

**Appendix 3. Literature search for annual monitoring on the general surveillance of Bayer GM oilseed rape in the EU**

## **APPENDIX 3**

### **LITERATURE SEARCH TO SUPPORT GENERAL SURVEILLANCE OF 2019/2020 ANNUAL POST MARKET ENVIRONMENTAL MONITORING REPORTS OF BAYER GM OILSEED RAPE PRODUCTS**

**Data protection.**

This application contains scientific data and other information which are protected in accordance with Art. 31 of Regulation (EC) No 1829/2003.

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## **SUMMARY**

This literature search was conducted to support general surveillance of 2019/2020 annual post market environmental monitoring reports in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019). It addresses the review question “Do Bayer GM oilseed rape products, derived food/feed products and their respective introduced traits have adverse effects on human and animal health and the environment?”.

In accordance with the 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019), eligibility/inclusion criteria to establish the relevance of retrieved publications was determined. Two electronic bibliographic databases (SciSearch and CABA databases) were selected for the literature search. Search strategies were developed together with an information specialist to perform the searches. In addition, literature searches were conducted in internet pages of relevant key organisations for Bayer GM oilseed rape products.

The literature search covered the time span 2019 – 2020 and retrieved 324 and 211 hits in SciSearch and CABA databases, respectively, and a total of 59 records in the internet pages of the relevant key organisations. From these, no publications were identified as relevant.

The comprehensive literature search found no new information that would invalidate the conclusions of the risk assessment for Bayer GM oilseed rape products.

## 1. INTRODUCTION

As part of the general surveillance requirements for Bayer GM oilseed rape products authorised in the European Union (EU) market under regulation (EC) No 1829/2003, Bayer Agriculture BV<sup>1</sup> has actively monitored the oilseed rape products by conducting quarterly literature searches covering the time span between June 2019 and May 2020.

The results of the literature search that were analysed in detail according to the relevance for the risk assessment of the Bayer GM oilseed rape products are presented here.

The completed form of EFSA Appendix E completeness checklist (EFSA, 2019) is provided as an attachment to this report.

## 2. FORMULATING THE REVIEW QUESTION AND CLARIFYING ITS PURPOSE

This literature search has been conducted to address the review question “Do Bayer GM oilseed rape products, derived food/feed products and respective introduced traits have adverse effects on human and animal health and the environment?”

The purpose for undertaking this literature search is to support general surveillance of 2019/2020 annual post market environmental monitoring (PMEM) reports in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019).

Key elements used for the review question are humans, animals, and/or the environment (= population), Bayer GM oilseed rape products, derived food/feed products and respective introduced 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 publications for inclusion in the literature review are provided in **Table 1**.

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<sup>1</sup> Hereafter, referenced as Bayer

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

<b>Key elements</b>	<b>Criteria</b>
Population	Humans, animals and the environment (taking into account the scope of the applications) <i>i.e.</i> authorisation for all uses as any other oilseed rape but excluding the cultivation of Bayer GM oilseed rape products are addressed as general protection goals.
Intervention/exposure	Bayer GM oilseed rape products derived food/feed products and corresponding introduced traits addressed in the publication 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 publications 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 applications).
<b>Additional key elements</b>	
Information/ data requirements, including source of publications data	The publication potentially contributes to the knowledge of the risk assessment of Bayer GM oilseed rape products intended for all uses as any other oilseed rape but excluding cultivation. Original/primary data are presented in the publication.

### 3. SEARCHING FOR/ IDENTIFYING RELEVANT PUBLICATIONS

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 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019), identification of bibliographic sources and development of search strategies was developed together with an information specialist who subsequently performed the literature search. The approach used to develop the search strategy follows a lumping method and includes a wide range of free-text terms and where available, controlled vocabulary that defines search terms.

#### 3.1. Sources of scientific literature

##### 3.1.1. Electronic bibliographic databases

Bayer selects the SciSearch (Science Citation Index)<sup>2</sup> and the CABA<sup>3</sup> (CAB Abstracts®)<sup>4</sup> databases to perform the literature search based on the coverage and relevance of the journals included in these databases. The literature search was conducted using the STN® database catalogue<sup>5</sup>.

The SciSearch, produced by from Clarivate Analytics (UK) Limited, includes over 45 million records in Science and technology published since 1974. It includes literatures captured under Science Citation Index Expanded™, a largest multidisciplinary scientific database and an international index covering all scientific topics. It contains also all the records published from the Current Contents series of publications as well as bibliographic information and cited references from over 5 600 scientific, technical and medical journals. In addition, “*Records from January 1991 on include abstracts, author keywords, and KeyWords Plus®. Bibliographic information, authors, cited references, and KeyWords Plus® are searchable*”<sup>3</sup>. The database is updated on a weekly basis.

The CABA, produced by CAB international (UK), includes over 8.9 million records in agriculture and life sciences published since 1973. The database “*covers worldwide literature from all areas of agriculture and related sciences including biotechnology, forestry, and veterinary medicine. Sources for CABA include journals, books, reports, published theses, conference proceedings, and patents. Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are searchable. An online thesaurus is available for the Con-trolled Term (/CT), the Geographic term (/GT), and the Organism (/ORGN) fields*”<sup>3</sup>. The database is updated on a weekly basis.

