Application for authorisation to place on the market MON 87429 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-NL-2019-XXX / EFSA-Q-2019-XXXXX

Part VII

Summary of Application

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

The Netherlands

(b) Application number

Not applicable at the time of initial submission (EFSA-GMO-NL-2019-XXX)

(c) Name of the product (commercial and any other names)

The Monsanto Company development code for this genetically modified (GM) maize is MON 87429. It is likely that this product will not be commercialized as a single event; hence, no commercial name will be attributed to this product.

(d) Date of acknowledgement of valid application

Not available at the time of initial submission.

1.2. Applicant

(a) Name of applicant

Monsanto Company, represented by Bayer Agriculture BVBA

(b) Address of applicant

Bayer Agriculture BVBA
Haven 627
Scheldelaan 460
B-2040 Antwerp
BELGIUM

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
USA

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

See above.

1.3. Scope of the application

(a) Genetically modified food

- ☑ Food containing or consisting of genetically modified plants
- ☑ Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

- ☑ Feed containing or consisting of genetically modified plants
- ☑ Feed produced from genetically modified plants

(c) Genetically modified plants for food or feed uses

- ☑ Products other than food and feed containing of consisting of genetically modified plants with the exception of cultivation
- ☐ Seeds and plant propagating material for cultivation in the Union

The scope of this application covers the import, processing and all uses of MON 87429 as any other maize but excludes cultivation.

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation procedure within the Union?

No ☑

Yes ☐ (in that case, specify)

1.5. Has the genetically modified plant been notified under Part B of Directive 2001/18/EC?

Yes ☐

No ☑ (in that case, provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

The risk assessment presented in this application includes data collected from field trials conducted at multiple United States (US) locations covering a range of environmental conditions. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 87429 to humans, animals and the environment, has been presented in the respective sections throughout this summary.

1.6. Has the genetically modified plant or derived products been previously notified for marketing in the Union under Part C of Directive 2001/18/EC?

No ☑

Yes ☐ (in that case, specify)

1.7. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

No ☐

Yes ☑ in that case, specify the third country, the date of application and, where available, a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application

MON 87429 regulatory submissions and reviews are currently in progress in selected countries around the world.

1.8. General description of the product

(a) Name of the recipient or parental plant and the intended function of the genetic modification

MON 87429, developed by Monsanto Company through *Agrobacterium*-mediated transformation of maize tissues, contains the *pat* gene from *Streptomyces viridochromogenes* that expresses the PAT protein to confer tolerance to glufosinate herbicide, the *dmo* gene from *Stenotrophomonas maltophilia* that expresses the DMO protein to confer tolerance to dicamba herbicide, and the *ft_t* gene, a modified version of the *Rdpa* gene from *Sphingobium herbicidovorans*, that expresses the FT_T protein that confers tolerance to quizalofop and 2,4-D herbicides. MON 87429 maize also contains the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 that expresses the CP4 EPSPS protein to provide a glyphosate-based hybridisation system for hybrid seed production. MON 87429 maize utilizes an endogenous maize RNAi regulatory element to reduce CP4 EPSPS protein expression in pollen. Appropriately timed glyphosate applications produce a non-viable pollen phenotype and allow for desirable cross pollinations to be made in maize without using mechanical or manual detasseling methods to control self-pollination in female inbred parents.

(b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be

placed on the market (such as seeds, cut-flowers, vegetative parts) as a proposed condition of the authorisation applied for

The scope of the current application is for authorisation of MON 87429 in the European Union (EU) for all uses according to Art 3 (1) and 15 (1) of Regulation (EC) No 1829/2003, with the exception of cultivation. The range of uses will be identical to the full range of equivalent uses of conventional maize.

(c) Intended use of the product and types of users

MON 87429 will be used and traded in the EU in the same manner as current commercial maize and by the same operators currently involved in the trade and use of maize.

(d) Any specific instructions and recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

MON 87429 is not different from conventional maize, except for the introduced traits (herbicide tolerance and/or hybridisation system). MON 87429 is shown to be as safe as conventional maize. Therefore, MON 87429 and derived products will be stored, packaged, transported, handeled and used in the same manner as current commercial maize. No specific instructions and/or recommendations are considered necessary for the placing on the market of MON 87429 for import, processing and all uses in the EU, as specified in Section 1.8.(b) of this document.

(e) If applicable, geographical areas within the Union to which the product is intended to be confined under the terms of the authorisation applied for

MON 87429 is suitable for use throughout the EU as any other maize. The scope of this application covers the import, processing and all uses of MON 87429, as any other maize but excludes cultivation.

(f) Any type of environment to which the product is unsuited

MON 87429 is suitable for use throughout the EU as any other maize. The scope of this application covers the import, processing and all uses of MON 87429, as any other maize but excludes cultivation.

(g) Any proposed packaging requirements

MON 87429 and derived products will be used in the same manner as other maize and no specific packaging is required.

(h) Any proposed labelling requirements in addition to those required by other applicable EU legislation than Regulation (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Article 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003. In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling has which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, a labelling threshold of 0.9 % is applied for the placing on the market of MON 87429 and derived products.

