



**Review of Scientific Literature Relevant to the
Food/Feed and Environmental Risk Assessment of
Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize , Bt11 x
MIR162 x 1507 x GA21 maize, Bt11 x MIR162 x MIR604 x GA21
maize, and their sub-combinations covered by the authorisations**

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AUTHOR(S):



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PERFORMING LABORATORY:

Syngenta Crop Protection, LLC
410 Swing Road
Post Office Box 18300
Greensboro, NC 27419-8300 USA

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SPONSOR(S):

Syngenta Crop Protection, LLC
410 Swing Road
Post Office Box 18300
Greensboro, NC 27419-8300 USA

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Company: *Syngenta Seeds, LLC*

Company Representative:

[REDACTED]

November 23, 2022

[REDACTED]

Date

Team Lead, Regulatory Affairs

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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.

Author:

[REDACTED]

November 22, 2022

[REDACTED]

Date

Technical Expert, Product Safety
Syngenta Crop Protection, LLC
9 Davis Drive
Post Office Box 12257
Research Triangle Park, NC 27709-2257 USA

Submitted by:

[REDACTED]

November 23, 2022

[REDACTED]

Date

Team Lead, Regulatory Affairs
Syngenta Crop Protection, LLC
9 Davis Drive
Post Office Box 12257
Research Triangle Park, NC 27709-2257 USA

Sponsor:

[REDACTED]

November 22, 2022

[REDACTED]

Date

Technical Leader, Product Safety
Syngenta Crop Protection, LLC
410 Swing Road
Post Office Box 18300
Greensboro, NC 27419-8300 USA

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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)
mEPSPS	Double-mutated 5-enolpyruvylshikimate-3-phosphate synthase
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
PMI	Phosphomannose isomerase
US EPA	US Environmental Protection Agency
US FDA	US Food and Drug Administration
USDA	US Department of Agriculture
Vip3Aa20	Vegetative insecticidal protein

1.0 EXECUTIVE SUMMARY

Syngenta has developed Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21maize, Bt11 × MIR162 × 1507 × GA21 maize and Bt11 × MIR162 × MIR604 × GA21 maize (*Zea mays* L., corn) by combining different individual transformation events using conventional breeding.

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 × MIR162 × MIR604 × 1507 × 5307 × GA21maize, Bt11 × MIR162 × 1507 × GA21 maize and Bt11 × MIR162 × MIR604 × GA21 maize, including all sub-combinations in scope and/or the combined intended traits, for use as food/feed. This literature search was performed in the context of an annual post-market environmental monitoring (PMEM) report on genetically modified organisms (GMOs) authorized in the European Union (EU) market, and was conducted in compliance with the 2019 European Food Safety Authority (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 201 records were retrieved from the database search. Of these, 2 records were determined to have unclear relevance and 199 were classified as not relevant. A total of 27 records were retrieved from the internet search, none of which were classified as relevant.

Since no relevant records were identified, the results of this literature search and scoping review do not change the risk assessment of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, Bt11 × MIR162 × 1507 × GA21maize, and Bt11 × MIR162 × MIR604 × GA21 maize.

2.0 INTRODUCTION

Syngenta developed Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, Bt11 × MIR162 × 1507 × GA21 maize, and Bt11 × MIR162 × MIR604 × GA21 maize (*Zea mays* L., corn) by combining different individual transformation events using conventional breeding. 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 insect 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.

Maize plants derived from Event MIR162 contain the transgene *vip3Aa20*, which encodes the insecticidal protein Vip3Aa20, and the transgene *pmi*. Vip3Aa20 is a variant of the native Vip3Aa1 protein from the soil bacterium *B. thuringiensis* strain AB88, and is active against certain lepidopteran pests of maize, including *Spodoptera frugiperda* and *Helicoverpa zea*. phosphomannose isomerase (PMI) was used as a selectable marker in the development of MIR162 maize.

Maize plants derived from Event MIR604 provide control of certain coleopteran insect pests. Event MIR604 maize plants contain the transgene *mcry3A*, which encodes the insecticidal protein mCry3A, and the transgene *pmi*, which encodes the enzyme PMI. The native Cry3A from the soil bacterium *B. thuringiensis* subsp. *tenebrionis* is active against certain coleopteran pests of maize. The mCry3A produced by MIR604 was modified to have enhanced activity against the *Diabrotica virgifera virgifera* and other related coleopteran pests. PMI was used as a selectable marker in the development of MIR604 maize. PMI expressed in MIR604 maize differs from the *E.coli* PMI by two amino acids and has been designated MIR604 PMI.

Maize plants derived from transformation Event 1507 (TC1507) contain the gene *cry1F* which encodes the insecticidal protein Cry1F, and the gene *pat*. The native, full-length Cry1F produced by *B. thuringiensis* var. *aizawai* is active against certain lepidopteran insect pests of maize, including *Ostrinia nubilalis* and *Spodoptera frugiperda*. The Cry1F produced by 1507 maize is a truncated version of the native Cry1F that retains activity against lepidopterans. PAT was used as a selectable marker in the development of 1507 maize.

Maize plants derived from transformation Event 5307 contain the gene *ecry3.1Ab* encoding an eCry3.1Ab protein and the gene *pmi* (also known as *manA*) encoding the enzyme phosphomannose isomerase (PMI). The eCry3.1Ab protein is an engineered chimera of modified Cry3A (mCry3A) and Cry1Ab proteins and confers insecticidal activity against certain corn rootworm (*Diabrotica*) species. . The gene *manA* was obtained from *Escherichia coli* strain K-12 and the protein it encodes was utilized as a plant selectable marker during development of 5307 maize.

Maize plants derived from transformation Event GA21 contain the transgene *mepsps*, which encodes the enzyme double-mutated 5-enol pyruvylshikimate-3-phosphate synthase (mEPSPS). The native 5-enol pyruvylshikimate-3-phosphate synthase (EPSPS) from *Z. mays* is involved in synthesis of aromatic amino acids and is inhibited by glyphosate. The double-mutated mEPSPS produced by GA21 maize has low affinity for glyphosate compared to the native EPSPS, thus conferring tolerance to glyphosate in herbicide products.

The objective of this systematic literature search and scoping review was to collect, identify, and assess information relevant to the risk assessment of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, Bt11 × MIR162 × 1507 × GA21 maize, and Bt11 × MIR162 × MIR604 × GA21 maize, including all sub-combinations in scope, and/or the combined intended traits for use as food/feed. Since Bt11 × MIR162 × 1507 × GA21 maize and Bt11 × MIR162 × MIR604 × GA21 maize are sub-combinations of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 (the highest order stack), the objective of this literature review was to assess the highest order stack and all sub-combinations in scope. 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 genetically modified organisms (GMOs) authorized in the European Union (EU) market, and was conducted in compliance with the 2019 European Food Safety Authority (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 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including all sub-combinations in scope and/or the combined intended traits, on human/animal health and the environment. Therefore, the associated review question was defined as:

Do either food/feed products derived from Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including all sub-combinations in scope, or the combined 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. The sub-combinations of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize that are in scope are outlined in Table 2.

TABLE 1 Review question in PICO/PECO structure

Element	Components of Review Question
<u>P</u> opulation	Human and animal health and the environment
<u>I</u> ntervention/ <u>E</u> xposure	Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including all sub-combinations in scope, derived food/feed products, and/or relevant combinations of the newly expressed proteins, eCry3.1Ab, mCry3A, Cry1Ab, PAT, Cry1F, mEPSPS, Vip3Aa20, and PMI, and closely related variants
<u>C</u> omparator	Conventional counterpart (if applicable)
<u>O</u> utcome	Adverse effects

Pre-defined eligibility/inclusion criteria (Table 3) 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 3 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 4. 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 whether the protein being evaluated was a closely-related variant.

