PART II

SUMMARY

Application

EFSA-GMO-NL-2011-XX

APPLICATION FOR AUTHORISATION OF
1507x59122xMON810xNK603 MAIZE
AND DERIVED FOOD AND FEED
IN ACCORDANCE WITH
REGULATION (EC) No 1829/2003

PART II

SUMMARY

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

The Netherlands

b) Application number

[*To be provided*]

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

The product described in this application is 1507x59122xMON810xNK603 maize and all sub-combinations with fewer of these events.

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 1507x59122xMON810xNK603 maize is:

DAS-Ø15Ø7-1xDAS-59122-7xMON-ØØ81Ø-6xMON-ØØ6Ø3-6.

d) Date of acknowledgement of valid application

[*To be provided*]

2. Applicant

a) Name of applicant

Pioneer Hi-Bred International, Inc. as represented by Pioneer Overseas Corporation

b) Address of applicant

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

As represented by:

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

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

Same as applicant

3. Scope of the application

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

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

Yes [ ]	**No** [x]

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

Yes [ ]	**No** [x]

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 [ ]	**No** [x]

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

Yes [x]	**No** [ ]

Notifications concerning all uses of 1507x59122xMON810xNK603 maize, including cultivation of 1507x59122xMON810xNK603 maize seed products, have been submitted in the US, Canada and Japan. Applications for an authorisation for food and feed use have been submitted in several other countries around the world where products of breeding stack combinations are regulated.

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 1507x59122xMON810xNK603 maize has been produced by conventional breeding between 1507 maize, 59122 maize, MON810 maize, and NK603 maize. The combined trait product expresses the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT and CP4 EPSPS proteins.

The CRY1F and CRY1Ab proteins are encoded by plant codon-optimised genes from *Bacillus thuringiensis* and confer a two-fold resistance against certain lepidopteran pests, such as the European corn borer (*Ostrinia nubilalis)* and the pink borer (*Sesamia* spp.). The binary CRY34Ab1 and CRY35Ab1 proteins are encoded by plant codon-optimised genes from *Bacillus thuringiensis*, and together confer protection against corn rootworm larvae (Coleoptera: Chrysomelidae;

Diabrotica spp.). The PAT and CP4 EPSPS proteins are encoded by plant codon-optimised genes from *Streptomyces viridochromogenes* and *Agrobacterium tumefaciens*, respectively, and confer tolerance to the application of respectively glufosinate-ammonium and glyphosate herbicides.

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

The types of products planned to be placed on the market according to the authorisation applied for include 1507x59122xMON810xNK603 maize for all food and feed uses, and for all food, feed and processed products derived from 1507x59122xMON810xNK603 maize in accordance with Regulation (EC) No 1829/2003. In addition, this application requests authorisation for import and processing of 1507x59122xMON810xNK603 maize in accordance with Part C of Directive 2001/18/EC. However, this application does not include authorisation for the cultivation of 1507x59122xMON810xNK603 maize seed products in the EU.

c) Intended use of the product and types of users

The 1507x59122xMON810xNK603 maize products placed on the market will be used in a manner consistent with current uses of commercial maize grain and maize products. The 1507x59122xMON810xNK603 maize will undergo existing methods of production and manufacturing used for commercial maize. No novel method of production and manufacturing is envisaged. There is no new genetic modification in 1507x59122xMON810xNK603 maize and the genetic modifications present in the parental breeding lines 1507, 59122, MON810 and NK603 maize do not impact the production processes used for maize.

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 1507x59122xMON810xNK603 maize has shown that no specific instructions and/or recommendations for use, storage and handling of 1507x59122xMON810xNK603 maize are necessary. Therefore, 1507x59122xMON810xNK603 maize can be used, stored and handled in the same way as is currently done for commercial maize. Labelling of 1507x59122xMON810xNK603 maize products will be carried out in accordance with Community law.

e) Any proposed packaging requirements

The packaging, handling, and storage systems that are currently used for commercial maize will apply. The 1507x59122xMON810xNK603 maize products will be packaged in the same manner as other commercial maize products.

f) A proposal for labelling in accordance with Article 13 and Article 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) No 1830/2003 and Annex IV of Directive 2001/18/EC

1.- PROPOSAL FOR THE LABELLING OF 1507X59122XMON810XNK603 MAIZE FOOD PRODUCTS ACCORDING TO ARTICLES 12 AND 13 OF REGULATION (EC) No 1829/2003

In accordance with Article 12(2) of Regulation (EC) No 1829/2003, labelling will apply to foods containing material which contains, consists of or is produced from 1507x59122xMON810xNK603 maize in a proportion at or higher than 0,9 per cent of the food ingredients considered individually or of the entire food if consisting of a single ingredient.

In accordance with Article 13 of Regulation (EC) No 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 1507x59122xMON810xNK603 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 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 (EC) No 1829/2003 would need to be specified on the label of 1507x59122xMON810xNK603 maize food products as 1507x59122xMON810xNK603 maize has been shown to be equivalent to non-GM control maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 1507x59122xMON810xNK603 maize does not give rise to any safety concerns.

