DAS-44406-6 soybean

Enlist E3™ soybean

Fact-sheet for operators

2021

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The placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, also referred to as Enlist E3™ soybean in the commercial context, was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by the European Commission on 21 December 2017 under Commission implementing decision (EU) 2017/2450 (EC, 2017)[1].

The authorisation decision for DAS-44406-6 soybean is published at:
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D2450&from=EN

Amended by:
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0239&from=EN

The following products are authorised:

(a) Food and food ingredients containing, consisting of, or produced from DAS-44406-6 soybean
(b) Feed containing, consisting of, or produced from DAS-44406-6 soybean
(c) DAS-44406-6 soybean in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation

General Characteristics of DAS-44406-6 soybean

DAS-44406-6 soybean has been developed to express the following proteins, 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS), aryloxyalkanoate dioxygenase-12 (AAD-12), and phosphinothricin acetyl transferase (PAT), which confer tolerance to glyphosate-based herbicides, 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, and glufosinate ammonium-based herbicides, respectively. With multiple herbicide tolerances, you have more weed control options in one complete, easy-to-use system. Farmers will have the flexibility to control weeds in different ways for improved weed resistance management. For further reading, please visit the following sites: www.enlist.com/en/traits.html

Safety of the DAS-44406-6 soybean

In February 2012, Dow AgroSciences LLC[2] and M.S. Technologies LLC submitted an application for the placing on the market of DAS-44406-6 soybean for food and feed uses, import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2012-106). On 17 February 2017, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) adopted a positive scientific opinion in which it concluded : "*the GMO Panel considers that the information available for soybean DAS-44406-6 addresses the scientific*

[1] EC, 2017. Commission Implementing Decision (EU) 2017/2450 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.
[2] Hereafter referred to as Dow AgroSciences

comments raised by Members States and that soybean DAS-44406-6, as described in this application, is as safe as its conventional counterpart and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of the application (EFSA, 2017)[4].

The EFSA GMO panel scientific opinion is available at:
https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2017.4738

Monitoring Conditions for DAS-44406-6 soybean

As indicated in the positive EFSA GMO Panel opinion on DAS-44406-6 soybean, "*Soybean DAS-44406-6 is as nutritious as its conventional counterpart and the non-GM soybean reference varieties tested*" (EFSA, 2017)[3]. Therefore, post-market monitoring of DAS-44406-6 soybean food/feed is not necessary, as confirmed by the EFSA GMO Panel (EFSA, 2017) and in the Commission authorisation decision for DAS-44406-6 soybean (EC, 2017).

Furthermore, no potential adverse effects to human and animal health or the environment have been identified in the environmental risk assessment from the uses of DAS-44406-6 soybean. Therefore, case-specific monitoring of DAS-44406 soybean is not necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2017). As specified by Commission decision (EC, 2017)[3], a post-market environmental monitoring (PMEM) plan for DAS-44406-6 soybean is in place and consists of a general surveillance plan, not based on a particular hypothesis, to report observed unanticipated adverse effects on human and animal health or the environment arising from handling or use of viable DAS-44406-6, if any.

As stated by the EFSA GMO Panel in its scientific opinion on DAS-44406-6 soybean for food and feed uses, import and processing "*The scope of the PMEM plan provided by the applicant and the reporting intervals are in line with the intended uses of soybean DAS-44406-6*" (EFSA, 2017).

The monitoring takes place in cooperation with monitoring networks of trade associations representing operators importing, handling and processing viable soybean commodity, which report back to CropLife Europe. The result of the monitoring activities is reported back to the European Commission by Dow AgroSciences on an annual basis.

The post-market environmental monitoring plan for DAS-44406-6 soybean has been published on the EU register for genetically modified food and feed: http://ec.europa.eu/food/dyna/gm_register/PMEM_DAS-44406-6_final_register.pdf

[3] EFSA, 2017. Scientific opinion on an application by Dow AgroSciences LLC (EFSA-GMO-NL-2012-106) for the placing on the market of genetically modified herbicide-tolerant soybean DAS-44406-6 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal 2017*; 15(3):4738, 33pp. doi:10.2903/j.efsa.2017.4738

Conditions for traceability and labelling for DAS-44406-6 soybean

Operators importing, handling and processing DAS-44406-6 soybean seeds[4] and derived foods and feeds in the EU shall comply with the conditions for traceability and labelling outlined in Regulations (EC) No 1829/2003 and 1830/2003 and in Commission Implementing Decision (EU) 2017/2450 for DAS-44406-6 soybean.

For the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be soybean.

The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DAS-44406-6 soybean with the exception of foods and food ingredients.

The unique identifier assigned to DAS-44406-6 soybean is DAS-444Ø6-6.

Methods for detection and reference material for DAS-44406-6 soybean

Validated DAS-44406-6 soybean detection method
In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of the DAS-44406-6 soybean, a validated event-specific detection method for the quantification of DAS-44406-6 soybean event has been published by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC). The validated detection method is publicly available from the JRC-EURL website:
http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

DAS-44406-6 soybean certified reference material
In accordance with Regulation (EC) No 1829/2003 and in line with the above application for authorisation of DAS-44406-6 soybean, certified reference material is available at Joint Research Centre's GMO Reference Unit. The corresponding certified reference material set ERM®-BF436 can be obtained via the JRC website: https://crm.jrc.ec.europa.eu/e/92/Catalogue-price-list-pdf

Contact points for Operators

As there are other technology providers for GM soybean and shipments entering the European harbours may be commingled, an industry wide approach has been developed. Therefore, CropLife Europe is the central communication point for the GM plant technology providers.

[4] Also referred to as soybean grain

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 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 can also be addressed to:
Corteva Agriscience
Rue Montoyer 25
1000 Bruxelles
Belgium
Email address: CortevaEUBiotech@corteva.com