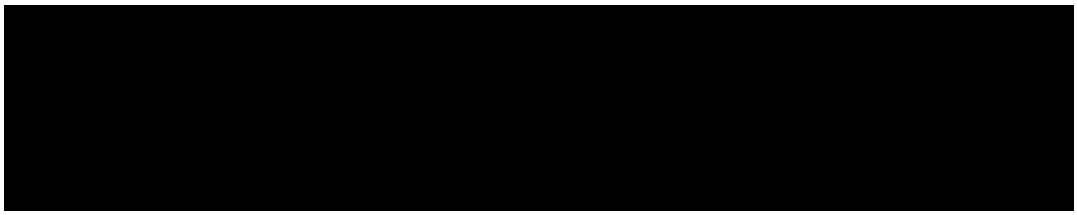
Review of literature for 305423 and 305423x40-3-2 soybeans in the scope of their authorisations for food and feed uses, import and processing in the EU (2022 update)



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1. Summary

An updated systematic search and review of peer-reviewed literature was conducted for 305423 soybean and 305423 x 40-3-2 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 305423 soybean or 305423 x 40-3-2 soybean 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. All portions of the search were conducted according to the methodologies outlined in the previous searches.

The outcome of this analysis showed that one publication relevant for the review question was identified during the selected time period. No safety concerns were identified for 305423 soybean nor 305423x40-3-2 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 (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[$]	8 August 2022	1 Jan 2021-8 August 2022	None	14
CAB Abstracts[$]	8 August 2022	1 Jan 2021-8 August 2022	None	15
MEDLINE[$]	8 August 2022	1 Jan 2021-8 August 2022	None	8
Europe PMC[$]	8 August 2022	1 Jan 2021-8 August 2022	None	13
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 305423 or 305423x40-3-2 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 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: "Does 305423 soybean or 305423 x 40-3-2 soybean 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 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 2021 monitoring reports)	32
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	29
Total number of full-text documents assessed in detail	3
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	1

The 32 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, one peer-reviewed publication relevant to the risk assessment was identified (Tu et al., 2022) (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).

Table 3: Review of a recent relevant paper in 2009/770/EC format. Food/Feed safety (305423 soybean oil) (Tu et al., 2022):

Publication	Summary of research and results	Protection goal	Observed parameter	Adverse effects	Feedback on initial risk assessment
Tu ML, Sun QC, Zhang JA and Zhang GD, **2022**. Comparative Effects of Traditional Versus Genetically Modified Soybean Oils on Colon Tumorigenesis in Mice. Foods 11. 10.3390/foods11131937	This study aims to evaluate the effects of the genetically modified Plenish® soybean oil, which has low abundance of LA as well as α-linolenic acid (ALA, 18:3ω-3), on development of azoxymethane (AOM)/dextran sulfate sodium (DSS)-induced colon tumorigenesis in mice. As concluded by the authors, compared with a diet rich in traditional soybean oil, administration of a diet enriched with the Plenish oil has little impact on AOM/DSS-induced colon tumorigenesis, colonic infiltration of immune cells, expressions of inflammatory genes, and tumor markers. These results suggest that the traditional and the Plenish soybean oils have similar effects on development of AOM/DSS-induced colon cancer in mice.	Food Feed safety	Toxicology	None	No change

4. Conclusion

One publication was identified as relevant for the molecular characterisation, food/feed and environmental safety of 305423 or 305423 x 40-3-2 soybean within the scope of the authorisations for the defined time period. No safety concerns have been identified for 305423 or 305423 x 40-3-2 soybeans 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.].

Tu ML, Sun QC, Zhang JA and Zhang GD, **2022**. Comparative Effects of Traditional Versus Genetically Modified Soybean Oils on Colon Tumorigenesis in Mice. Foods 11. 10.3390/foods11131937