Operators shall be required to label products containing or consisting of MON 87429 with the words “genetically modified maize” or “contains genetically modified maize” and shall be required to declare the unique identifier in the list of GMOs that have been used to constitute the mixture that contains or consists of any of these GMOs.

Operators shall be required to label foods and feeds derived from MON 87429 with the words "produced from genetically modified maize". In the case of products for which no list of ingredients exists, operators shall ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the products.

Operators handling or using MON 87429 and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003 and that authorised foods and feeds shall be entered in the EU Register for genetically modified food and feed, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 87429. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In the EU

There are no anticipated changes to the demand as a result of the introduction of MON 87429 into the maize supply. It is anticipated that the introduction of MON 87429 will replace some of the maize in exising food and feed products.

(ii) In EU export markets

There are no anticipated changes to the extent of maize production in exports markets as a result of the introduction of MON 87429. It is anticipated that the introduction of MON 87429 will replace some of the maize grain products.

(j) Unique identifier in accordance with Regulation (EC) No 65/2004

The OECD unique identifier for MON 87429 is MON-87429-9.

1.9. Measures suggested by the applicant to take in the case of unintended release or misuse of the product as well as measures for disposal and treatment

Because this application is for consent to import, process and all uses of MON 87429 as any other maize, but excludes the cultivation in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of MON 87429. However, modern methods of grain handling minimize losses of grain, so there is little chance of germination of spilt grain resulting in the development of mature plants of MON 87429 in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since maize cannot survive without human assistance and is not capable of surviving as a weed. Although maize seed can over-winter in mild conditions and can germinate the following year, the appearance of maize in rotational fields is rare under European conditions. Maize volunteers, if they occur, are usualy killed by frost or could be easily controlled by the use of selective herbicides (other than glufosinate-, dicamba-, quizalofop-, 2,4-D- and glyphosate-based herbicides) or by mechanical means. Moreover, the information presented in this application established that MON 87429 is not different in composition, nutritional and agronomic characteristics relative to the conventional counterpart, except for the introduced herbicide tolerance and/or hybridisation traits, and that MON 87429 is unlikely to pose any threat to the EU environment or to require special measures for its containment. Therefore, no special measures are considered to be required in case of misuse or unintended release, and no specific conditions are warranted or required for the placing on the market of MON 87429 for import, processing and all uses as specified in Section 1.8.(b).

2. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

2.1. Maize name

(a)	**Family name**	Poaceae (alternate Gramineae)
(b)	**Genus**	*Zea*
(c)	**Species**	*mays* (2n = 20)
(d)	**Subspecies**	Not applicable
(e)	**Cultivar, breeding line**	LH244
(f)	**Common name**	Maize / Corn

2.2. Geographical distribution and cultivation of the plant, including the distribution within the Union

Maize is widely grown in the EU and represents a significant portion of global maize production. Significant areas of maize production in Europe include the Danube Basin from southwest Germany to the Black Sea along with southern France through the Po Valley of northern Italy.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Maize is wind-pollinated, and the distances that viable pollen can travel depend on prevailing wind patterns, humidity, and temperature. Pollen is shed from the tassel and is viable for approximately 20 minutes to 24 hours depending on environmental conditions. maize plants shed pollen for up to 14 days.

(b) Specific factors affecting reproduction

Maize, as a thoroughly domesticated plant, has lost all ability to disseminate its seeds and relies entirely on the aid of man for its distribution.

(c) Generation time

As maize is a short-day plant, time to maturity is strongly influenced by photoperiod. Maize is an annual crop with cultural cycle ranging from as short as 60 to 70 days to as long as 43 to 48 weeks from grainling emergence to maturity.

2.4. Sexual compatibility with other cultivated or wild plant species (for environmental safety aspects)

Potential for cross-pollination with cultivated maize varieties

Maize morphology fosters cross-pollination; therefore, high levels of pollen mediated gene flow can occur in this species. Researchers recognize that (1) the amount of gene flow that occurs can be high because of open pollination; (2) the percent gene flow will vary by population, hybrid or inbred; (3) the level of gene flow decreases with greater distance between the source and recipient plants; (4) environmental factors affect the level of gene flow; (5) maize pollen is viable for a short period of time under field conditions; (6) maize produces ample pollen over an extended period of time; and, (7) maize is wind-pollinated; pollinating insects, especially bees, are occasional visitors to the tassels but rarely visit silks of maize.

Potential for cross-pollination with wild species

Maize and annual teosinte (*Zea mays* subsp. *mexicana*), are genetically compatible, wind-pollinated and hybridize when in close proximity to each other *e.g.*, in areas of Mexico and Guatemala. Outside its centre of origin, like the EU, teosinte cannot be regarded as a native wild relative of maize as its presence in Europe is currently limited to agricultural fields where it causes a weed management problem. There are no compatible wild relatives of maize in Europe. In addition, hybridization between maize and teosinte is very unlikely due to a variety of physical factors. If intraspecific hybridization were to happen, literature has demonstrated the process to be asymmetric, favoring teosinte cross-pollinating maize. The lack of relevance of the occurrence of teosinte in maize fields in the EU for the risk assessment of cultivation of several GM maize events has been confirmed by the EFSA (EFSA, 2016).

