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

APPENDIX 3

LITERATURE SEARCH TO SUPPORT GENERAL SURVEILLANCE OF 2020/2021 ANNUAL POST MARKET ENVIRONMENTAL MONITORING REPORTS OF BAYER GM COTTON PRODUCTS

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SUMMARY

This literature search was conducted in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications[1] (EFSA, 2019) to support general surveillance of 2020/2021 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?".

In accordance with the 2019 EFSA explanatory note on literature searching (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 cotton products.

The literature search covered the time span 2020 – 2021 and retrieved 170 and 147 hits in SciSearch and CABA databases, respectively, and a total of 72 records in the internet pages of the relevant key organisations. From these, two 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 cotton products.

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

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 1829/2003, Bayer Agriculture BV[2] has actively monitored the cotton products by conducting quarterly literature searches covering the time span between June 2020 and May 2021.

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 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 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 2020/2021 annual post market environmental monitoring (PMEM) reports in accordance with the 2019 EFSA explanatory note on literature searching (EFSA, 2019).

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** .

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[2] Hereafter, referenced as Bayer

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

Key elements	Criteria
Population	Humans, animals and the environment (taking into account the scope of the applications) *i.e.* authorisation for all uses as any other 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.

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 (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)[3] and the CABA[4] (CAB Abstracts®)[5] databases to perform the literature search based on the coverage and relevance of the journals included in these databases. The literature search was conducted using the STN® database catalogue[6].

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*"[4]. 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*"**Error! Bookmark not defined.**. 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[6,7]. 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

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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), eleven[8] are involved in risk assessment of Bayer GM cotton products. Three of the remaining three (CIBIOGEM, Environment and Climate Change Canada and OECD) are not involved in GM risk assessment. 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 searching (EFSA, 2019):

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

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

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[8] Internet pages of the relevant key organisations for Bayer GM cotton products:
US EPA (https://www.epa.gov/environmental-topics/science-topics) - Accessed on 06 July 21;
USDA (https://www.usda.gov/media) - Accessed on 06 July 21;
US FDA (https://www.fda.gov/) - Accessed on 06 July 21;
CFIA (http://www.inspection.gc.ca/eng/1297964599443/1297965645317) - Accessed on 06 July 21;
Health Canada (https://www.canada.ca/en/health-canada.html) - Accessed on 06 July 21;
FSANZ (http://www.foodstandards.gov.au/Pages/default.aspx) - Accessed on 06 July 21;
CTNBio (http://ctnbio.mctic.gov.br/) - Accessed on 06 July 21;
CONABIA (https://www.argentina.gob.ar/) - Accessed on 06 July 21;
Japan MAFF (http://www.maff.go.jp/e/) - Accessed on 06 July 21;
OGTR (http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/home-1) - Accessed on 06 July 21;
GEAC (http://www.geacindia.gov.in/approved-products.aspx) - Accessed on 06 July 21.

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(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.

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

3.2.2. Limits applied

An advanced literature search was conducted using the web-based STN® database catalogue for both the selected electronic databases (*see* section 3.1.1). STN® enables searching in each electronic database by making use of pre-defined fields, set combinations based on Boolean operators or a combination of both[9]. In STN®, the results of the search from each database can be merged and duplicates can be removed by de-duplication.

The STN® literature search utilised "Basic Index" (None (or /BI)) field which utilises free-text search terms and enables comprehensive searching in different sections (*e.g.* title, abstract, keywords, supplementary terms, controlled terms) within a record (Karlsruhe, 2007; STN, 2018a, 2018b). Where applicable, controlled vocabulary (subject indexes) offered by CABA (controlled terms (CT)) were also included in the search strategy. Controlled vocabulary is assigned by subject specialists to CAB records to represent the content of the source documents. It allows users to use only one term to search for a concept rather than using lots of terms[10]. 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** I.

3.2.3. Language

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

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[9] STNindex user guide: https://www.stn-international.com/sites/default/files/stn_training_center_document/User%20Documentation/mastering_stn_commands.pdf - Accessed on 27 08 2021

[10] 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 17 08 2021

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3.2.4. Time period

The literature searches covered the time span 1 June 2020 - 31 May 2021.

