

Title

**Summary of the Literature Review for GHB119 Cotton  
October 1, 2018 – September 30, 2019**

**Final Report**

Data or Guideline Requirement

Explanatory note on literature searching  
conducted in the context of GMO applications for (renewed) market authorization  
and annual post-market environmental monitoring reports on GMOs authorised in the EU market.  
EFSA supporting publications 2019:EN-1614

Completion date

November 25, 2019

Principal Author

[REDACTED]

Report Number  
**19-RSCT0061**

Activity ID  
**RSCT0061**

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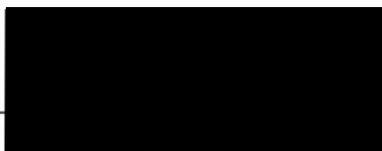
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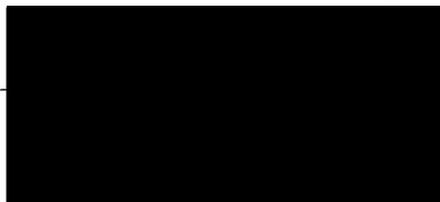
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**STUDY PERSONNEL**

<b>Electronic database search</b>	[REDACTED]
<b>Manual search</b>	[REDACTED] [REDACTED] [REDACTED] [REDACTED]
<b>Stage 1 assessment</b>	[REDACTED] [REDACTED]
<b>Stage 2 assessment</b>	<u>Food and Feed safety</u> [REDACTED] [REDACTED] <u>Molecular characterization</u> [REDACTED] [REDACTED] <u>Environmental safety</u> [REDACTED] [REDACTED]
<b>Report</b>	[REDACTED] [REDACTED] [REDACTED]

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## SUMMARY

The GHB119 cotton event expresses the *Bacillus thuringiensis* subsp. *dakota* Cry2Ae insecticidal protein that is effective in controlling lepidopteran larvae such as cotton bollworm, tobacco budworm, and fall armyworm. GHB119 cotton also expresses the herbicide tolerant phosphinothricin acetyl transferase (PAT/*bar*) as a selectable marker which confers tolerance to glufosinate-ammonium herbicides. The OECD identifier is BCS-GHØØ5-8..

A scoping review was performed for the GHB119 cotton and its newly expressed proteins, Cry2Ae and PAT/*bar*. The objective of this scoping review was to determine if there were studies about the molecular characterization of GHB119 cotton, its effects on food and feed safety, or on environmental safety, that might require in-depth examination. A set of broad literature searches was performed using several bibliographic databases covering scientific literature from October 1, 2018 to September 30, 2019. Additional sources of information, such as web pages of food safety, agriculture, and biotechnology-related authorities were searched for the same time window, along with the bibliographies of relevant reviews. The references identified were evaluated for potential relevance to the scoping review questions according to pre-defined criteria.

These literature searches identified a total of 191 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 9 publications were progressed for detailed assessment.

One of the 9 publications was determined to be relevant after detailed review. The relevant article did not constitute new data on molecular characterization of GHB119 cotton, or the Cry2Ae and PAT/*bar* proteins, nor did it suggest any potential adverse effects on human and animal health or on the environment. No evidence was identified that would warrant conducting a systematic review.

In summary, these literature searches and review of the retrieved articles identified only one relevant publication that supports the existing safety assessment of GHB119 cotton.

## 1. INTRODUCTION

The GHB119 cotton event expresses the *Bacillus thuringiensis* subsp. *dakota* Cry2Ae insecticidal protein that is effective in controlling lepidopteran larvae such as cotton bollworm, tobacco budworm, and fall armyworm. GHB119 cotton also expresses the herbicide tolerant phosphinothricin acetyl transferase (PAT/*bar*) as a selectable marker which confers tolerance to glufosinate-ammonium herbicides. The OECD identifier is BCS-GHØØ5-8.

The objective of the literature searches described here was to determine if there were publications published between October 1, 2018 and September 30, 2019 that mention the molecular characterization of the GHB119 cotton, and/or any adverse effect of GHB119 cotton in food, feed or the environment. In that context, a broad and inclusive literature search was performed and the articles retrieved were reviewed in a comprehensive and transparent manner. This was intended as a scoping review. The literature review was performed as recommended in the European Food Safety Authority (EFSA) explanatory note on literature searching conducted in the context of Genetically Modified Organisms (GMO)<sup>1</sup> applications and post-market environmental monitoring activities (2019).

The literature searches were performed for the GHB119 cotton and its newly expressed proteins Cry2Ae and PAT/*bar*. The search terms also included relevant synonyms, intended trait, plant species and general GMO terms.

## 2. OVERALL METHODS

### 2.1. Objective of the scoping review

The objective of the scoping review was to survey the evidence base for the GHB119 cotton and its newly expressed proteins Cry2Ae and PAT/*bar*, in order to identify any specific issues related to food or feed safety, molecular characterization or environmental safety that might require in-depth examination.

### 2.2. Review questions

Review questions were formulated to conform to PECO structure (Population, Exposure, Comparators, Outcome) if possible, and to address data requirements. They were modeled after the review question examples provided in the EFSA 2019 explanatory note<sup>1</sup>.

**Question 1:** Were any studies published during the reporting period that describe adverse effects on human or animal health or the environment of the GHB119 cotton and its newly expressed proteins Cry2Ae and PAT/*bar*?

**Key elements:**

**Population:** Human health; animal health; environmental safety

**Exposure:** GHB119 cotton, derived food/feed products, newly expressed proteins in GHB119 cotton

**Comparators:** When applicable, comparable populations or subjects exposed to appropriate controls (e.g., vehicle only, innocuous control protein, non-GM comparator) or conventional counterpart used for comparative analysis of plant material

**Outcome:** Adverse effects

**Question 2:** Were any studies published during the reporting period that focus on molecular characterization of the GHB119 cotton and its newly expressed proteins Cry2Ae and PAT/*bar*?

**Key elements:**

Population: GHB119 cotton and newly expressed protein in GHB119 cotton  
 Outcome: Molecular characterization (which would indicate the information/data requirement for molecular characteristics)

**2.3. Criteria for relevance**

Criteria for establishing the relevance of retrieved publications were defined prior to conduct of the search. These criteria were modeled after those given in the EFSA 2019 explanatory note<sup>1</sup> and are described in [Table 1](#).

**Table 1: Eligibility/inclusion criteria to establish the relevance of retrieved publications**

Concepts	Criteria	Comment
Key elements of review questions with PECO structure		
Intervention/exposure	The publication addresses the GMO, derived food/feed products, and/or the intended trait(s) (e.g., newly expressed protein(s)) that are identical or like those under regulatory review	This enables the selection of publications that address the GMO, derived food/feed products, and/or the intended trait(s) under consideration
Population	The publication addresses human and animal health, and/or the environment (including biodiversity, ecosystem services, service providing units, and endangered species) as general protection goals	From the publications that address the GMO under consideration, those that address protection goals relevant to the risk assessment of the GMO are eligible
Outcome	The publication addresses effects/impacts on human and animal health, and/or the environment	Publications that address the GMO under consideration also need to address effects/impacts on entities of concern, and potential determinants of exposure that place these entities at risk, in order to be relevant to the risk assessment of the GMO
Comparator	If the publication reports a comparative study that uses plant material as test material, eligible publications must report a non-GM variety as comparator	In those cases where the publication addresses the GMO under consideration, reports a comparative analysis study and uses plant material as test material, eligible publications also need to include an appropriate non-GM line as comparator

