

Title

**Summary of the Literature Review for T304-40 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.  
EFSA supporting publications 2019:EN-1614

Completion date

November 30, 2020

Main author



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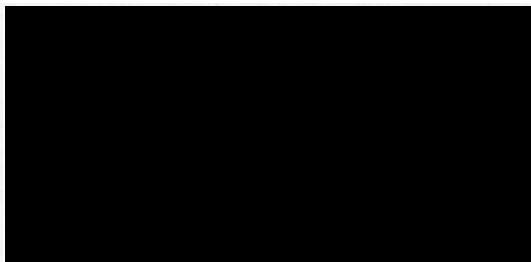
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Manual search	[REDACTED] [REDACTED] [REDACTED] [REDACTED]
Stage 1 assessment	[REDACTED] [REDACTED]
Stage 2 assessment	<u>Food and Feed safety</u> [REDACTED] [REDACTED] <u>Molecular characterization</u> [REDACTED] [REDACTED] <u>Environmental safety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

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## SUMMARY

The T304-40 cotton event produces the *Bacillus thuringiensis* subsp. *berliner* Cry1Ab protein that is effective in controlling lepidopteran larvae such as cotton bollworm and tobacco budworm. T304-40 cotton also expresses the herbicide tolerant inert ingredient phosphinothricin acetyl transferase (PAT/*bar*) as a selectable marker which confers tolerance to glufosinate-ammonium herbicides. The OECD identifier is BCS-GHØØ4-7.

A scoping review was performed for the T304-40 cotton and its newly expressed proteins, Cry1Ab and PAT/*bar*. The objective of this scoping review was to determine if there were studies about the molecular characterization of T304-40 cotton, its effect on food and feed safety, or in 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 218 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 9 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 T304-40 cotton and its newly expressed proteins, Cry1Ab and PAT/*bar*. Similarly, no new publications were found that suggested any potential adverse effects of T304-40 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

The T304-40 cotton event produces the *Bacillus thuringiensis* subsp. *berliner* Cry1Ab protein that is effective in controlling lepidopteran larvae such as cotton bollworm and tobacco budworm. T304-40 cotton also expresses the herbicide tolerant inert ingredient phosphinothricin acetyl transferase (PAT/*bar*) as a selectable marker which confers tolerance to glufosinate-ammonium herbicides. The OECD identifier is BCS-GHØØ4-7.

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 T304-40 cotton, and/or any adverse effect of T304-40 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 T304-40 cotton and its newly expressed proteins Cry1Ab 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 T304-40 cotton and its newly expressed proteins Cry1Ab 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 T304-40 cotton and its newly expressed proteins Cry1Ab and PAT/*bar*?

**Key elements:**

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

**Exposure:** T304-40 cotton, derived food/feed products, newly expressed proteins in T304-40 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 T304-40 cotton and its newly expressed proteins Cry1Ab and PAT/*bar* in corn?



**Key elements:**

Population: T304-40 cotton and newly expressed proteins in T304-40 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 proteins(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, or it is a risk assessment from a relevant key organisation (such as regulatory agencies and risk assessment bodies involved in the risk assessment of GMOs)	This permits the exclusion of publications that do not present original/primary data (e.g., editorials, position papers), and the inclusion of relevant risk assessments performed and reported by relevant key organisations. 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 the 2019 EFSA 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<sup>1</sup>.

## 2.4. Reference publication

One publication related to T304-40 cotton was previously identified and used to test and validate the search strategy:

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

This article was selected as reference publication because it mentions the event (T304-40), the newly expressed proteins (Cry1Ab and phosphinothricin acetyl transferase or PAT/bar), the intended traits (insect control; herbicide tolerance) and the crop (cotton). Since this article was published outside of the timeframe 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 for (renewed) market authorization and annual post-market environmental monitoring reports on GMOs authorised in the EU market<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 12, 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, newly expressed proteins and intended traits. Since the two 'newly expressed proteins' profiles and the two 'intended trait' profiles produced too many results when used on their own, they were combined with additional profiles: the two 'newly expressed proteins' profiles were combined with a 'plant species' profile while the two 'intended trait' profiles were combined with a 'general GMO' profile as well as with the 'plant species' profile. See [Table 2](#) for a detailed search profile.

