Application for authorization of MON 89034 × NK603 production and cultivation in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

Part II
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.

A. GENERAL INFORMATION

1. Details of application

a)	**Member State of application** The Netherlands
b)	**Notification number** Not available at the time of application.
c)	**Name of the product (commercial and other names)** The Monsanto development code for this genetically modified maize is: MON 89034 × NK603. In countries where MON 89034 × NK603 is being cultivated, packages of this maize are marketed under the name of the hybrid variety, in association with the trademark YieldGard VT PRO/RR2™.
d)	**Date of acknowledgement of notification** Not available at the time of application.

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 US
c)	**Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii))** MON 89034 × NK603 will be cultivated, traded and used in the European Union (EU) in the same manner as commercial maize and by the same growers and operators currently involved in the production, storage, transport, processing and use of maize.

3. Scope of the application

( )	GM plants for food use
( )	Food containing or consisting of GM plants
( )	Food produced from GM plants or containing ingredients produced from GM plants
( )	GM plants for feed use
( )	Feed containing or consisting of GM plants
( )	Feed produced from GM plants or containing ingredients produced from GM plants
( )	Import and processing (Part C of Directive 2001/18/EC)
(x)	Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

4. Is the product being simultaneously notified within the framework of another regulation (e.g. Seed legislation)?

Yes ( )	**No (x)**
If *yes*, specify	

5. Has the GM plant been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?

Yes (x)	**No ( )**
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC or Regulation (EC) 258/97?

Yes (x)	**No ( )**
If *yes*, specify An application pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed (EFSA-GMO-CZ-2007-38) which covers the use of MON 89034 × NK603 for food, feed, import and processing as any other maize in the EU was submitted on January 24, 2007 and was declared valid on August 24, 2007. Since then, the EFSA scientific review is ongoing.	

7. Has the product been notified in a third country either previously or simultaneously?

Yes (x)	No ( )

If *yes*, specify

MON 89034 × NK603 has been notified to and evaluated by international regulatory authorities. Japan and Taiwan, approved MON 89034 × NK603 for import and respectively food/feed and food uses.

The status of other pending regulatory reviews, which are currently in progress in other countries around the world, depends on the country and its local regulatory framework.

8. General description of the product

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

MON 89034 × NK603 was obtained by traditional breeding of two inbred lines, one derived from MON 89034 and the other derived from NK603. MON 89034 × NK603, as well as the parental lines containing either the MON 89034 or NK603 insert, have been developed by Monsanto Company.

MON 89034 has been developed to produce the Cry1A.105 and the Cry2Ab2 proteins that confer protection against certain lepidopteran pests (*e.g.* European corn borer (ECB) and Mediterranean corn borer (MCB)). MON 89034 was produced by *Agrobacterium*-mediated transformation of maize cells with plasmid vector PV-ZMIR245 that contains two separate T-DNAs (2 T-DNA system plasmid vector).

NK603 was produced by means of the particle acceleration method. NK603 expresses CP4 EPSPS proteins, derived from *Agrobacterium* sp. strain CP4, which confer tolerance to Roundup® agricultural herbicide (containing glyphosate).

As MON 89034 × NK603 inherits the introduced coding sequences from its parental inbreds, it expresses the Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins, and therefore it is protected from predation by the targeted lepidopteran insect pests as well as tolerant to glyphosate.

The use of MON 89034 × NK603 enables the farmer to effectively control the targeted lepidopteran insect pests in maize, ensuring maximum realization of yield potential, while removing the environmental burden of the production, packaging and transport of insecticides, previously used to control those pests. In addition, growers will have the ability to apply glyphosate over the top of maize for broad-spectrum weed control.

b) Types of products planned to be placed on the market according to the authorisation applied for

The range of uses of this maize will be identical to the full range of equivalent uses of conventional maize.

This application is for the authorisation of MON 89034 × NK603 production and cultivation in the EU. It complements the scope of Monsanto's pending application EFSA-GMO-NL-2007-38 that is for food, feed, import and processing. The placing on the market of MON 89034 × NK603 hybrids also includes the use of the single event inbred line MON 89034 in breeding and hybrid seed production of MON 89034 × NK603 and other combined trait hybrids but does not comprise commercial cultivation of MON 89034 hybrids .

c) Intended use of the product and types of users

MON 89034 × NK603 will be cultivated, traded and used in the EU in the same manner as current commercial maize and by the same growers and operators currently involved in the production, storage, transport, processing and use of maize.

d) Specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

MON 89034 × NK603 is substantially equivalent to other maize varieties except for its protection against target lepidopteran pests and its tolerance to glyphosate, which are traits of agronomic interest. This maize was shown to be as safe and as nutritious as conventional maize. Therefore MON 89034 × NK603 and derived products will be stored, packaged, transported, handled and used in the same manner as the commercial maize products. No specific instructions and recommendations for use, storage and handling are therefore warranted or required.

e) Any proposed packaging requirements

MON 89034 × NK603 is substantially equivalent to conventional maize varieties (except for its protection from target lepidopteran insect pests and its tolerance to glyphosate). Therefore, MON 89034 × NK603 and derived products will be used in the same manner as other maize and no specific packaging is foreseen. (For the labelling, *see* question A.8.(f)).

f) Any proposed labelling requirements in addition to those required by Community law (Annex IV of Directive 2001/18/EC; Regulation 1829/2003 art. 13 and 25)

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 89034 × NK603 and derived products.