It is with extreme difficulty and special techniques that maize and the closely related perennial species, *Tripsacum* (gamma grass) hybridize. Furthermore, the offspring of the cross show varying levels of sterility and are genetically unstable. No evidence was observed of gene flow from transgenic maize to eastern gamagrass in nature even though the two species have grown in close proximity for years and have had ample opportunities for outcrossing. Consequently, the possibility of gene transfer between cultivated maize and wild species of *Tripsacum* does not exist.

2.5. Survivability (for environmental safety aspects)

(a) Ability to form structures for survival or dormancy

Although grown extensively throughout the world, maize is not considered a persistent weed or a plant that is difficult to control. Maize, as we know it today, cannot survive in the wild because the female inflorescence (the ear) is covered by a husk thereby restricting seed dispersal. The transformation from a wild, weedy species to one dependent on humans for its survival most likely evolved over a long period of time through plant breeding by the indigenous inhabitants of the Western Hemisphere.

(b) Specific factors affecting survivability

See Section 2.5.(a).

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

Maize is not listed as a weed in the major weed references. In addition, maize has been grown throughout the world without any report that it is a serious weed. Modern maize does not survive as a weed because of past selection in the development of maize. During domestication of maize, traits often associated with weediness have been eliminated such as seed dormancy, a dispersal mechanism, and the ability to establish fertile populations outside of cultivation.

(b) Specific factors affecting dissemination

See Section 2.6.(a).

2.7. Geographical distribution within the Union of the sexually compatible species (for environmental safety aspects)

There are no sexually compatible wild relatives of maize present in the EU.

2.8. In the case of plant species not normally grown in the Union description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts (for environmental safety aspects)

Not applicable, as maize is grown in Europe.

2.9. Other potential interactions, relevant to the genetically modified plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms (for environmental safety aspects)

There are no known toxic effects of the maize plant to humans, animals or other organisms; it has a history of safe use for human food and animal feed. maize has been a staple of the human diet for centuries, and its processed fractions are consumed in a multitude of food and animal feed products. A thorough description of the anti-nutrients present in maize has been presented in an OECD consensus document.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

(a) Description of the methods used for the genetic modification

MON 87429 was developed through *Agrobacterium tumefaciens* mediated transformation of immature maize embryos utilizing the plasmid vector PV-ZMHT519224. During transformation, the T-DNA was inserted into the maize genome. Following transformation, traditional breeding, segregation, selection and screening were used to isolate those plants that contained the *pat*, *dmo*, *ft_t*, and *cp4 epsps* expression cassettes and did not contain the backbone sequences, leading to the selection of MON 87429.

(b) Nature and source of the vector used

Plasmid vector PV-ZMHT519224 is approximately 17.8 kb in length and contains a single T-DNA that is delineated by Right and Left Border regions. The T-DNA contains the *pat*, *dmo*, *ft_t*, and *cp4 epsps* expression cassettes. The backbone region of PV-ZMHT519224 contains two origins of replication for maintenance of the plasmid vector in bacteria (*ori V*, *ori pBR322*), and a bacterial selectable marker gene (*aadA*).

(c) Source of donor nucleic acid(s) used for transformation, size and intended function of each constituent fragment of the region intended for insertion

The T-DNA in PV-ZMHT519224 contains the *pat*, *dmo*, *ft_t*, and *cp4 epsps* expression cassettes. The *pat* expression cassette contains the following genetic elements: promoter, 5' UTR, and intron sequences for a ubiquitin gene (*Ubq*) from *Erianthus ravennae* (plume grass), and the 3' UTR sequence of the *fructose-bisphosphate aldolase* (*Fba*) gene from *Setaria italica* (foxtail millet). The *dmo* expression cassette contains the following genetic elements: Promoter, 5' UTR, and intron sequences for a ubiquitin gene (*Ubq*) from *Coix lacryma-jobi* (adlay millet), chloroplast-targeting sequence of the *Albino and pale green 6* (*Apg6)* gene from *Arabidopsis thaliana*, and the 3' UTR sequence of the *OsMt* gene from *Oryza sativa* (rice). The *ft_t* expression cassette contains the following genetic elements: promoter, 5' UTR, and intron sequences for a *ubiquitin* gene (*Ubq*) from *Arundo donax* (giant reed), chloroplast-targeting sequence from *Arabidopsis thaliana Mdh* gene, and the 3' UTR sequence from the gene coding for a no apical meristem (*Nam*) protein domain from *Oryza sativa* (rice). The *cp4 epsps* expression cassette contains the following genetic elements: promoter and leader sequence from the 35S RNA of cauliflower mosaic virus (CaMV), 5' UTR leader sequence from the gene coding for chlorophyll a/b-binding (*CAB*) protein of *Triticum aestivum* (wheat), intron and flanking UTR sequence of the *act1* gene from *Oryza sativa* (rice), chloroplast-targeting sequence of the *ShkG* gene from *Arabidopsis thaliana*, 3' UTR sequence of *Zea mays* cDNA (Genbank Accession: EU974548) that contains male tissue specific siRNA target sequence, and 3' UTR sequence of the glycine-rich RNA binding protein (*Grp3*) gene from *Oryza sativa* (rice).

