

APPENDIX 3

LITERATURE SEARCH TO SUPPORT GENERAL SURVEILLANCE OF 2021/2022 ANNUAL POST MARKET ENVIRONMENTAL MONITORING REPORTS OF BAYER GM COTTON PRODUCTS

Data protection.

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SUMMARY

The literature search was conducted in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications^{1,2} to support general surveillance of 2021/2022 annual post market environmental monitoring reports. It addresses the review question “Do Bayer GM cotton products, derived food/feed products and their respective introduced traits have adverse effects on human and animal health and the environment?”.

Eligibility/inclusion criteria to establish the relevance of retrieved publications was determined following the criteria described in the 2019 EFSA explanatory note on literature searching². Literature searching for Bayer GM cotton products was conducted in electronic bibliographic databases and internet pages of relevant key organisations.

In line with the requirements in the 2019 EFSA explanatory note on literature searching² the literature search covered the time span 2021 – 2022 to capture any publication published during the annual general surveillance of 2021/2022 post market environmental monitoring season.

The literature search retrieved three publications 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 cotton products.

¹ Hereafter referred to as 2019 EFSA explanatory note on literature searching.

² 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.](#) – Accessed on 19 September 2022.

1. INTRODUCTION

As part of the general surveillance requirements for Bayer GM cotton products authorised in the European Union (EU) market under regulation (EC) No 1829/2003³, Bayer Agriculture BV has actively monitored the cotton products by conducting quarterly literature searches covering the time span between June 2021 and May 2022.

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

The Appendix completeness checklist is provided with 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 cotton 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 2021/2022 annual post market environmental monitoring (PMEM) reports in accordance with the 2019 EFSA explanatory note on literature searching².

Key elements used for the review question are humans, animals, and/or the environment (= population), Bayer GM cotton products, derived food/feed products and respective introduced traits (= intervention/exposure), conventional counterpart or non-GM cotton (= 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**.

³ EC, 2003. [REGULATION \(EC\) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed](#). – Accessed 19 September 2022.

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 cotton but excluding the cultivation of Bayer GM cotton products are addressed as general protection goals.
Intervention/exposure	Bayer GM cotton 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 cotton 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	
Information/ data requirements, including source of publications data	The publication potentially contributes to the knowledge of the risk assessment of Bayer GM cotton products for all uses as any other cotton but excluding cultivation. Original/primary data are presented in the publication.

The eligibility/inclusion criteria implemented by Bayer for assessing the relevance of publications follow the recommendations described in the 2019 EFSA explanatory note on literature searching². Following a conservative approach, Bayer selected the broad inclusion/eligibility criteria that align with the review question and the scope of the Bayer GM cotton products' authorisations. Hence, given the conservative approach taken when selecting the eligibility/inclusion criteria, conducting a pilot study was considered unwarranted.

When necessary, the eligibility criteria and/or process may be modified/reviewed as a result of for example new regulatory guidance or novel topics on literature regarding the risk assessment of GM plants.

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 making⁴ and the 2019 EFSA explanatory note on literature searching², identification of bibliographic sources and development of search strategies were 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)⁵ and the CABA⁶ (CAB Abstracts®)⁷ 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 catalogue⁸.

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”⁵. 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”⁶. 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

⁴ EFSA, 2010. [Application of systematic review methodology to food and feed safety assessments to support decision making](#) The EFSA Journal, 1637, 1-90 - Accessed on 19 September 2022.

⁵ STN/SciSearch: <https://www.stn-international.com/sites/default/files/stn/dbss/SCISEARCH.pdf> - Accessed on 19 September 2022.

⁶ STN/CABA: <https://www.stn-international.com/sites/default/files/stn/dbss/CABA.pdf> – Accessed on 19 September 2022.

⁷ CAB Abstracts®: <https://www.cabi.org/publishing-products/online-information-resources/cab-abstracts/> - Accessed on 19 September 2022.

⁸ STN®: <http://stn-international.de/sites/default/files/STN/brochures/stnfile-kat.pdf> - Accessed on 19 September 2022.

bibliographic information (title, abstract, keywords) and be peer-reviewed^{7,9}. 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 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 searching², 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 searching², 11¹⁰ are involved in risk assessment of Bayer GM cotton products. The remaining three (CIBIOGEM, Environment and Climate Change Canada and OECD) are not involved in GM risk assessment of cotton. Therefore, the internet search focused on the eleven key organisations relevant for Bayer GM cotton 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 searching²:

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

⁹ Web of Science group; <https://clarivate.com/webofsciencegroup/solutions/webofscience-core-collection-editorial-selection-process/> - Accessed on 19 September 2022

¹⁰ Internet pages of the relevant key organisations for Bayer GM cotton products:
 US EPA (<https://www.epa.gov/environmental-topics/science-topics>) - Accessed on 19 September 2022;
 USDA (<https://www.usda.gov/media>) - Accessed on 19 September 2022;
 US FDA (<https://www.fda.gov/>) - Accessed on 19 September 2022;
 CFIA (<http://www.inspection.gc.ca/eng/1297964599443/1297965645317>) - Accessed on 19 September 2022;
 Health Canada (<https://www.canada.ca/en/health-canada.html>) - Accessed on 19 September 2022;
 FSANZ (<http://www.foodstandards.gov.au/Pages/default.aspx>) - Accessed on 19 September 2022;
 CTNBio (<http://ctnbio.mctic.gov.br/>) - Accessed on 19 September 2022;
 CONABIA (<https://www.argentina.gob.ar/>) - Accessed on 19 September 2022;
 Japan MAFF (<http://www.maff.go.jp/e/>) - Accessed on 19 September 2022;
 OGTR (<http://www.ogtr.gov.au/>) - Accessed on 19 September 2022;
 GEAC (<http://www.geacindia.gov.in/approved-products.aspx>) - Accessed on 19 September 2022.

