



GENETICALLY MODIFIED ORGANISMS UNIT

## Annex 2 Appraisal of systematic literature review

### Critical appraisal tool (CAT)

Applicants and risk assessors may wish to assess the information sources used and search approaches adopted using the CAT shown below. This CAT updates the former CAT on extensive literature searches developed by EFSA (Appendix D of EFSA, 2015) and integrates considerations given in EFSA (2010; 2019).

**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): MON 810

Plant species: *Maize*

Intended trait(s):

- Herbicide tolerance:
- Insect resistance: Lepidopteran protection
- Others:

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*



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
<b>A. Formulating review questions and clarifying their purpose</b>				
<b>A1</b>	<p><b>Review question</b> <i>Is/Are the review question/s appropriately translated into key elements/search concepts?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- The purpose of the review question(s) is clearly explained and reported;</li> <li>- The review question(s) is/are: (1) translated and broken down into clear and appropriate key elements/search concepts (e.g., Population, Intervention or Exposure, Comparator, Outcome); or (2) represented by the categories of information/data requirements outlined in relevant GMO Panel guidance documents, EFSA explanatory notes and the Implementing Regulation (EU) No 503/2013 (see Appendix A of EFSA (2019)).</li> </ul>	<p><b>Review question:</b> Do MON 810 maize, derived food/feed products and its respective introduced trait have adverse effects on human and animal health and the environment?</p> <p><b>Key elements:</b>  <b>Population:</b> Humans, animals, and/or the environment  <b>Intervention:</b> MON 810 maize, derived food/feed products and respective introduced traits  <b>Comparators:</b> conventional counterpart or non-GM maize  <b>Outcome:</b> adverse effect on human and animal health, and the environment            Report Number: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf, page 5.</p>	<input type="checkbox"/> Definitively appropriate <input checked="" type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input type="checkbox"/> Not applicable	<p>The review question is translated into PICO/PECO elements, which are covering relevant <b>P</b>opulation (humans, animals, environment), <b>I</b>ntervention (GM event, newly intended traits), <b>C</b>omparator (non-GM species) and <b>O</b>utcome (adverse effects on human or animal health or on the environment).</p> <p>The review question does not explicitly address the newly expressed proteins, but these are reflected in the search terms used by the applicant nonetheless, despite not being explicitly mentioned in the review question.</p>
<b>A2</b>	<p><b>Eligibility/inclusion criteria</b> <i>Are eligibility/inclusion criteria for assessing the relevance of publications appropriate/justified and clearly defined and reported?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- Clear eligibility/inclusion criteria are determined and reported to establish relevance (e.g., by using Table 1 of EFSA (2019) as example);</li> <li>- A rationale is provided for the selection of eligibility/inclusion criteria;</li> <li>- The eligibility/inclusion criteria are appropriate, e.g., not too restrictive to hamper the identification of relevant publications and easy to interpret and apply;</li> <li>- The applicability of eligibility/inclusion criteria was tested and refined on a subset of publications or full-text documents (pilot-testing);</li> </ul>	<p>The eligibility criteria for assessing the relevance of studies for inclusion in the literature review are provided in Table 1            Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf, page 6</p>	<input type="checkbox"/> Definitively appropriate <input checked="" type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input type="checkbox"/> Not applicable	<p>Eligibility/inclusion criteria are reported in a clear way in Table 1, following the format presented in Table 1 of EFSA Guidance Note 2017 and 2019.</p> <p>The applicant defines general inclusion criteria, there are no exclusion criteria set by the applicant.</p> <p>No scientific rationale is provided for the selection of eligibility/inclusion criteria, but the eligibility criteria are in general very unrestrictive and therefore appropriate without a high risk of omission of potentially relevant studies.</p>



