



**Review of Scientific Literature Relevant to the
Food/Feed and Environmental Risk Assessment of
Syngenta Genetically Modified maize Products**

Literature Review

TEST GUIDELINE(S):

Not Applicable

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LIST OF ACRONYMS AND ABBREVIATIONS

AGRICOLA	AGRICultural OnLine Access
CAB	Commonwealth Agricultural Bureaux
CFIA	Canadian Food Inspection Agency
CONABIA	National Advisory Commission on Agricultural Biotechnology (<i>Comisión Nacional Asesora de Biotecnología Agropecuaria</i>)
CTNBio	National Technical Commission on Biosafety (<i>Comissão Técnica Nacional de Biossegurança</i>)
EFSA	European Food Safety Authority
ERA	Environmental risk assessment
EU	European Union
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GM	Genetically Modified
GMO	Genetically Modified Organism
HC	Health Canada
MAFF	Ministry of Agriculture, Forestry and Fisheries
MEDLINE	MEDical Literature Analysis and Retrieval System (online version)
NTO	Nontarget organisms
OGTR	Office of the Gene Technology Regulator
PICO/PECO	Population, Intervention/Exposure, Comparator, Outcomes
PMEM	Post-market environmental monitoring
US EPA	US Environmental Protection Agency
US FDA	US Food and Drug Administration
USDA	US Department of Agriculture

1.0 EXECUTIVE SUMMARY

A systematic literature search and scoping review was conducted to collect, identify, and assess information (published between June 1, 2022 and July 7, 2023) relevant to the risk assessment of Syngenta genetically modified (GM) maize products, and the associated newly expressed proteins/intended traits, for use as food/feed. This literature search was performed in the context of an annual post-market environmental monitoring (PMEM) report on GMOs authorized in the European Union (EU) market, and was conducted in compliance with the 2019 EFSA explanatory note on literature searching for GMO applications (EFSA 2019).

Electronic databases and regulatory agency webpages were searched using a validated, comprehensive search strategy. Two technical experts independently reviewed the retrieved records to determine their relevance. A total of 486 records were retrieved from the database search, one of which was classified as relevant. A total of 79 records were retrieved from the internet search, 17 of which were classified as relevant. The reference lists of relevant internet publications were also manually searched for records published between June 1, 2022 and July 7, 2023. This manual search identified 3 additional record(s), none of which were found to be relevant during the review process. The two reviewers evaluated the relevant records in detail and assessed their implications on the current risk assessment of Syngenta GM maize products. Overall, the relevant records did not indicate any hazards, modified exposure pathways, or scientific uncertainties for Syngenta GM maize products.

In conclusion, the results of this literature search and scoping review do not change the risk assessment of Syngenta GM maize products.

2.0 INTRODUCTION

The objective of this systematic literature search and scoping review was to collect, identify, and assess information relevant to the risk assessment of Syngenta genetically modified (GM) maize products, and the associated newly expressed proteins/intended traits, for use as food/feed (see Appendix A for a list of Syngenta GM maize products in-scope of this application). Information published between June 1, 2022 and July 7, 2023 was evaluated. This literature search was performed in the context of an annual post-market environmental monitoring (PMEM) report on GMOs authorized in the European Union (EU) market, and was conducted in compliance with the 2019 EFSA explanatory note on literature searching for GMO applications (EFSA 2019). This scoping literature search and review was conducted by an experienced information specialist and a team of technical experts with knowledge of GM crop research, development, and safety assessment (Appendix B).

3.0 METHODS

3.1 Formulating the Review Question and Clarifying its Purpose

The literature search and scoping review outlined in this report was aimed at identifying potential adverse effects of Syngenta GM maize products, and the associated newly expressed proteins/intended traits, on human/animal health and the environment. Therefore, the associated review question was defined as:

Do either food or feed products derived from Syngenta GM maize products, or the respective intended traits, have adverse effects on human/animal health and/or the environment?

This review question follows the Population, Intervention/Exposure, Comparator, Outcome (PICO/PECO) structure. Key elements of the review question are defined in Table 1.

TABLE 1 **Review question in PICO/PECO structure**

Element	Components of Review Question
<u>P</u> opulation	Human and animal health, and the environment
<u>I</u> ntervention/ <u>E</u> xposure	Syngenta GM maize products, the derived food/feed products, and/or the respective newly expressed proteins/intended traits (see Appendix A for a list of Syngenta GM maize products in-scope of this application)
<u>C</u> omparator	Conventional counterpart (if applicable)
<u>O</u> utcome	Adverse effects

Pre-defined eligibility/inclusion criteria (Table 2) were used to identify records relevant to answering the review question. Eligibility/inclusion criteria were derived from relevant factors outlined in Section 3.1.2 of the 2019 EFSA explanatory note on literature searching for GMO applications (EFSA 2019) and refined by technical experts in the fields of GMO research, development, and product safety. The eligibility/inclusion criteria were assessed and validated using a pilot study (Appendix C) and have a history of successful use in literature reviews for identifying information relevant to the food/feed and environmental risk assessment of GM crops.

Table 2 provides high-level key concepts for eligibility/inclusion. A detailed breakdown of specific information/data requirements used to assess the associated eligibility/inclusion criteria is provided in Table 3. The criteria are ordered by importance/expected ease of locating the information in a publication. The first failed eligibility/inclusion criterion was used as the primary reason for exclusion and the remaining criteria were not assessed (Frampton *et al.* 2017).

TABLE 2 Eligibility/inclusion criteria to establish relevance

Concepts	Criteria	Comment
Intervention/exposure	The record addresses one or more Syngenta GM maize products, derived food/feed products, and/or the newly expressed proteins/intended traits.	A table of the Syngenta GM maize products that were considered in this literature search and review can be found in Appendix A.
Information/data requirements	The record contains data that answers the review question (Section 3.1) and contributes knowledge informing the human/animal health and/or environmental risk assessments of Syngenta GM maize products.	A non-exhaustive list of information/data that may answer the review question and contribute knowledge informing the human/animal health and environmental risk assessments is outlined in Table 3. Records that did not cover topics informing the review question or risk assessment (i.e., benefits, socioeconomics, ethics, crop protection, detection methods, efficacy, public perception, or risk communication) were excluded using this criterion.
Scope of GMO application	The record must address pathways and/or exposure routes that are relevant to the intended use of Syngenta GM maize products and derived food/feed products (i.e., import, processing, and use as food/feed).	Publications were considered for relevance if they addressed pathways and routes of exposure that were relevant to the scope of the application: import and processing of Syngenta GM maize products for food/feed uses.
Reporting format	The record presents original/primary data or is a risk assessment from a relevant key organization (i.e., regulatory agencies and risk assessment bodies involved in the safety assessment of GMOs).	Records that did not present original/primary data (e.g., editorials, reviews, position papers) were excluded. Risk assessments performed and reported by relevant key organizations were considered for relevance if they addressed the intervention/exposure. Documents posted to regulatory agency websites that were not authored by the key organizations (i.e., applications, dossiers, or risk assessments submitted by applicants) were not considered relevant. Draft and partial reports published by regulatory agencies were also excluded using this criterion, since they contain no new information and do not represent the final official opinion of the agency. Similarly, reports that reflect individual reviewer opinions were excluded from evaluation because they are considered when developing the official final opinion of the agency.
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 the EFSA/GO Panel output.	As indicated by EFSA (2019), publications previously considered by EFSA were excluded. Any cited/referenced publications contained within documents produced by EFSA and/or its GMO Panel were excluded.
Access	The full-text document is accessible.	If potentially relevant full-text documents could not be obtained, they were listed in a table with a description of the (unsuccessful) methods used in the attempt to obtain a copy.
Population	Human/animal health and/or the environment are addressed as general protection goals in the publication.	Publications that addressed protection goals relevant to the risk assessment of Syngenta GM maize products were considered for relevance.

Concepts	Criteria	Comment
Outcomes	The publication addresses topics relevant to effects/impacts on human/animal health and/or the environment.	Publications that addressed Syngenta GM maize products must have also addressed effects/impacts on entities of concern or provided information on potential determinants of exposure that placed these entities at risk, to be considered potentially relevant to the risk assessment of the GMO.
Comparator	If the publication is a comparative study using plant material from Syngenta GM maize products as a test material, the comparator must be plant material from a non-GM variety.	Publications that addressed Syngenta GM maize products must have also included a conventional counterpart as a comparator in cases where comparative analysis was conducted and plant material from a Syngenta GM maize product was used as test material. Any uncertainties about the appropriateness of the comparator were addressed in the assessment of the publication.
Plant species	The publication may address the same plant species as the GMO under consideration but could also address any plant species producing the newly expressed proteins in-scope.	The review question addressed the safe use of the newly expressed proteins in Syngenta GM maize products. Therefore, studies on GMOs of another species that contain the newly expressed proteins in-scope were also considered for relevance. However, for certain information/data requirements, publications regarding the presence of the transgenic proteins in a different plant species did not impact the assessment of Syngenta GM maize products and were not considered for relevance (Table 3, denoted by an asterisk to indicate the information/data must be “specific to Syngenta GM Maize products”).
Reporting format – Duplicate Studies	A study should only be presented once, but if it is presented in more than one publication, all publications will be listed and grouped.	Duplicate publications were excluded at the initial screening stage. If a specific study was represented in separate publications, all publications were grouped, and the study was only evaluated once.

TABLE 3 Overview of main categories of information/data requirements

Information/data requirement	Non-exhaustive list of specific information/data requirements
Molecular characterization of the genetic modification of the GMO	<ul style="list-style-type: none"> • Information on the insert including sequence, size, copy number, genetic element arrangement, deletions, location, sequence similarity searches, and analysis of open reading frames* • Expression data of inserted/modified sequences* • Genetic stability* • Molecular and biochemical characterization of the protein(s) such as: primary structure, molecular weight, post-translational modifications • Assessment of enzymatic activity including substrate specificity and reaction products with respect to safety and/or nutritional balance • Data on the equivalence between plant-produced and microbially produced proteins
Agronomic, phenotypic, and compositional characterization of the GM plant	<ul style="list-style-type: none"> • Comparative assessment of agronomic and phenotypic characteristics under field or controlled conditions* • Comparative analysis of key nutritional constituents (e.g., proximates, key macro- and micro-nutrients, anti-nutritional compounds, natural toxins, endogenous allergens)*
Toxicological assessment of newly expressed protein(s), new constituents other than proteins, and the whole GM food/feed	<ul style="list-style-type: none"> • Amino acid sequence comparison between the newly expressed protein(s) and toxic proteins • Stability of the protein(s) under relevant processing and storage conditions and expected treatment of food/feed • Investigation of proteolytic susceptibility of the newly expressed protein(s) • Animal toxicity studies using purified protein (e.g., 28-day repeated-dose oral toxicity studies) • Feeding studies using plant material (e.g., 90-d feeding studies in rodents, reproductive and development toxicity testing)* • Other animal feeding studies examining safety and characteristics of Syngenta GM maize products and derived food/feed products in target species such as livestock animal*
Allergenicity assessment of the newly expressed protein and the GM food/feed, and adjuvanticity	<ul style="list-style-type: none"> • Amino acid sequence comparison of the newly expressed protein(s) to known allergens or celiac disease peptide sequences • Serum screening • Pepsin susceptibility testing of newly expressed protein(s) • <i>In vitro</i> cell-based assays • <i>In vivo</i> tests in animal models • Expression data for endogenous allergens* • Comparison of functional aspects/structural similarities between newly expressed proteins and known strong adjuvants

Information/data requirement	Non-exhaustive list of specific information/data requirements
Nutritional assessment of the newly expressed protein(s), other new constituents, as well as potential alterations in the total diet of the consumer or the animal	<ul style="list-style-type: none"> • Anticipated dietary intake of food/feed derived from Syngenta GM maize products and the resulting nutritional impact(s)* • Target animal nutritional studies evaluating plant material or derived food/feed products* • Comparative growth performance studies with young rapidly growing animal species that evaluate plant material or derived food/feed products*
Post-market monitoring	<ul style="list-style-type: none"> • Description of mechanisms for determining actual changes to overall dietary intake patterns of the GM food, to what extent this has occurred and whether the product induces known (side) effects or unexpected side effects in human and animal consumers • Information on the reliability, sensitivity, and specificity of the post market monitoring methods
Persistence and invasiveness assessment, including plant-to-plant gene transfer	<ul style="list-style-type: none"> • Measurements of volunteer occurrence and establishment* • Testing of replacement capacity/competitiveness* • Fitness of the GM plant expressing the novel traits in various environmental conditions* • Description of relevant avenues and vectors for gene flow, as well as factors affecting these processes
Assessment of plant to micro-organism gene transfer	<ul style="list-style-type: none"> • Homology searches at the nucleotide level between the GM event and microorganisms*
Assessment of interactions with target organisms	<p>Publications in this category were excluded based on the scope of the application, which covers the import, processing, and food/feed use of Syngenta GM maize products in the EU. Cultivation of Syngenta GM maize products in the EU is not in scope. According to the EFSA Environmental Risk Assessment (ERA) Guidance (EFSA 2010), “...<i>resistance development is only relevant for applications with scope cultivation of GM plants and not for applications restricted to import and processing of GM plants and their products.</i>” Therefore, assessments of the potential resistance development in target organisms resulting from the import, processing, and food/feed use of Syngenta GM maize products are not relevant for this application.</p>
Assessment of interactions with non-target organisms (NTO)	<ul style="list-style-type: none"> • Studies focusing on indirect exposure of NTOs to Syngenta GM maize products (e.g., through manure/faeces from animals fed the GM plant, by-products of industrial processes) <p>Publications that discussed direct exposure of test proteins to non-target organisms (either from laboratory or field studies) were excluded based on the scope of this application and will be excluded. This is based on recommendation from the EFSA ERA Guidance (EFSA 2010), which states: “<i>In cases where the application does not include cultivation in the EU, direct environmental exposure of NTOs to the GM plant is via accidental release into the environment of seeds or propagules during transportation and processing. This may result in sporadic occurrence of feral plants and therefore exposure of NTO populations is likely to be negligible. The ERA will then focus on indirect exposure to products of the GM plant (e.g., through manure and faeces from animals fed the GM plant, and other by-products of industrial processes).</i>”</p>

Information/data requirement	Non-exhaustive list of specific information/data requirements
Assessment of interactions with biogeochemical and abiotic processes	Publications in this category were excluded based on the scope of the application, which covers the import, processing, and food/feed use of Syngenta GM maize in the EU. Cultivation of Syngenta GM maize products in the EU is not included in the scope. According to the EFSA ERA Guidance (EFSA 2010): “ <i>Applications concerning food/feed uses and import and processing do not require scientific information on possible environmental effects associated with the cultivation of the plant.</i> ” Therefore, an assessment of the impacts of Syngenta GM maize products on biogeochemical processes resulting from specific cultivation, management, and harvesting techniques is not relevant given the scope of this application.
Assessment of impact of specific cultivation, management and harvesting techniques	Publications in this category were excluded based on the scope of the application, which covers the import, processing, and food/feed use of Syngenta GM maize products in the EU. Cultivation of Syngenta GM maize products in the EU is not included in the scope. According to the EFSA ERA guidance (EFSA 2010): “ <i>...for GM plants for import and processing that are not intended for cultivation in the EU, there is no need for an ERA for altered cultivation, management and harvesting techniques.</i> ” Therefore, an assessment of impact of specific cultivation, management, and harvesting techniques of Syngenta GM maize products is not relevant for this application.
Risk mitigation	Publications in this category were excluded based on the scope of the application. Risk mitigation measures such as high dose/refuge strategy, isolation distance from protected habitats hosting species of conservation concern that are at risk, and integrated pest/weed management are only relevant to cultivation. The scope of this application covers the import, processing and food and feed use of Syngenta GM maize products.
Post-market environmental monitoring	Publications in this category were excluded based on the scope of the application. Monitoring such as insect resistance is relevant only to cultivation. The scope of this application covers the import, processing and food and feed use of Syngenta GM maize products.