The applicant and his licensees will sell certified MON 89034 × NK603 seed for planting in the EU. Seed vendors shall be required to label seed bags containing MON 89034 × NK603 varieties with the words "genetically modified maize" or "contains genetically modified maize" as well as the product's unique identifier MON-89Ø34-3 × MON-ØØ6Ø3-6.

Operators shall be required to label products containing or consisting of MON 89034 × NK603 with the words "genetically modified maize" or "contains genetically modified maize", and shall be required to declare the unique identifier MON-89Ø34-3 × MON-ØØ6Ø3-6 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 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.

Growers and operators handling or using MON 89034 × NK603 grain and derived foods and feeds in the EU are 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 Community Register, growers and operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 89034 × NK603.

Therefore, no further specific measures are to be taken by the applicant.

g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants)

MON-89Ø34-3 × MON-ØØ6Ø3-6

h) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for. Any type of environment to which the product is unsuited

MON 89034 × NK603 is suitable for cultivation in all maize production regions in the EU.

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

This application is for the authorisation of MON 89034 × NK603 production and cultivation in the EU.

MON 89034 × NK603 is substantially equivalent to conventional maize except for the introduced lepidopteran and glyphosate-tolerance traits which are traits of agronomic interest. Moreover, the information presented in this application establishes that MON 89034 × NK603 is as safe and as nutritious as conventional maize and unlikely to pose any threat to the environment or to require special measures for its containment. Therefore, any measures for waste disposal and treatment of MON 89034 ×NK603 are the same as those for conventional maize and no specific conditions are warranted or required for the placing on the market of MON 89034 × NK603.

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

1. Complete name

a)	**Family name** Poaceae (formerly Gramineae)
b)	**Genus** *Zea*
c)	**Species** *mays* (2n=20)
d)	**Subspecies** N/A
e)	**Cultivar/breeding line** MON 89034 × NK603
f)	**Common name** Maize; Corn

2. a) Information concerning reproduction

(i) Mode(s) of reproduction

Maize (*Zea mays*) is an annual, wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers. Self- and cross-pollination are generally possible, with frequencies of each normally determined by proximity and other physical influences on pollen transfer.

(ii) 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.

(iii) Generation time

Maize is an annual crop with a cultural cycle ranging from as short as 60 to 70 days to as long as 43 to 48 weeks from seedling emergence to maturity.

2 b) Sexual compatibility with other cultivated or wild plant species

Out-crossing with cultivated *Zea* varieties

In Europe, the potential for genetic transfer and exchange with other organisms is limited to other maize plants. Maize is wind pollinated, and the distance that viable pollen can travel depends on prevailing wind patterns, humidity, and temperature. All maize will inter-pollinate, except for certain popcorn varieties and hybrids that have one of the gametophyte factors (*GaS*, *Ga*, and *ga* allelic series) on chromosome 4. 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.

Out-crossing with wild *Zea* species

Wild relatives of maize do not exist in Europe.

3. Survivability

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 cultivation 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.

4. Dissemination

a) Ways and extent of dissemination

In general, dissemination of maize may occur by means of seed dispersal 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, due to its relatively large mass and size (90 – 100 μm), the vast majority does not move more than a few meters from the crop in significant quantities. Most maize pollen falls within five meters of the field edge with smaller amounts of pollen deposited usually in a downwind direction.

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.

5. Geographical distribution and cultivation of the plant, including the distribution in Europe of the compatible species

Because of its many divergent types, maize is grown over a wide range of climatic conditions. 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.

There are no close wild relatives of maize in Europe.

6. 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

Maize is widely grown in the EU and represents a significant portion of global maize production. The most important 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.

7. 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

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. Maize has a history of safe use for human food and animal feed and the toxic and allergenic risk posed from consumption of maize and derived products is likely to be very low.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

MON 89034 × NK603 was produced by crossing inbred plants of MON 89034 and NK603 using traditional breeding methods.

MON 89034 was developed through *Agrobacterium*-mediated transformation of maize tissue while NK603 was obtained by incorporation of a restriction fragment of plasmid DNA into the maize genome using a particle acceleration method.

2. Nature and source of the vector used

MON 89034 × NK603 has been obtained by traditional breeding of MON 89034 and NK603 and no vector has been used to produce this maize hybrid.

The plasmid vector PV-ZMIR245, used for the transformation of maize cells to produce MON 89034, is a binary *Agrobacterium tumefaciens* transformation vector that was constructed using standard molecular biology techniques. It contains two T-DNAs. T-DNA I includes the *cry1A.105* and the *cry2Ab2* expression cassettes, while T-DNA II includes the *nptII* expression cassette. It also contains sequences that are necessary for transfer of T-DNA into the plant cell. These sequences are contained in the Right and Left Border regions which flank both T-DNA I and T-DNA II allowing for independent integration of each T-DNA into the plant genome during transformation. The T-DNA I region containing the *cry1A.105* and *cry2Ab2* gene expression cassettes is the portion of plasmid PV-ZMIR245 maintained in MON 89034.

