Application for authorization to place on the market MON 87411 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part VII

Summary

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

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

The Netherlands

(b) Application number

EFSA-GMO-NL-2015-124

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

The Monsanto development code for this genetically modified maize is MON 87411. 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 submission

1.2. Applicant

(a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

(b) Address of applicant

Monsanto Europe S.A.
Avenue de Tervuren 270-272
B-1150 Brussels
BELGIUM

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

(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) GM food

- ☑ Food containing or consisting of GM plants
- ☑ Food produced from GM plants or containing ingredients produced from GM plants

(b) GM feed

- ☑ Feed containing or consisting of GM plants
- ☑ Feed produced from GM plants

(c) GM plants for food or feed use

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

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 GM 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 protein expression, the composition, the safety and the agronomic and phenotypic characteristics of MON 87411 have been studied at multiple locations in Argentina that cover a range of environmental conditions. The risk assessment presented in the MON 87411 application includes data collected from these field trials. A summary of the conclusions of the risk analysis that demonstrate the safety of MON 87411 to humans, animals and to the environment has been presented in the respective sections throughout this summary.

1.6. Has the GM 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 and provide a copy of the risk assessment conclusions, the date of the authorisation and the scope)

Regulatory submissions have been made in Argentian, Canada, U.S., Japan, Korea, Taiwan and Australia. The risk assessment conclusions are comparable to the conclusion in the current application.

Regulatory submissions will also be made to countries that import significant quantities of maize or food and feed products derived from maize and have functional regulatory review processes in place. Also, as appropriate, notifications will be made to countries that import significant quantities of maize and maize products and do not have a formal regulatory review process for biotechnology derived crops.

No approval from these agencies has been obtained yet.

1.8. General description of the product

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

MON 87411, developed through *Agrobacterium*-mediated transformation of maize, contains the DvSnf7 suppression cassette, the *cry3Bb1* expression cassette, and the *cp4 epsps* expression cassette. MON 87411 is protected against corn rootworm (*Diabrotica* spp.) and is tolerant to glyphosate. These proteins are identical to the respective proteins produced in commercial MON 88017 maize crop products.

(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 (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for

The scope of the current application is for authorization of MON 87411 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 of this maize will be identical to the full range of equivalent uses of conventional maize.

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

MON 87411 maize 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/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

MON 87411 is not different from conventional maize, except for its protection against corn rootworm (*Diabrotica* spp.) and glyphosate tolerance, which are traits of agronomic interest. MON 87411 was shown to be as safe and nutritious as conventional maize. Therefore MON 87411 and derived products will be stored, packaged, transported, handeled and used in the same manner as curent commercial maize. No specific instructions and/or recommendations are considered necessary for the placing on the market of MON 87411 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 EU to which the product is intended to be confined under the terms of the authorisation applied for

MON 87411 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 87411, as any other maize but excluding cultivation.

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

. The scope of this application covers the import, processing and all uses of MON 87411, as any other maize but excluding cultivation. MON 87411 is suitable for the described uses throughout the EU as any other maize.

(g) Any proposed packaging requirements

MON 87411 is not different from conventional maize, except for its protection against corn rootworm (*Diabrotica* spp.) and glyphosate tolerance which are traits of agronomic interest. Therefore, MON 87411 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 law and when necessary a proposal for specific labelling in accordance with Articles 13(2), (3) and 25(2)(c), (d) and 25(3) of Regulation (EC) No 1829/2003. In the case of GMO plants, food and/or feed containing or consisting of GMO plants, a proposal for labelling has to be included complying with the requirements of Annex IV, A(8) of Directive 2001/18/EC.

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, the current labelling threshold of 0.9% will continue to be applied for the marketing of MON 87411 and derived products.

Operators shall be required to label products containing or consisting of MON 87411 with the words "genetically modified maize" or "contains genetically modified maize" and shall continue to declare the unique identifier MON-87411-9 in the list of GMOs that have been used to constitute a mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 87411 with the words "produced from genetically modified maize". In the case of products for which no list of ingredients exists, operators shall continue to ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using MON 87411 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 authorized foods and feeds shall be entered in the EU Register of authorised GMOs, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 87411. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In 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.

The EU production of maize increased with the accession of new member states (Hungary and Romania) allowing the EU to become largely self sufficient for maize production. In 2013 the EU produced 64,190 Metric tones. Annual fluctuations in production are conducive to imports to cover deficit.

(ii) In export markets for EU supplies

Maize is grown in nearly all areas of the globe, and is the second largest cultivated crop in the in total global metric ton production. The top maize grain producers were the United States, China, Brazil, and the EU, accounting for 71% of average annual global maize production. Maize production trended upwards from 825 MMT in 2009 to over 960 MMT in 2013. In 2013, the top maize grain exporters were theU.S., Brazil, Ukraine and Argentina. Together, these countries accounted for approximately 82% of average annual exports. The major exporter of maize to the EU were Ukraine and Brazil, followed by Russia.