*Specific to Syngenta GM Maize Products

3.2 Searching for/Identifying Relevant Publications

3.2.1 Database searches

3.2.1.1 Electronic bibliographic databases

To search for different types of publications and unpublished work that could provide information on the review question, multidisciplinary citation databases, which include grey literature (i.e., not peer reviewed), were used. Two large, multi-disciplinary databases (Ovid Medline and BIOSIS Previews) and two databases specializing in topics relevant to agricultural and nutrition sciences (AGRICultural OnLine Access (AGRICOLA) and Commonwealth Agricultural Bureaux (CAB) abstracts) were searched via Ovid® search interface (provided by Ovid® Technologies). These four databases were selected because of their extensive coverage of scientific literature related to relevant subjects that include, but are not limited to, biomedicine, plant disease, agriculture, life sciences, pesticides, human health and nutrition, animal health, plant science, biotechnology, and environmental studies (see Appendix D for further details on each database and the reason(s) for selection). Each database has a thesaurus. The document types contained in these databases encompasses a wide range of formats, including journal articles, technical letters and notes, patents, conference proceedings, book chapters, reports, and/or articles in press. Detailed specifications of these databases are outlined in Appendix D.

The selection of databases for this study complied with the 2019 explanatory note on literature searching (EFSA 2019), which indicates that a minimum of two large/multi-disciplinary databases are necessary to provide adequate coverage while still providing some level of complementary results. Using a combination of multi-disciplinary and specialized databases provides valuable results (Stevinson and Lawlor 2004). Therefore, the present combination of databases was suitable for retrieving publications relevant to the risk assessment of Syngenta GM maize products as it relates to food/feed and the environment, while adhering to EFSA's definition of "best" search strategy practices (defined in Glanville *et al.* (2014) as "a situation whereas few resources as possible are searched with a high probability that most of the relevant research evidence will be identified").

3.2.1.2 Database search strategy

The electronic bibliographic databases search strategy was designed to retrieve information on all Syngenta GM maize products in-scope of this application (Appendix A). The same search strategy was used in all databases through the Ovid® search interface (outlined in Table 4). The search strategy was developed by an information specialist in collaboration with technical experts with experience in GM crop research, development, and safety assessment (Appendix B). Database search strategy construction is described in a detailed synopsis in Appendix E.

TABLE 4 Search string strategy

Set	Field	Search String	Concepts/Key Elements
1	Topic	Bt11 OR Bt 11 OR SYN-BT#11-1	Event Bt11 (also captures stacks containing Bt11) ^a
2	Topic	MIR162 OR MIR 162 OR SYN-IR162-4	Event MIR162 (also captures stacks containing MIR162)
3	Topic	MIR604 OR MIR 604 OR SYN-IR6#4-5	Event MIR604 (also captures stacks containing MIR604) ^a
4	Topic	GA21 OR GA 21 OR GA2I OR GA 2I OR "MON-ØØØ21-9" OR MON-ØØØ21-9 OR MON-00021-9 OR MON###21-9 OR "M0N-ØØØ21-9" OR M0N-ØØØ21-9 OR M0N-00021-9 OR M0N###21-9	Event GA21 (also captures stacks containing GA21) ^a
5	Topic	(5307 ADJ4 (event OR maize OR corn)) OR "SYN-Ø53Ø7-1" OR SYN-Ø53Ø7-1 OR SYN-Ø53Ø7-1	Event 5307 (also captures stacks containing 5307)
6	Topic	MZIR098 OR "SYN-ØØØ98-3" OR SYN-ØØØ98-3 OR SYN-00098-3	Event MZIR098
7		1 OR 2 OR 3 OR 4 OR 5 OR 6	All Events considered
8	Topic	Agrisure* OR Duracade* OR Viptera* OR Herculex* OR Roundup* Ready* Maize	Trade Names
9	Topic	Cry1Ab* OR Cry 1Ab* OR Cry1 Ab* OR Cry 1 Ab* OR Cry1Ab* OR Cry 1Ab* OR CryI Ab* OR Cry I Ab*	Newly expressed protein in Bt11
10	Topic	Phosphinothricin N acetyltransferase OR Phosphinothricin N acetyl transferase OR Phosphinothricin acetyltransferase OR Phosphinothricin acetyl transferase OR PPT acetyltransferase OR PPT acetyl transferase OR PT N acetyltransferase OR PT N acetyl transferase OR Glufosinate acetyltransferase OR Glufosinate acetyl transferase OR Gluphosinate acetyltransferase OR Gluphosinate acetyl transferase OR (pat ADJ5 protein) OR 111069-93-3 OR "EC 2.3.1.183" OR "E.C. 2.3.1.183"	Newly expressed protein in Bt11 and MZIR098
11	Topic	"eCry3.1AB" OR "eCry3.1 AB" OR "eCry 3.1AB" OR "eCry 3.1 AB" OR "e-Cry3.1AB" OR "e-Cry3.1 AB" OR "e-Cry 3.1AB" OR "e-Cry 3.1 AB"	Newly expressed protein in 5307 and MZIR098
12	Topic	mCry3A* OR mCry 3A* OR mCry 3 A* OR Cry3A* OR Cry 3A* OR Cry 3 A*	Newly expressed protein in MIR604 and MZIR098
13	Topic	5 enolpyruvyl shikimate 3 phosphate synthase OR 5 enolpyruvylshikimate 3 phosphate synthase OR EPSP synthase OR MEPSP synthase OR EPSPS OR MEPSPS OR "EC 2.5.1.19" OR "E.C.2.5.1.19")	Newly expressed protein in GA21
14	Topic	Phosphomannoisomerase OR Mannose 6-phosphate isomerase OR Phosphomannoseisomerase OR Phosphomannose isomerase OR 9023-88-5 OR AAA24109 OR "EC 5.3.1.8" OR "E.C. 5.3.1.8"	Newly expressed protein in MIR162, MIR604, and 5307
15	Topic	Vip3AA20* OR Vip3 AA20* OR Vip3 AA 20* OR Vip3A A 20*	Newly expressed protein in MIR162
16		9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15	All newly expressed proteins considered
17		((Insect OR insects OR Coleoptera* OR Lepidoptera* OR pest OR pests OR stalkborer* OR stalk borer* OR borer* OR cornborer* OR corn borer* OR Noctuidae OR Crambidae OR Chrysomelidae OR earworm* OR ear worm* OR armyworm* OR army worm* OR cutworm* OR cut worm* OR rootworm* OR root worm* OR Ostrinia OR O nubilalis OR Diatraea OR D grandiosella	Intended traits – Insect resistance and herbicide tolerance

	OR D crambidoides OR Helicoverpa OR H zea OR Spodoptera OR S frugiperda OR S exigua OR Papaipema OR P nebris OR Elasmopalpus OR E lignosellus OR D saccharalis OR Striacosta OR S albicosta OR Agrotis OR A ipsilon OR Feltia OR F jaculifera OR Pseudaletia OR P unipuncta OR Diabrotica OR D virgifera OR D barberi OR ECB OR SWCB OR SCSB OR CEW OR FAW OR SCB OR WBC OR WCRW OR WCR OR NCRW OR MCR OR MCRW) ADJ2 (toleran* OR resistan* OR protect* OR control*) OR Bacillus thuringiensis OR B thuringiensis OR ((glufosinate* OR gluphosinate* OR Basta* OR Liberty* OR Ignite* OR Rely* OR Finale* OR Challenge* OR gl#phosate OR gl#fosate OR roundup* OR round up* OR herbicide* OR pesticide*) ADJ2 (toleran* OR resistan* OR protect*))	
18	GMO* OR LMO* OR GM OR GE OR transgen* OR ((genetic* OR living OR biotech*) ADJ3 (modif* OR transform* OR manipul* OR improv* OR engineer* OR deriv*)) OR stack*	GMO general
19	17 AND 18	Intended trait AND GMO general
20	GMHT OR GEHT OR GMHR OR GEHR OR GMHTs OR GEHTs OR GMHRs OR GEHRs	GMO general × intended trait-HT
21	19 OR 20	(Intended trait AND GMO general) OR GMO general × intended trait-HT
22	Maize* OR corn* OR Zea mays OR Z mays	Plant species
23	21 AND 22	((Intended trait AND GMO general) OR GMO general × intended trait-HT) AND Plant species
24	((Bt OR Bacillus thuringiensis OR B thuringiensis) ADJ5 (maize* OR corn* OR mays)) OR Btmaize* OR Btcorn*	GMO general × intended trait-Bt
25	7 OR 8 OR 16 OR 23 OR 24	Events OR Trade name OR Newly expressed proteins OR (((Intended trait AND GMO general) OR GMO general × intended trait-HT) AND Plant species) OR GMO general × intended trait-Bt

a. The mandated wildcard symbol (#) is used as a substitute for one required character on the Ovid platform.

3.2.1.3 Reference Publications

Prior to starting this literature search and review, the search strategy was assessed and validated using reference publications. All reference publications were retrieved from at least one of the four searched databases (100% overall retrieval), indicating satisfactory performance of the search strategy for acquiring the breadth of information available for the key elements highlighted in the search strategy (event, newly expressed proteins, and intended traits). Details of this process (including rationale for selection of the reference publications) and the outcomes (including the percentage of reference publications retrieved from each database) are outlined in Appendix F.

3.2.2 Internet searches

3.2.2.1 Key organizations and internet search strategy for regulatory agency webpages

The internet pages of relevant regulatory agency websites (Table 5) were searched for documents related to GMO applications, risk assessments, and approvals. Only the websites of agencies that conduct and post risk assessments to their websites are considered relevant for searching. Records were collected from webpages (Table 5) that listed regulatory documents/information specific to the safety assessment of GMOs. All records from these webpages that were published during the relevant time period (June 1, 2022- July 7, 2023) were collected for full-text review as described in the “Search strategy and limits applied” column. If a record’s publication date could not be determined, it was retrieved for review.

TABLE 5 Key organization pages included in the search

Regulatory agency/risk assessment body ^{a,b}	Webpage address	Search strategy and limits applied ^d
Food Standards Australia New Zealand (FSANZ)	https://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx	The list of current GM applications and approvals was examined. Safety assessments and approval documents (when available) for foods produced using gene technology (plant origin) that have a status of “Approved” or “Under assessment” and were published during or after 2022 were retrieved for assessment.
Health Canada (HC) ^c	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html	The list of completed safety assessments of GM foods was examined. The technical summaries linked to the novel food safety assessments with a “Decision Date” listed as 2022 or later were retrieved for review.
Canadian Food Inspection Agency (CFIA) ^c	https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236	The table of decision documents for determination of environmental and livestock feed safety was examined. All documents for decisions made during or after 2022 were retrieved for review.

Regulatory agency/risk assessment body ^{a,b}	Webpage address	Search strategy and limits applied ^d
Ministry of Agriculture, Forestry and Fisheries (MAFF)	https://www.biodic.go.jp/bch/lmo/OpenSearch.do	The “Genetically modified organism search system approved under the Cartagena method” on the Japan Biosafety Clearing House website was examined (this website is referenced as the relevant repository for documents related to GM organism approvals on the MAFF webpage dedicated to the approval of GM crops - https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/). The documents were searched by limiting “Approval Dates” to 2022-2023 and “Content of Use” to “Cultivation.” Items were sorted by approval date. All documents with an approval date on or after 2022 were retrieved for review.
National Advisory Commission on Agricultural Biotechnology (CONABIA)	https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/ogm-vegetal-eventos-con-autorizacion-comercial	The table of "Plant GMO: Events with commercial authorization" was examined. All documents with an approval date on or after 2022 were retrieved for review.
National Technical Commission on Biosafety (CTNBIO)	http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo	The webpages dedicated to the commercial releases of plants (<i>plantas</i>) were searched for technical opinion documents. The subfolder “plantas” was accessed from the noted link, and each subfolder contained within (“Soja,” “Milho,” “Feijão,” “Eucalipto,” “Cana,” and “Algodão”) was searched for technical opinion documents. Those published during or after 2022 were retrieved for review.
Office of the Gene Technology Regulator (OGTR)	https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release	The list of dealings involving the intentional release of GMOs into the environment were examined. The list was filtered to include items with a “Category” of “Agricultural.” Documents with an “Issue Date” falling on or after 2022 were retrieved for review. If no “Issue Date” was listed, the document was collected for review.
US Department of Agriculture (USDA)	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/rsr-table/rsr-table	The regulatory status review table was sorted by “Response Date.” The “RSR Response” documents with a “Response Date” falling on or after 2022 were retrieved for review.
US Environmental Protection Agency (USEPA)	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated	The table of “PIP Active Ingredients” was sorted by “Year Registered” and all documents listed under “BRAD and other Regulatory Documents” with a “Year Registered” of 2022 or later, were retrieved for review.

