

Title

**Summary of the Literature Review for A2704-12 soybean
October 1, 2021 – June 30, 2022**

Final ReportData 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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Report No: 22-RSSB0479
Summary of the Literature Review for A2704-12 soybean
October 1, 2021 – June 30, 2022
Page 3 of 27

SIGNATURE PAGE

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<p>Report</p>	<p>████████████████████ ████████████████████ ████████████████████</p>

TABLE OF CONTENTS

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS	2
SIGNATURE PAGE	3
Study Personnel	4
TABLE OF CONTENTS	5
TABLES	6
Appendices	6
SUMMARY	7
1. INTRODUCTION	8
2. OVERALL METHODS	8
2.1. Objective of the scoping review	8
2.2. Review questions	8
2.3. Criteria for relevance	9
2.4. Reference publication	12
3. SEARCH METHODS AND OUTCOMES	12
3.1. Time window and date of the literature search	13
3.2. Databases used in the literature search	13
3.3. Search strategy	13
4. INTERNET and MANUAL SEARCHES	16
4.1. Internet Searches of food safety, agriculture, and biotechnology-related authority webpages	16
4.2. Manual searches of reference lists of recent review articles	17
5. RESULTS OF THE STUDY IDENTIFICATION AND SELECTION PROCESS	18
5.1. Screening of titles and abstracts to exclude obviously irrelevant references (Stage 1)	18
5.2. Detailed assessment of eligible references (Stage 2)	18
6. NARRATIVE SYNTHESIS/SUMMARY OF RELEVANT STUDIES	19
7. CONCLUSION	19
8. REFERENCES	19
9. APPENDICES	23

TABLES

Table 1:	Eligibility/inclusion criteria to establish the relevance of retrieved publications	9
Table 2:	Search profile for database search.....	13
Table 3:	Relevant controlled terms (CT) and index terms (IT) in each database.....	14
Table 4:	Overview of the selected databases and summary of search results from each database	15
Table 5:	Results of search of food safety, agriculture, and biotechnology-related authority websites.....	16
Table 6:	Documents for which reference lists were scanned for relevant studies	17
Table 7:	Results of the publication selection process	18
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)	20
Table 9:	Report of publications excluded from the risk assessment after detailed assessment of full-text documents.....	20
Table 10:	Report of unobtainable/unclear publications	21
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).....	22

APPENDICES

Appendix 1	Database descriptions	23
Appendix 2	Search history	25

SUMMARY

Glycine max (soybean) plants were transformed by direct gene transfer using transformation vector pB2/35S Δ CK. The vector contains a *pat* gene cassette conferring tolerance to the herbicide glufosinate-ammonium and the betalactamase (*bla*) antibiotic resistance gene. Prior to transformation, the vector was digested with the *PvuI* restriction enzyme to disrupt the coding sequence of the *bla* gene and thereby removing any remote possibility of its expression.

The *Glycine max* transformation A2704-12 soybean contains two copies of the *pat* gene cassette, which are integrated into the plant genome in a “head-to-tail” configuration at one insertion site. One fragment of the 3' *bla* sequence and one fragment of the 5' *bla* sequence are integrated in between the two *pat* cassettes. The OECD identifier is ACS-GMØØ5-3.

A scoping review was performed for the A2704-12 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 A2704-12 soybean, its effect on food and feed safety or environmental safety, that might require in-depth examination. A set of broad literature searches was performed using several bibliographic databases covering scientific literature from October 1, 2021 to June 30, 2022. 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 122 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 6 publications were progressed for detailed assessment.

The 6 publications were determined to be not relevant after detailed review. No publications were found that constituted new data on molecular characterization of A2704-12 soybean or the PAT/*pat* protein, or suggested 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 identified no relevant publication that supports the existing safety assessment of A2704-12 soybean.

1. INTRODUCTION

Glycine max (soybean) plants were transformed by direct gene transfer using transformation vector pB2/35SAcK. The vector contains a *pat* gene cassette conferring tolerance to the herbicide glufosinate-ammonium and the betalactamase (*bla*) antibiotic resistance gene. Prior to transformation, the vector was digested with the *PvuI* restriction enzyme to disrupt the coding sequence of the *bla* gene and thereby removing any remote possibility of its expression.

