

DAS-81419-2 x DAS-44406-6 soybean
Conkesta E3[®] soybean

Fact-sheet for operators

2021

Introduction

DAS-81419-2 x DAS-44406-6 soybean, also referred to as Conkesta E3[®] soybean¹ in the commercial context, has been developed by Corteva Agriscience LLC². The placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-81419-2 x DAS-44406-6 was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by the European Commission on 17 August 2021 under Commission Implementing Decision (EU) 2021/1387 (EC, 2021)³.

The authorisation Decision for DAS-81419-2 x DAS-44406-6 soybean is published at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021D1387&qid=1629801421584&from=EN>

The following products are authorised:

- (a) Food and food ingredients containing, consisting of, or produced from DAS-81419-2 x DAS-44406-6 soybean
- (b) Feed containing, consisting of, or produced from DAS-81419-2 x DAS-44406-6 soybean
- (c) DAS-81419-2 x 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-81419-2 x DAS-44406-6 soybean

DAS-81419-2 x DAS-44406-6 soybean has been obtained from traditional breeding methods between progeny of two genetically modified (GM) soybeans, the DAS-81419-2 and the DAS-44406-6 soybean. No new genetic modification has been introduced in DAS-81419-2 x DAS-44406-6 soybean.

Therefore, DAS-81419-2 x DAS-44406-6 soybeans express the transgenic proteins inherited from the single genetically modified events: Cry1F and Cry1Ac proteins, to confer protection against susceptible lepidopteran target pests based on the presence of independent modes of action for insect protection, the 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, farmers 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: <http://www.enlist.com/en/traits>

¹ [®] Registered Trademark of Corteva Agriscience LLC

² Hereafter referred to as Corteva

³ Commission Implementing Decision 2021/1387 of 17 August 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean DAS-81419-2 x DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.

Safety of the DAS-81419-2 x DAS-44406-6 soybean

On 2 March 2016, Dow AgroSciences Ltd submitted an application for the placing on the market of DAS-81419-2 x 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-2016-132). On 15 October 2020, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) adopted a positive scientific opinion in which it concluded: *“In conclusion, the GMO Panel considers that soybean DAS–81419–2 x DAS–44406–6, as described in this application, is as safe as the conventional counterpart and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.”* (EFSA, 2020).

The EFSA GMO panel scientific opinion is available at:

<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2020.6302>

Monitoring Conditions for DAS-81419-2 x DAS-44406-6 soybean

As indicated in the positive EFSA GMO Panel opinion on DAS-81419-2 x DAS-44406-6 soybean, *“Soybean DAS-81419-2 x DAS-44406-6 is as nutritious as its conventional counterpart and the non-GM soybean reference varieties tested”* (EFSA, 2020). Therefore, post-market monitoring of DAS-81419-2 x DAS-44406-6 soybean food/feed is not necessary, as confirmed by the EFSA GMO Panel (EFSA, 2020) and in the Commission authorisation Decision for DAS-81419-2 x DAS-44406-6 soybean (EC, 2021)³.

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-81419-2 x DAS-44406-6 soybean. Therefore, case-specific monitoring of DAS-81419-2 x DAS-44406-6 soybean is not necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2020)⁴. As specified by Commission Decision (EC, 2021), a post-market environmental monitoring (PMEM) plan for DAS-81419-2 x 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-81419-2 x DAS-44406-6 soybean, if any.

As stated by the EFSA GMO Panel in its scientific opinion on DAS-81419-2 x DAS-44406-6 soybean for food and feed uses, import and processing *“The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of soybean DAS–81419–2 x DAS–44406–6”* (EFSA, 2020).

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

⁴ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2020. Scientific Opinion on application EFSA-GMO-NL-2016-132 for authorisation of genetically modified of insect-resistant and herbicide-tolerant soybean DAS–81419–2 x DAS–44406–6 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Dow Agrosciences LLC. EFSA Journal 2020;18(11):6302, 37 pp.; <https://doi.org/10.2903/j.efsa.2020.6302>

The post-market environmental monitoring plan for DAS-81419-2 x DAS-44406-6 soybean has been published on the EU register for genetically modified food and feed:

https://webgate.ec.europa.eu/dyna/gm_register/soybeanDAS-81419-2xDAS-44406-6-environmentalmonitoringplan.pdf

Conditions for traceability and labelling for DAS-81419-2 x DAS-44406-6 soybean

Operators importing, handling and processing DAS-81419-2 x DAS-44406-6 soybean seeds⁵ and derived foods and feeds in the EU must comply with the conditions for traceability and labelling outlined in Regulations (EC) No 1829/2003 and 1830/2003 and in Commission Implementing Decision (EU) 2021/1387 for DAS-81419-2 x 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 is soybean.

The words 'not for cultivation' must appear on the label of and in documents accompanying products containing or consisting of DAS-81419-2 x DAS-44406-6 soybean with the exception of foods and food ingredients.

The unique identifier assigned to DAS-81419-2 x DAS-44406-6 soybean is DAS-81419-2 x DAS-44406-6.

Methods for detection and reference material for DAS-81419-2 x DAS-44406-6 soybean

Validated DAS-81419-2 x DAS-44406-6 soybean detection method

The detection, sampling and identification methods for DAS-81419-2 x DAS-44406-6 soybean consist of the same detection, sampling and identification methods available for DAS-81419-2 and DAS-44406-6 soybean, all of which have been validated by the JRC-EURL. In accordance with Regulation (EC) 1829/2003, Corteva provided the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC) with a PCR detection method that consists of the validated quantitative PCR detection methods for DAS-81419-2 and DAS-44406-6. The detection method was validated on DAS-81419-2 x DAS-44406-6 soybean in 2019 and is publicly available from the JRC-EURL website: <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>

DAS-81419-2 x 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-81419-2 x DAS-44406-6 soybean, certified reference materials are available at the Institute for Reference Materials and Measurements (IRMM). Reference Material: ERM[®]-BF437 (for DAS-81419-2) and ERM[®]-BF436 (for DAS-44406-6) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue>.

⁵ Also referred to as soybean grain

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.

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: <https://croplifeeurope.eu/product-information/>

If required, additional comments or questions can also be addressed to:

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