

## PART II

### SUMMARY

#### SUMMARY OF THE APPLICATION FOR THE AUTHORISATION OF GENETICALLY MODIFIED 1507xNK603 MAIZE AND DERIVED FOOD AND FEED IN ACCORDANCE WITH REGULATION (EC) 1829/2003

##### A. GENERAL INFORMATION

###### 1. Details of application

###### (a) Member State of application:

United Kingdom

###### (b) Application number:

EFSA/GMO/UK/2004/05

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

The product described in this application is 1507xNK603 maize for all food and feed uses, and all food, feed and processed products derived from 1507xNK603 maize. The 1507xNK603 maize has been obtained from traditional breeding methods between progeny of two genetically modified maize. The two GM maize are DAS-Ø15Ø7-1 maize, referred to as 1507 maize, and MON-ØØ6Ø3-6 maize, referred to as NK603 maize. No new genetic modification has been introduced in 1507xNK603 maize.

###### (d) Date of acknowledgment of valid application:

[To be provided]

###### 2. Applicant

###### (a) Name of applicant

This is a joint application submitted by Pioneer Hi-Bred, as represented by Pioneer Overseas Corporation, and Mycogen Seeds, c/o Dow AgroSciences LLC.

###### (b) Address of applicant

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

Pioneer Hi-Bred International, Inc.  
7250 NW 62<sup>nd</sup> Avenue  
P.O. Box 552  
Johnston, IA 50131-0552 (U.S.A.)

Dow AgroSciences Europe  
European Development Centre  
3 Milton Park, Abingdon  
Oxon OX14 4RN  
United Kingdom

Mycogen Seeds  
c/o DowAgroSciences LLC  
9330 Zionsville Road  
Indianapolis, IN 46268-1054  
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, 1507xNK603 maize has been notified in France and Spain for field trials under Part B of Directive 2001/18/EC.

<u>Year</u>	<u>Member State</u>	<u>Notification No</u>
2003	France	B/FR/03.02.02
2003	Spain	B/ES/03/10
2004	Spain	B/ES/04/03

**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 1507xNK603 maize was submitted to the US Food and Drug Administration (FDA) in November of 2003. A notification letter was sent on 12<sup>th</sup> June of 2003 to the Canadian Food Inspection Agency and to Health Canada.

In addition, applications have been submitted to Japan, Canada, South Korea, Australia/ New Zealand, and Argentina. The necessary approvals for animal feed use and food safety of 1507xNK603 maize in Japan were obtained on 1<sup>st</sup> September and 2<sup>nd</sup> March of 2003, respectively.

**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 1507xNK603 maize has been derived by traditional breeding methods from two GM maize, 1507 maize (expressing the CRY1F and PAT proteins), and NK603 maize (expressing the CP4 EPSPS protein). The CRY1F protein confers resistance to certain lepidopteran insect pests, such as the European corn borer and *Sesamia* spp. The PAT protein confers tolerance to glufosinate-ammonium herbicide and the CP4 EPSPS protein confers tolerance to glyphosate herbicide. No new genetic modification has been introduced in 1507xNK603 maize.

**(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 1507xNK603 maize for all food and feed uses, and all food, feed and processed products derived from 1507xNK603 maize in accordance with Regulation (EC) 1829/2003. In addition, this application requests authorisation for import and processing of 1507xNK603 maize in accordance with Part C of Directive 2001/18/EC. However, this application does not include authorisation for the cultivation of 1507xNK603 maize seed products in the EU.

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

Use of 1507xNK603 maize will be consistent with current uses of commercial maize products. Majority of maize is used for animal feeds, and about 8% of the

grain is processed for human food products mainly by wet-milling or dry-milling. Maize grain is also processed into industrial products (11%), such as ethyl alcohol by fermentation and highly refined starch by wet-milling to produce starch and sweetener products. In addition to milling, the maize germ can be processed to obtain maize oil. There are multiple categories of users of 1507xNK603 maize, e.g. animal feed and milling industry, agriculture, skilled trades and consumer use by public at large.

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

Use of 1507xNK603 maize will be consistent with current uses of maize products. Labelling of 1507xNK603 products will be carried out in accordance with Community law. See **Point A.8.f)** below for labelling of 1507xNK603 maize.

