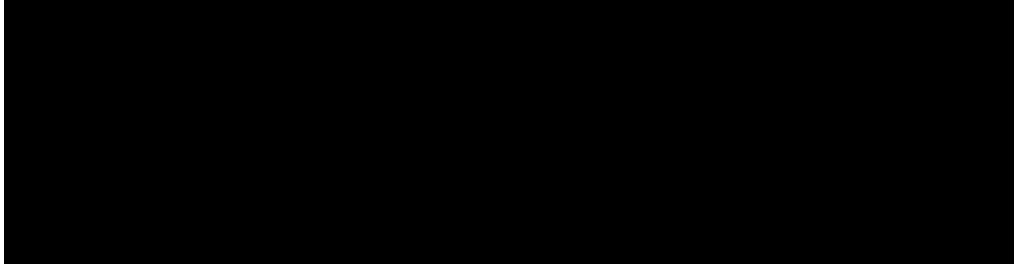


## **Annex 4**

### **Review of literature of DAS-40278-9 maize in the scope of the authorisation for food and feed uses, import and processing (2019 update)**

**Review of literature for authorised genetically modified maize 1507,  
59122, DAS-40278-9, 1507xNK603 and 1507x59122xMON810xNK603  
and its sub-combinations (except NK603xMON810) in the scope of  
their authorisations for food and feed uses, import and processing in  
the EU (2019 update)**



**PHI-R103-Y19**

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## 1. Summary

An updated systematic search and review of peer-reviewed literature in line with the EFSA Guidance on conducting a systematic review (EFSA, 2010) and taking into account the explanatory note on literature searching (EFSA, 2019), was conducted for the authorised genetically modified (GM) maize 1507, 59122, DAS-40278-9, 1507xNK603, 1507x59122xMON810xNK603 and its sub-combinations (except NK603xMON810) (hereafter collectively referred to as “authorised GM maize”) with the following review question “Do the authorised GM maize and derived food/feed products, or the intended traits (the newly expressed proteins or their combination) have adverse effects on human and animal health and the environment in the scope of their authorisations ?”.

The review question and the search procedure took into account the products and scope of the authorisations (i.e., authorisation for import into the EU of food and feed containing, consisting of, or produced from the authorised GM maize) and the objectives of the studies (i.e., assessment of potential adverse effects on human and animal health and the environment of the genetically modified food and feed containing, consisting of or produced from the authorised GM maize). The systematic searches were performed according to the relevant parts of the EFSA guidance on the application of systematic review methodology to food and feed safety assessments (EFSA, 2010). The fundamental principles followed in this study were (1) methodological rigour and coherence in the retrieval and selection of studies; (2) transparency; and (3) reproducibility. Each search used a procedure that was developed *a priori*.

The systematic search and review of studies published in the scientific literature followed a tiered approach that included: (i) a systematic literature search, (ii) a screening of the retrieved records for relevance to the review question, and (iii) a thorough analysis of potential studies that were considered relevant, if any.

The current systematic search complements the searches previously performed in 2018. Unless outlined below, all portions of the search were conducted according to the methodologies outlined in the previous searches.

The outcome of this analysis showed that no new publications relevant for the review question were identified during the selected time period. No safety concerns were identified for the authorised GM maize by this literature search exercise.

## 2. Eligibility/inclusion criteria

Search outputs were manually screened for relevance for the review question: “Do the authorised GM maize<sup>1</sup> and their respective derived food/feed products, or the intended trait(s) (the newly expressed protein(s) or their combination), have adverse effects on human and animal health and the environment in the scope of their authorisations?”. The systematic search uses *a priori* determined eligibility/inclusion criteria indicated in Table 1.

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<sup>1</sup> As previously defined, authorised GM maize include 1507, 59122, 1507xNK603, DAS-40278-9, and 1507x59122xMON810xNK603 and its subcombinations (with the exception of NK603xMON810)

**Table 1:** Eligibility/inclusion criteria to establish the relevance of retrieved publications based on the review question

