Appendix 3. Literature search for annual monitoring on the general surveillance of Bayer GM maize in the EU

APPENDIX 3

LITERATURE SEARCH TO SUPPORT GENERAL SURVEILLANCE OF 2019/2020 ANNUAL POST MARKET ENVIRONMENTAL MONITORING REPORTS OF BAYER GM MAIZE PRODUCTS

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SUMMARY

This literature search was conducted to support general surveillance of 2019/2020 annual post market environmental monitoring reports in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019). It addresses the review question "Do Bayer GM maize products, derived food/feed products and their respective introduced traits have adverse effects on human and animal health and the environment?".

In accordance with the 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019), eligibility/inclusion criteria to establish the relevance of retrieved publications was determined. Two electronic bibliographic databases (SciSearch and CABA databases) were selected for the literature search. Search strategies were developed together with an information specialist to perform the searches. In addition, literature searches were conducted in internet pages of relevant key organisations for Bayer GM maize products.

The literature search covered the time span 2019 – 2020 and retrieved 383 and 229 hits in SciSearch and CABA databases, respectively, and a total of 51 records in the internet pages of the relevant key organisations. From these, 13 publications were identified as relevant. These publications did not have any implication on the risk assessment, because no new hazard, modified exposure, or new scientific uncertainty is reported.

The comprehensive literature search found no new information that would invalidate the conclusions of the risk assessment for Bayer GM maize products.

1. INTRODUCTION

As part of the general surveillance requirements for Bayer GM maize products authorised in the European Union (EU) market under regulation (EC) No 1829/2003, Bayer Agriculture BV[1] has actively monitored the maize products by conducting quarterly literature searches covering the time span between June 2019 and May 2020.

The results of the literature search that were analysed in detail according to the relevance for the risk assessment of the Bayer GM maize products are presented here.

The completed form of EFSA Appendix E completeness checklist (EFSA, 2019) is provided as an attachment to this report.

2. FORMULATING THE REVIEW QUESTION AND CLARIFYING ITS PURPOSE

This literature search has been conducted to address the review question "Do Bayer GM maize products, derived food/feed products and respective introduced traits have adverse effects on human and animal health and the environment?"

The purpose for undertaking this literature search is to support general surveillance of 2019/2020 annual post market environmental monitoring (PMEM) reports in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019).

Key elements used for the review question are humans, animals, and/or the environment (= population), Bayer GM maize products, derived food/feed products and respective introduced traits (= intervention/exposure), conventional counterpart or non-GM maize (= comparator), and adverse effect on human and animal health, and the environment (= outcomes). Accordingly, the eligibility criteria for assessing the relevance of publications for inclusion in the literature review are provided in **Table 1**.

[1] Hereafter, referenced as Bayer

Table 1. Eligibility/inclusion criteria to establish the relevance of publications

Key elements	Criteria
Population	Humans, animals and the environment (taking into account the scope of the applications) *i.e.* authorisation for all uses as any other maize but excluding the cultivation of Bayer GM maize products are addressed as general protection goals.
Intervention/exposure	Bayer GM maize products derived food/feed products and corresponding introduced traits addressed in the publication are identical or similar to those under scientific review by the EFSA.
Comparator	In case of a comparative study that uses the GM plant material as test material, eligible publications must report a non-GM maize as a comparator.
Outcomes	Adverse effects on human and animal health and the environment are addressed (taking into consideration the scope of the applications).
	Additional key elements
Stacked events / sub-combinations	The single events addressed in the publication are the single events in stacked Bayer GM maize products. Stacked Bayer GM maize products or any of their sub-combinations is addressed in the study.
Information/ data requirements, including source of publications data	The publication potentially contributes to the knowledge of the risk assessment of Bayer GM maize products intended for all uses as any other maize but excluding cultivation. Original/primary data are presented in the publication.

3. SEARCHING FOR/ IDENTIFYING RELEVANT PUBLICATIONS

In accordance with the 2010 EFSA Guidance on application of systematic review methodology to food and feed safety assessments to support decision making (EFSA, 2010) and the 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019), identification of bibliographic sources and development of search strategies was developed together with an information specialist who subsequently performed the literature search. The approach used to develop the search strategy follows a lumping method and includes a wide range of free-text terms and where available, controlled vocabulary that defines search terms.

3.1. Sources of scientific literature

3.1.1. Electronic bibliographic databases

Bayer selects the SciSearch (Science Citation Index)[2] and the CABA[3] (CAB Abstracts®)[4] databases to perform the literature search based on the coverage and relevance of the journals included in these databases. The literature search was conducted using the STN® database catalogue[5].

The SciSearch, produced by from Clarivate Analytics (UK) Limited, includes over 45 million records in Science and technology published since 1974. It includes literatures captured under Science Citation Index Expanded™, a largest multidisciplinary scientific database and an international index covering all scientific topics. It contains also all the records published from the Current Contents series of publications as well as bibliographic information and cited references from over 5 600 scientific, technical and medical journals. In addition, "*Records from January 1991 on include abstracts, author keywords, and KeyWords Plus®. Bibliographic information, authors, cited references, and KeyWords Plus® are searchable*"[3]. The database is updated on a weekly basis.

The CABA, produced by CAB international (UK), includes over 8.9 million records in agriculture and life sciences published since 1973. The database "*covers worldwide literature from all areas of agriculture and related sciences including biotechnology, forestry, and veterinary medicine. Sources for CABA include journals, books, reports, published theses, conference proceedings, and patents. Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are searchable. An online thesaurus is available for the Con-trolled Term (/CT), the Geographic term (/GT), and the Organism (/ORGN) fields*". The database is updated on a weekly basis.

All journals included in the two databases must go through a verification process and as a minimum requirement, non-English language journals must include English-language bibliographic information (title, abstract, keywords) and be peer-reviewed[5,6]. In general, English is considered the universal language of science. For this reason, the journals most important to the international research community will publish either full text or a minimum of bibliographic information in English, which is especially true in the

[2] SciSearch: http://www.stn-international.de/sites/default/files/STN/summary-sheets/SCISEARCH.pdf - Accessed on 2 September 2020

[3] CABA: http://www.stn-international.de/sites/default/files/STN/summary-sheets/CABA.pdf– Accessed on 2 September 2020

[4] CAB Abstracts®: https://www.cabi.org/publishing-products/online-information-resources/cab-abstracts/ - Accessed on 14 July 2020

[5] STN®: http://www.stn-international.de/stnbrochures_gi.html - Accessed on 14 July 2020

[6] Web of Science group; https://clarivate.com/webofsciencegroup/solutions/webofscience-core-collection-editorial-selection-process/ - Accessed on 14 July 2020

scientific domain of natural sciences. Full text in English is highly desirable if the journal intends to serve an international community of researchers. Therefore, it is expected that even if there is a relevant article for the food and feed safety of GM plants in a language different than English, the article will include title/abstract/keywords in English, which will guarantee the retrievability of these articles when using keywords and keyword combinations in English.

Based on the above, the selected databases are, to our knowledge, comprehensive, multidisciplinary, conservative sources for literature searching and offer the broadest coverage to retrieve a largest breadth of possible relevant publications. Therefore, additional search sources are not deemed necessary.

3.1.2. Internet (world-wide-web) pages of relevant key organisations

In accordance with the 2019 Explanatory note on literature searching for GMO applications (EFSA, 2019), the search in electronic bibliographic databases has been complemented with internet search in webpages of relevant key organisations involved in the risk assessment of GM plants.

Of the 14 key organisations cited in the 2019 Explanatory note on literature searching for GMO applications (EFSA, 2019), nine[7] are involved in risk assessment of Bayer GM maize products. Three of the remaining five (CIBIOGEM, Environment and Climate Change Canada and OECD) are not involved in GM risk assessment while the other two (OGTR and GEAC), for the time being, only assess GM cotton and oilseed rape. Therefore, the internet search focused on the nine key organisations relevant for Bayer GM maize products.

3.2. Search strategy (electronic databases)

3.2.1. Search terms and search strings

The intervention/exposure key elements were defined and translated into search terms. These search terms were identified following the below listed approaches in line with the 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019):

- assessing words in reference publications,
- assessing subject indexing terms,
- searching for synonyms and related terms and
- consulting experts and stakeholders.

Following the aforementioned approaches, possible synonyms, related terms, abbreviations including acronyms and truncations, old and new as well as lay and scientific terminologies, brand and generic names, and spelling variants including common typos of the search terms were considered. Where applicable, the search was also adapted to controlled vocabulary (subject indexing). The search terms were designed

[7] Internet pages of the relevant key organisations for Bayer GM maize products:
US EPA (https://www.epa.gov/environmental-topics/science-topics) - Accessed on 14 July 2020;
USDA (https://www.usda.gov/media) - Accessed on 14 July 2020;
US FDA (https://www.fda.gov/) - Accessed on 14 July 2020
CFIA (http://www.inspection.gc.ca/eng/1297964599443/1297965645317) - Accessed on 14 July 2020;
Health Canada (https://www.canada.ca/en/health-canada.html) - Accessed on 14 July 2020;
FSANZ (http://www.foodstandards.gov.au/Pages/default.aspx) - Accessed on 14 July 2020;
CTNBio (http://ctnbio.mctic.gov.br/) - Accessed on 14 July 2020;
CONABIA (https://www.argentina.gob.ar/) - Accessed on 14 July 2020;
Japan MAFF (http://www.maff.go.jp/e/) - Accessed on 14 July 2020.

to give an excellent coverage and retrieve the broadest possible number of articles related to Bayer GM maize products.

Annex I presents the translation of the intervention key elements into search terms. The search terms, the fields and the Boolean operators used to combine them were defined as shown in **Annex II**. The search strings were built following the STN® commands (Karlsruhe, 2007) to allow the literature search in the STN® database catalogue. The free-text search terms, controlled vocabulary and the search strings are updated upon identification of a new search term.

The search sets belonging to each key element as described in **Annex I** and **Annex** II were combined by 'OR' to retrieve all the identified publications excluding duplicates. The separate assessment of these search sets, including those yielding only a small number of publications, was considered not necessary as this would duplicate the literature screening process and alter the consistency and comprehensiveness used in the literature search strategies.

3.2.2. Limits applied

An advanced literature search was conducted using the web-based STN® database catalogue for both the selected electronic databases (*see* section 3.1.1). STN® enables searching in each electronic database by making use of pre-defined fields, set combinations based on Boolean operators or a combination of both[8].In STN®, the results of the search from each database can be merged and duplicates can be removed by de-duplication.

The STN® literature search utilised "Basic Index" (None (or /BI)) field which utilises free-text search terms and enables comprehensive searching in different sections (*e.g.* title, abstract, keywords, supplementary terms, controlled terms) within a record (Karlsruhe, 2007; STN, 2018a, 2018b). Where applicable, controlled vocabulary (subject indexes) offered by CABA (controlled terms (CT)) were also included in the search strategy. Controlled vocabulary is assigned by subject specialists to CAB records to represent the content of the source documents. It allows users to use only one term to search for a concept rather than using lots of terms[9]. The most relevant, broad and controlled terms in the hierarchy of CAB Thesaurus terms and that were listed as preferred terms by CAB for a search query were selected and added to the search string, as shown in **Annex I** and **Annex** II.