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

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

The search results were limited to documents updated between October 1, 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	T304-40 or T304(w)40 or T(w)304(w)40 or BCS-GH004-7 or BCS-GH004-7 or BCS-GH004-7 or BCS(w)GH004(w)7 or BCS(w)GH004(w)7 or BCS(w)GH004(w)7 or BCSGH004(w)7 or BCSGH004(w)7 or BCSGH004(w)7	Event name
	none	Trade name
2	((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) or (crylab# or cry(w)l(w)ab# or cry(w)lab# or cryl(w)ab# or cryl(w)a(w)b# or cry(w)l(w)a(w)b# or cryla(w)b# or crylab# or cry(w)l(w)ab# or cry(w)lab# or cryl(w)ab# or cryl(w)a(w)b# or cry(w)l(w)a(w)b# or cryla(w)b# or crylab# or cry(w)l(w)ab# or cry(w)lab# or cryl(w)ab# or cryl(w)a(w)b# or cry(w)l(w)a(w)b# or cryla(w)b#)	Newly expressed proteins
3	(herbicid? or bialaphos or basta or glufosinate or glufosinate or phosphinothricin or liberty? or Insect# OR pest# OR Lepidoptera# OR Noctuidae OR Crambidae OR borer# OR cornborer# OR stalkborer# OR earworm# OR ear(w)worm# OR armyworm# OR army(w)worm# OR cutworm# OR cut(w)worm# OR Ostrinia OR O(w)nubilalis OR Sesamia OR S(w)nonagrioides or Diatraea OR D(w)grandiosella OR D(w)crambidoides OR Helicoverpa OR H(w)zea OR Spodoptera OR S(w)frugiperda OR Papaipema OR P(w)nebris OR Elasmopalpus OR E(w)lignosellus OR D(w)saccharalis OR Striacosta OR S(w)albicosta or Agrotis OR A(w)ipsilon OR S(w)cretica OR Mythimna OR M(w)unipuncta OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR SCB OR WBC (5a) (resist? OR protect? OR toleran?))	Intended traits
4	cotton# or gossypium or G(w)hirsutum or g(w)barbadense	Plant species
5	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
6	2 and 4	Newly expressed proteins AND Plant species
7	3 and 4 and 5	Intended traits AND Plant species AND GMO general
8	1 or 6 or 7	Event name OR (Newly expressed proteins AND Plant species) OR (Intended traits AND Plant species AND GMO general)

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

Database	AGRICOLA	BIOSIS	CAB Abstracts	CAPLUS	MEDLINE
Database Provider	STN International	STN International	STN International	STN International	STN International
Coverage	1970-present	1926-present	1973-present	1907-present	1946-present
Date of search	12 Oct 2020	12 Oct 2020	12 Oct 2020	12 Oct 2020	12 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	7 Oct 2020	7 Oct 2020	11 Oct 2020	11 Oct 2020
Number of records retrieved	26	57	87	73	58
Number of records after duplicate removal	22	37	64	37	58
Number of relevant records after rapid assessment	0	0	2	3	4

## 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 note<sup>1</sup>, 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 note<sup>1</sup>, two (Environment and Climate Change Canada and CIBIOGEM) are not involved in the risk assessment of GM plants. Therefore, the internet search was limited to 11 key organisations relevant for T304-40 cotton.

