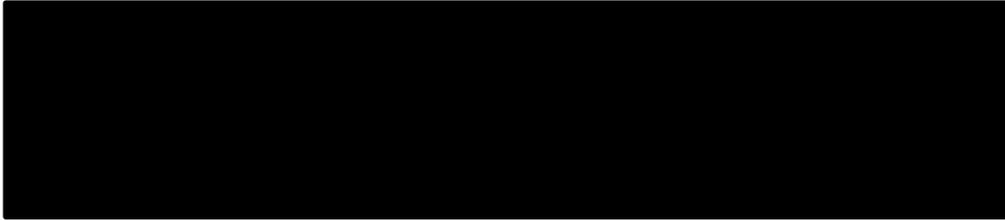


**Review of literature of DAS-44406-6 soybean in the scope of the
authorisations for food and feed uses, import and processing
(2021 update)**



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1. Summary

An updated systematic search and review of peer-reviewed literature was conducted for DAS-44406-6 soybean. 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 DAS-44406-6 soybean and derived food/feed products, or the intended traits (the newly expressed protein(s)), have adverse effects on human and animal health and the environment in the scope of the authorisation?”.

The current systematic search complements the search previously performed in 2020. Unless outlined below, all portions of the search were conducted according to the methodologies outlined in the previous search.

The outcome of this analysis showed that no publication relevant for the review question was identified during the selected time period. No safety concerns were identified for DAS-44406-6 soybean 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 literature search 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 2.

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 [§]	6 July 2021	2020-6 July 2021	None	67
CAB Abstracts [§]	6 July 2021	2020-6 July 2021	None	49
MEDLINE [§]	6 July 2021	2020-6 July 2021	None	35
Europe PMC [§]	6 July 2021	2020-6 July 2021	None	9
Screening reference lists	6 July 2021	-	2020-6 July 2021 [§]	0 **

[§] 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 DAS-44406-6 soybean 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: “Does DAS-44406-6 soybean and derived food/feed products, or the intended traits (the newly expressed protein(s)), have adverse effects on human and animal health and the environment in the scope of the authorisation?”	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)	51
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	47
Total number of full-text documents assessed in detail	4
Number of publications excluded from further consideration after detailed assessment for relevance based on full text	4
Total number of unobtainable/unclear publications	0
Total number of relevant publications	0

The 51 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 of DAS-44406-6 soybean 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).

4. Conclusion

No publications were identified as relevant for the molecular characterisation, food/feed and environmental safety of DAS-44406-6 soybean within the scope of the authorisations for the defined time period. No safety concerns have been identified for DAS-44406-6 soybean by this literature search exercise.

References

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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.].
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Appendix 1. Detailed search syntaxes for the DAS-44406-6 soybean**Web of Science Core collection**

Set	Search query
Event #1	TS=(DAS44406* OR DAS-44406 OR DAS-44406-6 OR DAS-444- circle-divide-6-6 OR DAS-444empty-set6-6 OR ((44406 OR Enlist*) AND (soy* OR soja* OR Glycine OR Dow OR Corteva OR herbicid*)))
Proteins #2	TS=((2m-epsps OR 2mepsps OR ((5-enolpyruvylshikimate-3-phosphate- synthase OR epsps OR 5-enol-pyruvyl-shikimate-3-phosphate-synthase OR EPSP-synthase) AND modified AND protein AND (maize OR corn OR zea OR mays)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin) OR aad-12 OR aryloxyalkanoate-dioxygenase-12) AND (Streptomyces OR viridochromogenes OR Delftia OR acidovorans OR soy* OR soja* OR glycine 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))
Traits #3	TS=((glyphosate* OR Roundup OR "Round-up" OR glyfosate* OR gliphosate* OR glifosate* OR ((2-4-D OR AOPP) AND herbicid*) OR 2-4-dichlorophenoxyacetic-acid OR 2-4-dichlorophenoxy-acetic-acid OR aryloxyphenoxypropionate OR aryloxyphenoxy-propionate OR (fop AND (herbicid* or aryloxyphen*)) OR quizalofop OR haloxyfop OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) AND (toler* OR resist* OR protect*) AND (soy* OR soja* OR Glycine OR max) 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*))))
#4	#1 OR #2 OR #3
Reporting Period #5	PY=(2020-2100)
Final Results #6	#4 AND #5

CAB Abstracts

Set	Search query
Event #1	TS=(DAS44406* OR DAS-44406 OR DAS-44406-6 OR DAS-44406-6 OR ((44406 OR Enlist*) AND (soy* OR soja* OR Glycine OR Dow OR Corteva OR herbicid*)))
Proteins #2	TS=((2m-epsps OR 2mepsps OR ((5-enolpyruvylshikimate-3-phosphate-synthase OR epsps OR 5-enol-pyruvyl-shikimate-3-phosphate-synthase OR EPSP-synthase) AND modified AND protein AND (maize OR corn OR zea OR mays)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin) OR aad-12 OR aryloxyalkanoate-dioxygenase-12) AND (Streptomyces OR viridochromogenes OR Delftia OR acidovorans OR soy* OR soja* OR glycine 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"))
Traits #3	TS=((glyphosate* OR Roundup OR "Round-up" OR glyfosate* OR gliphosate* OR glifosate* OR ((2-4-D OR AOPP) AND herbicid*) OR 2-4-dichlorophenoxyacetic-acid OR 2-4-dichlorophenoxy-acetic-acid OR aryloxyphenoxypropionate OR aryloxyphenoxy-propionate OR (fop AND (herbicid* or aryloxyphen*)) OR quizalofop OR haloxyfop OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) AND (toler* OR resist* OR protect*) AND (soy* OR soja* OR Glycine OR max) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipul* OR transform* OR "genetically engineered foods"))
#4	#1 OR #2 OR #3
Reporting Period #5	PY=(2020-2100)
Final Results #6	#4 AND #5

