

Title**Summary of the Literature Review for T45 *Brassica napus*
October 1, 2021 – June 30, 2022****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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Report No: 22-RSOS0209
Summary of the Literature Review for T45 *Brassica napus*
October 1, 2021 – June 30, 2022
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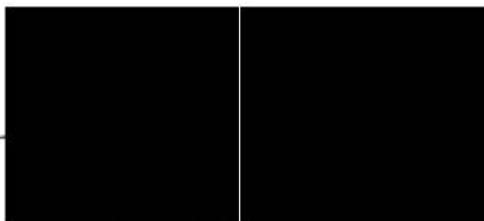
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SIGNATURE PAGE

Principal author:

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2022-09-27

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STUDY PERSONNEL

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Agency website search	██████████ PhD in Biomedical Sciences. Ten years of experience in Regulatory Affairs for plant biotechnology products.
Manual search (reference list from review articles)	██████████ PhD in Food Science and Technology. Twenty years of expertise in food chemistry, food allergy and safety assessment of GMOs.
Stage 1 assessment	██████████ ██████████
Stage 2 assessment	<p><u>Food and Feed safety</u></p> <p>██████████ PhD in Toxicology. Regulatory Toxicologist for plant biotechnology since 2013.</p> <p>██████████ PhD in Pathology with focus in Toxicology. Experience in regulatory toxicology for crop protection products. Regulatory Product Safety Manager for Environmental and Human Health for biotechnology products since 2021.</p> <p><u>Molecular characterization</u></p> <p>██████████ Bachelor Pharmaceutical and Biological Techniques. Expert in molecular characterization and plant biotechnology since 1999 and protein characterization since 2010.</p> <p>██████████ PhD in Plant Molecular Genetics. Ten years of expertise in molecular characterization and detection methods of GMOs.</p> <p><u>Environmental safety</u></p> <p>██████████ Agronomist Engineer, PhD in Agronomy (Vegetable Production/Integrated Pest Management). Ten years of expertise in field entomology and environmental safety assessment of GM crops.</p> <p>██████████</p>
Report	<p>██████████</p> <p>██████████</p> <p>██████████</p>

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SUMMARY

T45 *Brassica napus* (*B. napus*) was produced by means of *Agrobacterium*-mediated transformation using vector pHOE4/Ac(II). T45 *B. napus* contains the *pat* gene (origin *Streptomyces viridochromogenes*), coding for the phosphinothricin acetyltransferase (PAT) protein which confers tolerance to glufosinate-ammonium. The *pat* gene is driven by the 35S promoter that allows a high level of constitutive expression. The OECD identifier of T45 *B. napus* is ACS-BNØØ8-2.

A scoping review was performed for the T45 *B. napus* 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 T45 *B. napus*, 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 131 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. One publication was progressed for detailed assessment.

The one publication was determined not to be relevant after detailed review. No publications were found that contained new data on the molecular characterization of T45 *B. napus* and its newly expressed protein, PAT/*pat*. Similarly, no new publications were found that suggested any potential adverse effects on human health, animal health, or 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 publications that would impact the existing safety assessment of T45 *B. napus* or its newly expressed protein PAT/*pat*.

1. INTRODUCTION

T45 *Brassica napus* (*B. napus*) was produced by means of *Agrobacterium*-mediated transformation using vector pHOE4/Ac(II). T45 *B. napus* contains the *pat* gene (origin *Streptomyces viridochromogenes*), coding for the phosphinothricin acetyltransferase (PAT) protein which confers tolerance to glufosinate-ammonium. The *pat* gene is driven by the 35S promoter that allows a high level of constitutive expression. The OECD identifier of T45 *B. napus* is ACS-BNØØ8-2.

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 45 *B. napus*, and/or any adverse effect of T45 *B. napus* 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 T45 *B. napus* and its newly expressed protein, PAT/*pat*. The search terms also included relevant synonyms, trade name and intended trait, 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 T45 *B. napus* 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 T45 *B. napus* and its newly expressed protein PAT/*pat*?

Key elements:

Population: Human health; animal health; environmental safety

Exposure: T45 *B. napus*, derived food/feed products, newly expressed protein in T45 *B. napus*

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 T45 *B. napus* and its newly expressed protein PAT/*pat* in *B. napus*?

Key elements:

Population: T45 *B. napus* and newly expressed protein in T45 *B. napus*

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 proteins(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
Additional concepts		

Concepts	Criteria	Comment
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

One publication that refers to T45 *B. napus* was previously identified and was used to test and validate the search strategy:

- Naegeli, H.; Bresson, J. L.; Dalmay, T.; Dewhurst, I. C.; Epstein, M. 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 oilseed rape T45 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-012). EFSA Journal (2019), Volume 17, Number 2, e05597 p.

