

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

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

Data protection.

This application contains scientific data and other information which are protected in accordance with Art. 31 of Regulation (EC) No 1829/2003.

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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 soybean 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 soybean products.

The literature search covered the time span 2019 – 2020 and retrieved 249 and 184 hits in SciSearch and CABA databases, respectively, and a total of 51 records in the internet pages of the relevant key organisations. From these, 11 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 soybean products.

1. INTRODUCTION

As part of the general surveillance requirements for Bayer GM soybean products authorised in the European Union (EU) market under regulation (EC) No 1829/2003, Bayer Agriculture BV¹ has actively monitored the soybean 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 soybean 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 soybean 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 soybean products, derived food/feed products and respective introduced traits (= intervention/exposure), conventional counterpart or non-GM soybean (= 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>i.e.</i> authorisation for all uses as any other soybean but excluding the cultivation of Bayer GM soybean products are addressed as general protection goals.
Intervention/exposure	Bayer GM soybean 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 soybean 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	The single events addressed in the publication are the single events in stacked Bayer GM soybean products. Stacked Bayer GM soybean products 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 soybean product intended for all uses as any other soybean 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 CABA³ (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 catalogue⁵.

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

² SciSearch: <http://www.stn-international.de/sites/default/files/STN/summary-sheets/SCISEARCH.pdf> - Accessed on 02 September 2020

³ CABA: <http://www.stn-international.de/sites/default/files/STN/summary-sheets/CABA.pdf> - Accessed on 02 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/webofsciencgroup/solutions/webofscience-core-collection-editorial-selection-process/> - Accessed on 14 July 2020

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 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), nine⁷ are involved in risk assessment of Bayer GM soybean 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 soybean 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.

⁷ Internet pages of the relevant key organisations for Bayer GM soybean 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.

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 to give an excellent coverage and retrieve the broadest possible number of articles related to Bayer GM soybean 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 both⁸. 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 terms⁹. 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

⁸ STNindex user guide: <https://stn.products.fiz-karlsruhe.de/training-center/documentation/stn-index-user-guide->
Accessed on 02 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

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.

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
05 February 2020	SciSearch: 21 January 2020	04 October 2019 – 21 January 2020
	CABA: 30 January 2020	04 October 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 and **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 soybean 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 soybean products for all uses as any other soybean 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 249 and 184 hits in SciSearch and CABA databases, respectively (*see Annex II*). After de-duplication, the total number resulted in 333 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**. Nine 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**. Two 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. Implications of the retrieved relevant publications for the risk assessment

The comprehensive literature search relevant to the food, feed, and environmental safety of Bayer GM soybean products found no new information that would invalidate the conclusions of the risk assessment for Bayer GM soybean 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 soybean 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 soybean products risk assessment. Therefore, the conclusions of the risk assessment as presented in the initial applications of the Bayer GM soybean 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 soybean products literature search in STN[®] database catalogue

1. Free-text search terms for Bayer GM Soybean 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	40-3-2 or MON-Ø4Ø32-6 MON 89788 or MON-89788-1 MON 87769 or MON-87769-7 MON 87701 or MON-877Ø1-2 MON 87705 or MON-877Ø5-6 MON 87708 or MON-877Ø8-9 MON 87751 or MON-87751-7	40!3!2 OR MON 04032? OR MON04032? OR MON 04O32? OR MON04O32? OR MON EMPTY SET4EMPTY SET32? OR MONEMPTY SET4EMPTY SET32? OR MON!04032? OR MON!O4O32? OR MON!EMPTY SET4EMPTY SET32? MON 89788? OR MON89788? OR MON!89788? OR MON 87769? OR MON87769? OR MON!87769? MON87769? OR MON!87769? MON 87701? OR MON87701? OR MON 877O1? OR MON877O1? OR MON 877EMPTY SET1? OR MON877EMPTY SET1? OR MON!87701? OR MON!877O1? OR MON!877EMPTY SET1? MON 87705? OR MON87705? OR MON 877O5? OR MON877O5? OR MON 877EMPTY SET5? OR MON877EMPTY SET5? OR MON!87705? OR MON!877O5? OR MON!877EMPTY SET5? MON 87708? OR MON87708? OR MON 877O8? OR MON877O8? OR MON 877EMPTY SET8? OR MON877EMPTY SET8? OR MON!87708? OR MON!877O8? OR MON!877EMPTY SET8? MON 87751? OR MON87751? OR MON!87751?
Trade names	Roundup Ready [®] soybean Roundup Ready 2 Yield [®] soybean Vistive Gold [™] soybean Intacta RR2 Pro [®] soybean Roundup Ready 2 Xtend [®] soybean	ROUNDUPREADY? OR ROUND!UP!READY? OR ROUND!UP READY? OR ROUNDUP READY? OR ROUND UP READY? OR RR2Y? OR RRIIY? OR INTACTA OR RR2 PRO? OR RRII PRO? OR VISTIVE? OR VISTIVE? GOLD? OR XTEND?

