



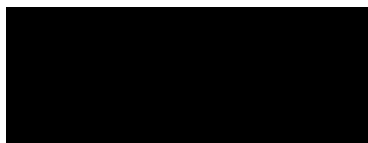
**Review of Scientific Literature Relevant to the
Food/Feed and Environmental Risk Assessment of
Event Bt11 Maize**

Literature Review

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LIST OF ACRONYMS AND ABBREVIATIONS

BIOSIS	Biological Abstracts
CAB	Commonwealth Agricultural Bureaux
EC	Effective Concentration
EFSA	European Food Safety Authority
ERA	Environmental Risk Assessment
EU	European Union
GMO	Genetically Modified Organism
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
MEDLINE	MEDical Literature Analysis and Retrieval System (online version)
NTO	Non-target organisms
PAT	Phosphinothricin acetyltransferase
PICO/PECO	Population, Intervention/Exposure, Comparator, Outcomes

1.0 OBJECTIVE

The purpose of this systematic literature search is to identify literature and/or information on Bt11 maize that is relevant to the risk assessment of genetically modified organisms. Maize plants derived from transformation event Bt11 contain the transgene *cry1Ab*, which encodes the insecticidal protein Cry1Ab, and the transgene *pat*, which encodes the enzyme phosphinothricin acetyltransferase (PAT). The native, full-length Cry1Ab produced by the soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* is active against certain lepidopteran pests of maize, including *Ostrinia nubilalis*. 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.

This report defines the 1) review question; 2) the search strategy; and 3) the explicit methods for selecting and categorizing the records. The results of the selection process are reported including consideration of the implications of any findings. This report aims to comply with the EFSA explanatory note on literature searching for GMO applications (EFSA 2019).

2.0 FORMULATING REVIEW QUESTIONS AND CLARIFYING THEIR PURPOSE

2.1 Review Question

The review question associated with this literature search is:

Do either food/feed products derived from Bt11 maize or the intended traits have adverse effects on human and animal health and/or the environment?

This review question follows the PICO/PECO structure with key elements “Population, Intervention/Exposure, Comparator, Outcomes” (Table 1).

TABLE 1 Review question in PICO/PECO structure

Element	Components of Review Question
Population	Human and animal health and the environment
Intervention/Exposure	Bt11 maize, derived food/feed products, Cry1Ab and PAT and closely related variants
Comparator	conventional counterpart (if applicable)
Outcome	adverse effects

2.2 Eligibility/Inclusion Criteria

Tables 2 and 3 summarize the eligibility/inclusion criteria for establishing relevance of retrieved records. Table 2 provides high level key concepts for inclusion/exclusion and Table 3 provides more explicit information on the information/data requirements concept. The eligibility/inclusion criteria are provided in the order of importance or ease of finding information on the criteria within a publication. The first failed eligibility/inclusion criterion was used as the primary reason for exclusion, and the remaining criteria was not assessed.

TABLE 2 Eligibility/inclusion criteria to establish relevance

Concepts	Criteria	Comment
Intervention/exposure	Bt11 maize, derived food/feed products, and/or the intended or closely related trait(s).	Intended traits are Glufosinate herbicide tolerance and Lepidopteran insect resistance. Closely related variants of Cry1Ab include various lengths of the Cry1Ab protein but no other Cry or Cry1 proteins (i.e. Cry protein that share the same tertiary Crickmore nomenclature). Any enzyme classified by the author as a phosphinothricin acetyl transferase was considered a closely related variant of the PAT protein.
Information/data requirements	Data inform one or more information/data requirement(s) for the GMO and derived food/feed products under consideration, including the intended trait(s)	Publications that potentially contribute to the knowledge informing the risk assessment of Bt11 maize (information/data requirements provided in Table 3) was considered relevant. Publications addressing issues such as benefits, socio-economics, ethics, crop protection, detection methods, efficacy, public perception and risk communication was excluded using this criterion, as they are not relevant to the risk assessment as defined in this document.
Scope of GMO application	The pathways and level of exposure to the GMO, derived food/feed products, and the intended trait(s) addressed in the publication are relevant for the intended uses of the GMO and derived food/feed products under regulatory review	Publications must address pathways and levels of exposure relevant to the scope of the application: import and processing of Bt11 maize for food/feed uses.
Reporting format	Original/primary data are presented in the publication or it is a risk assessment from a relevant key organization (such as regulatory agencies and risk assessment bodies involved in the risk assessment of GMOs)	Records that do not present original/primary data (e.g. editorials, reviews, position papers) were excluded. Risk assessments performed and reported by relevant key organizations were included if they address Bt11 maize or Cry1Ab or PAT proteins.
Previously risk assessed publications	As indicated by EFSA, a publication should be included if it has not been previously risk assessed by EFSA and/or its GMO Panel and is not cited/referenced in an EFSA/GMO Panel output	If a publication has previously been considered by EFSA, it was excluded. Any cited/referenced publications contained within documents produced by EFSA and/or its GMO Panel were excluded.
Access	Full-text document is accessible	If potentially relevant full-text documents cannot be obtained, they are listed in a table with a description of the (unsuccessful) methods used to try to obtain a copy. There were no unobtainable documents related to this review, so no table is present in this report.

Concepts	Criteria	Comment
Population	Human and animal health, and/or the environment are addressed as general protection goals	All of the information/data requirements categories described in Table 3 are thought to inform the risk assessment related to human and animal health, and/or the environment. Therefore, if a publication meets the inclusion criteria described in this Table and is relevant to the information/data requirements in Table 3, it was considered relevant.
Outcomes	Effects/impacts on human and animal health, and/or the environment are addressed	All of the information/data requirements categories described in Table 3 are thought to inform the risk assessment related to human and animal health, and/or the environment. Therefore, if a publication meets the inclusion criteria described in this Table and is relevant to the information/data requirements in Table 3, it was considered relevant.
Comparator	If the publication is a comparative study that uses plant material as a test material, eligible publications must report a non-GM variety	Publications that address Bt11 maize must also include a conventional counterpart as a comparator in those cases where comparative analysis is conducted and plant material is used as test material. Any uncertainties about the appropriateness of the comparator was addressed in the assessment of the publication.
Plant species	The publication may address the same plant species as the GMO under consideration, but could also address any plant species producing the Cry1Ab protein.	The review question addresses the safe use of the intended trait(s) of Bt11 maize. Therefore, GMOs that contain Cry1Ab or PAT or closely related variants, but are introduced into another plant species may be included. For certain types of data, the presence of the transgenic proteins in a different plant species will not impact the assessment of Bt11 maize. Those types of data are identified as event specific in Table 3.
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 is presented even if it is reported in different publications.

TABLE 3 Overview of main categories of information/data requirements

Expert knowledge on data used in the risk assessment of the GMO is required. The list below provides some examples of relevant data/information. If certain data in the record were considered event-specific or specific to the transgenic proteins expressed in Bt11 maize, it is noted. If the record did not contain enough information to determine if the protein being evaluated is a closely related variant then it was included.

