

Title

**Summary of the Literature Review for T25 corn
July 1, 2022 – June 30, 2023**

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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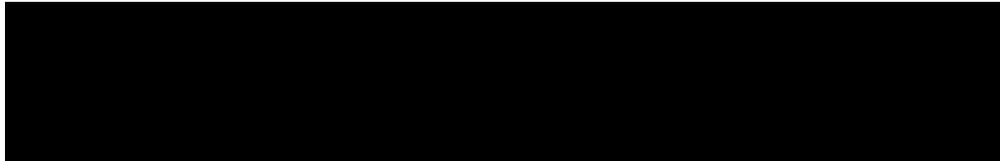
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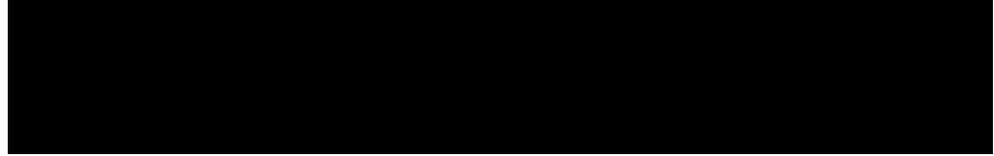


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TABLE OF CONTENTS

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	17
4.1. Internet Searches of food safety, agriculture, and biotechnology-related authority webpages	17
4.2. Manual searches of reference lists of recent review articles.....	18
5. RESULTS OF THE STUDY IDENTIFICATION AND SELECTION PROCESS.....	20
5.1. Screening of titles and abstracts to exclude obviously irrelevant references (Stage 1)...	21
5.2. Detailed assessment of eligible references (Stage 2).....	21
6. NARRATIVE SYNTHESIS/SUMMARY OF RELEVANT STUDIES	25
7. CONCLUSION	27
8. REFERENCES	27
9. APPENDICES.....	28

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	16
Table 4: Overview of the selected databases and summary of search results from each database	16
Table 5: Results of search of food safety, agriculture, and biotechnology-related authority websites	17
Table 6: Documents for which reference lists were scanned for relevant studies	18
Table 7: Results of the publication selection process	21
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)	22
Table 9: Report of publications excluded from the risk assessment after detailed assessment of full-text documents	22
Table 10: Report of unobtainable/unclear publications	24
Table 11: Summary report for all relevant publications retrieved after detailed assessment of full-text documents for and implications for the risk assessment: ordered by category of information/data requirement(s)	26

APPENDICES

Appendix 1: Database descriptions	28
Appendix 2: Search history	30

SUMMARY

The T25 Zea mays plant (maize, corn) 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 T25 tolerant to the glufosinate-ammonium herbicides. The OECD identifier is ACS-ZMØØ3-2.

A scoping review was performed for the T25 corn 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 T25 corn, 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 July 1, 2022 to June 30, 2023. 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 526 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 4 publications were progressed for detailed assessment.

No new publications were found that contained new data on the molecular characterization of T25 corn and its newly expressed protein PAT/*pat*. Similarly, no new publications were found that suggested any potential adverse effects of T25 corn on human health, animal health, or the environment. No issues or topics were identified that would warrant conducting a systematic review.

1. INTRODUCTION

The T25 Zea mays plant (maize, corn) 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 T25 tolerant to the glufosinate-ammonium herbicides. The OECD identifier is ACS-ZMØØ3-2.

The objective of the literature searches described here was to determine if there were publications published between July 1, 2022 and June 30, 2023 that mention the molecular characterization of the T25 corn, and/or any adverse effect of T25 corn 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)¹ applications and post-market environmental monitoring activities (2019).

The literature searches were performed for the T25 corn 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 the T25 corn 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 T25 corn and its newly expressed protein PAT/*pat*?

Key elements:

Population: Human health; animal health; environmental safety

Exposure: T25 corn, derived food/feed products, newly expressed protein in T25 corn

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 T25 corn and its newly expressed protein PAT/*pat* in corn?