The *Glycine max* transformation A2704-12 soybean contains two copies of the *pat* gene cassette, which are integrated into the plant genome in a “head-to-tail” configuration at one insertion site. One fragment of the 3' *bla* sequence and one fragment of the 5' *bla* sequence are integrated in between the two *pat* cassettes. The OECD identifier is ACS-GMØØ5-3.

The objective of the literature searches described here was to determine if there were studies published between October 1, 2021 and June 30, 2022 that mention the molecular characterization of the A2704-12 soybean, and/or any adverse effect of A2704-12 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 the A2704-12 soybean and its newly expressed protein, PAT/*pat*. The search terms also included relevant synonyms, trade name and intended traits, plant species and general GMO terms.

2. OVERALL METHODS

2.1. Objective of the scoping review

The objective of the scoping review was to survey the evidence base for the A2704-12 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 note¹.

Question 1: Were any studies published during the reporting period that describe adverse effects on human or animal health or the environment of the A2704-12 soybean and its newly expressed protein PAT/*pat*?

Key elements:

Population: Human health; animal health; environmental safety

Exposure: A2704-12 soybean, derived food/feed products, newly expressed protein in A2704-12 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 the A2704-12 soybean and its newly expressed protein PAT/*pat* in soybean?

Key elements:

Population: A2704-12 soybean and newly expressed protein in A2704-12 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 note¹ and are described in [Table 1](#).

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
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

Concepts	Criteria	Comment
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
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

Concepts	Criteria	Comment
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.

2.4. Reference publication

Two publications relevant for A2704-12 soybean were previously identified and used to test and validate the search strategy:

- Federici, S.; Paraskevopoulos, K. (2018). Risk assessment of new sequencing information for genetically modified soybean A2704-12. *EFSA Journal* 16(11):e05496.
- Naegeli, H.; Bresson, J. L.; Dalmay, T.; Dewhurst, I. C.; Epstein, M.; Firbank, L. G.; Guerche, P.; Hejatko, J.; Moreno, F. J.; Mullins, E.; Nogue, F.; Rostoks, N.; Serrano, J. J. S.; Savoini, G.; Veromann, E.; Veronesi, F.; Alvarez, F.; Ardizzone, M.; Papadopoulou, N.; Paraskevopoulos, K. (2019). Assessment of genetically modified soybean A2704-12 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-009). *EFSA Journal* 17(1):e05523

These articles selected as reference publications because they mention the event name (A2704-12), the intended trait (herbicide tolerance) and the crop (soybean). Since these reference were published outside the searched time, the profile was tested without applying the time limits used in the final search profile (UP>=20211001 and UP<=20220630).

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 activities¹. 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, designed search strategies, and conducted the searches.

3.1. Time window and date of the literature search

The database searches were performed on July 19, 2022. Only documents updated between October 1, 2021 and June 30, 2022, were considered in the search. The dates of most recent database updates are provided in [Table 3](#).

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 event name, newly expressed proteins and intended traits. The reference publication ([Section 2.4](#)) was identified by the search profiles confirming the validity of the applied search strategy. 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. See [Table 2](#) for a detailed search profile.

Table 2: Search profile for database search

Set	Search string	Concepts
1	LL27 or A2704-12 or A2704(w)12 or A(w)2704(w)12 or ACS-GM005-3 or ACS-GM005-3 or ACS(w)GM005(w)3 or ACS(w)GM005(w)3 or ACSGM005(w)3 or ACSGM005(w)3	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
4	(herbicide? 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)
- **CA-Plus:** 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"

Database	Event	New protein	Intended traits	Plant species	GM 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 October 1, 2021 and June 30, 2022 (UP>=20211001 and UP<=20220630), 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 CAPlus.

[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	CAB Abstracts	CAPLUS	MEDLINE
Database Provider	STN International				
Coverage	1970-present	1926-present	1973-present	1907-present	1946-present
Date of search	19 July 2022				
Datespan of the search	1 Oct 2021 – 30 Jun 2022				
Latest database update	8 July 2022	13 July 2022	13 July 2022	18 July 2022	18 July 2022
Number of records retrieved	12	27	36	58	26
Number of records after duplicate removal	5	20	25	46	26
Number of relevant records after rapid assessment	0	3	0	1	2