Information/data requirement	Non-exhaustive list of specific information/data requirements
Molecular characterization of the genetic modification of the GMO	<ul style="list-style-type: none"> Information on the insert including: sequence, size, copy number, genetic element arrangement, deletions, location, sequence similarity searches, analysis of open reading frames (Bt11 maize only) Expression data of inserted/modified sequences (Bt11 maize only) Genetic stability (Bt11 maize only) Molecular and biochemical characterization of the protein(s) such as: primary structure, molecular weight, post-translational modifications (Cry1Ab or PAT as expressed in Bt11 maize only) Assessment of enzymatic activity including substrate specificity and reaction products with respect to safety and/or nutritional balance Data on the equivalence between plant-produced and microbially-produced proteins (Cry1Ab or PAT from Bt11 maize plants and a microbial source)
Agronomic, phenotypic and compositional characterization of the GM plant	<ul style="list-style-type: none"> Comparative assessment of agronomic and phenotypic characteristics under field or controlled conditions (Bt11 maize only) Comparative analysis of analysis of agronomic, phenotypic and compositional parameters, including key nutritional constituents, were considered relevant if generated on Bt11 maize material.
Toxicological assessment of newly expressed protein(s), new constituents other than proteins, and the whole GM food/feed	<ul style="list-style-type: none"> Amino acid sequence comparison between the newly expressed protein(s) (Cry1Ab or PAT as expressed in Bt11 maize only) and toxic proteins Stability of the protein(s) under relevant processing and storage conditions Investigation of proteolytic susceptibility of the newly expressed protein Toxicity studies Feeding studies that used plant material (Bt11 maize only)
Allergenicity assessment of the newly expressed protein and the GM food/feed, and adjuvanticity	<ul style="list-style-type: none"> Amino acid sequence comparison between the newly expressed protein(s) and known allergens or celiac disease peptide sequences (Cry1Ab or PAT as expressed in Bt11 maize only) Serum screening Pepsin susceptibility testing <i>In vivo</i> tests in animal models Expression data for endogenous allergens (Bt11 maize only) Comparison of newly expressed proteins to known strong adjuvants
Nutritional assessment of the newly expressed protein(s), other new constituents, as well as potential alterations in the total diet of the consumer or the animal	<ul style="list-style-type: none"> Anticipated dietary intake of food/feed from Bt11 maize and the resulting nutritional impact Comparative growth performance studies with young rapidly growing animal species (Bt11 maize only if the diet contains transgenic plant material)

Information/data requirement	Non-exhaustive list of specific information/data requirements
Post-market monitoring	<ul style="list-style-type: none"> • Description of mechanisms for determining actual changes to overall dietary intake patterns of the GM food, to what extent this has occurred and whether or not the product induces known (side) effects or unexpected side effects • Information on the reliability, sensitivity and specificity of the post market monitoring
Persistence and invasiveness assessment, including plant-to-plant gene transfer	<ul style="list-style-type: none"> • Measurements of volunteer occurrence and establishment (Bt11 maize) • Replacement capacity (i.e. # of plants present at specific observation time/# of plants present after initial sowing) (Bt11 maize only) • Fitness of the GM plant expressing Cry1Ab or PAT proteins in various environmental conditions –in the same or in a different plant species were considered relevant.
Assessment of plant to micro-organism gene transfer	<ul style="list-style-type: none"> • Homology searches at nucleotide level between the GM event and microorganisms. (Bt11 maize only)
Assessment of interactions with target organisms	<ul style="list-style-type: none"> • Excluded based on the scope of the application. The scope of this application covers the import, processing and food and feed use of Bt11 maize in the EU. According to the EFSA ERA Guidance (EFSA, 2010): “...<i>resistance development is only relevant for applications with scope cultivation of GM plants and not for applications restricted to import and processing of GM plants and their products.</i>” (EFSA, 2010). Therefore, an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use Bt11 maize was not considered relevant for this application.
Assessment of interactions with non-target organisms	<ul style="list-style-type: none"> • The EFSA ERA Guidance (EFSA, 2010) states that: “In cases where the application does not include cultivation in the EU, direct environmental exposure of NTOs to the GM plant is via accidental release into the environment of seeds or propagules during transportation and processing. This may result in sporadic occurrence of feral plants and therefore exposure of NTO populations is likely to be negligible. The ERA will then focus on indirect exposure to products of the GM plant (e.g. through manure and faeces from animals fed the GM plant, and other by-products of industrial processes)...”. Therefore, publications that discuss direct exposure in test protein and laboratory studies or field survey data were considered not relevant based on scope of application.
Assessment of interactions with biogeochemical and abiotic processes	<ul style="list-style-type: none"> • Excluded based on the scope of the application. The scope of this application covers the import, processing and food and feed use of Bt11 maize in the EU. According to the EFSA ERA Guidance (EFSA, 2010): “<i>Applications concerning food/feed uses and import and processing do not require scientific information on possible environmental effects associated with the cultivation of the plant.</i>” Therefore, an assessment of the impacts of Bt11 maize on biogeochemical processes resulting from specific cultivation, management and harvesting techniques was considered not relevant given the scope of this application.
Assessment of impact of specific cultivation, management and harvesting techniques	<ul style="list-style-type: none"> • Excluded based on the scope of the application. The scope of this application covers the import, processing and food and feed use of Bt11 maize in the EU. Cultivation of Bt11 maize in the EU is not included in the scope. According to the EFSA ERA guidance (EFSA 2010): “...<i>for GM plants for import and processing that are not intended for cultivation in the EU, there is no need for an ERA for altered cultivation, management and harvesting techniques.</i>”. Therefore, an assessment of impact of specific cultivation, management and harvesting techniques of Bt11 maize was considered 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 species of conservation concern that are at risk, integrated pest/weed management are only relevant to cultivation. The scope of this application covers the import, processing and food and feed use of Bt11 maize.
Post-market environmental monitoring	<ul style="list-style-type: none"> Excluded based on the scope of the application. Monitoring such as insect resistance is relevant only to cultivation. The scope of this application covers the import, processing and food and feed use of Bt11 maize.

3.0 SEARCHING FOR/IDENTIFYING RELEVANT PUBLICATIONS

3.1 Electronic Bibliographic Databases

To search for different types of publications and unpublished work that could provide information on the review question, multidisciplinary citation databases which include grey literature (i.e. not peer reviewed) was used. Medline, Agricola, CAB Abstracts, and BIOSIS Previews (provided by Ovid Technologies) were searched. Each of the databases has a thesaurus. Searching these databases fulfills the requirement to search a minimum of at least two multi-disciplinary/large databases.

