PART II

SUMMARY

SUMMARY OF THE APPLICATION FOR THE AUTHORISATION OF GENETICALLY MODIFIED 59122xNK603 MAIZE AND DERIVED FOOD AND FEED IN ACCORDANCE WITH REGULATION (EC) 1829/2003 INCLUDING AUTHORISATION FOR CULTIVATION IN ACCORDANCE WITH DIRECTIVE 2001/18/EC

A. GENERAL INFORMATION

1. Details of application

(a) Member State of application:

United Kingdom

(b) Application number:

[To be provided]

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

The product described in this application is 59122xNK603 maize, including 59122xNK603 maize seed products for cultivation, for all food and feed uses, and for all food, feed and processed products derived from 59122xNK603 maize. The 59122xNK603 maize has been obtained from traditional breeding methods between progeny of two genetically modified (GM) maize. The two GM maize are DAS-59122-7 maize, referred to as 59122 maize, and MON-ØØ6Ø3-6 maize, referred to as NK603 maize. No new genetic modification has been introduced in 59122xNK603 maize.

In accordance with Commission Regulation (EC) 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identification code assigned to 59122xNK603 maize is DAS-59122-7xMON-ØØ6Ø3-6.

(d) Date of acknowledgment of valid application:

[To be provided]

2. Applicant

(a) Name of applicant

This application is submitted by Pioneer Hi-Bred International, Inc., as represented by Pioneer Overseas Corporation.

(b) Address of applicant

Pioneer Overseas Corporation
Avenue des Arts, 44
B-1040 Brussels
Belgium

Pioneer Hi-Bred International, Inc.
7100 NW 62nd Avenue
P.O. Box 1014
Johnston, IA 50131-1014, U.S.A.

(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))

Same as applicant

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
√ Import and processing (Part C of Directive 2001/18/EC)
√ 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)?

No

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

Yes, 59122xNK603 maize has been notified in France and Spain for field trials under Part B of Directive 2001/18/EC.

Year	Member State	Notification No
2004	France	B/FR/04.02.05
2004	Spain	B/ES/04/04
2005	France	B/FR/05.03.02
2005	Spain	B/ES/05/15

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

Not applicable.

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?

No

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

Yes, a notification concerning foods derived from 59122xNK603 maize has been submitted to the US Food and Drug Administration (FDA), the Canadian Food Inspection Agency and to Health Canada.

In addition, applications for authorisation of 59122xNK603 maize have been submitted in 2005 to Japan, South Africa, Mexico and will be submitted to other regions worldwide, such as Korea, Australia/ New Zealand and the Philippines.

8. General description of the product

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

The recipient plant is maize (*Zea mays* L.), which is extensively cultivated and has a long history of safe use. The 59122xNK603 maize has been obtained from traditional breeding methods between progeny of genetically modified 59122 maize (expressing the Cry34Ab1, Cry35Ab1 and PAT proteins) and NK603 maize (expressing the CP4 EPSPS protein). The Cry34Ab1 and Cry35Ab1 proteins act together in the control of

corn rootworm larvae (Coleoptera: Chrysomelidae; *Diabrotica* spp.). Expression of the PAT protein, used as a selectable marker, confers tolerance to the application of glufosinate-ammonium herbicide and the CP4 EPSPS protein confers tolerance to glyphosate herbicide. No new genetic modification has been introduced in 59122xNK603 maize.

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

The product described in this application is 59122xNK603 maize, including 59122xNK603 maize seed products for cultivation, for all food and feed uses, and for all food, feed and processed products derived from 59122xNK603 maize.

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

Use of 59122xNK603 maize will be consistent with current uses of commercial maize products. Therefore there are multiple categories of users of 59122xNK603 maize, including agricultural growers, the animal feed and milling industry, skilled trades and consumers.

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

Safety evaluation of 59122xNK603 maize has shown that no specific instructions and/or recommendations for use, storage and handling of 59122xNK603 maize are necessary. Therefore, 59122xNK603 maize can be used, stored and handled in the same way as is currently done for commercial maize. Labelling of 59122xNK603 maize products will be carried out in accordance with Community law. See Point **A.8(f)** below for labelling of 59122xNK603 maize.

(e) Any proposed packaging requirements

The packaging, handling, and storage systems that are currently used for commercial maize will apply. The 59122xNK603 maize products will be packaged in the same manner as other commercial maize products. See Point **A.8(f)** below for labelling of 59122xNK603 maize.

(f) A proposal for labelling in accordance with Articles 13 and Articles 25 of Regulation (EC) 1829/2003. In the case of GMOs, food and/or feed containing or consisting of GMOs, a proposal for labelling has to be included complying with the requirements of Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC

1.- PROPOSAL FOR THE LABELLING OF 59122xNK603 MAIZE FOOD PRODUCTS ACCORDING TO ARTICLES 12 AND 13 OF REGULATION (EC) 1829/2003

Proposal for the labelling of 59122xNK603 maize food products

In accordance with Article 12(2) of Regulation No (EC) 1829/2003, labelling will not apply to foods containing material which contains, consists of or is produced from 59122xNK603 maize in a proportion no higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient.

In accordance with Article 13 of Regulation (EC) 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods containing, consisting of, produced from, or containing ingredients produced from, 59122xNK603 maize should be labelled as follows:

(a) where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified maize' will appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned;

(b) where the ingredient is designated by the name of a category, the words 'contains genetically modified maize' or 'contains (name of ingredient) produced from genetically modified maize' will appear in the list of ingredients;

(c) where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified maize' will appear clearly on the labelling;

(d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they will appear clearly on the labelling;

(e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm^2, the information referred to above will be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

No other particulars such as those referred to in Article 13(2)(a) and (b) and Article 13(3) of Regulation No (EC) 1829/2003 would need to be specified on the label of 59122xNK603 maize food products as 59122xNK603 maize has been shown to be equivalent to non-GM maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the 59122xNK603 maize does not give rise to any ethical or religious concerns.

