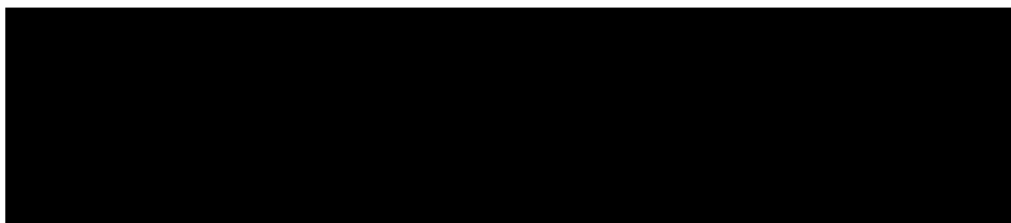


Review of literature for authorised genetically modified maize products in the scope of their authorisations for food and feed uses, import and processing (2022 update)



Products covered:

Single events

1507
59122
4114
DAS-40278-9

Stacks

1507xNK603
1507x59122xMON810xNK603
1507 × MIR162 × MON810 × NK603
MON89034x1507xMON88017x59122xDAS-40278-9
MON89034x1507xNK603xDAS-40278-9
and their subcombinations covered by the
authorisations

PHI-R098-Y22

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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, 1507xMIR162xMON810xNK603, 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 2021. 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 59122 maize) during the selected time period. No safety concerns were identified for the authorised GM maize by this literature search exercise.

2. Confirmation of the Suitability of the Search Strings

All updates are related to the inclusion of products that were approved since the last reporting period (1507xMIR162xMON810xNK603 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. As the

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

1507xMIR162xMON810xNK603 and the following subcombinations: 1507xMIR162xMON810, 1507xMIR162xNK603, MIR162xMON810xNK603, MIR162xMON810

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, 1507xDAS-40278-9, MON88017xDAS-40278-9, 59122xDAS-40278-9.

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

² As previously defined, 1507, 59122, 4114, DAS-40278-9, 1507xNK603, 1507x59122xMON810xNK603, 1507xMIR162xMON810xNK603, MON89034x1507xMON88017x59122xDAS-40278-9, MON89034x1507xNK603xDAS-40278-9 maize and their sub-combinations covered by their respective authorisations.

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

3. Results of the scoping exercise

3.1. Outcome of the literature searches

In August 2022, 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.

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 August 2022	1 Jan 2021-8 August 2022	None	117
CAB Abstracts [§]	8 August 2022	1 Jan 2021-8 August 2022	None	147
MEDLINE [§]	8 August 2022	1 Jan 2021-8 August 2022	None	57
Europe PMC [§]	8 August 2022	1 Jan 2021-8 August 2022	None	13
Screening reference lists	NA	-	NA	NA

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

* Period searched included an indexing date of 6 July 2021.

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 2021 annual monitoring reports were removed (see Appendix 3).

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 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 2021 monitoring reports)	205

Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	199
Total number of full-text documents assessed in detail	6
Number of publications excluded from further consideration after detailed assessment for relevance based on full text	5
Total number of unobtainable/unclear publications	0
Total number of relevant publications	1

The 205 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 maize (notably for 59122 maize) was identified (Gyurcsó et al., 2022) (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 (59122 maize) (Gyurcsó et al., 2022)

