

Title

**Summary of the Literature Review for GHB614 x LLCotton25 Cotton
October 1, 2019 – September 30, 2020**

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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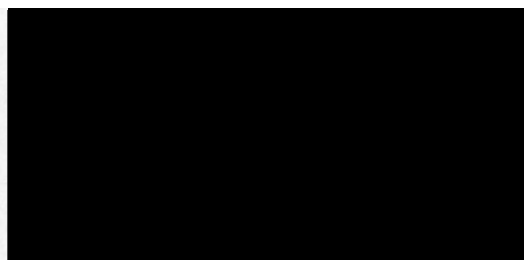


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SIGNATURE PAGE

Principal author:



Date

2020-11-30
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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, 2019 to September 30, 2020. 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 35 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 6 publications were progressed for detailed assessment and were determined to be not relevant after detailed review.

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 GTxLL cotton 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, 2019 and September 30, 2020 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)¹ 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 note¹.

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 note¹ 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 note¹: 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 .times. LLCotton25 .times. 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.

This article was selected as reference publications because even though it is not directly relevant to the GTxLL event, it mentions the event names (LLCotton25 and GHB614), the newly expressed proteins (PAT/*bar* and 2mEPSPS) and the crop (cotton). Since this article was published outside the search period of this report, the search profile was tested without applying the time filters used in the final profile (UP>=20191001 and UP<=20200930).

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 activities¹. 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 15, 2020. Only documents updated between October 1, 2019 and September 30, 2020, 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 produced too many results 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, 2019 and September 30, 2020 (UP>=20191001 and UP<=20200930), 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 ENOLPYRUVOYLSHIKIMATE OR ENOYLPYRUVOYLSHIKIMATE 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)PYRUVOYLSHIKIMATE 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	15 Oct 2020	15 Oct 2020	15 Oct 2020	15 Oct 2020	15 Oct 2020
Datespan of the search	1 Oct 2019 – 30 Sept 2020	1 Oct 2019 – 30 Sept 2020	1 Oct 2019 – 30 Sept 2020	1 Oct 2019 – 30 Sept 2020	1 Oct 2019 – 30 Sept 2020
Latest database update	24 Aug 2020	14 Oct 2020	14 Oct 2020	14 Oct 2020	14 Oct 2020
Number of records retrieved	2	10	11	11	6
Number of records after duplicate removal	2	9	9	9	6
Number of relevant records after rapid assessment	0	0	1	3	2

4. MANUAL SEARCHES

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

In accordance with the EFSA 2019 explanatory note¹, the search in electronic bibliographic databases has been complemented with an internet search in webpages of relevant key organisations involved in the risk assessment of GM plants. Of the 13 key organisations cited in the EFSA 2019 explanatory note¹, two (Environment and Climate Change Canada and CIBIOGEM) are not involved in the risk assessment of GM plants, the US Environmental Protection Agency (EPA) is only involved in the regulation of GM stacked products with plant-incorporated protectant (PIP) combinations, and six (the US Department of Agriculture (USDA), the US Food and Drug Administration (FDA), the Canadian Food Inspection Agency (CFIA), Health Canada, the Food Standards Australia New Zealand (FSANZ), and the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF)) do not regulate GM stacked products developed by conventional breeding techniques, and. Therefore, the internet search was limited to the four key organisations, OGTR, CTNBIO, CONABIA, and GEAC, relevant for GTxLL cotton.

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). Search results were manually examined for relevant records that were either published during the time period under consideration (date span of search: October 1, 2019 to September 30, 2020) 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](#).

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
Office of the Gene Technology Regulator (OGTR) Australia	http://www.ogtr.gov.au/	Oct 15 2020	Oct 28-30 2020	0
National Technical Commission on Biosafety (CTNBio) Brazil	http://ctnbio.mcti.gov.br/en	Okt 20	Oct 22-28 2020	0
National Advisory Commission on Agricultural Biotechnology (CONABIA) Argentina	https://www.argentina.gob.ar/agroindustria/bioeconomia/biotecnologia	later than Aug 21 2020	Oct 21-22 2020	0
Genetic Engineering Approval Committee (GEAC) India	http://moef.gov.in/*	Oct 27 2020	Nov 3 2020	0

* As the GEAC website does not have a search function the moef.gov.in website was searched instead.

