

Factsheet

GHB119 cotton

Unique Identifier BCS-GHØØ5-8

February 2025

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain GHB119 cotton (BCS-GHØØ5-8).

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 4 July 2017, Commission Implementing Decision (EU) 2017/1208 authorised the placing on the market of GHB119 cotton 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 GHB119 cotton;
- b) feed containing, consisting of, or produced from genetically modified GHB119 cotton;
- c) genetically modified GHB119 cotton in products containing them or consisting of them 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 Decision (EU) 2017/1208 as regards the authorisation holder and the representative for the placing on the market of genetically modified cotton has adopted the transfer of authorisation from Bayer CropScience NV to BASF Agricultural Solutions Seed US LLC.

For more information, please visit the Community Register of GM Food and Feed using the following link: [GMO register \(europa.eu\)](http://GMOregister.europa.eu)

B. General Product Information

GHB119 cotton plants express an insecticidal crystal protein, Cry2Ae, from the common soil bacterium, *Bacillus thuringiensis* subsp. *dakota* (*B.t. dakota*) and the PAT protein from the soil microorganism, *Streptomyces hygroscopicus*. The Cry2Ae protein is effective in controlling lepidopteran plant feeding larvae such as cotton bollworm larvae (CBW, *Helicoverpa zea*), tobacco budworm larvae (TBW, *Heliothis virescens*) and fall armyworm larvae (FAW, *Spodoptera frugiperda*), which are common pests of cotton. The *bar* gene, when expressed, enables the production of the enzyme, Phosphinothricin-Acetyl-Transferase (PAT) that acetylates L-glufosinate ammonium and thereby confers tolerance to glufosinate ammonium herbicides. GHB119 cotton is designated by the OECD unique identifier code as BCS-GHØØ5-8.

C. Food, Feed and Environmental Safety

The Scientific Panel on Genetically Modified Organisms (“the GMO Panel”) of the European Food Safety Authority (EFSA) has considered information related to 1) the molecular characterization and the expression of the inserted DNA in GHB119 cotton, 2) the comparative assessment of GHB119 cotton and its conventional counterpart, 3) the safety of the Cry2Ae and PAT proteins and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of GHB119 cotton.

The GMO Panel concluded that: “*GHB119 cotton, as described in the application, is as safe and as nutritious as its conventional counterpart as regards the potential effects on human and animal health and the environment in the context of the scope of the application*”. EFSA also 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.

Further information regarding the original Scientific Opinion can be retrieved from EFSA's website at: <https://www.efsa.europa.eu/en/efsajournal/pub/4586>

An event-specific quantitative detection method for GHB119 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:

[GHB119 documents | European Union Reference Laboratory for Genetically Modified Food and Feed \(EURL GMFF\)](#)

Certified reference material of GHB119 cotton is available from the EURL-JRC via the following link: [Certified Reference Materials catalogue of the JRC](#)

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 labeling and traceability outlined in Commission Implementing Decision (EU) 2017/1208 on GHB119 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 in 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 GHB119 cotton, with the exception of foods and food ingredients.

The Unique Identifier Code assigned to GHB119 cotton is BCS-GHØØ5- 8.

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 GHB119 cotton or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (ERA). 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 ports may be co-mingled.

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: [Product information - CropLife Europe](#)

If required, additional comments or questions relative to GHB119 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 (ERA).

In order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, a general surveillance plan for Event crop is in place. In the case of GHB119 cotton, EFSA concluded that: *"The scope of the post-market-environmental-monitoring (PMEM) plan provided by the applicant and the reporting intervals are in line with the intended uses of GHB119 cotton and the guidance document of the EFSA GMO Panel on PMEM of GM plants"*.

The general surveillance system for GHB119 cotton involves the authorisation holder and operators who are handling and using viable GHB119 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 GHB119 cotton. The authorisation holder will report the results of the general surveillance for GHB119 cotton to the European Commission on an annual basis.