



FG72 Soybean

**EU Authorisation for food, feed, import and
processing**

Information for Operators

November 2022

Introduction

This document summarizes the main characteristics of FG72 soybean and the requirements for post-market environmental monitoring of all operators handling viable beans from this product. It also includes references to the relevant detection method and contact points for operators to report on general surveillance activities and on any unanticipated adverse effects.

Characteristics and benefits of FG72 soybean

FG72 is a genetically modified soybean that contains 2 genes which produce proteins that confer tolerance to HPPD inhibitor and glyphosate herbicides.

FG72 herbicide tolerant soybean varieties provide growers with additional and new options for weed control by using HPPD inhibitor and glyphosate herbicides. Glyphosate is widely used in herbicide-tolerant soybean and other agricultural production systems. Tolerance to HPPD inhibitor herbicides offers an alternative weed control option for the soybean grower.

Safety of FG72 soybean

FG72 soybean has been assessed and endorsed by numerous independent scientific committees around the world. These conclusions have been based on a full range of scientific studies, including tests which examined the potential for human and animal health effects of the product, nutritional equivalency, the effects of the introduced genes and proteins, and the potential impacts of the soybean on the environment.

EFSA evaluation of FG72 soybean for food, feed, import and processing in the EU

On 16 July 2015, the EFSA Panel on Genetically Modified Organisms (GMO Panel) published its scientific opinion¹ and concluded that FG72 soybean (EFSA-GMO-BE-2011-98) 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.

Authorisation in the EU of FG72 soybean for food, feed, import and processing

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:

¹ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Arpaia S, Birch ANE, Chesson A, du Jardin P, Gathmann A, Gropp J, Herman L, Hoen-Sorteberg HG, Jones H, Kiss J, Kleter G, Løvik M, Messéan A, Naegeli H, Nielsen KM, Ovesná J, Perry J, Rostoks N and Tebbe C, 2015. Scientific Opinion on an application (EFSA-GMO-BE-2011-98) for the placing on the market of herbicide-tolerant genetically modified soybean FG72 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-BE-2011-98). EFSA Journal 2015;13(7):4167, 29 pp.
<https://doi.org/10.2903/j.efsa.2015.4167>

- (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.

On 15 November 2021, Commission implementing Decision (EU) 2021/1999 amending Implementing Decision (EU) 2016/1215 as regards the authorisation holder and the representative in the Union for the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 has adopted the transfer of authorisation from BASF Agricultural Solutions Seed US LLC to Syngenta Crop Protection NV/SA.

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

Conditions for traceability and labelling of FG72 soybean for food, feed, import and processing in the EU

The legal obligations relating to traceability and labelling are laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003.

For the purposes of the specific 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 'soybean'.

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 with the exception of products referred to in point (a) of Article 2 of the Commission Implementing Decision (foods and food ingredients containing, consisting of or produced from MST-FGØ72-2 soybean).

The unique identifier assigned to FG72 soybean is: MST-FGØ72-2.

Post market monitoring of FG72 soybean for food, feed, import, and processing in the EU

The Decision does not require post-market monitoring for the use of the food for human consumption.

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 a Post Market Environmental Monitoring Plan for FG72 soybean has been developed according to the principles

and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

The monitoring plan for environmental effects is accessible at the EU Register of authorised GMOs: [Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC](#)

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.

Methods for detection and reference material

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>

Contact point for Operators

As there are other technology providers for genetically modified soybean it is essential to develop an industry wide approach because the shipments entering the European ports may be co-mingled. CropLife Europe, plays an important role in this area and is the central communication point for all 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: <https://croplifeeurope.eu/product-information/> .

If required, additional comments or questions related to FG72 soybean can also be addressed at:

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