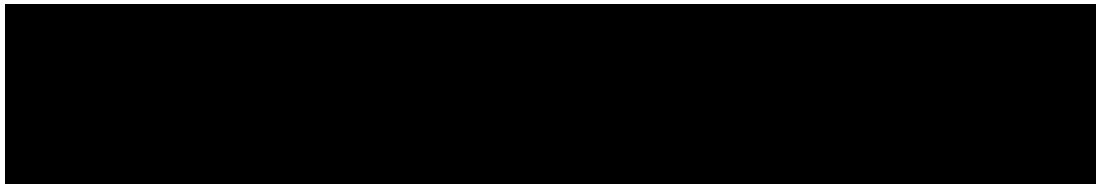


**Review of literature of DAS-44406-6, DAS-81419-2, and DAS-81419-2xDAS-44406-6 soybean in the scope of the authorisations for food and feed uses, import and processing  
(2022 update)**



**PHI-R100-Y22**

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## 1. Summary

An updated systematic search and review of peer-reviewed literature was conducted for DAS-44406-6, DAS-81419-2 and DAS-81419-2xDAS-44406-6 soybean (hereafter collectively referred to as “authorised GM soybean”). 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 soybean and derived food/feed products, or the intended traits (the newly expressed protein(s)), have adverse effects on human and animal health and the environment in the scope of the authorisation?”.

The current systematic search complements the search previously performed in 2020. Unless outlined below, all portions of the search were conducted according to the methodologies outlined in the previous search.

The outcome of this analysis showed that no publication relevant for the review question was identified during the selected time period. No safety concerns were identified for the authorised GM soybean 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 (DAS-81419-2 and DAS-81419-2xDAS-44406-6 soybean). 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. As the updated search is as sensitive and not more specific than the previous searches, no additional validation was conducted. Results of the literature search exercise

### 2.1. Outcome of 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 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 <sup>§</sup> | 8 August 2022  | 1 Jan 2021-8 August 2022 | None               | 168                         |
| CAB Abstracts <sup>§</sup>                  | 8 August 2022  | 1 Jan 2021-8 August 2022 | None               | 150                         |
| MEDLINE <sup>§</sup>                        | 8 August 2022  | 1 Jan 2021-8 August 2022 | None               | 97                          |
| Europe PMC <sup>§</sup>                     | 8 August 2022  | 1 Jan 2021-8 August 2022 | None               | 4                           |
| Screening reference lists                   | NA             | -                        | NA                 | NA                          |

<sup>§</sup> 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 soybean 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 2021 annual monitoring report were also 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

| <b>Review question: “Do the authorised GM soybean and derived food/feed products, or the intended traits (the newly expressed protein(s)), have adverse effects on human and animal health and the environment in the scope of the authorisation?”</b> | <b>Number of records</b> |
|--|--------------------------|
| Total number of publications retrieved after all searches of the scientific literature (excluding duplicates and publications retrieved by the previous searches conducted in the frame of the 2021 monitoring reports)                                | 241                      |
| Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract   | 239                      |
| Total number of full-text documents assessed in detail   | 2                        |
| Number of publications excluded from further consideration after detailed assessment for relevance based on full text  | 2                        |
| Total number of unobtainable/unclear publications  | 0                        |
| Total number of relevant publications  | 0                        |

The 241 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, no peer-reviewed publications relevant to the risk assessment of DAS-44406-6, DAS-81419-2 or DAS-81419-2xDAS-44406-6 soybean was identified (see Appendix 4, Table 4.1). 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).

### **3. Conclusion**

No publications were identified as relevant for the molecular characterisation, food/feed and environmental safety of the authorised GM soybean within the scope of the authorisations for the defined time period. No safety concerns have been identified for the authorised GM soybean 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.].

