

**Review of literature for authorised genetically modified maize products
in the scope of their authorisations for food and feed uses, import and
processing (2021 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 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 their respective authorisations¹ (hereafter collectively referred to as “authorised GM maize”). This exercise was performed 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), with the following review question “Do the authorised GM maize² 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 2020. Unless indicated below, all portions of the search were conducted according to the methodologies outlined in the previous searches.

The outcome of this analysis showed that one publication relevant for the review question was identified (notably for 1507 and 4114 maize) during the selected time period. No safety concerns were identified for the authorised GM maize² 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 (2020) in the frame of the 2020 annual monitoring reports is still relevant; updates were introduced only for consistency or to fine-tune the syntaxes to the databases queried. It was previously confirmed that searches on the single events would find results on the stack events covered by the authorisations.

3. Results of the scoping exercise

3.1. Outcome of the literature searches

In July 2021, 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 1.

¹ 1507x59122xMON810xNK603 maize and the following subcombinations: 1507x59122xMON810, 59122x1507xNK603, 1507xMON810xNK603, 59122xMON810xNK603, 1507x59122, 1507xMON810, 59122xMON810, 59122xNK603.

MON89034x1507xMON88017x59122xDAS-40278-9 and the following subcombinations: MON89034x1507xMON88017xDAS-40278-9, MON89034x1507x59122xDAS-40278-9, MON89034xMON88017x59122xDAS-40278-9, 1507xMON88017x59122xDAS-40278-9, MON89034x1507xDAS-40278-9, MON89034xMON88017xDAS-40278-9, MON89034x59122xDAS-40278-9, 1507xMON88017xDAS-40278-9, 1507x59122xDAS-40278-9, MON88017x59122xDAS-40278-9, MON89034xDAS-40278-9, 1507xDAS-40278-9, MON88017xDAS-40278-9, 59122xDAS-40278-9.

MON89034x1507xNK603xDAS-40278-9 and the following subcombinations: MON89034xNK603xDAS-40278-9, 1507xNK603xDAS-40278-9 and NK603xDAS-40278-9.

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 their respective authorisations.

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 [§]	6 July 2021	1 Jan 2020-6 July 2021	None	173
CAB Abstracts [§]	6 July 2021	1 Jan 2020-6 July 2021	None	109
MEDLINE [§]	6 July 2021	1 Jan 2020-6 July 2021	None	90
Europe PMC [§]	6 July 2021	1 Jan 2020-6 July 2021	None	23
Screening reference lists	NA	-	NA	NA

[§] The search syntaxes used for electronic bibliographic databases are reported in Appendix 1.

NA: Not applicable as no publications relevant for screening reference lists were identified.

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 relevant opinions were published within the selected time period, no further screening was performed.

The publications grouped in the Endnote® library were deduplicated and publications retrieved by the previous searches conducted in the frame of the 2020 annual monitoring reports were 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 2020 monitoring reports)	109
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	104
Total number of full-text documents assessed in detail	5
Number of publications excluded from further consideration after detailed assessment for relevance based on full text	4
Total number of unobtainable/unclear publications	0
Total number of relevant publications	1

The 109 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.

In the first stage of screening, entries were screened based on title/abstract. Records that were deemed to be irrelevant were not further retained. In cases where the record seemed relevant,

or if 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.

Publications assessed at full text level and found not to be relevant were not further assessed and a justification was provided. Records that are relevant were summarized and their potential to influence the initial risk assessment was evaluated in the format laid out by the Commission decision 2009/770/EC (EC, 2009).

In this literature search exercise, one peer-reviewed publication relevant to the risk assessment of the authorised GM maize² (notably for 1507 and 4114 maize) was identified (Vieira et al., 2021) (see Table 4.1 in Appendix 4 and Table 3 hereafter). Publications excluded after assessment of the full-text are presented in Table 4.2 in Appendix 4 and a reason for exclusion based on the eligibility/inclusion criteria is provided. No unclear publications were identified (see Appendix 4, Table 4.3).

Table 3: Review of a relevant peer-reviewed publication: Food/Feed safety (1507 and 4114 maize) (Vieira et al., 2021)

Publication	Summary of research and results	Protection goal	Observed parameter	Adverse effects	Feedback on initial risk assessment
Vieira L, Hissa DC, Souza T, Goncalves IFS, Evaristo JAM, Nogueira FCS, Carvalho AFU and Farias D, 2021. Assessing the effects of an acute exposure to worst-case concentration of Cry proteins on zebrafish using the embryotoxicity test and proteomics analysis. Chemosphere 264, 7.	As indicated by the authors, their work aimed to evaluate the toxicity of Cry1F (and Cry1C and Cry1Ab) on zebrafish embryos and larvae, allying the embryotoxicity test and dosage of enzyme biomarkers and proteomics analysis to investigate the acute effects of a predicted worst-case scenario concentration of Cry proteins (set to 1.1 mg/L). The authors show that, at the analysed concentration, after 96h exposure, “these proteins did not cause adverse effects observable in the zebrafish early life stages, either by verifying phenotypic endpoints of toxicity or alterations in representative enzymatic biomarkers. The authors demonstrate that at the molecular level, Cry proteins tested lead to very small changes in the proteome of zebrafish larvae. Overall, these data lead the authors to the conclusion that Cry1F” (and Cry1C and Cry1Ab proteins), “even at a very high concentration, have limited effects in the zebrafish early life stages”. The authors state that, “in a natural setting, these proteins would not have deleterious effects on aquatic vertebrates.”	Food Feed safety	Toxicology	None	No change

4. Conclusion

One publication was identified as relevant for the molecular characterisation, food/feed and environmental safety of the authorised GM maize² (notably for 1507 and 4114 maize) within the scope of the authorisations for the defined time period. No safety concerns have been identified for the authorised GM maize by this literature search exercise.