Appendix 1. Detailed search syntaxes for the authorized soybeans

Web of Science Core collection

Search Part	Search Syntax	Results
Event #1	TS=(3ø5423* OR 3-circle-divide-5423* OR 3empty-set5423* OR 305423* OR dp305423* OR dp3ø5423* OR dp3-circle-divide-5423* OR dp3empty-set5423* OR plenish*)	43
Stack #2	TS=(*DP-3Ø5423-1xMON-Ø4Ø32-6* OR *DP-3-circle-divide-5423-1xMON-circle-divide-4-circle-divide-32-6* OR *DP-3empty-set5423-1xMON-empty-set4empty-set32-6* OR *305423x40-3-2* OR *3Ø5423x40-3-2* OR Plenish*)	16
#3	#1 OR #2	43
Proteins #4	TS=((gm-fad2 OR gmfad2 OR gm-hra OR gmhra OR Glycine-max-HRA OR fad2 OR fatty-acid-desaturase-2-1 OR omega-6-fatty-acid-desaturase OR (hra AND acetolactate-synthase)) AND (soy* OR soja* OR glycine OR Rnai OR rna-interference OR siRNA OR small-RNA OR *silencing OR double-stranded-rna OR dsrna 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))	175
Traits #5	TS=(((high NEAR/1 oleic) OR (oleic NEAR/1 acid) OR sul*onylurea* OR ALS-inhibiting-herbicide*) AND (toler* OR resist* OR protec* OR Rnai OR rna-interference OR siRNA OR small-RNA OR *silencing OR double-stranded-rna OR dsrna) 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/3 (modif* OR transform* OR manipulat* OR engineer* OR stack))))	55
#6	#3 OR #4 OR #5	243
Reporting Period #7	PY=(2021-2100)	3,797,058
Final Results #8	#6 AND #7	14

CAB Abstracts

Search Part	Search Syntax[1]	Results
Event #1	TS=(3ø5423* OR 3<o>5423* OR 305423* OR dp305423* OR dp3ø5423* OR dp3<o>5423* OR plenish*)	36
Stack #2	TS=(*DP-3Ø5423-1xMON-Ø4Ø32-6* OR *DP-3-circle-divide-5423-1xMON-circle-divide-4-circle-divide-32-6* OR *DP-3empty-set5423-1xMON-empty-set4empty-set32-6* OR *305423x40-3-2* OR *3Ø5423x40-3-2* OR Plenish*)	10
#3	#1 OR #2	36
Proteins #4	TS=((gm-fad2 OR gmfad2 OR gm-hra OR gmhra OR Glycine-max-HRA OR fad2 OR fatty-acid-desaturase-2-1 OR omega-6-fatty-acid-desaturase OR (hra AND acetolactate-synthase)) AND (soy* OR soja* OR glycine OR Rnai OR rna-interference OR siRNA OR small-RNA OR *silencing OR double-stranded-rna OR dsrna 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))	158
Traits #5	TS=(((high NEAR/1 oleic) OR (oleic NEAR/1 acid) OR sul*onylurea* OR ALS-inhibiting-herbicide*) AND (toler* OR resist* OR protec* OR Rnai OR rna-interference OR siRNA OR small-RNA OR *silencing OR double-stranded-rna OR dsrna) AND (soy* OR soja* OR Glycine OR max) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipulat* OR transform* OR stack OR "genetically engineered foods"))	51
#6	#3 OR #4 OR #5	219
Reporting Period #7	PY=(2021-2100) (and added to the database on or since the 2021 HO PMEM search was run on July 7, 2021)	544,087
Final Results #8	#6 AND #7	15

[1] Terms indicated in yellow highlight are additional variants compared to the previously conducted search

MEDLINE

Search Part	Search Syntax[2]	Results
Event #1	TS=(3ø5423* OR 305423* OR dp305423* OR dp3ø5423* OR plenish*)	17
Stack #2	TS=(*DP-3Ø5423-1xMON-Ø4Ø32-6* OR *305423x40-3-2* OR *3Ø5423x40-3-2* OR Plenish*)	6
#3	#1 OR #2	17
Proteins #4	TS=((gm-fad2 OR gmfad2 OR gm-hra OR gmhra OR Glycine-max-HRA OR fad2 OR fatty-acid-desaturase-2-1 OR omega-6-fatty-acid-desaturase OR (hra AND acetolactate-synthase)) AND (soy* OR soja* OR glycine OR Rnai OR rna-interference OR siRNA OR small-RNA OR *silencing OR double-stranded-rna OR dsrna OR "RNA, Double-Stranded" 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))	101
Traits #5	TS=(((high NEAR/1 oleic) OR (oleic NEAR/1 acid) OR sul*onylurea* OR ALS-inhibiting-herbicide*) AND (toler* OR resist* OR protec* OR Rnai OR rna-interference OR siRNA OR small-RNA OR *silencing OR double-stranded-rna OR dsrna OR "RNA, Double-Stranded") AND (soy* OR soja* OR Glycine OR max) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipulat* OR transform* OR stack OR "Food, Genetically Modified"))	27
#6	#3 OR #4 OR #5	131
Reporting Period #7	PY=(2021-2100)	1,715,378
Final Results #8	#6 AND #7	8

