

2022 Annual Report on the General Surveillance of GHB614 x LLCotton25 cotton

**BASF Agricultural Solutions Seed US LLC
Represented by
BASF SE**

**Submitted on
8 December 2022**

The submitted information (this document and all the study reports attached to it) contain scientific data and other information which is protected under Article 31 of Regulation (EC) No 1829/2003 and copyright laws. This submitted information may only be used for the evaluation by the regulatory authority to which it has been submitted as requested in the application of BASF. Any other use of this information, in whole or in part, without prior written consent of BASF, is strictly prohibited. By submitting this information, BASF does not grant any person or entity any right to use or license the information, data or intellectual property contained in this submitted information.

ANNUAL REPORT ON THE GENERAL SURVEILLANCE OF GHB614 x LLCOTTON25 COTTON

1. General information

- 1.1 Crop/trait(s): GHB614 x LLCotton25 Cotton / Glyphosate and Glufosinate-ammonium herbicide tolerance**
- 1.2 Decision authorisation number pursuant to Directive 2001/18/EC and number and date of consent pursuant to Directive 2001/18/EC: NA¹**
- 1.3 Decision authorisation number and date of authorisation pursuant to Regulation (EC) No 1829/2003: Commission Implementing Decision (EU) 2015/690 of 24 April 2015**
- 1.4 Unique identifier: BCS-GHØØ2-5 x ACS-GHØØ1-3**
- 1.5 Reporting period from: July 2021 to June 2022**
- 1.6 Other monitoring reports have been submitted in respect of cultivation: No**

2. Executive summary

On 24 April 2015, Commission Implementing Decision (EU) 2015/690² (as amended by Commission Implementing Decision (EU) 2019/1195³ addressed to BASF SE) authorised the placing on the market of GHB614 x LLCotton25 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 x LLCotton25 cotton;
- b) feed containing, consisting of, or produced from GHB614 x LLCotton25 cotton;
- c) products other than food and feed containing or consisting of GHB614 x LLCotton25 cotton for the same uses as any other cotton with the exception of cultivation.

In accordance with Directive 2001/18/EC and Article 4 of Commission Implementing Decision (EU) 2015/690, the authorisation holder for GHB614 x LLCotton25 cotton, shall ensure that the monitoring plan, contained in the application and consisting of a general surveillance plan, is put in place and implemented. In addition, Article 4 of Commission Implementing Decision (EU) 2015/690 stipulates that the authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out

¹ NA: not applicable.

² Commission Implementing Decision (EU) of 24 April 2015 authorising the placing on the market of products containing, consisting of or produced from genetically modified GHB614 x LLCotton25 (BCS-GHØØ2-5 x ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council ((EU) 2015/690). *Official Journal of the European Union* L 112/35, 30.4.2015.

³ Commission Implementing Decision (EU) 2019/1195 of 10 July 2019 amending Decisions 2008/730/EC, 2008/837/EC, 2009/184/EC, 2011/354/EU, Implementing Decisions 2012/81/EU, 2013/327/EU, (EU) 2015/690, (EU) 2015/697, (EU) 2015/699, (EU) 2016/1215, (EU) 2017/1208 and (EU) 2017/2451 as regards the authorisation holder and the representative for the placing on the market of genetically modified soybean, cotton, oilseed rape and maize. *Official Journal of the European Union* L 187/43, 12.7.2019.

in the monitoring plan.

In view of the obligation to submit annual monitoring reports for GHB614 x LLCotton25 cotton, the authorisation holder has undertaken a number of general surveillance activities accompanying the placing on the market of GHB614 x LLCotton25 cotton in the EU and UK. An updated status on these activities is given in this annual monitoring report.

To date, the general surveillance accompanying the placing on the market of GHB614 x LLCotton25 cotton indicates that there have been no adverse health or environmental effects associated with the importation or use of GHB614 x LLCotton25 cotton. Therefore, no revisions to the general surveillance plan are considered necessary for GHB614 x LLCotton25 cotton.

