Application for authorisation to place on the market MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-NL-2017-139/ EFSA-Q-2017-00115

Part III

Cartagena Protocol

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

MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122

A maize product from Monsanto Company

Information on MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 maize, notified in accordance with Article 9(2) (Annex II) of Regulation (EC) No 1946/2003 of 15 July 2003 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety

Annex II of Regulation (EC) No 1946/2003

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 9(2) OF ANNEX II

This document contains the statutory information required by the European Union (EU) for the transboundary movement of a living genetically modified organism, as requested in Article 9 and Annex II of Regulation (EC) No 1946/2003. Annex II details the information required to complete the procedure for living modified organisms intended for direct use as food or feed, or for processing (LMO-FFP). The subject LMO-FFP in this document, hereafter referred to as MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, contains glyphosate/glufosinate-tolerance, drought tolerance and lepidopteran/coleopteran-protection traits. MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is a combined trait product developed through traditional breeding by Monsanto Company.

a) The name and contact details of the applicant for a decision for domestic use

Monsanto Company, represented by Monsanto Europe S.A./N.V.

Monsanto Europe S.A./N.V.
Avenue de Tervueren 270-272
Tervurenlaan 270-271
B-1150 Brussels
Belgium

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
U.S.A.

b) The name and contact details of the authority responsible for the decision

The information on MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 included in this document will be notified by the EU Commission, DG SANTE to the Biosafety Clearing-House, and will be accessible to all Parties to the Cartagena Protocol on Biosafety.

Contact details:

European Commission, DG SANTE
Unit Biotechnology and Plant health
Rue Belliard 232 03/100
B-1049 Brussels
Belgium

c) Name and identity of the GMO

The Monsanto development code for this product is MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122. It is tolerant to glyphosate/glufosinate, tolerant to drought and is protected against certain lepidopteran and coleopteran insect pests.

d) Description of the gene modification, the technique used, and the resulting characteristics of the GMO

MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is produced by crossing maize plants containing MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122 using traditional breeding methods. As a result, MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 expresses CP4 EPSPS, CspB, NptII, Cry1A.105, Cry2Ab2, Cry1F, PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and the DvSnf7 dsRNA, providing herbicide tolerance, drought tolerance and insect-protection.

e) Any unique identification of the GMO

The OECD unique identifier for MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 grain are[1]:

MON-87427-7 × MON-8746 Ø -4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON 87411-9
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON 87411-9
MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9
MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-87427-7 × MON-89Ø34-3 × MON 87411-9 × DAS-59122-7
MON-87427-7 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9
MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3 × MON 87411-9 × DAS-59122-7
MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3
MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1
MON-87427-7 × MON-8746Ø-4 × MON 87411-9
MON-87427-7 × MON-8746Ø-4 × DAS-59122-7
MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1
MON-87427-7 × MON-89Ø34-3 × MON 87411-9
MON-87427-7 × MON-89Ø34-3 × DAS-59122-7
MON-87427-7 × DAS-Ø15Ø7-1 × MON 87411-9
MON-87427-7 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-87427-7 × MON 87411-9 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1
MON-8746Ø-4 × MON-89Ø34-3 × MON 87411-9
MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7
MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON 87411-9
MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7

[1] List of the Unique Identifiers for the GMO's contained in MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, excluding the single event, for which EFSA overall opinion have already been issued and in case of MON 87411 for which EFSA's review is underway, and upon which the risk assessment of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and its sub-combinations is based.

MON-8746Ø-4 × MON 87411-9 × DAS-59122-7
MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9
MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-89Ø34-3 × MON 87411-9 × DAS-59122-7
DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4
MON-87427-7 × MON-89Ø34-3
MON-87427-7 × DAS-Ø15Ø7-1
MON-87427-7 × MON 87411-9
MON-87427-7 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3
MON-8746Ø-4 × DAS-Ø15Ø7-1
MON-8746Ø-4 × MON 87411-9
MON-8746Ø-4 × DAS-59122-7
MON-89Ø34-3 × DAS-Ø15Ø7-1
MON-89Ø34-3 × MON 87411-9
MON-89Ø34-3 × DAS-59122-7
DAS-Ø15Ø7-1 × MON 87411-9
DAS-Ø15Ø7-1 × DAS-59122-7
MON 87411-9 × DAS-59122-7

f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety

(i). Taxonomic status

Family name:	Poacea (alternate Gramineae)
Genus:	*Zea*
Species:	*mays* (2n=20)
Subspecies:	N/A

(ii). Common Name

Zea mays is known as “corn” and “maize” in many English-speaking countries.