Additional concepts		
Information/data requirements	The publication reports information pertaining to one or more information/data requirement(s) outlined in Appendix A for the GMO and derived food/feed products under consideration, including the intended trait(s)	Publications that potentially contribute to the knowledge informing the risk assessment of the GMO under consideration, and thus the risk hypotheses addressed, taking account of both hazard and exposure, can be considered relevant according to this eligibility/inclusion criterion. Publications addressing other issues such as benefits, socio-economics, ethics, crop protection, detection methods, efficacy, public perception and risk communication can be excluded, as they are not necessarily relevant to the risk assessment of GMOs
Plant species	The publication addresses the same plant species as the GMO under consideration	This eligibility/inclusion criterion permits the exclusion of publications on GMOs that contain the same intended trait(s) as the GMO under consideration, but which are introduced in another plant species
Scope of GMO application	The publication addresses pathways and levels of exposure to the GMO, derived food/feed products, and the intended trait(s) that are relevant for the intended uses of the GMO and derived food/feed products under regulatory review	From the publications that address the GMO under consideration, those that consider pathways and levels of exposure relevant to the scope of the GMO application (i.e., import and processing for food/feed uses, cultivation) are eligible
Target pests/organisms	The publication addresses target pests/organisms that are established in the EU	This permits the exclusion of publications that address interactions between the GMO and target pests/organisms that do not occur in the EU

<p>Stacked events obtained by conventional crosses/subcombinations</p>	<p>The publication addresses the higher stacked event and/or a subcombination or subcombinations of the single events of the higher stacked event, independently of its/their origin</p>	<p>This permits the selection of publications on the higher stacked event and/or subcombinations of the single events of the higher stacked event that are in the scope of the GMO application(e), independently of their origin. This permits the exclusion of publications on the single events of the higher stacked event, because the risk assessment of GMO applications for stacked events covers only the products in the scope of the GMO application – i.e., the higher stacked event and subcombinations of the singles involved, independently of their origin</p>
<p>Molecular stacks</p>	<p>The publication addresses: the molecular stack; all newly expressed proteins in the molecular stack; and/or one or several of the newly expressed proteins in the molecular stack that has/have not been previously risk assessed by EFSA and/or its GMO Panel and for which no safe use has been determined yet by EFSA and/or its GMO Panel</p>	<p>This permits the exclusion of publications that address one or several (not all) of the newly expressed proteins in the molecular stack that has/have been previously risk assessed by EFSA and/or its GMO Panel and for which the safe use has been determined by EFSA and/or its GMO Panel</p>
<p>Previously risk assessed publications</p>	<p>The publication has not been previously risk assessed by EFSA and/or its GMO Panel and is not cited/referenced in an EFSA/GMO Panel output</p>	<p>This permits the exclusion of publications that have been previously risk assessed by EFSA and/or its GMO Panel and cited/referenced in an EFSA/GMO Panel output</p>
<p>Access</p>	<p>Full-text document is accessible</p>	<p>If potentially relevant full-text documents cannot be obtained, they should be listed in a table with a description of the (unsuccessful) methods that have been used to try to obtain a copy</p>

Reporting format	The publication presents original/primary data.	This permits the exclusion of publications that do not present original/primary data (e.g., editorials, position papers). Reviews should only be included if they present data that are not available from a primary research study
Reporting format	A study in a publication should only be presented once, but if it is presented in more than one publication, all publications should be listed and grouped	Duplicate publications should be excluded at the screening stage. Only one copy of a study is required even if it is reported in different publications, and identified in more than one database

Table adapted from 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.

#### 2.4. Reference publication

One publication that is related to GHB119 cotton was previously identified and was used to test and validate the search strategy:

- Wu A-J; Chapman K; Sathischandra S; Massengill J; Araujo R; Soria M; Bugas M; Bishop Z; Haas C; Holliday B; Cisneros K; Lor J; Canez C; New S; Mackie S; Ghoshal D; Privalle L; Hunst P; Pallett K (2019). GHB614 x T304-40 x GHB119 x COT102 Cotton: Protein Expression Analyses of Field-Grown Samples. *Journal of Agriculture and Food Chemistry* 67(1):275-281

### 3. SEARCH METHODS AND OUTCOMES

The search strategies used here followed the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications and post-market environmental monitoring activities<sup>1</sup>. The search strategies were designed to be broad and sensitive enough to capture any relevant publications, if available.

An information specialist with background in plant biotechnology selected the databases, identified relevant search terms, developed search profiles, designed search strategies and conducted the searches.

#### 3.1. Time window and date of the literature search

The database searches were performed on October 23, 2019. Only documents updated between October 1, 2018 and September 30, 2019, were considered in the search. The dates of most recent database updates are provided in [Table 3](#).

#### 3.2. Databases used in the literature search

All searches were performed in the host STN (Scientific and Technical Information Network), an online database service operated jointly by CAS and FIZ Karlsruhe. STN provides access to a broad range of databases from the most renowned database producers worldwide.

The searches described here were performed in five databases: three multidisciplinary/large databases (Biosis, Medline and CA-Plus) and two subject-specific databases focused on agriculture-related topics (Agricola and CABA).

See [Appendix 1](#) for detailed database descriptions.

### 3.3. Search strategy

The search profiles were designed to cover event name, newly expressed proteins and intended traits. The search profile for GHB119 cotton didn't include "Trade name", because there is no trade name available for this product. Since one of the 'newly expressed protein' profiles and the 'intended traits' profile produced too many results when used on their own, they were combined with additional profiles: the 'newly expressed protein' profile for PAT/*bar* was combined with a 'plant species' profile while the 'intended traits' profile was combined with a 'general GMO' profile as well as with the 'plant species' profile. See [Table 2](#) for a detailed search profile.

All searches were performed in the Basic Index (BI) field, which includes the following subject headings/field names:

- **Agricola:** title (TI), controlled term (CT), supplementary term (ST), abstract (AB), named person (NA), corporate name (CO), note (NTE), geographic term, CABA and other fields (GT)
- **Biosis:** title (TI), abstract (AB), biosystematic codes (BC), chemical name (CN), controlled term (CT), gene name (GEN), geographic term (GT), organism (ORGN) and supplementary term (ST); as well as CAS Registry Numbers (RN)
- **CA-Plus:** title (TI), supplementary term (ST), index term (IT) and abstract (AB); as well as CAS Registry Numbers
- **CABA:** title (TI), controlled term (CT), supplementary term (ST), broader term (BT), abstract (AB), organism name (ORGN) and geographic term (GT); as well as CAS Registry Numbers
- **Medline:** title (TI), chemical name (CN), gene name (GEN), controlled term (excluding MeSH numbers) (CT), supplementary term (ST), named person (NA), other source (OS), and abstract (AB), as well as CAS Registry Numbers and GenBank Numbers

The search results were limited to documents updated between October 1, 2018 and September 30, 2019 (UP>=20181001 and UP<=20190930), and to non-patent documents (not P/DT). To ensure that documents with indexing errors where two DTs (one eligible and one ineligible) were attached to a single record were not missed, documents with both 'journal' and 'patent' as *document type* were also kept. These putative documents would be identified with (P/DT AND J/DT) in CABA and CAPlus.

[Table 3](#) summarizes the number of results obtained from each of the databases searched.

See [Appendix 2](#) for a complete search history.

