

Factsheet

LibertyLink® **LLCotton25**

Unique Identifier ACS-GHØØ1-3

June 2023

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: [GMO register \(europa.eu\)](http://GMOregister.europa.eu)

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.

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:
<https://www.efsa.europa.eu/en/efsajournal/pub/429>

Additionally, in delivering its scientific opinion on the renewal of LLCotton25 cotton, the GMO Panel of EFSA took into account application EFSA-GMO-RX-010, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-010 contained: post-market environmental monitoring reports, a systematic search and evaluation of the literature, updated bioinformatic analyses and additional documents of studies performed by or on behalf of the applicant. In addition, the applicant provided sequence data on the LLCotton25 event using the material from a commercial variety that, according to the applicant, may be imported into the EU at the time of this renewal application.

The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. The GMO Panel concluded that there is no evidence in the renewal application EFSA-GMO-RX-010 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on LLCotton25 cotton (EFSA, 2006).

Further information regarding the Scientific Opinion of the Renewal can be retrieved from EFSA website at: <https://www.efsa.europa.eu/en/efsajournal/pub/5473>

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): [AOCS store](#)

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 2019/2082 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.

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 LLCotton25 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 LLCotton25 is in place. In the case of LLCotton25, 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 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.