These databases were selected based on their coverage of scientific literature for relevant subjects including, but not limited to, biomedicine, plant diseases, agriculture, life sciences, pesticides, human health and nutrition, animal health, plant science, biotechnology and environmental studies. Detailed information (e.g., list of subjects covered, coverage dates, update schedule, and sources for data) regarding each of the databases searched can be obtained upon request. The document types in these databases include journal articles, technical letters and notes, conference proceedings, book chapters, reports, and articles in press.

3.2 Internet Searches

3.2.1 Key organizations

The internet pages of regulatory agencies and risk assessment bodies listed in Table 4 were searched for documents related to Bt11 maize.

TABLE 4 Internet pages included in the search

Regulatory agency/risk assessment body	Web address
Food Standards Australia New Zealand	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx
Health Canada ^a	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html
Ministry of Agriculture, Forestry and Fisheries	http://www.maff.go.jp/e/
Ministry of Environment, Forest and Climate change	http://moef.gov.in/
National Technical Commission on Biosafety ^b	http://ctnbio.mctic.gov.br/inicio
Office of the Gene Technology Regulator	http://www.ogtr.gov.au/
US Department of Agriculture	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology
US Environmental Protection Agency	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated
US Food and Drug Administration	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon
^a Also searches Environment and Climate Change Canada (https://www.ec.gc.ca/cc/) and Canadian Food Inspection Agency (http://www.inspection.gc.ca/plants/plants-with-novel-traits/notices-of-submission/eng/1300143491851/1300143550790)	
^b Partial reports are excluded from review since there is no new information contained in these reports and they are not the official final opinion of the agency.	

3.2.2 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 is considered to provide an adequately comprehensive search of literature.

3.2.3 Manual searches

3.2.3.1 Checking reference lists

For any reviews, methodological publications, guidelines and scientific opinions from regulatory agencies that were retrieved using the search strategy and classified as relevant to the review question, the reference list(s) from those records were manually searched for new records (June 2019 through the date the search was conducted) that met the eligibility/inclusion criteria.

3.2.3.2 Hand searching

Hand searching was not conducted. The search of the databases and key organization websites is considered to provide an adequately comprehensive search of literature.

3.2.3.3 Citation searching

Citation searching was not conducted. The search of the databases and key organization websites is considered to provide an adequately comprehensive search of literature.

3.3 Constructing the Search Strategy

3.3.1 Database searching

3.3.1.1 Approaches to develop searches

The “lumping” approach was utilized. A single search strategy was developed to capture all categories of information of interest in one search. This strategy was used because previous experience indicates that a manageable number of studies was returned.

3.3.1.2 Search terms

Identifying search terms

Search terms were identified by:

- Assessing subject indexing terms of relevant publications recorded in those electronic bibliographic databases that use thesauri
 - All publications returned from literature search reports that aim to comply with the EFSA explanatory note and deemed relevant to the review questions were examined to determine the subject indexing terms associated with it.

- Seeking suggestions from experts and stakeholders
 - The search terms were developed using a multi-disciplinary team (i.e. risk assessors, information specialists, regulatory affairs managers).

Free-text terms and subject indexing terms

The searches with the Ovid platform utilized the keyword search in the advanced search window. The keyword search uses a default set of fields designated .mp, which vary by database. Therefore, Ovid uses the term “keyword” to indicate that it is executing a multi-field search. In each database the specific fields searched are a different combination of free-text and controlled vocabulary fields, with Ovid switching automatically to the appropriate fields when a database is selected.¹

In Ovid, the fields used in the .mp keyword search are word searchable, therefore any search only has to find a single word in a controlled vocabulary field that contains phrases to return as search results all references indexed to that subject heading. Thus, a search strategy which includes “genetic*” will return the following (highlighted below):

- **Genetically modified foods** or **genetic engineering** in the Subject Headings field in Agricola,
- Zea mays: species, maize, common, **genetically modified**, strain-Bt10 [Gramineae] in the Organism field in BIOSIS Previews,
- **Genetically engineered organisms** in the Subject Headings field in CAB Abstracts,
- Plants, **Genetically Modified** / ge [**Genetics**] or **Genetic Engineering** in MeSH Subject Headings in Medline

Subsequent combining of terms, (genetic* AND (modif* OR engineer*)) (in bold), yields all references with these headings to be in the final results for that search set. Therefore, it is not necessary to search each exact controlled phrase in order to return all references for each of the specific headings.

¹ 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.

Appendix A provides 1) the search history (including the full strategy used and fields searched as run in the database) and number of publications identified (line by line) for each bibliographic database prior to de-duplication and 2) the subject indexing used by each database as shown within the brackets after each search term.

3.3.1.3 Free-text searching functions

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

3.3.1.4 Search strings

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

3.3.1.5 Key elements of review questions to use for best result

A very large number of publications were returned using only the four key elements of Event, Intended trait, newly expressed protein(s), and Trade Name. To prevent a very large number of publications from being returned while still achieving sensitivity, additional key elements were added to the search strategy. 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 (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 included the following search concepts/key elements; Event, Trade Name, Newly Expressed Protein(s), or Intended Trait in the same publications as terms describing plant species and/or GMO general terms. The search strategy employed was:

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

The search strategy employed captured literature relevant to Bt11 maize and is provided in Table 5. 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.

TABLE 5 Search string strategy

The search strategy employed captured literature relevant to Bt11 maize and is provided in Table 5. The same search string was used in all databases.