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

MON-87411-9

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

Because this application is for consent to import, process and all uses of MON 87411 as any other maize, but excluding the cultivation of varieties of MON 87411 in the EU, the

only potential means of environmental release would be more likely to occur during import, storage and processing of MON 87411. However, modern methods of maize handling minimize losses of seed, so there is little chance of germination of spilt maize resulting in the development of mature MON 87411 plants 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. The poor ability of maize to survive outside agricultural environments results from selection over many centuries of cultivation. Volunteer maize is not found growing in fencerows, ditches, and roadsides. Seeds are the only survival structures of maize and natural regeneration from vegetative tissue is not known to occur. MON 87411 is shown not to be different from conventional maize, except for its protection against corn rootworm (*Diabrotica* spp.) and glyphosate tolerance which are traits of agronomic interest. Therefore, MON 87411 is unlikely to pose any threat to the EU environment or to require special measures for its containment. Furthermore, maize volunteers can be easily controlled using currently available herbicides (not solely based on glyphosate) or by mechanical means. Therefore, no specific conditions are warranted or required for the placing on the market of MON 87411 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. Complete name

(a) Family name
Gramineae

(b) Genus
Zea

(c) Species
mays (2n = 20)

(d) Subspecies
Not applicable

(e) Cultivar/breeding line or strain
LH244

(f) Common name
Maize / Corn

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

The domestication of maize likely occurred in southern Mexico between 7,000 and 10,000 years ago. While the putative parents of maize have not been recovered, it is likely that teosinte played an important role in contributing to the genetic background of maize. 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. Today, maize is produced on every continent except Antarctica. 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. There are no compatible wild relatives of maize in Europe. 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. Pollination occurs with the transfer of pollen from the tassels to the silks of the ear. About 95% of the ovules are cross-pollinated and about 5% are self-pollinated, although plants are completely self-compatible. Individual maize kernels, or fruit, are unique in that mature seed is not covered by floral bracts as in most other grasses, but rather the entire structure is enclosed and protected by large modified leaf bracts, collectively referred to as the ear.

(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. Based on several studies conducted on the extent of pollen mediated gene flow between maize fields, results were found to vary depending on the experimental design, environmental conditions, and detection method, as expected. In general, the percent of gene flow diminished with increasing distance from the source field, generally falling below 1% at distances >200 m. This information is useful for managing gene flow during maize breeding, seed production, identity preservation or other applications.

Potential for cross-pollination with wilde 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. In an experimental field study where maize and teosinte species were planted together, very low hybridization rates were observed for maize and *Zea mays* subsp. *mexicana*. There are no compatible wild relatives of maize in Europe.

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

As maize is the product of domestication it does not have a natural habitat. Maize's closest wild relative, teosinte, is native to Mexico and Central America. Teosinte tends to thrive in areas that are seasonally dry and receive summer rain. During domestication of maize, traits often associated with weediness, such as, seed dormancy, a seed dispersal mechanism, or the ability to form reproducing populations outside of cultivation, have not been selected. Even if individual kernels of maize were distributed within a field or along transportation routes from the fields to storage or processing facilities, sustainable volunteer maize populations are not found growing in fence rows, ditches, or road sides. Maize is poorly suited to survive without human assistance and is not capable of surviving as a weed.

Pollination occurs with the transfer of pollen from the tassels to the silks of the ear. About 95% of the ovules are cross-pollinated and about 5% are self-pollinated, although plants are completely self-compatible. 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 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 species of cultivated maize present in Europe.

2.8. In the case of plant species not normally grown in the Member State(s), 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 GM 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)

As maize is the product of domestication it does not have a natural habitat. Maize's closest wild relative, teosinte, is native to Mexico and Central America. Maize is the target of a variety of microbial pathogens and insect pests. Rusts, smuts, leaf blights, and stalk rots are among the more common diseases of microbial origin. Fungi such as *Aspergillus* sp. and *FU.S.rium* sp. produce mycotoxins that can adversely impact humans and livestock that consume contaminated grain. Insect damage and abiotic stresses such as drought can exacerbate fungal infections. The primary insect pests of maize belong to the orders Lepidoptera and Coleoptera. Lepidopterans feed on leaves and stalks as larvae and ears as adults. Coleopterans feed on roots and stalks as larvae and silks, pollen, and leaves as adults.

