USA Submits Comments on EU's WTO Notification

G/TBT/N/EU/853 - Draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor

From: usatbtep <usatbtep@nist.gov>
To: GROW EU-TBT <grow-eu-tbt@ec.europa.eu>
Cc: usatbtep <usatbtep@nist.gov>
Date: Fri, 14 Jan 2022 10:52:36 -0500
Attachments: USG_Comments_on_EU853.pdf (166.78 kB); eu853.docx (50.17 kB)

Dear Colleagues in the EU WTO TBT Enquiry Point,

Please find attached comments from the Government of the United States (USG) on the following WTO notification distributed 17 November 2021:

G/TBT/N/EU/853 - Draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor

A copy of the notification is also attached.

Please acknowledge receipt of this email by return message; please let us know if you have any questions.

Many thanks for your consideration of these comments.

Best Regards,

MaryAnn Hogan
USA WTO TBT Enquiry Point
Standards Coordination Office (SCO)
National Institute of Standards and Technology (NIST)
Email: usatbtep@nist.gov
URL: >www.nist.gov/notifyus<
NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. **Notifying Member**: EUROPEAN UNION

   If applicable, name of local government involved (Article 3.2 and 7.2):

2. **Agency responsible**: European Commission

   Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:

   European Commission,
   EU-TBT Enquiry Point,
   Fax: + (32) 2 299 80 43,
   E-mail: grow-eu-tbt@ec.europa.eu
   Website: http://ec.europa.eu/growth/tools-databases/tbt/en/

3. **Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:

4. **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable)**: Sulfoxaflor (pesticide active substance); Pesticides and other agrochemicals (ICS 65.100)

5. **Title, number of pages and language(s) of the notified document**: Draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor (5 page(s), in English; 2 page(s), in English)

6. **Description of content**: This draft Commission Implementing Regulation provides that the approval conditions of the active substance sulfoxaflor are amended in accordance with Regulation (EC) No 1107/2009 based on the evaluation of confirmatory data as required in Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor for use in the EU. Existing authorised plant protection products containing sulfoxaflor will be reviewed in accordance with the restriction set in this act.

   This decision however only concerns the placing on the market of this substance. Following restriction of the approval and the consequent expiry of all grace periods for stocks of products, separate legal action will likely be taken on Maximum Residue Levels and a separate notification will be made in accordance with SPS procedures in due time.

7. **Objective and rationale, including the nature of urgent problems where applicable**: In order for an active substance to be approved in accordance with Regulation (EC) No 1107/2009 (concerning the placing of plant protection products on the market), it must be demonstrated that the substance is not harmful to human health, animal health or the environment. Criteria are listed in Article 4 of the Regulation (and also detailed in Annex II
thereto) which must be met to enable approval. Regulation (EU) No 2015/1295 approved sulfoxaflor as active substance for use in plant protection products and required the applicant to provide confirmatory information with regard to bees. Following the assessment of confirmatory information, the information provided did not demonstrate absence of risks to bees, in particular bumble bees and solitary bees, from outdoor use. Consequently, the notified draft Implementing Regulation aims at restricting the conditions of approval of the active substance sulfoxaflor to uses in permanent greenhouses only in order to protect bees.

The decision is based on a risk assessment peer reviewed at EU level, under the lead of the European Food Safety Authority. EU Member States shall, where necessary, withdraw or amend authorisations for plant protection products containing sulfoxaflor as active substance at the latest by 6 months from the date of entry into force. EU Member States may grant a period of grace in line with Article 46 of Regulation No 1107/2009 which shall expire at the latest 12 months from the entry into force of the notified draft Implementing Regulation.

8. Relevant documents:

9. **Proposed date of adoption:** 1st Quarter 2022.

**Proposed date of entry into force:** 20 days following publication in the Official Journal of the EU

10. **Final date for comments:** 60 days from notification
11. **Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

   European Commission,
   EU-TBT Enquiry Point,
   Fax: + (32) 2 299 80 43,
   E-mail: grow-eu-tbt@ec.europa.eu


   [https://members.wto.org/crnattachments/2021/TBT/EEC/21_7189_00_e.pdf](https://members.wto.org/crnattachments/2021/TBT/EEC/21_7189_00_e.pdf)

   [https://members.wto.org/crnattachments/2021/TBT/EEC/21_7189_01_e.pdf](https://members.wto.org/crnattachments/2021/TBT/EEC/21_7189_01_e.pdf)
The United States appreciates the opportunity to comment on the draft “Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor,” notified by the European Union (EU) to the World Trade Organization (WTO) on November 11, 2021 as G/TBT/N/EU/853. The United States offers the following comments for your consideration.

