



**Review of Scientific Literature Relevant to the
Food/Feed and Environmental Risk Assessment of
Bt11 maize**

TEST GUIDELINE(S):

Not Applicable

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This is not a study as defined by 40 CFR Part 160.3 and is therefore not subject to Federal Insecticide, Fungicide, and Rodenticide Act Good Laboratory Practice Standards (GLPS; US EPA, 1989). However, all components of this analysis were performed according to accepted scientific practices, and relevant records have been retained.

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LIST OF ACRONYMS AND ABBREVIATIONS

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>)
ECCC	Environment and Climate Change Canada
EFSA	European Food Safety Authority
EU	European Union
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
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
PAT	Phosphinothricin N-acetyltransferase
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

Syngenta has developed maize (*Zea mays* L., corn) line derived from transformation event Bt11.

A systematic literature search and scoping review was conducted to collect, identify, and assess information (published between June 1, 2021 and July 1, 2022) relevant to the risk assessment of Bt11 maize and its newly expressed proteins, Cry1Ab and phosphinothricin N-acetyltransferase (PAT) proteins, 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 235 records were retrieved from the database search. Of these, two were determined to have unclear relevance and 233 were classified as not relevant. A total of 60 records were retrieved from the internet search, 22 of which were classified as relevant. The reference lists of relevant internet publications were also manually searched for records published between June 1, 2021 and July 1, 2022. This manual search identified 19 additional records, 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 Bt11 maize. Overall, the relevant records did not indicate any hazards, modified exposure pathways, or scientific uncertainties for Bt11 maize.

In conclusion, the results of this literature search and scoping review do not change the risk assessment of Bt11 maize.

2.0 INTRODUCTION

Maize plants derived from transformation event Bt11 contain the transgene *cry1Ab*, which encodes the insecticidal protein Cry1Ab, and the transgene *pat*, which encodes the enzyme phosphinothricin acetyltransferase (PAT). The native, full-length Cry1Ab produced by the soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* is active against certain lepidopteran pests of maize, including *Ostrinia nubilalis* and *Sesamia nonagrioides*. The Cry1Ab produced by Bt11 maize is a truncated version of native Cry1Ab that retains activity against lepidopterans. The transgene *pat* was derived from the soil bacterium *Streptomyces viridochromogenes*. PAT acetylates glufosinate-ammonium, thus inactivating it and conferring tolerance to glufosinate-ammonium in herbicide products. PAT was used as a selectable marker in the development of Bt11 maize.

The objective of this systematic literature search and scoping review was to collect, identify, and assess information relevant to the risk assessment of Bt11 maize and its newly expressed proteins, Cry1Ab and PAT, for use as food/feed. Information published between June 1, 2021 and July 1, 2022 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 genetically modified (GM) crop research, development, and safety assessment (Appendix A).

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 Bt11 maize on human/animal health and the environment. Therefore, the associated review question was defined as:

Do either food/feed products derived from Bt11 maize, or the 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
Population	Human and animal health and the environment
Intervention/Exposure	Bt11 maize, derived food/feed products, and/or the newly expressed proteins, Cry1Ab and PAT, and closely related variants
Comparator	Conventional counterpart (if applicable)
Outcome	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 B) 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). A record was included if it did not contain enough information to determine if the protein being evaluated was a closely-related variant.

TABLE 2 Eligibility/inclusion criteria to establish relevance

Concepts	Criteria	Comment
Intervention/exposure	Bt11 maize, derived food/feed products, and/or the intended or closely related trait(s)	Intended traits are glufosinate herbicide tolerance and lepidopteran insect resistance. Closely-related variants of Cry1Ab include those that share the same tertiary Crickmore nomenclature. Any enzyme classified by the author as a phosphinothricin N-acetyltransferase were considered.
Information/data requirements	Data inform one or more information/data requirement(s) for the GMO and derived food/feed products under consideration, including the intended trait(s)	Publications that potentially contribute to the knowledge informing the risk assessment of Bt11 maize (information/data requirements provided in Table 3) were considered. Publications addressing issues such as benefits, socio-economics, ethics, crop protection, detection methods, efficacy, public perception, and risk communication were excluded using this criterion, as they were not relevant to the risk assessment as defined in this document.
Scope of GMO application	The pathways and level of exposure to the GMO, derived food/feed products, and the intended trait(s) addressed in the publication, are relevant for the intended uses of the GMO and derived food/feed products under regulatory review	Publications must address pathways and levels of exposure relevant to the scope of the application: import and processing of Bt11 maize for food/feed uses.
Reporting format	Original/primary data are presented in the publication or it is a risk assessment from a relevant key organization (such as regulatory agencies and risk assessment bodies involved in the risk 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 included if they addressed Bt11 maize or Cry1Ab and/or PAT proteins.
Previously risk assessed publications	As indicated by EFSA, a publication should be included if it has not been previously risk assessed by EFSA and/or its GMO Panel and is not cited/referenced in an EFSA/GMO Panel output	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	Full-text document is accessible	If potentially relevant full-text documents cannot be obtained, they were listed in a table with a description of the (unsuccessful) methods used to attempt obtaining a copy.
Population	Human and animal health, and/or the environment are addressed as general protection goals	All of the information/data requirements categories described in Table 3 are thought to inform the risk assessment related to human and animal health, and/or the environment. Therefore, a publication was considered relevant if it met the inclusion criteria described in this table and was relevant to the information/data requirements in Table 3.
Outcomes	Effects/impacts on human and animal health, and/or the environment are addressed	Publications need to address effects/impacts on entities of concern, and potential determinants of exposure that place these entities at risk to be relevant to the risk assessment of Bt11 maize.

Concepts	Criteria	Comment
Comparator	If the publication is a comparative study that uses plant material as a test material, eligible publications must report a non-GM variety	Publications that address Bt11 maize must also include a conventional counterpart as a comparator in those cases where comparative analysis is conducted, and plant material is used as test material. Any uncertainties about the appropriateness of the comparator will be 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 Cry1Ab and/or PAT proteins.	The review question addresses the safe use of the intended trait(s) of Bt11 maize. Therefore, GMOs that contain Cry1Ab and/or PAT proteins, or closely-related variants, but are introduced into another plant species were included. For event-specific information/data requirements (Table 3), the presence of the transgenic proteins in a different plant species do not impact the assessment of Bt11 maize.
Target pest/organisms	Target pests/organisms addressed in the study are established in the EU	Records related to the intervention/exposure and target pests/organisms were excluded because the scope of the application is import for food/feed uses and this would only be relevant for cultivation applications.
Reporting format	A study should only be presented once, but if it is presented in more than one publication, all publications should be listed and grouped.	Duplicate publications were excluded at the initial screening stage. Only one copy of a study is presented even if it is reported in different publications.