# Appendix 1. Detailed search syntaxes for the DAS-44406-6, DAS-81419-2 and DAS-81419-2 × DAS-44406-6 soybean

## Web of Science Core collection

| Set              | Search query  | Results |
|------------------|---|---------|
| Event 44406 #1   | TS=(DAS44406* OR DAS-44406 OR DAS-44406-6 OR DAS-444-circle-divide-6-6 OR DAS-444empty-set6-6 OR ((44406 OR Enlist*) AND (soy* OR soja* OR Glycine OR Dow OR Corteva OR herbicid*)))  | 77      |
| Event 81419 #2   | TS=(DAS81419* OR DAS-81419 OR DAS-81419-2 OR (81419 AND (soy* OR soja* OR Glycine OR Dow OR Corteva)) OR Conkesta*)   | 17      |
| Stack #3         | TS=(*DAS-44406-6xDAS-81419-2*)  | 0       |
| #4               | #1 OR #2 OR #3  | 88      |
| Protein 44406 #5 | TS=(2m-epsps OR 2mepsps OR ((5-enolpyruvylshikimate-3-phosphate-synthase OR epsps OR 5-enol-pyruvylshikimate-3-phosphate-synthase OR EPSP-synthase) AND modified AND protein AND (maize OR corn OR zea OR mays)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin) OR aad-12 OR aryloxyalkanoate-dioxygenase-12)                        | 472     |
| Protein 81419 #6 | TS=(cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR cry1Ac OR Cry1-Ac OR cry1a-c OR cryiAc OR Cryi-Ac OR cryia-c OR (cry AND (1Ac or 1-Ac or iAc or i-Ac)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))  | 2916    |
| General #7       | TS=(Streptomyces OR viridochromogenes OR Delftia OR acidovorans OR Bacillus OR thuringiensis OR bt OR soy* OR soja* OR glycine OR (((herbicid* AND (genetic* NEAR/3 (modif* or engineer*))) OR GMHT) AND (crop OR plant OR food OR feed)) OR gmo OR gmos OR lmo OR lmos OR gm OR ge)  | 686,271 |
| #8               | (#5 OR #6) AND #7   | 2692    |
| Trait 44406 #9   | TS=(glyphosate* OR Roundup OR "Round-up" OR glyphosate* OR glyphosate* OR glifosate* OR ((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 OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) | 28,177  |
| Trait 81419 #10  | TS=(lepidopter* OR velvetbean OR anticarsia OR gemmatialis OR soy*bean*-looper* OR chrysodeixis OR  | 70,627  |

|                             |   |           |
|-----------------------------|---|-----------|
|                             | includens OR pseudoplusia OR glufosinate* OR<br>gluphosinate* OR (Liberty* AND herbicid*)   |           |
| General<br>#11              | TS=((toler* OR resist* OR protec*) AND (soy* OR soja*<br>OR Glycine OR max) AND (gmo OR gmos OR lmo OR lmos<br>OR living-modified OR transgen* OR GMHT OR ((GM OR GE<br>OR genetic*) NEAR/3 (modif* OR transform* OR manipulat*<br>OR engineer*)))) | 2930      |
| #12                         | (#9 OR #10) AND #11   | 775       |
| Reporting<br>Period<br>#13  | PY=(2021-2100)<br>(limited to content added to database on or since date of<br>2021DAS44406 Soy PMEM search ran on July 6)  | 3,804,690 |
| <b>Final Results</b><br>#14 | (#4 OR #8 OR #12) AND #13   | 168       |