(iii). Point of collection or acquisition

The original transformations that produced the parental lines that are combined via traditional breeding to produce MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 used privately owned germplasm acquired for this purpose.

(iv). Characteristics of recipient organism or parental organism related to biosafety

Maize is the second largest cultivated crop in the world preceeded by sugar cane (*Saccharum officinarum* L.) and followed by wheat (*Triticum* sp.) and rice (*Oryza sativa* L.) in total global metric ton production. It has a long history of safe use as a raw material for processed products, and direct uses as a human food or animal feed. Today, maize is produced on every continent except Antarctica, and is exported and imported as viable grain for use as foods or feeds, or directly in processing, without risk to the environment.

According to OECD (OECD, 2003), "*Maize has lost the ability to survive in the wild due to its long process of domestication, and needs human intervention to disseminate its seed*". In addition, "*maize is incapable of sustained reproduction outside of domestic cultivation", and "[m]aize plants are non-invasive in natural habitats*". Despite the fact that maize frequently appears as a volunteer plant in a subsequent rotation, it has no inherent ability to persist or propagate. In all regions of the world, volunteer plants are managed with herbicides, tillage, or manual removal of plants. As such, maize is not considered a pest anywhere in the world. When it occurs outside of cultivation, it has no impact on the conservation and sustainable use of biological diversity.

Gene flow from maize occurs through dispersal of seed and pollen mediated exchange of genes to sexually compatible plants. Since maize has no biological mechanism to scatter seed, low-level, incidental dispersal of viable grain occurs as a result of human-based activities such as transport and harvesting operations. As was noted in the OECD consensus document, the few plants that might result from incidental release will not persist or meaningfully reproduce without human intervention. Maize reproduces sexually, is a wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers, which encourages natural cross-pollination between maize plants. The distance that viable pollen can travel depends on prevailing wind patterns, humidity, and temperature. Generally, the pollen dissemination period lasts three to seven days. Because incidental release of maize during importation occurs at very low levels, and because maize is not competitive, pollen mediated gene flow between local maize and rare volunteers have had no defined effect on the conservation and sustainable use of biological diversity.

g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate

(i). Centres of origin and genetic diversity

Maize originated in the highlands of Mexico 7, 000 to 10, 000 years ago. By the time Columbus discovered the Western Hemisphere, maize was being grown by the indigenous people from Chile to southern Canada. Columbus noted the presence of maize on the north coast of Cuba in November 1492, and introduced maize to Europe upon his return to Spain (Goodman, 1988). Within two generations after the introduction of maize to Europe, maize became distributed throughout those regions of the world where it could be cultivated.

Maize is a member of the genus *Zea,* which is broken into 2 sections: Zea and Luxurientes. The section Zea includes one species (*mays*), which includes three subspecies: ssp. *mays,* ssp. *mexicana* (formerly *Euchlaena mexicana),* and ssp. *parviglumis*. The former subspecies is known as maize (or corn) while the latter comprise a portion of the complex known as teosinte. Furthermore, ssp. *mexicana* and ssp. *parviglumis* are further separated into several races (OECD, 2003). Section Luxurientes encompasses 3 species: an annual *Z. luxurians,* and perennials *Z. diploperennis* and *Z. perennis.*

(ii). Description of the habitats where the organism may persist or proliferate

As noted by OECD, maize is not invasive of natural habitats, does not persist anywhere in the world without human intervention (OECD, 2003). Early domestication and diversification through selection occurred in Meso-America. Maize is grown across a wide range of ecological conditions including soil types, altitude and rainfall. Currently, maize is grown over a wide range of conditions because of its many divergent types that have been bred for this purpose. The bulk of the maize is produced between latitudes 30° and 55°,

with relatively little grown at latitudes higher than 47° latitude anywhere in the world. The greatest maize production occurs where the warmest month isotherms range between 21 and 27°C and the frost-free season lasts 120 to 180 days. A summer rainfall of 15 cm is approximately the lower limit for maize production without irrigation (Shaw, 1988).

Experience with maize imported for use as foods or feeds, or directly in processing, has demonstrated that stable populations do not establish, persist or proliferate as a result of incidental release during handling and transport.

h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety

(i). Taxonomic status

MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is produced by crossing maize plants containing MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122 using traditional breeding methods. There is no evidence of any biosafety issues related to the use of either MON 87427, MON 87460, MON 89034, 1507, MON 87411 or 59122.