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
	- The selection of eligibility/inclusion criteria is appropriate and does not require fine tuning.			
<b>A3</b>	<b>Any other comment: NONE</b> Insert here any additional relevant comment about formulating review questions and clarifying their purpose that has not been captured by the appraisal questions A1 and A2.			
<b>B. Searching for/identifying relevant publications</b>				
<b>B1</b>	<b>Information sources</b> <i>Is the search extensive enough (i.e., whether relevant and reliable combination of information sources is used)?</i> The appraisal should consider whether: - At least two multidisciplinary/large electronic bibliographic databases (e.g., Web of Science Core Collection, Scopus, CAB Abstracts, Medline) and internet pages of relevant key organisations (e.g., regulatory agencies and risk assessment bodies involved in the risk assessment of GMOs) are searched; - Other search approaches are used to identify any additional relevant publications (e.g., check/scan of the reference list of relevant publications including recent reviews on relevant topics, methodological publications, guidelines and scientific opinions from regulatory agencies involved in the risk assessment of GMOs; hand-searching; citation searching); - A description of the information sources searched and the reasons for their selection is provided.	The searches were performed in two different databases - SciSearch and CABA databases using the STN® database catalogue. Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf, page 7 and several other sections in the report. In accordance with the EFSA 2019 explanatory note on literature searching for GMO applications (EFSA, 2019), the search in electronic bibliographic databases has been complemented with internet search in webpages of relevant key organisations involved in the risk assessment of GM plants. Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf, page 8	<input type="checkbox"/> Definitely appropriate <input type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input checked="" type="checkbox"/> Definitely not appropriate <input type="checkbox"/> Not applicable	Two multidisciplinary/large electronic databases were used for the literature searches. A description of the information sources searched is provided, but without any discussion on the reasons for their selection and/or without discussion/justification why also other information sources were not included or considered (e.g. EMBASE) and what might be the impact of their non-inclusion. Besides multidisciplinary/large electronic databases, the applicant searched also websites of relevant key organisations (9 in total). Despite using selected reference publications for validating the search strategy, the applicant does not report whether reference lists of recent review articles to search for potentially relevant studies were screened as recommended in EFSA Guidance Note 2019 section 3.2.1.3.
<b>B2</b>	<b>Search strategy</b> <i>Is the search strategy designed to be sensitive to identify as many relevant publications as possible? Does</i>	Section 3.2.1 and Annex I	<input checked="" type="checkbox"/> Definitely appropriate <input type="checkbox"/> Probably	The searches are carried out in two different databases - SciSearch and CABA databases using STN® database catalogue



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
	<p><i>the search strategy result in an optimal combination of key elements of the review question/search concepts in terms of sensitivity?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- A rationale is provided for the construction of the search strategy (e.g., the choices made in terms of search terms and their combination);</li> <li>- The search strategy has high sensitivity;</li> <li>- A rationale is provided to justify adapting the search strategy to achieve higher specificity;</li> <li>- "Too many" key elements of the review question/search concepts are used (resulting in a low sensitivity);</li> <li>- The search concepts are too broad or too narrow;</li> <li>- The search retrieves too many or few publications;</li> <li>- The search has been adapted to the number of publications identified.</li> </ul>	<p>Report No.: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf, page 15</p>	<p>appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input type="checkbox"/> Definitively not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>The search strategy is adequately reflecting the key elements identified in the review question as well as other relevant search elements (e.g. trade name and intended traits), with clear discussion for the construction of the search strategy and of the choices made in terms of search terms and their combination.</p> <p>The search strategy has generally high sensitivity.</p>
<b>B3</b>	<p><b>Pilot study</b></p> <p><i>Was a pilot study performed to assess the performance of the search strategy?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- A pilot test was conducted with a set of reference publications;</li> <li>- The reference publications were retrieved in the queried information sources;</li> <li>- New publications not in the reference publications were identified;</li> <li>- The outcome of the pilot study was used to develop, test, fine-tune and validate the search strategy;</li> <li>- The reference publications used for each of the key elements of the review question were provided together with a rationale for their selection;</li> <li>- Alternative approaches were used for the identification of reference publications;</li> </ul>	<p>Three publications reported by the applicant were used in validating the literature search strategy.</p> <p>Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf, page 10 (section 3.2.5) and Annex III</p>	<p><input type="checkbox"/> Definitively appropriate</p> <p><input type="checkbox"/> Probably appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input checked="" type="checkbox"/> Definitively not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>The applicant claims to have used three reference publications for validating the search strategy as part of the protocol development. However, the conduct of the validating pilot study is not documented by the applicant. i.e., the applicant does not provide any information on the pilot study and its outcomes to confirm the validity of the selected search strategy/methodology or to allow its fine-tuning based on the outcome of the pilot study.</p> <p>The rationale for selection of the reference publications is discussed in very general terms and it is not reported whether new publications not included in the set of reference publications were identified/retrieved in the pilot study. The pilot study therefore does not provide sufficient evidence to assess</p>



