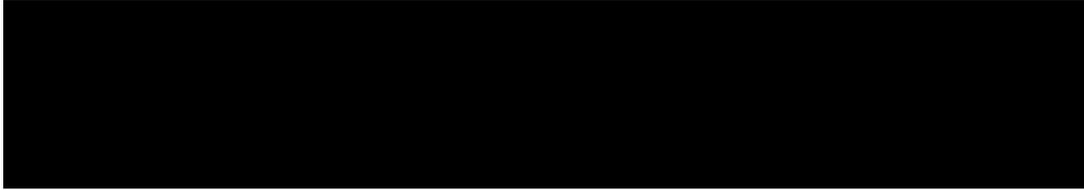


**Review of literature for 281-24-236 x 3006-210-23 and 281-24-236 x
3006-210-23 x MON 88913 cotton in the scope of their authorisations
for food and feed uses, import and processing (2022 update)**



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Table of contents

1. SUMMARY	3
2. CONFIRMATION OF THE SUITABILITY OF THE SEARCH STRINGS	3
3. RESULTS OF THE SCOPING EXERCISE.....	3
3.1. OUTCOME OF LITERATURE SEARCHES	3
4. CONCLUSION	5
REFERENCES.....	5
APPENDIX 1. DETAILED SEARCH SYNTAXES FOR THE AUTHORISED GM COTTON EVENTS	6
APPENDIX 2. ELIGIBILITY/INCLUSION CRITERIA.....	10
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 2021)	11
APPENDIX 4. PUBLICATIONS SCREENED FOR RELEVANCE BASED ON THE FULL TEXT.....	30

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 (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 2021. 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 (2021) is still relevant and no updates were identified.

3. Results of the Scoping Exercise

3.1. Outcome of literature searches

In August 2022, 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 [§]	8 August 2022	2021-8 August 2022	None	162
CAB Abstracts [§]	8 August 2022	2021-8 August 2022	None	167
MEDLINE [§]	8 August 2022	2021-8 August 2022	None	88
Europe PMC [§]	8 August 2022	2021-8 August 2022	None	5
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 6 July 2021.

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 2021 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 2021 monitoring reports)	244
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	242
Total number of full-text documents assessed in detail	2
Number of publications excluded from further consideration after detailed assessment for relevance based on full text	2
Total number of unobtainable/unclear publications	0
Total number of relevant publications	0

The 244 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 publications relevant to the risk assessment were identified (see Appendix 4, Table 4.1). 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).

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.

References

- EC, **2009**. Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council. Official Journal of the European Union 275, 9-27.
- 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)	55
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	55
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 gmo OR gmos OR lmo OR lmos OR gm OR ge OR stack))	2612
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/3 (modif* OR transform* OR manipul* OR engineer* OR stack))))	1254
#6	#3 OR #4 OR #5	3320
Reporting Period #7	PY=(2021-2100)	3,804,690
Final Results #8	#6 AND #7	162

CAB Abstracts

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)	57
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	57
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))	2703
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"))	1808
#6	#3 OR #4 OR #5	3967
Reporting Period #7	PY=(2021-2100) (also limited to articles added on or since the date of the prior PMEM search ran on July 6, 2021)	544,088
Final Results #8	#6 AND #7	167

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)	19
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	19
Proteins #4	TS=((cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry1-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))	1534
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 "Food, Genetically Modified"))	390
#6	#3 OR #4 OR #5	1741
Reporting Period #7	PY=(2021-2100) (also limited to articles added on or since the date of the prior PMEM search ran on July 6, 2021)	1,721,924
Final Results #8	#6 AND #7	88

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:[2021-01-01 TO 2022-12-31]) AND (FIRST_IDATE:[2021-07-06 TO 2022-12-31])

= 5 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 2021)

- Aguirre LA, Hernandez-Juarez A, Cerna E, Flores M, Frias GA and Ochoa YM, **2021**. Diversity, Abundance, and Effect of Genetically Modified Maize on Nontarget Predators in Sinaloa, Mexico. *Journal of Entomological Science* 56, 541-555. 10.18474/jes20-84
- Ahmad JN, Majeed D, Arshad M, Malik MA, Ali A, Nadeem S and Ahmad SJN, **2021**. Effect of methyl jasmonate on bt cotton (*Gossypium hirsutum* L.) gene expression and mortality of pink boll worm (*Pectinophora gossypiella*). *JAPS, Journal of Animal and Plant Sciences* 31, 1728-1738. 10.36899/japs.2021.6.0375
- Ahmad SF, Gulzar A, Tariq M and Asad MJ, **2021**. Field Evolved Resistance in *Earias vittella* (Lepidoptera: Noctuidae) From Punjab, Pakistan Against Commercial Formulations of *Bacillus thuringiensis kurstaki*. *Journal of Economic Entomology* 114, 2204-2213. 10.1093/jee/toab137
- Ahmad SJN, Dilawar M, Abid A, Muhammad S, Zubair A, Mujahid M and Ahmad JN, **2021**. Effect of natural high temperature and flooding conditions on Cry1Ac gene expression in different transgenic Bt cotton (*Gossypium hirsutum* L.) cultivars. *Pakistan Journal of Botany* 53, 127-134. 10.30848/pjb2021-1(38)
- Amin MR, Oh SD, Park SY, Ha K, Kang S, Park JH, Kim M, Eun CU, Kim YK and Suh SJ, **2022**. The effect of thioredoxin-gene-expressed transgenic soybean on associated non-target insects and arachnids. *Plant Biotechnology Reports* 16, 79-90. 10.1007/s11816-021-00724-y
- Ankesh P, Reena Y, Sanoj K, Anil K, Priya S, Ankita Y and Indraneel S, **2021**. Expression of the entomotoxic *Cocculus hirsutus* trypsin inhibitor (ChTI) gene in transgenic chickpea enhances its underlying resistance against the infestation of *Helicoverpa armigera* and *Spodoptera litura*. *Plant Cell, Tissue and Organ Culture* 146, 41-56. 10.1007/s11240-021-02041-2
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- Asif M, Siddiqui HA, Naqvi RZ, Amin I, Asad S, Mukhtar Z, Bashir A and Mansoor S, **2021**. Development of event-specific detection method for identification of insect resistant NIBGE-1601 cotton harboring double gene Cry1Ac-Cry2Ab construct. *Scientific Reports* 11. 10.1038/s41598-021-82798-w
- Avand-Faghih A, Shekharjan A, Bagheri A, Siyahooei MA and Famil M, **2021**. Damage control of *Helicoverpa armigera* on tomato by plant volatiles-based attract and kill approach. *Applied Entomology and Phytopathology* 89, fa75-fa94. 10.22092/jaep.2020.351194.1363
- Banazeer A, Afzal MBS, Hassan S, Ijaz M, Shad SA and Serrao JE, **2022**. Status of insecticide resistance in *Plutella xylostella* (Linnaeus) (Lepidoptera: Plutellidae) from 1997 to 2019: cross-resistance, genetics, biological costs, underlying mechanisms, and

