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): ⓧ Herbicide tolerance: PAT confers tolerance to glufosinate-ammonium ⓧ Insect resistance: Cry1Ab confers resistance to certain lepidopteran pests ☐ Others: not applicable
Scope: ⓧ Import/processing for food/feed uses ☐ Cultivation

Specify the context in which literature searching is performed
☐ GMO applications for market authorisation submitted under Regulation (EC) No 1829/2003 *after* the Implementing Regulation (EU) No 503/2013 entered into force on 8 December 2013 → *Review type: Scoping review to substantiate decisions about the value of conducting full or "rapid" systematic literature reviews*
☐ GMO applications for market authorisation submitted under Regulation (EC) No 1829/2003 *before* the Implementing Regulation (EU) No 503/2013 entered into force on 8 December 2013 → *Review type: Extensive/systematic literature search*
ⓧ Annual PMEM reports on GMOs authorised in the EU market → *Review type: Extensive/systematic literature search*
☐ GMO applications for the renewed market authorisation of genetically modified (GM) food/feed authorised under Regulation (EC) No 1829/2003 → *Review type: Extensive/systematic literature search*

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]	ⓧ Yes fully ☐ No ☐ Partially ☐ Unclear	☐ None ☐ 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]	ⓧ Yes fully ☐ No ☐ Partially ☐ Unclear	☐ None ☐ Justification required	
Searching for/identifying relevant publications			
Search a minimum of *at least* two multi-disciplinary/large electronic bibliographic databases, based on the recommendations given in Section 3.2.1.1 of the Explanatory note [APDESK check]	ⓧ Yes fully ☐ No ☐ Partially ☐ Unclear	☐ None ☐ Justification required	
Search internet pages of relevant key organisations delivering risk assessment guidelines and other risk assessment documents,	ⓧ Yes fully ☐ No ☐ Partially ☐ Unclear	☐ None ☐ Justification required	

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]	[x] Yes fully [ ] No [ ] Partially [ ] Unclear	[ ] None [ ] 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]	[x] Yes fully [ ] No [ ] Partially [ ] Unclear	[ ] None [ ] 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]	[x] Yes fully [ ] No [ ] Partially [ ] Unclear	[ ] None [ ] 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]	[x] Yes fully [ ] No [ ] Partially [ ] Unclear	[ ] None [ ] Justification required	
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]	[x] Yes fully [ ] No [ ] Partially [ ] Unclear	[ ] None [ ] 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]	[ ] Yes fully [x] No [ ] Partially [ ] Unclear	[ ] None [ ] Justification required	}[Ȧ˘à|Ȧǽɕ}•Ȧ^¦^Ȧ˘} 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]	[ ] Yes fully [x] No [ ] Partially [ ] Unclear	[ ] None [ ] 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	[x] Yes fully [ ] No [ ] Partially [ ] Unclear	[ ] None [ ] Justification required	

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]	☐ Yes fully ☒ No ☐ Partially ☐ Unclear	☐ None ☐ Justification required	not applicable
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]	☒ Yes fully ☐ No ☐ Partially ☐ Unclear	☐ None ☐ Justification required	