

## **APPENDIX 3**

### **LITERATURE SEARCH FOR ANNUAL MONITORING ON THE GENERAL SURVEILLANCE OF MON 88302 × MS8 × RF3 AND ITS SUB-COMBINATIONS IN THE EU**

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## 1. INTRODUCTION

As part of the general surveillance requirements for genetically modified (GM) MON 88302 × MS8 × RF3, MON 88302 × MS8 and MON 88302 × RF3 oilseed rapes authorised in the European Union (EU) market under regulation (EC) No 1829/2003, BASF and Bayer Agriculture BVBA<sup>1</sup> have actively monitored scientific literature related to MON 88302 × MS8 × RF3 and its sub-combinations covering the time span between June 2018 and May 2019.

The publications that resulted from this literature search have been analysed in detail according to the relevance for the risk assessment of these products and are presented here.

The completeness literature search checklist (EFSA's Annex 2) is provided as **Attachment I**.

## 2. IDENTIFYING THE REVIEW QUESTION AND PURPOSE FOR UNDERTAKING THE LITERATURE SEARCH

This literature search has been conducted to address the review question “Does MON 88302 × MS8 × RF3 and its sub-combinations, derived food/feed products and the introduced herbicide tolerance and/or hybrid system traits have adverse effects on human and animal health and the environment?”

The purpose for undertaking this literature search is to ensure compliance with the 2017 EFSA explanatory note on literature searching for annual post-market environmental monitoring (PMEM) on GM oilseed rape products authorised in the EU under regulation (EC) No 1829/2003 (EFSA, 2017).

Key elements used for the review question are humans, animals, and/or the environment (= population), MON 88302 × MS8 × RF3 and its sub-combinations, derived food/feed products and/or the introduced herbicide tolerance and hybrid system traits (= intervention/exposure), conventional counterpart or non-GM oilseed rape (= comparator), and adverse effect on human and animal health, and the environment (= outcomes). Accordingly, the eligibility criteria for assessing the relevance of studies for inclusion in the literature review are provided in **Table 1**.

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<sup>1</sup> Hereafter referenced as BASF and Bayer.

**Table 1. Eligibility/inclusion criteria to establish the relevance of retrieved studies**

Key elements	Criteria
Population	Humans, animals and the environment (taking into account the scope of the application <i>i.e.</i> authorisation for all uses as any other oilseed rape but excluding the cultivation of MON 88302 × MS8 × RF3 and its sub-combinations are addressed as general protection goals.
Intervention/ exposure	MON 88302 × MS8 × RF3 and its sub-combinations, derived /or hybrid system traits addressed in the study are identical or similar to those under scientific review by the EFSA.
Comparator	In case of a comparative study that uses the GM plant material as test material, eligible studies must report a non-GM oilseed rape as a comparator.
Outcomes	Adverse effects on human and animal health and the environment are addressed (taking into consideration the scope of the application).
<b>Additional key elements</b>	
Stacked events/sub-combinations	The single event(s) addressed in the study is/are the single event(s) in MON 88302 × MS8 × RF3 and its sub-combinations independently of their origin, are addressed in the study
Information/ data requirements, including source of studies data	The study potentially contributes to the knowledge of the risk assessment of MON 88302 × MS8 × RF3 and its sub-combinations intended for all uses as any other oilseed rape, but excluding cultivation. Original/primary data are presented in the study.

### 3. SEARCHING FOR IDENTIFYING RELEVANT STUDIES

The approach used to develop the search strategy follows the lumping method and a wide range of free-text terms to define search terms in accordance with the 2010 EFSA Guidance on application of systematic review methodology to food and feed safety assessments to support decision making (EFSA, 2010) and the 2017 EFSA Explanatory note on literature searching (EFSA, 2017).

#### 3.1. Search terms and their combination

The intervention/exposure key elements were defined and translated into search terms. Based on the key elements of the review question, the search terms, the field and the Boolean operators used to combine them were defined as shown in **Table 2**. These search terms considered possible synonyms, related terms, abbreviations and truncations, old and new as well as lay and scientific terminologies, brand and generic names, and spelling variants. Where available, the search was also adapted to controlled vocabulary (subject indexing). The search terms were designed to give an excellent coverage and retrieve the broadest possible number of articles related to MON 88302 × MS8 × RF3 and its sub-combinations. **Table 3** shows the translation of the intervention key elements into search terms and, when available, the reference publications used to test the search terms.

