LITERATURE SEARCH FOR ANNUAL POST MARKET ENVIRONMENTAL MONITORING REPORT OF MON 810 MAIZE

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1. INTRODUCTION

As part of the general surveillance requirements for genetically modified (GM) maize products authorised in the European Union (EU) market under regulation (EC) No 1829/2003, Monsanto has actively monitored peer-reviewed scientific literature related to MON 810 maize covering the time span between June 2017- May 2018.

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

Total hits and the checklist for the literature search are provided in **Appendix 5.1 - 5.3**.

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

This literature search has been conducted to address the review question "Does MON 810 maize derived food/feed products and the introduced insect protection trait have adverse effects on human and animal health and the environment?"

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

Key elements used for the review question are humans, animals, and/or the environment (= population), MON 810 maize, derived food/feed products and the introduced insect protection trait (= intervention/exposure), conventional counterpart or non-GM maize (= comparator), and adverse effect on human and animal health, and the environment (= outcomes). Accordingly, the eligibility criteria for assessing the relevance of studies for inclusion in the literature review are provided in **Table 1**.

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

Key elements	Criteria
Population	Humans, animals and the environment (taking into account the scope of the application *i.e.* authorisation for all uses as any other maize, including the cultivation of MON 810 maize) are addressed as general protection goals.
Intervention/exposure	MON 810 maize, derived food/feed products and the introduced insect protection trait addressed in the study are identical or similar to those under scientific review by the EFSA.
Comparator	In case of a comparative study that uses the GM plant material as test material, eligible studies must report a non-GM maize as a comparator.
Outcomes	Adverse effects on human and animal health and the environment are addressed (taking into consideration the scope of the application).
Additional key elements	
Information/ data requirements, including source of studies data	The study potentially contributes to the knowledge of the risk assessment of MON 810 maize intended for all uses as any other maize, including cultivation. Original/primary data are presented in the study.

3. SEARCHING FOR IDENTIFYING RELEVANT STUDIES

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

3.1. Search terms and their combination

The intervention/exposure key elements were defined and translated into search terms. Based on the key elements of the review question, the search terms, the field and the Boolean operators used to combine them were defined as shown in **Table 2**. These search terms considered possible synonyms, related terms, abbreviations and truncations, old and new as well as lay and scientific terminologies, brand and generic names, and spelling variants. Where available, the search was also adapted to controlled vocabulary (subject indexing). The search terms were designed to give an excellent coverage and retrieve the broadest possible number of articles related to MON 810 maize.

Table 3 shows the translation of the intervention key elements into search terms and, when available, the reference publications used to test the search terms. The table includes lists of search terms that are representative of each key element based on the criteria described above and the free-text terms and spelling variants representative of the indicated search terms. As shown in the table, the free-text terms and spelling variants are used to build the search string in the Web of Science™ and EBSCOhost platforms. Where available, controlled vocabularies based on Descriptors which are also representative of the indicated search terms are used to build the search string in EBSCOhost platform. The search terms, free-text terms, controlled vocabularies and the search strings are updated upon identification of a new search term.

Table 2. List of search terms and Boolean operators used to search for MON 810 related publications

Set	Field	Search string	Key elements (Intervention/Exposure)
Web of Science™ platform			
#11	Combination	#10 OR #9 OR #7 *DocType=All document types; Language=All languages;*	
#10	Topic	#8 AND (#2 OR #1) *DocType=All document types; Language=All languages;*	The newly expressed proteins in GM organisms, including maize
#9	Combination	(TS=(MON810 OR "MON 810")) *DocType=All document types; Language=All languages;*	Event
#8	Topic	(TS=(Cry1Ab OR "Cry1 Ab" OR "Cry 1 Ab" OR "Cry 1Ab" OR CryIAb OR "CryI Ab" OR "Cry I Ab" OR "Cry IAb")) *DocType=All document types; Language=All languages;*	Newly expressed proteins
#7	Combination	#6 OR #5 *DocType=All document types; Language=All languages;*	GM maize displaying the introduced insect protection trait OR GM maize with the indicated trade names
#6	Combination	#4 AND #2 AND #1 *DocType=All document types; Language=All languages;*	GM maize with the indicated trade names
#5	Combination	#3 AND #2 AND #1 *DocType=All document types; Language=All languages;*	GM maize displaying the introduced insect protection trait
#4	Topic	(TS=(Yield Gard OR Yieldg* OR "Bt maize" OR "Bt corn")) *DocType=All document types; Language=All languages;*	Trade names
#3	Topic	(TS=((TOLERAN* OR RESISTAN* OR PROTEC*) NEAR/3 (borer* OR Lepidoptera OR Ostrinia OR Sesamia))) *DocType=All document types; Language=All languages;*	Introduced insect protection trait
#2	Topic	(TS=(maize* OR corn* OR "zea mays" OR "z mays")) *DocType=All document types; Language=All languages;*	Plant species
#1	Topic	(TS=(GMO* OR LMO* OR GM OR GE OR transgen*OR ((genetic* OR living OR biotech*) NEAR/3 (modif* OR transform* OR manipulat* OR improv* OR engineer* OR deriv*)))) *DocType=All document types; Language=All languages;*	GMO general