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<sup>5,6</sup>. In general, English is considered the universal language of science. For this reason, the journals most

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<sup>2</sup> SciSearch: <http://www.stn-international.de/sites/default/files/STN/summary-sheets/SCISEARCH.pdf>- Accessed on 02 September 2020

<sup>3</sup> CABA<http://www.stn-international.de/sites/default/files/STN/summary-sheets/CABA.pdf> – Accessed on 02 September 2020

<sup>4</sup> CAB Abstracts®: <https://www.cabi.org/publishing-products/online-information-resources/cab-abstracts/> - Accessed on 14 July 2020

<sup>5</sup> STN®: [http://www.stn-international.de/stnbrochures\\_gi.html](http://www.stn-international.de/stnbrochures_gi.html) - Accessed on 14 July 2020

<sup>6</sup> Web of Science group; <https://clarivate.com/webofsciencegroup/solutions/webofscience-core-collection-editorial-selection-process/> - Accessed on 14 July 2020

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 publications. Therefore, additional search sources are not deemed necessary.

### **3.1.2. Internet (world-wide-web) pages of relevant key organisations**

In accordance with the 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.

Of the 14 key organisations cited in the 2019 Explanatory note on literature searching for GMO applications (EFSA, 2019), nine<sup>7</sup> are involved in risk assessment of Bayer GM oilseed rape products. Three of the remaining five (CIBIOGEM, Environment and Climate Change Canada and OECD) are not involved in GM risk assessment while one (GEAC), for the time being, only assess GM cotton and the US EPA is only involved in the assessment of events containing Plant-Incorporated Protectants (PIP). Therefore, the internet search focused on the nine key organisations relevant for Bayer GM oilseed rape products.

## **3.2. Search strategy (electronic databases)**

### **3.2.1. Search terms and search strings**

The intervention/exposure key elements were defined and translated into search terms. These search terms were identified following the below listed approaches in line with the 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019):

- assessing words in reference publications,
- assessing subject indexing terms,
- searching for synonyms and related terms and
- consulting experts and stakeholders.

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<sup>7</sup> Internet pages of the relevant key organisations for Bayer GM oilseed rape products:

USDA (<https://www.usda.gov/media>) - Accessed on 14 July 2020;  
US FDA (<https://www.fda.gov/>) - Accessed on 14 July 2020;  
CFIA (<http://www.inspection.gc.ca/eng/1297964599443/1297965645317>) - Accessed on 14 July 2020;  
Health Canada (<https://www.canada.ca/en/health-canada.html>) - Accessed on 14 July 2020;  
FSANZ (<http://www.foodstandards.gov.au/Pages/default.aspx>) - Accessed on 14 July 2020;  
CTNBio (<http://ctnbio.mctic.gov.br/>) - Accessed on 14 July 2020;  
CONABIA (<https://www.argentina.gob.ar/>) - Accessed on 14 July 2020;  
Japan MAFF (<http://www.maff.go.jp/e/>) - Accessed on 14 July 2020;  
OGTR (<http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/home-1>) - Accessed on 14 July 2020.

Following the aforementioned approaches, possible synonyms, related terms, abbreviations including acronyms and truncations, old and new as well as lay and scientific terminologies, brand and generic names, and spelling variants including common typos of the search terms were considered. Where applicable, 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 Bayer GM oilseed rape products.

**Annex I** presents the translation of the intervention key elements into search terms. The search terms, the fields and the Boolean operators used to combine them were defined as shown in **Annex II**. The search strings were built following the STN<sup>®</sup> commands (Karlsruhe, 2007) to allow the literature search in the STN<sup>®</sup> database catalogue. The free-text search terms, controlled vocabulary and the search strings are updated upon identification of a new search term.

The search sets belonging to each key element as described in **Annex I** and **Annex II** were combined by ‘OR’ to retrieve all the identified publications excluding duplicates. The separate assessment of these search sets, including those yielding only a small number of publications, was considered not necessary as this would duplicate the literature screening process and alter the consistency and comprehensiveness used in the literature search strategies.

### **3.2.2. Limits applied**

An advanced literature search was conducted using the web-based STN<sup>®</sup> database catalogue for both the selected electronic databases (*see* section 3.1.1). STN<sup>®</sup> enables searching in each electronic database by making use of pre-defined fields, set combinations based on Boolean operators or a combination of both<sup>8</sup>. In STN<sup>®</sup>, the results of the search from each database can be merged and duplicates can be removed by de-duplication.

The STN<sup>®</sup> literature search utilised “Basic Index” (None (or /BI)) field which utilises free-text search terms and enables comprehensive searching in different sections (*e.g.* title, abstract, keywords, supplementary terms, controlled terms) within a record (Karlsruhe, 2007; STN, 2018a, 2018b). Where applicable, controlled vocabulary (subject indexes) offered by CABA (controlled terms (CT)) were also included in the search strategy. Controlled vocabulary is assigned by subject specialists to CAB records to represent the content of the source documents. It 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 terms in the hierarchy of CAB Thesaurus terms and that were listed as preferred terms by CAB for a search query were selected and added to the search string, as shown in **Annex I** and **Annex II**.

