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Report Name: EU Early Alert - Pesticide Review - December 2024

Country: European Union

Post: Brussels USEU

Report Category: SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural

Exports

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Report Highlights:

The European Union (EU) follows a complex, rolling system of review for active ingredients and Maximum Residue Levels (MRLs) in food. For agricultural inputs, U.S. farmers must know early in the process of review to prevent or mitigate the loss of, and/or access to, chemical inputs. The information in this document provides interested stakeholders with advance notice of those active ingredients under review, highlighting those substances undergoing new restrictions or that may not be renewed. This is a quarterly update from December 2024.





The active ingredients of plant protection products (PPPs), along with Maximum Residue Levels (MRLs) and/or import tolerances, are an increasingly important concern in the EU given the decrease in the number of active ingredient substances approved for use. Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 regulate PPPs and MRLs, respectively. The EU follows a complex, rolling system of review for use of active ingredients and MRLs in food. For agricultural inputs, U.S. farmers must know early in the process of EU reviews to prevent or mitigate trade disruption due to new restrictions or non-renewals of chemical inputs.

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. This is a quarterly update. The arrows to the left of each section explain where a substance is in the EU review process as of November 30, 2024.

Please find the <u>EU Early Alert – Pesticide Review</u> attached below. USDA is seeking feedback from our stakeholders on this document and the information it presents. If it is considered useful, it may be updated and distributed quarterly according to your preferences. Please send comments and questions to <u>AgUSEUBrussels@usda.gov</u> and <u>PlantDivision@usda.gov</u>.

Disclaimer: Please note that while every effort is made to capture all upcoming and completed reviews, this list may not be all-inclusive.

Attachments:

EU Early Alert - Pesticide Review - December 2024.pdf





EU EARLY ALERT - PESTICIDE REVIEW

December 9, 2024

Active ingredients used in pesticides within the European Union undergo mandatory review every 10-15 years. This process typically spans three or more years. Registrants are required to submit renewal applications no later than thirty-six months before the expiration date. During these reviews, substances are assessed 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 and it can also result in the elimination of the associated Maximum Residue Levels (MRLs).

This document serves to provide advanced notification of active ingredients currently under review for renewal of approval in the EU. It also identifies substances that have expired, are nearing expiration, or face potential restrictions or non-renewal. While usage restrictions do not apply to US growers, MRLs for substances that have expired or are not approved may face future restrictions. Changes in MRLs resulting from EU restriction of approvals are monitored and detailed in the final table.

US exporters to the EU are strongly encouraged to monitor the MRL status of substances used on products destined for EU markets. The information presented in this report is based on publicly available data as of **November 30**, **2024**. For further insights into this report, please consult the User Guide provided.

APPLICATION FOR RENEWAL – EXPECTED TO EXPIRE (Up to November 2025)

Chemical companies must support the review of their substances. Failure to do so will result in automatic expiration of the active ingredient in the EU on a specified date. For the substances listed below, registrants have either not submitted the application for renewal of approval or have withdrawn it, leading to the expiration of approval. This may impact corresponding MRLs. The expiration date of each substance is indicated in parentheses.

- Metaflumizone (December 31, 2024)
- Gamma-cyhalothrin (March 31, 2025)
- Meptyldinocap (March 31, 2025)

APPLICATION FOR RENEWAL - EXPIRED (December 2023 – November 2024)

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.

- **Penflufen** (January 31, 2024)
- Spirotetramat (April 30, 2024)
- **Pyridalyl** (June 30, 2024)

- **Spinetoram** (June 30, 2024)
- Bacillus pumilus QST 2808* (August 31, 2024)
- Flubendiamide (August 31, 2024)

UP NEXT FOR REVIEW (Up to November 2026)

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 listed below in parentheses.

