PART II

SUMMARY

Application
EFSA-GMO-NL-2005-23

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

A. GENERAL INFORMATION

1. Details of application

a) Member State of application Netherlands
b) Application number EFSA-GMO-NL-2005-23
c) Name of the product (commercial and other names) The product described in this application is 59122 maize, including 59122 maize seed products for cultivation, for all food and feed uses, and for all food, feed and processed products derived from 59122 maize. The 59122 maize has been genetically modified to express the Cry34Ab1, Cry35Ab1 and PAT proteins. The maize product described in this application also consists of maize products from progeny, containing the genetic modification, from conventional breeding between 59122 maize and traditionally bred maize. The commercial name assigned to 59122 maize in the US market is HerculexRW[1]. In accordance with Commission Regulation (EC) 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identification code assigned to 59122 maize is DAS-59122-7.
d) Date of acknowledgement of valid application [To be provided]

[1] Herculex Rootworm Insect Protection by Dow AgroSciences and Pioneer Hi-Bred
Herculex is a trademark by Dow AgroSciences LLC

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 Hi-Bred International, Inc. 7100 NW 62nd Avenue Johnston, IA 50131-1014 U.S.A. Represented by: Pioneer Overseas Corporation Avenue des Arts, 44 B-1040 Brussels Belgium Mycogen Seeds c/o DowAgroSciences LLC. 9330 Zionsville Road Indianapolis, IN 46268-1054 U.S.A. Represented by: Dow AgroSciences 2nd Floor, 3 Milton Park Oxon OX14 4 RN United Kingdom
c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant
Same as applicant

3. Scope of the application

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

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

Yes [ ]	**No** [x]
If *yes*, specify	

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

Yes [x]	**No** [ ]
Year / *Member State* / *Notification N°* 2003 France B/FR/03/01/05 2004 Spain B/ES/04/01 2004 France B/FR/03/01/05 2005 Spain B/ES/05/18 2005 Hungary B/HU/05/02/2	

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

Yes [ ]	**No** [x]
If *yes*, specify	

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

Yes [x]	**No** [ ]
If *yes*, specify An application for registration of 59122 maize was submitted to the US Environmental Protection Agency (EPA) in October 2003 and an application for non-regulated status of 59122 maize was submitted to the US Department of Agriculture (USDA) in December 2003. EPA registration for 59122 maize has been obtained on 31 August 2005 and 59122 maize was deregulated by USDA on 5 October 2005. An application for food use of 59122 maize was submitted to the US Food and Drug Administration (FDA) in December 2003 and FDA approval for 59122 maize was received on 4 October 2004. Applications for import have been submitted to Canada, China, Japan, Korea and Switzerland. An application for food use of 59122 maize has been submitted to Taiwan and Australia/New Zealand. Authorisation for food/feed use of 59122 maize was granted by the Mexican Department of Health on 10 January 2005.	

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 in the EU and has a long history of safe use. The 59122 maize has been genetically modified to express the Cry34Ab1, Cry35Ab1 and PAT proteins.

The Cry34Ab1 and Cry35Ab1 proteins act together to control corn rootworm larvae (*Diabrotica* spp.). Expression of the PAT protein, used as a selectable marker, confers tolerance to application of glufosinate-ammonium herbicide.

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

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

c) Intended use of the product and types of users

The intended use of 59122 maize, including 59122 maize seed products, will be consistent with current uses of commercial maize products and 59122 maize will be used in the EU as any other maize. Therefore, there are multiple categories of users of 59122 maize, including agricultural growers, the animal feed 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

Use of 59122 maize will be consistent with current uses of commercial maize products. Labelling of 59122 maize products will be carried out in accordance with Community law. See Point **A.8.f)** below for labelling of 59122 maize.

e) Any proposed packaging requirements

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

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

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

Proposal for the labelling of 59122 maize food products

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

In accordance with Article 13 of Regulation (EC) 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods containing, consisting of, produced from, or containing ingredients produced from 59122 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 59122 maize food products as 59122 maize has been shown to be equivalent to non-GM control maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 59122 maize does not give rise to any ethical or religious concerns.

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

Proposal for the labelling of 59122 maize feed products

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

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

(a) where the feed contains or consists of 59122 maize, or where 59122 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 59122 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 59122 maize feed products as 59122 maize has been shown to be equivalent to non-GM control maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 59122 maize does not give rise to any ethical or religious concerns.