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
06 October 2021	SciSearch: 05 October 2020	28 May 2020 – 05 October 2020
	CABA: 30 September 2021	28 May 2020 – 05 October 2020
01 February 2021	SciSearch: 26 January 2021	05 October 2020– 26 January 2021
	CABA: 25 January 2021	05 October 2020– 26 January 2021
01 June 2021	SciSearch: 31 May 2021	26 January 2021– 31 May 2021
	CABA: 26 May 2021	26 January 2021– 31 May 2021

The literature search in the internet pages of the relevant key organisations was conducted on 06 July 2021.

3.2.5. Reference publications

In accordance with the 2019 EFSA explanatory note on literature searching (EFSA, 2019), a list of reference publications is provided in **0**.

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 cotton 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.

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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. Each reviewer performed its assessment in an independent sequential manner.

The reviewers involved in the publication screening process have adequate expertise and experience in the risk assessment of GM plants as well as in selection of relevant publications in literature searches for GM applications. Retrieved publications are screened by each reviewer independently and assessed against each other to conclude on inclusion or exclusion based on eligibility/relevance criteria. In case of disagreements, the reviewers discuss together considering the eligibility/ inclusion criteria for relevance. If uncertainty remains, the publication is *de facto* included for further consideration.

Internal and external reviewers were in constant communication and met on a regular basis to ensure consistent interpretation and implementation of eligibility/relevance criteria and/or screening process. When necessary, these 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.

This approach assures a high-quality process as it allows a harmonised continuous publication screening process across different GM applications in accordance with 2019 EFSA explanatory note on literature searching (EFSA, 2019) 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

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- 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 (EFSA, 2019) 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 170 and 147 hits in SciSearch and CABA databases, respectively (*see* **Annex I**). After de-duplication, the total number resulted in 240 hits.

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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 72 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 **0**. Two 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**. None of the retrieved documents needed further assessment.

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 cotton products found no new information that would invalidate the conclusions of the risk assessments for Bayer GM cotton products.

The relevant publications as well as their reliability and implications for the risk assessment are provided in **0.**

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 searching (EFSA, 2019) to support the general surveillance in the context of 2020/2021 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.

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REFERENCES

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

Copyright protected scientific publications that are cited to support this report shared only with the regulatory authorities involved in the assessment of the report. Therefore, any further distribution of these publications in a manner not specified in the current copyright order, including posting on websites, and without appropriate authorisation, may be an infringement of copyright rules. Therefore, the full text documents of these scientific publications are provided only in the confidential version of the report.

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.

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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?)

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Intended traits: Insect protection traits	*Bt* Cotton / *Bacillus thuringiensis,* 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 *Heliothis virescens* or *Helicoverpa zea* or *Pectinophora gossypiella*	(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? 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, *Gossypium*	COTTON OR GOSSYPIUM
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?))

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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	*Bt* Cotton / *Bacillus thuringiensis,* 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 *Heliothis virescens* or *Helicoverpa zea* or *Pectinophora gossypiella* 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, *Gossypium*	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

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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 (2020 - 2021)

Bayer GM Cotton products literature search – First quarter (June 2020 - September 2020)

Translation of query terms into STN search language:

(FILE 'STNGUIDE' ENTERED AT 10:22:20 ON 06 OCT 2020)

```
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 GOSSYPIUM
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 PYRUVYLSHIKIMATE OR ENOL!PYRUVYL!
            SHIKIMATE!)(W)3 PHOSPHATE SYNTHASE
L6          QUE SPE=ON  ABB=ON  PLU=ON  CRY1AC 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)
```

Appendix 3 – Annual general surveillance report in 2020/2021 season
Literature search - Bayer cotton GM products
Bayer Agriculture BV