**Table 2. List of search terms and Boolean operators used to search for MON 88302 × MS8 × RF3 and its sub-combinations related publications**

Set	Field	Search string	Key elements (Intervention/Exposure)
<b>Web of Science™ platform</b>			
#14		#7 OR #9 OR #13 <i>DocType=All document types; Language=All languages;</i>	
#13	Combination	#10 OR #11 OR #12 <i>DocType=All document types; Language=All languages;</i>	Stacked events or sub-combinations
#12	Topic	(TS=((RF3 OR "RF 3") AND ((MON88302 OR "MON 88302") OR (MS8 OR "MS 8"))))) <i>DocType=All document types; Language=All languages;</i>	Events
#11	Topic	(TS=((MS8 OR "MS 8") AND ((MON88302 OR "MON 88302") OR (RF3 OR "RF 3"))))) <i>DocType=All document types; Language=All languages;</i>	
#10	Topic	(TS=((MON88302 OR "MON 88302") AND ((MS8 OR "MS 8") OR (RF3 OR "RF 3"))))) <i>DocType=All document types; Language=All languages;</i>	
#9	Combination	#8 AND (#2 OR #1) <i>DocType=All document types; Language=All languages;</i>	The newly expressed proteins in GM organisms, including oilseed rape
#8	Topic	(TS=((("cp4 epsps" OR cp4epsps) OR ((barnase OR barstar OR bar) AND (PAT OR "phosphinothricin N-acetyltransferase"))))) <i>DocType=All document types; Language=All languages;</i>	Newly expressed proteins
#7	Combination	#6 OR #5 <i>DocType=All document types; Language=All languages;</i>	GM oilseed rape displaying the introduced herbicide tolerance and hybrid system traits OR GM oilseed rape with the indicated trade names
#6	Combination	#4 AND #2 AND #1 <i>DocType=All document types; Language=All languages;</i>	GM oilseed rape with the indicated trade names
#5	Combination	#3 AND #2 AND #1 <i>DocType=All document types; Language=All languages;</i>	GM oilseed rape displaying the introduced herbicide tolerance and hybrid system traits
#4	Topic	(TS=(Truflex OR "Tru Flex" OR "Roundup ready" OR RR OR InVigor OR "In Vigor" OR Libertylink OR SeedLink OR "Seed Link")) <i>DocType=All document types; Language=All languages;</i>	Trade names
#3	Topic	(TS=((((TOLERAN* OR RESISTAN* OR PROTEC*) NEAR/5 (GLYPHOSATE OR ROUNDUP OR GLUFOSINATE OR BASTA OR RELY OR FINALE OR IGNITE OR	Introduced herbicide tolerance and hybrid system traits

Appendix 3\_ Annual monitoring report on the general surveillance of MON 88302 × MS8 × RF3 and its sub-combinations in the EU

Set	Field	Search string	Key elements (Intervention/Exposure)
		CHALLENGE OR LIBERTY)) OR ((CONTROL* OR FERTIL* OR STERIL*) NEAR/5 (pollen OR pollination OR male))) <i>DocType=All document types; Language=All languages;</i>	
#2	Topic	(TS=(rapeseed OR "rape seed" OR oilseedrape OR "oilseed rape" OR canola OR brassica)) <i>DocType=All document types; Language=All languages;</i>	Plant species
#1	Topic	(TS=(GMO* OR LMO* OR GM OR GE OR transgen* OR ((genetic* OR living OR biotech*) NEAR/5 (modif* OR transform* OR manipulat* OR improv* OR engineer* OR deriv*))) <i>DocType=All document types; Language=All languages;</i>	GMO general
<b>EBSCOhost platform</b> ( <i>All document types and all languages</i> )			
S17	Combination	S10 OR S12 OR S16	
S16	Combination	S13 OR S14 OR S15	Stacked events or sub-combinations
S15	All Text	TX ((RF3 OR "RF 3") AND (MON88302 OR "MON 88302" OR MS8 OR "MS 8"))	Events
S14	All Text	TX ((MS8 OR "MS 8") AND (MON88302 OR "MON 88302" OR RF3 OR "RF 3"))	
S13	All Text	TX ((MON88302 OR "MON 88302") AND (MS8 OR "MS 8" OR RF3 OR "RF 3"))	
S12	Combination	S11 AND (S2 OR S1)	The newly expressed proteins in GM organisms, including oilseed rape
S11	All Text	TX (((cp4epsps OR "cp4 epsps") OR ((barnase OR barstar OR bar) AND (PAT OR "phosphinothricin N-acetyltransferase")))	Newly expressed proteins
S10	Combination	S8 OR S9	GM oilseed rape displaying the introduced herbicide tolerance and hybrid system traits OR GM oilseed rape with the indicated trade name
S9	Combination	S1 AND S2 AND S7	GM oilseed rape with the indicated trade name
S8	Combination	S1 AND S2 AND S6	GM oilseed rape displaying the introduced herbicide tolerance and hybrid system traits
S7	All Text	TX (Truflex OR "Tru Flex" OR "Roundup ready" OR RR OR InVigor OR "In Vigor" OR Libertylink OR SeedLink OR "Seed Link")	Trade name
S6	Combination	S5 OR (S4 AND S3)	
S5	Descriptor	DE "male fertility" OR DE "male sterility" OR	Controlled vocabularies (subject