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 cotton products.

The translation of the intervention key elements into search terms are presented in **Annex I**. 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[®] commands¹¹ 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 both¹². 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^{5,6,14}. 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 terms¹³. 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.

¹¹ STN. [Command summary chart for bibliographic and full-text databases](#). – Accessed on 19 September 2022.

¹² STNindex user guide: <https://stn.products.fiz-karlsruhe.de/training-center/documentation/stn-index-user-guide> - Accessed on 19 September 2022.

¹³ 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 19 September 2022.

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 June 2021 - 31 May 2022.

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	Last database update dates	Search period
12 October 2021	SciSearch: 11 October 2021	31 May 2021 – 11 October 2021
	CABA: 05 October 2021	31 May 2021 – 05 October 2021
02 February 2022	SciSearch: 31 January 2022	05 October 2021– 31 January 2022
	CABA: 01 February 2022	05 October 2021– 01 February 2022
09 June 2022	SciSearch: 06 June 2022	31 January 2022– 06 June 2022
	CABA: 07 June 2022	31 January 2022– 07 June 2022

3.2.5. Reference publications

In accordance with the 2019 EFSA explanatory note on literature searching², a list of reference publications is provided in **Annex III**. The reference publications were tested and retrieved using the search terms and strategy developed for Bayer GM cotton products.

3.3. Search strategy (relevant key organisations)

All records related to 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** and assessed for their relevance to Bayer GM cotton products.

The literature search in the internet pages of the relevant key organisations was conducted on 08 September/04 October 2022 and covered the time span 01 January 2021– 08 September/ 04 October 2022.

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

4.2.1. Number of 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.

4.2.2. Expertise of reviewers

Besides their academic background, the reviewers have adequate expertise in the risk assessment areas of GM crops (molecular characterisation, food and feed safety, environmental safety) and several years of experience in the analysis and selection of relevant publications in literature searches for GM applications.

4.2.3. Inter-reviewer agreement

Reviewers (internal and external) perform their assessment in an independent sequential manner. They are in communication and meet on a regular basis to ensure consistent interpretation and implementation of eligibility/inclusion criteria and/or screening process. During the rapid assessment stage, retrieved abstracts and titles of publications are screened by each reviewer independently and assessed against each other to conclude on inclusion or exclusion based on eligibility/inclusion criteria. If opinions on relevance differ, the discrepancies are discussed between the reviewers and if a disagreement persists, the publication under discussion is *de facto* included in the next stage for further consideration. In summary, publications which appear to be relevant and those of unclear relevance, are progressed to the next stage.

During the detailed assessment, the selected publications are assessed in detail, independently and sequentially by the two external reviewers based on the full text of the publications. The publications screened by each reviewer are assessed against each other to conclude on inclusion or exclusion based on eligibility/inclusion criteria. If opinions on relevance differ between reviewers, all reviewers (external and internal) discuss the discrepancy as necessary and, if needed, consult additional internal reviewers to resolve the discrepancy.

If uncertainty remains, the publication is *de facto* reported as unclear providing a justification as suggested by the reviewers. In summary, publications, which appear to be relevant and those of unclear relevance, are reported.

This approach ensures a high-quality process as it allows a harmonised continuous publication screening process across different GM applications in accordance with the

2019 EFSA explanatory note on literature searching² and avoids missing publications due to bias towards certain eligibility criteria.

4.3. Classification of publications

Taking account of i) the review question, ii) the scope of the application, *i.e.* authorisation of Bayer GM cotton products for all uses as any other cotton but excluding cultivation in the EU and iii) the eligibility criteria to establish the relevance of retrieved publications, the list of retrieved hits were 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 searching² by at least two individuals with technical expertise on the topic using the following steps categorised in two main areas:

Credibility of the publication

1. ***Does the publication include sufficient information to establish the reliability of the research?*** Publications with insufficient information (e.g., incomplete experimental design, publications for which only an abstract is publicly available) are categorised as “**not assignable**”. Others go to step 2.
2. ***Is the publication scientifically sound/reliable?*** Publications that do not contain scientifically sound/reliable information (e.g., inadequate methodology, test/control materials) are categorised as “**not reliable**”. Others go to step 3.

Appropriateness of the publication for the EFSA risk assessment

3. ***What is the relevance level of the publication for the EFSA risk assessment?*** Publications with low relevance for the EFSA risk assessment (e.g. publications dealing with wild relatives or pests not found in the EU) are categorised as “**low reliable**”. Publications with moderate relevance for the EFSA risk assessment (e.g., exploratory

studies, research with limited focus on risk assessment) are categorised as “**moderately reliable**”. Whereas publications with high relevance for the EFSA risk assessment (e.g. research based on data collected for regulatory studies) are categorised as “**highly reliable**”.

In cases of disagreements, the evaluators discuss together and collectively determine the reliability of the publication.

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 162 and 132 hits in SciSearch and CABA databases, respectively (see **Annex II**). After de-duplication¹⁴, the total number resulted in 250 hits (see **Annex V**).

5.1.2. Outcomes of literature search (relevant key organisations)

The literature search in the internet pages of the 11 relevant key organisations retrieved a total of 813 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**. Three 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 Appendix 3_Literature search 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**. None of the retrieved documents needed further assessment.

5.3. Considering the implications of the findings

The reliability assessment for the relevant publications is provided in **Annex V**. All the relevant publications have no implications for the risk assessment of Bayer GM cotton products because no new hazards, modified exposure, or new uncertainties are reported.