Search terms consisted of T304-40 or BCS-GH004-7; Cry1Ab; or PAT/*bar* or Phosphinothricin in T304-40 cotton (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
US Environmental Protection Agency (EPA)	<a href="https://www.epa.gov/">https://www.epa.gov/</a>	Oct 27 2020	Oct 30 2020	0
US Department of Agriculture (USDA)	<a href="https://www.usda.gov/">https://www.usda.gov/</a>	Oct 29 2020	Oct 30 2020	0
US Food and Drug Administration (FDA)	<a href="https://www.fda.gov/">https://www.fda.gov/</a>	Oct 30 2020	Oct 28-30 2020	0
Health Canada	<a href="https://www.canada.ca/en/health-canada.html">https://www.canada.ca/en/health-canada.html</a>	Oct 26 2020	Oct 28-30 2020	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>	Oct 30 2020	Oct 28-30 2020	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 28 2020	Oct 28-30 2020	0
Office of the Gene Technology Regulator (OGTR) Australia	<a href="http://www.ogtr.gov.au/">http://www.ogtr.gov.au/</a>	Oct 15 2020	Oct 28-30 2020	0
National Technical Commission on Biosafety (CTNBio) Brazil	<a href="http://ctnbio.mcti.gov.br/en">http://ctnbio.mcti.gov.br/en</a>	Oct 20	Oct 22-28 2020	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>	later than Aug 21 2020	Oct 21-22 2020	0
Genetic Engineering Approval Committee (GEAC) India	<a href="http://moef.gov.in/">http://moef.gov.in/</a> *	Oct 27 2020	Nov 3 2020	0
Ministry of Agriculture, Forestry and Fisheries (MAFF) Japan	<a href="http://www.maff.go.jp/">http://www.maff.go.jp/</a>	Oct 26 2020	Oct 26 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 301 references, which were reduced to 218 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 evaluation were in 100% agreement.

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

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

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

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

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

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

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

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

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

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

Total number of publications retrieved after all searches of the scientific literature (excluding duplicates)	218
Number of publications excluded from the search results after rapid assessment for relevance (Stage 1)	209
Total number of full-text documents assessed in detail	9
Number of publications excluded from further consideration after detailed assessment for relevance (Stage 2)	9
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>
Fast Brandon J Shan Guomin Herman Rod A Gampala Satyalinga Srinivas: 2020	Transgene expression in sprayed and non- sprayed herbicide - tolerant genetically engineered crops is equivalent.	Regulatory toxicology and pharmacology : RTP, (2020 Mar) Vol. 111, pp. 104572. Electronic Publication Date: 26 Dec 2019 Journal code: 8214983. E-ISSN: 1096- 0295. L-ISSN: 0273-2300.	Cotton event T304-40 cotton was included in the study. The ERA is not related to T304-40 cotton.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in <a href="#">Table 1</a>
Liu Laipan, Guo Ruqing Qin Qin, Fu Jianmei Liu Biao. 2020	Expression of Bt Protein in Transgenic Bt Cotton Plants and Ecological Fitness of These Plants in Different Habitats.	Frontiers in plant science, (2020) Vol. 11, pp. 1209. Electronic Publication Date: 7 Aug 2020 Journal code: 101568200. ISSN: 1664-462X. L-ISSN: 1664-462X. Report No.: PMC-PMC7427126.	The Bt variety used in the study was Zhong30. The ERA is not related to T304-40 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 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 Ardizzone Michele Fernandez-Dumont Antonio Gennaro Andrea Gomez Ruiz Jose Angel Lanzoni Anna Neri Franco Maria Papadopoulou Nikoletta Paraskevopoulos Konstantinos 2018	Assessment of genetically modified cotton GHB614 x T304 - 40 x GHB119 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014- 122).	EFSA journal. European Food Safety Authority, (2018 Jul) Vol. 16, No. 7, pp. e05349. Electronic Publication Date: 25 Jul 2018 Journal code: 101642076. E-ISSN: 1831- 4732. L-ISSN: 1831-4732. Report No.: PMC- PMC7009458.	The report is not specific to T304-40 cotton. The report focused on GHB614 x T304-40 x GHB119 cotton.



Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in <a href="#">Table 1</a>
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 T304-40 cotton.
Raeman Reben, Hua Gang Zhang Qi, Adang Michael J. 2020	Fluorescent analyses of Bacillus thuringiensis Cry1Fa and Cry1Ab toxin binding sites on brush border membrane vesicles of Ostrinia nubilalis (Hubner), Diatraea grandiosella (Dyar), and Helicoverpa zea (Boddie) larvae.	Pesticide biochemistry and physiology, (2020 Jul) Vol. 167, pp. 104592. Electronic Publication Date: 21 Apr 2020 Journal code: 1301573. E-ISSN: 1095-9939. L-ISSN: 0048-3575.	The study was about in vitro binding of pesticides to pest. No GM plant was included in the study
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 T304-40 cotton.