**Table 2: Search profile for database search**

Set	Search string	Concepts
1	GHB119 or GHB(w)119 or BCS-GH005-8 or BCS(w)GH005(w)8 or BCSGH005(w)8 or BCS-GH005-8 or BCS-(w)GH005(w)8 or BCSGH005(w)8 or BCS-GH005-8 or BCS-(w)GH005(w)8 or BCSGH005(w)8	Event name
2	s ((bar or pat) (2a) (gene# or protein# or enzyme#)) or ppt (2w) acetyltransferase or ppt (2w) acetyl (w) transferase or pt (w) n (2w) acetyltransferase or pt (w) n (2w) acetyl (w) transferase or phosphinothricin (w) n (w) acetyltransferase or phosphinothricin (2w) acetyltransferase or phosphinothricin (2w) acetyl (w) transferase or phosphinothricin acetyl (w) transferase	Newly expressed protein 1
3	cry2ae# or cry(w)2(w)ae# or cry(w)2ae# or cry2(w)ae# or cry2(w)a(w)e# or cry(w)2(w)a(w)e# or cry2a(w)e# or cryIIae# or cry(w)II(w)ae# or cry(w)IIae# or cryII(w)ae# or cryII(w)a(w)e# or cry(w)II(w)a(w)e# or cryIIa(w)e# or cryllae# or cry(w)ll(w)ae# or cry(w)llae# or cryll(w)ae# or cryll(w)a(w)e# or cry(w)ll(w)a(w)e# or crylla(w)e#	Newly expressed protein 2
4	(herbicid? or bialaphos or basta or glufosinate or phosphinothricin or liberty? Or Insect# OR pest# OR Lepidoptera# OR Noctuidae OR Crambidae OR borer# OR cornborer# OR stalkborer# OR earworm# OR ear(w)worm# OR armyworm# OR army(w)worm# OR cutworm# OR cut(w)worm# OR Ostrinia OR O(w)nubilalis OR Sesamia OR S(w)nonagrioides or Diatraea OR D(w)grandiosella OR D(w)crambidoides OR Helicoverpa OR H(w)zea OR Spodoptera OR S(w)frugiperda OR Papaipema OR P(w)nebris OR Elasmopalpus OR E(w)lignosellus OR D(w)saccharalis OR Striacosta OR S(w)albicosta or Agrotis OR A(w)ipsilon OR S(w)cretica OR Mythimna OR M(w)unipuncta OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR SCB OR WBC) (5a) (resist? OR protect? OR toleran?)	Intended traits
5	cotton# or gossypium or G(w)hirsutum or g(w)barbadense	Plant species
6	GMO OR GMOs OR LMO OR LMOs OR GM OR GE OR transgen? OR (genetic? (3a) (modif? OR transform? OR manipulat? OR improv? OR engineer?))	GMO general
7	2 and 5	Newly expressed protein 1 AND Plant species
8	4 and 5 and 6	Intended trait AND Plant species AND GMO general
9	1 or 3 or 7 or 8	Event name OR (Newly expressed protein 1 AND plant species) OR Newly expressed protein 2 OR (Intended traits AND Plant species AND GMO general)

**Table 3: Overview of the selected databases and summary of search results from each database**

Database	AGRICOLA	BIOSIS	CAB Abstracts	CAPLUS	MEDLINE
Database Provider	STN International				
Coverage	1970-present	1926-present	1973-present	1907-present	1946-present
Date of search	23 Oct 2019				
Datespan of the search	1 Oct 2018 – 30 Sept 2019				
Latest database update	4 Oct 2019	16 Oct 2019	16 Oct 2019	22 Oct 2019	22 Oct 2019
Number of records retrieved	31	62	74	55	68
Number of records after duplicate removal	15	35	47	26	68
Number of relevant records after rapid assessment	0	2	3	1	3

#### 4. MANUAL SEARCHES

##### 4.1. Manual searches of web pages of food safety, agriculture, and biotechnology-related authority webpages

A search of the web pages of food safety, agriculture, and biotechnology-related authorities was conducted. Search results were manually examined for relevant records that were either published during the time period under consideration (date span of search: October 1, 2018 to September 30, 2019) or refer to relevant records published during this time frame. Relevance of results were determined based on the criteria listed in [Table 1](#) and they were summarized in [Table 4](#). All web pages searched were justified by their recommendation in the EFSA 2019 explanatory note<sup>1</sup>. Search terms consisted of GHB119 or BCS-GH005-8, or Cry2Ae, or PAT/*bar* or Phosphinothricin in GHB119 cotton (all searched singly, with no search limits applied).

**Table 4: Results of search of food safety, agriculture, and biotechnology-related authority websites**

Source Site Name	Website URL	Date of Most Recent Site Update	Date of Search	No. of Relevant Records
US Environmental Protection Agency (EPA)	<a href="https://www.epa.gov/">https://www.epa.gov/</a>	Oct 4 2019	Oct 8 2019	0
US Department of Agriculture (USDA)	<a href="https://www.usda.gov/">https://www.usda.gov/</a>	Oct 8 2019	Oct 9 2019	0
US Food and Drug Administration (FDA)	<a href="https://www.fda.gov/">https://www.fda.gov/</a>	Oct 9 2019	Oct 9 2019	0
Health Canada	<a href="https://www.canada.ca/en/health-canada.html">https://www.canada.ca/en/health-canada.html</a>	Oct 7 2019	Oct 9 2019	0
Food Inspection Agency Canada	<a href="https://www.canada.ca/en/food-inspection-agency.html">https://www.canada.ca/en/food-inspection-agency.html</a>	Aug 23 2019	Oct 9 2019	0
Environment and Climate Change Canada	<a href="https://www.canada.ca/en/services/environment/weather/climate-change.html">https://www.canada.ca/en/services/environment/weather/climate-change.html</a>	Jul 26 2019	Oct 9 2019	0
Food Standards Australia New Zealand (FSANZ)	<a href="http://www.foodstandards.gov.au/Pages/default.aspx">http://www.foodstandards.gov.au/Pages/default.aspx</a>	Oct 9 2019	Oct 9 2019	0
Office of the Gene Technology Regulator (OGTR) Australia	<a href="http://www.ogtr.gov.au/">http://www.ogtr.gov.au/</a>	Oct 8 2019	Oct 9 2019	0
National Technical Commission on Biosafety (CTNBio) Brazil	<a href="http://ctnbio.mcti.gov.br/en">http://ctnbio.mcti.gov.br/en</a>	Sep 19	Oct 7-21 2019	0
National Advisory Commission on Agricultural Biotechnology (CONABIA) Argentina	<a href="https://www.argentina.gob.ar/agroindustria/bioeconomia/biotechnologia">https://www.argentina.gob.ar/agroindustria/bioeconomia/biotechnologia</a>	Oct 1 2019	Oct 2 2019	0
National Food Safety and Quality Service (SENASA) Argentina	<a href="https://www.argentina.gob.ar/senasa">https://www.argentina.gob.ar/senasa</a>	Oct 2 2019	Oct 2 2019	0
Genetic Engineering Approval Committee (GEAC) India	<a href="http://moef.gov.in/">http://moef.gov.in/</a>	Sep 30 2019	Oct 9 2019	0
Ministry of Agriculture, Forestry and Fisheries (MAFF) Japan	<a href="http://www.maff.go.jp/">http://www.maff.go.jp/</a>	Oct 30 2019	Oct 30 2019	0

Source Site Name	Website URL	Date of Most Recent Site Update	Date of Search	No. of Relevant Records
Ministry of Health, Labour and Welfare (MHLW) Japan	http://www.mhlw.go.jp /	Oct 30 2019	Oct 30 2019	0

#### 4.2. Manual searches of reference lists of recent review articles

Recent review articles as sources of reference lists to search for potentially relevant studies were identified via searches of PubMed.gov for general terms such as “GMO” or “GM crops” in the titles and abstracts. The search of PubMed.gov was also restricted to recent reviews published between October 1, 2018 and September 30, 2019. The resulting number of relevant studies found within the bibliographies of these review articles is given in [Table 5](#).