Set	Field	Search string	Key elements (Intervention/Exposure)
		DE "restorer genes"	indexes) offered by the database for introduced herbicide tolerance and hybrid system traits
S4	Descriptor	DE "glyphosate"	
S3	Descriptor	DE "weed control"	
S2	Descriptor	DE "rape" OR DE "rapeseed"	Controlled vocabularies (subject indexes) offered by the database for plant species. Note that the term 'Brassica' is covered by the term 'rape'.
S1	Descriptor	DE "genetic engineering" OR DE "genetic transformation" OR DE "genetically engineered foods" OR DE "genetically engineered organisms"	Controlled vocabularies (subject indexes) offered by the database for GMO general term

### 3.2. Limits applied

An advanced literature search was conducted in the Web of Science™ Core collection database using the Web of Science™ platform<sup>2</sup> and in the CAB Abstracts® database<sup>3</sup> using the EBSCOhost platform<sup>4</sup> (see section 3.6.1). Each platform enables searching in the specified electronic database by making use of pre-defined fields, set combinations based on Boolean operators or a combination of both<sup>5,6</sup>.

The literature search strategy utilises the “Topic” (TS) field in Web of Science™ platform and the “TX” field in EBSCOhost platform which have the broadest coverage of search terms and enable comprehensive searching within a record<sup>7,6</sup> (see **Table 2**). In the case of the Web of Science™ Core collection database, the “TS” field searches for topic terms in the following fields within a record: Title, Abstracts, Author Keywords and Keywords Plus®. The Keywords Plus® facility maximises the possibility of retrieving relevant records in the advanced search<sup>8</sup>. In the case of the CAB Abstracts® database, the “TX” field searches for the search terms “*within the full text of all articles for your term*”<sup>6</sup>.

In this literature search, the search strategy utilised also the controlled vocabulary (subject indexing) facility offered by the CAB Abstracts® database. Accordingly, the search string was refined by using the CAB Thesaurus-Descriptors field, which are assigned by subject specialists to CAB records to represent the content of the source documents. The Descriptor (“DE”) field enables selection of one or more controlled terms from the CAB Thesaurus to add to the search query. More importantly, having a controlled vocabulary

<sup>2</sup>[http://apps.webofknowledge.com/UA\\_GeneralSearch\\_input.do?product=UA&SID=X1sK9uHnF5WXHkLGPbw&search\\_mode=GeneralSearch](http://apps.webofknowledge.com/UA_GeneralSearch_input.do?product=UA&SID=X1sK9uHnF5WXHkLGPbw&search_mode=GeneralSearch) (Accessed on 25 September 2019).

<sup>3</sup>[http://support.ebsco.com/help/?int=ehost&lang=en&feature\\_id=Databases&TOC\\_ID=Always&SI=0&BU=0&GU=1&PS=0&ver=live&dbs=.lah](http://support.ebsco.com/help/?int=ehost&lang=en&feature_id=Databases&TOC_ID=Always&SI=0&BU=0&GU=1&PS=0&ver=live&dbs=.lah) (Accessed on 25 September 2019).

<sup>4</sup><https://help.ebsco.com/interfaces/EBSCOhost> (Accessed on 25 September 2019).

<sup>5</sup>[http://images.webofknowledge.com/WOKRS5251R3/help/WOS/hp\\_advanced\\_examples.html](http://images.webofknowledge.com/WOKRS5251R3/help/WOS/hp_advanced_examples.html) (Accessed on 25 September 2019).