Concept	Criteria
Population (taking into account scope of application)	Addressing human and animal health, and/or the environment relevant for the scope of the authorisation.  The pathways and level of exposure to the GMO, derived food/feed products, and the intended traits addressed in the study (as assessed under the Intervention/exposure part) are relevant for the intended uses of the GMO and derived food/feed products under regulatory review (e.g. in case of an import application, efficacy of the traits, pest susceptibility, etc. are not considered relevant).
Intervention/exposure Product	Authorised GM maize <sup>1</sup> and derived food/feed products, and/or the intended trait(s) (newly expressed protein(s) or their combinations when applicable).
Intervention/exposure Plant species	In case of studies using GM plants, only studies using maize are considered eligible. This criterion is not employed for studies regarding the newly expressed proteins.
Intervention/exposure Source organism of the protein	In case of publications using the protein of interest, only publications with the protein from the specific source organism will be considered eligible.
Comparator	If the study is a comparative study that uses plant material as test material, eligible publications must report a non-GM variety.
Outcomes	Effects/impacts on human and animal health, and/or the environment are addressed.  Publications addressing other issues such as benefits, socio-economics, ethics, crop protection, detection methods, efficacy, public perception and risk communication are to be excluded using this criterion, as they are not relevant to the risk assessment of GMOs.
Reporting format	Original/primary data are presented in the study. This permits the exclusion of publications that do not present original/primary data (e.g., reviews, editorial, position papers).  However, risk assessments from relevant risk assessment bodies (excluding EFSA) will not be excluded.

### 3. Confirmation of the Suitability of the Search Strings

The previous search strategies were analyzed to ensure that the original search terms were still relevant in the current search engine (described in Section 3.2 below).

#### 3.1. Electronic bibliographic databases

Due to changes in subscriptions to electronic bibliographic databases, updated descriptions are provided below.

### Web of Science™ Core collection<sup>2</sup>

Web of Science Core collection is one of the largest citation databases available with over 1.5 billion cited reference connections indexed from high quality peer reviewed journals, books and proceedings<sup>3</sup>. “Each cited reference is meticulously indexed to ensure that it is searchable and attributes credit to the appropriate publication”.<sup>4</sup>

### CABI’s CAB Abstracts® and Global Health®<sup>5</sup>

CAB Abstracts gives you instant access to over 9.5 million record<sup>6</sup>, with over 350,000 abstracts added each year. Covering publications from over 120 countries in 50 languages, including a number of niche, independent journals, CAB Abstracts gives you the fullest global picture for any subject.<sup>7</sup> This database also includes local publications.

Global Health gives researchers and students unparalleled access to all the world’s relevant public health research and practice – providing knowledge without borders. More than 3.3<sup>8</sup> million records, dedicated to public health, with full text hosted for over 100,000 articles including 375 CABI book chapters, over 160 reviews from CABI’s very own eJournal CAB Reviews and over 500 news items from 2014 – 2018. New content added each week.<sup>9</sup>

### MEDLINE<sup>10</sup>

MEDLINE is the U.S. National Library of Medicine® (NLM) premier bibliographic database that contains more than 25 million references to journal articles in life sciences with a concentration on biomedicine. A distinctive feature of MEDLINE is that the records are indexed with NLM Medical Subject Headings (MeSH®). MEDLINE is the online counterpart to MEDLARS® (MEDical Literature Analysis and Retrieval System) that originated in 1964. MEDLINE is the primary component of PubMed®.<sup>11</sup>

The WoS search engine can access one or more databases depending on your subscription. Web of Science Core collection is an interdisciplinary database covering all sciences including life, physical, health and social sciences which is updated on a daily basis including with articles in press. CABI covers agriculture, environment, applied life sciences, veterinary sciences, applied economics, food science and nutrition. The subject scope of MEDLINE is biomedicine and health, broadly defined to encompass those areas of the life sciences, behavioral sciences, chemical sciences, and bioengineering needed by health professionals and others engaged in basic research and clinical care, public health, health policy development, or related educational activities.

The WoS search interfaces feature advanced search options which include the use of complex search syntaxes. In addition, Europe PMC (as previously described for 2018 searches) was used to complement the searches as the database allows full text searching of publications stored at Europe PMC.

