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 (2020 update)

PHI-R105-Y20

Table of contents

1. Summary

An updated systematic search and review of peer-reviewed literature 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), was conducted 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 2019. All portions of the search were conducted according to the methodologies outlined in the previous searches.

The outcome of this analysis showed that two publications relevant for the review question were 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 (2019) is still relevant and no updates were identified.

3. Results of the Scoping Exercise

3.1. Outcome of literature searches

In October 2020, 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[#$]	7 Oct 2020	2019-7 Oct 2020	None	34
CAB Abstracts[#$]	7 Oct 2020	2019-7 Oct 2020	None	19
MEDLINE[#$]	7 Oct 2020	2019-7 Oct 2020	None	16
Europe PMC[#$]	7 Oct 2020	2019-7 Oct 2020	None	15
Screening reference lists	7 Oct 2020	-	2019-7 Oct 2020[§]	0**

[#] A justification for chosing these databases was provided in Section 2.2 of the previous literature search report (2019). The combination of these sources allows having a broad coverage of publications related to GMO risk assessment.

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

§ The time period was applied post-hoc.

** Number of records screened on full text.

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 2019 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 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 2019 monitoring reports)	20
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	16
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	2
Total number of unobtainable/unclear publications	0
Total number of relevant publications	2

The 20 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.
Entries that are deemed to be irrelevant based on title/abstract were not further retained. In cases where 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 (as listed in Appendix 4). The reason for excluding a result from the second screening is documented and a justification for not further assessing a reference is provided in Table 4.2 in Appendix 4. No unobtainable/unclear publications were identified (see Appendix 4, Table 4.3).

In this literature search exercise, two peer-reviewed publications relevant to the risk assessment of 305423 soybean or 305423 x 40-3-2 soybean were identified (Deol et al., 2019; Matsushita et al., 2020) (see Section **Error! Reference source not found.** and Table 4.1 in Appendix 4). Details are provided in **Error! Reference source not found.** and 4 in the format laid out by the Commission decision 2009/770/EC (EC, 2009).

Table 3: Review of relevant peer-reviewed publication in 2009/770/EC format: Toxicological assessment (Deol et al., 2019)

Publication	Summary of research and results	Protection goal	Observed parameter	Adverse effects	Feedback on initial risk assessment
Deol P, Kozlova E, Valdez M, Ho C, Yang EW, Richardson H, Gonzalez G, Truong E, Reid J, Valdez J, Deans JR, Martinez-Lomeli J, Evans JR, Jiang T, Sladek FM and Curras-Collazo MC, **2020**. Dysregulation of Hypothalamic Gene Expression and the Oxytocinergic System by Soybean Oil Diets in Male Mice. Endocrinology 161, 21. 10.1210/endocr/bgz044	The authors subjected C57BL/6N mice to 4 isocaloric high-fat diets composed of coconut oil, CO (largely medium-chain saturated fats), conventional soybean oil (high in linoleic acid, LA), a genetically modified soybean oil low in LA (Plenish, PL; DuPont Pioneer) or CO supplemented with stigmasterol, ST. They performed RNA-sequencing (RNA-seq) analysis on the hypothalamus of the mice fed the first 3 diets (and a low-fat control diet) and analyzed hypothalamic and peripheral levels of oxytocin in mice fed all 4 diets. The authors suggest that consumption of high-fat soybean oil diets increases transcriptomic markers of illness in the mouse hypothalamus compared to high-fat coconut oil diets or low-fat diets due to an unknown factor, but not linoleic acid or stigmasterol. Plenish high oleic soybean oil results in similar effects as conventional soybean oil, except it does not cause insulin resistance related to diabetes (health benefit) which is supported by previous studies from this group (Deol et al. 2017)[1].	Toxicological assessment	Endocrinal effects of high fat soybean oil diets on mice	None	No change

[1] Deol, P., Fahrmann, J., Yang, J. *et al.* Omega-6 and omega-3 oxylipins are implicated in soybean oil-induced obesity in mice. *Sci Rep* **7,** 12488 (2017). https://doi.org/10.1038/s41598-017-12624-9