Publication	Summary of research and results	Protection goal	Observed parameter	Adverse effects	Feedback on initial risk assessment
Gyurcsó G, Darvas B, Baska F, Simon L, Takacs E, Klatyik S and Szekacs A, 2022 . Herbivorous Juvenile Grass Carp (<i>Ctenopharyngodon idella</i>) Fed with Genetically Modified MON 810 and DAS-59122 Maize Varieties Containing Cry Toxins: Intestinal Histological, Developmental, and Immunological Investigations. Toxins 14. 10.3390/toxins14020153	<p>This study aims to evaluate any differences in body parameters or hematological indicators in sweetwater fish species grass carp (<i>Ctenopharyngodon idella</i>) at its stage of conversion to herbivorous behavior, after 1 to 6 months diet with genetically modified maize varieties MON 810 or 59122.</p> <p>The toxin analysis indicated a rapid degradation of Cry toxins in the fish gastrointestinal tract, with no significant differences detected in body parameters or hematological indicators, except for mild indications in certain serum indices: 59122 mildly increased the number of granulocytes compared to the near-isogenic line. The authors conclude that the feeding effects of different genetic events cannot be generally deemed harmless or hazardous.</p>	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 maize (notably for 59122 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.].
- Gyurcsó G, Darvas B, Baska F, Simon L, Takacs E, Klatyik S and Szekacs A, **2022**. Herbivorous Juvenile Grass Carp (*Ctenopharyngodon idella*) Fed with Genetically Modified MON 810 and DAS-59122 Maize Varieties Containing Cry Toxins: Intestinal Histological, Developmental, and Immunological Investigations. Toxins 14. 10.3390/toxins14020153.

Appendix 1. Detailed search syntaxes for the authorised GM maize

Web of Science Core collection

Set	Search query	Results
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)	160
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))	113
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)))	4
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*)))	71
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 *1507xMON810xMIR162xNK603* OR *1507xMON810xMIR162* OR *1507xMIR162xNK603* OR *MON810xMIR162xNK603* OR *1507xMIR162* OR *MON810xMIR162* OR *MON810xNK603* OR	13

	NK603xMON810 OR *MIR162xNK603* OR lepra OR acremax OR smartstax*-enlist* OR Powercore*-enlist* OR intrasect)	
#6	#1 OR #2 OR #3 OR #4 OR #5	315
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))	741
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))	470
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*)	838
Protein DAS-40278-9 #10	TS=(aad-1 OR aryloxyalkanoate-dioxygenase-1)	67
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)	931,953
#12	(#7 OR #8 OR #9 OR #10) AND #11	653
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*))	81,970
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*))	76,643
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)	150,485
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	11,230

	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))))	5130
#18	(#13 OR #14 OR #15 OR #16) AND #17	1896
Full search period #19	PY=(2021-2100)	3,804,690
Results indexed after July 6, 2021 #20	(#6 OR #12 OR #18) AND #19	117

CAB Abstracts

Set	Search query	Results
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)	222
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))	75
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)))	5
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*)))	84
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 *1507xMON810xMIR162xNK603* OR *1507xMON810xMIR162* OR *1507xMIR162xNK603* OR *MON810xMIR162xNK603* OR *1507xMIR162* OR *MON810xMIR162* OR *MON810xNK603* OR *NK603xMON810* OR *MIR162xNK603* OR lepra OR acremax OR smartstax*-enlist* OR Powercore*-enlist* OR intrasect)	12
#6	#1 OR #2 OR #3 OR #4 OR #5	355
Protein 1507	TS=(cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR	782

#7	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))	546
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*)	868
Protein DAS-40278-9 #10	TS=(aad-1 OR aryloxyalkanoate-dioxygenase-1)	21
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)	764,962
#12	(#7 OR #8 OR #9 OR #10) AND #11	721
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*))	224,229
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*))	187,089
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)	383,139
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)	45,831
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	6010

	transform* OR stack OR "genetically engineered foods"))	
#18	(#13 OR #14 OR #15 OR #16) AND #17	2070
Reporting Period #19	PY=(2021-2100)	544,088
Final Results #20	(#6 OR #12 OR #18) AND #19	147

MEDLINE

Set	Search query	Results
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)	77
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))	40
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)))	4
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*)))	26
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 *1507xMON810xMIR162xNK603* OR *1507xMON810xMIR162* OR *1507xMIR162xNK603* OR *MON810xMIR162xNK603* OR *1507xMIR162* OR *MON810xMIR162* OR *MON810xNK603* OR *NK603xMON810* OR *MIR162xNK603* OR lepra OR acremax OR smartstax*-enlist* OR Powercore*-enlist* OR intrasect)	11
#6	#1 OR #2 OR #3 OR #4 OR #5	132
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	447