**Table 5: Documents for which reference lists were scanned for relevant studies**

No	Author(s) and Year	Title	Source	Number of relevant bibliographic references retrieved
1	Agapito-Tenfen SZ, Okoli AS, Bernstein MJ, Wikmark OG, Myhr AI. 2018	Revisiting Risk Governance of GM Plants: The Need to Consider New and Emerging Gene-Editing Techniques.	Front Plant Sci. 2018 Dec 21;9:1874. doi: 10.3389/fpls.2018.01874.	0
2	Alarcon CM, Shan G, Layton DT, Bell TA, Whipkey S, Shillito RD. 2019	Application of DNA- and Protein-Based Detection Methods in Agricultural Biotechnology.	J Agric Food Chem. 2019 Jan 30;67(4):1019-1028. doi: 10.1021/acs.jafc.8b05157.	0
3	Bogner A, Torgersen H. 2018	Precaution, Responsible Innovation and Beyond - In Search of a Sustainable Agricultural Biotechnology Policy.	Front Plant Sci. 2018 Dec 18;9:1884. doi: 10.3389/fpls.2018.01884.	0
4	Boonchaisri S, Rochfort S, Stevenson T, Dias DA. 2019	Recent developments in metabolomics-based research in understanding transgenic grass metabolism.	Metabolomics. 2019 Mar 15;15(4):47. doi: 10.1007/s11306-019-1507-4.	0
5	Collins C, Lorenzen N, Collet B. 2019	DNA vaccination for finfish aquaculture.	Fish Shellfish Immunol. 2019 Feb;85:106-125. doi: 10.1016/j.fsi.2018.07.012.	0

6	Gaffar FY, Koch A. 2019	Catch Me If You Can! RNA Silencing-Based Improvement of Antiviral Plant Immunity.	Viruses. 2019 Jul 23;11(7). pii: E673. doi: 10.3390/v11070673.	0
7	Ghosh S, Ghosh S, Sil PC. 2019	Role of nanostructures in improvising oral medicine.	Toxicol Rep. 2019 Apr 15;6:358-368. doi: 10.1016/j.toxrep.2019.04.004.	0
8	Halford NG. 2019	Legislation governing genetically modified and genome-edited crops in Europe: the need for change.	J Sci Food Agric. 2019 Jan 15;99(1):8-12. doi: 10.1002/jsfa.9227.	0
9	Hamburger DJS. 2018	Normative Criteria and Their Inclusion in a Regulatory Framework for New Plant Varieties Derived From Genome Editing.	Front Bioeng Biotechnol. 2018 Dec 19;6:176. doi: 10.3389/fbioe.2018.00176.	0
10	Hundleby PAC, Harwood WA. 2019	Impacts of the EU GMO regulatory framework for plant genome editing.	Food Energy Secur. 2019 May;8(2):e00161. doi: 10.1002/fes3.161.	0
11	Ichim MC. 2019	The Romanian experience and perspective on the commercial cultivation of genetically modified crops in Europe.	Transgenic Res. 2019 Feb;28(1):1-7. doi: 10.1007/s11248-018-0095-9.	0
12	Ishaq N, Bilal M, Iqbal HMN. 2019	Medicinal Potentialities of Plant Defensins: A Review with Applied Perspectives.	Medicines (Basel). 2019 Feb 19;6(1). pii: E29. doi: 10.3390/medicines6010029.	0
13	Jyoti A, Kaushik S, Srivastava VK, Datta M, Kumar S, Yugandhar P, Kothari SL, Rai V, Jain A. 2019	The potential application of genome editing by using CRISPR/Cas9, and its engineered and ortholog variants for studying the transcription factors involved in the maintenance of phosphate homeostasis in model plants.	Semin Cell Dev Biol. 2019 Apr 6. pii: S1084-9521(18)30112-5. doi: 10.1016/j.semcdb.2019.03.010.	0
14	Kauffmann F, Van Damme P, Leroux-Roels G, Vandermeulen C, Berthels N, Beuneu C, Mali S. 2019	Clinical trials with GMO-containing vaccines in Europe: Status and regulatory framework.	Vaccine. 2019 Sep 30;37(42):6144-6153. doi: 10.1016/j.vaccine.2019.08.018.	0

15	Looi FY, Baker ML, Townson T, Richard M, Novak B, Doran TJ, Short KR. 2018	Creating Disease Resistant Chickens: A Viable Solution to Avian Influenza?	Viruses. 2018 Oct 15;10(10). pii: E561. doi: 10.3390/v10100561.	0
16	Mat Jalaluddin NS, Othman RY, Harikrishna JA. 2019	Global trends in research and commercialization of exogenous and endogenous RNAi technologies for crops.	Crit Rev Biotechnol. 2019 Feb;39(1):67-78. doi: 10.1080/07388551.2018.1496064.	0
17	Napier JA, Haslam RP, Tsalavouta M, Sayanova O. 2019	The challenges of delivering genetically modified crops with nutritional enhancement traits.	Nat Plants. 2019 Jun;5(6):563-567. doi: 10.1038/s41477-019-0430-z.	0
18	Rostoks N, Grantiņa-Ieviņa L, Ieviņa B, Evelone V, Valciņa O, Aleksejeva I. 2019	Genetically modified seeds and plant propagating material in Europe: potential routes of entrance and current status.	Heliyon. 2019 Feb 15;5(2):e01242. doi: 10.1016/j.heliyon.2019.e01242.	0
19	Tyczewska A, Wozniak E, Gracz J, Kuczynski J, Twardowski T. 2018	Towards Food Security: Current State and Future Prospects of Agrobiotechnology.	Trends Biotechnol. 2018 Dec;36(12):1219-1229. doi: 10.1016/j.tibtech.2018.07.008.	0
20	Wolt JD, Wolf C. 2018	Policy and Governance Perspectives for Regulation of Genome Edited Crops in the United States.	Front Plant Sci. 2018 Nov 8;9:1606. doi: 10.3389/fpls.2018.01606.	0
21	Wu Y, Li J, Li X, Zhai S, Gao H, Li Y, Zhang X, Wu G. 2019	Development and strategy of reference materials for the DNA-based detection of genetically modified organisms.	Anal Bioanal Chem. 2019 Mar;411(9):1729-1744. doi: 10.1007/s00216-019-01576-w.	0
22	Zimny T, Sowa S, Tyczewska A, Twardowski T. 2019	Certain new plant breeding techniques and their marketability in the context of EU GMO legislation - recent developments.	N Biotechnol. 2019 Jul 25;51:49-56. doi: 10.1016/j.nbt.2019.02.003.	0

## 5. RESULTS OF THE STUDY IDENTIFICATION AND SELECTION PROCESS

The database searches ([Section 3](#)) identified a total of 290 references, which were reduced to 191 after removal of duplicates ([Table 3](#)). No additional studies were identified in the manual searches ([Section 4](#)).

### 5.1. Screening of titles and abstracts to exclude obviously irrelevant references (Stage 1)

All references identified in the database searches described in Section 3 were assessed for relevance based on information in their title and abstract by two reviewers independently. If opinions of relevance differed, the discrepancies were discussed between the reviewers and if a disagreement persisted, the publication under the discussion was transferred to Stage 2 for detailed evaluation by the experts.