3.2. Information relating to the genetically modified plant

3.2.1. *Description of the trait(s) and characteristics which have been introduced or modified*

Monsanto Company has developed MON 87429 maize that expresses PAT, DMO, and FOPs and 2,4-D dioxygenase (FT_T) proteins, providing tolerance to glufosinate, dicamba, as well as quizalofop and 2,4-D herbicides, respectively. MON 87429 maize expresses also CP4 EPSPS and utilizes an endogenous maize RNAi regulatory element to suppress CP4 EPSPS expression in pollen, providing a glyphosate-based hybridisation system for hybrid seed production.

3.2.2. *Information on the nucleic acid(s) sequences actually inserted or deleted*

(a) The copy number of all detectable inserts, both complete and partial

The molecular characterization of the genetic modification in MON 87429 demonstrates that a single copy of the intended T-DNA was stably integrated at a single locus of the maize genome and that no plasmid backbone sequences are present in MON 87429.

(b) In case of deletion(s), size and function of the deleted region(s)

A sequence comparison between the PCR product generated from the conventional control and the sequence generated from the 5' and 3' flanking sequences of MON 87429 indicates that 54 bases of maize genomic DNA were deleted during integration of the T-DNA. There also was a 29 base insertion in the MON 87429 5′ flanking sequence and a 31 base insertion in the MON 87429 3' flanking sequence. Such changes are common during plant transformation and these changes presumably resulted from DNA repair mechanisms in the plant during *Agrobacterium*-mediated transformation processes.

(c) Sub-cellular location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form) and methods for its/their determination

The presence of MON 87429 insert in the nuclear genome is best shown by the Chi square (χ^2) analysis of the segregation results. The χ^2 analysis of the segregation pattern, according to Mendelian genetics, was consistent with a single site of insertion into maize nuclear DNA.

(d) The organisation of the inserted genetic material at the insertion site

Directed DNA sequence analysis demonstrate that the MON 87429 insert is 14,008 bp and that each genetic element within the T-DNA is intact compared to PV-ZMHT519224. The border regions both contain small terminal deletions with the remainder of the inserted border regions being identical to the sequence in PV-ZMHT519224. The sequence and organization of the insert was also shown to be identical to the corresponding T-DNA of PV-ZMHT519224 as intended.

(e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification

Not applicable.

3.2.3. *Information on the expression of the insert*

(a) Information on developmental expression of the insert during the life cycle of the plant

The PAT, DMO, FT_T and CP4 EPSPS protein expression levels were determined by validated multiplexed immunoassay or enzyme-linked immunosorbent assay (ELISA) in MON 87429 grain and forage tissues collected during the 2017 US growing season.

(b) Parts of the plant where the insert is expressed

In terms of food and feed safety, assessment of MON 87429 forage and grain are the most relevant tissues.

3.2.4. *Genetic stability of the insert and phenotypic stability of the genetically modified plant*

Generational stability analysis by Next Generation Sequencing (NGS) demonstrated that the single PV ZMHT519224 T-DNA insert in MON 87429 has been maintained through five breeding generations, thereby confirming the stability of the T-DNA in MON 87429. Segregation analysis corroborates the insert stability demonstrated by NGS and independently establishes the nature of the T-DNA as a single chromosomal locus that shows an expected pattern of inheritance

3.2.5. *Information (for environmental safety aspects) on how the genetically modified plant differs from the recipient plant in:*

(a) Mode(s) and/or rate of reproduction

Phenotypic and agronomic as well as environmental interaction data were collected from field trials conducted in 2017 in major US maize growing regions. In each of the assessments MON 87429, either treated or not with glufosinate, dicamba, quizalofop and 2,4-D herbicides was compared to an appropriate conventional counterpart which has a genetic background similar to MON 87429 but does not possess the *pat*, *dmo*, *ft_t* and *cp4 epsps* expression cassettes. In addition, multiple commercial reference varieties were included to provide a range of comparative values that are representative of existing conventional reference varieties for each measured phenotypic, agronomic, and environmental interaction characteristic.

Results of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 87429 compared to the conventional counterpart.

It is therefore possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or environmental interaction characteristics are expected in MON 87429 and that MON 87429 shows no difference to the conventional counterpart in its phenotypic and agronomic behaviour, except for its herbicide tolerance and hybridisation traits.

(b) Dissemination

See Section 3.2.5.(a).

(c) Survivability

See Section 3.2.5.(a).

(d) Other differences

See Section 3.2.5.(a).

