

Fact-sheet

Soybean GMB151

Unique Identifier BCS-GM151-6

April 2022

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported soybean which may contain GMB151 soybean (BCS-GM151-6)

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

A. Authorisation

On 31 March 2022, Commission Implementing Decision (EU) 2022/531 authorised placing on the market of products containing, consisting of or produced from genetically modified soybean GMB151 (BCS-GM151-6) 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 genetically modified soybean GMB151;
- (b) feed containing or consisting of genetically modified soybean GMB151;
- (c) products containing or consisting of genetically modified soybean GMB151, for uses other than those provided in points (a) and (b), with the exception of cultivation.

For more information, please visit the Community Register of GM Food and Feed using the following link: https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-register_en

B. General Product Information

GMB151 soybean has been developed through *Agrobacterium*-mediated transformation using the vector pSZ8832 containing the *cry14Ab-1.b* and *hppdPf-4Pa* gene cassettes. GMB151 soybean produces the Cry14Ab-1 protein, a crystal protein derived from *Bacillus thuringiensis*, which confers resistance to soybean cyst nematode (SCN). GMB151 also produces a modified 4-hydroxyphenylpyruvate dioxygenase (HPPD-4), derived from *Pseudomonas fluorescens*, which confers tolerance to HPPD inhibitor herbicides, such as isoxaflutole.

Planting SCN resistant and herbicide tolerant GMB151 soybean varieties allows growers to control soybean yield losses caused by SCN infestation. In addition, the GMB151 soybean provides with new options for weed control using HPPD inhibitors, such as isoxaflutole. This class of herbicides 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.

C. Food, Feed and Environmental Safety

The European Food Safety Authority (“EFSA”) GMO Panel evaluated the genetically modified soybean GMB151 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 soybean GMB151 is as safe as its conventional counterpart and the tested non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment.

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

<https://www.efsa.europa.eu/en/efsajournal/pub/6424>

Event-specific quantitative detection method for GMB151 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: <https://gmo-crl.jrc.ec.europa.eu/method-validation/details/all/2062/GMB151>

Certified reference material of GMB151 soybean is available from the EURL-JRC via the following link: <https://crm.jrc.ec.europa.eu/?q=bf443&page=1>

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 C(2022)1893.

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 GMB151, with the exception of foods and food ingredients.

The Unique Identifier Code assigned to GMB151 soybean is BCS-GM151-6.

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 GMB151 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.

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

If required, additional comments or questions relative to GMB151 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 GMB151 soybean is in place. In the case of GMB151 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 GMB151 soybean involves the authorisation holder and operators who are handling and using viable GMB151 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 GMB151 soybean. The authorisation holder will report the results of the general surveillance for GMB151 soybean to the European Commission on an annual basis.