



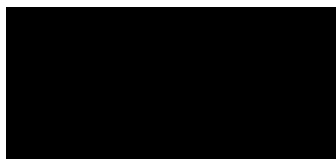
**Review of Scientific Literature Relevant to the
Food/Feed and Environmental Risk Assessment of
Event 5307 Maize**

Literature Review

TEST GUIDELINE(S):

Not Applicable

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LIST OF ACRONYMS AND ABBREVIATIONS

EU	European Union
GMO	Genetically modified organism
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
PICO/PECO	Population, Intervention/Exposure, Comparator, Outcomes
PMI	phosphomannose isomerase

1.0 OBJECTIVE

The purpose of this systematic literature search is to identify literature and/or information on 5307 maize that is relevant to the risk assessment of genetically modified organisms.

Syngenta transformed maize (*Zea mays* L., corn) to produce Event 5307 maize, which provides control of corn rootworm (*Diabrotica* spp.). Event 5307 maize plants contain the gene *ecry3.1Ab*, which encodes the insecticidal protein eCry3.1Ab, and the gene *pmi*, which encodes the enzyme phosphomannose isomerase (PMI). The engineered protein eCry3.1Ab is a chimera of mCry3A and Cry1Ab. The native, full-length Cry1Ab from the soil bacterium *Bacillus thuringiensis* subsp. *kurstaki* is active against certain lepidopteran insect pests; however, the portion of Cry1Ab included in eCry3.1Ab has not preserved the activity of Cry1Ab against lepidopterans. The native Cry3A from *B. thuringiensis* subsp. *tenebrionis* is active against certain coleopteran insect pests of maize; it was modified to have enhanced activity against Western corn rootworm (*Diabrotica virgifera virgifera*) and other related coleopteran pests. The gene *pmi* (also known as *manA*) was derived from *Escherichia coli* strain K-12. PMI enables transformed plant cells to utilize mannose as a primary carbon source; it was used as a selectable marker in the development of 5307 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 5307 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	5307 maize, derived food/feed products, eCry3.1Ab and closely related variants and PMI
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 results were screened by date to remove those published prior to 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	5307 maize, derived food/feed products, and/or the intended trait(s)	Intended traits include coleopteran pest resistance and mannose metabolism. Closely related variants of eCry3.1Ab (i.e., those that share the same tertiary level of Crickmore nomenclature) were included as relevant. Any records on enzymes classified as phosphomannose isomerase were considered relevant.
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 5307 maize (information/data requirements provided in Table 3) were considered relevant. Based on the scope of the application certain information/data requirements were 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. Risk assessments performed and reported by relevant key organizations were included if they address 5307 maize, eCry3.1Ab or closely related variants and PMI.
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 also 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	Publications that address 5307 maize also need to address effects/impacts on entities of concern, and potential determinants of exposure that place these entities at risk in order to be relevant to the risk assessment of 5307 maize.
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 5307 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 5307 maize. Therefore, GMOs that contain eCry3.1Ab or closely related variants, or PMI, but are introduced into another plant species may be included. For certain types of data, the presence of eCry3.1Ab and PMI in a different plant species will not impact the assessment of 5307 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.

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. If certain data are considered event-specific or specific to the transgenic proteins expressed in 5307 maize it is noted. If the record does 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 5307 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 (5307 maize only) • Expression data of inserted/modified sequences (5307 maize only) • Genetic stability (5307 maize only) • Molecular and biochemical characterization of the protein(s) such as: primary structure, molecular weight, post-translational modifications (eCry3.1Ab or PMI as expressed in 5307 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 (eCry3.1Ab or PMI from 5307 maize plants and a microbial source)
Agronomic, phenotypic and compositional characterization of the 5307 maize	<ul style="list-style-type: none"> • Comparative assessment of agronomic and phenotypic characteristics under field or controlled conditions (5307 maize only) • Comparative analysis of key nutritional constituents (5307 maize only)
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) (eCry3.1Ab or PMI as expressed in 5307 maize only) and toxic proteins • Stability of the protein(s) under relevant processing and storage conditions • Investigation of proteolytic susceptibility of the newly expressed proteins • Toxicity studies • Feeding studies that used plant material (5307 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 proteins (eCry3.1Ab or PMI as expressed in 5307 maize only) and known allergens or celiac disease peptide sequences • Serum screening • Pepsin susceptibility testing • <i>In vivo</i> tests in animal models • Expression data for endogenous allergens in maize (5307 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 5307 maize and the resulting nutritional impact • Comparative growth performance studies with young rapidly growing animal species. (5307 maize only if the diet is manufactured from 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 (5307 maize only) Replacement capacity (5307 maize only) Fitness of the GM plant expressing eCry3.1Ab or PMI in various environmental conditions – in the same or in 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. (5307 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 5307 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 5307 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: “<i>in cases where the application does not include cultivation in the EU, direct environmental exposure of NTOs to the GM plant is via accidental release into the environment of seeds or propagules during transportation and processing. This may result in sporadic occurrence of feral plants and therefore exposure of NTO populations is likely to be negligible. The ERA will then focus on indirect exposure to products of the GM plant (e.g. through manure and faeces from animals fed the GM plant, and other by-products of industrial processes)</i>”. Therefore, any publications that discuss direct exposure in test protein(s) 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 5307 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 5307 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 5307 maize in the EU. Cultivation of 5307 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 5307 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 5307 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 5307 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 5307 maize.

