

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 postmarket environmental monitoring reports on GMOs authorised in the EU market¹

Completeness checklist

Specifying the application number, event(s), plant species, intended trait(s), and the scope of the application for which literature searching is performed
Application number:
Event(s): MON 810
Plant species: maize
Intended trait(s):
Herbicide tolerance:
☐ Insect resistance: lepidopteran
U Others:
Scope:
Import/processing for food/feed uses
Specifying 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 \rightarrow 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 <i>before</i>
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 \rightarrow Review type: Extensive/systematic
Interest \rightarrow Review type. Extensive/systematic
GMO applications for the renewed market authorisation of genetically modified (GM) food/feed
authorised under Regulation (EC) No 1829/2003 \rightarrow Review type: Extensive/systematic literature
search
Specifying the context of literature searching
☐ Initial literature search
Updated literature search requested by EFSA
Revised literature search requested by EFSA

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
Identifying review questions and	clarifying their		
Clarify the purpose for undertaking		☐ None	
the literature review, and link it to	☐ No		
the review question(s)	Partially	Justification	
	Unclear	required	
Formulate clear, unambiguous and		☐ None	
structured question(s)	☐ No		
	☐ Partially	Justification	
	Unclear	required	
Identify and specify the key	Yes fully	None	
elements of the review question(s)	No		1
based on the recommendations	Partially	Justification	
given in Section 3.1 of the	Unclear	required	
Explanatory note		,	
Specify/report the	Yes fully	None	
eligibility/inclusion criteria for	No		7
assessing the relevance of studies	Partially	Justification	
for inclusion in the literature	Unclear	required	
review, using Table 1 of the		'	
Explanatory note			
Searching for/identifying relevan	nt studies		
Describe clearly how the search	Yes fully	None	
strategy is constructed, and provide	No		7
a scientific rationale for choices	Partially	Justification	
made in terms of search terms and	Unclear	required	
their combination, using			
Appendix B of the Explanatory note			
Report and justify any limits applied		☐ None	
to the search strategy	☐ No		
	☐ Partially	Justification	
	Unclear	required	
Specify the language of the search	Yes fully	None	
	□ No		7
	Partially	Justification	
	Unclear	required	
Specify the time period of the	Yes fully	None	
search	No		
	Partially	Justification	
	Unclear	required	
Use a subset of representative	Yes fully	None	
studies to refine the search and	□ No		1
test its validity	Partially	Justification	
	Unclear	required	
Search a minimum of at least two	Yes fully	None	
multi-disciplinary/large databases	No		1
(e.g., Web of Science Core	Partially	Justification	
Collection, Scopus, CAB Abstracts,	Unclear	required	
Medline)		required	



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



Perform citation searching	Yes fully	☐ None	Web of Science [™] core
[facultative]	⊠ No		collection database known
	☐ Partially	Justification	for its comprehensive
	Unclear	required	coverage of scientific
			journals with high quality
			and peer reviewed articles,
			allowing for both broad and
			in-depth exploration of
			focused scientific areas
Selecting studies		T 🗀	
Select relevant studies in two	Yes fully	│	_
stages (stage 1: rapid assessment	∐ No		
for relevance based on information	Partially	Justification	
in the title and abstract of studies;	Unclear	required	
stage 2: detailed assessment of			
full-text documents)	N		
Assess studies for their relevance	Yes fully	None None	_
by more than one reviewer at all	No		
stages of the screening process	Partially	Justification	
	Unclear	required	
Ensure inter-reviewer agreement	Yes fully	│	
	☐ No		
	Partially	Justification	
	Unclear	required	
Document the process for resolving	Yes fully	None	
disagreements/discrepancies	☐ No	」 □	
between reviewers during the	Partially	Justification	
screening process	Unclear	required	
Classify for each category of	Yes fully	☐ None	
information/data requirement: (1)	No No		
Studies that might provide data for	Partially	Justification	
establishing or refining risk	☐ Unclear	required	
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 Extracting of high level data from		hudiaa Cambu an	ulianbla ta accuina
reviews]	n the relevant s	tudies Lonly ap	plicable to scoping
Extract high level information from	Yes fully	None	Not required in the context
each relevant study to describe the	No		of literature search for
overall volume, strength and		_	PMEM
direction of the evidence base	Unclear	required	
Describe variables for which	Yes fully	None	Not required in the context
information is extracted	No		of literature search for
I III O I II I I I I I I I I I I I I I		_	PMEM
	Unclear	required	
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Develop a data-charting form			Not required in the context
	☐ No		of literature search for
	☐ Partially	Justification	PMEM
	Unclear	required	
Summarising and reporting the d	lata, and conside	ring the implic	ations of the findings
Provide report(s) that contain the	Yes fully	None	Partially applicable in the
following information/sections:	□ No		context of literature search
Title;	□ Partially	Justification	for PMEM
 Authors of the review; 	Unclear	required	
 Summary: a brief summary 			
indicating the purpose of			
the report, the			
methodology employed,			
and the results obtained;			
 Methods, which should 			
contain:			
 A statement of the 			
objective of the scoping			
review;			
 The review questions, 			
along with a rationale			
clarifying the choices			
made;			
The criteria for			
relevance with which			
decisions to select			
studies were made; – Information on and			
result of the reference			
study searches;			
Search methods and			
outcomes, including a			
descriptive summary and			
rationale clarifying the			
choices made;			
Results of the study			
identification and selection			
process, including a			
descriptive summary;			
A narrative			
synthesis/summary of the			
relevant studies, describing			
their overall volume,			
strength and direction (only			
applicable for scoping			
reviews			