The donor organism for the *epsps* coding regions was *Agrobacterium* sp. strain CP4. The associated regulatory genetic elements were obtained from the following sources: *Ract1,* rice (*Oryza sativa*)*; CTP2, Arabidopsis thaliana; e35S,* Cauliflower mosaic virus (CaMV); *TubA,* rice*; Hsp70,* maize (*Zea mays*) and *nos, Agrobacterium tumefaciens.*

The donor organism for the *CspB* coding region is *Bacillus subtilis*. The associated regulatory genetic elements were obtained from the following sources: *Ract1,* rice, and *tr*7, *Agrobacterium tumefaciens*.

The donor organism for the *Cry1A.105, Cry2Ab2*, *Cry3Bb1, Cry1F, Cry34Ab1* and *Cry35Ab1* coding regions was *Bacillus thuringiensis*. The associated regulatory genetic elements for *Cry1A.105 and Cry2Ab2* were obtained from the following sources: *e35S,* CaMV *Cab*, wheat (*Triticum sativum*); *Ract1*, rice; *Hsp17*, wheat; *FMV*, Figwort mosaic virus (FMV); *Hsp70*, maize; *SSUCTP*, maize and *nos*, *A. tumefaciens.* The associated regulatory genetic elements for *Cry3Bb1* were obtained from the following sources: *pIIG*, maize*; Cab*, wheat*; Ract*1, rice; and *Hsp17*, wheat. The associated regulatory genetic elements for *Cry1F* were obtained from the following sources: *ubi*ZM1(2), maize and ORF25PolyA, *A. tumefaciens.* The associated regulatory genetic elements for *Cry34Ab1* were obtained from the following sources: *ubi*ZM, maize; 315 bp proteinase inhibitor II gene terminator, potato (*Solanum tuberosum).* The associated regulatory genetic elements for *Cry35Ab1* were obtained from the following sources: 1298 bp peroxidase gene promoter, wheat; 315 bp terminator, potato.

The donor organism for the *PAT* coding regions was *Streptomyces viridochromogenes*. The associated regulatory genetic elements were obtained from the following source: 35S, CaMV.

The regulatory genetic elements associated to the DvSnf7 suppression cassette were obtained from the following sources: *e35S,* CaVM; *Hsp70,* maize and *E9*, pea (*Pisum sativum*).

A. tumefaciens, S. viridochromogenes, B. subtilis and B. thuringiensis are ubiquitous bacteria and do not have a history of toxicity or allergenicity to humans. FMV and CaMV are pathogenic only to certain plants and have no toxicity or allergenicity to animals or humans. The long history of safe consumption of RNA from a range of sources and the apparent lack of toxicity or allergenicity of dietary RNA, the DvSnf7 RNAi suppression sequence poses no observed risks to animals or humans. Maize, wheat, potato, peas and rice are all domesticated crops with a history of safe use.

In conclusion, all DNA components inherited in MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 are well understood and there is no evidence of any biosafety issues for any of the sequences that have been used, nor for any of the donor organisms of these sequences.

(ii). Common name

See Section h(i) above.

(iii). Point of collection or acquisition

1507 and 59122 were licensed from Dow AgroSciences. All other genetic elements were isolated or obtained from Monsanto research laboratories.

(iv). Characteristics of the donor organism(s) related to biosafety

There is no evidence of any human or animal pathogenicity for any of the donor organisms of the DNA sequences that were used to develop MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122.

i) Approved uses of the living modified organism

MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 has been authorised for cultivation in Canada. Additionally, MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 has been submitted to Japan MAFF/ MOE and will be submitted to multiple global agencies for import approval.

This application under Regulation (EC) No 1829/2003 is for authorisation of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, according to Articles 5 and 17 of the said Regulation.

The scope of this application includes:

- 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
- Genetically modified feed
  - Feed containing or consisting of genetically modified plants
  - Feed produced from genetically modified plants
- Genetically modified plants for food and feed uses
  - Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation

In accordance with the definitions of 'food' and 'feed' in Article 2(1), the scope of the application also includes all food additives and feed additives (approved according to Directives 89/107/EEC and 70/524/EEC, respectively).

The scope of this application does not include the cultivation of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 varieties in the EU. Once MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122[2] is authorised in the EU, the approved uses of this maize will be posted in the Community Register website[3].