¹⁴ Corresponds to the unique publications after STN® and manual de-duplication.

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

6. CONCLUSION

Taking into consideration all the above, Bayer confirms that this literature search, conducted in accordance with the 2019 EFSA explanatory note on literature searching² to support the general surveillance in the context of 2021/2022 annual PMEM for Bayer GM cotton products, identified no relevant publications that would invalidate the conclusions of the Bayer GM cotton products previous risk assessments. Therefore, the conclusions of the risk assessment as presented in the initial applications of the Bayer GM cotton products remain unchanged.

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

1. Free-text search terms for Bayer GM Cotton 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 15985 or MON-15985-7 MON 88913 or MON-88913-8	MON!15985? OR MON 15985? OR MON15985? OR MON!88913? OR MON 88913? OR MON88913?
Trade name	Genuity® Bollgard II® cotton Genuity® Roundup Ready® Flex cotton	BOLLGARD II? OR BOLLGARD!II? OR BOLLGARDII? OR BOLLGARD 2? OR BOLLGARD!2? OR BOLLGARD2? OR BG II OR BGII OR BG!II OR BG 2 OR BG2 OR BG!2 ROUNDUPREADY? OR ROUND!UP!READY? OR ROUND!UP READY? OR ROUNDUP READY? OR ROUND UP READY? OR RRFLEX OR RR FLEX OR RR!FLEX
Newly expressed proteins	CP4 EPSPS Cry1Ac Cry2Ab2	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 CRY1AC OR CRY1 AC OR CRY 1 AC OR CRY 1AC OR CRYIAC OR CRYI AC OR CRY I AC OR CRY IAC CRY2AB? OR CRY2 AB? OR CRY 2 AB? OR CRY 2AB? OR CRYIIAB? OR CRYII AB? OR CRY II AB? OR CRY IIAB?
Intended traits: Herbicide tolerance traits	Glyphosate/roundup tolerance	(TOLERAN? OR RESISTAN? OR PROTEC?)(5A)(GL!PHOSATE OR GL!FOSATE OR ROUNDUP? OR ROUND UP?)
Intended traits: Insect protection traits	<i>Bt</i> Cotton / <i>Bacillus thuringiensis</i> , Cotton providing Lepidopteran protection against Noctuidae and Gelechiidae insect pest families or Tobacco budworm (TBW) or cotton bollworm or corn ear worm	(BTCOTTON OR BT COTTON OR BT!COTTONOR THURINGIENSIS!COTTON OR THURINGIENSIS COTTON OR THURINGIENSISCOTTON) (TOLERAN? OR RESISTAN? OR PROTEC?)(5A)(LEPIDOPTERA? OR BOLLWORM? OR BOLL WORM? OR BUDWORM? OR BUD WORM? OR EARWORM? OR EAR WORM?

	(CBW/CEW) or pink bollworm (PBW) or <i>Heliothis virescens</i> or <i>Helicoverpa zea</i> or <i>Pectinophora gossypiella</i>	OR NOCTUIDAE OR GELECHIIDAE OR HELIOTHIS OR VIRESCENS OR HELICOVERPA OR ZEA OR PECTINOPHORA OR GOSSYPIELLA OR TBW OR CBW OR CEW)
Crop name	Cotton, <i>Gossypium</i>	COTTON OR GOSSYPIMUM
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 Cotton 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	<i>Bt</i> Cotton / <i>Bacillus thuringiensis</i> , Cotton providing Lepidopteran protection against Noctuidae and Gelechiidae insect pest families or Tobacco budworm (TBW) or cotton bollworm or corn ear worm (CBW/CEW) or pink bollworm (PBW) or <i>Heliothis virescens</i> or <i>Helicoverpa zea</i> or <i>Pectinophora gossypiella</i> Glyphosate/ roundup tolerance	(WEED CONTROL+UF,NT/CT OR INSECT CONTROL+UF,NT/CT) AND (LEPIDOPTERA+UF,NT2/CT,ORGN OR GLYPHOSATE+UF,NT/CT)
Crop name	Cotton, <i>Gossypium</i>	COTTON+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 cotton products literature search in SciSearch and CABA databases using STN® database catalogue, and outcomes of the search (2021-2022)

Bayer GM Cotton products literature search – First quarter (June 2021 - September 2021)

Translation of query terms into STN search language:

```
(FILE 'STNGUIDE' ENTERED AT 14:33:58 ON 12 OCT 2021)
      DEL HIS Y
L1      QUE SPE=ON ABB=ON PLU=ON MON!15985? OR MON 15985? OR
      MON15985? OR MON!88913? OR MON 88913? OR MON88913?
L2      QUE SPE=ON ABB=ON PLU=ON BOLLGARD II? OR BOLLGARD!II? OR
      BOLLGARDII? OR BOLLGARD 2? OR BOLLGARD!2? OR BOLLGARD2? OR BG
      II OR BGII OR BG!II OR BG 2 OR BG2 OR BG!2
L3      QUE SPE=ON ABB=ON PLU=ON ROUNDUPREADY? OR ROUND!UP!READY?
      OR ROUND!UP READY? OR ROUNDUP READY? OR ROUND UP READY? OR
      RRFLEX OR RR FLEX OR RR!FLEX
L4      QUE SPE=ON ABB=ON PLU=ON COTTON OR GOSSYPIMUM
L5      QUE SPE=ON ABB=ON PLU=ON 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
L6      QUE SPE=ON ABB=ON PLU=ON CRYIAC OR CRY1 AC OR CRY 1 AC OR
      CRY 1AC OR CRYIAC OR CRYI AC OR CRY I AC OR CRY IAC
L7      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?
L8      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?))
L9      QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR PROTEC?) (
      5A) (GL!PHOSATE OR GL!FOSATE OR ROUND!UP? OR ROUNDUP? OR ROUND
      UP?)
L10     QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR PROTEC?) (
      5A) (LEPIDOPTERA? OR BOLLWORM? OR BOLL WORM? OR BUDWORM? OR BUD
      WORM? OR EARWORM? OR EAR WORM?)
L11     QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR PROTEC?) (
      5A) (NOCTUIDAE OR GELECHIIDAE OR HELIOTHIS OR VIRESCENS OR
      HELICOVERPA OR ZEA OR PECTINOPHORA OR GOSSYPIELLA OR TBW OR
      CBW OR CEW)
L12     QUE SPE=ON ABB=ON PLU=ON (BTCOTTON OR BT COTTON OR BT!COTTON
      OR THURINGIENSIS!COTTON OR THURINGIENSIS COTTON OR THURINGIENS
      ISCOTTON)
L13     QUE SPE=ON ABB=ON PLU=ON COTTON+UF,NT/CT,ORGN
L14     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
L15     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)
```

