Yellow Mosaik Virus, weak strain	31/05/2020
Ametoctradin	20/07/2020
Mandipropamid	20/07/2020

STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED (PAFF)

Active ingredients below have been proposed for **non-renewal** or **restricted renewal** and are now **under consideration** by the Standing Committee on Plants, Animals, Food and Feed (PAFF). A final decision has not yet been made.

Indoxacarb
Methiocarb
Phenmedipham
Thiophanate-methyl
Thiacloprid

WTO NOTIFICATION (July 2018 – August 2019)

Active ingredients below have been notified to the **WTO as proposed for non-renewal** or **restricted renewal**. These WTO Technical Barrier to Trade (TBT) notifications advise that the active ingredient is subject to a proposed non-renewal for use in the EU. This is not necessarily indicative of the final EU decision, as further Committee work is done by the Commission and EU Member States after notification, which can change the proposal. Definitive non-renewal regulation may take a significant period of time after the WTO consultation has completed. These notifications do not advise what will happen with EU MRLs. This information is provided in notifications via WTO Sanitary and Phytosanitary (SPS), typically some years later. For full explanation on the justification for proposed restricted or non-renewal of approval, please refer to draft implementing regulation. Notification date is outlined in parentheses ( ).

Etoxazole: non-renewal based on persistent, bioaccumulative and toxic characteristics. (05/07/2018)

Thiophanate-methyl: non-renewal based on potential reproductive toxicity. (01/03/2019)

Methiocarb: non-renewal based on an unacceptable risk to workers, even when considering the use of personal protective equipment and a high risk to birds, mammals and earthworms. (23/04/2019)

Thiacloprid: non-renewal based on a critical concern in relation to the contamination of groundwater by metabolites containing carcinogenic properties. There is also an undetermined risk to aquatic organisms, bees, and non-target plants, as well as concerns on the impact on reproductive toxicity. (31/07/2019)

Proposed restricted renewal:

Dithianon: restricted use on non-edible crops based on an inconclusive consumer exposure assessment. (11/04/2018)

Mepanipyrim: restricted use in greenhouses based on endocrine disrupting potential. (03/09/2018)

COMMISSION IMPLEMENTING REGULATION (July 2018-August 2019)

The Commission has published the final decision on non-renewal or restricted renewal in the EU for the active ingredients below. For full explanation on the justification for restricted or non-renewal of approval, please refer to the published implementing regulation. Publication date is outlined in parentheses ( ).

Oxasulfuron: non-renewal based on inconclusive risk assessments for consumer exposure, aquatic organisms, and toxic groundwater metabolites. (19/07/2018)

Fenamidone: non-renewal based on inconclusive risk assessments for genotoxic potential, aquatic organisms, and a toxic groundwater metabolite. (25/07/2018)

Pymetrozine: non-renewal based on endocrine disrupting properties, potential toxic groundwater exposure, and potential risk to aquatic organisms. (09/10/2018)

Thiram: non-renewal based on high risk to consumers, birds, mammals, and endocrine disrupting potential. (10/10/2018)

Diquat: non-renewal due to high risk to bystanders and birds. (12/10/2018)

Propiconazole: non-renewal based on reproductive toxicity characteristics and endocrine disrupting potential. (28/11/2018)

Quinoxyfen: non-renewal based on persistent, bioaccumulative and toxic; very persistent and very bioaccumulative; and persistent organic pollutant properties. (07/12/2018)

Flurtamone: non-renewal based on inconclusive but potential high risk to groundwater pollution and endocrine disrupting properties. (07/12/2019)

Propanil: non-renewal based on withdrawal of application for renewal. (31/01/2019)

Ethoprophos: non-renewal based on health and environmental concerns that could not be finalized. (01/03/2019)

Chlorothalonil: non-renewal based on concerns of groundwater pollution, persistent biotoxicity and carcinogenic properties. (30/04/2019)

Chlorpropham: non-renewal based on concerns of endocrine disrupting properties and risk to non-target arthropods. (18/06/2019)

Dimethoate: non-renewal based on concerns of genotoxic, reproductive, persistent bioaccumulative toxicity, high risk to mammals and non-target arthropods, and a risk to honeybees. (27/06/2019)

Desmedipham: non-renewal based on potential endocrine disrupting, carcinogenic, and mutagenic properties. (28/06/2019)

Restricted renewal:

Malathion: approval restricted to permanent greenhouse use based on high risk to birds. (09/10/2018)

Copper Compounds: restricted renewal (5 years) as a candidate for substitution due to persistent, bioaccumulative and toxic properties. (14/12/2018)

Methoxyfenozide: restricted renewal as a candidate for substitution and limiting the uses to fruiting vegetables of Solanaceae in greenhouses. (01/02/2019)

Tolclofos-methyl: restricted renewal to ornamentals and potatoes only, to minimize the exposure for consumers to certain metabolites and to reduce the exposure of aquatic organisms and wild mammals to this substance. (28/06/2019)

MRL CHANGES (July 2018 – August 2019)

As a **result of non-renewal** or **expiration** of approval, restrictive MRLs have either been proposed (WTO notification) or implemented (Commission Regulation) for the substances below. Notifications of MRL changes will appear as WTO SPS notifications.