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, 2019 and September 30, 2020. 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	Ansari WA, Chandanshive SU, Bhatt V, Nadaf AB, Vats S, Katara JL, Sonah H, Deshmukh R. 2020	Genome Editing in Cereals: Approaches, Applications and Challenges	Int J Mol Sci. 2020 Jun 5;21(11):4040. doi: 10.3390/ijms21114040 .	0
2	Arpaia S, Christiaens O, Giddings K, Jones H, Mezzetti B, Moronta-Barrios F, Perry JN, Sweet JB, Taning CNT, Smagghe G, Dietz-Pfeilstetter A. 2020	Biosafety of GM Crop Plants Expressing dsRNA: Data Requirements and EU Regulatory Considerations	Front Plant Sci. 2020 Jun 24;11:940. doi: 10.3389/fpls.2020.00940. eCollection 2020.	0
3	Babar U, Nawaz MA, Arshad U, Azhar MT, Atif RM, Golokhvast KS, Tsatsakis AM, Shcherbakova K, Chung G, Rana IA. 2020	Transgenic crops for the agricultural improvement in Pakistan: a perspective of environmental stresses and the current status of genetically modified crops	GM Crops Food. 2020;11(1):1-29. doi: 10.1080/21645698.2019.1680078. Epub 2019 Nov 3.	0

4	Bachtarzi H, Farries T. 2019	The Genetically Modified Organism Medicinal Framework in Europe, United States, and Japan: Underlying Scientific Principles and Considerations Toward the Development of Gene Therapy and Genetically Modified Cell-Based Products	Hum Gene Ther Clin Dev. 2019 Sep;30(3):114-128. doi: 10.1089/humc.2019.042. Epub 2019 Jun 21.	0
5	Bedair M, Glenn KC. 2020	Evaluation of the use of untargeted metabolomics in the safety assessment of genetically modified crops	Metabolomics. 2020 Oct 9;16(10):111. doi: 10.1007/s11306-020-01733-8.	0
6	Feng XJ, Yi HM, Ren XX, Ren JL, Ge JR, Wang FG. 2020	[Digital PCR and its application in biological detection]	Yi Chuan. 2020 Apr 20;42(4):363-373. doi: 10.16288/j.ycz.19-351.	0
7	Giraldo PA, Shinozuka H, Spangenberg GC, Cogan NOI, Smith KF. 2019	Safety Assessment of Genetically Modified Feed: Is There Any Difference From Food?	Front Plant Sci. 2019 Dec 11;10:1592. doi: 10.3389/fpls.2019.01592. eCollection 2019.	0
8	Hameed A, Mehmood MA, Shahid M, Fatma S, Khan A, Ali S. 2020	Prospects for potato genome editing to engineer resistance against viruses and cold-induced sweetening	GM Crops Food. 2020 Oct 1;11(4):185-205. doi: 10.1080/21645698.2019.1631115. Epub 2019 Jul 6.	0
9	Holme IB, Gregersen PL, Brinch-Pedersen H. 2019	Induced Genetic Variation in Crop Plants by Random or Targeted Mutagenesis: Convergence and Differences	Front Plant Sci. 2019 Nov 14;10:1468. doi: 10.3389/fpls.2019.01468. eCollection 2019.	0

10	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 Dec;96:77-90. doi: 10.1016/j.semcdb.2019.03.010. Epub 2019 Apr 7.	0
11	Kadoić Balaško M, Mikac KM, Bažok R, Lemic D. 2020	Modern Techniques in Colorado Potato Beetle (<i>Leptinotarsa decemlineata</i> Say) Control and Resistance Management: History Review and Future Perspectives	Insects. 2020 Sep 1;11(9):581. doi: 10.3390/insects11090581.	0
12	Kamle M, Mahato DK, Devi S, Soni R, Tripathi V, Mishra AK, Kumar P. 2020	Nanotechnological interventions for plant health improvement and sustainable agriculture	3 Biotech. 2020 Apr;10(4):168. doi: 10.1007/s13205-020-2152-3. Epub 2020 Mar 14.	0
13	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. Epub 2019 Sep 4.	0
14	Kenter MJH, Clevers JC, Cornelissen J, Medema RH. 2019	[Environmental regulations impede cancer research and treatment]	Ned Tijdschr Geneesk. 2019 Dec 5;163:D4267.	0
15	Keshani P, Sharifi MH, Heydari MR, Joulaei H. 2020	The Effect of Genetically Modified Food on Infertility Indices: A Systematic Review Study	ScientificWorldJournal. 2020 Aug 13;2020:1424789. doi: 10.1155/2020/1424789. eCollection 2020.	0
16	Kumar K, Gambhir G, Dass A, Tripathi AK, Singh A, Jha AK, Yadava P, Choudhary M, Rakshit S. 2020	Genetically modified crops: current status and future prospects	Planta. 2020 Mar 31;251(4):91. doi: 10.1007/s00425-020-03372-8.	0