Regulatory agency/risk assessment body ^{a,b}	Webpage address	Search strategy and limits applied ^d
US Food and Drug Administration (USFDA)	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon	The list of New Plant Variety Consultations was sorted by “Date Completed” and all items completed on or after 2022 were retrieved for review.
<p>a. The regulatory agency of Mexico (Intersecretarial Commission on Biosafety of GMOs) does not post the relevant document types on their agency website and was not searched.</p> <p>b. The Genetic Engineering Appraisal Committee of India (part of the Ministry of Environment, Forest, and Climate Change) has not posted updates to their website regarding clearance decisions for GMOs since 2014 and, therefore, was not searched (https://moef.gov.in/en/project-approvals/geac-clearances/).</p> <p>c. HC and CFIA are responsible for regulating GM plants in Canada. Environment and Climate Change Canada (ECCC) does not regulate GM plants and, therefore, the ECCC website was not searched.</p> <p>d. Regulatory agency records are not always posted immediately upon approval. Therefore, the search date range for websites was extended to encompass all of 2022 and 2023. Any records reviewed during the previous year were removed from the search results and only new records were retained. This conservative approach ensured records were not omitted due to delayed posting online.</p>		

3.2.2.2 Web-based search engines and databases

General search engines such as GOOGLE Scholar and web-based databases known to contain information specifically on effects of GMOs were not searched. The search of the databases and key organization websites was considered adequate for a comprehensive search of literature.

3.2.3 Manual searches

3.2.3.1 Checking reference lists

If any relevant records were retrieved from the internet searches of regulatory agency websites, their reference lists were manually checked/scanned by both reviewers for new records within the relevant time period (June 1, 2022- July 7, 2023) and that met the eligibility/inclusion criteria. The full-text documents of any titles from the reference lists that appeared potentially relevant were obtained and evaluated by both reviewers to determine relevance.

3.2.3.2 Hand searching

Hand searching was not conducted. The search of the databases and key organization websites was considered adequate for a comprehensive search of literature.

3.2.3.3 Citation searching

Citation searching was not conducted. The search of the databases and key organization websites was considered adequate for a comprehensive search of literature.

3.2.4 Use of multiple languages

All search terms used in this study were in the English language (apart from Latin names) and utilized the Roman alphabet. The databases searched apply subject terms and commonly used descriptive terms in English. When available, the databases searched use English titles and abstracts for non-English articles. Additionally, translations are unlikely to exist for event and trade names that do not use words in the English language. Therefore, search terms were not translated.

3.2.5 Time period

All searches were conducted on or after July 7, 2023 (Table 8 and Table 9). The database search was limited, using the Ovid search platform, to records published between June 1, 2022 and the date of the last database update prior to the search (see Table 8). The records retrieved from regulatory agency webpages were limited by manually excluding publications dated prior to June 1, 2022. If a date could not be determined for a given record, it was retained for review.

3.3 Reviewing Publications for Relevance

3.3.1 Review of database records

The process for selecting relevant database publications was conducted in two stages, and was assessed/validated, using a pilot study, alongside the eligibility/inclusion criteria (Appendix C). Two independent reviewers evaluated each database record using the eligibility/inclusion criteria (Table 2 and Table 3) at all stages of the review process.

The first stage (Stage 1) was a preliminary assessment of titles and abstracts where records were classified as either (1) relevant/unclear relevance or (2) clearly not relevant. Records that were clearly irrelevant upon reviewing the title were excluded from further review. Records with titles that appeared relevant, or had unclear relevance, were retained for abstract review. Only records that were deemed clearly irrelevant by both reviewers upon assessment of the abstract were excluded from further review. This conservative approach ensured that all potentially relevant records were further evaluated. A kappa test was performed after Stage 1 review was completed and prior to discussing disagreements from Stage 1 abstract review. Records with abstracts that appeared relevant, or had unclear relevance, were retained for the second stage of review.

The second stage (Stage 2) was a detailed review of full-length articles. During Stage 2 review, a final decision on record relevance/irrelevance was made. Articles deemed relevant at Stage 2 were subjected to a reliability assessment and evaluation of the record's implications on the food and feed or environmental risk assessment for Syngenta GM maize products. An explanation of exclusion was provided for articles deemed irrelevant at Stage 2.

The reviewers discussed disagreements after Stage 2 (full-text) review of articles. If a disagreement on a record's relevance could not be resolved at Stage 2, an additional reviewer was brought in as a tie-breaker. Considering the tie-breaker's opinion, the majority position of relevance on the record became the agreed position.

3.3.2 Review of internet records from key organizations

Records from the webpages of key organizations were considered potentially relevant if they were risk assessments or scientific opinions/reports sponsored by the key organization. The regulatory agencies of interest (Table 5) do not post primary data; therefore, all other document types were considered irrelevant. The eligibility/inclusion criteria did not include risk assessments/dossiers submitted to regulatory authorities, only "risk assessments performed and reported by relevant key organizations." Therefore, only documents authored by the key organizations and not the applicants qualified as potentially relevant (i.e., dossiers and risk assessments submitted to regulatory authorities were excluded). Draft and partial reports were excluded since they contain no new information and do not represent the final official opinion of the agency. Similarly, reports that reflect individual reviewer opinions were excluded from evaluation because they are considered when developing the official final opinion of the agency. A rationale for exclusion, based on the eligibility/inclusion criteria, was provided when applicable, except for records excluded based on "Reporting Format" (e.g., submissions by applicants, meeting agendas, tables of approval dates, and draft documents,).

Two independent reviewers evaluated each internet record using the eligibility/inclusion criteria (Table 2 and Table 3). Internet records from key organizations were not amenable to a multi-stage review (i.e., title and abstract were often not provided in the search results), therefore, these records were only assessed in Stage 2 (full-text) review. Accordingly, a Kappa test (required for Stage 1 review only, as outlined in the 2019 explanatory note (EFSA 2019)) was not conducted for internet reviews.

Some agencies post information in languages other than English. During these instances, publications were translated to English using a neural machine translation software (i.e., Google Translate) prior to review. If translations were unclear or ambiguous, a native speaker of the language was consulted to provide a more accurate translation.

For the purposes of reporting and statistics, we defined a unique internet record as a unique uniform resource locator (URL). If the URLs for two documents were identical except for file format (e.g., pdf *versus* .doc or .docx), one of the documents was considered a duplicate document and it was excluded from reporting and review. Suspected duplicates (i.e., documents with similar URLs) were visually examined by the reviewer. If the content was identical, the record was removed so that only one record was reviewed and reported/used for statistics. If additional duplicates were identified during the review process (i.e., documents with different URLs, but identical content), they were removed such that only one document was used for reporting and statistics.

3.4 Summarizing and Reporting the Data

3.4.1 Results of the publication search and selection process

For the electronic bibliographic database search, the following information was collected: the date on which the search was conducted, the date of the most recent update of the database, the service provider used, date span of the search, any limits applied to the search (e.g., dates), and the total number of records retrieved before and after removing duplicates. The number of database records reviewed and excluded at each stage of review was also recorded. Additionally, the line-by-line strategy with the number of publications identified per line was captured.

For the internet search, the following information was collected (if available): the website/regulatory agency name and service publisher used, justification for choosing the source, the URL, the date on which the search was conducted, the date of the most recent website update at the time it was searched, the date span of the search, any limits to the search, and the total number of records retrieved. The number of internet records reviewed and excluded was also be recorded.

For manual searches of relevant internet record reference, the total number of records retrieved was recorded (those falling within the relevant time period). The number of manual search records reviewed and excluded at each stage of review was also be recorded.

3.4.2 Implications of relevant publications on risk assessment

The implications of the relevant publications on the risk assessment were assessed by considering whether any records presented new hazards, modified exposure pathways, or new scientific uncertainties. In addition, the reliability of each relevant record was assessed. “Reliability refers to the extent to which a publication is free from bias and the findings reported reflect true facts” (EFSA 2019). The reliability assessment process was developed following the recommendations outlined in the EFSA (2019) explanatory note on literature searching and in reference to previously established assessment methods (Klimisch *et al.* 1997; Moermond *et al.* 2016). Each reviewer performed a separate reliability assessment on all relevant records. Each record was evaluated using pre-defined reliability assessment criteria (outlined in Appendix G) that were derived from established quality criteria and EFSA guidance documents (EFSA 2010, 2015, 2017a, 2017b; Klimisch *et al.* 1997; Moermond *et al.* 2016) and refined by technical experts in the fields of GMO research, development, and product safety (Appendix B). Reviewers assigned each relevant record to a category of reliability (Table 6) based on their assessment. The reliability assessment results were compared, and reviewers discussed any conflicts to determine a consensus assignment for the category of reliability. If a consensus could not be met, the tie-breaker was consulted. Considering the tie-breaker’s opinion, the majority position on the reliability of the record became the agreed position. For each relevant record, the parameters contributing to the reliability rating were described (e.g., parameters potentially leading to false negatives, false positives, or inconclusive results).

TABLE 6 Description of reliability categories

Ranking and Utility	Description
High reliability <i>To be used as key studies in the risk assessment.</i>	All critical reliability criteria for this study are fulfilled (Appendix G). The experimental design is appropriate for answering the research question and the publication provides a clear description of the test conditions and procedures that allow for independent replication.
Moderate reliability <i>Useable as key studies in the risk assessment depending on their specific limitations.</i>	The study is well-documented and meets basic scientific principles with basic data provided. Most critical reliability criteria for this study are fulfilled (Appendix G). However, not all details are given, raw data are not provided, or there are some minor flaws in the experimental procedures or documentation. Despite the study limitations, it can still be assumed with reasonable certainty that the results are reliable.
Low reliability <i>Not useable as key studies but may be used as supporting information depending on their specific limitations.</i>	The study is subject to several limitations and multiple critical reliability criteria are not fulfilled (Appendix G). The flaws in the study design or reporting make it difficult to assume with reasonable certainty that the results are reliable.
Not reliable <i>Studies that are not reliable are not useful and should not be used in the risk assessment.</i>	The study does not comply with minimum reliability criteria (Appendix G) and does not meet basic scientific principles, resulting in a high level of uncertainty. There are clear flaws in the study design and/or how the study was performed (e.g., methods are not validated, the test system is not suitable for answering the research question, inappropriate controls are used).
Not assignable/evaluated	Due to the nature of the record, either no or insufficient information about experimental design is reported. This category is used for secondary literature, including risk assessments, which summarize data from primary research studies without providing a thorough description of the experimental methods. Published abstracts with no associated full-text may also be categorized using this ranking.

4.0 SUMMARISING AND REPORTING THE DATA, AND CONSIDERING THE IMPLICATIONS OF THE FINDINGS

4.1 Summary of the Search and Publication Selection Process

A complete summary of the search results and selection process, including the number of records reviewed, included, and excluded during each stage of review, is outlined in Table 7. Across all searches (database, internet, and manual), a total of 568 unique publications were retrieved for review after removal of duplicates. Of these, 486 were retrieved from the database search, 79 were retrieved from the internet search, and 3 were retrieved from the manual search of reference lists from relevant internet records.

For electronic bibliographic databases, the date on which the search was conducted, the date of the most recent update of the database, the service provider used, date span of the search, any limits applied to the search (e.g., dates) and the total number of records retrieved across all databases was recorded (Table 8). The records were de-duplicated after combining records retrieved from all the databases. Additionally, the search strategy as it was run for each database (including the fields searched), the number of publications identified for each bibliographic database prior to de-duplication (on a line-by-line basis), and the subject indexing used by each database (shown within brackets after each search term), were recorded (see Appendix H for screenshots of the search containing these details).

The database search returned a total of 486 records (after deduplication) that covered the dates of June 1, 2022 to July 7, 2023. During Stage 1, the reviewers agreed to include 4 records and exclude 479 records. Reviewers disagreed on the classification of 3 records at Stage 1: Reviewer A classified 3 as relevant that Reviewer B classified as irrelevant. This yielded a kappa score of 0.72, which is generally considered to indicate substantial agreement. We consider the level of reviewer agreement to be acceptable for identifying all relevant literature.

The reviewers discussed the 3 disagreements after Stage 1 review and agreed to move all 3 records forward to Stage 2 review. In total, 7 records were reviewed in Stage 2, during which one was classified as relevant (Table 10) and 6 were classified as not relevant (Table 12). There were no conflicts during Stage 2 review; therefore, a tie-breaker reviewer was not needed.

For internet webpages of regulatory agency websites, the date on which the search was conducted, the date of the most recent update of the webpage (if available), the date span of the search, and the total number of records retrieved from each site were recorded (Table 9). The records from each website were de-duplicated individually. In total, the internet search yielded 79 records from regulatory agency websites that were evaluated only at Stage 2 (full-text) review. The reviewers agreed that 17 of the internet publications were relevant (Table 11) and 62 were not relevant (Table 13). There were no conflicts between reviewers over internet records.

The reference lists of relevant internet publications were also searched for additional records published during the relevant time period (June 1, 2022-July 7, 2023), and 3 records were retrieved for review. Both reviewers determined none of the records retrieved in the manual search were relevant after reviewing titles and, therefore, none were reviewed further.