Study (Author(s) and year)	Title	Source	Reason(s) for exclusion based on eligibility/inclusion criteria listed in <a href="#">Table 1</a>
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 T304-40 cotton.
Zhang FuLi, Yin Quan, Mao JianFei, Guo Ling'an, Lei ShaoRong, Liu WenJuan, Luo Ping, Wang Dong, Song Jun, Yang XiaoFeng, Zhang, F. L., Yin, Q., Mao, J. F., Guo, L., Lei, S. R., Liu, W. J., Luo, P., Wang, D., Song, J., Yang, X. F. 2020	Effects of <i>Bacillus thuringiensis</i> transgenic cotton straw returning to field on soil fertility.	Zhongguo Shengtai Nongye Xuebao / Chinese Journal of Eco-Agriculture (2020), Volume 28, Number 5, pp. 734-744, 26 refs. ISSN: 2096-6237 DOI: 10.13930/j.cnki.cjea.190894 Published by: Science Press, Beijing	Four kinds of Bt cotton with different levels of insect resistance and one non-transgenic conventional cotton (Simian no. 3) straws were mechanically crushed and returned to the field after one or two years of planting in China. The content of residual Bt protein, activities of several soil enzymes, and nutrient contents in soil were detected and the changes were further analyzed. There was no significant differences between the transgenic field plots and non-transgenic ones. The ERA is not related to T304-40 cotton.
Zhao, Man, Li, Yunhe Yuan, Xiangdong Liang, Gemei, Wang, Bingjie Liu, Chen, Khaing, Myint Myint. 2018	Establishment of a dietary exposure assay for evaluating the toxicity of insecticidal compounds to <i>Apolygus lucorum</i> (Hemiptera: Miridae)	Environmental Pollution (Oxford, United Kingdom) (2018 ), 237, 414-423 CODEN: ENPOEK; ISSN: 0269-7491	The authors developed and validated a dietary exposure assay for screening insecticidal compds. and for assessing the potential effects of insecticidal proteins produced by GE plants (Cry1Ab , Cry1Ac, Cry1F, Cry2Aa, and Cry2Ab proteins) on <i>Apolygus lucorum</i> (Miridae). The results demonstrated that <i>A. lucorum</i> is not sensitive to the tested Cry proteins. The ERA is not related to T304-40 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 9 publications were selected during Stage 1 evaluation (rapid assessment based on title and abstract). After Stage 2 evaluation (detailed review based on full text), no relevant references were found in the searches on T304-40 cotton and its newly expressed proteins, Cry1Ab and PAT/*bar*, covering October 1, 2019 to September 30, 2020 to provide additional information.

## 7. CONCLUSION

The literature searches performed for the T304-40 cotton and its newly expressed proteins, Cry1Ab and PAT/*bar*, for the period from October 1, 2019 to September 30, 2020, identified a total of 218 unique publications (after duplicate removal). A total of 9 publications were progressed for detailed assessment after excluding 209 obviously irrelevant publications during Stage 1 evaluation (rapid assessment based on title and abstract).

The 9 publications that progressed to Stage 2 were evaluated in detail, based on full text, for potential relevance, following the pre-established criteria listed in [Table 1](#). 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.<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 09:50:26 ON 12 OCT 2020

L1 4 SEA T304-40 OR T304(W)40 OR T(W)304(W)40 OR BCS-GH004-7 OR  
BCS-GH004-7 OR BCS-GH004-7 OR BCS(W)GH004(W)7 OR BCS(W)GH004(W)  
7 OR BCS(W)GH004(W)7 OR BCSGH004(W)7 OR BCSGH004(W)7 OR  
BCSGH004(W)7

L2 1389 SEA ((BAR OR PAT) (2A) (GENE# OR PROTEIN# OR ENZYME#)) OR  
PPT(2W)ACETYLTRANSFERASE OR PPT(2W)ACETYL(W)TRANSFERASE OR  
PT(W)N(2W)ACETYLTRANSFERASE OR PT(W)N(2W)ACETYL(W)TRANSFERASE

L3 202 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI  
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER  
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L4 879 SEA CRY1AB# OR CRY(W)1(W)AB# OR CRY(W)1AB# OR CRY1(W)AB# OR  
CRY1(W)A(W)B# OR CRY(W)1(W)A(W)B# OR CRY1A(W)B#

