PART II

SUMMARY OF THE TRANSFORMED APPLICATION FOR 1507 MAIZE FOOD PRODUCTS IN ACCORDANCE WITH REGULATION (EC) 1829/2003

A. GENERAL INFORMATION

1. Details of application

(a) Member State of application:

The Netherlands

(b) Application number:

EFSA-GMO-NL-2004-02

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

The GM plant and derived food described in this transformed application is *B.t.* Cry1F maize line 1507, referred to as 1507 maize. It consists of maize products consisting of or derived from 1507 maize genetically modified to express CRY1F protein, conferring resistance to certain lepidopteran insect pests, and PAT protein, conferring tolerance to glufosinate-ammonium herbicide. The maize product also consists of grain and derived food from progeny derived from conventional breeding between 1507 maize with any traditionally bred maize. The commercial name assigned to 1507 maize seed in the US market is Herculex I *Insect Protection*.

(d) Date of acknowledgment of valid application:

03 September 2004

2. Applicant

(a) Name of applicant

This is a joint application submitted by Pioneer Hi-Bred International Inc., 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.
400 Locust Street, Suite 800
Des Moines, IA 50309
U.S.A.

Dow AgroSciences Europe	Mycogen Seeds
European Development Centre	c/o DowAgroSciences LLC
3 Milton Park, Abingdon	9330 Zionsville Road
Oxon OX14 4RN	Indianapolis, IN 46268-1054
United Kingdom	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)?

Yes, a separate notification (Ref. **C/NL/00/10**) for placing on the market (imports and feed use) of 1507 maize has been submitted to The Netherlands in accordance with Directive 2001/18/EC. In addition, another notification (Ref. **C/ES/01/01)** for placing on the market of 1507 maize, including cultivation, has been submitted to Spain in accordance with Directive 2001/18/EC.

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

Yes, 1507 maize has been notified in Italy, France and Spain for field trials under Part B of Directive 90/220/EEC.

Year	Member State	Notification No
1998	Italy	B/IT/98/19
1999	Italy	B/IT/98/19
1999	France	B/FR/99.03.09
2000	Italy	B/IT/98/19
2000	France	B/FR/99.03.09
2000	France	B/FR/00.03.04

2002 Spain B/ES/02/11

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?

Yes, this application is a transformed application of the previous application submitted to The Netherlands for food use of 1507 maize in accordance with Regulation (EC) No 258/97.

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

Yes, an application for registration of 1507 maize was submitted to the US Environment Protection Agency (EPA). Also, an application for non-regulated status of 1507 maize to the US Department of Agriculture (USDA) was submitted in May 2000, and a notification concerning foods derived from 1507 maize to the US Food and Drug Administration (FDA) was submitted in July 2000. The corresponding permits were granted as follows: by US EPA and FDA on 18th May 2001 and by USDA on 14th June 2001.

In addition, applications have been submitted to Argentina, Australia/New Zealand, Canada, China, Japan, Korea, Mexico, South Africa, Switzerland and Taiwan. The necessary approvals for import, animal feed use and food safety of 1507 maize in Japan were obtained on 15th June, 28th May and 8th July of 2002, respectively. In Canada permits were granted by Health Canada for novel food use of 1507 maize on 10th October 2002 and by the Canadian Food Inspection Agency for animal feed use and environmental release on 11th October 2002. Approval for import of 1507 maize for animal feed and food use in South Africa was obtained on 12th December 2002.

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 1507 maize has been genetically modified to express CRY1F protein, conferring resistance to certain lepidopteran insect pests, such as the European corn borer and *Sesamia* spp., and PAT protein, conferring tolerance to glufosinate-ammonium herbicide.

(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 1507 maize for all food uses in accordance with Regulation (EC) 1829/2003.