Set	Field	Search string	Key elements (Intervention/Exposure)
EBSCOhost platform *(All document types and all languages)*			
S13	Combination	S9 OR S11 OR S12	
S12	All Text	TX (MON810 OR "MON 810")	Events
S11	Combination	(S1 AND S10) OR (S2 AND S10)	The newly expressed proteins in GM organisms, including maize.
S10	All Text	TX (Cry1Ab OR "Cry1 Ab" OR "Cry 1 Ab" OR "Cry 1Ab" OR CryIAb OR "CryI Ab" OR "Cry I Ab" OR "Cry IAb")	Newly expressed proteins.
S9	Combination	S6 OR S8	GM maize displaying the introduced insect protection trait OR GM maize with the indicated trade names.
S8	Combination	S1 AND S2 AND S7	GM maize with the indicated trade name.
S7	All Text	TX (Yield Gard OR Yieldg* OR "Bt maize" OR "Bt corn")	Trade names
S6	Combination	S1 AND S2 AND S5	GM maize displaying the introduced insect protection trait.
S5	Combination	S3 AND S4	
S4	Descriptor	DE "Lepidoptera"	Controlled vocabularies (subject indexes) offered by the database for introduced insect protection trait.
S3	Descriptor	DE "insect control"	
S2	Descriptor	DE "Zea mays" OR DE "maize"	Controlled vocabularies (subject indexes) offered by the database for plant species. Note that the term '*corn*' is covered by the term 'maize'.
S1	Descriptor	DE "genetic engineering" OR DE "genetic transformation" OR DE "genetically engineered foods" OR DE "genetically engineered organisms"	Controlled vocabularies (subject indexes) offered by the database for GMO general term.

3.2. Limits applied

An advanced literature search was conducted in the Web of Science™ Core collection database using the Web of Science™ platform[1] and in the CAB Abstracts® database[2] using the EBSCOhost platform[3] (*see* section 3.6.1). Each platform enables searching in the specified electronic database by making use of pre-defined fields, set combinations based on Boolean operators or a combination of both[4,5].

[1] http://apps.webofknowledge.com/UA_GeneralSearch_input.do?product=UA&SID=X1sK9uHnF5WXHkLGpbw&search_mode=GeneralSearch - Accessed on 25 September 2018.
[2] http://support.ebsco.com/help/?int=ehost&lang=en&feature_id=Databases&TOC_ID=Always&SI=0&BU=0&GU=1&PS=0&ver=live&dbs=,lah - Accessed on 25 September 2018.
[3] https://help.ebsco.com/interfaces/EBSCOhost - Accessed on 25 September 2018.
[4] http://images.webofknowledge.com/WOKRS5251R3/help/WOS/hp_advanced_examples.html - Accessed on 25 September 2018.
[5] https://help.ebsco.com/interfaces/EBSCOhost/training_promotion/Advanced_Searching_EBSCOhost_Tutorial - Accessed on 25 September 2018.

The literature search strategy utilises the "Topic" (TS) field in Web of Science™ platform and the "TX" field in EBSCOhost platform which have the broadest coverage of search terms and enable comprehensive searching within a record[6,5] (*see* **Table 2**). In the case of the Web of Science™ Core collection database, the "TS" field searches for topic terms in the following fields within a record: Title, Abstracts, Author Keywords and Keywords Plus®. The Keywords Plus® facility maximises the possibility of retrieving relevant records in the advanced search[7]. In the case of the CAB Abstracts® database, the "TX" field searches for the search terms "*within the full text of all articles for your term*"[5].

In this literature search, the search strategy utilised also the controlled vocabulary (subject indexing) facility offered by the CAB Abstracts® database. Accordingly, the search string was refined by using the CAB Thesaurus-Descriptors field, which are assigned by subject specialists to CAB records to represent the content of the source documents. The Descriptor ("DE") field enables selection of one or more controlled terms from the CAB Thesaurus to add to the search query. More importantly, having a controlled vocabulary allows users to use only one term to search for a concept rather than using lots of terms[8]. The most relevant, broad and controlled search terms in the hierarchy of CAB Thesaurus terms that were listed as preferred terms by CAB for the search query were selected and added to the search string in combination with the "DE" field (*see* **Table 2**).

3.3. Language

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

3.4. Time period

This literature search covered the reporting period from June 2017 until May 2018.

3.5. Reference studies

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

[6] http://images.webofknowledge.com/WOKRS5251R3/help/WOS/hs_advanced_fieldtags.html - Accessed on 25 September 2018.
[7] http://clarivate.libguides.com/woscc/searchtips - Accessed on 25 September 2018.
[8] https://www.cabi.org/Uploads/CABI/publishing/training-materials/resources-by-interface/cab-direct-user-guides/advanced-searching-cab-abstracts.pdf - Accessed on 25 September 2018.

Table 3. Translation of intervention/exposure key elements into search terms for MON 810 literature search in the Web of Science™ Core Collection and CAB Abstracts® databases

Key elements		Search terms	Comments
GMO general			
	Reference publications	Not applicable.	This step is to focus the search on GM related papers. The search terms, free-text terms, controlled vocabularies and the search strings are updated upon identification of a new search term.
	Search 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.	
Web of science™ platform	*Search string based on free-text terms using the Topic (TS) field*	(TS=(GMO* OR LMO* OR GM OR GE OR transgen*OR ((genetic* OR living OR biotech*) NEAR/3 (modif* OR transform* OR manipulat* OR improv* OR engineer* OR deriv*))))	
	Truncations and spelling variants used and their meanings	GMO* = GMO, GMOs, GMO's GM = GM crop, GM plant, GM crops, GM plants GE = GE crop, GE plant, GE crops, GE plants LMO* = LMO, LMOs, LMO's Transgen* = transgene, transgenic, transgenesis Genetic* = genetic, genetically Biotech = biotech, biotechnology, biotechnological Modif* = modify, modified, modification Transform* = transform, transformed, transformation Manipulat* = manipulate, manipulated, manipulation Improv* = improve, improved, improvement Engineer* = engineer, engineered, engineering Deriv* = derive, derived	
EBSCOhost platform	*Search string based on controlled vocabularies using the Descriptors (DE) field*	DE "genetic engineering" OR DE "genetic transformation" OR DE "genetically engineered foods" OR DE "genetically engineered organisms"	