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	<ul style="list-style-type: none"> <li>- The percentage of reference publications finally identified by the search strategy is reported for each of the electronic bibliographic databases used;</li> <li>- In case that no suitable reference publications were identified, the approaches used for their identification were provided.</li> </ul>			whether the designed strategy is appropriate and fit-for-purpose
<b>B4</b>	<p><b>Search strategy adaptations for each database</b></p> <p><i>Is the search strategy appropriately adapted for each electronic bibliographic database used?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- The search strategy is appropriately adapted to run successfully in the different information sources or electronic bibliographic databases covering synonyms, abbreviations and spelling variants;</li> <li>- Adaptations are clearly reported.</li> </ul>	<p>Section 3.2 and Section 3.3.</p> <p>Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf, page 8-9</p>	<input checked="" type="checkbox"/> Definitively appropriate <input type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input type="checkbox"/> Not applicable	<p>The searches are carried out in 2 databases through a single search platform – Scientific and Technical Information Network (STN). It is therefore not necessary to adapt the search queries to different information sources.</p> <p>The search strategy is appropriately adapted to the STN search platform used by the applicant.</p>
<b>B5</b>	<p><b>Search terms</b></p> <p><i>Are search terms appropriately identified?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- The approaches used to identify search terms are reported and justified;</li> <li>- At least two of the approaches described in Section 3.2.2.2 of EFSA (2019) are used.</li> </ul>	<p>Section 3.2 and Annex I (Report No.: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf)</p>	<input checked="" type="checkbox"/> Definitively appropriate <input type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input type="checkbox"/> Not applicable	<p>The search terms include the event name, newly expressed proteins, newly expressed RNA, intended traits: herbicide resistance/tolerance traits, hybridisation system traits, insect protection traits, drought tolerance traits, increased biomass traits, crop name and GMO general terms are appropriately used by the applicant and described in Section 3.2 and Annex I.</p> <p>The breadth of the search terms used by the applicant is generally very high and well justified.</p> <p>Multiple approaches described in Section 3.2.2 of EFSA Guidance Note and 2010 were used by the applicant to identify search terms.</p>
<b>B6</b>	<p><b>Free-text terms</b></p> <p><i>Are free-text terms appropriate for each search concept?</i></p>	<p>Section 3.2 and Annex I (Report No.: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf)</p>	<input type="checkbox"/> Definitively appropriate <input checked="" type="checkbox"/> Probably	<p>Free-text search terms used by the applicant are generally very broad, including keywords related to plant species (Maize, Zea Mays),</p>



