

## **APPENDIX 3**

### **LITERATURE SEARCH TO SUPPORT GENERAL SURVEILLANCE OF 2022/2023 ANNUAL POST MARKET ENVIRONMENTAL MONITORING REPORTS OF BASF AND BAYER GM OILSEED RAPE PRODUCTS**

**Data protection.**

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## SUMMARY

The literature search was conducted in accordance with the 2019 EFSA explanatory note on literature searching conducted in the context of GMO applications<sup>1,2</sup> to support general surveillance of 2022/2023 annual post market environmental monitoring reports. It addresses the review question “Do BASF and 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?”.

Eligibility/inclusion criteria to establish the relevance of retrieved publications was determined following the criteria described in the 2019 EFSA explanatory note on literature searching<sup>2</sup>. Literature searching for BASF and Bayer GM oilseed rape products was conducted in electronic bibliographic databases and internet pages of relevant key organisations.

In line with the requirements in the 2019 EFSA explanatory note on literature searching<sup>2</sup> the literature search covered the time span 2022 – 2023 to capture any publication published during the annual general surveillance of 2022/2023 post market environmental monitoring season.

The literature search retrieved no relevant publications.

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

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<sup>1</sup> Hereafter referred to as 2019 EFSA explanatory note on literature searching.

<sup>2</sup> 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.](#) – Accessed on 18 September 2023

## 1. INTRODUCTION

As part of the general surveillance requirements for BASF and Bayer GM oilseed rape products authorised in the European Union (EU) market under regulation (EC) No 1829/2003, BASF Agricultural Solutions Seed US LLC and Bayer Agriculture BV<sup>3</sup> has actively monitored the oilseed rape products by conducting quarterly literature searches covering the time span between June 2022 and May 2023.

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

The Appendix completeness checklist is provided with this report.

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

This literature search has been conducted to address the review question “Do BASF and 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 2022/2023 annual post market environmental monitoring (PMEM) reports in accordance with the 2019 EFSA explanatory note on literature searching<sup>2</sup>.

Key elements used for the review question are humans, animals, and/or the environment (= population), BASF and 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>3</sup> Hereafter referred to as BASF and Bayer respectively.

**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 BASF and Bayer GM oilseed rape products are addressed as general protection goals. |
| Intervention/exposure   | BASF and 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>  |  |
| Stacked events / sub-combinations                                     | The single events addressed in the publication are the single events in stacked BASF and Bayer GM oilseed rape product.<br>Stacked BASF and Bayer GM oilseed rape product or any of its sub-combinations are addressed in the study.   |
| Information/ data requirements, including source of publications data | The publication potentially contributes to the knowledge of the risk assessment of BASF and Bayer GM oilseed rape products for all uses as any other oilseed rape but excluding cultivation.<br>Original/primary data are presented in the publication.                      |

The eligibility/inclusion criteria implemented by BASF and Bayer for assessing the relevance of publications follow the recommendations described in the 2019 EFSA explanatory note on literature searching<sup>2</sup>. Following a conservative approach, BASF and Bayer selected the broad inclusion/eligibility criteria that align with the review question and the scope of the BASF and Bayer GM oilseed rape products' authorisations. Hence, given the conservative approach taken when selecting the eligibility/inclusion criteria, conducting a pilot study was considered unwarranted.

When necessary, the eligibility criteria and/or process may be modified/reviewed as a result of for example new regulatory guidance or novel topics on literature regarding the risk assessment of GM plants.

### 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<sup>4</sup> and the 2019 EFSA explanatory note on literature searching<sup>2</sup>, identification of bibliographic sources and development of search strategies were 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

BASF and Bayer select the SciSearch (Science Citation Index)<sup>5</sup> and the CABA<sup>6</sup> (CAB Abstracts<sup>®</sup>)<sup>7</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<sup>®</sup> database catalogue<sup>8</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<sup>™</sup>, 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<sup>®</sup>. Bibliographic information, authors, cited references, and KeyWords Plus<sup>®</sup> are searchable*”<sup>5</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>6</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>7,9</sup>. In general, English is considered the universal language of science. For this reason, the journals most important to the international research community will publish either full text or a

