



**Review of Scientific Literature Relevant to the  
Food/Feed and Environmental Risk Assessment of  
MIR604 maize**

**TEST GUIDELINE(S):**

Not Applicable

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

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## LIST OF ACRONYMS AND ABBREVIATIONS

CAB	Commonwealth Agricultural Bureaux
CFIA	Canadian Food Inspection Agency
CONABIA	National Advisory Commission on Agricultural Biotechnology ( <i>Comisión Nacional Asesora de Biotecnología Agropecuaria</i> )
CTNBio	National Technical Commission on Biosafety ( <i>Comissão Técnica Nacional de Biossegurança</i> )
ECCC	Environment and Climate Change Canada
EFSA	European Food Safety Authority
EU	European Union
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GMO	Genetically Modified Organism
HC	Health Canada
MAFF	Ministry of Agriculture, Forestry and Fisheries
MEDLINE	Medical Literature Analysis and Retrieval System (online version)
NTO	Nontarget organisms
OGTR	Office of the Gene Technology Regulator
PICO/PECO	Population, Intervention/Exposure, Comparator, Outcomes
PMEM	Post-Market Environmental Monitoring
PMI	Phosphomannose Isomerase
US EPA	US Environmental Protection Agency
US FDA	US Food and Drug Administration
USDA	US Department of Agriculture

## 1.0 EXECUTIVE SUMMARY

Syngenta has developed a maize (*Zea mays* L., corn) line from transformation event MIR604 maize.

A systematic literature search and scoping review was conducted to collect, identify, and assess information (published between June 1, 2021 and July 1, 2022) relevant to the risk assessment of MIR604 maize and its newly expressed proteins, mCry3A and Phosphomannose Isomerase (PMI) proteins, for use as food/feed. This literature search was performed in the context of an annual post-market environmental monitoring (PMEM) report on GMOs authorized in the European Union (EU) market, and was conducted in compliance with the 2019 EFSA explanatory note on literature searching for GMO applications (EFSA 2019).

Electronic databases and regulatory agency webpages were searched using a validated, comprehensive search strategy. Two technical experts independently reviewed the retrieved records to determine their relevance. A total of 193 records were retrieved from the database search, none of which were classified as relevant. A total of 60 records were retrieved from the internet search, 7 of which were classified as relevant. The reference lists of relevant internet publications were also manually searched for records published between June 1, 2021 and July 1, 2022. This manual search identified one additional record, which was not found to be relevant during the review process. The two reviewers evaluated the relevant records in detail and assessed their implications on the current risk assessment of MIR604 maize. Overall, the relevant records did not indicate any hazards, modified exposure pathways, or scientific uncertainties for MIR604 maize.

In conclusion, the results of this literature search and scoping review do not change the risk assessment of MIR604 maize.

## 2.0 INTRODUCTION

Syngenta transformed maize (*Zea mays* L., corn) to produce Event MIR604 maize, which provides control of certain coleopteran insect pests. Event MIR604 maize plants contain the transgene *mcry3A*, which encodes the insecticidal protein mCry3A, and the transgene *pmi*, which encodes the enzyme phosphomannose isomerase (PMI). The native Cry3A from the soil bacterium *Bacillus thuringiensis* subsp. *tenebrionis* is active against certain coleopteran pests of maize. The mCry3A produced by MIR604 was modified to have enhanced activity against the Western corn rootworm (*Diabrotica virgifera virgifera*) and other related coleopteran pests. The transgene *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 MIR604 maize. The PMI protein expressed in MIR604 maize differs from the *E.coli* PMI by two amino acids and was designated MIR604 PMI.

The objective of this systematic literature search and scoping review was to collect, identify, and assess information relevant to the risk assessment of MIR604 maize and its newly expressed proteins, mCry3A and PMI, for use as food/feed. Information published between June 1, 2021 and July 1, 2022 was evaluated. This literature search was performed in the

context of an annual post-market environmental monitoring (PMEM) report on GMOs authorized in the European Union (EU) market, and was conducted in compliance with the 2019 EFSA explanatory note on literature searching for GMO applications (EFSA 2019). This scoping literature search and review was conducted by an experienced information specialist and a team of technical experts with knowledge of genetically modified (GM) crop research, development, and safety assessment (Appendix A).

### 3.0 METHODS

#### 3.1 Formulating the Review Question and Clarifying its Purpose

The literature search and scoping review outlined in this report was aimed at identifying potential adverse effects of MIR604 maize and its newly expressed proteins, mCry3A and PMI proteins, on human/animal health and the environment. Therefore, the associated review question was defined as:

*Do either food/feed products derived from MIR604 maize or the intended traits have adverse effects on human/animal health and/or the environment?*

This review question follows the Population, Intervention/Exposure, Comparator, Outcome (PICO/PECO) structure. Key elements of the review question are defined in Table 1.

**TABLE 1 Review question in PICO/PECO structure**

Element	Components of Review Question
<u>P</u> opulation	Human and animal health and the environment
<u>I</u> ntervention/ <u>E</u> xposure	MIR604 maize, derived food/feed products, and/or the newly expressed proteins, mCry3A and PMI, and closely related variants
<u>C</u> omparator	Conventional counterpart (if applicable)
<u>O</u> utcome	Adverse effects

Pre-defined eligibility/inclusion criteria (Table 2) were used to identify records relevant to answering the review question. Eligibility/inclusion criteria were derived from relevant factors outlined in Section 3.1.2 of the 2019 EFSA explanatory note on literature searching for GMO applications (EFSA 2019) and refined by technical experts in the fields of GMO research, development, and product safety. The eligibility/inclusion criteria were assessed and validated using a pilot study (Appendix B), and have a history of successful use in literature reviews for identifying information relevant to the food/feed and environmental risk assessment of GM crops.

Table 2 provides high-level key concepts for eligibility/inclusion. A detailed breakdown of specific information/data requirements used to assess the associated eligibility/inclusion criteria is provided in Table 3. The criteria are ordered by importance/expected ease of locating the information in a publication. The first failed eligibility/inclusion criterion was used as the primary reason for exclusion and the remaining criteria were not assessed (Frampton *et al.* 2017). A record was included if it did not contain enough information to determine whether the protein being evaluated was a closely-related variant.



**TABLE 2 Eligibility/inclusion criteria to establish relevance**

<b>Concepts</b>	<b>Criteria</b>	<b>Comment</b>
Intervention/exposure	MIR604 maize, derived food/feed products, and/or the intended or closely related trait(s)	Intended traits include Coleopteran insect resistance and mannose metabolism. The newly expressed proteins are mCry3A and PMI. Closely related variants were defined as any protein sharing the same secondary level of Crickmore nomenclature with mCry3A and any enzyme classified as a PMI.
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 MIR604 maize (information/data requirements provided in Table 3) were considered for relevance. Publications addressing issues such as benefits, socio-economics, ethics, crop protection, detection methods, efficacy, public perception, and risk communication were excluded using this criterion, as they were not relevant to the risk assessment as defined in this document.
Scope of GMO application	The pathways and level of exposure to the GMO, derived food/feed products, and the intended trait(s) addressed in the publication are relevant for the intended uses of the GMO and derived food/feed products under regulatory review	Publications must address pathways and levels of exposure relevant to the scope of the application: import and processing of MIR604 maize for food/feed uses.
Reporting format	Original/primary data are presented in the publication or it is a risk assessment from a relevant key organization (such as regulatory agencies and risk assessment bodies involved in the risk assessment of GMOs)	Records that did not present original/primary data (e.g., editorials, reviews, position papers) were excluded. Risk assessments performed and reported by relevant key organizations were included if they addressed MIR604 maize or the newly expressed proteins, mCry3A and/or 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	Publications previously considered by EFSA were excluded. Any cited/referenced publications contained within documents produced by EFSA and/or its GMO Panel were excluded.
Access	Full-text document is accessible	If potentially relevant full-text documents cannot be obtained, they were listed in a table with a description of the (unsuccessful) methods used to attempt obtaining a copy.
Population	Human and animal health, and/or the environment are addressed as general protection goals	All of the information/data requirements categories described in Table 3 are thought to inform the risk assessment related to human and animal health, and/or the environment. Therefore, a publication was considered relevant if it met the inclusion criteria described in this table and was relevant to the information/data requirements in Table 3.

Concepts	Criteria	Comment
Outcomes	Effects/impacts on human and animal health, and/or the environment are addressed	Publications need to address effects/impacts on entities of concern, and potential determinants of exposure that place these entities at risk to be relevant to the risk assessment of MIR604 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 MIR604 maize must also include a conventional counterpart as a comparator in those cases where comparative analysis is conducted and plant material is used as test material. Any uncertainties about the appropriateness of the comparator will be addressed in the assessment of the publication.
Plant species	The publication may address the same plant species as the GMO under consideration, but could also address any plant species producing the mCry3A and/or PMI proteins.	The review question addresses the safe use of the intended trait(s) of MIR604 maize. Therefore, GMOs that contain the newly expressed proteins, mCry3A and/or PMI, or closely-related variants, but are introduced into another plant species were included. For event-specific information/data requirements (noted in parentheses in Table 3), the presence of the transgenic proteins in a different plant species do not impact the assessment of MIR604 maize.
Target pest/organisms	Target pests/organisms addressed in the study are established in the EU	Records related to the intervention/exposure and target pests/organisms were excluded because the scope of the application is import for food/feed uses and this would only be relevant for cultivation applications.
Reporting format	A study should only be presented once, but if it is presented in more than one publication, all publications should be listed and grouped.	Duplicate publications were excluded at the initial screening stage. Only one copy of a study is presented even if it is reported in different publications.

