

**APPLICATION FOR RENEWAL OF AUTHORISATION OF
GENETICALLY MODIFIED PLANTS AND DERIVED FOOD AND
FEED IN ACCORDANCE WITH ARTICLES 11 AND 23 OF
REGULATION (EC) NO 1829/2003**

**281-24-236 x 3006-210-23 cotton
(DAS-24236-5 x DAS-21Ø23-5 cotton)**

**EFSA-GMO-RX-019
PART III – Summary**

Submitted by:

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PART III – SUMMARY

1. GENERAL INFORMATION

1.1 Details of application

a) Member State of application -
b) Application number [EFSA-GMO-RX-019]
c) Name of the product (commercial and other names) The product described in this application is 281-24-236 x 3006-210-23 cotton, the unique identification code assigned is: DAS-24236-5 x DAS-21Ø23-5 cotton and the commercial name assigned to 281-24-236 x 3006-210-23 cotton seed in the US market is WideStrike cotton.
d) Date of acknowledgement of valid application [To be provided]

1.2. Applicant

a) Name of applicant Corteva AgriScience LLC as represented by Corteva Agriscience Belgium B.V.
b) Address of applicant Corteva Agriscience LLC 9330 Zionsville Road Indianapolis, IN 46268-1054 U.S.A Represented by: Corteva Agriscience Belgium B.V. Rue Montoyer 25, B-1000 Brussels Belgium.
c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union) Same as applicant

1.3. Scope of the application

This application is for renewal of authorisation of food and feed from genetically modified 281-24-236 x 3006-210-23 cotton according to Articles 11 and 23 of Regulation (EC) No 1829/2003. (a) Genetically modified food

<p><input checked="" type="checkbox"/> Food containing or consisting of genetically modified plants</p> <p><input checked="" type="checkbox"/> Food produced from genetically modified plants or containing ingredients produced from genetically modified plants</p> <p>(b) Genetically modified feed</p> <p><input checked="" type="checkbox"/> Feed containing or consisting of genetically modified plants</p> <p><input checked="" type="checkbox"/> Feed produced from genetically modified plants</p> <p>(c) Genetically modified plants for food and feed use</p> <p><input checked="" type="checkbox"/> Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation</p> <p><input type="checkbox"/> Seeds and plant propagating material for cultivation in the Union</p>

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation procedure within the Union?

<p>Yes [x]</p> <p>281-24-236 x 3006-210-23 cotton and its uses have already been authorised in the EU as detailed in sections 1.3. and 1.6.</p>	<p>No []</p>
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1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?

<p>Yes [x]</p>	<p>No []</p>
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1.6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC?

<p>Yes [x]</p> <p>Decision authorisation number and date under Regulation (EC) No 1829/2003:</p> <p>COMMISSION DECISION of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 x 3006-210-23 (DAS-24236-5xDAS-21Ø23-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and the Commission implementing decision (EU) 2019/239, 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 (notified under document C(2019) 736) (</p>	<p>No []</p>
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<p>An overview has been published in the Community Register (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).</p>	
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1.7. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<p>281-24-236 x 3006-210-23 cotton was first authorised for food, feed and cultivation purposes in the United States (US) in 2004 and has been commercialised in the US since 2006. Cultivation of 281-24-236 x 3006-210-23 cotton has also been authorised in Australia, Brazil, Canada and Japan. 281-24-236 x 3006-210-23 cotton has been authorised in many major cotton trading countries in the world: to date, 38 countries (including the EU-28) around the world have authorised 281-24-236 x 3006-210-23 cotton for import and/or food and feed use.</p>	