17	Papadopoulou N, Devos Y, Álvarez-Alfageme F, Lanzoni A, Waigmann E. 2020	Risk Assessment Considerations for Genetically Modified RNAi Plants: EFSA's Activities and Perspective	Front Plant Sci. 2020 Apr 21;11:445. doi: 10.3389/fpls.2020.00445. eCollection 2020.	0
18	Pottinger SE, Innes RW. 2020	RPS5-Mediated Disease Resistance: Fundamental Insights and Translational Applications	Annu Rev Phytopathol. 2020 Aug 25;58:139-160. doi: 10.1146/annurev-phyto-010820-012733. Epub 2020 Apr 13.	0
19	Rumin J, Nicolau E, Junior RGO, Fuentes-Grünwald C, Picot L. 2020	Analysis of Scientific Research Driving Microalgae Market Opportunities in Europe	Mar Drugs. 2020 May 18;18(5):264. doi: 10.3390/md18050264.	0
20	Woźniak E, Waszkowska E, Zimny T, Sowa S, Twardowski T. 2019	The Rapeseed Potential in Poland and Germany in the Context of Production, Legislation, and Intellectual Property Rights	Front Plant Sci. 2019 Nov 5;10:1423. doi: 10.3389/fpls.2019.01423. eCollection 2019.	0

5. RESULTS OF THE STUDY IDENTIFICATION AND SELECTION PROCESS

The database searches ([Section 3](#)) identified a total of 40 references, which were reduced to 35 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. In this search, both stage 1 reviewers agreed in 100% of the evaluations