NK603 was produced by a particle acceleration transformation method using a gel-isolated *Mlu*I restriction fragment of plasmid vector PV-ZMGT32 (designated PV-ZMGT32L), containing a 5 enolpyruvylshikimate-3-phosphate synthase (*epsps*) gene from *Agrobacterium* sp. strain CP4 (*cp4 epsps*). The plant expression plasmid vector, PV-ZMGT32 contains two adjacent plant gene expression cassettes each containing a single copy of the *cp4 epsps* gene. The vector also contains a *nptII* selectable marker gene, which allowed selection of bacteria containing the plasmid, and an origin of replication (*ori*) necessary for replicating the plasmid in *Escherichia coli*.

The agarose gel-isolated *Mlu*I restriction fragment of plasmid vector, PV-ZMGT32L, contains only the *cp4 epsps* plant gene expression cassettes and does not contain the *nptII* selectable marker gene or origin of replication.

3. Source of donor DNA, size and intended function of each constituent fragment of the region intended for insertion

MON 89034 × NK603 results from a traditional cross of the inbred parental lines MON 89034 and NK603, which are made homozygous for their respective inserted sequences.

By crossing MON 89034 and NK603, MON 89034 × NK603 inherits the inserted DNA fragments from both parental maize lines.

The individual components and the function of these inherited DNA sequences are given in Tables 1 and 2.

Table 1. Components of the inserted DNA fragment inherited from MON 89034

Sequence	Size (Kb)	Source	Function
		T-DNA I	
B-Left Border^{r1}	0.24	*Agrobacterium tumefaciens*	Border
P-*e35S^{89}*	0.30	Cauliflower mosaic virus	Promotor
L-*Cab*	0.06	Wheat	Leader
I-*Ract1*	0.48	Rice actin gene	Intron
CS-*cry1A.105*	3.53	*Bacillus thuringiensis*	Coding sequence
T-*Hsp17*	0.21	Wheat heat shock protein	Transcript termination sequence
P-*FMV*	0.56	Figwort mosaic virus	Promotor
I-*Hsp70*	0.80	Maize heat shock protein	Intron
TS-*SSU-CTP*	0.40	Maize	Targeting sequence
CS-*cry2Ab2*	1.91	*Bacillus thuringiensis*	Coding sequence
T-*nos*	0.25	*Agrobacterium tumefaciens*	Transcript termination sequence
B-Left Border^{r2}	0.23	*Agrobacterium tumefaciens*	Border

Table 2. Components of the inserted DNA fragment inherited from NK603

Sequence	Size (Kb)	Source	Function
		***cp4 epsps* gene cassette (1)**	
P-*Ract1*/ I-*Ract1*	1.40	*Oryza sativa*	Promoter and Intron
TS-*CTP2*	0.20	*Arabidopsis thaliana*	Targeting sequence
CS-*cp4 epsps*	1.40	*Agrobacterium* sp. strain CP4	Coding sequence
T-*nos*	0.30	*Agrobacterium tumefaciens*	Transcript termination sequence
		***cp4 epsps* gene cassette (2)**	
P-*e35S*	0.60	*Cauliflower mosaic virus*	Promoter
I-*Hsp70*	0.80	*Zea mays L.*	Intron
TS-*CTP2*	0.20	*Arabidopsis thaliana*	Targeting sequence
CS-*cp4 epsps l214p*	1.40	*Agrobacterium* sp. strain CP4	Coding sequence
T-*nos*	0.30	*Agrobacterium tumefaciens*	Transcript termination sequence

B: Border region; P: Promoter; I: Intron; TS: Targeting sequence; CS: Coding sequence; T: Transcript termination sequence; L: Leader

D. INFORMATION RELATING TO THE GM PLANT

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

MON 89034 × NK603 expresses:

1. the Cry1A.105 and the Cry2Ab2 insecticidal proteins which provide protection from feeding damage caused by the European corn borer (ECB, *Ostrinia nubilalis*), the Mediterranean corn borer (MCB, *Sesamia* spp.) and other lepidopteran insect pests,
2. the CP4 EPSPS protein, derived from *Agrobacterium* sp. strain CP4, which provides tolerance to glyphosate.

Commercialization of MON 89034 × NK603 will therefore provide substantial benefits to growers by limiting yield losses from insects feeding damage and by limiting weed pressure, while reducing the risk from insecticide use to humans and the environment.

2. Information on the sequences actually inserted or deleted

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

MON 89034 and NK603 each contains a single DNA insert with a single copy of the introduced DNA fragment, and this at different loci in the maize genome in their progeny. Each fragment is inherited in a Mendelian fashion.

As the parental maize lines used in the traditional cross to produce MON 89034 × NK603 are inbred lines that are homozygous in the MON 89034 or NK603, both of the inserted fragments are inherited by MON 89034 × NK603. The presence of these inserts in the hybrid was confirmed through Southern blot analysis.

Therefore, MON 89034 × NK603 contains both of the parental inserts, as they were present in MON 89034 and NK603.

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

Not applicable.

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

The traditionally bred F_1 MON 89034 × NK603 contains the parental inserts on separate chromosomes in the nuclear genome, as they were present in the parental lines MON 89034 and NK603, respectively. The presence of the inserts from MON 89034 and NK603 in MON 89034 × NK603 was confirmed by Southern blot analyses.

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

Since the inserts present in MON 89034 × NK603 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences are likely to have been conserved in this hybrid.

3. Information on the expression of the insert

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

The levels of the Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins in various tissues of MON 89034 × NK603 produced in 2004-2005 in Argentina and in 2007 in the EU were assessed by enzyme-linked immunosorbent assay (ELISA).