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<sup>2</sup> Web of Science is a trademark of Clarivate Analytics

<sup>3</sup> <https://clarivate.com/products/web-of-science/web-science-form/web-science-core-collection/>; Last accessed 14 November 2019

<sup>4</sup> [https://clarivate.com/wp-content/uploads/2017/05/d6b7faae-3cc2-4186-8985-a6ecc8cce1ee\\_Crv\\_WoS\\_Upsell\\_Factbook\\_A4\\_FA\\_LR\\_edits.pdf](https://clarivate.com/wp-content/uploads/2017/05/d6b7faae-3cc2-4186-8985-a6ecc8cce1ee_Crv_WoS_Upsell_Factbook_A4_FA_LR_edits.pdf); Last accessed 14 November 2019

<sup>5</sup> CABI, CAB Abstracts, and Global Health are trademarks of C.A.B. International

<sup>6</sup> Figures as of September 2019

<sup>7</sup> As defined by CABI; <https://www.cabi.org/publishing-products/cab-abstracts/>; Last accessed 14 November 2019

<sup>8</sup> Figures as of September 2019

<sup>9</sup> As defined by CABI; <https://www.cabi.org/publishing-products/global-health/>; Last accessed 14 November 2019

<sup>10</sup> MEDLINE is a trademark of U.S. National Library of Medicine

<sup>11</sup> <https://www.nlm.nih.gov/bsd/medline.html>; Last accessed 14 November 2019

Therefore, it was confirmed that the combination of these sources allows having a broad coverage of publications related to GMO risk assessment.

### 3.2. Web of Science Search Engine

The Web of Science Core Collection, CABI (CAB Abstracts and Global Health), and MEDLINE databases were accessed using the Web of Science search engine by Clarivate Analytics (referred to as WoS search engine). Search syntaxes were fine-tuned taking into account the specificities of the WoS search engine:

- Preference is given for using a dash (“-“) as the WoS search will recognise it as either a dash, a space or a comma. When a dash is utilized, quotation marks around the connected terms are no longer needed (e.g., "acetyl transferase" replaced by acetyl-transferase will retrieve both acetyl transferase and acetyl-transferase), except if there is undesired lemmatisation of the first part of the term.
- Lemmatisation is utilized in the WoS search engine and as thus, terms were evaluated to determine if it was most appropriate to use truncation with a wildcard symbol or to utilize the root word and the lemmatisation feature. For example, using the root term Stack returns results that also include the terms stacks, stacking, stacked. However, searching for the truncated term Stack\* returns additional results that are not associated with the stack word, such as the Stackelberg model.

The different abstracting literature databases are searched individually using the WoS search engine in order to access all of the relevant fields. The employed search interfaces are used in a way so that each is searched more broadly than the title and abstract, also searching keywords (including indexing keywords, where applicable). For example, the topic search (TS) searches the following fields:

- Web of Science Core collection: Title; Abstract; Author Keywords; Keywords Plus<sup>12</sup>
- CABI: Abstract; BHTD Crital Abstract; Broad Descriptors; CABICODES Names; Descriptors; English Title; Foreign Title; Geographic Location; Identifiers; Organism Descriptors<sup>13</sup>
- MEDLINE: Title; Vernacular Title; Abstract; Other Abstract; MeSH Terms; Keyword List; Chemical; Gene Symbol; Personal Name Subject; Space Flight Mission<sup>14</sup>

In CABI, indexing terms are included in the Descriptor fields of the record and can be searched for utilising the topic search as described above. Web of Science Core collection does not utilize controlled vocabulary or thesaurus terms, therefore no further additions were made to the developed search string<sup>15</sup>.

It was observed that the symbol Ø used in the OECD identifier is sometimes replaced by empty-set, circle-divide, or < 0 > and therefore this was considered in the fine-tuning of the search strings (Appendix 1).

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<sup>12</sup> [http://images.webofknowledge.com/WOKRS532JR5/help/WOS/hs\\_topic.html](http://images.webofknowledge.com/WOKRS532JR5/help/WOS/hs_topic.html); Last accessed 14 November 2019

<sup>13</sup> [http://images.webofknowledge.com/WOKRS532JR5/help/CABI/hs\\_topic.html](http://images.webofknowledge.com/WOKRS532JR5/help/CABI/hs_topic.html); Last accessed 14 November 2019

<sup>14</sup> [http://images.webofknowledge.com/WOKRS532JR5/help/MEDLINE/hs\\_topic.html](http://images.webofknowledge.com/WOKRS532JR5/help/MEDLINE/hs_topic.html); Last accessed 14 November 2019

<sup>15</sup> [https://support.clarivate.com/ScientificandAcademicResearch/s/article/Web-of-Science-Core-Collection-No-controlled-vocabulary-or-thesaurus-in-assigning-subject-terms?language=en\\_US](https://support.clarivate.com/ScientificandAcademicResearch/s/article/Web-of-Science-Core-Collection-No-controlled-vocabulary-or-thesaurus-in-assigning-subject-terms?language=en_US)

### 3.3. Conclusion of the suitability of the search strategy

Introduced updates were for consistency or to fine tune the syntaxes to the databases queried. It was confirmed that searches on the single events would find results on the stack events. In addition, specific terms for relevant sub-combinations were added to the search strings when those terms were not already covered by single event terms. As the updated search is as sensitive and not more specific than the previous searches, no additional validation was conducted.