**TABLE 3 Overview of main categories of information/data requirements<sup>a</sup>**

Information/data requirement	Non-exhaustive list of specific information/data requirements
Molecular characterization of the genetic modification of the GMO	<ul style="list-style-type: none"> <li>• Information on the insert including: sequence, size, copy number, genetic element arrangement, deletions, location, sequence similarity searches, and analysis of open reading frames (MIR604 maize only)</li> <li>• Expression data of inserted/modified sequences (MIR604 maize only)</li> <li>• Genetic stability (MIR604 maize only)</li> <li>• Molecular and biochemical characterization of the protein(s) such as: primary structure, molecular weight, post-translational modifications (mCry3A and/or PMI proteins as expressed in MIR604 maize only)</li> <li>• Assessment of enzymatic activity including substrate specificity and reaction products with respect to safety and/or nutritional balance</li> <li>• Data on the equivalence between plant-produced and microbially-produced proteins (mCry3A and/or PMI proteins from MIR604 maize plants and a microbial source)</li> </ul>
Agronomic, phenotypic and compositional characterization of the GM plant	<ul style="list-style-type: none"> <li>• Comparative assessment of agronomic and phenotypic characteristics under field or controlled conditions (MIR604 maize only)</li> <li>• Comparative analysis of key nutritional constituents (MIR604 maize)</li> </ul>
Toxicological assessment of newly expressed protein(s), new constituents other than proteins, and the whole GM food/feed	<ul style="list-style-type: none"> <li>• Amino acid sequence comparison between the newly expressed protein(s) (mCry3A and/or PMI proteins as expressed in MIR604 maize only) and toxic proteins</li> <li>• Stability of the protein(s) under relevant processing and storage conditions</li> <li>• Investigation of proteolytic susceptibility of the newly expressed protein</li> <li>• Toxicity studies</li> <li>• Feeding studies that use plant material (MIR604 maize only)</li> </ul>
Allergenicity assessment of the newly expressed protein and the GM food/feed, and adjuvanticity	<ul style="list-style-type: none"> <li>• Amino acid sequence comparison between the newly expressed protein(s) (mCry3A and/or PMI proteins as expressed in MIR604 maize only) and known allergens or celiac disease peptide sequences</li> <li>• Serum screening</li> <li>• Pepsin susceptibility testing</li> <li>• <i>In vivo</i> tests in animal models</li> <li>• Expression data for endogenous allergens (MIR604 maize only)</li> <li>• Comparison of newly expressed proteins to known strong adjuvants</li> </ul>

Information/data requirement	Non-exhaustive list of specific information/data requirements
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"> <li>• Anticipated dietary intake of food/feed from MIR604 maize and the resulting nutritional impact</li> <li>• Comparative growth performance studies with young rapidly growing animal species (MIR604 maize only if the diet contains transgenic plant material)</li> </ul>
Post-market monitoring	<ul style="list-style-type: none"> <li>• 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</li> <li>• Information on the reliability, sensitivity, and specificity of the post market monitoring</li> </ul>
Persistence and invasiveness assessment, including plant-to-plant gene transfer	<ul style="list-style-type: none"> <li>• Measurements of volunteer occurrence and establishment (MIR604 maize only)</li> <li>• Replacement capacity (i.e., # of plants present at specific observation time/# of plants present after initial sowing) (MIR604 maize only)</li> <li>• Fitness of the GM plant expressing mCry3A and/or PMI proteins in various environmental conditions – in the same or in a different plant species may be considered relevant</li> </ul>
Assessment of plant to micro-organism gene transfer	<ul style="list-style-type: none"> <li>• Homology searches at nucleotide level between the GM event and microorganisms (MIR604 maize only)</li> </ul>
Assessment of interactions with target organisms	<ul style="list-style-type: none"> <li>• Excluded based on the scope of the application. The scope of this application covers the import, processing and food/feed use of MIR604 maize in the EU. According to the EFSA ERA Guidance (EFSA 2010): <i>“resistance development is only relevant for applications with scope cultivation of GM plants and not for applications restricted to import and processing of GM plants and their products.”</i> Therefore, an assessment of the potential resistance development in target organisms resulting from the import, processing and food/feed use of MIR604 maize was not relevant for this application.</li> </ul>
Assessment of interactions with non-target organisms (NTO)	<ul style="list-style-type: none"> <li>• The EFSA ERA Guidance (EFSA 2010) states that: <i>“In cases where the application does not include cultivation in the EU, direct environmental exposure of NTOs to the GM plant is via accidental release into the environment of seeds or propagules during transportation and processing. This may result in sporadic occurrence of feral plants and therefore exposure of NTO populations is likely to be negligible. The ERA will then focus on indirect exposure to products of the GM plant (e.g., through manure and faeces from animals fed the GM plant, and other by-products of industrial processes).”</i> Therefore, any publications that discussed direct exposure in test protein and laboratory studies or field survey data were considered not relevant based on the scope of application.</li> </ul>
Assessment of interactions with biogeochemical and abiotic processes	<ul style="list-style-type: none"> <li>• Excluded based on the scope of the application. The scope of this application covers the import, processing and food/feed use of MIR604 maize only in the EU. According to the EFSA ERA Guidance (EFSA 2010): <i>“Applications concerning food/feed uses and import and processing do not require scientific information on possible environmental effects associated with the cultivation of the plant.”</i> Therefore, an assessment of the impacts of MIR604 maize on biogeochemical processes resulting from specific cultivation, management, and harvesting techniques were not relevant given the scope of this application.</li> </ul>

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"><li>Excluded based on the scope of the application. The scope of this application covers the import, processing, and food/feed use of MIR604 maize in the EU. Cultivation of MIR604 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 MIR604 maize were not relevant for this application.</li></ul>
Risk mitigation	<ul style="list-style-type: none"><li>Excluded based on the scope of the application. Risk mitigation measures such as high dose/refuge strategy, isolation distance from protected habitats hosting species of conservation concern that are at risk, and integrated pest/weed management are only relevant to cultivation. The scope of this application covers the import, processing and food and feed use of MIR604 maize.</li></ul>
Post-market environmental monitoring	<ul style="list-style-type: none"><li>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 MIR604 maize.</li></ul>

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

## **3.2 Searching for/Identifying Relevant Publications**

### **3.2.1 Database searches**

#### **3.2.1.1 Electronic bibliographic databases**

To search for different types of publications and unpublished work that could provide information on the review question, multidisciplinary citation databases, which include grey literature (i.e., not peer reviewed), were used. Two large, multi-disciplinary databases (Ovid Medline and BIOSIS Previews) and two databases specializing in topics relevant to agricultural and nutrition sciences (AGRICOLA and Commonwealth Agricultural Bureaux (CAB) abstracts) were searched via Ovid® search interface (provided by Ovid® Technologies). These four databases were selected because of their extensive coverage of scientific literature related to relevant subjects that include, but are not limited to, biomedicine, plant disease, agriculture, life sciences, pesticides, human health and nutrition, animal health, plant science, biotechnology, and environmental studies (see Appendix C for further details on each database and the reason(s) for selection). Each database has a thesaurus. The document types contained in these databases encompasses a wide range of formats, including journal articles, technical letters and notes, conference proceedings, book chapters, reports, and articles in press. Detailed specifications of these databases are outlined in Appendix C.

The selection of databases for this study complied with the 2019 explanatory note on literature searching (EFSA 2019), which indicates that a minimum of two large/multi-disciplinary databases are necessary to provide adequate coverage while still providing some level of complementary results. Using a combination of multi-disciplinary and specialized databases provides valuable results (Stevinson and Lawlor 2004). Therefore, the present combination of databases was suitable for retrieving publications relevant to the risk assessment of MIR604 maize as it relates to food/feed and the environment, while adhering to EFSA's definition of "best" search strategy practices (defined in Glanville *et al.* (2014) as "a situation whereas few resources as possible are searched with a high probability that most of the relevant research evidence will be identified").

#### **3.2.1.2 Database search strategy**

The electronic bibliographic databases search strategy was designed to retrieve information on MIR604 maize. The same search strategy was used in all databases through the Ovid® search interface (outlined in Table 4). The search strategy was developed by an information specialist in collaboration with technical experts with experience in GM crop research, development, and safety assessment (Appendix A). Database search strategy construction is described in a detailed synopsis in Appendix D.