In 2004-2005, tissue samples for analysis were collected from five field trials locations representing the major maize growing region of Argentina and providing a variety of environmental conditions. At each site, three replicated plots of MON 89034 × NK603, MON 89034 and NK603, as well as the conventional control, were planted using a randomized complete block field design.

In 2007, tissue samples for analysis were collected from seven locations conducted in Germany and Spain. The locations of these trials represent geographical regions where maize is grown commercially. At each site, three replicated plots of MON 89034 × NK603, MON 89034 and NK603, as well as the conventional control, were planted using a randomized complete block field design.

Results of these analyses confirm the expression of the Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins throughout key developmental stages of MON 89034 × NK603 and in all parts of the plant. The range of Cry1A.105, Cry2Ab2 and CP4 EPSPS protein levels from MON 89034 × NK603 grown in the EU are similar to the corresponding range of expression levels obtained from data collected from other field trials where Cry1A.105, Cry2Ab2 and CP4 EPSPS protein expression levels in MON 89034 × NK603 were assessed.

b) Parts of the plant where the insert is expressed

Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins were found to be expressed in leaf, root, pollen, silk, forage, forage root, grain, stover and senescent root at appropriate times of plant development. Grain and forage are the most relevant tissues for the food and feed safety assessment of MON 89034 × NK603, while leaf, root, pollen, silk and stover are relevant tissues in terms of environmental risk assessment.

4. Information on how the GM plant differs from the recipient plant in

a) Reproduction

Agronomic data collected from trials performed with MON 89034 × NK603 in Argentina in 2004-2005 and in the EU in 2007 have demonstrated that MON 89034 × NK603 has not been altered in survival, multiplication or dissemination characteristics when compared to conventional maize varieties. The insect-protection and herbicide-tolerance traits have no influence on maize reproductive morphology and hence no changes in seed dissemination are to be expected.

b) Dissemination

The inherited traits have no influence on maize reproductive morphology and hence no changes in seed dissemination are to be expected.

c) Survivability

Maize is known to be a weak competitor in the wild, which cannot survive outside cultivation without human intervention. Field observations have demonstrated that MON 89034 × NK603 has not been altered in its survivability when compared to conventional maize.

d) Other differences

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

5. Genetic stability of the insert and phenotypic stability of the GM plant

MON 89034 × NK603 hybrid seed (F_1) is produced by crossing MON 89034 and NK603 parental inbred lines by traditional breeding. Thereby, each parental line passes on its inserted DNA sequence to the resulting MON 89034 × NK603 F_1 hybrid seed, which is sown by the grower.

The parental lines MON 89034 and NK603 each contain one insert with a single copy of the respective transformed DNA, which is stably integrated into the nuclear maize genome. Each trait is inherited as a single dominant gene in a Mendelian fashion. This has been confirmed by Southern blot analyses.

The harvested (F_2) grain of MON 89034 × NK603 is marketed by the grower for food, feed or industrial use and is not used for further breeding. Therefore, since MON 89034 × NK603 hybrid maize seed exists only for a single generation, there is no opportunity for its stability to be compromised.

6. Any change to the ability of the GM plant to transfer genetic material to other organisms

a) Plant to bacteria gene transfer

None of the genetic elements inherited in MON 89034 × NK603 has a genetic transfer function. Therefore, no changes are expected in the ability of these maize lines to transfer genetic material to bacteria.

b) Plant to plant gene transfer

Based on the observation that reproductive morphology in MON 89034 × NK603 is unchanged compared to conventional maize and that pollen production and pollen viability were unaffected by the genetic modification, the out-crossing frequency to other maize varieties or to wild relatives (which are not present in the EU) is unlikely to be different for MON 89034 × NK603 when compared to conventional maize varieties.

Further, as no intrinsic hazard is related to the potential outcrossing of the inserted traits, the environmental risk assessment for this maize concluded that the risk of harm arising from plant to plant gene transfer from MON 89034 × NK603 is negligible.

7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

7.1 Comparative assessment

Choice of the comparator

MON 89034 × NK603 was compared to a conventional control maize with similar genetic background, as well as with other commercially available maize hybrids.

7.2 Production of material for comparative assessment

a) number of locations, growing seasons, geographical spreading and replicates

MON 89034 × NK603 and the conventional control maize were grown at five field sites in major maize-growing areas of Argentina during the 2004-2005 field season.

In addition, MON 89034 × NK603 and the conventional control maize were grown at six field sites in geographical regions where maize is grown commercially in the EU (Germany and Spain) during the 2007 field season.

b) the baseline used for consideration of natural variations

The two compositional studies compared MON 89034 × NK603 (test) to the respective conventional control. Reference hybrids were grown in the same field locations and under the same conditions as the test and control. Where statistical differences occurred, the measured analyte was compared to a confidence interval developed from the reference hybrids. Differences were also compared to ILSI[5] ranges and ranges reported in literature.

7.3 Selection of material and compounds for analysis

The numerous compounds that were selected for analysis in the compositional studies were chosen on the basis of internationally accepted guidance provided by the OECD.

Based on the positive results of these extensive, compositional analyses conducted for MON 89034 × NK603 compared to conventional maize hybrids, there is no indication to further analyze other selected compounds in this maize.