L5 115 SEA CRYIAB# OR CRY(W)I(W)AB# OR CRY(W)IAB# OR CRYI(W)AB# OR  
CRYI(W)A(W)B# OR CRY(W)I(W)A(W)B# OR CRYIA(W)B#

L6 36 SEA CRYLAB# OR CRY(W)L(W)AB# OR CRY(W)LAB# OR CRYL(W)AB# OR  
CRYL(W)A(W)B# OR CRY(W)L(W)A(W)B# OR CRYLA(W)B#

L7 2464 SEA (L2 OR L3 OR L4 OR L5 OR L6)

L8 28612 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR GLUPHOSIN  
ATE OR PHOSPHINOTHRICIN OR LIBERTY?

L9 196019 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE  
OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WOR  
M# OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR  
OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES

L10 13410 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR  
HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR  
PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR  
D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA

L11 20944 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR  
M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR  
SCB OR WBC

L12 2247178 SEA (RESIST? OR PROTECT? OR TOLERAN?)

L13 10543 SEA ((L8 OR L9 OR L10 OR L11)) (5A)L12

L14 25105 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE

L15 3602269 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?))

L16 69 SEA L7 AND L14

L17 600 SEA L13 AND L14 AND L15

L18 638 SEA L1 OR L16 OR L17

L19 114 SEA L18 AND PY>=2018

L20 58 SEA L19 AND UP>=20190901 AND UP<=20200930

FILE 'BIOSIS' ENTERED AT 09:51:12 ON 12 OCT 2020

L21 2 SEA T304-40 OR T304(W)40 OR T(W)304(W)40 OR BCS-GH004-7 OR  
BCS-GH004-7 OR BCS-GH004-7 OR BCS(W)GH004(W)7 OR BCS(W)GH004(W)  
7 OR BCS(W)GH004(W)7 OR BCSGH004(W)7 OR BCSGH004(W)7 OR  
BCSGH004(W)7

L22 2747 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

L23 326 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI  
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER  
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L24 1490 SEA CRY1AB# OR CRY(W)1(W)AB# OR CRY(W)1AB# OR CRY1(W)AB# OR  
CRY1(W)A(W)B# OR CRY(W)1(W)A(W)B# OR CRY1A(W)B#

L25 227 SEA CRYIAB# OR CRY(W)I(W)AB# OR CRY(W)IAB# OR CRYI(W)AB# OR  
CRYI(W)A(W)B# OR CRY(W)I(W)A(W)B# OR CRYIA(W)B#

L26 262 SEA CRYLAB# OR CRY(W)L(W)AB# OR CRY(W)LAB# OR CRYL(W)AB# OR  
CRYL(W)A(W)B# OR CRY(W)L(W)A(W)B# OR CRYLA(W)B#

L27 4552 SEA (L22 OR L23 OR L24 OR L25 OR L26)

L28 85812 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR GLUPHOSIN  
ATE OR PHOSPHINOTHRICIN OR LIBERTY?  
L29 1383578 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE  
OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WORM#  
OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR  
OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES  
L30 26065 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR  
HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR  
PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR  
D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA  
L31 29977 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR  
M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR  
SCB OR WBC  
L32 2278018 SEA (RESIST? OR PROTECT? OR TOLERAN?)  
L33 32199 SEA ((L28 OR L29 OR L30 OR L31)) (5A)L32  
L34 72395 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE  
L35 446752 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?))  
L36 186 SEA L27 AND L34  
L37 905 SEA L33 AND L34 AND L35  
L38 1017 SEA L21 OR L36 OR L37  
L39 116 SEA L38 AND PY>=2018  
L40 57 SEA L39 AND UP>=20190901 AND UP<=20200930