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

Use of 1507 maize food products will be consistent with current uses of commercial maize food products. There are multiple categories of users of 1507 maize, e.g. food and milling industry, 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

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

(e) Any proposed packaging requirements

The packaging, handling, and storage systems that are currently used for maize will apply. The 1507 maize products will be packaged in the same manner as other commercial maize products. See **Point A.8.f)** below for labelling of 1507 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

The following proposal for the labelling of 1507 maize food products has been prepared in accordance with the above provisions (**Part IV** of this transformed application).

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 1507 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, 1507 maize should be labelled as follows:

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

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

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

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

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

No other particulars such as those referred to in Article 13(2)(a) and (b) and Article 13(3) of Regulation No (EC) 1829/2003 would need to be specified on the label of 1507 maize food products as 1507 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 1507 maize does not give rise to any ethical or religious concerns.

Proposal for the labelling of products consisting of, or containing, 1507 maize according to 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 1507 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 notifier 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 1507 maize products: further details are described below.

Proposal for the labelling of 1507 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 1507 maize:

- *Accompanying document*. See below.

- *Detection method.* To identify 1507 maize in imported products and assist with the labelling provisions for placing 1507 maize products on the EU market.

Proposal for the accompanying document

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

1. Name of the product:

Commercial name of the product. Grain and other products derived from 1507 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 1507 maize. In accordance with the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identification code assigned to 1507 maize is DAS-Ø15Ø7-1.

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.
400 Locust Street, Suite 800
Des Moines, IA 50309
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 1507 maize. The grain and other products derived from 1507 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 1507 maize has been approved for placing on the market (import) in the EU under specific *conditions of use:*

i) Labelling of 1507 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 1507 maize products.

Public register: [Yet to be determined]

No other restrictions or conditions of use apply to the placing on the market (import) of 1507 maize and therefore products from 1507 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 1507 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 1507 maize is not restricted to any specific geographical areas within the Community.

Approval for placing on the market of 1507 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 1507 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 1507 maize are necessary for the placing on the market (import) of 1507 maize, and therefore grain and grain products of 1507 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 1507 maize is DAS-Ø15Ø7-1.

(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 (e.r.a.) for the placing on the market of 1507 maize in accordance to Annex II of Directive 2001/18/EC (**Section 4** of the complementary information to notification **C/NL/00/10**) 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 1507 maize, current agronomic measures taken to control unintended release or misuse of non-GM maize can be applied, such as cultivation, selective use of herbicides (with the exception of glufosinate-ammonium herbicide), and crop rotation.

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

1. Complete name

(a) Family name:	Gramineae
(b) Genus:	*Zea*
(c) Species:	*Z. mays* L.
(d) Subspecies:	None
(e) Cultivar/breeding line:	Line Hi-II
(f) Common name:	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 16th 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 16th 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 particle acceleration method was used to introduce into maize cells a linear DNA fragment containing the *cry*1F and *pat* coding sequences and the necessary regulatory components (insert PHI8999A). Maize event 1507 expressing the CRY1F protein and the PAT protein was produced, referred to as 1507 maize.

2. Nature and source of the vector used

No vector was used for the transformation of 1507 maize. As described in the notification, the intended insert consists of a linear DNA fragment, containing the *cry*1F and *pat* coding sequences together with the necessary regulatory components only, which was introduced by particle acceleration for the transformation of 1507 maize. No additional DNA sequences were used for introduction of the insert into 1507 maize.

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

The intended insert PHI8999A contains the plant optimised coding sequences for the *cry*1F and *pat* genes, together with the necessary regulatory components to drive their expression.

The *cry*1F gene (1818 bp; origin: *Bacillus thuringiensis* subsp. *aizawai*) is under the control of the ubiquitin promoter *ubi*ZM1(2) (1986 bp; origin: *Zea mays*) and the ORF25PolyA terminator (714 bp; origin: *Agrobacterium tumefaciens* pTi15995). The function of the CRY1F protein in 1507 maize is to provide resistance against certain lepidopteran insect pests such as the European corn borer and *Sesamia* spp.