1.8. General description of the product

<p>a) Name of the recipient or parental plant and the intended function of the genetic modification</p> <p>Cotton (<i>Gossypium hirsutum</i>) is extensively cultivated and has a long history of safe use. The product consists of seeds derived from 281-24-236 x 3006-210-23 cotton, genetically modified to express Cry1F and Cry1Ac proteins (conferring resistance to certain lepidopteran insect pests under field conditions) and PAT protein (conferring tolerance to glufosinate-ammonium during the selection stages of the genetic modification).</p>
<p>b) Types of products planned to be placed on the market according to the authorisation applied for</p> <p>This application is for renewal of authorisation of food and feed produced from genetically modified 281-24-236 x 3006-210-23 cotton according to Articles 11 and 23 of Regulation (EC) No 1829/2003. The types of products placed on the market according to such authorisation include 281-24-236 x 3006-210-23 cotton for all food and feed uses, and for all food, feed and processed products derived from 281-24-236 x 3006-210-23 cotton in accordance with Regulation (EC) No 1829/2003. This application does not include authorisation for the cultivation of 281-24-236 x 3006-210-23 cotton seed products in the EU.</p>
<p>c) Intended use of the product and types of users</p> <p>The 281-24-236 x 3006-210-23 cotton products placed on the market will continue to be used in a manner consistent with current uses of commercial cotton grain and cotton products. The 281-24-236 x 3006-210-23 cotton will undergo existing methods of production and manufacturing used for commercial cotton. No novel method of production and manufacturing is envisaged.</p>

d) Specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

Safety evaluation of 281-24-236 x 3006-210-23 cotton has shown that no specific instructions and/or recommendations for use, storage and handling of 281-24-236 x 3006-210-23 cotton are necessary. Therefore, 281-24-236 x 3006-210-23 cotton can continue to be used, stored and handled in the same way as it is currently done for commercial cotton. Labelling of 281-24-236 x 3006-210-23 cotton products will be carried out in accordance with Community law.

e) Geographical areas within the Union to which the product is intended to be confined under the terms of the authorisation applied for

281-24-236 x 3006-210-23 cotton will be used throughout the European Union as any other commercial cotton products.

f) Any type of environment to which the product is unsuited

The application does not cover cultivation of 281-24-236 x 3006-210-23 cotton in the European Union. The 281-24-236 x 3006-210-23 cotton will be used throughout the European Union as any other commercial cotton products.

g) Any proposed packaging requirements

The packaging, handling, and storage systems that are currently used for commercial cotton will apply. The 281-24-236 x 3006-210-23 cotton products will be packaged in the same manner as other commercial cotton products.

h) Any proposed labelling requirements in addition to those required by other applicable EU legislation than Regulation (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Article 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003. In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

The labelling proposal remains as currently required by Article 3 (1) and (2) of Commission Decision 2011/891/EU.

i) Estimated potential demand

In the EU

Extra-EU cotton imports vary from year to year depending on annual EU cotton yields. The international currency exchange rates, cotton grain price and transportation costs are also factors influencing commodity crop imports into the EU. In 2018, a modest total of approximately 3 thousand tonnes of cotton were imported into the EU, from countries such as Azerbadjan, Benin, Myanmar, Togo, and the United States. Italy and Spain are the most important market for extra-EU cotton imports with a share representing approximately 83% of the total extra-EU cotton imports in 2018. Other significant import markets for extra-EU cotton in 2020 were the UK and Romania.

In EU export markets

The application does not cover cultivation of 281-24-236 x 3006-210-23 cotton in the European Union.

g) Unique identifier in accordance with Regulation (EC) No 65/2004

DAS-24236-5 x DAS-21Ø23-5 cotton

1.9. Measures suggested by the applicant to take in case of unintended release or misuse of the product as well as measures for disposal and treatment

Based on the conclusions from the environmental risk assessment of 281-24-236 x 3006-210-23 cotton, no specific measures need to be taken in case of unintended release or misuse, or for disposal and treatment. There are no sexually compatible endogenous wild plant species in Europe with which cotton can cross-hybridise, and cotton plants cannot survive as a weed outside agricultural fields. The establishment of cotton volunteer plants is therefore very unlikely.

In case of unintended release of 281-24-236 x 3006-210-23 cotton, current agronomic measures taken to control other commercially available cotton can be applied, such as use of mechanical means and selective use of herbicides.