2.- PROPOSAL FOR THE LABELLING OF 1507X59122XMON810XNK603 MAIZE FEED PRODUCTS ACCORDING TO ARTICLES 24 AND 25 OF REGULATION (EC) No 1829/2003

In accordance with Article 24(2) of Regulation (EC) No 1829/2003, labelling will apply to feed containing material which contains, consists of or is produced from 1507x59122xMON810xNK603 maize in a proportion at or higher than 0,9 per cent of the feed and of each feed of which it is composed.

In accordance with Article 25 of Regulation (EC) No 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) No 1829/2003, *i.e.* 1507x59122xMON810xNK603 maize for feed use, and feed containing, consisting of or produced from 1507x59122xMON810xNK603 maize, should be labelled as follows:

(a) where the feed contains or consists of 1507x59122xMON810xNK603 maize, or where 1507x59122xMON810xNK603 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 1507x59122xMON810xNK603 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 (EC) No 1829/2003 would need to be specified on the label of 1507x59122xMON810xNK603 maize feed products as 1507x59122xMON810xNK603 maize has been shown to be equivalent to non-GM control maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 1507x59122xMON810xNK603 maize does not give rise to any safety concerns.

3.- PROPOSAL FOR THE LABELLING OF PRODUCTS CONSISTING OF, OR CONTAINING, 1507X59122XMON810XNK603 MAIZE ACCORDING TO ARTICLE 4, B(6) OF REGULATION (EC) No 1830/2003 AND ANNEX IV OF DIRECTIVE 2001/18/EC

As specified in Section **A.8** of 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 1507x59122xMON810xNK603 maize will include the following:

(a) Commercial name of the product and the statement that 'this product contains genetically modified organisms';
(b) Name of the GMO;
(c) Information referred to in Section **A.2.** of Annex IV of Directive 2001/18/EC (name and full address of the notifier established in the Community who is responsible for the placing on the market);
(d) An indication on 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)

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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 1507x59122xMON810xNK603 maize (**Part I** of this application), no specific measures need to be taken in case of unintended release or misuse or for disposal and treatment. There are no sexually compatible wild plant species in Europe with which maize can cross-hybridise and maize plants cannot survive as a weed outside agricultural fields. The establishment of maize volunteer plants is therefore very unlikely.

In case of unintended release of 1507x59122xMON810xNK603 maize, current agronomic measures taken to control other commercially available maize can be applied, such as use of mechanical means and selective use of herbicides (with exception of glyphosate and glufosinate-ammonium).

B. INFORMATION RELATING TO THE RECIPIENT OR (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

1507; 59122; MON810; 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*, belonging to the Poaceae family. It is a highly domesticated annual 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 from a comparably low level of elevation.

(ii) Specific factors affecting reproduction

As a wind-pollinated, monoecious species, reproduction takes place by both self- 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 lead 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

In the EU, there are no other cultivated or wild plant species that are sexually compatible with maize. 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 significant agronomic 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 this has 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 restricts maize survival and reproduction capabilities mainly to the Central and 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 within 30 m from the source, with very low dispersal remaining at distances farther than 30-50 m from the source.

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 <19 °C or where the average night temperature is <13 °C. The majority of maize is produced between latitudes 30 and 55 degrees, with a relatively small amount grown at latitudes higher than 47 degrees anywhere in the world. 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. 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.

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 1507x59122xMON810xNK603 maize was produced by means of conventional breeding between 1507 maize, 59122 maize, MON810 maize, and NK603 maize. The parental GM lines used for the breeding of 1507x59122xMON810xNK603 maize were obtained by *Agrobacterium*-mediated transformation (59122 maize) or by the particle acceleration method (1507 maize, MON810 maize, NK603 maize).

2. Nature and source of the vector used

The 1507x59122xMON810xNK603 maize was produced by means of conventional breeding between 1507 maize, 59122 maize, MON810 maize, and NK603 maize. No vector has been used to produce this maize hybrid.

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

The 1507x59122xMON810xNK603 maize described in this application has been produced by combining the maize events 1507, 59122, MON810, and NK603 through conventional breeding techniques. The following constituent fragments were inserted in each of the parental GM lines:

1507 maize:

Genetic element	Size (kb)	Function
*ubi*ZM1	2.0	Promoter, 5'-UTR and first intron from *Zea mays* ubiquitin gene
*cry*1F	1.8	*cry*1F gene from *Bacillus thuringiensis* sbsp. *aizawai*
ORF25PolyA	0.7	Terminator from *Agrobacterium tumefaciens* pTi15955
CaMV 35S promoter	0.6	35S promoter from Cauliflower Mosaic Virus
pat	0.6	Phosphinothricin acetyltransferase coding sequence from *Streptomyces viridochromogenes*
CaMV 35S terminator	0.2	35S terminator from Cauliflower Mosaic Virus

59122 maize:

Genetic element	Size (kb)	Function
Right Border	0.2	Right T-DNA border from Ti plasmid of *Agrobacterium tumefaciens*
*ubi*1ZM	2.0	Promoter, 5'-UTR and first intron from *Zea mays* ubiquitin gene
*cry*34Ab1	0.4	Maize-optimised *cry*34Ab1 gene from *Bacillus thuringiensis*
*pin*II terminator	0.3	Terminator from *Solanum tuberosum* proteinase inhibitor II gene
TA perox. promoter	1.3	*Triticum aestivum* peroxidase promoter
*cry*35Ab1	1.2	Maize-optimised *cry*35Ab1 gene from *Bacillus thuringiensis*

*pin*II terminator	0.3	Terminator region from *Solanum tuberosum* proteinase inhibitor II gene
CaMV 35S promoter	0.5	35S promoter from Cauliflower Mosaic Virus
pat	0.6	Phosphinothricin acetyltransferase coding sequence from *Streptomyces viridochromogenes*
CaMV 35S terminator	0.2	35S terminator from Cauliflower Mosaic Virus
Left border	0.08	Left T-DNA border from Ti plasmid of *Agrobacterium tumefaciens*

MON810 maize:

Genetic element	**Size (kb)**	*Function*
e35S	0.6	The cauliflower mosaic virus (CaMV) promoter with duplicated enhancer region
Zmhsp70	0.8	Intron from the *Zea mays hsp70* gene (heat-shock protein)
Cry1A(b)	3.5	The gene from *Bacillus thuringiensis* encoding the CryIA(b) protein
NOS 3'	0.3	The 3' nontranslated region of the nopaline synthase gene from *Agrobacterium tumefaciens* T-DNA

NK603 maize:

Genetic element	**Size (kb)**	*Function*
***cp4 epsps* gene cassette (1)**		
P-ract1/ract1 intron	1.4	5' region of the rice actin 1 gene containing the promoter, transcription start site and first intron
ctp 2	0.2	DNA sequence from the chloroplast transit peptide, isolated from *Arabidopsis thaliana epsps* gene, present to direct the CP4 EPSPS protein to the chloroplast, the site of aromatic acid synthesis
cp4 epsps	1.4	The DNA sequence for CP4 EPSPS, isolated from *Agrobacterium* sp. strain CP4, which imparts tolerance to glyphosate
NOS 3'	0.3	A 3' nontranslated region of the nopaline synthase gene from *Agrobacterium tumefaciens* T-DNA
***cp4 epsps* gene cassette (2)**		
e35S	0.6	The cauliflower mosaic virus (CaMV) promoter with the duplicated enhancer region
Zmhsp70	0.8	Intron from the corn *hsp70* gene (heat-shock protein)
ctp 2	0.2	DNA sequence from chloroplast transit peptide, isolated from *Arabidopsis thaliana* EPSPS, present to direct the CP4 EPSPS protein to the chloroplast, the site of aromatic acid synthesis
cp4 epsps	1.4	The DNA sequence for CP4 EPSPS, isolated from *Agrobacterium* sp. strain CP4, which imparts tolerance to glyphosate
NOS 3'	0.3	A 3' nontranslated region of the nopaline synthase gene from *Agrobacterium tumefaciens* T-DNA

D. INFORMATION RELATING TO THE GM PLANT

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

The 1507x59122xMON810xNK603 maize has been obtained by means of traditional breeding between genetically modified 1507, 59122, MON810 and NK603 maize. No new genetic modification has been introduced in this GM maize. The 1507x59122xMON810xNK603 maize combines the herbicide tolerance traits, conferred by PAT and CP4 EPSPS proteins, with insect resistance traits, conferred by CRY1F, CRY1Ab and CRY34Ab1/CRY35Ab1 proteins:

- The CRY1F protein acts to control certain lepidopteran insect pests, such as the European corn borer (*Ostrinia nubilalis*) and the pink borer (*Sesamia* spp.);
- The binary CRY proteins CRY34Ab1 and CRY35Ab1 act together in the control of corn rootworm larvae (Coleoptera: Chrysomelidae; *Diabrotica* spp.);
- The CRY1Ab protein, like CRY1F, renders these maize plants resistant to attack by certain lepidopteran insect pests, such as the European corn borer;
- Expression of the PAT protein, a phosphinotricine acetyltransferase, confers tolerance to the application of glufosinate-ammonium herbicide through acetylation of the herbicide;
- The CP4 EPSPS protein confers tolerance to the application of glyphosate herbicide.

No other new traits have been introduced into 1507x59122xMON810xNK603 maize and, in particular, no trait for antibiotic resistance is present in 1507x59122xMON810xNK603 maize. As discussed in detail throughout the application, these characteristics of 1507x59122xMON810xNK603 maize have been confirmed by molecular characterisation, protein expression analysis, agronomic performance and comparison of 1507x59122xMON810xNK603 maize compositional data to non-GM control maize.

2. Information on the sequences actually inserted or deleted

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

The results of the molecular characterisation described in this application support the conclusion that 1507x59122xMON810xNK603 maize contains four separate copies of inserted DNA, one from 1507 maize, one from 59122 maize, one from MON810 maize, and one from NK603 maize. Southern blot analysis demonstrated that 1507x59122xMON810xNK603 maize does not contain other fragments from the inserts than those that were present in the respective single lines.