Search in SciSearch Database:

```
FILE 'SCISEARCH' ENTERED AT 10:23:04 ON 06 OCT 2020

L16          0 SEA SPE=ON  ABB=ON  PLU=ON  L1 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L17         25 SEA SPE=ON  ABB=ON  PLU=ON  (L2 OR L3) AND ED>=20200528 AND
               ED<=20201005 AND PY>=2020
L18       1725 SEA SPE=ON  ABB=ON  PLU=ON  L4 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L19          4 SEA SPE=ON  ABB=ON  PLU=ON  L17 AND L18
L20         17 SEA SPE=ON  ABB=ON  PLU=ON  L5 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L21         54 SEA SPE=ON  ABB=ON  PLU=ON  (L6 OR L7) AND ED>=20200528 AND
               ED<=20201005 AND PY>=2020
L22         70 SEA SPE=ON  ABB=ON  PLU=ON  L20 OR L21
L23       9777 SEA SPE=ON  ABB=ON  PLU=ON  L8 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L24         48 SEA SPE=ON  ABB=ON  PLU=ON  L22 AND (L23 OR L18)
L25         86 SEA SPE=ON  ABB=ON  PLU=ON  L9 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L26         64 SEA SPE=ON  ABB=ON  PLU=ON  (L10 OR L11) AND ED>=20200528 AND
               ED<=20201005 AND PY>=2020
L27         41 SEA SPE=ON  ABB=ON  PLU=ON  L12 AND ED>=20200528 AND ED<=202010
               05 AND PY>=2020
L28        149 SEA SPE=ON  ABB=ON  PLU=ON  L25 OR L26
L29         12 SEA SPE=ON  ABB=ON  PLU=ON  L28 AND L23 AND L18
L30         19 SEA SPE=ON  ABB=ON  PLU=ON  L27 AND L23
L31         29 SEA SPE=ON  ABB=ON  PLU=ON  L29 OR L30
L32         63 SEA SPE=ON  ABB=ON  PLU=ON  L16 OR L19 OR L24 OR L31
```

Search in CABA Database:

```
FILE 'CABA' ENTERED AT 10:24:14 ON 06 OCT 2020

L33          0 SEA SPE=ON  ABB=ON  PLU=ON  L1 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L34         10 SEA SPE=ON  ABB=ON  PLU=ON  (L2 OR L3) AND ED>=20200528 AND
               ED<=20201005 AND PY>=2020
L35        729 SEA SPE=ON  ABB=ON  PLU=ON  L4 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L36        439 SEA SPE=ON  ABB=ON  PLU=ON  L13 AND ED>=20200528 AND ED<=202010
               05 AND PY>=2020
L37        729 SEA SPE=ON  ABB=ON  PLU=ON  L35 OR L36
L38          1 SEA SPE=ON  ABB=ON  PLU=ON  L34 AND L37
L39          6 SEA SPE=ON  ABB=ON  PLU=ON  L5 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L40         17 SEA SPE=ON  ABB=ON  PLU=ON  (L6 OR L7) AND ED>=20200528 AND
               ED<=20201005 AND PY>=2020
L41         23 SEA SPE=ON  ABB=ON  PLU=ON  L39 OR L40
L42       2457 SEA SPE=ON  ABB=ON  PLU=ON  L8 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L43       1007 SEA SPE=ON  ABB=ON  PLU=ON  L14 AND ED>=20200528 AND ED<=202010
               05 AND PY>=2020
L44       2461 SEA SPE=ON  ABB=ON  PLU=ON  L42 OR L43
L45         13 SEA SPE=ON  ABB=ON  PLU=ON  L41 AND (L37 OR L44)
L46         58 SEA SPE=ON  ABB=ON  PLU=ON  L9 AND ED>=20200528 AND ED<=2020100
               5 AND PY>=2020
L47         32 SEA SPE=ON  ABB=ON  PLU=ON  (L10 OR L11) AND ED>=20200528 AND
               ED<=20201005 AND PY>=2020
L48         15 SEA SPE=ON  ABB=ON  PLU=ON  L12 AND ED>=20200528 AND ED<=202010
               05 AND PY>=2020
L49         62 SEA SPE=ON  ABB=ON  PLU=ON  L15 AND ED>=20200528 AND ED<=202010
               05 AND PY>=2020
L50        140 SEA SPE=ON  ABB=ON  PLU=ON  L46 OR L47 OR L49
L51          5 SEA SPE=ON  ABB=ON  PLU=ON  L50 AND L44 AND L37
```