A thorough description of the anti-nutrients present in maize has been presented in an OECD consensus document. These anti-nutrients include phytic acid, 2,4-dihydroxy-7-methoxy-2*H*-1,4-benzoxazin-3-(4*H*)-one (DIMBOA), raffinose, and low levels of trypsin and chymotrypsin inhibitors. Trypsin and chymotrypsin inhibitors occur at low levels in maize and are not considered nutritionally significant for human health. Phytic acid is considered an important anti-nutrient for animals, especially nonruminants, since it reduces the bioavailability of phosphorus in maize tissues to levels below 15%. Raffinose is a low molecular weight carbohydrate present in maize grain that is considered an anti-nutrient due to the gas production and resulting flatulence caused by consumption.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

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

MON 87411 was developed through *Agrobacterium*-mediated transformation of maize, using transformation plasmid vector PV-ZMIR10871.

(b) Nature and source of the vector used

PV-ZMIR10871 was used in the transformation of maize to produce MON 87411. PV-ZMIR10871 contains one T-DNA that is delineated by Left and Right Border regions. The T-DNA contains the DvSnf7 suppression cassette, the *cry3Bb1* expression cassette, and the *cp4 epsps* expression cassette. The backbone region of PV-ZMIR10871, located outside of the T-DNA, contains two origins of replication for maintenance of the plasmid vector in bacteria (*ori V*, *ori-pBR322*), a bacterial selectable marker gene (*aadA*), and a coding sequence for repressor of primer (ROP) protein for maintenance of plasmid vector copy number in *Escherichia coli* (*E. coli*).

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

PV-ZMIR10871 contains one T-DNA intended for insertion into the maize genome that is delineated by Left and Right Border regions. The T-DNA contains the DvSnf7 suppression cassette, the *cry3Bb1* expression cassette, and the *cp4 epsps* expression cassette. The genetic elements of the transformation plasmid are summarized in Table 1.

Table 1. Summary of Genetic Elements in PV-ZMIR10871

Genetic Element	~ Size (kb)	Function (Reference)
T-DNA		
B[1]-Left Border Region	400	DNA region from *Agrobacterium tumefaciens* containing the left border sequence used for transfer of the T-DNA
T[2]-*E9*	600	3′ UTR of the *rbcS* gene family from *Pisum sativum* (pea) encoding the small subunit of ribulose bisphosphate carboxylase protein that directs polyadenylation of the mRNA
DvSnf7[p]	200	Partial coding sequence of the *Snf7* gene designed to match that from *Diabrotica virgifera virgifera* encoding the SNF7 subunit of the ESCRT-III complex that forms part of the suppression cassette
DvSnf7[p]	200	Partial coding sequence of the *Snf7* gene designed to match that from *Diabrotica virgifera virgifera* encoding the SNF7 subunit of the ESCRT-III complex that forms part of the suppression cassette
I[3]-*Hsp70*	900	Intron and flanking exon sequence of the *hsp70* gene from *Zea mays* (maize) encoding the heat shock protein 70 (HSP70) that is involved in regulating gene expression
P[4]-*e35S*	600	Promoter from the *35S* RNA of cauliflower mosaic virus (CaMV) containing the duplicated enhancer region that directs transcription in plant cells
P-*pIIG*	900	Promoter sequence of the *pIIG* gene encoding the physical impedance induced protein from *Zea mays* (maize) that directs transcription in plant cells
L[5]-*Cab*	100	5' UTR leader sequence from chlorophyll a/b-binding (CAB) protein of *Triticum aestivum* (wheat) that is involved in regulating gene expression
I-*Ract1*	500	Intron and flanking UTR sequence of the *act1* gene from *Oryza sativa* (rice) encoding rice Actin 1 protein is involved in regulating gene expression
CS[6]-*cry3Bb1*	2000	Codon optimized coding sequence from Cry3Bb1 protein of *Bacillus thuringiensis* that provides insect resistance
T-*Hsp17*	200	3' UTR sequence from a heat shock protein, Hsp17, of *Triticum aestivum* (wheat) that directs polyadenylation of the mRNA
P-*TubA*	2200	Promoter, 5′UTR leader and intron sequences of the *OsTubA* gene family from *Oryza sativa* (rice) encoding α-tubulin that directs transcription in plant cells
TS[7]-*CTP2*	200	Targeting sequence of the *ShkG* gene from *Arabidopsis thaliana* encoding the EPSPS transit peptide region that directs transport of the protein to the chloroplast
CS-*cp4 epsps*	1300	Coding sequence of the *aroA* gene from *Agrobacterium* sp. strain CP4 encoding the CP4 EPSPS protein that provides herbicide tolerance

