



**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

EU	European Union
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
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* 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.

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 was:

Do either food/feed products derived from Bt11 maize or the intended trait have adverse effects on human and/or 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 were not assessed. Internet pages were screened first by date range June 1, 2018 to June 30, 2019. Pages without dates were evaluated further using the criteria in Tables 2 and 3.

TABLE 2 Eligibility/Inclusion Criteria to Establish Relevance

Concepts	Criteria	Comment
Intervention/exposure	Bt11 maize, derived food/feed products, and/or the intended trait(s)	Intended traits include Cry1Ab and PAT and closely related variants. Closely related variants of Cry1Ab include various lengths of the Cry1Ab protein but not other Cry or Cry1 proteins. 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) were considered relevant. Based on the scope of the application certain information/data requirements are excluded. These are also detailed in Table 3. 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 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	The scope of the application associated with this literature review is import and processing for food/feed uses. Therefore, publications must address pathways and levels of exposure relevant to the scope of the application to be included.
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. reviews, editorials, position papers) were excluded. Reviews were only included if they present data that are not available from a primary research study. Risk assessments performed and reported by relevant key organizations were included if they address Bt11 maize, Cry1Ab, or PAT 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	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 will also be excluded.
Access	Full-text document is accessible	If potentially relevant full-text documents could not be obtained, then they were listed in a table with a description of the (unsuccessful) methods that have been used to try to obtain a copy.

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 addresses the same plant species as the GMO under consideration	This literature review aims at determining the safe use of the intended traits(s) of Bt11 maize. Therefore, GMOs that contain the same transgenic proteins, but are introduced into another plant species may be included. For certain types of data, the presence of Cry1Ab and PAT in a different plant species will not impact the assessment of Bt11 maize. Those types of data are identified 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 was presented even if it is reported in different publications.
Date of information	For internet pages only, the date of the information presented should be within the date range of the literature review (from June 1, 2018 through the date the search was conducted).	Documents returned from the searches of the webpages that were out of date were excluded.

TABLE 3 Overview of Main Categories of Information/Data Requirements

Expert knowledge on data used in the risk assessment of the GMO is required but the list below provides some examples of relevant data/information.

Information/data requirement	Non-exhaustive list of specific information/data requirements
Molecular characterization of the genetic modification of Bt11 maize	<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 • Expression data of inserted/modified sequences • Genetic stability • Molecular and biochemical characterization of the protein(s) such as: primary structure, molecular weight, post-translational modifications • Assessment of enzymatic activity including substrate specificity and reaction products with respect to safety and/or nutritional balance • Data on the equivalence between plant-produced and microbially-produced proteins
Agronomic, phenotypic and compositional characterization of the Bt11 maize	<ul style="list-style-type: none"> • Comparative assessment of agronomic and phenotypic characteristics under field or controlled conditions • Comparative analysis of key nutritional constituents were only 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) 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 must use Bt11 maize as the source of plant material to be considered relevant
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 and known allergens or celiac disease peptide sequences • Serum screening • Pepsin susceptibility testing • <i>In vivo</i> tests in animal models • Expression data for endogenous allergens in maize • 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. If the diet contains plant material the source of the plant material must be Bt11 to be considered relevant.

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 Replacement capacity Fitness of the GM plant in various environmental conditions – if Cry1Ab, PAT or closely related variants are expressed in a different plant species then the publication may be considered relevant.
Assessment of plant to micro-organism gene transfer	<ul style="list-style-type: none"> Homology searches at nucleotide level between the GM event and microorganisms. Publications would have to utilize sequence from Bt11 maize specifically to be considered relevant
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 is not relevant for this application.
Assessment of interactions with nontarget 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 feces from animals fed the GM plant, and other by-products of industrial processes)”. Therefore, any publications that discuss direct exposure in test protein and laboratory studies or field survey data can be 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 is not relevant given the scope of this application.

Information/data requirement	Non-exhaustive list of specific information/data requirements
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): “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”. Therefore, an assessment of impact of specific cultivation, management and harvesting techniques of Bt11 maize is not relevant for this application.
Risk mitigation	<ul style="list-style-type: none"> Excluded based on the scope of the application. Risk mitigation measures such as high dose/refuge strategy, isolation distance from protected habitats hosting species of conservation concern that are at risk, 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) were 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 below (Table 4) were searched for documents related to Bt11 maize.

TABLE 4 Key Organizations Pages Included in the Search

Regulatory agency name	URL
US Environmental Protection Agency	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated
US Department of Agriculture	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology
US Food and Drug Administration	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon
Canadian Food Inspection Agency	http://www.inspection.gc.ca/plants/plants-with-novel-traits/notices-of-submission/eng/1300143491851/1300143550790
Health Canada*	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html
Food Standards Australia New Zealand	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx
Office of the Gene Technology Regulator	http://www.ogtr.gov.au/
Intersecretarial Commission on Biosafety of GMOs	http://www.conacyt.gob.mx/cibiogem/index.php/cibiogem
National Technical Commission on Biosafety	http://ctnbio.mcti.gov.br/
National Advisory Commission on Agriculture Biotechnology**	https://www.argentina.gob.ar/agroindustria/alimentos-y-bioeconomia/ogm-comerciales
Ministry of Environment, Forest and Climate change	http://moef.gov.in/
Ministry of Agriculture, Forestry and Fisheries	http://www.maff.go.jp/e/
European Food Safety Authority	http://www.efsa.europa.eu/

*Also searches Environment and Climate Change Canada

** The traditional website search method was ineffective. Therefore, this webpage was searched using the find function <control F>.