FILE 'AGRICOLA' ENTERED AT 09:51:47 ON 12 OCT 2020

L41 2 SEA T304-40 OR T304(W)40 OR T(W)304(W)40 OR BCS-GH004-7 OR  
BCS-GH004-7 OR BCS-GH004-7 OR BCS(W)GH004(W)7 OR BCS(W)GH004(W)  
7 OR BCS(W)GH004(W)7 OR BCSGH004(W)7 OR BCSGH004(W)7 OR  
BCSGH004(W)7  
L42 723 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 240 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICI  
N(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFER  
ASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE  
L44 857 SEA CRY1AB# OR CRY(W)1(W)AB# OR CRY(W)1AB# OR CRY1(W)AB# OR  
CRY1(W)A(W)B# OR CRY(W)1(W)A(W)B# OR CRY1A(W)B#  
L45 153 SEA CRYIAB# OR CRY(W)I(W)AB# OR CRY(W)IAB# OR CRYI(W)AB# OR  
CRYI(W)A(W)B# OR CRY(W)I(W)A(W)B# OR CRYIA(W)B#  
L46 10 SEA CRYLAB# OR CRY(W)L(W)AB# OR CRY(W)LAB# OR CRYL(W)AB# OR  
CRYL(W)A(W)B# OR CRY(W)L(W)A(W)B# OR CRYLA(W)B#  
L47 1793 SEA (L42 OR L43 OR L44 OR L45 OR L46)  
L48 54266 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR GLUPHOSIN  
ATE OR PHOSPHINOTHRICIN OR LIBERTY?  
L49 319327 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE  
OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WORM#  
OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR  
OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES  
L50 13147 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR  
HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR  
PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR  
D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA  
L51 4172 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR  
M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR  
SCB OR WBC  
L52 553695 SEA (RESIST? OR PROTECT? OR TOLERAN?)  
L53 27740 SEA ((L48 OR L49 OR L50 OR L51)) (5A)L52  
L54 61052 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE  
L55 93951 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?))  
L56 89 SEA L47 AND L54



L57 689 SEA L53 AND L54 AND L55  
L58 739 SEA L41 OR L56 OR L57  
L59 43 SEA L58 AND PY>=2018  
L60 26 SEA L59 AND UP>=20190901 AND UP<=20200930

FILE 'CABA' ENTERED AT 09:52:35 ON 12 OCT 2020

L61 6 SEA T304-40 OR T304(W)40 OR T(W)304(W)40 OR BCS-GH004-7 OR BCS-GH004-7 OR BCS-GH004-7 OR BCS(W)GH004(W)7 OR BCS(W)GH004(W)7 OR BCS(W)GH004(W)7 OR BCSGH004(W)7 OR BCSGH004(W)7

L62 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

L63 368 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFERASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L64 1614 SEA CRY1AB# OR CRY(W)1(W)AB# OR CRY(W)1AB# OR CRY1(W)AB# OR CRY1(W)A(W)B# OR CRY(W)1(W)A(W)B# OR CRY1A(W)B#

L65 217 SEA CRYIAB# OR CRY(W)I(W)AB# OR CRY(W)IAB# OR CRYI(W)AB# OR CRYI(W)A(W)B# OR CRY(W)I(W)A(W)B# OR CRYIA(W)B#

L66 27 SEA CRYLAB# OR CRY(W)L(W)AB# OR CRY(W)LAB# OR CRYL(W)AB# OR CRYL(W)A(W)B# OR CRY(W)L(W)A(W)B# OR CRYLA(W)B#

L67 3398 SEA (L62 OR L63 OR L64 OR L65 OR L66)

L68 147728 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR GLUPHOSINATE OR PHOSPHINOTHRICIN OR LIBERTY?

L69 881530 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WORM# OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES

L70 31275 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA

L71 12149 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR SCB OR WBC

L72 1215575 SEA (RESIST? OR PROTECT? OR TOLERAN?)

L73 82556 SEA ((L68 OR L69 OR L70 OR L71)) (5A)L72

L74 91934 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE

L75 173769 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?))

L76 213 SEA L67 AND L74

L77 2124 SEA L73 AND L74 AND L75

L78 2239 SEA L61 OR L76 OR L77

L79 178 SEA L78 AND PY>=2018

L80 87 SEA L79 AND UP>=20190901 AND UP<=20200930

L81 87 SEA L80 NOT P/DT

L82 0 SEA L80 AND (P/DT AND J/DT)

L83 87 SEA L81 OR L82

FILE 'HCAPLUS' ENTERED AT 09:53:26 ON 12 OCT 2020

L84 5 SEA T304-40 OR T304(W)40 OR T(W)304(W)40 OR BCS-GH004-7 OR BCS-GH004-7 OR BCS-GH004-7 OR BCS(W)GH004(W)7 OR BCS(W)GH004(W)7 OR BCS(W)GH004(W)7 OR BCSGH004(W)7 OR BCSGH004(W)7