3.2.3. Language

The search terms and their combinations are established in English. Therefore, the search is expected to result in a list of titles, abstracts or keywords written in English, covering also articles written in other languages with at least a title, abstract or keywords in English. Also, as technical terms on proteins names, event codes, trade names and Latin names are common in all languages, the search is expected to retrieve articles in all languages.

3.2.4. Time period

The literature searches covered the time span 1 May 2019 - 28 May 2020.

[8] STNindex user guide: https://stn.products.fiz-karlsruhe.de/training-center/documentation/stn-index-user-guide- Accessed on 2 September 2020

[9] CAB Direct advanced searching of CAB abstracts: https://www.cabi.org/Uploads/CABI/publishing/training-materials/resources-by-interface/cab-direct-user-guides/advanced-searching-cab-abstracts.pdf - Accessed on 14 July 2020

The literature search in the electronic databases was conducted on a quarterly basis considering the entry dates in the STN® database catalogue. **Table 2** shows the search dates and the time span of each search.

Table 2. Description of literature search periods in the electronic databases

Date of the search[1]	Last database update dates	Search period
04 October 2019	SciSearch: 30 September 2019	01 May 2019 – 04 October 2019
	CABA: 02 October 2019	01 May 2019 – 04 October 2019
18 February 2020	SciSearch: 18 February 2020	04 Oct 2019 – 21 January 2020
	CABA: 13 February 2020	04 Oct 2019 – 21 January 2020
01 June 2020	SciSearch: 28 May 2020	22 January 2020– 28 May 2020
	CABA: 29 May 2020	22 January 2020 – 28 May 2020

[1] The literature search in the electronic databases was conducted on a quarterly basis considering the entry dates in the STN® database catalogue. In addition, a final literature search was also conducted covering the full-time span of the season (01 May 2019 – 28 May 2020) on 22 June 2020. The search result presented in **Annex** II shows the final search covering the full-time span of the 2019-2020 season.

The literature search in the internet pages of the relevant key organisations was conducted on 21 July 2020 and 24 August 2020.

3.2.5. Reference publications

In accordance with the 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019), reference publications that are relevant to answer the review question and are within the scope of the applications shall be used for identifying search terms as well as validating the search strategy. A list of reference publications, complying with the above criteria and used in validating the search strategy as part of the protocol development are provided in **Annex III**.

3.3. Search strategy (relevant key organisations)

Information regarding the selection process for relevant records in the webpages are shown in **Annex IV**. For the selection of relevant publications, all records concerning GMO applications and approvals published in the webpage of each relevant key organisation were screened based on 'limits applied' as described in the **Annex IV**. Afterwards, all the records within the specified limits were assessed for their relevance to Bayer GM maize products.

4. SELECTING PUBLICATIONS

Publications retrieved from the literature search were screened for their relevance first and then the selected ones were evaluated for their reliability through detailed assessments. Relevance to the search scope and scientific reliability were rigorously assessed by internal and external technical experts.

4.1. Eligibility screening process

The process of selecting relevant publications was undertaken in two stages:

- ***Rapid assessment*** for the relevance based on information in the title and abstract of the publications, to exclude publications that are obviously irrelevant.
- ***Detailed assessment*** of full-text document if required. Full-text documents were obtained for those publications not excluded in the rapid assessment and those documents were assessed in detail for their relevance to the review question. Publications not excluded by the detailed assessment were classified as relevant. At this stage, publications must comply with all the eligibility/inclusion criteria and meet all key elements of the review question.

Experts with a solid experience in GM plants risk assessment performed the screening process. Based on the available comprehensive weight of evidence, the experts assessed if the conclusions of the risk assessment are still valid.

4.2. Reviewers

All publications that were identified by the search described in **Section 3** have been screened by three different reviewers (one internal and two external experts) with solid experience in the risk assessment of GM plants.

In case of disagreements on eligibility for the inclusion of publications, the reviewers, discuss together. If uncertainty remains, the publication is *de facto* included for further consideration.

4.3. Classification of publications

Taking account of i) the review question, ii) the scope of the application, *i.e.* authorisation of Bayer GM maize products for all uses as any other maize but excluding cultivation in the EU and iii) the eligibility criteria to establish the relevance of retrieved publications, the list of retrieved hits was assessed to conclude whether a certain publication was considered relevant or not. When a publication was considered relevant, the category the publication belongs to is indicated. The following is a non-exhaustive list of categories publications may belong to:

Food/Feed safety assessment

- Molecular characterisation
- Protein expression
- Crop composition
- Agronomic and phenotypic characteristics
- Toxicology - Animal feeding / *In vitro*
- Allergenicity of the protein or the whole food/feed
- Nutrition
- Protein / DNA/ RNA fate in digestive tract

Environmental safety assessment

- Spillage and consequences thereof

It should be noted that the selection criteria are well defined and reassessed annually.

4.4. Quality appraisal of the relevant publications

The relevant publications, if identified, are appraised in terms of reliability in accordance with the 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019) by at least two individuals with technical expertise on the topic. In cases of disagreements, the evaluators discuss together and collectively determine the reliability of the publication. For the list of reliability categories, *see* **Annex V**.

5. SUMMARISING AND REPORTING THE DATA, AND CONSIDERING THE IMPLICATIONS OF THE FINDINGS

5.1. Search outcomes

5.1.1. Outcomes of literature search (electronic databases)

The literature searches identified 383 and 229 hits in SciSearch and CABA databases, respectively (*see* **Annex II**). After de-duplication, the total number resulted in 490 hits.

5.1.2. Outcomes of literature search (relevant key organisations)

The literature search in the internet pages of the nine relevant key organisations retrieved a total of 51 records. The links to the results of the literature search and the summary of the retrieved data are shown in **Annex IV**.

5.2. Results of the publication selection process

5.2.1. Results of the publication selection process (electronic databases)

The results of the publication selection process for the retrieved hits from the electronic databases are provided in **Annex V**. Ten relevant publications were retrieved after detailed assessment of the full text documents. For bibliographic details regarding these publications in .RIS format, *see* **Annex VI**. For the full-text documents of the relevant publications, *see* the references folder within the literature searching folder.

5.2.2. Results of the publication selection process (relevant key organisations)

The results of the publication selection process for the retrieved records from the relevant key organisations are provided in **Annex IV**. A total of three records were identified as relevant. For the full-text documents of the relevant publications, *see* the references folder within the literature searching folder.

5.3. Implication/(s) of the retrieved relevant publications for the risk assessment

The comprehensive literature search relevant to the food, feed, and environmental safety of Bayer GM maize products found no new information that would invalidate the conclusions of the risk assessment for Bayer GM maize products.

The relevant publications as well as their reliability and implications for the risk assessment are provided in **Annex V.**

6. CONCLUSION

Taking into consideration all the above, Bayer confirms that this literature search, conducted to support the general surveillance in the context of 2019/2020 annual PMEM for Bayer GM maize products, in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019), identified no relevant publications that would invalidate the initial conclusions of the Bayer GM maize products

risk assessment. Therefore, the conclusions of the risk assessment as presented in the initial applications of the Bayer GM maize products remain unchanged.

REFERENCES

References highlighted in grey are EFSA publications. Therefore, their pdfs are not provided.

EFSA, 2010. Application of systematic review methodology to food and feed safety assessments to support decision making The EFSA Journal, 1637, 1-90.

EFSA, 2019. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market - Note on literature searching to GMO risk assessment guidance. EFSA journal, 2019:EN-1614, 1-62.

Karlsruhe F 2007. Command Summary Chart for bibliographic and full-text databases. 1-26.

STN 2018a. CABA. 1-12.

STN 2018b. SciSearch - Science Citation Index. 1-8.

Annex I. Translation of intervention/exposure key elements into search terms for Bayer GM maize products literature search in STN® database catalogue

1. Free-text search terms for Bayer GM Maize products

Key elements	Search terms	Synonyms, related terms, abbreviations/ acronyms/ truncations, lay/ scientific terms, brand/ generic names and spelling variants/ typos (adapted for performing search in STN® database catalogue)
Event names	MON 810 or MON-ØØ81Ø-6 NK603 or MON-ØØ6Ø3-6 MON 88017 or MON-88Ø17-3 MON 89034 or MON-89Ø34-3 MON 87460 or MON 8746Ø-4 MON 87427 or MON-87427-7 MON 87411 or MON-87411-9 MON 87403 or MON-874Ø3-1 TC1507 or 1507 or DAS-Ø15Ø7-1 59122 or DAS-59122-7 T25 or ACS-ZMØØ3-2	MON 810? OR MON810? OR MON!810? OR MON 00810? OR MON00810? OR MON!00810? OR MON OO81O? OR MONOO81O? OR MON!OO81O? OR MON EMPTY SETEMPTY SET81EMPTY SET? OR MON!EMPTY SETEMPTY SET81EMPTY SET? OR MONEMPTY SETEMPTY SET81EMPTY SET? OR NK603 OR NK 603 MON 00603? OR MON!00603? OR MON00603? OR MON OO6O3? OR MONOO6O3? OR MON!OO6O3? OR MON EMPTY SETEMPTY SET6EMPTY SET3? OR MON!EMPTY SETEMPTY SET6EMPTY SET3? OR MONEMPTY SETEMPTY SET6EMPTY SET3? MON 88017? OR MON!88017? OR MON88017? OR MON 88O17? OR MON!88O17? OR MON88O17? OR MON 88EMPTY SET17? OR MON!88EMPTY SET17? OR MON88EMPTY SET17? MON 89034? OR MON!89034? OR MON89034? OR MON 89O34? OR MON!89O34? OR MON89O34? OR MON 89EMPTY SET34? OR MON!89EMPTY SET34? OR MON89EMPTY SET34? MON 87460? OR MON!87460? OR MON87460? OR MON 8746O? OR MON!8746O? OR MON8746O? OR MON 8746EMPTY SET? OR MON!8746EMPTY SET? OR MON8746EMPTY SET? OR MON 87427? OR MON!87427? OR MON87427? OR MON 87411? OR MON!87411? OR MON87411? MON 87403? OR MON!87403? OR MON87403? OR MON 874O3? OR MON!874O3? OR MON874O3? OR MON 874EMPTY SET3? OR MON!874EMPTY SET3? OR MON874EMPTY SET3? 1507 OR 15O7 OR 15EMPTYSET7 OR TC1507 OR TC15O7 OR TC15EMPTYSET7 OR DAS 01507? OR DAS!01507? OR DAS01507? OR DAS O15O7? OR DAS!O15O7? OR DASO15O7?

