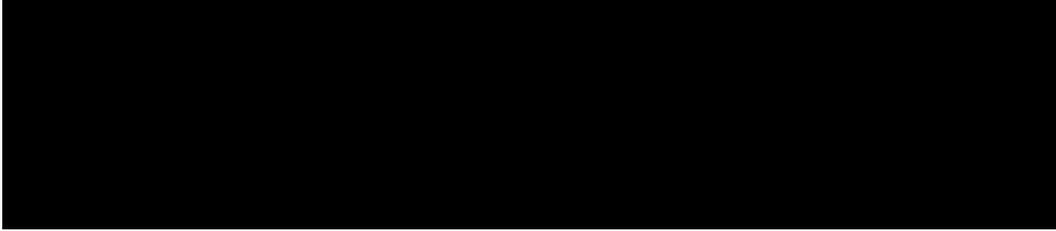


**Review of literature for 281-24-236 × 3006-210-23 and 281-24-236 ×
3006-210-23 × MON 88913 cotton in the scope of their authorisations
for food and feed uses, import and processing
(2023 update)**



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1. Summary

An updated systematic search and review of peer-reviewed literature was conducted for 281-24-236 × 3006-210-23 cotton and 281-24-236 × 3006-210-23 × MON 88913 cotton (hereafter collectively referred to as “authorised GM cotton”). This exercise was performed in line with the EFSA Guidance on conducting a systematic review (EFSA, 2010) and taking into account the explanatory note on literature searching (EFSA, 2019), with the following review question “Do the authorised GM cotton and derived food/feed products, or the intended traits (the newly expressed proteins or their combination) have adverse effects on human and animal health and the environment in the scope of their authorisation?”.

The current systematic search complements the searches previously performed in 2022. Unless outlined below, all portions of the search were conducted according to the methodologies outlined in the previous searches.

The outcome of this analysis showed that no new publications relevant for the review question were identified during the selected time period. No safety concerns were identified for the authorised GM cotton by this literature search exercise.

2. Confirmation of the Suitability of the Search Strings

All portions of the search were conducted according to the methodologies outlined in the previous searches. It was confirmed that the search strategy utilized in the previous literature search report (2022) is still relevant and no updates were identified.

3. Results of the Scoping Exercise

3.1. Outcome of literature searches

In May 2023, searches against electronic bibliographic databases and manual searches in view of screening of reference lists were performed. The search process is reported in line with EFSA guidance (EFSA, 2010 Appendix B4(2)) in Table 1.

Table 1. Documenting and reporting the search process

Resources	Date of search	Period searched*	Other restrictions	Number of records retrieved
Web of Science Core collection [§]	26 May 2023	1 Jan 2022-26 May 2023	None	103
CAB Abstracts [§]	26 May 2023	1 Jan 2022-26 May 2023	None	116
MEDLINE [§]	26 May 2023	1 Jan 2022-26 May 2023	None	62
Europe PMC [§]	26 May 2023	1 Jan 2022-26 May 2023	None	3
Screening reference lists	NA	-	NA	NA

[§] The search syntaxes used for electronic bibliographic databases are reported in Appendix 1.

* Period searched included an indexing date of 8 August 2022.

NA: Not applicable as no publications relevant for screening reference lists were identified.

The publications retrieved across all methods of searching (Web of Science Core collection, CAB Abstracts, MEDLINE, Europe PMC, and screening of reference lists) can be found in Appendix 3.

In the framework of the reference list screening exercise, no detailed risk assessments regarding the authorised GM cotton nor any reviews were retrieved that contained information on food and feed safety. Considering that no opinions were published within the selected time period no further screening was performed.

The publications grouped in the Endnote® library were deduplicated. Publications retrieved by the previous searches conducted in the frame of the 2022 annual monitoring report were also removed (see Appendix 3).

The results of the publication selection process are presented in Table 2.