The *pat* gene (552 bp; origin: *Streptomyces viridochromogenes* strain Tü494) is under the control of the CaMV35S promoter and terminator (554 and 204 bp, respectively; origin: cauliflower mosaic virus). The function of the PAT protein in 1507 maize is to tolerate application of glufosinate-ammonium herbicide.

D. INFORMATION RELATING TO THE GM PLANT

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

The 1507 maize expresses CRY1F protein conferring resistance to certain lepidopteran insect pests, and PAT protein conferring tolerance to glufosinate-ammonium herbicide.

The *cry*1F gene is expressed constitutively by the *ubi*ZM1(2) promoter. Expression of CRY1F protein provides control against lepidopteran insect pest damage to the above-ground parts of the maize plant including those parts which are beyond the reach of chemical insecticides. Specifically, the CRY1F protein confers season-long resistance against the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests such as the pink borer (*Sesamia* spp.). It is also highly effective against fall armyworm (*Spodoptera frugiperda*), black cutworm (*Agrotis ipsilon*) and southwestern corn borer (*Diatraea grandiosella*).

The *pat* gene is also expressed constitutively by the CaMV35S promoter. Expression of PAT protein confers tolerance to application of glufosinate-ammonium herbicide. Field trials show that 1507 maize will tolerate field application rates of 1600 g a.i./ha of glufosinate-ammonium herbicide without showing any phytotoxicity symptoms. Tolerance to glufosinate-ammonium herbicide provides for improved weed management.

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

2. Information on the sequences actually inserted or deleted

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

The genetic modification in 1507 maize has been characterised in detail by Southern blot and DNA sequence analyses. The analyses have confirmed that the inserted genetic material is integrated into the nuclear genome of the maize plant and consists of an almost full-length copy of the linear fragment used in the transformation (*i.e.*, 6186 bp from the 6235 bp of insert PHI8999A, containing the *cry*1F and *pat* genes together with the regulatory sequences necessary for their expression). The insert integrated in 1507 maize contains one copy of the almost full-length linear fragment used in the transformation, which includes one functional copy of the complete *cry*1F gene and one functional copy of the complete *pat* gene, together with the regulatory sequences necessary for their expression. The insert also contains two non-functional fragments of the *cry*1F

gene; three non-functional fragments of the *pat* gene; one non-functional fragment of the polylinker region and *ubi*ZM1(2) promoter; and, one non-functional fragment of the ORF25PolyA terminator sequence.

The 1507 maize does not contain the *nptII* gene nor any other detectable fragments from the portion of plasmid PHP8999 that was not intended for transformation of 1507 maize. Maize genomic DNA flanking regions at both the 5' and 3' borders of the 1507 maize insert have been sequenced and characterised in detail. Analysis by PCR amplification has confirmed the presence of both maize genomic flanking regions in non-GM Hi-II maize used in the transformation of 1507 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 insert is integrated into the maize plant genome as confirmed in the molecular characterisation of 1507 maize by detailed Southern blot analysis and DNA sequencing.

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

The insert integrated in 1507 maize contains one copy of the almost full-length linear fragment used in the transformation, which includes one functional copy of the complete *cry*1F gene and one functional copy of the complete *pat* gene, together with the regulatory sequences necessary for their expression. In addition, the 1507 maize insert contains the following non-functional fragments:

- one fragment (335 bp) of the *cry*1F gene, with no *ubi*ZM1(2) promoter sequence, and one 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(2) 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.

3. Information on the expression of the insert

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

Leaf, pollen, silk, stalk, whole plant, grain and senescent whole plant tissue samples from 1507 maize and control maize with comparable background genetics were obtained from field studies conducted during the growing seasons of 1998/99

in Chile, 1999 in France and Italy, and 2000 in France, Italy and Bulgaria. Expression levels of CRY1F and PAT proteins in these tissues were measured using specific Enzyme Linked Immunosorbent Assay (ELISA) developed for each protein. Results show that the CRY1F protein is expressed in all tissues and throughout the development of maize, while the PAT protein was measurable at the V9 developmental stage only.