- **Cypermethrin** (January 31, 2026)
- **Mefentrifluconazole** (March 20, 2026)
- **Flutianil** (April 14, 2026)
- Florpyrauxifen-benzyl* (July 24, 2026)

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

EU RENEWAL REVIEW: ACTIVE INGREDIENTS AT RISK OF APPROVAL RESTRICTION

These active ingredients are currently undergoing review for renewal of approval and have been presented by the European Commission for non-renewal or restricted renewal in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) meeting. This table does not list all substances currently under review¹ or those that have been proposed for renewal. It's important to note that EU approval status applies exclusively to EU uses and does not affect US growers directly. However, the Maximum Residue Levels (MRLs) for substances that have expired or are not approved may face future restrictions. US exporters to the EU are encouraged to monitor the MRL status of substances applied to US products intended for the EU market. To verify the approval status of substances in the EU, please refer to the EU Pesticides Database. Last updated on November 30, 2024.

Application	Renewal Assessment	EFSA Peer Review	EC Draft (PAFF)	WTO/TBT Notification	Commission Regulation (EU)	
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Active Ingredient	Registrant	Proposed Approval Status	SCoPAFF – Legislation	Proposed Restricted or Non-renewal Notified to the WTO ¹
Flufenacet	CropScience AG	Proposed non-renewal due to classification as an endocrine disruptor for humans and non-target organisms. High potential for groundwater contamination by flufenacet metabolite (TFA)	Listed for discussion in December 2024 meeting	
Flutolanil	Nichino Europe Co.	Proposed non-renewal due to missing data gaps resulting in the inability to finalize the consumer risk assessment.	Listed for discussion in December 2024 meeting	

¹ World Trade Organization (WTO) members have sixty days from date of notification to submit comments to proposed measure.

EU MRL RESTRICTION DUE TO APPROVAL STATUS

The active ingredients listed here are no longer approved for use in the EU due to expiration, restriction, or non-renewal of their approval. This table indicates whether EU actions regarding MRLs are being considered or have been implemented within the past year. It does not encompass all EU MRL actions resulting from other initiatives, such as import tolerances or Codex harmonization requests. For detailed information on currently established MRLs in the EU, please consult the FCID Regulatory Limits Database. Last updated on November 30, 2024.

Restricted or non renewal of approval - Commission Regulation (EU)		O/SPS Effication Commission Regulation (EU)	New MRL Effective Date
No channels of trade provision included.	Channels of trade provision included for all commodities.	Channels of trade provision included for some commodities.	Review on hold
Some Codex and/or import tolerances were maintained.	Blank cells indicate no action has taken place.	Shaded cells include new information since last update.	

Active Ingredient	EU Registrant	Approval Status ² (publication date)	SCoPAFF ³ – Residues (draft regulation presented)	Proposed MRL Notified to the WTO	MRL Restriction Implemented	MRL Restriction Effective Date
Abamectin	Task Force	Restricted renewal to greenhouse use based on high risk identified to aquatic organisms and wild terrestrial non-target organisms, others. (March 8, 2023)				
Acibenzolar S- methyl		Withdrawal of approval due to endocrine-disrupting attributes and its classification as toxic for reproduction, category 1B. (June 20, 2024)				

² The reasons for non-renewal or restriction of approval listed in the approval status column are not exhaustive. They reflect only the decisions made by EU authorities, which may differ from the conclusions of other regulatory authorities worldwide.

³ The Standing Committee on Plants, Animals, Food and Feed (<u>SCoPAFF</u>) is composed by representatives of all EU countries and presided by a European Commission representative. It delivers opinions on draft measures that the Commission intends to adopt. This section includes notes from the Section on Pesticide Residues meetings up to November 25-26, 2024.