Search in SciSearch Database:

FILE 'SCISEARCH' ENTERED AT 14:34:31 ON 12 OCT 2021

L16	1	SEA SPE=ON	ABB=ON	PLU=ON	L1 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L17	20	SEA SPE=ON	ABB=ON	PLU=ON	(L2 OR L3) AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L18	1997	SEA SPE=ON	ABB=ON	PLU=ON	L4 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L19	7	SEA SPE=ON	ABB=ON	PLU=ON	L17 AND L18
L20	25	SEA SPE=ON	ABB=ON	PLU=ON	L5 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L21	58	SEA SPE=ON	ABB=ON	PLU=ON	(L6 OR L7) AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L22	82	SEA SPE=ON	ABB=ON	PLU=ON	L20 OR L21
L23	11060	SEA SPE=ON	ABB=ON	PLU=ON	L8 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L24	53	SEA SPE=ON	ABB=ON	PLU=ON	L22 AND (L23 OR L18)
L25	104	SEA SPE=ON	ABB=ON	PLU=ON	L9 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L26	67	SEA SPE=ON	ABB=ON	PLU=ON	(L10 OR L11) AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L27	55	SEA SPE=ON	ABB=ON	PLU=ON	L12 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L28	170	SEA SPE=ON	ABB=ON	PLU=ON	L25 OR L26
L29	15	SEA SPE=ON	ABB=ON	PLU=ON	L28 AND L23 AND L18
L30	27	SEA SPE=ON	ABB=ON	PLU=ON	L27 AND L23
L31	38	SEA SPE=ON	ABB=ON	PLU=ON	L29 OR L30
L32	79	SEA SPE=ON	ABB=ON	PLU=ON	L16 OR L19 OR L24 OR L31

Search in CABA Database:

FILE 'CABA' ENTERED AT 14:34:50 ON 12 OCT 2021

L33	1	SEA SPE=ON	ABB=ON	PLU=ON	L1 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L34	13	SEA SPE=ON	ABB=ON	PLU=ON	(L2 OR L3) AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L35	880	SEA SPE=ON	ABB=ON	PLU=ON	L4 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L36	558	SEA SPE=ON	ABB=ON	PLU=ON	L13 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L37	880	SEA SPE=ON	ABB=ON	PLU=ON	L35 OR L36
L38	5	SEA SPE=ON	ABB=ON	PLU=ON	L34 AND L37
L39	9	SEA SPE=ON	ABB=ON	PLU=ON	L5 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L40	28	SEA SPE=ON	ABB=ON	PLU=ON	(L6 OR L7) AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L41	37	SEA SPE=ON	ABB=ON	PLU=ON	L39 OR L40
L42	3063	SEA SPE=ON	ABB=ON	PLU=ON	L8 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L43	1353	SEA SPE=ON	ABB=ON	PLU=ON	L14 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L44	3071	SEA SPE=ON	ABB=ON	PLU=ON	L42 OR L43
L45	27	SEA SPE=ON	ABB=ON	PLU=ON	L41 AND (L37 OR L44)
L46	60	SEA SPE=ON	ABB=ON	PLU=ON	L9 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L47	41	SEA SPE=ON	ABB=ON	PLU=ON	(L10 OR L11) AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L48	27	SEA SPE=ON	ABB=ON	PLU=ON	L12 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L49	49	SEA SPE=ON	ABB=ON	PLU=ON	L15 AND ED>=20210531 AND ED<=20211011 AND PY>=2021
L50	140	SEA SPE=ON	ABB=ON	PLU=ON	L46 OR L47 OR L49
L51	11	SEA SPE=ON	ABB=ON	PLU=ON	L50 AND L44 AND L37
L52	23	SEA SPE=ON	ABB=ON	PLU=ON	L48 AND L44
L53	30	SEA SPE=ON	ABB=ON	PLU=ON	L51 OR L52

L54 50 SEA SPE=ON ABB=ON PLU=ON L33 OR L38 OR L45 OR L53

Deduplication of Hit-sets from both sources:

FILE 'CABA, SCISEARCH' ENTERED AT 14:37:07 ON 12 OCT 2021
L55 116 DUP REM L54 L32 (13 DUPLICATES REMOVED)
 ANSWERS '1-50' FROM FILE CABA
 ANSWERS '51-116' FROM FILE SCISEARCH
 D L55 1-116 ALL PY

FILE SCISEARCH

FILE COVERS 1974 TO 11 Oct 2021 (20211011/ED)

