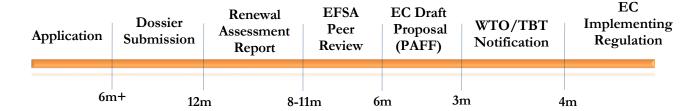




December 14, 2018

The information presented in this document provides interested stakeholders with advance notice of active ingredients under review for renewal of approval in the EU and highlights which substances may have restricted or non-renewal of approval. It analyzes all 2018 publications and will be updated quarterly. The arrows to the left of each section explain where a substance is in the EU review process as of December 7, 2018.

In the European Union active ingredients must be reviewed every 10-15 years. The review process takes about three years to complete. Registrants must submit an application for renewal no later than thirty-six months prior to the expiration date. The figure below highlights the general timeline between the main steps of the process. During these reviews, substances are checked against EU cut off criteria. Triggering the cut off criteria is likely to result in the removal of the pesticide from use in the EU. It can also result in the elimination of the associated MRLs. These reviews are separate and different from the ongoing MRL-specific reviews that are occurring simultaneously (Art. 12 Reviews). MRL-specific reviews are notified on a rolling basis.



Chemical companies must support the review of their substance. If they do not, the active ingredient will automatically expire in the EU on a set date. For the substances below registrants have not submitted the application for renewal of approval and **approval will expire.** Corresponding MRLs may be restricted to the limit of determination\* (LOD).

# Application for Renewal

- Fenbuconazole: expires on April 30, 2021
- Diethofencarb: expires on May 31, 2021
- Etridiazole: expires on May 31, 2021
- Myclobutanil: expires on May 31, 2021
- Oryzalin: expires on May 31, 2021

Under the EU pesticide review program, the substances listed in this section have **upcoming deadlines** for the submission of the renewal application.

# UP NEXT for Review *July-Dec 2018*

- 1-Naphthylacetamide (1-NAD)
- 1-Naphthylacetic acid (1-NAA)
- Azoxystrobin
- Bispyribac
- Fluazifop-P
- Fluroxypyr
- Imazalil (aka enilconazole)

- Kresoxim-methyl
- Oxyfluorfen†
- Prohexadione
- Spiroxamine
- Tefluthrin
- Triazoxide





Based on the European Food Safety Authority (EFSA) conclusions, the European Commission has proposed the substances in this section for **non-renewal** or **restricted renewal**. They are now **under consideration** by the Standing Committee on Plants, Animals, Food and Feed (PAFF). After the Committee's deliberation the Commission will notify the decision to the World Trade Organization (WTO).

# PAFF Meeting

- Propanil
- Desmedipham
- Phenmedipham
- Thiophanate-methyl
- Indoxacarb

The substances in this section have been notified to the **WTO** as proposed for non-renewal or restricted renewal. After the comment period, the Commission will analyze the comments received and publish the Implementing Regulation. Notification date is outlined in parentheses ().

## WTO Notification

Chlorpropham: non-renewal based on potential endocrine disrupting properties. (March 29, 2018)

**Dithianon:** restriction for use on non-edible crops based on an inconclusive consumer exposure assessment. (April 11, 2018)

Etoxazole: non-renewal based on persistent, bioaccumulative and toxic characteristics. (July 5, 2018)

**Copper Compounds:** 5-year renewal as a candidate for substitution<sup>†</sup> due to persistent, bioaccumulative and toxic properties. (August 31, 2018)

**Methoxyfenozide:** 7-year renewal as a candidate for substitution<sup>†</sup> and limiting the uses to fruiting vegetables of Solanaceae in greenhouses. (August 31, 2018)

Mepanipyrim: restricted use in greenhouses based on endocrine disrupting potential. (Sep 3, 2018)

**Ethoprophos:** non-renewal based on concerns that could not be finalized (high acute risk to birds, endocrine disrupting potential, secondary poisoning for birds and mammals, metabolite exposure to soil organisms). (November 1, 2018)

**Chlorothalonil**: non-renewal based on carcinogenic properties, genotoxicity concerns, high risk to amphibians and fish, in addition to lack of data to confirm several areas of the risk assessment as it regards consumer risk from dietary exposure and residue levels. (December 4, 2018)





The Commission has published the final decision on non-renewal or restricted renewal in the EU for the substances in this section. EU MRLs may be subject to reevaluation and change as a result. Publication date is outlined in parentheses ().

Commission Implementing Regulation **Penflufen:** approval restricted to use on seeds and other propagating materials. (February 7, 2018)

**Bifenthrin:** approval restricted to greenhouse use based on potential bioaccumulation and biomagnification in the aquatic environment. (February 26, 2018)

Fenazaquin: approval restricted to greenhouse and ornamental use only. (May 7, 2018)

**Propyzamide:** restricted renewal as a candidate for substitution<sup>†</sup> due to persistent and toxic properties for freshwater organisms with no observed long-term effect. (May 23, 2018)

**Imidacloprid:** approval restricted to permanent greenhouse use due to high risk to bees. (May 29, 2018)

Clothianidin: approval restricted to permanent greenhouse use due to risk to bees. (May 29, 2018)

**Thiamethoxam:** approval restricted to permanent greenhouse use due to high risk to bees. (May 29, 2018)

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

**Malathion:** approval restricted to permanent greenhouses use based on high risk to birds. (October 9, 2018)

**Pymetrozine:** non-renewal based on endocrine disrupting properties, potential toxic groundwater exposure, and potential risk to aquatic organisms. (October 9, 2018)

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

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

**Propiconazole:** non-renewal based on reproductive toxicity characteristics and endocrine disrupting potential. (November 28, 2018)

**Quinoxyfen:** non-renewal based on persistent, bioaccumulative and toxic; very persistent and very bioaccumulative; and persistent organic pollutant properties. (December 7, 2018)





As a **result of non-renewal** or **expiration** of approval, restrictive MRLs have either been proposed (WTO notification) or implemented (Implementing Regulation) for the substances below.

# MRL Changes

- Linuron: WTO notification SPS 262 on July 13, 2018
- Iprodione: WTO notification SPS 263 on July 17, 2018
- Buprofezin: WTO notification SPS 264 on July 19, 2018
- Diflubenzuron: WTO notification SPS 264 on July 19, 2018
- Picoxystrobin: WTO notification SPS 264 on July 19, 2018
- Tepraloxydim: WTO notification SPS 264 on July 19, 2018
- Diphenylamine: Implementing Regulation 2018/1515 on October 10, 2018

\*Level of determination (LOD) means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods.

<sup>†</sup>Candidates for substitution (CfS) are pesticides for which national authorities need to carry out an assessment to establish whether more favorable alternatives to using the plant protection product exist, including non-chemical methods. The aim is to encourage more sustainable crop protection.

The **EU Early Alert** project is comprised of two notification systems to U.S. stakeholders regarding 1) the EU pesticide review under EC 1107/2009 and 2) the MRL Review under Art. 12 of EC 395/2006 legislations. The project is funded by the Technical Assistance for Specialty Crops (TASC) Program of the U.S. Department of Agriculture and prepared by Bryant Christie Inc.