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: October 1, 2021 to June 30, 2022) or refer to relevant records published during this time frame. Relevance of results were determined based on the criteria listed in [Table 1](#) and they were summarized in [Table 5](#). All web pages searched were justified by their recommendation in the EFSA 2019 explanatory note¹. Of the 13 key organisations cited in the EFSA 2019 explanatory note¹, 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 the A2704-12 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 10 key organisations relevant for A2704-12 soybean. Search terms consisted of LL27 or A2704-12 or LIBERTYLINK SOY 27 or ACS-GMØØ5-3 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/	Sept 5 2022	Sept 5 2022	0
US Food and Drug Administration (FDA)	https://www.fda.gov/	Sept 7 2022	Sept 7 2022	0
Health Canada	https://www.canada.ca/en/health-canada.html	Aug 1 2022	Aug 31 2022 – Sept 1, 2022	0
Canadian Food Inspection Agency (CFIA)	https://www.canada.ca/en/food-inspection-agency.html	Aug 1 2022	Sept 2-7 2022	0
Food Standards Australia New Zealand (FSANZ)	http://www.foodstandards.gov.au/Pages/default.aspx	Aug 12, 2022	Aug 24, 2022	0
Office of the Gene Technology Regulator (OGTR) Australia	http://www.ogtr.gov.au/	Aug 1, 2022	Aug 29, 2022	0
National Technical Commission on Biosafety (CTNBio) Brazil	http://ctnbio.mcti.gov.br/en	Aug 1, 2022	Aug 29, 2022	0
National Advisory Commission on Agricultural Biotechnology (CONABIA) Argentina	https://www.argentina.gob.ar/agroindustria/bioeconomia/biotecnologia	Aug 9, 2022	Aug 9, 2022	0
Ministry of Agriculture, Forestry and Fisheries (MAFF) Japan	http://www.maff.go.jp/	Sept 6, 2022	Sept 6, 2022	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 October 1, 2021 and June 30, 2022. 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	Ahmad A, Munawar N, Khan Z, Qusmani AT, Khan SH, Jamil A, Ashraf S, Ghouri MZ, Aslam S, Mubarak MS, Munir A, Sultan Q, Abd-Elsalam KA, Qari SH. 2021	An Outlook on Global Regulatory Landscape for Genome-Edited Crops	Int J Mol Sci. 2021 Oct 29;22(21):11753.	0
2	Halder K, Chaudhuri A, Abdin MZ, Majee M, Datta A. 2022	RNA Interference for Improving Disease Resistance in Plants and Its Relevance in This Clustered Regularly Interspaced Short Palindromic Repeats-Dominated Era in Terms of dsRNA-Based Biopesticides	Front Plant Sci. 2022 May 13;13:885128.	0
3	Kawall K. 2021	The Generic Risks and the Potential of SDN-1 Applications in Crop Plants	Plants (Basel). 2021 Oct 22;10(11):2259.	0
4	Lafiandra D, Sestili F, Sissons M, Kiszonas A, Morris CF. 2022	Increasing the Versatility of Durum Wheat through Modifications of Protein and Starch Composition and Grain Hardness	Foods. 2022 May 24;11(11):1532.	0
5	Nagamine A, Ezura H. 2022	Genome Editing for Improving Crop Nutrition	Front Genome Ed. 2022 Feb 9;4:850104.	0
6	Niraula PM, Fondong VN. 2021	Development and Adoption of Genetically Engineered Plants for Virus Resistance: Advances, Opportunities and Challenges	Plants (Basel). 2021 Oct 29;10(11):2339.	0
7	Okoli AS, Blix T, Myhr AI, Xu W, Xu X. 2022	Sustainable use of CRISPR/Cas in fish aquaculture: the biosafety perspective	Transgenic Res. 2022 Feb;31(1):1-21.	0
8	Then C. 2022	Deficiencies in the Risk Assessment of Genetically Engineered Bt Cowpea Approved for Cultivation in Nigeria: A Critical Review	Plants (Basel). 2022 Jan 29;11(3):380.	0
9	Van Vu T. 2022	Genome editing and beyond: what does it mean for the future of plant breeding?	Planta. 2022 May 19;255(6):130.	0

5. RESULTS OF THE STUDY IDENTIFICATION AND SELECTION PROCESS

The database searches ([Section 3](#)) identified a total of 159 references, which were reduced to 122 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 the discussion was transferred to Stage 2 for detailed evaluation by the experts. In this search, both evaluator 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 resistant 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](#)).

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

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.