Newly expressed proteins	CP4 EPSPS DMO Cry1Ac Cry1A.105 Cry2Ab2 Primula juliae $\Delta 6$ desaturase (Pj.D6D) and Neurospora crassa $\Delta 15$ desaturase (Nc.Fad3)	CP4EPSPS? OR CP4 EPSPS? OR 5(W)(ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR ENOL!PYRUVYL! SHIKIMATE!)(W)3 PHOSPHATE SYNTHASE DICAMBA ?OXYGENASE OR DICAMBA ?DEMETHYLASE OR DMO? CRY1AC OR CRYIAC OR CRY1 AC OR CRY 1 AC OR CRY 1AC OR CRYI AC OR CRY I AC OR CRY IAC 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 CRYIAB? OR CRYII AB? OR CRY II AB? OR CRY IAB? OR PJ!D6D OR PJD6D OR PJ D6D OR NC!FAD3 OR NCFAD3 OR NC FAD3 OR NC!FAD 3 OR NCFAD 3 OR NC FAD 3 OR DESATURASE?
Newly expressed RNAs	FATB1-A and FAD2-1A gene segments	(RNA? OR DSRNA? OR SIRNA?)(5A) (FAT! B? OR FAD!2? OR FAT B? OR FAD 2? OR FADB? OR FAD2? OR THIOESTERASE? OR DESATURASE?)
Intended traits: Herbicide tolerance traits	Glyphosate/roundup tolerance Dicamba tolerance	(TOLERAN? OR RESISTAN? OR PROTEC?)(5A) (GL!PHOSATE OR GL!FOSATE OR ROUNDUP? OR ROUND!UP? OR ROUND UP? OR DICAMBA OR METHOXYBENZOIC ACID)
Intended traits: Insect protection traits	Bt soy (soybean) / Bacillus thuringiensis Soybean providing Lepidopteran protection or protection against <i>Anticarsia gemmatalis</i> or soybean looper (SBL) or <i>Chrysodeixis includens</i> or <i>Pseudoplusia includens</i> or Sunflower looper (SFL) or <i>Rachiplusia nu</i> or Black armyworm or <i>Spodoptera frugiperda</i> or corn earworm (CEW) or cotton bollworm (CBW) or soybean podworm or <i>Helicoverpa zea</i> or old world bollworm or african bollworm or american bollworm or cotton bollworm or corn earworm (CEW) or <i>Helicoverpa armigera</i> or sunflower looper or soybean anxil borer or soybean budborer	(TOLERAN? OR RESISTAN? OR PROTEC?)(5A) (BT SOY? OR BT SOY? OR BT!SOY? OR THURINGIENSIS OR LEPIDOPTERA? OR CATERPILLAR? OR ANTICARCIA OR GEMMATALIS OR CHRYSODEIXIS OR INCLUDENS OR PSEUDOPLUSIA OR INCLUDENS OR LOOPER? OR RACHIPLUSIA OR R. NU OR ARMYWORM OR ARMY WORM OR SPODOPTERA OR FRUGIPERDA OR H. ZEA OR MOTH OR EARWORM OR EAR WORM OR HELICOVERPA OR BORER? OR CROCIDOSEMA OR APOREMA OR EPINOTIA OR APOREMA)

	or <i>Crocidosema aporema</i> or <i>Epinotia aporema</i>	
Intended traits: improved fatty acid profile	Expression of stearidonic acid (SDA; 18:4) Improved fatty acid profile (high monounsaturated fatty acids and low saturated and polyunsaturated fatty acids)	STEARIDONIC ACID OR SDA OR (HIGH? OR INCRE? OR CHANG?)(5A)(OLEIC OR MONOUNSATURATED OR MONO!UNSATURATED OR MONO UNSATURATED OR MUFA OR FAT?) (LOW? OR DECRE? OR REDUC?)(5A)(SATURATED OR PALMITIC OR STEARIC OR LINOLEIC OR POLYUNSATURATED OR POLY!UNSATURATED OR POLY UNSATURATED OR PUFA)
Crop name	Soybean, Soy, <i>Glycine max</i>	SOYBEAN? OR SOY? OR GLYCINE MAX OR G. MAX OR SOY BEAN
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.	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?))

2. Controlled vocabulary, if applicable. Bayer GM Soybean 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 soy (soybean) / <i>Bacillus thuringiensis</i> Soybean providing Lepidopteran protection or protection against <i>Anticarsia gemmatilis</i> or soybean looper (SBL) or <i>Chrysodeixis includens</i> or <i>Pseudoplusia includens</i> or Sunflower looper (SFL) or <i>Rachiplusia nu</i> or Black armyworm or <i>Spodoptera frugipeda</i> or corn earworm (CEW) or cotton bollworm (CBW) or soybean podworm or <i>Helicoverpa zea</i> or old world bollworm or african bollworm or american bollworm or cotton	(WEED CONTROL+UF,NT/CT OR INSECT CONTROL+UF,NT/CT) AND (LEPIDOPTERA+UF,NT2/CT,ORGN OR GLYPHOSATE+UF,NT/CT OR DICAMBA+UF,NT/CT)