Clearly irrelevant records were tagged as “Not Relevant”. These included:

- Duplicated entries
- Secondary literature (reviews), other than assessments from Regulatory Agencies
- Articles on non-relevant topics like detection methods, socio-economic implications of GM crops, GM policy, agronomical performance, other herbicide resistant GM crops, other insect resistant GM crops, unrelated topics, etc.

Publications which appear to be relevant and those of unclear relevance were tagged as “Relevant” and progressed to Stage 2 (detailed assessment; see [Section 5.2](#)).

The number of publications excluded after rapid assessment for relevance is presented in [Table 6](#) documenting the selection process.

### 5.2. Detailed assessment of eligible references (Stage 2)

Publications tagged as “Relevant” in Stage 1 were assessed in detail independently by two scientific experts in each of three corresponding areas (i.e., Molecular Biology, Food and Feed Safety, Environmental Safety), based on the full text of the publications.

If opinions of relevance differed between reviewers within each area, the initial reviewers discussed the discrepancy as necessary and consulted additional reviewers to resolve the discrepancy if needed. All eligible references were assessed in detail. This detailed assessment included evaluation of the scope of the article and the study quality and reliability. Categorization of reliability (as described in the EFSA 2019 explanatory note<sup>1</sup> and reported in [Table 11](#)) was dependent upon the following:

- appropriateness of methodology
- whether the description of methodology would allow independent repetition of the study
- extent of characterization of test materials
- reporting of evidence of reproducibility

[Table 6](#) gives an overview of the reference selection process and results of the detailed assessment.

**Table 6: Results of the publication selection process**

Total number of publications retrieved after all searches of the scientific literature (excluding duplicates)	191
Number of publications excluded from the search results after rapid assessment for relevance (Stage 1)	182
Total number of full-text documents assessed in detail	9
Number of publications excluded from further consideration after detailed assessment for relevance (Stage 2)	8
Total number of unobtainable/unclear publications	0
Total number of relevant publications	1

[Table 7](#) lists the publications determined to be relevant along with their potential impact on the safety assessment based on detailed evaluation. Publications that were clearly not relevant after a detailed assessment are listed in [Table 8](#). [Table 9](#) lists the publications for which full-text documents were unobtainable for detailed assessment or for which relevance was unclear after detailed assessment.

**Table 7: Report of all relevant publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement(s)**

Main category of information/data requirement	Study (Author(s) and year)	Title	Source
Molecular Characterization	Wu A-J, Sathischandra S, Massengill J, Araujo R, Soria M, Bugas M, Bishop Z, Haas C, Cisneros K, Lor J, Canez C, New S, Mackie S, Ghoshal D, Privalle L, Hunst P, Chapman K, Holliday B, Pallett. 2019	GHB614 x T304-40 x GHB119 x COT102 Cotton: Protein Expression Analyses of Field-Grown Samples.	Journal of agricultural and food chemistry, (2019 Jan 09) Vol. 67, No. 1, pp. 275-281. Electronic Publication Date: 19 Dec 2018 Journal code: 0374755. E-ISSN: 1520-5118. L-ISSN: 0021-8561.

**Table 8: Report of publications excluded from the risk assessment after detailed assessment of full-text documents**

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in <a href="#">Table 1</a>
Guan ZhengJun; Lu ShunBao; Huo YanLin; Hao HaoYong; Cao JianBin; Wei Wei; Liu Biao; Guan Z J; Lu SB; Huo Y L; Hao HY; Cao JB; Wei W; Liu B. 2018	Effects of Bt crops on non-target insect pests.	Biodiversity Science (2018), Volume 26, Number 6, pp. 636-644, 85 refs. ISSN: 1005-0094 DOI: 10.17520/biods.2017315 Published by: Biodiversity Science, Beijing	Reviewed the characteristics and status of non-target insect pest outbreaks and analyzed the main causes. Also discussed the effects of GM crops on non-target pests over long term. Contained no primary data.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in <a href="#">Table 1</a>
Hernandez-Teran A, Wegier A, Benitez M, Lira R, Sosa Fuentes TG, Escalante AE [Reprint Author]. 2019	In vitro performance in cotton plants with different genetic backgrounds: the case of <i>Gossypium hirsutum</i> in Mexico, and its implications for germplasm conservation.	PeerJ, (JUN 10 2019 ) Vol. 7, pp. Article No.: e7017. <a href="https://peerj.com/">https://peerj.com/</a> . ISSN: 2167-8359. E-ISSN: 2167-8359.	Evaluated and compared in vitro performance of wild and domesticated cotton populations in Mexico. No environmental risk assessment (ERA) related to GHB119 cotton.
EFSA Panel on GMOs Naegeli H, Birch AN, Casacuberta J, de Schrijver A, Gralak M A, Jones H, Manachini B, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal JM, Poeting A, Alvarez F, Broll H, Ramon M. 2017	Scientific opinion on an application by Monsanto (EFSA-GMO -NL-2013-114) for the placing on the market of a herbicide-tolerant genetically modified cotton MON 88701 for food and feed uses, import and processing under Regulation (EC) No 1829/2003	EFSA Journal (2017 ), 15(3), n/a CODEN: EJFOA6; ISSN: 1831-4732	This publication was excluded because it does not contain original/primary data. In addition, report is not related to GHB119 cotton.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in <a href="#">Table 1</a>
<p>Naegeli H, Bresson J L, Dalmay T, Dewhurst I C, Epstein M M, Firbank L G, Guerche P, Hejatko J, Moreno F J, Mullins E, Nogue F, Rostoks N, Serrano J J S, Savoini G, Veromann E, Veronesi F, Alvarez F, Ardizzone M, Paraskevopoulos K.</p> <p>2018</p>	<p>Assessment of genetically modified LLCotton25 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO -RX-010).</p>	<p>EFSA Journal (2018), Volume 16, Number 11, e05473 p., 7 refs. ISSN: 1831-4732 DOI: 10.2903/j.efsa.2018.5473          Published by: Wiley, Oxford</p>	<p>This publication was excluded because it does not contain original/primary data. In addition, report is on LLCotton25 cotton and not related to GHB119 cotton.</p>
<p>Naegeli H, Birch AN, Casacuberta J, de Schrijver A, Gralak M A, Guerche P, Jones H, Manachini B, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal JM, Ardizzone M, Fernandez-Dumont A, Gennaro A, Ruiz J A G, Lanzoni A, Neri F M, Papadopoulou N, Paraskevopoulos K.</p> <p>2018</p>	<p>Assessment of genetically modified cotton GHB614 x T304-40 x GHB119 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-122).</p>	<p>EFSA Journal (2018), Volume 16, Number 7, e05349 p., 35 refs. ISSN: 1831-4732 DOI: 10.2903/j.efsa.2018.5349          Published by: Wiley, Oxford</p>	<p>This publication was excluded because it does not contain original/primary data. In addition, report is on stacked product involving GHB119 cotton but not on GHB119 cotton itself.</p>