Table 4: Review of relevant peer-reviewed publication in 2009/770/EC format: Agronomic characterisation/Persistance and invasiveness assessment (Matsushita et al., 2020)

Publication	Summary of research and results	Protection goal	Observed parameter	Adverse effects	Feedback on initial risk assessment
Matsushita A, Goto H, Takahashi Y, Tsuda M and Ohsawa R, **2020**. Consideration of familiarity accumulated in the confined field trials for environmental risk assessment of genetically modified soybean (Glycine max) in Japan. Transgenic research 29, 229-242.	The authors compiled data from 11 field trials of GM soybean events conducted in Japan in the context of regulatory requirements, in order to demonstrate how familiarity gained from data accumulated in the confined field trials in Japan can be used to inform on the ERA of new GM soybean events. The analysed parameters were agronomic characteristics that are commonly used by developers in field trials for ERA in Japan. No biologically relevant differences were reported between DP-3Ø5423- and its comparator for any of the measured parameters. The authors conclude that familiarity-based approaches to the ERAs of GM soybean which will have the potential to reduce the regulatory burden for both developers and regulatory authorities, while still ensuring the quality of risk assessment.	Agronomic characterization /Persistence and invasiveness assessment	Agronomic and environmental safety trait comparison	None	No change

4. Conclusion

Two publications were 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

Deol P, Valdez M, Yang E-W, Deans J, Ho C, Kozlova E, Evans J, Valdez J, Richardson H, Kyaw T, Jiang T, Sladek F and Curras-Collazo M, **2019**. SUN-101 Dysregulation of Hypothalamic Gene Expression by Soybean Oil Diets in Mice. Journal of the Endocrine Society 3.

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.].

Matsushita A, Goto H, Takahashi Y, Tsuda M and Ohsawa R, **2020**. Consideration of familiarity accumulated in the confined field trials for environmental risk assessment of genetically modified soybean (Glycine max) in Japan. Transgenic research 29, 229-242.

Appendix 1. Detailed search syntaxes for the authorized soybeans

Web of Science Core collection

Search Part	Search Syntax
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*)
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*)
#3	#1 OR #2
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 (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=(((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/5 (modif* OR transform* OR manipulat* OR engineer* OR stack))))
#6	#3 OR #4 OR #5
Reporting Period #7	PY=(2019-2100)
Final Results #8	#6 AND #7

CAB Abstracts

Search Part	Search Syntax
Event #1	TS=(3ø5423* OR 3<o>5423* OR 305423* OR dp305423* OR dp3ø5423* OR dp3<o>5423* OR plenish*)
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*)
#3	#1 OR #2
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 (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=(((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"))
#6	#3 OR #4 OR #5
Reporting Period #7	PY=(2019-2100)
Final Results #8	#6 AND #7

MEDLINE

Search Part	Search Syntax
Event #1	TS=(3ø5423* OR 305423* OR dp305423* OR dp3ø5423* OR plenish*)
Stack #2	TS=(*DP-3Ø5423-1xMON-Ø4Ø32-6* OR *305423x40-3-2* OR *3Ø5423x40-3-2* OR Plenish*)
#3	#1 OR #2
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 (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=(((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 "Food, Genetically Modified"))
#6	#3 OR #4 OR #5
Reporting Period #7	PY=(2019-2100)
Final Results #8	#6 AND #7

Europe PMC
(plenish OR 305423x40-3-2 OR dp305423 OR dp3ø5423 OR 305423 OR 3ø5423) AND (FIRST_PDATE:[2019-01-01 TO 2100-12-31])

Appendix 2. Eligibility/Inclusion Criteria

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.

Appendix 3. Entries retrieved by the performed searches to literature databases for the authorised soybeans 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 2020a in one appendix and EFSA 2020b in another)

1. Entries retrieved using Web of Science Core collection

2019. 46th ESAO Congress 3-7 September 2019 Hannover, Germany Abstracts. International Journal of Artificial Organs 42, 386-474.

al Amin N, Ahmad N, Wu N, Pu XM, Ma T, Du YY, Bo XX, Wang N, Sharif R and Wang PW, 2019. CRISPR-Cas9 mediated targeted disruption of FAD2-2 microsomal omega-6 desaturase in soybean (Glycine max.L). Bmc Biotechnology 19, 10.

al Amin N, Ahmad N, Wu N, Pu XM, Ma T, Du YY, Bo XX, Wang N, Sharif R and Wang PW, 2020. CRISPR-Cas9 mediated targeted disruption of FAD2-2 microsomal omega-6 desaturase in soybean (Glycine max.L) (vol 19, 9, 2019). Bmc Biotechnology 20, 2.