TABLE 2 **List of sub-combinations in scope for the authorized stacks: Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize , Bt11 x MIR162 x 1507 x GA21 maize, and Bt11 x MIR162 x MIR604 x GA21 maize**

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

TABLE 3 Eligibility/inclusion criteria to establish relevance

Concepts	Criteria	Comments and Justification for Criteria Selection
Stacked events obtained by conventional crosses/subcombinations	A publication is included when it addresses the highest order breeding stack and/or sub-combinations of the single events of the highest order breeding stack, independently of their origin.	This permitted the selection of publications on the highest order breeding stack (Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21) and/or relevant sub-combinations of the single events comprising the highest order stack (Table 2), independently of their origin. This permitted the exclusion of publications regarding only the single events of the highest order stack, because the risk assessment of GMO applications for stacked events covers only products in the scope of the GMO application.
Intervention/exposure	Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and all sub-combinations in-scope, derived food/feed products, and/or relevant combinations of the intended or closely related trait(s)	Intended traits include glufosinate herbicide tolerance, glyphosate herbicide tolerance, coleopteran insect resistance, lepidopteran insect resistance, and mannose metabolism. Herbicide tolerance is achieved by the expression of mEPSPS and PAT proteins. Insect resistance traits are achieved by the expression of the Cry1Ab, Vip3Aa, and Cry1F proteins for protection against specific lepidopteran pests, and by the expression of the mCry3A, and eCry3.1Ab proteins for protection against specific coleopteran pests. Closely related variants were considered proteins with the same tertiary level Crickmore nomenclature as Cry1Ab, Vip3Aa20, and eCry3.1Ab, and same secondary level Crickmore nomenclature for Cry1F and mCry3A. Any enzyme classified as an EPSPS that imparts glyphosate tolerance was considered a closely related variant. Any enzyme classified as a PAT enzyme was considered a closely related variant. Any enzyme classified as a PMI was considered a closely related variant. Only unique protein combinations relevant to the stack and relevant sub-combinations were considered in-scope.
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 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize (information/data requirements provided in Table 4) and/or relevant sub-combinations in scope (Table 2) were considered relevant. Based on the scope of the application, certain information/data requirements were excluded (Table 4). 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 are not relevant to the risk assessment according to EFSA.
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	Publications must have addressed pathways and levels of exposure relevant to the scope of the application: import and processing of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including all relevant sub-combinations in scope (Table 2), for food/feed uses.

Concepts	Criteria	Comments and Justification for Criteria Selection
	and derived food/feed products under regulatory review	
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 considered for relevance if they addressed Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, any of the relevant sub-combinations in scope (Table 2), and unique combinations of the newly expressed proteins, eCry3.1Ab, mCry3A, Cry1Ab, PAT, Cry1F, mEPSPS, Vip3Aa20, and PMI, and closely related variants.
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 could not 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 requirement categories described in Table 4 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 4.
Outcomes	Effects/impacts on human and animal health, and/or the environment are addressed.	Publications must address effects/impacts on entities of concern, and potential determinants of exposure that place these entities at risk, in order to be relevant to the risk assessment of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize or sub-combinations in scope (Table 2).
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 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize or sub-combinations in scope (Table 2), 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 unique combinations of eCry3.1Ab, mCry3A, Cry1Ab, PAT, Cry1F,	The review question addresses the safe use of the intended trait(s) of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and sub-combinations in scope (Table 2). Therefore, GMOs that contain combinations of eCry3.1Ab, mCry3A, Cry1Ab, PAT, Cry1F, mEPSPS, Vip3Aa20, and PMI, or closely-related variants, unique to the product and sub-combinations in scope, but are

Concepts	Criteria	Comments and Justification for Criteria Selection
	mEPSPS, Vip3Aa20, and PMI in the stack or sub-combinations in scope of the application.	introduced into another plant species may be included. For stack/sub-combination specific information/data requirements (Table 4), the presence of the transgenic proteins in a different plant species does not impact the assessment of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and sub-combinations in scope.
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 be relevant for cultivation applications only.
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 will be presented even if it is reported in different publications.

TABLE 4 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 Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and relevant sub-combinations	<ul style="list-style-type: none"> Information on the inserted/modified DNA, including sequence, size, copy number, genetic element arrangement, deletions, location, sequence similarity searches, analysis of open reading frames for each individual events in the stack maize (stack/sub-combination specific) Expression data of inserted/modified sequences (stack/sub-combination specific) Genetic stability (stack/sub-combination specific) Data on the equivalence between plant-produced and microbially-produced proteins (stack/sub-combination specific)
Agronomic, phenotypic and compositional characterization of the Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and relevant sub-combinations	<ul style="list-style-type: none"> Comparative assessment of agronomic and phenotypic characteristics under field or controlled conditions (stack/sub-combination specific) Comparative analysis of key nutritional constituents (stack/sub-combination specific)
Toxicological assessment of newly expressed protein(s), new constituents other than proteins, and the whole GM food/feed	<ul style="list-style-type: none"> Toxicity studies in rodents (protein combinations in scope) Whole food/feed animal feeding studies (stack/sub-combination specific)
Allergenicity assessment of the newly expressed protein and the GM food/feed, and adjuvanticity	<ul style="list-style-type: none"> Serum screening (protein combinations in scope) <i>In vivo</i> tests in animal models Expression data for endogenous allergens in maize (stack/sub-combination specific)
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 and the resulting nutritional impact (stack/sub-combination specific) Comparative growth performance studies with young rapidly growing animal species (stack/sub-combination specific).
Post-market monitoring	<ul style="list-style-type: none"> Description of mechanisms for determining actual changes to overall dietary intake patterns of the Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and sub-combinations in scope (Table 2), to what extent this has occurred and whether the product induces known (side) effects or unexpected side effects Information on the reliability, sensitivity, and specificity of the post market monitoring methods.
Persistence and invasiveness assessment, including plant-to-plant gene transfer	<ul style="list-style-type: none"> Measurements of volunteer occurrence and establishment (stack/sub-combination specific) Replacement capacity (stack/sub-combination specific) Fitness of the Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and sub-combinations in scope (Table 2) in various environmental conditions – if the relevant combinations or sub-combinations of newly expressed proteins are expressed in a different plant species then the publication may be considered relevant.
Assessment of plant to microorganism gene transfer	<ul style="list-style-type: none"> This type of data is covered in the scope of the single event literature review and is therefore excluded.

Information/data requirement	Non-exhaustive list of specific information/data requirements
Assessment of interactions with target organisms	<ul style="list-style-type: none"> Excluded based on the scope of the application, which covers the import, processing, and food/feed use of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21, maize, including relevant sub-combinations in the EU (Table 2). 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, assessments of potential resistance development in target organisms resulting from the import, processing, and food/feed use of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including relevant sub-combinations, is not relevant for this application.
Assessment of interactions with nontarget organisms	<ul style="list-style-type: none"> Excluded based on the scope of the application, which covers the import, processing, and food/feed use of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including relevant sub-combinations in the EU (Table 2). 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 feces from animals fed the GM plant, and other by-products of industrial processes).</i>” Therefore, any publications that discuss direct exposure in test protein and laboratory studies or field survey data was considered not relevant for this application.
Assessment of interactions with biogeochemical and abiotic processes	<ul style="list-style-type: none"> Excluded based on the scope of the application, which covers the import, processing, and food/feed use of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including relevant sub-combinations in the EU (Table 2). 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 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including relevant sub-combinations, on biogeochemical processes resulting from specific cultivation, management, and harvesting techniques is not relevant for 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, which covers the import, processing, and food/feed use of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including relevant sub-combinations in the EU (Table 2). Cultivation of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 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 impacts related to the specific cultivation, management, and harvesting techniques of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including relevant sub-combinations, is not relevant for this application.

Information/data requirement	Non-exhaustive list of specific information/data requirements
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 at-risk species of conservation concern, and integrated pest/weed management, are only relevant to cultivation. The scope of this application covers the import, processing, and food/feed use of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and sub-combinations in scope (Table 2).
Post-market environmental monitoring	<ul style="list-style-type: none">Excluded based on the scope of the application. Monitoring, such as insect resistance, is only relevant to cultivation. The scope of this application covers the import, processing, and food/feed use of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including relevant sub-combinations (Table 2).
a. This table provides some examples of relevant data/information, but expert knowledge on data used in the risk assessment of the GMO is required.	