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in <a href="#">Table 1</a>
Ricroch A [Reprint Author], Akkoyunlu S, Martin-Laffon J, Kuntz M. 2018	Assessing the Environmental Safety of Transgenic Plants: Honey Bees as a Case Study.	Kuntz, M [Editor]. Adv. Bot. Res., (2018 ) pp. 111-167. Transgenic Plants and Beyond. Publisher: ACADEMIC PRESS LTD-ELSEVIER SCIENCE LTD, 24-28 OVAL ROAD, LONDON NW1 7DX, UK. Series: Advances in Botanical Research. CODEN: ABTRAJ. ISSN: 0065-2296. ISBN: 978-0-12-809447-1(P).	Review on the impact of insecticidal and herbicidal trait on the health of honey bees. It does not contain original/primary data.
Salisu Ibrahim Bala; Shahid Ahmad Ali; Yaqoob Amina; Rao Abdul Qayyum; Husnain Tayyab. 2019	Effect of dietary supplementation of recombinant Cry and Cp4 epsps proteins on haematological indices of growing rabbits.	Journal of animal physiology and animal nutrition, (2019 Jan) Vol. 103, No. 1, pp. 305-316. Electronic Publication Date: 29 Oct 2018 Journal code: 101126979. E-ISSN: 1439-0396. L-ISSN: 0931-2439.	Study is not specific to the GHB119 cotton. It involves expression of other proteins.
Xiaoping P. 2019	Determining Pollen-Mediated Gene Flow in Transgenic Cotton .	Methods in molecular biology (Clifton, N.J.), (2019) Vol. 1902, pp. 309-321. Journal code: 9214969. E-ISSN: 1940-6029. L-ISSN: 1064-3745.	Evaluated the extent of gene flow for GM cotton (NewCott 33B and TFD) in field. No ERA related to GHB119 cotton.

**Table 9: Report of unobtainable/unclear publications**

<b>Study (Author(s) and year)</b>	<b>Title</b>	<b>Source</b>	<b>Description of (unsuccessful) methods used to try and obtain a copy of the publication</b>
No publications in this category.			

## 6. NARRATIVE SYNTHESIS/SUMMARY OF RELEVANT STUDIES

A total of 9 publications were selected during Stage 1 evaluation (rapid assessment based on title and abstract). After Stage 2 evaluation (detailed review based on full text), it was determined that one publication was relevant for the safety assessment of the GHB119 cotton and its newly expressed protein Cry2Ae and PAT/*bar*.

In the publication identified as relevant, Wu *et al.* 2018, protein expression level and pattern were compared between the single parent events including GHB119 and the stack events created by conventional breeding. The data and knowledge generated from this study does not impact on safety assessment of GHB119.

[Table 10](#) and [Table 11](#) list the relevant publication along with a summary of any adverse effects reported and the reliability of the publications.

**Table 10: Report of the summary of all relevant publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement(s)**

Main category of information/data requirement	Study (Author(s) and year)	Intervention/ test materials used	Adverse effects reported	Which adverse effect reported
Molecular Characterization	Wu A-J, Sathischandra S, Massengill J, Araujo R, Soria M, Bugas M, Bishop Z, Haas C, Cisneros K, Lor J, Canez C, New S, Mackie S, Ghoshal D, Privalle L, Hunst P, Chapman K, Holliday B, Pallett. 2019	Cry2Ae, Pat/ <i>bar</i>	None	Not applicable

**Table 11: Report of the reliability and implications for the risk assessment of all relevant publications retrieved after detailed assessment of full-text documents for relevance: ordered by category of information/data requirement(s)**

Main category of information/data requirement	Study (Author(s) and year)	Summary of reliability appraisal	Implications for risk assessment
Molecular Characterization	Wu A-J, Sathischandra S, Massengill J, Araujo R, Soria M, Bugas M, Bishop Z, Haas C, Cisneros K, Lor J, Canez C, New S, Mackie S, Ghoshal D, Privalle L, Hunst P, Chapman K, Holliday B, Pallett. 2019	Moderate	None, because no new hazards, modified exposure, or scientific uncertainties are reported.

## 7. CONCLUSION

The literature searches performed for the GHB119 cotton and its newly expressed protein Cry2Ae and PAT/*bar* for the period from October 1, 2018 to September 30, 2019, identified a total of 191 unique publications (after duplicate removal). A total of 9 publications were progressed for detailed assessment after excluding 182 obviously irrelevant publications during Stage 1 evaluation (rapid assessment based on title and abstract).

The 9 publications that progressed to Stage 2 were evaluated in detail, based on full text, for potential relevance, following the pre-established criteria listed in [Table 1](#). One relevant reference with bearing on molecular characterization was identified. The data and knowledge generated from this study does not impact the safety assessment of GHB119. No issues or topics were identified that would trigger or warrant more specific question formulation.

## 8. REFERENCES

No.	Author(s), title, source, edition, year, pages
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- |    |  |
|----|--|
| 1. | Devos Y, Guajardo IM, Alvarez F and Glanville J. 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. EFSA supporting publications 2019:EN-1614. 62 pages.<br>doi:10.2903/sp.efsa.2019.EN-1614. |
|----|--|

## 9. APPENDICES

### Appendix 1 Database descriptions

Host	File	Description
STN	AGRICOLA	<p>Agriculture Online Access is a bibliographic database containing selected worldwide literature of agriculture and related fields. AGRICOLA is the locator and bibliographic access and control system of the National Agricultural Library (NAL) collections and also includes records from other cooperating institutions. Coverage of the database includes agricultural economics and rural sociology, agricultural production, animal sciences, chemistry, entomology, food and human nutrition, forestry, natural resources, pesticides, plant science, soils and fertilizers, and water resources. Also covered are related areas such as biology and biotechnology, botany, ecology, and natural history.</p> <p>The database draws on bibliographies, serial articles, book chapters, monographs, computer files, serials, maps, audiovisuals, and reports. Bibliographic information, abstracts, geographic terms, controlled terms, and supplementary terms are searchable.</p>
STN	BIOSIS	<p>BIOSIS Previews® is the largest and most comprehensive life science database in the world. Amongst others subject coverage includes Agriculture, Biochemistry, Biophysics, Botany, Environmental Biology, Physiology, Toxicology.</p> <p>Sources include periodicals, journals, conference proceedings, reviews, reports, patents, and short communications. Nearly 6,000 life source journals, 1,500 international meetings as well as review articles, books, and monographs are reviewed for inclusion.</p> <p>Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are all searchable.</p>
STN	CABA/CAB	<p>The CAB Abstracts database covers worldwide literature from all areas of agriculture and related sciences including Agriculture, Agricultural chemicals, Animal sciences and production, Crop protection, Crop sciences and production, Environment, Soils and fertilizers.</p> <p>Sources for CABA include journals, books, reports, published theses, conference proceedings, and patents.</p> <p>Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are searchable.</p>
STN	CAS-CA/CAPLUS	<p>The Chemical Abstracts (CA) database covers all areas of Biochemistry, Chemistry and Chemical engineering, and related sciences.</p> <p>Sources include over 8,000 journals, patents from 38 national patent offices and two international patent organizations, technical reports, books, conference proceedings, and dissertations. Electronic only journals and Web preprints are also covered.</p> <p>Bibliographic terms, indexing terms, roles, CAS Registry Numbers, International Patent Classification, and abstracts are searchable.</p>

<b>Host</b>	<b>File</b>	<b>Description</b>
STN	MEDLINE	<p>MEDLINE contains information on every area of medicine. The MEDLINE database corresponds to Index Medicus, Index to Dental Literature, and International Nursing Index; OLDMEDLINE, with data from NLM's from the Cumulated Index Medicus (1960-1965) and Current List of Medical Literature (1958-1959); and, since August 2001, IN-PROCESS records, the latest documents before they have been completely indexed for inclusion on MEDLINE.</p> <p>Sources include journals and chapters in books or symposia. Bibliographic information, indexing terms, abstracts, chemical names, and CAS Registry Numbers are all searchable.</p> <p>Online thesauri are available for the Medical Subject Headings (/MN), Controlled Terms (/CT) and Chemical Name (/CN) fields.</p>