		OR DAS EMPTY SET15EMPTY SET7? OR DAS!EMPTY SET15EMPTY SET7? OR DASEMPTY SET15EMPTY SET7? OR 59122 OR DAS 59122? OR DAS!59122? OR DAS59122? OR T25 OR ACS ZM003? OR ACS!ZM003? OR ACSZM003? OR ACS ZMOO3? OR ACS!ZMOO3? OR ACSZMOO3? OR ACS ZMEMPTY SET EMPTY SET3? OR ACS!ZMEMPTY SET EMPTY SET3? OR ACSZMEMPTY SET EMPTY SET3?
Trade names	YieldGard® Corn Borer Roundup Ready® 2 YieldGard VT Rootworm/RR2® YieldGard® VT® PRO® DroughtGard® Hybrids Herculex™ I, Herculex™ CB Herculex™ RW Liberty Link™ Maize YieldGard® VT ® Triple® Genuity® VT Triple PRO® Genuity® VT Double PRO™ Genuity® PowerCore® SmartStax® Genuity® VT Double Pro® with Roundup® Hybridization System	YIELD GARD? OR YIELDG? OR YIELD!GARD? OR YIELDGARD? OR ROUNDUPREADY? OR ROUND UP READY? OR ROUND!UP!READY? OR ROUND!UP READY? OR ROUNDUP READY? OR RR2? OR RRII? OR VT? PRO? OR VT! PRO OR VT PRO? OR VT!PRO? OR VTPRO? OR DROUGHTGARD? OR DROUGHT GARD? OR HERCULEX? LIBERTY LINK? OR LIBERTYLINK? OR LIBERTY!LINK OR VT? TRIPLE? OR VTTRIPLE? OR VT!TRIPLE? OR VT TRIPLE? OR VT DOUBLE PRO? OR VT DOUBLEPRO? OR VTDOUBLE PRO? OR VTDOUBLEPRO? OR VT!DOUBLE PRO? OR VT DOUBLEPRO? OR VT!DOUBLEPRO? OR VT!2!PRO? OR VT 2 PRO? OR POWER CORE? OR POWERCORE? SMARTSTAX? OR SMART STAX? OR SMART!STAX? OR RHS OR HYBRIDIZATION SYSTEM
Newly expressed proteins	CP4 EPSPS CP4 EPSPS L214P PAT Cry1Ab Cry1A.105	CP4EPSPS? OR CP4 EPSPS? OR 5(W)(ENOLPYRUVYLSHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYLSHIKIMATE OR ENOL!PYRUVYL! SHIKIMATE!)(W)3 PHOSPHATE SYNTHASE OR PAT OR PHOSPHINOTHRICIN OR N!ACETYLTRANSFERASE OR N!ACETYL TRANSFERASE OR N!ACETYL!TRANSFERASE OR N ACETYL TRANSFERASE OR N ACETYL!TRANSFERASE OR N ACETYLTRANSFERASE CRY1AB OR CRY1 AB OR CRY 1 AB OR CRY 1AB OR CRYIAB OR CRYI AB OR CRY I AB

	Cry2Ab2 Cry3Bb1 Cold shock protein B (cspB) ATHB-17 Cry1F Cry34/35Ab1	OR CRY IAB OR CRY1A105 OR CRY1A 105 OR CRY 1A 105 OR CRY 1A105 OR CRYIA105 OR CRYIA 105 OR CRY IA 105 OR CRY IA105 OR CRY1A.105 CRY2AB? OR CRY2 AB? OR CRY 2 AB? OR CRY 2AB? OR CRYIIAB? OR CRYII AB? OR CRY II AB? OR CRY IIAB? OR CRY3BB? OR CRY3 BB? OR CRY 3 BB? OR CRY 3BB? OR CRYIIIBB? OR CRYIII BB? OR CRY III BB? OR CRY IIIBB? OR CSPB OR CSP B OR COLD SHOCK PROTEIN B OR COLD!SHOCKPROTEIN!B OR COLD!SHOCK PROTEIN!B OR COLD!SHOCK!PROTEIN!B OR ATHB17? OR ATHB!17? OR ATHB 17? OR HB17? OR HB!17? OR HB 17? CRY1F OR CRY1 F OR CRY 1 F OR CRY 1F OR CRYIF OR CRYI F OR CRY I F OR CRY IF CRY34AB1? OR CRY34AB 1? OR CRY 34AB 1? OR CRY 34AB1? OR CRY35AB1? OR CRY35AB 1? OR CRY 35AB 1? OR CRY 35AB1?
Newly expressed RNA	DvSnf7 RNA	(RNA? OR DSRNA? OR SIRNA?)(5A) (DVSNF7 OR WCR SNF7 OR CRW SNF7 OR DV SNF7 OR DVSNF 7 OR DV SNF 7 OR DV.SNF7 OR SNF7)
Intended traits: Herbicide tolerance traits	Glyphosate/ roundup tolerance, Glufosinate tolerance	(TOLERAN? OR RESISTAN? OR PROTEC?)(5A) (GL!PHOSATE OR GL!FOSATE OR ROUNDUP? OR ROUND UP? OR ROUND!UP OR GLUFOSINATE OR GLUPHOSINATE OR BASTA OR RELY OR FINALE OR IGNITE OR CHALLENGE OR LIBERTY)
Intended traits:-Hybridisation system traits	Glyphosate/ roundup-based hybridization system	(HYBRID? OR CROSS? OR POLLEN? OR POLLINAT? OR STERIL?(5A)MALE) AND (GL!PHOSATE OR GL!FOSATE OR ROUNDUP? OR ROUND UP? OR ROUND!UP?)
Intended traits: Insect protection traits	Bt maize / Bacillus thuringiensis maize providing Lepidopteran protection or protection against Noctuidae and Crambidae insect pest families or corn/stem borer or Ostrinia nubilalis or European corn borer (ECB) or Sesamia nonagrioides or Mediterranean corn	(TOLERAN? OR RESISTAN? OR PROTEC?)(5A) (BTMAIZE OR BTCORN OR BT MAIZE OR BT CORN OR BT!MAIZE OR BT!CORN OR THURINGIENSIS OR EARWORM OR CUTWORM OR ARMYWORM OR EAR WORM OR CUT WORM OR ARMY WORM OR NOCTUIDAE OR LEPIDOPTERA? OR BORER? OR LEPIDOPTERA? OR OSTRINIA OR SESAMIA OR NUBILALIS OR NONAGRIOIDES OR NOCTUIDAE OR CRAMBIDAE OR ECB OR MCB)

	borer (MCB) or fall armyworm or corn earworm or western bean cutworm	
	Bt maize / Bacillus thuringiensis maize providing Coleopteran protection, or protection against Chrysomel insect pest families or western corn rootworm (WCR / WCRW) or Diabrotica virgifera virgifera or Northern corn rootworm (NCR) or Diabrotica barberi (D barberi) or Southern corn rootworm (SCR) or Diabrotica undecimpunctata (D undecimpunctata) or Mexican corn rootworm (MCR) or Diabrotica virgifera zeae (D. virgifera zeae)	(TOLERAN? OR RESISTAN? OR PROTEC?)(5A) (ROOTWORM? OR ROOT WORM? OR COLEOPTERA? OR CHRYSOMEL? OR DIABROTICA OR VIRGIFERA OR BARBERI OR UNDECIMPUNCTATA OR CRW OR WCR? OR NCR? OR SCR? OR MCR? OR BTMAIZE OR BTCORN OR BT MAIZE OR BT CORN OR BT!MAIZE OR BT!CORN OR THURINGIENSIS)
Intended traits: Drought tolerance traits	Drought tolerant or water efficient maize	TOLERAN? OR RESISTAN? OR PROTEC?)(5A) DROUGHT OR (EFFICIEN? OR REDUC? OR LIMIT? OR DECRE? OR LOW?)(5A)WATER
Intended traits: Increased biomass traits	Increased ear biomass	(INCRE? OR ENHANCE?)(5A) (EAR SIZE OR EAR BIOMASS OR EAR GROWTH OR EAR WEIGHT OR EAR MASS OR SINK CAPACITY OR SINK POTENTIAL)
Crop name	maize, corn, *Zea mays*	MAIZE? OR CORN? OR "ZEA MAYS" OR "Z. MAYS"
GMO general terms	Genetically modified organism (GMO, GM); Living modified organism (LMO); biotechnology-derived organism (biotech-derived); Genetic engineering (GE); transgenesis (transgene); genetic	GMO? OR LMO? OR GM OR GE OR TRANSGEN? OR ((GENETIC? OR LIVING OR BIOTECH?)(5A)(MODIF? TRANSFORM? OR MANIPULAT? OR IMPROV? OR ENGINEER? OR DERIV?))

	transformation; genetic manipulation; genetic improvement.	

2. Controlled vocabulary, if applicable, for Bayer GM Maize products

Key elements	Search terms	Controlled terms offered by CABA (adapted for performing search in STN® database catalogue)
Event name	Not applicable	
Trade name	Not applicable	
Newly expressed proteins	Not applicable	
Intended traits: Insect protection and herbicide tolerance traits	Bt maize / Bacillus thuringiensis maize providing Lepidopteran protection or protection against Noctuidae and Crambidae insect pest families or corn/stem borer or Ostrinia nubilalis or European corn borer (ECB) or Sesamia nonagrioides or Mediterranean corn borer (MCB) or fall armyworm or corn earworm or western bean cutworm Bt maize / Bacillus thuringiensis maize providing Coleopteran protection, or protection against Chrysomel insect pest families or western corn rootworm (WCR / WCRW) or Diabrotica virgifera virgifera or Northern corn rootworm (NCR) or Diabrotica barberi (D barberi) or Southern corn rootworm (SCR) or Diabrotica undecimpunctata (D undecimpunctata) or Mexican corn rootworm (MCR) or Diabrotica virgifera zeae (D. virgifera zeae) Glyphosate/ roundup tolerance, Glufosinate tolerance	(WEED CONTROL+UF,NT/CT OR INSECT CONTROL+UF,NT/CT) AND (LEPIDOPTERA+UF,NT2/CT,ORGN OR COLEOPTERA+UF,NT2/CT,ORGN OR GLYPHOSATE+UF,NT/CT OR GLUFOSINATE+UF,NT/CT)
Intended traits: Hybridisation system traits	Glyphosate based hybridization system	(HYBRIDIZATION+UF,NT/CT OR CROSSING+UF,NT/CT OR PLANT BREEDING METHODS+UF,NT/CT OR POLLINATION+UF,NT/CT OR MALE STERILITY+UF,NT/CT) AND GLYPHOSATE+UF,NT/CT
Intended traits: Drought tolerance	Drought tolerance and increased ear biomass	DROUGHT RESISTANCE+UF,NT/CT OR BIOMASS

and increased ear biomass traits		PRODUCTION+UF,NT/CT
Crop name	maize, corn, *Zea mays*	ZEA MAYS+UF,NT/CT,ORGN OR MAIZE+UF, NT/CT,ORGN The term 'corn' is covered by 'maize'
GMO general terms	Genetically modified organism (GMO, GM); Living modified organism (LMO); biotechnology-derived organism (biotech-derived); Genetic engineering (GE); transgenesis (transgene); genetic transformation; genetic manipulation; genetic improvement	GENETIC ENGINEERING+UF,NT/CT OR GENETIC TRANSFORMATION+UF,NT/CT OR GENETICALLY ENGINEERED FOODS+UF,NT/CT OR GENETICALLY ENGINEERED ORGANISMS+UF,NT/CT OR FOOD BIOTECHNOLOGY+UF,NT/CT

Annex II. The search string used for Bayer GM maize products literature search in SciSearch and CABA databases using STN® database catalogue, and outcomes of the search (2019-2020)

The literature search covered the time span June 2019 - May 2020. The literature search in the electronic databases was conducted on a quarterly basis considering the entry dates in the STN® database catalogue. In addition, a final literature search was conducted covering the full-time span of the season. The search result presented below shows the final search conducted covering the full-time span of the 2019-2020 season.