Key elements:

Population: T25 corn and newly expressed protein in T25 corn

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

No relevant publications for T25 corn were known before starting the search, therefore, a related publication. This publication was selected as reference publication because it includes the intended trait (glufosinate resistance) and the crop of interest (corn)

- Krenchinski FH; Carbonari CA; Cesco VJ; Albrecht AJ; Campos Arcuri ML; de Godoy MI; Velini ED (2018). Glufosinate resistance level is proportional to phosphinothricin acetyltransferase gene expression in glufosinate-resistant maize. *Journal of Agriculture and Food Chemistry* 66(48):12641-12650

Since this article was published outside the search period, the search profiles were tested excluding the time limitation used in the final search profile (UP>=20220701 and UP<=20230630).

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 17, 2023. Only documents updated between July 1, 2022 and June 30, 2023, were considered in the search. The dates of 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 profile was designed to cover event name, trade name, newly expressed protein and intended trait. Since the 'trade name', the 'newly expressed protein' and the 'intended trait' profiles produced too many results when used on their own, they were combined with additional profiles: the 'trade name' and 'newly expressed protein' profiles were combined with a 'plant species' profile while the 'intended trait' profile was combined with a 'general GMO' profile as well as with the 'plant species' profile. The reference publication ([Section 2.4](#)) was identified by the search profile, 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	T25 or T(w)25 or ACS-ZM003-2 or ACS-ZMOO3-2 or ACS(w)ZM003(w)2 or ACS(w)ZMOO3(w)2 or ACSZM003-2 or ACSZMOO3-2	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	corn# or maize# or maiz or zea(w)mays or z(w)mays or chardon	Plant species

Set	Search string	Concepts
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"	CORN MAIZE "ZEA MAYS"	"TRANSGENIC PLANTS"
Biosis	None	None	No terms	None	None
CABA	None	None	"HERBICIDE RESISTANCE"	MAIZE	"TRANSGENIC PLANTS"
CAS	None	None	"HERBICIDE RESISTANCE"	CORN "ZEA MAYS"	"GENETICALLY MODIFIED PLANTS"
Medline	None	None	"HERBICIDE RESISTANCE"	"ZEA MAYS"	"PLANTS, GENETICALLY MODIFIED"

The search results were limited to documents updated between July 1, 2022 and June 30, 2023 (UP>=20220701 and UP<=20230630), 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	CABA	CA-Plus	Medline
Database Provider	STN International				
Coverage	1970-present	1926-present	1973-present	1907-present	1946-present
Date of search	17 Jul 2023				
Datespan of the search	1 Jul 2022 – 30 Jun 2023				
Latest database update	10 Jul 2023	12 Jul 2023	27 Jun 2023	16 Jul 2023	16 Jul 2023
Number of records retrieved	30	110	163	250	107
Number of records after duplicate removal	22	85	128	184	107
Number of relevant records after rapid assessment	0	0	2	0	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: July 1, 2022 to June 30, 2023) 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 T25 corn 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 T25 corn. Search terms consisted of T25 or Libertylink corn or ACS-ZMØØ3-2 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/	25/07/2023	25/07/2023	0
US Food and Drug Administration (FDA)	https://www.fda.gov/	25/07/2023	28/07/2023	0
Health Canada	https://www.canada.ca/en/health-canada.html	26/06/2023	10/07/2023	0
Canadian Food Inspection Agency (CFIA)	https://www.canada.ca/en/food-inspection-agency.html	26/06/2023	20/07/2023	0
Food Standards Australia New Zealand (FSANZ)	http://www.foodstandards.gov.au/Pages/default.aspx	30/06/2023	10/07/2023	0
Office of the Gene Technology Regulator (OGTR) Australia	http://www.ogtr.gov.au/	06/04/2023	10/07/2023	0
National Technical Commission on Biosafety (CTNBio) Brazil	http://ctnbio.mcti.gov.br/en	24/07/2023	7/17/2023 to 7/24/2023	0
National Advisory Commission on Agricultural Biotechnology (CONABIA) Argentina	https://www.argentina.gob.ar/agroindustria/bioeconomia/biotecnologia	17/07/2023	17/07/2023	0