This article was selected because it is relevant to the search and its title and abstract include the event name (T45), the plant species (oilseed rape) and the intended trait (herbicide tolerance). Since this article was published outside the search period, the search profiles were tested without applying the time limitation 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 8, 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 protein and intended trait. The reference publication ([Section 2.4](#)) was identified by the search profiles confirming the validity of the applied search strategy. Since the 'newly expressed protein' profiles and the 'intended trait' profiles produced too many results when used on their own, they were combined with additional profiles: the 'newly expressed protein' 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	T45 or t(w)45 or HCN28 or HCN(w)28 or ACS-BN008-2 or ACS-BN008-2 or ACS(w)BN008(w)2 or ACS(w)BN008(w)2 or ACSBN008(w)2 or ACSBN008(w)2	Event name
2	libertylink or libertylinktm or libertylinkrtm or liberty-link or liberty(w)link or liberty(w)linktm or liberty(w)linkrtm or LL or LLTM or LLRTM or invigor or in(w)vigor or invigortm or in(w)vigortm or invigorrtm or in(w)vigorrtm	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	(herbicid? or bialaphos or basta or glufosinate or phosphinothricin or liberty?)(5a)(resist? OR protect? OR toleran?)	Intended trait
5	((BRASSICA or B)(w)napus) or CANOLA# or colza OR OILSEED(w)RAPE# OR oil(w)seed(w)rape# OR RAPESEED# OR RAPE(w)SEED#	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	(1 or 3) and (5 or 6)	(Event name OR Newly expressed protein) AND (Plant species or GMO general)
8	2 and 5	Trade name AND Plant Species
9	4 and 5 and 6	Intended trait AND Plant species AND GMO general
10	7 or 8 or 9	((Event name OR Newly expressed protein) AND (Plant species or GMO general)) or (trade name 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 proteins	Intended traits	Plant species	GM plants
Agricola	None	None	"HERBICIDE RESISTANCE"	CANOLA	"TRANSGENIC PLANTS"
Biosis	None	None	No terms	No terms	No terms
CABA	None	None	"HERBICIDE RESISTANCE"	RAPE	"TRANSGENIC PLANTS"
CAS	None	None	"HERBICIDE RESISTANCE"	CANOLA "BRASSICA NAPUS"	"GENETICALLY MODIFIED PLANTS"
Medline	None	None	"HERBICIDE RESISTANCE"	"BRASSICA NAPUS"	"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	STN International	STN International	STN International	STN International
Coverage	1970-present	1926-present	1973-present	1907-present	1946-present
Date of search	8 July 2022	8 July 2022	8 July 2022	8 July 2022	8 July 2022
Datespan of the search	1 Oct 2021 – 30 Jun 2022	1 Oct 2021 – 30 Jun 2022	1 Oct 2021 – 30 Jun 2022	1 Oct 2021 – 30 Jun 2022	1 Oct 2021 – 30 Jun 2022
Latest database update	13 June 2022	6 July 2022	5 July 2022	7 July 2022	7 July 2022

Database	AGRICOLA	BIOSIS	CAB Abstracts	CAPLUS	MEDLINE
Number of records retrieved	9	26	29	51	40
Number of records after duplicate removal	6	24	21	40	40
Number of relevant records after rapid assessment	0	0	0	1	0

4. INTERNET and MANUAL SEARCHES

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

A search of the web pages of food safety, agriculture, and biotechnology-related authorities was conducted. Search results were manually examined for relevant records that were either published during the time period under consideration (date span of search: 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, two (Environment and Climate Change Canada and Intersecretarial Commission on Biosafety of GMOs (CIBIOGEM)) are not involved in the risk assessment of GM plants. The US-EPA website was excluded, since the T45 *B. napus* does not contain an insect-resistant trait. The Genetic Engineering Approval Committee (GEAC) website was excluded, since this agency has only regulated GM cotton products. The CTNBio (Brazil) and CONABIA (Argentina) websites were excluded, since these agencies do not regulate any GM products for canola. Therefore, the internet search was focused on 7 key organisations relevant for T45 *B. napus* as listed below in [Table 5](#).