7.4 Agronomic traits

Field trials with MON 89034 × NK603 were performed and the set of agronomic observations supports a conclusion that from an agronomic and phenotypic (morphological) point of view, MON 89034 × NK603 is equivalent to conventional maize, except for the inherited lepidopteran protection and tolerance to glyphosate.

7.5 Product specification

MON 89034 × NK603 will be used in the EU by growers and operators that have traditionally been involved in the production, commerce, processing and use of maize and maize-derived products in the European Union.

7.6 Effect of processing

Using both wet and dry milling processes, maize is converted into a diverse range of food and feed products and derivatives used as food and feed ingredients or additives. As MON 89034 × NK603 is substantially equivalent and as safe and as nutritious as conventional maize, the use of MON 89034 × NK603 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 89034 × NK603 are not expected to be any different from the production and processing of the equivalent foods and feeds, originating from conventional maize.

[5] International Life Science Institute Crop Composition Database.

7.7 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 such or in food or feed as a result of the addition of MON 89034 × NK603 to the conventional maize supply. MON 89034 × NK603 is expected to replace a portion of current maize hybrids such that its intake or use will represent some fraction of the total products derived from maize.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

MON 89034 × NK603 is produced by traditional breeding of MON 89034 with NK603. Both of the introduced traits from the parental lines are inherited by the MON 89034 × NK603 progeny. This resulted in the combined expression of the Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins in the same plant.

The conclusion of safety to humans of those proteins was based upon the following considerations:

- Those proteins have a demonstrated history of safe use;
- They have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- They do not exert any acute toxicity to mammals.

In addition, their low concentration in tissues that are consumed and their rapid digestibility in simulated digestive fluids provide additional assurance for their safety.

Furthermore, Cry1A.105, Cry2Ab2 and CP4 EPSPS have already been evaluated for toxicity in the context of MON 89034, and NK603 applications (EFSA-GMO-NL-2007-37 and C/ES/00/01, respectively) that received EFSA positive scientific opinions.

It is therefore highly unlikely that Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins would cause any toxic effects on human or animal health.

7.8.2 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 89034 × NK603 was shown to be substantially equivalent to conventional maize, no testing of any constituent other than the inherited proteins is indicated.

7.8.3 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.

7.8.4 Testing of the whole GM food/feed

The compositional and nutritional equivalence of grain from MON 89034 × NK603 and conventional maize have been established by compositional analysis. Additionally, the wholesomeness of MON 89034 × NK603 grain has been confirmed by a repeat-dose animal feeding study in broiler chickens using MON 89034 × NK603 -containing diets. These studies confirm the absence of any toxic effects associated to the introduced proteins and the absence of any unanticipated or pleiotropic effects linked to the genetic modification. There was no evidence of any adverse effects on human or animal health.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins have been assessed for their potential allergenicity according to the recommendations of Codex Alimentarius Commission. The proteins are from non-allergenic sources, lack structural similarity to known allergens, are rapidly digested in simulated gastric fluid, and constitute a very small portion of the total protein present in the grain of MON 89034 × NK603. Taken together these data lead to the conclusion that the Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins are unlikely to have any allergenic potential, and MON 89034 × NK603 is as safe as conventional maize regarding the risk for allergenicity.

Furthermore, Cry1A.105, Cry2Ab2 and CP4 EPSPS have already been evaluated for allergenicity in the context of MON 89034 and NK603 applications (EFSA-GMO-NL-2007-37 and C/ES/00/01, respectively) that received EFSA positive scientific opinions.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

As the introduced proteins do not have any allergenic potential, it was concluded that the use of 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.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The introduced traits in MON 89034 × NK603 are of agronomic interest, and are not intended to change any nutritional aspects of this maize. 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 upon commercialisation of MON 89034 × NK603, and no nutritional imbalances are expected as a result of the use of MON 89034 × NK603.

7.10.2 Nutritional assessment of GM feed

The introduced traits in MON 89034 × NK603 are of agronomic interest, and are not intended to change any nutritional aspects of this maize. In addition to the extensive compositional analyses which demonstrated the substantial equivalence of MON 89034 × NK603 to conventional maize (except for the introduced traits), a confirmatory feed performance study was conducted in rapidly growing broiler chickens. Test groups were fed diets containing grain from MON 89034 × NK603, and their performance was compared to control groups fed diets containing a non-gm control hybrid or commercially available reference hybrids. This study confirms the nutritional equivalence of MON 89034 × NK603 for use as feed, and demonstrates the absence of any pleiotropic or unanticipated effects from the introduced trait.

In conclusion, MON 89034 × NK603 is nutritionally equivalent to conventional control maize, as well as to maize varieties in commerce.

7.11 Post-market monitoring of GM food/feed

The assessment of the human and animal safety of MON 89034 × NK603 was conducted on the basis of its substantial equivalence to conventional maize (except for the inherited traits) and by extensive characterisation of the introduced traits, which are of agronomic interest, resulting in the expression of the Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins.

There are no intrinsic hazards related to MON 89034 × NK603 as no signs of adverse or unanticipated effects have been observed in a number of safety studies, including an animal feeding study using doses of administration that are orders of magnitude above expected consumption levels. The pre-market risk characterisation for food and feed use of MON 89034 × NK603 demonstrates that the risks of consumption of MON 89034 × NK603 or its derived products are consistently negligible and 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, feed or processing is neither warranted, nor appropriate.