<sup>6</sup>[https://help.ebsco.com/interfaces/EBSCOhost/training\\_promotion/Advanced\\_Searching\\_EBSCOhost\\_Tutorial](https://help.ebsco.com/interfaces/EBSCOhost/training_promotion/Advanced_Searching_EBSCOhost_Tutorial) (Accessed on 25 September 2019).

<sup>7</sup>[http://images.webofknowledge.com/WOKRS5251R3/help/WOS/hs\\_advanced\\_fieldtags.html](http://images.webofknowledge.com/WOKRS5251R3/help/WOS/hs_advanced_fieldtags.html) (Accessed on 25 September 2019)

<sup>8</sup><http://clarivate.libguides.com/woscc/searchtips> (Accessed on 25 September 2019).

allows users to use only one term to search for a concept rather than using lots of terms<sup>9</sup>. The most relevant, broad and controlled search terms in the hierarchy of CAB Thesaurus terms that were listed as preferred terms by CAB for the search query were selected and added to the search string in combination with the “DE” field (*see* **Table 2**).

### **3.3. Language**

The search terms and their combination are established in English; hence, the search is expected to result in a list of articles written in English and/or articles written in other languages with at least a title, abstract or keywords in English. Also, technical terms like proteins names, MON codes, latin names, ... are common in all languages and therefore, articles in all languages, as specified in **Table 2**, will be retrieved.

### **3.4. Time period**

This literature search covered the reporting period from June 2018 until May 2019.

### **3.5. Reference studies**

In accordance with the 2017 EFSA Explanatory note on literature searching (EFSA, 2017), a list of reference publications, complying with the eligibility/inclusion criteria, to test, fine-tune and validate the search strategy as part of the protocol development was used whenever available (**Table 3**).

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<sup>9</sup><https://www.cabi.org/Uploads/CABI/publishing/training-materials/resources-by-interface/cab-direct-user-guides/advanced-searching-cab-abstracts.pdf> (Accessed on 25 September 2019).



**Table 3. Translation of intervention/exposure key elements into search terms for MON 88302 × MS8 × RF3 and its sub-combinations literature search in the Web of Science™ Core Collection and CAB Abstracts® databases**

Key elements		Search terms	Comments
<b>GMO general</b>			
<i>Reference publications</i>		Not applicable.	<p>This step is to focus the search on GM related papers.</p> <p>The search terms, free-text terms, controlled vocabularies and the search strings are updated upon identification of a new search term.</p>
<i>Search terms</i>		Genetically modified organism (GMO, GM); Living modified organism (LMO); biotechnology-derived organism (biotech-derived); Genetic engineering (GE); transgenesis (transgene); genetic transformation; genetic manipulation; genetic improvement.	
<i>Web of science™ platform</i>	<i>Search string based on free-text terms using the Topic (TS) field</i>	(TS=(GMO* OR LMO* OR GM OR GE OR transgen*OR ((genetic* OR living OR biotech*) NEAR/5 (modif* OR transform* OR manipulat* OR improv* OR engineer* OR deriv*))))	
	<i>Truncations and spelling variants used and their meanings</i>	GMO* = GMO, GMOs, GMO's GM = GM crop, GM plant, GM crops, GM plants GE = GE crop, GE plant, GE crops, GE plants LMO* = LMO, LMOs, LMO's Transgen* = transgene, transgenic, transgenesis Genetic* = genetic, genetically Biotech* = biotech, biotechnology, biotechnological Modif* = modify, modified, modification Transform* = transform, transformed, transformation Manipulat* = manipulate, manipulated, manipulation Improv* = improve, improved, improvement Engineer* = engineer, engineered, engineering Deriv* = derive, derived	
<i>EBSCOhost platform</i>	<i>Search string based on controlled vocabularies using the Descriptors (DE) field</i>	DE "genetic engineering" OR DE "genetic transformation" OR DE "genetically engineered foods" OR DE "genetically engineered organisms"	

