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BASF Agricultural Solutions
Seed US LLC

Factsheet

LibertyLink®
Soybean A5547-127
Unique Identifier ACS-GMØØ6-4

June 2023

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported soybean which may contain A5547-127 soybean (ACS-GMØØ6-4)

The information set out in this document is principally directed to all operators handling and processing bulk mixtures of imported soybean.

A. Authorisation

On 10 February 2012, Commission Decision 2012/81/EU authorised the placing on the market of 5547- 127 soybean (ACS-GMØØ6-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. This authorization covers the following products:

a) foods and food ingredients containing, consisting of, or produced from ACS-GMØØ6-4 soybean;
b) feed containing, consisting of, or produced from ACS-GMØØ6-4 soybean;
c) products other than food and feed containing or consisting of ACS-GMØØ6-4 soybean for the same uses as any other soybean with the exception of cultivation.

On 10 July 2019, Commission implementing Decision (EU) 2019/1195 amending Decision 2012/81/EU as regards the authorisation holder and the representative for the placing on the market of genetically modified soybean 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) 2023/415 of 22 February 2023.

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 seed product is LibertyLink® Soybean (LL Soybean) and is tolerant to the herbicide active ingredient glufosinate ammonium. LL Soybean varieties are based upon a well characterized GM line, known as soybean event A5547-127, designated by the OECD unique identifier code as ACS-GMØØ6-4.

The A5547-127 soybean is modified by the addition of the *pat* gene. The modified plants produce the enzyme phosphinothricin acetyl-transferase (PAT). The expression of PAT confers plant tolerance to the herbicide active ingredient, glufosinate-ammonium.

C. Food, Feed and Environmental Safety

The Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA) has considered information related to 1) molecular characterization of the inserted DNA

and expression of the corresponding protein, 2) the comparative analysis of composition, phenotypic and agronomic characteristics and 3) the safety of the new proteins and the whole food/feed with respect to potential toxicity, allergenicity and nutritional wholesomeness.

On 10 May 2011, the EFSA issued a positive scientific opinion and concludes: "The EFSA GMO Panel considers that the information available for soybean A5547-127 addresses the scientific comments raised by the Member States and that the soybean A5547-127, as described in this application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses." Furthermore, the EFSA GMO Panel concludes that: "Soybean A5547-127 is phenotypically and agronomically not different from its conventional counterpart A5547, with the exception of the newly introduced trait."

Further information can be retrieved from EFSA website at:
https://doi.org/10.2903/j.efsa.2011.2147

Additionally, in delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-020, 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-020 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 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-020 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean A5547-127 (EFSA, 2011).

Further information regarding the Scientific Opinion of the Renewal can be retrieved from EFSA website at: https://doi.org/10.2903/j.efsa.2022.7340

An event-specific quantitative detection method for A5547-127 soybean has been validated by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC) and is publicly available on the JRC-CRL website:
http://gmo-crl.jrc.ec.europa.eu/summaries/A5547_validated%20Method.pdf

Certified reference material of A5547-127 is available from the American Oil Chemists Society (AOCS): https://www.aocs.org/store/shop-aocs/shop-aocs?productId=81070629

D. General obligations for operators

Each operator handling and processing bulk mixtures of imported GM soybean 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 labelling and traceability outlined in Commission Implementing Decision (EU) 2023/415 on A5547-127 soybean.

The words "Not for cultivation" shall appear on the label of and in documents accompanying

products containing or consisting of A5547-127 soybean.

The Unique Identifier Code assigned to A5547-127 soybean is **ACS-GMØØ6-4.**

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 A5547-127 soybean 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 soybean and with respect to clean-up practices.

E. Contact points for Operators

As there are other technology providers for GM soybean it is essential to develop an industry wide approach because the shipments entering the European harbours may be comingled.

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 A5547-127 soybean 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 A5547-127 soybean is in place. In the case of A5547-127 soybean, EFSA concluded that: “The scope of the post-market environmental monitoring plan provided by the applicant and the reporting intervals are in line with the intended uses of soybean A5547-127.”

The general surveillance system for A5547-127 soybean involves the authorisation holder and operators who are handling and using viable A5547-127 soybean. 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 A5547-127 soybean. The authorisation holder will report the results of the general surveillance for A5547- 127 soybean to the European Commission on an annual basis.