

## 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: not applicable                                                                                                                                                                                                                                                                                                                         |                                               |                               |                        |  |
| Event(s): Bt11 x MIR162 x 1507 x GA21 and all relevant sub-combinations in scope                                                                                                                                                                                                                                                                           |                                               |                               |                        |  |
| Plant species: maize                                                                                                                                                                                                                                                                                                                                       |                                               |                               |                        |  |
| Intended trait(s):                                                                                                                                                                                                                                                                                                                                         |                                               |                               |                        |  |
| <input checked="" type="checkbox"/> Herbicide tolerance: PAT confers tolerance to glufosinate-ammonium; mEPSPS to glyphosate                                                                                                                                                                                                                               |                                               |                               |                        |  |
| <input checked="" type="checkbox"/> Insect resistance: Cry1Ab, VIP3Aa20, Cry1F confer resistance to certain lepidopteran pests                                                                                                                                                                                                                             |                                               |                               |                        |  |
| <input checked="" type="checkbox"/> Others: PMI (selectable marker)                                                                                                                                                                                                                                                                                        |                                               |                               |                        |  |
| 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              |                               |                        |  |

|                                                                                                                                                                                                                                                       |                                                                                                                                                        |                                                                                     |                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------|
| 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<br><input type="checkbox"/> No<br><input type="checkbox"/> Partially<br><input type="checkbox"/> Unclear | <input type="checkbox"/> None<br><input type="checkbox"/><br>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<br><input type="checkbox"/> No<br><input type="checkbox"/> Partially<br><input type="checkbox"/> Unclear | <input type="checkbox"/> None<br><input type="checkbox"/><br>Justification required |                                            |
| <b>Summarising and reporting the data, and considering the implications of the findings</b>                                                                                                                                                           |                                                                                                                                                        |                                                                                     |                                            |
| 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<br><input type="checkbox"/> No<br><input type="checkbox"/> Partially<br><input type="checkbox"/> Unclear | <input type="checkbox"/> None<br><input type="checkbox"/><br>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<br><input checked="" type="checkbox"/> No<br><input type="checkbox"/> Partially<br><input type="checkbox"/> Unclear | <input type="checkbox"/> None<br><input type="checkbox"/><br>Justification required | no relevant publications were obtainable   |
| 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<br><input type="checkbox"/> No<br><input type="checkbox"/> Partially<br><input type="checkbox"/> Unclear | <input type="checkbox"/> None<br><input type="checkbox"/><br>Justification required |                                            |
| 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<br><input checked="" type="checkbox"/> No<br><input type="checkbox"/> Partially<br><input type="checkbox"/> Unclear | <input type="checkbox"/> None<br><input type="checkbox"/><br>Justification required | } [ Á ~ à   ß ~ } • Á ^ ! Á ~ } obtainable |
| 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<br><input checked="" type="checkbox"/> No<br><input type="checkbox"/> Partially<br><input type="checkbox"/> Unclear | <input type="checkbox"/> None<br><input type="checkbox"/><br>Justification required | no publications were 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 type="checkbox"/> Yes fully<br><input checked="" type="checkbox"/> No<br><input type="checkbox"/> Partially<br><input type="checkbox"/> Unclear | <input type="checkbox"/> None<br><input type="checkbox"/><br>Justification required | no relevant publications were obtainable   |

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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 type="checkbox"/> Yes fully     | <input type="checkbox"/> None | no relevant publications were obtainable |
|                                                                                                                                                                                                                                                                      | <input checked="" type="checkbox"/> No | <input type="checkbox"/>      |                                          |
|                                                                                                                                                                                                                                                                      | <input type="checkbox"/> Partially     | Justification required        |                                          |
|                                                                                                                                                                                                                                                                      | <input type="checkbox"/> Unclear       |                               |                                          |