Set	Field	Search String	Concepts/Key Elements
1	Topic	Bt11 OR Bt 11 OR SYN-BT?11-1	Event Bt11 ^a
2	Topic	Agrisure*	Trade name(s) for Event Bt11 ^b
3	Topic	Cry1Ab* OR Cry 1Ab* OR Cry1 Ab* OR Cry 1 Ab* OR Cry1Ab* OR Cry IAb* OR CryI Ab* OR Cry I Ab*	Newly expressed protein in Bt11 (Insecticidal)
4	Topic	Phosphinothricin N acetyltransferase OR Phosphinothricin N acetyl transferase OR Phosphinothricin acetyltransferase OR Phosphinothricin acetyl transferase OR PPT acetyltransferase OR PPT acetyl transferase OR PT N acetyltransferase OR PT N acetyl transferase OR Glufosinate acetyltransferase OR Glufosinate acetyl transferase OR Gluphosinate acetyltransferase OR Gluphosinate acetyl transferase OR pat OR 111069-93-3 OR EC 2.3.1.183 OR E.C. 2.3.1.183	Newly expressed protein in Bt11 (herbicide tolerance)
5		#3 OR #4	
6	Topic	((Insect OR insects OR Lepidoptera* OR pest OR pests OR stalkborer* OR stalk borer* OR borer* OR cornborer* OR corn borer* OR Noctuidae OR Crambidae OR earworm* OR ear worm* OR armyworm* OR army worm* OR Ostrinia OR O nubilalis OR Diatraea OR D grandiosella OR D crambidoides OR Helicoverpa OR H zea OR Spodoptera OR S frugiperda OR Papaipema OR P nebris OR Elasmopalpus OR E lignosellus OR D saccharalis OR ECB OR SWCB OR SCSB OR CEW OR FAW OR SCB) ADJ2 (toleran* OR resistan* OR protect* OR control*)) OR Bacillus thuringiensis OR B thuringiensis	Intended traits (insecticidal)
7	Topic	(glufosinate* OR gluphosinate* OR Basta* OR Liberty* OR Ignite* OR Rely* OR Finale* OR Challenge* OR herbicide* OR pesticide*) ADJ2 (toleran* OR resistan* OR protect*)	Intended traits (herbicide tolerance)
8	Topic	GMO* OR LMO* OR GM OR GE OR transgen* OR ((genetic* OR living OR biotech*) ADJ3 (modif* OR transform* OR manipul* OR improv* OR engineer* OR deriv*))	GMO general
9	Topic	GMHT OR GEHT OR GMHR OR GEHR OR GMHTs OR GEHTs OR GMHRs OR GEHRs	GMO general × intended traits (herbicide tolerance)
10	Topic	Maize* OR corn* OR Zea mays OR Z mays	Plant species
11	Topic	((Bt OR Bacillus thuringiensis OR B thuringiensis) ADJ5 (maize* OR corn* OR mays)) OR Btmaize* OR Btcorn*	GMO general × intended traits -insecticidal
12		#5 AND (#8 OR #10)	Newly expressed protein AND (GMO general OR plant species)
13		#6 AND (#8 AND #10)	Intended trait -insecticidal AND (GMO general AND Plant species)
14		((#7 AND #8) OR #9) AND #10	((Intended trait - herbicide tolerance AND GMO general) OR GMO general × Intended trait (herbicide tolerance)) AND Plant species

Set	Field	Search String	Concepts/Key Elements
15		#1 OR #2 OR #12 OR #13 OR # 14 OR #11	Event OR Trade name OR (Newly expressed protein AND (GMO general OR Plant species)) OR (Intended trait – insecticidal AND (GMO general AND Plant species)) OR (((Intended trait - herbicide tolerance AND GMO general) OR GMO general × Intended trait (herbicide tolerance)) AND Plant species) OR GMO general × intended trait – insecticidal
<p>*The use of a wildcard in the term SYN-BT?11-1 allows this search to return results for the following variations in spelling: SYN-BTØ11-1, SYN-BTO11-1, SYN-BT011-1, and SYN-BTEmpy set11-1</p> <p>*Trade names for Bt11 include Agrisure CB, Agrisure TL, Agrisure TD. Because the search strategy is not exclusionary by searching just Agrisure it is possible to return all possible trade names.</p>			

3.3.1.6 Use of multiple languages

The search terms used were in the English language or utilized the Roman alphabet. For Event name and trade names that do not use words in the English language, translations are unlikely to exist.

3.3.1.7 Time period

Due to the use of multiple (i.e. 4) multi-disciplinary databases and redundancy in coverage it is unlikely that late addition of a publication would be missed. Therefore, the returned literature was limited to that which was published between January 1, 2019 and the date of the last database update prior to the search (see Table 7). Ovid only allows for limiting search by year, so the results were deduplicated against the prior year's results (2019).

The records returned from the search of the regulatory agency webpages were manually excluded if they were dated prior to 2019. If a date could not be determined for the record, then the record was reviewed for relevance using the criteria in Tables 2 and 3.

3.3.1.8 Internet searching of regulatory agency webpages

The search terms selected are the event and protein names from the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) (Table 6). The descriptions and information for the top 50 hits or 10% of the total hits (whichever is greater) for each search term/web page was collected.

TABLE 6 Nomenclature for the single event and newly expressed proteins from the ISAAA database for use in searching regulatory agency web pages

Event	Search term	Concepts/Key Elements
Bt11	Bt11	Event name
Bt11	Cry1Ab	Newly expressed protein
Bt11	Phosphinothricin N-acetyltransferase	Newly expressed protein

3.4 Reference Publications

A previously conducted literature review successfully returned literature relevant to the risk assessment of Bt11 maize (██████████ 2019). The search strategy has not changed; therefore, validation of the search strategy is not required.

3.5 Summarizing and Reporting the Data

3.6 Selecting Publications

3.6.1 Database records

The process for selecting relevant publications was conducted in two stages. The first stage required a preliminary assessment of titles and abstracts. Those records that are clearly irrelevant from reviewing the title only were excluded from further review. For those records that appeared relevant or have unclear relevance the abstract was reviewed. Those records that are clearly irrelevant from reviewing the abstract were excluded from further review, while records that are relevant or have unclear relevance were reviewed in Stage 2.

Full-length articles were reviewed in Stage 2. An explanation of exclusion is provided for any full-length records that are deemed irrelevant in Stage 2. Any relevant records identified in Stage 2 were subjected to reliability assessment and evaluation of the implications of the record on the food and feed or environmental risk assessments.

Two independent reviewers examined the records for inclusion/exclusion for each eligible information/data requirement at all stages of review. Reviews and selections were conducted independently. During the rapid assessment process (Stage 1), only records that were deemed clearly irrelevant by all reviewers were excluded from further review. This conservative approach ensures that all potentially relevant records are evaluated until they are deemed to be either relevant or clearly irrelevant in Stage 2. Following the Stage 1 reviews, reviewers scored the records as either 1) relevant or unclear relevance, 2) clearly irrelevant.

A kappa test was performed after the Stage 1 review and before any discussion of abstracts over which there was disagreement by the reviewers. Of the 260 records reviewed from the databases in stage 1 there were 257 agreements to exclude, 1 agreement to include and 2 disagreements where one reviewer selected to include while the other selected exclude. This yielded a kappa test score of 0.50. The reviewers met to discuss abstract in which they disagreed and moved the 2 records over which there was disagreement forward to full-length review for a total of 3 records that were reviewed in stage 2. There was no disagreement among the reviewers after Stage 2 therefore no tie breaker reviewer was needed.

Because of the format of documents retrieved from internet searching of key organizations (i.e. title and abstract is not often provided) the kappa test was conducted only on the output of the database search.

3.6.2 Records from key organizations

The records returned from searching the websites of key organizations were considered relevant if they are risk assessments, scientific opinions/reports concerning the commercial release of GMO being examined or documents on the biology of the crop of interest. The regulatory agency webpages that are searched do not post primary data; therefore, all other document types were not considered relevant.

The format of records returned from regulatory agency websites does not often meet the format required to assess them using the 2-stage process followed for the database records. Those websites at which the records are published in English were assessed by two independent reviewers. Due to format full-text documents were assessed to determine relevance. For those websites where the records are not published in English, the results were reviewed by a native speaker. If the document was deemed to be a relevant document type then it was translated into English and two independent reviewers determined if it met the criteria for inclusion. The rationale for record exclusion is provided only for those records classified as one of the relevant document types and if excluded based on other eligibility criteria.