Translation of query terms into STN search language:

```
This alert run covers the time range from 20190501 until 20200528

     (FILE 'STNGUIDE' ENTERED AT 14:30:10 ON 22 JUN 2020)

L1              QUE SPE=ON  ABB=ON  PLU=ON  MON 810? OR MON810? OR MON!810?
OR
                MON 00810? OR MON00810? OR MON!00810? OR MON OO81O? OR
                MONOO81O? OR MON!OO81O? OR MON EMPTY SETEMPTY SET81EMPTY
SET?
                OR MON!EMPTY SETEMPTY SET81EMPTY SET? OR MONEMPTY SETEMPTY
                SET81EMPTY SET? OR NK603 OR NK 603
L2              QUE SPE=ON  ABB=ON  PLU=ON  MON 00603? OR MON!00603? OR
                MON00603? OR MON OO6O3? OR MONOO6O3? OR MON!OO6O3? OR MON
                EMPTY SETEMPTY SET6EMPTY SET3? OR MON!EMPTY SETEMPTY
SET6EMPTY
                SET3? OR MONEMPTY SETEMPTY SET6EMPTY SET3?
L3              QUE SPE=ON  ABB=ON  PLU=ON  MON 88017? OR MON!88017? OR
                MON88017? OR MON 88O17? OR MON!88O17? OR MON88O17? OR MON
                88EMPTY SET17? OR MON!88EMPTY SET17? OR MON88EMPTY SET17?
L4              QUE SPE=ON  ABB=ON  PLU=ON  MON 89034? OR MON!89034? OR
                MON89034? OR MON 89O34? OR MON!89O34? OR MON89O34? OR MON
                89EMPTY SET34? OR MON!89EMPTY SET34? OR MON89EMPTY SET34?
L5              QUE SPE=ON  ABB=ON  PLU=ON  MON 87460? OR MON!87460? OR
                MON87460? OR MON 8746O? OR MON!8746O? OR MON8746O? OR MON
                8746EMPTY SET? OR MON!8746EMPTY SET? OR MON8746EMPTY SET?
OR
                MON 87427? OR MON!87427? OR MON87427? OR 1507 OR 15O7 OR
                15EMPTYSET7 OR TC1507 OR TC15O7 OR TC15EMPTYSET7
L6              QUE SPE=ON  ABB=ON  PLU=ON  DAS 01507? OR DAS!01507? OR
                DAS01507? OR DAS O15O7? OR DAS!O15O7? OR DASO15O7? OR DAS
                EMPTY SET15EMPTY SET7? OR DAS!EMPTY SET15EMPTY SET7? OR
                DASEMPTY SET15EMPTY SET7? OR 59122 OR DAS 59122? OR
DAS!59122?
                OR DAS59122? OR T25
L7              QUE SPE=ON  ABB=ON  PLU=ON  ACS ZM003? OR ACS!ZM003? OR
                ACSZM003? OR ACS ZMOO3? OR ACS!ZMOO3? OR ACSZMOO3? OR ACS
                ZMEMPTY SET EMPTY SET3? OR ACS!ZMEMPTY SET EMPTY SET3? OR
                ACSZMEMPTY SET EMPTY SET3? OR MON 87411? OR MON!87411? OR
                MON87411?
L8              QUE SPE=ON  ABB=ON  PLU=ON  MON 87403? OR MON!87403? OR
                MON87403? OR MON 874O3? OR MON!874O3? OR MON874O3? OR MON
                874EMPTY SET3? OR MON!874EMPTY SET3? OR MON874EMPTY SET3?
L9                 QUE SPE=ON  ABB=ON  PLU=ON  YIELD GARD? OR YIELDG? OR
YIELD!GAR
```

```
                D? OR YIELDGARD? OR ROUNDUPREADY? OR ROUND UP READY? OR
                ROUND!UP!READY? OR ROUND!UP READY? OR ROUNDUP READY? OR
RR2?
                OR RRII? OR VT? PRO? OR VT! PRO OR VT PRO? OR VT!PRO? OR
                VTPRO? OR DROUGHTGARD? OR DROUGHT GARD? OR HERCULEX?
L10              QUE SPE=ON  ABB=ON  PLU=ON  LIBERTY LINK? OR LIBERTYLINK?
OR
                LIBERTY!LINK OR VT? TRIPLE? OR VTTRIPLE? OR VT!TRIPLE? OR
VT
                TRIPLE? OR VT DOUBLE PRO? OR VT DOUBLEPRO? OR VTDOUBLE PRO?
OR
                VTDOUBLEPRO? OR VT!DOUBLE PRO? OR VT DOUBLEPRO? OR
VT!DOUBLEPRO
                ? OR VT!2!PRO?
L11             QUE SPE=ON  ABB=ON  PLU=ON  SMARTSTAX? OR SMART STAX? OR
                SMART!STAX? OR RHS OR HYBRIDIZATION SYSTEM OR VT 2 PRO? OR
                POWER CORE? OR POWERCORE?
L12              QUE SPE=ON  ABB=ON  PLU=ON  MAIZE? OR CORN? OR "ZEA MAYS"
OR
                "Z. MAYS"
L13             QUE SPE=ON  ABB=ON  PLU=ON  CP4EPSPS? OR CP4 EPSPS? OR
                5(W)(ENOLPYRUVYLSHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR
                ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYLSHIKIMATE OR
ENOL!PYRUVYL!
                SHIKIMATE!)(W)3 PHOSPHATE SYNTHASE OR PAT OR
PHOSPHINOTHRICIN
L14             QUE SPE=ON  ABB=ON  PLU=ON  N!ACETYLTRANSFERASE OR N!ACETYL
                TRANSFERASE OR N!ACETYL!TRANSFERASE OR N ACETYL TRANSFERASE
OR
                N ACETYL!TRANSFERASE OR N ACETYLTRANSFERASE
L15              QUE SPE=ON  ABB=ON  PLU=ON  CRY1AB OR CRY1 AB OR CRY 1 AB
OR
                CRY 1AB OR CRYIAB OR CRYI AB OR CRY I AB OR CRY IAB OR
                CRY1A105 OR CRY1A 105 OR CRY 1A 105 OR CRY 1A105 OR
CRYIA105
                OR CRYIA 105 OR CRY IA 105 OR CRY IA105 OR CRY1A.105
L16              QUE SPE=ON  ABB=ON  PLU=ON  CRY2AB? OR CRY2 AB? OR CRY 2
AB?
                OR CRY 2AB? OR CRYIIAB? OR CRYII AB? OR CRY II AB? OR CRY
                IIAB? OR CRY1F OR CRY1 F OR CRY 1 F OR CRY 1F OR CRYIF OR
CRYI
                F OR CRY I F OR CRY IF
L17              QUE SPE=ON  ABB=ON  PLU=ON  CRY3BB? OR CRY3 BB? OR CRY 3
BB?
                OR CRY 3BB? OR CRYIIIBB? OR CRYIII BB? OR CRY III BB? OR
CRY
                IIIBB? OR CRY34AB1? OR CRY34AB 1? OR CRY 34AB 1? OR CRY
34AB1?
                OR CRY35AB1? OR CRY35AB 1? OR CRY 35AB 1? OR CRY 35AB1?
L18             QUE SPE=ON  ABB=ON  PLU=ON  CSPB OR CSP B OR COLD SHOCK
                PROTEIN B OR COLD!SHOCKPROTEIN!B OR COLD!SHOCK PROTEIN!B OR
                COLD!SHOCK!PROTEIN!B OR ATHB17? OR ATHB!17? OR ATHB 17? OR
                HB17? OR HB!17? OR HB 17?
L19                    QUE SPE=ON  ABB=ON  PLU=ON  (RNA? OR DSRNA? OR
SIRNA?)(5A)(DVSN
                F7 OR WCR SNF7 OR CRW SNF7 OR DV SNF7 OR DVSNF 7 OR DV SNF
7
                OR DV.SNF7 OR SNF7)
L20             QUE SPE=ON  ABB=ON  PLU=ON  GMO? OR LMO? OR GM OR GE OR
                TRANSGEN? OR ((GENETIC? OR LIVING OR BIOTECH?)(5A)(MODIF?
```

```
OR
                TRANSFORM?  OR  MANIPULAT?  OR  IMPROV?  OR  ENGINEER?  OR
DERIV?))
L21                QUE SPE=ON  ABB=ON  PLU=ON  (TOLERAN? OR RESISTAN? OR
PROTEC?)(
                5A)(GL!PHOSATE OR GL!FOSATE OR ROUNDUP? OR ROUND UP? OR
                ROUND!UP OR GLUFOSINATE OR GLUPHOSINATE OR BASTA OR RELY OR
                FINALE OR IGNITE OR CHALLENGE OR LIBERTY)
L22                QUE SPE=ON  ABB=ON  PLU=ON  (TOLERAN? OR RESISTAN? OR
PROTEC?)(
                5A)(BORER?  OR  LEPIDOPTERA?  OR  OSTRINIA  OR  SESAMIA  OR
NUBILALIS
                OR NONAGRIOIDES OR NOCTUIDAE OR CRAMBIDAE OR ECB OR MCB)
L23                QUE SPE=ON  ABB=ON  PLU=ON  (TOLERAN? OR RESISTAN? OR
PROTEC?)(
                5A)(BTMAIZE OR BTCORN OR BT MAIZE OR BT CORN OR BT!MAIZE OR
                BT!CORN OR THURINGIENSIS OR EARWORM OR CUTWORM OR ARMYWORM
OR
                EAR  WORM  OR  CUT  WORM  OR  ARMY  WORM  OR  NOCTUIDAE  OR
LEPIDOPTERA?)

L24                QUE SPE=ON  ABB=ON  PLU=ON  (TOLERAN? OR RESISTAN? OR
PROTEC?)(
                5A)(ROOTWORM? OR ROOT WORM? OR COLEOPTERA? OR CHRYSOMEL? OR
                DIABROTICA OR VIRGIFERA OR BARBERI OR UNDECIMPUNCTATA)
L25                QUE SPE=ON  ABB=ON  PLU=ON  (TOLERAN? OR RESISTAN? OR
PROTEC?)(
                5A)(CRW  OR  WCR?  OR  NCR?  OR  SCR?  OR  MCR?  OR  BTMAIZE  OR
BTCORN
                OR  BT  MAIZE  OR  BT  CORN  OR  BT!MAIZE  OR  BT!CORN  OR
THURINGIENSIS)

L26                QUE SPE=ON  ABB=ON  PLU=ON  (TOLERAN? OR RESISTAN? OR
PROTEC?)(
                5A)DROUGHT OR (EFFICIEN? OR REDUC? OR LIMIT? OR DECRE? OR
                LOW?)(5A)WATER
L27              QUE SPE=ON  ABB=ON  PLU=ON  (HYBRID? OR CROSS? OR POLLEN?
OR
                POLLINAT? OR STERIL?(5A)MALE) AND (GL!PHOSATE OR GL!FOSATE
OR
                ROUNDUP? OR ROUND UP? OR ROUND!UP?)
L28                QUE SPE=ON  ABB=ON  PLU=ON  (INCRE? OR ENHANCE?)(5A)(EAR
SIZE
                OR EAR BIOMASS OR EAR GROWTH OR EAR WEIGHT OR EAR MASS OR
SINK
                CAPACITY OR SINK POTENTIAL)
L29                QUE SPE=ON  ABB=ON  PLU=ON  ZEA MAYS+UF,NT/CT,ORGN OR
MAIZE+UF,
                NT/CT,ORGN
L30             QUE SPE=ON  ABB=ON  PLU=ON  GENETIC ENGINEERING+UF,NT/CT OR
                GENETIC TRANSFORMATION+UF,NT/CT OR GENETICALLY ENGINEERED
                FOODS+UF,NT/CT OR GENETICALLY ENGINEERED ORGANISMS+UF,NT/CT
OR
                FOOD BIOTECHNOLOGY+UF,NT/CT
L31                QUE SPE=ON  ABB=ON  PLU=ON  (WEED CONTROL+UF,NT/CT OR
INSECT
                CONTROL+UF,NT/CT)  AND  (LEPIDOPTERA+UF,NT2/CT,ORGN  OR
COLEOPTERA
                +UF,NT2/CT,ORGN  OR  GLYPHOSATE+UF,NT/CT  OR
GLUFOSINATE+UF,NT/CT)
```

```
L32             QUE SPE=ON  ABB=ON  PLU=ON  (HYBRIDIZATION+UF,NT/CT OR
                CROSSING+UF,NT/CT OR PLANT BREEDING METHODS+UF,NT/CT OR
                POLLINATION+UF,NT/CT   OR   MALE   STERILITY+UF,NT/CT)   AND
GLYPHOSATE
                +UF,NT/CT
L33             QUE SPE=ON  ABB=ON  PLU=ON  DROUGHT RESISTANCE+UF,NT/CT OR
                BIOMASS PRODUCTION+UF,NT/CT
```