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<sup>4</sup> EFSA, 2010. [Application of systematic review methodology to food and feed safety assessments to support decision making](#) *The EFSA Journal*, 1637, 1-90 - Accessed on 18 September 2023

<sup>5</sup> STN/SciSearch: <https://www.stn-international.com/sites/default/files/stn/dbss/SCISEARCH.pdf> - Accessed on 18 September 2023

<sup>6</sup> STN/CABA: <https://www.stn-international.com/sites/default/files/stn/dbss/CABA.pdf> – Accessed on 18 September 2023

<sup>7</sup> CAB Abstracts<sup>®</sup>: <https://www.cabi.org/publishing-products/online-information-resources/cab-abstracts/> - Accessed on 18 September 2023

<sup>8</sup> STN<sup>®</sup>: <http://stn-international.de/sites/default/files/STN/brochures/stnfile-kat.pdf>- Accessed on 18 September 2023

<sup>9</sup> Web of Science group; <https://clarivate.com/webofsciencelibrary/solutions/webofscience-core-collection-editorial-selection-process/> - Accessed on 18 September 2023

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<sup>2</sup>, 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<sup>2</sup>, three (CIBIOGEM, Environment and Climate Change Canada and OECD) are not involved in risk assessment of GM plants. Six (USDA, FDA, CFIA, Health Canada, FSANZ and MAFF) do not regulate stack products. GEAC, for the time being, only assesses GM cotton and US EPA is only involved in the assessment of events containing Plant-Incorporated Protectants (PIP). Therefore, the internet search focused on the three key organisations relevant for BASF and Bayer GM oilseed rape products<sup>10</sup>.

## **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<sup>2</sup>:

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

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 BASF and Bayer GM oilseed rape products.

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<sup>10</sup> Internet pages of the relevant key organisations for BASF and Bayer GM oilseed rape products: CTNBio (<http://ctnbio.mctic.gov.br/>) - Accessed on 18 September 2023; CONABIA (<https://www.argentina.gob.ar/>) - Accessed on 18 September 2023; OGTR (<http://www.ogtr.gov.au/>) - Accessed on 18 September 2023.

The translation of the intervention key elements into search terms are presented in **Annex I**. 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<sup>11</sup> 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>12</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<sup>5,6,11</sup>. 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>13</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 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 2022 - 31 May 2023.

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<sup>11</sup> STN. [Command summary chart for bibliographic and full-text databases](#). – Accessed on 18 September 2023

<sup>12</sup> STNindex user guide: <https://stn.products.fiz-karlsruhe.de/training-center/documentation/stn-index-user-guide> - Accessed on 18 September 2023

<sup>13</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 18 September 2023

The literature search in the electronic databases was conducted on a quarterly basis considering the entry dates in the STN<sup>®</sup> 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**

| <b>Date of the search</b>  | <b>Last database update dates</b> | <b>Search period</b>              |
|----------------------------|-----------------------------------|-----------------------------------|
| 10 October 2022            | SciSearch: 03 October 2022        | 06 June 2022 – 03 October 2022    |
|                            | CABA: 04 October 2022             | 06 June 2022 – 03 October 2022    |
| 01 February 2023           | SciSearch: 01 February 2023       | 03 October 2022 – 30 January 2023 |
|                            | CABA: 31 January 2023             | 03 October 2022 – 30 January 2023 |
| 06 June 2023 <sup>14</sup> | SciSearch: 06 June 2023           | 06 June 2022 – 06 June 2023       |
|                            | CABA: 30 May 2023                 | 06 June 2022 – 06 June 2023       |

### 3.2.5. Reference publications

In accordance with the 2019 EFSA explanatory note on literature searching<sup>2</sup>, a list of reference publications is provided in **Annex III**. The reference publications were tested and retrieved using the search terms and strategy developed for BASF and Bayer GM oilseed rape products.

### 3.3. Search strategy (relevant key organisations)

All records related to 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** and assessed for their relevance to BASF and Bayer GM oilseed rape products.

The literature search in the internet pages of the relevant key organisations was conducted on 16 August 2023 and covered the time span 01 June 2022 – 16 August 2023.