2.- PROPOSAL FOR THE LABELLING OF 59122xNK603 MAIZE FEED PRODUCTS ACCORDING TO ARTICLES 24 AND 25 OF REGULATION (EC) 1829/2003

Proposal for the labelling of 59122xNK603 maize feed products

In accordance with Article 24(2) of Regulation No (EC) 1829/2003, labelling will not apply to feed containing material which contains, consists of or is produced from 59122xNK603 maize in a proportion no higher than 0.9% of the feed and of each feed of which it is composed.

In accordance with Article 25 of Regulation (EC) 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) of Regulation (EC) 1829/2003, *i.e.* 59122xNK603 maize for feed use, and feed containing, consisting of or produced from 59122xNK603 maize, should be labelled as follows:

(a) where the feed contains or consists of 59122xNK603 maize, or where 59122xNK603 maize is used for the purpose of feed use, the words 'genetically modified maize' will appear in parentheses immediately following the specific name of the feed.

    Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed;

(b) where the feed is produced from 59122xNK603 maize, the words 'produced from genetically modified maize' will appear in parentheses immediately following the specific name of the feed;

    Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed;

No other particulars such as those referred to in Article 25(2)(c) and Article 25(3) of Regulation No (EC) 1829/2003 would need to be specified on the label of 59122xNK603 maize feed products as 59122xNK603 maize has been shown to be equivalent to non-GM maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the 59122xNK603 maize does not give rise to any ethical or religious concerns.

3.- PROPOSAL FOR THE LABELLING OF PRODUCTS CONSISTING OF, OR CONTAINING, 59122xNK603 MAIZE ACCORDING TO ARTICLE 4, B(6) OF REGULATION (EC) 1830/2003 AND ANNEX IV OF DIRECTIVE 2001/18/EC

In accordance with Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC, the information provided on a label or in an accompanying document for the purpose of satisfying the labelling requirements regarding placing on the market of 59122xNK603 maize will include the following:

i) Commercial name of the product and the statement that 'this product contains genetically modified maize';

ii) Name of the GMO;

iii) Information referred to in Point **A.2.** of Annex IV of Directive 2001/18/EC (name and full address of the person established in the Community who is responsible for the placing on the market);

iv) How to access the information in the publicly accessible part of the register.

(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)

In accordance with Commission Regulation (EC) 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identifier assigned to 59122xNK603 maize is DAS-59122-7xMON-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

Not applicable

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

Based on the conclusions from the environmental risk assessment of 59122xNK603 maize, no specific measures need to be taken in case of unintended release or misuse or for disposal and treatment.

In case of unintended release or misuse of 59122xNK603 maize, current measures taken to control unintended release or misuse of commercial maize can be applied,

such as selective use of herbicides (with the exception of glufosinate-ammonium and glyphosate herbicides), and manual or mechanical removal.

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

1. Complete name

(a) Family name:	Poaceae (Gramineae)
(b) Genus:	*Zea*
(c) Species:	*Z. mays* L.
(d) Subspecies:	None
(e) Cultivar/breeding line:	59122; NK603
(f) Common name:	Maize; corn

2 a. Information concerning reproduction

(i) Mode(s) of reproduction

Maize (*Zea mays* L.) is the only species usually included in the genus *Zea*, of the family Gramineae. It is a highly domesticated agricultural crop with well-characterised phenotypic and genetic traits. It reproduces sexually by wind-pollination and being a monoecious species has separate male staminate (tassels) and female pistillate (silk) flowers. This allows natural outcrossing between maize plants but also enables the control of pollination in the production of hybrid seed. Typical for wind-pollinated plants, a large amount of excess maize pollen is produced for each successful fertilisation of an ovule on the ear. Wind movements across the maize field cause pollen from the tassel to fall on the silks of the same or adjoining plants. Measuring about 0.1 mm in diameter, maize pollen is the largest of any pollen normally disseminated by wind.

(ii) Specific factors affecting reproduction

Being a wind-pollinated, monoecious species, maize is reproduced by self-pollination and fertilisation, and cross-pollination and fertilisation, with frequencies of each normally determined by proximity and other physical influences on pollen dispersal. Reproductive factors such as tasselling (pollen production), silking, and pollination are the most critical stages of maize development. Repeated cycles of self-pollination leads to homogeneity of the genetic characteristics within a single maize plant (inbred). Controlled cross-pollination of inbred lines from chosen genetic pools combines desired genetic traits resulting in a hybrid with improved agronomic performance and yield increase. This inbred-hybrid concept and improved yield response is the basis of the modern maize seed industry.

(iii) Generation time

Maize is an annual crop with a cultural cycle ranging from as short as 10 weeks to as long as 48 weeks covering the period of seedling emergence to maturity.

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

There are no other cultivated or wild plant species that are sexually compatible with maize, in the EU. Maize plants intra-pollinate and transfer genetic material between maize except for certain popcorn varieties. The extent of pollination between maize depends upon wind patterns, humidity and temperature. Low humidity and high temperatures cause the pollen to become desiccated and unviable.

3. Survivability

(a) Ability to form structures for survival or dormancy

During the domestication of maize, many agronomically significant attributes for cultivation have been gained, whilst maize has lost the ability to survive in the wild. Maize is a non-dormant annual crop and seeds are the only survival structures. Natural regeneration of maize from vegetative tissue is not known to occur.

