PART II

SUMMARY

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

A. GENERAL INFORMATION

1. Details of application

a) Member State of application Netherlands
b) Application number [To be provided]
c) Name of the product (commercial and other names) The product described in this application is 59122 maize 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 Herculex™ RW. 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]

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.
7250 NW 62nd Avenue
Johnston, IA 50131-0552
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)
[ ]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	

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. 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 and environmental release have been submitted to Canada, China, Japan and Korea. An application for food use of 59122 maize has been submitted to Mexico, Taiwan and Australia/New Zealand.	

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

The Cry34Ab1 and Cry35Ab1 proteins act together in the control of 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 types of products planned to be placed on the market according to the authorisation applied for include 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize in accordance with Regulation (EC) 1829/2003. In addition, this application requests authorisation for import and processing of 59122 maize in accordance with Part C of Directive 2001/18/EC. However, this application does not include authorisation for the cultivation of 59122 maize seed products in the EU.

c) Intended use of the product and types of users

The 59122 maize products placed on the market will be used in a manner consistent with current uses of commercial maize grain and maize products. The 59122 maize will undergo existing methods of production and manufacturing used for commercial maize. No novel method of production and manufacturing is envisaged. The majority of commercial maize is used for animal feeds, and only about 8% of the grain is processed for human food products mainly by wet-milling or dry-milling. Maize grain is also processed into industrial products (11%), such as ethyl alcohol by fermentation and highly refined starch by wet-milling to produce starch and sweetener products. In addition to milling, the maize germ can be processed to obtain maize oil. There are multiple categories of users of 59122 maize, e.g. animal feed and milling industry, agriculture, skilled trades and consumer use by public at large.

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

Safety evaluation of 59122 maize has shown that no specific instructions and/or recommendations for use, storage and handling of 59122 maize are necessary. Therefore, 59122 maize can be used, stored and handled in the same way as is currently done for commercial maize. 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 apply to foods containing material which contains, consists of or is produced from 59122 maize in a proportion at or higher than 0,9 per cent 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 apply to feed containing material which contains, consists of or is produced from 59122 maize in a proportion at or higher than 0.9% of the feed and of each feed of which it is composed.

In accordance with Article 25 of Regulation (EC) 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) of Regulation (EC) 1829/2003, *i.e.* 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

As specified in 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 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.

These specifications will be included in the label or in the accompanying document with regard to 59122 maize products: further details are described below.

Proposal for the labelling of 59122 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 59122 maize:

- ***Accompanying document***. See below.
- ***Detection method.*** To identify 59122 maize in imported products and assist with the labelling provisions for placing 59122 maize products on the EU market, a quantitative event-specific PCR detection method for 59122 maize has been developed and is submitted to the EC Joint Research Centre (Community Reference Laboratory) in Ispra (Italy).

Proposal for the accompanying document

The following information is proposed to be included on the accompanying document for 59122 maize products.

1. Name of the product:

Commercial name of the product. Grain and other products derived from 59122 maize will be imported into the EU as part of general maize commodity imports. The commercial name assigned to 59122 maize is Herculex™ RW. 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.

2. Name of the manufacturer or distributor:

Pioneer Hi-Bred and Mycogen Seeds are developers of the technology and producers of 59122 maize seed.

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

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

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

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

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

Mycogen Seeds, as represented by Dow AgroSciences Europe:

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

4. Conditions of use of the product:

This product contains genetically modified organisms.

The product consists of or contains 59122 maize. The grain and other products derived from 59122 maize can be imported, stored and processed for use in food, animal feed and industrial products in the same way as commercial maize.

The 59122 maize has been approved for placing on the market (import) in the EU under specific *conditions of use:*

i) Labelling of 59122 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 59122 maize products.

Public register: [Yet to be determined]

No other restrictions or conditions of use apply to the placing on the market (import) of 59122 maize and therefore products from 59122 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 59122 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 59122 maize is not restricted to any specific geographical areas within the Community.