TABLE 3 Overview of main categories of information/data requirements^a

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 (Bt11 maize only) • Expression data of inserted/modified sequences (Bt11 maize only) • Genetic stability (Bt11 maize only) • Molecular and biochemical characterization of the protein(s) such as: primary structure, molecular weight, post-translational modifications (Cry1Ab and/or PAT proteins as expressed in Bt11 maize only) • 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 (Cry1Ab and/or PAT proteins from Bt11 maize plants and a microbial source)
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 (Bt11 maize only) • Comparative analysis of key nutritional constituents (Bt11 maize)
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) (Cry1Ab and/or PAT proteins as expressed in Bt11 maize only) and toxic proteins • Stability of the protein(s) under relevant processing and storage conditions • Investigation of proteolytic susceptibility of the newly expressed protein • Toxicity studies • Feeding studies that use plant material (Bt11 maize only)
Allergenicity assessment of the newly expressed protein and the GM food/feed, and adjuvanticity	<ul style="list-style-type: none"> • Amino acid sequence comparison between the newly expressed protein(s) (Cry1Ab and/or PAT proteins as expressed in Bt11 maize only) and known allergens or celiac disease peptide sequences • Serum screening • Pepsin susceptibility testing • <i>In vivo</i> tests in animal models • Expression data for endogenous allergens (Bt11 maize only) • Comparison of newly expressed proteins to known strong adjuvants

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 from Bt11 maize and the resulting nutritional impact • Comparative growth performance studies with young rapidly growing animal species (Bt11 maize only if the diet contains transgenic plant material)
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 or not the product induces known (side) effects or unexpected side effects • Information on the reliability, sensitivity, and specificity of the post market monitoring
Persistence and invasiveness assessment, including plant-to-plant gene transfer	<ul style="list-style-type: none"> • Measurements of volunteer occurrence and establishment (Bt11 maize only) • Replacement capacity (i.e., # of plants present at specific observation time/# of plants present after initial sowing) (Bt11 maize only) • Fitness of the GM plant expressing Cry1Ab and/or PAT proteins in various environmental conditions – in the same or in a different plant species may be considered relevant
Assessment of plant to micro-organism gene transfer	<ul style="list-style-type: none"> • Homology searches at nucleotide level between the GM event and microorganisms (Bt11 maize only)
Assessment of interactions with target organisms	<ul style="list-style-type: none"> • Excluded based on the scope of the application. The scope of this application covers the import, processing and food/feed use of Bt11 maize in the EU. According to the EFSA 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, an assessment of the potential resistance development in target organisms resulting from the import, processing and food/feed use of Bt11 maize was not relevant for this application.
Assessment of interactions with non-target organisms (NTO)	<ul style="list-style-type: none"> • The EFSA ERA Guidance (EFSA 2010) states that: “<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>” Therefore, any publications that discussed direct exposure in test protein and laboratory studies or field survey data were considered not relevant based on the scope of application.
Assessment of interactions with biogeochemical and abiotic processes	<ul style="list-style-type: none"> • Excluded based on the scope of the application. The scope of this application covers the import, processing and food/feed use of Bt11 maize only in the EU. 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 Bt11 maize on biogeochemical processes resulting from specific cultivation, management, and harvesting techniques were not relevant given the scope of this application.

Assessment of impact of specific cultivation, management and harvesting techniques	<ul style="list-style-type: none">Excluded based on the scope of the application. The scope of this application covers the import, processing, and food/feed use of Bt11 maize in the EU. Cultivation of Bt11 maize 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 Bt11 maize were not relevant for this application.
Risk mitigation	<ul style="list-style-type: none">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 Bt11 maize.
Post-market environmental monitoring	<ul style="list-style-type: none">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 Bt11 maize.

a. If a record did not contain enough information to determine if the protein being evaluated is a closely related variant, it was included.

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 (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 C 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, conference proceedings, book chapters, reports, and articles in press. Detailed specifications of these databases are outlined in Appendix C.

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 Bt11 maize 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 where as 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 Bt11 maize. 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 A). Database search strategy construction is described in a detailed synopsis in Appendix D.

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 ^a
2	Topic	Agrisure*	Trade name(s) for Event Bt11
3	Topic	Cry1Ab* OR Cry 1Ab* OR Cry1 Ab* OR Cry 1 Ab* OR CryIAb* OR Cry IAb* OR CryI Ab* OR Cry I Ab*	Newly expressed protein in Bt11 (Insecticidal)
4	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 (Herbicide tolerance)
5		3 OR 4	
6	Topic	((Insect OR insects OR Lepidoptera* OR pest OR pests OR stalkborer* OR stalk borer* OR borer* OR cornborer* OR corn borer* OR Noctuidae OR Crambidae OR earworm* OR ear worm* OR armyworm* OR army 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 Papaipema OR P nebris OR Elasmopalpus OR E lignosellus OR D saccharalis OR ECB OR SWCB OR SCSB OR CEW OR FAW OR SCB) ADJ2 (toleran* OR resist* 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 herbicide* OR pesticide*) ADJ2 (toleran* OR resist* OR protect*))	Intended traits (insecticidal and herbicide tolerance)
7	Topic	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*))	GMO general
8	Topic	GMHT OR GEHT OR GMHR OR GEHR OR GMHTs OR GEHTs OR GMHRs OR GEHR	GMO general x intended trait-HT
9	Topic	Maize* OR corn* OR Zea mays OR Z mays	Plant species
10	Topic	((Bt OR Bacillus thuringiensis OR B thuringiensis) ADJ5 (maize* OR corn* OR mays)) OR Btmaize* OR Btcorn*	GMO general x intended trait-Bt
11		5 AND (7 OR 9)	Newly expressed proteins AND (GMO general OR Plant species)
12		(6 AND 7) OR 8	(Intended trait AND GMO general) OR GMO general × intended trait-HT
13		12 AND 9	((Intended trait AND GMO general) OR GMO general × intended trait-HT) AND Plant species

Set	Field	Search String	Concepts/Key Elements
14		1 OR 2 OR 11 OR 13 OR 10	Event OR Trade name OR (Newly expressed proteins AND (GMO general OR Plant species)) 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.
- b. Trade names for Bt11 include Agrisure CB/LL, Agrisure TL, Agrisure TD. Because the search strategy is not exclusionary, by searching just Agrisure it is possible to return all possible trade names.

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 E.

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, 2021-July 1, 2022) 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^{a,b}

Regulatory agency/risk assessment body	Webpage address	Search strategy and limits applied
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 2021 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 01/06/2021 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 2021 were retrieved for review.

Regulatory agency/risk assessment body	Webpage address	Search strategy and limits applied
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 2021-2022. Items were sorted by approval date. All documents with an approval date on or after 01/06/2021 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 01/06/2021 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” (Soybean), “Milho” (Corn), “Feijão” (Beans), “Eucalipto” (Eucalyptus), “Cana” (Cane), and “Algodão” (Cotton)) was searched for technical opinion documents. Those published during or after 2021 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. Documents with an “Issue Date” falling on or after 1-Jun-2021 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/permits-notifications-petitions/petitions/petition-status	The list of petitions was sorted by “Effective Date.” Documents from petitions with an “Effective Date” falling on or after 01/06/2021 were collected. Documents listed as “Final Environmental Assessment,” “Finding of No Significant Impact,” and/or “Final Plant Pest Risk Assessment” 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 (Plant Incorporated Protectants) Active Ingredients” was sorted by “Year Registered” and all documents listed under “BRAD (Biopesticides Registration Action Document) and other Regulatory Documents” with a “Year Registered” of 2021 or later, were retrieved for review.

Regulatory agency/risk assessment body	Webpage address	Search strategy and limits applied
US Food and Drug Administration (USFDA)	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon	The list of New Plant Variety Consulations was sorted by “Date Completed” and all items completed on or after June 1, 2021 were retrieved for review.

- 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.
- 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/>).
- 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.

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 list(s) were manually checked/scanned by both reviewers for new records within the relevant time period (June 1, 2021-July 1, 2022) 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 were in English or utilized the Roman alphabet. Translations are unlikely to exist for event and trade names, and therefore search terms were not translated.

3.2.5 Time period

All searches were conducted on or after July 1, 2022 (Table 7 and Table 8). The database search was limited, using the Ovid search platform, to records published between June 1, 2021 and the date of the last database update prior to the search (see Table 7). The records retrieved from regulatory agency webpages were limited by manually excluding publications dated prior to June 1, 2021. 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 B). 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 Bt11 maize. 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.

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 6. Across all searches (database, internet, and manual), a total of 314 unique publications were retrieved for review. Of these, 235 were retrieved from the database search, 60 were retrieved from the internet search, and 19 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 7). 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 F for screenshots of the search containing these details).

