

Latest pesticide non-renewals, withdrawals, restrictions, and non-approvals (2024)

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Non-renewals, withdrawals, restrictions, and non-approvals of pesticides for use in the EU introduced in 2024

Commission Implementing Regulation (EU) <u>2024/2197</u> concerning the non-approval of eggshell powder as a basic substance

<u>Draft</u> Commission Implementing Regulation concerning the non-renewal of approval of the active substance tritosulfuron

<u>Draft</u> Commission Implementing Regulation concerning the non-renewal of the approval of the active substance metribuzin

Commission Implementing Regulation (EU) <u>2024/1696</u> withdrawing the approval of the active substance acibenzolar-S-methyl

Commission Implementing Regulation (EU) <u>2024/1207</u> concerning the non-renewal of the approval of the active substance dimethomorph

Commission Implementing Regulation (EU) <u>2024/425</u> concerning the non-approval of the active substance asulam-sodium

Commission Implementing Regulation (EU) <u>2024/20</u> concerning non-renewal of the approval of the active substance S-metolachlor

Update

This report summarises recent EU decisions not to renew, or to withdraw, existing approvals for certain pesticide active substances. While these decisions primarily affect EU producers, they will probably be followed by legislation to reduce the maximum residue levels (MRLs) to 0.01 mg/kg or the limit of determination (LOD – the lowest level that can be detected using the most modern and reliable analytical methods). These decisions therefore provide an early indication of upcoming MRL changes, and the likely need to look for alternative solutions on crops for export to the EU.

This report also includes EU non-approval decisions. These are relevant to producers in exporting countries where these substances may be used locally. In such cases a default MRL of 0.01 mg/kg will be maintained.





What is changing?

The EU systematically reviews the status of all pesticide active substances that are approved for use within the European Union. Recent non-renewals and withdrawals of approvals are summarised in Table 1. To check the expiry or review dates of other pesticide active substances, see the EU Pesticides Database.

In addition to the withdrawals and approvals in Table 1, the EU has recently decided not to approve eggshell powder as a basic substance, and previously decided not to approve the active substance asulam-sodium.

Why?

<u>EFSA (2023b)</u> raised concerns about neurodevelopment effects associated with the use of eggshell powder due to its lead content, and therefore cannot consider its use as safe.

<u>EFSA (2021a)</u> identified endocrine-disrupting properties as the main hazard associated with the use of asulam-sodium. EFSA's approval criteria were not satisfied and the applicant ultimately withdrew its application for the approval of this substance. This decision does not prevent the submission of a further application for approval of asulam-sodium.

Timeline

Expiry dates for the substances affected are listed in Table 1. After these dates, the pesticides can no longer be used in the EU.

The European Commission is expected to follow up with proposals to reduce or remove the MRLs for these substances, which will affect their use on crops for export to the EU. Any changes to MRLs are notified to the World Trade Organization Sanitary and Phytosanitary (WTO SPS) Committee, and details will be provided on the AGRINFO website.

What are the major implications for exporting countries?

Decisions not to renew or to withdraw EU approvals for the use of certain pesticide active substances mainly affect their use within the EU. However, following a non-renewal or withdrawal of approval, in most cases the EU starts the process of lowering or removing the associated MRLs. These are typically set at 0.01 mg/kg or the LOD. In many circumstances this means that they can no longer be used on crops for export to the EU, and action is needed.





Recommended Actions

Export sectors affected should start looking for alternative crop protection solutions to S-metalochlor, or assess possible adaptations of GAP. Exporting countries could also consider requesting EU import tolerances (for guidelines see <u>European Commission 2021</u>). See <u>Pesticide</u> residue import tolerance MRLs explained.

Background

For decisions taken in 2023, see <u>Latest pesticide non-renewals</u>, <u>withdrawals</u>, <u>and restrictions</u> (2023).

Pesticide active substances are approved for up to a maximum period of 15 years. Manufacturers may apply for reapproval of a substance for a period not more than 15 years. The EU systematically reviews all active substances.

Substances can be:

- not reapproved: if there is insufficient data to permit reapproval, or because the manufacturer does not seek reapproval
- withdrawn: where specific consumer health or environmental issues are identified, sometimes before the normal expiry date
- restricted: where data supports renewal, but only under new specific conditions of use.