Active Ingredient	EU Registrant	Approval Status ² (publication date)	SCoPAFF ³ – Residues (draft regulation presented)	Proposed MRL Notified to the WTO	MRL Restriction Implemented	MRL Restriction Effective Date
Alpha- Cypermethrin	BASF	Withdrawal of approval as the applicant did not submit required confirmatory data. (May 17, 2021)	Draft presented for discussion in April 2024 meeting	12-Dec-23		
Benfluralin	Gowan	Non-renewal based on long-term risk to birds and the genotoxic potential. (January 20, 2023)	Draft presented for discussion in November 2024 meeting			
Bifenazate	UPL	Restricted renewal to non-edible crops in permanent greenhouses. (May 3, 2022)	Committee voted in favor of the proposed regulation in May 2023	17-Jan-23	25-Mar-24	14-Oct-24
Bifenthrin	FMC	Restricted renewal to greenhouse use based on potential bioaccumulation and biomagnification in the aquatic environment. (February 28, 2018)	Draft presented for discussion in November 2023 meeting.	■ <u>15-Dec-21</u>		
Bispyribac	K-I Chemical Europe	Expired on July 31, 2022 as registrant withdrew renewal application.	Draft presented for a vote in November 2023 meeting		16-Apr-24	06-May-24
Captan	ADAMA, UPL	The EU reviewed the proposal and renewed the approval including for outdoor uses. This substance will be deleted from this chart.				
Carboxin		Expired on May 31, 2021 as registrant withdrew renewal application.	Committee voted in favor of the proposed regulation in May 2023	23-Feb-23	05-Oct-23	25-Apr-24
Clothianidin	Sumitomo	Restricted to greenhouse use due to risk to bees. (May 29, 2018)	Committee voted in favor of the proposed regulation in September 2022	06-Jul-22	15-Feb-23	07-Mar-26
Clofentezine	ADAMA	Non-renewal due to endocrine disrupting properties that may cause adverse effects in humans, as well as a high, long-term risk to birds and wild mammals. (November 8, 2023)				
Cyproconazole		Expired on May 31, 2021 as registrant withdrew renewal application	Committee voted in favor of the proposed regulation in April 2024	24-Jan-24		

Active Ingredient	EU Registrant	Approval Status ² (publication date)	SCoPAFF ³ – Residues (draft regulation presented)	Proposed MRL Notified to the WTO	MRL Restriction Implemented	MRL Restriction Effective Date
Desmedipham	Bayer, UPL	Non-renewal based on potential endocrine disrupting, carcinogenic, and mutagenic properties. (June 27, 2019)	Draft presented for a vote in September 2023 meeting	07-Jul-23	23-Jan-24	12-Aug-24
Dimethomorph	BASF, UPL	Non-renewal based on multiple concerns, including its classification as toxic for reproduction, category 1B, and endocrine-disrupting properties. (April 20, 2024)				
Diuron		Expired on September 30, 2020 as registrant withdrew renewal application.	Committee voted in favor of the proposed regulation in May 2023	24-Feb-23	18-Sep-23	08-Apr-24
Etoxazole	Sumitomo	Restricted renewal to use on ornamental plants in permanent greenhouses. (December 15, 2020)	Committee voted in favor of the proposed regulation in May 2023	24-Feb-23	18-Sep-23	08-Apr-24
Etridiazole		Expired on May 31, 2021 as registrant did not apply for renewal.	Draft presented for a vote in September 2023 meeting	07-Jul-23	23-Jan-24	12-Aug-24
Famoxadone		Non-renewal due to high potential for workers exposure, high long- term risk for mammals and high risk for aquatic organisms. (August 19, 2021)	Draft presented for a vote in September 2023 meeting	13-Jun-23	23-Jan-24	12-Aug-24
Fenazaquin	Gowan	Restricted renewal to greenhouse and ornamental use only. (May 7, 2018)				
Fenbuconazole		Expired on April 30, 2021 as registrant did not apply for renewal	Draft presented for discussion in April 2024 meeting	2-Jul-24		
Flutriafol	FMC	Expired on May 31, 2021 as registrant withdrew renewal application	Draft presented for a vote in September 2023 meeting	29-Jun-23	23-Jan-24	12-Aug-24
Glufosinate	BASF	Expired on July 31, 2018 as registrant withdrew renewal application.	New EFSA mandate for MRL review.			
Indoxacarb	FMC	Non-renewal due to risks posed to mammals and bees, as well as insufficient data to complete consumer, groundwater, and	Draft presented for a vote in September 2023 meeting	07-Jul-23	25-Jan-24	14-Aug-24