## 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

<sup>14</sup> Note the search was revised on 06 June 2023 as the search scripts were modified to address some errors.

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**

### **4.2.1. Number of 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.

### **4.2.2. Expertise of reviewers**

Besides their academic background, the reviewers have adequate expertise in the risk assessment areas of GM crops (molecular characterisation, food and feed safety, environmental safety) and several years of experience in the analysis and selection of relevant publications in literature searches for GM applications.

### **4.2.3. Inter-reviewer agreement**

Reviewers (internal and external) perform their assessment in an independent sequential manner. They are in communication and meet on a regular basis to ensure consistent interpretation and implementation of eligibility/inclusion criteria and/or screening process. During the rapid assessment stage, retrieved abstracts and titles of publications are screened by each reviewer independently and assessed against each other to conclude on inclusion or exclusion based on eligibility/inclusion criteria. If opinions on relevance differ, the discrepancies are discussed between the reviewers and if a disagreement persists, the publication under discussion is *de facto* included in the next stage for further consideration. In summary, publications which appear to be relevant and those of unclear relevance, are progressed to the next stage.

During the detailed assessment, the selected publications are assessed in detail, independently and sequentially by the two external reviewers based on the full text of the publications. The publications screened by each reviewer are assessed against each other to conclude on inclusion or exclusion based on eligibility/inclusion criteria. If opinions on relevance differ between reviewers, all reviewers (external and internal) discuss the discrepancy as necessary and, if needed, consult additional internal reviewers to resolve the discrepancy.

If uncertainty remains, the publication is *de facto* reported as unclear providing a justification as suggested by the reviewers. In summary, publications, which appear to be relevant and those of unclear relevance, are reported.

This approach ensures a high-quality process as it allows a harmonised continuous publication screening process across different GM applications in accordance with the 2019 EFSA explanatory note on literature searching<sup>2</sup> and avoids missing publications due to bias towards certain eligibility criteria.

### 4.3. Classification of publications

Taking account of i) the review question, ii) the scope of the application, *i.e.* authorisation of BASF and 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 were 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<sup>2</sup> by at least two individuals with technical expertise on the topic using the following steps categorised in two main areas:

#### Credibility of the publication

1. ***Does the publication include sufficient information to establish the reliability of the research?*** Publications with insufficient information (e.g., incomplete experimental design, publications for which only an abstract is publicly available) are categorised as “**not assignable**”. Others go to step 2.
2. ***Is the publication scientifically sound/reliable?*** Publications that do not contain scientifically sound/reliable information (e.g., inadequate methodology, test/control materials) are categorised as “**not reliable**”. Others go to step 3.

#### Appropriateness of the publication for the EFSA risk assessment

3. ***What is the relevance level of the publication for the EFSA risk assessment?*** Publications with low relevance for the EFSA risk assessment (e.g. publications dealing with wild relatives or pests not found in the EU) are categorised as “**low reliable**”. Publications with moderate relevance for the EFSA risk assessment (e.g., exploratory studies, research with limited focus on risk assessment) are categorised as “**moderately reliable**”. Whereas publications with high relevance for the EFSA risk assessment (e.g.

research based on data collected for regulatory studies) are categorised as “**highly reliable**”.

In cases of disagreements, the evaluators discuss together and collectively determine the reliability of the publication.

## **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 95 and 153 hits in SciSearch and CABA databases, respectively (see **Annex II**). After de-duplication<sup>15</sup>, the total number resulted in 222 hits (see **Annex V**).

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

The literature search in the internet pages of the three relevant key organisations retrieved a total of 25 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. Considering the implications of the findings**

Not applicable as no relevant publication was identified.

## **6. CONCLUSION**

Taking into consideration all the above, BASF and Bayer confirm that this literature search, conducted in accordance with the 2019 EFSA explanatory note on literature searching<sup>2</sup> to support the general surveillance in the context of 2022/2023 annual PMEM for BASF and Bayer GM oilseed rape products, identified no relevant publications that would invalidate the conclusions of the BASF and Bayer GM oilseed rape products’ previous risk assessments. Therefore, the conclusions of the risk assessment as presented in the initial applications of the BASF and Bayer GM oilseed rape products remain unchanged.