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

In accordance with Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC, the information provided on a label or in an accompanying document for the purpose of satisfying the labelling requirements of products consisting of, or containing, 59122 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.

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 59122 maize is DAS-59122-7.

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 for the placing on the market of 59122 maize, no specific measures need to be taken in case of unintended release or misuse or for disposal and treatment.

In case of unintended release, misuse, disposal or treatment of 59122 maize, current measures taken to control unintended release, misuse, disposal or treatment of non-GM maize can be applied, such as selective use of herbicides (with the exception of glufosinate-ammonium herbicides), and manual or mechanical removal.

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

1. Complete name

a) Family name Poaceae (Gramineae)
b) Genus *Zea*
c) Species *Z. mays* L.
d) Subspecies None
e) Cultivar/breeding line Line Hi-II
f) Common name Maize, corn

2 a. Information concerning reproduction

(i) Mode(s) of reproduction Maize (*Zea mays* L.) is the only species usually included in the genus *Zea*, of the family Gramineae. It is a highly domesticated agricultural crop with well-characterised phenotypic and genetic traits. It reproduces sexually by wind-pollination and being a monoecious species has separate male staminate (tassels) and female pistillate (silk) flowers. This allows natural outcrossing between maize plants but also enables the control of pollination in the production of hybrid seed. Typical for wind-pollinated plants, a large amount of excess maize pollen is produced for each successful fertilisation of an ovule on the ear. Wind movements across the maize field cause pollen from the tassel to fall on the silks of the same or adjoining plants. Measuring about 0.1 mm in diameter, maize pollen is the largest of any pollen normally disseminated by wind from a comparably low level of elevation.
(ii) Specific factors affecting reproduction As a wind-pollinated, monoecious species, reproduction takes place by self pollination and fertilisation and, cross-pollination and fertilisation, with frequencies of each normally determined by proximity and other physical influences on pollen dispersal. Reproductive factors such as tasselling (pollen production), silking, and pollination are the most critical stages of maize development. Repeated cycles of self-pollination leads to homogeneity of the genetic characteristics within a single maize plant (inbred). Controlled cross-pollination of

inbred lines from chosen genetic pools combines desired genetic traits resulting in a hybrid with improved agronomic performance and yield increase. This inbred-hybrid concept and improved yield response is the basis of the modern maize seed industry.

(iii) Generation time

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

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

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

3. Survivability

a) Ability to form structures for survival or dormancy

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

b) Specific factors affecting survivability

Survival of maize seed is dependant upon temperature, moisture of seed, genotype, husk protection and stage of development. Maize seed can only survive under favourable climatic conditions. Freezing temperatures have an adverse effect on germination of maize seed and they have been identified as a major risk in limiting production of maize seed (Shaw, 1988). Furthermore, maize is a C_4 plant and therefore its vegetative growth is sensitive to low temperatures. Chlorosis will occur at temperatures below 15°C. The generative phase of maize is supported by short day conditions. The minimum temperature for germination of 8 to 10°C restrict maize survival and reproduction capabilities mainly to the Southern European geographical zones.

4. Dissemination

a) Ways and extent of dissemination

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

Pollen shedding from the tassels takes place over a period of 10 to 15 days. Pollen grains are round, heavy and contain a large amount of water, characteristics that limit their dispersal and attachment to plant surfaces, such as leaves. Generally, viability of shed pollen is 10 to 30 minutes, although it can remain viable for longer time under favourable conditions. However, dispersal of maize pollen tends to be limited as it is influenced by the large size and rapid settling rate of the pollen. Deposition of maize pollen has been found to rapidly decline from 2.3×10^7 grains per m^2 at a 1 m offset from the field edge to 7.1×10^3 grains per m^2 at 60 m: this represents a decline in pollen concentrations of over four orders of magnitude extending from radial distances of 1 m to 60 m from the field edge.

b) Specific factors affecting dissemination

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

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

Because of its many available cultivars, maize can grow in a wide range of climatic conditions. However, survival and reproduction in maize is limited by cool conditions (Shaw, 1988). Practically no maize can be cultivated where the mean mid-summer temperature is <19°C or where the average night temperature is <13°C. The majority of maize is produced between latitudes 30 and 55 degrees, with a relatively small amount grown at latitudes higher than 47 degrees anywhere in the world. The greatest maize production occurs where the warmest month isotherms range between 21 and 27°C and the freeze-free season lasts 120 to 180 days. Summer rainfall of 15 cm is the lower limit for maize production without irrigation. There is no upper limit of rainfall for growing maize, although excess rainfall will decrease yields. Maize has been cultivated in Europe starting in Spain since the 16th century.