**(e) Any proposed packaging requirements**

The packaging, handling, and storage systems that are currently used for maize will apply. The 1507xNK603 maize products will be packaged in the same manner as other commercial maize products. See **Point A.8.f)** below for labelling of 1507xNK603 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 1507xNK603 MAIZE FOOD PRODUCTS ACCORDING TO ARTICLES 12 AND 13 OF REGULATION (EC) 1829/2003**

**Proposal for the labelling of 1507xNK603 maize food products**

In accordance with Article 12(2) of Regulation No (EC) 1829/2003, labelling will apply to foods containing material which contains, consists of or is produced from 1507xNK603 maize in a proportion at or 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, 1507xNK603 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<sup>2</sup>, 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 1507xNK603 maize food products as 1507xNK603 maize has been shown to be equivalent to non-GM maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 1507xNK603 maize does not give rise to any ethical or religious concerns.

## **2.- PROPOSAL FOR THE LABELLING OF 1507xNK603 MAIZE FEED PRODUCTS ACCORDING TO ARTICLES 24 AND 25 OF REGULATION (EC) 1829/2003**

### **Proposal for the labelling of 1507xNK603 maize feed products**

In accordance with Article 24(2) of Regulation No (EC) 1829/2003, labelling will apply to feed containing material which contains, consists of or is produced from 1507xNK603 maize in a proportion at or 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.* 1507xNK603 maize for feed use, and feed containing, consisting of or produced from 1507xNK603 maize, should be labelled as follows:

- (a) where the feed contains or consists of 1507xNK603 maize, or where 1507xNK603 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 1507xNK603 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 1507xNK603 maize feed products as 1507xNK603 maize has been shown to be equivalent to non-GM maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 1507xNK603 maize does not give rise to any ethical or religious concerns.

### **3.- PROPOSAL FOR THE LABELLING OF PRODUCTS CONSISTING OF, OR CONTAINING, 1507xNK603 MAIZE ACCORDING TO ARTICLE 4, B(6) OF REGULATION (EC) 1830/2003 AND ANNEX IV OF DIRECTIVE 2001/18/EC**

As specified on Point **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 1507xNK603 maize will include the following:

- i)* Commercial name of the product and the statement that 'this product contains genetically modified organisms';
- 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.

These specifications will be included in the label or in the accompanying document with regard to 1507xNK603 maize products: further details are described below.

### **Proposal for the labelling of 1507xNK603 maize imports**

The following information is proposed to be provided to EU grain importers in order to label commodity maize grain imports (placed on the EU market) containing or consisting of 1507xNK603 maize:

- **Accompanying document.** See below.
  
- **Detection method.** To identify 1507xNK603 maize in imported products and assist with the labelling provisions for placing 1507xNK603 maize products on the EU market. The detection method for 1507xNK603 maize consists of the same detection methods available for 1507 and NK603 maize. The PCR detection methods to confirm the molecular identity of 1507 and NK603 maize have been developed and provided to the EC Joint Research Centre (Community Reference Laboratory) in Ispra (Italy).

### **Proposal for the accompanying document**

The following information is proposed to be included on the accompanying document for 1507xNK603 maize products.

#### **1. Name of the product:**

**Commercial name of the product.** Grain and other products derived from 1507xNK603 maize will be imported into the EU as part of general maize commodity imports. No new commercial name is expected to be assigned to the import of 1507xNK603 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 identifier assigned to 1507xNK603 maize is DAS-Ø15Ø7-1xMON-ØØ6Ø3-6.

#### **2. Name of the manufacturer or distributor:**

Pioneer Hi-Bred and Mycogen Seeds are developers of the technology and producers of 1507 maize seed.

*Pioneer Hi-Bred International, Inc.*  
*7250 NW 62<sup>nd</sup> Avenue*  
*P.O. Box 552*  
*Johnston, IA 50131-0552 (U.S.A.)*

*Mycogen Seeds*  
*c/o DowAgroSciences LLC*  
*9330 Zionsville Road*  
*Indianapolis, IN 46268-1054*  
*U.S.A.*

**3. Address of the manufacturer or distributor in the EU:**

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

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

Mycogen Seeds, as represented by Dow AgroSciences Europe:

*Dow AgroSciences Europe,  
European Development Centre  
3 Milton Park, Abingdon  
Oxon OX14 4RN  
United Kingdom*

**4. Conditions of use of the product:**

*This product contains genetically modified organisms.*

*The product consists of or contains 1507xNK603 maize. The grain and other products derived from 1507xNK603 maize can be imported, stored and processed for use in food, animal feed and industrial products in the same way as other conventional maize.*

The 1507xNK603 maize has been approved for placing on the market (import) in the EU under specific *conditions of use*:

- i) Labelling of 1507xNK603 maize products in accordance with EU legislation;
- ii) Reference to the public register.

