

Fact-sheet

LibertyLink® LLCotton25

Unique Identifier ACS-GHØØ1-3

December 2019

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain LLCotton25 (ACS-GHØØ1-3)

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 29 October 2008, Commission Decision 2008/837/EC authorised the placing on the market of LLCotton25 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 LLCotton25;
- b) feed containing, consisting of, or produced from LLCotton25;
- c) products other than food and feed containing or consisting of LLCotton25 for the same uses as any other cotton with the exception of cultivation.

On 10 July 2019, Commission implementing Decision (EU) 2019/1195 amending Decision 2008/837/EC 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 AG to BASF Agricultural Solutions Seed US LLC.

The authorisation was renewed pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by Commission Implementing Decision 2019/2082 of 28 November 2019.

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

The commercial name of the planting grain product is LibertyLink® cotton and is tolerant to the herbicide active ingredient glufosinate ammonium. LibertyLink cotton varieties are based upon a single, well-characterized transgenic line, known as transformation event LLCotton25, designated by the OECD unique identifier code as ACS-GHØØ1-3.

The cotton event LLCotton25 is modified by the addition of the *bar* gene. The modified plants produce the enzyme phosphinothricin acetyl-transferase (PAT). The expression of PAT protein confers plant tolerance to the herbicide active ingredient, glufosinate ammonium.

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 LLCotton25, 2) the comparative assessment of LLCotton25 and its non-transgenic comparator, 3) the safety of the PAT protein and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of LLCotton25.



We create chemistry

BASF Agricultural Solutions Seed US LLC

The GMO Panel concluded that: "GM cotton LLCotton25 for food and feed uses, import and processing is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses." The GMO Panel's opinion is that: "LLCotton25 is as safe as its non genetically modified counterpart with respect to potential effects on human and animal health or the

environment.” The GMO Panel also agrees with the conclusions of the environmental risk assessment of the authorisation holder that: “the likelihood of the establishment and spread of LLCotton25 is very low and that unintended environmental effects due to this GM cotton will be no different from that of conventional cotton varieties.”

Further information can be retrieved from EFSA website at:
<http://www.efsa.europa.eu/en/efsajournal/pub/429>

An event-specific quantitative detection method for LLCotton25 has been validated by the Community Reference Laboratory (CRL) of the Joint Research Centre (JRC) and is publicly available on the JRC-CRL website:
http://gmo-crl.jrc.ec.europa.eu/summaries/LLCotton25_validated_Method.pdf

Certified reference material of LLCotton25 is available from the American Oil Chemists Society (AOCS):
<https://www.aocs.org/store/shop-aocs/shop-aocs?productId=23500521>

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 Decision 2008/837/EC on LLCotton25. The words “Not for cultivation” shall appear either on the label or in a document accompanying the product. The Unique Identifier Code assigned to LLCotton25 is **ACS-GHØØ1-3**.

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 LLCotton25 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 harbours 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: <http://www.europabio.org/information-operators-product-information>

If required, additional comments or questions relative to LLCotton25 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 LLCotton25, the EFSA GMO panel concluded that: *"Since the environmental risk assessment identified no potential adverse environmental effects, case-specific monitoring is not considered 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 LLCotton25 is in place. The EFSA GMO Panel concluded that: *"the general approaches and measures of the monitoring plan proposed by the applicant are in line with the EFSA opinion on post-market environmental monitoring as well as with the intended uses of LLCotton25"*.

The general surveillance system for LLCotton25 involves the authorisation holder and operators who are handling and using viable LLCotton25. 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 LLCotton25.

The authorisation holder will report the results of the general surveillance for LLCotton25 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 LLCotton25 is lost during handling this may result in the germination and possible establishment of volunteer plants, including LLCotton25.

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 LLCotton25 will be no 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 LLCotton25 plants

In the event that volunteer plants include LLCotton25, 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 order to assist operators importing cotton grain in the EU, the authorisation holder has made available appropriate technical advice how to eradicate cotton volunteers which may include LLCotton25. Please refer to the Guideline for the Management of Cotton Volunteers.

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 harbours and/or crushing facilities or other non-agricultural environments.