TABLE 4 Key organizations 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

^aAlso 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>).

^bReports that reflect individual reviewer opinions are excluded from evaluation because they are considered when developing 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

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 within the relevant time period (2019 through the date the search was conducted) and 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 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.

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

¹In 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.

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 5307 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

Set	Field	Search string	Concepts/Key elements
1	Topic	5307 OR SYN-25377-1	Single Event 5307
2	Topic	Duracade*	Trade name for 5307
3		#1 OR #2	Event OR Trade name
4	Topic	(eCry3.1AB) OR (e-Cry3.1AB) OR (eCry3 1AB) OR (e-Cry3 1AB) OR (eCry3.1 AB) OR (e-Cry3.1 AB) OR (eCry3 1 AB) OR (e-Cry3 1 AB) OR (eCry 3.1AB) OR (e-Cry 3.1AB) OR (eCry 3 1AB) OR (e-Cry 3 1AB) OR (eCry 3.1 AB) OR (e-Cry 3.1 AB) OR (eCry 3 1 AB) OR (e-Cry 3 1 AB)	Newly expressed protein in 5307 (Insecticidal)
5	Topic	Phosphomannoisomerase OR Mannose 6-phosphate isomerase OR Phosphomannoseisomerase OR Phosphomannose isomerase OR 9023-88-5 OR AAA24109 OR EC 5.3.1.8 OR E.C. 5.3.1.8	Newly expressed protein in 5307
6		#4 OR #5	Newly expressed proteins
7	Topic	((Insect OR insects OR coleoptera* OR pest OR pests OR rootworm* OR root worm* OR Diabrotica OR D virgifera OR D barberi OR MCR OR MCRW OR NCRW OR WCRW OR WCR) ADJ2 (toleran* OR resistan* OR protect* OR control*)) OR Bacillus thuringiensis OR B thuringiensis	Intended traits - insecticidal
8		GMO* OR LMO* OR GM OR GE OR transgen* OR ((genetic* OR living OR biotech*) ADJ3 (modif* OR transform* OR manipulat* OR improv* OR engineer* OR deriv*))	GMO general
9		Maize* OR corn* OR Zea mays OR Z mays	Plant species
10		((Bt OR Bacillus thuringiensis OR B thuringiensis) ADJ5 (maize* OR corn* OR mays)) OR Btmaize* OR Btcorn*	GMO general x intended traits
11		#6 AND (#8 OR #9)	Newly expressed proteins AND (GMO general OR plant species)
12		#7 AND (#8 AND #9)	Intended trait - insecticidal AND (GMO general AND Plant species)
13		#3 OR #11 OR #12 OR #10	Event OR Trade name OR (Newly expressed proteins AND (GMO general OR plant species)) OR (Intended trait - insecticidal AND (GMO general AND Plant species)) OR GMO general x intended traits

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 January 1, 2019 (Ovid only allows for limiting search by year) and the date of the last database update prior to the search.

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 were collected.

TABLE 6 **Nomenclature for the single event and newly expressed protein(s) from the ISAAA database for use in searching regulatory agency web pages**

Event	Search term	Concepts/Key elements
5307	5307	Event name
5307	eCry3.1Ab	Newly expressed protein
5307	Phosphomannose isomerase	Newly expressed protein

3.4 Reference Publications

Previously conducted literature reviews have returned literature relevant to the risk assessment of eCry3.1Ab and PMI proteins. The search strategy defined in this protocol 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.

The reference publications utilized are identified in Table 7 (X indicates that the publication was retrieved in the database). The percentage of publications retrieved by database are specified for each electronic database.

TABLE 7 Reference publications

Data/Information requirement	Reference	Agricola	BIOSIS	CAB abstracts	Medline
Molecular characterization of the genetic modification of the GMO	Hart H, Chen JS, Defontes CM, Walters F. 2019. Insecticidal proteins. Official Gazette of the United States Patent & Trademark Office Patents.		X		
Molecular characterization of the genetic modification of the GMO	Burns, A., and Raybould, A. 2014. Nontarget organism effects tests on eCRY3.1Ab and their application to the ecological risk assessment for cultivation of Event 5307 maize. Transgenic Res. Published online: 10 January 2014. DOI 10.1007/s11248-013-9778-4.	X	X	X	X
	Percentage of records returned	50%	100%	50%	50%

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.