## 4. Results of the literature search exercise

In December 2019, searches against electronic bibliographic databases and manual searches in view of screening of reference lists were performed. The search process is reported in line with EFSA guidance (EFSA, 2010 Appendix B4(2)) in Table 2.

**Table 2.** Documenting and reporting the search process

Resources	Date of search	Period searched*	Other restrictions	Number of records retrieved
Web of Science Core collection <sup>§</sup>	11 Dec 2019	2018-11 Dec 2019	None	231
CABI <sup>§</sup>	11 Dec 2019	2018-11 Dec 2019	None	160
MEDLINE <sup>§</sup>	11 Dec 2019	2018-11 Dec 2019	None	110
Europe PMC <sup>§</sup>	11 Dec 2019	2018-11 Dec 2019	None	29
Screening reference lists <sup>^</sup>	17 Dec 2019	-	2018-17 Dec 2019 <sup>§</sup>	0**

<sup>§</sup> A justification for choosing these search interfaces/databases is provided in Section 3.1. The combination of these sources allows having a broad coverage of publications related to GMO risk assessment.

<sup>^</sup> No risk assessment opinions of the identified regulatory organisations concerning food and feed safety assessment of the authorised GM maize<sup>16</sup>, nor any reviews specifically addressing the safety of these authorised GM maize were identified within the selected literature search period.

<sup>§</sup> The time period was applied post-hoc.

\*\* Number of records screened on full text.

The publications retrieved across all methods of searching (Web of Science Core collection, CABI, Medline, Europe PMC, and screening of reference lists) can be found in Appendix 2. In the framework of the reference list screening exercise, no detailed risk assessments regarding the authorised GM maize<sup>16</sup> nor any reviews were retrieved that contained information on food and feed safety. Considering that no opinions were published within the selected time period no further screening was performed.

The publications grouped in the Endnote® library were deduplicated. Publications retrieved by the previous searches conducted in the frame of the 2018 annual monitoring reports for relevant authorised maize by Pioneer and/or DowAgroSciences were also removed (see Appendix 2, Section 6). The results of the publication selection process are presented in Table 3.

<sup>16</sup> Authorised GM maize include 1507, 59122, 1507xNK603, DAS-40278-9 and 1507x59122xMON810xNK603



**Table 3.** Results of the publication selection process, for the review question

<b>Review question: “Do the authorised GM maize<sup>1</sup> and their respective derived food/feed products, or the intended trait(s) (the newly expressed protein(s) or their combination), have adverse effects on human and animal health and the environment in the scope of their authorisations ?”</b>	<b>Number of records</b>
Total number of publications retrieved after all searches of the scientific literature (excluding duplicates and publications retrieved by the previous searches conducted in the frame of the 2018 monitoring reports)	231
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	219
Total number of full-text documents assessed in detail	12
Number of publications excluded from further consideration after detailed assessment for relevance based on full text	12
Total number of unobtainable/unclear publications	0
Total number of relevant publications	0

The 231 unique entries present in the Endnote database (Table 3) were manually screened for relevance to the review question by two independent reviewers using the a priori eligibility/inclusion criteria described in Table 1.

Entries that are deemed to be irrelevant based on title/abstract were not further retained. In cases where the title/abstract did not contain sufficient information, the publication was assessed for relevance at the level of the full text (as listed in Appendix 3). The reason for excluding a result from the second screening is documented and a justification for not further assessing a reference is provided in Table 3.2 in Appendix 3.

No publications were considered relevant (see Appendix 3, Table 3.1). No unobtainable/unclear publications were identified (see Appendix 3, Table 3.3).

## 5. Conclusion

No publications were identified as relevant for the molecular characterisation, food/feed and environmental safety of the authorised GM maize within the scope of the authorisations for the defined time period. No safety concerns have been identified for the authorised maize by this literature search exercise.

## References

- EFSA, **2010**. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 8(6):1637. [90 pp.].
- EFSA, **2019**. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA supporting publication 2019:EN-1614. [62 pp.].