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 note¹) 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)	35
Number of publications excluded from the search results after rapid assessment for relevance (Stage 1)	29
Total number of full-text documents assessed in detail	6
Number of publications excluded from further consideration after detailed assessment for relevance (Stage 2)	6
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
Molecular Characterization	No studies in this category		
Food & Feed Safety	No studies in this category		
Environmental Safety	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 Table 1
Naegeli Hanspeter Birch Andrew Nicholas Casacuberta Josep De Schrijver Adinda Gralak Mikolaj Antoni Guerche Philippe Jones Huw Manachini Barbara Messean Antoine Nielsen Elsa Ebbesen Nogue Fabien Robaglia Christophe Rostoks Nils Sweet Jeremy Tebbe Christoph Visioli Francesco Wal Jean-Michel Broll Hermann Gennaro Andrea Neri Franco Maria Paraskevopoulos Konstantinos 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. European Food Safety Authority, (2018 Apr) Vol. 16, No. 4, pp. e05213. Electronic Publication Date: 20 Apr 2018 Journal code: 101642076. E-ISSN: 1831-4732. L-ISSN: 1831-4732. Report No.: PMC-PMC7009700.	The report is not specific to GHB614 x LLCotton25 cotton. The report focuses on GHB614 x LLCotton25 x MON15985 cotton.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
Naegeli Hanspeter Bresson Jean-Louis Dalmay Tamas Dewhurst Ian Crawford Epstein Michelle M Firbank Leslie George Guerche Philippe Hejatko Jan Moreno Francisco Javier Mullins Ewen Nogue Fabien Rostoks Nils Sanchez Serrano Jose Juan Savoini Giovanni Veromann Eve Veronesi Fabio Alvarez Fernando Ardizzone Michele Paraskevopoulos Konstantinos 2018	Assessment of genetically modified LLCotton25 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO -RX-010).	EFSA journal. European Food Safety Authority, (2018 Nov) Vol. 16, No. 11, pp. e05473. Electronic Publication Date: 14 Nov 2018 Journal code: 101642076. E-ISSN: 1831-4732. L-ISSN: 1831-4732. Report No.: PMC-PMC7009552.	The report is not specific to GHB614 x LLCotton25 cotton. The report focuses on LLCotton25 cotton.
Pan, Xiaoping 2019	Determining pollen-mediated gene flow in transgenic cotton	Methods in Molecular Biology (New York, NY, United States) (2019), 1902(Transgenic Cotton), 309-321 CODEN: MMBIED; ISSN: 1940-6029	The paper evaluated the extent of gene flow of NewCott 33B and TFD cotton in the field. The ERA is not related to GHB614 x LLCotton25 cotton.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
Ricroch, A. Akkoyunlu, S. Martin-Laffon, J. Kuntz, M. Editor(s): Kuntz, M. 2018	Assessing the environmental safety of transgenic plants: honey bees as a case study. Special Issue: Transgenic plants and beyond.	Advances in Botanical Research (2018), Volume 86, pp. 111-167, 34 refs. ISSN: 0065-2296 Published by: Elsevier Ltd, Oxford	Review of 64 peer-reviewed papers (from 1994 to 2017) and 18 US EPA studies (from 1993 to 2002) related to the effect of GM crops (protease inhibitors, Cry, Vip, RNAi-producing and HT) such as cotton, soybean and maize on honey bees. No original/primary data related to the ERA of GHB614 x LLCotton25 cotton.
Singh, Monika Randhawa, Gurinderjit Bhoge, Rajesh K. Singh, Sushmita Kak, Anjali Sangwan, Omender. 2020	Monitoring Adventitious Presence of Transgenes in Cotton Collections from Genebank and Experimental Plots: Ensuring GM -Free Conservation and Cultivation of Genetic Resources	Agricultural Research (2020) Ahead of Print CODEN: ARGEFW; ISSN: 2249-7218	The authors tested adventitious presence of transgenes in 100 <i>ex situ</i> accessions of cotton being conserved in the National Genebank of India using Pentaplex PCR assay. The ERA is not related to GHB614 x LLCotton25 cotton.
Torres, Amada Reyes-Perez, Juan Jose Marquez-Hernandez, Cando Estrada-Arellano, Josue Esparza-Rivera, Juan Ramon Preciado-Rangel, Pablo Murillo-Amador, Bernardo. 2019	Potential transference of CP4 EPSPS to weed species from genetically modified <i>Gossypium hirsutum</i> in Northern Mexico	Notulae Botanicae Horti Agrobotanici Cluj-Napoca (2019), 47(2), 294-299 CODEN: NBHABI; ISSN: 0255-965X URL: http://www.notulaeobotanicae.ro/index.php/nbha/index	The objective of this study was to quantify and identify weed species associated to genetically modified cotton (BGII) fields and to detect the presence of glyphosate-insensitive EPSP synthases (CP4 EPSPS) in these species. The ERA is not related to GHB614 x LLCotton25 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 6 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, 2019 to September 30, 2020 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, 2019 to September 30, 2020, identified a total of 35 unique publications (after duplicate removal). A total of 6 publications were progressed for detailed assessment after excluding 47 obviously irrelevant publications during Stage 1 evaluation (rapid assessment based on title and abstract).

The 6 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, human or animal safety assessment, or environmental safety assessment 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
-----	--

- | | |
|----|--|
| 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.
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

