

**Application for authorization to place on the market
MON 87427 × MON 89034 × NK603 Maize
in the European Union, according to
Regulation (EC) No 1829/2003
on genetically modified food and feed**

**EFSA-GMO-BE-2013-117
EFSA-Q-2013-00765**

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

Belgium.

(b) Application number

EFSA-GMO-BE-2013-117.

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

The Monsanto development code for this genetically modified maize is MON 87427 × MON 89034 × NK603. Currently, no commercial name has been 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.	Monsanto Company
Avenue de Tervuren 270-272	800 N. Lindbergh Boulevard
B-1150 Brussels	St. Louis, Missouri 63167
Belgium	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 or 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, the agronomic and the phenotypic characteristics of MON 87427 × MON 89034 × NK603 have been studied at multiple locations in the U.S. that cover a range of environmental conditions. The risk assessment presented in this application includes data collected from these field trials. A summary of the conclusions of the risk analysis that demonstrates the safety of MON 87427 × MON 89034 × NK603 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 notified/authorised in a third country either previously or simultaneously?

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)

Applications for the full range of uses have been made in Canada and U.S. Regulatory submissions will also be made to countries that import significant quantities of maize from US and that have regulatory approval processes in place. These will include submissions to a number of countries and regulatory authorities, including Colombia, Japan, Korea, Mexico, Philippines and Taiwan. 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.

1.8. General description of the product

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

MON 87427 × MON 89034 × NK603 is produced by crossing MON 87427 and MON 89034 × NK603 parental lines using conventional breeding methods.

MON 87427 × MON 89034 × NK603 produces:

- Cry1A.105 and Cry2Ab2 proteins which provide a dual effective dose against feeding damage caused by the key lepidopteran pest complex in maize: European corn borer (ECB, *Ostrinia nubilalis*), southwestern corn borer (SWCB, *Diatraea grandiosella*), corn earworm (CEW, *Helicoverpa zea*) and other lepidopteran insect pests, such as the fall armyworm (FAW, *Spodoptera frugiperda*) and the sugarcane borer (SCB, *Diatraea saccharalis*). Cry1A.105 is a modified *Bacillus thuringiensis* (Bt) Cry1A-type protein with overall amino acid sequence identity of 93.4%, 90%, and 76.7% to the Cry1Ac (subsp. *kurstaki*), Cry1Ab (subsp. *kurstaki*)

and Cry1F (subsp. *aizawai*). Cry2Ab2 is a *Bacillus thuringiensis* subsp. *kurstaki* protein.

- CP4 EPSPS and CP4 EPSPS L214P proteins, derived from *Agrobacterium* sp. strain CP4 which provides tolerance to glyphosate.

While MON 87427 contains the e35s-hsp70 promoter intron combination that allows for full vegetative and female reproductive glyphosate tolerance and also results in limited or no production of CP4 EPSPS protein in two key male reproductive tissues: pollen microspores, which develop into pollen grains, and tapetum cells that supply nutrients to the pollen, MON 87427 × MON 89034 × NK603 F1 seed has full vegetative and male reproductive tolerance to glyphosate as CP4 EPSPS expressed in NK603 on the male parent during hybrid seed production of MON 87427 × MON 89034 × NK603 resets full glyphosate tolerance in the MON 87427 × MON 89034 × NK603 seed.

- (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 authorisation of MON 87427 × MON 89034 × NK603 for import, processing and all uses as any other maize in the EU, 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 87427 × MON 89034 × NK603 will be traded and used in the EU in the same manner as current conventional 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**

With the exception of the lepidopteran protection traits and herbicide tolerance traits that only have agronomical relevance, the characteristics of MON 87427 × MON 89034 × NK603 maize and products derived from it are comparable to those of its conventional counterpart and the conventional commercial reference varieties with a history of safe use. Therefore, MON 87427 × MON 89034 × NK603 and its derived products will be stored, packaged, transported, handled and used in the same manner as current commercial maize products. No specific instructions and/or recommendations are warranted or required for the placing on the market of MON 87427 × MON 89034 × NK603 for import, processing and all uses, excluding cultivation, in the EU as specified in Section 1.8(b) above.

- (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 87427 × MON 89034 × NK603 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 87427 × MON 89034 × NK603, excluding cultivation.

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

MON 87427 × MON 89034 × NK603 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 87427 × MON 89034 × NK603, excluding cultivation.

(g) Any proposed packaging requirements

Except for the lepidopteran and glyphosate tolerance traits, that only have agronomical relevance, the characteristics of MON 87427 × MON 89034 × NK603 are not different from those of its conventional counterpart. Therefore, MON 87427 × MON 89034 × NK603 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, a labelling threshold of 0.9 % is applied for the placing on the market of MON 87427 × MON 89034 × NK603 and derived products.

Operators shall be required to label products containing or consisting of MON 87427 × MON 89034 × NK603 with the words “genetically modified maize” or “contains genetically modified maize” and shall be required to declare the unique identifier in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 87427 × MON 89034 × NK603 with the words “produced from genetically modified maize”. In the case of products for which no list of ingredients exists, operators shall ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using MON 87427 × MON 89034 × NK603 and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003 and that authorised foods and feeds shall be entered in the EU Register for genetically modified food and feed, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 87427 × MON 89034 × NK603. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

(i) In the Union

There are no anticipated changes to the demand as a result of the introduction of MON 87427 × MON 89034 × NK603 into the maize supply. It is anticipated that the introduction of MON 87427 × MON 89034 × NK603 maize will replace some of the maize in existing food and feed products.

(ii) In export markets for EU supplies

There are no anticipated changes to the extent of maize production in exports markets as a result of the introduction of MON 87427 × MON 89034 × NK603 maize. It is anticipated that the introduction of MON 87427 × MON 89034 × NK603 maize will replace some of the maize seed products.

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

The unique identifier for this genetically modified maize is MON-87427-7 × MON-89034-3 × MON-00603-6.