The requested duration of the authorisation is 10 years.

j) A risk assessment report consistent with Annex III

Introduction

This section presents a risk assessment report consistent with Annex III of the Cartagena Protocol on Biosafety as required by Annex II.j. The information was collected following the general principles and methodology described in Annex III, which are, "*to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking into account risks to human health*". General principles outlined in Annex III paragraphs (3), (4), (5), and (6) were utilized in the risk assessment including: scientific soundness, transparency, consistency with international guidance and expert advice, and comparison of the non-modified recipient or parental organism within the likely receiving environment. The assessment was carried out considering the intended use and likely receiving environment. In addition, consideration was given to the potential risks to human health. The framework underlying the evaluation of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is consistent with guidance established by the OECD, United Nations World Health Organization (WHO), the FAO and Codex (Codex Alimentarius Commission, 2003; FAO, 1996; OECD, 2003; WHO, 1995), the US, Canada, Japan, the EU and other countries.

The conclusions of the risk assessment conducted herein demonstrate that MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 poses no increased risk to the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking into account risks to human health under the intended direct use as food or feed, or for processing compared to conventional maize.

(i). Identification of any novel genotypic or phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health

As mentioned above (*see* Section (d)), MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 was developed by traditional breeding to express the CP4 EPSPS protein which confers glyphosate-tolerance, the PAT protein which confers glufosinate-tolerance, the CspB protein which confers drought tolerance, the Cry1A.105, Cry1F, Cry2Ab2, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and DvSnf7 dsRNA which confer insect-protection. The NptII protein was used as a selection marker.

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[2] Maize grain is the product of genetic segregation of the seed from which it is produced. Consequently MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 grain includes a mixture of the combined event product, any combination of these events and the single events.

[3] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm – Accessed on 06 February 2017.

MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 was characterized to assess what, if any, novel genotypic or phenotypic characteristics might have adverse effects on biological diversity as a result of importation for processing as a food or feed. The characterization information included: molecular characterization, compositional analysis and extensive phenotypic analysis.

The results of the molecular characterization confirmed that MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 inheritated the inserts from MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122 that function as expected.

The results of the compositional analyses confirmed that MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is compositionally and nutritionally not different from conventional maize hybrids currently in commerce.

The results of the agronomic and phenotypic analyses confirmed that MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 has no biologically meaningful phenotypic differences from conventional maize except for its herbicide tolerance, drought tolerance and insect-protection traits.

In conclusion, any "novel characteristics" in this maize are limited to the intentionally introduced traits, which are of agronomic interest. These traits are imparted by the production of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and DvSnf7 dsRNA insecticidal proteins, and the CP4 EPSPS, CspB, and PAT proteins, encoded by the inserted DNA. Molecular analyses and comparative assessments of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 with conventional maize did not reveal any other novel characteristics or unintended adverse effects of the genetic modification, particularly changes to its persistence and invasiveness compared to conventional maize.

There is no evidence for allergenicity and toxicity to humans or other mammals from dietary exposure to the CP4 EPSPS, CspB, NptII, Cry1A.105, Cry2Ab2, Cry1F, PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and the DvSnf7 dsRNA. Toxicity studies with the CP4 EPSPS, CspB, NptII, Cry1A.105, Cry2Ab2, Cry1F, PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins showed no toxicity at high levels of exposure.

There is no evidence for allergenicity or toxicology in humans or other mammals based on the following lines of evidence: source of the trait; amino acid sequence similarity with known allergens or toxins; prevalence in food; biochemical properties of the protein, including *in vitro* digestibility in simulated gastric fluid and glycosylation and concentration in the food. Based on these properties it is reasonable to conclude that these proteins pose no meaningful potential to adversely affect biological diversity or human health in the EU from the intended use of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 as a LMO.

It is therefore concluded that MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 poses no increased risk to conservation and sustainable use of biodiversity, or to human or animal health in terms of allergenicity or toxicity compared to conventional maize.

(ii). Evaluation of the likelihood of [these] adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism

As noted above in Section j(i), no potentially adverse effects were detected based on extensive characterization of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, which included molecular analysis, protein characterization, compositional analyses and agronomic and phenotypic evaluations conducted in field trials over a wide range of environmental conditions.

The likelihood of adverse effects being realised in the EU is considered to be exceedingly low for the following reasons. Firstly, MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 grain has a negligible hazard potential. Field trials and laboratory evaluations have demonstrated that the hazards associated with MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 are no greater than those present with conventional maize. Based on the available information and experience in EU with conventional maize, the hazard characterization is not expected to change as a result of importing MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 grain for direct use in food, feed or processing.