3. Uses of GMOs other than cultivation

3.1 Commodity imports into the Community

3.1.1 Commodity crop (GM + non-GM) imports into the EU and UK by country of origin

Country of origin ⁴	Quantity ⁵ (EU import in tons)	Quantity ⁶ (UK import in tons)
Argentina*	0	0
Benin	246,2	0
Brazil*	0**	0
China	146,5	0
Colombia*	0	0
Ethiopia	58,0	0
Cameroon	44,9	0
Ukraine	19,7	0
United States*	0,7	0
All Other Countries	1,9	0
TOTAL	517,9	0

⁴ Data are provided for the main exporting countries, which combined make up approximately 99% of total cotton imports from outside the EU. There is no data for cotton imports from outside the UK. Data for exporting countries where GHB614 x LLCotton25 cotton is authorised for cultivation are marked with “*”. For the full list of exporting countries and detailed information on commodity types please refer to 2022_2054618 and 2022_2054994.

⁵ Source: Eurostat (2022) data covers 27 EU Member States (July 2021 to June 2022). Data extracted October 2022, collected by CropLife Europe (refer to 2022_2054618). Quantities below 0,1 tons are indicated as 0 and marked with “**”.

⁶ Source: HMRC/AHDB (2022) data for UK covers Great Britain and Northern Ireland (July 2021 to June 2022) as it is not possible to extract the data for Great Britain separately. Data extracted October 2022, collected by CropLife Europe (refer to 2022_2054994).

3.1.2 Commodity Crop (GM + non-GM) imports from outside the EU and UK by country of destination

Destination country	Quantity ⁷ (tons) July 2021 - June 2022
Denmark	146,5
Romania	136,2
Spain	110,0
Italy	58,5
Netherlands	45,9
Bulgaria	19,7
Germany	0,7
Greece	0,4
Ireland	0*
France	0*
Sweden	0*
Poland	0*
United Kingdom	0*

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The authorisation holder, via CropLife Europe, has collected data on cotton imports (GM and non-GM) into the EU and UK for the period of July 2021 to June 2022.

For the EU, according to this data, total imports of cotton were 517,889 tons and the main exporters of cotton to the EU were Benin, China, Ethiopia, Cameroon and Ukraine which together accounted for approximately 99% of total extra-EU cotton imports (**Table 3.1.1**).

GHB614 x LLCotton25 cotton was authorised for cultivation in Argentina, Brazil, Colombia, and the United States. The total EU cotton imports from Brazil and the United States were below 0.1 and 0.7 tons respectively. The Brazil and United States cotton exports to the EU accounted for around 0,14% of total extra-EU cotton imports. The Argentina and Colombia cotton exports to the EU accounted for 0% of total extra-EU cotton imports and therefore, market share data for Argentina and Colombia are not provided (**Table 3.1.1**).

The main import countries for cotton in the EU were Denmark, Romania, Spain, Italy and the

⁷ Sources: Eurostat (2022) data covers 27 EU Member States (July 2021 to June 2022). HMRC/AHDB (2022) data for UK covers Great Britain and Northern Ireland (July 2021 to June 2022). Quantities below 0,1 tons are indicated as 0 and marked with “*”.

Netherlands. They are accounting together for 96% of the total cotton imports. Another main import market of extra-EU cotton is Bulgaria (**Table 3.1.2**).

For the UK, according to this data, there were no extra-UK imports of cotton (**Table 3.1.1**).

GHB614 x LLCotton25 cotton was authorised for cultivation in Argentina, Brazil, Colombia, and the United States. The total UK cotton imports from Argentina, Brazil, Paraguay, and the United States were 0 tons. The Argentina, Brazil, Paraguay, and the United States cotton exports to the UK accounted for around 0% of total extra-UK cotton imports (**Table 3.1.1**).

3.2 General Surveillance

3.2.1 Description of General Surveillance

The current approach used for general surveillance represents the consensus between all authorisation holders within CropLife Europe and has been endorsed by the operators involved in the trade of viable cotton commodity (listed in Section 3.2.2).