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

If any reviews, methodological publications, guidelines and scientific opinions from regulatory agencies were retrieved using the search strategy and classified as relevant to the review question, then the reference lists from those records were manually searched for new records (June 2018 through the date the search was conducted) that meet 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 dated 2017 (EFSA 2017) 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, 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 OR Trade Name) or (Event OR Trade name OR ((Intended Trait OR Newly Expressed Protein) 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 Proteins, 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 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

1	Topic	Bt11 OR Bt 11 OR SYN-BT?11-1	Event Bt11
2	Topic	Agrisure*	Trade name(s) for Event Bt11 ^a
3	Topic	Cry1Ab* OR Cry 1Ab* OR Cry1 Ab* OR Cry 1 Ab* OR CryIAb* OR Cry IAb* OR CryI Ab* OR Cry I Ab*	Newly expressed protein in Bt11 (Insecticidal)
4	Topic	Phosphinothricin N acetyltransferase OR Phosphinothricin N acetyl transferase OR Phosphinothricin acetyltransferase OR Phosphinothricin acetyl transferase OR PPT acetyltransferase OR PPT acetyl transferase OR PT N acetyltransferase OR PT N acetyl transferase OR Glufosinate acetyltransferase OR Glufosinate acetyl transferase OR Gluphosinate acetyltransferase OR Gluphosinate acetyl transferase OR pat OR 111069-93-3 OR EC 2.3.1.183 OR E.C. 2.3.1.183	Newly expressed protein in Bt11 (herbicidal)
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 (herbicidal)
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 x intended traits (herbicidal)
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 x 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 -herbicidal AND GMO general) OR GMO general x Intended trait (herbicidal)) AND Plant species

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 -herbicidal AND GMO general) OR GMO general x Intended trait (herbicidal)) AND Plant species) OR GMO general x intended trait – insecticidal
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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-BT011-1, SYN-BT011-1, SYN-BT011-1, and SYN-BTempty set11-1**
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.

3.3.1.6 Use of multiple languages

The search terms used were in the English language or utilized the Roman alphabet. For the event name and trade name it is unlikely that there are translations because they are not words in the English language.

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 June 1, 2018 and June 30, 2019 (see Table 8).

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 were 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

Previously conducted literature reviews have successfully returned literature relevant to the risk assessment of Bt11 maize. The search strategy defined in this report was run and the reference publications listed below in Table 7 were returned. Therefore, the search terms selected are suitable to retrieve and/or identify the already known literature on the intervention/exposure of Bt11 maize.

The reference publications utilized are identified in Table 7 (X indicates that the publication was retrieved in the database). The percentage of publications retrieved in each database is provided.

TABLE 7 Reference publications

Data/Information requirement	Reference	Medline	CAB Abstracts	BIOSIS	Agricola	
Allergenicity assessment of newly expressed protein and the GM food/feed, and adjuvanticity	Adel-Patient K, Guimaraes VD, Paris A, Drumare MF, Ah-Leung S, Lamourette P, Nevers MC, Canlet C, Molina J, Bernard H, Creminon C and Wal JM, 2011. Immunological and metabolomic impacts of administration of Cry1Ab protein and MON 810 maize in mouse. <i>PLoS ONE</i> 6, e16346.	X	X	X		
	Andreassen M, Bohn T, Wikmark OG, Van den Berg J, Lovik M, Traavik T and Nygaard UC, 2015a. Cry1Ab protein from <i>Bacillus thuringiensis</i> and MON810 cry1Ab transgenic maize exerts no adjuvant effect after airway exposure. <i>Scandinavian Journal of Immunology</i> 81, 192-200.	X	X	X		
	Andreassen M, Rocca E, Bohn T, Wikmark OG, Berg Jvd, Lovik M, Traavik T and Nygaard UC, 2015b. Humoral and cellular immune responses in mice after airway administration of <i>Bacillus thuringiensis</i> Cry1Ab and MON810 cry1Ab-transgenic maize. <i>Food and Agricultural Immunology</i> 26, 521-537.			X	X	X
	Andreassen M, Bohn T, Wikmark OG, Bodin J, Traavik T, Lovik M and Nygaard UC, 2016. Investigations of immunogenic, allergenic and adjuvant properties of Cry1Ab protein after intragastric exposure in a food allergy model in mice. <i>BMC Immunology</i> 17, 10.	X	X	X		
	Guimaraes V, Drumare MF, Lereclus D, Gohar M, Lamourette P, Nevers MC, Vaisanen-Tunkelrott ML, Bernard H, Guillon B, Creminon C, Wal JM and Adel-Patient K, 2010. In vitro digestion of Cry1Ab proteins and analysis of the impact on their immunoreactivity. <i>Journal of Agricultural & Food Chemistry</i> 58, 3222-31.	X	X	X	X	
	Mathur C, Kathuria PC, Dahiya P and Singh AB, 2015. Lack of detectable allergenicity in genetically modified maize containing "Cry" proteins as compared to native maize based on in silico & in vitro analysis. <i>PLoS ONE</i> 10, e0117340.	X	X	X		
	Randhawa GJ, Singh M and Grover M, 2011. Bioinformatic analysis for allergenicity assessment of <i>Bacillus thuringiensis</i> Cry proteins expressed in insect-resistant food crops. <i>Food & Chemical Toxicology</i> 49, 356-62.	X	X	X	X	
	Razavi A, Malhotra I, Ghosh A, Pusztai-Carey M, Marks J and King C, 2017. Antibodies as epidemiological markers of genetically modified crop exposure: detection of Cry1Ab specific IgG. <i>Food and Agricultural Immunology</i> 28, 779-788.			X	X	X
	Schafer BW, Embrey SK and Herman RA, 2016. Rapid simulated gastric fluid digestion of in-seed/grain proteins expressed in genetically engineered crops. <i>Regulatory Toxicology & Pharmacology</i> 81, 106-112.	X			X	
	Gu J, Krogdahl A, Sissener NH, Kortner TM, Gelencser E, Hemre GI and Bakke AM, 2013. Effects of oral Bt-maize (MON810) exposure on growth and health parameters in normal and sensitised Atlantic salmon, <i>Salmo salar</i> L. <i>British Journal of Nutrition</i> 109, 1408-23.	X	X	X	X	X