The unique identifiers assigned to the sub-combinations of MON-87427-7 × MON-89034-3 × MON-00603-6, excluding the singles, are the following: MON-87427-7 × MON-89034-3, MON-89034-3 × MON-00603-6, MON-87427-7 × MON-00603-6.

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 87427 × MON 89034 × NK603 as any other maize, not including the cultivation in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of MON 87427 × MON 89034 × NK603. However, modern methods of grain handling minimize losses of grain, so there is little chance of germination of spilt grain resulting in the development of mature plants of MON 87427 × MON 89034 × NK603 in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since maize cannot survive without human assistance and is not capable of surviving as a weed. Although maize seed can over-winter in mild conditions and can germinate the following year, the appearance of maize in rotational fields is rare under European conditions. Maize volunteers, if they occur, are usually killed by frost or could be easily controlled by the use of selective herbicides or by mechanical means. Moreover, the information presented in this application established that MON 87427 × MON 89034 × NK603 is not different in composition, nutritional and agronomic characteristics relative to the conventional counterpart, except for the lepidopteran protection and tolerance to glyphosate and, therefore, it is unlikely to pose any threat to the EU environment or to require special measures for its containment. Therefore, no special measures are considered to be required in case of misuse or unintended release.

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

2.1. Complete name

- | | |
|---|------------------------------|
| (a) Family name | Poaceae (formerly Gramineae) |
| (b) Genus | <i>Zea</i> |
| (c) Species | <i>mays</i> (2n = 20) |
| (d) Subspecies | N/A |
| (e) Cultivar/breeding line or strain | MON 87427, MON 89034 × NK603 |
| (f) Common name | maize or corn |

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

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 freeze-free season lasts 120 to 180 days. A summer rainfall of 15 cm is approximately the lower limit for maize production without irrigation with no upper limit of rainfall for growing maize, although excess rainfall will decrease yields and increase the chance of fungal infection.

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 (*Zea mays* L.) reproduces sexually. It is an annual, wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers which encourages the natural outcrossing between maize plants. Wind movement across maize fields causes pollen from the tassel to fall on the silks of the same or adjoining plants. Self-pollination leads to homogeneity of the genetic characteristics within a single plant while cross-pollination combines the genetic traits of many plants.

(b) Specific factors affecting reproduction

Tasselling, silking and pollination are the most critical stages of maize development and, consequently, grain yield may ultimately be greatly impacted by moisture and fertility stress. Under conditions of high temperature and desiccation maize pollen viability is measured in minutes; these conditions may even destroy the tassel before any viable pollen is shed.

(c) Generation time

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. The different relative maturities occurring depend on prevailing weather patterns, topography, large bodies of water, and soil types.

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

Outcrossing with cultivated Zea varieties

Maize is wind pollinated, and the distance that viable pollen can travel depends on prevailing wind patterns, humidity, and temperature. Once in the atmosphere, pollen grains must remain viable long enough to be able to reach a viable silk to complete the pollination process. On average, maize pollen loses 100% viability after two hours of atmospheric exposure.

All maize will inter-pollinate, except for certain popcorn varieties and varieties that have one of the gametophyte factors (*GaS*, *Ga*, and *ga* allelic series on chromosome 4). Pollen of a specific variety can be carried by wind to pollinate other dent maize varieties, sweet maize and popcorn, if the popcorn does not carry the dent-sterile gametophyte factor (Hallauer, 1995). Maize pollen, therefore, moves freely within an area, lands on silks of the same variety or different varieties, germinates almost immediately after pollination and within 24 hours completes fertilisation.

However, the scope of the current application does not include cultivation of MON 87427 × MON 89034 × NK603 in the EU therefore any outcrossing between MON 87427 × MON 89034 × NK603 and cultivated *Zea* varieties is highly unlikely.

Outcrossing with wild Zea species

Gene flow in maize (*Zea mays* L.) is closely associated with the biology of the staminate and pistillate inflorescences. Gene flow between maize and its closest relative, teosinte (*Zea* ssp.) is specific to Mexico and Central America. In the Central Plateau and Valley of Mexico, maize can grow sympatrically with teosinte (*Zea* ssp.) providing the opportunity for hybridization.

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

Maize is an annual crop and seeds are the only survival structures. Natural regeneration from vegetative tissue is not known to occur.

(b) Specific factors affecting survivability

Maize cannot survive without human assistance and is not capable of surviving as a weed due to past selection in its evolution. Volunteer maize is not found growing in fencerows, ditches or roadsides as a weed. Although maize seed from the previous crop year can over-winter in mild winter conditions and germinate the following year, it cannot persist as a weed. The appearance of “volunteer” maize in fields following a maize crop from the previous year is rare under European conditions.

Maize volunteers are killed by frost or, in the unlikely event of their occurrence, are easily controlled by current agronomic practices including physical removal and the use of selective herbicides.

Maize grain survival is dependent upon temperature, moisture of seed, genotype, husk protection and stage of development. Freezing temperatures have an adverse effect on maize seed germination and have been identified as being a major risk in seed maize production. Temperatures above 45° C have also been reported as injurious to maize seed viability.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

In general, dissemination of maize may occur by means of seed and pollen dispersal. Dispersal of the maize grain is highly restricted in domesticated maize due to the ear structure including husk enclosure. For maize pollen, the vast majority is deposited in the same field due to its large size (90 to 100 µm) with smaller amounts of pollen deposited usually in a downwind direction.

The current application does not include the environmental release of MON 87427 × MON 89034 × NK603 in the EU.

(b) Specific factors affecting dissemination

Dispersal of maize seeds does not occur naturally because of the structure of the ears of maize. Dissemination of isolated seeds may result from mechanical harvesting and transport as well as insect or wind damage, but this form of dissemination is highly infrequent. Genetic material can be disseminated by pollen dispersal, which is influenced by wind and weather conditions. Maize pollen is the largest of any pollen normally disseminated by wind from a comparably low level of elevation. Dispersal of maize pollen is limited by its large size and rapid settling rate.