The authorisation holder is not involved in commodity trade with GHB614 x LLCotton25 cotton. The monitoring methodology hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable GHB614 x LLCotton25 cotton. They are exposed to the imported viable GHB614 x LLCotton25 cotton and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use. The routine surveillance is based on the HACCP principles.

Since traders may commingle GHB614 x LLCotton25 cotton with other commercial cotton, including authorised GM cotton, the authorisation holder is working together with other members of the industry within CropLife Europe and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology.

The different parties agreed to collaborate on the following basis:

⇒ The consent holder represented by CropLife Europe shall:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
- Inform the operators in a timely fashion of any newly approved GM plant products for import and processing under Regulation (EC) No 1829/2003 or Directive 2001/18/EC subject to general surveillance.
- Set up and maintain a website dedicated to operators that provides an overview and detailed information on approved GM plant products subject to general surveillance. The website, hosted on the CropLife Europe website under <https://croplifeeurope.eu/product-information/>, contains the following information:
 - An introduction to the purpose of the website
 - A table giving an overview of all currently approved GM plant products subject to general surveillance
 - A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decisions(s) authorising the GM plant product in the EU

- A contact point at CropLife Europe for information exchange on any of the GM plant products

The website will be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.

- Contact the selected networks of operators annually, providing them with an update on the approved GM plant products subject to general surveillance and reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).

⇒ The selected networks of operators (European trade associations) shall:

- Inform and remind their member organisations and companies on an annual basis
 - to monitor for potential unanticipated adverse effects
 - to inform and remind their own member companies of this requirement
 - to report back any adverse effect reported to them to the European trade associations
- Report to the consent holders directly or via CropLife Europe
 - at least annually, regardless of whether an adverse effect was observed or not
 - immediately any adverse effects reported to them

Consequently, the European trade associations shall notify CropLife Europe of the results of the general surveillance on an annual basis. The report shall cover all approved GM plant products subject to general surveillance. CropLife Europe shall forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission and UK's Food Standards Agency.

The general surveillance information reported to and collected by the authorisation holder from the European trade associations or other sources shall be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder will immediately investigate to determine and confirm whether a significant correlation between the effect and GHB614 x LLCotton25 cotton can be established. If the investigation establishes that GHB614 x LLCotton25 cotton was present when the adverse effect was identified and confirms that GHB614 x LLCotton25 cotton is the cause of the adverse effect, the authorisation holder shall immediately inform the European Commission and UK's Food Standards Agency. The authorisation holder, in collaboration with the European Commission and UK's Food Standards Agency and based on a scientific evaluation of the potential consequences of the observed adverse effect, shall define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

As described in the bullet points above, the authorisation holder shall submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report shall contain information on any unanticipated adverse effects that have arisen from handling and use of viable GHB614 x LLCotton25 cotton.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of GHB614 x LLCotton25 cotton and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

3.2.2 Details of industry, environmental, food and/or feed related surveillance networks used during General Surveillance

The authorisation holder, together with other members of the industry and CropLife Europe, will implement general surveillance of viable GM cotton, including GHB614 x LLCotton25 cotton, with the help of the selected networks described below, according to the methodology outlined in the authorisation holder's general surveillance plan and as detailed in Section 3.2.1. The following networks are currently involved:

⇒ *Importers / Traders*

COCERAL is the European association of trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply. It represents the interests of the European collectors, traders, importers, exporters, and port silo storekeepers of the above-mentioned agricultural products. The main importers of cereals and feedstuffs into the EU and UK are members of COCERAL.

Also see: <http://www.coceral.com>

⇒ *Silo Operators*

UNISTOCK is the European association representing professional storekeepers for agribulk commodities within the EU. UNISTOCK full and extraordinary members are present in twelve countries and UNISTOCK is itself a full member of COCERAL. Commodity imports enter the EU and UK by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.

Also see: <http://www.unistock.be/>

⇒ *Processors*

FEDIOL, the federation of the European vegetable Oil and Protein Meal Industry, represents the interests of the European crushers of oilseeds, meal producers and vegetable oil producers/processors.