Data/Information requirement	Reference	Medline	CAB Abstracts	BIOSIS	Agricola
Assessment of interactions with biogeochemical and abiotic processes	Gruber H, Paul V, Guertler P, Spiekers H, Tichopad A, Meyer HH and Muller M, 2011. Fate of Cry1Ab protein in agricultural systems under slurry management of cows fed genetically modified maize (<i>Zea mays</i> L.) MON810: a quantitative assessment. <i>Journal of Agricultural & Food Chemistry</i> 59, 7135-44.	X	X	X	X
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	Guertler P, Paul V, Steinke K, Wiedemann S, Preissinger W, Albrecht C, Spiekers H, Schwarz FJ and Meyer HHD, 2010. Long-term feeding of genetically modified corn (MON810) - Fate of cry1Ab DNA and recombinant protein during the metabolism of the dairy cow. <i>Livestock Science</i> 131, 250-259.		X	X	X
Persistence and invasiveness assessment, including plant-to-plant gene transfer	Devos Y, Ortiz-Garcia S, Hokanson KE and Raybould A, 2018. Teosinte and maize x teosinte hybrid plants in Europe-Environmental risk assessment and management implications for genetically modified maize. <i>Agriculture, Ecosystems & Environment</i> 259, 19-27.		X	X	
	Guertler P, Lutz B, Kuehn R, Meyer HHD, Einspanier R, Killermann B and Albrecht C, 2008. Fate of recombinant DNA and Cry1Ab protein after ingestion and dispersal of genetically modified maize in comparison to rapeseed by fallow deer (<i>Dama dama</i>). <i>European Journal of Wildlife Research</i> 54, 36-43.		X	X	
	Raybould A, Higgins LS, Horak MJ, Layton RJ, Storer NP, De La Fuente JM and Herman RA, 2012. Assessing the ecological risks from the persistence and spread of feral populations of insect-resistant transgenic maize. <i>Transgenic Research</i> 21, 655-64.	X	X	X	X
	Wiedemann S, Lutz B, Albrecht C, Kuehn R, Killermann B, Einspanier R and Meyer HHD, 2009. Fate of genetically modified maize and conventional rapeseed, and endozoochory in wild boar (<i>Sus scrofa</i>). <i>Mammalian Biology</i> 74, 191-197.		X	X	

Data/Information requirement	Reference	Medline	CAB Abstracts	BIOSIS	Agricola	
Toxicological assessment of newly expressed protein(s), new constituents other than proteins, and the whole GM food/feed	Aris A and Leblanc S, 2011. Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada. <i>Reproductive Toxicology</i> 31, 528-33.		X	X		
	Bondzio A, Lodemann U, Weise C and Einspanier R, 2013. Cry1Ab treatment has no effects on viability of cultured porcine intestinal cells, but triggers Hsp70 expression. <i>PLoS ONE</i> 8, e67079.	X		X		
	Bondzio A, Stumpff F, Schon J, Martens H and Einspanier R, 2008. Impact of <i>Bacillus thuringiensis</i> toxin Cry1Ab on rumen epithelial cells (REC) - a new in vitro model for safety assessment of recombinant food compounds. <i>Food & Chemical Toxicology</i> 46, 1976-84.	X	X	X	X	
	Daudu CK, Muchaonyerwa P and Mnkeni P, 2012. Carbon and nitrogen mineralisation and inactivation of the Cry1Ab protein in Bt maize (MON810) residues during composting. <i>South African Journal of Plant and Soil</i> 29, 57-63.			X	X	
	de Luis R, Lavilla M, Sanchez L, Calvo M and Perez MD, 2010. Pepsin degradation of Cry1A(b) protein purified from genetically modified maize (<i>Zea mays</i>). <i>Journal of Agricultural & Food Chemistry</i> 58, 2548-53.	X	X	X	X	
	de Luis R, Perez MD, Sanchez L, Lavilla M and Calvo M, 2008. Kinetic and thermodynamic parameters for heat denaturation of Cry1a(b) protein from transgenic maize (<i>Zea mays</i>). <i>Journal of Food Science</i> 73, C447-51.	X	X	X	X	
	Grisolia CK, Oliveira R, Domingues I, Oliveira-Filho EC, Monerat RG and Soares AM, 2009. Genotoxic evaluation of different delta-endotoxins from <i>Bacillus thuringiensis</i> on zebrafish adults and development in early life stages. <i>Mutation Research</i> 672, 119-23.	X	X	X		
	Haryu Y, Taguchi Y, Itakura E, Mikami O, Miura K, Saeki T and Nakajima Y, 2009. Longterm biosafety assessment of a genetically modified (GM) plant: the genetically modified (GM) insect-resistant Bt11 corn does not affect the performance of multigenerations or life span of mice. <i>Open Plant Science Journal</i> 3, 49-53.			X		
	Kamota A, Muchaonyerwa P and Mnkeni PNS, 2011. Effects of ensiling of <i>Bacillus thuringiensis</i> (Bt) maize (MON810) on degradation of the crystal 1Ab (Cry1Ab) protein and compositional quality of silage. <i>African Journal of Biotechnology</i> 10, 17484-17489.			X	X	
	Mesnager R, Clair E, Gress S, Then C, Szekacs A and Seralini GE, 2013. Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosatebased herbicide. <i>Journal of Applied Toxicology</i> 33, 695-9.	X			X	
	Mezzomo BP, Miranda-Vilela AL, Barbosa LC, Albernaz VL and Grisolia CK, 2016. Hematotoxicity and genotoxicity evaluations in Swiss mice intraperitoneally exposed to <i>Bacillus thuringiensis</i> (var <i>kurstaki</i>) spore crystals genetically modified to express individually Cry1Aa, Cry1Ab, Cry1Ac, or Cry2Aa. <i>Environmental Toxicology</i> 31, 970-8.	X			X	X
	Onose J, Imai T, Hasumura M, Ueda M, Ozeki Y and Hirose M, 2008. Evaluation of subchronic toxicity of dietary administered Cry1Ab protein from <i>Bacillus thuringiensis</i> var. <i>Kurstaki</i> HD-1 in F344 male rats with chemically induced gastrointestinal impairment. <i>Food & Chemical Toxicology</i> 46, 2184-9.	X	X	X	X	X