- implications for management. *Phytoparasitica* 50, 465-485. 10.1007/s12600-021-00959-z
- Benowitz KM, Allan CW, Degain BA, Li XC, Fabrick JA, Tabashnik BE, Carriere Y and Matzkin LM, **2022**. Novel genetic basis of resistance to Bt toxin Cry1Ac in *Helicoverpa zea*. *Genetics* 221. 10.1093/genetics/iyac037
- Bhullar HS and Gill RS, **2021**. Ovipositional preference of tobacco caterpillar, *Spodoptera litura* (Fabricius), to different transgenic Bt cotton cultivars. *Agricultural Research Journal* 58, 808-813. 10.5958/2395-146x.2021.00115.0
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- Chen YT, Liu ZX, Regniere J, Vasseur L, Lin J, Huang SG, Ke FS, Chen SP, Li JY, Huang JL, Gurr GM, You MS and You SJ, **2021**. Large-scale genome-wide study reveals climate adaptive variability in a cosmopolitan pest. *Nature Communications* 12. 10.1038/s41467-021-27510-2
- Chen K, Hu SL and Jiang Y, **2022**. Effects of Nitrogen Fertilizer on the Bt Protein Content in Transgenic Rice and Nitrogen Metabolism Mechanism. *Journal of Plant Growth Regulation* 41, 2375-2385. 10.1007/s00344-021-10451-x
- Chen ZK, Sun Y, Wang CL, Song LY, Li B, Qin L, Cai YC, Zhou DH, Ouyang LJ, Zhu CL, He HH and Peng XS, **2022**. Evaluation of *Chilo suppressalis* resistance and analysis of CRY1C expression in transgenic rice. *Agronomy Journal* 114, 915-926. 10.1002/agj2.21014
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- Cui ZJ, Wang Y, Zhu YQ, Zhang X, Feng XP and Ieee, **2021**. Terahertz Biosensing All-Dielectric Metasurface for *Bacillus Thuringiensis* Cry1Ac Protein Sensing. 46th International Conference on Infrared, Millimeter and Terahertz Waves (IRMMW-THz), Electr Network. 10.1109/IRMMW-THz50926.2021.9566936

- Cui ZJ, Wang Y, Shi YQ, Zhu YQ, Zhang DC, Hong ZQ and Feng XP, **2022**. Significant sensing performance of an all-silicon terahertz metasurface chip for *Bacillus thuringiensis* Cry1Ac protein. *Photonics Research* 10, 740-746. 10.1364/prj.450017
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- Deole S, Padakipatil S, Sandhya SR, Nanote A, Jadhav M, Bihani P, Parimi S, Zehr U, Narendran M and Char BR, **2021**. Development of marker-free insect resistant transgenic okra (*Abelmoschus esculentus* L. Moench) expressing the cry1Ac gene and identification of vector backbone-free events. *Physiology and Molecular Biology of Plants* 27, 2379-2387. 10.1007/s12298-021-01074-3
- Dessoky ES, Ismail RM, Elarabi NI, Abdelhadi AA and Abdallah NA, **2021**. Improvement of sugarcane for borer resistance using *Agrobacterium* mediated transformation of cry1Ac gene. *GM Crops and Food: Biotechnology in Agriculture and the Food Chain* 12, 47-56. 10.1080/21645698.2020.1809318
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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
Ahmad SJN, Dilawar M, Abid A, Muhammad S, Zubair A, Mujahid M and Ahmad JN, 2021 . Effect of natural high temperature and flooding conditions on Cry1Ac gene expression in different transgenic Bt cotton (<i>Gossypium hirsutum</i> L.) cultivars. <i>Pakistan Journal of Botany</i> 53, 127-134. 10.30848/pjb2021-1(38)	Intervention/exposure (not on 281-24-236 x 3006-210-23 or 281-24-236 x 3006-210-23 x MON 88913 cotton)
Organisms EPanel oGM, Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firkbank LG, Guerche P, Hejatko J, Naegeli H, Moreno FJ, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Fernandez Dumont A, Federici S, Kagkli DM, Lanzoni A, Papadopoulou N and Raffaello T, 2022 . Assessment of new sequencing information for genetically modified cotton DAS-24236-5 x DAS-21Ø23-5. In: EFSA journal European Food Safety Authority. p e07345. ^10.2903/j.efsa.2022.7345	Reporting format (not a primary study)

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