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
	<p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- A wide range of free-text terms is used. Search terms should include: truncation; possible synonyms; related terms; acronyms/abbreviations and full terms; spelling variants; old and new terminology; OECD, brand and generic/common names; lay and scientific terminology;</li> <li>- Synonyms in the thesaurus of electronic bibliographic databases have been identified and searched for as free-text terms, in addition to searching their associated subject indexing terms;</li> <li>- Apparently irrelevant or excessively broad free-text terms are used;</li> <li>- Appropriate fields have been searched;</li> <li>- The selection of search terms and their combination remain appropriate and do not require fine tuning (either by addition, deletion or changes to options such as truncation or the use of proximity operators) [NOTE: Only applicable to updated searches].</li> </ul>		<p>appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input type="checkbox"/> Definitively not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>newly expressed proteins (CP4 EPSPS), newly expressed RNA (DvSnf7), intended traits (herbicide resistance/tolerance, hybridisation system traits, insect protection traits, drought tolerance traits and increased biomass traits) (page 17).</p> <p>No scientific rationale is provided for the selection of search terms, however, the selection of search terms seems to be comprehensive.</p> <p>The applicant used also a wide range of synonyms of the keywords wherever possible. Appropriate fields have been searched ( “Basic Index” (None (or /BI)) field).</p>
<b>B7</b>	<p><b>Subject indexing terms</b></p> <p><i>Are subject indexing terms (controlled terms) appropriate for each search concept and information source used (when applicable)?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- The electronic bibliographic databases used enable the use of subject indexing terms;</li> <li>- The subject indexing terms used are relevant;</li> <li>- Any subject indexing terms are missing;</li> <li>- Appropriate subject indexing terms were identified for the desired key elements of the review questions by searching the thesauri of electronic bibliographic databases for matching indexing terms (if available), or by searching for obvious relevant publications and noting the indexing terms which have been added to those records by the database indexers;</li> </ul>	<p>All searches were performed in STN® literature search that utilised Basic Index (BI) field which utilises free-text search terms and enables comprehensive searching in different sections (e.g. title, abstract, keywords, supplementary terms, controlled terms.</p> <p>The search was also adapted to controlled vocabulary.</p> <p>Report No.: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf, Annex I and Annex II, page 15-21</p>	<p><input checked="" type="checkbox"/> Definitively appropriate</p> <p><input type="checkbox"/> Probably appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input type="checkbox"/> Definitively not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>The applicant used subject indexing terms in the searches wherever possible.</p> <p>The subject indexing terms were selected to provide extensive coverage of the subject matter and retrieve a high number of potentially relevant articles.</p> <p>The indexing terms used by the applicant in the searches are well documented in Table 2 of Annex I.</p>



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
	<ul style="list-style-type: none"> <li>- Any subject indexing terms are too broad or too narrow;</li> <li>- Any subject indexing terms are exploded where necessary and vice versa;</li> <li>- A rationale is given for not using subject indexing terms;</li> <li>- The use of any subheadings is helpful (i.e., not too focused);</li> <li>- The use of any floating subheadings would have been helpful and, if their use is appropriate;</li> <li>- Both subject indexing terms and free-text terms are used for each search concept, if permitted by the database interface.</li> </ul>			
<b>B8</b>	<p><b>Spelling</b></p> <p><i>Is the appropriate spelling used?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- Any spelling errors are identified in the free-text terms employed;</li> <li>- Deliberate spelling errors are used in the free-text terms.</li> </ul>	Spelling variants including common typos of the search terms were considered (page 9 and Annex I of the Report no. Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf)	<input checked="" type="checkbox"/> Definitively appropriate <input type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input type="checkbox"/> Not applicable	No spelling errors were identified in the search terms used by the applicant. In the free-text search terms, the applicant introduces deliberate spelling errors and variants which might occur in scientific literature, e.g. spelling errors/variants related to the names of the event e.g. MON 810 or MON-ØØ81Ø-6, MON-88Ø17-3, MON-89Ø34-3.
<b>B9</b>	<p><b>Truncation</b></p> <p><i>Is truncation appropriately applied?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- Any of the free-text terms used in the search miss truncation or are truncated at the wrong point;</li> <li>- Truncation is applied consistently;</li> <li>- Truncation symbols are adapted to each electronic bibliographic database used.</li> </ul>	Truncations of the search terms were considered (page 9 and Annex I of the Report no. Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf)	<input checked="" type="checkbox"/> Definitively appropriate <input type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input type="checkbox"/> Not applicable	Truncation characters are used in an appropriate and consistent way for relevant keywords/search terms used in the searches