[2] Terms indicated in yellow highlight are additional variants compared to the previously conducted search

Europe PMC
(plenish OR 305423x40-3-2 OR dp305423 OR dp3ø5423 OR 305423 OR 3ø5423) AND (FIRST_PDATE:[2021-01-01 TO 2022-12-31]) AND (FIRST_IDATE:[2021-07-07 TO 2022-12-31])

= 13 results

Appendix 2. Eligibility/Inclusion Criteria[3]

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 **I**ntervention/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	305423, 305423x40-3-2 soybeans and derived food/feed products, and/or the intended traits (newly expressed protein(s) or their combination).
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.

[3] 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 305423 and 305423x40-3-2 soybean within the indicated search period (excluding duplicates retrieved by the previous searches conducted in 2021)

Cappetta E, De Palma M, D'Alessandro R, Aiello A, Romano R, Graziani G, Ritieni A, Paolo D, Locatelli F, Sparvoli F, Docimo T and Tucci M, **2022**. Development of a High Oleic Cardoon Cell Culture Platform by SAD Overexpression and RNAi-Mediated FAD2.2 Silencing. Frontiers in Plant Science 13. 10.3389/fpls.2022.913374

Chen GQ, Johnson K, Nazarenus TJ, Ponciano G, Morales E and Cahoon EB, **2021**. Genetic engineering of Lesquerella with increased ricinoleic acid content in seed oil. Plants 10. 10.3390/plants10061093

Corbisier P, Buttinger G, Savini C, Sacco MG, Gatto F and Emons H, **2022**. Expression of GM content in mass fraction from digital PCR data. Food control 133, 108626. 10.1016/j.foodcont.2021.108626

Demeke T, Lee S-J and Eng M, **2022**. Increasing the Efficiency of Canola and Soybean GMO Detection and Quantification Using Multiplex Droplet Digital PCR. In: Biology. p 201. ^10.3390/biology11020201

Di Q, Piersanti A, Zhang Q, Miceli C, Li H and Liu XY, **2022**. Genome-Wide Association Study Identifies Candidate Genes Related to the Linoleic Acid Content in Soybean Seeds. International Journal of Molecular Sciences 23. 10.3390/ijms23010454

Eltit D, **2021**. Re-plenish, Re-think, Re-live. Mitologias Hoy-Revista De Pensamiento Critica Y Estudios Literarios Latinoamericanos 24, 87-93. 10.5565/rev/mitologias.832

Huang XY, He L, Huang Y, Zhao HS, Jin J and Iop, **2020.** Analysis on the Abnormal Distribution of Large-scale Rainstorm in Guangxi Caused by typhoon Bailu (1911). 3rd International Forum on Geoscience and Geodesy (IFGG), Electr Network. 10.1088/1755-1315/658/1/012041

Jarvis BA, Romsdahl TB, McGinn MG, Nazarenus TJ, Cahoon EB, Chapman KD and Sedbrook JC, **2021**. CRISPR/Cas9-induced fad2 and rod1 mutations stacked with fae1 confer high oleic acid seed oil in pennycress (Thlaspi arvense L.). Frontiers in Plant Science 12. 10.3389/fpls.2021.652319

Jo H, Kim M, Cho H, Ha B, Kang S, Song J and Lee J, **2021**. Identification of a potential gene for elevating omega-3 concentration and its efficiency for improving the omega-6/omega-3 ratio in soybean. Journal of Agricultural and Food Chemistry 69, 3836-3847. 10.1021/acs.jafc.0c05830

Karaman K, Kizil S, Basak M, Uzun B and Yol E, **2021**. Development of EMS-induced Mutagenized Groundnut Population and Discovery of Point Mutations in the ahFAD2 and Ara h 1 Genes by TILLING. Journal of Oleo Science 70, 1631-1640. 10.5650/jos.ess21075