[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)	122
Number of publications excluded from the search results after rapid assessment for relevance (Stage 1)	116
Total number of full-text documents assessed in detail	6
Number of publications excluded from further consideration after detailed assessment for relevance (Stage 2)	6
Total number of unobtainable/unclear publications	0
Total number of relevant publications	0

[Table 8](#) lists the publications determined to be relevant along with their potential impact on the safety assessment based on 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 6 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 the A2704-12 soybean and its newly expressed protein PAT/pat.

[Table 11](#) lists the relevant publication along with a summary of any adverse effects reported and the reliability of the publications.

7. CONCLUSION

The literature searches performed for the A2704-12 soybean and its newly expressed protein, PAT/pat, for the period from October 1, 2021 to June 30, 2022, identified a total of 122 unique publications (after duplicate removal). A total of 6 publications were progressed for detailed assessment after excluding 116 obviously irrelevant publications during Stage 1 evaluation (rapid assessment based on title and abstract).

The 6 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 reference with bearing on molecular characterization was identified. The data and knowledge generated from this study does not impact the safety assessment of A2704-12 soybean. 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
Yook, Min-Jung Park, Hae-Rim Zhang, Chuan-Jie Lim, Soo-Hyun Jeong, Soon-Chun Chung, Young Soo Kim, Do-Soon 2021	Environmental risk assessment of glufosinate -resistant soybean by pollen-mediated gene flow under field conditions in the region of the genetic origin.	Science of the Total Environment, (MAR 25 2021) Vol. 762, pp. Article No.: 143073. https://www.sciencedirect.com/journal/science-of-the-total-environment. CODEN: STENDL. ISSN: 0048-9697. E-ISSN: 1879-1026.	The authors conducted a two-year field experiment to quantify the gene flow from GM soybean (event AtSIZ #6) to wild soybean and model the potential gene flow under field conditions in Korea. In addition, field performance of hybrids resulted from gene flow was evaluated and compared with parent soybeans (GM and wild soybean) to estimate the potential weed risk of hybrids. A2704-12 soybean was not included in the study.
Lee, Hyosun Yoon, Jeongpyo Kim, Dong-Uk 2022	Molecular Analysis of Soil Bacterial Community Structures for Environmental Risk Assessment with Varieties of Genetically Modified Soybean and Hot Pepper	Processes (2022), 10(5), 1037 CODEN: PROCCO; ISSN: 2227-9717 URL: https://www.mdpi.com/journal/processes	The authors aimed to assess the impacts of GM soybean and hot pepper containing glufosinate-resistance gene (bar) on soil microbial communities and monitor the persistence of transgenes in the rhizosphere soil during two growing seasons in Korea. The germplasm tested were provided by the Crop Molecular Physiology & Weed Science Laboratory in Seoul National University and Nongwoobio Co., Ltd. in Yeosu-si, Korea. Soil microbial community structures were not significantly affected. A2704-12 soybean was not included in the study.
Yang Qianwen, Wang Yu, Liu Hua, Wang Jinbin, Zeng Haijuan, Liu Xiaofeng, Bao Huifang 2021	A Label-Free Immunosensor Based on Gold Nanoparticles/ Thionine for Sensitive Detection of PAT Protein in Genetically Modified Crops.	Frontiers in chemistry, (2021) Vol. 9, pp. 770584. Electronic Publication Date: 7 Dec 2021 Journal code: 101627988. ISSN: 2296-2646. L-ISSN: 2296-2646. Report No.: PMC-PMC8688707.	A thionine-based method for detection of PAT protein was tested using seed powder material of A2704-12 soybean. Detection methods are excluded from this search as they are not necessarily relevant to the risk assessment of GMOs. (see inclusion / exclusion criteria described in Table 1)