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 1507x59122xMON810xNK603 maize inserts are all integrated into different loci in the maize nuclear genome as confirmed by the inheritance of the inserts through conventional crosses and by the molecular characterisation of 1507x59122xMON810xNK603 maize by Southern blot and characterisation of the flanking sequences through BLAST searches.

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

A detailed molecular characterisation by Southern blot analysis has confirmed that the copy number, structure and organisation of the inserts in 1507x59122xMON810xNK603 maize are equivalent to

those found in the parental breeding lines 1507, 59122, MON810, and NK603 maize. The organisation of the inserted material in the parental lines is as follows:

For **1507 maize**, the Southern blot and sequence analyses demonstrated that the genetic material inserted in 1507 maize consists of an almost full-length copy of the linear fragment used in the transformation process, containing the *cry*1F and *pat* genes together with the regulatory sequences necessary for their expression. In addition, the single copy insert contains the following non-functional fragments:

- one fragment (335 bp) of the *cry*1F gene, with no *ubi*ZM1 promoter sequence, and one short fragment (15 bp) of the *cry*1F gene, both located at the 5' end of the almost full-length insert;
- two fragments (201 bp and 138 bp long, respectively) of the *pat* gene, without regulatory sequences associated, located at the 5' border and one fragment (188 bp) of the *pat* gene, located at the 3' border;
- one fragment (118 bp) of the polylinker region and *ubi*ZM1 promoter sequence located at the 5' border;
- one fragment (550 bp) of the ORF25PolyA terminator sequence in inverted position located immediately at the 3' end of the almost full-length insert.

Furthermore, analysis by PCR amplification has confirmed the presence of both maize genomic flanking regions in non-GM Hi-II maize, which was used as the recipient line in the transformation to create 1507 maize.

The results of the molecular characterisation of **59122 maize** confirmed that 59122 maize contains a single and full-length copy of the T-DNA region. The DNA sequences of the inserted genes in 59122 maize are identical to those in the original plasmid except for two nucleotide differences in the wheat peroxidase promoter. Southern blot analysis demonstrated that 59122 maize does not contain fragments from the vector backbone portion. Maize genomic DNA flanking regions at both the 5' and 3' borders of the 59122 maize insert have been sequenced and characterised in detail.

MON810 maize contains the enhanced 35S promoter (e35S), the maize *hsp70* intron, the *cry1Ab* coding sequence, and a portion of the 3' end of the e35S promoter as well as a portion of the 5' end of the *cry1Ab* coding sequence. No other portion of the plasmid PV-ZMBK07, including the *npt*II gene, has been integrated in MON810 maize. PCR analysis demonstrated that the DNA sequences flanking the 5' and 3' ends of the insert in MON810 are native to the maize genome.

Molecular data revealed that **NK603 maize** contains two adjacent copies of the *cp4 epsps* gene fused to chloroplast transit peptide (CTP) sequences, with both *ctp*2-*cp4 epsps* gene cassettes being intact in NK603 maize. The sequence of the *cp4 epsps* gene of the first cassette in NK603 maize is identical to that in the original plasmid, whilst in the second inserted cassette the sequence of the *cp4 epsps* gene differs by two nucleotides from that in the original plasmid. Sequencing of 5' and 3' flanking regions of the NK603 insert confirmed the sequences to be maize genomic DNA.

3. Information on the expression of the insert

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

Field studies have been carried out in order to estimate the level of expression of the insert-encoded proteins in 1507x59122xMON810xNK603 maize in comparison with the expression levels in the GM parental lines. Key plant tissues were collected from the plants at different developmental stages across the growing season. Protein concentrations were measured using Enzyme Linked

Immunosorbent Assay (ELISA) systems developed for each protein. The results of the field studies have shown that the expression of the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, and CP4 EPSPS proteins in various tissues of 1507x59122xMON810xNK603 maize was comparable to the expression of these proteins in the corresponding GM parental lines.

b) Parts of the plant where the insert is expressed

Field tests have shown that the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins are expressed in different plant tissues throughout maize development.

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

a) Reproduction

No unexpected changes in pollen production, pollen viability, seed production, seed viability or germination have been observed in field trials of 1507x59122xMON810xNK603 maize compared to non-GM control maize.

b) Dissemination

Maize hybrids have been domesticated to the extent that the seeds cannot be disseminated without human intervention and this remained unchanged in 1507x59122xMON810xNK603 maize.

c) Survivability

Cultivated maize has been domesticated to the extent that it cannot survive outside managed agricultural environments. Lack of dormancy prevents maize seed survival from one growing season to the next. The genetic modification in 1507x59122xMON810xNK603 maize results in the expression of proteins conferring tolerance to herbicides and insect resistance. The survival characteristics of 1507x59122xMON810xNK603 maize in the environment have remained unchanged in comparison to those of non-GM control maize.

d) Other differences

Except for the introduced herbicide tolerance and insect resistance traits, which are of agronomic interest, 1507x59122xMON810xNK603 maize did not show any unexpected changes in reproduction, dissemination and survivability in comparison with non-GM maize in field trials.