**Appendix 2 Search history**

```
FILE 'MEDLINE' ENTERED AT 09:32:07 ON 23 OCT 2019
L1      3 SEA GHB119 OR GHB(W)119 OR BCS-GH005-8 OR BCS(W)GH005(W)8 OR
      BCSGH005(W)8 OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8
      OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8
L2      1321 SEA ((BAR OR PAT) (2A) (GENE# OR PROTEIN# OR ENZYME#)) OR
      PPT(2W)ACETYLTRANSFERASE OR PPT(2W)ACETYL(W)TRANSFERASE OR
      PT(W)N(2W)ACETYLTRANSFERASE OR PT(W)N(2W)ACETYL(W)TRANSFERASE
L3      194 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
      N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
      ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE
L4      1392 SEA (L2 OR L3)
L5      8 SEA CRY2AE# OR CRY(W)2(W)AE# OR CRY(W)2AE# OR CRY1(W)AE# OR
      CRY2(W)A(W)E# OR CRY(W)2(W)A(W)E# OR CRY2A(W)E#
L6      0 SEA CRYIIAE# OR CRY(W)II(W)AE# OR CRY(W)IIAE# OR CRYII(W)AE#
      OR CRYII(W)A(W)E# OR CRY(W)II(W)A(W)E# OR CRYIIA(W)E#
L7      0 SEA CRYLLAE# OR CRY(W)LL(W)AE# OR CRY(W)LLAE# OR CRYLL(W)AE#
      OR CRYLL(W)A(W)E# OR CRY(W)LL(W)A(W)E# OR CRYLLA(W)E#
L8      8 SEA (L5 OR L6 OR L7)
L9      27043 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR PHOSPHINO
      THRICIN OR LIBERTY?
L10     185606 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE
      OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WOR
      M# OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR
      OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES
L11     12855 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR
      HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR
      PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR
      D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA
L12     19430 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR
      M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR
      SCB OR WBC
L13     2107506 SEA (RESIST? OR PROTECT? OR TOLERAN?)
L14     9628 SEA ((L9 OR L10 OR L11 OR L12)) (5A) L13
L15     23577 SEA COTTON# OR GOSSYPIUM OR G(W)HIRSUTUM OR G(W)BARBADENSE
L16     3442247 SEA GMO OR GMOS OR LMO OR LMOS OR GM OR GE OR TRANSGEN? OR
      (GENETIC?(3A) (MODIF? OR TRANSFORM? OR MANIPULAT? OR IMPROV? OR
      ENGINEER?))
L17     13 SEA L4 AND L15
L18     570 SEA L14 AND L15 AND L16
L19     578 SEA L1 OR L8 OR L17 OR L18
L20     112 SEA L19 AND PY>=2017
L21     68 SEA L20 AND UP>=20181001 AND UP<=20190930

FILE 'BIOSIS' ENTERED AT 09:33:29 ON 23 OCT 2019
L22     2 SEA GHB119 OR GHB(W)119 OR BCS-GH005-8 OR BCS(W)GH005(W)8 OR
      BCSGH005(W)8 OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8
      OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8
L23     2643 SEA ((BAR OR PAT) (2A) (GENE# OR PROTEIN# OR ENZYME#)) OR
      PPT(2W)ACETYLTRANSFERASE OR PPT(2W)ACETYL(W)TRANSFERASE OR
      PT(W)N(2W)ACETYLTRANSFERASE OR PT(W)N(2W)ACETYL(W)TRANSFERASE
L24     321 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
      N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
      ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE
L25     2741 SEA (L23 OR L24)
L26     13 SEA CRY2AE# OR CRY(W)2(W)AE# OR CRY(W)2AE# OR CRY1(W)AE# OR
      CRY2(W)A(W)E# OR CRY(W)2(W)A(W)E# OR CRY2A(W)E#
L27     0 SEA CRYIIAE# OR CRY(W)II(W)AE# OR CRY(W)IIAE# OR CRYII(W)AE#
      OR CRYII(W)A(W)E# OR CRY(W)II(W)A(W)E# OR CRYIIA(W)E#
L28     0 SEA CRYLLAE# OR CRY(W)LL(W)AE# OR CRY(W)LLAE# OR CRYLL(W)AE#
      OR CRYLL(W)A(W)E# OR CRY(W)LL(W)A(W)E# OR CRYLLA(W)E#
L29     13 SEA (L26 OR L27 OR L28)
```

L30 83351 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR PHOSPHINO  
THRICIN OR LIBERTY?  
L31 1347934 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE  
OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WOR  
M# OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR  
OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES  
L32 25023 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR  
HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR  
PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR  
D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA  
L33 27576 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR  
M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR  
SCB OR WBC  
L34 2165880 SEA (RESIST? OR PROTECT? OR TOLERAN?)  
L35 30787 SEA ((L30 OR L31 OR L32 OR L33)) (5A)L34  
L36 70275 SEA COTTON# OR GOSSYPIUM OR G(W)HIRSUTUM OR G(W)BARBADENSE  
L37 428965 SEA GMO OR GMOS OR LMO OR LMOS OR GM OR GE OR TRANSGEN? OR  
(GENETIC?(3A) (MODIF? OR TRANSFORM? OR MANIPULAT? OR IMPROV? OR  
ENGINEER?))  
L38 44 SEA L25 AND L36  
L39 864 SEA L35 AND L36 AND L37  
L40 902 SEA L22 OR L29 OR L38 OR L39  
L41 106 SEA L40 AND PY>=2017  
L42 62 SEA L41 AND UP>=20181001 AND UP<=20190930

FILE 'AGRICOLA' ENTERED AT 09:34:00 ON 23 OCT 2019

L43 1 SEA GHB119 OR GHB(W)119 OR BCS-GH005-8 OR BCS(W)GH005(W)8 OR  
BCSGH005(W)8 OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8  
OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8  
L44 710 SEA ((BAR OR PAT) (2A) (GENE# OR PROTEIN# OR ENZYME#)) OR  
PPT(2W)ACETYLTRANSFERASE OR PPT(2W)ACETYL(W)TRANSFERASE OR  
PT(W)N(2W)ACETYLTRANSFERASE OR PT(W)N(2W)ACETYL(W)TRANSFERASE  
L45 238 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI  
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER  
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE  
L46 784 SEA (L44 OR L45)  
L47 6 SEA CRY2AE# OR CRY(W)2(W)AE# OR CRY(W)2AE# OR CRY1(W)AE# OR  
CRY2(W)A(W)E# OR CRY(W)2(W)A(W)E# OR CRY2A(W)E#  
L48 0 SEA CRYIIAE# OR CRY(W)II(W)AE# OR CRY(W)IIAE# OR CRYII(W)AE#  
OR CRYII(W)A(W)E# OR CRY(W)II(W)A(W)E# OR CRYIIA(W)E#  
L49 0 SEA CRYLLAE# OR CRY(W)LL(W)AE# OR CRY(W)LLAE# OR CRYLL(W)AE#  
OR CRYLL(W)A(W)E# OR CRY(W)LL(W)A(W)E# OR CRYLLA(W)E#  
L50 6 SEA (L47 OR L48 OR L49)  
L51 52815 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR PHOSPHINO  
THRICIN OR LIBERTY?  
L52 312001 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE  
OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WOR  
M# OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR  
OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES  
L53 12767 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR  
HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR  
PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR  
D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA  
L54 3900 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR  
M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR  
SCB OR WBC  
L55 520326 SEA (RESIST? OR PROTECT? OR TOLERAN?)  
L56 27011 SEA ((L51 OR L52 OR L53 OR L54)) (5A)L55  
L57 59357 SEA COTTON# OR GOSSYPIUM OR G(W)HIRSUTUM OR G(W)BARBADENSE  
L58 90274 SEA GMO OR GMOS OR LMO OR LMOS OR GM OR GE OR TRANSGEN? OR  
(GENETIC?(3A) (MODIF? OR TRANSFORM? OR MANIPULAT? OR IMPROV? OR  
ENGINEER?))  
L59 20 SEA L46 AND L57