Search terms consisted of T45 Canola, T45 oilseed, T45 *Brassica*, ACS-BNØØ8-2, PAT/*pat* and 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/	9/5/2022	9/5/2022	0
US Food and Drug Administration (FDA)	https://www.fda.gov/	9/7/2022	9/7/2022	0

Source Site Name	Website URL	Date of Most Recent Site Update	Date of Search	No. of Relevant Records
Health Canada	https://www.canada.ca/en/health-canada.html	8/1/2022	8/31/2022 – 9/1/2022	0
Canadian Food Inspection Agency (CFIA)	https://www.canada.ca/en/food-inspection-agency.html	8/1/2022	9/2/2022 – 9/7/2022	0
Food Standards Australia New Zealand (FSANZ)	http://www.foodstandards.gov.au/Pages/default.aspx	8/12/2022	8/24/2022	0
Office of the Gene Technology Regulator (OGTR) Australia	http://www.ogtr.gov.au/	8/1/2022	8/29/2022	0
Ministry of Agriculture, Forestry and Fisheries (MAFF) Japan	http://www.maff.go.jp/	9/6/2022	9/6/2022	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, Mubarik 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.	RNA Interference for Improving Disease Resistance in Plants and Its Relevance in This Clustered	Front Plant Sci. 2022 May 13;13:885128.	0

No	Author(s) and Year	Title	Source	Number of relevant bibliographic references retrieved
	2022	Regularly Interspaced Short Palindromic Repeats-Dominated Era in Terms of dsRNA-Based Biopesticides		
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 155 references, which were reduced to 131 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 evaluators were in 100 % agreement and therefore there was no need to resolve any disagreements about relevance.

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 T45 *B. napus*, 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)	131
Number of publications excluded from the search results after rapid assessment for relevance (Stage 1)	130
Total number of full-text documents assessed in detail	1
Number of publications excluded from further consideration after detailed assessment for relevance (Stage 2)	1
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

One publication 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 the publication was not relevant for the safety assessment of the T45 *B. napus* and its newly expressed protein PAT/*pat*.

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

7. CONCLUSION

The literature searches performed for the T45 *B. napus* and its newly expressed protein, PAT/*pat*, for the period from October 1, 2021 to June 30, 2022, identified a total of 131 unique publications (after duplicate removal). One publication was progressed for detailed assessment after excluding 130 obviously irrelevant publications during Stage 1 evaluation (rapid assessment based on title and abstract).

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

8. REFERENCES

No.	Author(s), title, source, edition, year, pages
-----	--

- | | |
|----|---|
| 1. | Devos Y, Guajardo IM, Alvarez F and Glanville J. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA supporting publications 2019:EN-1614. 62 pages. doi:10.2903/sp.efsa.2019.EN-1614. |
|----|---|

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

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

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

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
Benevenuto R.F., Venter H.J., Zanatta, C.B., Nodari, R.O., Agapito-Tenfen, S.Z. (2022)	Alterations in genetically modified crops assessed by omics studies: Systematic review and meta-analysis	Trends in Food Science + Technology (2022), 120, 325-337 CODEN: TFTEEH; ISSN: 0924-2244	Review paper, no new data was generated in this paper.

Table 10: Report of unobtainable/unclear publications

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

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

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

9. APPENDICES

Appendix 1: Database descriptions

Host	File	Description
STN	AGRICOLA	<p>Agriculture Online Access is a bibliographic database containing selected worldwide literature of agriculture and related fields. AGRICOLA is the locator and bibliographic access and control system of the National Agricultural Library (NAL) collections and also includes records from other cooperating institutions. Coverage of the database includes agricultural economics and rural sociology, agricultural production, animal sciences, chemistry, entomology, food and human nutrition, forestry, natural resources, pesticides, plant science, soils and fertilizers, and water resources. Also covered are related areas such as biology and biotechnology, botany, ecology, and natural history.</p> <p>The database draws on bibliographies, serial articles, book chapters, monographs, computer files, serials, maps, audiovisuals, and reports. Bibliographic information, abstracts, geographic terms, controlled terms, and supplementary terms are searchable.</p>
STN	BIOSIS	<p>BIOSIS Previews® is the largest and most comprehensive life science database in the world. Amongst others subject coverage includes Agriculture, Biochemistry, Biophysics, Botany, Environmental Biology, Physiology, Toxicology.</p> <p>Sources include periodicals, journals, conference proceedings, reviews, reports, patents, and short communications. Nearly 6,000 life source journals, 1,500 international meetings as well as review articles, books, and monographs are reviewed for inclusion.</p> <p>Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are all searchable.</p>
STN	CABA/CAB	<p>The CAB Abstracts database covers worldwide literature from all areas of agriculture and related sciences including Agriculture, Agricultural chemicals, Animal sciences and production, Crop protection, Crop sciences and production, Environment, Soils and fertilizers.</p> <p>Sources for CABA include journals, books, reports, published theses, conference proceedings, and patents.</p> <p>Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are searchable.</p>
STN	CAS-CA/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 09:40:23 ON 08 JUL 2022