3.2 Searching for/Identifying Relevant Publications

3.2.1 Database searches

3.2.1.1 Electronic bibliographic databases

Multidisciplinary citation databases, which include grey literature (i.e., not peer reviewed), were used to search for different types of publications and unpublished work that could provide information on the review question. Two large, multi-disciplinary databases (Ovid Medical Literature Analysis and Retrieval System (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 (Stevenson and Lawlor 2004). Therefore, the present combination of databases was suitable for retrieving publications relevant to the risk assessment of the highest order stack, Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, and its relevant sub-combinations in scope (Table 2) as it relates to food/feed and the environment, while adhering to EFSA's definition of "best" search strategy practices (defined in Glanville *et al.* (2014) as "a situation whereas few resources as possible are searched with a high probability that most of the relevant research evidence will be identified").

3.2.1.2 Database search strategy

The electronic bibliographic databases search strategy was designed to retrieve information on the highest order stack of interest (Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize) and all relevant sub-combinations in scope (Table 2). Using search terms related to one event does not exclude records also containing information on another event (e.g., search terms for event "A" will retrieve records related to event "A" as well as stacked events that include event "A," such as "A × B", "A × B × C", "A × C"). Based on this premise, unique combinations of search terms related to the single events that constitute Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize (e.g., search terms for event names, newly expressed proteins, trade names) were used to capture the variety of sub-combinations relevant to this application (Table 5).

The same search strategy was used in all databases through the Ovid® search interface (outlined in Table 6). 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 5 Search term combinations used to capture the highest order stack and all relevant sub-combinations of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize^a

Binary Search Term Combinations	Relevant Stack Sub-combinations Captured
Bt11 and MIR162	Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 (highest order stack)
	Bt11 × MIR162 × MIR604 × 1507 × 5307
	Bt11 × MIR162 × MIR604 × 1507 × GA21
	Bt11 × MIR162 × MIR604 × 5307 × GA21
	Bt11 × MIR162 × 1507 × 5307 × GA21
	Bt11 × MIR162 × MIR604 × 1507
	Bt11 × MIR162 × MIR604 × 5307
	Bt11 × MIR162 × MIR604 × GA21
	Bt11 × MIR162 × 1507 × 5307
	Bt11 × MIR162 × 1507 × GA21
	Bt11 × MIR162 × 5307 × GA21
	Bt11 × MIR162 × 5307
	Bt11 × MIR162 × 1507
	Bt11 × MIR162 × MIR604
	Bt11 × MIR162 × GA21
	Bt11 × MIR162
Bt11 and MIR604	Bt11 × MIR604 × 1507 × 5307 × GA21
	Bt11 × MIR604 × 1507 × 5307
	Bt11 × MIR604 × 5307 × GA21
	Bt11 × MIR604 × 5307
	Bt11 × MIR604 × GA21
	Bt11 × MIR604
Bt11 and 5307	Bt11 × 1507 × 5307 × GA21
	Bt11 × 1507 × 5307
	Bt11 × 5307 × GA21
	Bt11 × 5307
Bt11 and GA21	Bt11 × GA21
MIR162 and MIR604	MIR162 × MIR604 × 1507 × 5307 × GA21
	MIR162 × MIR604 × 1507 × 5307
	MIR162 × MIR604 × 1507 × GA21
	MIR162 × MIR604 × 5307 × GA21
	MIR162 × MIR604 × 1507
	MIR162 × MIR604 × 5307
	MIR162 × MIR604 × GA21
	MIR162 × MIR604
MIR162 and 1507	MIR162 × 1507 × 5307 × GA21
	MIR604 × 1507 × 5307 × GA21
	MIR162 × 1507 × 5307
	MIR162 × 1507 × GA21
	MIR162 × 1507
MIR162 and 5307	MIR162 × 5307 × GA21

Binary Search Term Combinations	Relevant Stack Sub-combinations Captured
	MIR162 × 5307
MIR162 and GA21	MIR162 × GA21
MIR604 and 5307	MIR604 × 1507 × 5307 × GA21
	MIR604 × 5307 × GA21
	MIR604 × 5307
MIR604 and GA21	MIR604 × GA21
1507 and 5307	1507 × 5307 × GA21
	1507 × 5307
5307 and GA21	5307 × GA21

- a. This table illustrates that the binary search term combinations used in the search strategy capture all relevant sub-combinations of the highest order stack (Table 2). It is not an exclusive list of which interventions/exposures are captured by each combination of binary search terms.

TABLE 6 Search string strategy

Set	Field	Search String	Concepts/Key Elements
1	Topic	Bt11 OR Bt 11 OR SYN-BT#11-1	Single event Bt11 ^a
2	Topic	MIR162 OR MIR 162 OR SYN-IR162-4	Single event MIR162
3	Topic	MIR604 OR MIR 604 OR SYN-IR6#4-5	Single event MIR604 ^a
4	Topic	TC1507 OR TCI507 OR (1507 ADJ4 (event OR maize OR corn)) OR DAS1507 OR DASI507 OR "DAS-Ø15Ø7-1" OR DAS-O15O7-1 OR DAS-01507-1	Single event 1507
5	Topic	(5307 ADJ4 (event OR maize OR corn)) OR "SYN-Ø53Ø7-1" OR SYN-O53O7-1 OR SYN-05307-1	Single event 5307
6	Topic	GA21 OR GA 21 OR GA2I OR GA 2I OR "MON-ØØØ21-9" OR MON-OOO21-9 OR MON-00021-9 OR MON###21-9 OR "MØN-ØØØ21-9" OR MØN-OOO21-9 OR MØN-00021-9 OR MØN###21-9	Single event GA21 ^a
7		1 AND (2 OR 3 OR 5 OR 6)	Relevant event combinations
8		2 AND (3 OR 4 OR 5 OR 6)	Relevant event combinations
9		3 AND (5 OR 6)	Relevant event combinations
10		5 AND (4 OR 6)	Relevant event combinations
11		7 OR 8 OR 9 OR 10	All Single event combinations OR Higher stacked event
12		Agrisure*	Trade name MIR162, MIR604, Bt11 ^b
13		Herculex*	Trade name 1507 ^b
14		Duracade*	Trade name 5307 ^b
15		12 OR 13 OR 14	Relevant trade name combinations and commercial trade names
16		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
17		Phosphinothricin N acetyltransferase OR Phosphinothricin N acetyl transferase OR Phosphinothricin acetyltransferase OR Phosphinothricin acetyl transferase OR PPT acetyltransferase OR PPT acetyl transferase OR PT N acetyltransferase OR PT N acetyl transferase OR Glufosinate acetyltransferase OR Glufosinate acetyl transferase OR Gluphosinate acetyltransferase OR Gluphosinate acetyl transferase OR (pat ADJ5 protein) OR 111069-93-3 OR "EC 2.3.1.183" OR "E.C. 2.3.1.183"	Newly expressed protein in Bt11 and 1507
18		Vip3AA20* OR Vip3 AA20* OR Vip3 AA 20* OR Vip3A A 20*	Newly expressed protein in MIR162
19		Phosphomannoisomerase OR Mannose 6-phosphate isomerase OR Phosphomannoseisomerase OR Phosphomannose isomerase OR 9023-88-5 OR AAA24109 OR "EC 5.3.1.8" OR "E.C. 5.3.1.8"	Newly expressed protein in MIR162, 5307 and MIR604
20		mCry3A* OR mCry 3A* OR mCry 3 A* OR Cry3A* OR Cry 3A* OR Cry 3 A*	Newly expressed protein in MIR604
21		5 enolpyruvyl shikimate 3 phosphate synthase OR 5 enolpyruvylshikimate 3 phosphate synthase OR	Newly expressed protein in GA21

