

Title

**Summary of the Literature Review for GHB614 x LLCotton25 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.  
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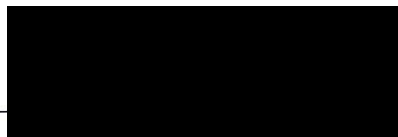
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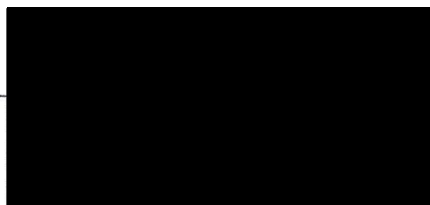
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**SIGNATURE PAGE**

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Stage 1 assessment	[REDACTED] [REDACTED]
Stage 2 assessment	<u>Food and Feed safety</u> [REDACTED] [REDACTED] <u>Molecular characterization</u> [REDACTED] [REDACTED] <u>Environmental safety</u> [REDACTED] [REDACTED]
Report	[REDACTED] [REDACTED] [REDACTED]

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## SUMMARY

BASF has used conventional breeding techniques to develop the stacked trait cotton product GHB614 x LLCotton25 (GlyTol x LL25 cotton; GTxLL cotton) which confers tolerance to glyphosate and glufosinate-ammonium herbicides. The OECD identifier is BCS-GHØØ2-5 x ACS-GHØØ1-3.

A scoping review was performed for the GTxLL cotton and its newly expressed protein, 2mEPSPS and PAT/*bar*. The objective of this scoping review was to determine if there were studies about the molecular characterization of GTxLL 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 52 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 5 publications were progressed for detailed assessment.

No new publications were found that contained new data on the molecular characterization of the GTxLL cotton and its newly expressed proteins, 2mEPSPS and PAT/*bar*. Similarly, no new publications were found that suggested any potential adverse effects of this event on human health, animal health, or the environment. No issues or topics were identified that would trigger or warrant more specific question formulation or indicate that a systematic review would be of value.

## 1. INTRODUCTION

BASF has used conventional breeding techniques to develop the stacked trait cotton product GHB614 x LLCotton25 (GlyTol x LL25 cotton; GTxLL cotton) which confers tolerance to glyphosate and glufosinate-ammonium herbicides. The OECD identifier is BCS-GHØØ2-5 x ACS-GHØØ1-3.

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 GTxLL cotton, and/or any adverse effect of GTxLL 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 GTxLL cotton and its newly expressed protein 2mEPSPS 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 GTxLL cotton and its newly expressed proteins, 2mEPSPS 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 GTxLL cotton and its newly expressed proteins 2mEPSPS and PAT/*bar*?

**Key elements:**

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

**Exposure:** GTxLL cotton, derived food/feed products, newly expressed protein in GTxLL 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 GTxLL cotton and its newly expressed proteins 2mEPSPS and PAT/*bar*?

**Key elements:**

**Population:** GTxLL cotton and newly expressed proteins in GTxLL 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

Stacked events obtained by conventional crosses/subcombinations	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	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
Molecular stacks	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	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
Previously risk assessed publications	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	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
Access	Full-text document is accessible	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

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 GTxLL cotton was previously identified and was used to test and validate the search strategy:

- Naegeli, H.; Birch, A. N.; Casacuberta, J.; Schrijver, A. de; Gralak, M. A.; Guerche, P.; Jones, H.; Manachini, B.; Messean, A.; Nielsen, E. E.; Nogue, F.; Robaglia, C.; Rostoks, N.; Sweet, J.; Tebbe, C.; Visioli, F.; Wal, J. M.; Broll, H.; Gennaro, A.; Neri, F. M.; Paraskevopoulos, K.; de Schrijver, A. (2018). Assessment of genetically modified cotton GHB614 x LLCotton25 x MON 15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94). EFSA Journal 16(4): e05213 p.