The current application does not include the environmental release of MON 87427 × MON 89034 × NK603 in the EU.

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

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

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)

Like other plants, cultivated maize is known to interact with other organisms in the environment including insects, birds, and mammals. It is susceptible to a range of fungal diseases and nematode, insect and mite pests.

There are no known toxic effects of the maize plant to humans, animals or livestock; it has a history of safe use for human food and animal feed. Maize has been a staple of the human diet for centuries, and its processed fractions are consumed in a multitude of food and animal feed products.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

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

MON 87427 × MON 89034 × NK603 is produced by crossing maize plants of MON 87427 and MON 89034 × NK603, using conventional breeding methods.

MON 87427 was developed through *Agrobacterium*-mediated transformation of maize tissues. MON 89034 × NK603 was also produced through conventional breeding methods, however, genetic modification was used to develop its constituent singles. MON 89034 was developed through *Agrobacterium*-mediated transformation of the maize embryonic cells, while NK603 was produced by means of a particle acceleration method.

(b) Nature and source of the vector used

MON 87427 × MON 89034 × NK603 has been obtained through conventional breeding by crossing MON 87427 and MON 89034 × NK603 and no vector has been used to produce this maize hybrid.

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

MON 87427 × MON 89034 × NK603 has been obtained through conventional breeding by crossing MON 87427 and MON 89034 × NK603 and therefore the DNA fragments present in MON 87427 × MON 89034 × NK603 are inherited from MON 87427 and MON 89034 × NK603.

The individual components, location, source and function of these inherited sequences are given in Table 1 and Table 2.

Table 1. Summary of the inserted DNA inherited from MON 87427 (Monsanto Company, 2012)

Genetic Element	Size (~ kb)	Function (Reference)
B¹-Left Border Region	0.44	DNA region from <i>Agrobacterium tumefaciens</i> containing the Left Border sequence used for transfer of the T-DNA (Barker <i>et al.</i> , 1983)
P²-<i>e35S</i>	0.62	Promoter for the cauliflower mosaic virus (CaMV) 35S RNA (Odell <i>et al.</i> , 1985) containing the duplicated enhancer region (Kay <i>et al.</i> , 1987) that directs transcription in plant cells
I³-<i>hsp70</i>	0.80	First intron from the maize heat shock protein 70 gene (Brown and Santino, 1995)
TS⁴-<i>CTP2</i>	0.22	Targeting sequence from the <i>ShkG</i> gene encoding the chloroplast transit peptide (CTP) region of <i>Arabidopsis thaliana</i> EPSPS (Herrmann, 1995; Klee <i>et al.</i> , 1987) that directs transport of the CP4 EPSPS protein to the chloroplast
CS⁵-<i>cp4 epsps</i>	1.36	Codon-optimized coding sequence of the <i>aroA</i> gene from the <i>Agrobacterium</i> sp. strain CP4 encoding the CP4 EPSPS protein (Barry <i>et al.</i> , 2001; Padgett and Re, 1996)
T⁶-<i>nos</i>	0.25	3' non-translated region of the <i>nopaline synthase (nos)</i> gene from <i>Agrobacterium tumefaciens</i> that terminates transcription and directs polyadenylation (Bevan <i>et al.</i> , 1983)
B¹-Right Border Region	0.35	DNA region from <i>Agrobacterium tumefaciens</i> containing the Right Border sequence used for transfer of the T-DNA (Depicker <i>et al.</i> , 1982; Zambryski <i>et al.</i> , 1982)

¹B, Border; ²P, Promoter; ³I, Intron; ⁴TS, Targeting Sequence; ⁵CS, Coding Sequence; ⁶T, Transcription Termination Sequence.

Table 2. Summary of the inherited DNA from MON 89034 × NK603 (Monsanto Company, 2007)

MON 89034		
Genetic Element	Size (~kb)	Function (Reference)
B1-Left Border¹	0.24	239 bp DNA region from the B-Left Border region remaining after integration
P2-e35S	0.30	Modified <i>e35s</i> promoter and 9 bp leader resulting from a recombination between the P- <i>e35s</i> and P-35s promoters. Differing from <i>e35S</i> in that it does not contain the duplicated enhancer element
L³-Cab	0.06	5' untranslated leader of the wheat chlorophyll a/b-binding protein (Lamppa <i>et al.</i> , 1985)
I⁴-Ract1	0.48	Intron from the rice actin gene (McElroy <i>et al.</i> , 1991)
CS⁵-cry1A.105	3.53	Coding sequence for the <i>Bacillus thuringiensis</i> (<i>Bt</i>) Cry1A.105 protein (Monsanto unpublished data)
T⁶-Hsp17	0.21	Transcript termination sequence of the coding sequence for wheat heat shock protein 17.3, which ends transcription and directs polyadenylation (McElwain and Spiker, 1989)
P²-FMV	0.56	Figwort Mosaic Virus 35S promoter (Rogers, 2000)
I⁴-Hsp70	0.80	First intron from the maize heat shock protein 70 gene (Brown and Santino, 1995)
TS⁷-SSU-CTP	0.40	DNA region containing the targeting sequence for the transit peptide region of maize ribulose 1,5-bisphosphate carboxylase small subunit and the first intron (Matsuoka <i>et al.</i> , 1987)
CS⁵-cry2Ab2	1.91	Coding sequence for a Cry2Ab2 protein from <i>Bacillus thuringiensis</i> (Donovan, 1991; Widner and Whiteley, 1989). This coding sequence uses a modified codon usage.
T⁶-nos	0.25	Transcript termination sequence of the nopaline synthase (<i>nos</i>) coding sequence from <i>Agrobacterium tumefaciens</i> which terminates transcription and directs polyadenylation (Bevan <i>et al.</i> , 1983)
B¹-Left Border^{r2}	0.23	230 bp DNA region from the B-Left Border region remaining after integration