Full-length articles were reviewed in Stage 2. An explanation of exclusion is provided for any full-length records that were deemed irrelevant in Stage 2. Any relevant records identified in Stage 2 were subjected to a 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 not relevant by both 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, or 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 303 records reviewed from the databases at Stage 1 there were 299 agreements to exclude, 2 records where both reviewers agreed to include it for Stage 2 review, and 2 disagreements: one where reviewer A selected to include while reviewer B selected exclude and one where reviewer A selected to exclude while reviewer B selected to include. This yielded a kappa test score of 0.66.

Subsequently, the reviewers met to discuss the abstracts in which they disagreed and moved the 2 records over which there was disagreement forward to full-length review for a total of 4 records that were reviewed in Stage 2. There was no disagreement among the reviewers after Stage 2 therefore no tie breaker review was needed.

Because of the format of document 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.

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. Those websites where 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 if the record was classified as a relevant document type and was then excluded based on other eligibility criteria.

The Intersecretarial Commission on Biosafety of GMOs and National Advisory Commission on Agricultural Biotechnology do not post the relevant document types on their websites; therefore those agency websites were not searched.

For the purposes of generating the statistics related to the records returned from the search of the regulatory agency websites certain assumptions were made. A unique internet record was defined as a unique URL. If the URLs for two documents were identical except for the file format (e.g., pdf versus .doc or .docx), one of the documents was considered a duplicate and excluded from statistical accounting. Documents that were classified as relevant were manually examined to determine if there were any duplicates among them. If a duplicate was identified then it was excluded.

Documents that are clearly labeled as draft or with a line for a signature that is blank were not reviewed for relevance.

4.2 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 (Table 8).

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 (dd/mm/yyyy)	Service provider	Date span of the search (dd/mm/yyyy)^a	Any limits applied to the search	Total number of records retrieved after removing duplicates
Agricola	06/07/2020	Ovid Technologies	01/01/2019 to 30/06/2020	Dates	4
BIOSIS Previews	06/07/2020	Ovid Technologies	01/01/2019 to 05/07/2020	Dates	83
CAB Abstracts	06/07/2020	Ovid Technologies	01/01/2019 to 05/07/2020	Dates	69
Medline	06/07/2020	Ovid Technologies	01/01/2019 to 05/07/2020	Dates	147

^aOvid only allows results to be limited by year. The results were de-duplicated across databases. 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.

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 9).

Table 6 contains the search terms used as a series of single searches for regulatory agency web pages.

The one relevant record returned from the regulatory agency website search did not contain any references so a manual search returned no additional records.

TABLE 9 **Regulatory agency webpage search details**

Regulatory agency name	URL	Date of search (dd/mm/yyyy)	Date of most recent website update	Date span of search ^a	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	05/08/2020	14/07/2020	No limitations	0	0
US Department of Agriculture	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology	03/08/2020 04/08/2020	No update information provided	No limitations	6	0
US Food and Drug Administration	https://www.accessdata.fda.gov/scrípts/fdcc/?set=Biocon	31/07/2020	11/10/2019	No limitations	0	0
Health Canada	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html	29/07/2020	28/05/2020	No limitations	37	0
Food Standards Australia New Zealand	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx	23/07/2020 24/07/2020	No update information provided	No limitations	5	1
Office of the Gene Technology Regulator	http://www.ogtr.gov.au/	23/07/2020	23/07/2020	No limitations	1	0
National Technical Commission on Biosafety	http://ctnbio.mctic.gov.br/inicio	15/07/2020	No update information provided	No limitations	1	0
Ministry of Environment, Forest and Climate change	http://moef.gov.in/	23/07/2020	No update information provided	No limitations	0	0
Ministry of Agriculture, Forestry and Fisheries	http://www.maff.go.jp/e/	20/07/2020	No update information provided	No limitations	3	0

^aRecords published prior to 2019 were manually excluded (if any).