Data/Information requirement	Reference	Medline	CAB Abstracts	BIOSIS	Agricola
	Paul V, Guertler P, Wiedemann S and Meyer HH, 2010. Degradation of Cry1Ab protein from genetically modified maize (MON810) in relation to total dietary feed proteins in dairy cow digestion. <i>Transgenic Research</i> 19, 683-9.	X	X	X	X
	Sanden M, Ornsrud R, Sissener NH, Jorgensen S, Gu J, Bakke AM and Hemre GI, 2013. Cross-generational feeding of Bt (<i>Bacillus thuringiensis</i>)-maize to zebrafish (<i>Danio rerio</i>) showed no adverse effects on the parental or offspring generations. <i>British Journal of Nutrition</i> 110, 2222-33.		X	X	X
	Tremblay GF, Laberge S, Castonguay Y, Chiquette J, Ouellet DR, Delaney S, Petit HV and Michaud R, 2008. Outcome of Bt transgenes and protein in corn silage, processed grains, and rumen content. <i>Canadian Journal of Animal Science</i> 88, 85-95.		X	X	X
	Walsh MC, Buzoianu SG, Gardiner GE, Rea MC, Gelencser E, Janosi A, Epstein MM, Ross RP and Lawlor PG, 2011. Fate of transgenic DNA from orally administered Bt MON810 maize and effects on immune response and growth in pigs. <i>PLoS ONE</i> 6, e27177.	X	X	X	
	Walsh MC, Buzoianu SG, Rea MC, O'Donovan O, Gelencser E, Ujhelyi G, Ross RP, Gardiner GE and Lawlor PG, 2012. Effects of feeding Bt MON810 maize to pigs for 110 days on peripheral immune response and digestive fate of the cry1Ab gene and truncated Bt toxin. <i>PLoS ONE</i> 7, e36141.	X	X	X	
	Wang X, Chen X, Xu J, Dai C and Shen W, 2015. Degradation and detection of transgenic <i>Bacillus thuringiensis</i> DNA and proteins in flour of three genetically modified rice events submitted to a set of thermal processes. <i>Food & Chemical Toxicology</i> 84, 89-98.	X		X	X
	Percentage of records returned	64.7% (22/34)	85.3% (29/34)	97.1% (33/34)	50% (17/34)

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

4.1 Selecting Publications

4.1.1 Database records

The process for selecting relevant publications was conducted in two stages. The first stage required a rapid assessment of titles and abstracts. Those records that were clearly not relevant from reviewing the title only were excluded from further review. For those records that appeared relevant or had unclear relevance the abstracts were reviewed. Those records that were clearly not relevant from reviewing the abstract were excluded from further review, while records that are relevant or have unclear relevance were reviewed in Stage 2.

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 not relevant by both reviewers were excluded from further review.

The reviewers met to discuss their disagreements and further refined their understanding of the criteria for relevance. The reviewers independently re-reviewed the potential relevance of those titles upon which they disagreed. Documents with vague and generic titles were moved forward for full-length document review.

A kappa test was performed after the title/abstract publication selection (stage 1) and before initiating the full-text screening process. The kappa test score was 0.492. Because the review only considers manuscripts published within a small duration (one year), the searches are expected to return a small number of relevant compared to a large number of non-relevant manuscripts. Therefore, the reviewers adopted a broad inclusion criteria to ensure that all potentially relevant publications were captured. At the completion of stage 1 there were 392 records retrieved from the databases (with duplicates removed). There were 386 agreements, including agreement regarding three manuscripts at the title/abstract phase which were subsequently moved to stage two. There were six disagreements due to conservative reviewer judgement rather than narrower reviewer judgement. These publications proceeded to the next phase of review (review of the full documents). In this case, a kappa value smaller than 0.6 should not be of concern as the reviewers applied a broad inclusion criteria to their ratings of the titles and abstracts to ensure vague and non-specific titles and abstracts were moved forward for full-length document review.

Full-length articles were reviewed in Stage 2. A reason for exclusion is provided for any records that were deemed not relevant in Stage 2. Any relevant records identified in Stage 2 were subjected to reliability assessments and evaluations of the implications of those records on the food and feed or environmental risk assessments. Reviewers came to a consensus on all records.

4.1.2 Records from key organizations

The records returned from searching the websites of key organizations were considered relevant if they were 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 were searched do not post primary data; therefore all other document types are not considered relevant.

The format of records returned from regulatory agency websites did not meet the format required to assess them using the two stage process followed for the database records. When the website records were published in English, they were assessed by two independent reviewers. Due to format the full-text documents were assessed to determine relevance. When the website records were not published in English a single reviewer that speaks the language of those documents determined if they should be classified as a risk assessment, scientific opinion/report or document on the biology of the crop of interest. If a document was classified as one of these document types then it was translated to English and two independent reviewers determined if it met the other criteria for inclusion. Only if records were classified as one of the relevant document types and excluded based on other eligibility criteria was the rationale for its exclusion provided. Internet pages with URLs that lead to meaningless or no information (broken links) were also excluded.

4.2 Summarizing and Reporting the Data

This report provides detail about the search process and its results. The methodological framework in this report involves summarizing and reporting the literature, and applying meaning to the results as outlined in the Explanatory Note (EFSA 2019).

4.3 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 were recorded. Additionally, the line by line strategy with the number of publications identified per line is presented. See Appendix A.