Appendix 3 – Annual general surveillance report in 2019/2020 season

Literature search – Bayer soybean GM products

Bayer Agriculture BV

	bollworm or corn earworm (CEW) or <i>Helicoverpa armigera</i> or sunflower looper or soybean anvil borer or soybean budborer or <i>Crociosema aporema</i> or <i>Epinotia aporema</i> Glyphosate/roundup tolerance Dicamba tolerance	
Intended traits: Improved fatty acid profile	Improved fatty acid profile	SATURATED FATTY ACIDS+UF,NT/CT OR UNSATURATED FATTY ACIDS+UF,NT/CT
Crop name	Soybean, Soy, <i>Glycine max</i>	SOYABEANS+UF,NT/CT,ORGN
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 soybean 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 14:51:32 ON 22 JUN 2020)
CHARGED TO COST=PAUSE
      DEL HIS Y
L1      QUE SPE=ON  ABB=ON  PLU=ON  40!3!2 OR MON 04032? OR
MON04032?
      OR MON 04032? OR MON04032? OR MON EMPTY SET4EMPTY SET32? OR
      MONEMPTY SET4EMPTY SET32? OR MON!04032? OR MON!04032? OR
      MON!EMPTY SET4EMPTY SET32?
L2      QUE SPE=ON  ABB=ON  PLU=ON  MON 89788? OR MON89788? OR
      MON!89788? OR MON 87769? OR MON87769? OR MON!87769?
L3      QUE SPE=ON  ABB=ON  PLU=ON  MON 87701? OR MON87701? OR MON
      87701? OR MON87701? OR MON 877EMPTY SET1? OR MON877EMPTY
      SET1?
      OR MON!87701? OR MON!87701? OR MON!877EMPTY SET1?
L4      QUE SPE=ON  ABB=ON  PLU=ON  MON 87705? OR MON87705? OR MON
      87705? OR MON87705? OR MON 877EMPTY SET5? OR MON877EMPTY
      SET5?
      OR MON!87705? OR MON!87705? OR MON!877EMPTY SET5?
L5      QUE SPE=ON  ABB=ON  PLU=ON  MON 87708? OR MON87708? OR MON
      87708? OR MON87708? OR MON 877EMPTY SET8? OR MON877EMPTY
      SET8?
      OR MON!87708? OR MON!87708? OR MON!877EMPTY SET8?
L6      QUE SPE=ON  ABB=ON  PLU=ON  MON 87751? OR MON87751? OR
      MON!87751?
L7      QUE SPE=ON  ABB=ON  PLU=ON  ROUNDUPREADY? OR
      ROUND!UP!READY?
      OR ROUND!UP READY? OR ROUNDUP READY? OR ROUND UP READY? OR
      RR2Y? OR RRIIY? OR INTACTA OR RR2 PRO? OR RRII PRO? OR
      VISTIVE? OR VISTIVE? GOLD? OR XTEND?
L8      QUE SPE=ON  ABB=ON  PLU=ON  SOYBEAN? OR SOY? OR GLYCINE MAX
      OR
      G. MAX OR SOY BEAN
L9      QUE SPE=ON  ABB=ON  PLU=ON  CP4EPSPTS? OR CP4 EPSPTS? OR
      5(W) (ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR
      ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR
      ENOL!PYRUVYL!
      SHIKIMATE!) (W)3 PHOSPHATE SYNTHASE
L10     QUE SPE=ON  ABB=ON  PLU=ON  CRY1AC OR CRYIAC OR CRY1 AC OR
      CRY
      1 AC OR CRY 1AC OR CRYI AC OR CRY I AC OR CRY IAC OR
      CRY1A105
```

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Literature search – Bayer soybean GM products

Bayer Agriculture BV

CRYIA OR CRY1A 105 OR CRY 1A 105 OR CRY 1A105 OR CRYIA105 OR
105 OR CRY IA 105 OR CRY IA105 OR CRY1A.105
L11 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
L12 IIAB? OR DICAMBA ?OXYGENASE OR DICAMBA ?DEMETHYLASE OR DMO?
QUE SPE=ON ABB=ON PLU=ON PJ!D6D OR PJD6D OR PJ D6D OR
FAD NC!FAD3 OR NCFAD3 OR NC FAD3 OR NC!FAD 3 OR NCFAD 3 OR NC
3 OR DESATURASE?
L13 QUE SPE=ON ABB=ON PLU=ON (RNA? OR DSRNA? OR
SIRNA?) (5A) (FAT!
B? OR FAD!2? OR FAT B? OR FAD 2? OR FADB? OR FAD2? OR
THIOESTER
ASE? OR DESATURASE?)
L14 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?))
L15 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 DICAMBA OR METHOXYBENZOIC ACID)
L16 QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR
PROTEC?) (
5A) (LEPIDOPTERA? OR ANTICARCIA OR GEMMATALIS OR
PSEUDOPUSIA
OR INCLUDENS OR EPINOTIA OR APOREMA)
L17 QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR
PROTEC?) (
5A) (RACHIPLUSIA OR R. NU OR CATERPILLAR? OR LOOPER? OR
BORER?
OR BT SOY? OR BTSOY? OR BT!SOY? OR THURINGIENSIS)
L18 QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR
PROTEC?) (
5A) (CROCIDOSEMA OR APOREMA OR SPODOPTERA OR FRUGIPERDA OR
CHRYSODEIXIS OR INCLUDENS OR HELICOVERPA)
L19 QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR
PROTEC?) (
5A) (H. ZEA OR MOTH OR ARMYWORM OR ARMY WORM OR EARWORM OR
EAR
WORM)
L20 QUE SPE=ON ABB=ON PLU=ON STEARIDONIC ACID OR SDA OR
(HIGH?
OR INCRE? OR CHANG?) (5A) (OLEIC OR MONOUNSATURATED OR
MONO!UNSAT
URATED OR MONO UNSATURATED OR MUFA OR FAT?)
L21 QUE SPE=ON ABB=ON PLU=ON (LOW? OR DECRE? OR
REDUC?) (5A) (SATU
RATED OR PALMITIC OR STEARIC OR LINOLEIC OR POLYUNSATURATED
OR
POLY!UNSATURATED OR POLY UNSATURATED OR PUFA)
L22 QUE SPE=ON ABB=ON PLU=ON SOYABEANS+UF,NT/CT,ORGN
L23 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

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Literature search – Bayer soybean GM products

Bayer Agriculture BV

FOOD BIOTECHNOLOGY+UF,NT/CT
 L24 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
 GLYPHOSATE +UF,NT/CT OR DICAMBA+UF,NT/CT)
 L25 QUE SPE=ON ABB=ON PLU=ON SATURATED FATTY ACIDS+UF,NT/CT
 OR UNSATURATED FATTY ACIDS+UF,NT/CT

Search in SciSearch Database:

FILE 'SCISEARCH' ENTERED AT 14:52:07 ON 22 JUN 2020
 CHARGED TO COST=PAUSE
 L26 11 SEA SPE=ON ABB=ON PLU=ON (L1 OR L2 OR L3 OR L4 OR L5 OR
 L6)
 AND ED>=20190501 AND ED<=20200528 AND PY>=2019
 L27 39 SEA SPE=ON ABB=ON PLU=ON L7 AND ED>=20190501 AND
 ED<=20200528
 8 AND PY>=2019
 L28 7507 SEA SPE=ON ABB=ON PLU=ON L8 AND ED>=20190501 AND
 ED<=20200528
 8 AND PY>=2019
 L29 15 SEA SPE=ON ABB=ON PLU=ON L27 AND L28
 L30 49 SEA SPE=ON ABB=ON PLU=ON L9 AND ED>=20190501 AND
 ED<=20200528
 8 AND PY>=2019
 L31 403 SEA SPE=ON ABB=ON PLU=ON (L10 OR L11) AND ED>=20190501
 AND
 ED<=20200528 AND PY>=2019
 L32 691 SEA SPE=ON ABB=ON PLU=ON L12 AND ED>=20190501 AND
 ED<=20200528
 28 AND PY>=2019
 L33 12 SEA SPE=ON ABB=ON PLU=ON L13 AND ED>=20190501 AND
 ED<=20200528
 28 AND PY>=2019
 L34 1143 SEA SPE=ON ABB=ON PLU=ON L30 OR L31 OR L32 OR L33
 L35 24653 SEA SPE=ON ABB=ON PLU=ON L14 AND ED>=20190501 AND
 ED<=20200528
 28 AND PY>=2019
 L36 204 SEA SPE=ON ABB=ON PLU=ON L34 AND (L35 OR L28)
 L37 233 SEA SPE=ON ABB=ON PLU=ON L15 AND ED>=20190501 AND
 ED<=20200528
 28 AND PY>=2019
 L38 184 SEA SPE=ON ABB=ON PLU=ON (L16 OR L17 OR L18 OR L19) AND
 ED>=20190501 AND ED<=20200528 AND PY>=2019
 L39 15872 SEA SPE=ON ABB=ON PLU=ON (L20 OR L21) AND ED>=20190501
 AND
 ED<=20200528 AND PY>=2019
 L40 16288 SEA SPE=ON ABB=ON PLU=ON L37 OR L38 OR L39
 L41 39 SEA SPE=ON ABB=ON PLU=ON L40 AND L35 AND L28
 L42 249 SEA SPE=ON ABB=ON PLU=ON L26 OR L29 OR L36 OR L41

Search in CABA Database:

FILE 'CABA' ENTERED AT 14:53:02 ON 22 JUN 2020
 CHARGED TO COST=PAUSE
 L43 7 SEA SPE=ON ABB=ON PLU=ON (L1 OR L2 OR L3 OR L4 OR L5 OR
 L6)
 AND ED>=20190501 AND ED<=20200528 AND PY>=2019

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Literature search – Bayer soybean GM products

Bayer Agriculture BV

L44 24 SEA SPE=ON ABB=ON PLU=ON L7 AND ED>=20190501 AND
 ED<=2020052 8 AND PY>=2019
 L45 5423 SEA SPE=ON ABB=ON PLU=ON L8 AND ED>=20190501 AND
 ED<=2020052 8 AND PY>=2019
 L46 3529 SEA SPE=ON ABB=ON PLU=ON L22 AND ED>=20190501 AND
 ED<=202005 28 AND PY>=2019
 L47 5423 SEA SPE=ON ABB=ON PLU=ON L45 OR L46
 L48 16 SEA SPE=ON ABB=ON PLU=ON L44 AND L47
 L49 39 SEA SPE=ON ABB=ON PLU=ON L9 AND ED>=20190501 AND
 ED<=2020052 8 AND PY>=2019
 L50 141 SEA SPE=ON ABB=ON PLU=ON (L10 OR L11) AND ED>=20190501
 AND ED<=20200528 AND PY>=2019
 L51 338 SEA SPE=ON ABB=ON PLU=ON L12 AND ED>=20190501 AND
 ED<=202005 28 AND PY>=2019
 L52 8 SEA SPE=ON ABB=ON PLU=ON L13 AND ED>=20190501 AND
 ED<=202005 28 AND PY>=2019
 L53 521 SEA SPE=ON ABB=ON PLU=ON L49 OR L50 OR L51 OR L52
 L54 7008 SEA SPE=ON ABB=ON PLU=ON L14 AND ED>=20190501 AND
 ED<=202005 28 AND PY>=2019
 L55 3384 SEA SPE=ON ABB=ON PLU=ON L23 AND ED>=20190501 AND
 ED<=202005 28 AND PY>=2019
 L56 7021 SEA SPE=ON ABB=ON PLU=ON L54 OR L55
 L57 145 SEA SPE=ON ABB=ON PLU=ON L53 AND (L47 OR L56)
 L58 139 SEA SPE=ON ABB=ON PLU=ON L15 AND ED>=20190501 AND
 ED<=202005 28 AND PY>=2019
 L59 179 SEA SPE=ON ABB=ON PLU=ON (L16 OR L17 OR L18 OR L19) AND
 ED>=20190501 AND ED<=20200528 AND PY>=2019
 L60 7401 SEA SPE=ON ABB=ON PLU=ON (L20 OR L21) AND ED>=20190501
 AND ED<=20200528 AND PY>=2019
 L61 4698 SEA SPE=ON ABB=ON PLU=ON (L24 OR L25) AND ED>=20190501
 AND ED<=20200528 AND PY>=2019
 L62 10609 SEA SPE=ON ABB=ON PLU=ON L58 OR L59 OR L60 OR L61
 L63 32 SEA SPE=ON ABB=ON PLU=ON L62 AND L56 AND L47
 L64 184 SEA SPE=ON ABB=ON PLU=ON L43 OR L48 OR L57 OR L63

Deduplication of Hit-sets from both sources:

FILE 'CABA, SCISEARCH' ENTERED AT 14:54:04 ON 22 JUN 2020
 CHARGED TO COST=PAUSE
 L65 345 DUP REM L64 L42 (88 DUPLICATES REMOVED)
 ANSWERS '1-183' FROM FILE CABA
 ANSWERS '184-345' FROM FILE SCISEARCH
 D L65 1-345 AN TI

FILE 'STNGUIDE' ENTERED AT 14:55:18 ON 22 JUN 2020
 CHARGED TO COST=PAUSE

FILE SCISEARCH

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Literature search – Bayer soybean GM products

Bayer Agriculture BV

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

Annex III. List of reference publications used in identifying search terms and in validating the literature search strategy for Bayer GM soybean 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.

Berman KH, Harrigan GG, Riordan SG, Nemeth MA, Hanson C, Smith M, Sorbet R, Zhu E, Ridley WP. (2009). Compositions of seed, forage, and processed fractions from insect-protected soybean MON 87701 are equivalent to those of conventional soybean. *Journal of Agricultural and Food Chemistry*, 57, 11360-11369.

Berman KH, Harrigan GG, Riordan SG, Nemeth MA, Hanson C, Smith M, Sorbet R, Zhu E, Ridley WP. (2010) Compositions of forage and seed from second-generation glyphosate-tolerant soybean MON 89788 and insect-protected soybean MON 87701 from Brazil are equivalent to those of conventional soybean (*Glycine max*). *Journal of Agricultural and Food Chemistry*, 58, 6270-6276.