Source Site Name	Website URL	Date of Most Recent Site Update	Date of Search	No. of Relevant Records
Ministry of Agriculture, Forestry and Fisheries (MAFF) Japan	http://www.maff.go.jp/	27/07/2023	27/07/2023	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, 2022 and June 30, 2023. 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	Bhattacharjee S, Bhowmick R, Kant L, Paul K. 2023	Strategic transgene-free approaches of CRISPR-based genome editing in plants.	Mol Genet Genomics. 2023 May;298(3):507-520	0
2	Cermakova E, Lencova S, Mukherjee S, Horka P, Vobruba S, Demnerova K, Zdenkova K. 2023	Identification of Fish Species and Targeted Genetic Modifications Based on DNA Analysis: State of the Art.	Foods. 2023 Jan 3;12(1):228.	0
3	Connolly JB, Romeis J, Devos Y, Glandorf DCM, Turner G, Coulibaly MB. 2023	Gene drive in species complexes: defining target organisms.	Trends Biotechnol. 2023 Feb;41(2):154-164.	0
4	Eckerstorfer MF, Dolezel M, Engelhard M, Giovannelli V, Grabowski M, Heissenberger A, Lener M, Reichenbecher W, Simon S, Staiano G, Wüst Saucy AG, Zünd J, Lüthi C. 2023	Recommendations for the Assessment of Potential Environmental Effects of Genome-Editing Applications in Plants in the EU.	Plants (Basel). 2023 Apr 25;12(9):1764.	0

No	Author(s) and Year	Title	Source	Number of relevant bibliographic references retrieved
5	Ghidoli M, Ponzoni E, Araniti F, Miglio D, Pilu R. 2023	Genetic Improvement of <i>Camelina sativa</i> (L.) Crantz: Opportunities and Challenges.	Plants (Basel). 2023 Jan 27;12(3):570.	0
6	Krasnodębski C, Sawuła A, Kaźmierczak U, Żuk M. 2023	Oligo-Not Only for Silencing: Overlooked Potential for Multidirectional Action in Plants.	Int J Mol Sci. 2023 Feb 24;24(5):4466.	0
7	Křížkovská B, Viktorová J, Lipov J. 2022	Approved Genetically Modified Potatoes (<i>Solanum tuberosum</i>) for Improved Stress Resistance and Food Safety.	J Agric Food Chem. 2022 Sep 28;70(38):11833-11843.	0
8	Liang J, Yang X, Jiao Y, Wang D, Zhao Q, Sun Y, Li Y, Wu K. 2022	The evolution of China's regulation of agricultural biotechnology.	aBIOTECH. 2022 Dec 5;3(4):237-249.	0
9	Platani M, Sokefun O, Bassil E, Apidianakis Y. 2023	Genetic engineering and genome editing in plants, animals, and humans: Facts and myths. Gene.	2023 Mar 10; 856:147141.	0
10	Pott A, Bundschuh M, Otto M, Schulz R. 2023	Assessing Effects of Genetically Modified Plant Material on the Aquatic Environment Using higher-tier Studies.	Bull Environ Contam Toxicol. 2023 Jan 2;110(1):35.	0
11	Rai GK, Kumar P, Choudhary SM, Kosser R, Khanday DM, Choudhary S, Kumar B, Magotra I, Kumar RR, Ram C, Rouphael Y, Corrado G, Behera TK. 2022	Biomimetic Strategies for Developing Abiotic Stress-Tolerant Tomato Cultivars:	An Overview. Plants (Basel). 2022 Dec 23;12(1):86	0
12	Rozas P, Kessi-Pérez EI, Martínez C. 2022	Genetically modified organisms: adapting regulatory frameworks for evolving genome editing technologies.	Biol Res. 2022 Oct 20;55(1):31.	0
13	Spök A, Sprink T, Allan AC, Yamaguchi T, Dayé C. 2022	Towards social acceptability of genome-edited plants in industrialised countries? Emerging evidence from Europe, United States, Canada, Australia, New Zealand, and Japan.	Front Genome Ed. 2022 Aug 31;4:899331.	0