## CAB Abstracts

| Set              | Search query  | Results |
|------------------|---|---------|
| Event 44406 #1   | TS=(DAS44406* OR DAS-44406 OR DAS-44406-6 OR DAS-44406-6 OR ((44406 OR Enlist*) AND (soy* OR soja* OR Glycine OR Dow OR Corteva OR herbicid*)))   | 81      |
| Event 81419 #2   | TS=(DAS81419* OR DAS-81419 OR DAS-81419-2 OR (81419 AND (soy* OR soja* OR Glycine OR Dow OR Corteva)) OR Conkesta*)   | 14      |
| Stack #3         | TS=(*DAS-44406-6xDAS-81419-2*)  | 0       |
| #4               | #1 OR #2 OR #3  | 89      |
| Protein 44406 #5 | TS=(2m-epsps OR 2mepsps OR ((5-enolpyruvylshikimate-3-phosphate-synthase OR epsps OR 5-enol-pyruvylshikimate-3-phosphate-synthase OR EPSP-synthase) AND modified AND protein AND (maize OR corn OR zea OR mays)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin) OR aad-12 OR aryloxyalkanoate-dioxygenase-12)                        | 515     |
| Protein 81419 #6 | TS=(cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR cry1Ac OR Cry1-Ac OR cry1a-c OR cryiAc OR Cryi-Ac OR cryia-c OR (cry AND (1Ac or 1-Ac or iAc or i-Ac)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))  | 3018    |
| General #7       | TS=(Streptomyces OR viridochromogenes OR Delftia OR acidovorans OR Bacillus OR thuringiensis OR bt OR soy* OR soja* OR glycine OR (((herbicid* AND (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR Imo OR Imos OR ge OR "genetically engineered foods")  | 562,364 |
| #8               | (#5 OR #6) AND #7   | 2641    |
| Trait 44406 #9   | TS=(glyphosate* OR Roundup OR "Round-up" OR glyphosate* OR glyphosate* OR glifosate* OR ((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 OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) | 66,131  |
| Trait 81419 #10  | TS=(lepidopter* OR velvetbean OR anticarsia OR gemmatilis OR soy*bean*-looper* OR chrysodeixis OR includens OR pseudoplusia OR glufosinate* OR gluphosinate* OR (Liberty* AND herbicid*))   | 223,262 |



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|                                   |   |         |
|-----------------------------------|---|---------|
| <b>General</b><br>#11             | TS=((toler* OR resist* OR protec*) AND (soy* OR soja* OR Glycine OR max) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipulat* OR transform* OR "genetically engineered foods")) | 3906    |
| #12                               | (#9 OR #10) AND #11   | 892     |
| <b>Reporting</b><br>Period<br>#13 | PY=(2021-2100)<br>(limited to content added to database on or since date of 2021DAS44406 Soy PMEM search ran on July 6)   | 544,088 |
| <b>Final Results</b><br>#14       | (#4 OR #8 OR #12) AND #13   | 150     |

## MEDLINE

| Set              | Search query  | Results |
|------------------|---|---------|
| Event 44406 #1   | TS=(DAS44406* OR DAS-44406 OR DAS-44406-6 OR ((44406 OR Enlist*) AND (soy* OR soja* OR Glycine OR Dow OR Corteva OR herbicid*)))  | 39      |
| Event 81419 #2   | TS=(DAS81419* OR DAS-81419 OR DAS-81419-2 OR (81419 AND (soy* OR soja* OR Glycine OR Dow OR Corteva)) OR Conkesta*)   | 10      |
| Stack #3         | TS=(*DAS-44406-6xDAS-81419-2*)  | 0       |
| #4               | #1 OR #2 OR #3  | 44      |
| Protein 44406 #5 | TS=(2m-epsps OR 2mepsps OR ((5-enolpyruvylshikimate-3-phosphate-synthase OR epsps OR 5-enol-pyruvyl-shikimate-3-phosphate-synthase OR EPSP-synthase) AND modified AND protein AND (maize OR corn OR zea OR mays)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin) OR aad-12 OR aryloxyalkanoate-dioxygenase-12)                       | 278     |
| Protein 81419 #6 | TS=(cry1f OR cry-1f OR cryif OR "cry-if" OR Cry1-f OR Cry-1-f OR cry1Ac OR Cry1-Ac OR cry1a-c OR cryiAc OR Cryi-Ac OR cryia-c OR (cry AND (1Ac or 1-Ac or iAc or i-Ac)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin))  | 1688    |
| General #7       | TS=(Streptomyces OR viridochromogenes OR Delftia OR acidovorans OR Bacillus OR thuringiensis OR bt OR soy* OR soja* OR glycine OR (((herbicid* AND (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR Imo OR Imos OR ge OR "Food, Genetically Modified")  | 351,608 |
| #8               | (#5 OR #6) AND #7   | 1559    |
| Trait 44406 #9   | TS=(glyphosate* OR Roundup OR "Round-up" OR glyphosate* OR gliphosate* OR glifosate* OR ((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 OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) | 11,438  |
| Trait 81419 #10  | TS=(lepidopter* OR velvetbean OR anticarsia OR gemmatilis OR soy*bean*-looper* OR chrysodeixis OR includens OR pseudoplusia OR glufosinate* OR gluphosinate* OR (Liberty* AND herbicid*))   | 21,168  |