**TABLE 4 Search string strategy**

Set	Field	Search String	Concepts/Key Elements
1	Topic	MIR604 OR MIR 604 OR SYN-IR6#4-5	Event MIR604 <sup>a</sup>
2	Topic	Agrisure* ADJ2 RW*	Trade name for MIR604
3	Topic	mCry3A* OR mCry 3A* OR mCry 3 A* OR Cry3A* OR Cry 3A* OR Cry 3 A*	Newly expressed protein in MIR604 (insecticidal)
4	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 MIR604 (selectable marker)
5		3 OR 4	
6	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 trait (insecticidal)
7	Topic	GMO* OR LMO* OR GM OR GE OR transgen* OR ((genetic* OR living OR biotech*) ADJ3 (modif* OR transform* OR manipul* OR improv* OR engineer* OR deriv*))	GMO general
8	Topic	Maize* OR corn* OR Zea mays OR Z mays	Plant species
9	Topic	((Bt OR Bacillus thuringiensis OR B thuringiensis) ADJ5 (maize* OR corn* OR mays)) OR Btmaize* OR Btcorn*	GMO general × intended trait-Bt
10		5 AND (7 OR 8)	Newly expressed proteins AND (GMO general OR Plant species)
11		(6 AND 7) AND 8	(Intended trait AND GMO general) AND Plant species
12		1 OR 2 OR 10 OR 11 OR 9	Event OR Trade name OR (Newly expressed proteins AND (GMO general OR Plant species)) OR ((Intended trait AND GMO general) AND Plant species) OR GMO general × Intended trait-Bt

a. The mandated wildcard symbol (#) is used as a substitute for one required character on the Ovid platform.

### 3.2.1.3 Reference Publications

Prior to starting this literature search and review, the search strategy was assessed and validated using reference publications. All reference publications were retrieved from at least one of the four searched databases (100% overall retrieval), indicating satisfactory performance of the search strategy for acquiring the breadth of information available for the key elements highlighted in the search strategy (event, newly expressed proteins, and intended traits). Details of this process (including rationale for selection of the reference publications) and the outcomes (including the percentage of reference publications retrieved from each database) are outlined in Appendix E.

3.2.2 Internet searches

3.2.2.1 Key organizations and internet search strategy for regulatory agency webpages

The internet pages of relevant regulatory agency websites (Table 5) were searched for documents related to GMO applications, risk assessments, and approvals. Only the websites of agencies that conduct and post risk assessments to their websites are considered relevant for searching. Records were collected from webpages (Table 5) that listed regulatory documents/information specific to the safety assessment of GMOs. All records from these webpages that were published during the relevant time period (June 1, 2021-July 1, 2022) were collected for full-text review as described in the “Search strategy and limits applied” column. If a record’s publication date could not be determined, it was retrieved for review.

TABLE 5 Key organization pages included in the search<sup>a,b</sup>

Regulatory agency/risk assessment body	Webpage address	Search strategy and limits applied
Food Standards Australia New Zealand (FSANZ)	<a href="https://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx">https://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx</a>	The list of current GM applications and approvals was examined. Safety assessments and approval documents (when available) for foods produced using gene technology (plant origin) that have a status of “Approved” or “Under assessment” and were published during or after 2021 were retrieved for assessment.
Health Canada (HC) <sup>c</sup>	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html</a>	The list of completed safety assessments of GM foods was examined. The technical summaries linked to the novel food safety assessments with a “Decision Date” listed as 01/06/2021 or later were retrieved for review.
Canadian Food Inspection Agency (CFIA) <sup>c</sup>	<a href="https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236">https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236</a>	The table of decision documents for determination of environmental and livestock feed safety was examined. All documents for decisions made during or after 2021 were retrieved for review.



Regulatory agency/risk assessment body	Webpage address	Search strategy and limits applied
Ministry of Agriculture, Forestry and Fisheries (MAFF)	<a href="https://www.biodic.go.jp/bch/lmo/OpenSearch.do">https://www.biodic.go.jp/bch/lmo/OpenSearch.do</a>	The “Genetically modified organism search system approved under the Cartagena method” on the Japan Biosafety Clearing House website was examined (this website is referenced as the relevant repository for documents related to GM organism approvals on the MAFF webpage dedicated to the approval of GM crops - <a href="https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/">https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/</a> ). The documents were searched by limiting “Approval Dates” to 2021-2022. Items were sorted by approval date. All documents with an approval date on or after 01/06/2021 were retrieved for review.
National Advisory Commission on Agricultural Biotechnology (CONABIA)	<a href="https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/ogm-vegetal-eventos-con-autorizacion-comercial">https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/ogm-vegetal-eventos-con-autorizacion-comercial</a>	The table of "Plant GMO: Events with commercial authorization" was examined. All documents with an approval date on or after 01/06/2021 were retrieved for review.
National Technical Commission on Biosafety (CTNBIO)	<a href="http://ctnbio.mctic.gov.br/liberacao-comercial/#/liberacao-comercial/consultar-processo">http://ctnbio.mctic.gov.br/liberacao-comercial/#/liberacao-comercial/consultar-processo</a>	The webpages dedicated to the commercial releases of plants ( <i>plantas</i> ) were searched for technical opinion documents. The subfolder “plantas” was accessed from the noted link, and each subfolder contained within (“Soja” (Soybean), “Milho” (Corn), “Feijão” (Beans), “Eucalipto” (Eucalyptus), “Cana” (Cane), and “Algodão” (Cotton)) was searched for technical opinion documents. Those published during or after 2021 were retrieved for review.
Office of the Gene Technology Regulator (OGTR)	<a href="https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release">https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release</a>	The list of dealings involving the intentional release of GMOs into the environment were examined. Documents with an “Issue Date” falling on or after 1-Jun-2021 were retrieved for review. If no “Issue Date” was listed, the document was collected for review.
US Department of Agriculture (USDA)	<a href="https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status">https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status</a>	The list of petitions was sorted by “Effective Date.” Documents from petitions with an “Effective Date” falling on or after 01/06/2021 were collected. Documents listed as “Final Environmental Assessment,” “Finding of No Significant Impact,” and/or “Final Plant Pest Risk Assessment” were retrieved for review.
US Environmental Protection Agency (USEPA)	<a href="https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated">https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated</a>	The table of “PIP (Plant Incorporated Protectants) Active Ingredients” was sorted by “Year Registered” and all documents listed under “BRAD (Biopesticides Registration Action Document) and other Regulatory Documents” with a “Year Registered” of 2021 or later, were retrieved for review.
US Food and Drug Administration (USFDA)	<a href="https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon">https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon</a>	The list of New Plant Variety Consultations was sorted by “Date Completed” and all items completed on or after June 1, 2021 were retrieved for review.

- The regulatory agency of Mexico (Intersecretarial Commission on Biosafety of GMOs) does not post the relevant document types on their agency website and was not searched.
- The Genetic Engineering Appraisal Committee of India (part of the Ministry of Environment, Forest, and Climate Change) has not posted updates to their website regarding clearance decisions for GMOs since 2014 and, therefore, was not searched (<https://moef.gov.in/en/project-approvals/geac-clearances/>).
- HC and CFIA are responsible for regulating GM plants in Canada. Environment and Climate Change Canada (ECCC) does not regulate GM plants and, therefore, the ECCC website was not searched.

### **3.2.2.2 Web-based search engines and databases**

General search engines such as GOOGLE Scholar and web-based databases known to contain information specifically on effects of GMOs were not searched. The search of the databases and key organization websites was considered adequate for a comprehensive search of literature.

### **3.2.3 Manual searches**

#### **3.2.3.1 Checking reference lists**

If any relevant records were retrieved from the internet searches of regulatory agency websites, their reference list(s) were manually checked/scanned by both reviewers for new records within the relevant time period (June 1, 2021-July 1, 2022) and that met the eligibility/inclusion criteria. The full-text documents of any titles from the reference lists that appeared potentially relevant were obtained and evaluated by both reviewers to determine relevance.

#### **3.2.3.2 Hand searching**

Hand searching was not conducted. The search of the databases and key organization websites was considered adequate for a comprehensive search of literature.

#### **3.2.3.3 Citation searching**

Citation searching was not conducted. The search of the databases and key organization websites was considered adequate for a comprehensive search of literature.

### **3.2.4 Use of multiple languages**

All search terms were in English or utilized the Roman alphabet. Translations are unlikely to exist for event and trade names, and therefore search terms were not translated.

### **3.2.5 Time period**

All searches were conducted on or after July 1, 2022 (Table 7 and Table 8). The database search was limited, using the Ovid search platform, to records published between June 1, 2021 and the date of the last database update prior to the search (see Table 7). The records retrieved from regulatory agency webpages were limited by manually excluding publications dated prior to June 1, 2021. If a date could not be determined for a given record, it was retained for review.

## **3.3 Reviewing Publications for Relevance**

### **3.3.1 Review of database records**

The process for selecting relevant database publications was conducted in two stages, and was assessed/validated, using a pilot study, alongside the eligibility/inclusion criteria (Appendix B). Two independent reviewers evaluated each database record using the eligibility/inclusion criteria (Table 2 and Table 3) at all stages of the review process.

The first stage (Stage 1) was a preliminary assessment of titles and abstracts where records were classified as either (1) relevant/unclear relevance or (2) clearly not relevant. Records that were clearly irrelevant upon reviewing the title were excluded from further review. Records with titles that appeared relevant, or had unclear relevance, were retained for abstract review. Only records that were deemed clearly irrelevant by both reviewers upon assessment of the abstract were excluded from further review. This conservative approach ensured that all potentially relevant records were further evaluated. A kappa test was performed after Stage 1 review was completed and prior to discussing disagreements from Stage 1 abstract review. Records with abstracts that appeared relevant, or had unclear relevance, were retained for the second stage of review.

