Review of literature for authorised genetically modified maize products in the scope of their authorisations for food and feed uses, import and processing in the EU (2020 update)

Products covered:

Single events: 1507, 59122, 4114, DAS-40278-9

Stacks: 1507xNK603, 1507x59122xMON810xNK603, MON89034x1507xMON88017x59122xDAS-40278-9, MON89034x1507xNK603xDAS-40278-9 and their subcombinations covered by the authorisations

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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, 4114, DAS-40278-9, 1507xNK603, 1507x59122xMON810xNK603, MON89034x1507xMON88017x59122xDAS-40278-9, MON89034x1507xNK603xDAS-40278-9 and their sub-combinations covered by the respective authorisations[1] (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 current systematic search complements the search performed in 2019 and further considers the maize products first authorised in the current reporting period (4114, MON89034x1507xMON88017x59122xDAS-40278-9 and MON89034x1507xNK603xDAS-40278-9 and their sub-combinations covered by the authorisations). Unless outlined below, all portions of the search were conducted according to the methodologies outlined in the previous search. Search string terms covering the newly authorised products were included based on the searches previously provided to EFSA.

The outcome of this analysis showed that three publications relevant for the review question were identified (notably for 1507, 1507xMON810, stacks with 1507 and DAS-40278-9 maize) during the selected time period. No safety concerns were identified for the authorised GM maize[2] by this literature search exercise.

2. Confirmation of the Suitability of the Search Strings

It was confirmed that the search strategy utilized in the previous literature search report (2019) is still relevant. All updates are related to the inclusion of products that were approved since the last reporting period (4114, MON89034x1507xMON88017x59122xDAS-40278-9 and sub-combinations, and MON89034x1507xNK603xDAS-40278-9 and sub-combinations). The included search terms were extracted from search strategies previously submitted to EFSA. 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 covered by the authorisations. 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.

[1] 1507x59122xMON810xNK603 maize and the following subcombinations: 1507x59122xMON810, 59122x1507xNK603, 1507xMON810xNK603, 59122xMON810xNK603, 1507x59122, 1507xMON810, 59122xMON810, 59122xNK603 as per Commission Implementing decision (EU) 2018/1110.

MON89034x1507xMON88017x59122xDAS-40278-9 and the following subcombinations: MON89034x1507x MON88017xDAS-40278-9, MON89034x1507x59122xDAS-40278-9, MON89034xMON88017x59122xDAS-40278-9, 1507xMON88017x59122xDAS-40278-9, MON89034x1507xDAS-40278-9, MON89034xMON88017 xDAS-40278-9, MON89034x59122xDAS-40278-9, 1507xMON88017xDAS-40278-9, 1507x59122xDAS-40278-9, MON88017x59122xDAS-40278-9, MON89034xDAS-40278-9, 1507xDAS40278-9, MON88017xDAS-40278-9, 59122xDAS-40278-9 as per Commission Implementing decision (EU) 2019/2086.

MON89034x1507xNK603xDAS-40278-9 and the subcombination: MON89034xNK603xDAS-40278-9, 1507x NK603xDAS-40278-9 and NK603xDAS-40278-9 as per Commission Implementing decision (EU) 2019/2085.

[2] As previously defined, 1507, 59122, 4114, DAS-40278-9, 1507xNK603, 1507x59122xMON810xNK603, MON89034x1507xMON88017x59122xDAS-40278-9, MON89034x1507xNK603xDAS-40278-9 maize and their sub-combinations covered by the respective authorisations.

As the updated search is as sensitive and not more specific than the previous searches, no additional validation was conducted.

3. Results of the scoping exercixe

3.1. Outcome of the literature searches

In October 2020, 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 1. Documenting and reporting the search process

Resources	Date of search	Period searched	Other restrictions	Number of records retrieved
Web of Science Core collection[#$]	8 Oct 2020	2019-8 Oct 2020	None	206
CAB Abstracts[#$]	8 Oct 2020	2019-8 Oct 2020	None	106
MEDLINE[#$]	8 Oct 2020	2019-8 Oct 2020	None	108
Europe PMC[#$]	8 Oct 2020	2019-8 Oct 2020	None	30
Screening reference lists	8 Oct 2020	-	2019-8 Oct 2020[§]	0*

[#] A justification for chosing these databases was provided in Section 2.2 of the previous literature search report (2019). The combination of these sources allows having a broad coverage of publications related to GMO risk assessment.
[$] The search syntaxes used are reported in Appendix 1 for electronic bibliographic databases.
§ 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, CAB Abstracts, MEDLINE, Europe PMC, and screening of reference lists) can be found in Appendix 3.