*Labelling:* Compliance with the labelling requirements in accordance with EU legislation and transmission of these requirements to other users of 1507xNK603 maize products.

*Public register:* [Yet to be determined]

*No other restrictions or conditions of use apply to the placing on the market (import) of 1507xNK603 maize and therefore products from 1507xNK603 maize can be used in a manner consistent with current uses of maize grain and maize products.*

*Approval for placing on the market (import) of 1507xNK603 maize includes import for use in food and animal feed and industrial processing, but does not include cultivation.*

***Approval for placing on the market (import) of 1507xNK603 maize is not restricted to any specific geographical areas within the Community.***

*Approval for placing on the market of 1507xNK603 maize is valid until ... [Yet to be determined]. The period for the first consent is requested for a maximum of ten years starting from the date on which the consent is issued.*

*Further information is available from the public register at ...[Yet to be determined]*

**5. Measures to take in case of unintended release or misuse:**

*In case of unintended release of 1507xNK603 maize, current management measures taken to control unintended release or misuse of other commercially available maize can be applied, such as selective use of herbicides (with the exception of glufosinate-ammonium herbicide), where necessary.*

**6. Specific instructions for storage and handling:**

*No specific instructions for storage and handling of 1507xNK603 maize are necessary for the placing on the market (import) of 1507xNK603 maize, and therefore grain and grain products of 1507xNK603 maize may be stored and handled in the same way as products from other commercial maize varieties.*

**(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 1507xNK603 maize is DAS-Ø15Ø7-1xMON-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 1507xNK603 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.

In case of unintended release of 1507xNK603 maize, current measures taken to control unintended release or misuse of non-GM 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**

<b>(a) Family name:</b>	Gramineae
<b>(b) Genus:</b>	<i>Zea</i>
<b>(c) Species:</b>	<i>Z. mays</i> L.
<b>(d) Subspecies:</b>	None
<b>(e) Cultivar/breeding line:</b>	Line Hi-II
<b>(f) Common name:</b>	Maize; corn

**2 a. Information concerning reproduction**

**(i) Mode(s) of reproduction**

As a wind-pollinated, monoecious grass species, self-pollination and fertilisation, and cross-pollination and fertilisation, are usually possible and frequencies of each are normally determined by proximity and other physical influences on pollen dispersal.

**(ii) Specific factors affecting reproduction**

Tasselling, silking, and pollination are the most critical stages of maize development, and grain yield is greatly impacted by moisture and fertility stress. Dispersal of maize pollen tends to be limited, as it is influenced by the large size and rapid settling rate of the pollen.

**(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. This variance in maturity allows maize to be grown over a range of climatic conditions.

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

Maize will intra-pollinate and will not transfer genetic material to other plant species in the EU. The extent of pollination will depend upon prevailing wind patterns, humidity and temperature. It is generally considered that teosinte (*Zea mays* ssp. *mexicana*) is an ancestor of maize. Teosinte is an ancient wild grass found in Mexico and Guatemala and it is not present in the EU.

### **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 losing its 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 dependent 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 it has been identified as a major risk in limiting production of maize seed.

### **4. Dissemination**

#### **(a) Ways and extent of dissemination**

Maize has a polystichous female inflorescence (ear) on a stiff central spike (cob) enclosed in husks (modified leaves). As a result, seed dispersal of individual kernels does not occur naturally.

#### **(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.

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

Maize is grown throughout Europe over a wide range of climatic conditions because of its many divergent types. However, survival and reproduction in maize is limited by cool conditions. 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. Maize has been cultivated in Europe starting in Southern Europe since the 16<sup>th</sup> century. There are no other species compatible with maize in Europe.

### **6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts**

Not applicable as maize has been cultivated in Europe since the 16<sup>th</sup> century.

**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 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 is extensively cultivated and has a history of safe use. Maize or derived products of maize are not considered to have harmful characteristics. Maize has no toxic or pathogenic characteristics.

**C. INFORMATION RELATING TO THE GENETIC MODIFICATION**

**1. Description of the methods used for the genetic modification**

The 1507xNK603 maize was derived from traditional breeding methods by crossing 1507 and NK603 maize. No new genetic modification has been introduced in 1507xNK603 maize.

The 1507 maize was obtained by insertion of a linear DNA fragment (insert PHI8999A) containing the *cry1F* and *pat* coding sequences and the necessary regulatory components into maize cells using the particle acceleration method.

The NK603 maize was obtained by insertion of a linear DNA fragment (insert PV-ZMGT32L) containing the *cp4 epsps* gene and the necessary regulatory components into maize cells using the particle acceleration method.