Regulatory agencies in Mexico and Argentina do not post the relevant document types on their respective agency websites; therefore those agency websites were not searched.

The following process applied to the types of internet agency documents is described below. We defined a unique internet record, for the purposes of reporting the statistics, as a unique URL. Documents that are clearly labeled as draft or with a line for a signature that is blank was not reviewed and was classified as not relevant. If the URLs for two documents are identical except for file format (e.g. pdf versus .doc or .docx), one of the documents were considered a duplicate document and it was excluded from statistical accounting. Documents were examined fully to determine if they are actual duplicates. If they are considered to be actual duplicate documents only one document is listed in the table of relevant internet documents contained in the final report.

3.7 Results of the Publication Selection Process

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. study types, dates, languages) and the total number of records retrieved before and after removing duplicates was be recorded. Additionally, the line-by-line strategy with the number of publications identified per line is presented in the final report.

For records from websites, the following was recorded (if available): the website name and service publisher used, justification for choosing the source, the URL, the date on which the search was conducted, the date of the most recent website update at the time it was searched, the date span of the search, the search terms used, any limits to the search, and the number of relevant records retrieved.

The reference lists of relevant publications from regulatory agencies involved in the risk assessment of GMOs was checked/scanned to identify any additional relevant publications which have not been retrieved through other search approaches. The number of additional relevant references is included in the final report.

TABLE 7 Electronic bibliographic database search results

Database	Search Date dd/mm/yyyy	Service provider	Date span of the search dd/mm/yyyy	Any limits applied to the search	Total number of records retrieved after removing duplicates
Agricola	01/07/2020	*Ovid Technologies	01/06/2019 – 01/07/2020	Dates	4
BIOSIS Previews	01/07/2020	Ovid Technologies	01/06/2019 – 29/06/2020	Dates	70
CAB Abstracts	01/07/2020	Ovid Technologies	01/06/2019 – 29/06/2020	Dates	75
Medline	01/07/2020	Ovid Technologies	01/06/2019 – 01/07/2020	Dates	111
<p>*Ovid only allows results to be limited by year. The results were de-duplicated across databases and then de-duplicated against the prior year's returned records. The frequency of database update varies. Ovid has provided us with the following update information: Agricola updated monthly on the 1st of the month, BIOSIS Previews updated weekly on Mondays, CAB Abstracts updated weekly on Mondays and Medline updated daily.</p>					

TABLE 8 Regulatory agency webpage search details

Regulatory agency name	URL	Date of Search	Date of Most Recent Website Update	Date Span of Search*	Total number of records retrieved after removing duplicates	Number of relevant records
Health Canada	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html	07/29/2020	05/28/2020	No limitations	4	0
Food Standards Australia New Zealand	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx	07/24/2020	No update information provided	No limitations	8	2
Ministry of Agriculture, Forestry and Fisheries	http://www.maff.go.jp/e/	07/20/2020	No update information provided	No limitations	2	0
Ministry of Environment, Forest and Climate change	http://moef.gov.in/	07/23/2020	No update information provided	No limitations	0	0
National Technical Commission on Biosafety	http://ctnbio.mcti.gov.br/	07/15/2020	No update information provided	No limitations	1	0
Office of the Gene Technology Regulator	http://www.ogtr.gov.au/	07/23/2020	July 23, 2020	No limitations	0	0
US Department of Agriculture	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology	8/03/2020	No update information provided	No limitations	5	2
US Environmental Protection Agency	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated	8/05/2020	7/14/2020	No limitations	0	0
US Food and Drug Administration	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon	7/31/2020	10/11/2019	No limitations	0	0

*Records published prior to 2019 were manually excluded (if any).

The results of the selection process are recorded in Table 9.

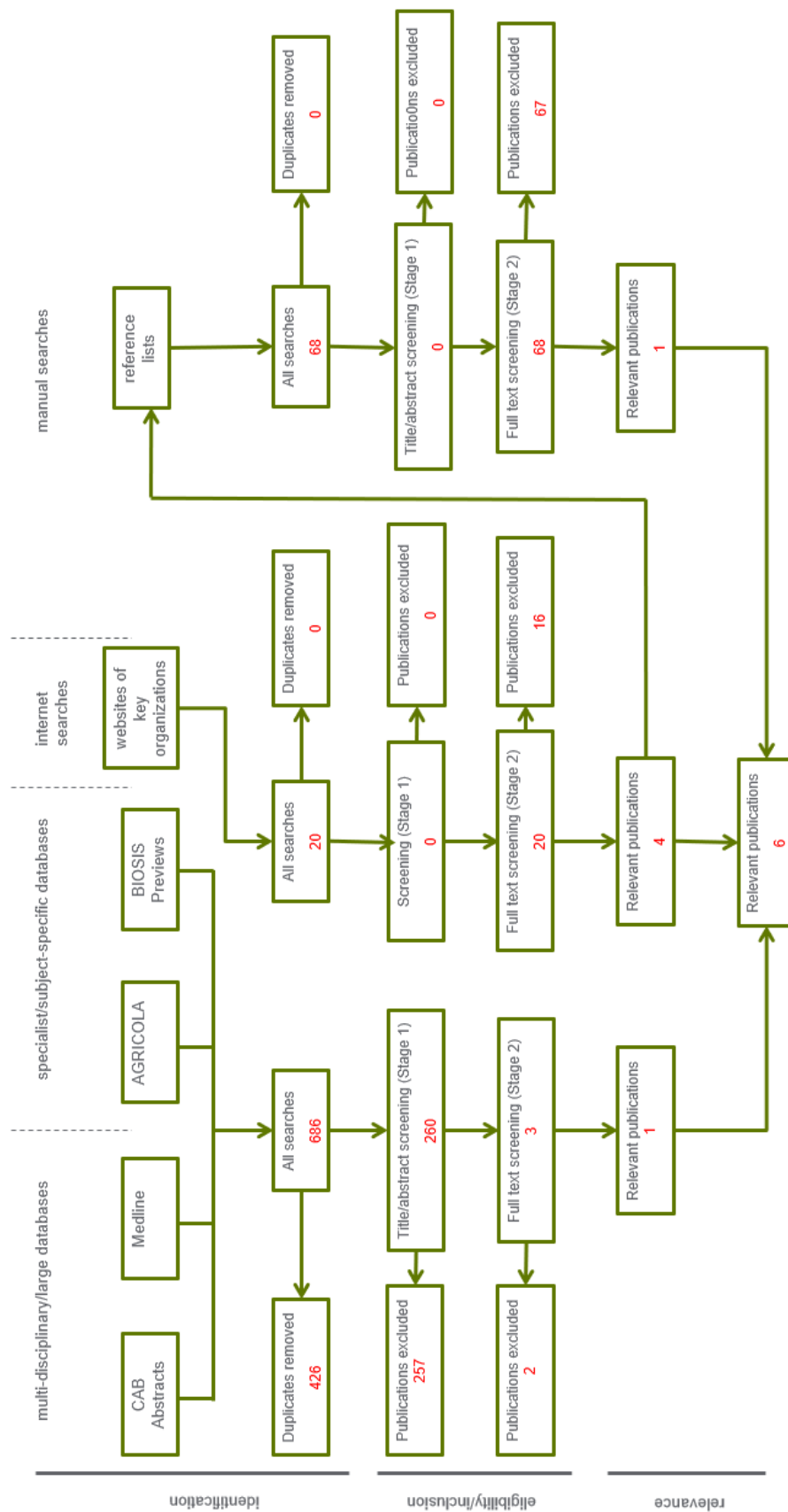
TABLE 9 Results of the publication selection process, for each review question and or group of information/data requirements searched