## 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 24, 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, trade name, newly expressed proteins and intended traits. Since the 'intended trait' profile retrieved a very large number of publications when used on their own, they were combined with additional profiles: a 'plant species' profile and a 'general GMO' 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	LLcotton25 or LLcotton(w)25 or LL(w)cotton25 or LL(w)cotton(w)25 or ACS-GH001-3 or ACS(w)GH001(w)3 or ACSGH001(w)3 or ACS-GH001-3 or ACS(w)GH001(w)3 or ACSGH001(w)3 or ACS-GH001-3 or ACS(w)GH001(w)3 or ACSGH001(w)3	Event name 1
2	GHB614 OR GHB(W)614 OR BCS-GH002-5 OR BCSGH002-5 OR BCS(W)GH002(W)5 OR BCSGH002(W)5 OR BCS-GH002-5 OR BCS(W)GH002(W)5 OR BCSGH002(W)5 or BCS-GH002-5 or BCS(W)GH002(W)5 or BCSGH002-5	Event name 2
3	GHB614xLLcotton25 or GHB614(w)time#(w)LLcotton25 or LLcotton25xGHB614 or LLcotton25(w)time#(w)GHB614	Event name stack
4	(1 and 2) or 3	Event name all
5	GLYTOL? OR GLYTOLTM? OR GLYTOLRTM? OR GLY(w)TOL? OR GLY(w)TOLTM? OR GLY(w)TOLRTM?	Trade name 1
6	libertylink or libertylinktm or libertylinkrtm or liberty(w)link or liberty(w)linktm or liberty(w)linkrtm or LL or LLTM or LLRTM	Trade name 2
7	5 and 6	Trade name all
8	(2MEPSPS or 2(w)MEPSPS or 2M(w)EPSPS or 2(w)M(w)EPSPS) or (EPSPS OR EPSP(W)SYNTHASE OR (ENOL(W)PYRUVYLSHIKIMATE OR ENOL(W)PYRUVYL(W)SHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOYLPYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC) (4W) (PHOSPHATE OR PHOSPHORIC) (2W) (SYNTHASE OR SYNTHETASE) or (ENOLPYRUVYL OR ENOLPYRUYL OR ENOLPYRUVOYL) (W) (PHOSPHOSHIKIMATE OR PHOSPHOSHIKIMIC or ENOLPYRUVYLSHIKIMATEPHOSPHATE) (2W) (SYNTHASE OR SYNTHETASE) or (ENOL(W)PYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC OR ENOL(W) (PYRUVYL OR PYRUVOYL) (W) SHIKIMATE) (3W) PHOSPHATE (W) (SYNTHASE OR SYNTHETASE) or (PHOSPHOSHIKIMATE (2W) CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIKIMATE (2W) CARBOXYVINYL (W) TRANSFERASE OR ENOLPYRUVOYL (W) SHIKIMIC (3W) PHOSPHOSYNTHASE)) (s) ((DOUBL# or DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M))	Newly expressed protein 1
9	((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 phosphinothricinacetyl(w)transferase	Newly expressed protein 2

10	8 and 9	Newly expressed protein all
11	s (herbicid? or GL!PHOSATE# or GL!FOSATE# OR G360 or g(w)360 or roundup? or round(w)up?) (5a) (resist? or toleran? or protect?)	Intended trait 1
12	s (herbicid? or bialaphos or basta or glufosinate or gluphosinate or phosphinothricin or liberty?) (5a) (resist? OR protect? OR toleran?)	Intended trait 2
13	11 and 12	Intended trait all
14	cotton# or gossypium or G(w)hirsutum or g(w)barbadense	Plant species
15	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
16	13 and 14 and 15	Intended trait all AND Plant species AND GMO general
17	4 or 7 or 10 or 16	Event name all OR Trade name all OR Newly expressed protein all or (Intended trait all 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	STN International	STN International	STN International	STN International
Coverage	1970-present	1926-present	1973-present	1907-present	1946-present
Date of search	20 Nov 2019	20 Nov 2019	20 Nov 2019	20 Nov 2019	20 Nov 2019
Datespan of the search	1 Oct 2018 – 30 Sept 2019	1 Oct 2018 – 30 Sept 2019	1 Oct 2018 – 30 Sept 2019	1 Oct 2018 – 30 Sept 2019	1 Oct 2018 – 30 Sept 2019
Latest database update	5 Nov 2019	13 Nov 2019	13 Nov 2019	19 Nov 2019	19 Nov 2019
Number of records retrieved	5	18	17	18	10
Number of records after duplicate removal	3	16	13	10	10

Number of relevant records after rapid assessment	1	1	1	1	1
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#### 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 GlyTol x LL25 or GHB614 x LL25 or Glytol x LLCotton25 or GHB614 x LLCotton25 or BCS-GHØØ2-5 x ACS-GHØØ1-3, 2mEPSPS or Double mutant 5-enolpyruvyl shikimate-3-phosphate synthase enzyme, or PAT/*bar* or Phosphinothricin in GTxLL (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