Table 2.(continued) Summary of the inherited DNA from MON 89034 × NK603 (Monsanto Company, 2007)

NK603		
Genetic Element	Size (~kb)	Function (Reference)
P²-Ract1/ I-Ract1	1.40	Intron from the rice actin gene, and promoter (McElroy <i>et al.</i> , 1990).
TS⁷-CTP2	0.20	DNA region containing the targeting sequence for the N-terminal chloroplast transit peptide, isolated from <i>Arabidopsis thaliana</i> , present to direct the CP4 EPSPS protein to the chloroplast, the site of aromatic amino acid synthesis (Klee <i>et al.</i> , 1987).
CS⁵-cp4 epsps	1.40	Coding sequence for the <i>Agrobacterium</i> CP4 EPSPS protein (Padgett <i>et al.</i> , 1996).
T⁶-nos	0.30	Transcript termination sequence of the nopaline synthase (nos) coding sequence from <i>Agrobacterium tumefaciens</i> which terminates transcription and directs polyadenylation (Bevan <i>et al.</i> , 1983).
P²-e35S	0.60	Promoter and leader for the Cauliflower Mosaic Virus (CaMV) 35S RNA (Odell <i>et al.</i> , 1985) containing the duplicated enhancer region (Kay <i>et al.</i> , 1987).
I⁴-Hsp70	0.80	First intron from the maize heat-shock protein 70 gene (Brown and Santino, 1995).
TS⁷-CTP2	0.20	DNA region containing the targeting sequence for the N-terminal chloroplast transit peptide, isolated from <i>Arabidopsis thaliana</i> , present to direct the CP4 EPSPS protein to the chloroplast, the site of aromatic amino acid synthesis (Klee <i>et al.</i> , 1987)
CS⁵-cp4 epsps l214p	1.40	Coding sequence for the CP4 EPSPS L214P protein (Padgett <i>et al.</i> , 1996).
T⁶-nos	0.30	Transcript termination sequence of the <i>nopaline synthase (nos)</i> coding sequence from <i>Agrobacterium tumefaciens</i> which terminates transcription and directs polyadenylation (Bevan <i>et al.</i> , 1983).

¹B, Border; ²P, Promoter; ³L, Leader ; ⁴I, Intron; ⁵CS, Coding Sequence; ⁶T, Transcription Termination Sequence; ⁷TS, Targeting 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 87427 × MON 89034 × NK603 is produced by crossing MON 87427 and MON 89034 × NK603 parental lines using conventional breeding methods.

MON 87427 × MON 89034 × NK603 produces:

- The Cry1A.105 and Cry2Ab2 insecticidal proteins which impart protection against feeding damage caused by the European corn borer (ECB, *Ostrinia nubilalis*) and other lepidopteran insect pests. Cry1A.105 is a modified *Bacillus thuringiensis* Cry1A-type protein with overall amino acid sequence identity of 93.4%, 90%, and 76.7% to the Cry1Ac (subsp. *kurstaki*), Cry1Ab (subsp. *kurstaki*) and Cry1F (subsp. *aizawai*), respectively. Cry2Ab2 is a *Bt* subsp. *kurstaki* protein. The combination of the Cry1A.105 and Cry2Ab2 insecticidal proteins in a single plant provides better insect control and offers an additional insect-resistance management (IRM) tool.
- Two CP4 EPSPS proteins (CP4 EPSPS and CP4 EPSPS L214P¹) which are structurally and functionally equivalent (EFSA 2009²) and which impart tolerance to glyphosate. EPSPS is an enzyme derived from *Agrobacterium* sp. strain CP4 which catalyses the penultimate step of the shikimic acid pathway for the biosynthesis of aromatic amino acids, which is present in all green plants. Inhibition of this enzyme by glyphosate leads to a reduction of aromatic amino acids, interfering with plant growth, and ultimately leading to plant death. Therefore, glyphosate has excellent, broad-spectrum weed control capabilities. However, the sensitivity of conventional maize to glyphosate-containing herbicides has hampered the in-season use of this herbicide in the crop. With the production of the glyphosate tolerant CP4 EPSPS enzymes, the continued function of the aromatic amino acid pathway is ensured in the crop, even in the presence of the herbicide.

While MON 87427 contains the *e35s-hsp70* promoter intron combination that allows for full vegetative and female reproductive glyphosate tolerance and also results in limited or no production of CP4 EPSPS protein in two key male reproductive tissues: pollen microspores, which develop into pollen grains, and tapetum cells that supply nutrients to the pollen, MON 87427 × MON 89034 × NK603 F1 seed has full vegetative and male reproductive tolerance to glyphosate as CP4 EPSPS expressed in NK603 on the male parent during hybrid seed production of MON 87427 × MON 89034 × NK603 resets full glyphosate tolerance in the MON 87427 × MON 89034 × NK603 seed.

3.2.2. Information on the sequences actually inserted or deleted

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

The genome of MON 87427 × MON 89034 × NK603 contains three different inserts, one inherited from MON 87427 and two inherited from MON 89034 × NK603. The results of Southern blot analyses on MON 87427 and MON 89034 × NK603 indicate that each of these parental lines contain a single copy of the T-DNA of interest at a single insertion site. The presence of these inserts in MON 87427 × MON 89034 × NK603 was confirmed through Southern blot analysis.

¹ Hereafter collectively referred to as the CP4 EPSPS proteins

² <http://www.efsa.europa.eu/en/efsajournal/pub/1137.htm> - Accessed 19 November 2013

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

Not applicable since MON 87427 × MON 89034 × NK603 was obtained through conventional breeding techniques.

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

The conventionally bred MON 87427 × MON 89034 × NK603F1 contains the inserts in the nuclear genome, as they were present in the parental lines. The fingerprints obtained by Southern blot analyses of the combined trait product MON 87427 × MON 89034 × NK603 are consistent with the corresponding fingerprints obtained with MON 87427, MON 89034 and NK603. These results confirmed the presence of the inserted sequences of MON 87427, MON 89034 and NK603 and that no detectable rearrangements of these inserts occurred in the combined trait maize product MON 87427 × MON 89034 × NK603.