In the framework of the reference list screening exercise, no detailed risk assessments regarding the authorised GM maize 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 2019 annual monitoring reports were also removed (see Appendix 3, Section 6).

The results of the publication selection process are presented in Table 2.

Table 2. Results of the publication selection process, for the review question

Review question: "Do the authorised GM maize[2] 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 ?"	**Number of records**
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 2019 monitoring reports)	137
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	127
Total number of full-text documents assessed in detail	10
Number of publications excluded from further consideration after detailed assessment for relevance based on full text	6
Total number of unobtainable/unclear publications	1
Total number of relevant publications	3

The 137 unique entries present in the Endnote database (Table 2) were manually screened for relevance to the review question by two independent reviewers using the *a priori* eligibility/inclusion criteria described in Appendix 2.

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 progressed to the second stage and assessed for relevance at the level of the full text (as listed in Appendix 4). 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 4.2 in Appendix 4. An unclear publication was identified (see Appendix 4, Table 4.3).

In this literature search exercise, three peer-reviewed publications relevant to the risk assessment of the authorised GM maize were identified (Chekan et al., 2019, de Cerqueira et al., 2019; Ramos et al., 2020) (see Section 4 and Appendix 4, Table 4.1). Details are provided in Tables 3 to 5, in the format laid out by the Commission decision 2009/770/EC (EC, 2009).

Table 3: Review of relevant peer-reviewed publication in 2009/770/EC format: Molecular characterisation - DAS-40278-9 maize (Chekan et al., 2019)

Publication	Summary of research and results[3]	Protection goal	Observed parameter	Adverse effects	Feedback on initial risk assessment
Chekan JR, Ongpipattanakul C, Wright TR, Zhang B, Bollinger JM, Jr., Rajakovich LJ, Krebs C, Cicchillo RM and Nair SK, 2019. Molecular basis for enantioselective herbicide degradation imparted by aryloxyalkanoate dioxygenases in transgenic plants. Proceedings of the National Academy of Sciences of the United States of America 116, 13299-13304.	The authors used a "genomic context based analysis to identify additional members of the AAD class". The authors also solved the structure of AAD-1 in complex with the synthetic auxin (R)-dichlorprop and with the AOPP herbicides (R)-cyhalofop and (R)-diclofop, as well as of AAD-2). As the authors mentioned, "one noteworthy outcome of this study is that, thus far, AAD-1 is the only characterized member that shows substrate specificity for the (R)-enantiomer, while members with the opposite (S) enantiospecificity are more prevalent (namely, AAD-2 and AAD-12, among others". This structure-based analysis revealed the basis for the broad substrate tolerance of AAD-1.	Molecular characterisation	Molecular and biochemical characterisation of the newly expressed protein	None	No change

[3] Text between double quotes is an excerpt from above-mentioned publication.

Table 4: Review of relevant peer-reviewed publication in 2009/770/EC format: Molecular characterisation – stacks with 1507 (De Cerqueira et al., 2019)

Publication	**Summary of research and results[4]**	**Protection goal[5]**	**Observed parameter**	**Adverse effects**	**Feedback on initial risk assessment**
De Cerqueira DT, Fast BJ, Silveira AC and Herman RA, 2019. Transgene-product expression levels in genetically engineered breeding stacks are equivalent to those of the single events. GM crops & food 10, 35-43.	The objective of this study was to determine if the expression levels of newly expressed proteins in single events, notably 1507 maize and other single events in maize and other crops, are "accurate predictors of trangene product expression" in breeding stacks, in particular MON89034x1507xMIR162xNK603 for maize. Particularly, the authors conducted ELISA expression studies with various 1507 maize and MON89034x1507xMIR162xNK603 maize stack tissue samples collected from 6 field trial sites in a randomized complete block design with four replicate blocks at each site, in Argentina in the 2014–2015 growing season. The authors plotted expression levels of Cry1F and PAT in the MON89034x1507xMIR162xNK603 maize stack against expression levels in the 1507 single event (as well as of newly expressed proteins from the other single events), to quantify "the ability of the single events to predict transgene product expression levels in the breeding stack." The authors used the coefficient of identity (I^2), based on the percent of variation of the plotted points accounted for by the line of identity (y = x). They conclude that "The similarity between transgene product expression levels in single events and breeding stacks indicates that expression of transgene products in single events is a reliable predictor of expression in breeding stacks."	Molecular characterisation	Expression data	None	No change

[5] Text between double quotes is an excerpt from above-mentioned publication.