**2. Nature and source of the vector used**

The 1507xNK603 maize has been derived from traditional breeding methods by crossing 1507 and NK603 maize. No new genetic modification has been introduced in 1507xNK603 maize.

In any case, no vector was used in the transformation of 1507 or NK603 maize.

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

The 1507xNK603 maize has been derived from traditional breeding methods by crossing 1507 and NK603 maize. No new genetic modification has been introduced in 1507xNK603 maize.

The insert used in the transformation of 1507 maize (insert PHI8999A) contained the plant optimised coding sequences for the *cry1F* and *pat* genes, together with the necessary regulatory components to drive their expression. The *cry1F* gene (1.8 kb; origin: *Bacillus thuringiensis* subsp. *aizawai*) was under the control of the ubiquitin promoter *ubiZM1(2)* (1.9 kb; origin: *Zea mays*) and the ORF25PolyA

terminator (0.7 kb; origin: *Agrobacterium tumefaciens* pTi15995). The intended function of the *cry1F* gene was to confer resistance against certain lepidopteran insect pests such as the European corn borer and *Sesamia* spp. The *pat* gene (0.5 kb; origin: *Streptomyces viridochromogenes* strain Tü494) was under the control of the CaMV35S promoter and terminator (0.5 and 0.2 kb, respectively; origin: cauliflower mosaic virus). The intended function of the *pat* gene was to confer tolerance to the application of glufosinate-ammonium herbicide.

The insert used in the transformation of NK603 maize (insert PV-ZMGT32L) contained two copies of the *cp4 epsps* gene (6.7 kb; origin: *Agrobacterium* sp. strain CP4). One of the copies of the *cp4 epsps* gene was under the control of the rice actin 1 gene intron (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 *cp4 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*). The intended function of the *cp4 epsps* gene was to confer tolerance to the application of glyphosate herbicide.

#### **D. INFORMATION RELATING TO THE GM PLANT**

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

The 1507xNK603 maize has been derived from traditional breeding methods by crossing 1507 and NK603 maize. No new genetic modification has been introduced in 1507xNK603 maize.

The 1507 maize was genetically modified to express the proteins CRY1F and phosphinothricin-N-acetyltransferase (PAT). When cultivated, expression of the CRY1F protein in 1507 and 1507xNK603 maize confers season-long resistance against certain lepidopteran pests, such as the European corn borer (*Ostrinia nubilalis*) and the pink borer (*Sesamia* spp.); and, expression of the PAT protein confers tolerance to the application of glufosinate-ammonium herbicide.

The NK603 maize was genetically modified to express the protein CP4 5-enolpyruvyl shikimate-3-phosphate synthase (CP4 EPSPS). When cultivated, expression of the CP4 EPSPS protein in NK603 and 1507xNK603 maize confers tolerance to the application of glyphosate herbicide.

No other new traits have been introduced or modified in 1507xNK603 maize.

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

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

A detailed molecular characterization consisting of Southern blot analyses has been carried out and it has confirmed that the copy number, structure and organisation of the 1507 and NK603 maize inserts are equivalent to those found in 1507xNK603 maize. There is no new genetic modification in 1507xNK603 maize.

**(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 into the maize plant genome as confirmed in the molecular characterisation of 1507xNK603 maize by detailed Southern blot analysis.

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

A detailed molecular characterization consisting of Southern blot analyses has been carried out and it has confirmed that the copy number, structure and organisation of the 1507 and NK603 maize inserts are equivalent to those found in 1507xNK603 maize. There is no new genetic modification in 1507xNK603 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 1507xNK603 maize has been derived from traditional breeding methods by crossing 1507 and NK603 maize. As a result, 1507xNK603 maize expresses the proteins CRY1F, PAT and CP4 EPSPS during the life cycle of the plant. No new genetic modification has been introduced in 1507xNK603 maize.

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

Addressed in **Point B.3.a)** above.

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

##### **(a) Reproduction**

No unexpected changes in pollen production, seed production, seed viability or germination compared to non-GM maize have been observed in field trials of 1507xNK603 maize.