TABLE 7 Results of the publication selection process, for each review question and/or category of information/data requirement or group of information/data requirements searched

Review question and/or category of information/data requirement(s) captured in the search	Number of publications in each subcategory			
	Databases	Internet	Manual ^b	Total
Publications identified after all searches (database, internet, and manual search of references from relevant internet publications) of the scientific literature (excluding duplicates ^a)	486	79	3	568
Publications excluded from the search results after screening of title and abstracts (Stage 1)	479	NA ^d	3	482
Publications screened using full-text (Stage 2) ^c	7	79	0	86
Publications excluded after full-text screening	6	62 ^c	0	68
Unobtainable/Unclear publications	0	0	0	0
Publications considered relevant	1	17	0	18

a. A total of 1283 publications were identified from the database search. Of these, 797 publications were removed because they were duplicates.

b. Manual refers to the records obtained from manually searching the reference lists of internet publications classified as relevant.

c. Internet results are not screened at Stage 1 because they have no title or abstract.

d. NA=Not Applicable.

e. Records that were excluded based on reporting format (e.g., drafts, data submitted by applicants) are included in the numbers reported on this table but are not listed with a reason for exclusion in Table 13.

TABLE 8 Electronic bibliographic database search details

Database	Search date (dd/mm/yyyy)	Service provider	Date span of the search (dd/mm/yyyy) ^a	Any limits applied to the search	Total number of records retrieved after removing duplicates ^b
Agricola	07/07/2023	Ovid Technologies	01/06/2022 to 29/06/2023	Dates	7
BIOSIS Previews	07/07/2023	Ovid Technologies	01/06/2022 to 05/07/2023	Dates	58
CAB Abstracts	07/07/2023	Ovid Technologies	01/06/2022 to 29/06/2023	Dates	143
Medline	07/07/2023	Ovid Technologies	01/06/2022 to 06/07/2023	Dates	278

a. Ovid only allows results to be limited by year. The end date reflects the most recent update for each database in the Ovid online platform. The frequency of database updates varies. Ovid has provided us with the following update information: Agricola updated monthly, BIOSIS Previews updated weekly, CAB Abstracts updated weekly, and Medline updated daily.

b. The results were de-duplicated across databases.

TABLE 9 Regulatory agency webpage search details

Regulatory agency name	URL	Date of search (dd/mm/yyyy)	Date of most recent website update (dd/mm/yyyy)	Total records retrieved after removing duplicates^a	Number of relevant records
Canadian Food Inspection Agency	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html	08/08/2023	08/07/2022	0	0
Food Standards Australia New Zealand	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx	08/08/2023	May 2023	5	1
Health Canada	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html	08/08/2023	02/03/2023	3	0
Ministry of Agriculture, Forestry and Fisheries	https://www.biodic.go.jp/bch/lmo/OpenSearch.do	10/08/2023	No update information provided	28 ^b	6
National Advisory Commission on Agriculture Biotechnology	https://www.argentina.gob.ar/agricultura/ali-mentos-y-bioeconomia/ogm-vegetal-eventos-con-autorizacion-comercial	09/08/2023	No update information provided	4	0
National Technical Commission on Biosafety	http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo	09/08/2023	No update information provided	7	2
Office of the Gene Technology Regulator	https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release	09/08/2023	No update information provided	2	0
US Department of Agriculture	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/rsr-table/rsr-table	09/08/2023	27/06/2023	14	2
US Environmental Protection Agency	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated	09/08/2023	15/11/2022	0	0
US Food and Drug Administration	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon	09/08/2023	31/07/2023	16	6

a. Record deduplication was conducted within the results from individual agency websites.

b. The number of records retrieved from MAFF includes 14 records that were excluded based on reporting format (all were documents submitted by applicants, not authored by the regulatory agency). These 14 records were not listed with a reason for exclusion in Table 13.

4.2 Lists of Bibliographic References for Relevant Publications

After detailed review of the full-text documents in Stage 2, one of the 7 database records reviewed was deemed relevant (Table 10), 17 out of 79 internet records were deemed relevant (Table 11), and none of the 3 manual search records reviewed were deemed relevant. Bibliographic information for the relevant records (author, publication year, title, and source) is presented in the tables below and organized alphabetically by the category of information/data requirement fulfilled (see Table 3 for a full list of the information/data requirements used during review). More detailed descriptions of the relevant publications, including an assessment of their reliability and significance to the risk assessment of Syngenta GM maize products, are provided in Section 4.7.

TABLE 10 Report of all relevant database publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement.

List of bibliographic references for all relevant database publications, classified by category of information/data requirements			
Category of Information/Data Requirement(s)	Study (Author(s) and Year)	Title	Source
Molecular characterisation of the genetic modification of GMO	Noe <i>et al.</i> (2022)	Corn elite event MZIR098	Official Gazette of the United States Patent & Trademark Office Patents., SEP 13

TABLE 11 Report of all relevant internet publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement.

List of bibliographic references for all relevant internet publications, classified by category of information/data requirements			
Category of information/data requirements	Study author(s) and year	Title	Source
Risk assessment or scientific opinion	CTNBio (2023)	Technical Opinion No. 8393-2023	http://ctnbio.mctic.gov.br/documents/566529/2313088/Parecer+T%C3%A9cnico+8393_2023/
Risk assessment or scientific opinion	CTNBio (2023)	Technical Opinion No. 8405 - 2023	http://ctnbio.mctic.gov.br/documents/566529/2313904/Parecer+T%C3%A9cnico+8405_2023/
Risk assessment or scientific opinion	FSANZ (2023)	A1270 -- DP-Ø51291-2 -- Supporting document 1 - Safety assessment	https://www.foodstandards.gov.au/code/applications/Documents/01_A1270_SD1%20.pdf
Risk assessment or scientific opinion	MAFF (2022)	Results of deliberations by the Agricultural Products Subcommittee. DP-202216-6	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1949&ref_no=2
Risk assessment or scientific opinion	MAFF (2022)	Results of deliberations by the Agricultural Products Subcommittee. DP-915635-4	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1992&ref_no=2
Risk assessment or scientific opinion	MAFF (2023)	Results of deliberations by the Agricultural Products Subcommittee. DP-023211-2	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1997&ref_no=2

Category of information/data requirements	Study author(s) and year	Title	Source
Risk assessment or scientific opinion	MAFF (2023)	Results of deliberations by the Agricultural Products Subcommittee. KB-KWS201-6	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=2000&ref_no=2
Risk assessment or scientific opinion	MAFF (2023)	Results of deliberations by the Agricultural Products Subcommittee. DBN-09004-6	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=2002&ref_no=2
Risk assessment or scientific opinion	MAFF (2023)	Results of deliberations by the Agricultural Products Subcommittee. MON-94313-8	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=2003&ref_no=2
Risk assessment or scientific opinion	US FDA (2022)	Biotechnology Notification File No. 173. Human Food Use - CFSAN (Jun 23, 2022)	https://www.fda.gov/media/161331/download
Risk assessment or scientific opinion	US FDA (2022)	Biotechnology Notification File No. 173. Animal food use - CVM (Jun 23, 2022)	https://www.fda.gov/media/161332/download
Risk assessment or scientific opinion	US FDA (2022)	Biotechnology Notification File No. 175. Human Food Use - CFSAN (Jul 29, 2022)	https://www.fda.gov/media/161445/download
Risk assessment or scientific opinion	US FDA (2022)	Biotechnology Notification File No. 175. Animal food use - CVM (Jul 18, 2022)	https://www.fda.gov/media/161446/download
Risk assessment or scientific opinion	US FDA (2023)	Biotechnology Notification File No. 182. Human Food Use - CFSAN (Jul 6, 2023)	https://www.fda.gov/media/170623/download
Risk assessment or scientific opinion	US FDA (2023)	Biotechnology Notification File No. 182. Animal food use - CVM (Jun 9, 2023)	https://www.fda.gov/media/170624/download
Risk assessment or scientific opinion	USDA (2022)	21-152-01rsr. Altered enzyme levels and Marker gene (carbon source) (Corn)	https://www.aphis.usda.gov/brs/pdf/rsr/21-152-01rsr-review-response.pdf
Risk assessment or scientific opinion	USDA (2022)	22-145-01rsr. Altered seed oil profile and Herbicide resistance (Safflower)	https://www.aphis.usda.gov/brs/pdf/rsr/22-145-01rsr-review-response.pdf

4.3 Lists of Bibliographic References for all Excluded Publications After Detailed Assessment of Full-Text Documents for Relevance

After detailed review of the full-text documents in Stage 2, 6 out of 7 database records reviewed were excluded (Table 12) and 62 out of 79 internet records reviewed were excluded (Table 13). No manual records were reviewed at Stage 2. Bibliographic information for the excluded records (author, publication year, title, and source) is included in the following tables, along with the eligibility/inclusion criteria used as a reason for exclusion (see Table 2 for a full list of the eligibility/inclusion criteria used during review). The eligibility/inclusion criteria used for exclusion was included for each record. Additional rationale for exclusion was included, when necessary.

TABLE 12 Report of database publications excluded from the risk assessment after detailed assessment of full-text documents, giving the reason(s) for exclusion.

List of bibliographic references for all database publications excluded from the risk assessment, classified by authors			
Study author(s) and year	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria
Alves <i>et al.</i> (2023)	<i>Bacillus thuringiensis</i> affects reproductive capacity of adult rat offspring	Biotechnic & Histochemistry	Intervention/exposure: This study evaluates the insecticides XenTari (<i>B. thuringiensis</i> containing Cry1Ac toxin), Dipel (<i>B. thuringiensis subsp. kurtaski</i> containing Cry1Aa, Cry1Ab, and Cry1Ac toxins), and deltamethrin on the reproductive development of pups and pregnant rats. Dipel is comprised of a mixture of ingredients in addition to Cry1Ab (e.g., dried <i>B. thuringiensis</i> bacteria). Any findings in this study cannot be attributed specifically to a single component of Dipel. Therefore, the intervention/exposure in this study is outside the scope of this review.
Liu <i>et al.</i> (2022)	Establishment of an ELISA method for quantitative detection of PAT/pat in GM crops	Agriculture	Intervention/exposure: This article outlined an ELISA method for measuring PAT protein expression in GM crops. As part of the validation, leaf extracts from a GM maize were evaluated for PAT expression. The GM maize used was C0010.3.1, which is not a Syngenta GM Maize product.
McLaughlin and Kelly (2022)	Evaluating the impact of Bt corn hybrids on mycotoxins	Phytopathology	Intervention/exposure: The original record identified was a conference abstract. A more detailed description of the same study was identified from a separate conference publication (McLaughlin <i>et al.</i> 2022) and used to evaluate the relevance. The abstract and conference publications were determined to be the same due to identical abstracts and lead authors. The interventions/exposures used in this study were GM maize hybrids from Bayer Crop Sciences and Corteva. No Syngenta GM Maize products were evaluated.
Meng <i>et al.</i> (2023)	Photoelectrochemical and visual dual-mode sensor for efficient detection of Cry1Ab protein based on the proximity hybridization driven specific desorption of multifunctional probe	Journal of Hazardous Materials	Information/data requirements: This study outlines a method for detection and measurement of Cry1Ab in different matrices. It does not measure the Cry1Ab concentration in any Syngenta GM maize products.
Wu (2022)	Mycotoxin risks are lower in biotech corn	Current Opinion in Biotechnology	Intervention/exposure: This record does not discuss Syngenta GM maize products. Additionally, this article is a review and does not contain any primary research findings.
Ye <i>et al.</i> (2022)	One-Pot Synthesis of HRP&SA/ZIF-8 Nanocomposite and Its Application in the Detection of Insecticidal Crystalline Protein Cry1Ab	Nanomaterials	Information/data requirements: This study outlines a method for measurement of Cry1Ab protein, but the authors do not measure or report Cry1Ab protein expression levels in any Syngenta GM maize products.

TABLE 13 Report of internet publications excluded from the risk assessment after detailed assessment of full-text documents, giving the reason(s) for exclusion

List of bibliographic references for all internet publications excluded from the risk assessment, classified by authors			
Study author(s) and year^a	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria
FSANZ (2022)	A1239 -- BPS-BFLFK-2 -- Approval report	https://www.foodstandards.gov.au/code/applications/Documents/A1239_ApprovalReport.pdf	Intervention/Exposure
FSANZ (n.d.)	A1239 -- BPS-BFLFK-2 -- Supporting document 2 - Nutrition Risk Assessment	https://www.foodstandards.gov.au/code/applications/Documents/A1239_SD2_changed.pdf	Intervention/Exposure
FSANZ (2023)	A1264 -- IND-00410-5 -- Supporting document 1 - Safety assessment	https://www.foodstandards.gov.au/code/applications/Documents/01_A1264_SD1.pdf	Intervention/Exposure
FSANZ (2023)	A1262 -- MON-95275-7 -- Supporting document 1 - Safety assessment	https://www.foodstandards.gov.au/code/applications/Documents/01_A1262_SD1%20.pdf	Intervention/Exposure
HC (2022)	Canola Protein Isolate and Cruciferin-rich Canola Protein Isolate – Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/canola-protein-isolate-cruciferin-rich-canola-protein-isolate/document.html	Intervention/Exposure
HC (2022)	Sugarcane CTC75064-3 – Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/sugarcane-ctc75064-3/technical-document.html	Intervention/Exposure
HC (2023)	ROXY® rice expressing an oxyfluorfen herbicide tolerance characteristic – Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/roxy-rice-expressing-oxyfluorfen-herbicide-tolerance/document.html	Intervention/Exposure
MAFF (2022)	Results of deliberations by the Agricultural Products Subcommittee. BCS-GM151-6	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1991&ref_no=2	Intervention/Exposure