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

Since the inserts present in MON 87427 × MON 89034 × NK603 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in this combined trait product.

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

Not applicable.

3.2.3. Information on the expression of the insert

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

The expression levels of CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins were determined by validated enzyme-linked immunosorbent assays (ELISAs) in tissues collected during the 2010 planting season at five representative maize-growing locations in the US from glyphosate treated MON 87427 × MON 89034 × NK603 and positive control plants MON 87427, MON 89034 and NK603.

The expression levels in grain and forage of Cry1A.105, Cry2Ab2, and CP4 EPSPS in MON 87427 × MON 89034 × NK603, indicate that the inserted transgenes are being expressed and are functioning properly when combined via conventional breeding methods. In addition, based on the reported expression levels of CP4 EPSPS in the combined trait MON 87427 × MON 89034 × NK603 there is no evidence for interaction between the two copies of *cp4 epsps* gene. The levels of CP4EPSPS were as expected for the combined expression in MON 87427 and MON 89034 × NK603

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

The expression of the CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins occurs throughout the plant at appropriate times of plant development. In terms of food and feed safety assessment of MON 87427 × MON 89034 × NK603 grain and forage are the most relevant tissues.

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

MON 87427 × MON 89034 × NK603 is produced through conventional breeding by crossing MON 87427 and MON 89034 × NK603 parental lines. Thereby, each parental line passes on its inserted DNA sequence to the resulting MON 87427 × MON 89034 × NK603 combined trait seed.

Based on the molecular characterisation of MON 87427 × MON 89034 × NK603, the MON 87427, MON 89034 and NK603 inserts are retained with their inherent properties. Furthermore, Southern blot analyses, carried out on MON 87427 × MON 89034 × NK603 plant materials, confirmed the presence of the inserted sequences of MON 87427, MON 89034 and NK603 and that no detectable rearrangements of these inserts occurred.

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 as well as environmental interaction data were collected from eight sites at field trials conducted in the 2010 growing season. The field sites provided a range of environmental and agronomic conditions representative of commercial maize production in the U.S. Randomized complete block design with four replicates at each field site was used. In each of the assessments MON 87427 × MON 89034 × NK603, either treated or not with glyphosate, was compared to an appropriate maize conventional counterpart which has a genetic background similar to MON 87427 × MON 89034 × NK603 with the exception of the *cp4 epsps*, *cry1a.105* and *cry2ab2* expression cassettes, thus, the effect of these expression cassettes and the expressed CP4 EPSPS, Cry1A105 and Cry2Ab2 proteins could be assessed in an unbiased manner. In addition, multiple conventional reference maize hybrids (references; four per site; a total of at least 19 different hybrids) were employed to provide a range of baseline values that are common to the existing commercial maize varieties for each measured phenotypic, agronomic, and ecological interaction characteristic.

Results of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 87427 × MON 89034 × NK603 compared to the conventional maize counterpart. These results concur with those obtained previously for the parental lines MON 87427 and MON 89034 × NK603.

On the basis of the studies 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 87427 × MON 89034 × NK603 and that MON 87427 × MON 89034 × NK603 is equivalent to conventional maize in its phenotypic and agronomic behaviour, except for the glyphosate-tolerance and insect resistance traits.

(b) Dissemination

No differences in the dissemination compared to the conventional counterpart have been observed in agronomic and phenotypic assessments conducted with MON 87427 × MON 89034 × NK603 maize.

(c) Survivability

No differences in the survivability compared to the conventional counterpart have been observed in agronomic assessments conducted with MON 87427 × MON 89034 × NK603 maize.

(d) Other differences

Except for the introduced traits that are of agronomic interest, the agronomic assessments in the field did not reveal any biologically significant differences between MON 87427 × MON 89034 × NK603 maize and its conventional counterpart.

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 in MON 87427 × MON 89034 × NK603 has a genetic transfer function. Therefore, no changes are expected in the ability of MON 87427 × MON 89034 × NK603 to transfer genetic material to bacteria.

(b) Plant to plant gene transfer

Based on the observation that reproductive morphology in MON 87427, MON 89034 × NK603 and MON 87427 × MON 89034 × NK603 is unchanged compared to conventional maize, the outcrossing frequency to other maize varieties or to wild relatives (which are not present in the EU) would be unlikely to be different for MON 87427 × MON 89034 × NK603 when compared to MON 87427 and MON 89034 × NK603, or when compared to other conventional maize varieties. Moreover, the scope of the current application does not include the cultivation of MON 87427 × MON 89034 × NK603 maize hybrids in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

MON 87427 × MON 89034 × NK603 was compared to a conventional maize variety with genetic background similar to MON 87427 × MON 89034 × NK603 (conventional counterpart), as well as with other conventional reference maize hybrids.

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

Data were collected from eight sites within the U.S. in the 2010 season. MON 87427 × MON 89034 × NK603, the conventional control and conventional commercial reference maize hybrids were evaluated at each site. The eight field sites provided a range of environmental and agronomic conditions representative of commercial maize production in the U.S.

At each field site, the test, the conventional counterpart and reference seed were planted in a randomized complete block design with four replicates per block. Field locations were acceptable environments for maize growth and are distributed across a wide geographical area to provide a variety of agronomic practices, soils and climatic factors. All the plants were grown under normal agronomic field conditions for their respective geographic regions.

An analysis of variance (ANOVA) was conducted in a combined-site analysis in which the data was pooled across all sites. ANOVA models were used to perform difference and equivalence tests according to the 2010 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 study were chosen on the basis of internationally accepted guidance provided by the OECD on compositional considerations for maize.

4.4. Comparative analysis of agronomic and phenotypic characteristics

An assessment of the phenotypic, agronomic and environmental interactions of MON 87427 × MON 89034 × NK603 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.