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

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

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

7. Other potential interactions, relevant to the GM plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms

Maize is extensively cultivated in the EU and has a long history of safe use. Maize is known to interact with other organisms in the environment including insects, birds, and mammals. It is susceptible to a range of fungal diseases and insect pests, as well as competition from surrounding weeds.

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

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

The 59122 maize was produced by means of *Agrobacterium*-mediated transformation. Transformation of 59122 maize resulted in the stable insertion of the T-DNA region of binary vector PHP17662 in the maize genome. The T-DNA region contains the *cry*34Ab1, *cry*35Ab1 and *pat* coding sequences in addition to the necessary regulatory components to drive gene expression. The plant regenerated from these maize cells expresses the Cry34Ab1, Cry35Ab1 and PAT proteins and is referred to as 59122 maize.

2. Nature and source of the vector used

For transformation of 59122 maize, binary vector PHP17662 was used.

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

The T-DNA intended for insertion is a 7390 bp sequence containing:

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

D. INFORMATION RELATING TO THE GM PLANT

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

The 59122 maize has been genetically modified (GM) to express the Cry34Ab1, Cry35Ab1 and PAT proteins.

In 59122 maize plants, the Cry34Ab1 and Cry35Ab1 proteins are expressed constitutively and they act together in the control corn rootworm larvae (*Diabrotica* spp.). Therefore, cultivation of 59122 maize provides growers with a specific control against corn rootworm pest damage.

Expression of the PAT protein, used as a selectable marker, confers tolerance to the application of glufosinate-ammonium herbicide.

No other new traits have been introduced into 59122 maize and, in particular, no trait for antibiotic resistance is present in 59122 maize. As discussed in detail throughout the application, these characteristics of 59122 maize have been confirmed by molecular characterisation, protein expression analysis, agronomic performance and comparison of 59122 maize composition data to non-GM control maize.

2. Information on the sequences actually inserted or deleted

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

The results of the molecular characterisation described in this application confirm that 59122 maize contains a single and full-length copy of the T-DNA region from binary vector PHP17662. Southern blot analysis demonstrated that 59122 maize does not contain fragments from the vector backbone portion of binary vector PHP17662.

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 59122 maize insert is integrated into the maize nuclear genome as confirmed by the molecular characterisation of 59122 maize by Southern blot and sequence analyses. Southern blot analysis within a single plant breeding generations indicates that the insert in 59122 maize segregates according to the rules of Mendelian inheritance.

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

The genetic material inserted in 59122 maize can be divided into three separate major sections:

i) the 5’ border sequence, comprising the flanking region of maize genomic DNA;

ii) the full-length, single copy PHP17662 T-DNA insert;

iii) the 3’ border sequence, comprising the flanking region of maize genomic DNA.

In particular, 59122 maize does not contain sequences derived from the PHP17662 vector backbone region outside of the left and right T-DNA borders. The genetic material inserted in 59122 maize and the 5’ and 3’ borders of maize genomic DNA flanking the 59122 maize insert have been sequenced and characterised in detail. In addition, analysis by PCR amplification has confirmed that the 5’ and 3’ regions flanking the 59122 maize insert are of maize genomic origin.

3. Information on the expression of the insert

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

Field trials with 59122 maize plants have been conducted at several geographical locations during more than one growing season. A range of 59122 maize tissues representing key developmental stages of a typical maize plant were collected during these field trials. For these tissues, the expression level of the Cry34Ab1, Cry35Ab1 and PAT proteins has been determined using a specific Enzyme Linked Immunosorbent Assay (ELISA) system developed for each protein. Results of these tests confirm expression of the Cry34Ab1, Cry35Ab1 and PAT proteins throughout key developmental stages of 59122 maize and in all plant parts of the 59122 maize, with the exception of the PAT protein for which the expression level was below the lower limit of quantitation (0.270 ng/mg tissue dry weight) in 59122 maize pollen.

b) Parts of the plant where the insert is expressed

As described Point **D.3. a)**, the expression level of the Cry34Ab1, Cry35Ab1 and PAT proteins in 59122 maize was analysed in leaf, root, pollen, stalk, forage, mature grain and whole plant tissues in field trials conducted at several geographical locations during more than one growing season. It was demonstrated that the Cry34Ab1, Cry35Ab1 and PAT proteins are expressed throughout the different parts of the maize plant, with the exception of the PAT protein for which the expression level was below the lower limit of quantitation in 59122 maize pollen.