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

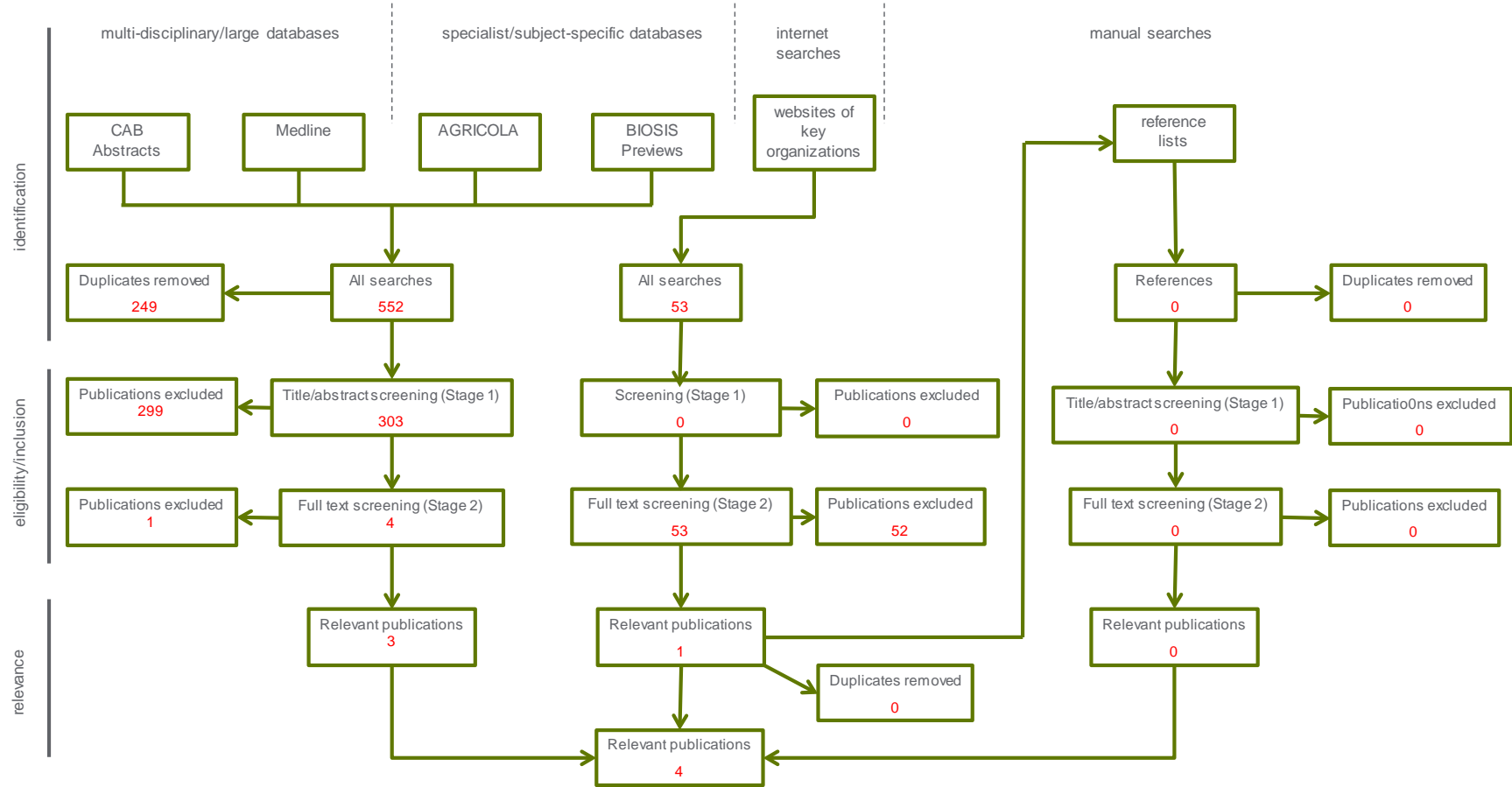
Review question and/or category of information/data requirement(s) captured in the search	Number of publications
Publications identified after all ^a searches of the scientific literature (excluding duplicates)	356
Database results identified	303
Internet results identified	53
Manual search – checking reference lists ^b	0
Publications excluded from the search results after screening of title and abstracts ^c (stage 1)	299
Database results excluded	299
Internet results excluded	0
Manual search – reference results excluded	0
Publications screened using full-text (stage 2)	57
Database results screened	4
Internet results screened	53
Manual search – reference results screened	0
Publications excluded after full-text screening	53
Database results full-text excluded	1
Internet results full-text excluded	52
Manual search – references excluded	0
Unobtainable publications	0
Unclear publications	0
Publications considered relevant	4
Database results relevant	3
Internet results relevant	1
Manual search – relevant references	0

^aBoth from electronic bibliographic databases and other sources of scientific literature.

^bOnly 1 relevant record was returned from the searching of regulatory agency websites. This record did not contain any references.

^cDue to the formatting of records from the websites of key organizations (i.e., a lack of abstracts and in some cases titles) these records were reviewed in a single stage in which the full-text document was reviewed.

FIGURE 1 **Flow chart of the publication selection process**



4.3 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 and 12.

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
Molecular characterisation of the genetic modification of GMO	De Framond <i>et al.</i> 2020	Corn event 5307	Official Gazette of the United States Patent & Trademark Office Patents
	Hart <i>et al.</i> 2020	Insecticidal proteins	Official Gazette of the United States Patent & Trademark Office Patents
	Walters <i>et al.</i> 2020	Meeting technical challenges for protein characterization and surrogate equivalence studies that resulted from insecticidal protein co-expression in maize event MZIR098.	Transgenic Research

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	Corteva Agrosience 2020	Application to Amend the Food Standards Code – Food Produced Using Gene Technology OECD Unique Identifier – DP-Ø23211-2	https://www.foodstandards.gov.au/code/applications/Documents/A1202%20Executive%20Summary_Redacted.pdf

4.4 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.