The database search returned a total of 235 records (after deduplication) that covered the dates of June 1, 2021 to July 1, 2022. During Stage 1, the reviewers agreed to include 2 records and exclude 232 records. Reviewers disagreed on the relevance of 1 record at Stage 1. This yielded a kappa score of 0.798, 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 1 disagreement after Stage 1 review, and agreed to exclude this record for Stage 2 review. In total, 233 records were excluded after Stage 1 and 2 records were reviewed in Stage 2, during which both were classified as unclear (Table 11). 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 8). The records from each website were de-duplicated individually. In total, the internet search yielded 60 records from regulatory agency websites that were evaluated only at Stage 2 (full-text) review. The reviewers agreed that 22 of the internet records were relevant (Table 9) and 38 were irrelevant (Table 10). 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, 2021-July 1, 2022), and 19 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 6 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)	235	60	19	314
Publications excluded from the search results after screening of title and abstracts (Stage 1)	233	NA ^d	19	252
Publications screened using full-text (Stage 2) ^c	2	60	0	62
Publications excluded after full-text screening ^e	0	38	0	38
Unobtainable/Unclear publications	2	0	0	2
Publications considered relevant	0	22	0	22

a. A total of 744 publications were identified from the database search. Of these, 509 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. There was one record excluded based on reporting format.

TABLE 7 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	01/07/2022	Ovid Technologies	01/06/2021 to 27/06/2022	Dates	9
BIOSIS Previews	01/07/2022	Ovid Technologies	01/06/2021 to 23/06/2022	Dates	41
CAB Abstracts	01/07/2022	Ovid Technologies	01/06/2021 to 30/06/2022	Dates	86
Medline	01/07/2022	Ovid Technologies	01/06/2021 to 30/06/2022	Dates	99

a. Ovid only allows results to be limited by year. The frequency of database update 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 8 Regulatory agency webpage search details^a

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 ^b	Number of relevant records
Canadian Food Inspection Agency	https://inspection.canada.ca/industry-guidance/eng/1374161650885/1374161737236?gp=3&gc=25&ga=4#gdr_results	12/07/2022	08/07/2022	0	0
Food Standards Australia New Zealand	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx	12/07/2022	May 2022	13	4
Health Canada	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html	12/07/2022	09/06/2022	12	2
Ministry of Agriculture, Forestry and Fisheries	https://www.biodic.go.jp/bch/lmo/OpenSearch.do	12/07/2022	No update information available	0	0
National Advisory Commission on Agriculture Biotechnology	https://www.argentina.gob.ar/agricultura/bioeconomia/biotecnologia/documentos-de-decision-conabia	13/07/2022	No update information available	1	1
National Technical Commission on Biosafety	http://ctnbio.mctic.gov.br/inicio	13/07/2022	No update information available	9	3
Office of the Gene Technology Regulator	https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release	13/07/2022	No update information available	5	4
US Department of Agriculture	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status	13/07/2022	14/03/2022	6	0
US Environmental Protection Agency	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated	13/07/2022	14/07/2020	0	0
US Food and Drug Administration	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon	13/07/2022	13/06/2022	14	8

a. Records published prior to June 1, 2021 were manually excluded.

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

4.2 Lists of Bibliographic References for Relevant Publications

After detailed review of the full-text documents in Stage 2, neither of the 2 database records reviewed were deemed relevant and 22 out of 60 internet records were deemed relevant (Table 9). Bibliographic information for the relevant records (author, publication year, title, and source) are included in the below table, and the records are organized alphabetically by the category of information/data requirement they fulfill (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 Bt11 maize, are provided in Section 4.7.

TABLE 9 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 Requirement(s)	Study (Author(s) and Year)	Title	Source
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2021)	Technical Opinion No. 7501 - 2021	http://ctnbio.mctic.gov.br/documents/566529/2302408/Parecer+T%C3%A9cnico+n%C2%BA+7501+-+2021/
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2022a)	Technical Opinion No. 7897 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2302517/Parecer+T%C3%A9cnico+n%C2%BA+7897+-+2022/
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2022b)	Technical Opinion No. 8035 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2302623/Parecer+T%C3%A9cnico+n%C2%BA+8035+-+2022/
Risk assessment or scientific opinion	National Advisory Commission on Agricultural Biotechnology (2021)	IND-00410-5	https://magyp.gob.ar/sitio/areas/biotecnologia/conabia/_pdf_dd/DD_soja_IND-oo41o-5_INDEAR.pdf
Risk assessment or scientific opinion	Health Canada (2021)	Insect Resistant and Herbicide Tolerant Maize Event DP-023211-2 -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/insect-resistant-herbicide-tolerant-maize-event-dp-023211-2/document.html

List of bibliographic references for all relevant internet publications, classified by category of information/data requirements			
Category of Information/Data Requirement(s)	Study (Author(s) and Year)	Title	Source
Risk assessment or scientific opinion	Health Canada (2022)	Insect Resistant and Herbicide Tolerant Zea maize event DP-915635 -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/insect-resistant-herbicide-tolerant-zea-maize/document.html
Risk assessment or scientific opinion	US Food and Drug Administration (2021a)	Biotechnology Notification File No. 166 . Animal food use - CVM (Jun 30, 2021)	https://www.fda.gov/media/151962/download
Risk assessment or scientific opinion	US Food and Drug Administration (2021b)	Biotechnology Notification File No. 166 . Human Food Use - CFSAN (Jul 21, 2021)	https://www.fda.gov/media/151963/download
Risk assessment or scientific opinion	US Food and Drug Administration (2021c)	Biotechnology Notification File No. 171 . Human Food Use - CFSAN (Aug 17, 2021)	https://www.fda.gov/media/153927/download
Risk assessment or scientific opinion	US Food and Drug Administration (2021d)	Biotechnology Notification File No. 171 . Animal food use - CVM (Aug 11, 2021)	https://www.fda.gov/media/153928/download
Risk assessment or scientific opinion	US Food and Drug Administration (2021e)	Biotechnology Notification File No. 168 . Human Food Use - CFSAN (Oct 20, 2021)	https://www.fda.gov/media/154779/download
Risk assessment or scientific opinion	US Food and Drug Administration (2021f)	Biotechnology Notification File No. 168 . Animal food use - CVM (Oct 14, 2021)	https://www.fda.gov/media/154780/download
Risk assessment or scientific opinion	US Food and Drug Administration (2022a)	Biotechnology Notification File No. 162 . Human Food Use - CFSAN (Mar 24, 2022)	https://www.fda.gov/media/157484/download
Risk assessment or scientific opinion	US Food and Drug Administration (2022b)	Biotechnology Notification File No. 162 . Animal food use - CVM (Mar 23, 2022)	https://www.fda.gov/media/157485/download
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021a)	A1198 -- DP-202216-6 _ Supporting document 1 - Risk assessment -- 6 August 2020	https://www.foodstandards.gov.au/code/applications/Documents/A1198_SD1.pdf
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021b)	A1202 -- DP-023211-2 _ Supporting document 1	https://www.foodstandards.gov.au/code/applications/Documents/A1202%20SD1.pdf?csf=1&e=JjOa8H
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021c)	A1202 -- DP-023211-2 _ Approval Report	https://www.foodstandards.gov.au/code/changes/circulars/Documents/A1202_Approval%20Report%20post%20Board.pdf?csf=1&e=skxrlQ
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2022)	A1232 -- IND-00412-7 _ Supporting document 1 - Safety assessment	https://www.foodstandards.gov.au/code/applications/Documents/01_A1232_SD1.pdf

