

Title

Summary of the Literature Review for A5547-127 Soybean
July 1, 2023 – June 30, 2024

Final Report

Data or guideline requirement

Explanatory note on literature searching
conducted in the context of GMO applications for (renewed) market authorization
and annual post-market environmental monitoring reports on GMOs authorised in the EU market.
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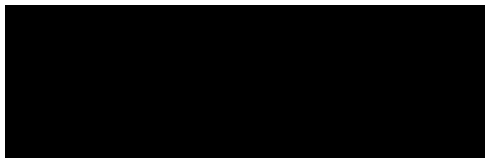
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Report	██████████

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SUMMARY

The A5547-127 *Glycine max* plant (soybean) was transformed by direct gene transfer using transformation vector pUC/Ac, carrying a phosphinothricin acetyltransferase (*pat*) gene and a beta-lactamase (*bla*) gene cassette. The *pat* gene encodes an enzyme conferring tolerance to glufosinate-ammonium herbicides and makes event A5547-127 tolerant to the glufosinate-ammonium herbicides. The OECD identifier is ACS-GMØØ6-4.

A scoping review was performed for A5547-127 Soybean and its newly expressed protein, PAT/*pat*. The objective of this scoping review was to determine if there were studies about the molecular characterization of A5547-127 Soybean, its effect on food and feed safety or on environmental safety, that might require in-depth examination. A set of broad literature searches was performed using several bibliographic databases covering scientific literature from July 1, 2023 to June 30, 2024. Additional sources of information, such as web pages of food safety, agriculture, and biotechnology-related authorities were searched for the same time window, along with the bibliographies of relevant reviews. The references identified were evaluated for potential relevance to the scoping review questions according to pre-defined criteria.

These literature searches identified a total of 107 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 8 publications were progressed for detailed assessment.

None of the 8 publications were determined to be relevant after detailed review. There was no new data on the molecular characterization of A5547-127 Soybean, or the PAT protein, nor did it suggest any potential adverse effects on human and animal health or on the environment. No evidence was identified that would warrant conducting a systematic review.

In summary, these literature searches and review of the retrieved articles did not identify relevant publications that would impact the existing safety assessment of A5547-127 Soybean.

1. INTRODUCTION

The A5547-127 *Glycine max* plant (soybean) was transformed by direct gene transfer using transformation vector pUC/Ac, carrying a phosphinothricin acetyltransferase (*pat*) gene and a beta-lactamase (*bla*) gene cassette. The *pat* gene encodes an enzyme conferring tolerance to glufosinate-ammonium herbicides and makes event A5547-127 tolerant to the glufosinate-ammonium herbicides. The OECD identifier for A5547-127 is ACS-GMØØ6-4.

The objective of the literature searches described here was to determine if there were publications published between July 1, 2023 and June 30, 2024 that mention the molecular characterization of A5547-127 Soybean, and/or any adverse effect of A5547-127 Soybean in food, feed or the environment. In that context, a broad and inclusive literature search was performed, and the articles retrieved were reviewed in a comprehensive and transparent manner. This was intended as a scoping review. The literature review was performed as recommended in the European Food Safety Authority (EFSA) explanatory note on literature searching conducted in the context of Genetically Modified Organisms (GMO) applications and post-market environmental monitoring activities (2019; (1)).

The literature searches were performed for A5547-127 Soybean and its newly expressed protein, PAT/*pat*. The search terms also included relevant synonyms, the trade name and intended trait. When needed, plant species and general GMO terms were used to limit the search results (described in section 3.3).

2. OVERALL METHODS

2.1. Objective of the scoping review

The objective of the scoping review was to survey the evidence base for A5547-127 Soybean and its newly expressed protein, PAT/*pat*, in order to identify any specific issues related to food or feed safety, molecular characterization or environmental safety that might require in-depth examination.

2.2. Review questions

Review questions were formulated to conform to PE(I)CO structure (Population, Exposure (Intervention), Comparators, Outcome) if possible, and to address data requirements. They were modeled after the review question examples provided in the EFSA 2019 explanatory note (1).

Question 1: Were any studies published during the reporting period that describe adverse effects on human or animal health or the environment of A5547-127 Soybean and its newly expressed protein PAT/*pat*?

Key elements:

Population: Human health; animal health; environmental safety

Exposure: A5547-127 Soybean, derived food/feed products, newly expressed protein in A5547-127 Soybean

Comparators: When applicable, comparable populations or subjects exposed to appropriate controls (e.g., vehicle only, innocuous control protein, non-GM comparator) or conventional counterpart used for comparative analysis of plant material

Outcome: Adverse effects

Question 2: Were any studies published during the reporting period that focus on molecular characterization of A5547-127 Soybean and its newly expressed protein PAT/*pat* in Soybean?

Key elements:

Population: A5547-127 Soybean and newly expressed protein in A5547-127 Soybean
Outcome: Molecular characterization (which would indicate the information/data requirement for molecular characteristics)

2.3. Criteria for relevance

Criteria for establishing the relevance of retrieved publications were defined prior to conduct of the search. These criteria were modeled after those given in the EFSA 2019 explanatory note (1) and are described in [Table 1](#).