TABLE 13 Report of all publications excluded after detailed assessment of full-text documents

List of bibliographic references for all relevant publications excluded classified by authors			
Study author(s) and year	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria
Dively <i>et.al.</i> 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 5307 maize.

TABLE 14 Report of all publications excluded after detailed assessment of full-text internet documents

List of bibliographic references for all relevant publications excluded classified by authors			
Study author(s) and year	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria
Agrivida, Inc. 2019	Petition for the Determination of Nonregulated Status of Maize Event PY203	https://www.aphis.usda.gov/brs/aphis/docs/19_17601p.pdf	Information/data requirements
BASF 2019	Application to FSANZ to Vary Food Standard 1.5.2 to Include the Nematode Resistant and Herbicide Tolerant Soybean (<i>Glycine max</i>) Event GMB151	https://www.foodstandards.gov.au/code/applications/Documents/A1196%20Application.pdf	Intervention/exposure

The other 50 records excluded and not presented in this table did not fulfill the eligibility criteria for report format.

4.5 Unobtainable Publications

No publications were considered unobtainable.

4.6 Unclear Publications

No publications were classified as unclear.

4.7 Full-Text Documents

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

4.8 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.

4.9 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 are recorded in Tables 15 and 16.

TABLE 15 **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	De Framond <i>et al.</i> 2020	High – use as a key study	The sequence generated for regulatory submissions (including those to EFSA) is the same sequence claimed in the Event patent. Any subsequent observations in sequence deviation from the regulatory submission are reported to EFSA.
			Because this process is followed, the information provided in this record does not change the conclusion of the risk assessment for 5307 maize.
	Hart <i>et al.</i> 2020	High – use as a key study	The sequence generated for regulatory submissions (including those to EFSA) is the same sequence claimed in the Event patent. Any subsequent observations in sequence deviation from the regulatory submission are reported to EFSA.
			Because this process is followed, the information provided in this record does not change the conclusion of the risk assessment for 5307 maize.
	Walters <i>et al.</i> 2020	High – use as a key study	This record summarizes data that characterizes eCry3.1Ab. The information provided in this publication does not change the conclusion of the risk assessment for 5307 maize.

TABLE 16 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	Corteva Agrosience 2020	Not assignable because no or insufficient information is reported in the document	This document summarizes data on PMI. The information provided in this document does not change the conclusion of the risk assessment for 5307 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.

7.0 REFERENCES

- Agrivida, Inc. 2019. Petition for the Determination of Nonregulated Status to Maize Event PY203. https://www.aphis.usda.gov/brs/aphisdocs/19_17601p.pdf
- BASF. 2019. Application to FSANZ to Vary Food Standard 1.5.2 to Include the Nematode Resistant and Herbicide Tolerant Soybean (*Glycine max*) Event GMB152. <https://www.foodstandards.gov.au/code/applications/Documents/A1196%20Application.pdf>
- Corteva Agriscience. 2020. Application to Amend the Food Standards Code – Food Produced Using Gene Technology OECD Unique Identifier – DP-Ø23211-2. https://www.foodstandards.gov.au/code/applications/Documents/A1202%20Executive%20Summary_Redacted.pdf
- De Framond AJ, Meghji MR, New SL, Prairie AU. Corn event 5307. Official Gazette of the United States Patent & Trademark Office Patents (Oct 1).
- Dively GP, Huang F, Oyediran I, Burd T, Morsello S. 2020. Evaluation of gene flow in structured and seed blend refuge systems on non-Bt and Bt corn. *J Pest Sci* 93:439-447.
- EFSA. 2010. Scientific Opinion on the environmental risk assessment of genetically modified plants. *The EFSA Journal* 8:1-111.
- EFSA. 2019. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorization and annual post-market environmental monitoring reports on GMOs authorized in the EU market. EFSA supporting publications 2019:EN-1614.
- Hart H, Chen JS, Defontes CM, Walters F. 2020. Insecticidal proteins. Official Gazette of the United States Patent & Trademark Office Patents (Mar 26).
- Walters FS, Young S, Graser G. 2020. Meeting technical challenges for protein characterization and surrogate equivalence studies that resulted from insecticidal protein co-expression in maize event MZIR098. *Transgenic Research* 29:109-124.