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

Genetic stability of the inserts in 1507x59122xMON810xNK603 maize was confirmed by molecular analysis of 1507x59122xMON810xNK603 maize. Phenotypic stability of the traits was shown by comparative agronomic evaluation.

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

a) Plant to bacteria gene transfer

The genetic modification in 1507x59122xMON810xNK603 maize does not change the inability of maize to transfer genetic material to bacteria. In particular, no sequences are present on the inserted regions that could potentially be involved in transfer of genetic material between maize and bacteria.

b) Plant to plant gene transfer

As discussed in Section **B.2.b**, there are no other cultivated or wild plant species sexually compatible with maize in the EU. Maize plants will intra-pollinate and transfer genetic material between maize. The extent of pollination between maize will depend upon wind patterns, humidity and temperature. Potential for gene transfer is therefore limited to other maize grown in culture. In addition, the genetic modification in 1507x59122xMON810xNK603 maize does not introduce any selective advantages to maize plants outside the agricultural environment.

It should be noted that this application is for authorisation of 1507x59122xMON810xNK603 maize for all food and feed uses, and for all food, feed and processed products derived from 1507x59122xMON810xNK603 maize, and not for cultivation of 1507x59122xMON810xNK603 maize seed products. Any plant to plant gene transfer is therefore limited to only occasional unintentional releases.

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

The comparator chosen for the safety evaluation of 1507x59122xMON810xNK603 maize consists of non-GM near-isogenic control maize. Wherever possible, data on other commercial non-GM maize hybrids have also been used in the comparisons with 1507x59122xMON810xNK603 maize.

7.2 Field trials

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

Field trials were conducted in 2008 at 6 separate locations in North America. Each location included a randomised block design containing 3 blocks (or replicates). Each block contained the 1507x59122xMON810xNK603 maize, treated with conventional herbicides or with the intended herbicides (tank mix of glyphosate and glufosinate), and a non-GM control maize for comparison (treated with conventional herbicides).

b) the baseline used for consideration of natural variations

The comparative assessment compared 1507x59122xMON810xNK603 maize from both herbicide treatment regimes with non-GM near-isogenic control maize. In addition, wherever statistically significant differences were observed, the data were compared to similar data obtained in field trials with commercial non-modified maize hybrids, and to historical analyte/agronomic ranges obtained from the published literature.

7.3 Selection of materials and compounds for analysis

The nutritional analysis was undertaken on a broad range of compounds such as protein, fiber, carbohydrates, fat, ash, minerals, fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients in accordance with OECD guidelines for the assessment of genetically modified maize.

7.4 Agronomic traits

As described in Section **D.7.2**, 1507x59122xMON810xNK603 maize has been tested at different locations across key maize growing regions of North America. The agronomic data obtained support the conclusion that there are no unexpected agronomic differences between 1507x59122xMON810xNK603 maize and non-GM control maize with comparable genetic background.

It should be noted that this application is for authorisation of 1507x59122xMON810xNK603 maize for all food and feed uses, and for all food, feed and processed products derived from 1507x59122xMON810xNK603 maize, and not for cultivation of 1507x59122xMON810xNK603 maize seed products.

7.5 Product specification

As discussed in this application, food and animal feed products derived from 1507x59122xMON810xNK603 maize can be considered to be as safe as and nutritionally equivalent to food and animal feed products derived from commercial maize. Therefore, the specification of food and animal feed products from 1507x59122xMON810xNK603 maize is equivalent to that of food and animal feed products derived from commercial maize.

7.6 Effect of processing

The production processes applied to maize are well known and have a long history of safe use. The 1507x59122xMON810xNK603 maize will undergo existing production processes used for commercial maize. No novel production process is envisaged.

The newly expressed proteins in 1507x59122xMON810xNK603 maize are susceptible to proteolytic digestion and are readily degraded when heated. Therefore, the technologies applied in the production and processing of processed foods and feeds derived from maize will lead to the denaturation and degradation of the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins.

7.7 Anticipated intake/extent of use

The 1507x59122xMON810xNK603 maize food products are expected to replace a portion of maize products in existing food products with total consumption of maize products remaining unchanged. In particular, human consumption of maize products in the developed world is in the form of high fructose maize syrup, starch, and oil, *i.e.* products that contain only negligible amounts of protein due to their degradation during food and feed processing. Moreover, it should be considered that maize products in Europe represent blended products, and actual occurrence of the newly expressed proteins originating from 1507x59122xMON810xNK603 maize will be a fraction of total dietary maize and maize products.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

1507x59122xMON810xNK603 maize was produced by combining the maize events 1507, 59122, MON810, and NK603 through conventional breeding and therefore produces the insert-encoded proteins inherited from their parents. Potential adverse effects to human and animal health from expression of the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins have previously been assessed taking into account the following considerations:

- the recipient organism and the donor organisms for each protein have a history of safe use;
- the molecular and biochemical characteristics of the proteins do not indicate toxicity risks;
- the proteins have no significant amino acid sequence homology to known toxins or other biologically active proteins that could cause adverse effects to humans or animals;
- the proteins show no acute oral toxicity to mammals.