Key elements		Search terms	Comments
Crop name			
Reference publications		Not applicable.	This step is to focus the search on oilseed rape related papers.
Search terms		Oilseed rape, canola, brassica	
Web of science™ platform	Search string based on free-text terms using the Topic (TS) field	(TS=(rapeseed OR "rape seed" OR oilseedrape OR "oilseed rape" OR canola OR brassica))	The search terms, free-text terms, controlled vocabularies and the search strings are updated upon identification of a new search term.
	Truncations and spelling variants used and their meanings	rapeseed, "rape seed" = oilseed rape	
EBSCOhost platform	Search string based on controlled vocabularies using the Descriptors (DE) field	DE "rape" OR DE "rapeseed"	
Intended trait			
Reference publications		Not available	There are no reference publications complying with the eligibility/inclusion criteria to test this set of keywords for the intended traits.
Search terms		Glyphosate/ roundup tolerance Glufosinate/ rely/ basta, finale/ ignite/ liberty tolerance, Pollination control, male sterility/fertility control	
Web of science™ platform	Search string based on free-text terms using the Topic (TS) field	(TS=(((TOLERAN* OR RESISTAN* OR PROTEC*) NEAR/5 (GLYPHOSATE OR ROUNDUP OR GLUFOSINATE OR BASTA OR RELY OR FINALE OR IGNITE OR CHALLENGE OR LIBERTY)) OR ((CONTROL* OR FERTIL* OR STERIL*) NEAR/5 (pollen OR pollination OR male))))	
	Truncations and spelling variants used and their meanings	Toleran* = tolerance, tolerant Resistan* = resistance, resistant Protect* = protection, protected Control* = control, controlling Fertile* = fertile, fertility Steril* = sterile, sterility	

Key elements		Search terms	Comments
<i>EBSCOhost platform</i>	<i>Search string based on controlled vocabularies using the Descriptors (DE) field</i>	DE "male fertility" OR DE "male sterility" OR DE "restorer genes" DE "glyphosate" DE "weed control"	
Trade names			
Reference publications		Not available	There are no reference publications complying with the eligibility/inclusion criteria to test this set of keywords for the trade names.
Search terms		Truflex, Roundup Ready, InVigor, LibertyLink, SeedLink	
<i>Web of science™ platform</i>	<i>Search string based on free-text terms using the Topic (TS) field</i>	(TS=(Truflex OR "Tru Flex" OR "Roundup ready" OR RR OR InVigor OR "In Vigor" OR Libertylink OR SeedLink OR "Seed Link"))	
	<i>Truncations and spelling variants used and their meanings</i>	The options shown in the search string above are spelling variants. Truncations are not applicable.	
<i>EBSCOhost platform</i>	<i>Search string based on free-text terms using the All Text (TX) field</i>	TX (Truflex OR "Tru Flex" OR "Roundup ready" OR RR OR InVigor OR "In Vigor" OR Libertylink OR SeedLink OR "Seed Link")	
	<i>Truncations and spelling variants used and their meanings</i>	The options shown in the search string above are spelling variants. Truncations are not applicable.	
Newly expressed protein			
Reference publications		Not available	There are no reference publications complying with the eligibility/inclusion criteria to test this set of keywords for the newly expressed protein.
Search terms		CP4 EPSPS, barnase/ bartar/ bar, phosphinothricin N acetyltransferase (PAT)	
<i>Web of science™ platform</i>	<i>Search string based on free-text terms using the Topic (TS) field</i>	(TS=((("cp4 epsps" OR cp4epsps) OR ((barnase OR barstar OR bar) AND (PAT OR "phosphinothricin N-acetyltransferase")))))	

Key elements		Search terms	Comments
	<i>Truncations and spelling variants used and their meanings</i>	The options shown in the search string above are spelling variants.  Truncations are not applicable.	
<i>EBSCOhost platform</i>	<i>Search string based on free-text terms using the All Text (TX) field</i>	TX (((cp4epsps OR "cp4 epsps") OR ((barnase OR barstar OR bar) AND (PAT OR "phosphinothricin N-acetyltransferase"))))	
	<i>Truncations and spelling variants used and their meanings</i>	The options shown in the search string above are spelling variants.  Truncations are not applicable.	
<b>Event</b>			
<i>Reference publications</i>		Not available	There are no reference publications complying with the eligibility/inclusion criteria to test this set of keywords for the combined events.
	<i>Search terms</i>	MON 88302, MON88302, MS8, MS 8, RF3, RF 3	
<i>Web of science™ platform</i>	<i>Search string based on free-text terms using the Topic (TS) field</i>	(TS=((RF3 OR "RF 3") AND ((MON88302 OR "MON 88302") OR (MS8 OR "MS 8"))))  (TS=((MS8 OR "MS 8") AND ((MON88302 OR "MON 88302") OR (RF3 OR "RF 3"))))  (TS=((MON88302 OR "MON 88302") AND ((MS8 OR "MS 8") OR (RF3 OR "RF 3"))))	
	<i>Truncations and spelling variants used and their meanings</i>	The options shown in the search string above are spelling variants.  Truncations are not applicable.	
<i>EBSCOhost platform</i>	<i>Search string based on free-text terms using the All Text (TX) field</i>	TX ((RF3 OR "RF 3") AND (MON88302 OR "MON 88302" OR MS8 OR "MS 8"))  TX ((MS8 OR "MS 8") AND (MON88302 OR "MON 88302" OR RF3 OR "RF 3"))  TX ((MON88302 OR "MON 88302") AND (MS8 OR "MS 8" OR RF3 OR "RF 3"))	