The second stage (Stage 2) was a detailed review of full-length articles. During Stage 2 review, a final decision on record relevance/irrelevance was made. Articles deemed relevant at Stage 2 were subjected to a reliability assessment and evaluation of the record's implications on the food and feed or environmental risk assessment for MIR604 maize. An explanation of exclusion was provided for articles deemed irrelevant at Stage 2.

The reviewers discussed disagreements after Stage 2 (full-text) review of articles. If a disagreement on a record's relevance could not be resolved at Stage 2, an additional reviewer was brought in as a tie-breaker. Considering the tie-breaker's opinion, the majority position of relevance on the record became the agreed position.

### **3.3.2 Review of internet records from key organizations**

Records from the webpages of key organizations were considered potentially relevant if they were risk assessments or scientific opinions/reports sponsored by the key organization. The regulatory agencies of interest (Table 5) do not post primary data; therefore, all other document types were considered irrelevant. The eligibility/inclusion criteria did not include risk assessments/dossiers submitted to regulatory authorities, only "risk assessments performed and reported by relevant key organizations." Therefore, only documents authored by the key organizations and not the applicants qualified as potentially relevant (i.e., dossiers and risk assessments submitted to regulatory authorities were excluded). Draft and partial reports were excluded since they contain no new information and do not represent the final official opinion of the agency. Similarly, reports that reflect individual reviewer opinions were excluded from evaluation because they are considered when developing the official final opinion of the agency. A rationale for exclusion, based on the eligibility/inclusion criteria, was provided when applicable, except for records excluded based on "Reporting Format" (e.g., submissions by applicants, meeting agendas, tables of approval dates, draft documents, etc.).

Two independent reviewers evaluated each internet record using the eligibility/inclusion criteria (Table 2 and Table 3). Internet records from key organizations were not amenable to a multi-stage review (i.e., title and abstract were often not provided in the search results), therefore, these records were only assessed in Stage 2 (full-text) review. Accordingly, a Kappa test (required for Stage 1 review only, as outlined in the 2019 explanatory note (EFSA 2019)) was not conducted for internet reviews.

Some agencies post information in languages other than English. During these instances, publications were translated to English using a neural machine translation software (i.e., Google Translate) prior to review. If translations were unclear or ambiguous, a native speaker of the language was consulted to provide a more accurate translation.

For the purposes of reporting and statistics, we defined a unique internet record as a unique uniform resource locator (URL). If the URLs for two documents were identical except for file format (e.g., pdf *versus* .doc or .docx), one of the documents was considered a duplicate document and it was excluded from reporting and review. Suspected duplicates (i.e., documents with similar URLs) were visually examined by the reviewer. If the content was identical, the record was removed so that only one record was reviewed and reported/used for statistics. If additional duplicates were identified during the review process (i.e., documents with different URLs, but identical content), they were removed such that only one document was used for reporting and statistics.

## **4.0 SUMMARISING AND REPORTING THE DATA, AND CONSIDERING THE IMPLICATIONS OF THE FINDINGS**

### **4.1 Summary of the Search and Publication Selection Process**

A complete summary of the search results and selection process, including the number of records reviewed, included, and excluded during each stage of review, is outlined in Table 6. Across all searches (database, internet, and manual), a total of 254 unique publications were retrieved for review. Of these, 193 were retrieved from the database search, 60 were retrieved from the internet search, and one was retrieved from the manual search of reference lists from relevant internet records.

For electronic bibliographic databases, the date on which the search was conducted, the date of the most recent update of the database, the service provider used, date span of the search, any limits applied to the search (e.g., dates) and the total number of records retrieved across all databases was recorded (Table 7). The records were de-duplicated after combining records retrieved from all the databases. Additionally, the search strategy as it was run for each database (including the fields searched), the number of publications identified for each bibliographic database prior to de-duplication (on a line-by-line basis), and the subject indexing used by each database (shown within brackets after each search term), were recorded (see Appendix F for screenshots of the search containing these details).

The database search returned a total of 193 records (after deduplication) that covered the dates of June 1, 2021 to July 1, 2022. During Stage 1, the reviewers agreed to include one record and exclude 192 records. There were no disagreements on relevance during Stage 1, which yielded a kappa score of 1, indicating perfect agreement. We consider the level of reviewer agreement to be acceptable for identifying all relevant literature.

In total, one record was reviewed in Stage 2, during which it was classified as not relevant (Table 10). There were no conflicts during Stage 2 review; therefore, a tie-breaker reviewer was not needed.

For internet webpages of regulatory agency websites, the date on which the search was conducted, the date of the most recent update of the webpage (if available), the date span of the search, and the total number of records retrieved from each site were recorded (Table 8). The records from each website were de-duplicated individually. In total, the internet search yielded 60 records from regulatory agency websites that were evaluated only at Stage 2 (full-text)

review. The reviewers agreed that 7 of the internet records were relevant (Table 9) and 53 were irrelevant (Table 11). There were no conflicts between reviewers over internet records.

The reference lists of relevant internet publications were also searched for additional records published during the relevant time period (June 1, 2021-July 1, 2022), and one record was retrieved for review. Both reviewers determined this record was not relevant after reviewing the title and, therefore, it was not reviewed further.

**TABLE 6      Results of the publication selection process, for each review question and/or category of information/data requirement or group of information/data requirements searched**

Review question and/or category of information/data requirement(s) captured in the search	Number of publications in each subcategory			Total
	Databases	Internet	Manual <sup>b</sup>	
Publications identified after all searches of the scientific literature (excluding duplicates <sup>a</sup> )	193	60	1	254
Publications excluded from the search results after screening of title and abstracts (Stage 1)	192	NA <sup>d</sup>	1	193
Publications screened using full-text (Stage 2) <sup>c</sup>	1	60	0	61
Publications excluded after full-text screening <sup>e</sup>	1	53	0	54
Unobtainable/Unclear publications	0	0	0	0
Publications considered relevant	0	7	0	7

a. A total of 630 publications were identified from the database search. Of these, 437 publications were removed because they were duplicates.

b. Manual refers to the records obtained from manually searching the reference lists of internet publications classified as relevant.

c. Internet results are not screened at Stage 1 because they have no title or abstract.

d. NA=Not Applicable.

e. There was one record excluded based on reporting format.

**TABLE 7      Electronic bibliographic database search details<sup>a</sup>**

Database	Search date (dd/mm/yyyy)	Service provider	Date span of the search (dd/mm/yyyy) <sup>a</sup>	Any limits applied to the search	Total number of records retrieved after removing duplicates <sup>b</sup>
Agricola	01/07/2022	Ovid Technologies	01/06/2021 to 27/06/2022	Dates	7
BIOSIS Previews	01/07/2022	Ovid Technologies	01/06/2021 to 23/06/2022	Dates	33
CAB Abstracts	01/07/2022	Ovid Technologies	01/06/2021 to 30/06/2022	Dates	74
Medline	01/07/2022	Ovid Technologies	01/06/2021 to 30/06/2022	Dates	79

a. Ovid only allows results to be limited by year. The frequency of database update varies. Ovid has provided us with the following update information: Agricola updated monthly, BIOSIS Previews updated weekly, CAB Abstracts updated weekly, and Medline updated daily.

b. The results were de-duplicated across databases.

**TABLE 8 Regulatory agency webpage search details<sup>a</sup>**

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

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

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



## 4.2 Lists of Bibliographic References for Relevant Publications

After detailed review of the full-text documents in Stage 2, 7 out of 60 internet records were deemed relevant (Table 9). None of the database records was classified as relevant. Bibliographic information for the relevant records (author, publication year, title, and source) are included in the tables, and the records are organized alphabetically by the category of information/data requirement they fulfill (see Table 3 for a full list of the information/data requirements used during review). More detailed descriptions of the relevant publications, including an assessment of their reliability and significance to the risk assessment of MIR604 maize, are provided in Section 4.7.

**TABLE 9 Report of all relevant internet publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement**

<b>List of bibliographic references for all relevant internet publications, classified by category of information/data requirements</b>			
<b>Category of Information/Data Requirement(s)</b>	<b>Study (Author(s) and Year)</b>	<b>Title</b>	<b>Source</b>
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2022a)	Technical Opinion No. 7897 - 2022	<a href="http://ctnbio.mctic.gov.br/documents/566529/2302517/Parecer+T%C3%A9cnico+n%C2%BA+7897+-+2022/">http://ctnbio.mctic.gov.br/documents/566529/2302517/Parecer+T%C3%A9cnico+n%C2%BA+7897+-+2022/</a>
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2022b)	Technical Opinion No. 7891 - 2022	<a href="http://ctnbio.mctic.gov.br/documents/566529/2302835/Parecer+T%C3%A9cnico+n%C2%BA+7891+-+2022/">http://ctnbio.mctic.gov.br/documents/566529/2302835/Parecer+T%C3%A9cnico+n%C2%BA+7891+-+2022/</a>
Risk assessment or scientific opinion	US Department of Agriculture (2021)	Producing Phytase/Maize Event PY203 -- Final Environmental Assessment	<a href="https://www.aphis.usda.gov/brs/aphisdocs/19-176-01p-ea.pdf">https://www.aphis.usda.gov/brs/aphisdocs/19-176-01p-ea.pdf</a>
Risk assessment or scientific opinion	Health Canada (2021)	Insect Resistant and Herbicide Tolerant Maize Event DP-023211-2 -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/insect-resistant-herbicide-tolerant-maize-event-dp-023211-2/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/insect-resistant-herbicide-tolerant-maize-event-dp-023211-2/document.html</a>
Risk assessment or scientific opinion	Health Canada (2022)	Insect Resistant and Herbicide Tolerant Zea maize event DP-915635 -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/insect-resistant-herbicide-tolerant-zea-maize/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/insect-resistant-herbicide-tolerant-zea-maize/document.html</a>
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021a)	A1202 -- DP-023211-2 _ Supporting document 1	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1202%20SD1.pdf?csf=1&amp;e=JjOa8H">https://www.foodstandards.gov.au/code/applications/Documents/A1202%20SD1.pdf?csf=1&amp;e=JjOa8H</a>
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021b)	A1202 -- DP-023211-2 _ Approval Report	<a href="https://www.foodstandards.gov.au/code/changes/circulars/Documents/A1202_Approval%20Report%20post%20Board.pdf?csf=1&amp;e=skxrlQ">https://www.foodstandards.gov.au/code/changes/circulars/Documents/A1202_Approval%20Report%20post%20Board.pdf?csf=1&amp;e=skxrlQ</a>