## Appendix 1. Detailed search syntaxes for the authorised GM maize<sup>1</sup>

### Web of Science Core collection

Set	Search query
Event 1507 #1	TS=(tc1507* OR das-01507-1 OR das01507* OR DAS-Ø15Ø7 OR DAS-circle-divide-15-circle-divide-7 OR DAS-empty-set15empty set7 OR das-01507 OR tc-1507 OR (1507 AND (maize OR corn OR zea OR mays OR Dupont OR Dow OR Pioneer OR Corteva)) OR herculex* or hx-corn or hx-maize)
Event 59122 #2	TS=((59122 AND (maize OR corn OR zea OR mays OR DuPont OR dow OR pioneer OR corteva)) OR das59122* OR das-59122 OR herculex-rw OR (herculex and rootworm) OR (hx AND rw))
Event DAS-40278-9 #3	TS=(DAS40278* OR DAS-40278 OR DAS-4Ø278-9 OR DAS-4-circle-divide-278-9 OR DAS-4empty-set278-9 OR (Enlist* AND (maize OR corn OR zea OR mays OR dow OR Corteva OR herbicid*)))
Stack and Subcombinations (except NK603xMON810) #4	TS=(*1507x59122xMON810xNK603* OR *1507x59122xMON810* OR *1507x59122xNK603* OR *59122x1507xNK603* OR *1507xMON810xNK603* OR *59122xMON810xNK603* OR *1507x59122* OR *1507xMON810* OR *1507xNK603* OR *59122xMON810* OR *59122xNK603* OR acremax OR intrasect)
#5	#1 OR #2 OR #3 OR #4
Protein 1507 #6	TS=(cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))
Protein 59122 #7	TS=(cry34ab1 OR cry34* OR cry35ab1 OR cry35* OR cry-34 OR cry-35 OR cry-34a* OR cry-35a* OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))
Protein DAS-40278-9 #8	TS=(aad-1 OR aryloxyalkanoate-dioxygenase-1)
General #9	TS=(Streptomyces OR viridochromogenes OR sphingobium OR herbicidovorans OR Bacillus OR thuringiensis OR bt OR maize OR corn OR zea OR mays OR (((herbicid* AND (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR gmo OR gmos OR lmo OR lmos OR gm OR ge OR stack)
#10	(#6 OR #7 OR #8) AND #9
Trait 1507 #11	TS=(lepidopter* OR ecb OR corn-borer OR cornborer OR ostrinia OR nubilalis OR earworm OR cutworm OR spodoptera OR frugiperda OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*))

Trait 59122 #12	TS=(coleopter* OR rootworm* OR root-worm* OR virgifera OR WCR OR barberi OR diabrotica* OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*))
Trait DAS-40278-9 #13	TS=((((2-4-D OR AOPP) AND herbicid*) OR 2-4-dichlorophenoxyacetic-acid OR 2-4-dichlorophenoxy-acetic-acid OR aryloxyphenoxypropionate OR aryloxyphenoxy-propionate OR (fop AND (herbicid* or aryloxyphen*)) OR quizalofop OR haloxyfop)
General #14	TS=((toler* OR resist* OR protec*) AND (maize OR corn OR zea OR mays) AND (GMO OR GMOS OR LMO OR LMOS OR living-modified OR transgen* OR GMHT OR ((GM OR GE OR genetic*) NEAR/5 (modif* OR transform* OR manipul* OR engineer* OR stack))))
#15	(#11 OR #12 OR #13) AND #14
Reporting Period #16	PY=(2018-2100)
<b>Final Results</b> #17	(#5 OR #10 OR #15) AND #16