Anderson EJ, Ali ML, Beavis WD, Chen PY, Clemente TE, Diers BW, Graef GL, Grassini P, Hyten DL, McHale LK, Nelson RL, Parrott WA, Patil GB, Stupar RM and Tilmon KJ, 2019. Soybean Glycine max (L.) Merr. Breeding: History, Improvement, Production and Future Opportunities. Springer International Publishing Ag, Cham, 431-516

Bai SY, Engelen S, Denolf P, Wallis JG, Lynch K, Bengtssonl JD, Van Thournout M, Haesendonckx B and Browse J, 2019. Identification, characterization and field testing of Brassica napus mutants producing high-oleic oils. Plant Journal 98, 33-41.

Bonawitz ND, Ainley WM, Itaya A, Chennareddy SR, Cicak T, Effinger K, Jiang K, Mall TK, Marri PR, Samue JP, Sardesai N, Simpson M, Folkerts O, Sarria R, Webb SR, Gonzalez DO, Simmonds DH and Pareddy DR, 2019. Zinc finger nuclease-mediated targeting of multiple transgenes to an endogenous soybean genomic locus via non-homologous end joining. Plant Biotechnology Journal 17, 750-761.

Bruno L, Picardi E, Pacenza M, Chiappetta A, Muto A, Gagliardi O, Muzzalupo I, Pesole G and Bitonti MB, 2019. Changes in gene expression and metabolic profile of drupes of Olea europaea L. cv Carolea in relation to maturation stage and cultivation area. Bmc Plant Biology 19, 17.

Combs R and Bilyeu K, 2019. Novel alleles of FAD2-1A induce high levels of oleic acid in soybean oil. Molecular Breeding 39, 11.

Darr L, Cunicelli M, Bhandari H, Bilyeu K, Chen F, Hewezi T, Li ZL, Sams C and Pantalone V, 2020. Field Performance of High Oleic Soybeans with Mutant FAD2-1A and FAD2-1B Genes in Tennessee. Journal of the American Oil Chemists Society 97, 49-56.

Deol P, Kozlova E, Valdez M, Ho C, Yang EW, Richardson H, Gonzalez G, Truong E, Reid J, Valdez J, Deans JR, Martinez-Lomeli J, Evans JR, Jiang T, Sladek FM and Curras-Collazo MC, 2020. Dysregulation of Hypothalamic Gene Expression and the Oxytocinergic System by Soybean Oil Diets in Male Mice. Endocrinology 161, 21.

Do PT, Nguyen CX, Bui HT, Tran LTN, Stacey G, Gillman JD, Zhang ZYJ and Stacey MG, 2019. Demonstration of highly efficient dual gRNA CRISPR/Cas9 editing of the homeologous GmFAD2-1A and GmFAD2-1B genes to yield a high oleic, low linoleic and alpha-linolenic acid phenotype in soybean. Bmc Plant Biology 19, 14.

Dong LM, Long LK, Xing ZJ, Li CC, He YX, Yan W, Xia W and Li FW, 2020.

Establishment of Multi-Fluorescence Real-Time PCR Assay for GM Soybean Detection. International Journal of Agriculture and Biology 24, 292-298.

Du C, Chen YY, Wang K, Yang Z, Zhao CZ, Jia QL, Taylor DC and Zhang M, 2019. Strong co-suppression impedes an increase in polyunsaturated fatty acids in seeds overexpressing FAD2. Journal of Experimental Botany 70, 985-994.

Golizadeh F and Kumleh HH, 2019. Physiological Responses and Expression Changes of Fatty Acid Metabolism-Related Genes in Wheat (Triticum aestivum) Under Cold Stress. Plant Molecular Biology Reporter 37, 224-236.