Review question and/or category of information/data requirement(s) captured in the search	Number of publications
Publications identified after all* searches of the scientific literature (excluding duplicates)	
Database results identified	348
Internet results identified	260
Manual searching – checking reference lists**	20
	68
Publications excluded from the search results after screening of title and abstracts*** (stage 1)	257
Database results excluded	257
Internet results excluded	0
Manual searching - reference results excluded	0
Publications screened using full-text (stage 2)	91
Database results screened	3
Internet results screened	20
Manual searching - reference results screened	68
Publications excluded after full-text screening	85
Database results full-text excluded	2
Internet results full-text excluded	16
Manual search – references excluded	67
Unobtainable publications	0
Unclear publications	0
Publications considered relevant	6
Database results relevant	1
Internet results relevant	4
References from relevant internet documents	1

*Both from electronic bibliographic databases and other sources of scientific literature.

** The reference list from records deemed relevant from search of regulatory agency websites were scanned for potential relevance. Only those records within the date range were included in the statistic and review. The reason for exclusion was not provided. These records went through a single stage review with no de-duplication against other records returned.

FIGURE 1 Flow chart of the publication selection process



3.8 Relevant Publications

A list of the full bibliographic references for all relevant publications, ordered by category of information/data requirement is recorded in Table 10 and 11.

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

List of bibliographic references for all relevant publications, classified by category of information/data requirements*			
Category of information/data requirement(s)	Study (Author(s) and year)	Title	Source
Molecular characterisation of the genetic modification of GMO	Erasmus R <i>et.al.</i> 2019	Introgression of a cry1Ab transgene into open pollinated maize and its effect on Cry protein concentration and target pest survival	PLoS ONE

TABLE 11 Report of all relevant publications retrieved after assessment of internet documents

List of bibliographic references for all relevant publications, classified by category of information/data requirements*			
Category of information/data requirement(s)	Study (Author(s) and year)	Title	Source
Risk Assessment	Australia New Zealand Food Authority, no date provided (FSANZ 2020a)	Application to Food Standards Australia New Zealand for the Inclusion of Corn MON 87429	https://www.foodstandards.gov.au/code/applications/Documents/A1192%20Application%20Document_redacted.pdf
Risk Assessment	Australia New Zealand Food Authority, no date provided (FSANZ 2020b)	Safety assessment – Application A1192	https://www.foodstandards.gov.au/code/applications/Documents/A1192%20SD1.pdf
Risk Assessment	United States Department of Agriculture, no date provided (USDA 2019a)	National Environmental Policy Act Decision: Finding Of No Significant Impact	https://www.aphis.usda.gov/brs/aphisdocs/17_22301p_fonsi.pdf

List of bibliographic references for all relevant publications, classified by category of information/data requirements*				
Category of information/data requirement(s)	Study (Author(s) and year)	Title	Source	
Risk Assessment	United States Department of Agriculture (USDA 2019b)	Pioneer Hi-Bred International, Inc. Petition (19-101-01p) for Determination of Nonregulated Status for Enhanced Grain Yield and Glufosinate-Ammonium Resistant DP202216 Corn	https://www.aphis.usda.gov/brs/aphisdocs/19-10101p-dea.pdf	
Risk Assessment	Pioneer Hi-Bred International, Inc. 2019	Petition for Determination of Nonregulated Status for Enhanced Grain Yield Potential and Glufosinate-ammonium Resistant DP202216 Maize.	https://www.aphis.usda.gov/brs/aphisdocs/19-10101p.pdf	

3.9 Excluded Publications After Detailed Assessment of Full-Text Documents

A list of the full bibliographic references for all excluded studies retrieved from database searching after detailed assessment of full-text documents for relevance (i.e. stage 2), with justification for their exclusion, is recorded in Table 12 and 13

TABLE 12 Report of all publications excluded after detailed assessment of full-text documents

List of bibliographic references for all relevant publications, classified by category of information/data requirements*			
Study Author(s) and year	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria table
Dively et.al., 2020	Evaluation of gene flow in structured and seed blend refuge systems of non-Bt and Bt corn	Journal of Pest Science	Intervention/exposure - This study was performed on Agrisure 3000GT which is a breeding stack, and not the single event Bt11 maize.
Fast et.al., 2020	Transgene expression in sprayed and non-sprayed herbicide-tolerant genetically engineered crops is equivalent	Regulatory Toxicology & Pharmacology	Intervention/exposure - The study reports expression data for the PAT protein, but not in Bt11 maize.

TABLE 13 Report of all publications excluded after assessment of internet documents

List of bibliographic references for all relevant publications, classified by category of information/data requirements*				
Category of information/data requirement(s)	Study (Author(s) and year)	Title	Source	
Information/data requirements	Food Standards Australia and New Zealand (FSANZ 2019)	A1192 Executive Summary	https://www.foodstandards.gov.au/code/applications/Documents/A1192%20Executive%20Summary.pdf	
Information/data requirements	National Technical Commission on Biosafety (CTNBio 2020)	Tabela de Plantas Aprovadas para Comercialização	http://ctnbio.mctic.gov.br/documents/566529/1684467/Tabela+de+Plantas+Aprovadas+para+Comercializa%C3%A7%C3%A3o/	
Information/data requirements	United States Department of Agriculture (USDA 2019)	USDA APHIS Home Landing Page	https://www.aphis.usda.gov/brs/aphisdocs/19_31601p.pdf	
Intervention/exposure	Food Standards Australia and New Zealand (FSANZ 2020)	A1192 Submissions	https://www.foodstandards.gov.au/code/applications/Documents/A1192%20Submissions.zip	
Intervention/exposure	Food Standards Australia and New Zealand (FSANZ 2019)	A1196 Application	https://www.foodstandards.gov.au/code/applications/Documents/A1196%20Application.pdf	
Intervention/exposure	Food Standards Australia and New Zealand (FSANZ 2020)	A1196 SD1	https://www.foodstandards.gov.au/code/applications/Documents/A1196%20SD1.pdf	
Reporting format	United States Department of Agriculture (USDA)	www.aphis.usda.gov/brs/data/brs-processed.json	https://www.aphis.usda.gov/brs/data/brs-processed.json	
Reporting format	United States Department of Agriculture (USDA 2019)	USDA APHIS Home Landing Page	https://www.aphis.usda.gov/brs/data/brs-courtesy.json	
Reporting format	Health Canada (HC 2020)	Plants with Novel Traits (PNT) and Novel Feeds from Plant Sources Approved in Canada - Plants	https://inspection.gc.ca/active/netapp/plantnoveltraitpnt-vegecanouvcn/pntvcne.aspx	
Reporting format	Health Canada (HC 2020)	Publications by F. Pelletier	https://www.cfs.mrcan.gc.ca/authors/read/20560	
Reporting format	Food Standards Australia and New Zealand (FSANZ 2020a)	Comparison of CFS1 to CFS2 Schedules	https://www.foodstandards.gov.au/code/proposals/Documents/Comparison%20of%20CFS1%20to%20CFS2%20Schedules.pdf	