(b) Specific factors affecting survivability

Survival of maize seed is dependant upon temperature, moisture of seed, genotype, husk protection and stage of development. Maize seed can only survive under favourable climatic conditions. Freezing temperatures have an adverse effect on germination of maize seed and they have been identified as a major risk in limiting production of maize seed. Furthermore, maize is a C_4 plant and therefore its vegetative growth is sensitive to low temperatures. Chlorosis will occur at temperatures below 15°C. The generative phase of maize is supported by short day conditions. The minimum temperature for germination of 8 to 10°C restrict maize survival and reproduction capabilities mainly to the Southern European geographical zones.

4. Dissemination

a. Ways and extent of dissemination

Maize dissemination occurs via kernel (seed/grain) and pollen. Maize has been domesticated for thousands of years and as a result, maize dispersal of individual kernels does not occur naturally.

Pollen shedding from the tassels takes place over a period of 10 to 15 days. Pollen grains are round, heavy and contain a large amount of water, characteristics that limit their dispersal and attachment to plant surfaces, such as leaves. Generally, viability of

shed pollen is 10 to 30 minutes, although it can remain viable for longer time under favourable conditions. However, dispersal of maize pollen tends to be limited as it is influenced by the large size and rapid settling rate of the pollen. Deposition of maize pollen has been found to rapidly decline from 2.3×10^7 grains per m^2 at a 1 m offset from the field edge to 7.1×10^3 grains per m^2 at 60 m: this represents a decline in pollen concentrations of over four orders of magnitude extending from radial distances of 1 m to 60 m from the field edge.

b. Specific factors affecting dissemination

Mechanical harvesting and transport are ways of disseminating grain and insect or wind damage may cause mature ears to fall to the ground and avoid harvest. Regardless of these routes of dissemination, maize cannot survive without human assistance in non-agricultural habitats in the EU. Because of its highly domesticated nature, maize seed requires the semi-uniform soil conditions resulting from cultivation in order to germinate and establish in agricultural habitats.

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

Because of its many available cultivars, maize can grow in a wide range of climatic conditions. However, survival and reproduction in maize is limited by cool conditions. Practically no maize can be cultivated where the mean mid-summer temperature is below 19°C or where the average night temperature is below 13°C. The majority of maize is produced between 30 and 55 degrees of latitude, with a relatively small amount grown at latitudes higher than 47 degrees 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. Summer rainfall of 15 cm is the lower limit for maize production without irrigation. There is no upper limit of rainfall for growing maize, although excess rainfall will decrease yields. Maize has been cultivated in Europe starting in Spain since the 16th century.

There are no wild plant species that are sexually compatible with maize in the EU.

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

Not applicable as maize is normally grown in the EU and its natural habitat consists of the relatively well-characterised agricultural environment.

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

Maize is extensively cultivated in the EU and has a long history of safe use. 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 insect pests, as well as competition from surrounding weeds.

Maize or derived products of maize, are not considered to have toxic effects on humans, animals and other organisms.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

The 59122xNK603 maize has been obtained from traditional breeding methods between progeny of genetically modified 59122 maize and NK603 maize. No new genetic modification has been introduced in 59122xNK603 maize.

The 59122 maize was obtained by means of *Agrobacterium*-mediated transformation, which resulted in the stable insertion of the T-DNA region from binary vector PHP17662 in the maize genome. The T-DNA region contains the *cry*34Ab1, *cry*35Ab1 and *pat* coding sequences and the necessary regulatory components to regulate gene expression. The plant regenerated from these maize cells expresses the Cry34Ab1 and Cry35Ab1 proteins that act together in the control of corn rootworm larvae (Coleoptera: Chrysomelidae; *Diabrotica* spp.), and the PAT protein, used as a selectable marker, that confers tolerance to the application of glufosinate-ammonium herbicides.

The NK603 maize was obtained by insertion of a linear DNA fragment (insert PV-ZMGT32L) containing two copies of the *cp*4 *epsps* gene isolated from the CP4 strain of the common soil bacterium *Agrobacterium tumefaciens,* using the particle acceleration method. As a result of the transformation, NK603 maize expresses the CP4 EPSPS protein that confers tolerance to glyphosate herbicides.

2. Nature and source of the vector used

No vector was used in the production of 59122xNK603 maize. The 59122xNK603 maize has been obtained from traditional breeding methods between progeny of genetically modified 59122 maize and NK603 maize. There is no new genetic modification in 59122xNK603 maize.

For transformation to obtain 59122 maize, binary vector PHP17662 was used. Molecular characterisation of 59122 maize confirmed that only the T-DNA region that is situated between the left and right borders of binary vector PHP17662 is inserted in 59122 maize.

No vector was used in transformation to obtain NK603 maize. As described in Point **C.1**, the intended insert in NK603 maize was a linear DNA fragment. No additional DNA sequences were used in the introduction of the intended insert into NK603 maize.

3. Source (name) of donor organism(s), size and intended function of each constituent fragment of the region intended for insertion

The 59122xNK603 maize has been obtained from traditional breeding methods between progeny of 59122 and NK603 maize. No new genetic modification has been introduced in 59122xNK603 maize.