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<sup>15</sup> Corresponds to the unique publications after STN® and manual de-duplication.

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

The search terms for oilseed rape MON 88302 ×MS8 ×RF3 are covered by the search terms for Bayer GM oilseed rape products.

### 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<br>(adapted for performing search in STN® database catalogue)  |
|--------------|---|--|
| Event names  | GT73 or RT73 or MON-ØØØ73-7<br>MON 88302 or MON-883Ø2-9<br>MS8 or ACS-BNØØ5-8<br>RF3 or ACS-BNØØ3-6<br>MON 94100 or MON-941ØØ-2 | ((GT!73 OR GT73 OR GT 73) AND (RAPESEED OR RAPE SEED OR OILSEEDRAPE OR OILSEED RAPE OR CANOLA OR BRASSICA)) OR ((RT!73 OR RT73 OR RT 73) AND (RAPESEED OR RAPE SEED OR OILSEEDRAPE OR OILSEED RAPE OR CANOLA OR BRASSICA)) 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?<br><br>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?<br><br>((MS!8 OR MS8 OR MS 8) AND (RAPESEED OR RAPE SEED OR OILSEEDRAPE OR OILSEED RAPE OR CANOLA OR BRASSICA)) 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<br><br>((RF!3 OR RF3 OR RF 3) AND (RAPESEED OR RAPE SEED OR OILSEEDRAPE OR OILSEED RAPE OR CANOLA OR BRASSICA)) 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?<br><br>(MON 94100? OR MON94100? OR MON 941OO? OR MON941OO? OR MON 941EMPTY SETEMPTY SET? OR MON941EMPTY SETEMPTY SET?) |

|  |   |  |
|--|---|--|
| Trade names  | Roundup Ready® canola<br>TruFlex™canola with Roundup Ready® technology<br>InVigor™ Canola   | ROUNDUPREADY? OR ROUND!UP!READY? ROUND UP READY? OR ROUNDUP READY? OR ROUND!UP READY? OR<br>TRU!FLEX? OR TRU FLEX? OR TRUFLEX OR<br>IN!VIGOR? OR INVIGOR? OR IN VIGOR?   |
| Newly expressed proteins                                 | CP4 EPSPS<br>GOX<br>PAT<br>Barnase<br>Barnase inhibitor<br>DMO  | CP4EPSPS? OR CP4 EPSPS? OR 5(W)( OR ENOL PYRUVYL SHIKIMATE OR ENOLPYRUVYL SHIKIMATE OR ENOL PYRUVYLSHIKIMATE OR ENOL!PYRUVYL! SHIKIMATE OR ENOLPYRUVYLSHIKIMATE)(W)3 PHOSPHATE(1W)SYNTHASE OR<br>OXIDOREDUCTASE OR (GOX AND (GENE OR ENZYME OR PROTEIN))<br>(PAT AND (GENE OR ENZYME OR PROTEIN)) OR (PHOSPHINOTHRICIN AND (ACETYL TRANSFERASE OR ACETYL!TRANSFERASE OR ACETYLTRANSFERASE)) OR DICAMBA ?OXYGENASE OR DICAMBA ?DEMETHYLASE OR (DMO? AND (GENE OR ENZYME OR PROTEIN))<br>BARNASE OR BAR OR BARSTAR |
| Intended traits: Herbicide tolerance traits              | Glyphosate/roundup tolerance,<br>Glufosinate tolerance,<br>Dicamba 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 IGNITE OR LIBERTY OR PHOSPHINOTHRICIN OR ?BUTANOIC ACID OR DICAMBA OR ?METHOXYBENZOIC ACID)   |
| Intended traits: Male sterility; male fertility restorer | Male sterility<br>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<br>(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<br>Glufosinate tolerance<br>Dicamba tolerance   | (WEED CONTROL+UF,NT/CT AND (GLYPHOSATE+UF,NT/CT OR GLUFOSINATE+UF,NT/CT OR DICAMBA+UF,NT/CT))  |
| Intended traits: male sterility; male fertility restorer | Male sterility<br>Male fertility restorer  | MALE STERILITY +UF,NT/CT OR 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 BASF and Bayer GM oilseed rape products literature search in SciSearch and CABA databases using STN® database catalogue, and outcomes of the search (2022-2023)