Approval for placing on the market of 59122 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 59122 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 59122 maize are necessary for the placing on the market (import) of 59122 maize, and therefore grain and grain products of 59122 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 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 of 59122 maize (**Part I** of this application), no specific measures need to be taken in case of unintended release or misuse or for disposal and treatment.

In the unlikely event of unintended release of 59122 maize, current agronomic measures taken to control other commercially available maize can be applied, such as use of mechanical means and selective use of herbicides (with the exception of glufosinate-ammonium herbicide).

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 m^{-2} at a 1 m offset from the field edge to 7.1×10^3 grains m^{-2} at 60 m: this represents a decline in pollen concentrations of over four orders magnitude extending from radial distances of 1 m to 60 m from the field edge.

This application is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize seed.

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.

This application is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize seed.

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.

It should be noted that this application is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize seed.

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* protease inhibitor II;
iii) a 1152 bp maize-optimised *cry*35Ab1 gene from *Bacillus thuringiensis* strain PS149B1 with transcription directed by the promoter from *Triticum aestivum* peroxidase (1298 bp) and with a 315 bp termination sequence derived from *Solanum tuberosum* protease inhibitor II;
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 of certain coleopteran insect pests, such as corn rootworm larvae (*Diabrotica* spp.). Therefore, cultivation of 59122 maize provides a specific control against corn rootworm pest damage.

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

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 characterization, 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 support the conclusion 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

The expression level of the Cry34Ab1 and Cry35Ab1 proteins has been determined in a range of 59122 maize tissues representing key developmental stages of a typical maize plant. Expression was characterised using a specific Enzyme Linked Immunosorbent Assay (ELISA) system developed for each protein. Results of these tests confirm expression of the Cry34Ab1 and Cry35Ab1 proteins throughout key developmental stages of 59122 maize and in all plant parts of the 59122 maize, including the 59122 maize grain. Expression of the PAT protein in 59122 maize was not detected in all 59122 maize tissues tested. Expression of the PAT protein in 59122 maize grain ranged from below the lower limit of quantitation to very low levels of expression.

b) Parts of the plant where the insert is expressed

Please, see Point **D.3. a)**

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

The genetic modification in 59122 maize does not change the inability of maize to transfer genetic material to bacteria. In particular, there are no sequences present on the T-DNA region from plasmid PHP17662 that could potentially be involved in transfer of genetic material between maize and bacteria.

b) Plant to plant gene transfer

As discussed in Point **B.2.b)**, there are no other cultivated or wild plant species sexually compatible with maize in the EU. Maize plants will intra-pollinate and transfer genetic material between maize except for certain popcorn varieties. The extent of pollination between maize will depend upon wind patterns, humidity and temperature. Potential for gene transfer is therefore limited to other maize grown in culture. In addition, the genetic modification in 59122 maize does not introduce any selective advantages to maize plants outside the agricultural environment.

It should be noted that this application is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize seed.

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 a non-GM control maize with comparable genetic background. Wherever possible, data on other commercial non-GM maize and data from a set of commercial Pioneer® Brand maize hybrids have also been used in the comparisons with 59122 maize.

7.2 Field trials

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

Field trials were conducted at 6 separate locations in Chile during the 2002-2003 growing season. Each location included a randomised block design containing 4 blocks (or replicates). Each block contained the 59122 maize and a non-GM control maize for comparison. In addition, field trials were conducted at 3 locations in the USA and 2 locations in Canada during the 2003 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 Pioneer® Brand 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 (1999), 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 results obtained confirm that there are no statistically significant differences between 59122 maize grain and non-GM control maize grain with comparable genetic background.

7.4 Agronomic traits

As discussed in Point **D.7.2**, 59122 maize has been tested at different locations and during different growing seasons across key maize growing regions of Chile, the USA and Canada. 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.

It should be noted that this application is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize seed.