Secondly, the containment systems used to transport and handle grain for direct use in food, feed or processing will markedly reduce exposure to the biodiversity in EU based on experience with conventional maize. In the case of the trans-boundary movement of maize for direct use as food or feed, or for processing, the grain is not intended for release into natural or agricultural environments. Rather, the grain is normally held, transported and handled in a confined manner that restricts the potential for escape into the local environment. Because the grain will be confined to conditions that are fixed in location (seaports, grain elevators and processing facilities), they meet the conditions of Article 3(b) of the Cartagena Protocol on Biosafety. Such conditions significantly limit exposure to the environment. Incidental release of spilled grain into the receiving environment occurs during export/import, handling, storage and processing of maize. However, modern methods of grain handling minimize such losses of grain. Furthermore, the locations of incidental release will be predictable, since they will be near the storage facilities and along transportation routes. Environmental conditions at these sites are unlikely to be conducive to germination, growth and reproduction of maize grain that is incidentally released.

Compared to conventional maize, MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 has not been adversely changed with respect to its dispersal or survival characteristics as assessed by phenotypic characteristics MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is also unchanged compared to conventional maize in terms of invasiveness of natural environments and persistence in the environment as assessed by the phenotypic characteristics described above. Importantly, there is no information to indicate that there is a reasonable potential for MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 grain to establish, persist and disperse in the EU to a greater extent than conventional maize. In cases where incidental release occurs and MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 plants establish, these plants will be easily controlled by currently available herbicides (other than glyphosate and glufosinate based herbicides) and by mechanical means. As such, MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 has no meaningful potential to disperse, persist without human intervention, or

invade non-agricultural areas as a result of importation for direct use in food, feed or processing.

Because of the lack of hazard potential and the factors that limit exposure to the environment, the likelihood of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 to result in adverse environmental effects on the biodiversity and human health is negligible compared to the impact of conventional maize grain imported for direct use in food, feed or processing.

(iii). Evaluation of the consequences should [these] adverse effects be realized

As noted above in Section j(i), no potentially adverse effects were detected based on extensive characterization of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, which included molecular, protein, compositional analyses and phenotypic evaluations conducted in field trials over a wide range of environmental conditions. As such, the potential consequences to biodiversity in the EU resulting from importation of maize grain containing MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 for direct use in food, feed or processing are the same as with conventional maize.

(iv). Estimation of overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized

The overall estimated risk posed by the importation of maize grain containing MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 for direct use in food, feed, or for processing is negligible. This conclusion is based on: a) the history of safe use of the host plant, maize, b) the extensive characterization of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 compared to conventionally bred maize including, phenotypic, compositional, and nutritional equivalence, c) the extensive characterization of the expressed CP4 EPSPS, CspB, NptII, Cry1A.105, Cry2Ab2, Cry1F, PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and DvSnf7 dsRNA, and d) the fact that, based on a combination of the history of experience with importing maize and the characteristics of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, there are no unique environmental conditions that would meaningfully change the environmental characteristics of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 compared to conventional maize.

(v). Recommendation whether the risks are acceptable or manageable; including where necessary, identification of strategies to manage these risks

Analysis of the characteristics of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 did not reveal any potential for adverse effects to human and animal health or the environment. Therefore, there are no unacceptable environmental or human health risks associated with the importation of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 for direct use as food or feed, or for processing. As the environmental and health risks of this maize are consistently negligible and no different than conventional maize, no specific strategies for risk management are required.

(vi). Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring [of] the living modified organism in the receiving environment

The above risk assessment for MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 was undertaken in accordance with the general principles and methodology laid out in the Cartagena Protocol on Biosafety and in the context of the scope of trans-boundary movement for direct use as food or feed, or for processing.

Results from the risk assessment for MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 support a conclusion that the import, processing and all uses as any other maize, but excluding the cultivation of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 in the EU 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 longterm adverse effects is also negligible.

k) Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate

In countries where planting of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 will be authorised, appropriate and comprehensive information will be provided on seed bags and in accompanying documents in order for purchasers to be fully informed about the use of this maize.

Transboundary shipments of commodity maize which "may contain" MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 will clearly be identified as such and will bear an indication that the LMO is not intended for intentional introduction into the environment. A contact point for further information will be added to the documentation accompanying this LMO in accordance with Art.18(2)(a) of the Cartagena Protocol on Biosafety.

Except for the traits providing herbicide tolerance, drought tolerance and insect protection, MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is not different from other conventional maize varieties, and therefore grain, foods and feeds produced from MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 will be stored, packaged, transported, used and handled in the same manner as the current commercial maize varieties, and the measures for waste disposal and treatment of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 products will be the same as those for conventional maize.

In the highly unlikely event of establishment of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 in the environment, volunteer plants could be easily controlled by currently available herbicides (except glyphosate and glufosinate based herbicides), cultural or mechanical means. Therefore, no specific measures are recommended or required in case of unintended release (spillage or other means) of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122.

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