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

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

**4.3 Lists of Bibliographic References for all Excluded Publications After Detailed Assessment of Full-Text Documents for Relevance**

After detailed review of the full-text documents in Stage 2, the one database record reviewed was excluded (Table 10) and 53 out of 60 internet records were excluded (Table 11). Bibliographic information for the excluded records (author, publication year, title, and source) are included in the following tables, along with the eligibility/inclusion criteria used as a reason for exclusion (see Table 2 for a full list of the eligibility/inclusion criteria used during review). Out of 53 irrelevant internet records, one was excluded based on reporting format. Documents excluded based on reporting format were not included in Table 11 and a rationale for exclusion was not provided. A rationale for exclusion was included for each record classified as one of the relevant document types, authored by the agency, and excluded based on an eligibility criteria other than “Reporting Format.”

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

List of bibliographic references for all database publications excluded from the risk assessment, classified by authors			
Study author(s) and year	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 2
Zhang <i>et al.</i> (2021)	Analysis of metabolites and metabolic mechanism in Bt transgenic and nontransgenic maize	<i>Microchemical Journal</i>	Intervention/exposure

**TABLE 11 Report of internet publications excluded from the risk assessment after detailed assessment of full-text documents, giving the reason(s) for exclusion <sup>a</sup>**

<b>List of bibliographic references for all internet publications excluded from the risk assessment, classified by authors</b>			
<b>Study author(s) and year</b>	<b>Title</b>	<b>Source</b>	<b>Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 2</b>
Food Standards Australia New Zealand (2021)	A1216 -- MON-94100-2 _ Supporting document 2 - Safety Assessment supplement	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1216%20SD2.pdf?csf=1&amp;e=sPWbFB">https://www.foodstandards.gov.au/code/applications/Documents/A1216%20SD2.pdf?csf=1&amp;e=sPWbFB</a>	Intervention/Exposure
Food Standards Australia New Zealand (2021)	A1216 -- MON-94100-2 _ Approval Report	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1216%20Approval%20Report.pdf?csf=1&amp;e=G7ey6C">https://www.foodstandards.gov.au/code/applications/Documents/A1216%20Approval%20Report.pdf?csf=1&amp;e=G7ey6C</a>	Intervention/Exposure
Food Standards Australia New Zealand (2021)	A1216 -- MON-94100-2 _ Supporting document 1 - Safety Assessment	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1216%20Health%20Canada%20SD1.pdf?csf=1&amp;e=w5Xbpw">https://www.foodstandards.gov.au/code/applications/Documents/A1216%20Health%20Canada%20SD1.pdf?csf=1&amp;e=w5Xbpw</a>	Intervention/Exposure
Food Standards Australia New Zealand (2021)	A1198 -- DP-202216-6 _ Supporting document 1 - Risk assessment	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1198_SD1.pdf">https://www.foodstandards.gov.au/code/applications/Documents/A1198_SD1.pdf</a>	Intervention/Exposure
Food Standards Australia New Zealand (2021)	A1198 -- DP-202216-6 _ Approval Report	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1198%20Approval%20Report.pdf">https://www.foodstandards.gov.au/code/applications/Documents/A1198%20Approval%20Report.pdf</a>	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1232 -- IND-00412-7 _ Approval report	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1232%20Approval%20Report%20final.pdf">https://www.foodstandards.gov.au/code/applications/Documents/A1232%20Approval%20Report%20final.pdf</a>	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1239 -- BPS-BFLFK-2 _ Supporting document 1 - Safety assessment	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1239%20SD1.pdf">https://www.foodstandards.gov.au/code/applications/Documents/A1239%20SD1.pdf</a>	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1239 -- BPS-BFLFK-2 _ Supporting document 2 - Nutrition Risk Assessment	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1239_SD2_changed.pdf">https://www.foodstandards.gov.au/code/applications/Documents/A1239_SD2_changed.pdf</a>	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1226 -- MON-95379-3 _ Supporting document 1 - Safety Assessment	<a href="https://www.foodstandards.gov.au/code/applications/Documents/01_A1226_SD1.pdf">https://www.foodstandards.gov.au/code/applications/Documents/01_A1226_SD1.pdf</a>	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1232 -- IND-00412-7 _ Supporting document 1 - Safety assessment	<a href="https://www.foodstandards.gov.au/code/applications/Documents/01_A1232_SD1.pdf">https://www.foodstandards.gov.au/code/applications/Documents/01_A1232_SD1.pdf</a>	Intervention/Exposure
Food Standards Australia New Zealand (2022)	A1226 -- MON-95379-3 _ Approval report - 10 February 2022	<a href="https://www.foodstandards.gov.au/code/applications/Documents/A1226%20GM%20corn%20ApprovalReport.pdf">https://www.foodstandards.gov.au/code/applications/Documents/A1226%20GM%20corn%20ApprovalReport.pdf</a>	Intervention/Exposure
Health Canada (2021)	Quizalofop tolerant rice - RTA1 -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/quizalofop-tolerant-rice/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/quizalofop-tolerant-rice/document.html</a>	Intervention/Exposure

<b>List of bibliographic references for all internet publications excluded from the risk assessment, classified by authors</b>			
<b>Study author(s) and year</b>	<b>Title</b>	<b>Source</b>	<b>Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 2</b>
Health Canada (2021)	Soy leghemoglobin (LegH) preparation as an ingredient in all simulated meat and poultry products -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/soy-leghemoglobin-simulated-meat-products/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/soy-leghemoglobin-simulated-meat-products/document.html</a>	Intervention/Exposure
Health Canada (2021)	Napin-rich Canola Protein Isolate -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/napin-rich-canola-protein-isolate/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/napin-rich-canola-protein-isolate/document.html</a>	Intervention/Exposure
Health Canada (2021)	Lepidopteran Protected Corn - MON 95379 -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/lepidopteran-protected-corn/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/lepidopteran-protected-corn/document.html</a>	Intervention/Exposure
Health Canada (2021)	D-tagatose -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/d-tagatose/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/d-tagatose/document.html</a>	Intervention/Exposure
Health Canada (2021)	Plum Pox Virus (PPV) Resistant C5 Plum -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/virus-resistant-plum/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/virus-resistant-plum/document.html</a>	Intervention/Exposure
Health Canada (2021)	2'-Fucosyllactose from genetically engineered E. coli K12 MG1655 strain -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/fucosyllactose-escherichia-coli/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/fucosyllactose-escherichia-coli/document.html</a>	Intervention/Exposure
Health Canada (2021)	D-tagatose -- The gastrointestinal effects of D-tagatose	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/d-tagatose/gastrointestinal-effects.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/d-tagatose/gastrointestinal-effects.html</a>	Intervention/Exposure