Active Ingredient	EU Registrant	Approval Status ² (publication date)	SCoPAFF ³ – Residues (draft regulation presented)	Proposed MRL Notified to the WTO	MRL Restriction Implemented	MRL Restriction Effective Date
		ecotoxicology risk assessments. (November 26, 2021)				
Ipconazole	UPL	Withdrawal of approval due to classification as toxic for reproduction category 1B. (May 11, 2023)				
Malathion	FMC	Restricted renewal to greenhouse use based on high risk to birds. (October 8, 2018)				
Mancozeb	EU Mancozeb Task Force	Non-renewal based on classification as toxic for reproduction category 1B. (December 14, 2020)	Draft presented for discussion in April 2024 meeting	22-Jul-24		
Methomyl		Expired on August 31, 2019 as registrant did not apply for renewal	Committee voted in favor of the proposed regulation in May 2023	24-Feb-23	18-Sep-23	08-Apr-24
Methoxyfenozide	Dow Agrisciences	Restricted renewal to greenhouse use based on classification as persistent and toxic. (January 31, 2019)				
Metiram	BASF	Non-renewal due to high risk to aquatic organisms and non-target arthropods, and exposure exceedance amongst operators, bystanders, and residents. (November 8, 2023)	Draft presented for discussion in April 2024 meeting	22-Jul-24		
Metribuzin		Non-renewal of approval due to endocrine disruption in humans and high risk of exposure to bystanders and residents. (November 4, 2024)				
Myclobutanil		Expired on May 31, 2021 as registrant did not apply for renewal.	Draft presented for discussion in November 2024 meeting			
Oryzalin		Expired on May 31, 2021 as registrant did not apply for renewal.	Draft presented for a vote in November 2023 meeting		16-Apr-24	06-May-24
Oxamyl	Corteva	Non-renewal due to concerns with operator exposure level, exceedance of the acute reference dose, others (April 5, 2023)	Draft presented for a vote in September 2023 meeting	28-Jun-23	22-Jan-24	11-May-24

Active Ingredient	EU Registrant	Approval Status ² (publication date)	SCoPAFF ³ – Residues (draft regulation presented)	Proposed MRL Notified to the WTO	MRL Restriction Implemented	MRL Restriction Effective Date
Quinoxyfen	Dow	Non-renewal based on persistent, bioaccumulative and toxic; very persistent and very bioaccumulative; and persistent organic pollutant properties. (December 6, 2018)				
S-metolachlor	Syngenta	Non-renewal based on multiple concerns, including contamination of groundwater risk for earthworm-eating mammals. (January 3, 2024)				
Sodium hypochlorite		Expired on August 31, 2019 as registrant did not apply for renewal.	Committee voted in favor of the proposed regulation in September 2023	13-Jun-23	23-Jan-24	12-Aug-24
Spirodiclofen		Expired on July 31, 2020 as registrant did not apply for renewal.	Committee voted in favor of the proposed regulation in April 2024	24-Jan-24		
Sulfoxaflor	Corteva	Restricted renewal to greenhouse uses due to risk to bumble bees and solitary bees from outdoor uses. (April 28, 2022)				
Teflubenzuron		Expired on November 30, 2019	Committee voted in favor of the proposed regulation in May 2023	24-Feb-23	18-Sep-23	08-Apr-24
Thiamethoxam	Syngenta	Restricted renewal to greenhouse use due to high risk to bees. (May 29, 2018)	Committee voted in favor of the proposed regulation in September 2022	06-Jul-22	15-Feb-23	07-Mar-26
Thiophanate- methyl	Nisso	Expired on October 19, 2020 as registrant withdrew renewal application.	Committee voted in favor of the proposed regulation in April 2024	23-Nov-23		
Triazoxide		Expired on September 30, 2021 as registrant did not apply for renewal.	Draft presented for a vote in November 2023 meeting		16-Apr-24	06-May-24
Triflusulfuron	Cheminova	Non-renewal based on multiple concerns, including groundwater metabolites and endocrine disrupting properties in humans. (November 17, 2023)				
Zeta- Cypermethrin	FMC	Expired on December 1, 2020 as registrant withdrew renewal application.	Draft presented for discussion in April 2024 meeting	12-Dec-23		

Important Note: The BCI EU Early Alert is intended to be an initial reference source only. Users must verify information obtained from it with knowledgeable parties prior to sale or shipments of any products. Users of the EU Early Alert acknowledge that BCI cannot and does not warrant that information will be one hundred percent (100%) accurate and free of omissions. BCI shall not be held liable for any losses or damages arising from errors or omissions from use of the information contained in the EU Early Alert.