List of bibliographic references for all relevant publications, classified by category of information/data requirements*				
Category of information/data requirement(s)	Study (Author(s) and year)	Title	Source	
Reporting format	Food Standards Australia and New Zealand (FSANZ 2020b)	P1025_CFS_Attach_A2_Schedules	https://www.foodstandards.gov.au/code/proposals/Documents/P1025_CFS_Attach_A2_Schedules.pdf	
Scope of GMO application	Ministry of Agriculture, Forestry and Fisheries (MAFF 2020a)	cry1Ab ,cry1F, cry1A.105, cry2Ab2, cry1Ac, vip3A, cry3Bb1, cry3Aa2	http://www.maff.go.jp/j/syouan/nouan/carta/c_data/pdf/gutairei.pdf	
Scope of GMO application	Ministry of Agriculture, Forestry and Fisheries (MAFF 2020b)	Specific examples of transgenic plants that can eliminate the need for isolated field tests c	http://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/attach/pdf/index-19.pdf	
Scope of GMO application	Health Canada (HC 2020)	Publications by L.P. Hamel	https://cfs.nrcan.gc.ca/authors/read/19908	
Scope of GMO application	Health Canada (HC 2020)	Publications by F. Pelletier	https://cfs.nrcan.gc.ca/authors/vue/20560?format=citation&lang=en_CA	

3.10 Unobtainable Publications

No publications were considered unobtainable.

3.11 Unclear Publications

No publications were considered unclear.

3.12 Full-Text Documents

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

3.13 Narrative Synthesis/Summary of Relevant Publications

A narrative synthesis/summary of the relevant studies describing their overall volume, strength, and direction per main category of information/data requirements was not reported because this literature review was conducted for annual PMEM reports on GMOs authorized in the EU market and therefore it is not required.

3.14 Implications of Relevant Publications on Risk Assessment

The implications of the relevant publications on the risk assessment was assessed by considering whether the record presents new hazards, modified exposure pathways, or new scientific uncertainties.

The record reliability and its implication on the risk assessment was recorded in Tables 13 and 14.

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

List of bibliographic references for all relevant publications, classified by category of information/data requirements			
Category of information/data requirement(s)	Publication (Author(s) and year)	Summary of reliability appraisal	Implications for the risk assessment
Molecular characterization of the genetic modification of GMO	Erasmus R et.al. 2019	High: clearly described experimental procedures and reported results provide evidence of reproducibility and accuracy of the findings	Concentrations of Cry1Ab in Bt11 maize leaves were reported. Concentrations were higher in leaves of F1 and F2 Bt11 maize expressing more than one copy of the cry1Ab gene. The increased concentration reported in expression data was in range of previously reported values for Bt11 maize expressing one copy of the cry1Ab gene, therefore, these data do not impact the current risk assessment for Bt11 maize.

TABLE 15 Report of the reliability and implications for the risk assessment of all relevant publications retrieved after assessment of internet documents.

List of bibliographic references for all relevant publications, classified by category of information/data requirements				
Category of information/data requirement(s)	Publication (Author(s) and year)	Summary of reliability appraisal	Implications for the risk assessment	
Risk assessment or scientific opinion	U.S. Department of Agriculture, no date provided (USDA 2019a)	Not assignable because no or insufficient information is reported in the document	This document is considered a risk assessment based on a data package provided by the sponsor company, and contains their conclusions related to specific protection goals. The information provided in this document does not change the conclusion of the risk assessment for Bt11 maize.	
Risk assessment or scientific opinion	Pioneer Hi-Bred International, Inc. 2019	Not assignable because no or insufficient information is reported in the document	This document is considered a risk assessment based on a data package provided by the sponsor company, and contains their conclusions related to specific protection goals. The information provided in this document does not change the conclusion of the risk assessment for Bt11 maize.	
Risk assessment or scientific opinion	U.S. Department of Agriculture, no date provided (USDA 2019b)	Not assignable because no or insufficient information is reported in the document	This document is considered a risk assessment based on a data package provided by the sponsor company, and contains their conclusions related to specific protection goals. The information provided in this document does not change the conclusion of the risk assessment for Bt11 maize.	
Risk assessment or scientific opinion	Food Standards Australia New Zealand, no date provided (FSANZ 2020a)	Not assignable because no or insufficient information is reported in the document	This document is considered a risk assessment based on a data package provided by the sponsor company, and contains their conclusions related to specific protection goals. The information provided in this document does not change the conclusion of the risk assessment for Bt11 maize.	

List of bibliographic references for all relevant publications, classified by category of information/data requirements			
Category of information/data requirement(s)	Publication (Author(s) and year)	Summary of reliability appraisal	Implications for the risk assessment
Risk assessment or scientific opinion	Food Standards Australia New Zealand, no date provided (FSANZ 2020b)	Not assignable because no or insufficient information is reported in the document	This document is considered a risk assessment based on a data package provided by the sponsor company, and contains their conclusions related to specific protection goals. The information provided in this document does not change the conclusion of the risk assessment for Bt11 maize.