8. Mechanism of interaction between the GM plant and target organisms (if applicable)

The Cry1A.105 and Cry2Ab2 proteins produced in MON 89034 × NK603 provide protection against certain lepidopteran pests. Those lepidopteran insects may be considered the target organisms which interact with MON 89034 × NK603 as the CP4 EPSPS protein does not have target organism.

A generalized mode of action of Cry proteins includes the following steps: ingestion of the protoxin crystal by the insect, solubilization of the crystal in the insect midgut, proteolytic processing of the released Cry protein by digestive enzymes to produce an active toxin termed delta-endotoxin, binding of the endotoxin to receptors on the surface of midgut epithelial cells of target organisms, formation of membrane ion channels or pores, and consequent disruption of cellular homeostasis. Electrolyte imbalance and pH changes render the gut paralyzed, which causes the insect to stop eating and die.

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

9.1 Persistence and invasiveness

Like for conventional maize, the likelihood of this maize to spread within cultivated fields or beyond the agricultural environment where it is grown is negligible, as maize is neither persistent nor invasive and these parameters are unaltered in MON 89034 × NK603 when compared to conventional maize. In the unlikely event of the establishment of MON 89034 × NK603 plants in the environment, the introduced traits would confer only a limited selective advantage (protection against European Corn Borer - ECB (*Ostrinia nubilalis*) and Mediterranean Corn Borer – MCB (*Sesamia* spp.) pests, tolerance to glyphosate) of short duration, narrow spatial context and with negligible consequences for the environment. Hence the risk of establishment and spreading of MON 89034 × NK603 in the environment is negligible.

9.2 Selective advantage or disadvantage

Compared with conventional maize, the presence of the inherited traits in MON 89034 × NK603 would only confer a meaningful advantage under specific conditions, *i.e.* where target insect pest species (*e.g.* ECB and MCB) would be present in sufficiently high numbers or where plants would be treated with glyphosate herbicide and if no other more important factors limiting its survival in the environment were present. This introduced "advantage" is only relevant in agricultural habitats (*i.e.* in maize fields) and is short in duration. The risk of the insect pest protection and the glyphosate-tolerance traits in MON 89034 × NK603 to be the cause of any adverse effects resulting from a competitive advantage or disadvantage is negligible, as maize is unlikely to establish outside cultivation under European conditions (*see* Section D.9.1). When viewed in the context of today's baseline agronomic practices for the production of maize, these advantages present negligible risk to the agricultural environment.

9.3 Potential for gene transfer

There is no potential for gene transfer from MON 89034 × NK603 to wild plant species in the EU (as not present), while the likelihood for gene transfer to other maize crops depends mainly on wind, flowering synchrony and distance between the crops. In the event that an introduced gene outcrossed to other maize, its transfer would only confer a selective advantage under specific conditions (*i.e.* upon attack by the target insects and /or applications of glyphosate-containing herbicide), as discussed in Section 9.2. Therefore, gene transfer from MON 89034 × NK603 to other maize crops is not considered to constitute an adverse environmental effect in itself and the environmental risk posed by this potential transfer to other maize crops, and hence by MON 89034 × NK603, is negligible.

9.4 Interactions between the GM plant and target organisms

Since the CP4 EPSPS protein expressed by MON 89034 × NK603 confers glyphosate-tolerance to the maize plant and does not have any target organism, target organisms for MON 89034 × NK603 will be limited to those of the Cry1A.105 and Cry2Ab2 proteins, *i.e.* certain lepidopteran insect pests.

Control of pest species is not considered adverse to the environment in an agro-ecosystem. The theoretical adverse effects of MON 89034 × NK603 on non-target organisms (through indirect interactions) cannot be considered different from the effects produced by other insect pest control measures, such as insecticide applications in conventional maize. Therefore, MON 89034 × NK603 poses no increased risk to these organisms, compared to conventional maize.

The only identified potential consequence from interactions between MON 89034 × NK603 and its target insect pests, if it occurs, would be the development of resistance in the target pests to the insecticidal Cry proteins expressed in MON 89034 × NK603. However, since an Insect

Resistance Management (IRM) plan will be put in place in those countries where MON 89034 × NK603 will be commercially planted, the risk for ECB and MCB resistance to the Cry1A.105 and Cry2Ab2 proteins to occur will be negligible.

9.5 Interactions of the GM plant with non-target organisms

As MON 89034 × NK603 and conventional maize are not different with respect to their phenotypic, agronomic characteristics and ecological interactions (except for the inherited lepidopteran-protection and glyphosate-tolerance traits), it was concluded that the impact of MON 89034 × NK603 on NTOs in the environment is not different from that of conventional maize. Furthermore, the potential exposure of NTOs to the inherited Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins presents no conceivable mechanism for causing adverse effects because of their specificity and properties.

A conclusion of negligible hazard for the Cry1A.105 and Cry2Ab2 proteins expressed in MON 89034 × NK603 on NTOs is supported by the history of safe use of *Bt* microbial pesticides, the mode of action of Cry proteins and their spectrum of activity. As well, based on the natural occurrence and history of exposure of NTOs to the CP4 EPSPS and related EPSPS proteins, which are known as a class of proteins without any conceivable mechanism for biological activity toward other organisms, there is no *a priori* reason to suspect that the CP4 EPSPS proteins could be harmful to NTOs. The non-hazardous nature of the Cry1A.105, Cry2Ab2 and the CP4 EPSPS proteins to NTOs was further confirmed in first tier NTO studies of the environmental risk assessment. Therefore, the risk for any adverse effects to NTOs, through their ecological interactions with MON 89034 × NK603 or through contact with the produced Cry1A.105 and Cry2Ab2 or CP4 EPSPS proteins, is negligible.