Berman KH, Harrigan GG, Riordan SG, Nemeth MA, Oliveira W, Tagliaferro F and Berger GU, (2011). Compositional equivalence of insect-protected glyphosate-tolerant soybean, MON 87701 x MON 89788, to conventional soybean extends across different world regions and multiple growing seasons. *Journal of Agricultural and Food Chemistry*, 59, 11643-11651.

Harrigan GG, Ridley WP, Riordan SG, Nemeth MA, Sorbet R, Trujillo WA, Breeze ML, Schneider RW. (2007). Chemical composition of glyphosate-tolerant soybean 40-3-2 grown in Europe remains equivalent with that of conventional soybean (*Glycine max* L.). *Journal of Agricultural and Food Chemistry*, 55, 6160-6168.

Horak MJ, Rosenbaum EW, Kendrick DL, Sammons B, Phillips SL, Nickson TE, Dobert RC, Perez T. (2015) Plant characterization of Roundup Ready 2 Yield® soybean, MON 89788, for use in ecological risk assessment. *TRANSGENIC RESEARCH*, 24, 213-225

Lundry DR, Ridley WP, Meyer JJ, Riordan SG, Nemeth MA, Trujillo WA, Breeze ML, Sorbet R. (2008) Composition of grain, forage, and processed fractions from second-generation glyphosate-tolerant soybean, MON 89788, is equivalent to that of conventional soybean (*Glycine max* L.). *Journal of Agricultural and Food Chemistry*, 56, 4611-4622.

McCann MC, Liu K, Trujillo WA, Dobert RC. (2005). Glyphosate-tolerant soybeans remain compositionally equivalent to conventional soybeans (*Glycine max* L.) during three years of field testing. *Journal of Agricultural and Food Chemistry*, 53, 5331-5335.

Taylor NB, Fuchs RL, MacDonald J, Shariff AR, Padgett SR. (1999). Compositional analysis of glyphosate-tolerant soybeans treated with glyphosate. *Journal of Agricultural and Food Chemistry*, 47, 4469- 4473.

Taylor M, Bickel A, Mannion R, Bell E, Harrigan GG. (2017). Dicamba-tolerant soybeans (*Glycine max* L.) MON 87708 and MON 87708 x MON 89788 are compositionally equivalent to conventional soybean. *Journal of Agricultural and Food Chemistry*, 65, 8037–8045.

Vries BD, Fehr WR. (2011) Impact of the MON89788 event for glyphosate tolerance on agronomic and seed traits of soybean. *Crop Science*, 51, 1023-1027.

Zhou J, Harrigan GG, Berman KH, Webb EG, Klusmeyer TH, Nemeth MA. (2011). Stability in the composition equivalence of grain from insect-protected maize and seed from glyphosate-tolerant soybean to conventional counterparts over multiple seasons, locations, and breeding germplasms. *Journal of Agricultural and Food Chemistry*, 59, 8822-8828.

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

Relevant key organisations	Link to the relevant information and summary of the retrieved records
US EPA	<p>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.</p> <p><i>Date of the most recent website update at the time of the search:</i> 14 July 2020</p> <p><i>Limits applied:</i> The list of PIP active ingredients registered was sorted by ‘Year Registered’ and those registered starting from 2019 were assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “1”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved record is not relevant to Bayer GM soybean products</p>
USDA	<p>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.</p> <p><i>Date of the most recent website update at the time of the search:</i> 17 July 2020</p> <p><i>Limits applied:</i> The list of the petitions was sorted by ‘Effective Date’ and those completed/ released starting from 01/01/2019 were assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “2”</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM soybean products.</p>
US FDA	<p>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.</p> <p><i>Date of the most recent website update at the time of the search:</i> 11 October 2010</p> <p><i>Limits applied:</i> The list of the consultations starting from the ‘FDA Letter Date’ of January 01, 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “3”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM soybean products.</p>

CFIA	<p>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 decision documents – The webpage dedicated to repository documents referring to plants with novel traits was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> not clear</p> <p><i>Limits applied:</i> The list of repository documents referring to plants with novel traits starting from 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “16”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM soybean products.</p>
Health Canada	<p>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.</p> <p><i>Date of the most recent website update at the time of the search:</i> 07 May 2020</p> <p><i>Limits applied:</i> The list of novel food decisions starting from the ‘Decision Date (20YY/MM/DD)’ of 2019/01/01 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “3”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM soybean products.</p>