Table 2. Results of the publication selection process, for the review question

Review question: “Do the authorised GM cotton and derived food/feed products, or the intended traits (the newly expressed protein(s) or their combination), have adverse effects on human and animal health and the environment in the scope of their applications?”	Number of records
Total number of publications retrieved after all searches of the scientific literature (excluding duplicates and publications retrieved by the previous searches conducted in the frame of the 2022 monitoring reports)	178
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	178
Total number of full-text documents assessed in detail	0
Number of publications excluded from further consideration after detailed assessment for relevance based on full text	0
Total number of unobtainable/unclear publications	0
Total number of relevant publications	0

The 178 unique entries present in the Endnote database (Table 2) were manually screened for relevance to the review question by two independent reviewers using the *a priori* eligibility/inclusion criteria described in Appendix 2.

In the first stage of screening, entries were screened based on title/abstract. Records that were deemed to be irrelevant were not further retained.

In this literature search exercise, no publications seemed relevant, and therefore no publications were progressed to the second stage and assessed for relevance at the level of the full text.

4. Conclusion

No publications were identified as relevant for the molecular characterisation, food/feed and environmental safety of the authorised GM cotton within the scope of the authorisations for the defined time period. No safety concerns have been identified for the authorised cotton by this literature search exercise.

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- EFSA, **2010**. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 8(6):1637. [90 pp.].
- EFSA, **2019**. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA supporting publication 2019:EN-1614. [62 pp.].

Appendix 1. Detailed search syntaxes for the authorised GM cotton events**Web of Science Core collection**

Set	Search query	Results
Event #1	TS=(DAS24236* OR DAS-24236 OR DAS-24236-5 OR 281-24-236 OR DAS21023* OR DAS-21023 OR DAS-21Ø23-5 OR DAS-21-circle-divide-23-5 OR DAS-21empty set23-5 OR 3006-210-23 OR 281-24-236x3006-210-23 OR DAS-24236-5xDAS-21Ø23-5 OR DAS-24236-5xDAS-21-circle-divide-23-5 OR DAS-24236-5xDAS-21empty-set23-5 OR *281x3006* OR WideStrike* OR MXB-13)	58
Stack #2	TS=(*DAS-24236-5xDAS-21Ø23-5xMON-88913-8* OR *DAS-24236-5xDAS-21-circle-divide-23-5xMON-88913-8* OR *DAS-24236-5xDAS-21empty-set23-5xMON-88913-8* OR *281-24-236x3006-210-23xMON88913* OR *281x3006x88913* OR *281x3006xMON*)	0
#3	#1 OR #2	58
Proteins #4	TS=((cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR (phosphinothricin AND (acetyltransferase OR acetyltransferase)) OR (pat AND phosphinothricin) OR cry1Ac OR Cry1-Ac OR cry1a-c OR cryAc OR Cryi-Ac OR cryia-c OR (cry AND (1Ac or 1-Ac or iAc or i-Ac))) AND (Streptomyces OR viridochromogenes OR Bacillus OR thuringiensis OR bt OR cotton OR gossypium OR hirsutum OR (((herbicid* AND (genetic* NEAR/3 (modif* or engineer*))) OR GMHT) AND (crop OR plant OR food OR feed)) OR gmo OR gmos OR lmo OR lmos OR gm OR ge OR stack))	2695
Traits #5	TS=((lepidopter* OR bollworm* OR pectinophora OR gossypiella OR corn -earworm* OR CEW OR sorghum-headworm* OR helicoverpa OR armigera OR tobacco-budworm* OR heliothis OR virescens OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) AND (toler* OR resist* OR protec*) AND (cotton OR gossypium OR hirsutum) AND (gmo OR gmos OR lmo OR lmos OR living-modified OR transgen* OR GMHT OR ((GM OR GE OR genetic*) NEAR/3 (modif* OR transform* OR manipulat* OR engineer* OR stack))))	1302
#6	#3 OR #4 OR #5	3425
Reporting Period #7	PY=(2022-2100) (and added to the database on or since date of 2022 PMEM search ran on Aug 8)	2,578,163
Final Results #8	#6 AND #7	103