Table 5: Review of relevant peer-reviewed publication in 2009/770/EC format: Food Feed / Agronomic and phenotypic characteristics – 1507 and 1507xMON810 maize (Ramos et al., 2020)

Publication	Summary of research and results[6]	Protection goal	Observed parameter	Adverse effects	Feedback on initial risk assessment
Ramos LN, Souza NOS and Vilela MS, 2020. Agronomic parameters and morpho-agronomic characteristics of genetically modified maize hybrids compared to conventional maize hybrids. Bioscience Journal 36, 1156-1166.	As indicated by the authors, the aim of this study was "to study the behavior of fifteen pre-commercial upland maize hybrids, analyze their agronomic performance regarding grain yield, and evaluate productivity components, as well as morpho-agronomic characteristics, in the Midwest Region of Brazil". The authors assessed five pre-commercial maize hybrids (HPA252, HPB262, HPB621, HPB646 and HPD354), each in three different versions: non-genetically modified, version with 1507 and version with 1507xMON810, in a randomized block experiment with four replications at two locations in the 2016-2017 growing season. The parameters analysed were plant height, ear insertion height, number of rows per ear, number of grains per row, grain depth, stem diameter, ear diameter, corncob diameter, thousand grains weight and productivity. From this experiment the authors recommend keeping some pre-commercial hydrids, however no consistent trend of the transgenic events has been observed on the overall agronomic performances across the tested hybrids.	Agronomic, phenotypic characterisation	Agronomic and phenotypic characteristics	None	No change

[6] Text between double quotes is an excerpt from above-mentioned publication.

4. Conclusion

Three publications were identified as relevant for the molecular characterisation, food/feed and environmental safety of the authorised GM maize (notably for 1507, 1507xMON810, stacks with 1507 and DAS-40278-9 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

Chekan JR, Ongpipattanakul C, Wright TR, Zhang B, Bollinger JM, Jr., Rajakovich LJ, Krebs C, Cicchillo RM and Nair SK, **2019**. Molecular basis for enantioselective herbicide degradation imparted by aryloxyalkanoate dioxygenases in transgenic plants. Proceedings of the National Academy of Sciences of the United States of America 116, 13299-13304.

de Cerqueira DT, Fast BJ, Silveira AC and Herman RA, **2019**. Transgene-product expression levels in genetically engineered breeding stacks are equivalent to those of the single events. GM crops & food 10, 35-43.

EC, **2009**. Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council. Official Journal of the European Union 275, 9-27.

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.].

Ramos LN, Souza NOS and Vilela MS, **2020**. Agronomic parameters and morpho-agronomic characteristics of genetically modified maize hybrids compared to conventional maize hybrids. Bioscience Journal 36, 1156-1166.

Appendix 1. Detailed search syntaxes for the authorised GM maize

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 4114 #3	TS=(DP-ØØ4114 OR DP-circle-divide-circle-divide-4114 OR DP-empty-setempty-set4114 OR dp-004114 OR dp004114* OR DP4114 OR (4114 AND (maize OR corn OR zea OR mays OR Dupont OR Corteva)))
Event DAS-40278-9 #4	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 relevant subcombinations #5	TS=(*1507x59122xMON810xNK603* OR *1507x59122xMON810* OR *1507x59122xNK603* OR *59122x1507xNK603* OR *1507xMON810xNK603* OR *59122xMON810xNK603* OR *1507x59122* OR *1507xMON810* OR *1507xNK603* OR *59122xMON810* OR *59122xNK603* OR *MON89034x1507xNK603xDAS-40278-9* OR *MON89034xNK603xDAS-40278-9* OR *1507xNK603xDAS-40278-9* OR *MON89034x1507xMON88017x59122xDAS-40278-9* OR *MON89034x1507xMON88017xDAS-40278-9* OR *MON89034x1507x59122xDAS-40278-9* OR *1507xMON88017x59122xDAS-40278-9* OR *MON89034x1507xDAS-40278-9* OR *MON89034xMON88017xDAS-40278-9* OR *MON89034x59122xDAS-40278-9* OR *1507xMON88017xDAS-40278-9* OR *1507x59122xDAS-40278-9* OR *MON88017x59122xDAS-40278-9* OR *MON89034xDAS-40278-9* OR *1507xDAS-40278-9* OR *MON88017xDAS-40278-9* OR *59122xDAS-40278-9* OR acremax OR smartstax*-enlist* OR Powercore*-enlist* OR intrasect OR stack)
#6	#1 OR #2 OR #3 OR #4 OR #5
Protein 1507 #7	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	TS=(cry34ab1 OR cry34* OR cry35ab1 OR cry35* OR cry-34 OR cry-35 OR cry-34a* OR cry-35a* OR (phosphinothricin AND