No reports have appeared in the scientific literature up to now that would invalidate these conclusions, nor did a re-analysis of the similarity searches with updated databases reveal any safety concerns. Furthermore, there is no evidence of potential interactions between the different insert-encoded proteins in 1507x59122xMON810xNK603 maize that would affect the safety of this combined trait maize. In addition, the low concentration of these proteins in maize tissues and their rapid digestibility in simulated digestive fluids provide further assurance for the safety of the consumed 1507x59122xMON810xNK603 maize products. It is therefore highly unlikely that the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins will cause any adverse effects to human and animal health.

7.8.2 Testing of new constituents other than proteins

Not applicable as the genetic modification in 1507x59122xMON810xNK603 maize does not give rise to the expression of any new constituents other than the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins.

7.8.3 Information on natural food and feed constituents

Detailed analyses of 1507x59122xMON810xNK603 maize have demonstrated that the composition of 1507x59122xMON810xNK603 maize is equivalent to that of control maize. In addition, the results obtained in 90-day oral toxicity feeding studies with the parental maize events in rats and those obtained in 42-day poultry feeding studies with the parental maize events and with 1507x59122xMON810xNK603 maize provide further confirmation of the safety of the natural food and feed constituents from 1507x59122xMON810xNK603 maize and nutritional equivalence between 1507x59122xMON810xNK603 maize and non-GM control maize.

7.8.4 Testing of the whole GM food/feed

As described throughout this application, the evaluation of the nutrient composition of 1507x59122xMON810xNK603 maize has confirmed that it is equivalent to non-GM control maize with comparable genetic background. Furthermore, 90-day oral toxicity feeding studies in rats fed the parental maize events, or the 1507x59122 maize stack, have not revealed any adverse effects.

A poultry feeding study over a period of 42 days has confirmed that that there are no diet-related differences in mortality, body weight gain, feed efficiency, carcass yield and organ yield between chickens fed a diet containing grain from 1507x59122xMON810xNK603 maize or a diet containing grain from non-GM control 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 CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins were evaluated for their allergenic potential through:

- assessing the allergenicity potential of the source of the gene;
- homology searches against allergen databases;
- *in vitro* simulated digestibility studies;
- analysis of protein glycosylation and heat stability.

No reports have appeared in the scientific literature up to now that would invalidate these conclusions, nor did a re-analysis of the similarity searches with updated allergen databases reveal any concerns. The results obtained confirm that the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins expressed in 1507x59122xMON810xNK603 maize are highly unlikely to be allergenic.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Maize has a long history of safe use as food and feed in the EU and is not considered to cause significant food allergies. Furthermore, the newly expressed proteins in 1507x59122xMON810xNK603 maize are highly unlikely to be allergenic.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

Composition analysis of grain from 1507x59122xMON810xNK603 maize has shown that the content of protein, fiber, carbohydrates, fat, ash, minerals, fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients is equivalent to that found in grain from non-GM control maize with comparable genetic background. Therefore, 1507x59122xMON810xNK603 maize can be considered nutritionally equivalent to non-GM control maize. Nutritional equivalence between 1507x59122xMON810xNK603 maize and non-GM control maize with comparable genetics has also been shown in a poultry feeding study where chickens were fed either maize grain over a 42-day period.

In conclusion and taking into account the anticipated dietary intake of 1507x59122xMON810xNK603 maize products, consumption of 1507x59122xMON810xNK603 maize foods or feed will not have any adverse nutritional impact.

7.10.2 Nutritional assessment of GM feed

As evaluated in Section **D.7.10.1** above, consumption of 1507x59122xMON810xNK603 maize feed will not give rise to any adverse nutritional impact.

7.11 Post-market monitoring of GM food/feed

As summarised in Section **D.7**, the nutritional assessment has concluded that 1507x59122xMON810xNK603 maize is nutritionally equivalent to non-GM control maize. In

addition, the use of 1507x59122xMON810xNK603 maize food and feed will not be different from that of commercially available maize food and feed.

Therefore, post-market monitoring of GM food and GM feed products containing, consisting of or derived from 1507x59122xMON810xNK603 maize is not necessary.

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

The interaction between the transgenic proteins expressed in 1507x59122xMON810xNK603 maize and target organisms is restricted to the interaction between CRY1F, CRY1Ab and CRY34Ab1/CRY35Ab1 proteins and certain lepidopteran and coleopteran pests, respectively. The mode of action of CRY proteins is well known and is based on the formation of ion channels in the membrane of insect epithelial midgut cells, following specific receptor binding. This leads to cell homeostasis and insect death.

Any significant interactions with these insects are, however, limited to those countries where cultivation of the 1507x59122xMON810xNK603 maize will be authorised. The cultivation of 1507x59122xMON810xNK603 maize in the EU is not within the scope of this application.