Set	Field	Search String	Concepts/Key Elements
		EPSP synthase OR MEPSP synthase OR EPSPS OR MEPSPS OR "EC 2.5.1.19" OR "E.C. 2.5.1.19"	
22		Cry1F* OR Cry 1F* OR Cry 1 F* OR Cry1 F* OR CryIF* OR Cry IF* OR Cry I F* OR CryI F*	Newly expressed protein in 1507
23		"eCry3.1AB" OR "eCry3.1 AB" OR "eCry 3.1AB" OR "eCry 3.1 AB" OR "e-Cry3.1AB" OR "e-Cry3.1 AB" OR "e-Cry 3.1AB" OR "e-Cry 3.1 AB"	Newly expressed protein in 5307
24		(16 OR 17) AND (18 OR 19 OR 20 OR 21 OR 23)	Unique combinations of the newly expressed proteins in Bt11 AND (MIR162 OR MIR604 OR GA21 OR 5307)
25		(18 OR 19) AND (20 OR 21 OR 22 OR 23)	Unique combinations of the newly expressed proteins in MIR162 AND (MIR604 OR GA21 OR 1507 OR 5307)
26		20 AND 21	Unique combinations of the newly expressed proteins in MIR604 AND GA21
27		23 AND (22 OR 21)	Unique combinations of the newly expressed proteins in 5307 AND (1507 OR GA21)
28		24 OR 25 OR 26 OR 27	All unique combinations of the newly expressed proteins
29		((Insect OR Insects OR coleoptera* OR lepidoptera* OR pest OR pests OR stalkborer* OR stalk borer* OR borer* OR cornborer* OR corn borer* OR noctuidae OR Crambidae OR Chrysomelidae OR earworm* OR ear worm* OR armyworm* OR army worm* OR cutworm* OR cut worm* OR rootworm* OR root worm* OR Ostrinia OR O nubilalis OR Diatraea OR D grandiosella OR D crambidoides OR Helicoverpa OR H zea OR Spodoptera OR S frugiperda OR S exigua OR Papaipema OR P nebris OR Elasmopalpus OR E lignosellus OR D saccharalis OR Striacosta OR S albicosta OR Agrotis OR A ipsilon OR Feltia OR F jaculifera OR Pseudaletia OR P unipuncta OR Diabrotica OR D virgifera OR D barberi OR ECB OR SWCB OR SCSB OR CEW OR FAW OR SCB OR WBC OR WCRW OR WCR OR NCRW OR MCR OR MCRW) ADJ2 (toleran* OR resisten* OR protect* OR control*)) OR B thuringiensis OR Bacillus thuringiensis OR ((glufosinate* OR gluphosinate* OR Basta* OR Liberty* OR Ignite* OR Rely* OR Finale* OR Challenge* OR gl#phosate OR gl#fosate OR roundup* OR round up* OR herbicide* OR pesticide*) ADJ2 (toleran* OR resisten* OR protect*))	Intended traits
30		GMO* OR LMO* OR GM OR GE OR transgen* OR ((genetic* OR living OR biotech*) ADJ3 (modif* OR transform* OR manipulat* OR improv* OR engineer* OR deriv*)) OR stack*	GMO general

Set	Field	Search String	Concepts/Key Elements
31		29 AND 30	Intended trait AND GMO general
32		GMHT OR GEHT OR GMHR OR GEHR OR GMHTs OR GEHTs OR GMHRs OR GEHRs	GMO general × intended trait-HT
33		31 OR 32	(Intended trait AND GMO general) OR GMO general × intended trait-HT
34		Maize* OR corn* OR Zea mays OR Z mays	Plant species
35		33 AND 34	((Intended trait AND GMO general) OR GMO general × intended trait-HT) AND Plant species
36		((Bt OR Bacillus thuringiensis OR B thuringiensis) ADJ5 (maize* OR corn* OR mays)) OR Btmaize* OR Btcorn*	GMO general × intended trait-Bt
37		11 OR 15 OR 28 OR 35 OR 36	Event OR Trade name OR Newly expressed proteins OR (((Intended trait AND GMO general) OR GMO general × intended trait-HT) AND Plant species) OR GMO general × intended trait-Bt

- a. The mandated wildcard symbol (#) is used as a substitute for one required character on the Ovid platform.
- b. Trade names for the highest order stack and commercial sub-combinations all have Agrisure, Duracade, or Herculex in their trade names:
 - Bt11 × MIR604 × 1507 × 5307 × GA21 – Agrisure Duracade 5122, Agrisure Duracade 5122A, Agrisure Duracade 5122 E-Z Refuge, Agrisure Duracade 5122A E-Z Refuge
 - Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 – Agrisure Duracade 5222, Agrisure Duracade 5222A, Agrisure Duracade 5222 E-Z Refuge, Agrisure Duracade 5222A E-Z Refuge
 - Bt11 × MIR162 – Agrisure Viptera 2; Bt11 × MIR604 × GA21 – Agrisure 3000GT, Agrisure Artesian 3011A, Agrisure 3000GT CL; Bt11 × MIR604 – Agrisure CB/LL/RW, Agrisure CB/RW, Agrisure CB/RW, Agrisure CB/LL/RWA
 - GA21 × Bt11 – Agrisure GT/CB/LL, Agrisure 3010, Agrisure 3010A, Agrisure Bt/GT, Agrisure TLTG
 - GA21 × Bt11 × MIR162 – Agrisure Viptera 3110, Agrisure Viptera 3110A, Agrisure TLTG Viptera, Agrisure Viptera 3
 - GA21 × Bt11 × MIR162 × MIR604 – Agrisure Viptera 3111, Agrisure Viptera 3111A, Agrisure Viptera 3111A, Agrisure Viptera 3111 CL, Agrisure Viptera 4
 - Bt11 × 1507 × MIR162 × GA21 - Agrisure Viptera 3220, Agrisure Viptera 3220A, Agrisure Viptera 3220 E-Z Refuge, Agrisure 3220A E-Z Refuge, and Agrisure Viptera 3220 Refuge Renew

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 (stack/sub-combinations, 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 7) 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 for stacked events are considered relevant for searching. Records were collected from webpages (Table 7) that listed regulatory documents/information specific to the safety assessment of GMOs. All records 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. Records were retrieved for review if the publication date could not be determined.

TABLE 7 Key organization pages included in the search^{a,b}

Regulatory agency/risk assessment body	Webpage address	Search strategy and limits applied
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.
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 June 1, 2021 or later were retrieved for review.
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 June 1, 2021 were retrieved for review.

Regulatory agency/risk assessment body	Webpage address	Search strategy and limits applied
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 June 1, 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 June 1, 2021 were retrieved for review. If no "Issue Date" was listed, the document was collected 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 Protectant) 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.

- 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.
- 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/>).
- 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 9 and Table 10). 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 9). 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 3 and Table 4) 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 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and its relevant sub-combinations in scope (Table 2). 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 7) 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, draft documents).

Two independent reviewers evaluated each internet record using the eligibility/inclusion criteria (Table 3 and Table 4). 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 8. Across all searches (database, internet, and manual), a total of 228 unique publications were retrieved for review. Of these, 201 were retrieved from the database search and 27 were retrieved from the internet search. There were no relevant internet publications to conduct a manual search of reference lists from; therefore, no manual results were retrieved.

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 9). 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 201 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 199 records. There were no disagreements at Stage 1, which resulted in a kappa score of 1. This score indicates perfect agreement. We consider the level of reviewer agreement to be acceptable for identifying all relevant literature.

In total, 2 records were reviewed in Stage 2, during which both were classified as unclear (Table 12). There were no conflicts during Stage 2 review; therefore, a tie-breaker reviewer was not needed.

For internet webpages of regulatory agency websites, the date on which the search was conducted, the date of the most recent update of the webpage (if available), the date span of the search, and the total number of records retrieved from each site were recorded (Table 10). The records from each website were de-duplicated individually. In total, the internet search yielded 27 records from regulatory agency websites that were evaluated only at Stage 2 (full-text) review. The reviewers agreed that none of the internet records were relevant and 27 were irrelevant (Table 11). There were no conflicts between reviewers over internet records.