T-*TubA*	600	3' UTR sequence of the *OsTubA* gene family from *Oryza sativa* (rice) encoding α-tubulin that directs polyadenylation of mRNA
B-Right Border Region	300	DNA region from *Agrobacterium tumefaciens* containing the right border sequence used for transfer of the T-DNA
Vector Backbone		
aadA	900	Bacterial promoter, coding sequence, and 3' UTR for an aminoglycoside-modifying enzyme, 3"(9)-*O*-nucleotidyltransferase from the transposon Tn*7* that confers spectinomycin and streptomycin resistance
OR[8]-*ori-pBR322*	600	Origin of replication from plasmid pBR322 for maintenance of plasmid in *E. coli*
CS-*rop*	200	Coding sequence for repressor of primer protein from the ColE1 plasmid for maintenance of plasmid copy number in *E. coli*
OR-*ori V*	400	Origin of replication from the broad host range plasmid RK2 for maintenance of plasmid in *Agrobacterium*

[1] B, Border
[2] T, Transcription Termination Sequence
[3] I, Intron
[4] P, Promoter
[5] L, Leader
[6] CS, Coding Sequence
[7] TS, Targeting Sequence
[8] OR, Origin of Replication
[p] Superscript in DvSnf7 indicates the partial sequence.

3.2. Information relating to the GM plant

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

MON 87411 contains the DvSnf7 suppression cassette, the *cry3Bb1* expression cassette, and the *cp4 epsps* expression cassette. The DvSnf7 suppression cassette expresses an inverted repeat sequence designed to match the sequence in western corn rootworm (WCR: *Diabrotica virgifera virgifera*) and thereby utilizes the RNAi pathway to control corn rootworm (CRW, *Diabrotica* spp.). MON 87411 also contains a *cry3Bb1* gene that produces a modified *Bacillus thuringiensis* (subsp. *kumamotoensis*) Cry3Bb1 protein to protect against CRW larval feeding. In addition, MON 87411 contains the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 that encodes the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein, which confers tolerance to glyphosate.

3.2.2. *Information on the sequences actually inserted or deleted*

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

MON 87411 contains one DNA insert integrated into a single locus. Additionally, no backbone sequences from PV-ZMIR10871 are present in MON 87411.

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

No deletion of maize genomic DNA was intended. However, 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 87411 indicates there was a 118 base pair deletion that occurred during integration of the T-DNA. Such changes

are common during plant transformation and these changes presumably resulted from double-stranded break repair mechanisms in the plant during the *Agrobacterium*-mediated transformation process.

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

The presence of MON 87411 insert in the nuclear genome is best shown by the Chi square analysis of the segregation results. The Chi square 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

Molecular characterization of MON 87411 confirmed the organization and intactness of the full T-DNA and all expected elements within the insert, with the exception of incomplete Right and Left Border sequences that do not affect the functionality of the DvSnf7 suppression cassette, the *cry3Bb1* expression cassette, and the *cp4 epsps* expression cassette.

(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

Tissue samples from MON 87411 were harvested from five field sites, four replicated plots, in Argentina during 2011 – 2012.

The mean DvSnf7 RNA level in untreated MON 87411 across all sites was 2.64×10^{-3} µg/g fw in forage and 0.162×10^{-3} µg/g fw in grain. The mean DvSnf7 RNA level in glyphosate-treated MON 87411 across all sites was 1.28×10^{-3} µg/g fw in forage and 0.091×10^{-3} µg/g fw in grain.

The mean Cry3Bb1 protein level in glyphosate-treated MON 87411 across all sites was 12 µg/g fw in forage and 3.5 µg/g fw in grain. The mean CP4 EPSPS protein level in glyphosate-treated MON 87411 across all sites was 2.4 µg/g fw in forage and 1.7 µg/g fw in grain.

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

In terms of food and feed safety assessment of MON 87411, grain and forage are the most relevant tissues.

3.2.4. *Genetic stability of the insert and phenotypic stability of the GM plant*

MON 87411 contains a single copy of the T-DNA sequence and was integrated into a single chromosomal locus of the maize genome. The inserted DNA is inherited in a Mendelian fashion and is stably maintained through multiple generations of breeding.

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

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

Phenotypic and agronomic characterization as well as environmental interaction data were collected from eight sites at field trials in major maize-growing areas of

Argentina during the 2011/2012 field season. Randomized complete block design with four replicates at each field site was used. In each of the assessments MON 87411 was compared to an appropriate conventional counterpart (control) which has a genetic background similar to MON 87411 but does not possess the DvSnf7 suppression cassette, the *cry3Bb1* expression cassette, and the *cp4 epsps* expression cassette. In addition, multiple conventional reference varieties were included to provide a range of comparative values that are representative of existing conventional varieties for each measured phenotypic, agronomic and environmental interaction characteristic.

Results of this field study demonstrate that the assessed characteristics of MON 87411 were within the range expected for maize. The statistical analyses of the field evaluations support a conclusion of no unexpected changes in the phenotype indicative of increased plant weed/pest potential of MON 87411 compared to the conventional maize counterpart.

Based on the study described above, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in MON 87411 and that MON 87411 is similar to the conventional counterpart in its phenotypic and agronomic behaviour, except for protection against corn rootworm (*Diabrotica* spp.) and glyphosate tolerance, which are traits of agronomic interest.