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 have been observed in field trials of 59122 maize compared to non-GM control maize.

b) Dissemination

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

c) Survivability

Cultivated maize has been domesticated to the extent that it cannot survive outside managed agricultural environments. Lack of dormancy prevents maize seed to readily survive from one growing season to the next. The genetic modification in 59122 maize results in expression of Cry34Ab1 and Cry35Ab1 proteins conferring resistance to certain coleopteran insect pests and expression of PAT conferring tolerance to the herbicide glufosinate-ammonium. The survival characteristics of 59122 maize in the environment remain comparable to those of non-GM control maize.

d) Other differences

Except for the combined tolerance to corn rootworm damage and to glufosinate-ammonium herbicide, 59122 maize did not show any unexpected changes in reproduction, dissemination and survivability when compared to non-GM control maize in field trials.

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

Genetic stability of the 59122 maize could be demonstrated by studying the pattern of inheritance and segregation of the introduced genetic material in different generations of 59122 maize. These studies confirm that the 59122 maize insert is genetically stable, following a typical pattern of Mendelian inheritance.

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

a) Plant to bacteria gene transfer

Transfer of genetic material originating from 59122 maize to bacteria is a negligible concern. There is no known mechanism for, or definitive demonstration of, DNA transfer from plants to microbes under natural conditions. Even if horizontal gene transfer were to take place, transfer of the *cry*34Ab1, *cry*35Ab1 or *pat* genes from 59122 maize does not represent a risk to human or animal health, nor is it of consequence as a plant pest risk.

b) Plant to plant gene transfer

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

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

7.1 Comparative assessment

Choice of the comparator

The comparator chosen for the safety evaluation of 59122 maize consists of non-GM control maize with comparable genetic background. Wherever possible, composition data derived from a set of commercial maize hybrids as well as publicly available literature references have been used in the comparison with 59122 maize.

7.2 Field trials

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

Field trials were conducted at several geographic locations during more than one growing season. Each location included a randomised block design containing 4 blocks (or replicates). Each block contained 59122 maize sprayed with glufosinate-ammonium herbicide, 59122 maize not sprayed with glufosinate-ammonium herbicide and a non-GM control maize for comparison.

b) the baseline used for consideration of natural variations

As discussed in Point **D.7.1**, publicly available data on commercial non-GM maize, compiled from the literature, as well as data from a set of commercial maize hybrids has been used as the baseline in the comparison with 59122 maize. In addition, a comparative assessment with non-GM control maize of comparable genetic background has been carried out.

7.3 Selection of materials and compounds for analysis

As recommended by the OECD (2002), the compounds selected for analysis of grain from 59122 maize were protein, fiber, carbohydrates, fat, ash, fatty acids, minerals, amino acids, vitamins, secondary metabolites and anti-nutrients. The compounds selected for analysis of forage from 59122 maize were protein, fiber, carbohydrates, fat, ash and minerals (calcium and phosphorous). The results obtained confirm that there are no statistically significant differences between forage and grain from 59122 maize and forage and grain from 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

As discussed in Point **D.7.2**, 59122 maize has been tested at different geographic locations during more than one growing season. The agronomic data obtained, support the conclusion that there are no unexpected agronomic differences between 59122 maize and a non-GM control maize with comparable genetic background.

7.5 Product specification

As discussed in this application, the 59122 maize can be considered to be substantially equivalent to commercial maize with no nutritionally or toxicologically significant changes. Therefore, the specification of 59122 maize, including 59122 maize seed products, and all food, feed and processed products derived from 59122 maize is the same as that of commercial maize and all food, feed and processed products derived from commercial maize.

7.6 Effect of processing

The production processes applied to maize are well known and have a long history of safe use. The 59122 maize will undergo existing production processes used for commercial maize. No novel production process is envisaged. In the EU, most of the maize is used for animal feed, and only about 8% is processed into human food products such as highly refined starch by the wet-milling process and maize flour by the dry-milling process. The majority of the starch is used for sweeteners and fermentation including high fructose maize syrup and ethanol. In addition to milling, the maize germ can be processed to obtain maize oil. These processed products of maize are used in a variety of food products. The genetic modification in 59122 maize will not impact the existing production processes used for maize.