The EU is proposing to amend the approval conditions for sulfoxaflor to restrict its use to crops grown exclusively inside permanent greenhouses, citing primarily risks to pollinators (e.g. honeybees and bumble bees). While the United States shares the EU’s concern for pollinators and is similarly committed to ensuring that plant protection products do not result in unreasonable adverse effects on the environment, the United States is concerned that restricting the use of sulfoxaflor to permanent greenhouses does not fully consider possible mitigation measures that allow sulfoxaflor to be used on a variety of field crops. Although the proposed measures affect current EU usage of this product, the United States is concerned that the EU will subsequently propose reducing or withdrawing maximum residue levels (MRL) for important crops, particularly those that are grown in open field conditions.

Sulfoxaflor is a relatively new crop protection tool that has seen increased use since it was first registered by the U.S. Environmental Protection Agency (EPA) in 2013. It is registered for several uses in crops grown in open field conditions, such as soybeans and cucurbits, in the United States. Sulfoxaflor is also an important pesticide for several crops in the EU, including open field crops like sugarbeets.

Sulfoxaflor is a key part of several integrated pest management (IPM) and insect resistance management (IRM) programs, particularly for soybean growers managing soybean aphid, and benefits U.S. soybean growers by providing a unique mode of action. Sulfoxaflor has not shown cross resistance with other pesticides. For cucurbits, Sulfoxaflor targets aphids and whiteflies, both of which are able to develop resistance fairly rapidly to sulfoxaflor alternatives. Thus, the new mode of action afforded by access to sulfoxaflor will benefit many IPM programs. The United States emphasizes that unnecessarily removing active ingredients, particularly when few modes of action are available to address a pest species, can increase the probability that pests may develop resistance to pesticides.

Both the United States and Codex have established maximum residue limits (MRLs) for sulfoxaflor that facilitate trade while protecting consumer health. The United States would like to draw attention to the following language in the EU’s WTO notification: “This decision only concerns the placing on the market of this substance and plant protection products containing it. Following non-approval and the expiry of all grace periods for stocks of products containing this substance, separate action will likely be taken on MRLs and a separate notification will be made in accordance with SPS procedures in due time.” In anticipation of this proposed revision, the United States requests that the EU maintain its current sulfoxaflor MRLs where no human health

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risks³ have been identified or follow Codex MRLs until it completes a comprehensive risk assessment to support any changes to existing MRLs. Additionally, the United States asks the EU to provide clarification regarding the timeframe for any future amendments to sulfoxaflor MRLs.

Table: Sulfoxaflor MRLs (ppm)

<table>
<thead>
<tr>
<th>Crop</th>
<th>Current EU MRL</th>
<th>U.S. Tolerance</th>
<th>Codex MRL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cucurbit, group 9 (watermelon and pumpkin)</td>
<td>0.5</td>
<td>0.4</td>
<td>0.5</td>
</tr>
<tr>
<td>Soybeans</td>
<td>0.2</td>
<td>0.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

The European Union is an important market for U.S. agricultural products and for farmers worldwide. The loss of important MRLs for sulfoxaflor will limit the United States’ ability to export agricultural crops to the EU market. In 2020, the United States exported $1.88 billion in soybeans and $274,000 in cucurbits to the European Union.

Sustainable global agricultural production relies on science-based decisions and international standards that support the safe and judicious use of diverse crop protection tools to manage endemic, emerging, and invasive pests. As the United States and the EU work toward a more sustainable and resilient agriculture system, it is important to allow farmers access to the necessary tools to efficiently provide safe and high-quality food and fiber products. The United States thanks the EU for consideration of these comments and looks forward to future cooperation with the EU.

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³ European Food Safety Authority. “Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor.” March 11, 2015. [Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor (wiley.com)]
EU Acknowledges Receipt of USA Comments on WTO Notification G/TBT/N/EU/853 - Draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval

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Date: Tue, 18 Jan 2022 07:54:40 -0500

USA thanks the EU for this acknowledgement.

Kind Regards,

Aubrey Covey
USA WTO TBT Enquiry Point
Standards Coordination Office (SCO)
National Institute of Standards and Technology (NIST)
Email: usatbtep@nist.gov
URL: www.nist.gov/notifyus

From: GROW EU-TBT <grow-eu-tbt@ec.europa.eu>
Sent: Monday, January 17, 2022 9:20 AM
To: usatbtep <usatbtep@nist.gov>
Subject: EU Acknowledges Receipt of USA Comments on WTO Notification G/TBT/N/EU/853 - Draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval

Dear MaryAnn

Thank you for your comments on G/TBT/N/EU/853 which will be given our careful attention.
Best regards
From: usatbtep <usatbtep@nist.gov>
Sent: Friday, January 14, 2022 4:53 PM
To: GROW EU-TBT <GROW-EU-TBT@ec.europa.eu>
Cc: usatbtep <usatbtep@nist.gov>
Subject: USA Submits Comments on EU’s WTO Notification G/TBT/N/EU/853 - Draft Commission Implementing Regulation amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor

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