Kim WN, Kim HJ, Chung YS and Kim HU, **2021**. Construction of Multiple Guide RNAs in CRISPR/Cas9 Vector Using Stepwise or Simultaneous Golden Gate Cloning: Case Study for Targeting the FAD2 and FATB Multigene in Soybean. Plants-Basel 10. 10.3390/plants10112542

Kowalczyk K, Bartnik-Głaska M, Smyk M, Plaskota I, Bernaciak J, Kędzior M, Wiśniowiecka-Kowalnik B, Deperas M, Domaradzka J, Łuszczek A, Dutkiewicz D, Kozar A, Grad D, Niemiec M, Ziemkiewicz K, Magdziak R, Braun-Walicka N, Barczyk A, Geremek M, Castañeda J, Kutkowska-Kaźmierczak A, Własienko P, Jakubów-Durska K, Dębska M, Kucińska-Chahwan A, Kozłowski S, Mikulska B, Issat T, Roszkowski T, Nawara-Baran A, Runge A, Jakubiuk-Tomaszuk A, Kruczek A, Kostyk E, Pietras G, Limon J, Zwoliński J, Ochman K, Szajner T, Węgrzyn P, Wielgoś M, Sąsiadek M, Obersztyn E and Nowakowska BA, **2022**. Comparative

Genomic Hybridization to Microarrays in Fetuses with High-Risk Prenatal Indications: Polish Experience with 7400 Pregnancies. In: Genes. p 690. ^10.3390/genes13040690

Lin H-Y, Liao J-W, Chen R-S, Chang C-H, Chang H-W, Chang S-C, Chu W-S, Lin C-K and Lin H-T, **2022**. Food Safety Assessment of Commercial Genetically Modified Soybeans in Rats. In: Foods (Basel, Switzerland). p 496. ^10.3390/foods11040496

Lin Y, Xu J, Hong J, Si Y, He Y and Zhang J, **2022**. Prognostic Impact of Surgical Margin in Hepatectomy on Patients With Hepatocellular Carcinoma: A Meta-Analysis of Observational Studies. In: Frontiers in surgery. p 810479. ^10.3389/fsurg.2022.810479

Litvinov DY, Karlov GI and Divashuk MG, **2021**. Metabolomics for Crop Breeding: General Considerations. In: Genes. p 1602. ^10.3390/genes12101602

Medina-Lozano I and Díaz A, **2022**. Applications of Genomic Tools in Plant Breeding: Crop Biofortification. In: International Journal of Molecular Sciences. p 3086. ^10.3390/ijms23063086

Murru C, Badía-Laíño R and Díaz-García ME, **2021**. Oxidative Stability of Vegetal Oil-Based Lubricants. ACS sustainable chemistry & engineering 9, 1459-1476. 10.1021/acssuschemeng.0c06988

Organisms EPoGM, Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Goumperis T and Raffaello T, **2022**. Risk assessment of a new bioinformatics evaluation of the insertion sites of genetically modified soybean event 40-3-2. In: EFSA journal European Food Safety Authority. p e07412. ^10.2903/j.efsa.2022.7412

Rahman SU, McCoy E, Raza G, Ali Z, Mansoor S and Amin I, Improvement of Soybean; A Way Forward Transition from Genetic Engineering to New Plant Breeding Technologies. Molecular Biotechnology. 10.1007/s12033-022-00456-6

Shin MK, Jeon SM and Koo YE, **2022**. Development of a rapid detection method for genetically modified rice using the ultra-fast PCR system. In: Food science and biotechnology. p 175-182. ^10.1007/s10068-021-01025-4

Silva AFM, Giraldeli AL, Silva GSd, Araujo LdS, Lima RJN, Oliveira DAGd, Albrecht AJP and Victoria Filho R, **2022**. Efficacy of alternative herbicides to glyphosate in the weed control in glyphosate and sulfonylurea-tolerant soybean. Acta Agronomica, Universidad Nacional de Colombia 70. 10.15446/acag.v70n3.72752

Silva LCC, Mayrink DB, Bueno RD, Piovesan ND, Ribeiro C and Dal-Bianco M, **2022**. Reference Genes and Expression Analysis of Seed Desaturases Genes in Soybean Mutant Accessions. Biochemical Genetics 60, 937-952. 10.1007/s10528-021-10135-x