(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 GM plant to transfer genetic material to other organisms (for environmental safety aspects)*

(a) Plant to bacteria gene transfer

None of the genetic elements inserted in MON 87411 has a genetic transfer function. Therefore, no changes are expected in the ability of this maize line 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 87411 varieties in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

MON 87411 was compared to NL6169, a conventional counterpart with background genetics similar to MON 87411, as well as with other conventional maize varieties.

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

MON 87411 maize and the appropriate conventional counterpart (control) were grown at eight field sites in during the 2011/2012 field season in Argentina. Additionally, conventional reference varieties were included at each field sites to provide reference substances representative for their respective growing regions. At each field site, the test, the conventional counterpart and reference seeds were planted in a randomized complete block design with four replicates per block. Field sites were representative of commercial maize growing areas and were distributed to reflect a variety of agronomic practices, soils and climatic factors. Analyses of variance (ANOVA) were conducted to statistically analyse the data in each study (compositional, agronomic and phenotypic) according to a randomized complete block design in a combined-site analysis in which the data was pooled across all sites. Difference and equivalence tests were conducted using statistical models consistent with EFSA guidance for risk assessment of food and feed from genetically modified plants and according to the EFSA Scientific Opinion on Statistical considerations for the safety evaluation of GMOs.

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.

4.4. Comparative analysis of agronomic and phenotypic characteristics

An assessment of the phenotypic, agronomic and environmental interactions of MON 87411 compared to conventional maize has been performed in the field. It was guided by the OECD concept of familiarity by scientists who are familiar with the production and evaluation of maize. The results of this field study demonstrated that there are no unexpected changes in the phenotype or ecological interactions indicative of increased plant weed or pest potential of MON 87411 compared to the conventional counterpart (*see* also Section 3.2.5).

4.5. Effect of processing

MON 87411 is substantially equivalent and as safe and as nutritious as conventional maize; therefore, the use of MON 87411 for the production of foods and feeds is no different from that of conventional maize. Consequently, any effects of the production and processing of MON 87411 are not expected to be any different from the production and processing of the equivalent foods and feeds, originating from conventional maize.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

The *cry3Bb1* and *cp4 epsps* genes are the only genes expressing novel proteins in MON 87411. With respect to the DvSnf7 suppression cassette, there is no evidence to suggest dietary consumption of RNA is associated with mammalian toxicity or allergenicity. Based on the ubiquitous nature of the RNA-based suppression mechanism utilizing dsRNA (named RNA interference or RNAi), the history of safe consumption of RNA and the apparent lack of proteins produced from the DvSnf7 suppression cassette, the RNA-based suppression technology used in MON 87411 poses no novel risks from a food or feed perspective Therefore, the safety assessment

of the newly expressed proteins is focused on the MON 87411 Cry3Bb1 and CP4 EPSPS proteins expressed in MON 87411.

The assessment of the potential toxicity of an introduced protein is based on comparing the biochemical characteristics of the introduced protein to characteristics of known toxins, based on the premise that a protein is not likely to have a toxic effect if:

- The protein has a demonstrated history of safe use;
- 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.

The Cry3Bb1 and CP4 EPSPS proteins have a substantial history of safe use. Moreover, they have been found to pose negligible risk to human and animal health upon consumption in foods and feeds derived from MON 88017 maize, that was reviewed and approved by regulatory agencies around the world, including the EFSA.

No relevant sequence similarities between the Cry3Bb1 and CP4 EPSPS proteins and any known toxins or other biologically active proteins with adverse effects was found. Finally, rapid degradation of both proteins was demonstrated in simulated gastric fluid analysis. Based on the available weight of evidence, it is possible to conclude that the Cry3Bb1 and CP4 EPSPS proteins are safe and pose no concerns for human and animal health.

(b) Testing of new constituents other than proteins

Maize has a long history of safe use and consumption around the world. MON 87411 has been shown to be compositionally equivalent to conventional maize. Therefore, no testing of any constituent other than the newly expressed proteins is required.

(c) Information on natural food and feed constituents

Maize is known to contain a number of natural anti-nutritional analytes, such as phytic acid and raffinose. These anti-nutrients were evaluated in MON 87411 compositional analyses and their levels were demonstrated to be comparable in MON 87411 and in conventional maize. Therefore the levels of food and feed constituents in MON 87411 have not been altered.

(d) Testing of the whole GM food/feed

The safety assessment demonstrated that MON 87411 is as safe as conventional maize for food and feed use through the compositional assessment of MON 87411. In addition, the safety for humans and animals of the newly expressed Cry3Bb1 and CP4 EPSPS proteins has been demonstrated on the basis of extensive characterization, history of safe use, lack of structural similarities with known protein toxins and allergens and rapid digestion in simulated digestive fluids. Also, the Cry3Bb1 and CP4 EPSPS proteins have no synergistic or antagonistic effects to each other. Taken together there is no evidence of any adverse effects of the Cry3Bb1 and CP4 EPSPS proteins to human or animal health.