The criteria listed under additional concepts were selected as appropriate to the GMO application. For example, the criteria “Stacked events obtained by conventional crosses/subcombinations” and “Molecular stacks” were not used for the relevance assessment of a “Single event” GMO search.

Table 1: Eligibility/inclusion criteria to establish the relevance of retrieved publications

Concepts	Criteria	Comment
Key elements of review questions with PECO structure		
Population	The publication addresses human and animal health, and/or the environment (including biodiversity, ecosystem services, service providing units, and endangered species) as general protection goals	From the publications that address the GMO under consideration, those that address protection goals relevant to the risk assessment of the GMO are eligible
Exposure (Intervention)	The publication addresses the GMO, derived food/feed products, and/or the intended trait(s) (e.g., newly expressed protein(s)) that are identical or like those under regulatory review	This enables the selection of publications that address the GMO, derived food/feed products, and/or the intended trait(s) under consideration
Comparator	If the publication reports a comparative study that uses plant material as test material, eligible publications must report a non-GM variety as comparator	In those cases where the publication addresses the GMO under consideration, reports a comparative analysis study and uses plant material as test material, eligible publications also need to include an appropriate non-GM line as comparator

Concepts	Criteria	Comment
Outcome	The publication addresses effects/impacts on human and animal health, and/or the environment	Publications that address the GMO under consideration also need to address effects/impacts on entities of concern, and potential determinants of exposure that place these entities at risk, in order to be relevant to the risk assessment of the GMO
Additional concepts		
Information/data requirements	The publication reports information pertaining to one or more information/data requirement(s) outlined in Appendix A for the GMO and derived food/feed products under consideration, including the intended trait(s)	Publications that potentially contribute to the knowledge informing the risk assessment of the GMO under consideration, and thus the risk hypotheses addressed, taking account of both hazard and exposure, can be considered relevant according to this eligibility/inclusion criterion. Publications addressing other issues such as benefits, socio-economics, ethics, crop protection, detection methods, efficacy, public perception and risk communication can be excluded, as they are not necessarily relevant to the risk assessment of GMOs
Plant species	The publication addresses the same plant species as the GMO under consideration	This eligibility/inclusion criterion permits the exclusion of publications on GMOs that contain the same intended trait(s) as the GMO under consideration, but which are introduced in another plant species
Scope of GMO application	The publication addresses pathways and levels of exposure to the GMO, derived food/feed products, and the intended trait(s) that are relevant for the intended uses of the GMO and derived food/feed products under regulatory review	From the publications that address the GMO under consideration, those that consider pathways and levels of exposure relevant to the scope of the GMO application (i.e., import and processing for food/feed uses, cultivation) are eligible

Concepts	Criteria	Comment
Target pests/organisms	The publication addresses target pests/organisms that are established in the EU	This permits the exclusion of publications that address interactions between the GMO and target pests/organisms that do not occur in the EU
Stacked events obtained by conventional crosses/subcombinations	The publication addresses the higher stacked event and/or a subcombination or subcombinations of the single events of the higher stacked event, independently of its/their origin	This permits the selection of publications on the higher stacked event and/or subcombinations of the single events of the higher stacked event that are in the scope of the GMO application(s), independently of their origin. This permits the exclusion of publications on the single events of the higher stacked event, because the risk assessment of GMO applications for stacked events covers only the products in the scope of the GMO application – i.e., the higher stacked event and subcombinations of the singles involved, independently of their origin
Molecular stacks	The publication addresses: the molecular stack; all newly expressed proteins in the molecular stack; and/or one or several of the newly expressed proteins in the molecular stack that has/have not been previously risk assessed by EFSA and/or its GMO Panel and for which no safe use has been determined yet by EFSA and/or its GMO Panel	This permits the exclusion of publications that address one or several (not all) of the newly expressed proteins in the molecular stack that has/have been previously risk assessed by EFSA and/or its GMO Panel and for which the safe use has been determined by EFSA and/or its GMO Panel
Previously risk assessed publications	The publication has not been previously risk assessed by EFSA and/or its GMO Panel and is not cited/referenced in an EFSA/GMO Panel output	This permits the exclusion of publications that have been previously risk assessed by EFSA and/or its GMO Panel and cited/referenced in an EFSA/GMO Panel output
Access	Full-text document is accessible	If potentially relevant full-text documents cannot be obtained, they should be listed in a table with a description of the (unsuccessful) methods that have been used to try to obtain a copy

Concepts	Criteria	Comment
Reporting format	The publication presents original/primary data, or it is a risk assessment from a relevant key organisation (such as regulatory agencies and risk assessment bodies involved in the risk assessment of GMOs)	This permits the exclusion of publications that do not present original/primary data (e.g., editorials, position papers), and the inclusion of relevant risk assessments performed and reported by relevant key organisations. Reviews should only be included if they present data that are not available from a primary research study
Reporting format	A study in a publication should only be presented once, but if it is presented in more than one publication, all publications should be listed and grouped	Duplicate publications should be excluded at the screening stage. Only one copy of a study is required even if it is reported in different publications, and identified in more than one database

Table adapted from 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 (1).