Also see: <http://www.fediol.eu/>

These associations represent the majority of European operators importing, handling and processing viable cotton commodity. They work closely together with a continuous and efficient flow of communication between them, particularly, through the documentation that needs to accompany any shipment containing GMOs in accordance with the labelling and traceability requirements of Regulation (EC) No 1830/2003 and are therefore best placed to observe and report any unanticipated adverse effects.

Other networks consisting of operators further down the food and feed chain have not been selected for the general surveillance of viable GHB614 x LLCotton25 cotton, because they focus on processed, non-viable material.

3.2.3 Details of information and/or training provided to importers, traders, handlers, processors, etc.

The authorisation holder directly informed the selected network of operators (i.e., COCERAL, UNISTOCK and FEDIOL) that GHB614 x LLCotton25 cotton was authorised pursuant to Regulation (EC) No 1829/2003 by Commission Implementing Decision (EU) 2015/690 and that a website dedicated to operators that provides an overview and detailed information on the authorised GHB614 x LLCotton25 cotton has been made available as described below.

Specific information concerning the safety, general characteristics and the general surveillance conditions for GHB614 x LLCotton25 cotton was uploaded in a website dedicated to trade associations representing the relevant operators that import, handle and process viable cotton commodity, providing an overview and detailed information on approved GM plant products subject to general surveillance. The website, hosted on the CropLife Europe website under <https://croplifeeurope.eu/product-information/>, contains the following information:

- An introduction to the purpose of the website
- A table giving an overview of all currently approved GM plant products subject to general surveillance
- A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU. The document providing documentation on characteristics and safety for GHB614 x LLCotton25 cotton is attached to this annual monitoring report (refer to 2022_2000960).
- A contact point at CropLife Europe for information exchange on any of the GM plant products

The website will be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.

3.2.4 Results of General Surveillance

The reporting by the trade associations takes place at the end of their business year, i.e., end of June. Therefore, CropLife Europe reminded the trade associations to provide their annual report on any occurrence of unanticipated adverse effects arising from the approved GM products, including GHB614 x LLCotton25 cotton placed on the market during the period from July 2021 to June 2022.

The trade associations implemented the monitoring in the framework of their routine surveillance of the commodities (GM and non-GM) they handle and use. As required in the monitoring plan, they reminded their members *“to monitor for potential unanticipated adverse effects; that, in the framework of their management or safety standards (ISO, HACCP, etc), procedures must be in place and implemented to limit losses and spillage of viable GMOs and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as potential adverse effects; To inform and remind their own member companies of this requirement; and to report back any adverse effect reported to them to the European trade*

associations;” .

COCERAL, UNISTOCK and FEDIOL members have in place Good Hygiene Practices and Good Manufacturing Practices in their daily operations, at the level of imports, storage, handling, and internal transport of grains and oilseeds commodities, as well as at the level of oilseed crushing and vegetable oil refining, irrespective of the botanical species of the commodity. Such practices form the pre-requisite programmes which are the foundation upon which their HACCP systems are built. Measures implemented in this context to limit losses and spillage of viable grains and oilseeds, as well as clean-up and eradication measures (in case of accidental spillage), allow trade associations to report any adverse effect that would be considered as “unusual” or “unanticipated” and potentially attributable to GMOs.

The trade associations informed CropLife Europe in a format that reiterates the terms of the agreement of the general surveillance system and reports on the outcome of the monitoring. The format allows the authorisation holder to comply with the requirement to give evidence to the Commission and the Competent Authorities that the system is in place; that the trade associations are aware of the requirement to monitor; and, that they are providing information on any observed unanticipated adverse effects, if any.

The reports received from COCERAL, UNISTOCK and FEDIOL indicate that no adverse effects were reported from their members, thus implying that no adverse effects were linked to the presence of GHB614 x LLCotton25 cotton in the time period from July 2021 to June 2022 (refer to 2022_2054498 and 2022_2054612). Furthermore, no incidents in relation to the placing on the market of GHB614 x LLCotton25 cotton have been reported to CropLife Europe or the authorisation holder since July 2022 to date.