2. INFORMATION TO BE SUBMITTED ACCORDING TO ARTICLES 11 AND 23 OF REGULATION (EC) No 1829/2003

2.1. A copy of the authorisation for placing the food and feed on the market

The placing on the market of 281-24-236 x 3006-210-23 cotton for the same uses as any other cotton, exception for cultivation, was authorised by Commission Decision 2011/891/EU.

An overview has been published in the Community Register (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).

2.2. A report on the results of the monitoring, if so specified in the authorisation

During the current years of reporting period of the placing on the market of 281-24-236 x 3006-210-23 cotton imports, Dow AgroSciences, as authorisation holders, have continued to implement the monitoring requirements in accordance with the relevant article of the authorising decision.

The general surveillance system put in place by the plant biotechnology industry and the European trade associations and utilised by the authorisation holder for 281-24-236 x 3006-210-23 cotton imports is functioning well. It provides for monitoring of potential unanticipated adverse effects that might arise from the presence of GMO material (including 281-24-236 x 3006-210-23 cotton) during import, handling and processing of crop commodities and ensures that any observed adverse effects are reported immediately to the authorisation holders. Furthermore, the trade associations provide annual reports to the authorisation holders via CropLife Europe for the period from July to June, every year at the end of their business year.

The annual reports provided by the trade associations for the period from July to June every year revealed no adverse effects in the context of the placing on the market of 281-24-236 x 3006-210-23 cotton imports. Thus, no adverse effects have been reported by the trade associations from the date of

approval of 281-24-236 x 3006-210-23 cotton for import and use as or in food, feed and processing to date.

Consequently, the results of the general surveillance of 281-24-236 x 3006-210-23 cotton carried out from December 2011 to date confirm that no adverse effects on human and animal health or the environment have arisen from the import of 281-24-236 x 3006-210-23 cotton into the EU for the reporting period.

2.3. Any other new information which has become available with regard to the evaluation of the safety in use of the food and feed and the risks of the food and feed to the consumer, animals or the environment

(i) introduction to 281-24-236 x 3006-210-23

As stated in the EFSA GMO Panel opinion related to 281-24-236 x 3006-210-23 “The GM cotton 281-24-236 x 3006-210-23 has been produced by conventional crossing between lines of the single cotton events 281-24-236 and 3006-210-23. The cotton 281-24-236 x 3006-210-23 expresses combined traits encoded by *cryIF* in event 281-24-236 and by *cryIAc* in event 3006-210-23, both genes conferring resistance to certain lepidopteran pests.”¹

(ii) New information obtained in the framework of applications for authorisation of related events

Literature searches

No publications have appeared in the scientific literature up to now that invalidate the previously reached conclusions of the food/feed safety assessment of 281-24-236 x 3006-210-23 cotton.

Bioinformatic analysis

The latest performed bioinformatic analyses do not change the conclusion of the food/feed safety assessment of 281-24-236 x 3006-210-23 cotton.

2.4. Where appropriate, a proposal for amending or complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring

The scope of this application does not include authorisation for the cultivation of 281-24-236 x 3006-210-23 cotton seed products in the EU.

In the light of the successful implementation of and results from current monitoring activities, which confirm the risk assessment and findings of previous annual monitoring reports, and the fact that no changes are foreseen to the existing use of the product, the authorisation holders consider that the environmental monitoring plan, including the general surveillance system, in place for the monitoring of 281-24-236 x 3006-210-23 cotton imports is fully appropriate and does not require amendment. However, the format of the monitoring plan for 281-24-236 x 3006-210-23 cotton has been updated based on the agreed harmonized monitoring plan.

¹ EFSA 2010 - Scientific Opinion on application (EFSA-GMO-NL-2005-16) for the placing on the market of insect resistant genetically modified cotton (*Gossypium hirsutum* L.) 281-24-236 x 3006-210-23 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Dow AgroSciences." Efsa Journal 8(6): 32