APPENDICES SECTION

APPENDIX A Search history and subject indexing


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[Feedback](#)

Logged in as

[Logoff](#)

[Search](#)
[My Workspace](#)

▼ Search History (98)

[View Saved](#)

<input type="checkbox"/>	# ▲	Searches	Results	Type	Actions	Annotations	
<input type="checkbox"/>	1	"5307".mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	28	Advanced	Display Results More		Contract
<input type="checkbox"/>	2	SYN-75377-1.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
<input type="checkbox"/>	3	1 or 2	28	Advanced	Display Results More		
<input type="checkbox"/>	4	Duracade*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	1	Advanced	Display Results More		
<input type="checkbox"/>	5	3 or 4	29	Advanced	Display Results More		
<input type="checkbox"/>	6	"eCry3.1AB".mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	15	Advanced	Display Results More		
<input type="checkbox"/>	7	"e-Cry3.1AB".mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
<input type="checkbox"/>	8	eCry3 1AB.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
<input type="checkbox"/>	9	e-Cry3 1AB.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
<input type="checkbox"/>	10	"eCry3.1 AB".mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
<input type="checkbox"/>	11	"e-Cry3.1 AB".mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
<input type="checkbox"/>	12	eCry3 1 AB.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
<input type="checkbox"/>	13	e-Cry3 1 AB.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
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<input type="checkbox"/>	16	eCry 3 1AB.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
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<input type="checkbox"/>	20	eCry 3 1 AB.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
<input type="checkbox"/>	21	e-Cry 3 1 AB.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More		
<input type="checkbox"/>	22	6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	15	Advanced	Display Results More		
<input type="checkbox"/>	23	Phosphomannoisomerase.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	3	Advanced	Display Results More		
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		words]					
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<input type="checkbox"/>	27	9023-88-5.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save	More	
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<input type="checkbox"/>	31	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30	143	Advanced	Display Results	More	
<input type="checkbox"/>	32	22 or 31	158	Advanced	Display Results	More	
<input type="checkbox"/>	33	Insect.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	183086	Advanced	Display Results	More	
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<input type="checkbox"/>	36	pest.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	68759	Advanced	Display Results	More	
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<input type="checkbox"/>	38	rootworm*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	1480	Advanced	Display Results	More	
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<input type="checkbox"/>	43	MCR.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	996	Advanced	Display Results	More	
<input type="checkbox"/>	44	MCRW.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	1	Advanced	Display Results	More	
<input type="checkbox"/>	45	NCRW.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save	More	
<input type="checkbox"/>	46	WCRW.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save	More	
<input type="checkbox"/>	47	WCR.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	219	Advanced	Display Results	More	
<input type="checkbox"/>	48	33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47	461948	Advanced	Display Results	More	
<input type="checkbox"/>	49	toleran*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	108997	Advanced	Display Results	More	
<input type="checkbox"/>	50	resistan*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	277758	Advanced	Display Results	More	
<input type="checkbox"/>	51	protect*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	263270	Advanced	Display Results	More	
<input type="checkbox"/>	52	control*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	936190	Advanced	Display Results	More	
<input type="checkbox"/>	53	49 or 50 or 51 or 52	1403078	Advanced	Display Results	More	
<input type="checkbox"/>	54	((Insect or insects or coleoptera* or pest or pests or rootworm* or root worm* or Diabrotica or D virgifera or D	117010	Advanced	Display Results	More	

barberi or MCR or MCRW or NCRW or WCRW or WCR) adj2
(toleran* or resistan* or protect* or control*),mp.

<input type="checkbox"/>	55	Bacillus thuringiensis.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	10329	Advanced	Display Results More	
<input type="checkbox"/>	56	B thuringiensis.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	1644	Advanced	Display Results More	
<input type="checkbox"/>	57	54 or 55 or 56	124232	Advanced	Display Results More	
<input type="checkbox"/>	58	GMO*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	1399	Advanced	Display Results More	
<input type="checkbox"/>	59	LMO*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	527	Advanced	Display Results More	
<input type="checkbox"/>	60	GM.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	7385	Advanced	Display Results More	
<input type="checkbox"/>	61	GE.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	5335	Advanced	Display Results More	
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<input type="checkbox"/>	63	genetic*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	614601	Advanced	Display Results More	
<input type="checkbox"/>	64	living.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	55362	Advanced	Display Results More	
<input type="checkbox"/>	65	biotech*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	36594	Advanced	Display Results More	
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<input type="checkbox"/>	74	((genetic* or living or biotech*) adj3 (modif* or transform* or manipulat* or improv* or engineer* or deriv*),mp.	57945	Advanced	Display Results More	
<input type="checkbox"/>	75	58 or 59 or 60 or 61 or 62 or 74	101863	Advanced	Display Results More	
<input type="checkbox"/>	76	Maize*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	65643	Advanced	Display Results More	
<input type="checkbox"/>	77	corn*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	129054	Advanced	Display Results More	
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<input type="checkbox"/>	79	Z mays.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	345	Advanced	Display Results More	
<input type="checkbox"/>	80	76 or 77 or 78 or 79	169500	Advanced	Display Results More	
<input type="checkbox"/>	81	Bt.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	6359	Advanced	Display Results More	
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<input type="checkbox"/>	85	maize*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	65643	Advanced	Display Results More	
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<input type="checkbox"/>	88	85 or 86 or 87	169630	Advanced	Display Results More	
<input type="checkbox"/>	89	((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or corn* or mays)).mp.	1184	Advanced	Display Results More	
<input type="checkbox"/>	90	Btmaize*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	1	Advanced	Display Results More	
<input type="checkbox"/>	91	Btcorn*.mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	Save More	
<input type="checkbox"/>	92	89 or 90 or 91	1185	Advanced	Display Results More	
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<input type="checkbox"/>	95	75 and 80	6517	Advanced	Display Results More	
<input type="checkbox"/>	96	57 and 95	1470	Advanced	Display Results More	
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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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Lopes, S R Cruz, I

