

Completeness checklist

(Appendix E of the 2019 EFSA Explanatory Note on literature searching)

| Specify the application number, event(s), plant species, intended trait(s), and the scope of the application for which literature searching is performed | | | | |
|--|---|-------------------------------|------------------------|--|
| Application number: EFSA-GMO-RX-016 | | | | |
| Event(s): Bt11 | | | | |
| Plant species: maize | | | | |
| Intended trait(s): | | | | |
| <input checked="" type="checkbox"/> Herbicide tolerance: PAT confers tolerance to glufosinate-ammonium | | | | |
| <input checked="" type="checkbox"/> Insect resistance: Cry1Ab confers resistance to certain lepidopteran pests | | | | |
| <input type="checkbox"/> Others: not applicable | | | | |
| Scope: | | | | |
| <input checked="" type="checkbox"/> Import/processing for food/feed uses | | | | |
| <input type="checkbox"/> Cultivation | | | | |
| Specify the context in which literature searching is performed | | | | |
| <input type="checkbox"/> GMO applications for market authorisation submitted under Regulation (EC) No 1829/2003 <i>after</i> the Implementing Regulation (EU) No 503/2013 entered into force on 8 December 2013 → <i>Review type: Scoping review to substantiate decisions about the value of conducting full or "rapid" systematic literature reviews</i> | | | | |
| <input type="checkbox"/> GMO applications for market authorisation submitted under Regulation (EC) No 1829/2003 <i>before</i> the Implementing Regulation (EU) No 503/2013 entered into force on 8 December 2013 → <i>Review type: Extensive/systematic literature search</i> | | | | |
| <input checked="" type="checkbox"/> Annual PMEM reports on GMOs authorised in the EU market → <i>Review type: Extensive/systematic literature search</i> | | | | |
| <input type="checkbox"/> GMO applications for the renewed market authorisation of genetically modified (GM) food/feed authorised under Regulation (EC) No 1829/2003 → <i>Review type: Extensive/systematic literature search</i> | | | | |
| Recommendation | Recommendation followed by the applicant | Action required | Justification | |
| Formulating review questions and clarifying their purpose | | | | |
| Break review questions down into their key elements and specify them based on the recommendations given in Sections 3.1 and 3.1.1 of the Explanatory note [GMO check] | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | Justification required | |
| | <input type="checkbox"/> No | Justification required | | |
| | <input type="checkbox"/> Partially | | | |
| | <input type="checkbox"/> Unclear | | | |
| Specify/report the eligibility/inclusion criteria for assessing the relevance of publications for inclusion in the literature review, with justification, based on the recommendations given in Section 3.1.2 of the Explanatory note [GMO check] | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | Justification required | |
| | <input type="checkbox"/> No | Justification required | | |
| | <input type="checkbox"/> Partially | | | |
| | <input type="checkbox"/> Unclear | | | |
| Searching for/identifying relevant publications | | | | |
| Search a minimum of <i>at least</i> two multi-disciplinary/large electronic bibliographic databases, based on the recommendations given in Section 3.2.1.1 of the Explanatory note [APDESK check] | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | Justification required | |
| | <input type="checkbox"/> No | Justification required | | |
| | <input type="checkbox"/> Partially | | | |
| | <input type="checkbox"/> Unclear | | | |
| Search internet pages of relevant key organisations delivering risk assessment guidelines and other risk assessment documents, | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | Justification required | |
| | <input type="checkbox"/> No | Justification required | | |
| | <input type="checkbox"/> Partially | | | |
| | <input type="checkbox"/> Unclear | | | |

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| based on the recommendations given in Section 3.2.1.2 of the Explanatory note [APDESK check] | | | |
| Describe clearly how the search strategy is constructed, with justifications, based on the recommendations given in Section 3.2.2 of the Explanatory note [GMO check] | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | |
| | <input type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |
| Report the reference publications used for each of the key elements of the review question, and provide a rationale for their selection, based on the recommendations given in Section 3.2.2.8 of the Explanatory note [APDESK check] | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | |
| | <input type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |
| Summarising and reporting the data, and considering the implications of the findings | | | |
| Report the results of the publication selection process, using either Table 2 of the Explanatory note or a flowchart for each category of information/data requirement or group of information/data requirements searched, if appropriate [GMO check] | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | |
| | <input type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |
| Provide a list of the bibliographic references for all relevant publications, ordered by category of information/data requirement, using Table 3 of the Explanatory note [APDESK check] | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | |
| | <input type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |
| Provide a list of the bibliographic references for all excluded publications after detailed assessment of full-text documents for relevance, with justification for their exclusion, using Table 4 of the Explanatory note [GMO check] | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | |
| | <input type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |
| Provide a list of the bibliographic references for all unobtainable publications, with explanation why they could not be obtained, using Table 5 of the Explanatory note [GMO check] | <input type="checkbox"/> Yes fully | <input type="checkbox"/> None | } [Á ~ à ß ~ } • Á ^ ! Á ~ } obtainable |
| | <input checked="" type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |
| Provide a list of the bibliographic references for all unclear publications, with explanation why they could not be classified, using Table 6 of the Explanatory note [GMO check] | <input type="checkbox"/> Yes fully | <input type="checkbox"/> None | no publications were unclear |
| | <input checked="" type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |
| Provide copies of the full-text documents listed in Table 3 of the Explanatory note, and the list of relevant publications compiled in | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | |
| | <input type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |

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| a reference management software (.RIS format) [APDESK check] | | | |
| Present a narrative synthesis/summary of the relevant publication describing their overall volume, strength and direction per main category of information/data requirements, using Table 7 of the Explanatory note [only applicable to scoping reviews] [GMO check] | <input type="checkbox"/> Yes fully | <input type="checkbox"/> None | not applicable |
| | <input checked="" type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |
| Discuss the implications of each publication that is clearly relevant to the risk assessment of the GMO under consideration, for each of the relevant categories of information/data requirements, using Table 8 of the Explanatory note [GMO check] | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | |
| | <input type="checkbox"/> No | <input type="checkbox"/> | |
| | <input type="checkbox"/> Partially | Justification required | |
| | <input type="checkbox"/> Unclear | | |