This alert run covers the time range from 20220606 until 20230606

This alert will only include literature published from 2022 onwards

and his full

```
(FILE 'STNGUIDE' ENTERED AT 15:06:20 ON 06 JUN 2023)
DEL HIS Y
L1 QUE SPE=ON ABB=ON PLU=ON ((GT 73 OR GT!73 OR GT73) AND
(RAPESEED OR RAPE SEED OR OILSEEDRAPE OR OILSEED RAPE OR
CANOLA OR BRASSICA)) OR ((RT 73 OR RT!73 OR RT73) AND (RAPESEED
OR RAPE SEED OR OILSEEDRAPE OR OILSEED RAPE OR CANOLA OR
BRASSICA))
L2 QUE SPE=ON ABB=ON PLU=ON MON!00073? OR MON00073? OR MON
00073? OR MON!00073 OR MON00073? OR MON 00073? OR MON!EMPTY
SETEEMPTY SETEMPTY SET73? OR MONEMPTY SETEMPTY SETEMPTY SET73?
OR MON EMPTY SETEMPTY SETEMPTY SET73?
L3 QUE SPE=ON ABB=ON PLU=ON MON!88302? OR MON88302? OR MON
88302? OR MON!88302? OR MON88302? OR MON 88302? OR MON!883EMPTY
SET2? OR MON883EMPTY SET2? OR MON 883EMPTY SET2?
L4 QUE SPE=ON ABB=ON PLU=ON ((MS 8 OR MS!8 OR MS8) AND
(RAPESEED OR RAPE SEED OR OILSEEDRAPE OR OILSEED RAPE OR
CANOLA OR BRASSICA)) OR ACS!BN005? OR ACSBN005? OR ACS BN005?
OR ACS!BNO05? OR ACSBNO05? OR ACS BNO05? OR ACS!BNEMPTY
SETEEMPTY SET5? OR ACSBNEMPTY SETEMPTY SET5? OR ACS BNEMPTY
SETEEMPTY SET5?
L5 QUE SPE=ON ABB=ON PLU=ON ((RF 3 OR RF!3 OR RF3) AND
(RAPESEED OR RAPE SEED OR OILSEEDRAPE OR OILSEED RAPE OR
CANOLA OR BRASSICA)) OR ACS BN003? OR ACS!BN003? OR ACSBN003?
OR ACS BNO03? OR ACS!BNO03? OR ACSBNO03? OR ACS BNEMPTY
SETEEMPTY SET3? OR ACS!BNEMPTY SETEMPTY SET3? OR ACSBNEMPTY
SETEEMPTY SET3?
L6 QUE SPE=ON ABB=ON PLU=ON (MON 94100? OR MON94100? OR MON
94100? OR MON94100? OR MON 941EMPTY SETEMPTY SET? OR MON941EMPT
Y SETEMPTY SET?)
L7 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?
L8 QUE SPE=ON ABB=ON PLU=ON RAPESEED OR RAPE SEED OR OILSEEDRAP
E OR OILSEED RAPE OR CANOLA OR BRASSICA
L9 QUE SPE=ON ABB=ON PLU=ON CP4 EPSPS? OR CP4 EPSPS? OR
5(W) (ENOL PYRUVYL SHIKIMATE OR ENOLPYRUVYL SHIKIMATE OR ENOL
PYRUVYL SHIKIMATE OR ENOL!PYRUVYL!SHIKIMATE OR ENOLPYRUVYL SHIKI
MATE) (W) 3 PHOSPHATE (1W) SYNTHASE OR OXIDOREDUCTASE
L10 QUE SPE=ON ABB=ON PLU=ON (GOX AND (GENE OR ENZYME OR
PROTEIN)) OR (PAT AND (GENE OR ENZYME OR PROTEIN)) OR (PHOSPHIN
OTHRICIN AND (ACETYL TRANSFERASE OR ACETYL!TRANSFERASE OR
ACETYLTRANSFERASE )) OR DICAMBA ?OXYGENASE OR DICAMBA ?DEMETHYL
ASE OR (DMO? AND (GENE OR ENZYME OR PROTEIN))
```