## CABI

Set	Search query
Event 1507 #1	TS=(tc1507* OR das-01507-1 OR das01507* OR DAS-Ø15Ø7 OR DAS-<o>15<o>7 OR das-01507 OR tc-1507 OR (1507 AND (maize OR corn OR zea OR mays OR Dupont OR Dow OR Pioneer OR Corteva)) OR herculex* or hx-corn or hx-maize)
Event 59122 #2	TS=((59122 AND (maize OR corn OR zea OR mays OR DuPont OR dow OR pioneer OR corteve)) OR das59122* OR das-59122 OR herculex-rw OR (herculex and rootworm) OR (hx AND rw))
Event DAS-40278-9 #3	TS=(DAS40278* OR DAS-40278 OR DAS-4Ø278-9 OR DAS-4<o>278-9 OR (Enlist* AND (maize OR corn OR zea OR mays OR dow OR Corteva OR herbicid*)))
Stack and Subcombinations (except NK603xMON810) #4	TS=(*1507x59122xMON810xNK603* OR *1507x59122xMON810* OR *1507x59122xNK603* OR *59122x1507xNK603* OR *1507xMON810xNK603* OR *59122xMON810xNK603* OR *1507x59122* OR *1507xMON810* OR *1507xNK603* OR *59122xMON810* OR *59122xNK603* OR acremax OR intrasect)
#5	#1 OR #2 OR #3 OR #4
Protein 1507 #6	TS=(cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))
Protein 59122 #7	TS=(cry34ab1 OR cry34* OR cry35ab1 OR cry35* OR cry-34 OR cry-35 OR cry-34a* OR cry-35a* OR (phosphinothricin AND

	(acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))
Protein DAS-40278-9 #8	TS=(aad-1 OR aryloxyalkanoate-dioxygenase-1)
General #9	TS=(Streptomyces OR viridochromogenes OR sphingobium OR herbicidovorans OR Bacillus OR thuringiensis OR bt OR maize OR corn OR zea OR mays OR (((herbicid* AND (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR lmo OR lmos OR ge OR "genetically engineered foods" OR stack)
#10	(#6 OR #7 OR #8) AND #9
Trait 1507 #11	TS=(lepidopter* OR ecb OR corn-borer OR cornborer OR ostrinia OR nubilalis OR earworm OR cutworm OR spodoptera OR frugiperda OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*))
Trait 59122 #12	TS=(coleopter* OR rootworm* OR root-worm* OR virgifera OR WCR OR barberi OR diabrotica* OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*))
Trait DAS-40278-9 #13	TS=((((2-4-D OR AOPP) AND herbicid*) OR 2-4-dichlorophenoxyacetic-acid OR 2-4-dichlorophenoxy-acetic-acid OR aryloxyphenoxypropionate OR aryloxyphenoxy-propionate OR (fop AND (herbicid* or aryloxyphen*)) OR quizalofop OR haloxyfop)
General #14	TS=((toler* OR resist* OR protec*) AND (maize OR corn OR zea OR mays) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipul* OR transform* OR stack OR "genetically engineered foods"))
#15	(#11 OR #12 OR #13) AND #14
Reporting Period #16	PY=(2018-2100)
<b>Final Results</b> #17	(#5 OR #10 OR #15) AND #16

## MEDLINE

Set	Search query
Event 1507 #1	TS=(tc1507* OR das-01507-1 OR das01507* OR DAS-Ø15Ø7 OR das-01507 OR tc-1507 OR (1507 AND (maize OR corn OR zea OR mays OR Dupont OR Dow OR Pioneer OR Corteva)) OR herculex* or hx-corn or hx-maize)
Event 59122 #2	TS=((59122 AND (maize OR corn OR zea OR mays OR DuPont OR dow OR pioneer OR corteva)) OR das59122* OR das-59122 OR herculex-rw OR (herculex and rootworm) OR (hx AND rw))