Furthermore, no adverse effects were brought forward by the people handling these products during the extensive field trials conducted in Argentina and in the EU.

9.6 Effects on human health

The likelihood for any adverse effects, occurring in humans as a result of their contact with this maize, is no different from conventional maize. MON 89034 × NK603 expresses the Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins, which have negligible potential to cause any toxic or allergenic effects in humans. Therefore, the risk of changes in the occupational health aspects of this maize is negligible.

9.7 Effects on animal health

The likelihood of potential adverse effects in animals fed MON 89034 × NK603 and in humans, consuming those animals, is negligible (*see* Sections D.7.8, D.7.9, D.7.10). Therefore, the risk of MON 89034 × NK603 for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

There is no evidence that MON 89034 × NK603 plants would be any different from conventional maize regarding their direct influence on biogeochemical processes or nutrient levels in the soil, as MON 89034 × NK603 is compositionally equivalent and has equivalent growth and development, morphology, yield, plant health and survival characteristics to conventional maize (*see* Sections D.4, D.7.1 and D.7.4). The Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins are subjected to rapid degradation in soil.

9.9 Impacts of the specific cultivation, management and harvesting techniques

As MON 89034 × NK603 is equivalent to conventional maize, except for the inherited lepidopteran-protection and glyphosate-tolerance traits, all the agronomic practices currently used to grow maize in the EU remain applicable for growing MON 89034 × NK603. Additionally, the possibility of using glyphosate herbicides for weed control in crop is added to the farmer's weeding options, which already include the use of glyphosate in inter-row treatments in some countries.

Pest and weed control is an established baseline management technique in maize. The introduced ECB and MCB-protection and glyphosate-tolerance traits in maize merely provide the farmer with an additional option or tool to control these pests and remove competing weeds from the crop. Therefore, cultivation of MON 89034 × NK603 instead of conventional maize does not change any basic management technique in maize as such, but gives growers more flexibility to apply the existing tools for management, while creating at the same time new opportunities to grow maize in a more sustainable way (*e.g.* reduced tillage, reduced insecticide applications or integrated pest management). It should be noted that the importance and aim of the basic management technique of removal of harmful insect pests and weeds from the MON 89034 × NK603 field in order to achieve optimal yield of the crop, is neither new nor different compared to conventional maize. In order to secure the valuable agronomic and other benefits of ECB and MCB-protected maize on a longer term, an IRM plan was developed, as described in Section D.9.4.

In conclusion, in comparison to any other maize, no typical characteristics of the genetically modified plant could be identified, which may cause adverse effects on the environment through a need to change management practices. Therefore, the environmental impact of farming practices to grow MON 89034 × NK603 in the EU is considered no different from any other maize.

10. Potential interactions with the abiotic environment

Like other plants, cultivated maize is known to interact with the abiotic environment (soil, water and air), *e.g.* establishment of roots in the soil, nutrient and water uptake and gas exchange. Maize production in general is known to have indirect impacts on biophysical and biogeochemical processes in the soil through tillage, fertilizer application, and establishment of a monoculture in a defined area. All the agronomic practices currently used to grow maize in the EU remain applicable for growing MON 89034 × NK603 and no specific techniques for cultivation, management and harvesting are required.

As MON 89034 × NK603 was shown to be substantially equivalent to conventional maize (except for the introduced lepidopteran protection and glyphosate-tolerance traits) with respect to its composition, phenotypic and agronomic characteristics, there is no evidence that this maize would be any different from conventional maize with regard to its baseline interactions with the abiotic environment.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants)

11.1 General (risk assessment, background information)

As the scope of this application under Regulation (EC) No 1829/2003 includes the use of MON 89034 × NK603 for the cultivation of varieties in the EU, a monitoring plan in accordance with Annex VII of Directive 2001/18/EC was included, as required by Articles 5(5) and 17(5) of the said Regulation.

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (ERA) for MON 89034 × NK603 was conducted as required by Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003. Analysis of the characteristics of MON 89034 × NK603 has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the proposed use of MON 89034 × NK603 in the EU is consistently negligible.

The ERA describes, however, that specific strategies for risk management are required with regards to the interaction between the GM plant and target organisms. IRM measures will be put in place in MON 89034 × NK603 cultivating countries to pro-actively avoid and in any case delay insect resistance development. Therefore, the applicant proposes to set up case-specific post marketing monitoring (CSM) actions, in the form of Insect Resistance Monitoring.

The monitoring will further concentrate on general surveillance (GS) to allow the identification of adverse effects of MON 89034 × NK603 or its use on human health or the environment, which were not anticipated in the ERA.

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

The conclusions of the ERA (described in Section D.9) consistently show that the placing on the market of MON 89034 × NK603 poses negligible risk to human and animal health and the environment. Specific strategies for risk management are however required with regard to the interactions between the GM plant and target organisms. IRM measures will be put in place in MON 89034 × NK603 cultivating countries to proactively avoid and in any case delay insect resistance development. The party placing the GM plant on the market will therefore set up CSM actions in the form of insect resistance monitoring, as described in the IRM plan presented by the applicant.