FSANZ	<p>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.</p> <p><i>Date of the most recent website update at the time of the search:</i> August 2019</p> <p><i>Limits applied:</i> The list for GM applications and approvals with ‘Status’ approved or under assessment starting from 2019, was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “1”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM soybean products.</p>

CTNBio	<p>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.</p> <p><i>Date of the most recent website update at the time of the search:</i> 10 June 2015</p> <p><i>Limits applied:</i> The list of commercial releases for plants (= plantas) starting from 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “3”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> One of the retrieved records is relevant to 40-3-2 (CTNBio, 2019). It does not have any implication on the risk assessment, because no new hazards, modified exposure, or new scientific uncertainties are reported.</p>
CONABIA	<p>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.</p> <p><i>Date of the most recent website update at the time of the search:</i> Not available</p> <p><i>Limits applied:</i> The list of events with commercial resolución starting from 2019 were checked.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “9”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM soybean products.</p>
MAFF	<p>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.</p> <p><i>Date of the most recent website update at the time of the search:</i> 17 June 2020</p> <p><i>Limits applied:</i> The list of GM agricultural crops with approval date (‘承認日’) starting from January 01, 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “13”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> One of the retrieved records is relevant to MON 87701. It does not have any implication on the risk assessment, because no new hazards, modified exposure, or new scientific uncertainties are reported. The record documents new import approval for MON 87701 on 20 February 2019. By granting the new import approval, MAFF abolished the post-market environmental monitoring of MON 87701 soybean, which was a condition for granting an earlier approval for MON87701 on 25 February 2013 (No specific report was published on this product by the MAFF).</p>

REFERENCES

CTNBio, 2019. Parecer Técnico: Liberação Comercial 6540/2019.

<http://ctnbio.mctic.gov.br/documents/566529/2260286/Parecer+T%C3%A9cnico+n%C2%BA%206450+-+2019/8596e606-2d11-4835-a196-03be2133b168?version=1.0>, 1-11.

Annex V. Results of the publication selection process for Bayer GM soybean 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)	333
Publications excluded after rapid assessment for relevance	321
Publications screened using full-text documents	12
Publications excluded after detailed assessment for relevance	2
Unobtainable publications	0
Unclear publications	1
Publications considered relevant	9

Table 2. List of all relevant publications for Bayer GM soybean 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			
40-3-2	(Xia <i>et al.</i> , 2019)	Compositional differences between conventional Chinese and genetically modified Roundup Ready soybeans	Crop & Pasture Science
MON 87705, MON 87701 × MON 89788	(Liu <i>et al.</i> , 2020)	iTRAQ-based quantitative proteomic analysis of two transgenic soybean lines and the corresponding non-genetically modified isogenic variety.	Journal of Biochemistry
Toxicology			
MON 87701 × MON 89788	(Nikitin, 2019)	180-day toxicological research of GM soybean line MON 87701 x MON 89788: the results of morphological examination	Toxicology Letters
40-3-2	(Eissa <i>et al.</i> , 2019)	Biochemical and histopathological studies on female and male Wistar rats fed on genetically modified soybean meals (Roundup Ready).	Journal of Basic and Applied Zoology
40-3-2	(Shi <i>et al.</i> , 2019)	Evaluation of the effects of feeding glyphosate-tolerant soybeans (CP4 EPSPS) on the testis of male Sprague-Dawley rats.	GM Crops and Food: Biotechnology in Agriculture and the Food Chain
MON 87701 × MON 89788	(Baranov <i>et al.</i> , 2019)	GM stack soybean MON 87701 x MON 89788 reproduction toxicity investigation	Toxicology Letters
40-3-2	(Chorna, 2019)	Structure and functions of kidneys of two generations of rats fed on glyphosate-resistant genetically modified soybean and Roundup	ScienceRise: Biological Science

Ag/Pheno			
40-3-2	(Chen <i>et al.</i> , 2020)	Registration of 'S14-15146GT' soybean, a high-yielding RR1 cultivar with high oil content and broad disease resistance and adaptation	Journal of Plant Registrations.
MON 87701 × MON 89788, 40-3-2	(Ferreira and de Carvalho, 2019)	Transgenic impact: analysis of the effect of storage on the physiological attribute of soybean seeds.	Applied Research & Agrotechnology