|                                   |   |           |
|-----------------------------------|---|-----------|
| <b>General</b><br>#11             | TS=((toler* OR resist* OR protec*) AND (soy* OR soja* OR Glycine OR max) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipul* OR transform* OR "Food, Genetically Modified")) | 2648      |
| #12                               | (#9 OR #10) AND #11   | 386       |
| <b>Reporting</b><br>Period<br>#13 | PY=(2021-2100)<br>(limited to content added to database on or since date of 2021DAS44406 Soy PMEM search ran on July 6)   | 1,721,924 |
| <b>Final Results</b><br>#14       | (#4 OR #8 OR #12) AND #13   | 97        |

### Europe PMC

("DAS-44406xDAS-81419" OR DAS44406 OR "DAS-44406" OR "DAS-44406-6" OR "44406 soy" OR "soy 44406" OR DAS81419 OR "DAS-81419" OR "81419 soy" OR "soy 81419") AND (FIRST\_PDATE:[2021-01-01 TO 2100-12-31]) AND (FIRST\_IDATE:[2021-07-06 TO 2100-12-31])

= 4 results

## Appendix 2. Eligibility/Inclusion Criteria<sup>1</sup>

| 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                                       | DAS-44406-6 soybean and derived food/feed products, and/or the intended traits (the newly expressed protein(s)).  |
| Intervention/exposure<br>Plant species                      | In case of studies using GM plants, only studies using soybean are considered eligible. This criterion is not employed for studies regarding the newly expressed proteins.  |
| Intervention/exposure<br>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>   |

<sup>1</sup> 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 soybean within the indicated search period (excluding duplicates retrieved by the previous searches conducted in 2021)**

