

Fact-sheet

Cotton GHB811

Unique Identifier BCS-GH811-4

April 2022

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain GHB811 cotton (BCS-GH811-4)

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

A. Authorisation

On 31 March 2022, Commission Implementing Decision (EU) 2022/530 authorised the placing on the market of products containing, consisting of or produced from genetically modified cotton GHB811 (BCS-GH811-4) 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 genetically modified cotton BCS-GH811-4;
- (b) feed containing, consisting of or produced from genetically modified cotton BCS-GH811-4;
- (c) products containing or consisting of genetically modified cotton BCS-GH811-4 for uses other than those provided for 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://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

B. General Product Information

GHB811 cotton was developed by means of *Agrobacterium*-mediated transformation using the vector pTSH09 containing the *2mepsps* and *hppdPfw336-1Pa* expression cassettes. The *2mepsps* gene encodes for the 2mEPSPS protein that confers tolerance to glyphosate herbicides. The *hppdPfw336-1Pa* gene encodes for the HPPD W336 protein that confers tolerance to HPPD inhibitors, such as isoxaflutole (IFT).

The dual herbicide tolerance to glyphosate herbicide and HPPD inhibitors, such as isoxaflutole (IFT) offers cotton growers additional weed control options.

C. Food, Feed and Environmental Safety

The scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (“EFSA”) conducted the assessment of cotton GHB811 in line with the principles described in Regulation (EU) No 503/2013 and its applicable guidelines for the risk assessment of genetically modified (GM) plants. The EFSA GMO Panel concluded that: “cotton GHB811 is as safe as its conventional counterpart and the tested non-GM cotton 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/6781>

Event-specific quantitative detection method for GHB811 cotton 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/2061/GHB811>

Certified reference material of GHB811 cotton is available from the EURL-JRC via the following link: <https://crm.jrc.ec.europa.eu/?q=ghb811+&page=1>

D. General obligations for operators

Each operator handling and processing bulk mixtures of imported GM cotton 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) 2022/530 on GHB811 cotton.

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 ‘cotton’. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified GHB811 cotton, with the exception of foods and food ingredients.

The Unique Identifier Code assigned to GHB811 cotton is BCS-GH811-4.

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 GHB811 cotton for 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 cotton and with respect to clean-up practices.

E. Contact points for Operators

As there are other technology providers for GM cotton 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 adverse effect to CropLife Europe at: www.ecpa.eu/product-info

If required, additional comments or questions relative to GHB811 cotton 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 GHB811 cotton is in place. In the case of GHB811 cotton, EFSA concluded that: “The monitoring plan for environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products”.

The general surveillance system for GHB811 cotton involves the authorisation holder and operators who are handling and using viable GHB811 cotton. 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 GHB811 cotton. The authorisation holder will report the results of the general surveillance for GHB811 cotton to the European Commission on an annual basis.