

Fact-sheet

Soybean FG72 x A5547-127
Unique Identifier MST-FGØ72-2 x ACS-
GMØØ6-4

July 2019

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported soybean which may contain FG72 x A5547-127 soybean (MST-FGØ72-2 x ACSGMØØ6-4)

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

A. Authorisation

On 21 December 2017, Commission Implementing Decision (EU) 2017/2451 authorised the placing on the market of FG72 x A5547-127 soybean (MST-FGØ72-2 x ACS-GMØØ6-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. This authorisation covers the following products:

- (a) foods and food ingredients containing, consisting of, or produced from soybean FG72 x A5547-127;
- (b) feed containing, consisting of, or produced from soybean FG72 x A5547-127 with the exception of forage;
- (c) soybean FG72 x A5547-127, 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 has amended Implementing Decision (EU) 2017/2451 as follows:

‘The authorisation holders shall be

- (a) BASF Agricultural Solutions Seed US LLC, United States, represented by BASF SE, Germany; And
- (b) BASF SE, Germany, representing M.S. Technologies, LLC, United States.’

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

FG72 x A5547-127 is a soybean stacked product that contains 3 genes which produce proteins that confer tolerance to HPPD inhibitor herbicides such as isoxaflutole (IFT), glyphosate and glufosinate ammonium herbicides.

FG72 x A5547-127 herbicide tolerant soybean varieties provide growers with additional and new options for weed control by using HPPD inhibitor herbicides such as IFT, glyphosate and glufosinate ammonium herbicides. Glyphosate is widely used in herbicide-tolerant soybean and other agricultural production systems. Tolerance to HPPD inhibitor herbicides such as IFT offers an alternative weed control option for the soybean grower. IFT controls weeds via a new herbicide mode of action for soybeans that is efficacious against many of the glyphosate resistant weeds currently found in soybean fields. IFT has the flexibility to be applied at the pre-plant and pre-emergence stage.

C. Food, Feed and Environmental Safety

The European Food Safety Authority (“EFSA”) GMO Panel evaluated the genetically modified soybean FG72 x A5547-127 with regard to the scope of its application and appropriate principles described in its guidelines for the risk assessment of GM plants. EFSA concluded that genetically modified soybean FG72 x A5547-127, as described in the application, is as safe as the non-genetically modified comparator and non-genetically modified soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses.

Further information can be retrieved from EFSA’s website at:

<http://www.efsa.europa.eu/en/efsajournal/pub/4744>

Event-specific quantitative detection methods for FG72 soybean and A5547-127 soybean have been validated and verified on FG72 x A5547-127 soybean by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC) and are publicly available on the JRC-EURL website:

<http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>

Certified reference materials of FG72 soybean and A5547-127 soybean are available from the American Oil Chemists Society (AOCS):

<https://www.aocs.org/crm#soybean>

D. General obligations for operators

Each operator handling and processing bulk mixtures of imported GM soybean 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 labelling and traceability outlined in Commission Implementing Decision (EU) 2017/2451.

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘soybean’. The words ‘not for cultivation’ shall appear on the label of the product and in the documents accompanying products containing or consisting of soybean FG72 x A5547-127, with the exception of foods and food ingredients.

The Unique Identifier Code assigned to FG72 x A5547-127 soybean is MST-FGØ72-2 x ACS-GMØØ6-4.

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 FG72 x A5547-127 soybean or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (e.r.a). In addition, these operators are requested to comply with all management measures in place to minimize spillage of viable soybean and with respect to clean-up practices.

E. Contact points for Operators

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

EuropaBio, the European Association for Bioindustries, plays an important role in this area and is the central communication point for all GM plant technology providers.

EuropaBio is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, EuropaBio 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 EuropaBio at: <https://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information>.

If required, additional comments or questions relative to FG72 x A5547-127 soybean 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 (e.r.a).

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 FG72 x A5547-127 soybean is in place. In the case of FG72 x A5547-127 soybean, EFSA concluded that: "The monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products".

The general surveillance system for FG72 x A5547-127 soybean involves the authorisation holder and operators who are handling and using viable FG72 x A5547-127 soybean. 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 FG72 x A5547-127 soybean. The authorisation holder will report the results of the general surveillance for FG72 x A5547-127 soybean to the European Commission on an annual basis.