Results of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 87427 × MON 89034 × NK603 compared to the maize conventional counterpart.

4.5. Effect of processing

With the exception of the lepidopteran protection traits and herbicide tolerance traits, MON 87427 × MON 89034 × NK603 is not different from the conventional counterpart. Therefore, the processing of MON 87427 × MON 89034 × NK603 is not expected to be any different from that of conventional maize.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

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 does not exert any acute toxic effects to mammals;
- If the protein is rapidly digested in mammalian gastrointestinal systems.

MON 87427 × MON 89034 × NK603 is produced by conventional breeding of MON 87427 and MON 89034 × NK603. All the introduced traits from the parental lines are inherited by the MON 87427 × MON 89034 × NK603 progeny resulting in the expression of the CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins in the same plant.

Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins have a demonstrated history of safe use, have no structural similarity to known toxins or other biologically active proteins, do not exert any acute toxic effects to mammals and are proven to be rapidly digested in mammalian gastrointestinal systems. The European Food Safety Authority (EFSA) has

concluded on the safety of these proteins in several occasions, (EFSA, 2004³, 2008⁴, 2009⁵, 2010^{6,7}).

Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins have no synergistic or antagonistic effects to each other. The modes and sites of biological activity are different for these protein and there is no known or conceivable mechanism of interaction between Cry1A.105, Cry2Ab2 and CP4 EPSPS which could lead to adverse health effects in animals or man.

On the basis of knowledge concerning the molecular characteristics and biochemistry of these proteins, including their high degree of substrate specificity, it can be concluded that there are no potential interactions between these three traits and other plant constituents that would impact safety.

(b) Testing of new constituents other than proteins

Since maize is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world and as MON 87427 × MON 89034 × NK603 was shown to be substantially equivalent to conventional maize, no testing of any constituent other than the introduced protein is warranted.

(c) Information on natural food and feed constituents

Maize is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world. No particular natural constituents of maize are considered to be of significant concern to require additional information or further risk assessment.

(d) Testing of the whole GM food/feed

The compositional and nutritional equivalence of grain from MON 87427 × MON 89034 × NK603 and conventional maize have been established by compositional analysis. In addition, the safety for humans and animals of the transgenic proteins produced in MON 87427 × MON 89034 × NK603 maize has been demonstrated on the basis of extensive characterization, history of safe use, rapid digestion, lack of acute toxicity and lack of significant homology to known protein toxins. Also, the respective function and mode of action of these newly expressed proteins are known and there is no evidence of interaction of safety concern between the proteins expressed in MON 87427 × MON 89034 × NK603 maize. Based on this weight of evidence, no more data is required to demonstrate that MON 87427 × MON 89034 × NK603 is as safe as conventional maize from a food and feed perspective.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

A protein is not likely to be allergenic if: (1) the protein is from a non-allergenic source, (2) the protein represents only a very small portion of the total protein in the seed, (3) the protein does not share structural similarities with known allergens based

³ <http://www.efsa.europa.eu/en/efsajournal/pub/9.htm> - Accessed on 19 November 2013.

⁴ <http://www.efsa.europa.eu/fr/efsajournal/pub/909.htm> - Accessed on 19 November 2013.

⁵ <http://www.efsa.europa.eu/en/efsajournal/pub/1320.htm> - Accessed on 19 November 2013.

⁶ <http://www.efsa.europa.eu/en/efsajournal/pub/1564.htm> - Accessed on 11 November 2013.

⁷ <http://www.efsa.europa.eu/en/efsajournal/pub/1781.htm> - Accessed on 11 November 2013.

on the amino acid sequence and (4) the protein does not demonstrate resistance to digestion by pepsin or other digestive enzymes.

The lack of allergenic potential of the CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins expressed in MON 89034 × NK603 respectively (inherited in MON 87427 × MON 89034 × NK603) has previously been established by the EFSA^{3, 4, 5, 6}. Taken together, these data lead to the conclusion that the CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins are unlikely to have any allergenic potential and MON 87427 × MON 89034 × NK603 is as safe as conventional maize with regards to allergenicity risk.

(b) Assessment of allergenicity of the whole GM plant

Maize is not considered a common allergenic food. Food allergies to maize are rare, of low frequency and mainly occur in populations of specific geographic areas. Rare cases of occupational allergy to maize dust have been reported. There is no reason to expect that the use of MON 87427 × MON 89034 × NK603 will significantly increase the intake and exposure to maize. 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.

As MON 87427 × MON 89034 × NK603 is comparable and as safe as conventional maize, there is no reason to expect that the use of MON 87427 × MON 89034 × NK603 will significantly increase the potential for allergenicity. Further, as the introduced proteins in MON 87427 × MON 89034 × NK603 do not have any allergenic potential, it was concluded that the use of MON 87427 × MON 89034 × NK603 for food or feed does not lead to an increased risk for allergenic reactions compared to the equivalent range of food and feed uses of conventional maize. Therefore, an assessment of the allergenicity of the whole MON 87427 × MON 89034 × NK603 plant is not considered necessary.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of GM food

The introduced traits in MON 87427 × MON 89034 × NK603 are of agronomic interest and are not intended to change any nutritional aspect of this maize. The presence of these traits is not expected to alter patterns or volumes of maize consumption. Results of the extensive compositional analyses indicate that observed differences fell within the range of natural variability for maize with a history of safe usage and the grain and forage composition of MON 87427 × MON 89034 × NK603 is not biologically relevantly different to the grain and forage composition of the conventional counterpart.

MON 87427 × MON 89034 × NK603 reveals comparable nutritional characteristics to the conventional counterpart maize, as well as to maize varieties in commerce. 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, 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 87427 × MON 89034 × NK603 in the maize supply.

(b) Nutritional assessment of GM feed

See Section 7 (a).