TABLE 8 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)	201	27	0	228
Publications excluded from the search results after screening of title and abstracts (Stage 1)	199	NA ^d	0	199
Publications screened using full-text (Stage 2) ^c	2	27	0	29
Publications excluded after full-text screening ^e	0	27	0	27
Unobtainable/Unclear publications	2	0	0	2
Publications considered relevant	0	0	0	0

a. A total of 656 publications were identified from the database search. Of these, 455 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 9 Electronic bibliographic database search details^a

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	8
BIOSIS Previews	01/07/2022	Ovid Technologies	01/06/2021 to 23/06/2022	Dates	34
CAB Abstracts	01/07/2022	Ovid Technologies	01/06/2021 to 30/06/2022	Dates	75
Medline	01/07/2022	Ovid Technologies	01/06/2021 to 30/06/2022	Dates	84

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 10 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
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	0
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	0
National Technical Commission on Biosafety	http://ctnbio.mctic.gov.br/inicio	13/07/2022	No update information available	9	0
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	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

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, none of the database or internet records were deemed relevant. Since no relevant internet records were identified, a manual search of reference lists was not conducted.

Report of all relevant database publications retrieved after detailed assessment of full-text documents for relevance

There were no relevant records retrieved during the database search.

Report of all relevant internet publications retrieved after detailed assessment of full-text documents for relevance

There were no relevant records retrieved during the internet search.

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

No manual search was conducted because no relevant internet records were identified.

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, all 27 internet records were excluded (Table 11). The two database records reviewed at Stage 2 were not excluded because they contained unclear details (Table 12). 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 3 for a full list of the eligibility/inclusion criteria used during review). A rationale for exclusion was included for each record classified as one of the relevant document types and authored by the agency.

Report of internet publications excluded from the risk assessment after detailed assessment of full-text documents

There were no relevant records retrieved during the database search.

TABLE 11 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 3
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	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
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)	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 (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)	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)	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

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 3
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
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
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	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
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	Intervention/Exposure
National Technical Commission on Biosafety (2021)	Technical Opinion No. 7788-2021	http://ctnbio.mctic.gov.br/documents/566529/2292301/Paracer+T%C3%A9cnico+7788-2021/	Intervention/Exposure
National Technical Commission on Biosafety (2021)	Technical Opinion No. 7482 - 2021	http://ctnbio.mctic.gov.br/documents/566529/2303766/Paracer+T%C3%A9cnico+n%C2%BA+7482+-+2021/	Intervention/Exposure
National Technical Commission on Biosafety (2021)	Technical Opinion No. 7501 - 2021	http://ctnbio.mctic.gov.br/documents/566529/2302408/Paracer+T%C3%A9cnico+n%C2%BA+7501+-+2021/	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 8035 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2302623/Paracer+T%C3%A9cnico+n%C2%BA+8035+-+2022/	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 7897 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2302517/Paracer+T%C3%A9cnico+n%C2%BA+7897+-+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 3
National Technical Commission on Biosafety (2022)	Technical Opinion No. 8064 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2302729/Par+T%C3%A9cnico+n%C2%BA+8064+-+2022/	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 7988 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2303872/Par+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/Par+T%C3%A9cnico+n%C2%BA+8038+-+2022/	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 7891 - 2022	http://ctnbio.mctic.gov.br/documents/566529/2302835/Par+T%C3%A9cnico+n%C2%BA+7891+-+2022/	Intervention/Exposure
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+-+Full+Risk+Assessemnet+and+Risk+Mangement+Plan.pdf	Intervention/Exposure
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
Office of the Gene Technology Regulator (2022)	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	Intervention/Exposure
Office of the Gene Technology Regulator (2022)	DIR 186 -- Risk assessment and risk management plan	https://www.ogtr.gov.au/sites/default/files/2022-02/Full+Risk+Assessment+and+Risk+Management+Plan_1.pdf	Intervention/Exposure
Office of the Gene Technology Regulator (2022)	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	Intervention/Exposure

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 12, 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 2019 explanatory note (EFSA, 2019). The findings described in these unclear publications would not change our risk assessment of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and the relevant sub-combinations in scope (Table 2).

TABLE 12 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 non-transgenic maize	<i>Microchemical Journal</i>	This study indicates that Bt maize expressing Cry1Ab was used, but does not indicate a specific event/stack. 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 indicates that Bt corn expressing Cry1Ab was used, but does not indicate a specific event/stack. The corresponding author was contacted to clarify, but no response was received.

4.6 Full-Text Documents

No relevant documents were identified. Therefore, no full-text documents accompany this final report.

4.7 Implications of Relevant Publications to the Risk Assessment of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and its relevant sub-combinations in scope

There were no relevant records identified during this comprehensive literature scoping search and review. As such, no hazards, modified exposure pathways, or scientific uncertainties for Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and its relevant sub-combinations were identified. Therefore, the results of this literature search and scoping review do not change the risk assessment of Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and its relevant subcombinations in scope.

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.

6.0 REFERENCES

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

APPENDIX B. Pilot Study

The eligibility/inclusion criteria for identifying records relevant to the food/feed and environmental risk assessment of stacked GM maize have been previously used for PMEM literature scoping reviews. The same criteria are used for all stacked GM maize crops (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 Syngenta stacked GM maize (intervention/exposure: Bt11 \times 59122 \times MIR604 \times 1507 \times GA21, Bt11 \times MIR162 \times MIR604 \times 1507 \times 5307 \times GA21, and relevant sub-combinations of these stacks 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 10 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 (i.e., definitely relevant, unclear relevance, definitely irrelevant) (Frampton *et al.* 2017). A kappa score and the percent agreement were calculated after Stage 1. Both reviewers agreed on the inclusion/exclusion of all articles during Stage 1 (percent agreement of 100%). This resulted in a kappa score = 1, suggesting perfect agreement between reviewers. Furthermore, at Stage 2 (full-text review) the percent agreement between reviewers was 100%. It was expected that reviewers should classify one known record (Dively *et al.* 2020) as relevant during the pilot study, and both reviewers classified this record as relevant during Stage 2. This outcome demonstrates that relevant publications are retained using the outlined review process and eligibility/inclusion criteria. Therefore, we conclude the eligibility/inclusion criteria are clear and sufficient for accurately categorizing records as relevant or irrelevant.

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

Reference	Stage 1 Decisions (Title/Abstract Review)		Stage 2 Decisions (Full-text Review)	
	Reviewer 1	Reviewer 2	Reviewer 1	Reviewer 2
Bernillon <i>et al.</i> (2018)	Include	Include	Exclude	Exclude
Campos <i>et al.</i> (2018)	Exclude	Exclude	—	—
Devos <i>et al.</i> (2018)	Exclude	Exclude	—	—
Dively <i>et al.</i> (2020)	Include	Include	Include	Include
Fast <i>et al.</i> (2020)	Include	Include	Exclude	Exclude
Liu <i>et al.</i> (2021)	Exclude	Exclude	—	—
Liu <i>et al.</i> (2020)	Include	Include	Exclude	Exclude
Pellegrino <i>et al.</i> (2018)	Exclude	Exclude	—	—
Snell <i>et al.</i> (2012)	Exclude	Exclude	—	—
Xie <i>et al.</i> (2017)	Exclude	Exclude	—	—
Percent Agreement	100%		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 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including all relevant sub-combinations in scope, and the relevant combinations of 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 events comprising this stack 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 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and the relevant subcombinations in scope and is provided in

Table 6 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. Since there were few known relevant records specific to Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize, including the relevant sub-combinations in scope, publications that contained information on one or more key elements of the review question (i.e., the highest order stack, sub-combinations in scope, or relevant combinations of the 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 × MIR162 × MIR604 × 1507 × 5307 × GA21 maize and all its relevant subcombinations in scope.