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<b>Study author(s) and year</b>	<b>Title</b>	<b>Source</b>	<b>Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 2</b>
Health Canada (2022)	Herbicide Tolerant DT Sorghum -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/herbicide-tolerant-dt-sorghum/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/herbicide-tolerant-dt-sorghum/document.html</a>	Intervention/Exposure
Health Canada (2022)	High oleic acid soybean line SVX-4003 -- Technical Summary	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/high-oleic-acid-soybean-line/document.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/high-oleic-acid-soybean-line/document.html</a>	Intervention/Exposure
National Advisory Commission on Agricultural Biotechnology (2021)	IND-00410-5	<a href="https://magyp.gob.ar/sitio/areas/biotecnologia/conabia/pdf/dd/DD_soja_IND-00410-5_INDEAR.pdf">https://magyp.gob.ar/sitio/areas/biotecnologia/conabia/pdf/dd/DD_soja_IND-00410-5_INDEAR.pdf</a>	Intervention/Exposure
National Technical Commission on Biosafety (2021)	Technical Opinion No. 7788-2021	<a href="http://ctnbio.mctic.gov.br/documents/566529/2292301/Parecer+T%C3%A9cnico+7788-2021/">http://ctnbio.mctic.gov.br/documents/566529/2292301/Parecer+T%C3%A9cnico+7788-2021/</a>	Intervention/Exposure
National Technical Commission on Biosafety (2021)	Technical Opinion No. 7501 - 2021	<a href="http://ctnbio.mctic.gov.br/documents/566529/2302408/Parecer+T%C3%A9cnico+n%C2%BA+7501+-+2021/">http://ctnbio.mctic.gov.br/documents/566529/2302408/Parecer+T%C3%A9cnico+n%C2%BA+7501+-+2021/</a>	Intervention/Exposure
National Technical Commission on Biosafety (2021)	Technical Opinion No. 7482 - 2021	<a href="http://ctnbio.mctic.gov.br/documents/566529/2303766/Parecer+T%C3%A9cnico+n%C2%BA+7482+-+2021/">http://ctnbio.mctic.gov.br/documents/566529/2303766/Parecer+T%C3%A9cnico+n%C2%BA+7482+-+2021/</a>	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 8035 - 2022	<a href="http://ctnbio.mctic.gov.br/documents/566529/2302623/Parecer+T%C3%A9cnico+n%C2%BA+8035+-+2022/">http://ctnbio.mctic.gov.br/documents/566529/2302623/Parecer+T%C3%A9cnico+n%C2%BA+8035+-+2022/</a>	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 8064 - 2022	<a href="http://ctnbio.mctic.gov.br/documents/566529/2302729/Parecer+T%C3%A9cnico+n%C2%BA+8064+-+2022/">http://ctnbio.mctic.gov.br/documents/566529/2302729/Parecer+T%C3%A9cnico+n%C2%BA+8064+-+2022/</a>	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 8038 - 2022	<a href="http://ctnbio.mctic.gov.br/documents/566529/2303342/Parecer+T%C3%A9cnico+n%C2%BA+8038+-+2022/">http://ctnbio.mctic.gov.br/documents/566529/2303342/Parecer+T%C3%A9cnico+n%C2%BA+8038+-+2022/</a>	Intervention/Exposure
National Technical Commission on Biosafety (2022)	Technical Opinion No. 7988 - 2022	<a href="http://ctnbio.mctic.gov.br/documents/566529/2303872/Parecer+T%C3%A9cnico+n%C2%BA+7988+-+2022/">http://ctnbio.mctic.gov.br/documents/566529/2303872/Parecer+T%C3%A9cnico+n%C2%BA+7988+-+2022/</a>	Intervention/Exposure

<b>List of bibliographic references for all internet publications excluded from the risk assessment, classified by authors</b>			
<b>Study author(s) and year</b>	<b>Title</b>	<b>Source</b>	<b>Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 2</b>
Office of the Gene Technology Regulator (2021)	DIR 178 -- Risk assessment and risk management plan	<a href="https://www.ogtr.gov.au/sites/default/files/2021-09/dir178+-Full+Risk+Assessemnet+and+Risk+Mangement+Plan.pdf">https://www.ogtr.gov.au/sites/default/files/2021-09/dir178+-Full+Risk+Assessemnet+and+Risk+Mangement+Plan.pdf</a>	Intervention/Exposure
Office of the Gene Technology Regulator (2022)	DIR 186 -- Risk assessment and risk management plan	<a href="https://www.ogtr.gov.au/sites/default/files/2022-02/Full+Risk+Assessment+and+Risk+Management+Plan_1.pdf">https://www.ogtr.gov.au/sites/default/files/2022-02/Full+Risk+Assessment+and+Risk+Management+Plan_1.pdf</a>	Intervention/Exposure
Office of the Gene Technology Regulator (2022)	DIR 188 -- Risk assessment and risk management plan	<a href="https://www.ogtr.gov.au/sites/default/files/2022-06/dir188_full_risk_assessment_and_risk_management_plan.pdf">https://www.ogtr.gov.au/sites/default/files/2022-06/dir188_full_risk_assessment_and_risk_management_plan.pdf</a>	Intervention/Exposure
Office of the Gene Technology Regulator (2022)	DIR 189 -- Risk assessment and risk management plan	<a href="https://www.ogtr.gov.au/sites/default/files/2022-06/dir189_full_risk_assessment_and_risk_management_plan.pdf">https://www.ogtr.gov.au/sites/default/files/2022-06/dir189_full_risk_assessment_and_risk_management_plan.pdf</a>	Intervention/Exposure
Office of the Gene Technology Regulator (2022)	DIR 190 -- Risk assessment and risk management plan	<a href="https://www.ogtr.gov.au/sites/default/files/2022-06/dir190_risk_assessment_and_risk_management_plan_consultation_version.pdf">https://www.ogtr.gov.au/sites/default/files/2022-06/dir190_risk_assessment_and_risk_management_plan_consultation_version.pdf</a>	Intervention/Exposure
US Department of Agriculture (2021)	Non-Browning/PG451 -- Record of Categorical Exclusion Determination	<a href="https://www.aphis.usda.gov/brs/aphisdocs/20-213-01ext-roced.pdf">https://www.aphis.usda.gov/brs/aphisdocs/20-213-01ext-roced.pdf</a>	Intervention/Exposure
US Department of Agriculture (2021)	Non-Browning/PG451 -- Preliminary Plant Pest Risk Assessment	<a href="https://www.aphis.usda.gov/brs/aphisdocs/20-213-01ext_det-pprsa.pdf">https://www.aphis.usda.gov/brs/aphisdocs/20-213-01ext_det-pprsa.pdf</a>	Intervention/Exposure
US Department of Agriculture (2022)	GMB 151 -- Final Environmental Assessment	<a href="https://www.aphis.usda.gov/brs/aphisdocs/19-31701p-fea.pdf">https://www.aphis.usda.gov/brs/aphisdocs/19-31701p-fea.pdf</a>	Intervention/Exposure
US Department of Agriculture (2022)	GMB 151 -- Final Plant Pest Risk Assessment	<a href="https://www.aphis.usda.gov/brs/aphisdocs/19-31701p-fppra.pdf">https://www.aphis.usda.gov/brs/aphisdocs/19-31701p-fppra.pdf</a>	Intervention/Exposure
US Food and Drug Administration (2021)	Biotechnology Notification File No. 171 . Animal food use - CVM (Aug 11, 2021)	<a href="https://www.fda.gov/media/153928/download">https://www.fda.gov/media/153928/download</a>	Intervention/Exposure
US Food and Drug Administration (2021)	Biotechnology Notification File No. 171 . Human Food Use - CFSAN (Aug 17, 2021)	<a href="https://www.fda.gov/media/153927/download">https://www.fda.gov/media/153927/download</a>	Intervention/Exposure
US Food and Drug Administration (2021)	Biotechnology Notification File No. 166 . Animal food use - CVM (Jun 30, 2021)	<a href="https://www.fda.gov/media/151962/download">https://www.fda.gov/media/151962/download</a>	Intervention/Exposure
US Food and Drug Administration (2021)	Biotechnology Notification File No. 166 . Human Food Use - CFSAN (Jul 21, 2021)	<a href="https://www.fda.gov/media/151963/download">https://www.fda.gov/media/151963/download</a>	Intervention/Exposure

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<b>Study author(s) and year</b>	<b>Title</b>	<b>Source</b>	<b>Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 2</b>
US Food and Drug Administration (2021)	Biotechnology Notification File No. 168 . Animal food use - CVM (Oct 14, 2021)	<a href="https://www.fda.gov/media/154780/download">https://www.fda.gov/media/154780/download</a>	Intervention/Exposure
US Food and Drug Administration (2021)	Biotechnology Notification File No. 174 . Human Food Use - CFSAN (Aug 18, 2021)	<a href="https://www.fda.gov/media/154204/download">https://www.fda.gov/media/154204/download</a>	Intervention/Exposure
US Food and Drug Administration (2021)	Biotechnology Notification File No. 174 . Animal food use - CVM (Aug 13, 2021)	<a href="https://www.fda.gov/media/154205/download">https://www.fda.gov/media/154205/download</a>	Intervention/Exposure
US Food and Drug Administration (2021)	Biotechnology Notification File No. 168 . Human Food Use - CFSAN (Oct 20, 2021)	<a href="https://www.fda.gov/media/154779/download">https://www.fda.gov/media/154779/download</a>	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 172 . Human food use - CFSAN (Apr 25, 2022)	<a href="https://www.fda.gov/media/158266/download">https://www.fda.gov/media/158266/download</a>	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 165 . Animal food use - CVM (Mar 18, 2022)	<a href="https://www.fda.gov/media/157488/download">https://www.fda.gov/media/157488/download</a>	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 172 . Animal food use - CVM (Apr 4, 2022)	<a href="https://www.fda.gov/media/158267/download">https://www.fda.gov/media/158267/download</a>	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 162 . Human Food Use - CFSAN (Mar 24, 2022)	<a href="https://www.fda.gov/media/157484/download">https://www.fda.gov/media/157484/download</a>	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 162 . Animal food use - CVM (Mar 23, 2022)	<a href="https://www.fda.gov/media/157485/download">https://www.fda.gov/media/157485/download</a>	Intervention/Exposure
US Food and Drug Administration (2022)	Biotechnology Notification File No. 165 . Human Food Use - CFSAN (Mar 24, 2022)	<a href="https://www.fda.gov/media/157486/download">https://www.fda.gov/media/157486/download</a>	Intervention/Exposure

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

#### **4.4 List of the Bibliographic References for all Unobtainable Publications**

There were no publications classified as unobtainable.

#### **4.5 List of the Bibliographic References for all Unclear Publications**

There were no publications with unclear details.