List of bibliographic references for all internet publications excluded from the risk assessment, classified by authors			
Study author(s) and year^a	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria
MAFF (2022)	Results of deliberations by the Agricultural Products Subcommittee. SYN-E3272-5 x SYN-BT011-1 x SYN-IR162-4 x SYN-IR604-5 x DAS-01507-1 x SYN-05307-1 x MON-00021-9	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1995&ref_no=2	Information/Data Requirements
MAFF (2022)	Results of deliberations by the Agricultural Products Subcommittee. OECD-UI: MON-95275-7	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1996&ref_no=2	Intervention/Exposure
MAFF (2022)	Results of deliberations by the Agricultural Products Subcommittee. BCS-BN0-12-7 x ACS-BN003-6 x MON-88302-9	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1993&ref_no=2	Intervention/Exposure
MAFF (2022)	Results of deliberations by the Agricultural Products Subcommittee. MON-95379-3	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1994&ref_no=2	Intervention/Exposure
MAFF (2023)	Results of deliberations by the Agricultural Products Subcommittee. MON-94804-4	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=2001&ref_no=2	Intervention/Exposure
MAFF (2023)	Results of deliberations by the Agricultural Products Subcommittee. BPS-BFLFK-2	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1999&ref_no=2	Intervention/Exposure
MAFF (2023)	Results of deliberations by the Agricultural Products Subcommittee.	https://www.biodic.go.jp/bch/lmo/OpenDocDownload.do?info_id=1998&ref_no=2	Intervention/Exposure
CONABIA (2022)	Resolution No. 27/2022 (05/11/2022). IND- ØØ412-7	http://www.magyp.gob.ar/sitio/pdf/RES_27-2022%20BO.pdf	Intervention/Exposure
CONABIA (2022)	Provision 21/2022. DNB-Ø8ØØ2-3	https://www.magyp.gob.ar/sitio/areas/biotecnologia/ogm/archivos/disposicion21-2022.pdf	Intervention/Exposure
CONABIA (2022)	Resolution No. 28/2022 (05/12/2022). MON-87751-7	http://www.magyp.gob.ar/sitio/pdf/RESOL-28-2022%20%20BO.pdf	Intervention/Exposure
CONABIA (2022)	Resolution 51/2022. MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 x DAS-4Ø278-9, Intermediate accumulators	https://magyp.gob.ar/sitio/areas/biotecnologia/pdf/Resolucion_512022.pdf	Intervention/Exposure
CTNBio (2022)	Technical Opinion No. 8072-2022	http://ctnbio.mctic.gov.br/documents/566529/2319671/Parecer+T%C3%A9cnico+8072_2022/	Intervention/Exposure
CTNBio (2022)	Technical Opinion No. 8281-2022	http://ctnbio.mctic.gov.br/documents/566529/2315217/Parecer+T%C3%A9cnico+8281_2022/	Intervention/Exposure

List of bibliographic references for all internet publications excluded from the risk assessment, classified by authors			
Study author(s) and year^a	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria
CTNBio (2023)	Technical Opinion No. 8396-2023	http://ctnbio.mctic.gov.br/documents/566529/2313404/Parecer+T%C3%A9cnico+8396_2023/	Intervention/Exposure
CTNBio (2023)	Technical Opinion No. 8407 - 2023	http://ctnbio.mctic.gov.br/documents/566529/2311588/Parecer+T%C3%A9cnico+n%C2%BA%208407+-+2023/	Intervention/Exposure
CTNBio (2023)	Technical Opinion No. 8352-2023	http://ctnbio.mctic.gov.br/documents/566529/2312772/PARECER+T%C3%89CNICO+N%C2%BA%208352_2023/	Intervention/Exposure
OGTR (2022)	DIR 190. Commercial release of Indian mustard genetically modified for herbicide tolerance (RF3)	https://www.ogtr.gov.au/sites/default/files/2022-10/dir190_full_risk_assessment_and_risk_management_plan.pdf	Intervention/Exposure
OGTR (2023)	DIR 191. Commercial import and distribution of chrysanthemum genetically modified for altered flower colour	https://www.ogtr.gov.au/sites/default/files/2023-02/dir191_full_risk_assessment_and_risk_management_plan.pdf	Intervention/Exposure
USDA (2022)	21-257-01rsr. Altered peroxidase and Herbicide Resistance (Corn)	https://www.aphis.usda.gov/brs/pdf/rsr/21-257-01rsr-review-response.pdf	Information/Data Requirements
USDA (2022)	21-270-01rsr. Altered tuber quality, Altered tuber sugar profile, Herbicide resistance, Fungal resistance, and Virus resistance, Resistance to potato late blight, (Potato)	https://www.aphis.usda.gov/brs/pdf/rsr/21-270-01rsr-review-response.pdf	Intervention/Exposure
USDA (2022)	21-166-01rsr. Product Quality and Marker Gene (Tomato)	https://www.aphis.usda.gov/brs/pdf/rsr/21-166-01rsr-review-response.pdf	Intervention/Exposure
USDA (2022)	21-245-01rsr. Altered tuber quality (Potato)	https://www.aphis.usda.gov/brs/pdf/rsr/21-245-01rsr-review-response.pdf	Intervention/Exposure
USDA (2022)	21-117-01rsr. Altered Seed Oil Profile and Protein Content (Soybean)	https://www.aphis.usda.gov/brs/pdf/rsr/21-117-01rsr-review-response.pdf	Intervention/Exposure
USDA (2022)	21-277-01rsr. Altered flower color and marker gene (antibiotic resistance) (Chrysanthemum)	https://www.aphis.usda.gov/brs/pdf/rsr/21-277-01rsr-review-response.pdf	Intervention/Exposure
USDA (2023)	22-276-01rsr. Altered appearance, Marker gene (antibiotic resistance) (Soybean)	https://www.aphis.usda.gov/brs/pdf/rsr/22-276-01rsr-review-response.pdf	Intervention/Exposure
USDA (2023)	22-224-01rsr. Altered nutritional profile (Potato)	https://www.aphis.usda.gov/brs/pdf/rsr/22-224-01rsr-review-response.pdf	Intervention/Exposure

List of bibliographic references for all internet publications excluded from the risk assessment, classified by authors			
Study author(s) and year^a	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria
USDA (2023)	22-235-01rsr. Altered appearance, Marker gene (antibiotic resistance) (Soybean)	https://www.aphis.usda.gov/brs/pdf/rsr/22-235-01rsr-review-response.pdf	Intervention/Exposure
USDA (2023)	22-152-01rsr. Altered plant architecture (Corn)	https://www.aphis.usda.gov/brs/pdf/rsr/22-152-01rsr-review-response.pdf	Intervention/Exposure
USDA (2023)	22-013-01rsr. Resistance to lodging (Teff)	https://www.aphis.usda.gov/brs/pdf/rsr/22-013-01rsr-review-response.pdf	Intervention/Exposure
USDA (2023)	22-276-02rsr. Altered appearance, Marker gene (antibiotic resistance) (Tomato)	https://www.aphis.usda.gov/brs/pdf/rsr/22-276-02rsr-review-response.pdf	Intervention/Exposure
US FDA (2022)	Biotechnology Notification File No. 170. Animal food use - CVM (Jun 7, 2022)	https://www.fda.gov/media/159911/download	Intervention/Exposure
US FDA (2022)	Biotechnology Notification File No. 177. Human Food Use - CFSAN (Sep 27, 2022)	https://www.fda.gov/media/162631/download	Intervention/Exposure
US FDA (2022)	Biotechnology Notification File No. 177. Animal food use - CVM (Sep 28, 2022)	https://www.fda.gov/media/162632/download	Intervention/Exposure
US FDA (2022)	Biotechnology Notification File No. 179. Animal food use - CVM (Nov 8, 2022)	https://www.fda.gov/media/164305/download	Intervention/Exposure
US FDA (2022)	Biotechnology Notification File No. 179. Human Food Use - CFSAN (Nov 7, 2022)	https://www.fda.gov/media/164304/download	Intervention/Exposure
US FDA (2022)	Biotechnology Notification File No. 170. Human food use - CFSAN (Jun 22, 2022)	https://www.fda.gov/media/159910/download	Intervention/Exposure
US FDA (2023)	Biotechnology Notification File No. 178. Animal Food Use - CVM (Jun 16, 2023)	https://www.fda.gov/media/170058/download	Intervention/Exposure
US FDA (2023)	Biotechnology Notification File No. 186. Human Food Use - CFSAN (Jun 8, 2023)	https://www.fda.gov/media/170396/download	Intervention/Exposure
US FDA (2023)	Biotechnology Notification File No. 178. Human Food Use - CFSAN (Jun 13, 2023)	https://www.fda.gov/media/170057/download	Intervention/Exposure

List of bibliographic references for all internet publications excluded from the risk assessment, classified by authors			
Study author(s) and year ^a	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria
US FDA (2023)	Biotechnology Notification File No. 186. Animal food use - CVM (May 31, 2023)	https://www.fda.gov/media/170397/download	Intervention/Exposure

- a. There were 14 records collected from MAFF that were excluded based on reporting format that are not listed in this table (all were documents submitted by applicants, not authored by the regulatory agency).
- b. n.d. = no date

4.4 List of the Bibliographic References for all Unobtainable Publications

There were no publications classified as unobtainable.

4.5 List of the Bibliographic References for all Unclear Publications

There were no publications with unclear details.

4.6 Full-Text Documents

Full-text documents for all relevant records (Section 4.2) were compiled using a reference management software (.RIS format) and accompany this final report.

4.7 Implications of Relevant Publications to the Risk Assessment of Syngenta GM maize products

For each relevant record, the reliability of the study and its implications on the risk assessment of Syngenta GM maize products were assessed (Table 14 and Table 15). Overall, the relevant records reviewed do not indicate any new hazards, modified exposure pathways, or new scientific uncertainties for Syngenta GM maize products. Therefore, we conclude, based on current available knowledge, that food/feed products derived from the event Syngenta GM maize products, and the associated intended traits/newly expressed proteins, do not pose a risk to human/animal health and/or the environment.

TABLE 14 Report of the reliability and implications for the risk assessment of all relevant database publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement(s)

List of bibliographic references for all relevant database publications, classified by category of information/data requirements			
Category of information/data requirement(s)	Study author(s) and year	Summary of reliability appraisal	Implications for the risk assessment
Molecular characterisation of the genetic modification of GMO	Noe <i>et al.</i> (2022)	Not assignable because no or insufficient information is reported in the study	This is a patent containing information on the development of MZIR098. It primarily contains information on the genetic insert. The information provided in this document does not change the risk assessment of MZIR098 or other Syngenta GM Maize products.

TABLE 15 **Report of the reliability and implications for the risk assessment of all relevant internet publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement(s)**

List of bibliographic references for all relevant internet publications, classified by category of information/data requirements			
Category of information/data requirements	Study author(s) and year	Summary of reliability appraisal	Implications for the Risk Assessment
Risk assessment or scientific opinion	CTNBio (2023)	Not assignable because no or insufficient information is reported in the study	This risk assessment evaluates Eucalyptus 1521K059, which expresses Cry1Ab. The safety of Cry1Ab protein was evaluated in the risk assessment. Specifically, it is stated that Cry1Ab has no significant homology to any allergens or toxins, is thermolabile, and rapidly hydrolyzed in simulated gastric and intestinal fluids. Therefore, this safety assessment concludes that Cry1Ab does not exhibit allergenic or toxic properties. There is no new information presented in this document and it does not affect the risk assessment of any Syngenta GM Maize products.
Risk assessment or scientific opinion	CTNBio (2023)	Not assignable because no or insufficient information is reported in the study	This is a technical opinion document regarding Bt11 x MIR162 x NK603 maize. It briefly discusses safety assessment summaries and regulatory agency opinions about the single events Bt11 and MIR162 and their newly expressed proteins (Cry1Ab, PAT, and Vip3Aa20; PMI was mentioned but not discussed). The record states that these events and proteins have a history of safe use individually and in combination and have previously been approved by multiple other regulatory agencies. This assessment does not provide any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	FSANZ (2023)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment document for DP51291 maize, which expresses PAT and PMI. It contains a safety assessment of the PAT and PMI proteins, including a summary of conclusions from updated bioinformatics analyses. The assessment states that PAT and PMI proteins do not share homology with any known toxins or allergens. This assessment does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	MAFF (2022)	Not assignable because no or insufficient information is reported in the study	This safety assessment is for DP202216 maize, which expresses the PAT protein. It concludes that PAT does not pose any known risks to human, animal, or environmental safety. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.

List of bibliographic references for all relevant internet publications, classified by category of information/data requirements			
Category of information/data requirements	Study author(s) and year	Summary of reliability appraisal	Implications for the Risk Assessment
Risk assessment or scientific opinion	MAFF (2022)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment for ipd079Ea maize, which expresses PAT and PMI proteins. A safety assessment of PAT and PMI is included in this record. The safety assessment notes that PAT and PMI do not share sequence similarity with known allergens. There is no new information presented in this document and the conclusions to not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	MAFF (2023)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of DP23211 maize which expresses PAT and PMI. It states that PAT and PMI have no sequence similarity to known allergens. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	MAFF (2023)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment for KWS20-1 sugar beet. It contains a brief safety assessment of PAT, stating that this protein does not have similarity to known allergen sequences and is not expected to produce toxic substances. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	MAFF (2023)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of DBN-09004-6 soybean. It contains a short safety assessment of the PAT protein that states PAT is not expected to produce toxic substances and is not considered to be allergenic. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	MAFF (2023)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of MON94313 soybean and contains a brief safety assessment on the PAT protein. It indicates that expression of PAT is not expected to produce a toxic substance. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	US FDA (2022)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of MON 87429 maize, which expresses PAT. There is a section containing a short safety assessment of the PAT protein, which concludes that PAT has a history of safe use in food and does not pose any meaningful risk to human health. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.

List of bibliographic references for all relevant internet publications, classified by category of information/data requirements			
Category of information/data requirements	Study author(s) and year	Summary of reliability appraisal	Implications for the Risk Assessment
Risk assessment or scientific opinion	US FDA (2022)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of MON 87429 maize, which expresses PAT. There is a section containing a short safety assessment of the PAT protein, which concludes that PAT has a history of safe use in food and does not pose any meaningful risk to animal health. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	US FDA (2022)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of IPD072Aa maize, which expresses PMI and PAT. The document notes that PMI is considered an inert ingredient. There is a short statement on the safety of the PAT protein, which concludes that there is reasonable certainty that the presence of PAT protein in food/feed does not result in any harm to humans or animals. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	US FDA (2022)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of IPD072Aa maize, which expresses PMI and PAT. The document notes that PMI is considered an inert ingredient. There is a short statement on the safety of the PAT protein, which concludes that there is reasonable certainty that the presence of PAT protein in food/feed does not result in any harm to humans or animals. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	US FDA (2023)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment for DP915635 maize. It contains a short safety assessment on PAT, which concludes that PAT has a long history of safe use and does not have any potential for allergenicity or toxicity. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	US FDA (2023)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment for DP915635 maize. It contains some statements on the safety assessment of PAT and concludes that PAT is not expected to cause any adverse effects and does not share any sequence homology with known toxins. This assessment does not contain any novel information and does not change the risk assessment of any Syngenta GM maize products.
Risk assessment or scientific opinion	USDA (2022)	Not assignable because no or insufficient information is reported in the study	This is an APHIS letter of exemption for GM maize expressing PMI. It notes a decision stating that the expressed traits (<i>i.e.</i> , PMI) do not pose a plant pest risk. This information does not change the risk assessment of any Syngenta GM Maize products.

