



September 7, 2022

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 that have **expired**, are expected to **expire**, may have **restricted renewal** or **non-renewal of approval**. The green arrows reflect where a substance is in the EU review process as of **August 31, 2022**.

In the European Union active ingredients must be reviewed every 10-15 years. The review process takes three or more 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.

The pesticide review process monitored here is different from the MRL review process (Article 12 Reviews). MRL-specific reviews are notified on a rolling basis according to the schedule shared at the end of this report.

| Application | Renewal Assessment Report | EFSA Peer Review | EC Draft Regulation (PAFF) | WTO/TBT Notification | Commission Regulation (EU) | |
|--|---------------------------------|------------------------|----------------------------------|-------------------------|----------------------------------|--|
| | | | | | | |
| | | | | | | |
| 13 months 11 months 6 months 3 months+ 4 months+ | | | | | | |

APPLICATION FOR RENEWAL – EXPECTED TO EXPIRE (Up to August 2023)

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 For the substances below, registrants have not submitted the application for renewal of approval or have withdrawn the application and approval will expire. Corresponding MRLs may be affected. The substance's expiration date is outlined in parentheses.

(None)

APPLICATION FOR RENEWAL - EXPIRED (September 2021 – August 2022)

Substances in this section have already expired due to non-submission of application for renewal or withdrawal of application for renewal. This list includes substances that have expired in the last year. Corresponding MRLs may be affected. Expiration date is outlined in parentheses.

- Bispyribac (07/31/2022)
- Plant oils /Citronella oil* (08/31/2022)

^{*}Substance is exempt from a tolerance in the United States





September 7, 2022

UP NEXT FOR REVIEW (Up to February 2023)

Under the EU pesticide review program, the substances listed in this section are scheduled to go through the periodic review process. They have **upcoming deadlines for the submission of the application for renewal.**

(None)

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

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) as available in the **May 17-18, 2022**, meeting summary and in the **July 14-15, 2022**, meeting agenda. Drafts are first presented for discussion and subsequently for a vote by the Committee. Draft proposals may be notified to the World Trade Organization (WTO) prior to the Committee's final vote. In these cases, substances are listed below and in the next section.

(None)

WTO NOTIFICATION (September 2021 – August 2022)

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 (). Please refer to the draft Commission Regulation for the full explanation of the justification for the restricted or non-renewal of approval.

(None)

COMMISSION IMPLEMENTING REGULATION (September 2021 – August 2022)

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 change as a result. Implementing regulation publication date is outlined in parentheses (). Please refer to the published Commission Regulation for the full explanation of the justification for the restricted or non-renewal of approval.

Non-renewal

Indoxacarb: non-renewal due to risks posed to mammals and bees, as well as insufficient data to complete consumer, groundwater, and ecotoxicology risk assessments. (November 29, 2021)

Phosmet: non-renewal based on environmental concerns and multiple data gaps. (January 24, 2022)





September 7, 2022

COMMISSION IMPLEMENTING REGULATION (continued)

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 change as a result. Implementing regulation publication date is outlined in parentheses (). Please refer to the published Commission Regulation for the full explanation of the justification for the restricted or non-renewal of approval.

Restricted renewal

Cypermethrin: renewal of approval as a candidate for substitution. (November 25, 2021)

Sulfoxaflor: restricted renewal to permanent greenhouse use only. (April 28, 2022)

Bifenazate: restricted renewal to non-edible crops in permanent greenhouses. (May 3, 2022)

MRL CHANGES (September 2021 – August 2022)

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.

WTO Notification:

- Imazaquin: WTO notification G/SPS/N/EU/527. (December 15, 2021)
- **Bromoxynil**: WTO notification G/SPS/N/EU/575. (July 4, 2022)
- **Chlorsulfuron**: WTO notification G/SPS/N/EU/575. (July 4, 2022)
- Clothianidin: WTO notification G/TBT/N/EU/908. (July 6, 2022)
- Thiamethoxam: WTO notification G/TBT/N/EU/908. (July 6, 2022)
- Triadimenol: WTO notification G/SPS/N/EU/581. (July 21, 2022)
- **Cyromazine**: WTO notification G/SPS/N/EU/582. (July 21, 2022)
- Topramezone: WTO notification G/SPS/N/EU/582. (July 21, 2022)
- Triflumizole: WTO notification G/SPS/N/EU/582. (July 21, 2022)
- Sodium aluminum silicate*: WTO notification G/SPS/N/EU/581. (July 21, 2022)
- Calcium phosphide*: WTO notification G/SPS/N/EU/582. (July 21, 2022)

Import tolerances and some Codex MRLs were maintained for the following substance:

- o **Bifenthrin**: WTO notification G/SPS/N/EU/527. (December 15, 2021)
- o **Cyfluthrin**: WTO notification G/SPS/N/EU/573. (June 22, 2022)
- o Beta Cyfluthrin: WTO notification G/SPS/N/EU/573. (June 22, 2022)

<u>Implementing Regulation</u>:

• Thiram: Commission Regulation 2022/1406 on August 3, 2022. Effective date: February 28, 2023

^{*}Substance is exempt from a tolerance in the United States





September 7, 2022

EU EARLY ALERT – ARTICLE 12 MRL REVIEW

The Article 12 of Regulation (EC) No. 396/2005 provides for the review of all MRLs established in the European Union. EFSA publishes a <u>progress report</u> that lays out the expected timeline for MRL-specific reviews (start of data collection and conclusion of EFSA's Reasoned Opinion). The table below lists active ingredients of interest to U.S. stakeholders that have started or are expected to start the MRL review process in 2022, according to information available as of **August 31, 2022**.

The Office of Plant Division at the Foreign Agriculture Service notifies stakeholders at the beginning of the MRL review process. This early notice provides stakeholders the opportunity to contact registrants and coordinate on actions to support the EU MRL at a critical point of the MRL review process.

| Active Substance | Start of MRL Review | Reasoned Opinion |
|--------------------|---------------------|------------------|
| Metiram | 11/16/2020 | 12/15/2022 |
| Ziram | 11/16/2020 | 12/15/2022 |
| Mancozeb | 12/15/2020 | 12/15/2022 |
| Alpha-cypermethrin | 04/16/2021 | 12/31/2022 |
| Cypermethrin | 04/15/2021 | 12/31/2022 |
| Zeta-cypermethrin | 05/12/2021 | 12/31/2022 |
| Pyriproxyfen | 08/16/2021 | 11/11/2022 |
| Difenoconazole | 09/17/2021 | 01/31/2023 |
| Zoxamide | 09/15/2022 | 09/15/2023 |
| Chlorsulfuron | Not applicable | 12/31/2022 |
| Topramezone | Not applicable | 12/31/2022 |

^{*}Substance is exempt from a tolerance in the United States

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