MEDLINE

Set	Search query
Event #1	TS=(DAS44406* OR DAS-44406 OR DAS-44406-6 OR ((44406 OR Enlist*) AND (soy* OR soja* OR Glycine OR Dow OR Corteva OR herbicid*)))
Proteins #2	TS=((2m-epsps OR 2mepsps OR ((5-enolpyruvylshikimate-3-phosphate-synthase OR epsps OR 5-enol-pyruvyl-shikimate-3-phosphate-synthase OR EPSP-synthase) AND modified AND protein AND (maize OR corn OR zea OR mays)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin) OR aad-12 OR aryloxyalkanoate-dioxygenase-12) AND (Streptomyces OR viridochromogenes OR Delftia OR acidovorans OR soy* OR soja* OR glycine 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"))
Traits #3	TS=((glyphosate* OR Roundup OR "Round-up" OR glyfosate* OR glyphosate* OR glifosate* OR ((2-4-D OR AOPP) AND herbicid*) OR 2-4-dichlorophenoxyacetic-acid OR 2-4-dichlorophenoxy-acetic-acid OR aryloxyphenoxypropionate OR aryloxyphenoxy-propionate OR (fop AND (herbicid* or aryloxyphen*)) OR quizalofop OR haloxyfop OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) AND (toler* OR resist* OR protect*) AND (soy* OR soja* OR Glycine OR max) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipul* OR transform* OR "Food, Genetically Modified"))
#4	#1 OR #2 OR #3
Reporting Period #5	PY=(2020-2100)
Final Results #6	#4 AND #5

Europe PMC

(DAS44406 OR DAS44406 OR "das-44406" OR "das-44406" OR "44406 soy*" OR "44406 soy*" OR "soy* 44406" OR "soy* 44406" OR "Enlist E3") AND (FIRST_PDATE:[2020-01-01 TO 2020-12-31])

Appendix 2. Eligibility/Inclusion Criteria¹

Concept	Criteria
Population (taking into account scope of the authorisation)	Publication addressing human and animal health, and/or the environment relevant for the scope of the authorisation. 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).
Intervention/exposure	DAS-44406-6 soybean and derived food/feed products, and/or the intended traits (the newly expressed protein(s)).
Intervention/exposure Plant species	In case of studies using GM plants, only studies using soybean 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	Effects/impacts on human and animal health, and/or the environment are addressed. 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.
Reporting format	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). However, risk assessments from relevant risk assessment bodies (excluding EFSA) will not be excluded.

¹ 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 DAS-44406-6 soybean 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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- Zhang L, Shen WJ, Fang ZX and Liu B, **2021**. Effects of genetically modified maize expressing Cry1Ab and EPSPS proteins on Japanese quail. *Poultry Science* 100, 1068-1075. 10.1016/j.psj.2020.11.014

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
Garcia JR, Vargas AAM, Perboni LT, Souza EA, Tessaro D, Lucio FR and Agostinetto D, 2020. Physiological attributes of Enlist E3 (TM) soybean seed submitted to herbicides application. <i>Planta Daninha</i> 38, 6.	Comparator: no Non-GM control
Naegeli H, Bresson JL, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogue F, Rostoks N, Serrano JJS, Savoini G, Veromann E, Veronesi F, Alvarez F, Ardizzone M, De Sanctis G, Devos Y, Dumont AF, Federici S, Gennaro A, Ruiz JAG, Lanzoni A, Neri FM, Papadopoulou N, Paraskevopoulos K, Raffaello T and Modified EPG, 2020. Scientific Opinion on application EFSA-GMO-NL-2016-132 for authorisation of genetically modified of insect-resistant and herbicide-tolerant soybean DAS-81419-2 x DAS-44406-6 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Dow Agrosiences LCC. <i>Efsa Journal</i> 18, 37.	Reporting format (not a primary research study); Intervention/exposure (not on DAS-44406-6 single)
Silva JB, Mori R, Marques LH, Santos AC, Nowatzki T, Dahmer ML, Bing J, Gratao PL and Rossi GD, 2021. Water Deprivation Induces Biochemical Changes Without Reduction in the Insecticidal Activity of Maize and Soybean Transgenic Plants. <i>Journal of Economic Entomology</i> .	Intervention/exposure (not on DAS-44406-6 single); Outcome
Zhang L, Li SF, Zhou QH, Liu YH, Zhang J and Qian ZY, 2021. Subchronic toxicity study in rats evaluating herbicide-tolerant soybean DAS-68416-4. <i>Regulatory Toxicology and Pharmacology</i> 119, 8.	Intervention/exposure (not on DAS-44406-6)

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