#### **4.6 Full-Text Documents**

Full-text documents for all relevant records (Table 9) were compiled using a reference management software (.RIS format) and accompany this final report.

#### **4.7 Implications of Relevant Publications to the Risk Assessment of MIR604 maize**

For each relevant record, the reliability of the study and its implications on the risk assessment of MIR604 maize were assessed (Table 12). Overall, the relevant records reviewed do not indicate any new hazards, modified exposure pathways, or new scientific uncertainties for MIR604 maize. Therefore, we conclude, based on current available knowledge, that food/feed products derived from the event MIR604 maize and intended traits do not pose a risk to human/animal health and/or the environment.



**TABLE 12 Report of the reliability and implications for the risk assessment of all relevant internet publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement(s)**

<b>List of bibliographic references for all relevant internet publications, classified by category of information/data requirements</b>			
<b>Category of information/data requirement(s)</b>	<b>Study author(s) and year</b>	<b>Summary of reliability appraisal</b>	<b>Implications for the risk assessment</b>
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2022a)	Not assignable because no or insufficient information is reported in the study	This risk assessment is for 3272 x Bt11 x MIR162 x GA21 maize. It contains a summary of allergenicity/toxicity assessments for PMI ( <i>pmi</i> ), a closely related variant of MIR604 PMI. Based on this risk assessment, PMI does not pose a risk to human/animal health. No new information is introduced in this study and the evaluation does not change the risk assessment of MIR604.
Risk assessment or scientific opinion	National Technical Commission on Biosafety (2022b)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of 3272 maize which expresses PMI ( <i>pmi</i> ), a closely related variant of MIR604 PMI. It contains a summary of information on the history of safe use, allergenicity, and toxicity of PMI. Conclusions of the risk assessment indicate that PMI does not pose any risks to human/animal health. No new information is presented in this assessment and it does not change the risk assessment of MIR604 maize.
Risk assessment or scientific opinion	US Department of Agriculture (2021)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of PY203 corn that contains a short statement on the safety of PMI ( <i>manA</i> ), a closely related variant of MIR604 PMI, which concludes that "there are no identifiable risks to human health, livestock health, or wildlife presented by PMI." No new information is presented in this assessment and it does not change the risk assessment of MIR604 maize.
Risk assessment or scientific opinion	Health Canada (2021)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of DP-023211-2 maize and summarizes findings on the toxicity and allergenicity of PMI ( <i>pmi</i> ), a closely related variant of MIR604 PMI. Conclusions of the risk assessment indicate that no allergenicity or toxicological concerns were identified for PMI. No new information is presented and this does not change the risk assessment of MIR604 maize.
Risk assessment or scientific opinion	Health Canada (2022)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment of DP-915635 maize, which expresses PMI ( <i>pmi</i> ), a closely related variant of MIR604 PMI. It summarizes information on toxicity/allergenicity assessments of PMI. Conclusions of the risk assessment indicate no allergenicity or toxicological concerns were identified for PMI. No new information is presented in this assessment and it does not change the risk assessment of MIR604 maize.
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021a)	Not assignable because no or insufficient information is reported in the study	This is a risk assessment DP23211 maize, which expresses PMI ( <i>pmi</i> ), a closely related variant of MIR604 PMI. The assessment states that PMI has a history of safe use and is unlikely to be allergenic or toxic. This does not change the risk assessment of MIR604 maize.

List of bibliographic references for all relevant internet publications, classified by category of information/data requirements			
Category of information/data requirement(s)	Study author(s) and year	Summary of reliability appraisal	Implications for the risk assessment
Risk assessment or scientific opinion	Food Standards Australia New Zealand (2021b)	Not assignable because no or insufficient information is reported in the study	This is an approval report for DP23211 maize, which expresses PMI ( <i>pmi</i> ), a closely related variant of MIR604 PMI. The document states that FSANZ has previously assessed PMI protein for human/animal safety. This assessment contains no new information and does not change the risk assessment for MIR604 maize.

## 5.0 STUDY RECORDS

### 5.1 Records Maintained

Records maintained include, but are not limited to, documentation of database search dates, database update dates, resolution of differences of opinion on records, the protocol, and any protocol amendments or deviations.

### 5.2 Archiving of Study Records

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

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- ██████████ 2021c. *Review of Scientific Literature Relevant to the Food/Feed and Environmental Risk Assessment of GA21 Maize*. Report No: SSB-104-21 (unpublished). Syngenta Crop Protection, LLC. 65 pp.
- ██████████ 2021d. *Review of Scientific Literature Relevant to the Food/Feed and Environmental Risk Assessment of MIR162 Maize*. Report No: SSB-107-21 (unpublished). Syngenta Crop Protection, LLC. 65 pp.
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## APPENDICES SECTION

### APPENDIX A. Key Personnel Qualifications and Expertise

**Table A1 Key Personnel**

Name and Role	Qualifications and Expertise
<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 5px;"></div> Author & Record Reviewer	<ul style="list-style-type: none"> <li>• Ph.D. Veterinary Medical Sciences (Toxicology concentration), University of Florida</li> <li>• M.S. Coastal Sciences, University of Southern Mississippi</li> <li>• B.S. Biochemistry and Molecular Biology, Michigan Technological University</li> <li>• 6 years of experience in toxicology and molecular biology research (including experience with genetic manipulation of organisms)</li> </ul>
<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 5px;"></div> Record Reviewer	<ul style="list-style-type: none"> <li>• M.S. Environmental Assessment, North Carolina State University (NCSU)</li> <li>• Graduate Certificate in Applied Statistical Analysis &amp; Data Management, NCSU</li> <li>• B.S. Agronomy with concentrations in Agronomic Business and Turfgrass Management, NCSU</li> <li>• 18 years of experience in regulatory science and product safety of GM crops.</li> </ul>
<div style="background-color: black; width: 50px; height: 1.2em; margin-bottom: 5px;"></div> Tie-Breaker*	<ul style="list-style-type: none"> <li>• Ph.D. Pharmacology and Toxicology, West Virginia School of Medicine</li> <li>• B.M. Preventative Medicine, Shandong Medical University</li> <li>• Over 15 years of experience in research and development, regulatory science and product safety for GM crops</li> </ul>
<div style="background-color: black; width: 100px; height: 1.2em; margin-bottom: 5px;"></div> Information Specialist	<ul style="list-style-type: none"> <li>• MLIS (Master of Library and Information Science), UNC Greensboro</li> <li>• M.A., Wake Forest University</li> <li>• B.A., East Carolina University</li> <li>• 23 years of experience as a librarian at Colleges, Universities, and Private Research Libraries</li> <li>• Library Services for Syngenta Crop Protection since 2008</li> </ul>

\*The role of tie-breaker was assigned prior to starting the study. However, all conflicts were resolved by the reviewers and a tie-breaker was not needed. Therefore, the tie-breaker listed here did not participate in this study.

## APPENDIX B. Pilot Study

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

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

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



## APPENDIX C. Database Information

**TABLE C1 Specifications of each database used in this study\***

Database	Database Description	No. of Journals/Records	Dates of Coverage	Frequency of Database Updates in Ovid
Ovid Medline	Database comprised of international literature related to a variety of biomedicine topics related to human health. Produced by the National Library of Medicine.	>5,600 Journals/ >23 Million Records	1946-Present	Daily
CAB Abstracts	Database constructed by CAB International. Includes journal articles, conference abstracts, and reports spanning a wide variety of topics in the life sciences that include (but are not limited to) agriculture, human health/nutrition, veterinary sciences, and natural resource management. Resources originate from over 120 countries.	>10.4 Million Records	1910-Present	Weekly
AGRICOLA	Database specializing in resources from agricultural and related sciences. Contains records from journal articles, book chapters, reports, and reprints. Developed by the National Agriculture Library (USDA). The article database provides citations to journal articles, book chapters, reports, and reprints.”	>5.2 Million Records	1970-Present	Monthly
BIOSIS Previews	Database covering a broad array of topics in the life sciences, and includes many publications and journals not found in Medline. Topics include a comprehensive coverage of biological, biochemical, biophysical, bioengineering, and biomedical research. Records include original research articles, national and international conferences, reviews, technical letters and notes, and books.	>5,000 Journals/ >18 Million Records	1969 -Present	Weekly

\*Information on these databases was retrieved from the Wolters Kluwer group, which hosts Ovid® Technologies. Additional information (i.e., sources for data) can be obtained upon request. (Medline: <https://www.wolterskluwer.com/en/solutions/ovid/ovid-medline-901>, CAB Abstracts: <https://www.wolterskluwer.com/en/solutions/ovid/cab-abstracts-31>, AGRICOLA: <https://www.wolterskluwer.com/en/solutions/ovid/agricola-9>, BIOSIS Previews: <https://www.wolterskluwer.com/en/solutions/ovid/biosis-previews-26>)

## APPENDIX D. Development of the Database Search Strategy

The database search strategy utilized a “lumping” approach to obtain a broad range of information related to MIR604 maize and the newly expressed proteins. A single search strategy was developed to capture all categories of information in one search. This strategy was expected to return a manageable number of records while still capturing the breadth of relevant information, based on previous experience.

### D.1. Search terms

Search terms were identified by:

- Assessing the subject indexing terms of related, relevant publications<sup>1</sup> from the thesauri of electronic bibliographic databases.
- Seeking suggestions from a multi-disciplinary team of experts and stakeholders (i.e., risk assessors, information specialists, regulatory affairs managers).