Appendix 3 – Annual general surveillance report in 2020/2021 season
Literature search - Bayer cotton GM products
Bayer Agriculture BV

```
L52           15 SEA SPE=ON  ABB=ON  PLU=ON  L48 AND L44
L53           18 SEA SPE=ON  ABB=ON  PLU=ON  L51 OR L52
L54           28 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 10:25:02 ON 06 OCT 2020
CHARGED TO COST=SLB76724REGEU
L55           86 DUP REM L54 L32 (5 DUPLICATES REMOVED)
                     ANSWERS '1-28' FROM FILE CABA
                     ANSWERS '29-86' FROM FILE SCISEARCH
              D L55 1-86 ALL PY

FILE SCISEARCH

     FILE COVERS 1974 TO 5 Oct 2020 (20201005/ED)

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

FILE CABA

     FILE LAST UPDATED: 30 SEP 2020       <20200930/UP>
     FILE COVERS 1973 TO DATE
```

Appendix 3 – Annual general surveillance report in 2020/2021 season
Literature search - Bayer cotton GM products
Bayer Agriculture BV

Bayer GM Cotton products literature search – Second quarter (October 2020 - January 2021)

Translation of query terms into STN search language:

```
        (FILE 'STNGUIDE' ENTERED AT 13:32:23 ON 01 FEB 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 GOSSYPIUM
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 PYRUVYLSHIKIMATE OR ENOL!PYRUVYL!
                SHIKIMATE!)(W)3 PHOSPHATE SYNTHASE
L6              QUE SPE=ON  ABB=ON  PLU=ON  CRY1AC 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)
```

Appendix 3 – Annual general surveillance report in 2020/2021 season
Literature search - Bayer cotton GM products
Bayer Agriculture BV

Search in SciSearch Database:

```
        FILE 'SCISEARCH' ENTERED AT 13:33:13 ON 01 FEB 2021

L16           0 SEA SPE=ON  ABB=ON  PLU=ON  L1 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L17          22 SEA SPE=ON  ABB=ON  PLU=ON  (L2 OR L3) AND ED>=20201005 AND
                ED<=20210126 AND PY>=2020
L18        1442 SEA SPE=ON  ABB=ON  PLU=ON  L4 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L19           2 SEA SPE=ON  ABB=ON  PLU=ON  L17 AND L18
L20          20 SEA SPE=ON  ABB=ON  PLU=ON  L5 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L21          37 SEA SPE=ON  ABB=ON  PLU=ON  (L6 OR L7) AND ED>=20201005 AND
                ED<=20210126 AND PY>=2020
L22          53 SEA SPE=ON  ABB=ON  PLU=ON  L20 OR L21
L23        8641 SEA SPE=ON  ABB=ON  PLU=ON  L8 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L24          33 SEA SPE=ON  ABB=ON  PLU=ON  L22 AND (L23 OR L18)
L25          73 SEA SPE=ON  ABB=ON  PLU=ON  L9 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L26          50 SEA SPE=ON  ABB=ON  PLU=ON  (L10 OR L11) AND ED>=20201005 AND
                ED<=20210126 AND PY>=2020
L27          47 SEA SPE=ON  ABB=ON  PLU=ON  L12 AND ED>=20201005 AND ED<=202101
                26 AND PY>=2020
L28         119 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          21 SEA SPE=ON  ABB=ON  PLU=ON  L27 AND L23
L31          27 SEA SPE=ON  ABB=ON  PLU=ON  L29 OR L30
L32          51 SEA SPE=ON  ABB=ON  PLU=ON  L16 OR L19 OR L24 OR L31
```