### **3.2.3. Language**

The search terms and their combinations are established in English. Therefore, the search is expected to result in a list of titles, abstracts or keywords written in English, covering

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<sup>8</sup> STNindex user guide: <https://stn.products.fiz-karlsruhe.de/training-center/documentation/stn-index-user-guide> - Accessed on 02 September 2020

<sup>9</sup> CAB Direct advanced searching of CAB abstracts: <https://www.cabi.org/Uploads/CABI/publishing/training-materials/resources-by-interface/cab-direct-user-guides/advanced-searching-cab-abstracts.pdf> - Accessed on 14 July 2020

also articles written in other languages with at least a title, abstract or keywords in English. Also, as technical terms on proteins names, event codes, trade names and Latin names are common in all languages, the search is expected to retrieve articles in all languages.

### 3.2.4. Time period

The literature searches covered the time span 1 June 2019 - 31 May 2020.

The literature search in the electronic databases was conducted on a quarterly basis considering the entry dates in the STN® database catalogue. **Table 2** shows the search dates and the time span of each search.

**Table 2. Description of literature search periods in the electronic databases**

Date of the search <sup>1</sup>	Last database update dates	Search period
04 October 2019	SciSearch: 30 September 2019	01 May 2019 – 04 October 2019
	CABA: 02 October 2019	01 May 2019 – 04 October 2019
03 February 2020	SciSearch: 21 January 2020	04 October 2019 – 21 January 2020
	CABA: 30 January 2020	04 October 2019 – 21 January 2020
01 June 2020	SciSearch: 28 May 2020	22 January 2020 – 28 May 2020
	CABA: 29 May 2020	22 January 2020 – 28 May 2020

<sup>1</sup> The literature search in the electronic databases was conducted on a quarterly basis considering the entry dates in the STN® database catalogue. In addition, a final literature search was also conducted covering the full-time span of the season (01 May 2019 – 28 May 2020) on 22 June 2020. The search result presented in **Annex II** shows the final search covering the full-time span of the 2019-2020 season.

The literature search in the internet pages of the relevant key organisations was conducted on 21 July 2020 and 24 August 2020.

### 3.2.5. Reference publications

In accordance with the 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019), reference publications that are relevant to answer the review question and are within the scope of the applications shall be used for identifying search terms as well as validating the search strategy. A list of reference publications, complying with the above criteria and used in validating the search strategy as part of the protocol development are provided in **Annex III**.

## 3.3. Search strategy (relevant key organisations)

Information regarding the selection process for relevant records in the webpages are shown in **Annex IV**. For the selection of relevant publications, all records concerning GMO applications and approvals published in the webpage of each relevant key organisation were screened based on ‘limits applied’ as described in the **Annex IV**. Afterwards, all the records

within the specified limits were assessed for their relevance to Bayer GM oilseed rape products.

## 4. SELECTING PUBLICATIONS

Publications 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. Eligibility screening process

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

- **Rapid assessment** for the relevance based on information in the title and abstract of the publications, to exclude publications that are obviously irrelevant.
- **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.

Experts with a solid experience in GM plants risk assessment performed the screening process. Based on the available comprehensive weight of evidence, the experts assessed if the conclusions of the risk assessment are still valid.

### 4.2. Reviewers

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.

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.

### 4.3. Classification of publications

Taking account of i) the review question, ii) the scope of the application, *i.e.* authorisation of Bayer GM oilseed rape products 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 publications, the list of retrieved hits was assessed 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 may 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.

#### **4.4. Quality appraisal of the relevant publications**

The relevant publications, if identified, are appraised in terms of reliability in accordance with the 2019 EFSA Explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019) by at least two individuals with technical expertise on the topic. In cases of disagreements, the evaluators discuss together and collectively determine the reliability of the publication. For the list of reliability categories, *see Annex V*.

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

### **5.1. Search outcomes**

#### **5.1.1. Outcomes of literature search (electronic databases)**

The literature searches identified 324 and 211 hits in SciSearch and CABA databases, respectively (*see Annex II*). After de-duplication, the total number resulted in 462 hits.

#### **5.1.2. Outcomes of literature search (relevant key organisations)**

The literature search in the internet pages of the nine relevant key organisations retrieved a total of 59 records. The links to the results of the literature search and the summary of the retrieved data are shown in **Annex IV**.

### **5.2. Results of the publication selection process**

#### **5.2.1. Results of the publication selection process (electronic databases)**

The results of the publication selection process for the retrieved hits from the electronic databases are provided in **Annex V**. No relevant publications were identified.

#### **5.2.2. Results of the publication selection process (relevant key organisations)**

The results of the publication selection process for the retrieved records from the relevant key organisations are provided in **Annex IV**. None of the retrieved documents needed further assessment.

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

No relevant publications were identified in this literature search.