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

FILE CABA

FILE LAST UPDATED: 5 OCT 2021 <20211005/UP>
FILE COVERS 1973 TO DATE

Bayer GM Cotton products literature search – Second quarter (October 2021 - January 2022)

Translation of query terms into STN search language:

```
(FILE 'STNGUIDE' ENTERED AT 10:08:38 ON 02 FEB 2022)
DEL HIS Y
L1      QUE SPE=ON  ABB=ON  PLU=ON  MON!15985? OR MON 15985? OR
MON15985? OR MON!88913? OR MON 88913? OR MON88913?
L2      QUE SPE=ON  ABB=ON  PLU=ON  BOLLGARD II? OR BOLLGARD!II? OR
BOLLGARDII? OR BOLLGARD 2? OR BOLLGARD!2? OR BOLLGARD2? OR BG
II OR BGII OR BG!II OR BG 2 OR BG2 OR BG!2
L3      QUE SPE=ON  ABB=ON  PLU=ON  ROUNDUPREADY? OR ROUND!UP!READY?
OR ROUND!UP READY? OR ROUNDUP READY? OR ROUND UP READY? OR
RRFLEX OR RR FLEX OR RR!FLEX
L4      QUE SPE=ON  ABB=ON  PLU=ON  COTTON OR GOSSYPIMUM
L5      QUE SPE=ON  ABB=ON  PLU=ON  CP4EPSPS? OR CP4 EPSPS? OR
5(W) (ENOLPYRUVYLSHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR
ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR ENOL!PYRUVYL!
SHIKIMATE!) (W) 3 PHOSPHATE SYNTHASE
L6      QUE SPE=ON  ABB=ON  PLU=ON  CRYIAC OR CRY1 AC OR CRY 1 AC OR
CRY 1AC OR CRYIAC OR CRYI AC OR CRY I AC OR CRY IAC
L7      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?
L8      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?))
L9      QUE SPE=ON  ABB=ON  PLU=ON  (TOLERAN? OR RESISTAN? OR PROTEC?) (
5A) (GL!PHOSATE OR GL!FOSATE OR ROUND!UP? OR ROUNDUP? OR ROUND
UP?)
L10     QUE SPE=ON  ABB=ON  PLU=ON  (TOLERAN? OR RESISTAN? OR PROTEC?) (
5A) (LEPIDOPTERA? OR BOLLWORM? OR BOLL WORM? OR BUDWORM? OR BUD
WORM? OR EARWORM? OR EAR WORM?)
L11     QUE SPE=ON  ABB=ON  PLU=ON  (TOLERAN? OR RESISTAN? OR PROTEC?) (
5A) (NOCTUIDAE OR GELECHIIDAE OR HELIOTHIS OR VIRESCENS OR
HELICOVERPA OR ZEA OR PECTINOPHORA OR GOSSYPIELLA OR TBW OR
CBW OR CEW)
L12     QUE SPE=ON  ABB=ON  PLU=ON  (BTCOTTON OR BT COTTON OR BT!COTTON
OR THURINGIENSIS!COTTON OR THURINGIENSIS COTTON OR THURINGIENS
ISCOTTON)
L13     QUE SPE=ON  ABB=ON  PLU=ON  COTTON+UF,NT/CT,ORGN
L14     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
L15     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)
```

Search in SciSearch Database:

```
FILE 'SCISEARCH' ENTERED AT 10:09:13 ON 02 FEB 2022
L16      0 SEA SPE=ON ABB=ON PLU=ON L1 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L17      14 SEA SPE=ON ABB=ON PLU=ON (L2 OR L3) AND ED>=20211005 AND
        ED<=20220131 AND PY>=2021
L18      1508 SEA SPE=ON ABB=ON PLU=ON L4 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L19      1 SEA SPE=ON ABB=ON PLU=ON L17 AND L18
L20      14 SEA SPE=ON ABB=ON PLU=ON L5 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L21      36 SEA SPE=ON ABB=ON PLU=ON (L6 OR L7) AND ED>=20211005 AND
        ED<=20220131 AND PY>=2021
L22      50 SEA SPE=ON ABB=ON PLU=ON L20 OR L21
L23      8810 SEA SPE=ON ABB=ON PLU=ON L8 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L24      26 SEA SPE=ON ABB=ON PLU=ON L22 AND (L23 OR L18)
L25      68 SEA SPE=ON ABB=ON PLU=ON L9 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L26      48 SEA SPE=ON ABB=ON PLU=ON (L10 OR L11) AND ED>=20211005 AND
        ED<=20220131 AND PY>=2021
L27      28 SEA SPE=ON ABB=ON PLU=ON L12 AND ED>=20211005 AND ED<=202201
        31 AND PY>=2021
L28      115 SEA SPE=ON ABB=ON PLU=ON L25 OR L26
L29      10 SEA SPE=ON ABB=ON PLU=ON L28 AND L23 AND L18
L30      17 SEA SPE=ON ABB=ON PLU=ON L27 AND L23
L31      21 SEA SPE=ON ABB=ON PLU=ON L29 OR L30
L32      39 SEA SPE=ON ABB=ON PLU=ON L16 OR L19 OR L24 OR L31
```

