

Fact-sheet

Soybean FG72

Unique Identifier MST-FGØ72-2

July 2019

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

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

A. Authorisation

On 22 July 2016, Commission Implementing Decision (EU) 2016/1215 authorised the placing on the market of FG72 soybean (MST-FGØ72-2) 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 MST-FGØ72-2 soybean;
- (b) feed containing, consisting of, or produced from MST-FGØ72-2 soybean;
- (c) MST-FGØ72-2 soybean 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 Implementing Decision (EU) 2016/1215 as regards the authorisation holder and the representative for the placing on the market of genetically modified soybean 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

FG72 is a soybean owned by MS Technologies LLC that contains 2 genes which produce proteins that confer tolerance to HPPD inhibitor herbicides such as isoxaflutole (IFT) and glyphosate herbicides.

FG72 herbicide tolerant soybean varieties provide growers with additional and new options for weed control by using HPPD inhibitor herbicides such as IFT and glyphosate 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 herbicides control 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 herbicides have the flexibility to be applied at the pre-sowing and pre-field-emergence stage.

C. Food, Feed and Environmental Safety

The European Food Safety Authority ("EFSA") GMO Panel evaluated the genetically modified soybean FG72 with regard to the scope of its application and appropriate principles described in its guidelines for the risk assessment of GM plants. The evaluation addressed the following components of the risk assessment: the molecular characterization of the inserted DNA and analysis of the expression of the corresponding proteins; the comparative analyses of compositional, agronomic and phenotypic characteristics; the safety of the newly expressed proteins and the whole food/feed

with respect to potential toxicity, allergenicity and nutritional characteristics; and the environmental risk assessment and the post-market environmental monitoring plan.

The GMO Panel concluded that: “the information available for soybean FG72 addresses the scientific comments raised by Member States and that soybean FG72, as described in this application, is as safe as its conventional counterpart and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of this application”.

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

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4167.pdf

An event-specific quantitative detection method for FG72 soybean 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:

<http://gmo-crl.jrc.ec.europa.eu/summaries/EURL-VL-04-10%20VP.pdf>

Certified reference material of FG72 soybean is available from the American Oil Chemists Society (AOCS):

<https://www.aocs.org/store/shop-aocs/shop-aocs?productId=81070691>

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) 2016/1215.

The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying products containing or consisting of MST-FGØ72-2 soybean.

The Unique Identifier Code assigned to FG72 soybean is **MST-FGØ72-2**.

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 FG72 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 co-mingled.

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 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 soybean is in place. In the case of FG72 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 soybean involves the authorisation holder and operators who are handling and using viable FG72 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 soybean. The authorisation holder will report the results of the general surveillance for FG72 soybean to the European Commission on an annual basis.