L85 6885 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

L86 761 SEA PHOSPHINOTHRICIN(W)N(W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYLTRANSFERASE OR PHOSPHINOTHRICIN(2W)ACETYL(W)TRANSFERASE OR PHOSPHINOTHRICINACETYL(W)TRANSFERASE

L87 1737 SEA CRY1AB# OR CRY(W)1(W)AB# OR CRY(W)1AB# OR CRY1(W)AB# OR

CRY1(W)A(W)B# OR CRY(W)1(W)A(W)B# OR CRY1A(W)B#  
L88 1328 SEA CRYIAB# OR CRY(W)I(W)AB# OR CRY(W)IAB# OR CRYI(W)AB# OR  
CRYI(W)A(W)B# OR CRY(W)I(W)A(W)B# OR CRYIA(W)B#  
L89 56 SEA CRYLAB# OR CRY(W)L(W)AB# OR CRY(W)LAB# OR CRYL(W)AB# OR  
CRYL(W)A(W)B# OR CRY(W)L(W)A(W)B# OR CRYLA(W)B#  
L90 9351 SEA (L85 OR L86 OR L87 OR L88 OR L89)  
L91 149812 SEA HERBICID? OR BIALAPHOS OR BASTA OR GLUFOSINATE OR GLUPHOSIN  
ATE OR PHOSPHINOTHRICIN OR LIBERTY?  
L92 291841 SEA INSECT# OR PEST# OR LEPIDOPTERA# OR NOCTUIDAE OR CRAMBIDAE  
OR BORER# OR CORNBORER# OR STALKBORER# OR EARWORM# OR EAR(W)WORM#  
OR ARMYWORM# OR ARMY(W)WORM# OR CUTWORM# OR CUT(W)WORM# OR  
OSTRINIA OR O(W)NUBILALIS OR SESAMIA OR S(W)NONAGRIOIDES  
L93 21818 SEA DIATRAEA OR D(W)GRANDIOSELLA OR D(W)CRAMBIDOIDES OR  
HELICOVERPA OR H(W)ZEA OR SPODOPTERA OR S(W)FRUGIPERDA OR  
PAPAIPEMA OR P(W)NEBRIS OR ELASMOPALPUS OR E(W)LIGNOSELLUS OR  
D(W)SACCHARALIS OR STRIACOSTA OR S(W)ALBICOSTA  
L94 21669 SEA AGROTIS OR A(W)IPSILON OR S(W)CRETICA OR MYTHIMNA OR  
M(W)UNIPUNCTA OR ECB OR MCB OR SWCB OR SCSB OR CEW OR FAW OR  
SCB OR WBC  
L95 5486362 SEA (RESIST? OR PROTECT? OR TOLERAN?)  
L96 52520 SEA ((L91 OR L92 OR L93 OR L94)) (5A)L95  
L97 250469 SEA COTTON# OR GOSSYPIMUM OR G(W)HIRSUTUM OR G(W)BARBADENSE  
L98 663877 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?))  
L99 474 SEA L90 AND L97  
L100 2330 SEA L96 AND L97 AND L98  
L101 2563 SEA L84 OR L99 OR L100  
L102 705 SEA L101 AND PY>=2018  
L103 169 SEA L102 AND UP>=20190901 AND UP<=20200930  
L104 73 SEA L103 NOT P/DT  
L105 0 SEA L103 AND (P/DT AND J/DT)  
L106 73 SEA L104 OR L105

FILE 'MEDLINE, BIOSIS, AGRICOLA, CABA, HCAPLUS' ENTERED AT 09:54:08 ON 12  
OCT 2020

L107 218 DUP REM L20 L40 L60 L83 L106 (83 DUPLICATES REMOVED)  
ANSWERS '1-58' FROM FILE MEDLINE  
ANSWERS '59-95' FROM FILE BIOSIS  
ANSWERS '96-117' FROM FILE AGRICOLA  
ANSWERS '118-181' FROM FILE CABA  
ANSWERS '182-218' FROM FILE HCAPLUS