As discussed in Point **D.7.8.1**, the Cry34Ab1, Cry35Ab1 and PAT proteins expressed in 59122 maize are highly susceptible to proteolytic digestion and are rapidly degraded when heated. Therefore, the technologies applied in the production and processing of processed foods and feeds derived from maize will lead to the denaturation and degradation of the Cry34Ab1, Cry35Ab1 and PAT proteins expressed in 59122 maize.

7.7 Anticipated intake/extent of use

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

The comparative and nutritional assessments of 59122 maize together with the absence of any adverse effects to human and animal health from Cry34Ab1, Cry35Ab1 and PAT proteins confirm that there are no concerns related to the anticipated intake/extent of use of 59122 maize.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

The safety of the Cry34Ab1, Cry35Ab1 and PAT proteins expressed in 59122 maize grain has been thoroughly characterised and evaluated. Based on a very broad body of evidence, which has been summarised below, the Cry34Ab1, Cry35Ab1 and PAT proteins can be regarded as safe for human food and animal feed use. The evidence includes previous use of the protein; mode of action; specificity of the biological activity; absence of toxicity to mammals; absence of adverse effects on fast growing species; a biochemical characterisation of the proteins; absence of significant amino acid sequence similarity to known protein toxins; lack of resistance to proteolysis; and, lack of stability when heated.

The Cry34Ab1 and Cry35Ab1 proteins have specific toxicity against certain coleopteran insect pests (*Diabrotica* spp., target organisms). There is no evidence for Cry34Ab1 and Cry35Ab1 proteins originating from *Bacillus thuringiensis* to have harmful effects on the health of humans or animals. The potential toxicity to humans and animals of the 59122 maize expressed Cry34Ab1 and Cry35Ab1 proteins was examined in acute oral toxicology studies. In these studies Cry34Ab1 and Cry35Ab1 proteins were evaluated either separately or as a Cry34Ab1/Cry35Ab1 protein mixture for acute toxicity potential in mice. No mortality, toxicity or adverse clinical signs were observed.

A thirteen-week (90-day) oral toxicity feeding study in rats has been carried out with 59122 maize grain in order to confirm the absence of toxicity of the Cry34Ab1, Cry35Ab1 and PAT proteins expressed in 59122 maize grain. Exposure of male and female rats to diets containing grain from 59122 maize produced no toxicologically significant differences, compared to rats fed diets containing grain from non-GM control maize with comparable genetic background or grain from commercial non-GM maize.

A poultry feeding study over a period of 42 days has also been carried out with grain from 59122 maize and grain from non-GM control maize with comparable genetics. No biologically significant, diet-related differences were observed on mortality, body weight gain, feed efficiency, organ yield, carcass yield, breast, thigh, wing and leg yield and abdominal fat between chickens fed a diet containing grain from 59122 maize or grain from a non-GM control maize. These results provide further evidence to confirm the absence of toxicity of the Cry34Ab1, Cry35Ab1 and PAT proteins expressed in 59122 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 59122 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 control maize.

7.8.4 Testing of the whole GM food/feed

As described throughout this application, the nutritional assessment of 59122 maize has confirmed that whole food and feed consisting of or derived from 59122 maize is equivalent to whole food and feed consisting of or derived from commercial maize.

A poultry feeding study over a period of 42 days has been carried out confirming that there are no biologically significant, diet-related differences on mortality, body weight gain, feed efficiency, carcass yield and organ yield between chickens fed a diet containing grain from 59122 maize or a diet containing grain from non-GM control maize.