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
<b>B10</b>	<p><b>Wild cards and phrase searching</b></p> <p><i>Are wild cards and quotation marks appropriately applied?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- Wild cards are used in any of the free-text terms to account for spelling variants;</li> <li>- Quotation marks are used (when required) for multi-word terms;</li> <li>- Wild cards and quotation marks (if required) are adapted to each electronic bibliographic database used.</li> </ul>	Annex I of the Report no. Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf)	<input checked="" type="checkbox"/> Definitively appropriate <input type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input type="checkbox"/> Not applicable	Wild cards and quotation marks are used in an appropriate and consistent way for relevant keywords/search terms used in the searches.
<b>B11</b>	<p><b>Boolean and proximity operators</b></p> <p><i>Are Boolean and proximity operators appropriately used to combine search terms?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- There are any mistakes in the use of Boolean or proximity operators, e.g., if "AND" is inadvertently replaced by OR (or vice versa);</li> <li>- There are any mistakes in the use of nesting with brackets;</li> <li>- If "NOT" is used, there is an unintended exclusion; or if another mechanism would have been a more suitable alternative (e.g., a proximity operator);</li> <li>- The width of any proximity operators is too wide, or not wide enough;</li> <li>- The potential importance of word order, when using such operators, is accounted for.</li> </ul>	Annex I of the Report no. Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf)	<input type="checkbox"/> Definitively appropriate <input checked="" type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input type="checkbox"/> Not applicable	<p>Mainly the "OR" operator is used to combine keywords into search queries in most cases, broadening the searches. This is considered appropriate and fit-for-purpose.</p> <p>Boolean operator "AND" is used to combine certain sets of keywords (intended traits "herbicide", combined with terms that indicate resistance/tolerance, "hybridisation system", insect protection trait, drought tolerance traits and increased biomass traits), the "AND" operator is used in an appropriate way.</p> <p>Boolean operator "NOT" is not used in the searches, minimising the risk of prohibitively narrow searches.</p> <p>Proximity operators are also used in the searches carried out by the applicant in an appropriate way.</p>
<b>B12</b>	<p><b>Line numbers</b></p> <p><i>Are the line numbers appropriately reported and combined?</i></p> <p>The appraisal should consider whether:</p>	Report no. Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf	<input checked="" type="checkbox"/> Definitively appropriate <input type="checkbox"/> Probably	The number of publications identified in each search / after each search query is reported in a clear and transparent way.





#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
	<ul style="list-style-type: none"> <li>- The number of publications identified is reported for each line;</li> <li>- Line numbers are appropriately combined;</li> <li>- Search sets that already yield only a small number of publications are combined;</li> <li>- Screenshots are provided when a single search line is used.</li> </ul>		<p>appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input type="checkbox"/> Definitely not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>Annex II presents number of references retrieved from each database after each search query.</p> <p>The line numbers were combined in an appropriate manner.</p>
<b>B13</b>	<p><b>Search limits</b></p> <p><i>Are limits appropriately applied?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- Limits to the search strategy (e.g., dates, publication types), if applied, are adequately justified and clearly reported;</li> <li>- The limits used are appropriate. In case of updated searches, it should be considered whether there is an overlapping period with the previously performed search).</li> </ul>	<p>ED&gt;=20190501 AND ED&lt;=20200528 AND PY&gt;=2019</p> <p>Annex II of the Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf</p>	<p><input type="checkbox"/> Definitely appropriate</p> <p><input type="checkbox"/> Probably appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input checked="" type="checkbox"/> Definitely not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>The applicant limited the searches to publications published in 2019 or later (PY&gt;=2019) and with the Entry Date between 1 May 2019 and 28 May 2020 (ED&gt;=20190501 AND ED&lt;=20200528). This is in direct conflict with the methodology proposed in section 3.6.2 of EFSA Guidance Note 2019.</p> <p>Furthermore, the applicant does not provide any justification for applying these search limits.</p>
<b>B14</b>	<p><b>Search filters</b></p> <p><i>Are filters appropriately used?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- A rationale is provided for using filters;</li> <li>- Search filters used are pre-tested and validated;</li> <li>- The filters used are appropriate;</li> <li>- Any helpful/relevant available filters are missing;</li> <li>- The limiting effects are reported.</li> </ul>	<p>Annex II of the Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf</p>	<p><input checked="" type="checkbox"/> Definitely appropriate</p> <p><input type="checkbox"/> Probably appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input type="checkbox"/> Definitely not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>No filters were applied to filter out any retrieved references before screening of titles/abstracts.</p>
<b>B15</b>	<p><b>Any other comment: NONE</b></p> <p>Insert here any additional relevant comment about searching/identifying relevant publications that has not been captured by the appraisal questions B1 to B15.</p>			