3.2.6. *Any change to the ability of the genetically modified plant to transfer genetic material to other organisms (for environmental safety aspects)*

(a) Plant to bacteria gene transfer

None of the genetic elements in MON 87429 has a genetic transfer function. Therefore, no changes are expected in the ability of this maize to transfer genetic material to bacteria.

(b) Plant to plant gene transfer

Not applicable, the scope of the current application does not include the cultivation of MON 87429 in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

MON 87429 was compared to a conventional counterpart with similar genetic background, as well as with other commercially available maize.

4.2. Experimental design and statistical analysis of data from field trials for comparative analysis

Field trials for comparative analysis were conducted in multiple field sites in major growing areas of the US during 2017 field season. Additionally, commercial reference hybrids were included at each field sites to provide reference substances representative for their respective growing regions. Field sites were representative of commercial maize growing areas and were distributed to reflect a variety of agronomic practices, soils and climatic factors. Difference and equivalence tests were conducted using statistical models provided in EFSA guidance and according to the 2010 EFSA Scientific Opinion on Statistical considerations for the safety evaluation of GMOs (EFSA, 2010b, 2011a).

4.3. Selection of material and compounds for analysis

The key nutrients and other nutritionally important components that were selected for analysis in the compositional studies were chosen on the basis of internationally accepted guidance provided by the OECD on compositional considerations for new varieties of maize (OECD, 2002).

Certain characteristics together with environmental interactions were studied to assess for a potential indicator of phenotypic changes.

4.4. Comparative analysis of composition

The compositional assessment of MON 87429 compared to conventional maize demonstrated that MON 87429 is compositionally similar to conventional maize and that MON 87429 is not a significant contributor to compositional variability in maize.

4.5. Comparative analysis of agronomic and phenotypic characteristics

The assessment of the phenotypic, agronomic and environmental interactions of MON 87429 compared to conventional maize demonstrated that there are no unexpected changes in the phenotype or ecological interactions indicative of increased plant weed or pest potential of MON 87429 compared to conventional maize.

4.6. Effect of processing

MON 87429 has been shown not to be different from conventional maize, except for its herbicide tolerance and hybridisation traits. The processing of MON 87429 is therefore not expected to be any different from that of conventional maize.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

The *pat, dmo, ft-t and cp4 epsps* genes are the only genes expressing novel proteins in MON 87429. Therefore, the safety assessment of the newly expressed proteins is focused on the PAT, DMO, FT_T and CP4 EPSPS proteins expressed in MON 87429.

Following the guidelines adopted by the Codex Alimentarius (Codex Alimentarius, 2009), an assessment of the potential toxicity of the newly expressed proteins was conducted. The assessment demonstrated that it is unlikely that the PAT, DMO, FT_T and CP4 EPSPS proteins will cause toxicity concerns due to the following considerations:

- The protein has a demonstrated history of safe use and pose negligible risk to human and aimal health. The PAT, DMO, FT_T and CP4 EPSPS proteins are derived from the bacterial species *S. viridochromogenes, S. maltophilia, S. herbicidovorans* and *Agrobacterium* sp. strain CP4 respectively, which have a long history of safe use and are ubiquitous in the environment with widespread human exposure and no adverse safety reports.
- The protein has no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- The protein is rapidly digested in mammalian gastrointestinal systems. *In vitro* experiments conducted with PAT, MON 87429 DMO, FT_T and CP4 EPSPS proteins demonstrated that all the proteins are rapidly digested by proteases found in the human gastrointestinal tract (pepsin and pancreatin) under physiological conditions.

Furthermore, the low concentrations of the PAT, DMO, FT_T and CP4 EPSPS proteins in tissues that are consumed provide additional assurance for their safety.

It should be further noted that the safety of the PAT, DMO and CP4 EPSPS proteins and their donor organisms was reviewed by the numerous global regulatory agencies[1], including the EFSA (EFSA, 2006, 2008, 2009a, 2009b, 2009c, 2009d, 2011c, 2012, 2013a, 2013b, 2013c, 2013d, 2014, 2015, 2017a, 2017b, 2018) in the context of various applications for food and feed uses and no safety concerns were identified. The FT_T protein in MON 87429 has also been assessed for its potential toxicity based on these criteria and the results from these assessments, as described throughout this dossier, support a conclusion that food and feed products containing the MON 87429 FT_T protein pose no meaningful risk to human or animal health.

(b) Testing of new constituents other than proteins

The components analysed in MON 87429 were compositionally similar compared to conventional maize. Therefore, no testing of any constituent other than the introduced proteins is required.

(c) Information on natural food or feed constituents

No relevant changes in the composition of MON 87429 were detected compared to conventional maize. Therefore, the levels of food and feed constituents in MON 87429 have not been altered.

[1] CropLife International: http://www.biotradestatus.com/ - Accessed on 6 August 2019.