The search strategy was assessed by obtaining a preliminary set of results using the methods outlined in Section 3.2.1. No date limits were applied to this search in order 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

sReason for Selection: Key concepts of the review question that are highlighted in the reference are noted in parentheses (stack/sub-combination, newly expressed proteins, and intended traits)	Reference	Agricola	BIOSIS Previews	CAB Abstracts	Medline
Gene flow assessment of Agrisure brand corn (stack/sub-combination trade-name)	Dively <i>et al.</i> (2020)	X	X	X	
Compositional assessment of insect- and herbicide-resistant plants (intended traits) expressing Cry1Ab, EPSPS, and PAT proteins (newly expressed proteins)	Liu <i>et al.</i> (2020)	X	X	X	
Assessment of Cry1F and EPSPS proteins (newly expressed proteins).	Pálincás <i>et al.</i> (2017)		X	X	X
Risk assessment of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize (stack/relevant subcombination).	EFSA <i>et al.</i> (2019)			X	X
Risk assessment of Bt11 x MIR162 x 1507 x GA21 maize (stack/relevant subcombination).	EFSA <i>et al.</i> (2018)			X	X
Assessment of the digestibility of PAT and EPSPS proteins (newly expressed proteins).	Mao <i>et al.</i> (2020)				X
Number of articles identified in each database		2	3	5	4
Percentage of articles identified in each database		33%	50%	83%	67%

APPENDIX F. Search History and Subject Indexing

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Search Journals Multimedia My Workspace What's New

▼ **Search History** (38) [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	(MIR162 or MIR 162 or SYN-IR162-4).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	41	Advanced	Display Results More	
<input type="checkbox"/>	3	(MIR604 or MIR 604 or SYN-IR6#4-5).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	27	Advanced	Display Results More	
<input type="checkbox"/>	4	(TC1507 or TCI507 or ("1507" adj4 (event or maize or corn)) or DAS1507 or DASI507 or "DAS-Ø15Ø7-1" or DAS-O15O7-1 or DAS-01507-1).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	63	Advanced	Display Results More	
<input type="checkbox"/>	5	((("5307" adj4 (event or maize or corn)) or "SYN-Ø53Ø7-1" or SYN-O53O7-1 or SYN-05307-1).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	5	Advanced	Display Results More	
<input type="checkbox"/>	6	(GA21 or GA 21 or GA2I or GA 2I or "MON-ØØØ21-9" or MON-OOO21-9 or MON-00021-9 or MON###21-9 or "M0N-ØØØ21-9" or M0N-OOO21-9 or M0N-00021-9 or M0N###21-9).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	53	Advanced	Display Results More	
<input type="checkbox"/>	7	1 and (2 or 3 or 5 or 6)	34	Advanced	Display Results More	
<input type="checkbox"/>	8	2 and (3 or 4 or 5 or 6)	7	Advanced	Display Results More	
<input type="checkbox"/>	9	3 and (5 or 6)	9	Advanced	Display Results More	
<input type="checkbox"/>	10	5 and (4 or 6)	0	Advanced	Save More	
<input type="checkbox"/>	11	7 or 8 or 9 or 10	39	Advanced	Display Results More	
<input type="checkbox"/>	12	Agrisure*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	20	Advanced	Display Results More	

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<input type="checkbox"/>	13	Herculex*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	14	Advanced	Display Results More	
<input type="checkbox"/>	14	Duracade*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	2	Advanced	Display Results More	
<input type="checkbox"/>	15	12 or 13 or 14	29	Advanced	Display Results More	
<input type="checkbox"/>	16	(Cry1Ab* or Cry 1Ab* or Cry1 Ab* or Cry 1 Ab* or Cry1Ab* or Cry 1Ab* 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"/>	17	(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"/>	18	(Vip3AA20* or Vip3 AA20* or Vip3 AA 20* or Vip3A A 20*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	20	Advanced	Display Results More	
<input type="checkbox"/>	19	(Phosphomannoisomerase or Mannose 6-phosphate isomerase or Phosphomannoseisomerase or Phosphomannose isomerase or 9023-88-5 or AAA24109 or "EC 5.3.1.8" or "E.C. 5.3.1.8").mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	150	Advanced	Display Results More	
<input type="checkbox"/>	20	(mCry3A* or mCry 3A* or mCry 3 A* or Cry3A* or Cry 3A* or Cry 3 A*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	170	Advanced	Display Results More	
<input type="checkbox"/>	21	(5 enolpyruvyl shikimate 3 phosphate synthase or 5 enolpyruvylshikimate 3 phosphate synthase or EPSP synthase or MEPSP synthase or EPSPS or MEPSPS or "EC 2.5.1.19" or "E.C. 2.5.1.19").mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	709	Advanced	Display Results More	
<input type="checkbox"/>	22	(Cry1F* or Cry 1F* or Cry 1 F* or Cry1 F* or Cry1F* or Cry 1F* or Cry l F* or Cryl F*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	297	Advanced	Display Results More	

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<input type="checkbox"/>	23	("eCry3.1AB" or "eCry3.1 AB" or "eCry 3.1AB" or "eCry 3.1 AB" or "e-Cry3.1AB" or "e-Cry3.1 AB" or "e-Cry 3.1AB" or "e-Cry 3.1 AB").mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	21	Advanced	Display Results More	
<input type="checkbox"/>	24	(16 or 17) and (18 or 19 or 20 or 21 or 23)	57	Advanced	Display Results More	
<input type="checkbox"/>	25	(18 or 19) and (20 or 21 or 22 or 23)	12	Advanced	Display Results More	
<input type="checkbox"/>	26	20 and 21	3	Advanced	Display Results More	
<input type="checkbox"/>	27	23 and (22 or 21)	0	Advanced	Save More	
<input type="checkbox"/>	28	24 or 25 or 26 or 27	62	Advanced	Display Results More	
<input type="checkbox"/>	29	((((Insect or Insects or coleoptera* or lepidoptera* or pest or pests or stalkborer* or stalk borer* or borer* or cornborer* or corn borer* or noctuidae or Crambidae or Chrysomelidae or earworm* or ear worm* or armyworm* or army worm* or cutworm* or cut worm* or rootworm* or root worm* or Ostrinia or O nubilalis or Diatraea or D grandiosella or D crambidoides or Helicoverpa or H zea or Spodoptera or S frugiperda or S exigua or Papaipema or P nebris or Elasmopalpus or E lignosellus or D saccharalis or Striacosta or S albicosta or Agrotis or A ipsilon or Feltia or F jaculifera or Pseudaletia or P unipuncta or Diabrotica or D virgifera or D barberi or ECB or SWCB or SCSB or CEW or FAW or SCB or WBC or WCRW or WCR or NCRW or MCR or MCRW) adj2 (toleran* or resistan* or protect* or control*)) or B thuringiensis or Bacillus thuringiensis or ((glufosinate* or gluphosinate* or Basta* or Liberty* or Ignite* or Rely* or Finale* or Challenge* or gl#phosate or gl##fosate or roundup* or round up* or herbicide* or pesticide*) adj2 (toleran* or resistan* or protect*))).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	89052	Advanced	Display Results More	
<input type="checkbox"/>	30	(GMO* or LMO* or GM or GE or transgen* or ((genetic* or living or biotech*) adj3 (modif* or transform* or manipulat* or improv* or engineer* or deriv*)) or stack*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	129136	Advanced	Display Results More	
<input type="checkbox"/>	31	29 and 30	7679	Advanced	Display Results More	
<input type="checkbox"/>	32	(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	

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<input type="checkbox"/>	33	31 or 32	7766	Advanced	Display Results	More	
<input type="checkbox"/>	34	(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"/>	35	33 and 34	1866	Advanced	Display Results	More	
<input type="checkbox"/>	36	((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"/>	37	11 or 15 or 28 or 35 or 36	2195	Advanced	Display Results	More	
<input type="checkbox"/>	38	limit 37 to yr="2021 -Current"	100	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