The T-DNA inserted in 59122 maize contains: a 372 bp maize-optimised *cry*34Ab1 gene from *Bacillus thuringiensis* strain PS149B1 with transcription directed by the 1993 bp ubiquitin promoter *ubi*1ZM from *Zea mays* and with a 315 bp termination sequence derived from *Solanum tuberosum* proteinase inhibitor II gene; a 1152 bp maize-optimised *cry*35Ab1 gene from *Bacillus thuringiensis* strain PS149B1 with transcription directed by the promoter from *Triticum aestivum* peroxidase (1298 bp) and with a 315 bp termination sequence derived from *Solanum tuberosum* proteinase inhibitor II gene; and, a 552 bp plant-optimised phosphinothricin acetyltransferase gene, *pat*, from *Streptomyces viridochromogenes* with transcription directed by the CaMV 35S promoter (530 bp) and CaMV 35S terminator (194 bp), both from cauliflower mosaic virus.

The insert used in the transformation to obtain NK603 maize (insert PV-ZMGT32L; 6.7 kb) contained two copies of the *cp*4 *epsps* gene (origin: *Agrobacterium* sp. strain CP4). One of the copies of the *cp*4 *epsps* gene was under the control of the rice actin 1 gene promoter (1.4 kb; origin: *Oryza sativa*); the chloroplast transit peptide of the *epsps* gene (0.2 kb, origin: *Arabidopsis thaliana*); and, the terminator of the nopaline synthase gene (0.4 kb; origin: *Agrobacterium tumefaciens*). The second copy of the *cp*4 *epsps* gene was under the control of the *e35S* promoter with a duplicated enhancer region (0.6 kb; origin: cauliflower mosaic virus); the *hsp70* gene intron (0.8 kb; origin: *Zea mays*); the chloroplast transit peptide of the *epsps* gene (0.2 kb, origin: *Arabidopsis thaliana*); and, the terminator of the nopaline synthase gene (0.4 kb; origin: *Agrobacterium tumefaciens*).

D. INFORMATION RELATING TO THE GM PLANT

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

The 59122xNK603 maize has been obtained from traditional breeding methods between progeny of genetically modified 59122 maize and NK603 maize. No new genetic modification has been introduced in 59122xNK603 maize.

The 59122 maize was genetically modified to express the Cry34Ab1, Cry35Ab1 and PAT proteins. The Cry34Ab1 and Cry35Ab1 proteins act together in the control of corn rootworm larvae (Coleoptera: Chrysomelidae; *Diabrotica* spp.). Therefore, cultivation of 59122 and 59122xNK603 maize provides a specific control against corn rootworm pest damage. Expression of the PAT protein, used as a selectable marker, confers tolerance to the application of glufosinate-ammonium herbicide.

The NK603 maize was genetically modified to express the CP4 5-enolpyruvyl shikimate-3-phosphate synthase protein (CP4 EPSPS). When cultivated, expression of the CP4 EPSPS protein in NK603 and 59122xNK603 maize confers tolerance to the application of glyphosate herbicide.

No other new traits have been introduced or modified in 59122xNK603 maize.

2. Information on the sequences actually inserted or deleted

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

The molecular equivalence and identical copy number of the inserts present in 59122xNK603 maize to those present in 59122 and NK603 maize, respectively, have been confirmed by a detailed molecular characterisation, consisting of Southern blot analyses. There is no new genetic modification in 59122xNK603 maize.

The results of the molecular characterisation of 59122 maize confirm that 59122 maize contains a single and full-length copy of the T-DNA region from binary vector PHP17662. Southern blot analysis demonstrated that 59122 maize does not contain fragments from the vector backbone portion of binary vector PHP17662. Maize genomic DNA flanking regions at both the 5' and 3' borders of the 59122 maize insert have been sequenced and characterised in detail.

A detailed description of the copy number of all detectable inserts in NK603 maize has been included in the notification of NK603 maize pursuant to Directive 2001/18/EC (C/ES/00/01) and in the application for authorisation of NK603 maize pursuant to Regulation (EC) No. 258/97 submitted by Monsanto Europe S.A., which have been authorised by Commission Decisions 2004/643/EC and 2005/448/EC, respectively.

(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 inserts are integrated in the nuclear genome.

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

The molecular equivalence and identical copy number of the inserts present in 59122xNK603 maize to those present in 59122 and NK603 maize, respectively, have been confirmed by a detailed molecular characterisation, consisting of Southern blot analyses. There is no new genetic modification in 59122xNK603 maize.

3. Information on the expression of the insert

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

The 59122xNK603 maize has been obtained from traditional breeding methods between progeny of 59122 maize and NK603 maize. As a result, 59122xNK603 maize expresses the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins during the life cycle of the plant. No new genetic modification has been introduced in 59122xNK603 maize.

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

The Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins are expressed at comparable levels in the 59122xNK603 maize regardless of the herbicide treatment used. The Cry34Ab1, Cry35Ab1 and CP4 EPSPS proteins are expressed in the grain, leaf, root and stalk of the 59122xNK603 maize. The PAT protein is expressed in the leaf, root and stalk of the 59122xNK603 maize. The expression level of the PAT protein in 59122xNK603 maize grain was below the lower limit of quantitation of the assay used.

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

(a) Reproduction

No biologically significant changes in pollen production, seed production, seed viability or germination compared to non-GM control maize have been observed in field trials of 59122xNK603 maize.

(b) Dissemination

Cultivated maize has been domesticated to the extent that the seeds cannot be disseminated without human intervention. The 59122xNK603 maize plants show no difference in dissemination compared to non-GM control maize.

(c) Survivability

Cultivated maize has been domesticated to the extent that it cannot survive outside well-managed agricultural environments. Lack of dormancy prevents maize seed from readily surviving from one growing season to the next. When cultivated, expression of the Cry34Ab1 and Cry35Ab1 proteins in 59122xNK603 maize confers resistance to certain coleopteran insect pests, expression of PAT (used as a selectable marker) confers tolerance to the herbicide glufosinate-ammonium and expression of CP4 EPSPS confers tolerance to the herbicide glyphosate. The survival characteristics of 59122xNK603 maize in the environment remain comparable to those of non-GM control maize. Resistance against certain coleopteran insect pests is not sufficient to allow survival of maize outside the agricultural habitat and, the broad-spectrum herbicides glufosinate-ammonium and glyphosate are not normally used outside agricultural habitats.