## **6. CONCLUSION**

Taking into consideration all the above, Bayer confirms that this literature search, conducted to support the general surveillance in the context of 2019/2020 annual PMEM for Bayer GM

oilseed rape products, in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications (EFSA, 2019), identified no relevant publications that would invalidate the initial conclusions of the Bayer GM oilseed rape products risk assessment. Therefore, the conclusions of the risk assessment as presented in the initial applications of the Bayer GM oilseed rape products remain unchanged.

## REFERENCES

*References highlighted in grey are EFSA publications. Therefore, their pdfs are not provided.*

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

EFSA, 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 - Note on literature searching to GMO risk assessment guidance. EFSA journal, 2019:EN-1614, 1-62.

Karlsruhe F 2007. Command Summary Chart for bibliographic and full-text databases. 1-26.

STN 2018a. CABA. 1-12.

STN 2018b. SciSearch - Science Citation Index. 1-8.

## Annex I. Translation of intervention/exposure key elements into search terms for Bayer GM oilseed rape products literature search in STN<sup>®</sup> database catalogue

### 1. Free-text search terms for Bayer GM Oilseed rape products

Key elements	Search terms	Synonyms, related terms, abbreviations/ acronyms/ truncations, lay/ scientific terms, brand/ generic names and spelling variants/ typos (adapted for performing search in STN <sup>®</sup> database catalogue)
Event names	GT73 or RT73 or MON-ØØØ73-7 MON 88302 or MON-883Ø2-9 MS8 or ACS-BNØØ5-8 RF3 or ACS-BNØØ3-6	GT!73 OR GT73 OR GT 73 OR RT!73 OR RT73 OR RT 73 OR MON!OOO73? OR MONOOO73? OR MON OOO73? OR MON!00073 OR MON00073? OR MON 00073? OR MON!EMPTY SETEMPTY SETEMPTY SET73? OR MONEMPTY SETEMPTY SETEMPTY SET73? OR MON EMPTY SETEMPTY SETEMPTY SET73?  MON!88302? OR MON88302? OR MON 88302? OR MON!883O2? OR MON883O2? OR MON 883O2? OR MON!883EMPTYSET2? OR MON883EMPTY SET2? OR MON 883EMPTY SET2?  MS!8 OR MS8 OR MS 8 OR ACS!BN005? OR ACSBN005? OR ACS BN005? OR ACS!BNOO5? OR ACSBNOO5? OR ACS BNOO5? OR ACS!BNEMPTY SETEMPTY SET5? OR ACSBNEMPTY SETEMPTY SET5? OR ACS BNEMPTY SETEMPTY SET5? OR  RF!3 OR RF3 OR RF 3 OR ACS!BN003? OR ACSBN003? OR ACS BN003? OR ACS!BNOO3? OR ACSBNOO3? OR ACS BNOO3? OR ACS!BNEMPTY SETEMPTY SET3? OR ACSBNEMPTY SETEMPTY SET3? OR ACS BNEMPTY SETEMPTY SET3?
Trade names	Roundup Ready <sup>®</sup> canola TruFlex <sup>™</sup> canola with Roundup Ready <sup>®</sup> technology InVigor <sup>™</sup> Canola	ROUNDUPREADY? OR ROUND!UP!READY? ROUND UP READY? OR ROUNDUP READY? OR ROUND!UP READY? OR  TRU!FLEX? OR TRU FLEX? OR TRUFLEX OR  IN!VIGOR? OR INVIGOR? OR IN VIGOR?
Newly expressed proteins	CP4 EPSPS GOX PAT Barnase	CP4EPSPS? OR CP4 EPSPS? OR 5(W)(ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR ENOL!PYRUVYL! SHIKIMATE!)(W)3 PHOSPHATE SYNTHASE OR  OXIDOREDUCTASE OR GOX  PAT OR PHOSPHINOTHRICIN OR N ACETYLTRANSFERASE OR N ACETYL

	Barnase inhibitor	TRANSFERASE OR N ACETYL!TRANSFERASE OR N!ACETYLTRANSFERASE OR N!ACETYL TRANSFERASE OR N!ACETYL!TRANSFERASE BARNASE OR BAR OR BARSTAR
Intended traits: Herbicide tolerance traits	Glyphosate/roundup tolerance, Glufosinate tolerance	(TOLERAN? OR RESISTAN? OR PROTEC?)( 5A)(GL!PHOSATE OR GL!FOSATE OR ROUNDUP? OR ROUND UP? OR ROUND!UP? OR GLUFOSINATE OR GLUPHOSINATE OR BASTA OR RELY OR FINALE OR IGNITE OR CHALLENGE OR LIBERTY)
Intended traits: Male sterility; male fertility restorer	Male sterility Male fertility restorer	(CONTROL? OR FERTIL? OR STERIL?) (5A) (POLLEN OR POLLINATION OR MALE)
Crop name	Rape, rapeseed, oilseed rape, canola, <i>Brassica</i>	RAPESEED OR RAPE SEED OR OILSEEDRAPE OR OILSEED RAPE OR CANOLA OR BRASSICA
GMO general terms	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.	GMO? OR LMO? OR GM OR GE OR TRANSGEN? OR ((GENETIC? OR LIVING OR BIOTECH?)(5A)(MODIF? OR TRANSFORM? OR MANIPULAT? OR IMPROV? OR ENGINEER? OR DERIV?))