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
Chang <i>et al.</i>	2019	Effects of severe drought and glyphosate stress on physiological characteristics and protein expression of photosystem II in genetically modified soybean	Plant Diseases and Pests	The study did not use a non-GM comparator
Islam <i>et al.</i>	2019	Quantitative Proteomic Analysis of Low Linolenic Acid Transgenic Soybean Reveals Perturbations of Fatty Acid Metabolic Pathways	Proteomics	The hybrid used to conduct the study is not Bayer GM soybean product

Table 5. List of unclear publications, with explanation why they could not be classified

Study authors	Year	Title	Source	Explanation of why the publication could not be classified, with a description of methods used to resolve the remaining uncertainty
Matsuo <i>et al.</i>	2020	Comparison of various soybean allergen levels in genetically and non-genetically modified soybeans.	Foods	Based on the available information regarding the “soybean expressing CP4 EPSPS” that is mentioned in the publication, it was not possible to determine which event was used in the study.

Table 6. 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		
(Xia <i>et al.</i> , 2019)	Not reliable	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Liu <i>et al.</i> , 2020)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Toxicology		
(Nikitin, 2019)	Not assignable	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Eissa <i>et al.</i> , 2019)	Low ³	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Shi <i>et al.</i> , 2019)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Baranov <i>et al.</i> , 2019)	Not assignable	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Chorna, 2019)	Not reliable ⁴	None, because no new hazards, modified exposure, or new scientific uncertainties are

		reported
Ag/Pheno		
(Chen <i>et al.</i> , 2020)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
(Ferreira and de Carvalho, 2019)	Moderate	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 **Eissa et al. (2019)**

The objective of this paper was to evaluate effects of a diet containing GN soybean meal on male and female Wistar rats. The data presented do not support the author's conclusion which indicates the necessity to revise the safety standards of consumption of diets containing GM soybean. The study didn't follow OECD guidelines (e.g., 18-week study), lacked dose-dependent effects and the results were inconclusive as stated by the authors: "*The observed histopathological alterations and blood biochemical changes in our study may be related to consumption of GM soybean diet. The mechanisms responsible for this change are still unknown and further studies essentially required.*"

⁴ **Chrona et al. (2019)**

The objective of this paper was to study potential effects of Roundup and glyphosate-resistant soybean on the kidney morphology of two generations of rats. An assessment of the paper demonstrated that the experimental design is not consistent with 2-Gen guideline studies, the methods not clearly defined (mating and reproductive parameters) and the observed effects are not related to the GM soybean treatment.

REFERENCES

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

- Baranov EA, Shestakova S, Sadykova E and Tyshko N, 2019. GM stack soybean MON87701xMON89788 reproduction toxicity investigation. *Toxicology Letters*, 1-2.
- Chen P, Shannon G, Scaboo A, Crisel M, Smothers S, Clubb M, Selves S, Canella Vieira C, Liakat Ali M, Goellner Mitchum M, Nguyen H, Li Z, Bond J, Meinhardt C, Klepadlo M, Li S, Mengistu A and Robbins RT, 2020. Registration of 'S14-15146GT' soybean, a high-yielding RR1 cultivar with high oil content and broad disease resistance and adaptation. *Journal of Plant Registrations*, 14, 35-42.
- Chorna IV, 2019. Structure and functions of kidneys of two generations of rats fed on glyphosate-resistant genetically modified soybean and Roundup. *ScienceRise: Biological Science*, 1 (16), 25-29.
- 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.
- Eissa MI, El-Sherbiny MA, Ibrahim AM, Abdelsadik A, Mohamed MM and El-Halawany MS, 2019. Biochemical and histopathological studies on female and male Wistar rats fed on genetically modified soybean meals (Roundup Ready). *The Journal of Basic and Applied Zoology*, 80:54, 1-12.
- Ferreira R and de Carvalho TC, 2019. Transgenic impact: analysis of the effect of storage on the physiological attribute of soybean seeds. *Impacto dos transgenicos: analise do efeito do armazenamento no atributo fisiologico de sementes de soja. Brazilian Journal of Applied Technology for Agricultural Science*, 12, 7-15.
- Liu W, Zhang Z, Liu H and Jin W, 2020. iTRAQ-based quantitative proteomic analysis of two transgenic soybean lines and the corresponding non-genetically modified isogenic variety. *The Journal of Biochemistry*, 167(1), 67-78.