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

The exposure assessment in humans and animals indicates that there is minimal dietary exposure to Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins from consumption of foods and feed derived from MON 87427 × MON 89034 × NK603.

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 87427 × MON 89034 × NK603 to the maize supply. MON 87427 × MON 89034 × NK603 is expected to replace a portion of current maize such that its 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 87427 × MON 89034 × NK603 is as safe as conventional maize. The molecular characterization of MON 87427 × MON 89034 × NK603 did not raise any safety concern and did not show any evidence of unintended changes in MON 87427 × MON 89034 × NK603. Detailed compositional comparisons of MON 87427 × MON 89034 × NK603, its conventional counterpart and conventional commercial reference varieties demonstrated that MON 87427 × MON 89034 × NK603 is compositionally similar to the conventional maize counterpart and that MON 87427 × MON 89034 × NK603 is not a contributor to compositional variability in maize. The assessed phenotypic and agronomic characteristics of MON 87427 × MON 89034 × NK603 were within the range expected for maize and did not show any phenotypic changes indicative of increased plant weed/pest potential of MON 87427 × MON 89034 × NK603 compared to conventional maize. An extensive characterisation of the CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins expressed in MON 87427 × MON 89034 × NK603 confirmed that the protein is safe for human and animal consumption. Additionally, the exposure assessment in humans and animals did not indicate any safety concerns.

In summary, there are no signs of adverse or unanticipated effects observed in a number of safety studies and the pre-market risk characterisation for food and feed use of MON 87427 × MON 89034 × NK603. The consumption of food and feed derived from GM plants is as safe as the consumption of its respective comparators. It can be concluded that the food derived from a GM plant is not nutritionally disadvantageous for the consumer compared to the food which is intended to replace. Finally, it can be also concluded that the feed derived from a GM plant does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

10. POST-MARKET MONITORING ON GM FOOD/FEED

Based on the information provided in this application, it is reasonable to conclude that MON 87427 × MON 89034 × NK603 is as safe as conventional maize. There are no intrinsic hazards related to MON 87427 × MON 89034 × NK603 which would indicate that MON 87427 × MON 89034 × NK603 is less safe than its conventional counterpart. The pre-market risk characterisation for food and feed use of MON 87427 × MON 89034 × NK603 demonstrates that the risks of consumption of MON 87427 × MON 89034 × NK603 or its derived products are not different from the risks associated with the

consumption of conventional maize or its derived products. As a consequence, specific risk management measures are not warranted 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 87427 × MON 89034 × NK603 in the EU. Hence, no deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this event. Therefore 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 87427 × MON 89034 × NK603 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 the conclusion that the abilities of MON 87427 × MON 89034 × NK603 to persist in agricultural fields or invade non-agricultural habitats are comparable to those of conventional maize in the EU. Thus, MON 87427 × MON 89034 × NK603 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

It was previously demonstrated that the inherited genetic sequences in MON 87427 × MON 89034 × NK603 did not lead to any biologically meaningful alterations of the phenotypic characteristics, such as plant growth and development, morphology, agronomic performance, composition, nutritional value or safety characteristics, when compared to conventional maize. Therefore, it was concluded that MON 87427 × MON 89034 × NK603 is not meaningfully different from conventional maize, with the exception of the intentionally introduced agronomically beneficial traits.

Compared with conventional maize, the introduced insect protection and herbicide tolerance traits in MON 87427 × MON 89034 × NK603 confer a selective advantage only under specific conditions (i.e. upon attack by the target insects or following treatment with glyphosate), which are short in duration. The advantage is of purely agronomic interest and presents negligible risk to the non-agricultural environments, because of the poor survival characteristics of maize under most European conditions.

Therefore, the likelihood is negligible for the inherited traits in MON 87427 × MON 89034 × NK603 to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

(c) Potential for gene transfer

The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × NK603 as any other maize in the EU, excluding cultivation. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87427 × MON 89034 × NK603 with the biotic environment will be limited. Given the low likelihood of occurrence of horizontal gene transfer and lack of adverse consequences if it were to occur, the import, processing, and food and feed use of MON 87427 × MON 89034 × NK603 in the EU is not likely to pose any risk to human and animal health or the environment.

Considering the low exposure and lack of hazard from horizontal gene transfer of the *cp4 epsps*, *cry1A.105* and *cry2Ab2* genes from MON 87427 × MON 89034 × NK603 to micro-organisms resulting from the import, processing and all uses of MON 87427 × MON 89034 × NK603, the risk that this would result in adverse effects on human or animal health or the environment is negligible.

(d) Interactions between the GM plant and target organisms

The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × NK603 as any other maize, but excludes the cultivation of MON 87427 × MON 89034 × NK603 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 of MON 87427 × MON 89034 × NK603 in the EU is not relevant for this submission.

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

The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × NK603 as any other maize, but excludes the cultivation of MON 87427 × MON 89034 × NK603 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87427 × MON 89034 × NK603 with the biotic environment will be limited. Importantly, CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins are heat inactivated during processing for feed and CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins can also be inactivated in the digestive tract of animals. Given the low levels of environmental exposure combined with low hazard from exposure of MON 87427 × MON 89034 × NK603 to NTOs, the likelihood of adverse effects from the import of MON 87427 × MON 89034 × NK603 to NTO communities that perform in-field ecological functions and NTO communities outside of the field from import of MON 87427 × MON 89034 × NK603, is negligible.

The conclusion from the risk characterization is that the probability that direct or indirect interactions between MON 87427 × MON 89034 × NK603 and NTOs that could lead to direct or indirect, immediate or delayed environmental harm as a result of import, processing and use of MON 87427 × MON 89034 × NK603 in the EU (excluding cultivation) is negligible.