No	Author(s) and Year	Title	Source	Number of relevant bibliographic references retrieved
14	Tatineni S, Hein GL. 2023	Plant Viruses of Agricultural Importance: Current and Future Perspectives of Virus Disease Management Strategies.	Phytopathology. 2023 Feb;113(2):117-141.	0
15	Tripathi S, Purchase D, Chandra R, Nadda AK, Bhargava PC. 2022	Mitigation of hazards and risks of emerging pollutants through innovative treatment techniques of post methanated distillery effluent - A review.	Chemosphere. 2022 Aug;300:134586. doi: 10.1016/j.chemosphere.2022.134586.	0
16	Wang M, Wang H, Li K, Li X, Wang X, Wang Z. 2023	Review of CRISPR/Cas Systems on Detection of Nucleotide Sequences.	Foods. 2023 Jan 19;12(3):477.	0
17	Zimny T. 2023	Regulation of GMO field trials in the EU and new genomic techniques: will the planned reform facilitate experimenting with gene-edited plants?	BioTechnologia (Pozn). 2023 Mar 27;104(1):75-83.	0

5. RESULTS OF THE STUDY IDENTIFICATION AND SELECTION PROCESS

The database searches ([Section 3](#)) identified a total of 660 references, which were reduced to 526 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](#)).

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.

In the relevance assessment of the literature review for the T25 corn, 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)	526
Number of publications excluded from the search results after rapid assessment for relevance (Stage 1)	522
Total number of full-text documents assessed in detail	4
Number of publications excluded from further consideration after detailed assessment for relevance (Stage 2)	4
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.

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
Liu TingTing Tong Tao Huang KunLun Liu, T. T. Tong, T. Huang, K. L. 2022	Research progress and safety evaluation of transgenic corn .	Current Biotechnology (2022), Volume 12, Number 4, pp. 523-531, 65 refs. ISSN: 2095-2341 DOI: https://doi.org/10.19586/j.2095-2341.2021.0196 Published by: Editorial Department of Current Biotechnology, Beijing	The article is a review and does not include primary data.
Ren Zhentao Yang Muzhi Xue Kun He Haopeng Ma Yanjie Zhou Yijun Liu Biao 2022	Transgenic Maize Has Insignificant Effects on the Diversity of Arthropods: A 3-Year Study.	Plants (Basel, Switzerland), (2022 Aug 30) Vol. 11, No. 17. Electronic Publication Date: 30 Aug 2022 Journal code: 101596181. ISSN: 2223-7747. L-ISSN: 2223-7747. Report No.: PMC-PMC9460771.	T25 corn is 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
<p>Mullins Ewen, Bresson Jean-Louis, Dalmay Tamas, Dewhurst Ian Crawford, Epstein Michelle M, Firbank Leslie George, Guerche Philippe, Hejatko Jan, Moreno Francisco Javier, Naegeli Hanspeter, Nogue Fabien, Rostoks Nils, Serrano Jose Juan Sanchez, Savoini Giovanni, Veromann Eve, Veronesi Fabio, Alvarez Fernando, Ardizzone Michele, De Sanctis Giacomo, Devos Yann, Federici Silvia, Fernandez Dumont Antonio, Gennaro Andrea, Gomez Ruiz Jose Angel, Goumperis Tilemachos, Kagkli Dafni Maria, Lanzoni Anna, Lenzi Paolo, Camargo Ana Martin, Neri Franco Maria, Papadopoulou Nikoletta, Paraskevopoulos Konstantinos, Raffaello Tommaso, Streissl Franz</p> <p>2023</p>	<p>Assessment of genetically modified maize GA21 × T25 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2016-137).</p>	<p>EFSA journal. European Food Safety Authority, (2023 Jan) Vol. 21, No. 1, pp. e07729. Electronic Publication Date: 27 Jan 2023 Journal code: 101642076. E-ISSN: 1831-4732. L-ISSN: 1831-4732. Report No.: PMC-PMC9880721.</p>	<p>EFSA evaluation of GA21 × T25. Stacked events are not considered relevant for single events.</p>