Torabi S, Sukumaran A, Dhaubhadel S, Johnson SE, Lafayette P, Parrott WA, Rajcan I and Eskandari M, **2021**. Effects of type I Diacylglycerol O-acyltransferase (DGAT1) genes on soybean (Glycine max L.) seed composition. Scientific Reports 11. 10.1038/s41598-021-82131-5

Tu ML, Sun QC, Zhang JA and Zhang GD, **2022**. Comparative Effects of Traditional Versus Genetically Modified Soybean Oils on Colon Tumorigenesis in Mice. Foods 11. 10.3390/foods11131937

Wallis JG, Bengtsson JD and Browse J, **2022**. Molecular Approaches Reduce Saturates and Eliminate trans Fats in Food Oils. In: Frontiers in Plant Science. p 908608. ^10.3389/fpls.2022.908608

Wang L, Ruan CJ, Bao AM and Li H, **2021**. Small RNA profiling for identification of microRNAs involved in regulation of seed development and lipid biosynthesis in yellowhorn. Bmc Plant Biology 21. 10.1186/s12870-021-03239-4

Willette A, Fallen B, Bhandari H, Sams C, Chen F, Sykes V, Smallwood C, Bilyeu K, Li ZL and Pantalone V, **2021**. Agronomic performance of high oleic, low linolenic soybean in Tennessee. Journal of the American Oil Chemists Society 98, 861-869. 10.1002/aocs.12517

Wu M, Pei W, Wedegaertner T, Zhang J and Yu J, **2022**. Genetics, Breeding and Genetic Engineering to Improve Cottonseed Oil and Protein: A Review. In: Frontiers in Plant Science. p 864850. ^10.3389/fpls.2022.864850

Xiao ZF, Jin YK, Zhang Q, Lamboro A, Dong BZ, Yang ZY and Wang PW, **2022**. Construction and Functional Analysis of CRISPR/Cas9 Vector of FAD2 Gene Family in Soybean. Phyton-International Journal of Experimental Botany 91, 349-361. 10.32604/phyton.2022.017451

Zhang YP, Zhang YY, Thakur K, Zhang F, Hu F, Zhang JG, Wei PC and Wei ZJ, **2021**. Integration of miRNAs, Degradome, and Transcriptome Omics Uncovers a Complex Regulatory Network and Provides Insights Into Lipid and Fatty Acid Synthesis During Sesame Seed Development. Frontiers in Plant Science 12. 10.3389/fpls.2021.709197

Zhou C, Pan W, Peng Q, Chen Y, Zhou T, Wu C, Hartley W, Li J, Xu M, Liu C, Li P, Rao L and Wang Q, **2021**. Characteristics of metabolites by seed-specific inhibition of FAD2 in Brassica napus L. Journal of Agricultural and Food Chemistry 69, 5452-5462. 10.1021/acs.jafc.0c06867

Zhou YL, Wang S, Hu HM, Shen YZ, Zhu YJ, Liu XL, Wei JP, Yu XW, Liu SS and Ma H, **2022**. GmCDPKSK5 Interacting with GmFAD2-1B Participates in Regulation of Seed Development in Soybean Under High Temperature and Humidity Stress. Plant Molecular Biology Reporter 40, 402-417. 10.1007/s11105-021-01329-z

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 info/ data requirement(s)	Publication
Toxicological assessment of the newly expressed protein(s)	Tu ML, Sun QC, Zhang JA and Zhang GD, **2022**. Comparative Effects of Traditional Versus Genetically Modified Soybean Oils on Colon Tumorigenesis in Mice. Foods 11. 10.3390/foods11131937

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
Lin H-Y, Liao J-W, Chen R-S, Chang C-H, Chang H-W, Chang S-C, Chu W-S, Lin C-K and Lin H-T, **2022**. Food Safety Assessment of Commercial Genetically Modified Soybeans in Rats. In: Foods (Basel, Switzerland). p 496. ^10.3390/foods11040496	Intervention/exposure (mixture of GM seeds)
Willette A, Fallen B, Bhandari H, Sams C, Chen F, Sykes V, Smallwood C, Bilyeu K, Li ZL and Pantalone V, **2021**. Agronomic performance of high oleic, low linolenic soybean in Tennessee. Journal of the American Oil Chemists Society 98, 861-869. 10.1002/aocs.12517	Intervention/exposure (not on 305423 or 305423 x 40-3-2 soybean)

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