### C. Selecting publications



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
C1	<p><b>Eligibility screening process</b></p> <p><i>Is the process of selecting relevant publications appropriately reported and performed?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- Relevant publications are selected following a two-stage approach: (1) screening of title and abstract of retrieved publications; and (2) screening of full-text documents;</li> <li>- Attempts are made to obtain all full-text of publications;</li> <li>- Clarifications/additional information are/is requested to establish relevance (if needed);</li> <li>- Any limitations in the eligibility screening process are reported.</li> </ul>	<p>The process of selecting relevant publications was undertaken in two stages:</p> <ul style="list-style-type: none"> <li>- Rapid assessment for the relevance based on information in the title and abstract of the publications, to exclude publications that are obviously irrelevant.</li> <li>- Detailed assessment of full-text document if required. Full-text documents were obtained for those publications not excluded in the rapid assessment and those documents were assessed in detail for their relevance to the review question. Publications not excluded by the detailed assessment were classified as relevant. At this stage, publications must comply with all the eligibility/inclusion criteria and meet all key elements of the review question.</li> </ul> <p>(Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf)</p>	<p><input checked="" type="checkbox"/> Definitively appropriate</p> <p><input type="checkbox"/> Probably appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input type="checkbox"/> Definitively not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>Two-step selection process was followed (1) screening based on rapid assessment of titles and abstracts; and (2) retrieval of full-text documents for detailed assessment.</p> <p>466 references were excluded after stage 1 screening of titles and abstracts (out of 490 total references screened after removal of duplicates) and 24 full-text publications were further considered for detailed assessment, i.e. stage 2 screening of full-text documents.</p> <p>These 24 studies were assessed in detail based on the full text of the studies.</p> <p>10 out of the 24 retrieved publications were excluded after the assessment of the fulltext reports.</p> <p>The selection process is documented in a clear and transparent way in Annex V.</p>
C2	<p><b>Review team</b></p> <p><i>Is the review team properly allocated to the selection of relevant publications?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- The relevance of the identified publications is independently assessed by at least two reviewers at the level of title and abstract as well as of full-text;</li> <li>- The number of reviewers involved at each eligibility screening step are reported, with justifications;</li> <li>- The review team consists of reviewers with different backgrounds and expertise in evidence synthesis</li> </ul>	<p>All publications that were identified by the search described in Section 3 have been screened by three different reviewers (one internal and two external experts) with solid experience in the risk assessment of GM plants.</p> <p>Section 4.2 of the Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf</p>	<p><input type="checkbox"/> Definitively appropriate</p> <p><input checked="" type="checkbox"/> Probably appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input type="checkbox"/> Definitively not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>In accordance with EFSA Guidance Note 2010 and 2019, the relevance of identified publications is assessed by more than one reviewer in each step of the review process (abstract+title screening and screening of fulltext publications).</p> <p>solid</p> <p>The applicant claims that the reviewers have solid experience in the risk assessment of GM plants, the particular expert profile(s) of the reviewers is not presented in more detail by the applicant.</p>



