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Factsheet

Cotton GHB614

Unique Identifier BCS-GHØØ2-5

June 2023

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain GHB614 (BCS-GHØØ2-5).

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 17 June 2011, Commission Decision 2011/354/EU authorised the placing on the market of GHB614 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 GHB614 cotton;
b) feed containing, consisting of, or produced from GHB614 cotton;
c) products other than food and feed containing or consisting of GHB614 cotton 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 2011/354/EU 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 2022/560 of 31 March 2022.

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

B. General Product Information

The commercial name of the planting grain product is GlyTol™ cotton and is tolerant to the herbicide active ingredient glyphosate. GlyTol™ cotton varieties are based upon a single, well-characterized transgenic line, known as GHB614 cotton, designated by the OECD unique identifier code as BCS-GHØØ2-5.

GHB614 cotton is modified by the addition of the 2mEPSPS gene. The modified plants encode a modified 5-enolpyruvylshikimate-3-phosphate synthase (2mEPSPS) enzyme, that is insensitive to the action of glyphosate, and thereby allows the plant to grow in the presence of the herbicide. The expression of 2mEPSPS protein confers plant tolerance to the herbicide active ingredient glyphosate.

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 GHB614 cotton, 2) the comparative assessment of GHB614 cotton and its non-transgenic comparator, 3) the safety of the 2mEPSPS protein and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of GHB614 cotton.

The GMO Panel concluded that: "GHB614 cotton is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses." The GMO Panel's opinion is that: "cotton GHB614 is as safe as its conventional counterpart with respect to potential effects on human and animal health and 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 cotton GHB614 is very low and that unintended environmental effects due to this GM cotton will be no different from that of other cotton varieties."

Further information regarding the original Scientific Opinion can be retrieved from EFSA website at: http://www.efsa.europa.eu/en/efsajournal/pub/985.htm

Additionally, in delivering its scientific opinion on the renewal of GHB614 cotton, the GMO Panel of EFSA took into account application EFSA-GMO-RX-018, 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-018 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, additional studies performed by or on behalf of the applicant during the whole application period and updated bioinformatics analyses.

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-018 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton GHB614 (EFSA, 2009)."

Further information regarding the Scientific Opinion of the Renewal can be retrieved from EFSA website at: https://www.efsa.europa.eu/en/efsajournal/pub/6671

An event-specific quantitative detection method for GHB614 cotton 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/GHB614_validated_Method.pdf

Certified reference material of GHB614 cotton 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 2022/560 on GHB614 cotton. The words "Not for cultivation" shall appear either on the label or in a document

accompanying the product. The Unique Identifier Code assigned to GHB614 cotton is BCS-GHØØ2-5.

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 GHB614 cotton 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 all 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 GHB614 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 GHB614 cotton is in place. In the case of GHB614 cotton, 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 GHB614 cotton involves the authorisation holder and operators who are handling and using viable GHB614 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 GHB614 cotton. The authorisation holder will report the results of the general surveillance for GHB614 cotton to the European Commission on an annual basis.