The characteristics of the CRY1F and PAT proteins expressed in 1507 maize were further examined by Western blot analysis. The CRY1F protein was detected as two bands of approximately 65 and 68 kDa, respectively, which result from limited N-terminal processing of maize expressed CRY1F protein by a plant protease with trypsin-like specificity. No other bands indicative of a partial CRY1F protein or a fusion protein of greater molecular weight were observed.

The PAT protein is known to be a homodimer of approximately 43 kDa in its native form, and it is comprised of two components of approximately 22 kDa. The results of the Western blot analysis of 1507 maize confirmed the presence of the ~22 kDa PAT monomeric form and of the ~43 kDa PAT homodimer in leaf tissue. No other bands indicative of a partial PAT protein or fusion protein of greater molecular weight were observed in 1507 maize.

The genetic modification in 1507 maize results in expression of CRY1F protein conferring resistance to certain lepidopteran insect pests, and PAT protein conferring tolerance to glufosinate-ammonium herbicide. Specifically, the CRY1F protein confers season-long resistance against the European corn borer (*Ostrinia nubilalis*) and *Sesamia* spp. It is also highly effective against fall armyworm (*Spodoptera frugiperda*), black cutworm (*Agrotis ipsilon*) and southwestern corn borer (*Diatraea grandiosella).*

(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 1507 maize.

(b) Dissemination

Maize hybrids have been domesticated to the extent that the seeds cannot be disseminated without human intervention. The 1507 maize plants show no difference in dissemination compared to non-GM maize.

(c) Survivability

Cultivated maize has been domesticated to the extent that it can not survive outside managed agricultural environments. Lack of dormancy prevents maize seed to readily survive from one growing season to the next. The genetic modification in 1507 maize results in expression of CRY1F conferring resistance to certain lepidopteran insect pests and expression of PAT conferring tolerance to the herbicide glufosinate-ammonium. The survival characteristics of 1507 maize in the environment remain comparable to those of non-GM maize.

(d) Other differences

Maize does not exhibit any weedy tendencies and is non-invasive in natural ecosystems. Based on the agronomic data, there is no evidence for altered survival, multiplication, or dissemination of 1507 maize in the environment as compared to non-GM maize. In addition, the inserted traits do not alter the phenotype of maize in a way that would confer a fitness advantage for maize outside managed agricultural environments.

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

The inserted genetic material in 1507 maize is stable for at least six generations, and the *cry*1F and *pat* genes are inherited as Mendelian dominant genes. Results from Southern blot and DNA sequencing analyses show that the additional non-functional fragments were present in the BC4 backcross generation, thus supporting the conclusion that they are genetically linked to the almost full-length insert containing the *cry*1F and *pat* genes.

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 1507 maize to bacteria is a negligible concern. There is no known mechanism for, or definitive demonstration of, DNA transfer from plants to microbes under natural conditions. Even if horizontal gene transfer were to take place, transfer of the *cry*1F or *pat* genes from 1507 maize does not represent a risk to human or animal health, nor is it of consequence as a plant pest risk. The *nptII* gene coding for resistance to the antibiotic kanamycin is not present in 1507 maize.

(b) Plant to plant gene transfer

The potential for transfer of genetic material from 1507 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 1507 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 1507 maize.

7.2 Production of material for comparative assessment

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

Composition data was obtained from trials carried out in Chile in 1998-1999 (4 locations; six replicates at each location) and in France and Italy (6 locations) in 1999. At each location in France, the trials involved six replicates of 1507 maize unsprayed with glufosinate-ammonium, and a non-GM control maize with comparable genetics. At each location in Italy, the trials involved three replicates of 1507 maize sprayed with glufosinate-ammonium, 1507 maize unsprayed with glufosinate-ammonium, and of a non-GM control maize with comparable genetics. In 2000, additional field trials were carried out within commercial maize growing regions of Europe at a total of six locations in France (3 locations), Italy (2 locations) and Bulgaria (1 location). Nutrient composition of 1507 maize treated and untreated with glufosinate-ammonium herbicide, was evaluated and compared with non-GM maize with comparable genetic background. At each location there were three replicates of 1507 maize sprayed with glufosinate ammonium, 1507 maize unsprayed and non-GM maize with comparable genetic background.