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

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

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

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

<sup>1</sup> Relevant publications from previous literature search reports (that comply with the EFSA explanatory note on literature searching (EFSA, 2019)) were examined to identify associated subject indexing terms.

<sup>2</sup> 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.

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

Similarly, controlled vocabulary fields can also be called using combined search terms. Thus, a search strategy that uses “genetic\* AND (modif\* OR engineer\*)” will also return all records indexed to the above example fields (words captured by the search terms are indicated by bold font).

### D.3. Free-text searching functions

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

### D.4. Search strings

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

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

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

Therefore, the search structure was built to identify records that contained some or all of the four main concepts/key elements (Event, Trade Name, Newly Expressed Protein(s), and Intended Trait) and terms describing plant species and/or GMO general terms. The search strategy employed was:

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

The search strategy employed captured literature relevant to MIR604 maize and is provided in Table 4 of the main report text. The same search string was used in all databases. Since the Ovid search platform simultaneously searches free-text and subject headings there is no disadvantage to using all search terms in all databases. For example, if ‘Genetically engineered organisms’ is a subject heading in CAB Abstracts, but not in Agricola, including this term in the search of the Agricola databases still allows for free-text searching of this term.

## APPENDIX E. Reference Publications

Reference publications were used to assess the performance of the database search strategy before it was finalized. Reference publications were selected from relevant records identified in previous years' literature reviews on the risk assessment of MIR604 maize. If there were few or no known relevant records, publications that contained information on one or more key elements of the review question (i.e., event, newly expressed proteins, and/or intended traits), but would otherwise be considered irrelevant in this study, were used as reference publications. This ensured the search strategy was capable of retrieving the breadth of available information for the risk assessment of MIR604 maize.

The search strategy was assessed by obtaining a preliminary set of results using the methods outlined in Section 3.2.1. No date limits were applied to this search in order to capture the known reference publications from previous years. The presence/absence of reference publications within the preliminary search results was recorded for each database (Table E1). In total, 100% of the reference publications were retrieved using this search strategy. Therefore, the search strategy was considered sufficient for capturing the breadth of relevant literature available for this topic.

**TABLE E1. Reference publication retrieval using the database search strategy**


<b>Reason for Selection: Key concepts of the review question that are covered by the reference are noted in parentheses (event, newly expressed proteins, and intended traits)</b>	<b>Reference</b>	<b>Agricola</b>	<b>BIOSIS Previews</b>	<b>CAB Abstracts</b>	<b>Medline</b>
A risk assessment and bioinformatics analysis of PMI (newly expressed protein)	Herman <i>et al.</i> (2021)			X	
Evaluated phenotypic effects of expressing PMI (newly expressed protein) in transgenic crops	Zhang <i>et al.</i> (2015)	X	X	X	X
Summarizes data that characterizes mCry3A (newly expressed protein)	Walters <i>et al.</i> (2020)	X	X	X	X
Discusses risk assessment of insect-resistant transgenic crops (intended traits)	Raybould <i>et al.</i> (2012)	X	X	X	X
Risk assessment of MIR604 maize (event) with special focus on mCry3A (newly expressed protein) used for insect control (intended traits)	Raybould <i>et al.</i> (2007)	X	X	X	
Number of articles identified in each database		4	4	5	3
Percentage of articles identified in each database		80%	80%	100%	60%

## **APPENDIX F. Search History and Subject Indexing**

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▼ Search History (13)





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<input type="checkbox"/>	# ▲	Searches	Results	Type	Actions	Annotations
<input type="checkbox"/>	1	(MIR604 or MIR 604 or SYN-IR6#4-5).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	27	Advanced	<a href="#">Display Results</a>   <a href="#">More</a>	 <a href="#">Contract</a>
<input type="checkbox"/>	2	(Agrisure* adj2 RW*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	0	Advanced	<a href="#">Save</a>   <a href="#">More</a>	
<input type="checkbox"/>	3	(mCry3A* or mCry 3A* or mCry 3 A* or Cry3A* or Cry 3A* or Cry 3 A*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	170	Advanced	<a href="#">Display Results</a>   <a href="#">More</a>	
<input type="checkbox"/>	4	(Phosphomannoisomerase or Mannose 6-phosphate isomerase or Phosphomannoseisomerase or Phosphomannose isomerase or 9023-88-5 or AAA24109 or "EC 5.3.1.8" or "E.C. 5.3.1.8").mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	150	Advanced	<a href="#">Display Results</a>   <a href="#">More</a>	
<input type="checkbox"/>	5	3 or 4	320	Advanced	<a href="#">Display Results</a>   <a href="#">More</a>	
<input type="checkbox"/>	6	((((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).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	78132	Advanced	<a href="#">Display Results</a>   <a href="#">More</a>	
<input type="checkbox"/>	7	(GMO* or LMO* or GM or GE or transgen* or ((genetic* or living or biotech*) adj3 (modif* or transform* or manipul* or improv* or engineer* or deriv*))).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	112025	Advanced	<a href="#">Display Results</a>   <a href="#">More</a>	
<input type="checkbox"/>	8	(Maize* or corn* or Zea mays or Z mays).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]	180958	Advanced	<a href="#">Display Results</a>   <a href="#">More</a>	
<input type="checkbox"/>	9	((((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or	1261	Advanced	<a href="#">Display Results</a>   <a href="#">More</a>	

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Ovid: Search Form

AGRICOLA


corn* or mays)) or Btmaize* or Btcorn*).mp. [mp=meeting information, title, original title, map information, note, abstract, heading words]					
<input type="checkbox"/>	10	5 and (7 or 8)	176	Advanced	<a href="#">Display Results</a> <a href="#">More</a> 
<input type="checkbox"/>	11	6 and 7 and 8	1535	Advanced	<a href="#">Display Results</a> <a href="#">More</a> 
<input type="checkbox"/>	12	1 or 2 or 10 or 11 or 9	1970	Advanced	<a href="#">Display Results</a> <a href="#">More</a> 
<input type="checkbox"/>	13	limit 12 to yr="2021 -Current"	98	Advanced	<a href="#">Display Results</a> <a href="#">More</a> 

Save Remove Combine with: AND OR

Save All Edit Create RSS Create Auto-Alert Email All Search History Copy Search History Link Copy Search History Details View Saved

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


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

 **AGRICOLA** 1970 to June 2022

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

☒ Keyword ☐ Author ☐ Title ☐ Journal

Search

 **Limits** *(expand)*

☐ Include Multimedia ☒ Map Term to Subject Heading

Options

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Search Information

You searched:

Print Email Export + My Projects Keep Selected

☐ All Range Clear  5 Per Page 1 Go Next

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

 Cite  + My Projects  + Annotate

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limit 12 to yr="2021 -Current"

Search terms used:

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bacillus  
biotech\*  
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btcorn\*  
btmaize\*  
coleoptera\*  
control\*  
corn\*  
cry  
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3a\*  
cry3a\*  
d  
barberi  
virgifera  
deriv\*  
diabrotica  
e.c.  
5.3.1.8  
ec  
engineer\*  
ge  
genetic\*  
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gmo\*  
improv\*  
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insects  
living  
lmo\*  
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Ovid: Search Form

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

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

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

 Cite  + My Projects  + Annotate

- ☐ 5. [Performance of Bt maize event MON810 in controlling maize stem borers Chilo partellus and Busseola fusca in Uganda](#)

 Cite  + My Projects  + Annotate



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<https://ovidsp.dc2.ovid.com/ovid-a/ovidweb.cgi>

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Ovid: Search Form

BIOSIS

<input type="checkbox"/>	9	(((Bt or Bacillus thuringiensis or B thuringiensis) adj5 (maize* or corn* or mays)) or Btmaize* or Btcorn*).mp. [mp=abstract, original language book title (non-english), book title (english), title, heading words]	2644	Advanced	<a href="#">Display Results</a> <a href="#">More</a>	
<input type="checkbox"/>	10	5 and (7 or 8)	434	Advanced	<a href="#">Display Results</a> <a href="#">More</a>	
<input type="checkbox"/>	11	6 and 7 and 8	4048	Advanced	<a href="#">Display Results</a> <a href="#">More</a>	
<input type="checkbox"/>	12	1 or 2 or 10 or 11 or 9	5472	Advanced	<a href="#">Display Results</a> <a href="#">More</a>	
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Email All Search History Copy Search History Link Copy Search History Details

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

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

**BIOSIS Previews** 1969 to 2022 Week 31

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

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

Search

**Limits** *(expand)*

☐ Include Multimedia ☐ Map Term to Subject Heading

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☐ 1. **Transgenerational responses to heat and fasting acclimation in the Angoumois grain moth**

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**You searched:**  
limit 12 to yr="2021 -Current"

**Search terms used:**  
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604  
9023-88-5  
aaa24109  
agrisure\*  
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bacillus  
biotech\*  
bt  
btcorn\*  
btmaize\*  
coleoptera\*  
control\*  
corn\*  
cry  
a\*  
3a\*  
cry3a\*  
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barberi  
virgifera  
deriv\*  
diabrotica  
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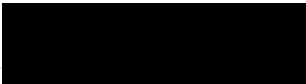
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