List of bibliographic references for all relevant internet publications, classified by category of information/data requirements			
Category of Information/Data Requirement(s)	Study (Author(s) and Year)	Title	Source
Risk assessment or scientific opinion	Office of the Gene Technology Regulator (2021)	DIR 178 -- Risk assessment and risk management plan	https://www.ogtr.gov.au/sites/default/files/2021-09/dir178%20-%20Full%20Risk%20Assessemnet%20and%20Risk%20Mangement%20Plan.pdf
Risk assessment or scientific opinion	Office of the Gene Technology Regulator (2022a)	DIR 186 -- Risk assessment and risk management plan	https://www.ogtr.gov.au/sites/default/files/2022-02/Full%20Risk%20Assessment%20and%20Risk%20Management%20Plan_1.pdf
Risk assessment or scientific opinion	Office of the Gene Technology Regulator (2022b)	DIR 188 -- Risk assessment and risk management plan	https://www.ogtr.gov.au/sites/default/files/2022-06/dir188_full_risk_assessment_and_risk_management_plan.pdf
Risk assessment or scientific opinion	Office of the Gene Technology Regulator (2022c)	DIR 190 -- Risk assessment and risk management plan	https://www.ogtr.gov.au/sites/default/files/2022-06/dir190_risk_assessment_and_risk_management_plan_consultation_version.pdf

Report of all relevant manually retrieved publications after review of references from relevant internet documents

There were no relevant records retrieved during the manual search of reference lists from relevant internet documents.

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, neither of the two database records reviewed were excluded as they were considered unclear and 38 out of 60 internet records were excluded (Table 10). Bibliographic information for the excluded records (author, publication year, title, and source) are 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). Out of 38 irrelevant internet records, 1 was excluded based on reporting format (this document was a draft). Documents excluded based on reporting format were not included in Table 10. A rationale for exclusion was included for each record classified as one of the relevant document types, authored by the agency, and excluded based on an eligibility criterion other than “Reporting Format.”

TABLE 10 Report of internet publications excluded from the risk assessment after detailed assessment of full-text documents, giving the reason(s) for exclusion ^a

List of bibliographic references for all internet 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 listed in Table 2
Food Standards Australia New Zealand (2021)	A1216 -- MON-94100-2 _ Approval Report - 12 May 2021	https://www.foodstandards.gov.au/code/applications/Documents/A1216+Approval+Report.pdf	Intervention/Exposure
Food Standards Australia New Zealand (2021)	A1216 -- MON-94100-2 _ Supporting document 2 - Safety Assessment supplement	https://www.foodstandards.gov.au/code/applications/Documents/A1216+SD2.pdf	Intervention/Exposure
Food Standards Australia New Zealand (2021)	A1216 -- MON-94100-2 _ Supporting document 1 - Safety Assessment	https://www.foodstandards.gov.au/code/applications/Documents/A1216+Health+Canada+SD1.pdf	Intervention/Exposure
Food Standards Australia New Zealand (2021)	A1198 -- DP-202216-6 _ Approval Report - 15 December 2020	https://www.foodstandards.gov.au/code/applications/Documents/A1198+Approval+Report.pdf	Information/Data Requirements
Food Standards Australia New Zealand (2022)	A1226 -- MON-95379-3 _ Supporting document 1 - Safety Assessment	https://www.foodstandards.gov.au/code/applications/Documents/01_A1226_SD1.pdf	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1239 -- BPS-BFLFK-2 _ Supporting document 1 - Safety assessment	https://www.foodstandards.gov.au/code/applications/Documents/A1239+SD1.pdf	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1239 -- BPS-BFLFK-2 _ Supporting document 2 - Nutrition Risk Assessment	https://www.foodstandards.gov.au/code/applications/Documents/A1239+SD2.pdf	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1226 -- MON-95379-3 _ Approval report - 10 February 2022	https://www.foodstandards.gov.au/code/applications/Documents/A1226+GM+corn+ApprovalReport.pdf	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1232 -- IND-00412-7 _ Approval report - 6 May 2022	https://www.foodstandards.gov.au/code/applications/Documents/A1232+Approval+Report+final.pdf	Intervention/Exposure
Health Canada (2021)	Lepidopteran Protected Corn - MON 95379 -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/lepidopteran-protected-corn/document.html	Intervention/Exposure

List of bibliographic references for all internet 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 listed in Table 2
Health Canada (2021)	2'-Fucosyllactose from genetically engineered E. coli K12 MG1655 strain -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/fucosyllactose-escherichia-coli/document.html	Intervention/Exposure
Health Canada (2021)	Soy leghemoglobin (LegH) preparation as an ingredient in all simulated meat and poultry products - - Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/soy-leghemoglobin-simulated-meat-products/document.html	Intervention/Exposure
Health Canada (2021)	Napin-rich Canola Protein Isolate -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/napin-rich-canola-protein-isolate/document.html	Intervention/Exposure
Health Canada (2021)	D-tagatose -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/d-tagatose/document.html	Intervention/Exposure
Health Canada (2021)	Plum Pox Virus (PPV) Resistant C5 Plum -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/virus-resistant-plum/document.html	Intervention/Exposure
Health Canada (2021)	Quizalofop tolerant rice - RTA1 -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/quizalofop-tolerant-rice/document.html	Intervention/Exposure

List of bibliographic references for all internet 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 listed in Table 2
Health Canada (2021)	D-tagatose -- The gastrointestinal effects of D-tagatose	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/d-tagatose/gastrointestinal-effects.html	Intervention/Exposure
Health Canada (2022)	High oleic acid soybean line SVX-4003 -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/high-oleic-acid-soybean-line/document.html	Intervention/Exposure
Health Canada (2022)	Herbicide Tolerant DT Sorghum -- Technical Summary	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/herbicide-tolerant-dt-sorghum/document.html	Intervention/Exposure
National Technical Commission on Biosafety (2021)	Technical Opinion No. 7482 - 2021	http://ctnbio.mctic.gov.br/documents/566529/2303766/Parecer+T%C3%A9cnico+n%C2%BA+7482+-+2021/	Intervention/Exposure
National Technical Commission on Biosafety (2021)	Technical Opinion No. 7788-2021	http://ctnbio.mctic.gov.br/documents/566529/2292301/Parecer+T%C3%A9cnico+7788-2021/	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 7988 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2303872/Parecer+T%C3%A9cnico+n%C2%BA+7988+-+2022/	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 8038 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2303342/Parecer+T%C3%A9cnico+n%C2%BA+8038+-+2022/	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 8064 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2302729/Parecer+T%C3%A9cnico+n%C2%BA+8064+-+2022/	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 7891 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2302835/Parecer+T%C3%A9cnico+n%C2%BA+7891+-+2022/	Intervention/Exposure

List of bibliographic references for all internet 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 listed in Table 2
Office of the Gene Technology Regulator (2022)	DIR 189 -- Risk assessment and risk management plan	https://www.ogtr.gov.au/sites/default/files/2022-06/dir189_full_risk_assessment_and_risk_management_plan.pdf	Intervention/Exposure
US Department of Agriculture (2021)	Producing Phytase/Maize Event PY203 -- Final Environmental Assessment	https://www.aphis.usda.gov/brs/aphis/docs/19-176-01p-ea.pdf	Intervention/Exposure
US Department of Agriculture (2021)	Non-Browning/PG451 -- Record of Categorical Exclusion Determination	https://www.aphis.usda.gov/brs/aphis/docs/20-213-01ext-roced.pdf	Intervention/Exposure
US Department of Agriculture (2021)	Non-Browning/PG451 -- Preliminary Plant Pest Risk Assessment	https://www.aphis.usda.gov/brs/aphis/docs/20-213-01ext_det-pprsa.pdf	Intervention/Exposure
US Department of Agriculture (2022)	GMB 151 -- Final Environmental Assessment	https://www.aphis.usda.gov/brs/aphis/docs/19-31701p-fea.pdf	Intervention/Exposure
US Department of Agriculture (2022)	GMB 151 -- Final Plant Pest Risk Assessment	https://www.aphis.usda.gov/brs/aphis/docs/19-31701p-fppra.pdf	Intervention/Exposure
US Food and Drug Administration (2021)	Biotechnology Notification File No. 174 . Human Food Use - CFSAN (Aug 18, 2021)	https://www.fda.gov/media/154204/download	Intervention/Exposure
US Food and Drug Administration (2021)	Biotechnology Notification File No. 174 . Animal food use - CVM (Aug 13, 2021)	https://www.fda.gov/media/154205/download	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 172 . Animal food use - CVM (Apr 4, 2022)	https://www.fda.gov/media/158267/download	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 172 . Human food use - CFSAN (Apr 25, 2022)	https://www.fda.gov/media/158266/download	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 165 . Animal food use - CVM (Mar 18, 2022)	https://www.fda.gov/media/157488/download	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 165 . Human Food Use - CFSAN (Mar 24, 2022)	https://www.fda.gov/media/157486/download	Intervention/Exposure

a. There was one record not presented in this table because it was excluded based on reporting format.

