

## Annex 2

# Requirements/recommendations according to the Explanatory note to the guidance 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<sup>1</sup>

### Completeness checklist

<b>Specifying the application number, event(s), plant species, intended trait(s), and the scope of the application for which literature searching is performed</b>
Application number:
Event(s): MON 87769
Plant species: soybean
Intended trait(s): <input type="checkbox"/> Herbicide tolerance: <input type="checkbox"/> Insect resistance: <input checked="" type="checkbox"/> Others: improved fatty acid profile
Scope: <input checked="" type="checkbox"/> Import/processing for food/feed uses <input type="checkbox"/> Cultivation
<b>Specifying the context in which literature searching is performed</b>
<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>
<b>Specifying the context of literature searching</b>
<input checked="" type="checkbox"/> Initial literature search
<input type="checkbox"/> Updated literature search requested by EFSA
<input type="checkbox"/> Revised literature search requested by EFSA

<sup>1</sup> EFSA (European Food Safety Authority), Devos Y, Guajardo IM, Glanville J and Waigmann E, 2017. 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 publications 2017:EN-1207. 8 pp. doi:10.2903/sp.efsa.2017.EN-1207; <http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2017.EN-1207/pdf>

Subject	Completeness Check (CC) performed by the applicant	Action required	Justification
<b>Identifying review questions and clarifying their purpose</b>			
Clarify the purpose for undertaking the literature review, and link it to the review question(s)	<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	
Formulate clear, unambiguous and structured question(s)	<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	
Identify and specify the key elements of the review question(s) based on the recommendations given in Section 3.1 of the Explanatory note	<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 studies for inclusion in the literature review, using Table 1 of the Explanatory note	<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	
<b>Searching for/identifying relevant studies</b>			
Describe clearly how the search strategy is constructed, and provide a scientific rationale for choices made in terms of search terms and their combination, using Appendix B of the Explanatory note	<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 and justify any limits applied to the search strategy	<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 the language of the search	<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 the time period of the search	<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	
Use a subset of representative studies to refine the search and test its validity	<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	
Search a minimum of <i>at least</i> two multi-disciplinary/large databases (e.g., Web of Science Core Collection, Scopus, CAB Abstracts, Medline)	<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	

Consider searching specialist/subject-specific databases (e.g., Agricola) [facultative]	<input checked="" type="checkbox"/> Yes fully	<input type="checkbox"/> None	
	<input type="checkbox"/> No	Justification required	
	<input type="checkbox"/> Partially		
	<input type="checkbox"/> Unclear		
Describe the information sources searched, and the reasons for their selection in terms of the coverage of the literature of interest	<input checked="" type="checkbox"/> Yes fully	<input type="checkbox"/> None	
	<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, using the examples given in Section 3.2.2.2 of the Explanatory note	<input checked="" type="checkbox"/> Yes fully	<input type="checkbox"/> None	
	<input type="checkbox"/> No	Justification required	
	<input type="checkbox"/> Partially		
	<input type="checkbox"/> Unclear		
Search scientific literature by using general search engines such as GOOGLE Scholar, and checking and assessing the relevance of the first 200 to 300 results, if available [facultative]	<input type="checkbox"/> Yes fully	<input type="checkbox"/> None	Covered by Web of Science™ core collection database. The Web of Science™ Core Collection database is connected to Google Scholar to allow a seamless movement between the open web and the Web of Science™ Core Collection for the literature search.
	<input checked="" type="checkbox"/> No	Justification required	
	<input type="checkbox"/> Partially		
	<input type="checkbox"/> Unclear		
Search web-based databases known to contain information specifically on effects of GMOs on human and animal health and the environment [facultative]	<input type="checkbox"/> Yes fully	<input type="checkbox"/> None	Covered by Web of Science™ core collection database and CAB Abstracts® database
	<input checked="" type="checkbox"/> No	Justification required	
	<input type="checkbox"/> Partially		
	<input type="checkbox"/> Unclear		
Identify any additional relevant studies by checking the reference lists from recent reviews on relevant topics, methodological studies and scientific opinions from regulatory agencies involved in the risk assessment of GMOs	<input type="checkbox"/> Yes fully	<input type="checkbox"/> None	Web of Science™ core collection database known for its comprehensive coverage of scientific journals with high quality and peer reviewed articles, allowing for both broad and in-depth exploration of focused scientific areas
	<input checked="" type="checkbox"/> No	Justification required	
	<input type="checkbox"/> Partially		
	<input type="checkbox"/> Unclear		
Hand-search key journals or assess journal contents pages [facultative]	<input type="checkbox"/> Yes fully	<input type="checkbox"/> None	Web of Science™ core collection database known for its comprehensive coverage of scientific journals with high quality and peer reviewed articles, allowing for both broad and in-depth exploration of focused scientific areas
	<input checked="" type="checkbox"/> No	Justification required	
	<input type="checkbox"/> Partially		
	<input type="checkbox"/> Unclear		

