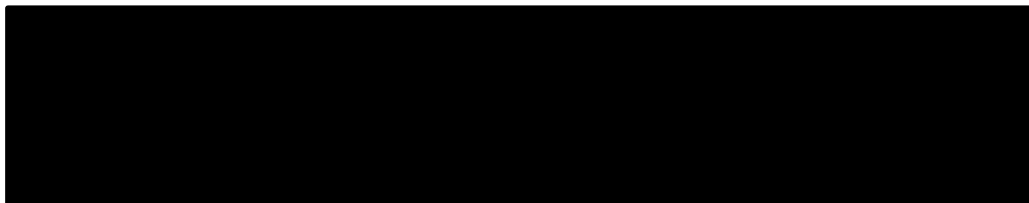


**Review of literature for 281-24-236 x 3006-210-23 and 281-24-236 x
3006-210-23 x MON 88913 cotton in the scope of their authorisations
for food and feed uses, import and processing (2021 update)**



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1. Summary

An updated systematic search and review of peer-reviewed literature was conducted for 281-24-236 x 3006-210-23 cotton and 281-24-236 x 3006-210-23 x MON 88913 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 “Does 281-24-236 x 3006-210-23 cotton or 281-24-236 x 3006-210-23 x MON 88913 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 2020. 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 281-24-236 x 3006-210-23 or 281-24-236 x 3006-210-23 x MON 88913 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 (2020) is still relevant and no updates were identified.

3. Results of the Scoping Exercise

3.1. Outcome of literature searches

In July 2021, 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 ^{\$}	7 July 2021	2020-7 July 2021	None	251
CAB Abstracts ^{\$}	7 July 2021	2020-7 July 2021	None	140
MEDLINE ^{\$}	7 July 2021	2020-7 July 2021	None	137
Europe PMC ^{\$}	7 July 2021	2020-7 July 2021	None	9
Screening reference lists	NA	-	NA	NA

^{\$} The search syntaxes used for electronic bibliographic databases are reported in Appendix 1.
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 281-24-236 x 3006-210-23 x MON 88913 or 281-24-236 x 3006-210-23 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 2020 annual monitoring report were also removed (see Appendix 3, Section 6).

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 cotton events ¹ 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 2020 monitoring reports)	143
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	143
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 143 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 cases where the record seemed relevant, or if the title/abstract did not contain sufficient information, the publication was progressed to the second stage and assessed for relevance at the level of the full text.

Publications assessed at full text level and found not to be relevant were not further assessed and a justification was provided. Records that are relevant were summarized and their potential to influence the initial risk assessment was evaluated in the format laid out by the Commission decision 2009/770/EC (EC, 2009).

In this literature search exercise, no peer-reviewed publications relevant to the risk assessment was identified (see Appendix 4, Table 4.1 and Table 3). Publications excluded after assessment of the full-text are presented in Table 4.2 in Appendix 4 and a reason for exclusion based on the eligibility/inclusion criteria is provided. No unclear publications were identified (see Appendix 4, Table 4.3).

¹ Authorised cotton events include 281-24-236 x 3006-210-23 and 281-24-236 x 3006-210-23 x MON 88913

4. Conclusion

No publications were identified as relevant for the molecular characterisation, food/feed and environmental safety of the 281-24-236 x 3006-210-23 or 281-24-236 x 3006-210-23 x MON 88913 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.

References

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- 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 cotton events

Web of Science Core collection

Set	Search query
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)
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*)
#3	#1 OR #2
Proteins #4	TS=((cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) 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 (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR gmo OR gmos OR lmo OR lmos OR gm OR ge OR stack))
Traits #5	TS=((lepidopter* OR bollworm* OR pectinophora OR gossypiella OR corn-earworm* 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/5 (modif* OR transform* OR manipulat* OR engineer* OR stack))))
#6	#3 OR #4 OR #5
Reporting Period #7	PY=(2020-2100)
Final Results #8	#6 AND #7

CAB Abstracts

Set	Search query
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)
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*)
#3	#1 OR #2
Proteins #4	TS=((cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) 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 (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR lmo OR lmos OR ge OR "genetically engineered foods" OR stack))
Traits #5	TS=((lepidopter* OR bollworm* OR pectinophora OR gossypiella OR corn-earworm* 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"))
#6	#3 OR #4 OR #5
Reporting Period #7	PY=(2020-2100)
Final Results #8	#6 AND #7

MEDLINE

Set	Search query
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)
Stack #2	TS=(DAS-24236-5xDAS-21Ø23-5xMON-88913-8 OR 281-24-236x3006-210-23xMON88913 OR *281x3006x88913* OR *281x3006xMON*)
#3	#1 OR #2
Proteins #4	TS=((cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) 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 (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR lmo OR lmos OR ge OR "Food, Genetically Modified" OR stack))
Traits #5	TS=((lepidopter* OR bollworm* OR pectinophora OR gossypiella OR corn-earworm* 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 manipulac* OR transform* OR stack OR "Food, Genetically Modified"))
#6	#3 OR #4 OR #5
Reporting Period #7	PY=(2020-2100)
Final Results #8	#6 AND #7

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:[2020-01-01 TO 2100-12-31])

Appendix 2. Eligibility/Inclusion Criteria²

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>

² This table is provided for ease of reference, no updates have been introduced since the previous report.

Appendix 3. Entries retrieved by the performed searches to literature databases for the authorised cotton events within the indicated search period

Note: the numbering of the references in the different appendixes is independent of each other (e.g. a certain reference might be called EFSA 2021a in one appendix and EFSA 2021b in another)

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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