Search in SciSearch Database:

```
     FILE 'SCISEARCH' ENTERED AT 14:31:04 ON 22 JUN 2020
CHARGED TO COST=SLB76724 REG EU ALLYRMAIZE
L34          123 SEA SPE=ON  ABB=ON  PLU=ON  (L1 OR L2 OR L3 OR L4 OR L5 OR
L6
                OR L7 OR L8) AND ED>=20190501 AND ED<=20200528 AND PY>=2019
L35             484 SEA SPE=ON   ABB=ON   PLU=ON   (L9 OR L10 OR L11) AND
ED>=20190501
                 AND ED<=20200528 AND PY>=2019
L36           23300 SEA SPE=ON   ABB=ON   PLU=ON   L12 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L37           21 SEA SPE=ON  ABB=ON  PLU=ON  L35 AND L36
L38           840 SEA SPE=ON  ABB=ON  PLU=ON  (L13 OR L14) AND ED>=20190501
AND
                ED<=20200528 AND PY>=2019
L39           110 SEA SPE=ON  ABB=ON  PLU=ON  (L15 OR L16) AND ED>=20190501
AND
                ED<=20200528 AND PY>=2019
L40             7 SEA SPE=ON   ABB=ON   PLU=ON   L17 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L41             71 SEA SPE=ON   ABB=ON   PLU=ON   L18 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L42             8 SEA SPE=ON   ABB=ON   PLU=ON   L19 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L43          1034 SEA SPE=ON  ABB=ON  PLU=ON  L38 OR L39 OR L40 OR L41 OR L42
L44           24653 SEA SPE=ON   ABB=ON   PLU=ON   L20 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L45           175 SEA SPE=ON  ABB=ON  PLU=ON  L43 AND (L44 OR L36)
L46             1927 SEA SPE=ON   ABB=ON   PLU=ON   L21 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L47           118 SEA SPE=ON  ABB=ON  PLU=ON  (L22 OR L23) AND ED>=20190501
AND
                ED<=20200528 AND PY>=2019
L48           2008 SEA SPE=ON  ABB=ON  PLU=ON  (L24 OR L25) AND ED>=20190501
AND
                ED<=20200528 AND PY>=2019
L49           24080 SEA SPE=ON   ABB=ON   PLU=ON   L26 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L50             89 SEA SPE=ON   ABB=ON   PLU=ON   L27 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L51             17 SEA SPE=ON   ABB=ON   PLU=ON   L28 AND ED>=20190501 AND
ED<=202005
```

```
                28 AND PY>=2019
L52        28033 SEA SPE=ON  ABB=ON  PLU=ON  L46 OR L47 OR L48 OR L49 OR L50
OR
                L51
L53          118 SEA SPE=ON  ABB=ON  PLU=ON  L52 AND L44 AND L36
L54          383 SEA SPE=ON  ABB=ON  PLU=ON  L34 OR L37 OR L45 OR L53
```

Search in CABA Database:

```
     FILE 'CABA' ENTERED AT 14:32:20 ON 22 JUN 2020
CHARGED TO COST=SLB76724 REG EU ALLYRMAIZE
L55           49 SEA SPE=ON  ABB=ON  PLU=ON  (L1 OR L2 OR L3 OR L4 OR L5 OR
L6
                OR L7 OR L8) AND ED>=20190501 AND ED<=20200528 AND PY>=2019
L56            101 SEA SPE=ON  ABB=ON  PLU=ON  (L9 OR L10 OR L11) AND
ED>=20190501
                 AND ED<=20200528 AND PY>=2019
L57          10310 SEA SPE=ON  ABB=ON  PLU=ON  L12 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L58           5986 SEA SPE=ON  ABB=ON  PLU=ON  L29 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L59        10319 SEA SPE=ON  ABB=ON  PLU=ON  L57 OR L58
L60           12 SEA SPE=ON  ABB=ON  PLU=ON  L56 AND L59
L61            232 SEA SPE=ON  ABB=ON  PLU=ON  L13 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L62           76 SEA SPE=ON  ABB=ON  PLU=ON  (L14 OR L15) AND ED>=20190501
AND
                ED<=20200528 AND PY>=2019
L63            39 SEA SPE=ON  ABB=ON  PLU=ON  L16 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L64            8 SEA SPE=ON  ABB=ON  PLU=ON  (L17 OR L18) AND ED>=20190501
AND
                ED<=20200528 AND PY>=2019
L65              3 SEA SPE=ON  ABB=ON  PLU=ON  L19 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L66          343 SEA SPE=ON  ABB=ON  PLU=ON  L61 OR L62 OR L63 OR L64 OR L65
L67            7008 SEA SPE=ON  ABB=ON  PLU=ON  L20 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L68           3384 SEA SPE=ON  ABB=ON  PLU=ON  L30 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L69         7021 SEA SPE=ON  ABB=ON  PLU=ON  L67 OR L68
L70          117 SEA SPE=ON  ABB=ON  PLU=ON  L66 AND (L59 OR L69)
L71             713 SEA SPE=ON  ABB=ON  PLU=ON  L21 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L72           118 SEA SPE=ON  ABB=ON  PLU=ON  (L22 OR L23) AND ED>=20190501
AND
                ED<=20200528 AND PY>=2019
L73           755 SEA SPE=ON  ABB=ON  PLU=ON  (L24 OR L25) AND ED>=20190501
AND
                ED<=20200528 AND PY>=2019
L74          10815 SEA SPE=ON  ABB=ON  PLU=ON  L26 AND ED>=20190501 AND
ED<=202005
```

```
                28 AND PY>=2019
L75             45 SEA SPE=ON   ABB=ON   PLU=ON   L27 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L76             13 SEA SPE=ON   ABB=ON   PLU=ON   L28 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L77            226 SEA SPE=ON   ABB=ON   PLU=ON   L31 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L78              5 SEA SPE=ON   ABB=ON   PLU=ON   L32 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L79           2687 SEA SPE=ON   ABB=ON   PLU=ON   L33 AND ED>=20190501 AND
ED<=202005
                28 AND PY>=2019
L80       13538 SEA SPE=ON  ABB=ON  PLU=ON  L71 OR L72 OR L73 OR L74 OR L75
OR
                L76 OR L77 OR L78 OR L79
L81          88 SEA SPE=ON  ABB=ON  PLU=ON  L80 AND L69 AND L59
L82         229 SEA SPE=ON  ABB=ON  PLU=ON  L55 OR L60 OR L70 OR L81
```