2.4. Reference publication

Two publications related to A5547-127 soybean were previously identified and used to test and validate the search strategy:

- EFSA Panel on Genetically Modified Organisms, Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal JM, Gennaro A, Neri FM and Olaru I, 2017. Scientific opinion on application EFSA-GMO-NL-2013-120 for authorization of genetically modified soybean FG72 x A5547-127 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Bayer CropScience LP and M.S.Technologies LLC. EFSA Journal 2017;15(4):4744, 23 pp.
- EFSA Panel on Genetically Modified Organisms (GMO). Scientific Opinion on application (EFSA-GMO-NL-2008-52) for the placing on the market of herbicide tolerant genetically modified soybean A5547-127 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. The EFSA Journal (2011); 9(5):2147, 1-28. [27 pp.] doi:10.2903/j.efsa.2011.2147

These articles selected as reference publications because they mention the event name (A5547-127), the intended trait (herbicide tolerance) and the crop (soybean). Since this reference was published before the current search period, the search profile was tested without applying the time limit used in the final search profile (UP>=20230701 and UP<=20240630).

3. SEARCH METHODS AND OUTCOMES

The search strategies used here followed the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications and post-market environmental monitoring activities (1).

The search strategies were designed to be broad and sensitive enough to capture any relevant publications, if available.

An information specialist with background in plant biotechnology selected the databases, identified relevant search terms, developed search profiles and designed search strategies.

3.1. Time window and date of the literature search

The database searches were performed on July 17, 2024. Only documents updated between July 1, 2023 and June 30, 2024, were considered in the search. The dates of the most recent database updates are provided in [Table 4](#).

3.2. Databases used in the literature search

All searches were performed in the host STN (Scientific and Technical Information Network), an online database service operated jointly by CAS and FIZ Karlsruhe. STN provides access to a broad range of databases from the most renowned database producers worldwide.

The searches described here were performed in five databases: three multidisciplinary/large databases (Biosis, Medline and CA-Plus) and two subject-specific databases focused on agriculture-related topics (Agricola and CABA).

See [Appendix 1](#) for detailed database descriptions.

3.3. Search strategy

The search profiles were designed to cover the event name, the trade name, the newly expressed proteins and intended traits. Since the 'newly expressed proteins' profiles and the 'intended trait' profiles produced too many results when used on their own, they were combined with additional profiles: the 'newly expressed proteins' profiles were combined with a 'plant species' profile while the 'intended trait' profiles were combined with a 'general GMO' profile as well as with the 'plant species' profile. The reference publications ([Section 2.4](#)) were identified by the search profiles confirming the validity of the applied search strategy. See [Table 2](#) for a detailed search profile.

Table 2: Search profile for database search

Set	Search string	Concepts
1	LL55 or A5547-127 or A5547(w)127 or A(w)5547(w)127 or ACS-GM006-4 or ACS-GMO06-4 or ACS(w)GM006(w)4 or ACS(w)GMO06(w)4 or ACSGM006(w)4 or ACSGMO06(w)4	Event name
2	libertylink or libertylinktm or libertylinkrtm or liberty(w)link or liberty(w)linktm or liberty(w)linkrtm or LL or LLTM or LLRTM	Trade name
3	((bar or pat)(2a)(gene# or protein# or enzyme#)) or ppt(2w)acetyltransferase or ppt(2w)acetyl(w)transferase or pt(w)n(2w)acetyltransferase or pt(w)n(2w)acetyl(w)transferase or phosphinothricin(w)n(w)acetyltransferase or phosphinothricin(2w)acetyltransferase or phosphinothricin(2w)acetyl(w)transferase or phosphinothricinacetyl(w)transferase	Newly expressed protein

Set	Search string	Concepts
4	(herbicid? or bialaphos or basta or glufosinate or phosphinothricin or liberty?) (5a) (resist? or toleran? or protect?)	Intended trait
5	soy or soya or soja or soybean# or soyabean# or sojabean# or glycine(w)max or g(w)max	Plant species
6	GMO OR GMOs OR LMO OR LMOs OR GM OR GE OR transgen? OR (genetic?(3a) (modif? OR transform? OR manipulat? OR improv? OR engineer?))	GMO general
7	2 and 5	Trade name AND Plant species
8	3 and 5	Newly expressed protein AND Plant species
9	4 and 5 and 6	Intended trait AND Plant species AND GMO general
10	1 or 7 or 8 or 9	Event name OR (Trade name AND plant species) OR (Newly expressed protein AND Plant species) OR (Intended trait AND Plant species AND GMO general)

All searches were performed in the Basic Index (BI) field, which includes the following subject headings/field names:

- **Agricola:** title (TI), controlled term (CT), supplementary term (ST), abstract (AB), named person (NA), corporate name (CO), note (NTE), geographic term, CABA and other fields (GT)
- **Biosis:** title (TI), abstract (AB), biosystematic codes (BC), chemical name (CN), controlled term (CT), gene name (GEN), geographic term (GT), organism (ORGN) and supplementary term (ST); as well as CAS Registry Numbers (RN)
- **HCAPlus:** title (TI), supplementary term (ST), index term (IT) and abstract (AB); as well as CAS Registry Numbers
- **CABA:** title (TI), controlled term (CT), supplementary term (ST), broader term (BT), abstract (AB), organism name (ORGN) and geographic term (GT); as well as CAS Registry Numbers
- **Medline:** title (TI), chemical name (CN), gene name (GEN), controlled term (excluding MeSH numbers) (CT), supplementary term (ST), named person (NA), other source (OS), and abstract (AB), as well as CAS Registry Numbers and GenBank Numbers

Relevant controlled terms (Table 3) were not searched separately because they are included in the Basic Index and were captured by the free-text searches.