(d) Other differences

No biologically significant changes were observed between 59122xNK603 maize and non-GM maize with relation to other agronomic traits, such as stalk lodging, root lodging, plant height, ear height, stay green, disease incidence and insect damage.

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

The 59122xNK603 maize has been shown to be genetically and phenotypically stable. Results from Southern blot analyses and evaluation of agronomic characteristics and protein expression analysis of 59122xNK603 maize plants have confirmed the stable inheritance and expression of Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins in 59122xNK603 maize.

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

(a) Plant to bacteria gene transfer

Transfer of genetic material originating from 59122xNK603 maize to bacteria is a negligible concern. There is no known mechanism for, or definitive demonstration of, DNA transfer from plants to microbes under natural conditions. Even if horizontal gene transfer were to take place, transfer of the *cry*34Ab1, *cry*35Ab1, *pat* or *cp*4 *epsps*

genes from 59122xNK603 maize does not represent a risk to human or animal health, nor is it of consequence as a plant pest risk.

(b) Plant to plant gene transfer

The potential for transfer of genetic material from 59122xNK603 maize to other organisms has not been changed and it will be negligible, as there are no sexually compatible wild or weedy relatives of *Zea mays* known to exist in the EU. In addition, maize pollen grains are heavy, with a rapid settling rate, and show limited dispersal and viability capacities.

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

The comparator chosen for the safety evaluation of 59122xNK603 maize consists of non-GM maize with comparable genetic background. Wherever possible, available data on commercial maize have also been used in the comparisons with 59122xNK603 maize.

7.2 Production of material for comparative assessment

(a) Number of locations, growing seasons, geographical spreading and replicates

A field study was conducted at five locations in Europe during the 2004 growing season. Each location included a randomized complete block design containing four blocks (or replicates). Each block contained the 59122xNK603 maize and a non-GM control maize for comparison.

(b) The baseline used for consideration of natural variations

Available data on commercial maize was used as the baseline for consideration of natural variations in the comparisons with 59122xNK603 maize. In addition, a comparative assessment with non-GM control maize of comparable genetic background has been carried out.

7.3 Selection of compounds for analysis

As recommended by the OECD (1999), the compounds selected for composition analysis of forage and grain from 59122xNK603 maize consisted of protein, fibre, carbohydrates, fat, ash, fatty acids, minerals, amino acids, vitamins, secondary metabolites and anti-nutrients. The results confirmed that there are no statistically significant differences between 59122xNK603 maize and non-GM control maize with

comparable genetic background that would fall outside the normal ranges of natural variation for non-GM maize.

7.4 Agronomic traits

The 59122xNK603 maize was tested at five locations in Europe during the 2004 growing season. The results confirmed that there are no biologically significant agronomic differences between 59122xNK603 maize and non-GM control maize with comparable genetic background.

7.5 Product specification

The 59122xNK603 maize is substantially and nutritionally equivalent to commercial maize. Therefore, the specification of 59122xNK603 maize, including 59122xNK603 maize seed products, and all food, feed and processed products derived from 59122xNK603 maize is the same as that of commercial maize and of all food, feed and processed products derived from commercial maize.

7.6 Effect of the production and processing

The 59122xNK603 maize will undergo existing production processes used for commercial maize. No novel production process is envisaged.

The Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins expressed in 59122xNK603 maize are susceptible to conditions used in the production and processing of maize. In particular, heating of maize derived products will lead to the denaturation and degradation of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins expressed in 59122xNK603 maize.

7.7 Anticipated intake/extent of use

The 59122xNK603 maize and all food, feed and processed products derived from 59122xNK603 maize are expected to replace a portion of similar products from commercial maize with total consumption of maize products in the EU remaining unchanged. Therefore, the total anticipated intake/extent of use of maize and all food, feed and processed products derived from maize will remain the same. The majority of maize products in the EU, either from imports or cultivation, are fed to livestock. In particular, human consumption of maize products in the developed world is in the form of high fructose maize syrup, starches, and oil, *i.e.* products that contain only negligible amounts of protein.

According to GEMS/FOOD Dietary Tables (2003) maize consumption by the European population is estimated to be 8.8 grams/person/day. The comparative and nutritional assessments of 59122xNK603 maize together with the absence of any adverse effects to human and animal health from the Cry34Ab1, Cry35Ab1, PAT and

CP4 EPSPS proteins confirm that there are no concerns related to the anticipated intake/extent of use of 59122xNK603 maize and all food, feed and processed products derived from 59122xNK603 maize.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

The 59122xNK603 maize has been obtained from traditional breeding methods between progeny of 59122 maize and NK603 maize and no new genetic modification has been introduced in 59122xNK603 maize. As a result, 59122xNK603 maize expresses the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins. The safety of these proteins has already been confirmed in the detailed and thorough safety evaluations carried out by a number of scientific and regulatory panels around the world.

The Cry34Ab1 and Cry35Ab1 proteins have specific toxicity against certain coleopteran insect pests (corn rootworm larvae, target organisms). There is no evidence for Cry34Ab1 and Cry35Ab1 proteins originating from *Bacillus thuringiensis* to have harmful effects on the health of humans and animals. The potential toxicity to humans and animals of the Cry34Ab1 and Cry35Ab1 proteins was examined in acute oral toxicology studies. In these studies, Cry34Ab1 and Cry35Ab1 proteins were evaluated either separately or as a Cry34Ab1/Cry35Ab1 protein mixture for acute toxicity potential in mice. No mortality, toxicity or adverse clinical signs were observed.