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
Mullins Ewen, Bresson Jean-Louis, Dalmay Tamas, Dewhurst Ian Crawford, Epstein Michelle M, Firbank Leslie George, Guerche Philippe, Hejtko Jan, Moreno Francisco Javier, Naegeli Hanspeter, Nogue Fabien, Rostoks Nils, Sanchez Serrano Jose Juan, Savoini Giovanni, Veromann Eve, Veronesi Fabio, Ardizzone Michele, Fernandez Antonio, Kagkli Dafni Maria, Lewandowska Aleksandra, Raffaello Tommaso, Streissl Franz 2022	Assessment of genetically modified soybean A5547-127 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO -RX-020).	EFSA journal. European Food Safety Authority. (2022 Jun) Vol. 20, No. 6, pp. e07340. Electronic Publication Date: 20 Jun 2022 Journal code: 101642076. E-ISSN: 1831-4732. L-ISSN: 1831-4732. Report No.: PMC-PMC9207747.	Risk assessment related to A5547-127 soybean. Not related with A2704-12 soybean.
Fast, Brandon J. Shan, Guomin Gampala, Satyalinga Srinivas Herman, Rod A. 2020	Transgene expression in sprayed and non-sprayed herbicide - tolerant genetically engineered crops is equivalent.	Regulatory Toxicology and Pharmacology. (MAR 2020) Vol. 111, pp. Article No.: 104572. http://www.journals.elsevier.com/regulatory-toxicology-and-pharmacology/#description. CODEN: RTOPDW. ISSN: 0273-2300. E-ISSN: 1096-0295.	A2704-12 soybean was not considered in this study.
Albrecht, Alfredo Junior P. de Brito, Ivana Paula F. S. Albrecht, Leandro P. Silva, Andre Felipe M. de Matos, Ana Karollyna A. Carbonari, Caio Antonio Velini, Edivaldo D.	Metabolic changes, agronomic performance, and quality of seeds in soybean with the pat gene after application of glufosinate.	Weed Science. (NOV 2020) Vol. 68, No. 6, pp. 594-604. https://www.cambridge.org/core/journals/weed-science. CODEN: WEESA6. ISSN: 0043-1745. E-ISSN: 1550-2759.	The paper mainly focus in the effects of glufosinate and is not direct related to the safety of A2704-12 soybean.

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/CAPLUS	<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

FILE 'MEDLINE' ENTERED AT 15:18:13 ON 19 JUL 2022

L1 17 SEA LL27 OR A2704-12 OR A2704(W)12 OR A(W)2704(W)12 OR
ACS-GM005-3 OR ACS-GMO05-3 OR ACS(W)GM005(W)3 OR ACS(W)GMO05(W)
3 OR ACSGM005(W)3 OR ACSGMO05(W)3

L2 14597 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 1513 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 204 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L5 1587 SEA (L3 OR L4)

L6 3571 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR
PROTECT?)

L7 70108 SEA SOY OR SOYA OR SOJA OR SOYBEAN# OR SOYABEAN# OR SOJABEAN#
OR GLYCINE(W)MAX OR G(W)MAX

L8 4014335 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 53 SEA L2 AND L7

L10 55 SEA L5 AND L7

L11 255 SEA L6 AND L7 AND L8

L12 350 SEA L1 OR L9 OR L10 OR L11

L13 51 SEA L12 AND PY>=2020

L14 26 SEA L13 AND UP>=20211001 AND UP<=20220630

FILE 'BIOSIS' ENTERED AT 15:18:19 ON 19 JUL 2022

L15 31 SEA LL27 OR A2704-12 OR A2704(W)12 OR A(W)2704(W)12 OR
ACS-GM005-3 OR ACS-GMO05-3 OR ACS(W)GM005(W)3 OR ACS(W)GMO05(W)
3 OR ACSGM005(W)3 OR ACSGMO05(W)3

L16 15203 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY(W)
)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM OR LL OR LLTM
OR LLRTM

L17 2901 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

L18 334 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L19 3005 SEA (L17 OR L18)

L20 10245 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR
PROTECT?)

L21 172881 SEA SOY OR SOYA OR SOJA OR SOYBEAN# OR SOYABEAN# OR SOJABEAN#
OR GLYCINE(W)MAX OR G(W)MAX

L22 478634 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?))