Table 3: Relevant controlled terms (CT) and index terms (IT) in each database

Database	Event	New protein	Intended traits	Plant species	GM plants
Agricola	None	None	"HERBICIDE RESISTANCE"	"GLYCINE MAX"	"TRANSGENIC PLANTS"
Biosis	None	None	No terms for herbicide resistance	none	None
CABA	None	None	"HERBICIDE RESISTANCE"	SOYABEANS	"TRANSGENIC PLANTS"
CAS	None	None	"HERBICIDE RESISTANCE"	"GLYCINE MAX"	"GENETICALLY MODIFIED PLANTS"
Medline	None	None	"HERBICIDE RESISTANCE"	SOYABEANS/CT	"PLANTS, GENETICALLY MODIFIED"

The search results were limited to documents updated between July 1, 2023 and June 30, 2024 (UP>=20230701 and UP<=20240630), and to non-patent documents (not P/DT). To ensure that documents with indexing errors where two document types (DTs) (one eligible and one ineligible) were attached to a single record were not missed, documents with both 'journal' and 'patent' as document type were also kept. These putative documents would be identified with (P/DT AND J/DT) in CABA and CAPIus.

Table 4 summarizes the number of results obtained from each of the databases searched.

See [Appendix 2](#) for a complete search history.

Table 4: Overview of the selected databases and summary of search results from each database

Database	AGRICOLA	BIOSIS	CABA	HCAPIus	Medline
Database Provider	STN International	STN International	STN International	STN International	STN International
Coverage	1970-present	1926-present	1973-present	1907-present	1946-present
Date of search	July 17, 2024	July 17, 2024	July 17, 2024	July 17, 2024	July 17, 2024
Datespan of the search	July 1, 2023 - June 30, 2024	July 1, 2023 - June 30, 2024	July 1, 2023 - June 30, 2024	July 1, 2023 - June 30, 2024	July 1, 2023 - June 30, 2024
Latest database update	11 July 2024	17 July 2024	15 July 2024	16 July 2024	16 July 2024
Number of records retrieved	21	38	37	33	16
Number of records after duplicate removal	16	31	23	21	16

Database	AGRICOLA	BIOSIS	CABA	HCAPlus	Medline
Number of relevant records after rapid assessment	2	3	1	2	0

4. INTERNET and MANUAL SEARCHES

4.1. Internet Searches of food safety, agriculture, and biotechnology-related authority webpages

A search of the web pages of food safety, agriculture, and biotechnology-related authorities was conducted. Search results were manually examined for relevant records that were either published during the time period under consideration (date span of search: July 1, 2023 - June 30, 2024) or refer to relevant records published during this time frame. Relevance of results was determined based on the criteria listed in Table 1 and the results are summarized in Table 5. All web pages searched were justified by their recommendation in the EFSA 2019 explanatory note (1). Of the 13 key organisations cited in the EFSA 2019 explanatory note (1), Environment and Climate Change Canada and Intersecretarial Commission on Biosafety of GMOs (CIBIOGEM) were excluded, since they are not involved in the risk assessment of GM plants. The US-EPA website was excluded, since A5547-127 Soybean does not contain an insect-resistant trait. The GEAC website was excluded, since this agency has only regulated GM cotton products. Therefore, the internet search was limited to 9 key organisations relevant for A5547-127 Soybean. Search terms consisted of LL55 or A5547-127 or libertylink soy 55 or ACS-GMØ6-4 or PAT/pat or phosphinothricin (all searched singly, with no search limits applied).

Table 5: Results of search of food safety, agriculture, and biotechnology-related authority websites

Source Site Name	Website URL	Date of Most Recent Site Update	Date of Search	No. of Relevant Records
US Department of Agriculture (USDA)	https://www.usda.gov/	7/25/2024	7/25/2024	0
US Food and Drug Administration (FDA)	https://www.fda.gov/	7/29/2024	7/29/2024	0
Health Canada	https://www.canada.ca/en/health-canada.html	7/10/2024	7/11/2024	0
Canadian Food Inspection Agency (CFIA)	https://www.canada.ca/en/food-inspection-agency.html	7/10/2024	7/12/2024 to 7/16/2024	0
Food Standards Australia New Zealand (FSANZ)	http://www.foodstandards.gov.au/Pages/default.aspx	7/17/2024	7/17/2024	0
Office of the Gene Technology Regulator (OGTR) Australia	http://www.ogtr.gov.au/	7/17/2024	7/17/2024	0