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 2 publications with unclear details. The bibliographic information for these publications is listed in Table 11, along with an explanation of the (unsuccessful) methods for resolving the uncertainty. These records await assessment until the additional information is obtained from the authors, as recommended in the explanatory note on literature searching (EFSA, 2019).

TABLE 11 Report of unclear publications

List of bibliographic references for all unclear publications, classified by authors, classified by authors			
Study (author(s) and year)	Title	Source	Explanation of why the publication could not be classified, with a description of methods used to resolve the remaining uncertainty
Zhang <i>et al.</i> (2021)	Analysis of metabolites and metabolic mechanism in Bt transgenic and nontransgenic maize	<i>Microchemical Journal</i>	This study evaluates a Bt transgenic maize that expresses Cry1Ab, but does not specify exactly which event. The corresponding author was contacted to clarify, but no response was received.
Macar <i>et al.</i> (2021)	A comparative assessment of the unintended effects of genetic modification on Bt corn	<i>Fresenius Environmental Bulletin</i>	This study only indicates that Bt corn expressing Cry1Ab was used, but does not indicate a specific event. The corresponding author was contacted to clarify, but no response was received.

4.6 Full-Text Documents

Full-text documents for all relevant records (Table 9) 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 Bt11 maize

For each relevant record, the reliability of the study and its implications on the risk assessment of Bt11 maize were assessed (Table 12). Overall, the relevant records reviewed do not indicate any new hazards, modified exposure pathways, or new scientific uncertainties for Bt11 maize. Therefore, we conclude, based on current available knowledge, that food/feed products derived from the event Bt11 maize and intended traits do not pose a risk to human/animal health and/or the environment.

TABLE 12 **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 requirement(s)	Study author(s) and year	Summary of reliability appraisal	Implications for the risk assessment
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2021)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment for DP-ØØ4114-3, which expresses PAT protein encoded by the <i>pat</i> gene. It summarizes findings of allergenicity/toxicity assessments for PAT. The conclusion of this risk assessment indicates that PAT poses no known risks to human/animal health. No new information is presented and this does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2022a)	Not assignable because no or insufficient information is reported in the study	This risk assessment is for 3272 × Bt11 × MIR162 × GA21 maize. It summarizes information from previous studies on the allergenicity and toxicity of the PAT and Cry1Ab proteins. It also contains information on the nutritional content, genetic modifications, and PAT/Cry1Ab expression in the individual event Bt11. Based on this risk assessment, Bt11 and its newly expressed proteins do not pose any risks to human/animal health or the environment. No new information is introduced in this study and the evaluation does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2022b)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of MON 87429, which expresses PAT protein encoded by the <i>pat</i> gene. It summarizes information on toxicity/allergenicity assessments of the PAT protein. Conclusions of the risk assessment indicate that PAT does not pose any risks to human/animal health. No new information is presented in this assessment, and it does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	National Advisory Commission on Agricultural Biotechnology (2021)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of the IND-ØØ41Ø5 soybean that expresses PAT protein encoded by the <i>bar</i> gene, a closely related variant of PAT expressed in Bt11. The overall conclusions of this report indicate that there are no suspected risks to human/animal health because of PAT exposure. This does not contain any new information and does not change the risk assessment of Bt11 maize.

List of bibliographic references for all relevant internet 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
Risk assessment or scientific opinion	Health Canada (2021)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of DP-023211-2 maize, which expresses the PAT protein encoded by the <i>mo-pat</i> gene, a closely related variant of PAT expressed in Bt11 that shares an identical amino acid sequence. Data is summarized regarding animal toxicity testing and digestibility studies for PAT and conclusions of the risk assessment indicate that PAT does not pose any risks to human/animal health. No new information is presented in this assessment and it does not change the risk assessment Bt11 maize.
Risk assessment or scientific opinion	Health Canada (2022)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of DP-915635 maize, which expresses the PAT protein encoded by the <i>mo-pat</i> gene, a closely related variant of PAT expressed in Bt11 that shares an identical amino acid sequence. Data is summarized regarding animal toxicity testing and digestibility studies for PAT. Conclusions of the risk assessment indicate that PAT does not pose any risks to human/animal health. No new information is presented in this assessment, and it does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	US Food and Drug Administration (2021a)	Not assignable because no or insufficient information is reported in the study	This contains information on DBN9936 maize, which expresses Cry1Ab. It states that the EPA has granted a tolerance exemption for Cry1Ab protein, indicating that no negative effects on dietary health for humans/animals is expected because of Cry1Ab exposure in food. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	US Food and Drug Administration (2021b)	Not assignable because no or insufficient information is reported in the study	This contains information on DBN9936 maize, which expresses Cry1Ab. It states that the EPA has granted a tolerance exemption for Cry1Ab protein, indicating that no negative effects on dietary health for humans/animals is expected because of Cry1Ab exposure in food. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	US Food and Drug Administration (2021c)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of DP202216 maize, which expresses the PAT protein encoded by the <i>mo-pat</i> gene, a closely related variant of PAT expressed in Bt11 that shares an identical amino acid sequence. It describes a weight of evidence supporting the conclusion that PAT does not raise toxicity or allergenicity concerns. This does not contain new information and does not change the risk assessment of Bt11 maize.

List of bibliographic references for all relevant internet 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
Risk assessment or scientific opinion	US Food and Drug Administration (2021d)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of DP202216 maize, which expresses the PAT protein encoded by the <i>mo-pat</i> gene, a closely related variant of PAT expressed in Bt11 that shares an identical amino acid sequence. It describes a weight of evidence supporting the conclusion that PAT does not raise safety concerns. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	US Food and Drug Administration (2021e)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of DBN9858 maize, which expresses PAT protein encoded by the <i>pat</i> gene. It contains a safety assessment for PAT which describe results of toxicity/allergenicity studies. The conclusions of this assessment state that PAT does not raise safety concerns. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	US Food and Drug Administration (2021f)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of DBN9858 maize, which expresses PAT protein encoded by the <i>pat</i> gene. It contains a safety assessment for PAT which describe results of toxicity studies. The conclusions of this assessment state that PAT does not raise safety concerns. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	US Food and Drug Administration (2022a)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of NS-B50027-4 canola, which expresses PAT protein encoded by the <i>pat</i> gene. It contains a PAT protein safety assessment which outlines a weight of evidence supporting PAT safety, indicating it does not present toxicity or allergenicity concerns. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	US Food and Drug Administration (2022b)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of NS-B50027-4 canola, which expresses PAT protein encoded by the <i>pat</i> gene. This document reported a brief statement of the history of safe use for the PAT protein. The statements do not contain new information and do not change our current risk assessment for Bt11 maize.
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021a)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of DP202216 maize, which expresses PAT which expresses the PAT protein encoded by the <i>mo-pat</i> gene, a closely related variant of PAT expressed in Bt11 that shares an identical amino acid sequence. It describes a history of safe use of the PAT protein and the overall conclusions of the assessment indicate that no adverse effects to human/animal health are expected because of PAT exposure. There is no new information presented and this does not change the risk assessment of Bt11.