Source Site Name	Website URL	Date of Most Recent Site Update	Date of Search	No. of Relevant Records
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/biotecnologia">https://www.argentina.gob.ar/agroindustria/bioeconomia/biotecnologia</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
Ministry of Health, Labour and Welfare (MHLW) Japan	<a href="http://www.mhlw.go.jp/">http://www.mhlw.go.jp/</a>	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, Hari Krishna 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, Grantina-Ievina L, Ievina B, Evelone V, Valcina 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 69 references, which were reduced to 52 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, one member of the stack, other herbicide 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> 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)	52
Number of publications excluded from the search results after rapid assessment for relevance (Stage 1)	47
Total number of full-text documents assessed in detail	5
Number of publications excluded from further consideration after detailed assessment for relevance (Stage 2)	5
Total number of unobtainable/unclear publications	0
Total number of relevant publications	0

[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). Year	Title	Source
<b>Molecular Characterization</b>	No studies in this category		
<b>Food &amp; Feed Safety</b>	No studies in this category		
<b>Environmental Safety</b>	No studies in this category		

**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>
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, Broll H, Gennaro A, Neri F M, Paraskevopoulos K. 2018	Assessment of genetically modified cotton GHB614 x LLCotton25 x MON 15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94).	EFSA Journal (2018), Volume 16, Number 4, e05213 p., many ref. ISSN: 1831-4732 DOI: 10.2903/j.efsa.2018.5213 Published by: Wiley, Oxford	This publication was excluded because it does not contain original/primary data. In addition, it is on a higher stacked product than GTxLL cotton.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in <a href="#">Table 1</a>
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, Broll H, Gennaro A, Neri F M, Paraskevopoulos K. 2018	Assessment of genetically modified cotton GHB614 .times . LLCotton25 .times. MON 15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94)	EFSA Journal (2018 ), 16(4), n/a CODEN: EJFOA6; ISSN: 1831-4732	This publication was excluded because it does not contain original/primary data. Duplicate record as above. In addition, report is on a higher stacked product than GTxLL cotton.
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. The Environmental Risk Assessment (ERA) is not related to GTxLL cotton.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in <a href="#">Table 1</a>
Wu A-J, Holliday B, Canez C, Haas C, Ghoshal D, Lor J, Massengill J, Chapman K, Cisneros K, Pallett K, Privalle L, Bugas M, Soria M, Hunst P, Araujo R, Mackie S, New S, Sathischandra S, Bishop Z. 2018	GHB614 x T304-40 x GHB119 x COT102 Cotton : Protein Expression Analyses of Field-Grown Samples	Journal of agricultural and food chemistry (2018), Volume 67, Number 1, pp. 275-281 ISSN: 1520-5118 Published by: American Chemical Society Source Note: 2018 Dec. 06, v. 67, no. 1	The study was not performed with the stacked product GTxLL cotton.
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 GTxLL cotton.

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

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



## 6. NARRATIVE SYNTHESIS/SUMMARY OF RELEVANT STUDIES

A total of 5 publications were selected during Stage 1 evaluation (rapid assessment based on title and abstract). After Stage 2 evaluation (detailed review based on full text), no relevant references were found in the searches on GTxLL cotton and its newly expressed proteins, 2mEPSPS and PAT/*bar*, covering October 1, 2018 to September 30, 2019 to provide additional information.

## 7. CONCLUSION

The literature searches performed for the GTxLL cotton and its newly expressed proteins, 2mEPSPS and PAT/*bar* for the period from October 1, 2018 to September 30, 2019, identified a total of 52 unique publications (after duplicate removal). A total of 5 publications were progressed for detailed assessment after excluding 47 obviously irrelevant publications during Stage 1 evaluation (rapid assessment based on title and abstract).