TABLE 8 Electronic bibliographic database search details

Database	Search Date	Service provider	Date span of the search	Any limits applied to the search	Total number of records retrieved after removing duplicates
Agricola	05/07/2019	Ovid Technologies	01/06/2018 to 30/06/2019	Dates	8
BIOSIS Previews	05/07/2019	Ovid Technologies	01/06/2018 to 30/06/2019	Dates	90
CAB Abstracts	05/07/2019	Ovid Technologies	01/06/2018 to 30/06/2019	Dates	101
Medline	05/07/2019	Ovid Technologies	01/06/2018 to 30/06/2019	Dates	193

For records from websites the following were 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. TABLE 6 contains the search terms used as a series of single searches for regulatory agency web pages.

For records from reference lists from manual searches, the following was recorded: the bibliographic details of the documents whose reference lists were scanned and the number of relevant bibliographic references retrieved.

TABLE 9 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
US Environmental Protection Agency	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated	7/23/2019	10/24/2018	June 1, 2018 to June 30, 2019	5	0
US Department of Agriculture	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology	7/23/2019	No update information provided	June 1, 2018 to June 30, 2019	64	1
US Food and Drug Administration	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon	7/23/2019	5/9/2019	June 1, 2018 to June 30, 2019	18	0
Canadian Food Inspection Agency	http://www.inspection.gc.ca/plants/plants-with-novel-traits/notices-of-submission/eng/1300143491851/1300143550790	7/24/2019	1/17/2019	June 1, 2018 to June 30, 2019	28	2

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	7/24/2019	1/24/2019	June 1, 2018 to June 30, 2019	64	2
Food Standards Australia New Zealand	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx	7/25/2019	No update information provided	June 1, 2018 to June 30, 2019	89	3
Office of the Gene Technology Regulator	http://www.ogtr.gov.au/	7/25/2019	7/25/2019	June 1, 2018 to June 30, 2019	72	6
Intersecretarial Commission on Biosafety of GMOs	http://www.conacyt.gob.mx/cibiogem/index.php/cibiogem	7/19/2019	No update information provided	June 1, 2018 to June 30, 2019	6	0
National Technical Commission on Biosafety	http://ctnbio.mcti.gov.br/	7/17/2019	No update information provided	June 1, 2018 to June 30, 2019	136	0
National Advisory Commission on Agriculture Biotechnology	https://www.argentina.gob.ar/agroindustria/alimentos-y-bioeconomia/ogm-comerciales	8/6/2019	No update information provided	June 1, 2018 to June 30, 2019	5	0
Ministry of Environment, Forest and Climate change	http://moef.gov.in/	7/23/2019	No update information provided	June 1, 2018 to June 30, 2019	0	0
Ministry of Agriculture, Forestry and Fisheries	http://www.maff.go.jp/e/	7/19/2019	No update information provided	June 1, 2018 to June 30, 2019	127	7
European Food Safety Authority	http://www.efsa.europa.eu/	7/25/2019	No update information provided	June 1, 2018 to June 30, 2019	64	0

The results of the selection process are recorded in Table 10 and a flow chart of the publication selection process is shown in Figure 1.

TABLE 10 Results of the publication selection process, for each review question and or group of information/data requirements searched

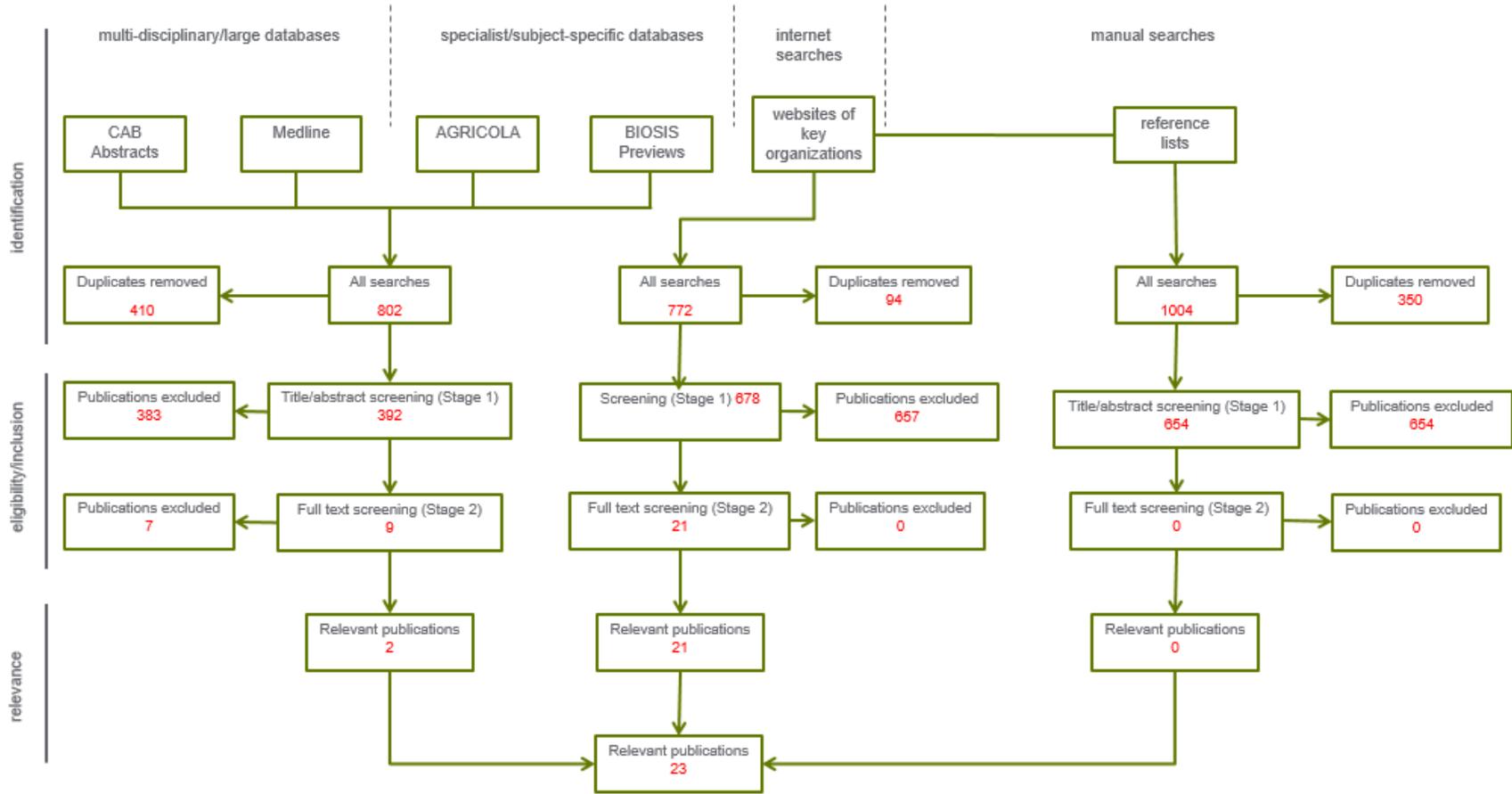
Review question and/or category of information/data requirement(s) captured in the search	Number of publications
Publications identified after all* searches of the scientific literature (excluding duplicates)	1724
Database results identified	392
Internet results identified	678
**References from relevant database results identified	654
Publications excluded from the search results after screening of title and abstracts*** (stage 1)	1694
Database results excluded	383
Internet results excluded	657
References from relevant database results excluded	654
Publications screened using full-text (stage 2)	9
Database results screened	9
Internet results screened	0
References from relevant database results screened (all already excluded)	0
Publications excluded after full-text screening	7
Database results full-text excluded	7
Internet results full-text excluded	0
References from relevant database results full-text excluded (all already excluded)	0
Unobtainable publications	0
Unclear publications	0
Publications considered relevant	23
Database results relevant	2
Internet results relevant	21
References from relevant database results relevant	0