List of bibliographic references for all relevant internet publications, classified by category of information/data requirements			
Category of information/data requirements	Study author(s) and year	Summary of reliability appraisal	Implications for the Risk Assessment
Risk assessment or scientific opinion	USDA (2022)	Not assignable because no or insufficient information is reported in the study	This is an APHIS letter of exemption for genetically engineered safflower expressing PAT. It notes a decision stating that the expressed traits (<i>i.e.</i> , PAT) do not pose a plant pest risk. This information does not change the risk assessment of any Syngenta GM Maize products.

5.0 STUDY RECORDS

5.1 Records Maintained

Records maintained include, but are not limited to, documentation of database search dates, database update dates, resolution of differences of opinion on records, the protocol, and any protocol amendments or deviations.

5.2 Archiving of Study Records

The protocol amendments, deviations, raw data, related documentation, and final report are archived at Syngenta in Research Triangle Park, NC, USA.

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APPENDICES SECTION

APPENDIX A. Syngenta GM Maize Products in Scope of this Application

The Syngenta GM maize products in-scope of this application are listed in the Table A1. For the authorized breeding stacks listed, the relevant sub-combinations of the single events comprising the highest order stacks are also considered in-scope of this application (independently of their origin). The relevant sub-combinations of the authorized breeding stacks are listed in Table A2 and Table A3.

TABLE A1 List of authorized GM Maize Events and Stacks in-scope of this application

Type	Authorized Syngenta GM Maize Products
Event	<ul style="list-style-type: none"> • Bt11 • MIR162 • MIR604 • GA21 • MZIR098 • 5307
Breeding Stack	<ul style="list-style-type: none"> • Bt11 × 59122 × MIR604 × 1507 × GA21^a • Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21^b • Bt11 × MIR162 × 1507 × GA21^b • Bt11 × MIR162 × MIR604 × GA21^b

- a. Table A2 lists the relevant sub-combinations for Bt11 × 59122 × MIR604 × 1507 × GA21 maize that are in-scope of this application.
- b. Table A3 lists the relevant sub-combinations for Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, Bt11 × MIR162 × 1507 × GA21 maize, and Bt11 × MIR162 × MIR604 × GA21 maize that are in-scope of this application.

TABLE A2 **List of sub-combinations in-scope for the authorized stack: Bt11 × 59122 × MIR604 × 1507 × GA21 maize**

Highest order stack	Bt11 × 59122 × MIR604 × 1507 × GA21
Five sub-combinations of four events	Bt11 × 59122 × MIR604 × 1507
	Bt11 × 59122 × MIR604 × GA21
	Bt11 × 59122 × 1507 × GA21
	Bt11 × MIR604 × 1507 × GA21
	59122 × MIR604 × 1507 × GA21
Nine sub-combinations of three events	Bt11 × 59122 × MIR604
	Bt11 × 59122 × 1507
	Bt11 × 59122 × GA21
	59122 × MIR604 × GA21
	59122 × MIR604 × 1507
	Bt11 × MIR604 × 1507
	Bt11 × 1507 × GA21
	MIR604 × 1507 × GA21
	59122 × 1507 × GA21
Six sub-combinations of two events	Bt11 × 59122
	59122 × MIR604
	Bt11 × 1507
	MIR604 × 1507
	1507 × GA21
	59122 × GA21

TABLE A3 **List of sub-combinations in scope for the authorized stacks: Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, Bt11 x MIR162 x 1507 x GA21 maize, and Bt11 x MIR162 x MIR604 x GA21 maize**

Highest Order Stack	Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21
Six sub-combinations of five events	Bt11 × MIR162 × MIR604 × 1507 × 5307
	Bt11 × MIR162 × MIR604 × 1507 × GA21
	Bt11 × MIR162 × MIR604 × 5307 × GA21
	Bt11 × MIR162 × 1507 × 5307 × GA21
	Bt11 × MIR604 × 1507 × 5307 × GA21
	MIR162 × MIR604 × 1507 × 5307 × GA21
Fourteen sub-combinations of four events	Bt11 × MIR162 × MIR604 × 1507
	Bt11 × MIR162 × MIR604 × 5307
	Bt11 × MIR162 × MIR604 × GA21
	Bt11 × MIR162 × 1507 × 5307
	Bt11 × MIR162 × 1507 × GA21
	Bt11 × MIR162 × 5307 × GA21
	Bt11 × MIR604 × 1507 × 5307
	Bt11 × MIR604 × 5307 × GA21
	Bt11 × 1507 × 5307 × GA21
	MIR162 × MIR604 × 1507 × 5307
	MIR162 × MIR604 × 1507 × GA21
	MIR162 × MIR604 × 5307 × GA21
	MIR162 × 1507 × 5307 × GA21
	MIR604 × 1507 × 5307 × GA21
Seventeen sub-combinations of three events	Bt11 × MIR162 × 5307
	Bt11 × MIR162 × 1507
	Bt11 × MIR162 × MIR604
	Bt11 × MIR162 × GA21
	Bt11 × MIR604 × 5307
	Bt11 × MIR604 × GA21
	Bt11 × 1507 × 5307
	Bt11 × 5307 × GA21
	MIR162 × MIR604 × 1507
	MIR162 × MIR604 × 5307
	MIR162 × MIR604 × GA21
	MIR162 × 1507 × 5307
	MIR162 × 5307 × GA21
	MIR604 × 1507 × 5307
	MIR604 × 5307 × GA21
	MIR162 × 1507 × GA21
Twelve sub-combinations of two events	1507 × 5307 × GA21
	Bt11 × 5307
	Bt11 × MIR162
	Bt11 × MIR604
	Bt11 × GA21
	MIR162 × 5307
	MIR162 × 1507
	MIR162 × MIR604
	MIR162 × GA21
	MIR604 × 5307
	MIR604 × GA21
	1507 × 5307
	5307 × GA21

APPENDIX B. Key Personnel Qualifications and Expertise

Table B1 Key Personnel

Name and Role	Qualifications and Expertise
██████████, Author & Record Reviewer	<ul style="list-style-type: none"> • Ph.D. Veterinary Medical Sciences (Toxicology concentration), University of Florida • M.S. Coastal Sciences, University of Southern Mississippi • B.S. Biochemistry and Molecular Biology, Michigan Technological University • 6 years of experience in toxicology and molecular biology research (including experience with genetic manipulation of organisms)
██████████, Record Reviewer	<ul style="list-style-type: none"> • Ph.D. Biochemistry and Molecular Biology, Peking University • B.S. Biochemistry, Lanzhou University • More than 15 years of experience conducting research in molecular biology, cell biology, pharmacology, and toxicology; extensive experience working with GM organisms including fungi, plants, and animals.
██████████, Tiebreaker*	<ul style="list-style-type: none"> • Ph.D. Pharmacology and Toxicology, West Virginia School of Medicine • B.M. Preventative Medicine, Shandong Medical University • Over 15 years of experience in research and development, regulatory science, and product safety for GM crops
██████████, Information Specialist	<ul style="list-style-type: none"> • MLIS (Master of Library and Information Science), UNC Greensboro • M.A., Wake Forest University • B.A., East Carolina University • 23 years of experience as a librarian at Colleges, Universities, and Private Research Libraries • Library Services for Syngenta Crop Protection since 2008

*The role of tie-breaker was assigned prior to starting the study. However, all conflicts were resolved by the reviewers and a tie-breaker was not needed. Therefore, the tie-breaker listed here did not participate in this study.

APPENDIX C. Pilot Study

The eligibility/inclusion criteria and process for selecting relevant database publications were assessed/validated using a pilot study. In particular, the pilot study evaluated whether the criteria and review process were suitable for properly categorizing records as relevant or not relevant to the risk assessment of Syngenta GM maize products (see Appendix A for the list of maize products in-scope of this application). The pilot study followed recommendations from the explanatory note on literature searching (EFSA 2019) and Frampton *et al.* (2017). A set of 9 known publications (Table C1) were assessed following the two-stage review process outlined in Section 3.3.1. One record reviewer selected a variety of publications for evaluation in the pilot study that spanned a range of relevance (e.g., definitely relevant, unclear relevance, definitely irrelevant) (Frampton *et al.* 2017). A kappa score and percent agreement were calculated following Stage 1 review. At Stage 1, Reviewer A included 4 records that Reviewer B excluded. This resulted in a kappa score of 0.70, which suggests substantial agreement between reviewers. The percent agreement at Stage 1 was 85.2%, indicating that the reviewers agreed on the classification of most records. Taking both metrics into account, we would consider this an acceptable level of agreement for identifying all relevant publications. Furthermore, at Stage 2 (full-text review) it was expected that the reviewers should classify 10 known records (Andreassen *et al.* 2015; De Framond *et al.* 2019; Dively *et al.* 2020; Haryu *et al.* 2009; Herman *et al.* 2021; Liu *et al.* 2020; Mao *et al.* 2020; Raybould *et al.* 2012; Schafer *et al.* 2016; Walters *et al.* 2020) as relevant during the pilot study, and all 10 records were classified as clearly relevant after Stage 2. This outcome demonstrated that relevant publications are retained using the outlined review process and eligibility/inclusion criteria. Therefore, we conclude the eligibility/inclusion criteria are clear and sufficient for accurately categorizing records as relevant or irrelevant.

Table C1 **Results of the pilot study, including reviewer decisions and percent agreement for each stage of review**

Reference	Stage 1 (Title/Abstract Review)		Stage 2 ^a (Full-text Review)	
	Reviewer A	Reviewer B	Reviewer A	Reviewer B
	Decision	Decision	Decision	Decision
Andreassen <i>et al.</i> (2015)	Yes	No	Yes	Yes
Bernillon <i>et al.</i> (2018)	Yes	Yes	No	No
Campos <i>et al.</i> (2018)	No	No	-	-
Carzoli <i>et al.</i> (2018)	No	No	-	-
De Framond <i>et al.</i> (2019)	Yes	Yes	Yes	Yes
de Vendômois <i>et al.</i> (2009)	No	No	-	-
Devos <i>et al.</i> (2018)	No	No	-	-
Dively <i>et al.</i> (2020)	Yes	No	Yes	Yes
Dreesen <i>et al.</i> (2018)	No	No	-	-
Erasmus <i>et al.</i> (2019)	No	No	-	-
Fast <i>et al.</i> (2020)	Yes	Yes	No	No
Haryu <i>et al.</i> (2009)	Yes	Yes	Yes	Yes
Herman <i>et al.</i> (2021)	Yes	Yes	Yes	Yes
Kim <i>et al.</i> (2019)	No	No	-	-
Liu <i>et al.</i> (2020)	Yes	No	Yes	Yes
Liu <i>et al.</i> (2021)	No	No	-	-
Mao <i>et al.</i> (2020)	Yes	Yes	Yes	Yes
Pálinkás <i>et al.</i> (2017)	No	No	-	-
Pellegrino <i>et al.</i> (2018)	No	No	-	-
Raybould <i>et al.</i> (2012)	Yes	No	Yes	Yes
Reddy <i>et al.</i> (2018)	Yes	Yes	No	No
Schafer <i>et al.</i> (2016)	Yes	Yes	Yes	Yes
Shi <i>et al.</i> (2019)	No	No	-	-
Snell <i>et al.</i> (2012)	No	No	-	-
Walters <i>et al.</i> (2020)	Yes	Yes	Yes	Yes
Xie <i>et al.</i> (2017)	No	No	-	-
Xie <i>et al.</i> (2018)	No	No	-	-
Percent Agreement	85.2%		100%	

a. A dash (-) denotes that a paper was not reviewed at Stage 2 due to exclusion by both reviewers at Stage 1.

APPENDIX D. Database Information

TABLE D1 Specifications of each database used in this study*

Database	Database Description	No. of Journals/Records	Dates of Coverage	Frequency of Database Updates in Ovid
Ovid Medline	Database comprised of international literature related to a variety of biomedicine topics related to human health. Produced by the National Library of Medicine.	>5,600 Journals/ >23 Million Records	1946-Present	Daily
CAB Abstracts	Database constructed by CAB International. Includes journal articles, patents, conference abstracts, and reports spanning a wide variety of topics in the life sciences that include (but are not limited to) agriculture, human health/nutrition, veterinary sciences, and natural resource management. Resources originate from over 120 countries.	>10.4 Million Records	1910-Present	Weekly
AGRICOLA	Database specializing in resources from agricultural and related sciences. Contains records from journal articles, book chapters, reports, and reprints. Developed by the National Agriculture Library (USDA). The article database provides citations to journal articles, book chapters, reports, and reprints. A limited selection of patents are also available in this library, although none have been indexed recently (past 10 years).	>5.2 Million Records	1970-Present	Monthly
BIOSIS Previews	Database covering a broad array of topics in the life sciences, and includes many publications and journals not found in Medline. Topics include a comprehensive coverage of biological, biochemical, biophysical, bioengineering, and biomedical research. Records include original research articles, national and international conferences, reviews, United States patents, technical letters and notes, and books.	>5,000 Journals/ >18 Million Records	1969 -Present	Weekly

*Information on these databases was retrieved from the Wolters Kluwer group, which hosts Ovid® Technologies. Additional information (i.e., sources for data) can be obtained upon request. (Medline database guide: <https://ospguides.ovid.com/OSPguides/medline.htm>, description: <https://www.wolterskluwer.com/en/solutions/ovid/ovid-medline-901>, CAB Abstracts database guide: <https://ospguides.ovid.com/OSPguides/cabadb.htm>, description: <https://www.wolterskluwer.com/en/solutions/ovid/cab-abstracts-31>; AGRICOLA database guide: <https://ospguides.ovid.com/OSPguides/agradb.htm>, description: <https://www.wolterskluwer.com/en/solutions/ovid/agricola-9>; BIOSIS Previews database guide: <https://ospguides.ovid.com/OSPguides/biopdb.htm>, description: <https://www.wolterskluwer.com/en/solutions/ovid/biosis-previews-26>)

APPENDIX E. Development of the Database Search Strategy

The database search strategy utilized a “lumping” approach to obtain a broad range of information related to Syngenta GM maize products and the intended traits/newly expressed proteins. A single search strategy was developed to capture all categories of information in one search. This strategy was expected to return a manageable number of records while still capturing the breadth of relevant information, based on previous experience.