- Abbes S, Duy SV, Munoz G, Dinh QT, Simon DF, Husk B, Baulch HM, Vincon-Leite B, Fortin N, Greer CW, Larsen ML, Venkiteswaran JJ, Jeronimo FFM, Giani A, Lowe CD, Tromas N and Sauve S, **2022**. Occurrence of BMAA Isomers in Bloom-Impacted Lakes and Reservoirs of Brazil, Canada, France, Mexico, and the United Kingdom. *Toxins* 14. 10.3390/toxins14040251
- Aguirre LA, Hernandez-Juarez A, Cerna E, Flores M, Frias GA and Ochoa YM, **2021**. Diversity, Abundance, and Effect of Genetically Modified Maize on Nontarget Predators in Sinaloa, Mexico. *Journal of Entomological Science* 56, 541-555. 10.18474/jes20-84
- Ahmad JN, Majeed D, Arshad M, Malik MA, Ali A, Nadeem S and Ahmad SJN, **2021**. EFFECT OF METHYL JASMONATE ON Bt COTTON (*Gossypium hirsutum* L.) GENE EXPRESSION AND MORTALITY OF PINK BOLL WORM (*Pectinophora gossypiella*). *Journal of Animal and Plant Sciences-Japs* 31, 1728-1738. 10.36899/japs.2021.6.0375
- Ahmad SF, Gulzar A, Tariq M and Asad MJ, **2021**. Field Evolved Resistance in *Earias vittella* (Lepidoptera: Noctuidae) From Punjab, Pakistan Against Commercial Formulations of *Bacillus thuringiensis kurstaki*. *Journal of Economic Entomology* 114, 2204-2213. 10.1093/jee/toab137
- Ahmad SJN, Dilawar M, Abid A, Muhammad S, Zubair A, Mujahid M and Ahmad JN, **2021**. Effect of natural high temperature and flooding conditions on Cry1Ac gene expression in different transgenic Bt cotton (*Gossypium hirsutum* L.) cultivars. *Pakistan Journal of Botany* 53, 127-134. 10.30848/pjb2021-1(38)
- Al-Masud MA, Hamid S, Alam MS, Karim MM, Momin MA, Islam MA and Khan GMA, **2021**. Green synthesis of silk sericin-embedded silver nanoparticles and their antibacterial application against multidrug-resistant pathogens. *Journal of Genetic Engineering and Biotechnology* 19. 10.1186/s43141-021-00176-5
- Almeida GPDd, Mendes KF, Regitano JB, Dias NMP, Guimaraes ACD and Tornisielo VL, **2021**. Using <sup>14</sup>C-glyphosate to investigate the distribution of two formulations in transgenic glyphosate-resistant soybean. *Journal of Environmental Science and Health Part B, Pesticides, Food Contaminants, and Agricultural Wastes* 56, 809-813. 10.1080/03601234.2021.1956250
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- 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
- Arends B, Reisig DD, Gundry S, Huseth AS, Reay-Jones FPF, Greene JK and Kennedy GG, **2021**. Effectiveness of the natural resistance management refuge for Bt-cotton is dominated by local abundance of soybean and maize. *Scientific Reports* 11. 10.1038/s41598-021-97123-8
- Arias ACR, Chaparro-Giraldo A and Lopez-Pazos SA, **2021**. A basic scheme of soybean transformation for glyphosate tolerance using *Agrobacterium tumefaciens* through an

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- Asif M, Siddiqui HA, Naqvi RZ, Amin I, Asad S, Mukhtar Z, Bashir A and Mansoor S, **2021**. Development of event-specific detection method for identification of insect resistant NIBGE-1601 cotton harboring double gene Cry1Ac-Cry2Ab construct. *Scientific Reports* 11. 10.1038/s41598-021-82798-w
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- Benowitz KM, Allan CW, Degain BA, Li XC, Fabrick JA, Tabashnik BE, Carriere Y and Matzkin LM, **2022**. Novel genetic basis of resistance to Bt toxin Cry1Ac in *Helicoverpa zea*. *Genetics* 221. 10.1093/genetics/iyac037
- Calvin W, Yang F, Brown SA, Catchot AL, Crow WD, Cook DR, Gore J, Kurtz R, Lorenz GM, Seiter NJ, Stewart SD, Towles T and Kerns DL, **2021**. Development of Economic Thresholds Toward Bollworm (Lepidoptera: Noctuidae), Management in Bt Cotton, and Assessment of the Benefits From Treating Bt Cotton With Insecticide. *Journal of Economic Entomology* 114, 2493-2504. 10.1093/jee/toab173
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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/<br>data requirement(s) | Reference (Author, year, title, source) |
|---|---|
| None  | Not applicable                          |

**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                                |
|---|--|
| Lin H-Y, Liao J-W, Chen R-S, Chang C-H, Chang H-W, Chang S-C, Chu W-S, Lin C-K and Lin H-T, <b>2022</b> . Food Safety Assessment of Commercial Genetically Modified Soybeans in Rats. In: Foods (Basel, Switzerland). p 496. ^10.3390/foods11040496   | Intervention/exposure (mixture of GM seeds)  |
| Mullins E, Bresson JL, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogue F, Rostoks N, Serrano JJS, Savoini G, Veromann E, Veronesi F, Goumperis T, Raffaello T and Or EPGM, <b>2022</b> . Risk assessment of a new bioinformatics evaluation of the insertion sites of genetically modified soybean event 40-3-2. Efsa Journal 20. 10.2903/j.efsa.2022.7412 | Reporting format (not a primary study)<br>Intervention/exposure (not on authorised GM soybean) |

**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  |