Key elements		Search terms	Comments
Crop name			
Reference publications		Not applicable.	This step is to focus the search on maize related papers. The search terms, free-text terms, controlled vocabularies and the search strings are updated upon identification of a new search term.
Search terms		Maize, corn, *Zea mays*, *Z mays*	
Web of science™ platform	*Search string based on free-text terms using the Topic (TS) field*	(TS=(maize* OR corn* OR "zea mays" OR "z mays"))	
	Truncations and spelling variants used and their meanings	Maize* = maize, maizes, maize's Corn* = corn, corns, corn's	
EBSCOhost platform	*Search string based on controlled vocabularies using the Descriptors (DE) field*	DE "Zea mays" OR DE "maize"	
Intended trait			
Reference publications		Castañera P, Farinós G, Ortego F and Andow D, 2016. Sixteen Years of Bt Maize in the EU Hotspot: Why Has Resistance Not Evolved? Plos One, 1-13. Farinós GP, Hernández-Crespo P, Ortego F and Castañera P, 2017. Monitoring of Sesamia nonagrioides resistance to MON 810 maize in the European Union: lessons from a long-term harmonized plan. Pest Management Science, 74, 557-568. Hammond BG, Dudek R, Lemen JK and Nemeth MA, 2006. Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. Food and Chemical Toxicology, 44, 1092-1099. Thieme T, Buuk C, Gloyna K, Ortego F and Farinós G, 2017. Ten years of MON 810 resistance monitoring of field populations of Ostrinia nubilalis in Europe. Journal of Applied Entomology, 00, 1-9.	
Search terms		Protection against *Ostrinia spp*./ *Sessamia spp*./ corn borer/ lepidopteran insect pests	

Key elements		Search terms	Comments
Web of science™ platform	*Search string based on free-text terms using the Topic (TS) field*	(TS=((TOLERAN* OR RESISTAN* OR PROTEC*) NEAR/3 (borer* OR Lepidoptera OR Ostrinia OR Sesamia)))	
	Truncations and spelling variants used and their meanings	Toleran* = tolerance, tolerant Resistan* = resistance, resistant Protect* = protection, protected Borer* = borer, borers, borer's	
EBSCOhost platform	*Search string based on controlled vocabularies using the Descriptors (DE) field*	DE "Lepidoptera" DE "insect control"	
Trade names			
	Reference publications	Hammond BG, Dudek R, Lemen JK and Nemeth MA, 2006. Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. Food and Chemical Toxicology, 44, 1092-1099.	
	Search terms	YieldGard, *Bt* maize, *Bt* corn	
Web of science™ platform	*Search string based on free-text terms using the Topic (TS) field*	(TS=("Yield Gard" OR Yieldg* OR "Bt maize" OR "Bt corn"))	
	Truncations and spelling variants used and their meanings	"Yield Gard" = Yield Gard Yieldg* = YieldGard	
EBSCOhost platform	*Search string based on free-text terms using the All Text (TX) field*	TX ("Yield Gard" OR Yieldg* OR "Bt maize" OR "Bt corn")	
	Truncations and spelling variants used and their meanings	"Yield Gard" = Yield Gard Yieldg* = YieldGard	

Key elements		Search terms	Comments
Newly expressed protein			
	Reference publications	Castañera P, Farinós G, Ortego F and Andow D, 2016. Sixteen Years of Bt Maize in the EU Hotspot: Why Has Resistance Not Evolved? Plos One, 1-13. Farinós GP, Hernández-Crespo P, Ortego F and Castañera P, 2017. Monitoring of Sesamia nonagrioides resistance to MON 810 maize in the European Union: lessons from a long-term harmonized plan. Pest Management Science, 74, 557-568. Hammond BG, Dudek R, Lemen JK and Nemeth MA, 2006. Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. Food and Chemical Toxicology, 44, 1092-1099. Thieme T, Buuk C, Gloyna K, Ortego F and Farinós G, 2017. Ten years of MON 810 resistance monitoring of field populations of Ostrinia nubilalis in Europe. Journal of Applied Entomology, 00, 1-9.	
	Search terms	Cry1Ab	
Web of science™ platform	*Search string based on free-text terms using the Topic (TS) field*	(TS=(Cry1Ab OR "Cry1 Ab" OR "Cry 1 Ab" OR "Cry 1Ab" OR CryIAb OR "CryI Ab" OR "Cry I Ab" OR "Cry IAb"))	
	Truncations and spelling variants used and their meanings	The options shown in the search string above are spelling variants. Truncations are not applicable.	
EBSCOhost platform	*Search string based on free-text terms using the All Text (TX) field*	TX (Cry1Ab OR "Cry1 Ab" OR "Cry 1 Ab" OR "Cry 1Ab" OR CryIAb OR "CryI Ab" OR "Cry I Ab" OR "Cry IAb")	
	Truncations and spelling variants used and their meanings	The options shown in the search string above are spelling variants. Truncations are not applicable.	