L1 372 SEA T45 OR T(W)45 OR HCN28 OR HCN(W)28 OR ACS-BN008-2 OR
ACS-BN008-2 OR ACS(W)BN008(W)2 OR ACS(W)BNO08(W)2 OR ACSBN008(W)
)2 OR ACSBN008(W)2

L2 14557 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY-L
INK OR LIBERTY(W)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM
OR LL OR LLTM OR LLRTM

L3 167 SEA INVIGOR OR IN(W)VIGOR OR INVIGORTM OR IN(W)VIGORTM OR
INVIGORRTM OR IN(W)VIGORRTM

L4 14724 SEA (L2 OR L3)

L5 1511 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

L6 204 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L7 1585 SEA (L5 OR L6)

L8 3563 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?)(5A)(RESIST? OR PROTECT? OR
TOLERAN?)

L9 12606 SEA ((BRASSICA OR B)(W)NAPUS) OR CANOLA# OR COLZA OR OILSEED(W)
RAPE# OR OIL(W)SEED(W)RAPE# OR RAPESEED# OR RAPE(W)SEED#

L10 4009536 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?))

L11 1158 SEA (L1 OR L7) AND (L9 OR L10)

L12 20 SEA L4 AND L9

L13 192 SEA L8 AND L9 AND L10

L14 1348 SEA L11 OR L12 OR L13

L15 112 SEA L14 AND PY>=2020

L16 40 SEA L15 AND UP>=20211001 AND UP<=20220630

FILE 'BIOSIS' ENTERED AT 09:40:31 ON 08 JUL 2022

L17 354 SEA T45 OR T(W)45 OR HCN28 OR HCN(W)28 OR ACS-BN008-2 OR
ACS-BN008-2 OR ACS(W)BN008(W)2 OR ACS(W)BNO08(W)2 OR ACSBN008(W)
)2 OR ACSBN008(W)2

L18 15192 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY-L
INK OR LIBERTY(W)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM
OR LL OR LLTM OR LLRTM

L19 60 SEA INVIGOR OR IN(W)VIGOR OR INVIGORTM OR IN(W)VIGORTM OR
INVIGORRTM OR IN(W)VIGORRTM

L20 15251 SEA (L18 OR L19)

L21 2899 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

L22 334 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L23 3003 SEA (L21 OR L22)

L24 10239 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?)(5A)(RESIST? OR PROTECT? OR
TOLERAN?)

L25 37034 SEA ((BRASSICA OR B)(W)NAPUS) OR CANOLA# OR COLZA OR OILSEED(W)
RAPE# OR OIL(W)SEED(W)RAPE# OR RAPESEED# OR RAPE(W)SEED#

L26 478392 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?))

L27 1274 SEA (L17 OR L23) AND (L25 OR L26)

L28 94 SEA L20 AND L25

L29 357 SEA L24 AND L25 AND L26

L30 1673 SEA L27 OR L28 OR L29

L31 71 SEA L30 AND PY>=2020
L32 26 SEA L31 AND UP>=20211001 AND UP<=20220630

FILE 'AGRICOLA' ENTERED AT 09:40:39 ON 08 JUL 2022

L33 97 SEA T45 OR T(W)45 OR HCN28 OR HCN(W)28 OR ACS-BN008-2 OR
ACS-BNO08-2 OR ACS(W)BN008(W)2 OR ACS(W)BNO08(W)2 OR ACSBN008(W)
)2 OR ACSBNO08(W)2

L34 3521 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY-L
INK OR LIBERTY(W)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM
OR LL OR LLTM OR LLRTM

L35 136 SEA INVIGOR OR IN(W)VIGOR OR INVIGORTM OR IN(W)VIGORTM OR
INVIGORRTM OR IN(W)VIGORRTM

L36 3657 SEA (L34 OR L35)

L37 811 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

L38 255 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L39 892 SEA (L37 OR L38)

L40 8633 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?)(5A)(RESIST? OR PROTECT? OR
TOLERAN?)

L41 23967 SEA ((BRASSICA OR B)(W)NAPUS) OR CANOLA# OR COLZA OR OILSEED(W)
RAPE# OR OIL(W)SEED(W)RAPE# OR RAPESEED# OR RAPE(W)SEED#

L42 109651 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?))