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

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

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

☒ **Keyword** ☐ Author ☐ Title ☐ Journal

Search

☒ **Limits** *(expand)* ☐ Include Multimedia ☒ Map Term to Subject Heading

Options

View By

Text (100 Results)

Multimedia (0 Results)

Print

Email

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Keep Selected

☐ All

Range

Clear

5 Per Page

1

Go

Next >

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

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Report Number: RIR-0002883-22

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Search Information

You searched:

limit 37 to yr="2021 -Current"

Search terms used:

- 1
- 3
- 5
- 11
- 21
- 162
- 604
- 1507
- 5307
- 111069-93-3
- enolpyruvyl
- shikimate
- phosphate
- synthase
- enolpyruvylshikimate
- 9023-88-5
- a
- ipsilon
- aaa24109
- agrisure*
- agrotis
- army
- worm*
- armyworm*
- b
- thuringiensis
- bacillus
- basta*
- biotech*
- borer*
- bt
- bt11
- btcorn*
- btmaize*

 Cite  + My Projects  + Annotate

- ☐ 2. [Transgenic overexpression of P450 genes confers deltamethrin resistance in the fall armyworm, Spodoptera frugiperda](#)

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- ☐ 3. [A maize gene coding for a chimeric superlectin reduces growth of maize fungal pathogens and insect pests when expressed transgenically in maize callus](#)

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- ☐ 4. [Feeding corn germ instead of corn grain on the performance of Holstein dairy cows fed low forage diet and Human-edible feed conversion efficiency](#)

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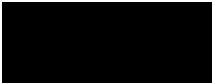
- ☐ 5. [Early warning of resistance to Bt toxin Vip3Aa in Helicoverpa zea](#)

 Cite  + My Projects  + Annotate

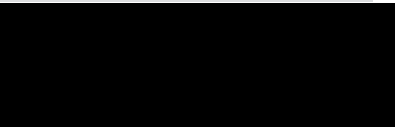
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Search Journals Multimedia My Workspace What's New












▼ **Search History** (38) [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=abstract, original language book title (non-english), book title (english), title, heading words]	364	Advanced	Display Results More	 Contract
<input type="checkbox"/>	2	(MIR162 or MIR 162 or SYN-IR162-4).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	140	Advanced	Display Results More	
<input type="checkbox"/>	3	(MIR604 or MIR 604 or SYN-IR6#4-5).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	84	Advanced	Display Results More	
<input type="checkbox"/>	4	(TC1507 or TCI507 or ("1507" adj4 (event or maize or corn)) or DAS1507 or DASI507 or "DAS-Ø15Ø7-1" or DAS-O15Ø7-1 or DAS-015Ø7-1).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	157	Advanced	Display Results More	
<input type="checkbox"/>	5	((("5307" adj4 (event or maize or corn)) or "SYN-Ø53Ø7-1" or SYN-O53Ø7-1 or SYN-053Ø7-1).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	22	Advanced	Display Results More	
<input type="checkbox"/>	6	(GA21 or GA 21 or GA2l or GA 2l or "MON-ØØØ21-9" or MON-OOO21-9 or MON-00021-9 or MON###21-9 or "MØN-ØØØ21-9" or MØN-OOO21-9 or MØN-00021-9 or MØN###21-9).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	164	Advanced	Display Results More	
<input type="checkbox"/>	7	1 and (2 or 3 or 5 or 6)	92	Advanced	Display Results More	
<input type="checkbox"/>	8	2 and (3 or 4 or 5 or 6)	19	Advanced	Display Results More	
<input type="checkbox"/>	9	3 and (5 or 6)	40	Advanced	Display Results More	
<input type="checkbox"/>	10	5 and (4 or 6)	4	Advanced	Display Results More	
<input type="checkbox"/>	11	7 or 8 or 9 or 10	110	Advanced	Display Results More	

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<input type="checkbox"/>	12	Agrisure*.mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	40	Advanced	Display Results More	
<input type="checkbox"/>	13	Herculex*.mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	40	Advanced	Display Results More	
<input type="checkbox"/>	14	Duracade*.mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	1	Advanced	Display Results More	
<input type="checkbox"/>	15	12 or 13 or 14	66	Advanced	Display Results More	
<input type="checkbox"/>	16	(Cry1Ab* or Cry 1Ab* or Cry1 Ab* or Cry 1 Ab* or Cry1Ab* or Cry lAb* or Cryl Ab* or Cry l Ab*).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	2419	Advanced	Display Results More	
<input type="checkbox"/>	17	(Phosphinothricin N acetyltransferase or Phosphinothricin N acetyl transferase or Phosphinothricin acetyltransferase or PPT acetyltransferase or PPT acetyl transferase or PT N acetyltransferase or PT N acetyl transferase or Glufosinate acetyltransferase or Glufosinate acetyl transferase or Glufosinate acetyltransferase or Glufosinate acetyl transferase or (pat adj5 protein) or 111069-93-3 or "EC 2.3.1.183" or "E.C. 2.3.1.183").mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	774	Advanced	Display Results More	
<input type="checkbox"/>	18	(Vip3AA20* or Vip3 AA20* or Vip3 AA 20* or Vip3A A 20*).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	58	Advanced	Display Results More	
<input type="checkbox"/>	19	(Phosphomannoisomerase or Mannose 6-phosphate isomerase or Phosphomannoseisomerase or Phosphomannose isomerase or 9023-88-5 or AAA24109 or "EC 5.3.1.8" or "E.C. 5.3.1.8").mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	883	Advanced	Display Results More	
<input type="checkbox"/>	20	(mCry3A* or mCry 3A* or mCry 3 A* or Cry3A* or Cry 3A* or Cry 3 A*).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	476	Advanced	Display Results More	
<input type="checkbox"/>	21	(5 enolpyruvyl shikimate 3 phosphate synthase or 5 enolpyruvylshikimate 3 phosphate synthase or EPSP synthase or MEPSP synthase or EPSPS or MEPSPS or "EC 2.5.1.19" or "E.C. 2.5.1.19").mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	6035	Advanced	Display Results More	
<input type="checkbox"/>	22	(Cry1F* or Cry 1F* or Cry 1 F* or Cry1 F* or CrylF* or Cry lF* or Cry	755	Advanced	Display Results More	

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		I F* or Cryl F*).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]				
<input type="checkbox"/>	23	("eCry3.1AB" or "eCry3.1 AB" or "eCry 3.1AB" or "eCry 3.1 AB" or "e-Cry3.1AB" or "e-Cry3.1 AB" or "e-Cry 3.1AB" or "e-Cry 3.1 AB").mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	53	Advanced	Display Results More	
<input type="checkbox"/>	24	(16 or 17) and (18 or 19 or 20 or 21 or 23)	153	Advanced	Display Results More	
<input type="checkbox"/>	25	(18 or 19) and (20 or 21 or 22 or 23)	37	Advanced	Display Results More	
<input type="checkbox"/>	26	20 and 21	12	Advanced	Display Results More	
<input type="checkbox"/>	27	23 and (22 or 21)	5	Advanced	Display Results More	
<input type="checkbox"/>	28	24 or 25 or 26 or 27	164	Advanced	Display Results More	
<input type="checkbox"/>	29	(((Insect or Insects or coleoptera* or lepidoptera* or pest or pests or stalkborer* or stalk borer* or borer* or cornborer* or corn borer* or noctuidae or Crambidae or Chrysomelidae or earworm* or ear worm* or armyworm* or army worm* or cutworm* or cut worm* or rootworm* or root worm* or Ostrinia or O nubilalis or Diatraea or D grandiosella or D crambidoides or Helicoverpa or H zea or Spodoptera or S frugiperda or S exigua or Papaipema or P nebris or Elasmopalpus or E lignosellus or D saccharalis or Striacosta or S albicosta or Agrotis or A ipsilon or Feltia or F jaculifera or Pseudaletia or P unipuncta or Diabrotica or D virgifera or D barberi or ECB or SWCB or SCSB or CEW or FAW or SCB or WBC or WCRW or WCR or NCRW or MCR or MCRW) adj2 (toleran* or resistan* or protect* or control*)) or B thuringiensis or Bacillus thuringiensis or ((glufosinate* or gluphosinate* or Basta* or Liberty* or Ignite* or Rely* or Finale* or Challenge* or gl#phosate or gl#fosate or roundup* or round up* or herbicide* or pesticide*) adj2 (toleran* or resistan* or protect*))).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	663596	Advanced	Display Results More	
<input type="checkbox"/>	30	(GMO* or LMO* or GM or GE or transgen* or ((genetic* or living or biotech*) adj3 (modif* or transform* or manipul* or improv* or engineer* or deriv*)) or stack*).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	654369	Advanced	Display Results More	
<input type="checkbox"/>	31	29 and 30	22346	Advanced	Display Results More	