Key elements		Search terms	Comments
	<i>Truncations and spelling variants used and their meanings</i>	The options shown in the search string above are spelling variants. Truncations are not applicable.	

### 3.6. Information sources

#### 3.6.1. Electronic bibliographic databases

Based on the coverage and relevance of the journals included, BASF and Bayer select the Web of Science™ Core Collection database<sup>10</sup> and the CAB Abstracts® database<sup>11</sup> for performing the literature searches. The advanced literature search was conducted using the Web of Science™ platform<sup>2</sup> for the Web of Science™ Core collection database and using the EBSCOhost platform<sup>4</sup> for the CAB Abstracts® database<sup>3</sup>.

The Web of Science™ Core Collection database<sup>10</sup> includes literature captured under the following two catalogues: 1) the Science Citation Index Expanded (1995-present); and 2) the Conference Proceedings Citation Index-Science (1990-present). These catalogues offer a complete view of item from a journal, including original research articles, reviews, editorials, chronologies, conference proceedings, bulletins, monographs, and technical reports. This database is “*indisputably the largest citation database available, with over 1 billion cited reference connections indexed from high quality peer reviewed journals, books and proceedings. Each cited reference is meticulously indexed to ensure that it is searchable and attributes credit to the appropriate publication.*”<sup>10</sup>. Further, 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<sup>10</sup>.

The CAB Abstracts® database<sup>11</sup> includes literature capture under the CAB Abstracts (1972-present) catalogue. This catalogue offers a complete view of items from a journal, including original research articles, reviews, books, conference proceedings/ papers, correspondences, editorials, patents, thesis, reports, and bulletins on international agricultural literature, including plant protection, animal husbandry, animal and plant breeding, genetics, and nutrition.

All journals included in the two databases must go through a verification process and as a minimum requirement, non-English language journals must include English-language bibliographic information (title, abstract, keywords) and be peer-reviewed. In general, English is considered the universal language of science<sup>12</sup>. For this reason, the journals most important to the international research community will publish either full text or a minimum of bibliographic information in English, which is especially true in the scientific domain of natural sciences. Full text in English is highly desirable if the journal intends to serve an international community of researchers. Therefore, it is expected that even if there is a relevant article for the food and feed safety of GM plants in a language different than English, the article will include title/abstract/keywords in English, which will guarantee the retrievability of these articles when using keywords and keyword combinations in English.

Based on the above, the selected databases are, to our knowledge, comprehensive, multidisciplinary, conservative sources for literature searching and offer the broadest coverage to retrieve a largest breadth of possible relevant studies. Therefore, additional search sources are not deemed necessary.

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<sup>10</sup> Web of Science Core Collection; <https://clarivate.com/products/web-of-science/web-science-form/web-science-core-collection/> (Accessed on 25 September 2019).

<sup>11</sup> CABI CAB Abstracts® database; <http://www.cabi.org/cab-direct/> (Accessed on 25 September 2019).

<sup>12</sup> Web of Science™; <http://wokinfo.com/essays/journal-selection-process/> (Accessed on 25 September 2019).

### 3.6.2. Relevant key organisations

In accordance with the 2017 Explanatory note on literature searching (EFSA, 2017) and additional EFSA recommendations, the search in electronic bibliographic databases has been complemented with an internet search in webpages of relevant key organisations involved in the risk assessment of GM plants.