Furthermore, a thirteen-week (90-day) oral toxicity feeding study in rats has been carried out with 59122 maize grain in order to confirm the absence of toxicity of the Cry34Ab1, Cry35Ab1 and PAT proteins expressed in 59122 maize. The study involved a total of 10 groups of 12 young rats each. The rats were fed for 90 days with either a diet containing on average 35% grain from 59122 maize, a diet containing on average 35% non-GM control maize with comparable genetic background, a diet containing on average 35% from a commercial non-GM maize or a standard PMI® Nutrition International, LLC Certified Rodent LabDiet. 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 confirm that exposure of male and female rats to diets containing grain from 59122 maize produced no toxicologically significant differences, compared to rats fed diets containing grain from non-GM control 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

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

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Maize has a long history of safe use as food in the EU and constitutes a traditional counterpart to 59122 maize that can be used as a baseline to facilitate the assessment of potential toxicity and allergenicity of 59122 maize. Maize is not considered to be an allergenic food crop and 59122 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

As discussed in Point **D.7.3**, composition analysis of 59122 maize grain has shown that the content of protein, fiber, carbohydrates, fat, ash, minerals, fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients is equivalent to that found in grain from non-GM control maize with comparable genetic background. As a consequence, 59122 maize can be considered nutritionally equivalent to non-GM control maize.

As discussed in Point **D.7.8.4**, nutritional equivalence between 59122 maize and non-GM control maize with comparable genetics has also been shown in a poultry feeding study where chickens were fed over a 42-day period with diets containing either grain from 59122 maize, grain from non-GM control maize with comparable genetics, or grain from commercial non-GM maize. No biologically significant, diet-related differences were observed on mortality, body weight gain, feed efficiency, carcass yield and organ yield between chickens fed a diet containing grain from 59122 maize or a diet containing grain from non-GM control maize.

In conclusion, the comparable composition and nutritional value of 59122 maize together with the results of the assessment of dietary intake and nutritional impact confirm that food and feed products from 59122 maize are substantially equivalent to, nutritionally equivalent to, and as safe as food and feed products derived from commercial maize.

7.10.2 Nutritional assessment of GM feed

Please, see Point **D. 7.10.1**

7.11 Post-market monitoring of GM food/feed

Based on the safety assessment discussed throughout Point **D.7.**, no risks to human and animal health or the environment have been identified from the food or feed use of 59122 maize as compared to food or feed use of commercial maize. In addition, the nutritional characteristics and use of food, feed and processed products derived from 59122 maize are no different from those of food, feed and processed products derived from commercial maize.

Therefore, post-market monitoring of GM food and GM feed products containing, consisting of or derived from 59122 maize is not necessary.

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

Laboratory bioassays have been conducted in order to better understand the activity of the Cry34Ab1 and Cry35Ab1 proteins. The Cry34Ab1 and Cry35Ab1 proteins were tested alone and in mixtures for activity against corn rootworm larvae. This study demonstrated that:

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

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

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

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

9.1 Persistence and invasiveness

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

Weediness traits have been generally described by Baker (1974) as 1) the ability for weed seed to germinate in many different environments; 2) discontinuous germination and great longevity of seed; 3) rapid growth through vegetative phase to flowering; 4) continuous seed production for as long as growing conditions permit; 5) self-compatibility but partially autogamous and apomictic; 6) ability to be cross-pollinated by unspecialised visitors or wind pollinated; 7) high seed output in favourable environments and some seed production in a wide range of environments; 8) adaptation for short and long distance dispersal; 9) vegetative production or regeneration from fragments and brittleness (hard to remove from the ground); and, 10) ability to compete interspecifically by special means.

Maize does not exhibit the above weedy tendencies and is therefore non-invasive in natural ecosystems. Some *Zea* species are successful wild plants in Central America but they have no pronounced weedy tendencies. Maize has been domesticated to the extent that the seeds cannot be separated from the cob and disseminated without human intervention. Maize plants are annuals that generally will not survive in Europe from one growing season to the next because of poor dormancy and sensitivity to low temperature. Despite its non-dormant nature, maize seed can occasionally persist from one growing season to the next under favourable climatic conditions. When the temperature and moisture are adequate, the seed will germinate. These volunteers are easily identified and controlled through current agronomic measures taken to control other commercially available maize, such as selective use of herbicides (with the exception of glufosinate-ammonium herbicides), and manual or mechanical removal.

9.2 Selective advantage or disadvantage

As intended and when cultivated, expression of the Cry34Ab1 and Cry35Ab1 proteins in 59122 maize confers specific advantages in agricultural environments: resistance to corn rootworm larvae (Coleoptera: Chrysomelidae; *Diabrotica* spp.). In addition, expression of the PAT protein, used as a selectable marker, confers tolerance to glufosinate-ammonium herbicides.