Source Site Name	Website URL	Date of Most Recent Site Update	Date of Search	No. of Relevant Records
National Technical Commission on Biosafety (CTNBio) Brazil	http://ctnbio.mcti.gov.br/en	7/22/2024	7/11/2024 to 07/30/2024	0
National Advisory Commission on Agricultural Biotechnology (CONABIA) Argentina	https://www.argentina.gob.ar/agroindustria/bioeconomia/biotecnologia	7/11/2024	7/11/2024 to 7/12/2024	0
Ministry of Agriculture, Forestry and Fisheries (MAFF) Japan	http://www.maff.go.jp/	7/17/2024	7/17/2024	0

4.2. Manual searches of reference lists of recent review articles

Recent review articles as sources of reference lists to search for potentially relevant studies were identified via searches of PubMed.gov for general terms such as “GMO” or “GM crops” in the titles and abstracts. The search of PubMed.gov was also restricted to recent reviews published between July 1, 2023 and June 30, 2024. The resulting number of relevant studies found within the bibliographies of these review articles is given in Table 6.

Table 6: Documents for which reference lists were scanned for relevant studies

No	Author(s) and Year	Title	Source	Number of relevant bibliographic references retrieved
1	Ahmar S, Hensel G, Gruszka D. 2023	CRISPR/Cas9-mediated genome editing techniques and new breeding strategies in cereals - current status, improvements, and perspectives	Biotechnol Adv. 2023 Dec;69:108248.	0
2	Chaudhury R, Chakraborty A, Rahaman F, Sarkar T, Dey S, Das M. 2024	Mycorrhization in trees: ecology, physiology, emerging technologies and beyond	Plant Biol (Stuttg). 2024 Mar;26(2):145-156.	0
3	Dolezel M, Lang A, Greiter A, Miklau M, Eckerstorfer M, Heissenberger A, Willée E, Züghart W. 2024	Challenges for the Post-Market Environmental Monitoring in the European Union Imposed by Novel Applications of Genetically Modified and Genome-Edited Organisms	BioTech (Basel). 2024 May 15;13(2):14.	0
4	Goodman RE. 2024	Twenty-eight years of GM Food and feed without harm: why not accept them?	GM Crops Food. 2024 Dec 31;15(1):40-50.	0

No	Author(s) and Year	Title	Source	Number of relevant bibliographic references retrieved
5	Koller F, Cieslak M. 2023	A perspective from the EU: unintended genetic changes in plants caused by NGT-their relevance for a comprehensive molecular characterisation and risk assessment	Front Bioeng Biotechnol. 2023 Oct 27;11:1276226.	0
6	Ledesma AV, Van Eenennaam AL. 2024	Global status of gene edited animals for agricultural applications	Vet J. 2024 May 22:106142.	0
7	Mat Jalaluddin NS, Ahmad Fuaad AA, Othman RY. 2024	Regulatory landscape and public perception for gene-edited bananas in the Southeast Asian region.	Transgenic Res. 2024 Jun;33(3):89-97.	0
8	Mmbando GS. 2023	The legal aspect of the current use of genetically modified organisms in Kenya, Tanzania, and Uganda.	GM Crops Food. 2023 Dec 31;14(1):1-12.	0
9	Ruiz-Zambrano NL, Pérez-Carrillo E, Serna-Saldivar SO, Tejada-Ortigoza V. 2023	Effect of thermal, nonthermal, and combined treatments on functional and nutritional properties of chickpeas	Crit Rev Food Sci Nutr. 2023 Jul 27:1-19.	0
10	Salazar-Cerezo S, de Vries RP, Garrigues S. 2023	Strategies for the Development of Industrial Fungal Producing Strains	J Fungi (Basel). 2023 Aug 8;9(8):834.	0
11	Sarker PK, Paul AS, Karmoker D. 2023	Mitigating climate change and pandemic impacts on global food security: dual sustainable agriculture approach (2S approach)	Planta. 2023 Oct 25;258(6):104.	0
12	Tanny T, Sallam M, Soda N, Nguyen NT, Alam M, Shiddiky MJA. 2023	CRISPR/Cas-Based Diagnostics in Agricultural Applications	J Agric Food Chem. 2023 Aug 9;71(31):11765-11788.	0
13	Vasudevan SN, Pooja SK, Raju TJ, Damini CS. 2023	Cisgenics and intragenics: boon or bane for crop improvement	Front Plant Sci. 2023 Nov 28;14:1275145.	0

5. RESULTS OF THE STUDY IDENTIFICATION AND SELECTION PROCESS

The database searches ([Section 3](#)) identified a total of 145 references, which were reduced to 107 references after removal of duplicates ([Table 4](#)). No additional studies were identified in the manual searches ([Section 4](#)).

5.1. Screening of titles and abstracts to exclude obviously irrelevant references (Stage 1)

All references identified in the database searches described in [Section 3](#) were assessed for relevance based on information in their title and abstract by two reviewers independently. If opinions of relevance differed, the discrepancies were discussed between the reviewers and if a disagreement persisted, the publication under discussion was transferred to Stage 2 for detailed evaluation by the experts. In this search, both evaluators were in 100 % agreement.