Based on this weight of evidence, no more data are required to demonstrate that MON 87411 is as safe as conventional maize from a food and feed perspective. Nonetheless, inspite not being scientifically justified, but requested in accordance with Commission Implementing Regulation (EU) No 503/2013, a 90-day feeding

study in rats with ground maize grain from MON 87411 was performed. The study supports the conclusion that MON 87411 is as safe as conventional maize from a food and feed perspective.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The *cry3Bb1* and *cp4 epsps* genes are the only genes expressing new proteins in MON 87411. With respect to the DvSnf7 suppression cassette, there is no evidence to suggest dietary consumption of RNA is associated with mammalian toxicity or allergenicity. Based on the ubiquitous nature of the RNA-based suppression mechanism utilizing dsRNA, the history of safe consumption of RNA and the apparent lack of proteins produced from the DvSnf7 suppression cassette, the RNA-based suppression technology used in MON 87411 poses no novel risks from a food or feed perspective. Therefore, the safety assessment of the newly expressed proteins is focused on the MON 87411 Cry3Bb1 and CP4 EPSPS proteins expressed in MON 87411.

The allergenic potential of a novel protein is assessed by comparing the characteristics of the novel protein to characteristics of known allergens. A protein is not likely to be associated with allergenicity if:

- the protein is from a non-allergenic source;
- the protein does not share structural similarities with known allergens based on the amino acid sequence;
- the protein is rapidly digested by pepsin, a key enzyme in the mammalian gastrointestinal system.

Maize is not a common allergenic food. Bioinformatic analyses demonstrated the absence of any immunologically relevant amino acid sequence similarities with known allergens and adjuvants. Moreover, rapid digestion of the proteins was shown in digestive fate assays.

The Cry3Bb1 and CP4 EPSPS proteins expressed in MON 87411 have a substantial history of safe use, and are identical to to the Cry3Bb1 and CP4 EPSPS expressed proteins in commercially approved MON 88017 maize that has already been assessed by EFSA. Based on the available weight of evidence, it can be concluded that the allergenic potential of the Cry3Bb1 and CP4 EPSPS proteins is negligible and therefore, the proteins do not pose a significant allergenic risk.

(b) Assessment of allergenicity of the whole GM 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 87411 is comparable to and as safe as conventional maize. Further, as the introduced proteins in MON 87411 do not have any allergenic potential, it was concluded that the use of MON 87411 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 GM food

The introduced traits in MON 87411 are of agronomic interest and are not intended to change any nutritional aspect of this maize. The presence of these traits in MON 87411 is not expected to alter patterns or volumes of maize consumption.

MON 87411 was shown to have comparable nutritional characteristics to the conventional counterpart, as well as to conventional reference varieties, and does not express any traits resulting in improved nutrition. Hence this maize is not expected to be more or less attractive for use as food (or feed), for processing, or as a food (or feed) ingredient. Therefore, the anticipated dietary intake of maize-derived foods (and feeds) is not expected to be altered, and no nutritional imbalances are expected as a result of the presence of MON 87411 in the maize supply.

(b) Nutritional assessment of GM feed

See section 7(a).

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

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 87411 to the maize supply. MON 87411 is not expected to affect current U.S.ge patterms of maize, but to replace a portion of the commodity grain from current maize varieties such that their intake or use will represent some fraction of the total products derived from maize.

9. RISK CHARACTERISATION FOR THE SAFETY ASSESSMENT OF GM FOOD AND FEED

Based on the information provided in this application, it can be concluded that MON 87411 is as safe as conventional maize. The assessment of the human and animal safety of MON 87411 was conducted on the basis of no biological difference to conventional maize (except for the inserted traits), the long history of safe consumption of RNA molecules independent of their sequence and the extensive characterisation of the newly expressed proteins. 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 87411. The consumption of food and feed derived from MON 87411 is as safe as the consumption of that of the conventional couterpart. It can be concluded that the food derived from MON 87411 is not nutritionally disadvantageous for the consumer compared to the food which is intended to replace. It can also be concluded that the feed derived from MON 87411 does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed. Finally, it is unlikely that MON 87411 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.