Deduplication of Hit-sets from both sources:

```
     FILE 'CABA, SCISEARCH' ENTERED AT 14:33:49 ON 22 JUN 2020
CHARGED TO COST=SLB76724 REG EU ALLYRMAIZE
L83         511 DUP REM L82 L54 (101 DUPLICATES REMOVED)
                    ANSWERS '1-228' FROM FILE CABA
                    ANSWERS '229-511' FROM FILE SCISEARCH
                D L83 1-511 AN TI

     FILE 'STNGUIDE' ENTERED AT 14:35:17 ON 22 JUN 2020
CHARGED TO COST=SLB76724 REG EU ALLYRMAIZE

     FILE SCISEARCH

     FILE COVERS 1974 TO 15 Jun 2020 (20200615/ED)

     To bring you the most up-to-date SciSearch information,
     SciSearch SDIs now run on Mondays.

     FILE CABA
     FILE LAST UPDATED: 17 JUN 2020       <20200617/UP>
     FILE COVERS 1973 TO DATE

     <<< SIMULTANEOUS LEFT AND RIGHT TRUNCATION IS AVAILABLE IN
         THE BASIC INDEX (/BI), ABSTRACT (/AB), AND TITLE (/TI) FIELDS  >>>

     FILE STNGUIDE
     FILE CONTAINS CURRENT INFORMATION.
     LAST RELOADED: Apr 24, 2020 (20200424/UP).
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Annex III. List of reference publications used in identifying search terms and in validating the literature search strategy for Bayer GM maize products literature search

The list below includes reference publications used for each relevant key element, namely event name, trade name, newly expressed proteins and intended traits. For GMO general and crop name search terms, given the breadth of the terms and as they are used to focus the search to GM crops, reference publications were considered not applicable.

Castañera P, Farinós G, Ortego F and Andow D. (2016). Sixteen Years of Bt Maize in the EU Hotspot: Why Has Resistance Not Evolved? Plos One, 1-13. Farinós GP, Hernández-Crespo P, Ortego F and Castañera P, 2017. Monitoring of Sesamia nonagrioides resistance to MON 810 maize in the European Union: lessons from a long-term harmonized plan. Pest Management Science, 74, 557-568.

Castillo-Lopez E, Clark KJ, Paz HA, Ramirez Ramirez HA, Klusmeyer TH, Hartnell GF, Kononoff PJ. (2014). Performance of dairy cows fed silage and grain produced from second-generation insect-protected (Bacillus thuringiensis) corn (MON 89034), compared with parental line corn or reference corn. J. Dairy Sci., 97, 3832–3837.

Curran KL, Festa AR, Goddard SD, Harrigan GG, Taylor ML. (2015). Kernel compositions of glyphosate-tolerant and corn rootworm-protected MON 88017 sweet corn and insect-protected MON 89034 sweet corn are equivalent to that of conventional sweet corn (Zea mays). Agricultural and Food Chemistry, 63, 3046-3052.

Drury SM, Reynolds TL, Ridley WP, Bogdanova N, Riordan S, Nemeth MA, Sorbet R, Trujillo WA, Breeze ML. (2008). Composition of forage and grain from second-generation insect-protected corn MON 89034 is equivalent to that of conventional corn (Zea mays L.). Journal of Agricultural and Food Chemistry, 56(12), 4623-4630.

Hammond BG, Dudek R, Lemen JK and Nemeth MA. (2006). Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. Food and Chemical Toxicology, 44, 1092-1099.

Harrigan GG, Ridley WP, Miller KD, Sorbet R, Riordan SG, Nemeth MA, Reeves W, Pestert TA (2009). The forage and grain of MON 87460, a drought-tolerant corn hybrid, are compositionally equivalent to that of conventional corn. JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY. Volume: 57, Issue: 20, Pages: 9754-9763, DOI: 10.1021/jf9021515

Healy C, Hammond B, Kirkpatrick J. (2008). Results of a 13-week safety assurance study with rats fed grain from corn rootworm-protected, glyphosate-tolerant MON 88017 corn. Food and Chemical Toxicology, 46, 2517-2524.

Heck GR, Armstrong CL, Astwood JD, Behr CF, Bookout JT, BrownSM, Cavato TA, DeBoer DL, Deng MY, George C (2005). Development and characterization of a CP4 EPSPS-based, glyphosate-tolerant corn event. CROP SCIENCE. Volume: 45, Issue: 1, Pages: 329-339, DOI: 10.2135/cropsci2005.0329

Hyun Y, Bressner GE, Ellis M, Lewis AJ, Fischer R, Stanisiewski EP, Hartnell GF. (2004). Performance of growing-finishing pigs fed diets containing Roundup Ready corn (event NK603), a nontransgenic genetically similar corn, or conventional corn lines. JOURNAL OF ANIMAL SCIENCE. Volume: 82. Issue: 2. Pages: 571-580

Lundry DR, Burns A, Nemeth MA and Riordan SG (2013). Composition of grain and forage from insect-protected and herbicide-tolerant corn, MON 89034 × TC1507 × MON 88017 × DAS-59122 7 (SmartStax), is equivalent to that of conventional corn (Zea mays L.). dx.doi.org/10.1021/jf304005n | J. AGRIC. FOOD CHEM., 61, 1991−1998

Ridley WP, Hartnell GF, Hammond BG. (2005). Role of composition and animal feeding studies in the safety assessment of biotech crops. NEW DISCOVERIES IN AGROCHEMICALS. Edited by: Clark, JM, Ohkawa, H. Book Series: ACS SYMPOSIUM SERIES. Volume: 892. Pages: 28-39

Ridley WP, Harrigan GG, Breeze ML, Nemeth MA, Sidhu RS, Glenn KC (2011). Evaluation of compositional equivalence for multitrait biotechnology crops. JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY. Volume: 59, Issue: 11, Pages: 5865-5876, DOI: 10.1021/jf103874t

Taylor ML, Hartnell GF, Riordan SG, Nemeth MA, Karunanandaa K, George B, Astwood, JD. (2003). Comparison of broiler performance when fed diets containing grain from Roundup Ready (NK603), YieldGard x Roundup Ready (MON810 x NK603), non-transgenic control, or commercial corn. POULTRY SCIENCE. Volume: 82, Issue: 3, Pages: 443-453, DOI: 10.1093/ps/82.3.443

Taylor M, Hartnell G, Nemeth M, Lucas D, Davis S. (2007). Comparison of broiler performance when fed diets containing grain from second-generation insect-protected and glyphosate-tolerant, conventional control or commercial reference corn. POULTRY SCIENCE, 86(9), 1972-1979, DOI: 10.1093/ps/86.9.1972.

Taylor M, Lucas D, Nemeth M, David S, Hartnell G (2007). Comparison of broiler performance and carcass parameters when fed diets containing combined trait insect-protected and glyphosate-tolerant corn (MON 89034 x NK603), control, or conventional reference corn. POULTRY SCIENCE, 86(9), 1988-1994, DOI: 10.1093/ps/86.9.1988

Thieme T, Buuk C, Gloyna K, Ortego F and Farinós G, (2017). Ten years of MON 810 resistance monitoring of field populations of Ostrinia nubilalis in Europe. Journal of Applied Entomology, 00, 1-9.

Venkatesh TV, Breeze ML, Liu K, Harrigan GG, Culler AH (2014). Compositional analysis of grain and forage from MON 87427, an inducible male sterile and tissue selective glyphosate-tolerant maize product for hybrid seed production. JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY. Volume: 62, Issue: 8, Pages: 1964-1973, DOI: 10.1021/jf4041589

Venkatesh TV, Cook K, Liu B, Perez T, Willse A, Tichich R, Feng P, Harrigan GG. (2015). Compositional differences between near-isogenic GM and conventional maize hybrids are associated with backcrossing practices in conventional breeding. PLANT BIOTECHNOLOGY JOURNAL. Volume: 13, Issue: 2, Pages: 200-210, DOI: 10.1111/pbi.12248

Venkatesh TV, Cook K, Liu B, Perez T, Willse A, Tichich R, Feng P, Harrigan G. (2015). Compositional differences between near-isogenic GM and conventional maize hybrids are associated with backcrossing practices in conventional breeding. Plant Biotechnology Journal, 13, 200–210.

Xu Y, Goodacre R, Harrigan GG. (2014). Compositional equivalence of grain from multi-trait drought-tolerant maize hybrids to a conventional comparator: univariate and multivariate

assessments. JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY. Volume: 62, Issue: 39, Pages: 9597-9608, DOI: 10.1021/jf5019609

Annex IV. Literature search in internet pages of relevant key organisations for Bayer GM maize products covering time span 2019 - 2020

Relevant key organisations	Link to the relevant information and summary of the retrieved records
US EPA	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated – Accessed on 21 July 2020. The webpage dedicated to PIP registrations was checked. *Date of the most recent website update at the time of the search*: 14 July 2020 *Limits applied*: The list of PIP active ingredients registered was sorted by 'Year Registered' and those registered starting from 2019 were assessed. *Number of records retrieved matching the abovementioned criteria*: "1". *Number of relevant records or full-text documents retrieved*: The retrieved record is not relevant to Bayer GM maize products.
USDA	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status - Accessed on 21 July 2020. The webpage dedicated to petitions for determination of nonregulated status was checked. *Date of the most recent website update at the time of the search*: 17 July 2020 *Limits applied*: The list of the petitions was sorted by 'Effective Date' and those completed/ released starting from 01/01/2019 were assessed. *Number of records retrieved matching the abovementioned criteria*: "2" *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM maize products.
US FDA	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon – Accessed on 21 July 2020. The webpage dedicated to biotechnology consultations on food from GE plant varieties was checked. *Date of the most recent website update at the time of the search*: 11 October 2010 *Limits applied*: The list of the consultations starting from the 'FDA Letter Date' of January 01, 2019 was assessed. *Number of records retrieved matching the abovementioned criteria*: "3". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM maize products.

CFIA	https://www.inspection.gc.ca/industry-guidance/eng/1374161650885/1374161737236?gp=3&gc=25&ga=4#gdr_results - Accessed on 24 August 2020. The webpage dedicated to repository documents referring to plants with novel traits was checked. *Date of the most recent website update at the time of the search*: not clear *Limits applied*: The list of repository documents referring to plants with novel traits starting from 2019 was assessed. *Number of records retrieved matching the abovementioned criteria*: "16". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM maize products.
Health Canada	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html - Accessed on 21 July 2020. The webpage dedicated to approved products of genetically modified (GM) foods and other novel foods was checked. *Date of the most recent website update at the time of the search*: 07 May 2020 *Limits applied*: The list of novel food decisions starting from the 'Decision Date (20YY/MM/DD)' of 2019/01/01 was assessed. *Number of records retrieved matching the abovementioned criteria*: "3". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM maize products.
FSANZ	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx - Accessed on 21 July 2020. The webpage dedicated to current GM applications and approvals was checked. *Date of the most recent website update at the time of the search*: August 2019 *Limits applied*: The list for GM applications and approvals with 'Status' approved or under assessment starting from 2019, was assessed. *Number of records retrieved matching the abovementioned criteria*: "1". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM maize products.