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
Mullins, E., Bresson, J. L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Naegeli, H., Moreno, F. J., Nogue, F., Rostoks, N., Serrano, J. J. S., Savoini, G., Veromann, E., Veronesi, F., Ardizzone, M., Sanctis, G. de, Dumont, A. F., Federici, S., Gennaro, A., Ruiz, J. A. G., Kagkli, D. M., Lanzoni, A., Neri, F. M., Papadopoulou, N., Paraskevopoulos, K., Raffaello, T., de Sanctis, G. 2021	Assessment of genetically modified maize NK603 × T25 × DAS-40278-9 and subcombinations, for food and feed uses, under Regulation (EC) no 1829/2003 (application EFSA-GMO-NL-2019-164).	EFSA Journal (2021), Volume 19, Number 12, 56 refs. ISSN: 1831-4732 DOI: https://doi.org/10.2903/j.efsa.a.2021.6942 Published by: Wiley, Oxford	EFSA evaluation of NK603 × T25 × DAS-40278-9. Stacked events are not considered relevant for single events.

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.			

6. NARRATIVE SYNTHESIS/SUMMARY OF RELEVANT STUDIES

A total of 4 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 publication was relevant for the safety assessment of the T25 corn and its newly expressed protein, PAT/*pat*.

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

Table 11: Summary report for all relevant publications retrieved after detailed assessment of full-text documents for 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.					

7. CONCLUSION

The literature searches performed for the T25 corn and its newly expressed protein, PAT/*pat*, for the period from July 1, 2022 to June 30, 2023, identified a total of 526 unique publications (after duplicate removal). A total of 4 publication(s) were progressed for detailed assessment after excluding 522 obviously irrelevant publications during Stage 1 evaluation (rapid assessment based on title and abstract). The 4 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 new publications were found that contained new data on the molecular characterization of T25 corn and its newly expressed protein PAT/*pat*. Similarly, no new publications were found that suggested any potential adverse effects of T25 corn on human health, animal health, or the environment. No issues or topics were identified that would warrant conducting a systematic review.

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. |
|----|---|

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/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 13:28:34 ON 17 JUL 2023

L1 1296 SEA T25 OR T(W)25 OR ACS-ZM003-2 OR ACS-ZMOO3-2 OR ACS(W)ZM003(W)2 OR ACS(W)ZMOO3(W)2 OR ACSZM003-2 OR ACSZMOO3-2

L2 15619 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 1591 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 208 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L5 1666 SEA (L3 OR L4)

L6 3819 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR PROTECT?)

L7 87358 SEA CORN# OR MAIZE# OR MAIZ OR ZEA(W)MAYS OR Z(W)MAYS OR CHARDON

L8 4179324 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 58 SEA L2 AND L7

L10 135 SEA L5 AND L7

L11 421 SEA L6 AND L7 AND L8

L12 1827 SEA L1 OR L9 OR L10 OR L11

L13 260 SEA L12 AND PY>=2021

L14 107 SEA L13 AND UP>=20220701 AND UP<=20230630

FILE 'BIOSIS' ENTERED AT 13:28:39 ON 17 JUL 2023

L15 1343 SEA T25 OR T(W)25 OR ACS-ZM003-2 OR ACS-ZMOO3-2 OR ACS(W)ZM003(W)2 OR ACS(W)ZMOO3(W)2 OR ACSZM003-2 OR ACSZMOO3-2

L16 15869 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 2987 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 337 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L19 3094 SEA (L17 OR L18)

L20 10592 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR PROTECT?)

L21 264176 SEA CORN# OR MAIZE# OR MAIZ OR ZEA(W)MAYS OR Z(W)MAYS OR CHARDON

L22 495499 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 166 SEA L16 AND L21

L24 310 SEA L19 AND L21

L25 619 SEA L20 AND L21 AND L22

L26 2308 SEA L15 OR L23 OR L24 OR L25

L27 200 SEA L26 AND PY>=2021

L28 110 SEA L27 AND UP>=20220701 AND UP<=20230630

FILE 'AGRICOLA' ENTERED AT 13:28:44 ON 17 JUL 2023

L29 455 SEA T25 OR T(W)25 OR ACS-ZM003-2 OR ACS-ZMOO3-2 OR ACS(W)ZM003(W)2 OR ACS(W)ZMOO3(W)2 OR ACSZM003-2 OR ACSZMOO3-2