Key elements		Search terms	Comments
Event			
	Reference publications	Castañera P, Farinós G, Ortego F and Andow D, 2016. Sixteen Years of Bt Maize in the EU Hotspot: Why Has Resistance Not Evolved? Plos One, 1-13. Farinós GP, Hernández-Crespo P, Ortego F and Castañera P, 2017. Monitoring of Sesamia nonagrioides resistance to MON 810 maize in the European Union: lessons from a long-term harmonized plan. Pest Management Science, 74, 557-568. Hammond BG, Dudek R, Lemen JK and Nemeth MA, 2006. Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. Food and Chemical Toxicology, 44, 1092-1099. Thieme T, Buuk C, Gloyna K, Ortego F and Farinós G, 2017. Ten years of MON 810 resistance monitoring of field populations of Ostrinia nubilalis in Europe. Journal of Applied Entomology, 00, 1-9.	
	Search terms	MON 810	
Web of science™ platform	*Search string based on free-text terms using the Topic (TS) field*	(TS=(MON810 OR "MON 810"))	
	Truncations and spelling variants used and their meanings	The options shown in the search string above are spelling variants. Truncations are not applicable.	
EBSCOhost platform	*Search string based on free-text terms using the All Text (TX) field*	TX (MON810 OR "MON 810")	
	Truncations and spelling variants used and their meanings	The options shown in the search string above are spelling variants. Truncations are not applicable.	

3.6. Information sources

3.6.1. Electronic bibliographic databases

Based on the coverage and relevance of the journals included, Monsanto selects the Web of Science™ Core Collection database[9] and the CAB Abstracts® database[10] for performing the literature searches. The advanced literature search was conducted using the Web of Science™ platform[3] for the Web of Science™ Core collection database and using the EBSCOhost platform[5] for the CAB Abstracts® database[2].

The Web of Science™ Core Collection database[9] includes literature captured under the following two catalogues: 1) the Science Citation Index Expanded (1995-present); and 2) the Conference Proceedings Citation Index- Science (1990-present). These catalogues offer a complete view of item from a journal, including original research articles, reviews, editorials, chronologies, conference proceedings, bulletins, monographs, and technical reports. This database is "*indisputably the largest citation database available, with over 1 billion cited reference connections indexed from high quality peer reviewed journals, books and proceedings. Each cited reference is meticulously indexed to ensure that it is searchable and attributes credit to the appropriate publication.*"[9]. Further, The Web of Science™ Core Collection database is connected to Google Scholar to allow a seamless movement between the open web and the Web of Science™ Core Collection for the literature search[9].

The CAB Abstracts® database[10] includes literature capture under the CAB Abstracts (1972-present) catalogue. This catalogue offers a complete view of item from a journal, including original research articles, reviews, books, conference proceedings/ papers, correspondences, editorials, patents, thesis, reports, and bulletins on international agricultural literature, including plant protection, animal husbandry, animal and plant breeding, genetics, and nutrition.

All journals included in the two databases must go through a verification process and as a minimum requirement, non-English language journals must include English-language bibliographic information (title, abstract, keywords) and be peer-reviewed. In general, English is considered the universal language of science[11]. For this reason, the journals most important to the international research community will publish either full text or a minimum of bibliographic information in English, which is especially true in the scientific domain of natural sciences. Full text in English is highly desirable if the journal intends to serve an international community of researchers. Therefore, it is expected that even if there is a relevant article for the food and feed safety of GM plants in a language different than English, the article will include title/abstract/keywords in English, which will guarantee the retrievability of these articles when using keywords and keyword combinations in English.

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

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[9] Web of Science Core Collection; https://clarivate.com/products/web-of-science/web-science-form/web-science-core-collection/ - Accessed on 25 September 2018.

[10] CABI CAB Abstracts® database; http://www.cabi.org/cab-direct/ - Accessed on 25 September 2018.

[11] Web of Science™; http://wokinfo.com/essays/journal-selection-process/ - Accessed on 25 September 2018.

3.6.2. Relevant key organisations

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

Of the 13 key organisations cited in the 2017 Explanatory note on literature searching (EFSA, 2017), nine[12] are involved in risk assessment of single GM maize products. Two of the remaining four (CIBIOGEM and Environment and Climate Change Canada) are not involved in GM risk assessment. The other two (OGTR and GEAC), for the time being, only assess GM cotton and oilseed rape. Therefore, the nine are the relevant key organisations for MON 810 and the internet search focused on these organisations.

4. SELECTING STUDIES

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

4.1. Process

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

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

4.2. Quality assurance

All publications that were identified by the search described in Section 3 have been screened by three different reviewers (one internal and two external experts) with solid experience in the risk assessment of GM plants.

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

[12] Internet pages of the relevant key organisations for MON 810 maize:
US EPA (https://www.epa.gov/environmental-topics/science-topics) - Accessed on 25 September 2018;
USDA (https://www.usda.gov/media) - Accessed on 25 September 2018;
US FDA (https://www.fda.gov/) - Accessed on 25 September 2018;
CFIA (http://www.inspection.gc.ca/eng/1297964599443/1297965645317) - Accessed on 25 September 2018;
Health Canada (https://www.canada.ca/en/health-canada.html) - Accessed on 25 September 2018;
FSANZ (http://www.foodstandards.gov.au/Pages/default.aspx) - Accessed on 25 September 2018;
CTNBio (http://ctnbio.mcti.gov.br/) - Accessed on 25 September 2018;
CONABIA(https://www.argentina.gob.ar/) - Accessed on 25 September 2018;
Japan MAFF (http://www.maff.go.jp/e/) - Accessed on 25 September 2018.