## 2. Controlled vocabulary, if applicable. Bayer GM Oilseed rape products

Key elements	Search terms	Controlled terms offered by CABA (adapted for performing search in STN <sup>®</sup> database catalogue)
Event name	Not applicable	
Trade name	Not applicable	
Newly expressed proteins	Not applicable	
Intended traits : herbicide tolerance traits	Glyphosate tolerance Glufosinate tolerance	(WEED CONTROL+UF,NT/CT AND (GLYPHOSATE+UF,NT/CT OR GLUFOSINATE+UF,NT/CT)) OR MALE STERILITY +UF,NT/CT OR

Intended traits: male sterility; male fertility restorer	Male sterility Male fertility restorer	MALE FERTILITY +UF,NT/CT OR RESTORER GENES +UF,NT/CT
Crop name	Rape, rapeseed, oilseed rape, canola, <i>Brassica</i>	RAPESEED+UF,NT/CT,ORGN
GMO general terms	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	GENETIC ENGINEERING+UF,NT/CT OR GENETIC TRANSFORMATION+UF,NT/CT OR GENETICALLY ENGINEERED FOODS+UF,NT/CT OR GENETICALLY ENGINEERED ORGANISMS+UF,NT/CT OR FOOD BIOTECHNOLOGY+UF,NT/CT

## Annex II. The search string used for Bayer GM oilseed rape products literature search in SciSearch and CABA databases using STN® database catalogue, and outcomes of the search (2019-2020)

The literature search covered the time span June 2019 - May 2020. The literature search in the electronic databases was conducted on a quarterly basis considering the entry dates in the STN® database catalogue. In addition, a final literature search was conducted covering the full-time span of the season. The search result presented below shows the final search conducted covering the full-time span of the 2019-2020 season.

### Translation of query terms into STN search language:

This alert run covers the time range from 20190501 until 20200528

(FILE 'STNGUIDE' ENTERED AT 15:15:57 ON 22 JUN 2020)

```
L1          QUE SPE=ON  ABB=ON  PLU=ON  GT!73 OR GT73 OR GT 73 OR RT!73
OR
          RT73 OR RT 73 OR MON!00073? OR MON00073? OR MON 00073? OR
          MON!00073 OR MON00073? OR MON 00073? OR MON!EMPTY SETEMPTY
          SETEMPTY SET73? OR MONEMPTY SETEMPTY SETEMPTY SET73? OR MON
          EMPTY SETEMPTY SETEMPTY SET73?
L2          QUE SPE=ON  ABB=ON  PLU=ON  MON!88302? OR MON88302? OR MON
MON!883EMPTY
          88302? OR MON!88302? OR MON88302? OR MON 88302? OR
          SET2? OR MON883EMPTY SET2? OR MON 883EMPTY SET2?
L3          QUE SPE=ON  ABB=ON  PLU=ON  MS!8 OR MS8 OR MS 8 OR RF!3 OR
RF3
          OR RF 3 OR ACS!BN005? OR ACSBN005? OR ACS BN005? OR
          ACS!BNOO5?
          OR ACSBN005? OR ACS BNOO5? OR ACS!BNEMPTY SETEMPTY SET5? OR
          ACSBNEMPTY SETEMPTY SET5? OR ACS BNEMPTY SETEMPTY SET5?
L4          QUE SPE=ON  ABB=ON  PLU=ON  ACS!BN003? OR ACSBN003? OR ACS
ACS!BNEMPTY
          BN003? OR ACS!BNOO3? OR ACSBN003? OR ACS BNOO3? OR
          SETEMPTY SET3? OR ACSBNEMPTY SETEMPTY SET3? OR ACS BNEMPTY
          SETEMPTY SET3?
L5          QUE SPE=ON  ABB=ON  PLU=ON  ROUNDUPREADY? OR
ROUND!UP!READY?
          ROUND UP READY? OR ROUNDUP READY? OR ROUND!UP READY? OR
          TRU!FLEX? OR TRU FLEX? OR TRUFLEX OR IN!VIGOR? OR INVIGOR?
OR
          IN VIGOR?
L6          QUE SPE=ON  ABB=ON  PLU=ON  RAPESEED OR RAPE SEED OR
OILSEEDRAP
          E OR OILSEED RAPE OR CANOLA OR BRASSICA
L7          QUE SPE=ON  ABB=ON  PLU=ON  CP4EPSPS? OR CP4 EPSPS? OR
5(W) (ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR
ENOL!PYRUVYL!
          ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYL SHIKIMATE OR
          SHIKIMATE!) (W)3 PHOSPHATE SYNTHASE OR OXIDOREDUCTASE
L8          QUE SPE=ON  ABB=ON  PLU=ON  N ACETYLTRANSFERASE OR N ACETYL
OR
          TRANSFERASE OR N ACETYL!TRANSFERASE OR N!ACETYLTRANSFERASE
OR
          N!ACETYL TRANSFERASE OR N!ACETYL!TRANSFERASE BARNASE OR BAR
```