L30 3716 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 829 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 258 SEA PHOSPHINOTHRICIN (W) N (W) ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N (2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN (2W) ACETYL (W) TRANSFER
ASE OR PHOSPHINOTHRICINACETYL (W) TRANSFERASE
L33 911 SEA (L31 OR L32)
L34 8885 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR
PROTECT?)
L35 160057 SEA CORN# OR MAIZE# OR MAIZ OR ZEA (W) MAYS OR Z (W) MAYS OR
CHARDON
L36 113690 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 105 SEA L30 AND L35
L38 141 SEA L33 AND L35
L39 443 SEA L34 AND L35 AND L36
L40 1056 SEA L29 OR L37 OR L38 OR L39
L41 101 SEA L40 AND PY>=2021
L42 30 SEA L41 AND UP>=20220701 AND UP<=20230630

FILE 'CABA' ENTERED AT 13:28:49 ON 17 JUL 2023
L43 793 SEA T25 OR T (W) 25 OR ACS-ZM003-2 OR ACS-ZMOO3-2 OR ACS (W) ZM003 (W) 2 OR ACS (W) ZMOO3 (W) 2 OR ACSZM003-2 OR ACSZMOO3-2
L44 6044 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 1630 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 387 SEA PHOSPHINOTHRICIN (W) N (W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN (2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN (2W) ACETYL (W) TRANSFERASE OR PHOSPHINOTHRICINACETYL (W) TRANSFERASE
L47 1736 SEA (L45 OR L46)
L48 19754 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR PROTECT?)
L49 377245 SEA CORN# OR MAIZE# OR MAIZ OR ZEA (W) MAYS OR Z (W) MAYS OR CHARDON
L50 204631 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 213 SEA L44 AND L49
L52 301 SEA L47 AND L49
L53 1020 SEA L48 AND L49 AND L50
L54 2133 SEA L43 OR L51 OR L52 OR L53
L55 197 SEA L54 AND PY>=2021
L56 163 SEA L55 AND UP>=20220701 AND UP<=20230630
L57 163 SEA L56 NOT P/DT
L58 0 SEA L56 AND (P/DT AND J/DT)
L59 163 SEA L57 OR L58

FILE 'HCAPLUS' ENTERED AT 13:28:57 ON 17 JUL 2023
L60 3623 SEA T25 OR T (W) 25 OR ACS-ZM003-2 OR ACS-ZMOO3-2 OR ACS (W) ZM003 (W) 2 OR ACS (W) ZMOO3 (W) 2 OR ACSZM003-2 OR ACSZMOO3-2
L61 22229 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 5706 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 809 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFERASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L64 6023 SEA (L62 OR L63)

L65 30990 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR TOLERAN? OR PROTECT?)

L66 434883 SEA CORN# OR MAIZE# OR MAIZ OR ZEA(W)MAYS OR Z(W)MAYS OR CHARDON

L67 747777 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 180 SEA L61 AND L66

L69 808 SEA L64 AND L66

L70 7501 SEA L65 AND L66 AND L67

L71 11712 SEA L60 OR L68 OR L69 OR L70

L72 1921 SEA L71 AND PY>=2021

L73 825 SEA L72 AND UP>=20220701 AND UP<=20230630

L74 249 SEA L73 NOT P/DT

L75 1 SEA L73 AND (P/DT AND J/DT)

L76 250 SEA L74 OR L75

FILE 'MEDLINE, BIOSIS, AGRICOLA, CABA, HCAPLUS' ENTERED AT 07:29:03 ON 17 JUL 2023

CHARGED TO COST=89331119

L77 526 DUP REM L14 L28 L42 L59 L76 (134 DUPLICATES REMOVED)
ANSWERS '1-107' FROM FILE MEDLINE
ANSWERS '108-192' FROM FILE BIOSIS
ANSWERS '193-214' FROM FILE AGRICOLA
ANSWERS '215-342' FROM FILE CABA
ANSWERS '343-526' FROM FILE HCAPLUS