4.0 RECORDS TO BE 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 report, and any amendments or deviations.

5.0 ARCHIVING OF RECORDS

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

6.0 REFERENCES

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APPENDICES SECTION

APPENDIX A Search history and subject indexing


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▼ Search History (147)

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<input type="checkbox"/>	# ▲	Searches	Results	Type	Actions	Annotations
<input type="checkbox"/>	1	Bt11.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	95	Advanced	Display Results More	Contract
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<input type="checkbox"/>	3	SYN-BT711-1.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More	
<input type="checkbox"/>	4	1 or 2 or 3	118	Advanced	Display Results More	
<input type="checkbox"/>	5	Agrisure*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	16	Advanced	Display Results More	
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<input type="checkbox"/>	17	Phosphinothricin acetyltransferase.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	213	Advanced	Display Results More	
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<input type="checkbox"/>	31	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30	2693	Advanced	Display Results More	<input type="checkbox"/>
<input type="checkbox"/>	32	14 or 31	3608	Advanced	Display Results More	<input type="checkbox"/>
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<input type="checkbox"/>	67	FAW.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	123	Advanced	Display Results More	
<input type="checkbox"/>	68	SCB.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	472	Advanced	Display Results More	
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<input type="checkbox"/>	71	resistan*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	277758	Advanced	Display Results More	
<input type="checkbox"/>	72	protect*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	263270	Advanced	Display Results More	
<input type="checkbox"/>	73	control*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	936190	Advanced	Display Results More	
<input type="checkbox"/>	74	70 or 71 or 72 or 73	1403078	Advanced	Display Results More	
<input type="checkbox"/>	75	((Insect or insects or Lepidoptera* or pest or pests or stalkborer* or stalk borer* or borer* or cornborer* or corn borer* or Noctuidae or Crambidae or earworm* or ear worm* or armyworm* or army worm* or Ostrinia or O nubilalis or Diatraea or D grandiosella or D crambidoides or Helicoverpa or H zea or Spodoptera or S frugiperda or Papaipema or P nebris or Elasmopalpus or E lignosellus or D saccharalis or ECB or SWCB or SCSB or CEW or FAW or SCB) adj2 (toleran* or resistan* or protect* or control*)),mp.	117760	Advanced	Display Results More	
<input type="checkbox"/>	76	Bacillus thuringiensis.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	10329	Advanced	Display Results More	
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<input type="checkbox"/>	92	protect*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	263270	Advanced	Display Results More	
<input type="checkbox"/>	93	90 or 91 or 92	601177	Advanced	Display Results More	
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<input type="checkbox"/>	95	GMO*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	1399	Advanced	Display Results More	
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<input type="checkbox"/>	107	improv*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	501851	Advanced	Display Results More	
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heading words]				Display Results	More	
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<input type="checkbox"/>	137	Btcorn*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save	More
<input type="checkbox"/>	138	135 or 136 or 137	1185	Advanced	Display Results	More
<input type="checkbox"/>	139	112 or 126	264846	Advanced	Display Results	More
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<input type="checkbox"/>	143	94 and 112	2174	Advanced	Display Results	More
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<input type="checkbox"/>	146	4 or 5 or 138 or 140 or 142 or 145	2691	Advanced	Display Results	More
<input type="checkbox"/>	147	limit 146 to yr="2019 -Current"	86	Advanced	Display Results	More

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Text (86 Results)

Multimedia (0 Results)

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limit 146 to yr="2019 -Current"

Search terms used:

1
 11
 111069-93-3
 agrisure*
 army
 worm*
 armyworm*
 b
 thuringiensis
 bacillus
 basta*
 biotech*
 borer*
 bt
 bt11
 btcorn*
 btmaize*
 cew
 challenge*
 control*
 corn
 corn*

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☐ 1. **Effect of Bt Corn (Bt 38) Cultivation on Community Structure of Collembola**

Chang, Liang Song, Xinyuan Wang, Baifeng Wu, Donghui Reddy, Gadi V. P.

Annals of the Entomological Society of America. 2019 July 30. 113(1) p. 1-5.

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☐ 2. **Management of Euxesta spp. in Sweet Corn with McPhail Traps**

Lopes, S R Cruz, I

Neotropical entomology. 2020 Feb. 49(1) p. 139-146.

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Kim, Yang-Ji [Reprint Author, Author]; Yang, Dae-Hwa [Author, Reprint Author; E-mail: dhyang79@gmail.com]; Park, Mi-Young [Author]; Sun, Hyeon-Jin [Author]; Song, Pill-Soon [Author]; Kang, Hong-Gyu [Author]; Suh, Seok-Cheol [Author]; Lee, Yong-Eok [Author]; Lee, Hyo-Yeon [Author, Reprint Author; E-mail: hyoyeon@jejunu.ac.kr].

Plant Biotechnology Reports. 14(1). FEB 2020.

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Rozadilla, Gaston [Author]; Cabrera, Natalia A. [Author]; Viria, Eduardo G. [Author]; Greco, Nancy M. [Author]; McCarthy, Christina B. [Author, Reprint Author; E-mail: mccarthychristina@gmail.com].

Journal of Applied Entomology. 144(5). JUN 2020.

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- ☐ 1. **Results from ten years of post-market environmental monitoring of genetically modified MON 810 maize in the European Union.**

Bertho, L. Schmidt, K. Schmidtke, J. Brants, I. Cantón, R. F. Novillo, C. Head, G.
PLoS ONE; 2020. 15(4)54 ref.
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- ☐ 2. **Assessment of genetically modified maize MON 88017 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA -GMO -RX -014).**

Naegeli, H. Bresson, J. L. Dalmay, T. Dewhurst, I. C. Epstein, M. M. Firbank, L. G. Guerche, P. Hejatkó, J. Moreno, F. J. Mullins, E. Nogué, F. Rostoks, N. Serrano, J. J. S. Savoini, G. Veromann, E. Veronesi, F. Álvarez, F. Ardizzone, M. Raffaello, T.
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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]

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	Challenge* or herbicide* or pesticide*) adj2 (toleran* or resist* or protect*)),mp.				
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<input type="checkbox"/>	122	Maize*.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]	30994	Advanced	Display Results More	
<input type="checkbox"/>	123	corn*.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]	209515	Advanced	Display Results More	
<input type="checkbox"/>	124	Zea 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]	35974	Advanced	Display Results More	
<input type="checkbox"/>	125	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]	355	Advanced	Display Results More	
<input type="checkbox"/>	126	122 or 123 or 124 or 125	243675	Advanced	Display Results More	
<input type="checkbox"/>	127	Bt.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]	14618	Advanced	Display Results More	
<input type="checkbox"/>	128	Bacillus thuringiensis.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]	8710	Advanced	Display Results More	
<input type="checkbox"/>	129	B thuringiensis.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]	2261	Advanced	Display Results More	
<input type="checkbox"/>	130	127 or 128 or 129	20955	Advanced	Display Results More	
<input type="checkbox"/>	131	maize*.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]	30994	Advanced	Display Results More	
<input type="checkbox"/>	132	corn*.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]	209515	Advanced	Display Results More	
<input type="checkbox"/>	133	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]	36226	Advanced	Display Results More	
<input type="checkbox"/>	134	131 or 132 or 133	243883	Advanced	Display Results More	
<input type="checkbox"/>	135	((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or corn* or mays)).mp.	790	Advanced	Display Results More	
<input type="checkbox"/>	136	Btmaize*.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]	0	Advanced	Save More	

concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

<input type="checkbox"/>	137	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]	0	Advanced	Save More	
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- ☐ 1. **Resistance of the fall armyworm, *Spodoptera frugiperda*, to transgenic *Bacillus thuringiensis* Cry1F corn in the Americas: lessons and implications for Bt corn IRM in China.**

Huang F.

Insect Science. 2020 Jun 01.

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