#8	(acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))
Protein 4114 #9	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) OR cry34ab1 OR cry34* OR cry35ab1 OR cry35* OR (cry NEAR/0 (34 OR 35 OR 34a* OR 35a*)))
Protein DAS-40278-9 #10	TS=(aad-1 OR aryloxyalkanoate-dioxygenase-1)
General #11	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)
#12	(#7 OR #8 OR #9 OR #10) AND #11
Trait 1507 #13	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 #14	TS=(coleopter* OR rootworm* OR root-worm* OR virgifera OR WCR OR barberi OR diabrotica* OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*))
Trait 4114 #15	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*) OR coleopter* OR rootworm* OR root-worm* OR diabrotica OR virgifera OR WCR OR barberi)
Trait DAS-40278-9 #16	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 #17	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 manipulat* OR engineer* OR stack))))
#18	(#13 OR #14 OR #15 OR #16) AND #17
Reporting Period #19	PY=(2019-2100)
Final Results #20	(#6 OR #12 OR #18) AND #19

CAB Abstracts

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 corteva)) OR das59122* OR das-59122 OR herculex-rw OR (herculex and rootworm) OR (hx AND rw))
Event 4114 #3	TS=(DP-ØØ4114 OR DP-<o><o>4114 OR dp-004114 OR dp004114* OR DP4114 OR (4114 AND (maize OR corn OR zea OR mays OR Dupont OR Corteva)))
Event DAS-40278-9 #4	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 relevant subcombinations #5	TS=(*1507x59122xMON810xNK603* OR *1507x59122xMON810* OR *1507x59122xNK603* OR *59122x1507xNK603* OR *1507xMON810xNK603* OR *59122xMON810xNK603* OR *1507x59122* OR *1507xMON810* OR *1507xNK603* OR *59122xMON810* OR *59122xNK603* OR *MON89034x1507xNK603xDAS-40278-9* OR *MON89034xNK603xDAS-40278-9* OR *1507xNK603xDAS-40278-9* OR *MON89034x1507xMON88017x59122xDAS-40278-9* OR *MON89034x1507xMON88017xDAS-40278-9* OR *MON89034x1507x59122xDAS-40278-9* OR *1507xMON88017x59122xDAS-40278-9* OR *MON89034x1507xDAS-40278-9* OR *MON89034xMON88017xDAS-40278-9* OR *MON89034x59122xDAS-40278-9* OR *1507xMON88017xDAS-40278-9* OR *1507x59122xDAS-40278-9* OR *MON88017x59122xDAS-40278-9* OR *MON89034xDAS-40278-9* OR *1507xDAS-40278-9* OR *MON88017xDAS-40278-9* OR *59122xDAS-40278-9* OR acremax OR smartstax*-enlist* OR Powercore*-enlist* OR intrasect OR stack)
#6	#1 OR #2 OR #3 OR #4 OR #5
Protein 1507 #7	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 #8	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 4114 #9	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) OR cry34ab1 OR cry34* OR cry35ab1 OR cry35* OR (cry NEAR/0 (34 OR 35 OR 34a* OR 35a*)))
Protein DAS-40278-9 #10	TS=(aad-1 OR aryloxyalkanoate-dioxygenase-1)
General #11	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)
#12	(#7 OR #8 OR #9 OR #10) AND #11
Trait 1507 #13	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 #14	TS=(coleopter* OR rootworm* OR root-worm* OR virgifera OR WCR OR barberi OR diabrotica* OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*))
Trait 4114 #15	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*) OR coleopter* OR rootworm* OR root-worm* OR diabrotica OR virgifera OR WCR OR barberi)
Trait DAS-40278-9 #16	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 #17	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 manipulat* OR transform* OR stack OR "genetically engineered foods"))
#18	(#13 OR #14 OR #15 OR #16) AND #17
Reporting Period #19	PY=(2019-2100)
Final Results #20	(#6 OR #12 OR #18) AND #19

