

Fact-sheet

Cotton GHB119

Unique Identifier BCS-GHØØ5-8

July 2019

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain GHB119 (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 cotton GHB119 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 cotton GHB119;
- b) feed containing, consisting of, or produced from cotton GHB119;
- c) Cotton GHB119 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 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: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

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. Cotton GHB119 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 cotton GHB119, 2) the comparative assessment of cotton GHB119 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 cotton GHB119.

The GMO Panel concluded that: “cotton GHB119, 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 can be retrieved from the EFSA website at:

<https://www.efsa.europa.eu/en/efsajournal/pub/4586>

An event-specific quantitative detection method for cotton GHB119 has been validated by the European Union Reference Laboratory for GM Food and Feed (EU-RL GMFF) of the Joint Research Centre (JRC) and is publicly available on the JRC-EU-RL GMFF website:

<http://gmo-crl.jrc.ec.europa.eu/summaries/2012-10-11%20EURL%20VL0411%20VP.pdf>

The Certified reference material (CRM) of cotton GHB119 is ERM-BF428 and it is accessible via the Joint Research Centre (JRC) of the European Commission, the Institute for Reference Materials and Measurements (IRMM), at

<https://ec.europa.eu/jrc/en/reference-materials/catalogue>

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 cotton GHB119. The words "Not for cultivation" shall appear either on the label or in a document accompanying the product. The Unique Identifier Code assigned to cotton GHB119 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 cotton GHB119 or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (see point F). 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.

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 cotton GHB119 can also be addressed at gent.info.operators@basf.com

F. General surveillance

F1. Monitoring and General Surveillance

In the authorisation procedure for a GMO, an environmental risk assessment (e.r.a.) is included. This identifies and evaluates on a case-by-case basis potential adverse effects either direct or indirect, immediate or delayed, on human health and the environment which may result from the deliberate release or the placing on the market of the GMO.

To evaluate the conclusions reached in the environmental risk assessment, monitoring is required. The objective of the monitoring is:

1. To confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment is correct. This is referred to as case-specific-monitoring and;
2. To identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment. This is referred to as general surveillance.

In the case of cotton GHB119, the EFSA GMO panel concluded that: “As the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects, no case-specific monitoring is necessary.”

However, and 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 cotton GHB119 is in place. The EFSA GMO Panel 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 cotton GHB119 and the guidance document of the EFSA GMO Panel on PMEM of GM plants.”

The general surveillance system for cotton GHB119 involves the authorisation holder and operators who are handling and using viable cotton GHB119. 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 cotton GHB119.

The authorisation holder will report the results of the general surveillance for cotton GHB119 to the European Commission on an annual basis.

F2. Awareness of accidental spillage

Accidental spillage of imported cotton grains in ports and crushing facilities should be minimized. In the event that grain containing cotton GHB119 is lost during handling this may result in the germination and possible establishment of volunteer plants, including cotton GHB119.

Volunteers are plants emerging from grain losses. The likelihood of accidental spillage of viable grain is highest in ports and crushing facilities during storage and handling prior to processing into derived,

non-viable products, where grain lots might be exposed to the open environment. It is essential that good practices are followed to manage the accidental spillage of viable grains at those locations.

However, and in the case of accidental spillage of imported cotton grains, it is very unlikely it would establish a feral population or that it would outcross to commercial cotton. Unintended environmental effects due to the unintended release of cotton GHB119 will not be different than that of other commercial cotton. The only difference, tolerance to the herbicide glufosinate ammonium, would not provide a survival advantage as long as the herbicide glufosinate ammonium is not used.

In any case, environmental exposure from accidental spillage is highly unlikely to give rise to an adverse effect and can be easily controlled by clean up measures and the application of current practices used for the control of any adventitious cotton plants, such as manual or mechanical removal and the application of herbicides (see Point F3).

F3. Eradication of volunteer cotton GHB119 plants

In the event that volunteer plants include cotton GHB119, these plants should be eradicated to minimize the potential for unanticipated adverse effects arising from the GM plant. In that perspective it is essential that good practices are followed to control the establishment of volunteer plants.

In the event that herbicides are used to eliminate volunteer plants it is essential not to use products based on glufosinate ammonium but to apply other broad-leaf herbicides. In the case of doubt it is advised to seek technical advice and support with the local supplier of pesticides regarding the appropriate product to use in areas such as ports and/or crushing facilities or other non-agricultural environments.