Appendix 3 – Annual general surveillance report in 2019/2020 season

Literature search - Bayer oilseed rape GM products

Bayer Agriculture BV

L9 BARSTAR OR GOX OR PAT OR PHOSPHINOTHRICIN  
 QUE SPE=ON ABB=ON PLU=ON GMO? OR LMO? OR GM OR GE OR  
 TRANSGEN? OR ((GENETIC? OR LIVING OR BIOTECH?) (5A) (MODIF?  
 OR  
 TRANSFORM? OR MANIPULAT? OR IMPROV? OR ENGINEER? OR  
 DERIV?))  
 L10 QUE SPE=ON ABB=ON PLU=ON (TOLERAN? OR RESISTAN? OR  
 PROTEC?) (  
 5A) (GL!PHOSATE OR GL!FOSATE OR ROUNDUP? OR ROUND UP? OR  
 ROUND!UP? OR GLUFOSINATE OR GLUPHOSINATE OR BASTA OR RELY  
 OR  
 FINALE OR IGNITE OR CHALLENGE OR LIBERTY)  
 L11 QUE SPE=ON ABB=ON PLU=ON (CONTROL? OR FERTIL? OR  
 STERIL?)  
 (5A) (POLLEN OR POLLINATION OR MALE)  
 L12 QUE SPE=ON ABB=ON PLU=ON RAPESEED+UF,NT/CT,ORGN  
 L13 QUE SPE=ON ABB=ON PLU=ON GENETIC ENGINEERING+UF,NT/CT OR  
 GENETIC TRANSFORMATION+UF,NT/CT OR GENETICALLY ENGINEERED  
 FOODS+UF,NT/CT OR GENETICALLY ENGINEERED ORGANISMS+UF,NT/CT  
 OR  
 FOOD BIOTECHNOLOGY+UF,NT/CT  
 L14 QUE SPE=ON ABB=ON PLU=ON (WEED CONTROL+UF,NT/CT AND  
 (GLYPHOSATE+UF,NT/CT OR GLUFOSINATE+UF,NT/CT)) OR MALE  
 STERILITY +UF,NT/CT OR MALE FERTILITY +UF,NT/CT OR RESTORER  
 GENES +UF,NT/CT

### Search in SciSearch Database:

FILE 'SCISEARCH' ENTERED AT 15:16:25 ON 22 JUN 2020  
 CHARGED TO COST=PAUSE  
 L15 93 SEA SPE=ON ABB=ON PLU=ON (L1 OR L2 OR L3 OR L4) AND  
 ED>=20190501 AND ED<=20200528 AND PY>=2019  
 L16 261 SEA SPE=ON ABB=ON PLU=ON L5 AND ED>=20190501 AND  
 ED<=2020052  
 8 AND PY>=2019  
 L17 3251 SEA SPE=ON ABB=ON PLU=ON L6 AND ED>=20190501 AND  
 ED<=2020052  
 8 AND PY>=2019  
 L18 3 SEA SPE=ON ABB=ON PLU=ON L16 AND L17  
 L19 1249 SEA SPE=ON ABB=ON PLU=ON L7 AND ED>=20190501 AND  
 ED<=2020052  
 8 AND PY>=2019  
 L20 16666 SEA SPE=ON ABB=ON PLU=ON L8 AND ED>=20190501 AND  
 ED<=2020052  
 8 AND PY>=2019  
 L21 17905 SEA SPE=ON ABB=ON PLU=ON L19 OR L20  
 L22 24653 SEA SPE=ON ABB=ON PLU=ON L9 AND ED>=20190501 AND  
 ED<=2020052  
 8 AND PY>=2019  
 L23 211 SEA SPE=ON ABB=ON PLU=ON L21 AND (L22 OR L17)  
 L24 1927 SEA SPE=ON ABB=ON PLU=ON L10 AND ED>=20190501 AND  
 ED<=202005  
 28 AND PY>=2019  
 L25 2907 SEA SPE=ON ABB=ON PLU=ON L11 AND ED>=20190501 AND  
 ED<=202005  
 28 AND PY>=2019  
 L26 4831 SEA SPE=ON ABB=ON PLU=ON L24 OR L25  
 L27 21 SEA SPE=ON ABB=ON PLU=ON L26 AND L22 AND L17  
 L28 324 SEA SPE=ON ABB=ON PLU=ON L15 OR L18 OR L23 OR L27

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Literature search - Bayer oilseed rape GM products