The 5 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](#). No relevant publications with bearing on molecular characterization, or safety assessment on human and animal health or the environment were identified. 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>

Host	File	Description
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 15:13:44 ON 20 NOV 2019

L1 1 SEA LLCOTTON25 OR LLCOTTON(W)25 OR LL(W)COTTON25 OR LL(W)COTTON  
(W)25 OR ACS-GH001-3 OR ACS(W)GH001(W)3 OR ACSGH001(W)3 OR  
ACS-GH001-3 OR ACS(W)GH001(W)3 OR ACSGH001(W)3 OR ACS-GH001-3  
OR ACS(W)GH001(W)3 OR ACSGH001(W)3

L2 1 SEA GHB614 OR GHB(W)614 OR BCS-GH002-5 OR BCSGH002-5 OR  
BCS(W)GH002(W)5 OR BCSGH002(W)5 OR BCS-GH002-5 OR BCS(W)GH002(W)  
)5 OR BCSGH002(W)5 OR BCS-GH002-5 OR BCS(W)GH002(W)5 OR  
BCSGH002-5

L3 0 SEA GHB614XLLCOTTON25 OR GHB614(W)TIME#(W)LLCOTTON25 OR  
LLCOTTON25XGHB614 OR LLCOTTON25(W)TIME#(W)GHB614

L4 0 SEA (L1 AND L2) OR L3

L5 2 SEA GLYTOL? OR GLYTOLTM? OR GLYTOLRTM? OR GLY(W)TOL? OR  
GLY(W)TOLTM? OR GLY(W)TOLRTM?

L6 12136 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY(W)  
)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM OR LL OR LLTM  
OR LLRTM

L7 0 SEA L5 AND L6

L8 9 SEA 2MEPSPS OR 2(W)MEPSPS OR 2M(W)EPSPS OR 2(W)M(W)EPSPS

L9 4079 SEA EPSPS OR EPSP(W)SYNTHASE OR (ENOL(W)PYRUVYLSHIKIMATE OR  
ENOL(W)PYRUVYL(W)SHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUV  
OYLSHIKIMATE OR ENOYLPRUVOYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC) (4W)  
(PHOSPHATE OR PHOSPHORIC) (2W) (SYNTHASE OR SYNTHETASE)

L10 0 SEA (ENOLPYRUVYL OR ENOLPYRUYL OR ENOLPYRUVOYL) (W) (PHOSPHOSHIKI  
MATE OR PHOSPHOSHIKIMIC OR ENOLPYRUVYLSHIKIMATEPHOSPHATE) (2W) (S  
YNTHASE OR SYNTHETASE)

L11 344 SEA (ENOL(W)PYRUVOYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR  
ENOLPYRUVYLSHIKIMIC OR ENOL(W) (PYRUVYL OR PYRUVOYL) (W) SHIKIMATE  
) (3W) PHOSPHATE (W) (SYNTHASE OR SYNTHETASE)

L12 443 SEA (PHOSPHOSHIKIMATE (2W) CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIK  
IMATE (2W) CARBOXYVINYL (W) TRANSFERASE OR ENOLPYRUVOYL (W) SHIKIMIC (3W)  
PHOSPHOSYNTHASE)

L13 22855 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)

L14 14 SEA L8 OR ((L9 OR L10 OR L11 OR L12)) (S) L13)

L15 1325 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

L16 194 SEA PHOSPHINOTHRICIN (W) N (W) ACETYLTRANSFERASE OR PHOSPHINOTHRICI  
N (2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN (2W) ACETYL (W) TRANSFER  
ASE OR PHOSPHINOTHRICINACETYL (W) TRANSFERASE

L17 1396 SEA L15 OR L16

L18 7 SEA L14 AND L17

L19 2961 SEA (HERBICID? OR GL!PHOSATE# OR GL!FOSATE# OR G360 OR G(W)360  
OR ROUNDUP? OR ROUND(W)UP?) (5A) (RESIST? OR TOLERAN? OR  
PROTECT?)

L20 2837 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR  
GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR  
PROTECT? OR TOLERAN?)

L21 2598 SEA L19 AND L20

L22 23674 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE

L23 3454655 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?))