4.3. Eligibility/inclusion criteria to establish relevance

From the full reference list of retrieved hits (*see* **Appendix 5.1** and **Appendix 5.2**), taking into account i) the review question, ii) the scope of the application, *i.e.* authorisation of MON 810 maize for all uses as any other maize including cultivation in the EU and iii) the eligibility criteria to establish the relevance of retrieved studies, an assessment was conducted in order to conclude whether a certain publication was considered relevant or not. When a publication was considered relevant, the category the publication belongs to is indicated. The following is a non-exhaustive list of categories publications can belong to:

Food/Feed safety assessment

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

Environmental safety assessment

- Spillage and consequences thereof
- Non target organisms (NTO)
- Gene flow
- Protein/ DNA/ RNA fate in soil or in stream water
- Insect resistance management (IRM)
- Impact of management practices
- Ecology

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

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

5.1. Search outcomes

5.1.1. Outcomes of literature search in electronic bibliographic databases

The literature search was run using Web of Science™ Core Collection and the CAB Abstracts® databases on a monthly basis[13], covering the time span June 2017 - May 2018. As a result, 84 hits were identified using Web of Science™ Core Collection database while 125 hits were retrieved from the search conducted using the CAB Abstracts® database. For the full reference list of retrieved hits (*see* **Appendix 5.1** and **Appendix 5.2** provided as electronic version only).

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

The literature search in the internet pages of the relevant key organisations was conducted on 25 September 2018. The links to the results of the literature search and the summary of the retrieved data are shown in **Table 4**. There was no publication based on primary/original data that needed further assessment.

[13] For CAB Abstracts®, the literature search covering the period of the annual monitoring had to be repeated at the end of the season due to changes made in the search platform of the database during mid-season.

Table 4. Results of the literature search in internet pages of relevant key organisations for MON 810 maize

Relevant key organisations	Link to relevant information and summary of the retrieved data
US EPA	https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated – Accessed on 25 September 2018. The webpage dedicated to PIP registrations was checked. *Date of the most recent website update at the time of the search*: 19 July 2017 *Date span of the search*: 2017 – 2018 *Limits applied*: The list for registrations was assessed. *Number of records*: "1". *Number of relevant records or full-text documents retrieved*: The retrieved record is not relevant to MON 810.
USDA	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status - Accessed on 25 September 2018. The webpage dedicated to petitions for determination of nonregulated status was checked. *Date of the most recent website update at the time of the search*: 5 September 2018 *Date span of the search*: 2017 – 2018 *Limits applied*: The list of the petitions was assessed. *Number of records*: "4". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to MON 810.
US FDA	https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon – Accessed on 25 September 2018. The webpage dedicated to biotechnology consultations on food from GE plant varieties was checked. *Date of the most recent website update at the time of the search*: 10 August 2018 *Date span of the search*: 2017 – 2018 *Limits applied*: The list of the consultations was assessed. *Number of records*: "8". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to MON 810.

Relevant key organisations	Link to relevant information and summary of the retrieved data
CFIA	http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236 - Accessed on 25 September 2018. The webpage dedicated to decision documents – determination of environmental and livestock feed safety was checked. *Date of the most recent website update at the time of the search*: 6 June 2018 *Date span of the search*: 2017 – 2018 *Limits applied*: The list of decision documents was assessed. *Number of records*: "1". *Number of relevant records or full-text documents retrieved*: The retrieved record is not relevant to MON 810.
Health Canada	https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html - Accessed on 25 September 2018. The webpage dedicated to approved products of genetically modified (GM) foods and other novel foods was checked. *Date of the most recent website update at the time of the search*: 9 July 2018 *Date span of the search*: 2017 – 2018 *Limits applied*: The list of novel food decisions was assessed. *Number of records*: "10". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to MON 810.
FSANZ	http://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx - Accessed on 25 September 2018. The webpage dedicated to current GM applications and approvals was checked. *Date of the most recent website update at the time of the search*: August 2018 *Date span of the search*: 2017 – 2018 *Limits applied*: The list for GM applications and approvals was assessed. *Number of records*: "8". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to MON 810.

Relevant key organisations	Link to relevant information and summary of the retrieved data
CTNBio	http://ctnbio.mcti.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo – Accessed on 25 September 2018. The webpage dedicated to commercial releases (= Liberações Comerciais) was checked. *Date of the most recent website update at the time of the search*: Not clear *Date span of the search*: 2017 – 2018 *Limits applied*: The list of commercial releases for plants (= plantas) was assessed. *Number of records*: "5". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to MON 810.
CONABIA	https://www.agroindustria.gob.ar/sitio/areas/biotecnologia/convocatoria/ – Accessed on 25 September 2018. The webpage of the national advisory commission on agricultural biotechnology (= Comisión Nacional Asesora de Biotecnología Agropecuaria) was checked. *Date of the most recent website update at the time of the search*: Not available *Date span of the search*: 2017 – 2018 *Limits applied*: The list of decision documents open for public comment was assessed. Note: decision documents are available for 60 days to allow the public to give comments and are removed afterwards. *Number of records*: "2". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to MON 810.
MAFF	http://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-164.pdf - Accessed on 25 September 2018. The webpage dedicated to list of approved genetically modified agricultural crops was checked. *Date of the most recent website update at the time of the search*: Not available. *Date span of the search*: 2017-2018 *Limits applied*: The list of approved GM agricultural crops was assessed. *Number of records*: "31". *Number of relevant records or full-text documents retrieved*: The retrieved records are not relevant to MON 810.