CABI

Set	Search query	Results
Event #1	TS=(DAS24236* OR DAS-24236 OR DAS-24236-5 OR 281-24-236 OR DAS21023* OR DAS-21023 OR DAS-21Ø23-5 OR DAS-21<o>23-5 OR 3006-210-23 OR 281-24-236x3006-210-23 OR DAS-24236-5xDAS-21Ø23-5 OR DAS-24236-5xDAS-21<o>23-5 OR *281x3006* OR WideStrike* OR MXB-13)	59
Stack #2	TS=(DAS-24236-5xDAS-21Ø23-5xMON-88913-8 OR DAS-24236-5xDAS-21<o>23-5xMON-88913-8 OR 281-24-236x3006-210-23xMON88913 OR *281x3006x88913* OR *281x3006xMON*)	0
#3	#1 OR #2	59
Proteins #4	TS=((cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR (phosphinothricin AND (acetyltransferase OR acetyltransferase)) OR (pat AND phosphinothricin) OR cry1Ac OR Cry1-Ac OR cry1a-c OR cryiAc OR Cryi-Ac OR cryia-c OR (cry AND (1Ac or 1-Ac or iAc or i-Ac))) AND (Streptomyces OR viridochromogenes OR Bacillus OR thuringiensis OR bt OR cotton OR gossypium OR hirsutum OR (((herbicid* AND (genetic* NEAR/3 (modif* or engineer*))) OR GMHT) AND (crop OR plant OR food OR feed)) OR lmo OR lmos OR ge OR "genetically engineered foods" OR stack))	2778
Traits #5	TS=((lepidopter* OR bollworm* OR pectinophora OR gossypiella OR eorn-earworm* OR CEW OR sorghum-headworm* OR helicoverpa OR armigera OR tobacco-budworm* OR heliothis OR virescens OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) AND (toler* OR resist* OR protec*) AND (cotton OR gossypium OR hirsutum) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipul* OR transform* OR stack OR "genetically engineered foods"))	1873
#6	#3 OR #4 OR #5	4087
Reporting Period #7	PY=(2022-2100) (and added to the database on or since date of 2022 PMEM search ran on Aug 8)	360,901
Final Results #8	#6 AND #7	116

MEDLINE

Set	Search query	Results
Event #1	TS=(DAS24236* OR DAS-24236 OR DAS-24236-5 OR 281-24-236 OR DAS21023* OR DAS-21023 OR DAS-21Ø23-5 OR 3006-210-23 OR 281-24-236x3006-210-23 OR DAS-24236-5xDAS-21Ø23-5 OR *281x3006* OR WideStrike* OR MXB-13)	21
Stack #2	TS=(DAS-24236-5xDAS-21Ø23-5xMON-88913-8 OR 281-24-236x3006-210-23xMON88913 OR *281x3006x88913* OR *281x3006xMON*)	0
#3	#1 OR #2	21
Proteins #4	TS=((cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR (phosphinothricin AND (acetyltransferase OR acetyltransferase)) OR (pat AND phosphinothricin) OR cry1Ac OR Cry1-Ac OR cry1a-c OR cryiAc OR Cryi-Ac OR cryia-c OR (cry AND (1Ac or 1-Ac or iAc or i-Ac))) AND (Streptomyces OR viridochromogenes OR Bacillus OR thuringiensis OR bt OR cotton OR gossypium OR hirsutum OR (((herbicid* AND (genetic* NEAR/3 (modif* or engineer*))) OR GMHT) AND (crop OR plant OR food OR feed)) OR lmo OR lmos OR ge OR "Food, Genetically Modified" OR stack))	1587
Traits #5	TS=((lepidopter* OR bollworm* OR pectinophora OR gossypiella OR corn earworm* OR CEW OR sorghum-headworm* OR helicoverpa OR armigera OR tobacco-budworm* OR heliothis OR virescens OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) AND (toler* OR resist* OR protec*) AND (cotton OR gossypium OR hirsutum) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipul* OR transform* OR stack OR "Food, Genetically Modified"))	409
#6	#3 OR #4 OR #5	1803
Reporting Period #7	PY=(2022-2100) (and added to the database on or since date of 2022 PMEM search ran on Aug 8)	1,261,461
Final Results #8	#6 AND #7	62