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Lee MW, Padilla CS, Gupta C, Galla A, Pereira A, Li JM and Goggin FL, 2020. The FATTY ACID DESATURASE2 Family in Tomato Contributes to Primary Metabolism and Stress Responses. Plant physiology 182, 1083-1099.

Liu F, Ma LH, Wang YW, Li YJ, Zhang XY, Xue F, Nie XH, Zhu QH and Sun J, 2019. GhFAD2-3 is required for anther development in Gossypium hirsutum. Bmc Plant Biology 19, 17.

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, Dumont A, Devos Y, Gennaro A, Ruiz JAG, Lanzoni A, Neri FM, Papadopoulou N, Paraskevopoulos K, Raffaello T and Modified EPG, 2020. Assessment of genetically modified soybean MON 87705 x MON 87708 x MON 89788, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-126). Efsa Journal 18, 36.

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Ranjan PN, Ram CJ, Anurag T, Nilesh J, Kumar PB, Suresh Y, Santosh K and Rahul K, 2020. Breeding for herbicide tolerance in crops: a review. Research Journal of Biotechnology 15, 154-162.

Seemamahannop R, Bilyeu K, He YX, Kapila S, Vander T, Pompili M and Ieee, 2019. Assessment of Oxidative Stability and Physical Properties of High Oleic Natural Esters. In: 2019 Ieee 20th International Conference on Dielectric Liquids. Ieee, New York,

Vogel PA, de Noyer SB, Park H, Nguyen H, Hou LL, Changa T, Khang HL, Ciftci ON, Wang T, Cahoon EB and Clemente TE, 2019. Expression of the Arabidopsis

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Zhao M, Wang WY, Wei L, Chen P, Peng L, Qin Z, Yuan FJ, Wang Z and Ying XX, 2019. The Evolution and Biocatalysis of FAD2 Indicate Its Correlation to the Content of Seed Oil in Plants. International Journal of Molecular Sciences 20, 12.

2. <u>Entries retrieved using CAB Abstracts</u>

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Dong L, Long L, Xing Z, Li C, He Y, Yan W, Xia W and Li F, 2020. Establishment of multi-fluorescence real-time PCR assay for GM soybean detection. International Journal of Agriculture and Biology 24, 292-298.

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and comparative study of a pat/bar real-time PCR assay for integrating the screening strategy of a GMO testing laboratory. Journal of the Science of Food and Agriculture 100, 2121-2129.

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5. <u>Entries retrieved using reference lists of opinions of regulatory bodies and screened on full text</u>[2]

None

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Deol P, Kozlova E, Valdez M, Ho C, Yang EW, Richardson H, Gonzalez G, Truong E, Reid J, Valdez J, Deans JR, Martinez-Lomeli J, Evans JR, Jiang T, Sladek FM and Curras-Collazo MC, 2020. Dysregulation of Hypothalamic Gene Expression and the Oxytocinergic System by Soybean Oil Diets in Male Mice. Endocrinology 161, 21.

Dong LM, Long LK, Xing ZJ, Li CC, He YX, Yan W, Xia W and Li FW, 2020. Establishment of Multi-Fluorescence Real-Time PCR Assay for GM Soybean Detection. International Journal of Agriculture and Biology 24, 292-298.

Kim H and Choi J, 2020. A robust and practical CRISPR/crRNA screening system for

[2] The time-period is applied post-hoc as described in Table 2

soybean cultivar editing using LbCpf1 ribonucleoproteins. Plant cell reports.

Liu X, Hewings GJD, Wang S, Qin M, Xiang X, Zheng S and Li X, 2020. Modeling the situation of COVID-19 and effects of different containment strategies in China with dynamic differential equations and parameters estimation. In: medRxiv.

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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, Dumont A, Devos Y, Gennaro A, Ruiz JAG, Lanzoni A, Neri FM, Papadopoulou N, Paraskevopoulos K, Raffaello T and Modified EPG, 2020. Assessment of genetically modified soybean MON 87705 x MON 87708 x MON 89788, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-126). Efsa Journal 18, 36.