(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 1507 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 1507 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 1507 maize and non-GM control maize with comparable genetic background that would fall outside the normal ranges of natural variation for non-GM maize.

7.4 Agronomic traits

The 1507 maize was tested in the USA during the 1999 growing season in up to 15 locations and in 2000 at six locations in France (3 locations), Italy (2 locations) and Bulgaria (1 location). The results obtained confirmed that there are no unexpected agronomic differences between 1507 maize and non-GM maize with comparable genetic background.

7.5 Product specification

Maize (*Zea mays* L.) has well characterised specification belonging to the Gramineae family, the genus *Zea* and the species *Z. mays* (2n = 20). The evidence presented in this transformed application confirms that 1507 maize food products can be considered to be substantially equivalent to food products from traditionally-bred non-GM maize with no nutritional or toxicological changes. Traditionally-bred maize does not contain any toxic or anti-nutritional factors that need to be controlled by a specification and the characteristics, compositional analyses and safety evaluation of the genetic modification in 1507 maize does not entail a separate specification of the food products.

7.6 Effect of the production and processing

The 1507 maize will undergo existing production processes used for non-GM maize. No novel production process is envisaged.

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

7.7 Anticipated intake/extent of use

The 1507 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, starches, and oil, *i.e.* products that contain only negligible amounts of protein.

According to GEMS/FOOD Dietary Tables (2004) maize consumption by the European population is estimated to be of 3.21 kg/person/year. The comparative and nutritional assessments of 1507 maize together with the absence of any adverse effects to human and animal health from CRY1F and PAT proteins confirm that there are no concerns related to the anticipated intake/extent of use of 1507 maize.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

The genetic modification in 1507 maize results in expression of CRY1F and PAT proteins. 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.

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

7.8.2 Testing of new constituents other than proteins

Not applicable.

7.8.3 Information on natural food and feed constituents

The comparisons carried out between the natural constituents of 1507 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 non-GM maize.

7.8.4 Testing of the whole GM food/feed

As described throughout this application, the evaluation of the nutrient composition of 1507 maize has confirmed that it is equivalent to non-GM control maize with comparable genetic background.

A poultry feeding study over a period of 42 days has been carried out confirming that there are no statistically significant differences on mortality, body weight gain or feed conversion between chickens fed a diet containing grain from 1507 maize or from non-GM maize.

Furthermore, a thirteen-week (90-day) oral toxicity feeding study in rats has been carried out with 1507 maize grain in order to confirm the absence of toxicity of the proteins CRY1F and PAT expressed in 1507 maize. The study involved a total of 10 groups of 12 young rats each, which were fed with diets containing 33% or 11% grain from 1507 maize, non-GM maize with comparable genetic background (33P66 maize) or from commercial non-GM maize (33J56 maize) for approximately 90 days. All diets contained a total of 33% maize grain. Diets formulated with 11% of GM or near isogenic non-GM maize (groups VII – X) also contained 22% commercial hybrid maize (33J56) for a final concentration of 33% maize. Body weights, food consumption, food efficiency and clinical signs were evaluated weekly. Neurobehavioural and ophthalmological evaluations were carried out at the start and near the end of the study. Clinical, gross and microscopic pathological evaluations were also conducted at the end of the study. The results also confirmed that no toxicologically significant diet-related differences were observed among the groups fed with any of the different diets with respect to clinical signs of toxicity, ophthalmological observations, neurobehavioral assessments, clinical pathology (hematology, clinical chemistry, coagulation, or urinalysis parameters), organ weights, and gross or microscopic pathology. In conclusion, exposure of male and female rats to diets containing grain from 1507 maize produced no toxicologically significant differences, compared to rats fed diets containing grain from non-GM maize with comparable genetic background or grain from commercial non-GM maize.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

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 *cry*1F gene) nor *Streptomyces viridochromogenes* (the source of the *pat* gene) have a history of causing allergy. Also, both donor organisms are common soil bacteria.