(d) Testing of the whole genetically modified food and feed

The safety assessment demonstrates that MON 87429 is as safe as conventional maize for food and feed use through the compositional assessment of MON 87429 harvested forage and grain to harvested forage and grain from conventional maize. The safety for humans and animals of the PAT, DMO, FT_T and CP4 EPSPS proteins has been demonstrated on the basis of extensive characterisation, history of safe use, lack of structural similarities with known protein toxins and allergens, absence of acute toxicity in oral gavage studies in rodents and rapid digestion in simulated digestive fluids. Moreover, the history of safe use of the introduced proteins and the familiarity of the host organisms from which the genes are derived have been demonstrated.

Based on this weight of evidence, no more data are required to demonstrate that MON 87429 is as safe as conventional maize from a food and feed perspective and therefore it can be concluded that there was no evidence of any adverse effects on human or animal health.

Nonetheless, inspite not being scientifically justified, in accordance with Commission Implementing Regulation (EU) No 503/2013, a 90-day feeding study with maize grain from MON 87429 in rats was performed. As expected, the study supports the conclusion that MON 87429 is as safe as conventional soybean from a food and feed perspective.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed proteins

The *pat, dmo, ft_t* and *cp4 epsps* genes are the only genes expressing novel proteins in MON 87429. Therefore, the safety assessment of the newly expressed proteins is focused on the PAT, DMO, FT_T and CP4 EPSPS proteins expressed in MON 87429.

Following the guidelines adopted by the Codex Alimentarius, an assessment of the allergenic potential of the newly expressed proteins was conducted. The assessment demonstrated that it is unlikely that the PAT, DMO, FT_T and CP4 EPSPS proteins will cause allergenicity concerns due to the following considerations:

- The protein is from a non-allergenic source;
- The protein does not share structural similarities with known allergens; and
- The protein is rapidly digested by proteases found in the human gastrointestinal tract (pepsin and pancreatin) under physiological conditions.

It should be noted also that the PAT, DMO and CP4 EPSPS proteins expressed in MON 87429 are identical or highly homologous to PAT, DMO and CP4 EPSPS proteins expressed in several other crops that were reviewed and approved by numerous global regulatory agencies[1] around the world, including EFSA (EFSA, 2006, 2008, 2009a, 2009b, 2009c, 2009d, 2011c, 2012, 2013a, 2013b, 2013c, 2013d, 2014, 2015, 2017a, 2017b, 2018). The FT_T protein in MON 87429 has also been assessed for its potential allergenicity based on the same criteria. The safety assessments support the conclusion that exposure to the FT_T protein derived from MON 87429 would not pose any meaningful risk to human or animal health or the environment.

Based on this weight of evidence, no more data are required to demonstrate the safety of the newly expressed proteins in MON 87429.

(b) Assessment of allergenicity of the whole genetically modified plant

Maize is not considered a common allergenic food. Therefore, a possible overexpression of any endogenous protein, which is not known to be allergenic, would be unlikely to alter the overall allergenicity of the whole plant or the allergy risk for consumers. MON 87429 is comparable to and is as safe as conventional maize in terms of allergenic potential. Further, as the expressed proteins in MON 87429 do not have any allergenic potential, it was concluded that the use of MON 87429 for food and feed does not lead to an increased risk for allergenic reactions compared to the equivalent range of food and feed uses of conventional maize.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

Detailed compositional and nutritional comparisons of MON 87429, a conventional counterpart and commercially available reference maize hybrids confirmed that MON 87429 is compositionally not different from conventional maize.

(b) Nutritional assessment of the genetically modified feed

See Section 7 (a).

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

The exposure assessment in humans and animals indicates that there is minimal dietary exposure to PAT, DMO, FT_T and CP4 EPSPS proteins from consumption of foods and feed derived from MON 87429. There are no anticipated changes in the intake and/or extent of use of maize or derived products for use as or in food or feed as a result of the addition of MON 87429 to the maize supply. MON 87429 is expected to replace a portion of current maize such that the intake or use will represent some fraction of the total products derived from maize.

9. RISK CHARACTERISATION

Based on the information provided in this application, it can be concluded that MON 87429 is as safe as conventional maize.

The molecular characterisation of MON 87429 did not raise any safety concern and did not show any evidence of unintended changes in MON 87429. Detailed compositional comparisons of MON 87429, its conventional counterpart and commercial reference varieties demonstrated that MON 87429 is compositionally similar to the conventional counterpart and that MON 87429 is not a contributor to compositional variability in maize. The assessed phenotypic and agronomic characteristics of MON 87429 were within the range expected for maize and did not show any phenotypic changes indicative of increased plant weed/pest potential of MON 87429 compared to conventional maize. An extensive characterisation of the PAT, DMO, FT_T and CP4 EPSPS proteins expressed in MON 87429 confirmed that these proteins are safe for human and animal consumption. Additionally, the exposure assessment in humans and animals did not indicate any safety concerns.

In summary, there are no signs of adverse or unanticipated effects observed in a number of safety studies and the pre-market risk characterisation for food and feed use of MON 87429. The consumption of food and feed derived from MON 87429 is as safe as the consumption of its conventional counterpart. It can be concluded that the food derived from MON 87429 is not nutritionally disadvantageous for the consumer compared to the food which it is intended to replace. Finally, it can be also concluded that the feed derived from MON 87429 does not harm or mislead

the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

Based on the above, it is unlikely that MON 87429 will have an adverse effect on human and animal health and the environment, in the context of its intended uses, which cover food and feed uses, import and processing as any other maize.