Where an authorisation for an active substance is withdrawn or expires due to withdrawal of approval or non-renewal, the European Commission will prepare a draft measure to delete the relevant existing MRLs. In practice, the Commission starts this procedure once all existing authorisations for that active substance have been revoked. MRLs are set either to a default value of 0.01 mg/kg, or to the lowest limit technically possible using current analytical methods. MRLs based on the Codex MRLs (CXLs) are not deleted where there is no risk to EU consumers, or no global environmental concern. Changes to MRLs that impact trade are always notified to the WTO SPS Committee.

The precise timing of changes to MRLs resulting from the withdrawal or non-renewal of active substances is difficult to predict. In its review of pesticide policy, the Commission committed to "enhance communication efforts on the impacts of the PPP Regulation on MRLs as well as the timing of the various procedures to make the EU system more predictable for non-EU countries, including for the cut-off criteria" (European Commission 2020).





Import tolerances can be requested in anticipation of potential changes to MRLs (see <u>Overview table 2009–2020</u>), but applicants must demonstrate the existence of relevant good agricultural practices (GAP) in the country of origin, and the safety of the proposed MRLs. Guidelines are available on the requirements and process for establishing MRLs and import tolerances (<u>European Commission 2021</u>).

Resources

Bryant Christie Inc. & CropLife International: <u>EU Pesticide Renewal Monitors</u> [select Topic = Renewal Monitor].

EFSA (2021a) <u>Updated peer review of the pesticide risk assessment of the active substance asulam (variant evaluated asulam sodium)</u>. EFSA Journal, 19(11): 6921.

EFSA (2021b) Peer review of the pesticide risk assessment for the active substance acibenzolar methyl in light of confirmatory data submitted. EFSA Journal, 19(7): 6687.

EFSA (2023a) Peer review of the pesticide risk assessment of the active substance dimethomorph. EFSA Journal, 21(6): 8032.

EFSA (2023b) Overall conclusions on the application for approval of eggshell powder as a basic substance to be used in plant protection as a fungifuge on grapevines. EFSA supporting publication, 20(11): EN-8434.

European Commission: Overview table 2009–2020.

European Commission (2020) <u>Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides</u>.

European Commission (2021) <u>Technical Guidelines: MRL Setting Procedure in Accordance with</u> Article 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 107/2009.

ITC, UN, and WTO: ePing SPS & TBT Platform

Sources

<u>Draft</u> Commission Implementing Regulation concerning the non-renewal of approval of the active substance tritosulfuron (WTO notification <u>G/TBT/N/EU/1078</u>)

<u>Draft</u> Commission Implementing Regulation concerning the non-renewal of the approval of the active substance metribuzin (WTO notification <u>G/TBT/N/EU/1076</u>)





Commission Implementing Regulations:

- 2024/20 concerning non-renewal of the approval of the active substance S-metolachlor
- 2024/425 concerning non-approval of the active substance asulam-sodium
- 2024/1207 concerning the non-renewal of the approval of the active substance dimethomorph
- 2024/1696 withdrawing the approval of the active substance acibenzolar-S-methyl
- 2024/2197 concerning the non-approval of eggshell powder as a basic substance

Table & Figures

Table 1 Latest pesticide non-renewals, withdrawals, and restrictions (2024)			
Active substance	Date of expiry/ authorisation/ withdrawal	Legal basis	Status
Acibenzolar-S- methyl	20 Jul 2024	Implementing Reg. (EU) 2024/1696	Withdrawal: insufficient data to evaluate endocrine- disrupting properties; applicant self-classified it as toxic for reproduction
Dimethomorph	20 May 2024	Implementing Reg. (EU) 2024/1207	Non-renewal: concerns about toxicity to reproduction and endocrine disruption in humans and mammals
Metribuzin	End 2024	WTO notification G/TBT/N/EU/1076	Non-renewal: endocrine-disrupting properties and high risk to bees
S-metolachlor	23 Jan 2024	Implementing Reg. (EU) 2024/20	Non-renewal: unacceptable risk to mammals and of groundwater contamination
Tritosulfuron	End 2024	WTO notification G/TBT/N/EU/1078	Non-renewal: withdrawal of application for renewal of approval by manufacturer
Www.agrinfo.eu			

Source: based on Regulations <u>2024/20;</u> <u>2024/1207;</u> <u>2024/1696;</u> WTO notifications <u>G/TBT/N/EU/1076;</u> <u>G/TBT/N/EU/1078</u>

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