The assessment of the allergenic potential of the CRY1F and PAT proteins has been made following the recommendations and the application of the decision-tree from FAO/WHO. The analyses have 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 confirm that CRY1F and PAT proteins do not pose any significant risk of being a potential allergen.

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 1507 maize that can be used as a baseline to facilitate the assessment of potential toxicity and allergenicity of 1507 maize. Maize is not considered to be an allergenic food crop and 1507 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 1507 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 1507 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 1507 maize products, consumption of 1507 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 1507 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 1507 maize food products are nutritionally equivalent to those from non-GM maize. In addition, the use of 1507 maize food products will not be different from that of food products from non-GM maize.

Therefore, post-market monitoring of 1507 maize food products 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 1507 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 1507 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 transformed application does not include authorization for the cultivation of 1507 maize. Therefore, any exposure to the environment from 1507 maize will be limited to unintended release of 1507 maize e.g. via spillage during transportation of the grain. In case of any unintended release of 1507 maize, current agronomic measures taken to control other 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.

9.1 Persistence and invasiveness

There is negligible likelihood for 1507 maize to become environmentally persistent or invasive giving rise to any weediness. Maize does not possess any traits for weediness and expression of CRY1F, and PAT proteins in 1507 maize does not give rise to traits for weediness.

In case of any unintended release of 1507 maize, current agronomic measures taken to control other 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

When cultivated, expression of CRY1F and PAT proteins in 1507 maize confers specific advantages in agricultural environments: resistance to certain lepidopteran insect pests, such as the European corn borer and *Sesamia* spp., and tolerance to glufosinate-ammonium herbicide.

However, 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 1507 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 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, do not commonly occur outside the agricultural environment, and

therefore expression of PAT protein in 1507 maize does not confer a selective advantage outside the agricultural environment.

9.3 Potential for gene transfer

The scope of this transformed application does not include authorization for the cultivation of 1507 maize. In any case, 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.

9.4 Interactions between the GM plant and target organisms

The scope of this transformed application does not include authorization for the cultivation of 1507 maize and any unintended release of 1507 maize will be controlled with the agronomic measures used to control other commercially available maize. Therefore there will be no significant interaction between 1507 maize and target organisms.

9.5 Interactions of the GM plant with non-target organisms

The scope of this transformed application does not include authorization for the cultivation of 1507 maize and any unintended release of 1507 maize will be controlled with the agronomic measures used to control other commercially available maize. Therefore there will be no significant interaction between 1507 maize and non-target organisms.

9.6 Effects on human health

As summarised in **Point D.7.**, the results obtained from the safety evaluation contained throughout this application confirm that expression of CRY1F and PAT proteins in 1507 maize does not introduce any new compounds known to cause, or expected to cause, any potential immediate and/or delayed adverse effects on human health.

9.7 Effects on animal health

As summarised in **Point D.7.**, the results obtained from the safety evaluation contained throughout this application confirm that expression of CRY1F and PAT proteins in 1507 maize does not introduce any new compounds known to cause, or expected to cause, any potential immediate and/or delayed adverse effects on animal health.

9.8 Effects on biogeochemical processes

The scope of this application does not include authorization for the cultivation of 1507 maize and any unintended release of 1507 maize will be controlled with the agronomic measures used to control other 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 1507 maize.

10. Potential interactions with the abiotic environment

The scope of this application does not include authorization for the cultivation of 1507 maize and any unintended release of 1507 maize will be controlled with the agronomic measures used to control other commercially available maize. Therefore there will be no significant interactions with the abiotic environment.