- Nikitin NS, 2019. 180-day toxicological research of GM soybean line MON87701xMON89788: the results of morphological examination. *Toxicology Letters*, 1-1.
- Shi Z, Zou S, Lu C, Wu B, Huang K, Zhao C and He X, 2019. Evaluation of the effects of feeding glyphosate-tolerant soybeans ((CP4 EPSPS) on the testis of male Sprague-Dawley rats. *GM Crops & Food*, 10, 181-190.
- Xia Y, Chen F, Liu K, Zhang L, Duan X, Zhang X and Zhu Z, 2019. Compositional differences between conventional Chinese and genetically modified Roundup Ready soybeans. *Crop & Pasture Science*, 70, 526-534.

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

TY - JOUR

AU - Baranov, E.A.

AU - Shestakova, S.

AU - Sadykova, E.

AU - Tyshko, N.

PY - 2019

SP - 1-2

ST - GM stack soybean MON87701xMON89788 reproduction toxicity investigation

T2 - Toxicology Letters

TI - GM stack soybean MON87701xMON89788 reproduction toxicity investigation

ID - 17

ER -

TY - JOUR

AU - Chen, P.

AU - Shannon, G.

AU - Scaboo, A.

AU - Crisel, M.

AU - Smothers, S.

AU - Clubb, M.

AU - Selves, S.

AU - Canella Vieira, C.

AU - Liakat Ali, Md.

AU - Goellner Mitchum, M.

AU - Nguyen, H.

AU - Li, Z.

AU - Bond, J.

AU - Meinhardt, C.

AU - Klepadlo, M.

AU - Li, S.

AU - Mengistu, A.

AU - Robbins, R.T.

PY - 2020

SP - 35-42

ST - Registration of 'S14-15146GT' soybean, a high-yielding RR1 cultivar with high oil content and broad disease resistance and adaptation

T2 - Journal of Plant Registrations

TI - Registration of 'S14-15146GT' soybean, a high-yielding RR1 cultivar with high oil content and broad disease resistance and adaptation

VL - 14

ID - 2

ER -

TY - JOUR

AU - Chorna, I.V.

PY - 2019

SP - 25-29

ST - Structural-functional state of kidneys of rats of two generations when using glyphosate-resistant genetically modified soy and herbicide Roundup

T2 - ScienceRise: Biological Science

TI - Structural-functional state of kidneys of rats of two generations when using glyphosate-resistant genetically modified soy and herbicide Roundup

VL - 1 (16)

ID - 16

ER -

TY - JOUR

AU - Eissa, M.I.

AU - El-Sherbiny, M.A.

AU - Ibrahim, A.M.

AU - Abdelsadik, A.

AU - Mohamed, M.M.

AU - El-Halawany, M.S.

PY - 2019

SP - 1-12

ST - Biochemical and histopathological studies on female and male Wistar rats fed on genetically modified soybean meals (Roundup Ready)

T2 - The Journal of Basic and Applied Zoology

TI - Biochemical and histopathological studies on female and male Wistar rats fed on genetically modified soybean meals (Roundup Ready)

VL - 80:54

ID - 15

ER -

TY - JOUR

AU - Ferreira, R.

AU - de Carvalho, T.C.

IS - 3

PY - 2019

SP - 7-15

ST - Transgenic impact: analysis of the effect of storage on the physiological attribute of soybean seeds.Impacto dos transgenicos: analise do efeito do armazenamento no atributo fisiologico de sementes de soja

T2 - Brazilian Journal of Applied Technology for Agricultural Science

TI - Transgenic impact: analysis of the effect of storage on the physiological attribute of soybean seeds.Impacto dos transgenicos: analise do efeito do armazenamento no atributo fisiologico de sementes de soja

VL - 12

ID - 1

ER -

TY - JOUR

AU - Liu, W.

AU - Zhang, Z.

AU - Liu, H.

AU - Jin, W.

PY - 2020

SP - 67-78

ST - iTRAQ-based quantitative proteomic analysis of two transgenic soybean lines and the corresponding non-genetically modified isogenic variety

T2 - The Journal of Biochemistry

TI - iTRAQ-based quantitative proteomic analysis of two transgenic soybean lines and the corresponding non-genetically modified isogenic variety

VL - 167(1)

ID - 3

ER -

TY - JOUR

AU - Nikitin, N.S.

PY - 2019

SP - 1-1

ST - 180-day toxicological research of GM soybean line MON87701xMON89788: the results of morphological examination

T2 - Toxicology Letters

TI - 180-day toxicological research of GM soybean line MON87701xMON89788: the results of morphological examination

ID - 14

ER -

TY - JOUR

AU - Shi, Z.

AU - Zou, S.

AU - Lu, C.

AU - Wu, B.

AU - Huang, K.

AU - Zhao, C.

AU - He, X.

PY - 2019

SP - 181-190

ST - Evaluation of the effects of feeding glyphosate-tolerant soybeans ((CP4 EPSPS) on the testis of male Sprague-Dawley rats

T2 - GM Crops & Food

TI - Evaluation of the effects of feeding glyphosate-tolerant soybeans ((CP4 EPSPS) on the testis of male Sprague-Dawley rats

VL - 10

ID - 9

ER -

TY - JOUR

AU - Xia, Y.

AU - Chen, F.

AU - Liu, K.

AU - Zhang, L.

AU - Duan, X.

AU - Zhang, X.

AU - Zhu, Z.

PY - 2019

SP - 526-534

ST - Compositional differences between conventional Chinese and genetically modified Roundup Ready soybeans

T2 - Crop & Pasture Science

TI - Compositional differences between conventional Chinese and genetically modified Roundup Ready soybeans

VL - 70

ID - 13

ER -