10. POST-MARKET MONITORING ON GM FOOD/FEED

As demonstrated in this application, there are no intrinsic hazards related to MON 87411. No data have emerged to indicate that MON 87411 is less safe than its conventional counterpart. The pre-market risk characterisation for food and feed use of MON 87411

demonstrates that the risks of consumption of MON 87411 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 GM plant and target organisms

According to the EFSA ERA Guidance, the primary focus for the assessment on target organisms is the development of resistance to the insect or pathogen tolerance traits expressed by the GM plant. The scope of this application covers the import, processing and all uses as any other maize, but excludes the cultivation of MON 87411 in the EU. Therefore, the likelihood is negligible that the import of MON 87411 will result in plants of this maize being present in the environment, and the potential for interactions between MON 87411 and its target organisms is, therefore, considered to be minimal if existing at all. As a consequence, an assessment of the potential resistance development in target organisms resulting from import, processing and all uses as any other maize, but excluding the cultivation of MON 87411 in the EU is not relevant for this submission.

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

(a) Persistence and invasiveness

Results from the assessment support a conclusion that the abilities of MON 87411 to persist in agricultural fields or invade non-agricultural habitats are comparable to those of conventional maize in the EU. Thus, MON 87411 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. Given the negligible hazard and the low levels of environmental exposure that could arise from the import, processing and all uses as any other maize of this product and the fact that any exposure would be limited spatially and temporally, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

(b) Selective advantage or disadvantage

Compared with conventional commercial maize, the introduced insect-protection and glyphosate-tolerance traits confer a selective advantage only under specific conditions (*i.e.* upon attack by the target insects, or by spraying glyphosate-containing herbicides, respectively), which are short in duration. The advantage is purely of agronomic interest and presents negligible risk to non-agricultural environments, because of the poor survival characteristics of maize under most European conditions. Therefore, it is concluded that the potential hazard is negligible.

(c) Potential for gene transfer

The scope of this application covers the import, processing and all uses as any other maize, but excluding the cultivation of MON 87411 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 87411 with the biotic environment will be limited. The exposure of micro-organisms that could lead to horizontal gene transfer (HGT) of the

DvSnf7 suppression cassette or the *cry3Bb1* and *cp4 epsps* expression cassettes from MON 87411 is negligible. Moreover, there is a lack of adverse consequences if it were to occur. In conclusion, the import, processing and all uses of MON 87411 as any other maize in the EU is not likely to adversely impact human, animal, or environmental health, and poses negligible risk. Considering negligible exposure and lack of hazard from horizontal gene transfer of the DvSnf7 suppression cassette or the *cry3Bb1* and *cp4 epsps* expression cassettes from MON 87411 to micro-organisms, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

(d) Interactions between the GM plant and target organisms

The scope of this application covers the import, processing and all uses as any other maize, but excluding the cultivation of MON 87411 in the EU, no deliberate release of viable plant material in the EU environment is expected. Therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and all uses as any other maize, but excluding the cultivation of MON 87411 in the EU is not relevant for this application.

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

The scope of this application covers the import, processing and all uses as any other maize, but excluding the cultivation of MON 87411 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87411 with the biotic environment will be very limited. Importantly, Cry3Bb1 and CP4 EPSPS can be inactivated in the digestive tract of animals thereby limiting any exposure via faeces of animals fed processed or unprocessed grain of MON 87411. Given the low levels of environmental exposure combined with low hazard from exposure to MON 87411 to 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 87411 is negligible. Considering low exposure and hazard from MON 87411 to NTOs, there is a low level of uncertainties associated with the conclusion of this NTO risk assessment and therefore the probability of long-term adverse environmental effects on NTOs is negligible.

(f) Effects on human health

The likelihood for any adverse effects occurring in humans and animals as a result of their contact with this maize is no different from that of conventional maize, as MON 87411 expresses the DvSnf7 dsRNA, Cry3Bb1 and CP4 EPSPS proteins, which have negligible potential to cause any toxic or allergenic effects in humans or animals. Therefore, the risk of changes in the occupational health aspects of this maize is negligible.

(g) Effects on animal health

See section 11.2(f).

(h) Effects on biogeochemical processes

The scope of this application covers the import, processing, and all uses as any other maize, but excluding the cultivation of MON 87411 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 87411 with the biotic environment will be very limited. The expression levels of DvSnf7 dsRNA, Cry3Bb1 and CP4 EPSPS proteins are very low. Importantly, Cry3Bb1 and CP4 EPSPS proteins are heat inactivated during

processing for feed, and Cry3Bb1 and CP4 EPSPS proteins can also be inactivated in the digestive tract of animals thereby limiting any exposure via faeces of animals fed processed or unprocessed seed of MON 87411.

Given the low level of environmental exposure combined with a lack of hazard, the import, processing and all uses of MON 87411 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. Considering the low exposure and hazard from MON 87411 to soil micro-organisms, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

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

The scope of this application covers the import, processing and all uses as any other maize, but excluding the cultivation of MON 87411 in the EU, and no deliberate release of viable plant material in the EU environment is expected. Therefore an assessment of the impacts of specific cultivation, management and harvesting techniques is not relevant.

