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Fact-sheet

Cotton GHB614

Unique Identifier BCS-GHØØ2-5

April 2022

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

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 Decision2011/354/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 (EU) 2022/560 of 31 March 2022.

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 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 after application 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):
https://myaccount.aocs.org/PersonifyEbusiness/Store/Product-Details?productId=110703179

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 2011/354/EU 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, the European Association for Bioindustries, 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: www.ecpa.eu/product-info

If required, additional comments or questions relative to GHB614 cotton 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 GHB614 cotton, the EFSA GMO panel concluded that: “Since 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 GHB614 cotton is

in place. The EFSA GMO Panel concluded that: “Considering the intended uses of cotton GHB614 the monitoring plan provided by the applicant is in line with EFSA GMO Panel guidance document on the risk assessment of GM plants and the opinion of the EFSA GMO Panel on post-market environmental monitoring”.

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.

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 GHB614 cotton is lost during handling this may result in the germination and possible establishment of volunteer plants, including GHB614 cotton.

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 GHB614 cotton will not be different than that of other commercial cotton. The only difference, tolerance to the herbicide glyphosate, would not provide a survival advantage as long as the herbicide glyphosate 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 GHB614 cotton plants

In the event that volunteer plants include GHB614 cotton, 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 GHB614 cotton. 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 glyphosate 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.