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

The results of the study selection process are provided in **Table 5**. The 25 relevant studies retrieved after detailed assessment of the full text document (ordered by category of information) are listed in **Table 6.** Excluded studies after detailed assessment of the full text documents for relevance are listed in **Table 7**. In **Table 8**, unobtainable/unclear studies are listed. A copy of the full-text documents listed in **Table 6** are provided as pdf files in the references folder of this document.

Table 5. Results of the study selection process.

Review question captured in the search	**Number of studies**	
	Web of Science™ Core Collection database	**CAB Abstracts® database**
Total number of *studies* retrieved after all searches of the scientific literature (excluding duplicates)	84	125
Number of *studies* excluded from the search results after rapid assessment for relevance	53	100
Total number of *full-text documents* assessed in detail (excluding duplicates)	42	
Number of *studies* excluded from further consideration after detailed assessment for relevance	7	
Total number of unobtainable/unclear studies	10	
Total number of relevant studies	25	

Table 6. Report of all relevant studies retrieved after detailed assessment of full-text documents for relevance: ordered by category of information.

Study (author(s) and year)	Title	Source
Food/Feed safety assessment		
Crop compositional studies		
Bernillon *et al.* (2018)	Characterization of GMO or glyphosate effects on the composition of maize grain and maize-based diet for rat feeding	Metabolomics
Toxicology/animal feeding studies		
Schmidt *et al.* (2017)	Variability of control data and relevance of observed group differences in five oral toxicity studies with genetically modified maize MON810 in rats	Archives of Toxicology
Sharbati *et al.* (2017)	Transcriptomic analysis of intestinal tissues from two 90-day feeding studies in rats using genetically modified MON810 maize varieties	Frontiers in Genetics
Nutritional studies		
Oliveira *et al.* (2018)	Nutritional composition and aerobic stability of wheat and corn silages stored under different environmental conditions	Semina-Ciencias Agrarias
Environmental safety assessment		
Protein/DNA fate in soil or in stream water		
Griffiths *et al.* (2017)	Occurrence, leaching, and degradation of Cry1Ab protein from transgenic maize detritus in agricultural streams	Science of the Total Environment
Yuan *et al.* (2017)	Cry1Ab adsorption and transport in humic acid-coated geological formation of alumino-silica clays	Water Air and Soil Pollution
Gene flow		
Urechan and Bonea (2017)	Coexistence in cultivation of genetically modified maize (MON810) with conventional maize	Romanian Agricultural Research

Study (author(s) and year)	Title	Source
Insect Resistance Management (IRM)		
Kotey *et al.* (2017)	Monitoring resistance to *Bt* maize in field populations of *Busseola fusca* (Fuller) (Lepidoptera: Noctuidae) from smallholder farms in the Eastern Cape province of South Africa	African Entomology
Farinós *et al.* (2017)	Monitoring of *Sesamia nonagrioides* resistance to MON 810 maize in the European Union: lessons from a long-term harmonized plan	Pest Management Science
Camargo *et al.* (2018)	First detection of a *Sesamia nonagrioides* resistance allele to *Bt* maize in Europe	Scientific Reports
Yang *et al.* (2016)	Performance of Cry1Ab-susceptible and -heterozygous resistant populations of sugarcane borer in sequential feedings on non-*Bt* and *Bt* maize plant tissue	Entomologia Experimentalis et Applicata
Thieme *et al.* (2018)	Ten years of MON 810 resistance monitoring of field populations of *Ostrinia nubilalis* in Europe	Journal of Applied Entomology
Ecology		
Mashiane *et al.* (2017)	Metagenomic analyses of bacterial endophytes associated with the phyllosphere of a *Bt* maize cultivar and its isogenic parental line from South Africa	World Journal of Microbiology & Biotechnology
Van Wyk *et al.* (2017)	Ecological guild and enzyme activities of rhizosphere soil microbial communities associated with *Bt*-maize cultivation under field conditions in North West Province of South Africa	Journal of Basic Microbiology
Non target organisms (NTO's)		
Shu *et al.* (2017)	Effects of Cry1Ab *Bt* maize straw return on bacterial community of earthworm *Eisenia fetida*	Chemosphere
Twardowski *et al.* (2017)	Effects of maize expressing the insecticidal protein Cry1Ab on non-target ground beetle assemblages (Coleoptera, Carabidae)	Romanian Agricultural Research

Study (author(s) and year)	Title	Source
Arias-Martin *et al.* (2018)	Farm-scale evaluation of the impact of Cry1Ab *Bt* maize on canopy nontarget arthropods: a 3-year study	Insect Science
Barbosa de Assis *et al.* (2018)	Transgenic *Bt* maize does not affect the soil ant community	Pesquisa Agropecuaria Brasileira
Ferreira *et al.* (2017)	Phytophagous mites on genetically modified maize with *Bacillus thuringiensis* genes	Ciência Rural
Yinghua *et al.* (2017)	Responses of the cutworm *Spodoptera litura* (Lepidoptera: Noctuidae) to two *Bt* corn hybrids expressing Cry1Ab	Scientific Reports
Szabó *et al.* (2017)	Long-term consumption and food replacement of near-isogenic by *Bt*-maize alter life-history traits of *Folsomia candida Willem* 1902 (Collembola)	Applied Ecology and Environmental Research
Leclerc *et al.* (2018)	Spatial exposure-hazard and landscape models for assessing the impact of GM crops on non-target organisms	Science of the Total Environment
Nicodemo *et al.* (2018)	Transgenic corn decreased total and key storage and lipid transport protein levels in honey bee hemolymph while seed treatment with imidacloprid reduced lipophorin levels	Journal of Apicultural Research
Cerevková *et al.* (2018)	The responses of soil nematode communities to *Bt* maize cultivation at four field sites across Europe	Soil Biology & Biochemistry
Fahse *et al.* (2018)	Estimating acute mortality of Lepidoptera caused by the cultivation of insect-resistant *Bt* maize - the LepiX model	Ecological Modelling