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

**There were additional record titles (654) reviewed from the references of relevant internet documents retrieved from searching regulatory agency websites. These were excluded from search results after screening of titles. There were no relevant records found among these references.

***Due to the formatting of records (e.g. lack of abstracts) from the websites of key organizations the stage 1 review was performed by a first scanning through the documents.

FIGURE 1 Flow chart of the publication selection process



4.4 Relevant Publications

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

TABLE 11 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
Assessment of interactions with nontarget organisms	Campos RC <i>et al.</i> 2018	Indirect exposure to Bt maize through pig feces causes behavioural changes in dung beetles	Journal of Applied Entomology
Persistence and invasiveness assessment, including plant-to-plant gene transfer	Devos Y <i>et al.</i> 2018	Teosinte and maize × teosinte hybrid plants in Europe – Environmental risk assessment and management implications for genetically modified maize	Agriculture, Ecosystems & Environment

TABLE 12 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	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019a)	Lepidoptera pest resistance and herbicide glufosinate resistant maize (modified cry1Ab, pat, <i>Zea mays</i> subsp. <i>mays</i> (L.) Iltis) (Bt11, OECD UI: SYN-BT011-1	http://www.affrc.maff.go.jp/docs/committee/diversity/061219/pdf/siryou4_1.pdf
Risk Assessment	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019b)	Lepidoptera resistant cotton (modified cry1Ab, <i>Gossypium hirsutum</i> L.) (COT67B, OECD (UI: SYN-IR67B-1)	http://www.affrc.maff.go.jp/docs/committee/diversity/070226/pdf/siryou4_1.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	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019c)	Lepidoptera pest resistance and herbicide glufosinate resistant maize (modified cry1Ab, bar, Zea mays subsp. mays (L.) Iltis) (Event176, OECD UI: SYN-EV176-9)	http://www.affrc.maff.go.jp/docs/committee/diversity/091217/pdf/siryou_3-1.pdf
Risk Assessment	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019d)	Resistance to Lepidoptera and Coleoptera and herbicides glufosinate and glyphosate Resistant maize (modified cry1F, cry1Ab, cry34Ab1, cry35Ab1, pat, cp4 epsps, Zea Mays. Subsp Mays (L.) Iltis) (1507 × 59122 × MON810 × NK603, OECD	http://www.affrc.maff.go.jp/docs/committee/diversity/101209/pdf/siryu_4-1.pdf
Risk Assessment	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019e)	Resistance to Lepidoptera and Coleoptera and herbicides glufosinate and glyphosate Resistant maize (modified cry1F , pat , cry34Ab1 , cry35Ab1 , cry1Ab , modified cp4 epsps , modified Strange Cry3Aa2, Zea Mays Subsp. Mays (L.) Iltis) (1507 × 59122 × MON810 × NK603 × MIR604, OECD UI: DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 × SYN-IR6Ø4-5)	http://www.affrc.maff.go.jp/docs/committee/diversity/120124/pdf/siryu_4_1.pdf
Risk Assessment	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019f)	Herbicide glufosinate and Lepidoptera resistant cotton (modified bar, modified cry1Ab, Gossypium hirsutum L.) (T304-40, OECD UI: BCS-GHØØ4-7)	http://www.affrc.maff.go.jp/docs/committee/diversity/120907/pdf/siryu_4_1.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	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019g)	Opinions of academics	http://www.maff.go.jp/j/press/syouan/nouan/pdf/091111-06.pdf
Risk Assessment	Office of the Gene Technology Regulator, 2018 (OGTR 2018a)	DIR 162 - Limited and controlled release of bread wheat and durum wheat genetically modified for enhanced rust disease resistance	http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir162/\$FILE/Full%20Risk%20Assessment%20and%20Risk%20Management%20Plan.docx
Risk Assessment	Office of the Gene Technology Regulator, 2018 (OGTR 2018b)	DIR 162 - Limited and controlled release of bread wheat and durum wheat genetically modified for enhanced rust disease resistance	http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir162/\$FILE/Full%20Risk%20Assessment%20and%20Risk%20Management%20Plan.pdf
Risk Assessment	Office of the Gene Technology Regulator, 2018 (OGTR 2018c)	DIR 163 - Limited and controlled release of canola genetically modified for altered oil content and herbicide tolerance	http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir163/\$FILE/Full%20Risk%20Assessment%20and%20Risk%20Management%20Plan.docx
Risk Assessment	Office of the Gene Technology Regulator, 2018 (OGTR 2018d)	DIR 163 - Limited and controlled release of canola genetically modified for altered oil content and herbicide tolerance	http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir163/\$FILE/Full%20Risk%20Assessment%20and%20Risk%20Management%20Plan.pdf
Risk Assessment	Office of the Gene Technology Regulator, 2019 (OGTR 2019a)	DIR 165 - Limited and controlled release of wheat genetically modified for altered iron uptake, transport and bioavailability	http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir165/\$FILE/Full%20Risk%20Assessment%20and%20Risk%20Management%20Plan.docx

