

WideStrike
281-24-236x3006-210-23 cotton
Fact-sheet for operators

2021

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The placing on the market of products containing, consisting of or produced from genetically modified cotton 281-24-236x3006-210-23, also known as WideStrike® (WS) Cotton insect protection was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by the European Commission on 22 December 2011 under Commission implementing decision 2011/891/EU¹, amended by Commission implementing decision 2019/239².

The authorisation decision for WideStrike Cotton maize is published at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011D0891&qid=1561381368923&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) Foods and food ingredients containing, consisting of, or produced from WS cotton.
- (b) Feed containing, consisting of, or produced from WS cotton.
- (c) Products, other than food and feed, containing or consisting of WS cotton for the same uses as any other cotton with the exception of cultivation.

For the purpose of this document above uses will be summarised as “import, food and feed”.

General Characteristics of WS cotton

WS cotton expresses the three proteins Cry1F, Cry1Ac and PAT:

- Cry1F and Cry1Ac are natural proteins from the common soil bacterium *Bacillus thuringiensis* (Bt) that provide protection against a broad spectrum of lepidopteran insect pests that affect the quality and quantity of cotton production.
- The protein phosphinothricin acetyltransferase (PAT) used as selectable marker is a natural protein from *Streptomyces viridochromogenes*, another soil organism that is widespread in the environment

¹ EC, 2011. Commission Implementing Decision (EU) 2011/891/EU of 6 February 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5x/DAS-21Ø23-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

² EC, 2019. Commission Implementing Decision (EU) 2019/239 of 6 February 2019 amending Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449 and (EU) 2017/2450 as regards the representative or the authorisation holder

Safety of WS cotton

In June 2005, Dow AgroSciences submitted an application for the placing on the market of 281-24-236x3006-210-23 cotton for food and feed uses, import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2005-16). On June 14th 2010, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) first published a positive scientific opinion as a result of its safety assessment in accordance with the latest EU regulatory requirements and following consultation with Competent Authorities of the EU Member States, in which it concluded *“In conclusion, the EFSA GMO Panel considers that information available for cotton 281-24-236 x 3006-210-23 addresses the scientific comments raised by Member States and that the cotton 281-24-236 x 3006-210-23 as described in this application is as safe as its conventional counterpart and other appropriate comparators with respect to potential effects on human and animal health and the environment in the context of its intended uses. The EFSA GMO Panel concludes that cotton 281-24-236 x 3006-210-23 is unlikely to have any adverse effect on human and animal health and the environment, in the context of its intended uses.”*

The EFSA GMO panel scientific opinion is available at:

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1644>

Monitoring and General Surveillance

As stated above, WS cotton is nutritionally equivalent to and as safe as conventional cotton. Therefore, post-market monitoring of import, food and feed of WS cotton is not necessary as confirmed by the EFSA GMO Panel in the positive safety opinion on WS cotton:

“An evaluation of the risk assessment concluded that no data have emerged to indicate that cotton 281-24-236 x 3006-210-23 is any less safe than its conventional counterpart. In addition, cotton 281-24-236 x 3006-210-23 is, from a nutritional point of view, substantially equivalent to commercial non-GM cotton. Therefore, and in line with the Guidance Document (EFSA, 2006a), the EFSA GMO Panel is of the opinion that post-market monitoring of the GM food/feed derived from cotton 281-24- 236 x 3006-210-23 is not necessary.”

Furthermore, no adverse effects to human and animal health or the environment have been identified in the environmental risk assessment from the uses of WS cotton. Therefore, case-specific monitoring of WS cotton is not considered necessary. Nonetheless, an environmental monitoring plan for WS cotton is in place which consists of a general surveillance plan to report any unanticipated adverse effects on human and animal health or the environment arising from handling or use of viable WS cotton. The monitoring will take place in cooperation with monitoring networks of importers and feed manufacturers,

whom will report back to the authorisation holders on an annual basis. The EFSA positive opinion on WS cotton for import, food and feed concludes that:

“The scope of the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of cotton since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects.”

The post-market environmental monitoring plan for 281-24-236 x 3006-210-23 cotton has been published on the EU register for genetically modified food and feed:

http://ec.europa.eu/food/dyna/gm_register/100914-281-24-2363006-210-23-monitoring%20plan.pdf

Conditions for traceability and labelling for WS cotton

Operators importing, handling and processing WS cotton 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 2011/891/EU and (EU) 2019/239 for WS cotton.

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 cotton.

The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of WS cotton with the exception of foods and food ingredients containing, consisting of or produced from WS cotton.

The unique identifier assigned to WS cotton is DAS-24236-5 x DAS-21Ø23-5.

Methods for detection and reference material for WS cotton

Validated WS cotton maize detection method

In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of the WS cotton, a validated event-specific detection method for the quantification of WS cotton 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/summaries/281-3006_val_report.pdf

WS cotton certified reference material

In accordance with Regulation (EC) No 1829/2003 and in line with the above applications for approval of 281-24-236x3006-210-23 cotton, the certified reference materials (CRM) for 281-24-236x3006-210-23 cotton consist of the CRMs for WS cotton produced by the Joint Research Centre’s GMO Reference Unit. The CRM sets are ERM- BF422a, ERM-BF422b, ERM-BF422c and ERM-BF422d

http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm

Contact Points for Operators

CropLife Europe is the general contact point for reporting general surveillance activities or any unanticipated adverse effects. This can be done via the CropLife Europe website under: 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