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 4114 #3	TS=(DP-ØØ4114 OR dp-004114 OR dp004114* OR DP4114 OR (4114 AND (maize OR corn OR zea OR mays OR Dupont OR Corteva)))
Event DAS-40278-9 #4	TS=(DAS40278* OR DAS-40278 OR DAS-4Ø278-9 OR (Enlist* AND (maize OR corn OR zea OR mays OR dow OR Corteva OR herbicid*)))
Stack and relevant subcombinations #5	TS=(*1507x59122xMON810xNK603* OR *1507x59122xMON810* OR *1507x59122xNK603* OR *59122x1507xNK603* OR *1507xMON810xNK603* OR *59122xMON810xNK603* OR *1507x59122* OR *1507xMON810* OR *1507xNK603* OR *59122xMON810* OR *59122xNK603* OR *MON89034x1507xNK603xDAS-40278-9* OR *MON89034xNK603xDAS-40278-9* OR *1507xNK603xDAS-40278-9* OR *MON89034x1507xMON88017x59122xDAS-40278-9* OR *MON89034x1507xMON88017xDAS-40278-9* OR *MON89034x1507x59122xDAS-40278-9* OR *1507xMON88017x59122xDAS-40278-9* OR *MON89034x1507xDAS-40278-9* OR *MON89034xMON88017xDAS-40278-9* OR *MON89034x59122xDAS-40278-9* OR *1507xMON88017xDAS-40278-9* OR *1507x59122xDAS-40278-9* OR *MON88017x59122xDAS-40278-9* OR *MON89034xDAS-40278-9* OR *1507xDAS-40278-9* OR *MON88017xDAS-40278-9* OR *59122xDAS-40278-9* OR acremax OR smartstax*-enlist* OR Powercore*-enlist* OR intrasect OR stack)
#6	#1 OR #2 OR #3 OR #4 OR #5
Protein 1507 #7	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 #8	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 4114 #9	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) OR cry34ab1 OR cry34* OR cry35ab1 OR cry35* OR (cry NEAR/0 (34 OR 35 OR 34a* OR 35a*)))
Protein DAS-40278-9 #10	TS=(aad-1 OR aryloxyalkanoate-dioxygenase-1)
General #11	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)
#12	(#7 OR #8 OR #9 OR #10) AND #11
Trait 1507 #13	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 #14	TS=(coleopter* OR rootworm* OR root-worm* OR virgifera OR WCR OR barberi OR diabrotica* OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*))
Trait 4114 #15	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*) OR coleopter* OR rootworm* OR root-worm* OR diabrotica OR virgifera OR WCR OR barberi)
Trait DAS-40278-9 #16	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 #17	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 manipulat* OR transform* OR stack OR "Food, Genetically Modified"))
#18	(#13 OR #14 OR #15 OR #16) AND #17
Reporting Period #19	PY=(2019-2100)
Final Results #20	(#6 OR #12 OR #18) AND #19

Europe PMC

(1507x59122xMON810xNK603 OR 1507x59122xMON810 OR 1507x59122xNK603 OR 1507xMON810xNK603 OR 59122xMON810xNK603 OR 1507x59122 OR 1507xMON810 OR 1507xNK603 OR 59122xMON810 OR 59122xNK603 OR "MON89034x1507xNK603xDAS-40278" OR "MON89034xNK603xDAS-40278" OR "1507xNK603xDAS-40278" OR "MON89034x1507xMON88017x59122xDAS-40278" OR "MON89034x1507xMON88017xDAS-40278" OR "MON89034x1507x59122xDAS-40278" OR "1507xMON88017x59122xDAS-40278" OR "MON89034x1507xDAS-40278" OR "MON89034xMON88017xDAS-40278" OR "MON89034x59122xDAS-40278" OR "1507xMON88017xDAS-40278" OR "1507x59122xDAS-40278" OR "MON88017x59122xDAS-40278" OR "MON89034xDAS-40278" OR "1507xDAS-40278" OR "MON88017xDAS-40278" OR "59122xDAS-40278" 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 "DP-ØØ4114" OR "dp-004114" OR dp004114 OR DP4114 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:[2019-01-01 TO 2100-12-31])

Appendix 2. Eligibility/Inclusion Criteria

Concept	Criteria
Population (taking into account scope of the authorisation)	Publication 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 **I**ntervention/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 authorisation for food, food, import, efficacy of the traits, pest susceptibility, etc. are not considered relevant).
Intervention/exposure	Publication addressing authorised GM maize[2] and derived food/feed products, and/or the intended traits (newly expressed protein(s) or their combination, 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.