CTNBio	http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo – Accessed on 24 August 2020. The webpage dedicated to commercial releases (= Liberações Comerciais) was checked. *Date of the most recent website update at the time of the search*: 21 August 2020 *Limits applied*: The list of commercial releases for plants (= plantas) starting from 2019 was assessed. *Number of records retrieved matching the abovementioned criteria*: "3". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM maize products.

CONABIA	https://www.argentina.gob.ar/agroindustria/alimentos-y-bioeconomia/ogm-comerciales – Accessed on 21 July 2020. The webpage of the national advisory commission on agricultural biotechnology (= Comisión Nacional Asesora de Biotecnología Agropecuaria) was checked. *Date of the most recent website update at the time of the search*: Not available *Limits applied*: The list of events with commercial resolución starting from 2019 were checked. *Number of records retrieved matching the abovementioned criteria*: "9". *Number of relevant records or full-text documents retrieved*: Three of the retrieved records are relevant to MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 (CONABIA, 2019a, 2019b) and MON 87427 × MON 89034 × NK603 (CONABIA, 2019c). They do not have any implication on the risk assessment, because no new hazards, modified exposure, or new scientific uncertainties are reported.
MAFF	https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-217.pdf - Accessed on 20 August 2020. The weblink dedicated to list of approved genetically modified agricultural crops was checked. *Date of the most recent website update at the time of the search*: 17 June 2020 *Limits applied*: The list of GM agricultural crops with approval date ('承認日') starting from January 01, 2019 was assessed. *Number of records retrieved matching the abovementioned criteria*: "13". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM maize products.

REFERENCES

CONABIA, 2019a. Resistencia a Lepidópteros y Coleópteros, y tolerancia a glufosinato de amonio y a glifosato (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7). https://www.boletinoficial.gob.ar/detalleAviso/primera/213595/20190816,

CONABIA, 2019b. Resistencia a Lepidópteros y Coleópteros, y tolerancia a glufosinato de amonio y a glifosato (MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7). https://www.boletinoficial.gob.ar/detalleAviso/primera/213596/20190816?busqueda=1,

CONABIA, 2019c. Resistencia a Lepidópteros y Coleópteros, y tolerancia a glufosinato de amonio y a glifosato (MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6). https://www.boletinoficial.gob.ar/detalleAviso/primera/213597/20190816?busqueda=1,

Annex V. Results of the publication selection process for Bayer GM maize products literature search in SciSearch and CABA databases using STN® database catalogue

Table 1. Results of the publication selection process.

Review question captured in the search	Number of publications
Publications identified after searches of the scientific literature in SciSearch and CABA databases (following de-duplication)	490
Publications excluded after rapid assessment for relevance	466
Publications screened using full-text documents	24
Publications excluded after detailed assessment for relevance	14
Unobtainable publications	0
Unclear publications	0
Publications considered relevant	10

Table 2. List of all relevant publications for Bayer GM maize products retrieved after detailed assessment of full-text documents for relevance: ordered by category of information.

Products[1]	Study (author(s) and year)	Title	Source
Food/Feed safety assessment			
Composition			
MON 810	(Corujo *et al.*, 2019)	Use of omics analytical methods in the study of genetically modified maize varieties tested in 90 days feeding trials	Food Chemistry
Toxicology			
MON 810	(Al-Harbi *et al.*, 2019)	A proteomic-based approach to study underlying molecular responses of the small intestine of Wistar rats to genetically modified corn (MON810)	Transgenic Research
MON 810	(Stein *et al.*, 2019)	Expression profiling of key pathways in rat liver after a one-year feeding trial with transgenic maize MON810	Scientific Reports
NK603	(Steinberg *et al.*, 2019)	Lack of adverse effects in subchronic and chronic toxicity/carcinogenicity studies on the glyphosate-resistant genetically modified maize NK603 in Wistar Han RCC rats	Archives of Toxicology
MON 810, NK603	(Mesnage *et al.*, 2019)	Relationship between faecal microbiota and plasma metabolome in rats fed NK603 and MON810 GM maize from the GMO90+ study	Food and Chemical Toxicology
MON 810, NK603	(Coumoul *et al.*, 2019)	The GMO90+ project: absence of evidence for biologically meaningful effects of genetically modified maize-based diets on Wistar rats after 6-months feeding comparative trial	Toxicological Sciences
Ag/Pheno			
MON 87427 × MON 89034 × 1507 × MON 88017 × 59122	(Pruter *et al.*, 2019)	Association of insect-derived ear injury with yield and aflatoxin of maize hybrids varying in Bt transgenes	Environmental Entomology
MON 810	(Holderbaum *et al.*, 2019)	Comparison of in vitro callus-cultures from transgenic maize	Crop Breeding and

		AG-5011YG (MON810) and conventional near-isogenic maize AG-5011	Applied Biotechnology
MON 87460	(Bruns, 2019)	Comparison of yield components and physiological parameters of drought tolerant and conventional corn hybrids	Agronomy Journal
MON 89034, NK603, MON 89034 × NK603	(Clawson *et al.*, 2019)	Consistent risk assessment outcomes from agronomic characterization of GE maize in diverse regions and as single-event and stacked products	Crop Science

[1] Products not listed above don't have relevant publication retrieved in this monitoring season.

Table 3. **List of publications excluded from the risk assessment after detailed assessment of full-text documents, with the reason(s) for exclusion**

Study authors	Year	Title	Source	Reasons for exclusion based on the eligibility/ inclusion criteria
Horn *et al.*	2019	A first assessment of glyphosate, 2,4-D and Cry proteins in surface water of South Africa	South African Journal of Science	It is not a safety study on Bayer's GM maize products
Szoboszlay *et al.*	2019	Annual replication is essential in evaluating the response of the soil microbiome to the genetic modification of maize in different biogeographical regions	PLoS ONE	It is not a safety study on Bayer's GM maize products
West *et al.*	2019	*Bt* Proteins Exacerbate Negative Growth Effects in Juvenile Rusty (F. rusticus) Crayfish Fed Corn Diet	Archives of Environmental Contamination and Toxicology	It is not a safety study on Bayer's GM maize products
Xu *et al.*	2019	Effects of Bacillus thuringiensis genetic engineering on induced volatile organic compounds emission in maize and the attractiveness to a parasitic wasp	Frontiers in Bioengineering and Biotechnology	It is not a safety study on Bayer's GM maize products
Eghrari *et al.*	2019	Homozygosis of *Bt* locus increases *Bt* protein expression and the control of Spodoptera frugiperda (Lepidoptera: Noctuidae) in maize hybrids	Crop Protection	It is not a safety study on Bayer's GM maize products
Erasmus *et al.*	2019	Introgression of a cry1Ab transgene into open pollinated maize and its effect on Cry protein concentration and target pest survival	PLoS ONE	The hybrid used to conduct the study is not in scope for Bayer's GM maize products

Study authors	Year	Title	Source	Reasons for exclusion based on the eligibility/ inclusion criteria
Steinberg *et al.*	2020	Lack of adverse effects in subchronic and chronic toxicity/carcinogenicity studies on the glyphosate-resistant genetically modified maize NK603 in Wistar Han RCC rats	Archives of Toxicology	It is not a safety study on Bayer's GM maize products
Visser *et al.*	2020	Plant Abandonment by Busseola fusca (Lepidoptera: Noctuidae) Larvae: Do *Bt* Toxins Have an Effect?	Insects	It is not a safety study on Bayer's GM maize products
Visser *et al.*	2019	Preference of *Bt*-resistant and susceptible Busseola fusca moths and larvae for *Bt* and non-*Bt* maize	Entomologia Experimentalis et Applicata	It is not a safety study on Bayer's GM maize products
Shu *et al.*	2019	Presence of Cry1Ab in the *Bt* maize - aphid (Rhopalosiphum maidis) - ladybeetle (Propylea japonica) system has no adverse effects on insect biological parameters	Entomologia Experimentalis et Applicata	It is not a safety study on Bayer's GM maize products
Fernandes *et al.*	2019	Species richness and community composition of ants and beetles in *Bt* and non-*Bt* maize fields	Environmental Entomology	It is not a safety study on Bayer's GM maize products
du Pisanie *et al.*	2019	The rate of release of Cry1Ab protein from *Bt* maize leaves into water	Water SA	It is not a safety study on Bayer's GM maize products
Fast *et al.*	2020	Transgene expression in sprayed and non-sprayed herbicide-tolerant genetically engineered crops is equivalent	Regulatory Toxicology and Pharmacology	The hybrid used to conduct the study is not in scope for Bayer's GM maize products
Shogren *et al.*	2019	Transport and instream removal of the Cry1Ab protein from genetically	PLoS ONE	The hybrid used to conduct the study is not in scope for Bayer's

Study authors	Year	Title	Source	Reasons for exclusion based on the eligibility/ inclusion criteria
		engineered maize is mediated by biofilms in experimental streams		GM maize products

Table 4. Report of the reliability and implications for the risk assessment of the relevant publication retrieved after detailed assessment of full-text document for relevance.

Study author(s) and year	Reliability appraisal[1]	Implications for the risk assessment[2]
Food/Feed Safety assessment		
Composition		
(Corujo *et al.,* 2019)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Toxicology		
(Al-Harbi *et al.,* 2019)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Stein *et al.,* 2019)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Steinberg *et al.*, 2019)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Mesnage *et al.*, 2019)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Coumoul *et al.*, 2019)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Ag/Pheno		
(Pruter *et al.* 2019)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported

(Holderbaum *et al.,* 2019)	Not reliable[3]	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Bruns, 2019)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Clawson *et al.*, 2019)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported

[1] **High** (use as key study); **Moderate** because the study reported is subject to some limitations (useable as key study depending on the limitations of the study); **Low** because the study reported is subject to several limitations (limited use or not useful; generally not to be used as key study, but depending on the limitations of the study, it may be useful in weight of evidence approaches or as supporting information); **Not reliable** because the study reported does not comply with minimum reliability criteria carrying a high level of uncertainty (not useful); **Not assignable** because no or insufficient information is reported in the study (EFSA, 2019)

[2] Identification of a new hazard, modified exposure, or new scientific uncertainty requiring further consideration in the risk assessment; **None**, because no new hazards, modified exposure, or new scientific uncertainties are reported; **None**, because the findings reported in the study are not reliable; Implications for risk assessment were previously considered by EFSA and/or its GMO Panel, and are therefore not addressed further here (EFSA, 2019).