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FILE 'MEDLINE' ENTERED AT 09:30:42 ON 15 OCT 2020
L1      3 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      3 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      1 SEA GHB614XLLCOTTON25 OR GHB614(W)TIME#(W)LLCOTTON25 OR
        LLCOTTON25XGHB614 OR LLCOTTON25(W)TIME#(W)GHB614
L4      1 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      12926 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      12 SEA 2MEPSPS OR 2(W)MEPSPS OR 2M(W)EPSPS OR 2(W)M(W)EPSPS
L9      4135 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     357 SEA (ENOL(W)PYRUVOYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR
        ENOLPYRUVYLSHIKIMIC OR ENOL(W) (PYRUVYL OR PYRUVOYL) (W)SHIKIMATE
        ) (3W)PHOSPHATE(W) (SYNTHASE OR SYNTHETASE)
L12     458 SEA (PHOSPHOSHIKIMATE(2W)CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIK
        IMATE(2W)CARBOXYVINYL(W)TRANSFERASE OR ENOLPYRUVOYL(W)SHIKIMIC (
        3W)PHOSPHOSYNTHASE)
L13     23584 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)
L14     18 SEA L8 OR ((L9 OR L10 OR L11 OR L12)) (S)L13)
L15     1390 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     202 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
        N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
        ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE
L17     1464 SEA L15 OR L16
L18     8 SEA L14 AND L17
L19     3230 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     3079 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
        GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR
        PROTECT? OR TOLERAN?)
L21     2829 SEA L19 AND L20
L22     25116 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE
L23     3603280 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     104 SEA L21 AND L22 AND L23
L25     113 SEA L4 OR L7 OR L18 OR L24
L26     21 SEA L25 AND PY>=2018
L27     6 SEA L26 AND UP>=20191001 AND UP<=20200930
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FILE 'BIOSIS' ENTERED AT 09:31:26 ON 15 OCT 2020
L28     4 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

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 14024 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 4944 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 682 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 26139 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)

L41 18 SEA L35 OR ((L36 OR L37 OR L38 OR L39)) (S)L40)

L42 2749 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 326 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L44 2849 SEA L42 OR L43

L45 8 SEA L41 AND L44

L46 10484 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 9424 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR
PROTECT? OR TOLERAN?)

L48 9034 SEA L46 AND L47

L49 72448 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE

L50 447208 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 234 SEA L48 AND L49 AND L50

L52 244 SEA L31 OR L34 OR L45 OR L51

L53 23 SEA L52 AND PY>=2018

L54 10 SEA L53 AND UP>=20191001 AND UP<=20200930

FILE 'AGRICOLA' ENTERED AT 09:32:06 ON 15 OCT 2020

L55 2 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

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 2881 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 594 SEA EPSPS OR EPSP (W) SYNTHASE OR (ENOL (W) PYRUVYLSHIKIMATE OR ENOL (W) PYRUVYL (W) SHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUV OYLSHIKIMATE OR ENOYLPYRUV OYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC) (4W) (PHOSPHATE OR PHOSPHORIC) (2W) (SYNTHASE OR SYNTHETASE)

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

L65 287 SEA (ENOL (W) PYRUV OYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC OR ENOL (W) (PYRUVYL OR PYRUV OYL) (W) SHIKIMATE) (3W) PHOSPHATE (W) (SYNTHASE OR SYNTHETASE)

L66 210 SEA (PHOSPHOSHIKIMATE (2W) CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIKIMATE (2W) CARBOXYVINYL (W) TRANSFERASE OR ENOLPYRUV OYL (W) SHIKIMIC (3W) PHOSPHOSYNTHASE)

L67 6202 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)

L68 7 SEA L62 OR (((L63 OR L64 OR L65 OR L66)) (S) L67)

L69 727 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 240 SEA PHOSPHINOTHRICIN (W) N (W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN (2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN (2W) ACETYL (W) TRANSFERASE OR PHOSPHINOTHRICINACETYL (W) TRANSFERASE

L71 802 SEA L69 OR L70

L72 3 SEA L68 AND L71

L73 8050 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 7715 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR PROTECT? OR TOLERAN?)

L75 7555 SEA L73 AND L74

L76 61291 SEA COTTON# OR GOSSYPIMUM OR G (W) HIRSUTUM OR G (W) BARBADENSE

L77 94680 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 209 SEA L75 AND L76 AND L77

L79 213 SEA L58 OR L61 OR L72 OR L78

L80 6 SEA L79 AND PY>=2018

L81 2 SEA L80 AND UP>=20191001 AND UP<=20200930

FILE 'CABA' ENTERED AT 09:32:50 ON 15 OCT 2020

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 4875 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 1022 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 400 SEA (ENOL(W)PYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR ENOLPYRUVYLSHIKIMIC OR ENOL(W) (PYRUVYL OR PYRUVOYL) (W) SHIKIMATE) (3W) PHOSPHATE(W) (SYNTHASE OR SYNTHETASE)