##### **(b) Dissemination**

Maize hybrids have been domesticated to the extent that the seeds cannot be disseminated without human intervention. The 1507xNK603 maize plants show no difference in dissemination compared to non-GM 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 from readily surviving from one growing season to the next. When cultivated, expression of the CRY1F protein in 1507xNK603 maize confers resistance to certain lepidopteran insect pests, expression of PAT confers tolerance to the herbicide glufosinate-ammonium and expression of CP4 EPSPS confers tolerance to the herbicide glyphosate. The survival characteristics of 1507xNK603 maize in the environment remain comparable to those of non-GM maize. Resistance against certain lepidopteran 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**

The 1507xNK603 maize shows no unexpected differences from non-GM maize with comparable genetic background with relation to other agronomic traits, such as stalk lodging, root lodging, plant height, ear height, final population, stay green, disease incidence, insect damage and grain moisture.

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

The 1507xNK603 maize has been shown to be genetically and phenotypically stable. Results from the Southern analysis, agronomic characteristics and protein expression analysis of 1507xNK603 maize plants have confirmed the stable inheritance and expression of CRY1F, PAT and CP4 EPSPS proteins as a result of traditional breeding between 1507 and NK603 maize.

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

**(a) Plant to bacteria gene transfer**

Transfer of genetic material originating from 1507xNK603 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 *cry1F*, *pat* or *cp4 epsps* genes from 1507xNK603 maize does not represent a risk to human or animal health, nor is it of consequence as a plant pest risk. In addition, maize pollen grains are heavy, with a rapid settling rate, and show limited dispersal and viability capacities.

**(b) Plant to plant gene transfer**

The potential for transfer of genetic material from 1507xNK603 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.

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

**7.1 Comparative assessment**

The comparator chosen for the safety evaluation of 1507xNK603 maize consists of non-GM maize with comparable genetic background. Wherever possible, publicly available data on commercial maize has also been used in the comparisons with 1507xNK603 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 six separate field locations in Chile during the 2002-2003 growing season (6 locations). Each location included a randomized block design containing four blocks (or replicates). Each block contained the 1507xNK603 maize and a non-GM control for comparison.

**(b) The baseline used for consideration of natural variations**

Publicly available data on commercial maize was compiled from the literature and was used as the baseline for consideration of natural variations in the comparisons with 1507xNK603 maize. In addition, a comparative assessment with non-GM 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 analysis of grain from 1507xNK603 maize consisted of protein, fiber, carbohydrates, fat, ash, fatty acids, minerals, amino acids, vitamins, secondary metabolites and anti-nutrients. The results obtained confirmed that there are no statistically significant differences between 1507xNK603 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 1507xNK603 maize was tested in Chile during the 2002-2003 growing season (6 locations). The results obtained confirmed that there are no unexpected agronomic differences between 1507xNK603 maize and non-GM maize with comparable genetic background.

### **7.5 Product specification**

The 1507xNK603 maize and all food, feed and processed products derived from 1507xNK603 maize are substantially equivalent to commercial maize and all food, feed and processed products derived from commercial maize. Therefore, the specification of 1507xNK603 maize and all food, feed and processed products derived from 1507xNK603 maize is the same as that of commercial maize and all food, feed and processed products derived from commercial maize.

### **7.6 Effect of the production and processing**

The 1507xNK603 maize will undergo existing production processes used for commercial maize. No novel production process is envisaged.

The proteins CRY1F, PAT and CP4 EPSPS expressed in 1507xNK603 maize degrade rapidly under conditions used in the production and processing of maize. In particular, heating of maize derived products will lead to the rapid denaturation and degradation of the CRY1F, PAT and CP4 EPSPS proteins expressed in 1507xNK603 maize.

### **7.7 Anticipated intake/extent of use**

The 1507xNK603 maize food and animal feed products are expected to replace a portion of maize products in existing food and animal feed products with total consumption of maize products remaining unchanged. In any case, in the EU, the majority of maize products, 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 of 8.8 grams/person/day. The comparative

and nutritional assessments of 1507xNK603 maize together with the absence of any adverse effects to human and animal health from CRY1F, PAT and CP4 EPSPS proteins confirm that there are no concerns related to the anticipated intake/extent of use of 1507xNK603 maize.

## 7.8 Toxicology

### 7.8.1 Safety evaluation of newly expressed proteins

The 1507xNK603 maize has been derived from traditional breeding between 1507 and NK603 maize and no new genetic modification has been introduced in 1507xNK603 maize. As a result, 1507xNK603 maize expresses the proteins CRY1F, PAT and CP4 EPSPS. The safety of these proteins has already been confirmed by the detailed and thorough safety evaluations carried out by a number of scientific and regulatory panels around the world.

