BASF
We create chemistry

BASF Agricultural Solutions
Seed US LLC

Factsheet

LibertyLink®
Soybean A2704-12
Unique Identifier ACS-GMØØ5-3

June 2023

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported soybean which may contain A2704-12 soybean (ACS-GMØØ5-3)

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

A. Authorisation

On 8 September 2008, Commission Decision 2008/730/EC authorised the placing on the market of A2704-12 soybean 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 A2704-12 soybean;
b) feed containing, consisting of, or produced from A2704-12 soybean;
c) products other than food and feed containing or consisting of A2704-12 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 2008/730/EC 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 2019/2084 of 28 November 2019.

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 transgenic line, known as transformation event A2704-12, designated by the OECD unique identifier code as ACS-GMØØ5-3.

The soybean event A2704-12 is modified by the addition of the *pat* gene. The modified plants produce the enzyme phosphinothricin acetyl-transferase (PAT). The expression of PAT protein confers plant tolerance to the herbicide active ingredient, glufosinate ammonium.

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 A2704-12 soybean, 2) the comparative analysis of A2704-12 soybean and its non-transgenic comparator, 3) the safety of the PAT protein and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of A2704-12 soybean.
The GMO Panel concluded that: "GM soybean A2704-12 for food and feed uses, import and processing is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses." The GMO Panel's opinion is that: "A2704-12 soybean is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment." The GMO Panel also agrees with the conclusions of the environmental risk assessment of the authorisation holder that: "the likelihood of the spread and establishment of soybean A2704-12 is very low and that unintended environmental effects due to this soybean will be not different from that of conventional soybean varieties."

Further information can be retrieved from EFSA website at:
http://www.efsa.europa.eu/en/efsajournal/pub/524

Additionally, in delivering its scientific opinion on the renewal of A2704-12 soybean, the GMO Panel of EFSA took into account application EFSA-GMO-RX-009, 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 this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant. In addition, the applicant provided sequence data on the soybean A2704-12 event using material from a commercial variety currently on the market and intended to be marketed in the coming years.

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 concludes that there is no evidence in the renewal application EFSA-GMO-RX-009 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean A2704-12.

Further information regarding the Scientific Opinion of the Renewal can be retrieved from EFSA website at: https://www.efsa.europa.eu/en/efsajournal/pub/5523

An event-specific quantitative detection method for A2704-12 soybean 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/A2704-12_soybean_validated_Method.pdf

Certified reference material of A2704-12 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 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 2019/2084 on A2704-12

soybean. The words “Not for cultivation” shall appear either on the label or in a document accompanying the product. The Unique Identifier Code assigned to A2704-12 soybean is **ACS-GMØØ5-3.**

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 A2704-12 soybean 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 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 A2704-12 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 A2704-12 soybean is in place. In the case of A2704-12 soybean, 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 A2704-12 soybean involves the authorisation holder and operators who are handling and using viable A2704-12 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 A2704-12 soybean. The authorisation holder will report the results of the general surveillance for A2704-12 soybean to the European Commission on an annual basis.