Clearly irrelevant records were tagged as “Not Relevant”. These included:

- Duplicated entries
- Secondary literature (reviews), other than assessments from regulatory agencies
- Articles on non-relevant topics like detection methods, socio-economic implications of GM crops, GM policy, agronomical performance, other herbicide tolerant GM crops, other insect resistant GM crops, unrelated topics, etc.

Publications which appeared to be relevant and those of unclear relevance were tagged as “Relevant” and progressed to Stage 2 (detailed assessment; see [Section 5.2](#)).

To document the selection process, the number of publications excluded after rapid assessment for relevance is presented in [Table 7](#).

5.2. Detailed assessment of eligible references (Stage 2)

Publications tagged as “Relevant” in Stage 1 were assessed in detail independently by two scientific experts in each of three corresponding areas (*i.e.*, Molecular Biology, Food and Feed Safety, Environmental Safety), based on the full text of the publications. If opinions of relevance differed between reviewers within each area, the initial reviewers discussed the discrepancy as necessary and consulted additional reviewers to resolve the discrepancy if needed.

In the relevance assessment of the literature review for A5547-127 Soybean, reviewers agreed in 100% of the Stage 2 evaluations.

[Table 7](#) gives an overview of the reference selection process and results of the detailed assessment.

Table 7: Results of the publication selection process

Total number of publications retrieved after all searches of the scientific literature (excluding duplicates)	107
Number of publications excluded from the search results after rapid assessment for relevance (Stage 1)	99
Total number of full-text documents assessed in detail	8
Number of publications excluded from further consideration after detailed assessment for relevance (Stage 2)	8
Total number of unobtainable/unclear publications	0
Total number of relevant publications	0

[Table 8](#) lists the publications determined to be relevant based on the detailed evaluation. Publications that were clearly not relevant after a detailed assessment are listed in [Table 9](#). [Table 10](#) lists the publications for which full-text documents were unobtainable for detailed assessment or for which relevance was unclear after detailed assessment.

6. NARRATIVE SYNTHESIS/SUMMARY OF RELEVANT STUDIES

A total of 8 publications were selected during Stage 1 evaluation (rapid assessment based on title and abstract). After Stage 2 evaluation (detailed review based on full text), it was determined that no publications were relevant for the safety assessment of A5547-127 Soybean and its newly expressed protein, PAT/pat.

Table 11 lists the relevant publications along with a summary of any adverse effects.

7. CONCLUSION

The literature searches performed for A5547-127 Soybean and its newly expressed protein, PAT/pat, for the period from July 1, 2023 to June 30, 2024, identified a total of 107 unique publications (after duplicate removal). A total of 8 publications were progressed for detailed assessment after excluding 99 obviously irrelevant publications during Stage 1 evaluation (rapid assessment based on title and abstract).

The 8 publications that progressed to Stage 2 were evaluated in detail, based on full text, for potential relevance, following the pre-established criteria listed in Table 1. No relevant publications with bearing on molecular characterization, human and animal safety or environmental safety were identified. No issues or topics were identified that would trigger or warrant more specific question formulation.

8. REFERENCES

No.	Author(s), title, source, edition, year, pages
1.	Devos Y, Guajardo IM, Alvarez F and Glanville J. 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 publications 2019:EN-1614. 62 pages. doi:10.2903/sp.efsa.2019.EN-1614.

Table 8: Report of all relevant publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement(s)

Main category of information/data requirement	Study (Author(s) and year)	Title	Source
No publications in this category			

Table 9: Report of publications excluded from the risk assessment after detailed assessment of full-text documents