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
	(e.g., information specialist) and the topic area (domain).			
<b>C3</b>	<p><b>Reviewer agreement</b></p> <p><i>Is a suitable reviewer agreement system put in place to select relevant publications?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- A process for assessing the level of agreement between reviewers is in place and documented;</li> <li>- The size of the sample of identified publications used to assess reviewer agreement is reported and appropriate, and whether the sample was selected randomly;</li> <li>- Inter-reviewer agreement is determined (e.g., by performing a kappa-test) and pilot tested, and whether enough level of agreement is reached;</li> <li>- The methods used for assessing inter-reviewer agreement are adequate;</li> <li>- A pilot to test the eligibility/relevance criteria and selection process is run;</li> <li>- A process for resolving any disagreements/discrepancies between reviewers is put in place and documented.</li> </ul>	<p>In case of disagreements on eligibility for the inclusion of publications, the reviewers, discuss together. If uncertainty remains, the publication is de facto included for further consideration.</p> <p>Section 4.2 of the Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf</p>	<p><input type="checkbox"/> Definitively appropriate</p> <p><input type="checkbox"/> Probably appropriate</p> <p><input type="checkbox"/> Probably not appropriate</p> <p><input checked="" type="checkbox"/> Definitively not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>Inter-reviewer agreement is not at all discussed or reported by the applicant, which is considered not in line with EFSA Guidance Note 2019 stating that "Applicants should report any assessment of reviewer agreement for all steps of the publication selection process".</p>
<b>C4</b>	<p><b>Classification of publications</b></p> <p><i>Are relevant publications appropriately classified and summarised?</i></p> <p>The appraisal should consider whether:</p> <ul style="list-style-type: none"> <li>- Each publication is appropriately classified according to the review question or category of information/data requirement that it may inform;</li> <li>- Each relevant publication is summarised in detail;</li> <li>- Publications which could not be obtained as full-text document and publications of unclear relevance are reported and the reasons for it provided.</li> </ul>	<p>Section 4 and Annex V</p> <p>Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf</p>	<p><input type="checkbox"/> Definitively appropriate</p> <p><input type="checkbox"/> Probably appropriate</p> <p><input checked="" type="checkbox"/> Probably not appropriate</p> <p><input type="checkbox"/> Definitively not appropriate</p> <p><input type="checkbox"/> Not applicable</p>	<p>Publications regarded as relevant are listed in Table 2 of Annex V, classified according to category of information/data requirement that they may inform. Only titles of the relevant publications are provided, without detailed summary of the publications.</p> <p>Full texts of all publications regarded as potentially relevant were obtained and screened by the applicant.</p>



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
				Table 3 provides justification/reasoning for exclusion of studies from risk assessment after screening of full-text documents.
<b>C4</b>	<b>Any other comment: NONE</b> Insert here any additional relevant comment about selecting publications that has not been captured by the appraisal questions C1 to C3			
<b>D. Extracting of high-level data from the relevant publications</b>				
<b>D1</b>	<b>Extracting of high-level data</b> <i>Are the methods of extracting data appropriately summarised and reported? [NOTE: Only applicable to scoping reviews]</i> The appraisal should consider whether: - The methods of extracting data are appropriately described and reported - Inter-reviewer agreement is ensured if several reviewers are involved in the extraction process of high-level data from the relevant publications.	N/A	<input type="checkbox"/> Definitely appropriate <input type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input checked="" type="checkbox"/> Definitely not appropriate <input type="checkbox"/> Not applicable	No description of the methodology on the extraction of high-level data after detailed assessment of full-text documents is provided by the applicant. There is no indication whether the extraction of data was carried out by a single reviewer or by multiple reviewers.
<b>D42</b>	<b>Any other comment: NONE</b> Insert here any additional relevant comment about extracting high-level data that has not been captured by the appraisal question D1.			
<b>E. Summarising and reporting the data, and considering the implications of the findings</b>				
<b>E1</b>	<b>Summarising and reporting the data</b> <i>Are the search methods and results appropriately summarised and reported?</i> The appraisal should consider whether: - The search process and its results are clearly documented and reported for each information source searched (including how the actual searches were run in the electronic bibliographic databases and which terms, and in what combination, were searched in the websites of relevant key organisations); - The results of the selection process are appropriately reported, e.g., by using Tables 2 (or, alternatively, a	Search methods: Annex I Search strings: Annex II Study selection: Annex IV Search history: Annex II Report No: Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf	<input type="checkbox"/> Definitely appropriate <input checked="" type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitely not appropriate <input type="checkbox"/> Not applicable	The search process and its results are clearly documented and reported, the report also includes the set of retrieved references excluded after screening of fulltext reports. The results of the selection process are appropriately reported, using tables similar to tables presented in EFSA Guidance Note 2019 Full search history is reported by the applicant. A narrative synthesis/summary of the relevant publications describing their overall volume, strength and direction per main category of