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Springmann M, Spajic L, Clark MA, Poore J, Herforth A, Webb P, Rayner M and Scarborough P, 2020. The healthiness and sustainability of national and global food based dietary guidelines: modelling study. In: BMJ (Clinical research ed). p m2322.

Verginelli D, Paternò A, De Marchis ML, Quarchioni C, Vinciguerra D, Bonini P, Peddis S, Fusco C, Misto M, Marfoglia C, Pomilio F and Marchesi U, 2020. Development and comparative study of a pat/bar real-time PCR assay for integrating the screening strategy of a GMO testing laboratory. Journal of the Science of Food and Agriculture 100, 2121-2129.

Wu H, Qian C, Wu C, Wang Z, Wang DC, Ye ZZ, Ping JF, Wu J and Ji F, 2020. End-point dual specific detection of nucleic acids using CRISPR/Cas12a based portable biosensor. Biosensors & Bioelectronics 157, 7.

Wu N, Lu Q, Wang PW, Zhang Q, Zhang J, Qu J and Wang N, 2020. Construction and Analysis of GmFAD2-1A and GmFAD2-2A Soybean Fatty Acid Desaturase

Mutants Based on CRISPR/Cas9 Technology. International Journal of Molecular Sciences 21, 12.

Yeom WW, Kim HJ, Lee KR, Cho HS, Kim JY, Jung HW, Oh SW, Jun SE, Kim HU and Chung YS, 2020. Increased Production of alpha-Linolenic Acid in Soybean Seeds by Overexpression of Lesquerella FAD3-1. Frontiers in Plant Science 10, 14.

Zhang W, Xue M, Ren M, Tang K, Zhang Y and Wang M, 2019. Cloning and functional analysis of AmFAD2-1 gene from Ammopiptanthus mongolicus. Acta Botanica Boreali-Occidentalia Sinica 39, 1901-1910.

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	Deol P, Kozlova E, Valdez M, Ho C, Yang EW, Richardson H, Gonzalez G, Truong E, Reid J, Valdez J, Deans JR, Martinez-Lomeli J, Evans JR, Jiang T, Sladek FM and Curras-Collazo MC, **2020**. Dysregulation of Hypothalamic Gene Expression and the Oxytocinergic System by Soybean Oil Diets in Male Mice. Endocrinology 161, 21. 10.1210/endocr/bgz044
Agronomic characterization/Persistence and invasiveness assessment	Matsushita A, Goto H, Takahashi Y, Tsuda M and Ohsawa R, **2020**. Consideration of familiarity accumulated in the confined field trials for environmental risk assessment of genetically modified soybean (Glycine max) in Japan. Transgenic research 29, 229-242. 10.1007/s11248-020-00193-z

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
Wu N, Lu Q, Wang PW, Zhang Q, Zhang J, Qu J and Wang N, **2020**. Construction and Analysis of GmFAD2-1A and GmFAD2-2A Soybean Fatty Acid Desaturase Mutants Based on CRISPR/Cas9 Technology. International Journal of Molecular Sciences 21, 12. 10.3390/ijms21031104	Intervention/Exposure (Not on 305423 or 305423x40-3-2 soybean)
Seemamahannop R, Bilyeu K, He YX, Kapila S, Vander T, Pompili M and Ieee, **2019**. Assessment of Oxidative Stability and Physical Properties of High Oleic Natural Esters. 2019 Ieee 20th International Conference on Dielectric Liquids. New York, Ieee.	Population (does not address human and animal health or the environment); Outcome (does not address effect on human and animal health or environment)[1]

[1] Plenish oil was evaluated along with oil from Vistive Gold (Monsanto-Bayer), Soyleic (high oleic soybean derived through traditional breeding at the University of Missouri), generic soybean oil, soybean-based insulating oil FR-3 (from Cargill), and canola oil for use as insulating and heat transfer fluids in electrical devices such as transformers. The intent is to use natural esters to replace mineral oil. Oils with higher oleic and lower polyunsaturates (e.g. Plenish) were more stable than the other oils in aging experiments. Note that Soyleic was comparable to Plenish with respect to composition and properties in this 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