Of the 13 key organisations cited in the 2017 Explanatory note on literature searching (EFSA, 2017), two (Environment and Climate Change Canada and CIBIOGEM) are not involved in the risk assessment of GM plants. Six (USDA, FDA, CFIA, Health Canada, FSANZ and MAFF) don't regulate stack products. One (GEAC), for the time being, only assesses in GM cotton. From the remaining four, EPA regulates only stacks with Plant-Incorporated Protectant (PIP) combinations while CTNBio, CONABIA and OGTR regulate oilseed rape stacks. Therefore, the internet search focused on the three key organisations (CTNBio, CONABIA and OGTR)<sup>13</sup> relevant for MON 88302 × MS8 × RF3 and its sub-combinations.

For the selection of studies, all records concerning GMO applications and approvals published in the webpages of each relevant key organisation were screened based on 'limits applied' as shown in **Table 4**. Afterwards, all the records within the specified limits were assessed for their relevance to MON 88302 × MS8 × RF3 and the results are presented in **Section 5.1.2**.

## 4. SELECTING STUDIES

Studies retrieved from the literature search were screened for their relevance first and then the selected ones were evaluated for their reliability through detailed assessments. Relevance to the search scope and scientific reliability were rigorously assessed by internal and external technical experts.

### 4.1. Process

The process of selecting relevant studies was undertaken in two stages:

- **Rapid assessment** for the relevance based on information in the title and abstract of the studies, to exclude publications that are obviously irrelevant.
- **Detailed assessment** of full-text document if required. Experts with a solid experience in the risk assessment of GM plants and experts with technical experience in the specific area of the selected publication performed this analysis. This stage was conducted to formally assess the identified studies (methodological quality) and the result has then been used to assess if the conclusions on the food/feed safety of the risk assessment, based on the comprehensive weight of evidence, are still valid.

### 4.2. Quality assurance

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.

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<sup>13</sup> Internet pages of the relevant key organisations for MON 88302 × MS8 × RF3 and its sub-combinations:  
CTNBio (<http://ctnbio.mcti.gov.br/>) (Accessed on 25 September 2019);  
CONABIA (<https://www.argentina.gob.ar/>) (Accessed on 25 September 2019);  
OGTR (<http://www.ogtr.gov.au/>) (Accessed on 25 September 2019).

In case of disagreements on eligibility for the inclusion of studies, the reviewers discuss together. If uncertainty remains, the study is *de facto* included for further consideration.

### **4.3. Eligibility/inclusion criteria to establish relevance**

From the full reference list of retrieved, taking into account i) the review question, ii) the scope of the application, *i.e.* authorisation of MON 88302 × MS8 × RF3 and its sub-combinations for all uses as any other oilseed rape but excluding cultivation in the EU and iii) the eligibility criteria to establish the relevance of retrieved studies, an assessment was conducted in order to conclude whether a certain publication was considered relevant or not. When a publication was considered relevant, the category the publication belongs to is indicated. The following is a non-exhaustive list of categories publications can belong to:

#### *Food/Feed safety assessment*

- Molecular characterisation
- Protein expression
- Crop composition
- Agronomic and phenotypic characteristics
- Toxicology - Animal feeding / *In vitro*
- Allergenicity of the protein or the whole food/feed
- Nutrition
- Protein / DNA/ RNA fate in digestive tract

#### *Environmental safety assessment*

- Spillage and consequences thereof

It should be noted that the selection criteria are well defined and reassessed annually.

## **5. SUMMARISING AND REPORTING THE DATA, AND CONSIDERING THE IMPLICATIONS OF THE FINDINGS**

### **5.1. Search outcomes**

#### **5.1.1. Outcomes of literature search in electronic bibliographic databases**

The literature search was run using Web of Science<sup>TM</sup> Core Collection and the CAB Abstracts<sup>®</sup> databases on a monthly basis, covering the time span June 2018-May 2019. As a result, 21 hits were identified using Web of Science<sup>TM</sup> Core Collection database while 12 hits were retrieved from the search conducted using the CAB Abstracts<sup>®</sup> database.

#### **5.1.2. Outcomes of literature search in internet pages of relevant key organisations**

The literature search in the internet pages of the relevant key organisations was conducted on 15 October 2019. The links to the results of the literature search and the summary of the retrieved data are shown in **Table 4**. There was no publication based on primary/original data that needed further assessment.