Appendix 3. 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 2020a in one appendix and EFSA 2020b in another)

1. Entries retrieved using Web of Science Core collection

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Appendix 4. Publications screened for relevance based on the full text

Table 4.1. 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)
Agronomic, phenotypic characterisation (1507, 1507xMON810)	Ramos LN, Souza NOS and Vilela MS, 2020. Agronomic parameters and morpho-agronomic characteristics of genetically modified maize hybrids compared to conventional maize hybrids. Bioscience Journal 36, 1156-1166.
Molecular characterisation (1507 stacks)	de Cerqueira DT, Fast BJ, Silveira AC and Herman RA, 2019. Transgene-product expression levels in genetically engineered breeding stacks are equivalent to those of the single events. GM crops & food 10, 35-43.
Molecular characterisation (DAS-40278-9)	Chekan JR, Ongpipattanakul C, Wright TR, Zhang B, Bollinger JM, Jr., Rajakovich LJ, Krebs C, Cicchillo RM and Nair SK, 2019. Molecular basis for enantioselective herbicide degradation imparted by aryloxyalkanoate dioxygenases in transgenic plants. Proceedings of the National Academy of Sciences of the United States of America 116, 13299-13304.

Table 4.2. 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
de Souza MWR, Ferreira EA, dos Santos JB, Soares MA, Castro B and Zanuncio JC, 2020. Fluorescence of chlorophyll a in transgenic maize with herbicide application and attacked by Spodoptera frugiperda (Lepidoptera: Noctuidae). Phytoparasitica 48, 567-573.	Outcome (chlorophyll fluorescence measurement in relation to insect efficacy/damage)
Fast BJ, Shan GM, Gampala SS and Herman R, 2020. Transgene expression in sprayed and non-sprayed herbicide-tolerant genetically engineered crops is equivalent. Regulatory Toxicology and Pharmacology 111, 8.	Intervention/exposure (not on authorised GM maize) ; Comparator (no non-GM variety)
Jose M, Vertuan H, Soares D, Sordi D, Bellini LF, Kotsubo R and Berger GU, 2020. Comparing agronomic and phenotypic plant characteristics between single and stacked events in soybean, maize, and cotton. In: PLoS One. p e0231733.	Intervention/exposure (not on authorised GM maize)
Krenchinski FH, Carbonari CA, Castro EBd, Rodrigues DM, Cesco VJS, Costa RN and Velini ED, 2020. Post-emergence application of glufosinate on maize hybrids containing the phosphinothricin acetyltransferase gene	Comparator (no non-GM variety); Population (herbicide treatment effect)

(pat). Australian Journal of Crop Science 14, 1095-1101.	
McDonald J, Burns A and Raybould A, 2020. Advancing ecological risk assessment on genetically engineered breeding stacks with combined insect-resistance traits. Transgenic Research 29, 135-148.	Intervention/exposure (not on authorised GM maize)
Mendes RR, Franchini LHM, Lucio FR, Zobiole LHS and Oliveira RS, 2020. Aryloxyphenoxypropionates tolerant and non-tolerant corn: plant-back interval after acetyl-coA-carboxylase inhibitors applications. Planta Daninha 38, 8.	Population (herbicide regime and efficacy)

Table 4.3. Report of unobtainable/unclear publications

Reference (Author, year, title, source)	**Description of (unsuccessful) methods used to try to obtain a copy of the publication**
de Souza LT, Pereira J and de Oliveira SM, 2019. Transgenic events interference on maize morphological and productive attributes. Revista Agrogeoambiental 11, 35-44	The GM plant material used in this study is unclear. The authors were contacted; they confirmed that both 1507 and T25 single events were used. They seem to think that PAT is from T25 event, although we would have thought that 1507 hybrids (with both Cry1F and PAT) were used as the single event in the experiment.[8]

[8] In this publication, the authors assessed morphological characteristics and yield from experiments in Brazil and concluded that the transgenic hybrids used (single events and stacks) "presented 5% higher plant height and 10% higher grain yield than the conventional hybrids." This does not impact on persistence and invasiveness and does not change the previous risk assessement for 1507 maize, should 1507 have been used in the experiment.