E.1. Search terms

Search terms were identified by:

- Assessing the subject indexing terms of related, relevant publications¹ from the thesauri of electronic bibliographic databases.
- Seeking suggestions from a multi-disciplinary team of experts and stakeholders (i.e., risk assessors, information specialists, regulatory affairs managers).

E.2. Free-text terms and subject indexing terms

All searches were conducted from the Ovid[®] platform using the keyword search in the advanced search window. The keyword search executes a multi-field search across a specific combination of free-text and controlled vocabulary fields. The default set of fields (designated as “.mp”), which were used in this study, vary by database². Ovid automatically switches to the appropriate fields when a database is selected (the “.mp” designations for each search are shown in Appendix H).

In Ovid, all “.mp” fields are word searchable. Therefore, records indexed to a controlled vocabulary field containing a phrase are captured by searches using any part of that subject heading. For example, a search strategy that includes the search term “genetic*” will return all records indexed to the example fields listed below (words captured by the search term are highlighted in yellow):

- **Genetically modified** foods or **genetic engineering** in the Subject Headings field of Agricola,

¹ Relevant publications from previous literature search reports (that comply with the EFSA explanatory note on literature searching (EFSA, 2019)) for the risk assessment of events and stacks in-scope of this report were examined to identify associated subject indexing terms.

² In Agricola the .mp fields are: free-text—abstract; geographic area; identifier; meeting information; map information; note; original title; personal name as subject; title—and controlled vocabulary—category code; subject heading. In BIOSIS Previews the .mp fields are: free-text—abstract; book title; gene name; miscellaneous descriptors; methods & equipment; original language book title; title—and controlled vocabulary—biosystematic codes; chemicals & biochemicals; concept codes; diseases; geopolitical locations; major concepts; organisms; parts, structure & systems of organisms; sequence data; super taxa; taxa notes; time. In CAB Abstracts the .mp fields are: free-text—abstract; identifiers; original title; title—and controlled vocabulary—broad terms; geographic location; organism descriptors; subject headings. In Medline the .mp fields are: free-text—abstract; keyword heading word; original title; synonyms; title; unique identifier—and controlled vocabulary—floating sub-heading word; name of substance word; organism supplementary concept word; protocol supplementary concept word; rare disease supplementary concept word; subject heading word.

- *Zea mays*: species, maize, common, **genetically modified** in the Organism field of BIOSIS Previews,
- **Genetically engineered organisms** in the Subject Headings field of CAB Abstracts,
- Plants, **Genetically Modified** / ge [**Genetics**] or **Genetic Engineering** of MeSH Subject Headings in Medline

Similarly, controlled vocabulary fields can also be called using combined search terms. Thus, a search strategy that uses “genetic* AND (modif* OR engineer*)” will also return all records indexed to the above example fields (words captured by the search terms are indicated by bold font).

Notably, Ovid® search platform simultaneously searches free-text and controlled-vocabulary subject headings. Therefore, using all search terms in all databases does not present a disadvantage. Therefore, the same search strategy was used across all databases.

E.3. Search terms

The search terms were selected to ensure a wide variety of synonymous and related terms were included. Truncation and wildcards were used, when appropriate, to capture different spelling conventions and variation in the endings of terms.

E.4. Search strings

Search strings were combined with Boolean and proximity operators appropriate for the scope of the review.

E.5. Key elements of the review question used for best results

Based on previous experience, the search strategy returns a very large number of results when only targeting the four key elements of Events, Intended Traits, Newly Expressed Proteins, and Trade Names, as shown below:

- Event OR Intended Trait OR Newly Expressed Protein(s) OR Trade Name

“A very large number” is not defined in the explanatory note on literature searching (EFSA 2019). However, the numbers returned were so large that they could not be de-duplicated by the search platform. Example of these search strategies are listed below:

Therefore, additional key elements (e.g., GMO General, Plant Species) were added to the search strategy. The search strategy employed was:

- Event OR Trade name OR (Newly Expressed Protein(s) AND (GMO general OR Plant Species)) OR (Intended Trait – Insecticidal AND (GMO general AND Plant Species)) OR GMO general × Intended Traits

The altered search strategy retrieved a more manageable number of results without sacrificing sensitivity (defined as the ability to return the previously deemed relevant articles with the new search string). The sensitivity of the search strategy was demonstrated using reference publications (Appendix F).

E.6. The search strategy captures information for both single Events and Stacks

Using search terms related to one event does not exclude records also containing information on another event (e.g., search terms for event “A” will retrieve records related to event “A” as well as stacked events that include event “A,” such as “A × B”, “A × B × C”, “A × C”). Based on this premise, the search strategy employed (Table 4) captures information on both the single events and stacks in-scope of this application (listed in Appendix A). For example, search terms for Bt11 will also capture stacks containing Bt11 (e.g., Bt11 × MIR162, Bt11 × 1507 × 5307, Bt11 × MIR162 × MIR604 × 1507 × 5307). The search strategy includes terms related to the single events Bt11, MIR162, MIR604, GA21, MZIR098, and 5307 (including terms related to their newly expressed proteins, intended traits, and trade names). One or more of these single events is present in each of the authorized stacks or relevant sub-combinations in-scope of this application. Therefore, the search strategy is suitable for capturing information relevant to all Syngenta GM maize products in-scope of this application.

APPENDIX F. Reference Publications

Reference publications were used to assess the performance of the database search strategy before it was finalized. Reference publications were selected from relevant records identified in previous years' literature reviews on the risk assessment of Syngenta GM maize products (Table E1). A preliminary set of search results was obtained using the methods outlined in Section 3.2.1, with extended relevant search dates to capture the known reference publications from previous years. The presence/absence of reference publications within the preliminary search results was recorded for each database (Table E1). In total, 100% of the reference publications were retrieved using this search strategy. Therefore, the search strategy was considered sufficient for capturing the breadth of relevant literature available for this topic.

TABLE F1 Reference publication retrieval using the database search strategy

Reason for Selection	Reference	Agricola	BIOSIS Previews	CAB Abstracts	Medline
Assessment of adjuvanticity of Cry1Ab protein using a mouse model of airway allergy	Andreassen <i>et al.</i> (2015)		X	X	X
Patent for corn event 5307 describing the DNA sequences and recombinant constructs inserted into the corn genome and the genomic sequences flanking the insertion site	De Framond <i>et al.</i> (2019)		X		
Evaluation of gene flow in refuge systems (including a comparison of Agrisure hybrid NK1284-3000GT to a conventional counterpart)	Dively <i>et al.</i> (2020)	X	X	X	
Multi-generational assessment on the performance and life span of mice fed diets containing Bt11 maize	Haryu <i>et al.</i> (2009)			X	
Bioinformatics assessment of PMI protein sequences against known allergenic protein sequences	Herman <i>et al.</i> (2021)	X	X	X	X
Measurement of Vip3Aa protein expression in MIR162 maize using a novel ELISA assay	Liu <i>et al.</i> (2020)	X	X	X	X
Assessment of the digestibility of PAT and EPSPS proteins	Mao <i>et al.</i> (2020)				X
Assessment of invasiveness potential of transgenic maize events compared to their near-isogenic lines and maize landraces (including Bt11 maize)	Raybould <i>et al.</i> (2012)	X	X	X	X
Comparison of the newly expressed proteins derived from MZIR098 maize (eCry3.1Ab and mCry3A) to microbially produced proteins	Walters <i>et al.</i> (2020)	X	X	X	X
Number of articles identified in each database		5	7	7	6
Percentage of articles identified in each database		56%	78%	78%	67%

APPENDIX G. Reliability Assessment Criteria

TABLE G1 Reliability assessment criteria

Category/Categories of Information/Data Requirement	Critical Reliability Criteria
General <i>All primary research studies, regardless of category of data/information requirement, should meet these criteria.</i>	<ul style="list-style-type: none">- The objectives of the study are clearly defined and the hypotheses, where appropriate, are clearly stated.- The study design and methods are well-described in a way that allows for independent replication of experiments.- The methods used are validated and acceptable for measuring the outcomes/endpoints evaluated in the study.- The results are well described and, if applicable, sufficient information/data are provided to check the calculation of outcomes/endpoints.- Appropriate statistical methods/tests are used and clearly described.- Where appropriate, a description of the feasibility of the data to fit the assumptions of the statistical test(s) is included and any data manipulations are justified and described (e.g., transformations, removal of extreme observations).
Agronomic, phenotypic, and compositional characterization of the GM plant Persistence and invasiveness assessment, including plant-to-plant gene transfer	<p>Field studies</p> <ul style="list-style-type: none">- Test and control substances/organisms<ul style="list-style-type: none">▪ The test and control substances/organisms are clearly described, including the origin/source of the seed used to plant the field trial(s).▪ The control substance/organism is derived from non-transgenic seed/plants that are near-isogenic to the test substance/organism.- Experimental design<ul style="list-style-type: none">▪ Enough replicates are used (biological and/or technical) and, where applicable, enough organisms per replicate are used.▪ The location of field trial site(s) and approximate planting dates are well described.▪ A description of environmental conditions and abnormalities during field growing are reported (e.g., extreme weather conditions, extreme crop pest pressure).▪ A description of the field trial design (e.g., size, plot shape, inter-plot distances) is provided.▪ Clear and well-defined descriptions of the agronomic and/or phenotypic characteristics measured are provided, along with the methods used for measurement/assessment.- Statistical evaluation<ul style="list-style-type: none">▪ The design of field trial(s) (e.g., randomized complete block design, completely randomized, split-plot) and the experimental unit(s) are appropriate and well-described. <p>Compositional characterization</p> <ul style="list-style-type: none">- Test and control substances/organisms

Category/Categories of Information/Data Requirement	Critical Reliability Criteria
	<ul style="list-style-type: none">▪ The test and control substances/organisms are clearly described.▪ The test control substances/organisms were grown in the same location, during the same growing season, under similar environmental conditions.▪ The control substance/organism is derived from non-transgenic seed/plants that are near-isogenic to the test substance/organism.- Experimental design<ul style="list-style-type: none">▪ Enough replicates are used (biological and/or technical) and, where applicable, enough organisms per replicate are used.▪ Clear and well-defined descriptions of the compositional characteristics measured are provided, along with the methods used for measurement/assessment.▪ A clear description of procedures used to collect samples for compositional analysis is provided.▪ A description of and references for the analytical methods used to measure compositional analytes is provided.
Toxicological assessment of newly expressed protein(s), new constituents other than proteins, and the whole GM food/feed	<i>In vivo</i> Toxicity Testing <ul style="list-style-type: none">- Test and control substance<ul style="list-style-type: none">▪ The test substance is clearly described including its purity, composition, and origin.▪ The experimental system and any solvents used are appropriate for the test substance, considering its physicochemical characteristics.▪ Appropriate controls are used in this study (e.g., solvent control, negative and positive controls).- Test organisms<ul style="list-style-type: none">▪ The test organisms used in the study are well described (e.g., scientific name, weight, length, growth, age/life stage, strain/clone, gender if appropriate), and the test organism is appropriate for answering the research question.▪ The test organisms originate from a trustworthy source and were acclimatized to test conditions.- Experimental design and exposure conditions<ul style="list-style-type: none">▪ Enough replicates are used (biological and/or technical) and, where applicable, enough organisms per replicate are used.▪ The test conditions are well described and appropriate for the test organisms used (e.g., description of housing setup, light intensity, temperature, number of organisms per cage).▪ A description of the route of exposure and methods for dose administration are provided (preferably accompanied by analytical verification of the dose administered).▪ The exposure duration and frequency are described.▪ The measured parameters and endpoints examined are clearly described and defined. The methods for endpoint measurement are well-defined, validated, and appropriate.
Amino acid sequence comparison to known toxins	

Category/Categories of Information/Data Requirement	Critical Reliability Criteria
	<ul style="list-style-type: none">- Query sequence<ul style="list-style-type: none">▪ A complete description of the query sequence should be provided.▪ The experimental system and any solvents used are appropriate for the test substance, considering its physicochemical characteristics.▪ Appropriate controls are used in this study (e.g., solvent control, negative and positive controls).- Algorithms/parameters and sequence databases<ul style="list-style-type: none">▪ Sequence similarity searches should be performed with common local alignment tools such as BLAST or FASTA.▪ In general, default parameters for alignment tools should be used and the default parameters of the specific system should be listed (e.g., E-value threshold, word size, match/mismatch scores and gap costs). Any deviations from the default parameters should be listed and justified.▪ The sequence database(s) selected should be publicly available, up-to-date, and contain appropriate information/details for answering the research question.▪ Details on the sequence database(s) used, including the database version, should be provided.- Results and reporting<ul style="list-style-type: none">▪ Sequence similarity searches should be performed with common local alignment tools such as BLAST or FASTA.
Allergenicity assessment of the newly expressed protein and the GM food/feed, and adjuvanticity	<p><i>In vitro</i> digestion studies and experiments using cellular based assays</p> <ul style="list-style-type: none">- Test and control substances<ul style="list-style-type: none">▪ The test substance is clearly described including its purity, composition, and origin.▪ Appropriate controls are used in the study (e.g., solvent control, negative and positive controls).▪ For <i>in vitro</i> digestion assays, controls are used to demonstrate the effectiveness of the test system employed (e.g., appropriate control proteins are used to demonstrate the effectiveness of an <i>in vitro</i> digestion system). The controls are commercially available and well characterized.▪ For <i>in vitro</i> digestion assays, the concentration, source, purity, and specific activities of the digestive enzymes used are described.- Experimental design<ul style="list-style-type: none">▪ Enough replicates are used (biological and/or technical).▪ The conditions of the test system are reported (e.g., pH, addition of biosurfactants, and temperature for <i>in vitro</i> digestion studies; cell-culture conditions, cell strain, temperature, and seeding density for <i>in vitro</i> cell-based assays).▪ The end-points and read-outs are clearly defined and appropriate to address the research question. <p>Amino acid sequence comparison to known allergens</p> <ul style="list-style-type: none">- Query sequence<ul style="list-style-type: none">▪ A complete description of the query sequence should be provided.▪ The experimental system and any solvents used are appropriate for the test substance, considering its physicochemical characteristics.