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
Weidner, Christopher; Koeppel, Rene; Freyer, Regina; Richl, Petra; Lieske, Kathrin; Mankertz, Joachim; Waiblinger, Hans-Ulrich (2024)	Development and validation of a multiplex real-time PCR method for screening genetically modified plants	Journal fuer Verbraucherschutz und Lebensmittelsicherheit (2024), 19(2), 165-174 CODEN: JVLOA5; ISSN: 1661-5751	This paper studied a qualitative triplex PCR method that can be used for detection of multiple GMO crops. Commercially available certified reference materials of GMO crops including A5547-127 were used for development and validation of this detection method. Safety of GMO including A5547-127 was not considered in this paper.
Yin, Yue (1); Ren, Zhen-tao (2); Xue, Kun (2); Zhang, Li (3); Liu, Lai-pan (3); Liu, Biao (3); Qin, Liang (4); Chen, Lu-lu (4); Wang, Xiao-dong (4); Jia, Rui-zong (5); Yin, Y.; Ren, Z. T.; Zhang, L.; Qin, L.; Chen,	In situ proteomic analysis of herbicide - resistant soybean and hybrid seeds via matrix-assisted laser desorption/ionization-mass spectrometry imaging.	Journal of Agricultural and Food Chemistry (2023), Volume 71, Number 18, pp. 7140-7151 ISSN: 0021-8561; 1520-5118 DOI: https://doi.org/10.1021/acs.jafc.3c00301 Published by: American Chemical Society, Washington	A5547-127 soybean was not considered in this paper.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
L. L.; Liu, L. P.; Jia, R. Z.; Xue, K.; Liu, B.; Wang, X. D. (2023)			
Liang, Rong; Liu, Jia-Li; Ji, Xue-Qin; Olsen, Kenneth M.; Qiang, Sheng; Song, Xiao-Ling (2023)	Fitness and Hard Seededness of F2 and F3 Descendants of Hybridization between Herbicide -Resistant Glycine max and G. soja	Plants (2023), 12(21), 3671 CODEN: PLANCD; ISSN: 2223-7747 URL: https://www.mdpi.com/journal/plants	A5547-127 soybean was not considered in this paper.
Yang Xiao-ran; Liu Jing; Yao Shu-jun; Shen Wen-jing; Guo Hui; Liu Biao; Xue Kun (2023)	Effects of Three Different Herbicide -resistant Transgenic Soybeans on Arthropod Diversity in Field.	Journal of Ecology and Rural Environment, (2023) Vol. 39, No. 4, pp. 504-510. http://www.ere.ac.cn/EN/column/column79.shtml . ISSN: 1673-4831.	A5547-127 soybean was not considered in this paper.
Ren, Zhentao; Qin, Liang; Chen, Lulu; Xu, Hualei; Liu, Haiqiang; Guo, Hua; Li, Jinrong; Yang, Chenyu; Hu, Hao; Wu, Ran; Zhou, Yijun; Xue, Kun; Liu, Biao; Wang, Xiaodong (2023)	Spatial Lipidomics of EPSPS and PAT Transgenic and Non-Transgenic Soybean Seeds Using Matrix-Assisted Laser Desorption/Ionization Mass Spectrometry Imaging	Journal of Agricultural and Food Chemistry (15 Jun 2023), Volume 71, Number 26, pp. 10190-10202, 13 p. ISSN: 1520-5118 Published by: American Chemical Society Source Note: 2023June15, v. 71, no. 26	A5547-127 soybean was not considered in this paper.
Xiang, Dan; Luo, Mingzhong; Jiang, Fukun; Wen, Zhengrong; Chen, Xiaoyun; Wang, Xiaofu; Xu, Xiaoli; Wei, Wei; Xu, Junfeng (2023)	Safety assessment of subchronic feeding of insect-resistant and herbicide-resistant transgenic soybeans to juvenile channel catfish (<i>Ictalurus punctatus</i>).	Scientific Reports, (APR 3 2023) Vol. 13, No. 1, pp. Article No.: 5445. https://www.nature.com/srep . ISSN: 2045-2322. E-ISSN: 2045-2322.	A5547-127 soybean was not considered in this paper.
Varunjikar, M.S.; Bohn, T.; Sanden, M.; Belghit, I.; Pineda-Pampliega, J.; Palmblad, M.; Broell, H.;	Proteomics analyses of herbicide -tolerant genetically modified , conventionally, and organically farmed soybean seeds	Food Control (18 Apr 2023), pp. 109795 ISSN: 0956-7135 Published by: Elsevier Ltd Source Note: 2023Apr18, v.	A5547-127 soybean was not considered in this paper.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
Braeuning, A.; Rasinger, J.D. (2023)			
Liang, Rong; Ji, Xueqin; Sheng, Zewen; Liu, Jinyue; Qiang, Sheng; Song, Xiaoling (2022)	Fitness and Rhizobacteria of F2, F3 Hybrids of Herbicide -Tolerant Transgenic Soybean and Wild Soybean.	Plants-Basel, (NOV 2022) Vol. 11, No. 22, pp. Article No.: 3184. http://www.mdpi.com/journal/plants . ISSN: 2223-7747. E-ISSN: 2223-7747.	A5547-127 soybean was not considered in this paper.

Table 10: Report of unobtainable/unclear publications

Study (Author(s) and year)	Title	Source	Description of (unsuccessful) methods used to try and obtain a copy of the publication
No publications in this category			

Table 11: Summary report for all relevant publications retrieved after detailed assessment of full-text documents for relevance and implications for the risk assessment: ordered by category of information/data requirement(s)

Main category of information/data requirement	Study (Author(s) and year)	Intervention/ test materials used	Adverse effects reported	Which adverse effect reported	Implications for risk assessment
No publications in this category					