Search in CABA Database:

```
FILE 'CABA' ENTERED AT 13:33:41 ON 01 FEB 2021

L33           1 SEA SPE=ON  ABB=ON  PLU=ON  L1 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L34          12 SEA SPE=ON  ABB=ON  PLU=ON  (L2 OR L3) AND ED>=20201005 AND
                ED<=20210126 AND PY>=2020
L35         676 SEA SPE=ON  ABB=ON  PLU=ON  L4 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L36         419 SEA SPE=ON  ABB=ON  PLU=ON  L13 AND ED>=20201005 AND ED<=202101
                26 AND PY>=2020
L37         676 SEA SPE=ON  ABB=ON  PLU=ON  L35 OR L36
L38           5 SEA SPE=ON  ABB=ON  PLU=ON  L34 AND L37
L39          13 SEA SPE=ON  ABB=ON  PLU=ON  L5 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L40          27 SEA SPE=ON  ABB=ON  PLU=ON  (L6 OR L7) AND ED>=20201005 AND
                ED<=20210126 AND PY>=2020
L41          38 SEA SPE=ON  ABB=ON  PLU=ON  L39 OR L40
L42        2546 SEA SPE=ON  ABB=ON  PLU=ON  L8 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L43        1173 SEA SPE=ON  ABB=ON  PLU=ON  L14 AND ED>=20201005 AND ED<=202101
                26 AND PY>=2020
L44        2551 SEA SPE=ON  ABB=ON  PLU=ON  L42 OR L43
L45          31 SEA SPE=ON  ABB=ON  PLU=ON  L41 AND (L37 OR L44)
L46          60 SEA SPE=ON  ABB=ON  PLU=ON  L9 AND ED>=20201005 AND ED<=2021012
                6 AND PY>=2020
L47          41 SEA SPE=ON  ABB=ON  PLU=ON  (L10 OR L11) AND ED>=20201005 AND
                ED<=20210126 AND PY>=2020
L48          26 SEA SPE=ON  ABB=ON  PLU=ON  L12 AND ED>=20201005 AND ED<=202101
                26 AND PY>=2020
L49          68 SEA SPE=ON  ABB=ON  PLU=ON  L15 AND ED>=20201005 AND ED<=202101
                26 AND PY>=2020
L50         148 SEA SPE=ON  ABB=ON  PLU=ON  L46 OR L47 OR L49
L51           8 SEA SPE=ON  ABB=ON  PLU=ON  L50 AND L44 AND L37
```

Appendix 3 – Annual general surveillance report in 2020/2021 season
Literature search - Bayer cotton GM products
Bayer Agriculture BV

```
L52            18 SEA SPE=ON  ABB=ON  PLU=ON  L48 AND L44
L53            24 SEA SPE=ON  ABB=ON  PLU=ON  L51 OR L52
L54            51 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 13:34:26 ON 01 FEB 2021
CHARGED TO COST=SLB76724 REG EU
L55            95 DUP REM L54 L32 (7 DUPLICATES REMOVED)
                    ANSWERS '1-51' FROM FILE CABA
                    ANSWERS '52-95' FROM FILE SCISEARCH
               D L55 1-95 ALL PY


FILE SCISEARCH

     FILE COVERS 1974 TO 26 Jan 2021 (20210126/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
```

Appendix 3 – Annual general surveillance report in 2020/2021 season
Literature search - Bayer cotton GM products
Bayer Agriculture BV

Bayer GM Cotton products literature search – Third quarter (February 2021 – May 2021)

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 GOSSYPIUM
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 PYRUVYLSHIKIMATE OR ENOL!PYRUVYL!
                SHIKIMATE!)(W)3 PHOSPHATE SYNTHASE
L6              QUE SPE=ON  ABB=ON  PLU=ON  CRY1AC 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
L23       9833 SEA SPE=ON  ABB=ON  PLU=ON  L8 AND ED>=20210126 AND ED<=2021053
                1 AND PY>=2020
```

Appendix 3 – Annual general surveillance report in 2020/2021 season
Literature search - Bayer cotton GM products
Bayer Agriculture BV

```
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<=2021053
                  1 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<=202105
                  31 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<=2021053
                  1 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<=2021053
                  1 AND PY>=2020
L36         613 SEA SPE=ON  ABB=ON  PLU=ON  L13 AND ED>=20210126 AND ED<=202105
                  31 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<=2021053
                  1 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<=2021053
                  1 AND PY>=2020
L43        1244 SEA SPE=ON  ABB=ON  PLU=ON  L14 AND ED>=20210126 AND ED<=202105
                  31 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<=2021053
                  1 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<=202105
                  31 AND PY>=2020
L49          91 SEA SPE=ON  ABB=ON  PLU=ON  L15 AND ED>=20210126 AND ED<=202105
                  31 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)