Search in CABA Database:

```
FILE 'CABA' ENTERED AT 10:09:28 ON 02 FEB 2022
L33      1 SEA SPE=ON ABB=ON PLU=ON L1 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L34      17 SEA SPE=ON ABB=ON PLU=ON (L2 OR L3) AND ED>=20211005 AND
        ED<=20220131 AND PY>=2021
L35      1260 SEA SPE=ON ABB=ON PLU=ON L4 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L36      898 SEA SPE=ON ABB=ON PLU=ON L13 AND ED>=20211005 AND ED<=202201
        31 AND PY>=2021
L37      1260 SEA SPE=ON ABB=ON PLU=ON L35 OR L36
L38      8 SEA SPE=ON ABB=ON PLU=ON L34 AND L37
L39      20 SEA SPE=ON ABB=ON PLU=ON L5 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L40      36 SEA SPE=ON ABB=ON PLU=ON (L6 OR L7) AND ED>=20211005 AND
        ED<=20220131 AND PY>=2021
L41      55 SEA SPE=ON ABB=ON PLU=ON L39 OR L40
L42      4277 SEA SPE=ON ABB=ON PLU=ON L8 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L43      1943 SEA SPE=ON ABB=ON PLU=ON L14 AND ED>=20211005 AND ED<=202201
        31 AND PY>=2021
L44      4284 SEA SPE=ON ABB=ON PLU=ON L42 OR L43
L45      34 SEA SPE=ON ABB=ON PLU=ON L41 AND (L37 OR L44)
L46      85 SEA SPE=ON ABB=ON PLU=ON L9 AND ED>=20211005 AND ED<=2022013
        1 AND PY>=2021
L47      78 SEA SPE=ON ABB=ON PLU=ON (L10 OR L11) AND ED>=20211005 AND
        ED<=20220131 AND PY>=2021
L48      44 SEA SPE=ON ABB=ON PLU=ON L12 AND ED>=20211005 AND ED<=202201
        31 AND PY>=2021
L49      82 SEA SPE=ON ABB=ON PLU=ON L15 AND ED>=20211005 AND ED<=202201
        31 AND PY>=2021
L50      227 SEA SPE=ON ABB=ON PLU=ON L46 OR L47 OR L49
L51      17 SEA SPE=ON ABB=ON PLU=ON L50 AND L44 AND L37
```

Appendix 3 – Annual general surveillance report in 2021/2022 season
Literature search – Bayer GM cotton products

Bayer Agriculture BV

L52 38 SEA SPE=ON ABB=ON PLU=ON L48 AND L44
L53 47 SEA SPE=ON ABB=ON PLU=ON L51 OR L52
L54 72 SEA SPE=ON ABB=ON PLU=ON L33 OR L38 OR L45 OR L53

Deduplication of Hit-sets from both sources:

FILE 'CABA, SCISEARCH' ENTERED AT 10:10:18 ON 02 FEB 2022
L55 104 DUP REM L54 L32 (7 DUPLICATES REMOVED)
 ANSWERS '1-72' FROM FILE CABA
 ANSWERS '73-104' FROM FILE SCISEARCH
 D L55 1-104 ALL PY

FILE SCISEARCH

FILE COVERS 1974 TO 31 Jan 2022 (20220131/ED)

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

FILE CABA

FILE LAST UPDATED: 25 JAN 2021 <20210125/UP>
FILE COVERS 1973 TO DATE

Bayer GM Cotton products literature search – Third quarter (February 2022 – May 2022)

Translation of query terms into STN search language:

(FILE 'STNGUIDE' ENTERED AT 12:01:33 ON 01 JUN 2021)

L1 QUE SPE=ON ABB=ON PLU=ON MON!15985? OR MON 15985? OR
MON15985? OR MON!88913? OR MON 88913? OR MON88913?
L2 QUE SPE=ON ABB=ON PLU=ON BOLLGARD II? OR BOLLGARD!II? OR
BOLLGARDII? OR BOLLGARD 2? OR BOLLGARD!2? OR BOLLGARD2? OR BG
II OR BGII OR BG!II OR BG 2 OR BG2 OR BG!2
L3 QUE SPE=ON ABB=ON PLU=ON ROUNDUPREADY? OR ROUND!UP!READY?
OR ROUND!UP READY? OR ROUNDUP READY? OR ROUND UP READY? OR
RRFLEX OR RR FLEX OR RR!FLEX
L4 QUE SPE=ON ABB=ON PLU=ON COTTON OR GOSSYPIMUM
L5 QUE SPE=ON ABB=ON PLU=ON 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
L6 QUE SPE=ON ABB=ON PLU=ON CRYIAC OR CRY1 AC OR CRY 1 AC OR
CRY 1AC OR CRYIAC OR CRYI AC OR CRY I AC OR CRY IAC
L7 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?
L8 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?))
L9 QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR PROTEC?) (5A) (GL!PHOSATE OR GL!FOSATE OR ROUND!UP? OR ROUNDUP? OR ROUND
UP?)
L10 QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR PROTEC?) (5A) (LEPIDOPTERA? OR BOLLWORM? OR BOLL WORM? OR BUDWORM? OR BUD
WORM? OR EARWORM? OR EAR WORM?)
L11 QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR PROTEC?) (5A) (NOCTUIDAE OR GELECHIIDAE OR HELIOTHIS OR VIRESCENS OR
HELICOVERPA OR ZEA OR PECTINOPHORA OR GOSSYPIELLA OR TBW OR
CBW OR CEW)
L12 QUE SPE=ON ABB=ON PLU=ON (BTCOTTON OR BT COTTON OR BT!COTTON
OR THURINGIENSIS!COTTON OR THURINGIENSIS COTTON OR THURINGIENS
ISCOTTON)
L13 QUE SPE=ON ABB=ON PLU=ON COTTON+UF,NT/CT,ORGN
L14 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
L15 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)

Search in SciSearch Database:

