BASF Agricultural Solutions
Seed US LLC

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Fact-sheet

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

January 2021

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: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

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

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):
https://www.aocs.org/store/shop-aocs/shop-aocs?productId=199307730

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 Decision 2008/730/EC 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: www.ecpa.eu/product-info

If required, additional comments or questions relative to A2704-12 soybean can also be addressed at 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 A2704-12 soybean, the EFSA GMO panel concluded that: "*Since the environmental risk assessment identified no potential adverse environmental effects, case-specific monitoring is not considered 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 A2704-12 soybean is in place. The EFSA GMO Panel concluded that: "*the general approaches and measures of the monitoring plan proposed by the applicant are in line with the EFSA opinion on post-market environmental monitoring as well as with the intended uses of soybean A2704-12*".

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.