However, maize is highly domesticated, to the extent that it cannot become established as a feral species outside the agricultural environment due to its poor survival characteristics within European conditions. The specific advantages present in 59122 maize do not confer any selective advantage to the plants in the natural environment, *i.e.* outside the agricultural environment. Insect attack is only one of the multiple biotic and abiotic factors that prevent growth of maize outside the agricultural environment. Therefore, expression of the Cry34Ab1 and Cry35Ab1 proteins conferring resistance to corn rootworm larvae (*Diabrotica* spp.) cannot be considered a selective advantage.

Furthermore, application of broad spectrum herbicides, such as glufosinate-ammonium, does not commonly occur outside the agricultural environment. In conclusion, expression of the PAT protein in 59122 maize does not confer a selective advantage outside the agricultural environment.

9.3 Potential for gene transfer

There are no sexually compatible wild or weedy relatives of *Zea mays* known to exist in the EU, which eliminates the possibility of potential gene transfer to such species. In addition and as discussed in Points **D.9.1** and **D.9.2**, there is negligible likelihood for 59122 maize plants to become environmentally persistent or invasive giving rise to any weediness. Furthermore, expression of the Cry34Ab1, Cry35Ab1 and PAT proteins does not present any selective advantage outside the agricultural environment.

9.4 Interactions between the GM plant and target organisms

As discussed in Point D.8, expression of the Cry34Ab1 and Cry35Ab1 proteins in cultivated 59122 maize provides growers with a highly effective and environmentally beneficial tool to control corn rootworm pest damage (Coleoptera: Chrysomelidae; *Diabrotica* spp.). The Cry34Ab1 and Cry35Ab1 proteins have been shown to act together to control corn rootworm larvae in a highly specific manner that is similar to the well-characterised interactions between *Bacillus thuringiensis* Cry proteins and target organisms.

9.5 Interactions of the GM plant with non-target organisms

As discussed in Points **D.1**, **D.7.8** and **D.7.9**, the specificity of the biological activity and the absence of toxicity to non-target organisms of the Cry34Ab1, Cry35Ab1 and PAT proteins confirms that there will be no adverse effects on non-target organisms arising from 59122 maize.

In addition, microbially-derived Cry34Ab1 and Cry35Ab1 proteins show a very limited persistence in the soil environment, which, together with the natural ubiquity of the *cry*34Ab1, *cry*35Ab1 and *pat* genes in the soil environment and the absence of adverse effects on soil biota, means negligible possibility for effects on populations of soil dwelling organisms.

In conclusion, negligible effects are expected on the dynamics of populations of non-target organisms in the receiving environment and the genetic diversity of each of these populations.

9.6 Effects on human health

Maize is not considered to have any harmful effects on human health. Maize has a long history of safe use in human food and animal feed. As discussed in Points **D.7.8** and **D.7.9**, a very detailed evaluation of the potential toxicity and allergenicity to humans of the Cry34Ab1 and Cry35Ab1 proteins as expressed in 59122 maize, has been carried out. As a result and in conclusion, 59122 maize does not express any known toxic or allergenic proteins. Therefore, consumption of 59122 maize or derived food products will result in no adverse consequences to human health.

9.7 Effects on animal health

The genetic modification in 59122 maize does not introduce any new compounds known to cause, or expected to cause, any possible immediate and/or delayed effects on animal health. Use of 59122 maize and any animal feed products derived from it will result in no adverse consequences for the feed/food chain.

This conclusion is based on a detailed safety evaluation concerning 59122 maize. As discussed in Points **D.7.8.1**, **D.7.8.4**, and **D.7.10.2**, safety evaluation of 59122 maize included compositional analyses comprising protein, fiber, carbohydrates, ash, minerals, fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients; nutritional equivalence evaluation in a poultry feeding study; toxicological assessment in a thirteen-week (90-day) oral toxicity feeding study in rats and biochemical characterisation of the 59122 maize expressed Cry34Ab1, Cry35Ab1 and PAT proteins. In summary, feed products from 59122 maize are substantially and nutritionally equivalent to feed products derived from commercially available maize.

9.8 Effects on biogeochemical processes

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

9.9 Impacts of the specific cultivation, management and harvesting techniques

Cultivation of 59122 maize expressing the Cry34Ab1 and Cry35Ab1 proteins provides growers with a highly effective and environmentally beneficial tool to control corn rootworm larvae (Coleoptera: Chrysomelidae; *Diabrotica* spp.). Expression of the PAT protein, used as a selectable marker, confers tolerance to glufosinate-ammonium herbicides.