Event DAS-40278-9 #3	TS=(DAS40278* OR DAS-40278 OR DAS-40278-9 OR (Enlist* AND (maize OR corn OR zea OR mays OR dow OR Corteva OR herbicid*)))
Stack and subcombinations (except NK603xMON810) #4	TS=(*1507x59122xMON810xNK603* OR *1507x59122xMON810* OR *1507x59122xNK603* OR *59122x1507xNK603* OR *1507xMON810xNK603* OR *59122xMON810xNK603* OR *1507x59122* OR *1507xMON810* OR *1507xNK603* OR *59122xMON810* OR *59122xNK603* OR acremax OR intrasect)
#5	#1 OR #2 OR #3 OR #4
Protein 1507 #6	TS=(cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))
Protein 59122 #7	TS=(cry34ab1 OR cry34* OR cry35ab1 OR cry35* OR cry-34 OR cry-35 OR cry-34a* OR cry-35a* OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))
Protein DAS-40278-9 #8	TS=(aad-1 OR aryloxyalkanoate-dioxygenase-1)
General #9	TS=(Streptomyces OR viridochromogenes OR sphingobium OR herbicidovorans OR Bacillus OR thuringiensis OR bt OR maize OR corn OR zea OR mays OR (((herbicid* AND (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR lmo OR lmos OR ge OR "Food, Genetically Modified" OR stack)
#10	(#6 OR #7 OR #8) AND #9
Trait 1507 #11	TS=(lepidopter* OR ecb OR corn-borer OR cornborer OR ostrinia OR nubilalis OR earworm OR cutworm OR spodoptera OR frugiperda OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*))
Trait 59122 #12	TS=(coleopter* OR rootworm* OR root-worm* OR virgifera OR WCR OR barberi OR diabrotica* OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*))
Trait DAS-40278-9 #13	TS=((((2-4-D OR AOPP) AND herbicid*) OR 2-4-dichlorophenoxyacetic-acid OR 2-4-dichlorophenoxy-acetic-acid OR aryloxyphenoxypropionate OR aryloxyphenoxy-propionate OR (fop AND (herbicid* OR aryloxyphen*)) OR quizalofop OR haloxyfop)
General #14	TS=((toler* OR resist* OR protec*) AND (maize OR corn OR zea OR mays) AND (GMHT OR transgen* OR engineer* OR lmo OR lmos OR ge OR manipul* OR transform* OR stack OR "Food, Genetically Modified"))
#15	(#11 OR #12 OR #13) AND #14
Reporting Period #16	PY=(2018-2100)

<b>Final Results</b> #17	(#5 OR #10 OR #15) AND #16
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### Europe PMC

(1507x59122xMON810xNK603 OR 1507x59122xMON810 OR 1507x59122xNK603 OR 1507xMON810xNK603 OR 59122xMON810xNK603 OR 1507x59122 OR 1507xMON810 OR 1507xNK603 OR 59122xMON810 OR 59122xNK603 OR tc1507 OR “tc-1507” OR DAS01507\* OR “DAS-01507” OR DASØ15Ø7 OR “DAS-Ø15Ø7” OR “1507 corn” OR “1507 maize” OR “maize 1507” OR “corn 1507” OR das59122 OR “das-59122” OR “59122 corn” OR “59122 maize” OR “maize 59122” OR “corn 59122” OR DAS40278 OR “DAS-40278” OR DAS4Ø278 OR “DAS-4Ø278” OR “40278 corn” OR “40278 maize” OR “maize 40278” OR “corn 40278”) AND (FIRST\_PDATE:[2018-01-01 TO 2100-12-31])

## **Appendix 2. Entries retrieved by the performed searches to literature databases for the authorised GM maize within the indicated search period**

Note: the numbering of the references in the different appendixes is independent of each other (e.g. a certain reference might be called EFSA 2018a in one appendix and EFSA 2018b in another)

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**5. Entries retrieved using reference lists of opinions of regulatory bodies and screened on full text**<sup>17</sup>

None

**6. New entries retrieved using all search strategies (excluding duplicates and studies retrieved by the previous searches conducted in 2018)**

2019. Scientific advice on the Testbiotech's request for internal review of Commission

<sup>17</sup> The time-period is applied post-hoc as described in Table 2

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### Appendix 3. Publications screened for relevance based on the full text

**Table 3.1.** Report of all relevant publications retrieved after detailed assessment of full-text documents for relevance

Category of information/ data requirement(s)	Reference (Author, year, title, source)
None	Not applicable