L24 97 SEA L21 AND L22 AND L23

L25 104 SEA L4 OR L7 OR L18 OR L24

L26 24 SEA L25 AND PY>=2017

L27 10 SEA L26 AND UP>=20181001 AND UP<=20190930

FILE 'BIOSIS' ENTERED AT 15:14:32 ON 20 NOV 2019

L28 4 SEA LLCOTTON25 OR LLCOTTON(W)25 OR LL(W)COTTON25 OR LL(W)COTTON  
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ACS-GH001-3 OR ACS(W)GH001(W)3 OR ACSGH001(W)3 OR ACS-GH001-3  
OR ACS(W)GH001(W)3 OR ACSGH001(W)3  
L29 4 SEA GHB614 OR GHB(W)614 OR BCS-GH002-5 OR BCSGH002-5 OR  
BCS(W)GH002(W)5 OR BCSGH002(W)5 OR BCS-GH002-5 OR BCS(W)GH002(W)  
)5 OR BCSGH002(W)5 OR BCS-GH002-5 OR BCS(W)GH002(W)5 OR  
BCSGH002-5  
L30 0 SEA GHB614XLLCOTTON25 OR GHB614(W)TIME#(W)LLCOTTON25 OR  
LLCOTTON25XGHB614 OR LLCOTTON25(W)TIME#(W)GHB614  
L31 1 SEA (L28 AND L29) OR L30  
L32 5 SEA GLYTOL? OR GLYTOLTM? OR GLYTOLRTM? OR GLY(W)TOL? OR  
GLY(W)TOLTM? OR GLY(W)TOLRTM?  
L33 13422 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY(W)  
)LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM OR LL OR LLTM  
OR LLRTM  
L34 1 SEA L32 AND L33  
L35 12 SEA 2MEPSPS OR 2(W)MEPSPS OR 2M(W)EPSPS OR 2(W)M(W)EPSPS  
L36 4865 SEA EPSPS OR EPSP(W)SYNTHASE OR (ENOL(W)PYRUVYLSHIKIMATE OR  
ENOL(W)PYRUVYL(W)SHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUV  
OYLSHIKAMATE OR ENOYLPYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC) (4W)  
(PHOSPHATE OR PHOSPHORIC) (2W) (SYNTHASE OR SYNTHETASE)  
L37 0 SEA (ENOLPYRUVYL OR ENOLPYRUYL OR ENOLPYRUVOYL) (W) (PHOSPHOSHIKI  
MATE OR PHOSPHOSHIKIMIC OR ENOLPYRUVYLSHIKIMATEPHOSPHATE) (2W) (S  
YNTHASE OR SYNTHETASE)  
L38 650 SEA (ENOL(W)PYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR  
ENOLPYRUVYLSHIKIMIC OR ENOL(W) (PYRUVYL OR PYRUVOYL) (W)SHIKIMATE  
) (3W)PHOSPHATE(W) (SYNTHASE OR SYNTHETASE)  
L39 27 SEA (PHOSPHOSHIKIMATE(2W)CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIK  
IMATE(2W)CARBOXYVINYL(W)TRANSFERASE OR ENOLPYRUVOYL(W)SHIKIMIC (3W)  
PHOSPHOSYNTHASE)  
L40 25471 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)  
L41 17 SEA L35 OR ((L36 OR L37 OR L38 OR L39)) (S)L40)  
L42 2654 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  
L43 321 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI  
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER  
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE  
L44 2752 SEA L42 OR L43  
L45 8 SEA L41 AND L44  
L46 10052 SEA (HERBICID? OR GL!PHOSATE# OR GL!FOSATE# OR G360 OR G(W)360  
OR ROUNDUP? OR ROUND(W)UP?) (5A) (RESIST? OR TOLERAN? OR  
PROTECT?)  
L47 9071 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR  
GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR  
PROTECT? OR TOLERAN?)  
L48 8689 SEA L46 AND L47  
L49 70403 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE  
L50 430194 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?))  
L51 228 SEA L48 AND L49 AND L50  
L52 238 SEA L31 OR L34 OR L45 OR L51  
L53 27 SEA L52 AND PY>=2017  
L54 18 SEA L53 AND UP>=20181001 AND UP<=20190930

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(W)25 OR ACS-GH001-3 OR ACS(W)GH001(W)3 OR ACSGH001(W)3 OR  
ACS-GH001-3 OR ACS(W)GH001(W)3 OR ACSGH001(W)3 OR ACS-GH001-3  
OR ACS(W)GH001(W)3 OR ACSGH001(W)3  
L56 2 SEA GHB614 OR GHB(W)614 OR BCS-GH002-5 OR BCSGH002-5 OR  
BCS(W)GH002(W)5 OR BCSGH002(W)5 OR BCS-GH002-5 OR BCS(W)GH002(W)  
)5 OR BCSGH002(W)5 OR BCS-GH002-5 OR BCS(W)GH002(W)5 OR

BCSGH002-5

L57 0 SEA GHB614XLLCOTTON25 OR GHB614 (W) TIME# (W) LLCOTTON25 OR LLCOTTON25XGHB614 OR LLCOTTON25 (W) TIME# (W) GHB614

L58 0 SEA (L55 AND L56) OR L57

L59 3 SEA GLYTOL? OR GLYTOLTM? OR GLYTOLRTM? OR GLY (W) TOL? OR GLY (W) TOLTM? OR GLY (W) TOLRTM?