L11 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  
 L12 TRANSFORM? OR MANIPULAT? OR IMPROV? OR ENGINEER? OR DERIV?))  
 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 IGNITE OR  
 LIBERTY OR PHOSPHINOTHRICIN OR ?BUTANOIC ACID OR DICAMBA OR  
 ?METHOXYBENZOIC ACID)  
 L13 QUE SPE=ON ABB=ON PLU=ON (CONTROL? OR FERTIL? OR STERIL?)  
 (5A) (POLLEN OR POLLINATION OR MALE)  
 L14 QUE SPE=ON ABB=ON PLU=ON RAPESEED+UF,NT/CT,ORGN  
 L15 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  
 L16 QUE SPE=ON ABB=ON PLU=ON (WEED CONTROL+UF,NT/CT AND  
 (GLYPHOSATE+UF,NT/CT OR GLUFOSINATE+UF,NT/CT OR DICAMBA+UF,NT/C  
 T)) OR MALE STERILITY +UF,NT/CT OR MALE FERTILITY +UF,NT/CT OR  
 RESTORER GENES +UF,NT/CT

FILE 'SCISEARCH' ENTERED AT 15:06:36 ON 06 JUN 2023

L17 6 SEA SPE=ON ABB=ON PLU=ON (L1 OR L2 OR L3 OR L4 OR L5 OR L6)  
 AND ED>=20220606 AND ED<=20230606 AND PY>=2022  
 L18 309 SEA SPE=ON ABB=ON PLU=ON L7 AND ED>=20220606 AND ED<=2023060  
 6 AND PY>=2022  
 L19 3568 SEA SPE=ON ABB=ON PLU=ON L8 AND ED>=20220606 AND ED<=2023060  
 6 AND PY>=2022  
 L20 4 SEA SPE=ON ABB=ON PLU=ON L18 AND L19  
 L21 1320 SEA SPE=ON ABB=ON PLU=ON L9 AND ED>=20220606 AND ED<=2023060  
 6 AND PY>=2022  
 L22 458 SEA SPE=ON ABB=ON PLU=ON L10 AND ED>=20220606 AND ED<=202306  
 06 AND PY>=2022  
 L23 1773 SEA SPE=ON ABB=ON PLU=ON L21 OR L22  
 L24 29150 SEA SPE=ON ABB=ON PLU=ON L11 AND ED>=20220606 AND ED<=202306  
 06 AND PY>=2022  
 L25 98 SEA SPE=ON ABB=ON PLU=ON L23 AND (L24 OR L19)  
 L26 213 SEA SPE=ON ABB=ON PLU=ON L12 AND ED>=20220606 AND ED<=202306  
 06 AND PY>=2022  
 L27 2898 SEA SPE=ON ABB=ON PLU=ON L13 AND ED>=20220606 AND ED<=202306  
 06 AND PY>=2022  
 L28 3111 SEA SPE=ON ABB=ON PLU=ON L26 OR L27  
 L29 13 SEA SPE=ON ABB=ON PLU=ON L28 AND L24 AND L19  
 L30 116 SEA SPE=ON ABB=ON PLU=ON L17 OR L20 OR L25 OR L29

FILE 'CABA' ENTERED AT 15:06:56 ON 06 JUN 2023

L31 6 SEA SPE=ON ABB=ON PLU=ON (L1 OR L2 OR L3 OR L4 OR L5 OR L6)  
 AND ED>=20220606 AND ED<=20230606 AND PY>=2022  
 L32 149 SEA SPE=ON ABB=ON PLU=ON L7 AND ED>=20220606 AND ED<=2023060  
 6 AND PY>=2022  
 L33 4567 SEA SPE=ON ABB=ON PLU=ON L8 AND ED>=20220606 AND ED<=2023060  
 6 AND PY>=2022  
 L34 354 SEA SPE=ON ABB=ON PLU=ON L14 AND ED>=20220606 AND ED<=202306  
 06 AND PY>=2022  
 L35 4567 SEA SPE=ON ABB=ON PLU=ON L33 OR L34  
 L36 2 SEA SPE=ON ABB=ON PLU=ON L32 AND L35  
 L37 1137 SEA SPE=ON ABB=ON PLU=ON L9 AND ED>=20220606 AND ED<=2023060  
 6 AND PY>=2022  
 L38 91 SEA SPE=ON ABB=ON PLU=ON L10 AND ED>=20220606 AND ED<=202306  
 06 AND PY>=2022