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<input type="checkbox"/>	37	11 or 15 or 28 or 35 or 36	5541	Advanced	Display Results More	
<input type="checkbox"/>	38	limit 37 to yr="2021 -Current"	215	Advanced	Display Results More	

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- 5307
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- enolpyruvyl
- shikimate
- phosphate
- synthase
- enolpyruvylshikimate
- 9023-88-5
- a
- ipsilon
- aaa24109
- agrisure*
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<input type="checkbox"/>	1	(Bt11 or Bt 11 or SYN-BT#11-1).mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	284	Advanced	Display Results	More	Contract
<input type="checkbox"/>	2	(MIR162 or MIR 162 or SYN-IR162-4).mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	80	Advanced	Display Results	More	
<input type="checkbox"/>	3	(MIR604 or MIR 604 or SYN-IR6#4-5).mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	54	Advanced	Display Results	More	
<input type="checkbox"/>	4	(TC1507 or TCI507 or ("1507" adj4 (event or maize or corn)) or DAS1507 or DASI507 or "DAS-Ø15Ø7-1" or DAS-O15O7-1 or DAS-01507-1).mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	122	Advanced	Display Results	More	
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<input type="checkbox"/>	14	Duracade*.mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	2	Advanced	Display Results More	
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<input type="checkbox"/>	16	(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=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	1705	Advanced	Display Results More	
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<input type="checkbox"/>	19	(Phosphomannoisomerase or Mannose 6-phosphate isomerase or Phosphomannoseisomerase or Phosphomannose isomerase or 9023-88-5 or AAA24109 or "EC 5.3.1.8" or "E.C. 5.3.1.8").mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	246	Advanced	Display Results More	
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<input type="checkbox"/>	24	(16 or 17) and (18 or 19 or 20 or 21 or 23)	113	Advanced	Display Results	More	
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<input type="checkbox"/>	29	((((Insect or Insects or coleoptera* or lepidoptera* or pest or pests or stalkborer* or stalk borer* or borer* or cornborer* or corn borer* or noctuidae or Crambidae or Chrysomelidae or earworm* or ear worm* or armyworm* or army worm* or cutworm* or cut worm* or rootworm* or root worm* or Ostrinia or O nubilalis or Diatraea or D grandiosella or D crambidoides or Helicoverpa or H zea or Spodoptera or S frugiperda or S exigua or Papaipema or P nebris or Elasmopalpus or E lignosellus or D saccharalis or Striacosta or S albicosta or Agrotis or A ipsilon or Feltia or F jaculifera or Pseudaletia or P unipuncta or Diabrotica or D virgifera or D barberi or ECB or SWCB or SCSB or CEW or FAW or SCB or WBC or WCRW or WCR or NCRW or MCR or MCRW) adj2 (toleran* or resistan* or protect* or control*)) or B thuringiensis or Bacillus thuringiensis or ((glufosinate* or gluphosinate* or Basta* or Liberty* or Ignite* or Rely* or Finale* or Challenge* or gl#phosate or gl##fosate or roundup* or round up* or herbicide* or pesticide*) adj2 (toleran* or resistan* or protect*))).mp. [mp=abstract, title, original title, broad terms, heading words, identifiers, cabicodes]	233803	Advanced	Display Results	More	
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<input type="checkbox"/>	31	29 and 30	18029	Advanced	Display Results	More	
<input type="checkbox"/>	32	(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	

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<input type="checkbox"/>	33	31 or 32	18156	Advanced	Display Results	More	
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<input type="checkbox"/>	37	11 or 15 or 28 or 35 or 36	4448	Advanced	Display Results	More	
<input type="checkbox"/>	38	limit 37 to yr="2021 -Current"	186	Advanced	Display Results	More	

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aaa24109
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3. **Global crop impacts, yield losses and action thresholds for fall armyworm (*Spodoptera frugiperda*): a review.**

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4. **Efficient and genotype independent maize transformation using pollen transfected by DNA-coated magnetic nanoparticles.**

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5. **Transgenic Bt maize in south-and Central America: the pros and cons.**

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<input type="checkbox"/>	4	(TC1507 or TC1507 or ("1507" adj4 (event or maize or corn)) or DAS1507 or DAS1507 or "DAS-Ø15Ø7-1" or DAS-O15O7-1 or DAS-01507-1).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	58	Advanced	Display Results More	
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<input type="checkbox"/>	16	(Cry1Ab* or Cry 1Ab* or Cry1 Ab* or Cry 1 Ab* or CrylAb* or Cryl Ab* or Cryl Ab* or Cry l Ab*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	955	Advanced	Display Results More	
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<input type="checkbox"/>	27	23 and (22 or 21)	1	Advanced	Display Results More	
<input type="checkbox"/>	28	24 or 25 or 26 or 27	71	Advanced	Display Results More	
<input type="checkbox"/>	29	((([Insect or Insects or coleoptera* or lepidoptera* or pest or pests or stalkborer* or stalk borer* or borer* or cornborer* or corn borer* or noctuidae or Crambidae or Chrysomelidae or earworm* or ear worm* or armyworm* or army worm* or cutworm* or cut worm* or rootworm* or root worm* or Ostrinia or O nubilalis or Diatraea or D grandiosella or D crambidoides or Helicoverpa or H zea or Spodoptera or S frugiperda or S exigua or Papaipema or P nebris or Elasmopalpus or E lignosellus or D saccharalis or Striacosta or S albicosta or Agrotis or A ipsilon or Feltia or F jaculifera or Pseudaletia or P unipuncta or Diabrotica or D virgifera or D barberi or ECB or SWCB or SCSB or CEW or FAW or SCB or WBC or WCRW or WCR or NCRW or MCR or MCRW) adj2	49638	Advanced	Display Results More	

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(toleran* or resistan* or protect* or control*)) or B thuringiensis or Bacillus thuringiensis or ((glufosinate* or gluphosinate* or Basta* or Liberty* or Ignite* or Rely* or Finale* or Challenge* or glt#fosate or roundup* or round up* or herbicide* or pesticide*) adj2 (toleran* or resistan* or protect*)))].mp.
[mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism
supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

<input type="checkbox"/>	30	(GMO* or LMO* or GM or GE or transgen* or ((genetic* or living or biotech*) adj3 (modif* or transform* or manipulat* or improv* or engineer* or deriv*)) or stack*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	497288	Advanced	Display Results More	
<input type="checkbox"/>	31	29 and 30	6389	Advanced	Display Results More	
<input type="checkbox"/>	32	(GMHT or GEHT or GMHR or GEHR or GMHTs or GEHTs or GMHRs or GEHRs).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	953	Advanced	Display Results More	
<input type="checkbox"/>	33	31 or 32	7309	Advanced	Display Results More	
<input type="checkbox"/>	34	(Maize* or corn* or Zea mays or Z mays).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	273269	Advanced	Display Results More	
<input type="checkbox"/>	35	33 and 34	1582	Advanced	Display Results More	
<input type="checkbox"/>	36	((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or corn* or mays)) or Btmaize* or Btcorn*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	888	Advanced	Display Results More	
<input type="checkbox"/>	37	11 or 15 or 28 or 35 or 36	1847	Advanced	Display Results More	
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