BASF Agricultural Solutions
Seed US LLC

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Fact-sheet

LibertyLink®
Maize T25

Unique Identifier
ACS-ZMØØ3-2

January
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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 maize T25 and renewing the existing maize T25 products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. The scope of the authorisation includes all scopes, except the authorisation of T25 seeds for cultivation in the European Union.

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: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm.

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 maize T25, 2) the comparative assessment of maize T25 and its non-transgenic comparator, 3) the safety of the newly expressed protein in maize T25 and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of maize T25.

The EFSA GMO Panel concluded that: "*maize T25 is as safe and nutritious as its conventional counterpart in the context of its intended use.*"

Further information can be retrieved from EFSA website at:
http://www.efsa.europa.eu/en/efsajournal/doc/3356.pdf

An event-specific quantitative detection method for maize T25 was validated by the EU Reference Laboratory (EU-RL GMFF) established under Regulation (EC) No 1829/2003 is publicly available at: http://gmo-crl.jrc.ec.europa.eu/summaries/CRLVL0804VP%20corrected%20version%201%20-%20EURL%20Web.pdf

Certified reference material of maize T25 is accessible via the American Oil Chemists Society at https://www.aocs.org/store/shop-aocs/shop-aocs?productId=120158987.

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.

The words 'not for cultivation' shall appear on the label and in the documents accompanying the products containing or consisting of maize T25 with the exception of products referred to in point (a) of Article 2 of Commission Implementing Decision 2015/697/EC.
The Unique Identifier Codes assigned to maize T25 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 maize T25 or its use for human and animal health or the environment that were not predicted in the e.r.a. (see point F). 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: www.ecpa.eu/product-info

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

F. General surveillance

F1. Monitoring and General Surveillance

In the authorisation procedure for a GMO, an environmental risk assessment is included to identify and evaluate on a case by case basis potential adverse effects either direct or indirect, immediate or delayed of the GMO, on human health and the environment which the deliberate release or the placing on the market of GMOs may have.

To evaluate the conclusions reached in the environmental risk assessment, monitoring is required. The objective of the monitoring is:

1. To confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment is correct. This is referred to as case-specific monitoring, and;

2. To identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment. This is referred to as general surveillance.

In the case of maize T25, the EFSA GMO panel concluded that “as the environmental risk assessment did not identify potential adverse environmental effects due to maize T25, no case-specific monitoring is required”.

However, and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the e.r.a., a general surveillance plan for maize T25 is in place. The EFSA GMO Panel concluded that: “the scope of the PMEM plan proposed by the applicant is in line with the intended uses of maize T25 as the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in the PMEM plan”.

The general surveillance system for maize T25 will involve the authorisation holder and operators handling and using viable maize T25. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable maize T25.

The authorisation holder will report the results of the general surveillance for maize T25 to the European Commission on an annual basis.