Bayer Agriculture BV

## Search in CABA Database:

```
FILE 'CABA' ENTERED AT 15:16:48 ON 22 JUN 2020
CHARGED TO COST=PAUSE
L29      22 SEA SPE=ON  ABB=ON  PLU=ON  (L1 OR L2 OR L3 OR L4) AND
          ED>=20190501 AND ED<=20200528 AND PY>=2019
L30      101 SEA SPE=ON  ABB=ON  PLU=ON  L5 AND ED>=20190501 AND
ED<=2020052
          8 AND PY>=2019
L31      3000 SEA SPE=ON  ABB=ON  PLU=ON  L6 AND ED>=20190501 AND
ED<=2020052
          8 AND PY>=2019
L32      458 SEA SPE=ON  ABB=ON  PLU=ON  L12 AND ED>=20190501 AND
ED<=202005
          28 AND PY>=2019
L33      3000 SEA SPE=ON  ABB=ON  PLU=ON  L31 OR L32
L34      2 SEA SPE=ON  ABB=ON  PLU=ON  L30 AND L33
L35      1516 SEA SPE=ON  ABB=ON  PLU=ON  L7 AND ED>=20190501 AND
ED<=2020052
          8 AND PY>=2019
L36      1039 SEA SPE=ON  ABB=ON  PLU=ON  L8 AND ED>=20190501 AND
ED<=2020052
          8 AND PY>=2019
L37      2547 SEA SPE=ON  ABB=ON  PLU=ON  L35 OR L36
L38      7008 SEA SPE=ON  ABB=ON  PLU=ON  L9 AND ED>=20190501 AND
ED<=2020052
          8 AND PY>=2019
L39      3384 SEA SPE=ON  ABB=ON  PLU=ON  L13 AND ED>=20190501 AND
ED<=202005
          28 AND PY>=2019
L40      7021 SEA SPE=ON  ABB=ON  PLU=ON  L38 OR L39
L41      178 SEA SPE=ON  ABB=ON  PLU=ON  L37 AND (L40 OR L33)
L42      713 SEA SPE=ON  ABB=ON  PLU=ON  L10 AND ED>=20190501 AND
ED<=202005
          28 AND PY>=2019
L43      1134 SEA SPE=ON  ABB=ON  PLU=ON  L11 AND ED>=20190501 AND
ED<=202005
          28 AND PY>=2019
L44      470 SEA SPE=ON  ABB=ON  PLU=ON  L14 AND ED>=20190501 AND
ED<=202005
          28 AND PY>=2019
L45      1937 SEA SPE=ON  ABB=ON  PLU=ON  L42 OR L43 OR L44
L46      11 SEA SPE=ON  ABB=ON  PLU=ON  L45 AND L40 AND L33
L47      211 SEA SPE=ON  ABB=ON  PLU=ON  L29 OR L34 OR L41 OR L46
```

## Deduplication of Hit-sets from both sources:

```
FILE 'CABA, SCISEARCH' ENTERED AT 15:17:20 ON 22 JUN 2020
CHARGED TO COST=PAUSE
L48      482 DUP REM L47 L28 (53 DUPLICATES REMOVED)
          ANSWERS '1-210' FROM FILE CABA
          ANSWERS '211-482' FROM FILE SCISEARCH
          D L48 1-482 AN TI
```

```
FILE 'STNGUIDE' ENTERED AT 15:18:47 ON 22 JUN 2020
CHARGED TO COST=PAUSE
```

```
FILE SCISEARCH
```

Appendix 3 – Annual general surveillance report in 2019/2020 season

Literature search - Bayer oilseed rape GM products

Bayer Agriculture BV

FILE COVERS 1974 TO 15 Jun 2020 (20200615/ED)

To bring you the most up-to-date SciSearch information,  
SciSearch SDIs now run on Mondays.

FILE CABA

FILE LAST UPDATED: 17 JUN 2020 <20200617/UP>

FILE COVERS 1973 TO DATE

<<< SIMULTANEOUS LEFT AND RIGHT TRUNCATION IS AVAILABLE IN  
THE BASIC INDEX (/BI), ABSTRACT (/AB), AND TITLE (/TI) FIELDS >>>

FILE STNGUIDE

FILE CONTAINS CURRENT INFORMATION.

LAST RELOADED: Apr 24, 2020 (20200424/UP).

### **Annex III. List of reference publications used in identifying search terms and in validating the literature search strategy for Bayer GM oilseed rape products literature search**

The list below includes reference publications used for each relevant key element, namely event name, trade name, newly expressed proteins and intended traits. For GMO general and crop name search terms, given the breadth of the terms and as they are used to focus the search to GM crops, reference publications were considered not applicable.

Brown, PB; Wilson, KA; Jonker, Y; Nickson, TE (2003). Glyphosate tolerant canola meal is equivalent to the parental line in diets fed to rainbow trout. *JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY*. Volume: 51, Issue: 15, Pages: 4268-4272, DOI: 10.1021/jf034018f

Taylor, ML; Stanisiewski, EP; Riordan, SG; Nemeth, MA; George, B; Hartnell, GF (2004). Comparison of broiler performance when fed diets containing roundup ready (Event RT73), nontransgenic control, or commercial canola meal. *POULTRY SCIENCE*. Volume: 83, Issue: 3, Pages: 456-461, DOI: 10.1093/ps/83.3.456

EFSA (2017). Scientific Opinion on application EFSA-GMO-NL-2013-119 for authorisation of genetically modified glufosinate-ammonium- and glyphosate-tolerant oilseed rape MON 88302 × MS8 × RF3 and subcombinations independently of their origin, for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto Company and Bayer CropScience, *EFSA Journal*, 10.2903/j.efsa.2017.4767, **15**, 4.