L60 2672 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY (W) LINK OR LIBERTY (W) LINKTM OR LIBERTY (W) LINKRTM OR LL OR LLTM OR LLRTM

L61 2 SEA L59 AND L60

L62 2 SEA 2MEPSPS OR 2 (W) MEPSPS OR 2M (W) EPSPS OR 2 (W) M (W) EPSPS

L63 560 SEA EPSPS OR EPSP (W) SYNTHASE OR (ENOL (W) PYRUVYL SHIKIMATE OR ENOL (W) PYRUVYL (W) SHIKIMATE OR ENOLPYRUVYL SHIKIMATE OR ENOLPYRUV OYL SHIKIMATE OR ENOYL PYRUV OYL SHIKIMATE OR ENOLPYRUVYL SHIKIMIC) (4W) (PHOSPHATE OR PHOSPHORIC) (2W) (SYNTHASE OR SYNTHETASE)

L64 0 SEA (ENOLPYRUVYL OR ENOLPYRUYL OR ENOLPYRUV OYL) (W) (PHOSPHOSHIKIMATE OR PHOSPHOSHIKIMIC OR ENOLPYRUVYL SHIKIMATE PHOSPHATE) (2W) (SYNTHASE OR SYNTHETASE)

L65 270 SEA (ENOL (W) PYRUV OYL SHIKIMATE OR ENOLPYRUVYL SHIKIMATE OR ENOLPYRUVYL SHIKIMIC OR ENOL (W) (PYRUVYL OR PYRUV OYL) (W) SHIKIMATE) (3W) PHOSPHATE (W) (SYNTHASE OR SYNTHETASE)

L66 180 SEA (PHOSPHOSHIKIMATE (2W) CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIKIMATE (2W) CARBOXYVINYL (W) TRANSFERASE OR ENOLPYRUV OYL (W) SHIKIMIC (3W) PHOSPHOSYNTHASE)

L67 5879 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)

L68 6 SEA L62 OR (((L63 OR L64 OR L65 OR L66)) (S) L67)

L69 711 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

L70 238 SEA PHOSPHINOTHRICIN (W) N (W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN (2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN (2W) ACETYL (W) TRANSFERASE OR PHOSPHINOTHRICIN ACETYL (W) TRANSFERASE

L71 785 SEA L69 OR L70

L72 3 SEA L68 AND L71

L73 7718 SEA (HERBICID? OR GL!PHOSATE# OR GL!FOSATE# OR G360 OR G (W) 360 OR ROUNDUP? OR ROUND (W) UP?) (5A) (RESIST? OR TOLERAN? OR PROTECT?)

L74 7419 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR PROTECT? OR TOLERAN?)

L75 7262 SEA L73 AND L74

L76 59520 SEA COTTON# OR GOSSYPIMUM OR G (W) HIRSUTUM OR G (W) BARBADENSE

L77 90652 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?))

L78 207 SEA L75 AND L76 AND L77

L79 211 SEA L58 OR L61 OR L72 OR L78

L80 11 SEA L79 AND PY>=2017

L81 5 SEA L80 AND UP>=20181001 AND UP<=20190930

FILE 'CABA' ENTERED AT 15:16:17 ON 20 NOV 2019

L82 5 SEA LLCOTTON25 OR LLCOTTON (W) 25 OR LL (W) COTTON25 OR LL (W) COTTON (W) 25 OR ACS-GH001-3 OR ACS (W) GH001 (W) 3 OR ACSGH001 (W) 3 OR ACS-GH001-3 OR ACS (W) GH001 (W) 3 OR ACSGH001 (W) 3 OR ACS-GH001-3 OR ACS (W) GH001 (W) 3 OR ACSGH001 (W) 3