References

- 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.].
- Vieira L, Hissa DC, Souza T, Goncalves IFS, Evaristo JAM, Nogueira FCS, Carvalho AFU and Farias D, **2021**. Assessing the effects of an acute exposure to worst-case concentration of Cry proteins on zebrafish using the embryotoxicity test and proteomics analysis. Chemosphere 264, 7.

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)
#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-34 OR cry-35 OR cry-34a* OR cry-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 manipul* OR engineer* OR stack))))
#18	(#13 OR #14 OR #15 OR #16) AND #17
Reporting Period #19	PY=(2020-2100)
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 *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-34 OR cry-35 OR cry-34a* OR cry-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 manipul* OR transform* OR stack OR "genetically engineered foods"))
#18	(#13 OR #14 OR #15 OR #16) AND #17
Reporting Period #19	PY=(2020-2100)
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-34 OR cry-35 OR cry-34a* OR cry-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 manipul* OR transform* OR stack OR "Food, Genetically Modified"))
#18	(#13 OR #14 OR #15 OR #16) AND #17
Reporting Period #19	PY=(2020-2100)
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:[2020-01-01 TO 2100-12-31])

Appendix 2. Eligibility/Inclusion Criteria³

Concept	Criteria
Population (taking into account scope of the authorisation)	<p>Publication addressing human and animal health, and/or the environment relevant for the scope of the authorisation.</p> <p>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 authorisation for food, food, import, efficacy of the traits, pest susceptibility, etc. are not considered relevant).</p>
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	<p>Effects/impacts on human and animal health, and/or the environment are addressed.</p> <p>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.</p>
Reporting format	<p>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).</p> <p>However, risk assessments from relevant risk assessment bodies (excluding EFSA) will not be excluded.</p>

³ This table is provided for ease of reference, no updates have been introduced since the previous report.

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 2021a in one appendix and EFSA 2021b in another)

1. Entries retrieved using Web of Science Core collection

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None

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- Zhao Z, Elisk CG, Hibbard BE and Shelby KS, Detection of alternative splicing in western corn rootworm (*Diabrotica virgifera virgifera* LeConte) in association with eCry3.1Ab resistance using RNA-seq and PacBio Iso-Seq. *Insect Molecular Biology* 10. 10.1111/imb.12709

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)
Toxicological assessment of the newly expressed protein(s)	Vieira L, Hissa DC, Souza T, Goncalves IFS, Evaristo JAM, Nogueira FCS, Carvalho AFU and Farias D, 2021 . Assessing the effects of an acute exposure to worst-case concentration of Cry proteins on zebrafish using the embryotoxicity test and proteomics analysis. Chemosphere 264, 7.

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 listed in Appendix 2
Lohn AF, Trtikova M, Chapela I, Binimelis R and Hilbeck A, 2021 . Transgene behavior in genetically modified teosinte hybrid plants: transcriptome expression, insecticidal protein production and bioactivity against a target insect pest. Environmental Sciences Europe 33, 13.	Intervention/exposure (not on authorised GM maize); Population (mainly relevant for cultivation in the EU) ⁴
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, De Sanctis G, Devos Y, Fernandez A, Gennaro A, Ruiz JAG, Lanzoni A, Neri FM, Papadopoulou N, Paraskevopoulos K and Raffaello T, 2021 . Assessment of genetically modified maize 1507 x MIR162 x MON810 x NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-127). EFSA Journal 19, 40.	Reporting format (not a primary study)
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, De Sanctis G, Dumont AF, Gennaro A, Ruiz JAG, Lanzoni A, Neri FM, Papadopoulou N, Paraskevopoulos K, and Raffaello T. 2021 . Assessment of genetically modified maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON	Reporting format (not a primary study)

⁴ The EFSA Working Group on Comparative analysis and Environmental Risk Assessment has previously assessed this publication (see the [minutes of the 228th meeting](#) held on 6 July 2021): it does not invalidate the assumptions made by EFSA.

87411 x 59122 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2017-139). EFSA Journal 19, 45. 10.2903/j.efsa.2021.6351	
Shwe SM, Wang YQ, Gao ZP, Li X, Liu S, Bai SX, Zhang TT, He KL and Wang ZY, 2021 . Toxicity of Cry1-Class, Cry2Aa, and Vip3Aa19 Bt proteins and their interactions against yellow peach Moth, <i>Conogethes punctiferalis</i> (Guenée) (Lepidoptera: Crambidae). Journal of Invertebrate Pathology 178, 6.	Population; Intervention/exposure (relevant protein combinations for these GM maize not assessed)

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
None	Not applicable