Table 7. Report of studies excluded from the risk assessment after detailed assessment of full-text documents (classified by authors)

Study (author(s) and year)	Title	Source	Reason(s) for exclusion:
Devos, Y.; Ortiz-García, S.; Hokanson, K. E.; Raybould, A. (2018)	Teosinte and maize × teosinte hybrid plants in Europe-Environmental risk assessment and management implications for genetically modified maize	Agriculture, Ecosystems & Environment	It is a review paper and contains no original data.
Li, PG; Yang, C; Yue, R; Zhen, YP; Zhuo, Q; Piao, JH; Yang, XG; Xiao, R (2018)	Modulation of the Fecal Microbiota in Sprague-Dawley Rats Using Genetically Modified and Isogenic Corn Lines	Journal of Agricultural and Food Chemistry	The event addressed in the study is not MON 810.
Masetti, A; Arpaia, S; Ghesini, S; Magagnoli, S; Baldacchino, F; Magarelli, RA; Neri, U; Lener, M; Rastelli, V; Staiano, G; Lang, A; Marini, M; Burgio, G (2017)	Macro-moths as possible assessment endpoints for non-target effects of *Bt*-maize pollen: a faunistic study in three Italian protected areas	Bulletin of Insectology	The event addressed in the study is not MON 810.
Perry, JN; Barberi, P; Bartsch, D; Birch, ANE; Gathmann, A; Kiss, J; Manachini, B; Nuti, M; Rauschen, S; Schiemann, J; Schuppener, M; Sweet, J; Tebbe, CC; Veronesi, F (2017)	Response to Kruse-Plass et al (2017) regarding the risk to non-target lepidopteran larvae exposed to pollen from one or more of three *Bt* maize events (MON810, Bt11 and 1507)	Environmental Sciences Europe	It is an opinion paper and contains no original data.

Study (author(s) and year)	Title	Source	Reason(s) for exclusion:
Svobodova, Z; Burkness, EC; Habustova, OS; Hutchison, WD (2017)	Predator Preference for *Bt*-Fed Spodoptera frugiperda (Lepidoptera: Noctuidae) Prey: Implications for Insect Resistance Management in Bt	Journal of Economic Entomology	The event addressed in the study is not MON 810.
Yao JianXiu; Zhu YuCheng; Lu NanYan; Buschman, L. L.; Zhu KunYan (2017)	Comparisons of transcriptional profiles of gut genes between Cry1Ab-resistant and susceptible strains of *Ostrinia*	International Journal of Molecular Sciences	It is not a safety study.
Razavi, A; Malhotra, I; Ghosh, A; Pusztai-Carey, M; Marks, J; King, C (2017)	Antibodies as epidemiological markers of genetically modified crop exposure: detection of Cry1Ab-specific IgG	Food and Agricultural Immunology	It is not a safety study.

Table 8. Report of unobtainable/unclear studies (classified by authors)

Study (author(s) and year)	Title	Source	Description of (unsuccessful) methods used to try to obtain a copy of the study
Campagne, P.; Capdevielle-Dulac, C.; Pasquet, R.; Cornell, S. J.; Kruger, M.; Silvain, J. F.; LeRü, B.; Berg, J. van den (2017)	Genetic hitchhiking and resistance evolution to transgenic *Bt* toxins: insights from the African stalk borer *Busseola fusca* (Noctuidae)	Heredity	The event addressed in the study is not specified.
Zhong Wang; Zeng HuiLan; Wang JianWu (2017)	Effect of *Bt* gene insertion on growth, physiology and gene expression of phosphorus transporter gene of corn after arbuscular mycorrhizal fungi colonization	Chinese Journal of Eco-Agriculture	Article in Chinese
Ali, I; Zhang, S; Muhammad, MS; Iqbal, M; Cui, JJ (2018)	*Bt* proteins have no detrimental effects on larvae of the green lacewing, *Chrysopa pallens* (Rambur) (Neuroptera: Chrysopidae)	Neotropical Entomology	It is unclear if the purified Cry1Ab protein used in the study is equivalent to the Cry1Ab protein in MON 810.
Alves, VM; Hernandez, MIM (2017)	Morphometric modifications in *Canthon quinquemaculatus* Castelnau 1840 (Coleoptera: Scarabaeinae): Sublethal effects of transgenic maize?	Insects	The event addressed in the study is not specified.
Czerwinski, J; Slizewska, K; Korwin-Kossakowska, A; Bachanek, I; Smulikowska, S (2017)	Effects of genetically modified maize and soybean meal on the diversity and activity of gut microbiota in broiler chicken	Animal Science Papers and Reports	Copyright to assess the full document could not be obtained.