**Table 3.2.** Report of publications excluded from the risk assessment after detailed assessment of full-text documents

Reference (Author, year, title, source)	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
Brancato A, Brocca D, Cabrera LC, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Riemenschneider C, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Villamar-Bouza L and Efsa, 2018. Setting of import tolerance for quizalofop-P-ethyl in genetically modified maize. Efsa Journal 16, 23.	Population (setting Import tolerance) Reporting format (not primary research)
EFSA, 2019. Scientific advice on the Testbiotech's request for internal review of Commission Implementing Decision (EU) No 2018/2046 on maize MON 87427 * MON 89034 * 1507 * MON 88017 * 59122 and subcombinations (application EFSA-GMO-BE-2013-118). EFSA Supporting Publications 16, 1603E.	Reporting format (not primary research)
Coradi PC, de Souza AHS, Camilo LJ, Lemes AFC and Milane LV, 2019. Analysis of the physical quality of genetically modified and conventional maize grains in the drying and wetting processes. Revista Ciencia Agronomica 50, 370-377.	Population (physical qualitative analysis); Comparator
Costa FR, Rech R, Duke SO and Carvalho LB, 2018. Lack of effects of glyphosate and glufosinate on growth, mineral content, and yield of glyphosate- and glufosinate-resistant maize. Gm Crops & Food-Biotechnology in Agriculture and the Food Chain 9, 189-198.	Population (comparison of different herbicide treatments)
Dolezel M, Miklau M, Heissenberger A and Reichenbecher W, 2018. Limits of Concern: suggestions for the operationalisation of a concept to determine the relevance of adverse effects in the ERA of GMOs. Environmental Sciences Europe 30, 21.	Population; Intervention/Exposure (not on the authorised GM maize)
Krenchinski FH, Carbonari CA, Cesco VJS, Albrecht AJP, Arcuri MDC, Maia ID and Velini ED, 2018. Glufosinate Resistance Level is Proportional to Phosphinothricin Acetyltransferase Gene Expression in Glufosinate-Resistant Maize. Journal of Agricultural and Food Chemistry 66, 12641-12650.	Outcome (pat mRNA expression <sup>18</sup> used to address a question related to herbicide efficacy)

<sup>18</sup> In addition, for risk assessment purpose, gene expression for genes expressing a protein is conducted by analyzing protein levels.

Krenchinski FH, Cesco VJS, Castro EB, Carbonari CA and Velini ED, 2019. Ammonium glufosinate associated with post-emergence herbicides in corn with the cp4-epsps and pat genes. <i>Planta Daninha</i> 37.	Intervention/exposure (not on the authorised GM maize); Population (weed control with different herbicide regimes - herbicide selectivity); Comparator
Larue CT, Goley M, Shi L, Evdokimov AG, Sparks OC, Ellis C, Wollacott AM, Rydel TJ, Halls CE, Van Scoyoc B, Fu XR, Nageotte JR, Adio AM, Zheng MY, Sturman EJ, Garvey GS and Varagona MJ, 2019. Development of enzymes for robust aryloxyphenoxypionate and synthetic auxin herbicide tolerance traits in maize and soybean crops. <i>Pest Management Science</i> 75, 2086-2094.	Intervention/Exposure (Not on the authorised GM maize or corresponding proteins)
Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal JM, Alvarez F, Ardizzone M, De Sanctis G, Dumont AF, Gomez JAR, Lanzoni A, Papadopoulou N, Paraskevopoulos K and Modified EPG, 2018. Assessment of genetically modified maize 1507 x NK603 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-008). <i>Efsa Journal</i> 16, 11.	Reporting format (not primary research) <sup>19</sup>
Naegeli H, Bresson JL, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogue F, Rostoks N, Serrano JJS, Savoini G, Veromann E, Veronesi F, Alvarez F, Ardizzone M, Dumont AF, Gennaro A, Ruiz JAG, Lanzoni A, Neri FM, Papadopoulou N, Ramon M and Modified EPG, 2019. Assessment of genetically modified maize MON89034x1507xNK603xDAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing, under Regulation (EC) No1829-2003 (application EFSA-GMO-NL-2013-112). <i>Efsa Journal</i> 17, 30.	Reporting format (not primary research) <sup>19</sup>
Naegeli H, Bresson JL, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogue F, Rostoks N, Serrano JJS, Savoini G, Veromann E, Veronesi F, Ardizzone M, Dumont AF, Gennaro A, Ruiz JAG, Lanzoni A, Neri FM, Papadopoulou N, Ramon M and Modified EPG, 2019. Assessment of genetically modified maize MON89034x1507xMON88017x59122xDAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No1829/2003 (application EFSA-GMO-NL-2013-113). <i>Efsa Journal</i> 17, 30.	Reporting format (not primary research) <sup>19</sup>
Wang X, Zhang X, Yang J, Liu X, Song Y and Wang Z, 2019. Genetic variation assessment of stacked-trait transgenic maize via conventional breeding. In: <i>Bmc Plant Biology</i> . p 346.	Intervention/Exposure (Not on the authorised GM maize)

<sup>19</sup> In line with the eligibility/inclusion criteria described in Table 1, this publication is a risk assessment from an international body however as it is from EFSA it is excluded and not considered further.



**Table 3.3.** Report of unobtainable/unclear publications

Reference (Author, year, title, source)	Description of (unsuccessful) methods used to try to obtain a copy of the publication
None	Not applicable