

Voluntary Report – Voluntary - Public Distribution

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Report Name: European Commission Approves Import of GE Soybean

Country: European Union

Post: Brussels USEU

Report Category: Biotechnology - Plants and Animals, Grain and Feed

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Report Highlights:

On September 28, the European Commission (EC) approved Bayer's herbicide tolerant soybean MON 87708 x MON 89788 x A5547-127, also known as XtendFlex.® The EC last authorized a GE crop ten months ago. Normally, the EC approves groups of events twice a year - during the December holiday season and in mid-summer.

General Information:

On September 28, the European Commission (EC) approved Bayer's herbicide tolerant soybean MON 87708 x MON 89788 x A5547-127.¹ This approval demonstrates tolerance to herbicides containing dicamba, glyphosate, and glufosinate-ammonium. The authorization is valid for 10 years and applies to food, feed, import, and processing, but not cultivation in the EU. All products will be subject to the EU's strict labelling and traceability rules.

Authorization Process:

Under Directive 2001/18/EC,² all GE events for import or domestic cultivation must initially undergo a comprehensive risk assessment and scientific review by the European Food Safety Authority (EFSA). EFSA received Bayer's application in March 2016 and published its favorable assessment in May 2019.

A positive determination by EFSA typically results in the EC proposing authorization of the event to the European Union Member States who vote on each event in the Standing Committee on Plants, Animals, Food and Feed (PAFF) comprised of Member State experts and government officials. A positive vote in the PAFF requires a qualified majority.³ That threshold is never met, resulting in an inconclusive vote and a subsequent appeal. This was indeed the case for this event as well. On December 9, 2019, the PAFF Committee reached an inconclusive decision.

The Appeal Committee then reviews the biotech event, invariably resulting in a "no opinion" determination, placing the final decision with the College of Commissioners, an entity representing the top leadership of the EC. The College can either approve or deny the proposed biotech event. In this case, Member States did not reach a conclusion in the January 23, 2020 Appeal Committee. Consequently, the authorization proposal moved to the Commission, who approved the application on September 28, 2020.

Consideration and Outlook:

This is the new Commission's first GE authorization, 10 months after their predecessors' last approval. As the EU seems to steer away from pesticides and glyphosate in particular, this authorization is a positive sign that the new Commission is still following EU regulation. The EC has now processed all GE applications on its bench that cover import. Due to the COVID-19 outbreak and the suspension of Standing Committee meetings, the Member States still have 16 EFSA approved GE crops currently waiting in the authorization pipeline. PAFF Committee votes on eight of these are expected this month (October 2020). The PAFF Committee will then convene two more times this year, giving it the opportunity to work its way through all 16 waiting applications before 2021.

¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2020.316.01.0001.01.ENG&toc=OJ:L:2020:316:TOC

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0018>

³ <https://www.consilium.europa.eu/en/council-eu/voting-system/qualified-majority/>

Bayer will launch sales of the XtendFlex® soybean in North America next year and expects to supply 20 million U.S. soy acres.⁴

⁴ <https://media.bayer.com/baynews/baynews.nsf/id/Bayers-XtendFlex-Soybeans-Gain-Final-Key-Regulatory-Approval>

Attachments:

No Attachments.