Study (author(s) and year)	Title	Source	Description of (unsuccessful) methods used to try to obtain a copy of the study
Haller, S; Romeis, J; Meissle, M (2017)	Effects of purified or plantproduced Cry proteins on *Drosophila melanogaster* (Diptera: Drosophilidae) larvae	Scientific Reports	It is unclear if the purified Cry1Ab protein used in the study is equivalent to the Cry1Ab protein in MON 810.
Ingber, DA; Mason, CE; Flexner, L (2018)	Cry1 *Bt* susceptibilities of fall armyworm (Lepidoptera: Noctuidae) host strains	Journal of Economic Entomology	It is unclear if the purified Cry1Ab protein used in the study is equivalent to the Cry1Ab protein in MON 810.
Van den Berg, J; Warren, JF; Du Plessis, H (2017)	The potential effect of *Bt* maize on *Chrysoperla pudica* (Neuroptera: Chrysopidae)	Environmental Entomology	The event addressed in the study is not specified.
Zhao, M; Li, YH; Yuan, XD; Liang, GM; Wang, BJ; Liu, C; Khaing, MM (2018)	Establishment of a dietary exposure assay for evaluating the toxicity of insecticidal compounds to *Apolygus lucorum* (Hemiptera: Miridae)	Environmental Pollution	It is unclear if the purified Cry1Ab protein used in the study is equivalent to the Cry1Ab protein in MON 810.
Ondrejkova, J; Alacova, R; Hanicova, DL (2017)	Genetically modified MON810 maize: Wistar rats biochemical serum analysis	Toxicology Letters	No sufficient information is available for a detailed assessment.

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

Table 9 reports the reliability and implications of all the relevant studies in the risk assessment of MON 810. The relevant studies did not identify any new information that would require further consideration in the risk assessment of MON 810 which found no adverse effects on human, animal health and the environment.

The literature search conducted by Monsanto provides a comprehensive analysis of reliable scientific publications that are relevant to the food, feed, and environmental safety of MON 810. A systematic review would not add value to the risk assessment of this product.

Table 9. **Report of the reliability and implications for the risk assessment of all relevant studies retrieved after detailed assessment of full-text documents for relevance: ordered by category of information.**

Study (author(s) and year)	Reliability appraisal[1]	Implications for the risk assessment[2]
Food/Feed safety assessment		
Crop compositional studies		
Bernillon *et al.* (2018)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Toxicology/animal feeding studies		
Schmidt *et al.* (2017)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Sharbati *et al.* (2017)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Nutritional studies		
Oliveira *et al.* (2018)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Environmental safety assessment		
Protein/DNA fate in soil or in stream water		
Griffiths *et al.* (2017)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Yuan *et al.* (2017)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Gene flow		
Urechan and Bonea (2017)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported

Study (author(s) and year)	Reliability appraisal[1]	Implications for the risk assessment[2]
Insect Resistance Management (IRM)		
Kotey *et al.* (2017)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Farinós *et al.* (2017)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Camargo *et al.* (2018)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported. Bayer agrees with the conclusion of Camargo *et al.* (2018) that the high-dose/refuge (HDR) strategy appears to be successfully delaying resistance evolution in *Sesamia* to the Cry1Ab protein in MON 810. This conclusion is consistent with global reviews (Tabashnik *et al.*, 2013; Tabashnik and Carrière, 2015) that the HDR strategy has been highly effective in managing resistance risk for key corn pests in North America and Europe. To ensure the continued success of this strategy, Bayer and the industry are working closely together to maintain high rates of grower compliance with refuge plantings. Bayer also is continually refining resistance monitoring methods to ensure they are as robust and sensitive as practically possible, particularly through careful tracking and investigation of any farmer reports of unexpected pest damage.
Yang *et al.* (2016)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Thieme *et al.* (2018)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported

Study (author(s) and year)	Reliability appraisal[1]	Implications for the risk assessment[2]
Ecology		
Mashiane *et al.* (2017)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Van Wyk *et al.* (2017)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Non target organisms (NTO's)		
Shu *et al.* (2017)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Twardowski *et al.* (2017)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Arias-Martin *et al.* (2018)	High	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Barbosa de Assis *et al.* (2018)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Ferreira *et al.* (2017)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Yinghua *et al.* (2017)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Szabó *et al.* (2017)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Leclerc *et al.* (2018)	Not assignable	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Nicodemo *et al.* (2018)	Low	None, because no new hazards, modified exposure, or new scientific uncertainties are reported

Study (author(s) and year)	Reliability appraisal[1]	Implications for the risk assessment[2]
Cerevková *et al.* (2018)	Moderate	None, because no new hazards, modified exposure, or new scientific uncertainties are reported
Fahse *et al.* (2018)	Not assignable	None, because no new hazards, modified exposure, or new scientific uncertainties are reported

[1] **High** (use as key study); **Moderate** because the study reported is subject to some limitations (useable as key study depending on the limitations of the study); **Low** because the study reported is subject to several limitations (limited use or not useful; generally not to be used as key study, but depending on the limitations of the study, it may be useful in weight of evidence approaches or as supporting information); **Not reliable** because the study reported does not comply with minimum reliability criteria carrying a high level of uncertainty (not useful); **Not assignable** because no or insufficient information is reported in the study (EFSA, 2017).

[2] Identification of a new hazard, modified exposure, or new scientific uncertainty requiring further consideration in the risk assessment; **None**, because no new hazards, modified exposure, or new scientific uncertainties are reported; **None**, because the findings reported in the study are not reliable; Implications for risk assessment were previously considered by EFSA and/or its GMO Panel, and are therefore not addressed further here (EFSA, 2017).

6. CONCLUSION

Taking into consideration all the above, Monsanto confirms that this literature search, conducted in accordance with the 2017 EFSA explanatory note on literature searching (EFSA, 2017) and within the context of the general surveillance for the annual MON 810 post-market environmental monitoring in the EU, identified no relevant publications that would invalidate the initial conclusions of the MON 810 risk assessment. Therefore, the conclusions of the risk assessment as presented in the initial application remain unchanged. No adverse effects are to be expected from all uses as any other maize including cultivation of MON 810 in the EU.

7. REFERENCES

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