The CRY1F protein has specific toxicity against certain lepidopteran insect pests (target organisms). An acute toxicity study with CRY1F protein in mice has confirmed the safety of the CRY1F protein to human and animal health. No mortality, toxicity or adverse clinical signs were observed at the highest dose tested of 5050 mg of test material per kg of body weight, which was equivalent to 576 mg of pure CRY1F protein per kg of body weight. In addition, there is no evidence for CRY proteins originating from *Bacillus thuringiensis* to have harmful effects on the health of humans and animals.

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. Toxicity studies carried out on rats and mice containing up to 50000 and 5000 mg/kg body weight respectively, 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 *cp4 epsps* gene was originally obtained from *Agrobacterium* sp. strain CP4, which has no known toxic or pathogenic potential. Toxicity studies carried out on mice containing up to 5000 mg/kg body weight have confirmed the absence of any adverse treatment-related clinical signs.

In addition, a poultry feeding study has been carried out with diets containing grain from 1507xNK603 maize or from non-GM maize over a period of 42 days. The results obtained have confirmed that there are no statistically significant differences on mortality, body weight gain or feed conversion between chickens fed a diet containing grain from 1507xNK603 maize or from non-GM maize.

### **7.8.2 Testing of new constituents other than proteins**

Detailed compositional analyses of 1507xNK6032 maize demonstrated that the composition of 1507xNK603 maize grain is equivalent to that of non-GM 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 1507xNK603 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 1507xNK603 maize. In addition, the nutritional assessment of 1507xNK603 maize has confirmed that whole food and feed consisting of or derived from 1507xNK603 maize is equivalent to whole food and feed consisting of or derived from commercial maize.

In addition, a poultry feeding study over a period of 42 days has also been carried out with grain from 1507xNK603 maize; grain from non-GM control maize with comparable genetics; and, grain from three commercial maize hybrids. The results have confirmed that there are no statistically significant differences on mortality, body weight gain or feed conversion between chickens fed a diet containing grain from 1507xNK603 maize or any of the other diets.

## **7.9 Allergenicity**

### **7.9.1 Assessment of allergenicity of the newly expressed protein**

The assessment of the allergenic potential of the CRY1F, PAT and CP4 EPSPS proteins has been made following the recommendations and the application of the decision-tree from FAO/WHO. The evaluation has consisted of amino acid sequence comparison with known allergens, rapid degradation in simulated gastric fluids, relatively low level of expression, lack of glycosylation and thermolability. The results obtained confirm that CRY1F, PAT and CP4 EPSPS proteins do not pose any significant risk of being a potential allergen.

The most important factor to consider in assessing allergenic potential is whether the source of the gene being introduced into plants is known to be allergenic. Neither *Bacillus thuringiensis* (the source of the *cry1F* gene), *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 use as food in the EU and constitutes a traditional counterpart to 1507xNK603 maize that can be used as a baseline to facilitate the assessment of potential toxicity and allergenicity of 1507xNK603 maize. Maize is not considered to be a common allergenic food crop and 1507xNK603 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 grain from 1507xNK603 maize have shown that the contents of protein, fiber, 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. In addition, nutritional equivalence between 1507xNK603 maize and non-GM control maize with comparable genetic background has also been shown in a poultry feeding study over a 42-day period.

Furthermore and taking into account the anticipated dietary intake of 1507xNK603 maize products, consumption of 1507xNK603 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 1507xNK603 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** above, the nutritional assessment has concluded that 1507xNK603 maize food and feed products are nutritionally equivalent to those from non-GM maize. In addition, the use of 1507xNK603 maize food and feed products will not be different from that of food and feed products from non-GM maize.

Therefore, post-market monitoring of GM food/feed products derived from 1507xNK603 maize is not necessary.

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

The mechanism of interaction between CRY1F protein expressed in 1507xNK603 maize and target organisms can be summarized as follows:

Maize expressed CRY1F protein consists of residues 1 to 605 of the native CRY1F sequence from *B. thuringiensis* sbsp. *aizawai*, with a single and conservative amino acid substitution (F to L at position 604). Upon ingestion of 1507xNK603

maize tissue by susceptible insects (target pests) the maize expressed CRY1F protein will reach the alkaline conditions of the insect gut where proteolytic processing of CRY1F protein by trypsin-like proteases may occur before it binds to specific receptors on the apical microvilli of epithelial midgut cells of the insect and the CRY1F protein undergoes a conformational change that allows insertion into the membrane of the cell. Protein oligomerization will then occur with formation of pores in the membrane of the midgut cells of the insect causing osmotic cell lysis leading to insect death.

## **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 authorization for the cultivation of 1507xNK603 maize. Exposure to the environment from the import of 1507xNK603 maize will be limited to unintended release of 1507xNK603 maize e.g. via spillage during transportation of the grain.