The safety in terms of toxicity for the PAT protein has already been determined in detail during the assessment of glufosinate-ammonium tolerant maize. The *pat* gene was originally obtained from *Streptomyces viridochromogenes* strain Tü494 which has no known toxic or pathogenic potential. Acute oral toxicity studies of the PAT protein, carried out on mice, have confirmed the absence of any adverse treatment-related clinical signs.

The safety in terms of toxicity for the CP4 EPSPS protein has already been determined in detail during the assessment of glyphosate tolerant maize. The *cp*4 *epsps* gene was originally obtained from *Agrobacterium* sp. strain CP4, which has no known toxic or pathogenic potential. Acute oral toxicity studies of the CP4 EPSPS protein, carried out on mice, have confirmed the absence of any adverse treatment-related clinical signs.

7.8.2 Testing of new constituents other than proteins

Detailed compositional analyses of forage and grain from 59122xNK603 maize demonstrated that the composition of 59122xNK603 maize is equivalent to that of

non-GM control maize with comparable genetic background. Therefore, no testing of any other constituent is necessary.

7.8.3 Information on natural food and feed constituents

The comparisons carried out between the natural constituents of 59122xNK603 maize and non-GM control maize with comparable genetic background confirm that there are no statistically significant differences that would fall outside the normal ranges of variation for commercial maize.

7.8.4 Testing of the whole GM food/feed

As described throughout this application, there is no new genetic modification in 59122xNK603 maize. In addition, the nutritional assessment of 59122xNK603 maize has confirmed that whole food and feed consisting of or derived from 59122xNK603 maize is equivalent to whole food and feed consisting of or derived from commercial maize.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

In accordance with a weight-of-evidence approach, which accounts for a variety of factors and experimental approaches for an overall assessment of the allergenic potential of the new proteins, the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins were assessed for their allergenic potential through: (i) assessing the allergenicity potential of the source of the gene, (ii) homology searches with known protein allergens, (iii) susceptibility to *in vitro* simulated digestion and thermolability, (iv) evaluation of protein glycosylation and (v) assessment of protein exposure. The results obtained confirm that the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins do not pose any significant risk of being a potential allergen. In addition, neither *Bacillus thuringiensis* (the source of the *cry*34Ab1 and *cry*35Ab1 genes), *Streptomyces viridochromogenes* (the source of the *pat* gene) nor *Agrobacterium* sp. strain CP4 (the source of the *cp4 epsps* gene) have a history of causing allergy.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Maize has a long history of safe use as food in the EU and constitutes a traditional counterpart to 59122xNK603 maize that can be used as a baseline to facilitate the assessment of potential toxicity and allergenicity of 59122xNK603 maize. Maize is not considered to be a common allergenic food crop and 59122xNK603 maize does not express any new proteins with allergenic characteristics.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

Composition analyses of forage and grain from 59122xNK603 maize have shown that the contents of protein, fibre, carbohydrates, fat, ash, minerals, fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients are all equivalent to that found in non-GM maize with comparable genetic background and to the published range of values in the literature.

Furthermore and taking into account the anticipated dietary intake of 59122xNK603 maize products, consumption of 59122xNK603 maize foods will not give rise to any adverse nutritional impact.

7.10.2 Nutritional assessment of GM feed

As summarised in **Point D.7.10.1** above, consumption of 59122xNK603 maize feed will not give rise to any adverse nutritional impact.

7.11 Post-market monitoring of GM food/feed

As summarised in **Point D.7.10**, the nutritional assessment has concluded that 59122xNK603 maize is nutritionally equivalent to commercial maize. In addition, the use of 59122xNK603 maize food and feed products will not be different from that of food and feed products from commercial maize.

Therefore, post-market monitoring of 59122xNK603 maize food and feed is not necessary.

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

In order to better understand the contribution of the Cry34Ab1 and Cry35Ab1 proteins to the *in vivo* mode of action of the binary insecticidal crystal protein, laboratory bioassays were conducted. The Cry34Ab1 and Cry35Ab1 proteins were tested alone and in mixtures for activity against corn rootworm. This study showed that:

(i) the Cry35Ab1 protein alone does not cause mortality or growth inhibition to corn rootworm larvae;
(ii) the Cry34Ab1 protein alone does cause mortality and growth inhibition to corn rootworm larvae, however, for maximal insecticidal activity both the Cry34Ab1 and Cry35Ab1 proteins are required and;
(iii) bioassay results from a Cry34Ab1 and Cry35Ab1 protein mixture suggest that both proteins contribute to toxicity

The observation, that a mixture of Cry34Ab1 and Cry35Ab1 proteins are required for maximal insecticidal activity, while the Cry35Ab1 protein is not active on its own, suggest that the Cry34Ab1 and Cry35Ab1 proteins have distinct, yet contributing roles in insecticidal toxicity.

Furthermore, feeding studies have been done to confirm the mode of action and biological activity of the Cry34Ab1 and Cry35Ab1 proteins on corn rootworm larvae. These studies demonstrate that the midgut epithelium is the primary target tissue of the Cry34Ab1 and Cry35Ab1 proteins, indicating that the mode and site of action of the Cry34Ab1 and Cry35Ab1 proteins is comparable with that of other *B. thuringiensis* Cry toxins.