11.3. Potential interactions with the abiotic environment

Overall results of the comparative analysis of MON 87411 with respect to its conventional counterpart indicate that observed differences in composition and agronomic and phenotypic characteristics fell within the range of natural variability for maize with a history of safe use. Therefore, there is no evidence that this maize would be any different from conventional maize with regard to its baseline interactions with the abiotic environment. In addition, because this application is for import, processing and all uses as any maize, but excluding cultivation of MON 87411 in the EU, interactions of MON 87411 with the environment will be limited. Moreover, no negative impact of MON 87411 is expected to result from the import, processing and all uses as any other maize in the EU.

11.4. Risk characterisation for the environmental risk assessment

Results from the environmental risk assessment which takes into consideration risk characterization and includes results described above addressing risk hypotheses for the specific areas of assessment laid down in the 2010 EFSA guidance on environmental risk assessment of genetically modified plants, support a conclusion that the import, processing and all uses as any other maize, but excluding the cultivation of MON 87411 in the EU represents negligible risk to human and animal health and the environment, and poses no greater risk than the import, processing and all uses 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 monitoring plan for MON 87411 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 monitoring plan also takes into account the EFSA Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants.

(b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MON 87411 for import, processing and all uses as any other maize in the EU under Regulation (EC) No 1829/2003. The scope of the application does not include authorisation for the cultivation of MON 87411 seed products in the EU.

An environmental risk assessment (ERA) was carried out for MON 87411 according to the principles laid down in Annex II to Directive 2001/18/EC, Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC and the EFSA guidance on the environmental risk assessment of genetically modified plants. The scientific evaluation of the characteristics of MON 87411 in the ERA 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 87411 relative to:

- Persistence and invasiveness including plant-to-pant gene flow
- Plant to micro-organims gene transfer
- Interactions of the GM plant with target organisms
- Interactions of the GM plant with non-target organisms (NTOs)
- Impacts of the specific cultivation, management and harvesting techniques
- Effects on biogeochemical processes
- Effects on human and animal health

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

The scientific evaluation of the characteristics of MON 87411 in the ERA 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 87411. It is therefore considered that there is no need for case-specific monitoring.

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

Any potential adverse effects of MON 87411 on human health and the environment, which were not anticipated in the ERA, 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 genetically modified (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 87411 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 this maize in the EU, the consent holder will approach key stakeholders and key networks of stakeholders of the product (including international grain traders, maize processors and users of maize grain for animal feed) and inform

them that the product has 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 this 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 their use of this 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 this product. Appropriate technical information on MON 87411 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 87411 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 87411 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 observed 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 any unanticipated adverse effects that have arisen from handling and use of viable MON 87411.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MON 87411 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 to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30.

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

The presence of the DvSnf7 suppression cassette and the *cry3Bb1* and *cp4 epsps* genes as well as the DvSnf7 dsRNA and the Cry3Bb1 and CP4 EPSPS proteins can be identified by employing different techniques. PCR can identify the inserted nucleotide sequence and

the DvSnf7 dsRNA, while the Cry3Bb1 and CP4 EPSPS proteins can be detected, by optimised tissue extraction, standardised electrophoretic blotting and immunodetection methodologies.

A MON 87411-specific PCR-based assay allowing the identification and quantification of MON 87411 has been provided to the Joint Research Centre (JRC)[1], acting as the European Union Reference Laboratory for GM Food and Feed (EU-RL-GMFF).

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

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

(a) Notification number

There is no history of field release of MON 87411 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 GM plant carried out outside the Union by the same notifier

(a) Release country

MON 87411 has been field tested in Argentina, Brazil, Canada, Chile, Japan and the U.S since 2010.

(b) Authority overseeing the release

Argentina National Advisory Commission on Agricultural Biotechnology (CONABIA)
Brazil: Coordenação-Geral da Comissão Técnica Nacional de Biossegurança (CTNBio)
Canada: Canadian Food Inspection Agency (CFIA)
Chile: Servicio Agricola y Ganadero (SAG)
Japan: Ministry of Agriculture, Forestry and Fisheries (MAFF) and Ministry of the Environment (MOE)
U.S.: United States Department of Agriculture (USDA)

(c) Release site

In major maize growing regions of the respective countries.

(d) Aim of the release

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

(e) Duration of the release

One growing season

[1] Joint Research Centre, European Union Reference Laboratory for GM Food and Feed; http://gmo-crl.jrc.ec.europa.eu/; Accessed on 28 November 2014.

(f) Aim of post-releases monitoring

Assessment of volunteers.

(g) Duration of post-releases monitoring

12 months

(h) Conclusions of post-release monitoring

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 in respect to any risk to human health and the environment

Field-testing provided no evidence that MON 87411 would be the cause of any adverse effects to human health or to the environment.