List of bibliographic references for all relevant internet 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
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021b)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment DP23211 maize, which expresses the PAT protein encoded by the <i>mo-pat</i> gene, a closely related variant of PAT expressed in Bt11 that shares an identical amino acid sequence. The assessment describes the results of updated bioinformatics analyses evaluating PAT toxicity/allergenicity. Conclusions of the safety assessment state that PAT is unlikely to be toxic or allergenic. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021c)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of DP23211 maize, which expresses the PAT protein encoded by the <i>mo-pat</i> gene, a closely related variant of PAT expressed in Bt11 that shares an identical amino acid sequence. The document states that PAT has previously been assessed by FSANZ for safety. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2022)	Not assignable because no or insufficient information is reported in the study	This risk assessment document reported a brief summary of the history of safe use for the PAT protein. The statements do not contain new information and do not change our current risk assessment for Bt11 maize.
Risk assessment or scientific opinion	Office of the Gene Technology Regulator (2021)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of GM canola. It contains a safety assessment of the PAT protein encoded by the <i>bar</i> gene; a closely related variant of PAT expressed in Bt11. Data from toxicity assessments of PAT is summarized. The assessment concludes that PAT proteins are not toxic to humans/animals. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	Office of the Gene Technology Regulator (2022a)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of GM wheat/barley. It contains a safety assessment of the PAT protein encoded by the <i>bar</i> gene a closely related variant of PAT expressed in Bt11. Data is summarized regarding animal toxicity testing for PAT. These assessments conclude that PAT lacks toxicity to humans/animals. This does not contain new information and does not change the risk assessment of Bt11 maize.
Risk assessment or scientific opinion	Office of the Gene Technology Regulator (2022b)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment for GM Indian mustard and canola expressing PAT protein encoded by the <i>pat</i> gene. The document describes a weight of evidence approach to support the conclusion that PAT poses no known risks to human/animal safety. There is no new information presented and the assessment does not change the risk assessment of Bt11.

List of bibliographic references for all relevant internet 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
Risk assessment or scientific opinion	Office of the Gene Technology Regulator (2022c)	Not assignable because no or insufficient information is reported in the study	This is a safety assessment of GM canola. It contains a safety assessment of It contains a safety assessment of the PAT protein encoded by the <i>bar</i> gene, a closely related variant of PAT expressed in Bt11. Data is summarized regarding animal toxicity testing and digestibility studies for PAT. These assessments conclude that PAT protein lacks toxicity to humans/animals. This does not contain new information and does not change the risk assessment of Bt11 maize.

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. Key Personnel Qualifications and Expertise

Table A1 Key Personnel

Name and Role	Qualifications and Expertise
<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 5px;"></div> 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)
<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 5px;"></div> Record Reviewer	<ul style="list-style-type: none"> • M.S. Environmental Assessment, North Carolina State University (NCSU) • Graduate Certificate in Applied Statistical Analysis & Data Management, NCSU • B.S. Agronomy with concentrations in Agronomic Business and Turfgrass Management, NCSU • 18 years of experience in regulatory science and product safety of GM crops.
<div style="background-color: black; width: 50px; height: 1.2em; margin-bottom: 5px;"></div> 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
<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 5px;"></div> 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 tiebreaker was assigned prior to starting the study. However, all conflicts were resolved by the reviewers and a tiebreaker was not needed. Therefore, the tiebreaker listed here did not participate in this study.

APPENDIX B. Pilot Study

The eligibility/inclusion criteria and process for selecting relevant database publications were assessed/validated using a pilot study. The same criteria are used for all single event GM maize (only the specific intervention/exposure differ between literature scoping reviews). Therefore, the criteria were assessed for their ability to properly categorize records as relevant or irrelevant in relation to all Syngenta GM maize single events simultaneously (intervention/exposure: Bt11, 5307, MIR162, MIR604, GA21, and the intended traits). The pilot study followed recommendations from the explanatory note on literature searching (EFSA 2019) and Frampton *et al.* (2017). A set of 18 known publications (Table B1) were assessed following the two-stage review process outlined in Section 3.3. One record reviewer selected a variety of publications for evaluation in the pilot study that spanned a range of relevance (i.e., 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 1 record that Reviewer B excluded, and Reviewer B included 1 record that reviewer A excluded. This resulted in a kappa score of 0.774, which suggests substantial agreement between reviewers. The percent agreement at Stage 1 was 89%, 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 eight known records (Andreassen *et al.* 2015; De Framond *et al.* 2019; Haryu *et al.* 2009; Herman *et al.* 2021; Jeong *et al.* 2020; Liu *et al.* 2020; Mao *et al.* 2020; Raybould *et al.* 2012) as relevant during the pilot study, and all eight records were classified as clearly relevant after Stage 2. This outcome demonstrates that relevant publications are retained using the outlined review process and eligibility/inclusion criteria. Additionally, the review process and criteria have been successfully used in previous PMEM literature scoping reviews for these GM maize events (██████ and ██████ 2021a, 2021b, 2021c, 2021d, 2021e). Therefore, we conclude the eligibility/inclusion criteria are clear and sufficient for accurately categorizing records as relevant or irrelevant.

Table B1 **Results of the pilot study, including reviewer decisions and percent agreement for each stage of review**

Reference	Stage 1 (Title/Abstract Review)		Stage 2 (Full-text Review)	
	Reviewer A Decision	Reviewer B Decision	Reviewer A Decision	Reviewer B Decision
Andreassen <i>et al.</i> (2015)	Include	Include	Include	Include
Bernillon <i>et al.</i> (2018)	Include	Include	Exclude	Exclude
Campos <i>et al.</i> (2018)	Exclude	Exclude	—	—
Carzoli <i>et al.</i> (2018)	Exclude	Exclude	—	—
De Framond <i>et al.</i> (2019)	Include	Include	Include	Include
Devos <i>et al.</i> (2018)	Exclude	Exclude	—	—
Dively <i>et al.</i> (2020)	Include	Include	Exclude	Exclude
Erasmus <i>et al.</i> (2019)	Include	Include	Unclear	Unclear
Fast <i>et al.</i> (2020)	Include	Exclude	Exclude	Exclude
Haryu <i>et al.</i> (2009)	Include	Include	Include	Include
Herman <i>et al.</i> (2021)	Include	Include	Include	Include
Jeong <i>et al.</i> (2020)	Include	Include	Include	Include
Liu <i>et al.</i> (2020)	Include	Include	Include	Include
Mao <i>et al.</i> (2020)	Include	Include	Include	Include
Pálinkás <i>et al.</i> (2017)	Exclude	Exclude	—	—
Pellegrino <i>et al.</i> (2018)	Exclude	Exclude	—	—
Raybould <i>et al.</i> (2012)	Include	Include	Include	Include
Reddy <i>et al.</i> (2018)	Exclude	Include	Exclude	Exclude
Xie <i>et al.</i> (2017)	Exclude	Exclude	—	—
Percent Agreement	89%		100%	

APPENDIX C. Database Information

TABLE C1 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, 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.”	>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, 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: <https://www.wolterskluwer.com/en/solutions/ovid/ovid-medline-901>, CAB Abstracts: <https://www.wolterskluwer.com/en/solutions/ovid/cab-abstracts-31>, AGRICOLA: <https://www.wolterskluwer.com/en/solutions/ovid/agricola-9>, BIOSIS Previews: <https://www.wolterskluwer.com/en/solutions/ovid/biosis-previews-26>)

APPENDIX D. Development of the Database Search Strategy

The database search strategy utilized a “lumping” approach to obtain a broad range of information related to Bt11 maize and the 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.