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
	<p>flowchart for each category/group of information/data requirement), 3, 4, 5 and 6 of EFSA (2019);</p> <ul style="list-style-type: none"> <li>- A narrative synthesis/summary of the relevant publication describing their overall volume, strength and direction per main category of information/data requirements is provided, e.g., by using Table 7 of EFSA (2019) [<i>NOTE</i>: Only applicable to scoping reviews].</li> </ul>			information/data requirements is not provided as the presented literature search is not a scoping review.
<b>E2</b>	<p><b>Value of undertaking a systematic review</b></p> <p><i>Is the value of undertaking a systematic review appropriately reported? [<i>NOTE</i>: Only applicable to scoping reviews]</i></p> <p>The appraisal should consider whether the applicant clearly reported the value of undertaking a systematic review, accounting for the below considerations:</p> <ul style="list-style-type: none"> <li>- The considerations given in Section 3.5.2.1 of EFSA (2019) are considered;</li> <li>- Relevant publications that have been previously risk assessed/referenced by EFSA and/or its GMO Panel and that have been excluded from the scoping review (according to the criteria outlined in Table 1 of EFSA (2019) are considered.</li> </ul>	N/A	<input type="checkbox"/> Definitively appropriate <input type="checkbox"/> Probably appropriate <input type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input checked="" type="checkbox"/> Not applicable	Not applicable, not a scoping review
<b>E3</b>	<p><b>Implications for risk assessment</b></p> <p><i>Are the implications for risk assessment of each relevant publication appropriately reported?</i></p> <p>The appraisal should consider whether</p> <ul style="list-style-type: none"> <li>- The implications for risk assessment of each relevant publication is assessed (i.e., whether the publication contains any information pointing to new hazards, modified exposure or new scientific uncertainties that would change the conclusions of the risk assessment) and reported, e.g., by using Table 8 of EFSA (2019);</li> <li>- The reliability of each publication is assessed, and a summary of the appraisal is reported;</li> </ul>	<p>The comprehensive literature search relevant to the food, feed, and environmental safety of MON 810 maize found no new information that would invalidate the conclusions of the risk assessment for MON 810 maize. The relevant publications as well as their reliability and implications for the risk assessment are provided in Annex V.</p> <p>Section 5.3 of the Report No. Appendix 5. Results of annual literature search (June 2019 - May 2020).pdf</p>	<input type="checkbox"/> Definitively appropriate <input type="checkbox"/> Probably appropriate <input checked="" type="checkbox"/> Probably not appropriate <input type="checkbox"/> Definitively not appropriate <input type="checkbox"/> Not applicable	<p>The applicant discusses the implications for risk assessment of each relevant publication.</p> <p>The reliability of each publication is assessed, and a summary of the appraisal is reported</p> <p>The process followed/quality criteria considered to assess the reliability and quality of relevant publications are described in general terms.</p>



#	Appraisal question	Information as reported	Appraisal	Rationale for appraisal
	<ul style="list-style-type: none"> <li>- Enough information is provided on the process followed/quality criteria considered to assess the reliability of the publication;</li> <li>- The methods for the quality appraisal of the relevant publications are appropriately described and reported</li> <li>- Inter-reviewer agreement is ensured if several reviewers are involved in the process.</li> </ul>			Inter-reviewer agreement in the process of assessing implications for risk assessment is not discussed.
<b>E4</b>	<p><b>Any other comment: NONE</b></p> <p>Insert here any additional relevant comment about summarising and reporting data that has not been captured by the appraisal questions E1 to E3.</p>			

### References

- EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal, 8, 1–90. Available from <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1637/epdf>
- 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, 14(4), EN- 1207, 1–48. Available from <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2017.EN-1207>.
- EFSA (European Food Safety Authority), Devos Y, Guajardo IM, Álvarez F and Glanville J, 2019. 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 2019:EN-1614. 62 pp. Available from <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2019.EN-1614>