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

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```
FILE CABA

    FILE LAST UPDATED: 26 MAY 2021        <20210526/UP>
    FILE COVERS 1973 TO DATE
```

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Annex III. List of reference publications used in identifying search terms and in validating the literature search strategy for Bayer GM 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, Wulfkuhle B, Shan G, Bradfisch GA and Herman RA, 2017. Single-event transgene product levels predict levels in genetically modified breeding stacks. J Agric Food Chem, 65, 7885-7892.

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Annex IV. Literature search in internet pages of relevant key organisations for Bayer GM cotton products covering time span 2020 – 2021

Relevant key organisations	Link to the relevant information and summary of the retrieved records
US EPA	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated – Accessed on 06 July 2021. The webpage dedicated to PIP registrations was checked. *Date of the most recent website update at the time of the search*: 14 July 2020 *Limits applied*: The list of PIP active ingredients registered was sorted by 'Year Registered' and those registered starting from 2020 were assessed. *Number of records retrieved matching the abovementioned criteria*: "1". *Number of relevant records or full-text documents retrieved*: The retrieved record is not relevant to Bayer GM cotton products.
USDA	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status - Accessed on 06 July 2021. The webpage dedicated to petitions for determination of nonregulated status was checked. *Date of the most recent website update at the time of the search*: 24 June 2021 *Limits applied*: The list of the petitions was sorted by 'Effective Date' and those completed/ released starting from 01/01/2020 were assessed. *Number of records retrieved matching the abovementioned criteria*: "4". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM cotton products.
US FDA	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon – Accessed on 06 July 2021. The webpage dedicated to biotechnology consultations on food from GE plant varieties was checked. *Date of the most recent website update at the time of the search*: 16 March 2021 *Limits applied*: The list of the consultations starting from the 'FDA Letter Date' of 01 01, 2020 was assessed. *Number of records retrieved matching the abovementioned criteria*: "2". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM cotton products.

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CFIA	https://inspection.canada.ca/industry-guidance/eng/1374161650885/1374161737236?gp=3&gc=25&ga=4#gdr_results - Accessed on 06 July 2021. The webpage dedicated to repository documents referring to plants with novel traits was checked.
	Date of the most recent website update at the time of the search: not clear
	Limits applied: The list of repository documents referring to plants with novel traits starting from 'Date modified' of 2020-01-01 was assessed.
	Number of records retrieved matching the abovementioned criteria: "21".
	Number of relevant records or full-text documents retrieved: The retrieved records are not relevant to Bayer GM cotton products.
Health Canada	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html - Accessed on 06 July 2021. The webpage dedicated to approved products of genetically modified (GM) foods and other novel foods was checked.
	Date of the most recent website update at the time of the search: 29 June 2021
	Limits applied: The list of novel food decisions starting from the 'Decision Date (20YY/MM/DD)' of 2020/01/01 was assessed.
	Number of records retrieved matching the abovementioned criteria: "12".
	Number of relevant records or full-text documents retrieved: The retrieved records are not relevant to Bayer GM cotton products.
FSANZ	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx - Accessed on 06 July 2021. The webpage dedicated to current GM applications and approvals was checked.
	Date of the most recent website update at the time of the search: June 2021
	Limits applied: The list for GM applications and approvals with 'Status' approved or under assessment starting from 2020 was assessed.
	Number of records retrieved matching the abovementioned criteria: "7".
	Number of relevant records or full-text documents retrieved: The retrieved records are not relevant to Bayer GM cotton products.
CTNBio	http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo – Accessed on 06 July 2021. The webpage dedicated to commercial releases (= Liberações Comerciais) was checked.
	Date of the most recent website update at the time of the search: Not clear (several dates mentioned)
	Limits applied: The list of commercial releases for plants (= plantas) starting from 2020 was assessed.
	Number of records retrieved matching the abovementioned criteria: "2".
	Number of relevant records or full-text documents retrieved: The retrieved records are not relevant to Bayer GM cotton products.