### **9.1 Persistence and invasiveness**

There is negligible likelihood for 1507xNK603 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 CRY1F, PAT and CP4 EPSPS proteins in 1507xNK603 maize does not give rise to traits for weediness.

In case of any unintended release of 1507xNK603 maize, current measures taken to control spillage of commercially available maize can be applied, such as selective use of herbicides (with the exception of glufosinate-ammonium and glyphosate 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 specific advantages contained in 1507xNK603 maize do not confer any selective advantage to the plants in the natural environment, *i.e.* outside the agricultural environment. Insect attack is one of the multiple biotic and abiotic factors that prevent growth of maize outside heavily managed agricultural environments, and therefore, expression of the CRY1F protein conferring resistance to certain lepidopteran insect pests cannot be considered a selective advantage outside the agricultural environment.

In addition, application of broad spectrum herbicides, such as glufosinate-ammonium and glyphosate, do not commonly occur outside the agricultural environment, and therefore expression of PAT and CP4 EPSPS proteins in 1507xNK603 maize do 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 1507xNK603 maize plants to become environmentally persistent or invasive giving rise to any weediness. Furthermore, expression of the proteins CRY1F, PAT and CP4 EPSPS does not present any selective advantage outside the agricultural environment.

### **9.4 Interactions between the GM plant and target organisms**

The scope of this application does not include authorisation for the cultivation of 1507xNK603 maize. Exposure to the environment from the import of 1507xNK603 maize will be limited to unintended release of 1507xNK603 maize e.g. via spillage during transportation of the grain. Therefore, there will be no significant interactions between 1507xNK603 maize and target organisms.

### **9.5 Interactions of the GM plant with non-target organisms**

The scope of this application does not include authorisation for the cultivation of 1507xNK603 maize. Exposure to the environment from the import of 1507xNK603 maize will be limited to unintended release of 1507xNK603 maize e.g. via spillage during transportation of the grain. Therefore, there will be no significant interactions between 1507xNK603 maize and non-target organisms.

### **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 CRY1F, PAT and CP4 EPSPS proteins expressed in 1507xNK603 maize has been carried out. The conclusion obtained is that 1507xNK603 maize does not express any known toxic or allergenic proteins.

Furthermore, the nutritional assessment of 1507xNK603 maize has confirmed that 1507xNK603 maize and all food, feed and processed products derived from 1507xNK603 maize are nutritionally equivalent to commercial maize and all food, feed and processed products derived from commercial maize.

Therefore, consumption of 1507xNK603 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 1507xNK603 maize or any derived food, feed and processed products will result in no adverse consequences to human or animal health. Therefore, use of 1507xNK603 maize as feed and consumption of any food, feed and processed products derived from 1507xNK603

maize will result in no adverse consequences to animal health or the food/feed chain.

## **9.8 Effects on biogeochemical processes**

The scope of this application does not include authorization for the cultivation of 1507xNK603 maize. Exposure to the environment from the import of 1507xNK603 maize will be limited to unintended release of 1507xNK603 maize e.g. via spillage during transportation of the grain, which can be controlled with current measures used to control spillage of commercially available maize. Therefore, there will be no potential immediate or delayed adverse effects on biogeochemical processes.

## **9.9 Impacts of the specific cultivation, management and harvesting techniques**

The scope of this application does not include authorization for the cultivation of 1507xNK603 maize.

## **10. Potential interactions with the abiotic environment**

The scope of this application does not include authorization for the cultivation of 1507xNK603 maize. Exposure to the environment from the import of 1507xNK603 maize will be limited to unintended release of 1507xNK603 maize e.g. via spillage during transportation of the grain, which can be controlled with current measures used to control spillage of commercially available maize. 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 authorization for the cultivation of 1507xNK603 maize. Exposure to the environment from the import of 1507xNK603 maize will be limited to unintended release of 1507xNK603 maize e.g. via spillage during transportation of the grain. In addition and as described throughout this application, there is no new genetic modification in 1507xNK603 maize, as it has been obtained from traditional breeding methods.

The proposal for an environmental monitoring plan for the placing on the market of 1507xNK603 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.) carried out for this application for

authorisation of genetically modified 1507xNK603 maize and derived food and feed (**Points D.9 and D.10**).

The e.r.a. for for this application for authorisation of genetically modified 1507xNK603 maize and derived food and feed 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, which is 1507xNK603 maize for all food and feed uses, and all food, feed and processed products derived from 1507xNK603 maize. Therefore, the risk to human and animal health or the environment from 1507xNK603 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 the risk to human and animal health or the environment from 1507xNK603 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 1507xNK603 maize for all food and feed purposes and the import and processing of 1507xNK603 maize.