**Table 4. Results of literature search in internet pages of relevant key organisations for MON 88302 × MS8 × RF3 and its sub-combinations**

Relevant key organisations	Link to relevant information and summary of the retrieved data
CTNBio	<p><a href="http://ctnbio.mcti.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo">http://ctnbio.mcti.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo</a> – Accessed on 15 October 2019. The webpage dedicated to commercial releases (= Liberações Comerciais) was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> Not clear (several dates mentioned)</p> <p><i>Date span of the search:</i> 2018-2019</p> <p><i>Limits applied:</i> The list of commercial releases for plants (= plantas) starting from 2018 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “11”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to MON 88302 × MS8 × RF3 and its sub-combinations.</p>
CONABIA	<p><a href="https://www.argentina.gob.ar/agroindustria/alimentos-y-bioeconomia/ogm-comerciales/">https://www.argentina.gob.ar/agroindustria/alimentos-y-bioeconomia/ogm-comerciales/</a> – Accessed on 15 October 2019. The webpage of the national advisory commission on agricultural biotechnology (= Comisión Nacional Asesora de Biotecnología Agropecuaria) was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> Not available</p> <p><i>Date span of the search:</i> 2018-2019</p> <p><i>Limits applied:</i> The list of decision documents open for public comment was assessed. Note: decision documents are available for 60 days to allow the public to give comments and are removed afterwards.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “17”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to MON 88302 × MS8 × RF3 and its sub-combinations.</p>
OGTR	<p><a href="http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1">http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1</a> - Accessed on 15 October 2019. The webpage dedicated to list of GMOs released into the environment was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> Not clear (several dates mentioned)</p> <p><i>Date span of the search:</i> 2018-2019</p> <p><i>Limits applied:</i> Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment was assessed.</p> <p><i>Number of records:</i> “1”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to MON 88302 × MS8 × RF3 and its sub-combinations.</p>

## 5.2. Results of the study selection process for electronic bibliographic databases

The results of the study selection process are provided in **Table 5**. No relevant studies were identified. Excluded study after detailed assessment of the full text document for relevance is listed in **Table 6**.

**Table 5. Results of the study selection process.**

Review question captured in the search	Number of studies	
	Web of Science™ Core Collection database	CAB Abstracts® database
Total number of <i>studies</i> retrieved after all searches of the scientific literature (excluding duplicates)	21	12
Number of <i>studies</i> excluded from the search results after rapid assessment for relevance	20	12
Total number of <i>full-text documents</i> assessed in detail (excluding duplicates)	1	
Number of <i>studies</i> excluded from further consideration after detailed assessment for relevance	1	
Total number of unobtainable/unclear studies	0	
Total number of relevant studies	0	

**Table 6. Report of studies excluded from the risk assessment after detailed assessment of full-text documents (classified by authors)**

<b>Study Author(s)</b>	<b>Year</b>	<b>Title</b>	<b>Source</b>	<b>Reason(s) for exclusion</b>
Suassuna, ND <i>et al.</i>	2018	BRS 430 B2RF and BRS 432 B2RF: Insect-resistant and glyphosate-tolerant high-yielding cotton cultivars	Crop Breeding and Applied Biotechnology	The hybrid used to conduct the study is not MON 88302 × MS8 × RF3 or its sub-combinations

### **5.3. Implications of the retrieved relevant studies for the risk assessment**

No relevant publications were identified in this literature search. The literature search conducted by BASF and Bayer provides a comprehensive analysis of reliable scientific publications that are relevant to the food, feed, and environmental safety of MON 88302 × MS8 × RF3 and its sub-combinations. Therefore, a systematic review would not add value to the risk assessment of these products.

## 6. CONCLUSION

Taking into consideration all the above, BASF and Bayer confirms that this literature search, conducted in accordance with the 2017 EFSA explanatory note on literature searching (EFSA, 2017) and within the context of general surveillance for MON 88302 × MS8 × RF3, MON 88302 × MS8 and MON 88302 × RF3 oil seed rapes in the EU, identified no relevant publications that would invalidate the initial conclusions of the risk assessment. Therefore, the conclusions of the risk assessment as presented in the initial application remain unchanged. No adverse effects are to be expected from authorised uses of MON 88302 × MS8 × RF3, MON 88302 × MS8 and MON 88302 × RF3 in the EU.

## REFERENCES

*References in grey are EFSA publications and are therefore not provided with this response.*

EFSA, 2010. Application of systematic review methodology to food and feed safety assessments to support decision making The EFSA Journal, 1637, 1-90.

EFSA, 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 Journal, 2017:EN-1207, 1-48.