L93 151 SEA (PHOSPHOSHIKIMATE(2W) CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIK IMATE (2W) CARBOXYVINYL(W) TRANSFERASE OR ENOLPYRUVOYL(W) SHIKIMIC (3W) PHOSPHOSYNTHASE)

L94 6860 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)

L95 17 SEA L89 OR ((L90 OR L91 OR L92 OR L93)) (S) L94)

L96 1482 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 368 SEA PHOSPHINOTHRICIN(W)N(W) ACETYLTRANSFERASE OR PHOSPHINOTHRICI N(2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W) ACETYL(W) TRANSFER ASE OR PHOSPHINOTHRICINACETYL(W) TRANSFERASE

L98 1582 SEA L96 OR L97

L99 8 SEA L95 AND L98

L100 18048 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 17371 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR PROTECT? OR TOLERAN?)

L102 16988 SEA L100 AND L101

L103 92012 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE

L104 173943 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 465 SEA L102 AND L103 AND L104

L106 475 SEA L85 OR L88 OR L99 OR L105

L107 36 SEA L106 AND PY>=2018

L108 11 SEA L107 AND UP>=20191001 AND UP<=20200930

L109 11 SEA L108 NOT P/DT

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

L111 11 SEA L109 OR L110

FILE 'HCAPLUS' ENTERED AT 09:33:31 ON 15 OCT 2020

L112 10 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 8 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 5 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 18908 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     4246 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     1039 SEA (ENOL(W)PYRUVYOYLSHIKIMATE OR ENOLPYRUVYLSHIKIMATE OR
          ENOLPYRUVYLSHIKIMIC OR ENOL(W) (PYRUVYL OR PYRUVOYL) (W) SHIKIMATE
          ) (3W) PHOSPHATE(W) (SYNTHASE OR SYNTHETASE)
L123      87 SEA (PHOSPHOSHIKIMATE(2W) CARBOXYVINYLTRANSFERASE OR PHOSPHOSHIK
          IMATE(2W) CARBOXYVINYL(W) TRANSFERASE OR ENOLPYRUVOYL(W) SHIKIMIC (
          3W) PHOSPHOSYNTHASE)
L124     73372 SEA ((DOUBL# OR DOBL#) (W) (MUTANT# OR MUTAT?) OR 2M)
L125      41 SEA L119 OR ((L120 OR L121 OR L122 OR L123)) (S) L124)
L126     6894 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      761 SEA PHOSPHINOTHRICIN(W) N(W) ACETYLTRANSFERASE OR PHOSPHINOTHRICI
          N(2W) ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W) ACETYL(W) TRANSFER
          ASE OR PHOSPHINOTHRICINACETYL(W) TRANSFERASE
L128     7183 SEA L126 OR L127
L129      20 SEA L125 AND L128
L130     27433 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     26446 SEA (HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR
          GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?) (5A) (RESIST? OR
          PROTECT? OR TOLERAN?)
L132     25898 SEA L130 AND L131
L133     250667 SEA COTTON# OR GOSSYPIMUM OR G(W) HIRSUTUM OR G(W) BARBADENSE
L134     664388 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     1254 SEA L132 AND L133 AND L134
L136     1276 SEA L115 OR L118 OR L129 OR L135
L137     452 SEA L136 AND PY>=2018
L138      76 SEA L137 AND UP>=20191001 AND UP<=20200930
L139      11 SEA L138 NOT P/DT
L140      0 SEA L138 AND (P/DT AND J/DT)
L141      11 SEA L139 OR L140

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FILE 'MEDLINE, BIOSIS, AGRICOLA, CABA, HCAPLUS' ENTERED AT 09:34:22 ON 15
OCT 2020

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L142      35 DUP REM L27 L54 L81 L111 L141 (5 DUPLICATES REMOVED)
          ANSWERS '1-6' FROM FILE MEDLINE
          ANSWERS '7-15' FROM FILE BIOSIS
          ANSWERS '16-17' FROM FILE AGRICOLA
          ANSWERS '18-26' FROM FILE CABA
          ANSWERS '27-35' FROM FILE HCAPLUS

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