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

The scope of this application does not include authorisation for the cultivation of 1507x59122xMON810xNK603 maize seed products in the EU. Exposure to the environment from the import of 1507x59122xMON810xNK603 maize will be limited to unintended release of 1507x59122xMON810xNK603 maize, e.g. via spillage during transportation of the grain.

9.1 Persistence and invasiveness

There is negligible likelihood for 1507x59122xMON810xNK603 maize to become environmentally persistent or invasive giving rise to any weediness. The cultivation of 1507x59122xMON810xNK603 maize in the EU is not within the scope of this application.

Furthermore, cultivated maize does not possess any trait for weediness and the expression of the insert-encoded proteins in 1507x59122xMON810xNK603 maize does not introduce new traits for weediness. Maize is a highly domesticated crop and cannot survive without human intervention.

9.2 Selective advantage or disadvantage

As discussed in Section **D.9.1**, maize is highly domesticated to the extent that it cannot become established as a feral species outside the agricultural environment. The specific advantages introduced by the genetic modification in 1507x59122xMON810xNK603 maize do not confer any selective advantage to the plants in the natural environment, *i.e.* outside the agricultural environment.

In conclusion, expression of the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins in 1507x59122xMON810xNK603 maize does not confer any 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 such species. Potential for gene transfer is therefore limited to other maize grown in culture. Cultivation of 1507x59122xMON810xNK603

maize is, however, not part of the scope of this application. The potential for gene transfer to other cultivated maize is, therefore, limited and the environmental risk of such gene transfer is negligible.

9.4 Interactions between the GM plant and target organisms

Considering the scope of this application, which does not included cultivation of 1507x59122xMON810xNK603 maize in the EU, it is unlikely that any target organisms will be significantly exposed to the CRY proteins expressed in this maize. In the eventual case of such exposure, the environmental risks are limited.

9.5 Interactions of the GM plant with non-target organisms

Considering the scope of this application, which does not included cultivation of 1507x59122xMON810xNK603 maize in the EU, it is unlikely that any non-target organisms will be significantly exposed to the CRY proteins expressed in this maize. In the eventual case of an accidental release in the environment, the absence of any toxicity to humans or non-target animals of the insert-encoded proteins in 1507x59122xMON810xNK603 maize, whether alone or in combination, indicates that any adverse effects on non-target organisms are highly unlikely.

9.6 Effects on human health

Maize has a long history of safe use in human food and animal feed. A detailed evaluation of the potential toxicity and allergenicity to humans of the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins as expressed in 1507x59122xMON810xNK603 maize, has been carried out (Sections **D.7.8 and D.7.9**). As a result and in conclusion, 1507x59122xMON810xNK603 maize does not express any known toxic or allergenic proteins. Therefore, consumption of 1507x59122xMON810xNK603 maize or derived food products will result in no adverse effects on human health.

9.7 Effects on animal health

As discussed in Sections **D.7.8** and **D.7.9**, consumption of 1507x59122xMON810xNK603 maize or any derived food, feed and processed products will not result in any adverse effects on human or animal health. Therefore, use of 1507x59122xMON810xNK603 maize as feed and consumption of any food, feed and processed products derived from 1507x59122xMON810xNK603 maize will not result in adverse effects on animal health or the food/feed chain.

9.8 Effects on biogeochemical processes

Because of the natural ubiquity of the *cry*, *pat* and *epsps* genes and of the CRY1F, CRY34Ab1, CRY35Ab1, CRY1Ab, PAT, and CP4 EPSPS proteins in the soil environment, the specific biochemical activity of these proteins, and taking into account the scope of this application, which does not include cultivation, 1507x59122xMON810xNK603 maize will not cause any significant immediate and/or delayed effects on biogeochemical processes.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable as cultivation is not part of the scope of this application.

10. Potential interactions with the abiotic environment

The scope of this application does not include authorisation for the cultivation of 1507x59122xMON810xNK603 maize seed products in the EU. Exposure to the environment from

the import of 1507x59122xMON810xNK603 maize will be limited to unintended release of 1507x59122xMON810xNK603 maize. This can be controlled with current measures used to control unintended release of commercially available maize, such as use of mechanical means and selective use of herbicides (with the exception of glyphosate and glufosinate-ammonium). Moreover, maize cannot survive in the environment without human intervention. Therefore, the likelihood of adverse interactions with the abiotic environment is negligible.

11. Environmental monitoring plan

11.1 General (risk assessment, background information)

The scope of this application does not include authorisation for the cultivation of 1507x59122xMON810xNK603 maize seed products in the EU. Exposure to the environment from the import of 1507x59122xMON810xNK603 maize will be limited to unintended release of 1507x59122xMON810xNK603 maize which can be controlled with current measures used to control unintended release of commercially available maize, such as use of mechanical means and selective use of herbicides (with the exception of glyphosate and glufosinate-ammonium).

A proposal for an environmental monitoring plan for 1507x59122xMON810xNK603 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, and following the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified organisms and derived food and feed (EFSA, 2006).