Perform citation searching [ <b>facultative</b> ]	<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	Web of Science™ core collection database known for its comprehensive coverage of scientific journals with high quality and peer reviewed articles, allowing for both broad and in-depth exploration of focused scientific areas
<b>Selecting studies</b>			
Select relevant studies in two stages (stage 1: <i>rapid assessment</i> for relevance based on information in the title and abstract of studies; stage 2: <i>detailed assessment</i> of full-text documents)	<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	
Assess studies for their relevance by more than one reviewer at all stages of the screening process	<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	
Ensure inter-reviewer agreement	<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	
Document the process for resolving disagreements/discrepancies between reviewers during the screening process	<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	
Classify for each category of information/data requirement: (1) Studies that might provide data for establishing or refining risk assessment parameters/conclusions, or supplementary information that might be relevant to the review question; and (2) studies for which relevance cannot be clearly determined, or which cannot be obtained as full-text documents	<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	
<b>Extracting of high level data from the relevant studies [<b>only applicable to scoping reviews</b>]</b>			
Extract high level information from each relevant study to describe the overall volume, strength and direction of the evidence base	<input 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	Not applicable as monitoring
Describe variables for which information is extracted	<input 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	Not applicable as monitoring

Develop a data-charting form	<input 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	Not applicable as monitoring
<b>Summarising and reporting the data, and considering the implications of the findings</b>			
Provide report(s) that contain the following information/sections: <ul style="list-style-type: none"> <li>• Title;</li> <li>• Authors of the review;</li> <li>• Summary: a brief summary indicating the purpose of the report, the methodology employed, and the results obtained;</li> <li>• Methods, which should contain:             <ul style="list-style-type: none"> <li>– A statement of the objective of the scoping review;</li> <li>– The review questions, along with a rationale clarifying the choices made;</li> <li>– The criteria for relevance with which decisions to select studies were made;</li> <li>– Information on and result of the reference study searches;</li> </ul> </li> <li>• Search methods and outcomes, including a descriptive summary and rationale clarifying the choices made;</li> <li>• Results of the study identification and selection process, including a descriptive summary;</li> <li>• A narrative synthesis/summary of the relevant studies, describing their overall volume, strength and direction (only applicable for scoping reviews)</li> </ul>	<input type="checkbox"/> Yes fully <input type="checkbox"/> No <input checked="" type="checkbox"/> Partially <input type="checkbox"/> Unclear	<input type="checkbox"/> None <input type="checkbox"/> Justification required	Partially applicable as monitoring

<p>Provide the following information for each of the electronic bibliographic databases searched in a series of tables:</p> <ul style="list-style-type: none"> <li>• The bibliographic database name and the service provider used;</li> <li>• The justification for choosing the database;</li> <li>• The date on which the search was conducted;</li> <li>• The date of the most recent update of the database that was searched;</li> <li>• The date span of the search;</li> <li>• The complete search strategy or strategies used, including all the search terms, text-words (words in titles or abstracts), subject index headings (thesaurus terms or descriptors), and the relationship between the search terms (how they have been combined using Boolean operators);</li> <li>• Any limits applied to the search (e.g., study types, dates, languages);</li> <li>• The total number of records retrieved from the information source before and after removing duplicates</li> </ul>	<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	
<p>If literature is found in information sources other than electronic bibliographic databases, then report the following information:</p> <ul style="list-style-type: none"> <li>• For a website (e.g., a conference or organisation website containing scientific literature):             <ul style="list-style-type: none"> <li>– The website name and the service publisher used (e.g., Author/Editor/Organisation's name and Title of the page);</li> <li>– A justification for choosing the source;</li> <li>– The URL (internet address);</li> </ul> </li> </ul>	<input 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	Not applicable as Web of Science™ and EBSCOhost platforms are used

<ul style="list-style-type: none"> <li>- The date on which the search was conducted;</li> <li>- The date of the most recent website update at the time it was searched;</li> <li>- The date span of the search;</li> <li>- The search terms used. Often a series of single searches will be carried out but if searches with combinations of terms are possible then these should also be reported;</li> <li>- Any limits applied to the search (e.g., study types);</li> <li>- The number of relevant records or full-text documents retrieved.</li> <li>• For journal tables of contents: <ul style="list-style-type: none"> <li>- The journal name;</li> <li>- A justification for choosing the source;</li> <li>- The journal URL (internet address) or publisher;</li> <li>- The dates, volumes and issues searched;</li> <li>- The method of searching, e.g., scanning tables of contents for each issue, or using a search engine;</li> <li>- The search terms used (if any);</li> <li>- The number of relevant records or full-text documents retrieved.</li> </ul> </li> <li>• For reference lists: <ul style="list-style-type: none"> <li>- The bibliographic details of the documents whose reference lists were scanned;</li> <li>- The number of relevant bibliographic references retrieved</li> </ul> </li> </ul>			
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Report the results of the 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	<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 studies, ordered by category of information/data requirement, recorded, using Table 3 of the Explanatory note	<input 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	Not applicable since there was no such study
Provide a list of the bibliographic references for all excluded studies after detailed assessment of full-text documents for relevance, with justification for their exclusion, recorded, using Table 4 of the Explanatory note	<input 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	Not applicable since there was no such study
Provide a list of the bibliographic references for all unobtainable/unclear studies, recorded, using Table 5 of the Explanatory note	<input 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	Not applicable since there was no such study
Provide copies of the full-text documents listed in Table 3 of the Explanatory note	<input 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	Not applicable since there was no such study
Translate relevant full-text documents in non-EU languages into English	<input 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	Not applicable since there was no such study
Present a narrative synthesis/summary of the relevant studies describing their overall volume, strength and direction per main category of information/data requirements, using Table 6 of the Explanatory note [only applicable to scoping reviews]	<input 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	Not applicable as monitoring
Determine whether a systematic literature review is of value [only applicable to scoping reviews]	<input 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	Not applicable as monitoring
Discuss the implications of each study 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 7 of the Explanatory note	<input 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	Not applicable since there was no such study