L23 121 SEA L16 AND L21

L24 123 SEA L19 AND L21

L25 422 SEA L20 AND L21 AND L22

L26 643 SEA L15 OR L23 OR L24 OR L25

L27 57 SEA L26 AND PY>=2020

L28 27 SEA L27 AND UP>=20211001 AND UP<=20220630

FILE 'AGRICOLA' ENTERED AT 15:18:25 ON 19 JUL 2022

L29 17 SEA LL27 OR A2704-12 OR A2704(W)12 OR A(W)2704(W)12 OR
ACS-GM005-3 OR ACS-GMO05-3 OR ACS(W)GM005(W)3 OR ACS(W)GMO05(W)

3 OR ACSGM005(W)3 OR ACSGM005(W)3
L30 3541 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY(W)
)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM OR LL OR LLTM
OR LLRTM
L31 813 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
L32 255 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE
L33 894 SEA (L31 OR L32)
L34 8673 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR
PROTECT?)
L35 97946 SEA SOY OR SOYA OR SOJA OR SOYBEAN# OR SOYABEAN# OR SOJABEAN#
OR GLYCINE(W)MAX OR G(W)MAX
L36 110181 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?))
L37 79 SEA L30 AND L35
L38 47 SEA L33 AND L35
L39 407 SEA L34 AND L35 AND L36
L40 525 SEA L29 OR L37 OR L38 OR L39
L41 36 SEA L40 AND PY>=2020
L42 12 SEA L41 AND UP>=20211001 AND UP<=20220630

FILE 'CABA' ENTERED AT 15:18:38 ON 19 JUL 2022

L43 32 SEA LL27 OR A2704-12 OR A2704(W)12 OR A(W)2704(W)12 OR
ACS-GM005-3 OR ACS-GMO05-3 OR ACS(W)GM005(W)3 OR ACS(W)GMO05(W)
3 OR ACSGM005(W)3 OR ACSGM005(W)3
L44 5676 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY(W)
)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM OR LL OR LLTM
OR LLRTM
L45 1580 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
L46 380 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE
L47 1682 SEA (L45 OR L46)
L48 19007 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR
PROTECT?)
L49 200737 SEA SOY OR SOYA OR SOJA OR SOYBEAN# OR SOYABEAN# OR SOJABEAN#
OR GLYCINE(W)MAX OR G(W)MAX
L50 193516 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?))
L51 155 SEA L44 AND L49
L52 113 SEA L47 AND L49
L53 805 SEA L48 AND L49 AND L50
L54 1033 SEA L43 OR L51 OR L52 OR L53
L55 1033 SEA L54 NOT P/DT
L56 0 SEA L54 AND (P/DT AND J/DT)
L57 1033 SEA L55 OR L56
L58 108 SEA L57 AND PY>=2020
L59 36 SEA L58 AND UP>=20211001 AND UP<=20220630

FILE 'HCAPLUS' ENTERED AT 15:18:48 ON 19 JUL 2022

L60 43 SEA LL27 OR A2704-12 OR A2704(W)12 OR A(W)2704(W)12 OR
ACS-GM005-3 OR ACS-GMO05-3 OR ACS(W)GM005(W)3 OR ACS(W)GMO05(W)
3 OR ACSGM005(W)3 OR ACSGM005(W)3
L61 21031 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY(W)

) LINK OR LIBERTY(W) LINKTM OR LIBERTY(W) LINKRTM OR LL OR LLTM
OR LLRTM

L62 5402 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

L63 793 SEA PHOSPHINOTHRICIN(W)N(W) ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W) ACETYL(W) TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W) TRANSFERASE

L64 5708 SEA (L62 OR L63)

L65 29163 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR
PROTECT?)

L66 427964 SEA SOY OR SOYA OR SOJA OR SOYBEAN# OR SOYABEAN# OR SOJABEAN#
OR GLYCINE(W)MAX OR G(W)MAX

L67 717310 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?))

L68 240 SEA L61 AND L66

L69 531 SEA L64 AND L66

L70 6402 SEA L65 AND L66 AND L67

L71 6975 SEA L60 OR L68 OR L69 OR L70

L72 787 SEA L71 NOT P/DT

L73 0 SEA L71 AND (P/DT AND J/DT)

L74 787 SEA L72 OR L73

L75 107 SEA L74 AND PY>=2020

L76 58 SEA L75 AND UP>=20211001 AND UP<=20220630

FILE 'MEDLINE, BIOSIS, AGRICOLA, CABA, HCAPLUS' ENTERED AT 09:18:54 ON 19
JUL 2022

L77 122 DUP REM L14 L28 L42 L59 L76 (37 DUPLICATES REMOVED)
ANSWERS '1-26' FROM FILE MEDLINE
ANSWERS '27-46' FROM FILE BIOSIS
ANSWERS '47-51' FROM FILE AGRICOLA
ANSWERS '52-76' FROM FILE CABA
ANSWERS '77-122' FROM FILE HCAPLUS