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BASF Agricultural Solutions
Seed US LLC

Factsheet

T304-40 cotton

Unique Identifier BCS-GHØØ4-7

February 2025

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain T304-40 cotton (BCS-GHØØ4-7).

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 24 April 2015, Commission Implementing Decision (EU) 2015/699 authorised the placing on the market of T304-40 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 T304-40 cotton;
- b) feed containing, consisting of, or produced from T304-40 cotton;
- c) products other than food and feed containing or consisting of T304-40 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 (EU) 2015/699 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.

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

T304-40 cotton plants express an insecticidal crystal protein, Cry1Ab, from the common soil bacterium, *Bacillus thuringiensis* subsp. *berliner* (*B.t. berliner*) and the PAT protein from the soil microorganism, *Streptomyces hygrosopicus* *insec.* The Cry1Ab protein is effective in controlling lepidopteran larvae such as cotton bollworm larvae (CBW, *Helicoverpa zea*) and tobacco budworm larvae (TBW, *Heliothis virescens*), which are common pests of cotton. The *bar* gene, when expressed, enables the production of the enzyme, Phosphinothricin-Acetyl-Transferase (PAT) that acetylates L-glufosinate ammonium and thereby confers tolerance to glufosinate ammonium herbicides. T304-40 cotton is designated by the OECD unique identifier code as BCS-GHØØ4-7.

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 T304-40 cotton, 2) the comparative assessment of T304-40 cotton and its non-transgenic comparator, 3) the safety of the Cry1Ab and PAT proteins and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of T304-40 cotton.

The GMO Panel concluded that: “*The information available for T304-40 cotton addresses the scientific issues indicated by the guidance document of the EFSA GMO Panel and the scientific comments raised by the Member States, and that T304-40 cotton is as safe as its comparator with respect to*

potential effects on human and animal health or the environment in the context of its intended uses.”
Further information regarding the original Scientific Opinion can be retrieved from EFSA’s website at: <http://www.efsa.europa.eu/en/efsajournal/pub/3251.htm>

An event-specific quantitative detection method for T304-40 cotton has been validated by the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) of the Joint Research Centre (JRC) and is publicly available on the JRC-EURL GMFF website:
[T304-40 documents | European Union Reference Laboratory for Genetically Modified Food and Feed \(EURL GMFF\)](#)

The Certified reference material (CRM) of T304-40 cotton is accessible via the JRC of the European Commission, the Institute for Reference Materials and Measurements (IRMM) at [Certified Reference Materials catalogue of the JRC](#)

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 (EU) 2015/699 on T304-40 cotton.

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘cotton’. The words ‘not for cultivation’ shall appear on the label of and in documents accompanying products containing or consisting of T304-40 cotton with the exception of foods and food ingredients.

The Unique Identifier Code assigned to T304-40 cotton is BCS-GHØØ4-7.

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 T304-40 cotton or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (ERA). 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 ports 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 T304-40 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 T304-40 cotton is in place. In the case of T304-40 cotton, EFSA concluded that: *“The scope of the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of T304-40 cotton. Furthermore, the EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in the post-market environmental monitoring plan.”*

The general surveillance system for T304-40 cotton involves the authorisation holder and operators who are handling and using viable T304-40 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 T304-40 cotton. The authorisation holder will report the results of the general surveillance for T304-40 cotton to the European Commission on an annual basis.