L60 673 SEA L56 AND L57 AND L58  
L61 686 SEA L43 OR L50 OR L59 OR L60  
L62 57 SEA L61 AND PY>=2017  
L63 31 SEA L62 AND UP>=20181001 AND UP<=20190930

FILE 'CABA' ENTERED AT 09:35:35 ON 23 OCT 2019

L64 6 SEA GHB119 OR GHB(W)119 OR BCS-GH005-8 OR BCS(W)GH005(W)8 OR  
BCSGH005(W)8 OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8  
OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8

L65 1437 SEA ((BAR OR PAT)(2A)(GENE# OR PROTEIN# OR ENZYME#)) OR  
PPT(2W)ACETYLTRANSFERASE OR PPT(2W)ACETYL(W)TRANSFERASE OR  
PT(W)N(2W)ACETYLTRANSFERASE OR PT(W)N(2W)ACETYL(W)TRANSFERASE

L66 364 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI  
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER  
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L67 1535 SEA (L65 OR L66)

L68 11 SEA CRY2AE# OR CRY(W)2(W)AE# OR CRY(W)2AE# OR CRY1(W)AE# OR  
CRY2(W)A(W)E# OR CRY(W)2(W)A(W)E# OR CRY2A(W)E#

L69 0 SEA CRYIIAE# OR CRY(W)II(W)AE# OR CRY(W)IIAE# OR CRYII(W)AE#  
OR CRYII(W)A(W)E# OR CRY(W)II(W)A(W)E# OR CRYIIA(W)E#

L70 0 SEA CRYLLAE# OR CRY(W)LL(W)AE# OR CRY(W)LLAE# OR CRYLL(W)AE#  
OR CRYLL(W)A(W)E# OR CRY(W)LL(W)A(W)E# OR CRYLLA(W)E#

L71 11 SEA (L68 OR L69 OR L70)

L72 144092 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR PHOSPHINO  
THRICIN OR LIBERTY?

L73 851638 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE  
OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WOR  
M# OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR  
OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES

L74 30278 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR  
HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR  
PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR  
D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA

L75 11435 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR  
M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR  
SCB OR WBC

L76 1152527 SEA (RESIST? OR PROTECT? OR TOLERAN?)

L77 79815 SEA ((L72 OR L73 OR L74 OR L75))(5A)L76

L78 89132 SEA COTTON# OR GOSSYPIUM OR G(W)HIRSUTUM OR G(W)BARBADENSE

L79 166048 SEA GMO OR GMOS OR LMO OR LMOS OR GM OR GE OR TRANSGEN? OR  
(GENETIC?(3A)(MODIF? OR TRANSFORM? OR MANIPULAT? OR IMPROV? OR  
ENGINEER?))

L80 32 SEA L67 AND L78

L81 2048 SEA L77 AND L78 AND L79

L82 2066 SEA L64 OR L71 OR L80 OR L81

L83 185 SEA L82 AND PY>=2017

L84 74 SEA L83 AND UP>=20181001 AND UP<=20190930

L85 74 SEA L84 NOT P/DT

L86 0 SEA L84 AND (P/DT AND J/DT)

L87 74 SEA L85 OR L86

FILE 'HCAPLUS' ENTERED AT 09:36:21 ON 23 OCT 2019

L88 7 SEA GHB119 OR GHB(W)119 OR BCS-GH005-8 OR BCS(W)GH005(W)8 OR  
BCSGH005(W)8 OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8  
OR BCS-GH005-8 OR BCS-(W)GH005(W)8 OR BCSGH005(W)8

L89 6273 SEA ((BAR OR PAT)(2A)(GENE# OR PROTEIN# OR ENZYME#)) OR  
PPT(2W)ACETYLTRANSFERASE OR PPT(2W)ACETYL(W)TRANSFERASE OR  
PT(W)N(2W)ACETYLTRANSFERASE OR PT(W)N(2W)ACETYL(W)TRANSFERASE

L90 744 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI  
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER  
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L91 6553 SEA (L89 OR L90)

L92 38 SEA CRY2AE# OR CRY(W)2(W)AE# OR CRY(W)2AE# OR CRY1(W)AE# OR

L93                    3 SEA CRYIIAE# OR CRY(W)II(W)AE# OR CRY(W)IIAE# OR CRYII(W)AE#  
OR CRYII(W)A(W)E# OR CRY(W)II(W)A(W)E# OR CRYIIA(W)E#  
L94                    0 SEA CRYLLAE# OR CRY(W)LL(W)AE# OR CRY(W)LLAE# OR CRYLL(W)AE#  
OR CRYLL(W)A(W)E# OR CRY(W)LL(W)A(W)E# OR CRYLLA(W)E#  
L95                    38 SEA (L92 OR L93 OR L94)  
L96                    144827 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR PHOSPHINO  
THRICIN OR LIBERTY?  
L97                    275212 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE  
OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WORM#  
OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR  
OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES  
L98                    20732 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR  
HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR  
PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR  
D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA  
L99                    19877 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR  
M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR  
SCB OR WBC  
L100                  5168889 SEA (RESIST? OR PROTECT? OR TOLERAN?)  
L101                  49497 SEA ((L96 OR L97 OR L98 OR L99)) (5A)L100  
L102                  236377 SEA COTTON# OR GOSSYPIUM OR G(W)HIRSUTUM OR G(W)BARBADENSE  
L103                  636411 SEA GMO OR GMOS OR LMO OR LMOS OR GM OR GE OR TRANSGEN? OR  
(GENETIC?(3A) (MODIF? OR TRANSFORM? OR MANIPULAT? OR IMPROV? OR  
ENGINEER?))  
L104                  192 SEA L91 AND L102  
L105                  2229 SEA L101 AND L102 AND L103  
L106                  2337 SEA L88 OR L95 OR L104 OR L105  
L107                  713 SEA L106 AND PY>=2017  
L108                  140 SEA L107 AND UP>=20181001 AND UP<=20190930  
L109                  55 SEA L108 NOT P/DT  
L110                  0 SEA L108 AND (P/DT AND J/DT)  
L111                  55 SEA L109 OR L110

FILE 'MEDLINE, BIOSIS, AGRICOLA, CABA, HCAPLUS' ENTERED AT 09:37:03 ON 23  
OCT 2019

L112                  191 DUP REM L21 L42 L63 L87 L111 (99 DUPLICATES REMOVED)  
ANSWERS '1-68' FROM FILE MEDLINE  
ANSWERS '69-103' FROM FILE BIOSIS  
ANSWERS '104-118' FROM FILE AGRICOLA  
ANSWERS '119-165' FROM FILE CABA  
ANSWERS '166-191' FROM FILE HCAPLUS