

Appendix E – Completeness checklist

Applicants should provide the completed completeness checklist shown below as part of the submission when submitting a GMO application to EFSA.

Appendix E of this explanatory note supersedes Appendix G of EFSA (2013).

| 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: Not applicable | | | |
| Events: MON 88302 × MS8 × RF3 and its sub-combinations. | | | |
| Plant species: oilseed rape | | | |
| Intended trait(s): <input checked="" type="checkbox"/> Herbicide tolerance: Glyphosate and glufosinate <input type="checkbox"/> Insect resistance: <input checked="" type="checkbox"/> Others: Male sterility and male sterility inhibitor | | | |
| 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"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | |
| 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"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | |
| 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"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | |
| | <input checked="" type="checkbox"/> Yes fully | <input type="checkbox"/> None | |

| | | | |
|---|--|--|-----------------------------------|
| Search internet pages of relevant key organisations delivering risk assessment guidelines and other risk assessment documents, based on the recommendations given in Section 3.2.1.2 of the Explanatory note [APDESK check] | <input type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> Justification required | |
| 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"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | |
| 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"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | |
| 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"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | |
| 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 type="checkbox"/> Yes fully <input checked="" type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | No such publication is identified |
| 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 type="checkbox"/> Yes fully <input checked="" type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | No such publication is identified |
| 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 checked="" type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | No such publication is identified |
| 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 checked="" type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | No such publication is identified |

| | | | |
|--|--|---|---|
| Provide copies of the full-text documents listed in Table 3 of the Explanatory note, and the list of relevant publications compiled in a reference management software (.RIS format) [APDESK check] | <input type="checkbox"/> Yes fully <input checked="" type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | No such publication is identified |
| 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 checked="" type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | Not required as annual post-market environmental monitoring |
| 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 type="checkbox"/> Yes fully <input checked="" type="checkbox"/> No <input type="checkbox"/> Partially <input type="checkbox"/> Unclear | <input type="checkbox"/> None <input type="checkbox"/> Justification required | No such publication is identified |