WTO SPS Notification

Amitrole: WTO notification G/SPS/N/EU/313. 20/03/2019
Flupyrsulfuron: WTO notification G/SPS/N/EU/313. 20/03/2019
Isoproturon: WTO notification G/SPS/N/EU/313. 20/03/2019
Triasulfuron: WTO notification G/SPS/N/EU/313. 20/03/2019
Fipronil: WTO notification G/SPS/N/EU/313. 20/03/2019
Imazosulfuron: WTO notification G/SPS/N/EU/313. 20/03/2019
Flufenoxuron: WTO notification G/SPS/N/EU/313. 20/03/2019
Orthosulfamuron: WTO notification G/SPS/N/EU/313. 20/03/2019

Implementing Regulation

Diphenylamine: Commission Regulation 2018/1515 on 10/10/2018. *Effective date: 01/05/2019*
Oxadixyl: Commission Regulation 2018/1515 on 10/10/2018. *Effective date: 01/05/2019*
Iprodione: Commission Regulation 2019/38 on 11/01/2019. *Effective date: 31/07/ 2019*
Linuron: Commission Regulation 2019/58 on 15/01/2019. *Effective date: 04/08/2019*
Buprofezin: Commission Regulation 2019/91 on 24/01/2019. *Effective date: 13/08/2019*
Diflubenzuron: Commission Regulation 2019/91 on 24/01/2019. *Effective date: 13/08/2019*
Picoxystrobin: Commission Regulation 2019/91 on 24/01/2019. *Effective date: 13/08/2019*
Tepraloxydim: Commission Regulation 2019/91 on 24/01/2019. *Effective date: 13/08/2019*

EU PESTICIDE RENEWAL MONITOR Q&A

What is the EU Pesticide Renewal Monitor report?

- Provides an overview on the active ingredients that are scheduled for the periodic review or are currently undergoing the periodic review. The periodic review is a normal and regular procedure for all pesticides approved in the EU, according to Regulation 1107/2009 that regulates market access for pesticides in the EU.
- Active ingredients that have not been renewed, have a restricted renewal or are expired (no renewal dossier submitted) are also listed.

Why was this report created?

- CropLife International commissioned the Pesticide Renewal Monitor report to support governments, farmers and the agri-food value chain to better understand which active ingredients are currently undergoing the pesticide renewal process in the European Union.
- The EU pesticide renewal procedure can be complex, challenging to track and the status of products in the review process may be difficult to interpret.
- Information on review status of active ingredients is publicly available but spread over multiple websites and reports. Most information is not available in one place.
- The EU needs to notify WTO member states when an active ingredient registration is changed or not renewed (TBT notification). WTO notifications are only made late in the EU renewal process, consequently stakeholders are informed late in the process. A subsequent decision to lower or revoke MRLs (including ITs and Codex MRLs), which is done through a SPS notification, may be too late for stakeholders to adapt their supply and/or to engage in the discussion.
- The US Department of Agriculture (USDA) has commissioned a similar report for US relevant active ingredients which has been valuable for US stakeholders.

What is the difference between the USDA Early Alert list and the CropLife International EU Pesticide Monitor?

- The USDA Early Alert list covers active ingredients undergoing the EU renewal that are registered in the US.
- The CropLife International report covers all active ingredients undergoing the renewal in the EU. i.e. the CropLife International report covers more substances (96) than the USDA report (66).

Why was the report developed?

- To inform interested stakeholders on the process and timing of active ingredient renewal in the EU, to create awareness for non-EU stakeholders
- In case of restrictive or non-renewal: alert stakeholders that/when MRLs may be lowered to the Limit of Quantification (LOQ).
- Provide timely information so stakeholders could engage in support of adequate transition periods or maintenance of MRLs that are important for trade with the EU.

Who is responsible for submitting a dossier for active ingredient renewal in the European Union?

- All stakeholders are invited to provide information relevant for the renewal of the active ingredients.
- Data requirements for active ingredient approval are in place (Regulation EU 283/2013).
- Normally, industry (individual companies, several companies jointly or task forces) generates the data and compiles and submits the dossier. A list of dossier submitters is available on the EFSA website: http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin (then click on the "Pesticide Dossier" tab)

What is the relationship between active ingredient renewal and MRL / IT?

- When an active ingredient is not renewed in the EU or if the conditions of use were amended, MRLs may be deleted or lowered.

Deletion of MRLs following the revocation of pesticide authorizations in the EU does not apply to MRLs based on Codex MRLs and Import Tolerances established to facilitate global trade, provided that they are deemed acceptable with regard to consumer safety.

Whom can I contact for questions on a specific active ingredient?

- Companies that submitted a dossier for EU renewal can be retrieved through the EFSA website: http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin (then click on the "Pesticide Dossier" tab)
- Individual companies will have the relevant information on the active ingredient, products they sell to farmers and the range of crops that the product is approved for use.
- In case of issues in identifying the relevant authorization holder for a specific active ingredient, please feel free to contact CropLife International.

Is this a complete list of substances registered in the EU?

- No. Only active ingredients are listed that will undergo or currently undergo the renewal process. Also, substances that expired, were not renewed or had a restricted renewal are mentioned.
- For more information and for information on the registration status and expiry dates for active ingredient that are not listed in this document, we refer to the EU pesticide database: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

When will this report be updated?

- This report will be updated on a quarterly basis or at the discretion of CropLife International.