L83 6 SEA GHB614 OR GHB (W) 614 OR BCS-GH002-5 OR BCSGH002-5 OR BCS (W) GH002 (W) 5 OR BCSGH002 (W) 5 OR BCS-GH002-5 OR BCS (W) GH002 (W) 5 OR BCSGH002 (W) 5

L84 2 SEA GHB614XLLCOTTON25 OR GHB614 (W) TIME# (W) LLCOTTON25 OR LLCOTTON25XGHB614 OR LLCOTTON25 (W) TIME# (W) GHB614

L85 2 SEA (L82 AND L83) OR L84

L86 5 SEA GLYTOL? OR GLYTOLTM? OR GLYTOLRTM? OR GLY (W) TOL? OR

GLY(W)TOLTM? OR GLY(W)TOLRTM?

L87 4577 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY(W) LINK OR LIBERTY(W)LINKTM OR LIBERTY(W)LINKRTM OR LL OR LLTM OR LLRTM

L88 4 SEA L86 AND L87

L89 12 SEA 2MEPSPS OR 2(W)MEPSPS OR 2M(W)EPSPS OR 2(W)M(W)EPSPS

L90 948 SEA EPSPS OR EPSP(W)SYNTHASE OR (ENOL(W)PYRUVYLSHIKIMATE OR ENOL(W)PYRUVYL(W)SHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUV OYLSHIKIMATE OR ENOYLPYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC) (4W) (PHOSPHATE OR PHOSPHORIC) (2W) (SYNTHASE OR SYNTHETASE)

L91 0 SEA (ENOLPYRUVYL OR ENOLPYRUYL OR ENOLPYRUVOYL) (W) (PHOSPHOSHIKI MATE OR PHOSPHOSHIKIMIC OR ENOLPYRUVYLSHIKIMATEPHOSPHATE) (2W) (S YNTHASE OR SYNTHETASE)

L92 373 SEA (ENOL(W)PYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC OR ENOL(W) (PYRUVYL OR PYRUVOYL) (W) SHIKIMATE ) (3W) PHOSPHATE(W) (SYNTHASE OR SYNTHETASE)

L93 142 SEA (PHOSPHOSHIKIMATE(2W) CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIK IMATE (2W) CARBOXYVINYL(W) TRANSFERASE OR ENOLPYRUVOYL(W) SHIKIMIC (3W) PHOSPHOSYNTHASE)

L94 6654 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)

L95 16 SEA L89 OR ((L90 OR L91 OR L92 OR L93)) (S) L94)

L96 1441 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

L97 364 SEA PHOSPHINOTHRICIN(W)N(W) ACETYLTRANSFERASE OR PHOSPHINOTHRICI N(2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W) ACETYL(W) TRANSFER ASE OR PHOSPHINOTHRICINACETYL(W) TRANSFERASE

L98 1539 SEA L96 OR L97

L99 8 SEA L95 AND L98

L100 17316 SEA (HERBICID? OR GL!PHOSATE# OR GL!FOSATE# OR G360 OR G(W)360 OR ROUNDUP? OR ROUND(W)UP?) (5A) (RESIST? OR TOLERAN? OR PROTECT?)

L101 16690 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR PROTECT? OR TOLERAN?)

L102 16317 SEA L100 AND L101

L103 89355 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE

L104 166680 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?))

L105 459 SEA L102 AND L103 AND L104

L106 469 SEA L85 OR L88 OR L99 OR L105

L107 46 SEA L106 AND PY>=2017

L108 17 SEA L107 AND UP>=20181001 AND UP<=20190930

L109 17 SEA L108 NOT P/DT

L110 0 SEA L108 AND (P/DT AND J/DT)

L111 17 SEA L109 OR L110

FILE 'HCAPLUS' ENTERED AT 15:17:06 ON 20 NOV 2019

L112 9 SEA LLCOTTON25 OR LLCOTTON(W)25 OR LL(W)COTTON25 OR LL(W)COTTON (W)25 OR ACS-GH001-3 OR ACS(W)GH001(W)3 OR ACSGH001(W)3 OR ACS-GH001-3 OR ACS(W)GH001(W)3 OR ACSGH001(W)3 OR ACS-GH001-3 OR ACS(W)GH001(W)3 OR ACSGH001(W)3

