281-24-236x3006-210-23 cotton

Fact-sheet for operators

2023

281-24-236x3006-210-23 cotton

Commission Decision 2011/891/EU[1] of 22 December 2011 authorised the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5xDAS-21Ø23-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The authorisation was amended by Commission Implementing Decision (EU) 2019/239[2] of February 2019 and by Commission Implementing Decision (EU) 2021/1161[3] of 13 July 2021 consecutively as regards to the authorisation holder and/or its representative in the Union for the placing on the market of products containing, consisting of, or produced from certain genetically modified organisms.

Since then, the Commission Implementing Decision (EU) 2023/1210[4] of 21 June 2023 renewed the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified cotton 281-24-236 × 3006-210-23 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The following products are re-authorised:

(a) Foods and food ingredients containing, consisting of or produced from genetically modified cotton 281-24-236x3006-210-23.
(b) Feed containing, consisting of or produced from genetically modified cotton 281-24-236x3006-210-23.
(c) Products containing or consisting of genetically modified cotton 281-24-236x3006-210-23, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

---

1 EC, 2011. Commission Decision 2011/891/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5xDAS-21Ø23-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011D0891&qid=1561381368923&from=EN

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

3 EC, 2021. Commission Implementing Decision (EU) 2021/1161 of 13 July 2021 amending Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449, (EU) 2019/2085 and (EU) 2019/2086 as regards the authorisation holder and its representative in the Union for the placing on the market of products containing, consisting of, or produced from certain genetically modified organisms. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021D1161&qid=1627290004338&from=EN

4 EC, 2023. Commission Implementing Decision (EU) 2023/1210 of 21 June 2023 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified cotton 281-24-236 × 3006-210-23 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023D1210

General Characteristics

281-24-236x3006-210-23 cotton has been obtained by traditional breeding between genetically modified 281-24-236 and 3006-210-23 cotton single events. No new genetic modifications were introduced to obtain 281-24-236x3006-210-23 cotton.

Therefore, 281-24-236x3006-210-23 cotton expresses the cry1F and cry1Ac genes, which confer resistance to certain lepidopteran pests, and the pat gene, used as a selectable marker, which confers tolerance to glufosinate-ammonium based herbicides.

281-24-236x3006-210-23 cotton therefore confers i.) control of certain lepidopteran pests based on the presence of the Cry1F and Cry1Ac proteins, conferring multiple modes of action for insect protection; and ii) herbicide tolerance to glufosinate due to the presence of the PAT protein. Trait pyramids such as 281-24-236x3006-210-23 cotton provide greater potential durability compared to products expressing a single mode of action, because each mode of action controls insects that are partially or completely resistant to the other mode of action.

Safety

In June 2005, Dow AgroSciences [5] submitted to the competent authority of the Netherlands 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 15 June 2010, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) adopted a positive scientific opinion in which it concluded: "*The EFSA GMO Panel concludes that cotton 281-24-236x3006-210-23 is unlikely to have any adverse effect on human and animal health and the environment, in the context of its intended uses.*"[6]

In December 2020 Dow AgroSciences[5] submitted to the Commission an application for the renewal of the authorisation 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 11 and 23 of Regulation (EC) No 1829/2003 (EFSA-GMO-RX-019). On 28 September 2022, the EFSA Panel on GMOs adopted a positive scientific opinion in which it concluded that: *"there is no evidence in renewal application EFSA-GMO-RX-019 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton 281-24-236x3006-210-23."*[7]

---

5 As of January 4th, 2021 Dow AgroSciences LLC changed its name to Corteva Agriscience LLC.

6 EFSA GMO Panel, 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). https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1644

7 EFSA GMO Panel, 2022. Scientific opinion on the assessment of genetically modified cotton 281-24-236× 3006-210-23 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-019). EFSA Journal, 20(11), p.e07587. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7587

Monitoring conditions

As indicated in the positive EFSA GMO Panel opinions, 281-24-236x3006-210-23 cotton is as safe and as nutritious as its non-GM comparator[6,7]. Therefore, post-market monitoring of food/feed derived from 281-24-236x3006-210-23 cotton is not necessary, as reconfirmed in the Commission authorisation decision[4] for 281-24-236x3006-210-23 cotton.

Furthermore, no potential adverse effects to human and animal health or the environment have been identified in the environmental risk assessment from the intended uses of 281-24-236x3006-210-23 cotton[6,7]. Therefore, case-specific monitoring of 281-24-236x3006-210-23 cotton is not necessary, as confirmed by the EFSA GMO panel in its scientific opinions[6,7] and Commission decision 2023/1210[4].

As specified by the Commission decision, a post-market environmental monitoring (PMEM) plan for of 281-24-236x3006-210-23 cotton 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 of 281-24-236x3006-210-23 cotton, if any. As stated by the EFSA GMO Panel in its scientific opinion on 281-24-236x3006-210-23 cotton for renewal of the authorisation for food and feed uses, import and processing "*The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of application EFSA-GMO-RX-019*"[7]. The monitoring takes place in cooperation with monitoring networks of trade associations representing operators importing, handling and processing viable cotton 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.

The post-market environmental monitoring plan for 281-24-236x3006-210-23 cotton has been published on the EU register for genetically modified food and feed[8].

Conditions for traceability and labelling

Operators importing, handling and processing 281-24-236x3006-210-23 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 (EU) 2023/1210[4] for 281-24-236x3006-210-23 cotton.

For the purposes of the 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 281-24-236x3006-210-23 cotton

[8] EC. EU Register of authorized GMOs. https://webgate.ec.europa.eu/dyna2/gm-register/

with the exception of foods and food ingredients containing, consisting of or produced from 281-24-236x3006-210-23 cotton.

The unique identifier assigned to 281-24-236x3006-210-23 cotton is DAS-24236-5xDAS-21Ø23-5.

Methods for detection and reference material

Validated detection method

The detection, sampling and identification methods for 281-24-236x3006-210-23 cotton consist of the same detection, sampling and identification methods available for 281-24-236 and 3006-210-23 cottons, which have been validated by the Joint Research Centre (JRC) of the European Union Reference Laboratory (EURL). In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of 281-24-236x3006-210-23 cotton, the applicant provided the JRC-EURL with a detection method that consists of the validated event-specific PCR method for the quantification of 281-24-236 and 3006-210-23 cotton, for verification. The detection method has been validated by EURL in April 2006 and is publicly available from the JRC-EURL website[9].

Certified reference material

The Certified Reference Materials (CRM) for 281-24-236x3006-210-23 cotton consists of the CRM sets ERM-BF422a, ERM-BF422b, ERM-BF422c and ERM-BF422d, which are accessible via the JRC of the European Commission[10].

Contact Points for Operators

As there are other technology providers for GM cotton 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:

[9] JRC, D.G., 2006. Event-specific methods for the quantitation of the hybrid cotton line 281-24-236/3006-210-23 using real-time PCR. http://gmo-crl.jrc.ec.europa.eu/summaries/281-3006_val_report.pdf

[10] JRC. Certified Reference Materials catalogue of the JRC. https://crm.jrc.ec.europa.eu/

Corteva Agriscience
Rue Montoyer, 25
1000 Brussels
Belgium
Email address: CortevaEUBiotech@corteva.com