3.2.5 Additional Information

Not applicable since no adverse or unanticipated effects were reported.

3.2.6 Review of peer-reviewed publications

The authorisation holder actively monitors peer-reviewed scientific literature related to its products. In the light of the 2022 annual general surveillance report for GHB614 x LLCotton25 cotton, a scoping review was performed for the GHB614 x LLCotton25 cotton and its newly expressed proteins, 2mEPSPS and PAT/*bar*. The objective of this scoping review was to determine if there were studies about the molecular characterization of GHB614 x LLCotton25 cotton, its effect on food and feed safety or environmental safety, that might require in-depth examination. A set of broad literature searches was performed using several bibliographic databases covering scientific literature from October 1, 2021 to June 30, 2022. Additional sources of information, such as web pages of food safety, agriculture, and biotechnology-related authorities were searched for the same time window, along with the bibliographies of relevant reviews. The references identified were evaluated for potential relevance to the scoping review questions according to pre-defined criteria.

These literature searches identified a total of 40 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. One publication was progressed for detailed assessment and was determined to be not relevant after detailed review.

No new publications were found that contained new data on the molecular characterization of the GHB614 x LLCotton25 cotton and its newly expressed proteins, 2mEPSPS and PAT/*bar*.

Similarly, no new publications were found that suggested any potential adverse effects of GHB614 x LLCotton25 cotton on human health, animal health, or the environment. No issues or topics were identified that would trigger or warrant more specific question formulation or indicate that a systematic review would be of value.

In summary, these literature searches and review of the retrieved articles identified no publication that would adversely impact the existing safety assessment of GHB614 x LLCotton25 cotton (refer to 2022_2049891).

3.3 Case-Specific Monitoring

3.3.1 Description and results of Case-Specific Monitoring (if applicable)

The scientific evaluation of the characteristics of GHB614 x LLCotton25 cotton in the environmental risk assessment (ERA) has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of GHB614 x LLCotton25 cotton. It is therefore considered that there is no need for case-specific monitoring.

3.3.2 Processing (if applicable)

Not applicable.

3.3.3 Monitoring and reporting of adverse effects resulting from accidental spillage (Not applicable)

3.4 Concluding remarks

The information reported to and collected by the authorisation holder within the frame of the general surveillance accompanying the placing on the market of GHB614 x LLCotton25 cotton in the EU and UK indicates that there have been no adverse health or environmental effects associated with the importation or use of GHB614 x LLCotton25 cotton. The reports received from COCERAL, UNISTOCK and FEDIOL show that no adverse effects linked to the presence of GHB614 x LLCotton25 cotton were recorded and no adverse findings from independent research relating to GHB614 x LLCotton25 cotton have been published.

4. Summary of Results and Conclusions

To date, the general surveillance accompanying the placing on the market of GHB614 x LLCotton25 cotton in the EU and UK indicates that there have been no adverse health or environmental effects associated with the importation or use of GHB614 x LLCotton25 cotton.

Taking into account:

- a) the favourable scientific evaluations by scientists and regulatory agencies around the world;
- b) our experience with this product;
- c) the reports from the European trade associations (operators involved in the import, handling and processing of viable GHB614 x LLCotton25 cotton) who are selected as the most appropriate participants in the general surveillance network;
- d) the lack of adverse findings from independent research, available through the public literature;

e) the fact that no adverse effects for GHB614 x LLCotton25 cotton have been reported to the authorisation holder

there is, to the best of our knowledge, no information available that questions the conclusion that GHB614 x LLCotton25 cotton does not pose any greater risk to health or the environment than conventional cotton.

5. Adaptation of the Monitoring Plan and Associated Methodology for future years

In view of the results given in this report, no revisions to the general surveillance plan are considered necessary for GHB614 x LLCotton25 cotton.

Signed: BASF

Date: 8 December 2022