Given the weight of evidence supporting the safety of MON 87429 specific risk management measures for MON 87429 in the EU are not considered necessary.

10. POST-MARKET MONITORING ON THE GENETICALLY MODIFIED FOOD OR FEED

As demonstrated in this application, there are no intrinsic hazards related to MON 87429. No data have emerged to indicate that MON 87429 is less safe than its conventional counterpart. The pre-market risk characterisation for food and feed use of MON 87429 demonstrates that the risks of consumption of MON 87429 or its derived products are no different from the risks associated with the consumption of conventional maize and maize-derived products. As a consequence, specific risk management measures are not indicated and post-market monitoring of the use of this maize for food and feed is not considered necessary.

11. ENVIRONMENTAL ASSESSMENT

11.1. Mechanism of interaction between the genetically modified plant and target organisms

Not relevant given the scope of the application.

11.2. Potential changes in the interactions of the genetically modified plant with the biotic environment resulting from the genetic modification

The scope of this application covers the import, processing and all uses as any other maize, but excludes the cultivation of MON 87429 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected, and interaction of MON 87429 with the biotic environment will be limited.

(a) Persistence and invasiveness

Results from the environmental assessment support the conclusion that the ability of MON 87429 to persist in agricultural fields or invade non-agricultural habitats is comparable to that of conventional maize in the EU. Thus, MON 87429 is not more likely to represent an agronomic problem in agricultural fields or become more invasive in natural habitats and no adverse effects on ecological functions within agricultural production fields or on biodiversity is expected as a result of the import, processing and all uses as any other maize.

(b) Selective advantage or disadvantage

Compared with conventional maize, the introduced herbicide tolerance and hybridisation traits in MON 87429 confer a selective advantage only under specific conditions (*i.e.* following treatments with glufosinate, dicamba, quizalofop and 2,4-D herbicides), which are short in duration. These advantages are of purely agronomic interest and present negligible risk to the non-agricultural environments, because of the poor survival characteristics of maize under most European conditions. Therefore, the likelihood is negligible for the introduced traits in MON 87429 to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

(c) Potential for gene transfer

Given the low likelihood of occurrence of horizontal gene transfer and lack of adverse consequences if it were to occur, the import, processing, and food and feed use of MON 87429 in the EU is not likely to adversely impact human, animal, or environmental health, and poses negligible risk.

(d) Interactions between the genetically modified plant and target organisms

Not relevant given the scope of the application.

(e) Interactions of the genetically modified plant with non-target organisms

Given the low levels of environmental exposure combined with low hazard from exposure of MON 87429 to non-target organisms (NTOs), the likelihood of adverse effects to NTO communities that perform in-field ecological functions and NTO communities outside of the field from import of MON 87429, is negligible.

(f) Effects on human health

Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact with MON 87429 grain, the likelihood for any adverse effects on humans and animals handling MON 87429 import and processing in the EU is negligible.

(g) Effects on animal health

See Section 11.2.(f).

(h) Effects on biogeochemical processes

Given the low level of environmental exposure combined with a lack of hazard, the import, processing and all uses of MON 87429 as any other maize in the EU is not likely to adversely impact soil micro-organisms that perform ecological functions in-field or in non-agricultural habitats, and therefore poses negligible environmental risk.

(i) Impacts of the specific cultivation, management and harvesting techniques

Not relevant given the scope of the application.

11.3. Potential interactions with the abiotic environment

MON 87429 carry traits of agronomic interest: herbicide tolerance and hybridisation system. As MON 87429 is shown not to be different from conventional maize (with the exception of the introduced traits, imparted by the expression of the PAT, DMO, FT_T and CP4 EPSPS proteins), with respect to its composition and agronomic and phenotypic characteristics, there is no evidence that theis maize would be any different from conventional maize with regard to its baseline interactions with the abiotic environment.

Although the PAT, DMO, FT_T and CP4 EPSPS proteins are expressed in maize, they already have a safe history of use and they have no known negative interactions with the abiotic environment.

In addition, because this application is for import, processing and all uses as any other maize in the EU, but excludes cultivation, interaction of MON 87429 with the environment will be limited. Moreover, no negative impact of MON 87429 on the abiotic environment is expected to result from the import, processing and all uses as any other maize in the EU.

11.4. Risk characterisation

Results from the environmental risk assessment which takes into consideration the risk characterisation and includes results described above addressing risk hypotheses for the specific areas of assessment laid down in EFSA (2010a) guidance, support a conclusion that the import, processing and all uses in the EU (excluding cultivation) of MON 87429, as any

other maize, represents negligible risk to human and animal health and the environment, and poses no greater risk than the import and processing of conventional maize. Because no immediate adverse effects are expected, the probability of long-term adverse effects is also negligible.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 the proposed Post-Market Environmental Monitoring (PMEM) plan for MON 87429 has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The PMEM also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring of genetically modified plants (EFSA, 2011b).