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	Office of the Gene Technology Regulator, 2019 (OGTR 2019b)	DIR 165 - Limited and controlled release of wheat genetically modified for altered iron uptake, transport and bioavailability	http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir165/\$FILE/Full%20Risk%20Assessment%20and%20Risk%20Management%20Plan.pdf
Risk Assessment	Food Standards Australia New Zealand, no date provided (FSANZ 2019a)	Application A1080 – Food derived from Herbicide-tolerant Cotton Line MON88701	http://www.foodstandards.gov.au/code/applications/Documents/A1080-GM-SD1.docx
Risk Assessment	Food Standards Australia New Zealand, no date provided (FSANZ 2019b)	Safety assessment (at Approval) – Application A1081 Food derived from Herbicide-tolerant Soybean Line SYHT0H2	http://www.foodstandards.gov.au/code/applications/Documents/A1081-GM-AppR-SD1.docx
Risk Assessment	Food Standards Australia New Zealand, no date provided (FSANZ 2019c)	Safety assessment – Application A1087 (at Approval) Food derived from Insect-protected Soybean Line DAS-81419-2	http://www.foodstandards.gov.au/code/applications/Documents/A1087-GM-AppR-SD1.docx
Risk Assessment	Canadian Food Inspection Agency, 2018 (CFIA 2018a)	Decision Document DD2016-116 - Determination of the Safety of Syngenta Canada Inc.'s Corn (Zea mays L.) Event MZHG0JG	http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd2016-116/eng/1542814694637/1542814694922
Risk Assessment	Canadian Food Inspection Agency, 2018 (CFIA 2018b)	Decision Document DD2016-118 - Determination of the Safety of Syngenta Canada Inc.'s Corn (Zea mays L.) Event MZIR098	http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd2016-118/eng/1542814733003/1542814733217

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	Health Canada, 2018 (HC 2018a)	Decision Document DD2016-116 - Determination of the Safety of Syngenta Canada Inc.'s Corn (Zea mays L.) Event MZHG0JG	http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd2016-116/eng/1542814694637/1542814694922
Risk Assessment	Health Canada, 2018 (HC 2018b)	Decision Document DD2016-118 - Determination of the Safety of Syngenta Canada Inc.'s Corn (Zea mays L.) Event MZIR098	http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd2016-118/eng/1542814733003/1542814733217
Risk Assessment	U.S. Department of Agriculture, no date provided (USDA 2019)	In response to Bayer CropScience Petition 06-234-01P seeking Extension of Determination of Non-regulated Status for Glufosinate Resistant rice, Oryza sativa, event LLRICE601	http://www.aphis.usda.gov/brs/aphis/docs/06_23401p_pea.pdf

*Canadian Food Inspection Agency and Health Canada provide the same search results and URLs are from the same database; this refers to documents DD2016-116 and DD2016-118. Office of the Gene Technology Regulator provide the same document but in two different formats (.docx and .pdf); this refers to documents DIR162, DIR163 and DIR165. Therefore, of the 21 relevant internet results, 5 appear to be document duplicates. These documents were kept because they were counted in the original search results. The reviewers assessed the webpages by agency. Deduplications were done by agency.

4.5 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 13.

TABLE 13 Report of publications excluded from the risk assessment after detailed assessment of full-text documents

List of bibliographic references for all studies excluded from the risk assessment, classified by authors			
Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria
Agapito-Tenfen SZ et al. 2018	Systematic miRNome profiling reveals differential microRNAs in transgenic maize metabolism	Environmental Sciences Europe	Intervention/exposure not relevant
Bernillon S et al. 2018	Characterization of GMO or glyphosate effects on the composition of maize grain and maize-based diet for rat feeding	Metabolomics	Intervention/exposure not relevant
Carzoli AK et al. 2018	Risks and opportunities of GM crops: Bt maize example	Global Food Security	Reporting format – no primary data
Costa FR et al. 2018	Lack of effects of glyphosate and glufosinate on growth, mineral content and yield of glyphosate- and glufosinate-resistant maize	GM Crops & Food	Intervention/exposure not relevant
Du L et al. 2019	Cadherin CsCad plays differential functional roles in Cry1Ab and Cry1C intoxication in <i>Chilo suppressalis</i>	Scientific Reports	Information/data requirements – data are related to efficacy
Liu L et al. 2018	The defined toxin-binding region of the cadherin G-protein coupled receptor, BT-R1, for the active Cry1Ab toxin of <i>Bacillus thuringiensis</i>	Journal of Proteomics & Bioinformatics	Information/data requirements – data are related to efficacy
Oliveira MR et al. 2018	Nutritional composition and aerobic stability of wheat and corn silages stored under different environmental conditions	Semina: Ciencias Agrarias	Intervention/exposure not relevant

4.6 Unobtainable Publications

No publications were considered unobtainable.