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

9.1 Persistence and invasiveness

There is negligible likelihood for 59122xNK603 maize to become environmentally persistent or invasive giving rise to any weediness. First, because maize does not possess any traits for weediness and second, expression of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins in 59122xNK603 maize do not give rise to traits for weediness.

Maize plants are annuals that generally will not survive in Europe from one growing season to the next because of poor dormancy and sensitivity to low temperature. Despite its non-dormant nature, maize seed can occasionally persist from one growing season to the next under favourable climatic conditions. When the temperature and moisture are adequate, the seed will germinate. These volunteers are easily identified and controlled through current agronomic measures taken to control commercial maize, such as selective use of herbicides (with the exception of glyphosate and glufosinate-ammonium herbicides), and manual or mechanical removal.

9.2 Selective advantage or disadvantage

Maize is highly domesticated, to the extent that it cannot become established as a feral species outside the agricultural environment, and the expression of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins in 59122xNK603 maize does not confer any selective advantage or disadvantage to the plants in the natural environment, *i.e.* outside the agricultural environment. Insect attack is only one of the multiple biotic and abiotic factors that prevent growth of maize outside well-managed agricultural environments, and therefore, expression of the Cry34Ab1 and Cry35Ab1 proteins conferring resistance to certain coleopteran insect pests cannot be considered a selective advantage. In addition, application of broad spectrum herbicides, such as glufosinate-ammonium and glyphosate, does not commonly occur in the natural environment, and therefore expression of PAT and

CP4 EPSPS proteins in 59122xNK603 maize does not confer a selective advantage outside the agricultural environment.

9.3 Potential for gene transfer

There are no sexually compatible wild or weedy relatives of *Zea mays* known to exist in the EU, which eliminates any potential for gene transfer to other species.

In addition, there is negligible likelihood for 59122xNK603 maize plants to become environmentally persistent or invasive giving rise to any weediness. Furthermore, expression of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins does not present any selective advantage outside the agricultural environment.

9.4 Interactions between the GM plant and target organisms

Expression of the Cry34Ab1 and Cry35Ab1 proteins in cultivated 59122xNK603 maize provides growers with a highly effective and environmentally beneficial tool to control corn rootworm pest damage (Coleoptera: Chrysomelidae; *Diabrotica* spp.). The Cry34Ab1 and Cry35Ab1 proteins have been shown to act together to control corn rootworm larvae in a highly specific manner that is similar to the well-characterised interactions between *Bacillus thuringiensis* Cry proteins and target organisms.

9.5 Interactions of the GM plant with non-target organisms

The specificity of the biological activity and the absence of toxicity to non-target organisms of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins confirm that there will be no adverse effects on non-target organisms arising from 59122xNK603 maize.

9.6 Effects on human health

Maize is not considered to have harmful effects on human health. Maize has a long history of safe use in human food and animal feed. A very detailed assessment of the potential toxicity and allergenicity to humans of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins expressed in 59122xNK603 maize has been carried out. The conclusion obtained is that 59122xNK603 maize does not express any known toxic or allergenic proteins.

Furthermore, the nutritional assessment of 59122xNK603 maize has confirmed that 59122xNK603 maize is nutritionally equivalent to commercial maize. Therefore, consumption of 59122xNK603 maize or any derived food and processed products will result in no adverse consequences to human health.

9.7 Effects on animal health

As discussed in **Point D.9.6**, consumption of 59122xNK603 maize or any derived food, feed and processed products will result in no adverse consequences to human or animal health. Therefore, use of 59122xNK603 maize as feed and consumption of any food, feed and processed products derived from 59122xNK603 maize will result in no adverse consequences to animal health or the food/feed chain.

9.8 Effects on biogeochemical processes

Expression of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins in 59122xNK603 maize will not cause any possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of 59122xNK603 maize and target or non-target organisms in the vicinity of 59122xNK603 maize.

9.9 Impacts of the specific cultivation, management and harvesting techniques

The specific cultivation, management and harvesting techniques used for 59122xNK603 maize are comparable to those used for other commercially available maize, with the exception of the herbicide regime and the environmental monitoring plan proposed specifically for the cultivation of 59122xNK603 maize seed products. As a result, the occurrence of possible immediate and/or delayed, direct and indirect environmental impacts arising from cultivation, management or harvesting techniques used for 59122xNK603 maize seed products is not expected.

10. Potential interactions with the abiotic environment

Expression of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins in 59122xNK603 maize does not alter the natural interactions of maize plants with the abiotic environment. The natural ubiquity of the Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS proteins in the soil environment and the absence of adverse effects on soil biota means negligible possibility for adverse interactions with the abiotic environment and no adverse effects on the biogeochemical cycles.

11. Environmental monitoring plan

11.1 General (risk assessment, background information)

The scope of this application includes authorisation for the cultivation of 59122xNK603 maize seed products in the EU. In addition and as described throughout this application, there is no new genetic modification in 59122xNK603 maize, as it has been obtained from traditional breeding methods between progeny of two genetically modified maize: 59122 maize and NK603 maize.

The proposal for an environmental monitoring plan for 59122xNK603 maize has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

11.2 Interplay between environmental risk assessment and monitoring

The design of the environmental monitoring plan is based on the conclusions of the environmental risk assessment (e.r.a) for placing on the market of 59122xNK603 maize.

The e.r.a. has been carried out in accordance with Annex II of Directive 2001/18/EC and Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The overall conclusion obtained from the e.r.a. confirms that there are no identified adverse effects to human and animal health or the environment arising from the product described in this application. Therefore the risk to human and animal health or the environment from 59122xNK603 maize and any derived products is as negligible as for any commercial maize and any derived products.