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Boaventura, Debora Ulrich, Julia Lueke, Bettina Bolzan, Anderson Okuma, Daniela Gutbrod, Oliver Geibel, Sven Zeng, Qin Dourado, Patrick M. Martinelli, Samuel Flágel, Lex Head, Graham Nauen, Ralf

Insect biochemistry and molecular biology. 2020 Jan. 116(116)

[Journal Article. Government Publication]

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☐ 4. **Efficient Biolistic Transformation of Immature Citrus Rootstocks Using Phosphomannose-isomerase Selection**

Wu, Hao Acanda, Yosvanis Canton, Michel Zale, Janice

Plants. 2019 Sept. 30. 8(10)

[Journal Article. Government Publication]

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☐ 5. **Survival and Development of *Striacosta albicosta* (Smith) (Lepidoptera: Noctuidae) Immature Stages on Dry Beans, non-Bt, Cry1F, and Vip3A Maize**

G. Montezano, Delia bora Hunt, Thomas E. Specht, Alexandre C. Luz, Priscila M. Peterson, Julie A.

Insects. 2019 Oct. 13. 10(10)

[Journal Article. Government Publication]

AN: IND606745068.

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Jiang, Zhilei [Author]; Zhou, Lin [Author]; Wang, Baifeng [Author]; Wang, Daming [Author]; Wu, Fengci [Author]; Yin, Junqi [Author]; Song, Xinyuan [Author, Reprint Author]; E-mail: songxinyuan1980@163.com].

PLoS One. 15(5). MAY 6 2020. e0232747.

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Nwosu, Onyeka Kingsley [Author, Reprint Author]; Ubajoi, Kingsley Ikechukwu [Author].

Egbuna, C [Editor], Sawicka, B [Editor]. Natural Remedies for **Pest, Disease and Weed Control**. 2020. 203-208.

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Su Hong-hua [Author; E-mail: susugj@126.com]; Jiang Tao [Author]; Sun Yu [Author]; Gu Hui-jie [Author]; Wu Jiao-jiao [Author]; Yang Yi-zhong [Author, Reprint Author; E-mail: yzyang@yzu.edu.cn].

Journal of Integrative Agriculture. 19(7). JUL 2020. 1842-1849.

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Yen, Shuo [Author]; Ren, Binyuan [Author]; Zeng, Bo [Author]; Shen, Jie [Author, Reprint Author; E-mail: shenjie@cau.edu.cn].

BioTechniques. 68(5). MAY 2020. 283-290.

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Rozadilla, Gaston [Author]; Cabrera, Natalia A. [Author]; Virla, 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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Bertho, L. Schmidt, K. Schmidtke, J. Brants, I. Cantón, R. F. Novillo, C. Head, G.
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Naegeli, H. Bresson, J. L. Dalmay, T. Dewhurst, I. C. Epstein, M. M. Firbank, L. G.
 Guerche, P. Hejatk, J. Moreno, F. J. Mullins, E. Nogué, F. Rostoks, N. Serrano, J. J.

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S. Savoini, G. Veromann, E. Veronesi, F. Álvarez, F. Ardizzzone, M. Raffaello, T.
EFSA Journal; 2020. 18(3)8 ref.
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☐ 3. **Gene stacking as a strategy to confer characteristics of agronomic importance in plants by genetic engineering.**

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Ciência Rural; 2020. 50(6)39 ref.
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☐ 4. **Influence of heat processing on DNA degradation and PCR-based detection of wild-type and transgenic maize.**

Bitskinashvili, K. Gabriadze, I. Kutateladze, T. Vishnepolsky, B. Mikeladze, D. Datukishvili, N.
Journal of Food Quality; 2019. 2019(5657640)37 ref.
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☐ 5. **Partial diallel and potential of super sweet corn inbred lines *Bt*₂ to obtain hybrids.**