FILE 'SCISEARCH' ENTERED AT 12:02:03 ON 01 JUN 2021

L16 0 SEA SPE=ON ABB=ON PLU=ON L1 AND ED>=20210126 AND ED<=2021053
1 AND PY>=2020
L17 16 SEA SPE=ON ABB=ON PLU=ON (L2 OR L3) AND ED>=20210126 AND
ED<=20210531 AND PY>=2020
L18 1676 SEA SPE=ON ABB=ON PLU=ON L4 AND ED>=20210126 AND ED<=2021053
1 AND PY>=2020
L19 4 SEA SPE=ON ABB=ON PLU=ON L17 AND L18
L20 22 SEA SPE=ON ABB=ON PLU=ON L5 AND ED>=20210126 AND ED<=2021053
1 AND PY>=2020
L21 36 SEA SPE=ON ABB=ON PLU=ON (L6 OR L7) AND ED>=20210126 AND
ED<=20210531 AND PY>=2020
L22 56 SEA SPE=ON ABB=ON PLU=ON L20 OR L21

Appendix 3 – Annual general surveillance report in 2021/2022 season Literature search – Bayer GM cotton products

L23	9833	SEA SPE=ON	ABB=ON	PLU=ON	L8 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L24	39	SEA SPE=ON	ABB=ON	PLU=ON	L22 AND (L23 OR L18)
L25	82	SEA SPE=ON	ABB=ON	PLU=ON	L9 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L26	55	SEA SPE=ON	ABB=ON	PLU=ON	(L10 OR L11) AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L27	37	SEA SPE=ON	ABB=ON	PLU=ON	L12 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L28	135	SEA SPE=ON	ABB=ON	PLU=ON	L25 OR L26
L29	6	SEA SPE=ON	ABB=ON	PLU=ON	L28 AND L23 AND L18
L30	20	SEA SPE=ON	ABB=ON	PLU=ON	L27 AND L23
L31	25	SEA SPE=ON	ABB=ON	PLU=ON	L29 OR L30
L32	56	SEA SPE=ON	ABB=ON	PLU=ON	L16 OR L19 OR L24 OR L31

Search in CABA Database:

FILE 'CABA' ENTERED AT 12:02:26 ON 01 JUN 2021

L33	0	SEA SPE=ON	ABB=ON	PLU=ON	L1 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L34	21	SEA SPE=ON	ABB=ON	PLU=ON	(L2 OR L3) AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L35	953	SEA SPE=ON	ABB=ON	PLU=ON	L4 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L36	613	SEA SPE=ON	ABB=ON	PLU=ON	L13 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L37	953	SEA SPE=ON	ABB=ON	PLU=ON	L35 OR L36
L38	8	SEA SPE=ON	ABB=ON	PLU=ON	L34 AND L37
L39	16	SEA SPE=ON	ABB=ON	PLU=ON	L5 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L40	39	SEA SPE=ON	ABB=ON	PLU=ON	(L6 OR L7) AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L41	53	SEA SPE=ON	ABB=ON	PLU=ON	L39 OR L40
L42	3005	SEA SPE=ON	ABB=ON	PLU=ON	L8 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L43	1244	SEA SPE=ON	ABB=ON	PLU=ON	L14 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L44	3005	SEA SPE=ON	ABB=ON	PLU=ON	L42 OR L43
L45	41	SEA SPE=ON	ABB=ON	PLU=ON	L41 AND (L37 OR L44)
L46	105	SEA SPE=ON	ABB=ON	PLU=ON	L9 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L47	65	SEA SPE=ON	ABB=ON	PLU=ON	(L10 OR L11) AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L48	25	SEA SPE=ON	ABB=ON	PLU=ON	L12 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L49	91	SEA SPE=ON	ABB=ON	PLU=ON	L15 AND ED>=20210126 AND ED<=20210531 AND PY>=2020
L50	231	SEA SPE=ON	ABB=ON	PLU=ON	L46 OR L47 OR L49
L51	15	SEA SPE=ON	ABB=ON	PLU=ON	L50 AND L44 AND L37
L52	22	SEA SPE=ON	ABB=ON	PLU=ON	L48 AND L44
L53	34	SEA SPE=ON	ABB=ON	PLU=ON	L51 OR L52
L54	68	SEA SPE=ON	ABB=ON	PLU=ON	L33 OR L38 OR L45 OR L53

Deduplication of Hit-sets from both sources:

FILE 'CABA, SCISEARCH' ENTERED AT 12:03:01 ON 01 JUN 2021
 CHARGED TO COST=SLB76724 REG EU
 L55 115 DUP REM L54 L32 (9 DUPLICATES REMOVED)
 ANSWERS '1-68' FROM FILE CABA
 ANSWERS '69-115' FROM FILE SCISEARCH
 D L55 1-115 ALL PY

FILE SCISEARCH

FILE COVERS 1974 TO 31 May 2021 (20210531/ED)

Appendix 3 – Annual general surveillance report in 2021/2022 season
 Literature search – Bayer GM cotton products

Bayer Agriculture BV

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

FILE CABA

FILE LAST UPDATED: 26 MAY 2021 <20210526/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 cotton 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.

Dhanaraj AL, Willse AR and Kamath SP, 2019. Stability of expression of Cry1Ac and Cry2Ab2 proteins in Bollgard-II hybrids at different stages of crop growth in different genotypes across cropping seasons and multiple geographies. *Transgenic Res*, 28, 33-50.

Faldu GO, Patel HB, Vadodariya GD and Solanki BG, 2015. Response and Expression Pattern of Bt Toxin in Bollgard Cotton Hybrids with Respect to Crop Age under Different Environmental Conditions. *Trends in Biosciences*, 8, 1237-1242.

Gampala SS, Fast BJ, Richey KA, Gao Z, Hill R, Wulfschlegel B, Shan G, Bradfish GA and Herman RA, 2017. Single-event transgene product levels predict levels in genetically modified breeding stacks. *J Agric Food Chem*, 65, 7885-7892.