[3] **Holderbaum *et al.* (2019)**

The imaging and algorithm used are not the main reason for classifying the paper as "not reliable", but rather the focus is on the association of the phenotypes observed with a presumed direct effect of the transgene.

- **Variable response to tissue culture -** It is well understood that callus response and regeneration varies widely between explants used for tissue culture and visual biases in selection will confound a study like this one.
- **Sample size -** The small number of initial explants and lack of replication are insufficient in the published work to rely on the measurements.
- **Cause for differential response -** Near iso-line (NIL) plants contain hundreds or thousands of mutations relative to the transgenic event. The paper does not address if these mutations are the cause behind the presumed differential response.
    - The paper would have had to perform Genome Wide Association studies to link specifically the transgene or a different region of the genome to the response observed. This is a gap in the study and the conclusions made.
- **Molecular characterization of commercialized transgene -** The commercialized transgene event undergoes molecular studies in regulatory before approval for sale. This includes demonstrating a single insertion point which does not interfere with an endogenous gene (does not land or break an ORF). In addition, 100 Kb upstream and downstream of the transgene are sequenced to ensure not additional changes occur into the genome. Composition and nutritional equivalence are also part of the safety studies on the commercialized event. These two pieces of data would contradict the assertion made in the paper.

References

References highlighted in grey are EFSA publications. Therefore, their pdfs are not provided.

Al-Harbi A, Sahira L, Edwards MG, Qusti S, Cockburn A, Poulsen M and Gatehouse AMR, 2019. A proteomic-based approach to study underlying molecular responses of the small intestine of Wistar rats to genetically modified corn (MON810). Transgenic Res, 28, 479-498.

Bruns HA, 2019. Comparison of yield components and physiological parameters of drought tolerant and conventional corn hybrids. Crop Ecology and Physiology, 3 (2), 565-571.

Clawson EL, Perrett JJ, Cheng L, Ahmad A, Stojsin D, McGowan Y, Heredia Diaz O, Muhammad A, Vertuan H, Quddusi M and Soares DJ, 2019. Consistent Risk Assessment Outcomes from Agronomic Characterization of GE Maize in Diverse Regions and as Single-Event and Stacked Products. Crop Sci, 59, 1681-1691.

Corujo M, Pla M, van Dijk J, Voorhuijzen M, Staats M, Slot M, Lommen A, Barros E, Nadal A, Puigdomènech P, La Paz JL, van der Voet H and Kok E, 2019. Use of omics analytical methods in the study of genetically modified maize varieties tested in 90 days feeding trials. Food Chemistry, 292, 359-371.

Coumoul X, Servien R, Juricek L, Kaddouch-Amar Y, Lippi Y, Berthelot L, Naylies C, Morvan ML, Antignac JP, Desdoits-Lethimonier C, Jegou B, Tremblay-Franco M, Canlet C, Debrauwer L, Le Gall C, Laurent J, Gouraud PA, Cravedi JP, Jeunesse E, Savy N, Dandere-Abdoulkarim K, Arnich N, Fourès F, Cotton J, Broudin S, Corman B, Moing A, Laporte B, Richard-Forget F, Barouki R, Rogowsky P and Salles B, 2019. The GMO90+ Project: Absence of Evidence for Biologically Meaningful Effects of Genetically Modified Maize-based Diets on Wistar Rats After 6-Months Feeding Comparative Trial. Toxicological Sciences, 168(2), 315-338.

EFSA, 2019. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market - Note on literature searching to GMO risk assessment guidance. EFSA journal, 2019:EN-1614, 1-62.

Holderbaum DF, Traavik TI, Onofre Nodari R and Guerra MP, 2019. Comparison of *in vitro* callus-cultures from transgenic maize AG-5011YG (MON810) and conventional near-isogenic maize AG-5011. Crop Breeding and Applied Biotechnology, 19, 169-175.

Mesnage R, Biserni M, Antoniou MN, Le Roy C and Salles B, 2019. Relationship between faecal microbiota and plasma metabolome in rats fed NK603 and MON810 GM maize from the GMO90+ study. Food and Chemical Toxicology, 131, 1-8.

Pruter LS, Brewer MJ, Weaver MA, Murray SC, Isakeit TS and Bernal JS, 2019. Association of Insect-Derived Ear Injury With Yield and Aflatoxin of Maize Hybrids Varying in Bt Transgenes. Environmental Entomology, 48(6), 1401-1411.

Stein T, GuangYao R, Bohmer M, Sharbati S and Einspanier R, 2019. Expression profiling of key pathways in rat liver after a one-year feeding trial with transgenic maize MON810. Scientific Reports, 9, 1-10.

Steinberg P, van der Voet H, Goedhart PW, Kleter G, Kok EJ, Pla M, Nadal A, Pla M, Zeljenkova D, Alacova R, Babincova J, Rollerova E, Jadudova S, Kebis A, Szabova E, Tulinska J, Liskova A, Takacsova M, Mikusova ML, Krivosikova Z, Spok A, Racovita M, de Vriend H, Alison R, Alison C, Baumgaertner W, Becker K, Lempp C, Schmicke M, Schrenk D, Poting A, Schiemann J and Wilhelm R, 2019. Lack of adverse effects in subchronic and chronic toxicity/carcinogenicity studies on the

glyphosate-resistant genetically modified maize NK603 in Wistar Han RCC rats. Archives of Toxicology, 93, 1095-1139.

Annex VI. List of relevant publications retrieved from SciSearch and CABA databases using STN® database catalogue (provided in .RIS format)

TY - JOUR

AU - Al-Harbi, A.

AU - Sahira, L.

AU - Edwards, M.G.

AU - Qusti, S.

AU - Cockburn, A.

AU - Poulsen, M.

AU - Gatehouse, A.M.R.

PY - 2019

SP - 479-498

ST - A proteomic-based approach to study underlying molecular responses of the small intestine of Wistar rats to genetically modified corn (MON810)

T2 - Transgenic Res

TI - A proteomic-based approach to study underlying molecular responses of the small intestine of Wistar rats to genetically modified corn (MON810)

VL - 28

ID - 29

ER -

TY - JOUR

AU - Bruns, H.A.

PY - 2019

SP - 565-571

ST - Comparison of yield components and physiological parameters of drought tolerant and conventional corn hybrids

T2 - Crop Ecology and Physiology

TI - Comparison of yield components and physiological parameters of drought tolerant and conventional corn hybrids

VL - 3 (2)

ID - 6

ER -

TY - JOUR

AU - Clawson, E.L.

AU - Perrett, J.J.;

AU - Cheng, L.

AU - Ahmad, A.

AU - Stojsin, D.

AU - McGowan, Y.

AU - Heredia Diaz, O.

AU - Muhammad, A.

AU - Vertuan, H.

AU - Quddusi, M.

AU - Soares, D.J.

PY - 2019

SP - 1681-1691

ST - Consistent Risk Assessment Outcomes from Agronomic Characterization of GE Maize in Diverse Regions and as Single-Event and Stacked Products

T2 - Crop Sci

TI - Consistent Risk Assessment Outcomes from Agronomic Characterization of GE Maize in Diverse Regions and as Single-Event and Stacked Products

VL - 59

ID - 25

ER -

TY - JOUR

AU - Corujo, M.

AU - Pla, M.

AU - van Dijk, J.

AU - Voorhuijzen, M.

AU - Staats, M.

AU - Slot, M.

AU - Lommen, A.

AU - Barros, E.

AU - Nadal, A.

AU - Puigdomènech, P.

AU - La Paz, J.L.

AU - van der Voet, H.

AU - Kok, E.

PY - 2019

SP - 359-371

ST - Use of omics analytical methods in the study of genetically modified maize varieties tested in 90 days feeding trials

T2 - Food Chemistry

TI - Use of omics analytical methods in the study of genetically modified maize varieties tested in 90 days feeding trials

VL - 292

ID - 27

ER -

TY - JOUR

AU - Coumoul, X.

AU - Servien, R.

AU - Juricek, L.

AU - Kaddouch-Amar, Y.

AU - Lippi, Y.

AU - Berthelot, L.

AU - Naylies, C.

AU - Morvan, M.L.

AU - Antignac, J.P.

AU - Desdoits-Lethimonier, C.

AU - Jegou, B.

AU - Tremblay-Franco, M.

AU - Canlet, C.

AU - Debrauwer, L.

AU - Le Gall, C.

AU - Laurent, J.

AU - Gouraud, P.A.

AU - Cravedi, J.P.

AU - Jeunesse, E.

AU - Savy, N.

AU - Dandere-Abdoulkarim, K.

AU - Arnich, N.

AU - Fourès, F.

AU - Cotton, J.

AU - Broudin, S.

AU - Corman, B.

AU - Moing, A.

AU - Laporte, B.

AU - Richard-Forget, F.

AU - Barouki, R.

AU - Rogowsky, P.

AU - Salles, B.

PY - 2019

SP - 315-338

ST - The GMO90+ Project: Absence of Evidence for Biologically Meaningful Effects of Genetically Modified Maize-based Diets on Wistar Rats After 6-Months Feeding Comparative Trial

T2 - Toxicological Sciences

TI - The GMO90+ Project: Absence of Evidence for Biologically Meaningful Effects of Genetically Modified Maize-based Diets on Wistar Rats After 6-Months Feeding Comparative Trial

VL - 168(2)

ID - 28

ER -

TY - JOUR

AU - Holderbaum, D.F.

AU - Traavik, T.I.

AU - Onofre Nodari, R.

AU - Guerra, M.P.

PY - 2019

SP - 169-175

ST - Comparison of *in vitro* callus-cultures from transgenic maize AG-5011YG (MON810) and conventional near-isogenic maize AG-5011

T2 - Crop Breeding and Applied Biotechnology

TI - Comparison of *in vitro* callus-cultures from transgenic maize AG-5011YG (MON810) and conventional near-isogenic maize AG-5011

VL - 19

ID - 23

ER -

TY - JOUR

AU - Mesnage, R.

AU - Biserni, M.

AU - Antoniou, M.N.

AU - Le Roy, C.

AU - Salles, B.

PY - 2019

SP - 1-8

ST - Relationship between faecal microbiota and plasma metabolome in rats fed NK603 and MON810 GM maize from the GMO90+ study

T2 - Food and Chemical Toxicology

TI - Relationship between faecal microbiota and plasma metabolome in rats fed NK603 and MON810 GM maize from the GMO90+ study

VL - 131

ID - 22

ER -

TY - JOUR

AU - Pruter, L.S.

AU - Brewer, M.J.

AU - Weaver, M.A.

AU - Murray, S.C.

AU - Isakeit, T.S.

AU - Bernal, J.S.

PY - 2019

SP - 1401-1411

ST - Association of Insect-Derived Ear Injury With Yield and Aflatoxin of Maize Hybrids Varying in Bt Transgenes

T2 - Environmental Entomology

TI - Association of Insect-Derived Ear Injury With Yield and Aflatoxin of Maize Hybrids Varying in Bt Transgenes

VL - 48(6)

ID - 7

ER -

TY - JOUR

AU - Stein, T.

AU - GuangYao, R.

AU - Bohmer, M.

AU - Sharbati, S.

AU - Einspanier, R.

PY - 2019

SP - 1-10

ST - Expression profiling of key pathways in rat liver after a one-year feeding trial with transgenic maize MON810

T2 - Scientific Reports

TI - Expression profiling of key pathways in rat liver after a one-year feeding trial with transgenic maize MON810

VL - 9

ID - 5

ER -

TY - JOUR

AU - Steinberg, P.

AU - van der Voet, H.

AU - Goedhart, P.W.

AU - Kleter, G.

AU - Kok, E.J.

AU - Pla, M.

AU - Nadal, A.

AU - Pla, M.

AU - Zeljenkova, D.

AU - Alacova, R.

AU - Babincova, J.

AU - Rollerova, E.

AU - Jadudova, S.

AU - Kebis, A.

AU - Szabova, E.

AU - Tulinska, J.

AU - Liskova, A.

AU - Takacsova, M.

AU - Mikusova, M.L.

AU - Krivosikova, Z.

AU - Spok, A.

AU - Racovita, M.

AU - de Vriend, H.

AU - Alison, R.

AU - Alison, C.

AU - Baumgaertner, W.

AU - Becker, K.

AU - Lempp, C.

AU - Schmicke, M.

AU - Schrenk, D.

AU - Poting, A.

AU - Schiemann, J.

AU - Wilhelm, R.

PY - 2019

SP - 1095-1139

ST - Lack of adverse effects in subchronic and chronic toxicity/carcinogenicity studies on the glyphosate-resistant genetically modified maize NK603 in Wistar Han RCC rats

T2 - Archives of Toxicology

TI - Lack of adverse effects in subchronic and chronic toxicity/carcinogenicity studies on the glyphosate-resistant genetically modified maize NK603 in Wistar Han RCC rats

VL - 93

ID - 19

ER -