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

Any potential adverse effects of MON 89034 × NK603 on human health and the environment, which were not anticipated in the environmental risk assessment, are addressed by the GS plan.

GS 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.

For GS, the party placing MON 89034 × NK603 on the market will use several tools. The central tool is an annual farm questionnaire addressed to a subset of farmers cultivating MON 89034 × NK603. Additionally, information from other sources (company stewardship programmes, scientific literature, official websites and existing observation networks) will be incorporated, where appropriate.

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 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.

11.5 Reporting the results of the monitoring

Any recorded observations of adverse findings that are linked to the cultivation and/or use of this maize, which come to the attention of the party placing the GM plant on the market, will receive careful analysis in real time and remediating action, where applicable. Adverse reports will be discussed in the mandatory general surveillance report. The general surveillance reports will be sent to the European Commission, which will distribute to all Competent Authorities in the EU. General Surveillance reports will be prepared on an annual basis, except in case of adverse findings that need immediate risk mitigation, which will be reported as soon as possible.

Since monitoring of GM plants is a new topic and a creative process, the monitoring plan and especially the questionnaires can be improved based on experience from year to year.

12. Detection and event-specific identification techniques for the GM plant

As MON 89034 × NK603 is the result of a traditional cross of MON 89034 and NK603, it contains both inserts in combination. Therefore, MON 89034 × NK603 is detectable using either the event-specific PCR method for detecting the introduced DNA present in MON 89034 or the equivalent method for NK603. However, as for all plants in which one or more events are combined by traditional breeding, the unambiguous detection of MON 89034 × NK603 in mixed consignments of grain will require single grains to be subjected to detection methods for both MON 89034 and NK603, and to test positive for both.

E. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT AND/OR DERIVED PRODUCTS

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

Monsanto notifications under Part B of the Directive 2001/18/EC for MON 89034 × NK603 are listed on the JRC website[6]:

b) Conclusions of post-release monitoring

The EU field trials with MON 89034 × NK603 conducted to date aimed at collecting data for regulatory purposes. Post-release monitoring provided no significant evidence that MON 89034 × NK603 is likely to pose any risk of adverse effects to human or animal health or to the environment.

[6] http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx - Accessed on May 14, 2009

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)

Post-release monitoring provided no significant evidence that MON 89034 × NK603 is likely to pose any risk of adverse effects to human or animal health or to the environment.

2. History of previous releases of the GM plant carried out outside the Community by the same notifier

a) Release country

MON 89034 × NK603 has been field tested in the US since 2004. It has also been tested in Argentina and in Brazil.

b) Authority overseeing the release

US: United States Department of Agriculture and Environmental Protection Agency.
Argentina: Secretary of Agriculture (SAGPyA) – CONABIA.
Brazil: CTNBio and Agriculture Ministry (MAPA)

c) Release site

US/Argentina/Brazil: major maize growing regions.

d) Aim of the release

US/Argentina: performance assessments (efficacy, yield, breeding, etc)
Brazil: Regulatory trials.

e) Duration of the release

US/Argentina: 12 months.
Brazil: 10 months.

f) Aim of post-releases monitoring

US/Argentina/Brazil: assessment/removal of volunteers.

g) Duration of post-releases monitoring

US/Argentina: 12 months.

Brazil: 4 to 6 months, depending on irrigation in the planting area.

h) Conclusions of post-release monitoring

US/Argentina/Brazil: Volunteers have been eliminated to prevent persistence in the environment

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

US/Argentina/Brazil: no evidence that MON 89034 × NK603 is likely to cause any adverse effects to human or animal health and the environment.

3. Links (some of these links may be accessible only to the competent authorities of the Member States, to the Commission and to EFSA):

a) Status/process of approval

The EFSA website[7] provides information related to the applications submitted under Regulation (EC) No 1829/2003 on genetically modified food and feed.

b) Assessment Report of the Competent Authority (Directive 2001/18/EC)

A notification for MON 89034 × NK603 according to Part C of Directive 2001/18/EC has not been submitted by Monsanto.

c) EFSA opinion

An EFSA opinion specifically for MON 89034 × NK603, is not available at the time of submission of this application. However, favourable EFSA opinions have been issued for MON 89034 and NK603[8].

d) Commission Register (Commission Decision 2004/204/EC)

Once authorized, food and feed products will be entered in the Community Register of GM food and feed[9].

e) Molecular Register of the Community Reference Laboratory/Joint Research Centre

Information on detection protocols can be found on the JRC website[10].

f) Biosafety Clearing-House (Council Decision 2002/628/EC)

The publicly accessible portal site of the Biosafety Clearing-House (BCH) can be found online[11].

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7 http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO – Accessed May 14, 2009

8 http://www.efsa.europa.eu/EFSA/ScientificOpinionPublicationReport/efsa_locale-1178620753812_ScientificOpinions.htm – Accessed May 14, 2009

9 http://ec.europa.eu/food/dyna/gm_register/index_en.cfm – Accessed May 14, 2009

10 http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm - Accessed May 14, 2009

11 http://bch.biodiv.org – Accessed May 14, 2009

g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC)

A notification and SNIF according to Directives 2001/18/EC and 2002/812/EC, respectively, have not been submitted for MON 89034 × NK603. The EFSA website[12] does provide a link to this summary of the application for MON 89034 × NK603 under Regulation (EC) No 1829/2003.

[12] http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO – Accessed May 14, 2009