Annex IV. Literature search in internet pages of relevant key organisations for Bayer GM cotton products covering time span 2021 - 2022

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 08 September 2022. 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 01/01/2021 were assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “Zero”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> No record was retrieved.</p>
USDA	<p>https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status - Accessed on 08 September 2022. 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> 23 August 2022</p> <p><i>Limits applied:</i> The list of the petitions was sorted by ‘Effective Date’ and those deregulated starting from 01/01/2021 were assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “Six”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton products.</p>
US FDA	<p>https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon – Accessed on 08 September 2022. 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> 01 September 2022</p> <p><i>Limits applied:</i> The list of the consultations starting from the ‘FDA Letter Date’ of 01/01/2021 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “10”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton products.</p>
CFIA	<p>https://inspection.canada.ca/industry-guidance/eng/1374161650885/1374161737236?gp=3&gc=25&ga=4#gdr_results - Accessed on 08 September 2022. 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 (several dates mentioned)</p> <p><i>Limits applied:</i> The list of repository documents referring to plants with novel traits starting from ‘Date modified’ of 01/01/2021 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “43”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton 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 08 September 2022. 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> 10 August 2022</p> <p><i>Limits applied:</i> The list of novel food decisions starting from the ‘Decision Date (YYYY/MM/DD)’ of 01/01/2021 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “18”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton products.</p>
FSANZ	<p>http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx - Accessed on 04 October 2022. 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> May 2022</p> <p><i>Limits applied:</i> The list for GM applications and approvals with ‘Status’ approved or under assessment starting from 2021 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “Six”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton products.</p>
CTNBio	<p>http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo – Accessed on 08 September 2022. 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> Not clear (several dates mentioned)</p> <p><i>Limits applied:</i> The list of commercial releases for plants (= plantas) starting from 01/01/2021 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “10”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton products.</p>
CONABIA	<p>https://www.argentina.gob.ar/agroindustria/alimentos-y-bioeconomia/ogm-comerciales – Accessed on 08 September 2022. 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 authorisation (= Eventos con autorización comercial) starting from 01/01/2021 were checked.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “Five”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton products.</p>

MAFF	<p>https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-23.pdf Accessed on 08 September 2022. 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> 27 May, 2022</p> <p><i>Limits applied:</i> The list of GM agricultural crops with approval date (‘承認日’) starting from 01/01/2021 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “15”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton products.</p>
GEAC	<p>http://www.geacindia.gov.in/approved-products.aspx - Accessed on 08 September 2022. The weblink of Agriculture applications - Commercially Approved, 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 ‘commercially released <i>Bt</i> cotton hybrids/varieties’ starting from 01/01/2021 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “Zero”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton products.</p>
OGTR	<p>https://www.ogtr.gov.au/what-weve-approved - Accessed on 08 September 2022. The webpage dedicated to details on approved applications, dealings and licences, accredited organisations, and active crop field trial sites were checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> Not clear (several dates mentioned)</p> <p><i>Limits applied:</i> Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment starting from ‘Issue Date’ of 01/01/2021 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “700”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM cotton products.</p>

Annex V. Results of the publication selection process for Bayer GM cotton 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)	250
Publications excluded after rapid assessment for relevance	246
Publications screened using full-text	4
Publications excluded after detailed assessment for relevance	1
Unobtainable publications	0
Unclear publications	0
Publications considered relevant	3

Table 2. List of all relevant publications 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			
Protein expression			
MON 15985	Nagamalla <i>et al.</i> , 2021	Morpho-physiological and proteomic response of <i>Bt</i> -cotton and non- <i>Bt</i> cotton to drought stress	Frontiers in Plant Science
Crop composition			
MON 15985	Sankaranarayanan <i>et al.</i> , 2021	Assessing production potential and quality parameters of ELS cotton (<i>Gossypium barbadense</i>) genotypes	Indian Journal of Agricultural Sciences
Agronomic and phenotypic characteristics			
MON 15985	Smitha <i>et al.</i> , 2021	Correlation of Cry1Ac mRNA and protein abundance in transgenic <i>Gossypium hirsutum</i> plant	3 Biotech

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
Suassuna <i>et al</i>	2021	BRS 500 B2RF: transgenic cotton cultivar expressing Cry1Ac , Cry2Ab , and CP4 - EPSPS with multiple disease resistance	Crop Breeding and Applied Technology	It is not a safety study on Bayer's GM cotton 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	Implications for the risk assessment
Food/Feed Safety assessment		
Protein expression		
Nagamalla <i>et al.</i> , 2021	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Crop composition		
Sankaranarayanan <i>et al.</i> , 2021	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Agronomic and phenotypic characteristics		
Smitha <i>et al.</i> , 2021	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported

REFERENCES

- Nagamalla SS, Alaparathi MD, Mellacheruvu S, Gundeti R, Earrawandla JPS and Sagurthi SR, 2021. Morpho-physiological and proteomic response of *Bt*-cotton and non-*Bt* cotton to drought stress. *Frontiers in plant science*, 12, 663576.
- Sankaranarayanan K, Prakash A, Manivannan A and Sabesh M, 2021. Assessing production potential and quality parameters of ELS cotton (*Gossypium barbadense*) genotypes.
- Smitha P, Bathula C, Kumar AM, Chandrashekara K, Dhar SK and Das M, 2021. Correlation of Cry1Ac mRNA and protein abundance in transgenic *Gossypium hirsutum* plant. *3 Biotech*, 11, 1-9.

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

The list of the relevant publications is enclosed with this report (*see* cotton.txt file).