L43 679 SEA (L33 OR L39) AND (L41 OR L42)

L44 31 SEA L36 AND L41

L45 244 SEA L40 AND L41 AND L42

L46 919 SEA L43 OR L44 OR L45

L47 33 SEA L46 AND PY>=2020

L48 9 SEA L47 AND UP>=20211001 AND UP<=20220630

FILE 'CABA' ENTERED AT 09:40:54 ON 08 JUL 2022

L49 214 SEA T45 OR T(W)45 OR HCN28 OR HCN(W)28 OR ACS-BN008-2 OR
ACS-BNO08-2 OR ACS(W)BN008(W)2 OR ACS(W)BNO08(W)2 OR ACSBN008(W)
)2 OR ACSBNO08(W)2

L50 5665 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY-L
INK OR LIBERTY(W)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM
OR LL OR LLTM OR LLRTM

L51 277 SEA INVIGOR OR IN(W)VIGOR OR INVIGORTM OR IN(W)VIGORTM OR
INVIGORRTM OR IN(W)VIGORRTM

L52 5940 SEA (L50 OR L51)

L53 1579 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

L54 380 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L55 1681 SEA (L53 OR L54)

L56 18999 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?)(5A)(RESIST? OR PROTECT? OR
TOLERAN?)

L57 59698 SEA ((BRASSICA OR B)(W)NAPUS) OR CANOLA# OR COLZA OR OILSEED(W)
RAPE# OR OIL(W)SEED(W)RAPE# OR RAPESEED# OR RAPE(W)SEED#

L58 193299 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?))

L59 1375 SEA (L49 OR L55) AND (L57 OR L58)

L60 67 SEA L52 AND L57

L61 591 SEA L56 AND L57 AND L58

L62 1959 SEA L59 OR L60 OR L61
L63 85 SEA L62 AND PY>=2020
L64 29 SEA L63 AND UP>=20211001 AND UP<=20220630
L65 29 SEA L64 NOT P/DT
L66 0 SEA L64 AND (P/DT AND J/DT)
L67 29 SEA (L65 OR L66)

FILE 'HCAPLUS' ENTERED AT 09:41:06 ON 08 JUL 2022

L68 817 SEA T45 OR T(W)45 OR HCN28 OR HCN(W)28 OR ACS-BN008-2 OR
ACS-BN008-2 OR ACS(W)BN008(W)2 OR ACS(W)BN008(W)2 OR ACSBN008(W)
2 OR ACSBN008(W)2
L69 20977 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY-L
INK OR LIBERTY(W)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM
OR LL OR LLTM OR LLRTM
L70 9 SEA INVIGOR OR IN(W)VIGOR OR INVIGORTM OR IN(W)VIGORTM OR
INVIGORRTM OR IN(W)VIGORRTM
L71 20986 SEA (L69 OR L70)
L72 5394 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
L73 793 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE
L74 5700 SEA (L72 OR L73)
L75 29140 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
PHOSPHINOTHRICIN OR LIBERTY?)(5A)(RESIST? OR PROTECT? OR
TOLERAN?)
L76 76997 SEA ((BRASSICA OR B)(W)NAPUS) OR CANOLA# OR COLZA OR OILSEED(W)
RAPE# OR OIL(W)SEED(W)RAPE# OR RAPESEED# OR RAPE(W)SEED#
L77 716303 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?))
L78 2573 SEA (L68 OR L74) AND (L76 OR L77)
L79 46 SEA L71 AND L76
L80 1086 SEA L75 AND L76 AND L77
L81 3567 SEA L78 OR L79 OR L80
L82 539 SEA L81 AND PY>=2020
L83 77 SEA L82 AND UP>=20211001 AND UP<=20220630
L84 51 SEA L83 NOT P/DT
L85 0 SEA L83 AND (P/DT AND J/DT)
L86 51 SEA (L84 OR L85)

FILE 'MEDLINE, BIOSIS, AGRICOLA, CABA, HCAPLUS' ENTERED AT 03:41:16 ON 08
JUL 2022

L87 131 DUP REM L16 L32 L48 L67 L86 (24 DUPLICATES REMOVED)
ANSWERS '1-40' FROM FILE MEDLINE
ANSWERS '41-64' FROM FILE BIOSIS
ANSWERS '65-70' FROM FILE AGRICOLA
ANSWERS '71-91' FROM FILE CABA
ANSWERS '92-131' FROM FILE HCAPLUS