The specific cultivation, management and harvesting techniques used for 59122 maize are comparable to those used for other commercially available maize, with the exception of the environmental monitoring plan proposed specifically for the cultivation of 59122 maize seed products.

In conclusion, the occurrence of any possible immediate and/or delayed, direct and indirect environmental impacts arising from cultivation, management or harvesting techniques is not expected

10. Potential interactions with the abiotic environment

Expression of the Cry34Ab1, Cry35Ab1 and PAT proteins in 59122 maize does not alter the natural interactions of maize plants with the abiotic environment. The natural ubiquity of the Cry34Ab1, Cry35Ab1 and PAT proteins in the soil environment and the absence of adverse effects on soil biota (Point **D.9.5**) means negligible possibility for adverse interactions with the abiotic environment and no adverse effects on the biogeochemical cycles.

11. Environmental monitoring plan

11.1 General (risk assessment, background information)

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

11.2 Interplay between environmental risk assessment and monitoring

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

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

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

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

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

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

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

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

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

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

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

11.5 Reporting the results of monitoring

The applicants will inform the European Commission of any adverse effects arising from 59122 maize reported to them. Furthermore, the applicants will investigate such reports and inform the outcome to the European Commission.

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

A PCR-based quantitative event-specific detection method for 59122 maize has been developed and was validated by the Community Reference Laboratory (CRL) of the European Commission.

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/03.01.05
b) Conclusions of post-release monitoring Up to the destruction of the field trials, the 59122 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
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/04/01
b) Conclusions of post-release monitoring During the release of the 59122 maize, the plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
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 USA
b) Authority overseeing the release USDA
c) Release site multiple sites
d) Aim of the release Research and/or regulatory

e) Duration of the release multiple seasons: 2001, 2002, 2003 and 2004
f) Aim of post-releases monitoring Control of potential volunteers
g) Duration of post-releases monitoring One season
h) Conclusions of post-release monitoring The 59122 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
i) Results of the release in respect to any risk to human health and the environment No adverse effects on human health and the environment observed

a) Release country Chile
b) Authority overseeing the release Ministry of Agriculture
c) Release site Multiple sites
d) Aim of the release Research and/or regulatory
e) Duration of the release Two seasons: 2002 and 2003
f) Aim of post-releases monitoring Control of potential volunteers
g) Duration of post-releases monitoring One season
h) Conclusions of post-release monitoring The 59122 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
i) Results of the release in respect to any risk to human health and the environment

No adverse effects on human health and the environment observed

a) Release country Argentina
b) Authority overseeing the release Secretary of Agriculture
c) Release site Three sites
d) Aim of the release Research
e) Duration of the release One season (2003)
f) Aim of post-releases monitoring Control of potential volunteers
g) Duration of post-releases monitoring One season
h) Conclusions of post-release monitoring The 59122 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
i) Results of the release in respect to any risk to human health and the environment No adverse effects on human health and the environment observed

a) Release country Bulgaria
b) Authority overseeing the release Ministry of Agriculture and Forestry
c) Release site Three sites
d) Aim of the release Regulatory trials

e) Duration of the release Two seasons: 2003 and 2004
f) Aim of post-releases monitoring Control of potential volunteers
g) Duration of post-releases monitoring One season
h) Conclusions of post-release monitoring The 59122 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
i) Results of the release in respect to any risk to human health and the environment No adverse effects on human health and the environment observed

a) Release country Hungary
b) Authority overseeing the release Ministry of Agriculture and Regional Development
c) Release site One site
d) Aim of the release Regulatory trials
e) Duration of the release One season: 2004
f) Aim of post-releases monitoring Control of potential volunteers
g) Duration of post-releases monitoring One season
h) Conclusions of post-release monitoring The 59122 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
i) Results of the release in respect to any risk to human health and the environment

No adverse effects on human health and the environment observed

a) Release country Canada
b) Authority overseeing the release Canadian Food Inspection Agency
c) Release site Multiple sites
d) Aim of the release Research and/or regulatory
e) Duration of the release Two seasons: 2003 and 2004
f) Aim of post-releases monitoring Control of potential volunteers
g) Duration of post-releases monitoring One season
h) Conclusions of post-release monitoring The 59122 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
i) Results of the release in respect to any risk to human health and the environment No adverse effects on human health and the environment observed

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

a) Status/process of approval [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]