EFSA (2005). Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the application (Reference C/BE/96/01) for the placing on the market of glufosinate-tolerant hybrid oilseed rape Ms8xRf3, derived from genetically modified parental lines (Ms8, Rf3), for import and processing for feed and industrial uses, under Part C of Directive 2001/18/EC from Bayer CropScience. *EFSA Journal* 2005; **3**(10): 281, 23 pp. doi:[10.2903/j.efsa.2005.281](https://doi.org/10.2903/j.efsa.2005.281)

EFSA (2012). Scientific Opinion on application (EFSAGMO-BE-2010-81) for the placing on the market of genetically modified herbicide-tolerant oilseed rape Ms8, Rf3 and Ms8 9 Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from, oilseed rape Ms8, Rf3 and Ms8 9 Rf3 (with the exception of processed oil) under Regulation (EC) No 1829/2003 from Bayer. *EFSA Journal* 2012; **10**(9): 2875, 32 pp. doi:[10.2903/j.efsa.2012.2875](https://doi.org/10.2903/j.efsa.2012.2875)

EFSA (2014). Scientific Opinion on application (EFSA-GMO-BE-2011-101) for the placing on the market of herbicide-tolerant genetically modified oilseed rape MON 88302 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2014; **12**(6): 3701, 37 pp. doi:[10.2903/j.efsa.2014.3701](https://doi.org/10.2903/j.efsa.2014.3701)

## Annex IV. Literature search in internet pages of relevant key organisations for Bayer GM oilseed rape products covering time span 2019 - 2020

Relevant key organisations	Link to the relevant information and summary of the retrieved records
USDA	<p><a href="https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status">https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status</a> - Accessed on 21 July 2020. The webpage dedicated to petitions for determination of nonregulated status was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> 17 July 2020</p> <p><i>Limits applied:</i> The list of the petitions was sorted by 'Effective Date' and those completed/ released starting from 01/01/2019 were assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> "2"</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM oilseed rape products.</p>
US FDA	<p><a href="https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon">https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon</a> – Accessed on 21 July 2020. The webpage dedicated to biotechnology consultations on food from GE plant varieties was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> 11 October 2010</p> <p><i>Limits applied:</i> The list of the consultations starting from the 'FDA Letter Date' of January 01, 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> "3".</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM oilseed rape products.</p>
CFIA	<p><a href="https://www.inspection.gc.ca/industry-guidance/eng/1374161650885/1374161737236?gp=3&amp;gc=25&amp;ga=4#gdr_results">https://www.inspection.gc.ca/industry-guidance/eng/1374161650885/1374161737236?gp=3&amp;gc=25&amp;ga=4#gdr_results</a> - Accessed on 24 August 2020. The webpage dedicated to repository documents referring to plants with novel traits was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> not clear</p> <p><i>Limits applied:</i> The list of repository documents referring to plants with novel traits starting from 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> "16".</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM oilseed rape products.</p>

Health Canada	<p><a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html</a> - Accessed on 21 July 2020. The webpage dedicated to approved products of genetically modified (GM) foods and other novel foods was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> 07 May 2020</p> <p><i>Limits applied:</i> The list of novel food decisions starting from the ‘Decision Date (20YY/MM/DD)’ of 2019/01/01 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “3”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM oilseed rape products.</p>
FSANZ	<p><a href="http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx">http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx</a> - Accessed on 24 August 2020. The webpage dedicated to current GM applications and approvals was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> August 2019</p> <p><i>Limits applied:</i> The list for GM applications and approvals with ‘Status’ approved or under assessment starting from 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “1”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM oilseed rape products.</p>
CTNBio	<p><a href="http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo">http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo</a> – Accessed on 24 August 2020. 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> 21 August 2020</p> <p><i>Limits applied:</i> The list of commercial releases for plants (= plantas) starting from 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “3”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM oilseed products.</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 21 July 2020. 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>Limits applied:</i> The list of events with commercial resolución starting from 2019 were checked.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “9”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM oilseed rape products.</p>

MAFF	<p><a href="https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-217.pdf">https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-217.pdf</a> - Accessed on 20 August 2020. The weblink dedicated to list of approved genetically modified agricultural crops was checked.</p> <p><i>Date of the most recent website update at the time of the search:</i> 17 June 2020</p> <p><i>Limits applied:</i> The list of GM agricultural crops with approval date (‘承認日’) starting from January 01, 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “13”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM oilseed rape products.</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 21 July 2020. 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>Limits applied:</i> Table of applications and authorisations for Dealings involving Intentional Release (DIR) into the environment starting from ‘Issue Date’ of 01 01 2019 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “9”.</p> <p><i>Number of relevant records or full-text documents retrieved:</i> The retrieved records are not relevant to Bayer GM oilseed rape products.</p>

## **Annex V. Results of the publication selection process for Bayer GM oilseed rape products literature search in SciSearch and CABA databases using STN<sup>®</sup> database catalogue**

**Table 1. Results of the publication selection process.**

<b>Review question captured in the search</b>	<b>Number of publications</b>
Publications identified after searches of the scientific literature in SciSearch and CABA databases (following de-duplication)	462
Publications excluded after rapid assessment for relevance	462
Publications screened using full-text documents	0
Publications excluded after detailed assessment for relevance	0
Unobtainable publications	0
Unclear publications	0
Publications considered relevant	0