L39 1224 SEA SPE=ON ABB=ON PLU=ON L37 OR L38  
L40 11384 SEA SPE=ON ABB=ON PLU=ON L11 AND ED>=20220606 AND ED<=202306  
06 AND PY>=2022  
L41 6177 SEA SPE=ON ABB=ON PLU=ON L15 AND ED>=20220606 AND ED<=202306  
06 AND PY>=2022  
L42 12121 SEA SPE=ON ABB=ON PLU=ON L40 OR L41  
L43 131 SEA SPE=ON ABB=ON PLU=ON L39 AND (L42 OR L35)  
L44 216 SEA SPE=ON ABB=ON PLU=ON L12 AND ED>=20220606 AND ED<=202306  
06 AND PY>=2022  
L45 1486 SEA SPE=ON ABB=ON PLU=ON L13 AND ED>=20220606 AND ED<=202306  
06 AND PY>=2022  
L46 688 SEA SPE=ON ABB=ON PLU=ON L16 AND ED>=20220606 AND ED<=202306  
06 AND PY>=2022  
L47 1852 SEA SPE=ON ABB=ON PLU=ON L44 OR L45 OR L46  
L48 21 SEA SPE=ON ABB=ON PLU=ON L47 AND L42 AND L35  
L49 153 SEA SPE=ON ABB=ON PLU=ON L31 OR L36 OR L43 OR L48

FILE 'STNGUIDE' ENTERED AT 15:07:31 ON 06 JUN 2023

FILE 'CABA, SCISEARCH' ENTERED AT 15:07:32 ON 06 JUN 2023

L50 248 DUP REM L49 L30 (21 DUPLICATES REMOVED)  
ANSWERS '1-153' FROM FILE CABA  
ANSWERS '154-248' FROM FILE SCISEARCH  
D L50 1-248 ALL PY

FILE SCISEARCH

FILE COVERS 1974 TO 6 Jun 2023 (20230606/ED)

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

FILE CABA

FILE LAST UPDATED: 30 MAY 2023 <20230530/UP>

FILE COVERS 1973 TO DATE

### **Annex III. List of reference publications used in identifying search terms and in validating the literature search strategy for BASF and 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.

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* 2017; **15**(4): 4767, 25 pp. doi:[10.2903/j.efsa.2017.4767](https://doi.org/10.2903/j.efsa.2017.4767).

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 BASF and Bayer GM oilseed rape products covering time span 2022 - 2023

| Relevant key organisations | Link to the relevant information and summary of the retrieved records   |
|----------------------------|---|
| 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 16 August 2023. 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>Limits applied:</i> The list of commercial releases for plants (= plantas) starting from 2022 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 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 16 August 2023. 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 authorisation (= Eventos con autorización comercial) starting from 2022 were checked.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> “Four”.</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="https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release">https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release</a> - Accessed on 16 August 2023. The webpage dedicated to details on applications and licences for Dealings involving an Intentional Release (DIR) of a GMO 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> List of agricultural applications and authorisations for DIR into the environment starting from 'Issue Date' of 01 01 2022 was assessed.</p> <p><i>Number of records retrieved matching the abovementioned criteria:</i> "Eight".</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> |
|------|---|

## **Annex V. Results of the publication selection process for BASF and Bayer GM oilseed rape products literature search in SciSearch and CABA databases using STN® 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) | 222                           |
| Publications excluded after rapid assessment for relevance   | 222                           |
| 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                             |

**Annex VI. List of relevant publications retrieved from SciSearch and CABA databases using STN® database catalogue (provided in .RIS format)**

Not applicable as no relevant publications were retrieved.