4.7 Unclear Publications

No publications were classified as unclear.

4.8 Full-Text Documents

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

4.9 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.

4.10 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 Table 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
Assessment of interactions with nontarget organisms	Campos RC et al. 2018	High: clearly described experimental procedures and reported results provide evidence of reproducibility and accuracy of the findings	<p>The authors claim a non-lethal effect of Cry1Ab exposure to dung beetles that may cause population decline based on endpoint observations of dung beetles fed feces of pigs fed diets with MON810 corn, but the overall results do not support this claim</p> <p>Beetles of one (<i>C. rutilans</i>) of the three species tested for foraging behaviors were slower to reach the GM resource than to reach the non-GM resource. Although all beetles reached the resource equally by 24 hours, the authors caution that this result could indicate that competition for resource among dung beetle species may lead to a potential population decline for <i>C. rutilans</i> in the wild. However, the authors do not comment on the control foraging behavior of <i>C. rutilans</i> compared to that of other species. In other words, it is possible that <i>C. rutilans</i> are naturally less competitive compared to other dung beetle species. European dung beetles are not expected to be widely exposed to Cry1Ab through pig feces as typical swine production utilizes barns to maintain the animals and therefore a lack of resource available to dung beetles in the wild. In the abnormal scenario in which dung beetles would have unlimited access to swine confinement buildings, competition for pig feces among dung beetle species resulting in a scarce resource for <i>C. rutilans</i> would be unlikely due to the abundance of resource that would be available in a pig farm setting. (Nguyen and Hermansen et al. 2010) (Basset-Mens and Van der Werf 2005). Additionally, the fertility of <i>C. rutilans</i> was similar between GM and non-GM treatments, and reproductive success was also similar, which would not lead to an indication of a potential decline in <i>C. rutilans</i> populations.</p>

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
Persistence and invasiveness assessment, including plant-to-plant gene transfer	Devos Y et al. 2018	High: clearly described experimental procedures and reported results provide evidence of reproducibility and accuracy of the findings	<p>The authors note a significantly greater amount of non-GM resource was buried by <i>C. saphirinus</i> over the three-month period. However, the experiment resulted in a lack of a decline over time for GM treatment.</p> <p>Cry1Ab activity against coleopterans is not expected and has not been established (Van Frankenhuyzen 2013). Composition of the feces was not reported, therefore, we do not have a clear indication that any observed effect could be due to exposure to the small amount of Cry1Ab in the feces or some other difference in the composition in the feces.</p> <p>Therefore, the information in this publication does not change the conclusion of the risk assessment for Bt11 maize because no new hazards, no modified exposure, nor new scientific uncertainties were reported.</p> <p>“While scientific uncertainties about certain steps in the pathways remain – indeed there can never be complete certainty about the occurrence of any natural phenomenon – this does not preclude completing the risk assessment because these uncertainties can be handled by making worst-case assumptions (Raybould and Cooper, 2005).”</p> <p>The information in this publication does not change the conclusion of the risk assessment for Bt11 maize.</p>

TABLE 15 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)	Publication (Author(s) and year)	Summary of reliability appraisal	Implications for the risk assessment
Risk assessment or scientific opinion	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 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	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 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	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019c)	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	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019d)	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	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019e)	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	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019f)	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	Ministry of Agriculture, Forestry and Fisheries, no date provided (MAFF 2019g)	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	Office of the Gene Technology Regulator, 2018 (OGTR, 2018a)	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	Office of the Gene Technology Regulator, 2018 (OGTR, 2018b)	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	Office of the Gene Technology Regulator, 2018 (OGTR, 2018c)	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	Office of the Gene Technology Regulator, 2018 (OGTR, 2018d)	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	Office of the Gene Technology Regulator, 2018 (OGTR, 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.

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	Office of the Gene Technology Regulator, 2018 (OGTR, 201b)	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 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	Food Standards Australia New Zealand, no date provided (FSANZ 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 2019c)	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	Canadian Food Inspection Agency, 2018 (CFIA, 2018a)	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	Canadian Food Inspection Agency, 2018 (CFIA, 2018b)	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	Health Canada, (HC,2018a)	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	Health Canada, 2018 (HC, 2018b)	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	U.S. Department of Agriculture, no date provided (USDA 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.

5.0 RECORDS TO BE MAINTAINED

Records maintained include, but are not be 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.

6.0 ARCHIVING OF STUDY RECORDS

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

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[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir165/\\$FILE/Full%20Risk%20Assessment%20and%20Risk%20Management%20Plan.docx](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir165/$FILE/Full%20Risk%20Assessment%20and%20Risk%20Management%20Plan.docx) (April 2019)
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APPENDICES SECTION

APPENDIX A Search history and subject indexing

Ovid® Terms were searched individually line by line, however when the proximity operator adj2 is used the Ovid platform displays the terms on one line as a group such as (term,term2,term3)adj2 (term4,term5,term6).



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▼ Search History (147)

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<input type="checkbox"/>	2	Bt 11.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	23	Advanced	Display Results More	
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<input type="checkbox"/>	4	1 or 2 or 3	112	Advanced	Display Results More	
<input type="checkbox"/>	5	Agrisure*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	15	Advanced	Display Results More	
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Enter keyword or phrase (* or \$ for truncation)

Keyword Author Title Journal

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 Literature Reviews Latest Update

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▼ Search History (147)

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<input type="checkbox"/>	3	SYN-BT?11-1.mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	0	Advanced	Save More	
<input type="checkbox"/>	4	1 or 2 or 3	250	Advanced	Display Results More	
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Ovid® Terms were searched individually line by line, however when the proximity operator adj2 is used the Ovid platform displays the terms on one line as a group such as (term,term2,term3)adj2 (term4,term5,term6).



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

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