(b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MON 87429 for import, processing, food and feed use in the European Union (EU) under Regulation (EC) No 1829/2003. The scope of the application does not include authorisation for the cultivation of MON 87429 in the EU.

An environmental risk assessment (e.r.a.) was carried out for MON 87429 according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of MON 87429 in the e.r.a. (Section 5 of Part II – Scientific information) has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MON 87429.

(c) Case-specific genetically modified plant monitoring (approach, strategy, method and analysis)

The scientific evaluation of the characteristics of MON 87429 in the e.r.a. has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of MON 87429. It is therefore considered that there is no need for case-specific monitoring.

(d) General surveillance of the impact of the genetically modified plant (approach, strategy, method and analysis)

Any potential adverse effects of MON 87429 on human health and the environment, which were not anticipated in the e.r.a., can be addressed under the general surveillance. General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a GM crop in its receiving environment.

In order to allow detection of the broadest possible scope of unanticipated adverse effects, general surveillance is performed by either selected, existing networks, or by specific company stewardship programmes, or by a combination of both. The consent holder will ensure that appropriate technical information on MON 87429 and relevant legislation will be available for the relevant networks, in addition to further relevant information from a number of sources, including industry and government websites, official registers and government publications.

Following the approval of these maize in the EU, the consent holder will approach key stakeholders and key networks of stakeholders of the products (including international grain

traders, maize processors and users of maize grain for animal feed) and inform them that the products have been authorised. The consent holder will request key stakeholders and networks for their participation in the general surveillance of the placing on the market of these maize, in accordance with the provisions of Directive 2001/18/EC and the consent. Key stakeholders and networks will be requested to be aware of the use of these maize and to inform the consent holder in case of potential occurrence of any unanticipated adverse effects to health or the environment, which they might attribute to the import or use of these products. Appropriate technical information on MON 87429 will be provided to them.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with available baseline information. Relevant baseline information will reflect prevalent use practices and the associated impact of these practices on the environment. Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of MON 87429 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

(e) Reporting the results of monitoring

In accordance with Regulation (EC) No 1829/2003, the authorisation holder is responsible to inform the European Commission of the results of the general surveillance.

If information that confirms an adverse effect of MON 87429 and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the confirmed effect.

The authorisation holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on unanticipated adverse effects, if any, that have arisen from handling and use of viable MON 87429.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MON 87429 and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are considered confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts of such report shall be submitted in separate documents.

13. DETECTION AND EVENT-SPECIFIC IDENTIFICATION TECHNIQUES FOR THE GENETICALLY MODIFIED PLANT

The presence of the *pat*, *dmo*, *ft_t* and *cp4 epsps* genes and the PAT, DMO, FT_T and CP4 EPSPS proteins can be identified by employing different techniques. PCR can identify the inserted nucleotide sequence, while the newly expressed proteins can be detected, by optimised tissue extraction, standardized electrophoretic blotting and immunodetection methodologies. A MON 87429-specific PCR-based assay allowing the identification and quantification of MON 87429 has been provided to the European Union Reference Laboratory for GM Food and Feed (EU-RL-GMFF), Joint Research Centre (JRC)[2].

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GENETICALLY MODIFIED PLANT (FOR ENVIRONMENTAL SAFETY ASPECTS)

14.1. History of previous releases of the genetically modified plant notified under Part B of Directive 2001/18/EC or under Part B of Directive 90/220/EEC by the same notifier

(a) Notification number

There is no history of release of MON 87429 in the EU.

(b) Conclusions of post-release monitoring

Not applicable

(c) Results of the release in respect to any risk to human health and the environment, submitted to the competent authority according to Article 10 of Directive 2001/18/EC)

Not applicable

14.2. History of previous releases of the genetically modified plant carried out outside the Union by the same notifier

(a) Release country

MON 87429 has been field tested in the US since 2014.

(b) Authority overseeing the release

US and Puerto Rico: United States Department of Agriculture (USDA) and United States Environmental Protection Agency (U.S. EPA)

(c) Release site

US: In major maize growing regions.

(d) Aim of the release

US: Regulatory, efficacy, yield, breeding, product development and demonstration trials.

(e) Duration of the release

US: 2014-2019.

(f) Aim of post-releases monitoring

US: Assessment of volunteers.

[2] European Union Reference Laboratory for GM Food and Feed, Joint Research Centre: http://gmo-crl.jrc.ec.europa.eu/ - Accessed on 30 August 2019.

(g) Duration of post-releases monitoring

US: 12 months.

(h) Conclusions of post-release monitoring

US: In general, no volunteers have been observed since maize is an annual crop. If volunteers occur, practice is to eliminate them manually or chemically to prevent occurrence in subsequent crops.

(i) Results of the release with respect to any risk to human health and the environment

Field-testing provided no evidence that MON 87429 or derived products would be the cause of any adverse effects to human health or to the environment.

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