Xavier, L. F. S. Pestana, J. K. Sekiya, A. Krause, M. D. Moreira, R. M. Ferreira, J. M.
Horticultura Brasileira; 2019. 37(3):278-284. 25 ref.
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<input type="checkbox"/>	2	SYN-75377-1.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	0	Advanced	Save More	
<input type="checkbox"/>	3	1 or 2	207	Advanced	Display Results More	
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	word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]				
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<input type="checkbox"/>	17 e-Cry 3 1AB.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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<input type="checkbox"/>	22 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	20	Advanced	Display Results More	
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<input type="checkbox"/>	28	AAA24109.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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<input type="checkbox"/>	31	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30	484	Advanced	Display Results More	
<input type="checkbox"/>	32	22 or 31	504	Advanced	Display Results More	
<input type="checkbox"/>	33	Insect.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]	124103	Advanced	Display Results More	
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		word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]				
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<input type="checkbox"/>	49	toleran*.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]	332651	Advanced	Display Results More	
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<input type="checkbox"/>	53	49 or 50 or 51 or 52	6902962	Advanced	Display Results More	
<input type="checkbox"/>	54	((Insect or insects or coleoptera* or pest or pests or rootworm* or root worm* or Diabrotica or D virgifera or D barberi or MCR or MCRW or NCRW or WCRW or WCR) adj2 (toleran* or resistan* or protect* or control*))).mp.	29407	Advanced	Display Results More	

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<input type="checkbox"/>	55	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]	8713	Advanced	Display Results More	
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<input type="checkbox"/>	57	54 or 55 or 56	35317	Advanced	Display Results More	
<input type="checkbox"/>	58	GMO*.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]	1910	Advanced	Display Results More	
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<input type="checkbox"/>	69	manipulat*.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]	196618	Advanced	Display Results More	

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	word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]					
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<input type="checkbox"/>	71	engineer*.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]	259622	Advanced	Display Results More	
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<input type="checkbox"/>	73	67 or 68 or 69 or 70 or 71 or 72	5845373	Advanced	Display Results More	
<input type="checkbox"/>	74	((genetic* or living or biotech*) adj3 (modif* or transform* or manipulat* or improv* or engineer* or deriv*)),mp.	154548	Advanced	Display Results More	
<input type="checkbox"/>	75	58 or 59 or 60 or 61 or 62 or 74	398665	Advanced	Display Results More	
<input type="checkbox"/>	76	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"/>	77	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]	209558	Advanced	Display Results More	
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<input type="checkbox"/>	80	76 or 77 or 78 or 79	243718	Advanced	Display Results More	
<input type="checkbox"/>	81	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]	14617	Advanced	Display Results More	
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supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]					
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<input type="checkbox"/>	87	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]	36233	Advanced	Display Results More
<input type="checkbox"/>	88	85 or 86 or 87	243926	Advanced	Display Results More
<input type="checkbox"/>	89	((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or corn* or mays)).mp.	790	Advanced	Display Results More
<input type="checkbox"/>	90	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
<input type="checkbox"/>	91	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
<input type="checkbox"/>	92	89 or 90 or 91	790	Advanced	Display Results More
<input type="checkbox"/>	93	75 or 80	635184	Advanced	Display Results More
<input type="checkbox"/>	94	32 and 93	81	Advanced	Display Results More
<input type="checkbox"/>	95	75 and 80	7199	Advanced	Display Results More
<input type="checkbox"/>	96	57 and 95	1136	Advanced	Display Results More
<input type="checkbox"/>	97	5 or 92 or 94 or 96	1589	Advanced	Display Results More
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Saldanha G; Khanna A; O'Riordan M; Bamford M.

American Journal of Surgical Pathology. 2020 Jun 26.

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e-cry3.1
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ecry
ecry3
ecry3.1
ecry3.1ab
engineer*
ge
genetic*
gm
gmo*
improv*
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maize*
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resistan*
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Authors Full Name

Saldanha, Gerald; Khanna, Aarushi; O'Riordan, Marie; Bamford, Mark.

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Huang F.

Insect Science. 2020 Jun 01.

[Journal Article]

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Huang, Fangneng.

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- ☐ 3. **Gene Flow Between Bt and Non-Bt Plants in a Seed Mixture Increases Dominance of Resistance to Pyramided Bt Corn in *Helicoverpa zea* (Lepidoptera: Noctuidae).**

Carriere Y; Degain BA; Harpold VS; Unnithan GC; Tabashnik BE.

Journal of Economic Entomology. 2020 Jun 25.

[Journal Article]

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Carriere, Yves; Degain, Ben A; Harpold, Virginia S; Unnithan, Gopalan C; Tabashnik, Bruce E.

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- ☐ 4. **Dynamics of canopy-dwelling arthropods under different weed management options, including glyphosate, in conventional and genetically modified insect-resistant maize.**

Garcia-Ruiz E; Cobos G; Sanchez-Ramos I; Pascual S; Chueca MC; Escorial MC; Santin-Montanya I; Loureiro I; Gonzalez-Nunez M.

Insect Science. 2020 May 27.

[Journal Article]

UI: 32458593

Authors Full Name

Garcia-Ruiz, Esteban; Cobos, Guillermo; Sanchez-Ramos, Ismael; Pascual, Susana; Chueca, Maria-Cristina; Escorial, Maria-Concepcion; Santin-Montanya, Ines; Loureiro, Inigo; Gonzalez-Nunez, Manuel.

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