(f) Effects on human / animal health

This application is for the import, processing and all uses as any other maize, but excludes the cultivation of MON 87427 × MON 89034 × NK603 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87427 × MON 89034 × NK603 with humans and animal health will be limited to the occupational hazards associated with the cultivation, storage, handling and processing of MON 87427 × MON 89034 × NK603. Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact with MON 87427 × MON 89034 × NK603 grain, the likelihood for any adverse effects, occurring in humans and animals as a result of their contact with this maize, is no different from conventional maize. MON 87427 × MON 89034 × NK603 contains the CP4 EPSPSP, Cry1A.105 and Cry2Ab2 proteins, which have negligible potential to cause any toxic or allergenic effects in humans and animals.

Therefore, the risk of changes in the occupational health aspects of this maize is negligible.

(g) Effects on biogeochemical processes

The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × NK603 in the EU as any other maize (excluding the cultivation of MON 87427 × MON 89034 × NK603). Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87427 × MON 89034 × NK603 with the biotic environment will be very limited. Importantly, CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins are rapidly inactivated (either during processing for feed, or in the digestive tract of animals) thereby limiting any exposure via faeces of animals fed processed or unprocessed MON 87427 × MON 89034 × NK603 grain. Given the low level of environmental exposure combined with a lack of hazard, the import, processing, and food and feed use of MON 87427 × MON 89034 × NK603 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.

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

Cultivation of MON 87427 × MON 89034 × NK603 in the EU is not included in the scope of this application. An assessment of the impacts of specific cultivation, management and harvesting techniques of MON 87427 × MON 89034 × NK603 is therefore not relevant for this application.

11.3. Potential interactions with the abiotic environment

Although the MON 87427 × MON 89034 × NK603 proteins are introduced in maize, they already have a safe history of use and they have no known negative interactions with the abiotic environment.

Overall results of the comparative analysis of MON 87427 × MON 89034 × NK603 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 usage. 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 other maize in the EU, but excluding cultivation, interactions of MON 87427 × MON 89034 × NK603 with the environment will be limited. Moreover, no negative impact of MON 87427 × MON 89034 × NK603 on the abiotic environment is expected to result from the import, processing and all uses as any other maize in the EU.

11.4. Risk characterisation for the environmental risk assessment

Results from the environmental risk assessment which takes into consideration the risk characterization and includes results described above addressing risk hypotheses for the specific areas of assessment laid down in 2010 EFSA guidance, support a conclusion that the import, processing and all uses of MON 87427 × MON 89034 × NK603 (excluding cultivation) as any other maize, 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.

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 87427 × MON 89034 × NK603 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 Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants⁸.

(b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MON 87427 × MON 89034 × NK603 for import, processing and the use of food and feed produced from MON 87427 × MON 89034 × NK603 in the European Union under Regulation (EC) No. 1829/2003. The scope of the application does not include authorisation for the cultivation of MON 87427 × MON 89034 × NK603 seed products in the EU.

An environmental risk assessment (ERA) was carried out for MON 87427 × MON 89034 × NK603 according to the principles laid down in Annex II to Directive 2001/18/EC, the Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC and the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed⁹. The scientific evaluation of the characteristics of MON 87427 × MON 89034 × NK603 in the ERA (*see* Section E of Part II of this application) 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 87427 × MON 89034 × NK603 relative to:

- Persistence and invasiveness including plant to plant gene flow,
- Plant to micro-organisms gene transfer,
- Interactions between the GM plant and target organisms,
- Interactions of the GM plant with non-target organisms,

⁸ www.efsa.europa.eu/en/efsajournal/doc/2316.pdf -Accessed 11 November 2013.

⁹ www.efsa.europa.eu/en/scdocs/doc/1879.pdf -Accessed 11 November 2013.

- Impacts of the specific cultivation, management and harvesting techniques,
- Effects on biochemical processes,
- Effects on human and animal health.

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

As discussed in Section E.4.2 of Part II of this application, the scientific evaluation of the characteristics of MON 87427 × MON 89034 × NK603 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 87427 × MON 89034 × NK603. 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 87427 × MON 89034 × NK603 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 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, by specific company stewardship programmes or by a combination of both. The consent holder will ensure that appropriate technical information on MON 87427 × MON 89034 × NK603 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 seed 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 animal or human health or the environment, which they might attribute to the import or use of this product. Appropriate technical information on MON 87427 × MON 89034 × NK603 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, 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 87427 × MON 89034 × NK603 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 87427 × MON 89034 × NK603 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 87427 × MON 89034 × NK603.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MON 87427 × MON 89034 × NK603 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 of Regulation 1829/2003

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

As MON 87427 × MON 89034 × NK603 was produced by crossing plants containing MON 87427 and MON 89034 × NK603 using conventional breeding methods, it contains inserts in combination. Therefore, MON 87427 × MON 89034 × NK603 is detectable using the combination of the individual event detection methods. For all plants in which two or more events are combined by conventional breeding, the events involved will segregate in the grain; therefore such detection methods when applied to individual grains from MON 87427 × MON 89034 × NK603 will detect any combination of the three events.

A MON 87427-specific PCR-based assay allowing the identification and quantification of MON 87427 has been provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EURL). The detection methods for MON 89034 and NK603 have already been validated by the European Union Reference Laboratory (EURL).

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 87427 × MON 89034 × NK603 in 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 87427 × MON 89034 × NK603 has been field tested in the US and Puerto Rico in 2010 and Argentina (2012)

(b) Authority overseeing the release

US and Puerto Rico: United States Department of Agriculture (USDA)
Argentina: Secretary of Agriculture, Livestock, Fisheries, and Food (SAGPyA)

(c) Release site

US: multiple major maize growing states and Puerto Rico
Aim of the release
Argentina: multiple sites in major maize growing areas

(d) Aim of the release:

US / Argentina: Regulatory trials, efficacy, yield, product development, and demonstration

(e) Duration of the release

US / Argentina: One growing season.

(f) Aim of post-releases monitoring

US / Argentina: Assessment of volunteers.

(g) Duration of post-releases monitoring

US / Argentina: 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 87427 × MON 89034 × NK603 would be the cause of any adverse effects to human health or to the environment.

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