	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))	310
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*)	522
Protein DAS-40278-9 #10	TS=(aad-1 OR aryloxyalkanoate-dioxygenase-1)	22
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)	335,907
#12	(#7 OR #8 OR #9 OR #10) AND #11	422
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*))	32,648
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*))	23,311
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)	54,327
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)	5333
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"))	2192

#18	(#13 OR #14 OR #15 OR #16) AND #17	601
Reporting Period #19	PY=(2021-2100)	1,721,924
Final Results #20	(#6 OR #12 OR #18) AND #19	57

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 “1507xMON810xMIR162xNK603” OR “1507xMON810xMIR162” OR “1507xMIR162xNK603” OR “MON810xMIR162xNK603” OR “1507xMIR162” OR “MON810xMIR162” OR “MON810xNK603” OR “NK603xMON810” OR “MIR162xNK603” 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:[2021-01-01 TO 2100-12-31]) AND (FIRST_IDATE:[2021-07-06 TO 2100-12-31])

= 13 results

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 ^{Error! Bookmark not defined.} 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. New entries retrieved by the performed searches to literature databases for the authorised GM maize within the indicated search period (excluding duplicates retrieved by the previous searches conducted in 2021)

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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)
Toxicological assessment of the newly expressed protein(s)	Gyurcsó G, Darvas B, Baska F, Simon L, Takacs E, Klatyik S and Szekacs A, 2022 . Herbivorous Juvenile Grass Carp (Ctenopharyngodon idella) Fed with Genetically Modified MON 810 and DAS-59122 Maize Varieties Containing Cry Toxins: Intestinal Histological, Developmental, and Immunological Investigations. Toxins 14. 10.3390/toxins14020153

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
Araujo GVd, Albrecht AJP, Albrecht LP, Carvalho HWPd, Migliavacca RA and Silva AFM, 2021 . Effect of glyphosate and glufosinate on nutritional content and agronomic performance of maize possessing cp4epsps and pat transgenes. Australian Journal of Crop Science 15, 773-779. 10.21475/ajcs.21.15.05.p3193	Comparator (no Non-GM control) Outcomes (focusing on pesticide use)
Mullins E, Bresson JL, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Naegeli H, Moreno FJ, Nogue F, Rostoks N, Serrano JJS, Savoini G, Veromann E, Veronesi F, Ardizzone M, Dumont AF, Federici S, Gennaro A, Ruiz JAG, Goumperis T, Kagkli DM, Lanzoni A, Lenzi P, Neri FM, Papadopoulou N, Paraskevopoulos K, Raffaello T, Streissl F, De Sanctis G and Or EPGM, 2022 . Assessment of genetically modified maize DP4114 x MON 810 x MIR604 x NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-150). Efsa Journal 20. 10.2903/j.efsa.2022.7134	Reporting format (not a primary study) Intervention/exposure (not on authorised stack GM maize)
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, Raffaello T and Or EPGM, 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. 10.2903/j.efsa.2021.6348	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,	Reporting format (not a primary study) Intervention/exposure (not on authorised stack GM maize)

Papadopoulou N, Paraskevopoulos K, Raffaello T and Or EPGM, 2021 . Assessment of genetically modified maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 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. 10.2903/j.efsa.2021.6351	
Nie CR, Wang JW, Luo SM, Peng ZS, Guo JW and Xin MG, 2021 . Spatial and temporal distribution of Bt proteins in Bt maize leaves. Food and Agricultural Immunology 32, 450-459. 10.1080/09540105.2021.1960956	Intervention/exposure (not on authorised GM maize, Bt maize varieties 1426 × 1482 and Nongda 61);

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