9. APPENDICES

Appendix 1: Database descriptions

Host	File	Description
STN	AGRICOLA	<p>Agriculture Online Access is a bibliographic database containing selected worldwide literature of agriculture and related fields. AGRICOLA is the locator and bibliographic access and control system of the National Agricultural Library (NAL) collections and also includes records from other cooperating institutions. Coverage of the database includes agricultural economics and rural sociology, agricultural production, animal sciences, chemistry, entomology, food and human nutrition, forestry, natural resources, pesticides, plant science, soils and fertilizers, and water resources. Also covered are related areas such as biology and biotechnology, botany, ecology, and natural history.</p> <p>The database draws on bibliographies, serial articles, book chapters, monographs, computer files, serials, maps, audiovisuals, and reports. Bibliographic information, abstracts, geographic terms, controlled terms, and supplementary terms are searchable.</p>
STN	BIOSIS	<p>BIOSIS Previews® is the largest and most comprehensive life science database in the world. Amongst others subject coverage includes Agriculture, Biochemistry, Biophysics, Botany, Environmental Biology, Physiology, Toxicology.</p> <p>Sources include periodicals, journals, conference proceedings, reviews, reports, patents, and short communications. Nearly 6,000 life source journals, 1,500 international meetings as well as review articles, books, and monographs are reviewed for inclusion.</p> <p>Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are all searchable.</p>
STN	CABA/CAB	<p>The CAB Abstracts database covers worldwide literature from all areas of agriculture and related sciences including Agriculture, Agricultural chemicals, Animal sciences and production, Crop protection, Crop sciences and production, Environment, Soils and fertilizers.</p> <p>Sources for CABA include journals, books, reports, published theses, conference proceedings, and patents.</p> <p>Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are searchable.</p>
STN	CAS-CA/HCAPlus	<p>The Chemical Abstracts (CA) database covers all areas of Biochemistry, Chemistry and Chemical engineering, and related sciences.</p> <p>Sources include over 8,000 journals, patents from 38 national patent offices and two international patent organizations, technical reports, books, conference proceedings, and dissertations. Electronic only journals and Web preprints are also covered.</p> <p>Bibliographic terms, indexing terms, roles, CAS Registry Numbers, International Patent Classification, and abstracts are searchable.</p>

Host	File	Description
STN	MEDLINE	<p>MEDLINE contains information on every area of medicine. The MEDLINE database corresponds to Index Medicus, Index to Dental Literature, and International Nursing Index; OLDMEDLINE, with data from NLM's from the Cumulated Index Medicus (1960-1965) and Current List of Medical Literature (1958-1959); and, since August 2001, IN-PROCESS records, the latest documents before they have been completely indexed for inclusion on MEDLINE.</p> <p>Sources include journals and chapters in books or symposia. Bibliographic information, indexing terms, abstracts, chemical names, and CAS Registry Numbers are all searchable.</p> <p>Online thesauri are available for the Medical Subject Headings (/MN), Controlled Terms (/CT) and Chemical Name (/CN) fields.</p>

Appendix 2: Search history

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FILE 'MEDLINE, BIOSIS, CABA, AGRICOLA, HCAPLUS' ENTERED AT 15:56:53 ON 17
JUL 2024
L1          76 SEA LL55 OR A5547-127 OR A5547(W) 127 OR A(W) 5547(W) 127 OR
ACS-GM006-4 OR ACS-GMO06-4 OR ACS(W) GM006(W) 4 OR ACS(W)
GMO06(W) 4 OR ACSGM006(W) 4 OR ACSGMO06(W) 4
L2          66839 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY(W
) LINK OR LIBERTY(W) LINKTM OR LIBERTY(W) LINKRTM OR LL OR
LLTM OR LLRTM
L3          13187 SEA ((BAR OR PAT) (2A) (GENE# OR PROTEIN# OR ENZYME#)) OR
PPT(2W) ACETYLTRANSFERASE OR PPT(2W) ACETYL(W) TRANSFERASE OR
PT(W) N(2W) ACETYLTRANSFERASE OR PT(W) N(2W) ACETYL(W)
TRANSFERASE
L4          2029 SEA PHOSPHINOTHRICIN(W) N(W) ACETYLTRANSFERASE OR PHOSPHINOTHRI
CIN(2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W) ACETYL(W)
TRANSFERASE OR PHOSPHINOTHRICINACETYL(W) TRANSFERASE
L5          13889 SEA (L3 OR L4)
L6          77418 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR
PROTECT?)
L7          1053756 SEA SOY OR SOYA OR SOJA OR SOYBEAN# OR SOYABEAN# OR SOJABEAN#
OR GLYCINE(W) MAX OR G(W) MAX
L8          5981290 SEA GMO OR GMOS OR LMO OR LMOS OR GM OR GE OR TRANSGEN? OR
(GENETIC?(3A) (MODIF? OR TRANSFORM? OR MANIPULAT? OR IMPROV? OR
ENGINEER?))
L9          722 SEA L2 AND L7
L10         962 SEA L5 AND L7
L11         9242 SEA L6 AND L7 AND L8
L12         10575 SEA L1 OR L9 OR L10 OR L11
L13         1689 SEA L12 AND PY>=2022
L14         544 SEA L13 AND UP>=20230701 AND UP<=20240630
L15         145 SEA L14 NOT P/DT
L16         0 SEA L14 AND (P/DT AND (J/DT OR A/DT))
SET MSTEPS ON
D SET
L17         16 SEA L15 OR L16
L18         38 SEA L15 OR L16
L19         37 SEA L15 OR L16
L20         21 SEA L15 OR L16
L21         33 SEA L15 OR L16
TOTAL FOR ALL FILES
L22         145 SEA L15 OR L16
L23         107 DUP REM L22 (38 DUPLICATES REMOVED)
D L23 ALL TOT
```