11. Environmental monitoring plan

11.1 General (risk assessment, background information)

The scope of this application does not include authorization for the cultivation of 1507 maize. Therefore, any exposure to the environment of 1507 maize will be limited to unintended release of 1507 maize e.g. via spillage during transportation of the grain.

Notification C/NL/00/10 includes a proposal for an environmental monitoring plan for the placing on the market (import) of 1507 maize. This proposal 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. The design of the environmental monitoring plan is based on the conclusions of the environmental risk assessment (e.r.a.) for the placing on the market (import) of 1507 maize.

The e.r.a. for the placing on the market (import) of 1507 maize 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 conclusions obtained from the e.r.a. confirm that there are no identified adverse effects to human and animal health or the environment arising from the placing on the market (import) of genetically modified 1507 maize. Therefore the risk to human and animal health or the environment from placing on the market (import) of 1507 maize is as negligible as for any commercial maize.

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

The e.r.a. concluded that expression of the CRY1F and PAT proteins in 1507 maize and interaction with the environment of imported 1507 maize will not give rise to any identified adverse effects to human and animal health or the environment. Therefore, the risk to human and animal health or the environment arising from the placing on the market (import) of 1507 maize is as negligible as

for any conventional maize. As a result, case-specific monitoring is not applicable to the placing on the market (import) of 1507 maize.

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

The general surveillance will take into consideration and be proportionate to the extent of imports of 1507 maize and use thereof in the Member States.

The provisions concerning traceability and labelling for placing on the market of 1507 maize in accordance with Regulation EC (No) 1830/2003 will identify products containing 1507 maize, and thus enable any unanticipated adverse effects to be effectively traced.

It is expected that the majority of 1507 maize imports will be used for animal feed purposes. The notifiers therefore undertake to inform operators in the animal feed industry of the safety and general characteristics of the 1507 maize together with the requirement to report to the notifiers any adverse effect arising from handling and use of imported 1507 maize.

The notifiers will provide a format to the relevant parties in the animal feed industry to facilitate reporting of any adverse effect arising from the handling and use of imported 1507 maize. The format will include guidance and reporting procedures (eg, point of contact) in the case of any observation of adverse effects of 1507 maize.

11.4 Reporting the results of monitoring

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

The notifiers will submit a report on the monitoring plan including results of the general surveillance in accordance with the conditions of the consent.

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

A PCR detection method to confirm the molecular identity of 1507 maize has been developed and provided to the EC Joint Research Centre (Community Reference Laboratory) in Ispra (Italy) for validation. In addition, samples of 1507 maize and control samples have been made provided to the EC JRC Institute of Reference Materials and Measurements in Geel (Belgium) for the production of certified reference material.

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/IT/98/19

(b) Conclusions of post-release monitoring
The 1507 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 1507 maize.

(c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)
No adverse effects on human health and the environment observed.

(a) Notification number
B/FR/99.03.09

(b) Conclusions of post-release monitoring
The 1507 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 1507 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/02/11

(b) Conclusions of post-release monitoring
The 1507 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 1507 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
Argentina.

(b) Authority overseeing the release
Secretary of Agriculture.

(c) Release site
Pergamino area, 3 sites; Buenos Aires Province.
(d) Aim of the release
Efficacy trials and hybrid registration.
(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 1507 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 1507 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
Brazil
(b) Authority overseeing the release
CTNBio
(c) Release site
One site.
(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 1507 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 1507 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 1507 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 1507 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
South Africa.

(b) Authority overseeing the release
Ministry of Agriculture.

(c) Release site
One site.

(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 1507 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 1507 maize.

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

(a) Release country
U.S.A.

(b) Authority overseeing the release
USDA and EPA.

(c) Release site
Multiple sites.

(d) Aim of the release
Research.

(e) Duration of the release
Five seasons.

(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 1507 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 1507 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]