D.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).

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

All searches were conducted in the Ovid platform and utilized the keyword search in the advanced search window. The keyword search uses a default set of fields which are designated as “.mp” and vary by database (see Appendix E. Search History to see the .mp designations associated with each search). Hence, the “keyword search” in Ovid refers to executing a multi-field search across a specific combination of free-text and controlled vocabulary fields. The set of fields varies by database.² Ovid automatically switches to the appropriate fields when a database is selected.

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

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 this event 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.

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

D.3. Free-text searching functions

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

D.4. Search strings

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

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

Based on previous experience, a very large number of publications is returned when the search strategy uses only the four key elements of Event, Intended Trait, Newly Expressed Proteins, and Trade Name. Therefore, additional key elements were added to the search strategy. Doing so resulted in a manageable number of records being retrieved while still achieving sensitivity. Sensitivity was defined as the ability to return the previously deemed relevant articles with the new search string. ‘A very large number’ is not defined in the Explanatory Note on literature searching (EFSA 2019); however, the number returned with other search strategies (e.g., (Event OR Intended Trait OR Newly Expressed Protein(s) OR Trade Name) or (Event OR Trade name OR ((Intended Trait OR Newly Expressed Protein(s)) AND (Plant Species or GMO)))) was so large that it could not be de-duplicated by the search platform.

Therefore, the search structure was built to identify records that contained some or all of the four main concepts/key elements (Event, Trade Name, Newly Expressed Protein(s), and Intended Trait) and terms describing plant species and/or GMO general terms. 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 search strategy employed captured literature relevant to Bt11 maize and is provided in Table 4 of the main report text. The same search string was used in all databases. Since the

Ovid search platform simultaneously searches free-text and subject headings there is no disadvantage to using all search terms in all databases. For example, if 'Genetically engineered organisms' is a subject heading in CAB Abstracts, but not in Agricola, including this term in the search of the Agricola databases still allows for free-text searching of this term.

APPENDIX E. 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 Bt11 maize. If there were few or no known relevant records, publications that contained information on one or more key elements of the review question (i.e. event, newly expressed proteins, and/or intended traits), but would otherwise be considered irrelevant in this study, were used as reference publications. This ensured the search strategy was capable of retrieving the breadth of available information for the risk assessment of Bt11 maize.

The search strategy was assessed by obtaining a preliminary set of results 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 E1. Reference publication retrieval using the database search strategy

Reason for Selection: Key concepts of the review question that are highlighted in the reference are noted in parentheses (event, newly expressed proteins, and intended traits)	Reference	Agricola	BIOSIS Previews	CAB Abstracts	Medline
Assessment of exposure to Cry1Ab (newly expressed protein) from insect resistant maize (intended trait) on health outcomes in mouse.	Adel-Patient <i>et al.</i> (2011)		X	X	X
Assessment of the adjuvanticity of Cry1Ab (newly expressed protein) from insect resistant maize (intended trait) .	Andreassen <i>et al.</i> (2015)		X	X	X
Digestibility and allergenicity assessment of Cry1Ab (newly expressed protein).	Guimaraes <i>et al.</i> (2010)	X	X	X	X
Toxicity and safety assessment of Bt11 maize (event) on health outcomes in multiple generations of mice.	Haryu <i>et al.</i> (2009)			X	
Digestibility of PAT protein (newly expressed protein).	Mao <i>et al.</i> (2020)				X
Number of articles identified in each database		1	3	4	4
Percentage of articles identified in each database		20%	60%	80%	80%

APPENDIX F. Search History and Subject Indexing

7/1/22, 11:58 AM

Ovid: Search Form

AGRICOLA



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▼ **Search History** (15)

[View Saved](#)

<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	Agrisure*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	20	Advanced	Display Results More	
<input type="checkbox"/>	3	(Cry1Ab* or Cry 1Ab* or Cry1 Ab* or Cry 1 Ab* or CrylAb* or Cry lAb* or Cryl Ab* or Cry l Ab*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	909	Advanced	Display Results More	
<input type="checkbox"/>	4	(Phosphinothricin N acetyltransferase or Phosphinothricin N acetyl transferase or Phosphinothricin acetyltransferase or PPT acetyltransferase 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. [mp=meeting information, title, original title, map information, note, abstract, heading words]	286	Advanced	Display Results More	
<input type="checkbox"/>	5	3 or 4	1189	Advanced	Display Results More	
<input type="checkbox"/>	6	((((Insect or insects or Lepidoptera* or pest or pests or stalkborer* or stalk borer* or borer* or cornborer* or corn borer* or Noctuidae or Crambidae or earworm* or ear worm* or armyworm* or army 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 Papaipema or P nebris or Elasmopalpus or E lignosellus or D saccharalis or ECB or SWCB or SCSB or CEW or FAW or SCB) adj2 (toleran* or resistan* or protect* or control*)) or Bacillus thuringiensis or B thuringiensis or ((glufosinate* or glufosinate* or Basta* or Liberty* or Ignite* or Rely* or Finale* or Challenge* or herbicide* or pesticide*) adj2 (toleran* or resistan* or protect*))).mp.	87824	Advanced	Display Results More	

Report Number: RIR-0002772-22

7/1/22, 11:58 AM

Ovid: Search Form

AGRICOLA

[mp=meeting information, title, original title, map information, note, abstract, heading words]						
<input type="checkbox"/>	7	(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*))).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	112025	Advanced	Display Results More	
<input type="checkbox"/>	8	(GMHT or GEHT or GMHR or GEHR or GMHTs or GEHTs or GMHRs or GEHRs).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	116	Advanced	Display Results More	
<input type="checkbox"/>	9	(Maize* or corn* or Zea mays or Z mays).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	180958	Advanced	Display Results More	
<input type="checkbox"/>	10	((((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or corn* or mays)) or Btmaize* or Btcorn*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	1261	Advanced	Display Results More	
<input type="checkbox"/>	11	5 and (7 or 9)	943	Advanced	Display Results More	
<input type="checkbox"/>	12	(6 and 7) or 8	7516	Advanced	Display Results More	
<input type="checkbox"/>	13	12 and 9	1805	Advanced	Display Results More	
<input type="checkbox"/>	14	1 or 2 or 11 or 13 or 10	2654	Advanced	Display Results More	
<input type="checkbox"/>	15	limit 14 to yr="2021 -Current"	112	Advanced	Display Results More	

Save

Remove

Combine with:

AND

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Save All

Edit

Create RSS

Create Auto-Alert

Email All Search History

Copy Search History Link

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Basic Search | Find Citation | Search Tools | Search Fields | **Advanced Search** | Multi-Field Search

1 Resource selected | [Hide](#) | [Change](#)

AGRICOLA 1970 to June 2022

7/1/22, 11:58 AM

Ovid: Search Form

AGRICOLA

Enter keyword or phrase
(* or \$ for truncation)

☒ Keyword

☐ Author

☐ Title

☐ Journal

Search

► Limits (expand)

☐ Include Multimedia

☒ Map Term to Subject Heading

Options

PrintEmailExport+ My ProjectsKeep Selected

View By

Text (112 Results)

Multimedia (0 Results)

Search Information

You searched:

limit 14 to yr="2021 -Current"

Search terms used:

1

11

111069-93-3

agrisure*

army

worm*

armyworm*

b

thuringiensis

bacillus

basta*

biotech*

borer*

bt

bt11

btcorn*

btmaize*

cew

challenge*

control*

corn

corn*

- ☐ All

Range

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1

Go

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- ☐ 1.

Enhancement of Productivity of Maize (Zea mays L.) by Adoption of Scientific Method of Cultivation

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- ☐ 2.