Europe PMC

("DAS-24236-5xDAS-21Ø23-5xMON-88913-8" OR "281-24-236x3006-210-23xMON88913" OR 281x3006x88913 OR 281x3006xMON OR DAS24236 OR "DAS-24236" OR "281-24-236" OR DAS21023 OR "DAS-21023" OR DAS21Ø23 OR "DAS-21Ø23" OR "3006-210-23" OR "281-24-236x3006-210-23" OR "DAS-24236-5xDAS-21Ø23-5" OR 281x3006 OR WideStrike) AND (FIRST_PDATE:[2022-01-01 TO 2100-12-31]) AND (FIRST_IDATE:[2022-08-08 TO 2100-12-31])

= 3 results

Appendix 2. Eligibility/Inclusion Criteria¹

Concept	Criteria
Population (taking into account scope of the authorisation)	<p>Publication addressing human and animal health, and/or the environment relevant for the scope of the authorisation.</p> <p>The pathways and level of exposure to the GMO, derived food/feed products, and the intended traits addressed in the study (as assessed under the Intervention/exposure part) are relevant for the intended uses of the GMO and derived food/feed products under regulatory review (e.g. in case of an authorisation for food, food, import, efficacy of the traits, pest susceptibility, etc. are not considered relevant).</p>
Intervention/exposure	Publications addressing the authorised GM cotton and derived food/feed products, and/or the intended traits (newly expressed protein(s) or their combination, when applicable).
Intervention/exposure Plant species	In case of studies using GM plants, only studies using cotton are considered eligible. This criterion is not employed for studies regarding the newly expressed proteins.
Intervention/exposure Source organism of the protein	In case of publications using the protein of interest, only publications with the protein from the specific source organism will be considered eligible.
Comparator	If the study is a comparative study that uses plant material as test material, eligible publications must report a non-GM variety.
Outcomes	<p>Effects/impacts on human and animal health, and/or the environment are addressed.</p> <p>Publications addressing other issues such as benefits, socio-economics, ethics, crop protection, detection methods, efficacy, public perception and risk communication are to be excluded using this criterion, as they are not relevant to the risk assessment of GMOs.</p>
Reporting format	<p>Original/primary data are presented in the study. This permits the exclusion of publications that do not present original/primary data (e.g., reviews, editorial, position papers).</p> <p>However, risk assessments from relevant risk assessment bodies (excluding EFSA) will not be excluded.</p>

¹ This table is provided for ease of reference, no updates have been introduced since the previous report.

Appendix 3. New entries retrieved by the performed searches to literature databases for the authorised GM cotton within the indicated search period (excluding duplicates retrieved by the previous searches conducted in 2022)

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Appendix 4. Publications screened for relevance based on the full text

Table 4.1. Report of all relevant publications retrieved after detailed assessment of full-text documents for relevance

Category of information/ data requirement(s)	Reference (Author, year, title, source)
None	Not applicable

Table 4.2. Report of publications excluded from the risk assessment after detailed assessment of full-text documents

Reference (Author, year, title, source)	Reason(s) for exclusion based on eligibility/inclusion criteria
None	Not applicable

Table 4.3. Report of unobtainable/unclear publications

Reference (Author, year, title, source)	Description of (unsuccessful) methods used to try to obtain a copy of the publication
None	Not applicable