### **11.4 General Surveillance of the impact of the GM plant**

The scope of this application is for the authorisation of 1507xNK603 maize for all food and feed uses in accordance with Articles 3(1) and 15(1) of Regulation (EC) 1829/2003 and for import and processing of 1507xNK603 maize in accordance with Part C of Directive 2001/18/EC. In this application we are not seeking approval for cultivation of 1507xNK603 maize seed products.

As discussed in detail in the e.r.a., exposure to the environment will be limited to any unintended release of 1507xNK603 maize, which could occur via accidental spillage of commodity grain including 1507xNK603 maize destined for processing into animal feed or human food products. However, such limited exposure is highly unlikely to give rise to any adverse effect and, if necessary, can be easily controlled by the application of current practices used for the control of spillage of commercial maize, such as the application of non-selective herbicides with the exception of glufosinate-ammonium and glyphosate herbicides.

Therefore, application of established routine surveillance practices (e.g. the monitoring of agricultural cultivars or plant protection products) is not necessary for the general surveillance of the occurrence of unanticipated adverse effects to

commercial agricultural practice due to the use of 1507xNK603 maize for all food and feed purposes and the import and processing of 1507xNK603 maize.

### **11.5 Reporting the results of monitoring**

Case-specific monitoring is not applicable for the use of 1507xNK603 maize for all food and feed purposes and the import and processing of 1507xNK603 maize. As a result, no case-specific monitoring is proposed for this application for authorisation of 1507xNK603 maize and derived food and feed.

The applicants will inform the rapporteur Competent Authority and the European Commission, without delay, of any adverse effects arising from the handling and use of imported 1507xNK603 maize reported to them. Furthermore, the applicants will investigate such reports and inform the outcome to the rapporteur Competent Authority and the European Commission.

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

The 1507xNK603 maize has been derived from traditional breeding methods between progeny of 1507 maize (DAS-Ø15Ø7-1), and NK603 (MON-ØØ6Ø3-6 maize). No new genetic modification has been introduced in 1507xNK603 maize. As a result, detection and event-specific identification techniques for 1507xNK603 maize consist of the same detection and event-specific identification techniques available for 1507 and NK603 maize.

The PCR detection methods for 1507 and NK603 maize have been made available to JRC-IHCP (Joint Research Centre-Institute of Health and Consumer Protection) for purposes of validation by the Community Reference Laboratory.

## **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/FR/03.02.02

#### **(b) Conclusions of post-release monitoring**

The 1507xNK603 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 1507xNK603 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/ES/03/10

**(b) Conclusions of post-release monitoring**

The 1507xNK603 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 1507xNK603 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/ES/04/03

**(b) Conclusions of post-release monitoring**

The 1507xNK603 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 1507xNK603 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**

Biosafety Committee

**(c) Release site**

Tchavdarzi and Letniza

**(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 1507xNK603 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 1507xNK603 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**  
Not regulated.
- (c) **Release site**  
Multiple sites.
- (d) **Aim of the release**  
Research.
- (e) **Duration of the release**  
Not applicable.
- (f) **Aim of post-release monitoring**  
Not applicable.
- (g) **Duration of post-release monitoring**  
Not applicable.
- (h) **Conclusions of post-release monitoring**  
Not applicable. In any case, the 1507xNK603 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 1507xNK603 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**  
Four sites.
- (d) **Aim of the release**  
Research.
- (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 1507xNK603 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 1507xNK603 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**  
Not regulated.
  - (c) **Release site**  
Multiple sites.
  - (d) **Aim of the release**  
Research.
  - (e) **Duration of the release**  
Not applicable.
  - (f) **Aim of post-release monitoring**  
Not applicable.
  - (g) **Duration of post-release monitoring**  
Not applicable.
  - (h) **Conclusions of post-release monitoring**  
Not applicable. In any case, the 1507xNK603 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 1507xNK603 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):**
- (a) **Status/process of approval**  
  
[To be provided]
  - (b) **Assessment report of the Competent Authority (Directive 2001/18/EC)**  
  
[To be provided]
  - (c) **EFSA opinion**  
  
[To be provided]
  - (d) **Commission Register (Commission Decision 2004/204/EC)**  
  
[To be provided]
  - (e) **Molecular Register of the Community Reference Laboratory/Joint Research Centre**  
  
[To be provided]

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

[To be provided]

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

[To be provided]