Provide the following information			
for each of the electronic	No		
bibliographic databases searched in	☐ Partially	Justification	
a series of tables:	Unclear	required	
The bibliographic database	Officieal	required	
name and the service			
provider used;			
 The justification for 			
choosing the database;			
 The date on which the 			
search was conducted;			
 The date of the most 			
recent update of the			
database that was			
searched;			
•			
The date span of the			
search;			
 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);			
 Any limits applied to the 			
search (e.g., study types,			
dates, languages);			
 The total number of 			
records retrieved from the			
information source before			
and after removing			
duplicates			
If literature is found in information	Yes fully	None	Not applicable as Web of
sources other than electronic	⊠ No		Science™ and EBSCOhost
bibliographic databases, then report	Partially	Justification	platforms are used
the following information:	Unclear Unclear	required	
• For a website (e.g., a			
conference or organisation			
website containing scientific			
literature):			
 The website name and 			
the service publisher			
used (e.g.,			
Author/Editor/Organisat			
ion's name and Title of			
the page);			
 A justification for 			
choosing the source;			
 The URL (internet 			
address);			



 The date on which the 		
search was conducted;		
 The date of the most 		
recent website update		
at the time it was		
searched;		
 The date span of the 		
search;		
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;		
 Any limits applied to the 		
search (e.g., study		
types);		
The number of relevant		
records or full-text		
documents retrieved.		
 For journal tables of 		
contents:		
 The journal name; 		
 A justification for 		
choosing the source;		
 The journal URL 		
(internet address) or		
publisher;		
 The dates, volumes and 		
issues searched;		
 The method of 		
searching, e.g.,		
scanning tables of		
contents for each issue,		
or using a search		
engine;		
 The search terms used 		
(if any);		
 The number of relevant 		
records or full-text		
documents retrieved.		
For reference lists:		
 The bibliographic details 		
of the documents		
whose reference lists		
were scanned;		
The number of relevant hiblingraphic references.		
bibliographic references		
retrieved		



process, using either Table 2 of the Explanatory note or a flowchart for each category of information/data requirements searched, if appropriate Provide a list of the bibliographic references for all relevant studies, ordered, using Table 3 of the Explanatory note Provide a list of the bibliographic references for all excluded studies after detailed assessment of till-text documents for relevance, with justification for their exclusion, recorded, using Table 4 of the Explanatory note 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 5 of the Explanatory note Provide a list of the bibliographic references for all unobtainable/unclear studies, recorded, using Table 5 of the Explanatory note Provide a list of the bibliographic references for all unobtainable/unclear studies, recorded, using Table 5 of the Explanatory note Provide copies of the full-text documents listed in Table 3 of the Explanatory note 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] Discuss the implications of each study that is clearly relevant to the risk assessment of the GMO under Discuss the implications of each study that is clearly relevant to the risk assessment of the GMO under Partially Justification Partially Justification required Ves fully	Report the results of the selection		☐ None	
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