Transgenic overexpression of P450 genes confers deltamethrin resistance in the fall armyworm, Spodoptera frugiperda

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- ☐ 3.

Effect of the Cry1, Cry2 and Vip3 protein combinations on the control of Anticarsia gemmatilis (Erebidae) and Chrysodeixis includens (Noctuidae) Lepidoptera

Cite

+ My Projects

+ Annotate
- ☐ 4.

The development of RPA and CRISPR-Cas12a based immunoassay strip for sensitive detection of genetically modified crops

Cite

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Report Number: RIR-0002772-22

7/1/22, 12:00 PM

Ovid: Search Form

BIOSIS

[mp=abstract, original language book title (non-english), book title (english), title, heading words]						
<input type="checkbox"/>	7	(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*))).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	613419	Advanced	Display Results More	
<input type="checkbox"/>	8	(GMHT or GEHT or GMHR or GEHR or GMHTs or GEHTs or GMHRs or GEHRs).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	158	Advanced	Display Results More	
<input type="checkbox"/>	9	(Maize* or corn* or Zea mays or Z mays).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	476914	Advanced	Display Results More	
<input type="checkbox"/>	10	((((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or corn* or mays)) or Btmaize* or Btcorn*).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	2644	Advanced	Display Results More	
<input type="checkbox"/>	11	5 and (7 or 9)	2191	Advanced	Display Results More	
<input type="checkbox"/>	12	(6 and 7) or 8	21528	Advanced	Display Results More	
<input type="checkbox"/>	13	12 and 9	4208	Advanced	Display Results More	
<input type="checkbox"/>	14	1 or 2 or 11 or 13 or 10	6584	Advanced	Display Results More	
<input type="checkbox"/>	15	limit 14 to yr="2021 -Current"	244	Advanced	Display Results More	

Save Remove

Combine with: AND OR

Save All Edit Create RSS Create Auto-Alert

Email All Search History Copy Search History Link Copy Search History Details

View Saved

Basic Search | Find Citation | Search Tools | Search Fields | **Advanced Search** | Multi-Field Search

1 Resource selected | [Hide](#) | [Change](#)
 BIOSIS Previews 1969 to 2022 Week 31

7/1/22, 12:00 PM

Ovid: Search Form

BIOSIS

Enter keyword or phrase
(* or \$ for truncation)

☒ Keyword

☐ Author

☐ Title

☐ Journal

Search

► Limits (expand)

☐ Include Multimedia

☐ Map Term to Subject Heading

Options

To search Open Access content on Ovid, go to [Basic Search](#).

View By

Text (244 Results)

Multimedia (0 Results)

Search Information

You searched:

limit 14 to yr="2021 -Current"

Search terms used:

1

11

111069-93-3

agrisure*

army

worm*

armyworm*

b

thuringiensis

bacillus

basta*

biotech*

borer*

bt

bt11

btcorn*

btmaize*

cew

challenge*

control*

corn

corn*

Print Email Export + My Projects Keep Selected

- ☐ All

Range

Clear

5 Per Page

1

Go

Next >
- ☐ 1.

Transgenerational responses to heat and fasting acclimation in the Angoumois grain moth

Cite

+ My Projects

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- ☐ 2.

The development of RPA and CRISPR-Cas12a based immunoassay strip for sensitive detection of genetically modified crops

Cite

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+ Annotate
- ☐ 3.

Evaluation of the impact of transgenic maize BT799 on growth, development and reproductive function of Sprague-Dawley rats in three generations

Cite

+ My Projects

+ Annotate
- ☐ 4.

Utility of isoxaflutole-based herbicide programs in HPPD-tolerant cotton production systems

Cite

+ My Projects

+ Annotate

7/1/22, 12:00 PM

cornborer*
crambidae
cry
ab*
1ab*
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iab*
cry1
cry1ab*
cryi
cryiab*
d
crambidoides
grandiosella
saccharalis
deriv*
diatraea
e
lignosellus
e.c.
2.3.1.183
ear
earworm*
ec
ecb
elasmopalpus
engineer*
faw
finale*
ge
gehr
gehrs
geht
gehts
genetic*
glufosinate
acetyl
transferase
acetyltransferase
glufosinate*
gluphosinate

Ovid: Search Form

BIOSIS

☐ 5. **Bt Cry1Ab/2Ab toxins disrupt the structure of the gut bacterial community of Locusta migratoria through host immune responses**

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☐ All [Clear](#) [Next >](#)

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7/1/22, 11:41 AM

Ovid: Search Form

CAB

[mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]						
<input type="checkbox"/>	7	(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*))).mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	200941	Advanced	Display Results More	
<input type="checkbox"/>	8	(GMHT or GEHT or GMHR or GEHR or GMHTs or GEHTs or GMHRs or GEHRs).mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	227	Advanced	Display Results More	
<input type="checkbox"/>	9	(Maize* or corn* or Zea mays or Z mays).mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	406546	Advanced	Display Results More	
<input type="checkbox"/>	10	((((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or corn* or mays)) or Btmaize* or Btcorn*).mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	2357	Advanced	Display Results More	
<input type="checkbox"/>	11	5 and (7 or 9)	1719	Advanced	Display Results More	
<input type="checkbox"/>	12	(6 and 7) or 8	17595	Advanced	Display Results More	
<input type="checkbox"/>	13	12 and 9	3434	Advanced	Display Results More	
<input type="checkbox"/>	14	1 or 2 or 11 or 13 or 10	5299	Advanced	Display Results More	
<input type="checkbox"/>	15	limit 14 to yr="2021 -Current"	211	Advanced	Display Results More	

Combine with:

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1 Resource selected | [Hide](#) | [Change](#)

CAB Abstracts 1973 to 2022 Week 26

Enter keyword or phrase ☒ **Keyword** ☐ Author ☐ Title ☐ Journal
(* or \$ for truncation)

7/1/22, 11:41 AM

Ovid: Search Form

CAB

► Limits (expand)

☐ Include Multimedia

☐ Map Term to Subject Heading

Options

View By

Text (211 Results)

Multimedia (0 Results)

Search Information

You searched:

limit 14 to yr="2021 -Current"

Search terms used:

1

11

111069-93-3

agrisure*

army

worm*

armyworm*

b

thuringiensis

bacillus

basta*

biotech*

borer*

bt

bt11

btcorn*

btmaize*

cew

challenge*

control*

corn

corn*

cornborer*

Print

Email

Export

+ My Projects

Keep Selected

☐ All

Range

Clear

5 Per Page

▼

1

Go

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☐ 1. Comparison of pathogenicity of Austrian isolates of *Tilletia caries* on common wheat (*Triticum aestivum*).

Cite

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+ Annotate

☐ 2. Ectopic expression of a rice triketone dioxygenase gene confers mesotrione tolerance in soybean.

Cite

+ My Projects

+ Annotate

☐ 3. Multiple and non-recessive resistance to Bt proteins in a Cry2Ab2-resistant population of *Helicoverpa zea*.

Cite

+ My Projects

+ Annotate

☐ 4. Global crop impacts, yield losses and action thresholds for fall armyworm (*Spodoptera frugiperda*): a review.

Cite

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- crambidae
- cry
- ab*
- 1ab*
- i
- iab*
- cry1
- cry1ab*
- cryi
- cryiab*
- d
- crambidoides
- grandiosella
- saccharalis
- deriv*
- diatraea
- e
- lignosellus
- e.c.
- 2.3.1.183
- ear
- earworm*
- ec
- ecb
- elasmopalpus
- engineer*
- faw
- finale*
- ge
- gehr
- gehrs
- geht
- gehts
- genetic*
- glufosinate
- acetyl
- transferase
- acetyltransferase
- glufosinate*
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saccharalis
deriv*
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lignosellus
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elasmopalpus
engineer*
faw
finale*
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genetic*
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