L113 7 SEA GHB614 OR GHB(W)614 OR BCS-GH002-5 OR BCSGH002-5 OR BCS(W)GH002(W)5 OR BCSGH002(W)5 OR BCS-GH002-5 OR BCS(W)GH002(W)5 OR BCSGH002(W)5 OR BCS-GH002-5 OR BCS(W)GH002(W)5 OR BCSGH002-5

L114 1 SEA GHB614XLLCOTTON25 OR GHB614(W)TIME#(W)LLCOTTON25 OR LLCOTTON25XGHB614 OR LLCOTTON25(W)TIME#(W)GHB614

L115 4 SEA (L112 AND L113) OR L114

L116 8 SEA GLYTOL? OR GLYTOLTM? OR GLYTOLRTM? OR GLY(W)TOL? OR GLY(W)TOLTM? OR GLY(W)TOLRTM?

L117 17880 SEA LIBERTYLINK OR LIBERTYLINKTM OR LIBERTYLINKRTM OR LIBERTY(W)



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) LINK OR LIBERTY(W) LINKTM OR LIBERTY(W) LINKRTM OR LL OR LLTM
OR LLRTM
L118      3 SEA L116 AND L117
L119      29 SEA 2MEPSPS OR 2(W)MEPSPS OR 2M(W)EPSPS OR 2(W)M(W)EPSPS
L120      4130 SEA EPSPS OR EPSP(W)SYNTHASE OR (ENOL(W)PYRUVYLSHIKIMATE OR
          ENOL(W)PYRUVYL(W)SHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUV
          OYLSHIKIMATE OR ENOYLPYRUVYOYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC) (
          4W) (PHOSPHATE OR PHOSPHORIC) (2W) (SYNTHASE OR SYNTHETASE)
L121      9 SEA (ENOLPYRUVYL OR ENOLPYRUYL OR ENOLPYRUVOYL) (W) (PHOSPHOSHIKI
          MATE OR PHOSPHOSHIKIMIC OR ENOLPYRUVYLSHIKIMATEPHOSPHATE) (2W) (S
          YNTHASE OR SYNTHETASE)
L122      1008 SEA (ENOL(W)PYRUVYOYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR
          ENOLPYRUVYLSHIKIMIC OR ENOL(W) (PYRUVYL OR PYRUVOYL) (W)SHIKIMATE
          ) (3W)PHOSPHATE(W) (SYNTHASE OR SYNTHETASE)
L123      79 SEA (PHOSPHOSHIKIMATE(2W)CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIK
          IMATE(2W)CARBOXYVINYL(W)TRANSFERASE OR ENOLPYRUVOYL(W)SHIKIMIC (
          3W)PHOSPHOSYNTHASE)
L124      71955 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)
L125      39 SEA L119 OR ((L120 OR L121 OR L122 OR L123)) (S)L124)
L126      6313 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
L127      744 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
          N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
          ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE
L128      6593 SEA L126 OR L127
L129      20 SEA L125 AND L128
L130      25936 SEA (HERBICID? OR GL!PHOSATE# OR GL!FOSATE# OR G360 OR G(W)360
          OR ROUNDUP? OR ROUND(W)UP?) (5A) (RESIST? OR TOLERAN? OR
          PROTECT?)
L131      25012 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
          GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR
          PROTECT? OR TOLERAN?)
L132      24481 SEA L130 AND L131
L133      237581 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE
L134      638304 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?))
L135      1203 SEA L132 AND L133 AND L134
L136      1224 SEA L115 OR L118 OR L129 OR L135
L137      489 SEA L136 AND PY>=2017
L138      80 SEA L137 AND UP>=20181001 AND UP<=20190930
L139      18 SEA L138 NOT P/DT
L140      0 SEA L138 AND (P/DT AND J/DT)
L141      18 SEA L139 OR L140

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FILE 'MEDLINE, BIOSIS, AGRICOLA, CABA, HCAPLUS' ENTERED AT 15:17:57 ON 20  
NOV 2019

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L142      52 DUP REM L27 L54 L81 L111 L141 (16 DUPLICATES REMOVED)
          ANSWERS '1-10' FROM FILE MEDLINE
          ANSWERS '11-26' FROM FILE BIOSIS
          ANSWERS '27-29' FROM FILE AGRICOLA
          ANSWERS '30-42' FROM FILE CABA
          ANSWERS '43-52' FROM FILE HCAPLUS
D L142 ALL 1-52

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