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.) carried out for this application for authorisation of genetically modified 1507x59122xMON810xNK603 maize and derived food and feed in accordance with Regulation (EC) No 1829/2003.

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 1507x59122xMON810xNK603 maize. Therefore, the risk to human and animal health or the environment from 1507x59122xMON810xNK603 maize and any derived products is as negligible as for any commercial maize and any derived products.

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

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 the risk to human and animal health or to the environment from 1507x59122xMON810xNK603 maize and any derived products is as negligible as for any commercial maize and any derived products. As a result, case-specific monitoring is not applicable for the use of 1507x59122xMON810xNK603 maize for all food and feed purposes and the import and processing of 1507x59122xMON810xNK603 maize.

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

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 unanticipated adverse effects of the GMO or its use for human and animal health and the environment that were not predicted in the risk assessment.

The scope of this application is for the authorisation of 1507x59122xMON810xNK603 maize for all food and feed uses in accordance with Articles 3(1) and 15(1) of Regulation (EC) No 1829/2003 and for import and processing of 1507x59122xMON810xNK603 maize in accordance with Part C of Directive 2001/18/EC. In this application we are not seeking approval for cultivation of 1507x59122xMON810xNK603 maize seed products in the EU.

As discussed in detail in the e.r.a., exposure to the environment will be limited to unintended release of 1507x59122xMON810xNK603 maize. However, such limited exposure is highly unlikely to give rise to any adverse effect and, if necessary, can be controlled with current measures used to control unintended release of commercially available maize, such as use of mechanical means and selective use of herbicides (with the exception of glyphosate and glufosinate herbicides).

However and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the e.r.a., general surveillance on 1507x59122xMON810xNK603 maize will be undertaken for the duration of the authorisation.

11.5 Reporting the results of monitoring

As discussed in Sections **D.11.1** to **D.11.4**, case-specific monitoring is not applicable for the use of 1507x59122xMON810xNK603 maize for all food and feed purposes and the import and processing of 1507x59122xMON810xNK603 maize. As a result, no case-specific monitoring is proposed for this application for authorisation of 1507x59122xMON810xNK603 maize.

The applicant will inform the European Commission, without delay, of any adverse effects reported arising from the handling and use of imported 1507x59122xMON810xNK603 maize. Furthermore, the applicant will submit an annual monitoring report to the European Commission including results of the general surveillance in accordance with the conditions of the authorisation. The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of 1507x59122xMON810xNK603 maize and, as appropriate, any measures that were taken to ensure the safety of human and animal health or the environment.

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

PCR-based quantitative event-specific detection methods are available for each of these single events and have been validated by the European Union Reference Laboratory (EURL) for GM Food and Feed (Joint Research Centre, Italy). In addition, an in-house validation study on the performance of the single event detection methods on the 1507x59122xMON810xNK603 maize stacked product has been submitted to the EURL for verification, in accordance with the requirements of the EURL/ENGL Guidance document “Definition of minimum performance requirements for analytical methods of GMO testing” of 13 October 2008.

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
Not applicable – no previous releases in the EU.
b) Conclusions of post-release monitoring
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)

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

a) Release country
USA
b) Authority overseeing the release
EPA
c) Release site
Multiple sites
d) Aim of the release
Research and/or regulatory trials
e) Duration of the release
2009
f) Aim of post-releases monitoring
Control of potential volunteers
g) Duration of post-releases monitoring
One season
h) Conclusions of post-release monitoring
The 1507x59122xMON810xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
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 Servicio Agrícola y Ganadaro (SAG), Dpto. Protección Agricola
c) Release site Multiple locations
d) Aim of the release Research trials
e) Duration of the release Multiple years
f) Aim of post-releases monitoring Control of potential volunteers
g) Duration of post-releases monitoring One season
h) Conclusions of post-release monitoring The 1507x59122xMON810xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
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 Argentina
b) Authority overseeing the release Conabia
c) Release site Multiple locations
d) Aim of the release Research and regulatory trials
e) Duration of the release One year

f) Aim of post-releases monitoring

Control of potential volunteers

g) Duration of post-releases monitoring

One season

h) Conclusions of post-release monitoring

The 1507x59122xMON810xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.

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):

a) Status/process of approval

See: http://registerofquestions.efsa.europa.eu/roqFrontend/login

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

Not applicable.

c) EFSA opinion

Not yet available.

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

See: http://ec.europa.eu/food/food/biotechnology/authorisation/index_en.htm

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

For event 1507: http://gmo-crl.jrc.ec.europa.eu/summaries/TC1507-report_mm.pdf

For event 59122: http://gmo-crl.jrc.ec.europa.eu/summaries/59122_val_report.pdf

For event MON810: http://gmo-crl.jrc.ec.europa.eu/summaries/Mon810_validation_report.pdf

For event NK603:

http://gmo-crl.jrc.ec.europa.eu/summaries/NK603_CRLVL_27_04_val_report_.pdf

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

See: http://bch.cbd.int/

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

Not applicable.