

Factsheet

LibertyLink® T25 maizeUnique Identifier ACS-ZMØØ3-2

February 2025



Information, obligations and recommendations to operators handling and processing bulk mixtures of imported maize which may contain T25 maize (ACS-ZMØØ3-2)

The information set out in this document is principally directed to all operators handling and processing bulk mixtures of imported maize.

A. Authorisation

On 24 April 2015, the European Commission issued Commission Implementing Decision 2015/697/EC approving the placing on the market of genetically modified T25 maize and renewing the existing T25 maize products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. This authorisation covers the following products:

- a) foods and food ingredients containing, consisting of, or produced from ACS-ZMØØ3-2 maize;
- b) feed containing, consisting of, or produced from ACS-ZMØØ3-2 maize;
- c) ACS-ZMØØ3-2 maize in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation.

On 10 July 2019, Commission implementing Decision (EU) 2019/1195 amending Decision 2015/697/EC as regards the authorisation holder and the representative for the placing on the market of genetically modified maize has adopted the transfer of authorisation from Bayer CropScience AG to BASF Agricultural Solutions Seed US LLC.

For more information, please visit the Community Register of GM Food and Feed using the following link: GMO register (europa.eu).

B. General Product Information

The commercial name of the planting seed product is LibertyLink® Maize (LL Maize) and is tolerant to the herbicide active ingredient glufosinate-ammonium. LL maize varieties are based upon a well-characterized GM line, known as maize event T25, designated by the OECD unique identifier code as ACS-ZMØØ3-2.

The T25 maize is modified by the addition of the *pat* gene. The modified plants produce the enzyme phosphinothricin acetyl-transferase (PAT). The expression of PAT confers plant tolerance to the herbicide active ingredient, glufosinate-ammonium.

C. Food, Feed and Environmental Safety

The Scientific Panel on Genetically Modified Organisms ("the GMO Panel") of the European Food Safety Authority (EFSA) has considered information related to 1) the molecular characterization and expression of the inserted DNA in T25 maize, 2) the comparative assessment of T25 maize and its non-transgenic comparator, 3) the safety of the newly expressed protein in T25 maize and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of T25 maize.

BASF Agricultural Solutions Seed US LLC



The EFSA GMO Panel concluded that: "T25 maize is as safe as its conventional counterpart with respect to potential effects on human and animal health or the environment in the context of its intended uses for food and feed, import and processing".

Further information regarding the original Scientific Opinion can be retrieved from EFSA's website at: http://www.efsa.europa.eu/en/efsajournal/doc/3356.pdf

An event-specific quantitative detection method for T25 has been validated by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC) and is publicly available on the JRC-EURL website: T25 documents | European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF)

Certified reference material of T25 maize is accessible via the American Oil Chemists Society at Certified Reference Materials (CRMs) - AOCS

D. General obligations for Operators

Each operator handling and processing bulk mixtures of imported GM maize shall comply with the requirements laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003, handling the labelling and traceability of genetically modified organisms and the conditions for labeling and traceability outlined in Commission Implementing Decision 2015/697/EC on maize T25.

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'. The words 'not for cultivation' shall appear on the label and in the documents accompanying the products containing or consisting of ACS-ZMØØ3-2 maize with the exception of foods and food ingredients.

The Unique Identifier Codes assigned to T25 maize is ACS-ZMØØ3-2.

In addition, the operators are requested to collaborate with the authorisation holder in the general surveillance to identify the occurrence of unanticipated adverse effects of the viable T25 maize or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (ERA). In addition, these operators are requested to comply with all management measures in place to minimize spillage of viable maize and with respect to clean-up practices.

E. Contact points for Operators

As there are other technology providers for GM maize it is essential to develop an industry wide approach because the shipments entering the European harbours may be co-mingled.

CropLife Europe, plays an important role in this area and is the central communication point for GM plant technology providers. CropLife Europe is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, CropLife Europe will transfer the messages to the relevant GMO industry partner if further action is required.

Operators are requested to report, if possible via their branch representative, any unanticipated adverse effect to CropLife Europe at: Product information - CropLife Europe

BASF Agricultural Solutions Seed US LLC



If required, additional comments or questions relative to T25 maize can also be addressed at gent.info.operators@basf.com.

F. General surveillance

General surveillance is not based on a particular hypothesis, and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (ERA).

In order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, a general surveillance plan for T25 maize is in place. In the case of T25 maize, EFSA concluded that: "The scope of the post-market environmental monitoring plan provided by the applicant was in line with the intended uses of maizeT25. Furthermore, the EFSA GMO Panel agreed with the reporting intervals proposed by the applicant in the post-market environmental monitoring plan."

The general surveillance system for T25 maize involves the authorisation holder and operators who are handling and using viable T25 maize. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect that may arise from the handling and use of viable T25 maize. The authorisation holder will report the results of the general surveillance for T25 maize to the European Commission on an annual basis.