11.3 Case-specific GM plant monitoring

In accordance with Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC, case-specific monitoring should only be carried out in those cases where potential adverse effects have been identified in the e.r.a.

The e.r.a. concluded that there are no identified adverse effects to human and animal health or the environment arising from the placing on the market of 59122xNK603 maize and therefore the risk to human and animal health or the environment from 59122xNK603 maize is as negligible as for any commercial maize.

However, the e.r.a. indicated that there is a limited potential for development of resistance within the target pest population to cultivated 59122xNK603 maize seed products. Therefore, a case-specific monitoring plan is considered appropriate as a part of the risk management strategy. It will ensure that cultivation of 59122xNK603 maize seed products poses negligible risk and that the efficacy of the 59122xNK603 maize to control corn rootworm pest damage will be maintained, thereby sustaining the environmental benefits of this technology.

The case-specific monitoring plan for cultivation of 59122xNK603 maize seed products will consist of an insect resistance management plan (IRM plan).

11.4 General Surveillance of the impact of the GM plant

The overall conclusion obtained from the e.r.a. for the placing on the market of 59122xNK603 maize is that there are no identified adverse effects to human and animal health or the environment arising from 59122xNK603 maize. Therefore, the risk to human and animal health or the environment from 59122xNK603 maize is as negligible as for any commercial maize.

In accordance with Council Decision 2002/811/EC, general surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unforeseen adverse effects of the GMO or its use for human health and the environment that were not predicted in the risk assessment.

As a result and in order to safeguard against any adverse effect on human health and the environment that was not anticipated in the e.r.a., the applicant will undertake to have a general surveillance plan for 59122xNK603 maize throughout the period of validity of the authorisation.

11.5 Reporting the results of monitoring

The applicant will inform the European Commission, without delay, of any adverse effects arising from 59122xNK603 maize reported to them. Furthermore, the applicant will investigate such reports and inform the outcome to the European Commission.

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

The 59122xNK603 maize has been obtained from traditional breeding methods between progeny of 59122 maize and NK603 maize. No new genetic modification has been introduced in 59122xNK603 maize. As a result, PCR detection of 59122xNK603 maize will be carried out using the same PCR detection methods developed for 59122 maize and NK603 maize. PCR detection methods for 59122 maize and for NK603 maize have already been validated by the JRC-CRL (Joint Research Centre–Community Reference Laboratory) (http://gmo-crl.jrc.it/statusofdoss.htm). In addition, complementary information on PCR detection of 59122xNK603 maize and samples of 59122xNK603 maize and non-GM maize have been submitted to the JRC-CRL.

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
B/ES/04/04

(b) Conclusions of post-release monitoring
The 59122xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 59122xNK603 maize.

(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)
No adverse effects on human health and the environment observed.

(a) Notification number
B/FR/04.02.05

(b) Conclusions of post-release monitoring
Not applicable as the trial was not carried out.

(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 as the trial was not carried out.

(a) Notification number
B/ES/05/15

(b) Conclusions of post-release monitoring
During the trial, the 59122xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 59122xNK603 maize.

(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)
No adverse effects on human health and the environment observed.

(a) Notification number
B/FR/05.03.02

(b) Conclusions of post-release monitoring
During the trial, the 59122xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 59122xNK603 maize.

(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)
No adverse effects on human health and the environment observed.

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

(a) Release country
Bulgaria
(b) Authority overseeing the release
Ministry of Agriculture and Forestry
(c) Release site
Two locations
(d) Aim of the release
Regulatory trials
(e) Duration of the release
One season
(f) Aim of post-release monitoring
Control of potential volunteers
(g) Duration of post-release monitoring
One season
(h) Conclusions of post-release monitoring
The 59122xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 59122xNK603 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed

(a) Release country
Canada
(b) Authority overseeing the release
Canadian Food Inspection Agency
(c) Release site
One location
(d) Aim of the release
Regulatory trials
(e) Duration of the release
One season: 2003
(f) Aim of post-release monitoring
Control of potential volunteers
(g) Duration of post-release monitoring
One season

(h) Conclusions of post-release monitoring
The 59122xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 59122xNK603 maize.

(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
Chile

(b) Authority overseeing the release
Ministry of Agriculture

(c) Release site
Multiple sites

(d) Aim of the release
Research and regulatory trials

(e) Duration of the release
Two seasons: 2003 and 2004

(f) Aim of post-release monitoring
Control of potential volunteers

(g) Duration of post-release monitoring
One season

(h) Conclusions of post-release monitoring
The 59122xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 59122xNK603 maize.

(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
U.S.A.

(b) Authority overseeing the release
USDA

(c) Release site
Multiple sites

(d) Aim of the release
Research and regulatory trials

(e) Duration of the release
One season: 2003

(f) Aim of post-release monitoring
Control of potential volunteers

(g) Duration of post-release monitoring
One season

(h) Conclusions of post-release monitoring
The 59122xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 59122xNK603 maize.

(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
Hungary

(b) Authority overseeing the release
Ministry of Agriculture and Regional Development

(c) Release site
One location

(d) Aim of the release
Research and regulatory trials

(e) Duration of the release
One season: 2004

(f) Aim of post-release monitoring
Control of potential volunteers

(g) Duration of post-release monitoring
One season

(h) Conclusions of post-release monitoring
The 59122xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 59122xNK603 maize.

(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

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

Status/process of approval

[To be provided]

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

[To be provided]

EFSA opinion

[To be provided]

Commission Register (Commission Decision 2004/204/EC)

[To be provided]

Molecular Register of the Community Reference Laboratory/Joint Research Centre

[To be provided]

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

[To be provided]

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

[To be provided]