

The United States appreciates the opportunity to review and comment on the European Union (EU) “Draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance bifenthrin,” notified to the World Trade Organization (WTO) as G/TBT/N/EU/508 on September 12, 2017.

The EU is proposing to amend the approval conditions for bifenthrin in order to restrict its use to application in permanent greenhouses. As the basis for these restrictions, the EU cites concerns about bioaccumulation and bio-magnification in the aquatic and terrestrial food chain, and risk to non-target arthropods. While the proposed measure only affects current EU usage of bifenthrin and does not state the EU’s intentions regarding maximum residue limits (MRLs), the United States understands that there may be future actions to lower or withdraw MRLs for which there are no corresponding use patterns (i.e., good agricultural practices, or GAPs) in the EU, or for which there are no Codex MRLs.

Bifenthrin is currently authorized in the United States for uses beyond crops that can be exclusively grown in greenhouses (e.g., almonds, grapes). In order to maintain/establish EU import tolerances for these uses, the United States seeks clarification on what information—if any—must be submitted in order to comply with EU data requirements. For almonds and grapes, for example, Codex MRLs have been established. Will the EU harmonize with the existing Codex MRLs for bifenthrin?

Commodity	U.S. MRL (mg/kg)	Codex MRL (mg/kg)	EU MRL (mg/kg)
Almond	0.05	0.05	0.05
Grape	0.2	0.3	0.01

The United States notes that the existing EU MRL for bifenthrin on grapes is not harmonized with the current Codex MRL, established in 2016. The document “Scientific support for preparing an EU position in the 48th Session of the Codex Committee on Pesticide Residues (CCPR)”¹ does not appear to identify any risk to EU consumers from bifenthrin residues on grapes. Furthermore, the official report from CCPR48² does not indicate that the EU conveyed a reservation on the advancement of the Codex MRL for bifenthrin on grapes. Therefore, will the EU harmonize its grape MRL with the Codex MRL for grapes?

As no human health risks or human health related data gaps appear to have been identified as the basis for the proposed restriction of bifenthrin to use in greenhouses, the United States assumes that there is no human health concern that would preclude the setting of import tolerances for bifenthrin. If the existence of a Codex MRL is not sufficient, will it then be necessary to submit residue trial data reflecting the critical U.S. GAP for commodities of interest? If this is the case, the United States would be pleased to also submit the relevant residue chemistry data evaluation records from the U.S. Environmental Protection Agency to assist the EU in its review.

¹ <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4571/full>

² http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-48%252FReport%252FREP16_PRe.pdf

The notification indicates that a grace period of no more than 15 months will be observed for placing on the market, disposal, storage, and use of existing stocks of plant protection products containing bifenthrin. Consequently, the United States also seeks clarification on the timeframe under which revisions to existing EU MRLs may occur. In order to minimize disruption to international trade, the United States respectfully requests that the EU consider an extended grace period for existing EU MRLs, which would allow for the submission and review of import tolerance applications required by the EU to retain existing MRLs supporting the import of almonds and grapes from the United States.

Bifenthrin is a significant crop protection tool for the U.S. almond industry, and is essential for managing naval orangeworm, a key pest/vector associated with aflatoxin contamination. It is also an important component of integrated pest management programs for California grapes. In 2016, the United States exported \$1.5 billion of almonds, \$681 million of wine, \$80 million of raisins, and \$12 million of fresh grapes to the EU.

The EU is an important market for U.S. agricultural products. We thank you again for your consideration of these comments and look forward to your response.