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CONABIA	https://www.argentina.gob.ar/agroindustria/alimentos-y-bioeconomia/ogm-comerciales – Accessed on 06 July 2021. The webpage of the national advisory commission on agricultural biotechnology (= Comisión Nacional Asesora de Biotecnología Agropecuaria) was checked. *Date of the most recent website update at the time of the search*: Not available *Limits applied*: The list of events with commercial authorisation (= Eventos con autorización comercial) starting from 2020 were checked. *Number of records retrieved matching the abovementioned criteria*: "1". *Number of relevant records or full-text documents retrieved*: The retrieved record is not relevant to Bayer GM cotton products.
MAFF	https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-254.pdf - Accessed on 08 July 2021. The weblink dedicated to list of approved genetically modified agricultural crops was checked. *Date of the most recent website update at the time of the search*: 03 March 2021 *Limits applied*: The list of GM agricultural crops with approval date ('承認日') starting from 01 01, 2020 was assessed. *Number of records retrieved matching the abovementioned criteria*: "10". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM cotton products.
GEAC	http://www.geacindia.gov.in/approved-products.aspx - Accessed on 06 July 2021. The weblink of Agriculture applications - Commercially Approved, was checked. *Date of the most recent website update at the time of the search*: Not available. *Limits applied*: The list of 'commercially released *Bt* cotton hybrids/varieties' starting from 2020 was assessed. *Number of records retrieved matching the abovementioned criteria*: "0". *Number of relevant records or full-text documents retrieved*: No records were retrieved.
OGTR	http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1 - Accessed on 06 July 2021. The webpage dedicated to list of GMOs released into the environment was checked. *Date of the most recent website update at the time of the search*: Not clear (several dates mentioned) *Limits applied*: Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment starting from 'Issue Date' of 01 01 2020 was assessed. *Number of records retrieved matching the abovementioned criteria*: "12". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to Bayer GM cotton products.

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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)	240
Publications excluded after rapid assessment for relevance	233
Publications screened using full-text documents	7
Publications excluded after detailed assessment for relevance	5
Unobtainable publications	0
Unclear publications	0
Publications considered relevant	2

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Table 2. **List of all relevant publications for Bayer GM cotton 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			
Protein expression			
MON 15985	(Britz *et al.*, 2020)	Susceptibility of Spodoptera littoralis (Boisduval) (*Lepidoptera: Noctuidae*) to *Bt* cotton, expressing Cry1Ac and Cry2Ab toxins, in South Africa	African Entomology
Ag/Pheno			
MON 15985	(Veeraputhiran and Thiruvarasan, 2021)	Effect of bio stimulant application on growth, yield and economics of cotton	Journal of Cotton Research and Development

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

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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
Bourgou *et al.*	2020	*Bt* cotton seed purity in Burkina Faso: status and lessons learnt	Journal of Cotton Research and Development	It is not a safety study on Bayer GM cotton products
Li *et al.*	2020	Excessive Chinese concerns over genetically engineered food safety are unjustified	Nature Plants	It is not a safety study on Bayer GM cotton products
Liu *et al.*	2020	Expression of *Bt* Protein in Transgenic *Bt* Cotton Plants and Ecological Fitness of These Plants in Different Habitats	Frontiers in Plant Science	The hybrid used to conduct the study is not Bayer GM cotton product
Jamil *et al.*	2021	The level of Cry1Ac endotoxin and its efficacy against H. armigera in Bt cotton at large scale in Pakistan	GM Crops & Food- Biotechnology in Agriculture and the Food Chain	It is not a safety study on Bayer GM cotton products
Wheeler *et al.*	2020	The relationship between commercial cotton cultivars with varying Meloidogyne incognita resistance genes and yield	Journal of Nematology	It is not a safety study on Bayer GM cotton products

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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[1]
Food/Feed Safety assessment		
Protein expression		
(Britz *et al.*, 2020)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Ag/Pheno		
(Veeraputhiran and Thiruvarasan, 2021)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported

[1] 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).

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REFERENCES

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

Britz C, Van den Berg J and Du Plessis H, 2020. Susceptibility of Spodoptera littoralis (Boisduval) (Lepidoptera: Noctuidae) to Bt cotton , expressing Cry1Ac and Cry2Ab toxins, in South Africa. African Entomology, 28(1), 182-186.

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.

Veeraputhiran R and Thiruvarasan S, 2021. Effect of bio stimulant application on growth, yield and economics of cotton. J. Cotton Res. Dev. , 35(1), 154-158.

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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).

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