Category/Categories of Information/Data Requirement	Critical Reliability Criteria
	<ul style="list-style-type: none">▪ Appropriate controls are used in this study (e.g., solvent control, negative and positive controls).- Algorithms/parameters and sequence databases<ul style="list-style-type: none">▪ Sequence similarity searches should be performed with common local alignment tools such as BLAST or FASTA.▪ In general, default parameters for alignment tools should be used and the default parameters of the specific system should be listed (e.g., E-value threshold, word size, match/mismatch scores and gap costs). Any deviations from the default parameters should be listed and justified.▪ The sequence database(s) selected should be publicly available, up-to-date, and contain appropriate information/details for answering the research question.▪ Details on the sequence database(s) used, including the database version, should be provided.- Results and reporting<ul style="list-style-type: none">▪ Sequence similarity searches should be performed with common local alignment tools such as BLAST or FASTA.
Nutritional assessment of the newly expressed protein(s), other new constituents, as well as potential alterations in the total diet of the consumer or the animal	<p><i>In vivo</i> feeding studies</p> <ul style="list-style-type: none">- Test and control substances/diets<ul style="list-style-type: none">▪ The origin/source of the test and control substances are well defined.▪ If the test-substance is GM plant material, the control substance is a non-transgenic and near-isogenic variety.▪ An appropriate control diet is used and formulated with a similar nutrient profile.- Experimental design<ul style="list-style-type: none">▪ Enough replicates are used (biological and/or technical) and, where applicable, enough organisms per replicate are used.▪ The animal species used is appropriate for answering the research question.▪ The test conditions are well described and appropriate for the test organisms used (e.g., description of housing/pens, number of animals per pen).▪ For target animal feeding studies, the study spans an appropriate time period (e.g., from the growing and/or finishing period to slaughter for chickens, pigs, and cattle, a major part of the lactation cycle for dairy cows, and the laying cycle for laying hens or quails).▪ For target animal feeding studies, the endpoints measured in the study are appropriate to answer the research question, but should also include animal health and welfare, animal losses, feed intake, body weight, and animal performance.- Statistical evaluation<ul style="list-style-type: none">▪ Justification for the choice of experimental design (e.g., randomized complete block design, completely randomized) is provided.▪ The statistical approaches are provided and consider the animal species under consideration.

Category/Categories of Information/Data Requirement	Critical Reliability Criteria
Assessment of plant to micro-organism gene transfer	<p>Bioinformatics assessment for plant-to-plant/microorganism gene transfer</p> <ul style="list-style-type: none"> - Query sequence <ul style="list-style-type: none"> ▪ A complete description of the query sequence should be provided. ▪ The experimental system and any solvents used are appropriate for the test substance, considering its physicochemical characteristics. ▪ Appropriate controls are used in this study (e.g., solvent control, negative and positive controls). ▪ The query sequence should be a minimum of 200-bp in length to consider DNA regions with increased recombination potential. - Algorithms/parameters and sequence databases <ul style="list-style-type: none"> ▪ Sequence similarity searches should be performed with common local alignment tools such as BLAST or FASTA. ▪ In general, default parameters for alignment tools should be used and the default parameters of the specific system should be listed (e.g., E-value threshold, word size, match/mismatch scores and gap costs). Any deviations from the default parameters should be listed and justified. ▪ The sequence database(s) selected should be publicly available, up-to-date, and contain appropriate information/details for answering the research question. ▪ Details on the sequence database(s) used, including the database version, should be provided. - Results and reporting <ul style="list-style-type: none"> ▪ The analysis should be presented in a graphic summary that depicts the results against the insert and flanking region. ▪ Results of significant matches should report the target organism, the length and percentage of identity, and the orientation of the alignment.
Assessment of interactions with non-target organisms (NTO)	<p><i>In vivo</i> toxicity/feeding studies assessing indirect exposure routes</p> <ul style="list-style-type: none"> - Test and control substances <ul style="list-style-type: none"> ▪ The origin/source of the test and control substances are well defined. ▪ Appropriate controls are used in the study (e.g., negative and positive controls). - Test species <ul style="list-style-type: none"> ▪ The test organisms used in the study are well described (e.g., scientific name, weight, length, growth, age/life stage, strain/clone, gender if appropriate), healthy, and of similar age. ▪ Justification for selection of the test organism is provided and appropriate. ▪ The biological performance of organisms used as controls shall be within acceptable limits (e.g., control mortality less than 20% depending on the testing system and organism) ▪ The test organisms originate from a trustworthy source and were acclimatized to test conditions. - Experimental design <ul style="list-style-type: none"> ▪ A sufficient number of replicates are used (biological and/or technical) and, where applicable, a sufficient number of organisms per replicate are used.

Category/Categories of Information/Data	
Requirement	Critical Reliability Criteria
	<ul style="list-style-type: none">▪ The environmental test conditions in growth chambers, mesocosms, and greenhouses are explicitly described and justified.▪ Exposure pathways are clearly defined in the experimental setup and exposure to known quantities of testing material is maintained throughout the study.▪ The experiment is conducted for a time span adequate to reliably estimate measurement endpoints.▪ If reproduction is an endpoint, the processes of the reproductive biology are included in the testing phase and the life-history of the test-organisms is reported (age at maturation, duration of egg development, and instars subjected to exposure).▪ If reproduction is an endpoint, optimization of conditions for growth and reproduction must be provided.

APPENDIX H. Search History and Subject Indexing

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<input type="checkbox"/>	# ▲	Searches	Results	Type	Actions	Annotations
<input type="checkbox"/>	1	(Bt11 or Bt 11 or SYN-BT#11-1).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	116	Advanced	Display Results More	Contract
<input type="checkbox"/>	2	(MIR162 or MIR 162 or SYN-IR162-4).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	43	Advanced	Display Results More	
<input type="checkbox"/>	3	(MIR604 or MIR 604 or SYN-IR6#4-5).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	28	Advanced	Display Results More	
<input type="checkbox"/>	4	(GA21 or GA 21 or GA2I or GA 2I or "MON-ØØØ21-9" or MON-ØØØ21-9 or MON-ØØØ21-9 or MON###21-9 or "MON-ØØØ21-9" or MON-ØØØ21-9 or MON-ØØØ21-9 or MON###21-9).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	53	Advanced	Display Results More	
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<input type="checkbox"/>	6	(MZIRØ98 or "SYN-ØØØ98-3" or SYN-ØØØ98-3 or SYN-ØØØ98-3).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	1	Advanced	Display Results More	
<input type="checkbox"/>	7	1 or 2 or 3 or 4 or 5 or 6	196	Advanced	Display Results More	
<input type="checkbox"/>	8	(Agrisure* or Duracade* or Viptera* or Herculex* or Roundup* Ready* Maize).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	35	Advanced	Display Results More	
<input type="checkbox"/>	9	(Cry1Ab* or Cry 1Ab* or Cry1 Ab* or Cry 1 Ab* or Cry1Ab* or Cry 1Ab* or Cry1 Ab* or Cry 1 Ab*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	894	Advanced	Display Results More	
<input type="checkbox"/>	10	(Phosphinothricin N acetyltransferase or Phosphinothricin N acetyl transferase or Phosphinothricin acetyltransferase or Phosphinothricin acetyl transferase or PPT acetyltransferase or PPT acetyl transferase or PT N acetyltransferase or PT N acetyl transferase or Glufosinate acetyltransferase or Glufosinate acetyl transferase or Glufosinate acetyltransferase or Glufosinate acetyl transferase or (pat adj5 protein) or 111069-93-3 or "EC 2.3.1.183" or "E.C. 2.3.1.183").mp.	246	Advanced	Display Results More	

[mp=meeting information, title, original title, map information, note, abstract, heading words]

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<input type="checkbox"/>	13	(5 enolpyruvyl shikimate 3 phosphate synthase or 5 enolpyruvylshikimate 3 phosphate synthase or EPSP synthase or MEPSP synthase or EPSPS or MEPSPS or "EC 2.5.1.19" or "E.C.2.5.1.19").mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	708	Advanced	Display Results More	
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<input type="checkbox"/>	17	((((Insect or insects or Coleoptera* or Lepidoptera* or pest or pests or stalkborer* or stalk borer* or borer* or cornborer* or corn borer* or Noctuidae or Crambidae or Chrysomelidae or earworm* or ear worm* or armyworm* or army worm* or cutworm* or cut worm* or rootworm* or root worm* or Ostrinia or O nubilalis or Diatraea or D grandiosella or D crambidoides or Helicoverpa or H zea or Spodoptera or S frugiperda or S exigua or Papaipema or P nebris or Elasmopalpus or E lignosellus or D saccharalis or Striacosta or S albicosta or Agrotis or A ipsilon or Feltia or F jaculifera or Pseudaletia or P unipuncta or Diabrotica or D virgifera or D barberi or ECB or SWCB or SCSB or CEW or FAW or SCB or WBC or WCRW or WCR or NCRW or MCR or MCRW) adj2 (toleran* or resistan* or protect* or control*)) or Bacillus thuringiensis or B thuringiensis or ((glufosinate* or gluphosinate* or Basta* or Liberty* or Ignite* or Rely* or Finale* or Challenge* or gl#phosate or gl#fosate or roundup* or round up* or herbicide* or pesticide*) adj2 (toleran* or resistan* or protect*))).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	58088	Advanced	Display Results More	
<input type="checkbox"/>	18	(GMO* or LMO* or GM or GE or transgen* or ((genetic* or living or biotech*) adj3 (modif* or transform* or manipul* or improv* or engineer* or deriv*)) or stack*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	117475	Advanced	Display Results More	
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<input type="checkbox"/>	21	19 or 20	6699	Advanced	Display Results	More	
<input type="checkbox"/>	22	(Maize* or corn* or Zea mays or Z mays).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	132904	Advanced	Display Results	More	
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<input type="checkbox"/>	25	7 or 8 or 16 or 23 or 24	3730	Advanced	Display Results	More	
<input type="checkbox"/>	26	limit 25 to yr="2022 -Current"	141	Advanced	Display Results	More	


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[Genome-scale analysis of ABC transporter genes and characterization of the ABCC type transporter genes in the oriental armyworm, Mythimna separata \(Walker\)](#)

limit 25 to yr="2022 -Current"

Search terms used:

- 1
- 3
- 5
- 11
- 21
- 162
- 604
- 5307
- 111069-93-3
- enolpyruvyl
- shikimate
- phosphate
- synthase
- enolpyruvylshikimate
- 9023-88-5
- a
- ipsilon
- aaa24109
- agrisure*
- agrotis
- army
- worm*
- armyworm*
- b
- thuringiensis
- bacillus
- basta*
- biotech*
- borer*
- bt
- bt11
- btcorn*
- btmaize*
- cew
- challenge*
- chrysomelidae
- coleoptera*
- control*
- corn
- corn*
- cornborer*
- crambidae

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☐ 4. [Bt maize can provide non-chemical pest control and enhance food safety in China](#)

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☐ 5. [Constitutive overexpression of EPSPS by gene duplication is involved in glyphosate resistance in Salsola tragus](#)

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<input type="checkbox"/>	# ▲	Searches	Results	Type	Actions	Annotations
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<input type="checkbox"/>	16	9 or 10 or 11 or 12 or 13 or 14 or 15	10943	Advanced	Display Results More	
<input type="checkbox"/>	17	((((Insect or insects or Coleoptera* or Lepidoptera* or pest or pests or stalkborer* or stalk borer* or borer* or cornborer* or corn borer* or Noctuidae or Crambidae or Chrysomelidae or earworm* or ear worm* or armyworm* or army worm* or cutworm* or cut worm* or rootworm* or root worm* or Ostrinia or O nubilalis or Diatraea or D grandiosella or D crambidoides or Helicoverpa or H zea or Spodoptera or S frugiperda or S exigua or Papaipema or P nebris or Elasmopalpus or E lignosellus or D saccharalis or Striacosta or S albicosta or Agrotis or A ipsilon or Feltia or F jaculifera or Pseudaletia or P unipuncta or Diabrotica or D virgifera or D barberi or ECB or SWCB or SCSB or CEW or FAW or SCB or WBC or WCRW or WCR or NCRW or MCR or MCRW) adj2 (toleran* or resistan* or protect* or control*)) or Bacillus thuringiensis or B thuringiensis or ((glufosinate* or gluphosinate* or Basta* or Liberty* or Ignite* or Rely* or Finale* or Challenge* or gl#phosate or gl#fosate or roundup* or round up* or herbicide* or pesticide*) adj2 (toleran* or resistan* or protect*))).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	708867	Advanced	Display Results More	
<input type="checkbox"/>	18	(GMO* or LMO* or GM or GE or transgen* or ((genetic* or living or biotech*) adj3 (modif* or transform* or manipulat* or improv* or engineer* or deriv*)) or stack*).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	703550	Advanced	Display Results More	
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<input type="checkbox"/>	7	1 or 2 or 3 or 4 or 5 or 6	306	Advanced	Display Results More	
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<input type="checkbox"/>	23	21 and 22	1669	Advanced	Display Results More	
<input type="checkbox"/>	24	(((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or corn* or mays)) or Btmaize* or Btcorn*)mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]	932	Advanced	Display Results More	
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