7.5 Product specification

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

7.6 Effect of processing

The production processes applied to maize are well known and have a long history of safe use. The 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 food products are expected to replace a portion of maize products in existing food products with total consumption of maize products remaining unchanged. In particular, human consumption of maize products in the developed world is in the form of high fructose maize syrup, starch, and oil, *i.e.* products that contain only negligible amounts of protein. Furthermore, during food and feed processing the Cry34Ab1, Cry35Ab1 and PAT proteins will be degraded. Moreover, we should consider that maize products in Europe represent blended products, and actual occurrence of the Cry34Ab1, Cry35Ab1 and the PAT proteins originating from 59122 maize will be a minor fraction of total dietary maize and maize products.

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 human food and animal feed 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 and 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 evaluation of the nutrient composition of 59122 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 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 common allergens, (iii) *in vitro* simulated digestibility studies, (iv) evaluation of protein glycosylation and (vi) 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 and feed 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 grain (Chile, Canada and USA) from 59122 maize has shown that the content of protein, fiber, carbohydrates, fat, ash, minerals,

fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients is equivalent to that found in grain from non-GM control maize with comparable genetic background. 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 and 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)

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

It is generally recognised that domestication of crop plants over thousands of generations has resulted in modern crop cultivars that have lost common distinctive attributes of weeds. As a consequence, modern maize cultivars do not exhibit weedy characteristics and are therefore non-invasive in natural ecosystems.

The 59122 maize has been field tested in different locations worldwide, such as Chile, USA and Canada and analysis of field data collected from these trials established that the introduced traits in 59122 maize do not result in differences regarding maize reproductive morphology and persistence or invasiveness compared to commercial maize.

Furthermore, within the context of this application which is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize and not for cultivation of 59122 maize seed, release of 59122 maize would be strictly confined to grain spillage during import, storage and processing of the 59122 maize.

Taking into account all the above, it is concluded that there is negligible likelihood for 59122 maize to become environmentally persistent or invasive giving rise to any weediness.

9.2 Selective advantage or disadvantage

As discussed in Point **D.9.1**, maize is highly domesticated to the extent that it cannot become established as a feral species outside the agricultural environment. The specific advantages introduced by the genetic modification in 59122 maize do not confer any selective advantage to the plants in the natural environment, *i.e.* outside the agricultural environment.

Furthermore, within the context of this application which is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize, release of 59122 maize would be strictly confined to grain spillage during import, storage and processing of the 59122 maize.

Therefore, it is concluded that there is negligible likelihood for increased survival of 59122 maize in the agricultural or natural environment within the context of this application.

9.3 Potential for gene transfer

There are no sexually compatible wild or weedy relatives of *Zea mays* known to exist in the EU, which eliminates any potential for gene transfer to such species. Potential for gene transfer is therefore limited to other maize grown in culture. As discussed in Point **D.9.1** and Point **D.9.2**, there is negligible likelihood for 59122 maize to become environmentally persistent or invasive giving rise to any weediness, nor does the introduced traits in 59122 maize result in any selective advantage to maize plants outside the agricultural environment.

The genetic modification in 59122 maize does not change the inability of maize to transfer genetic material to bacteria. In particular, there are no sequences present on the T-DNA region from binary vector PHP17662 that could potentially be involved in transfer of genetic material between maize and bacteria (Table 2).

In conclusion, within the context of this application which is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize, the potential for gene transfer is considered negligible.

9.4 Interactions between the GM plant and target organisms

The genetic modification in 59122 maize provides growers with a highly specific, effective and environmentally beneficial tool to control certain coleopteran insect pests (corn rootworm, *Diabrotica* spp.).

However, within the context of this application which is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize, the likelihood that 59122 maize plants will emerge giving rise to a suffcient maize population applying a selective pressure on *Diabrotica* populations is considered negligible.

9.5 Interactions of the GM plant with non-target organisms

There is no potential toxicity in the interaction of 59122 maize with non-target organisms resulting from the genetic modification. This has been confirmed by the specificity of the biological activities of Cry34Ab1 and Cry35Ab1 proteins and by thoroughly assessing the absence of toxicity of Cry34Ab1 and Cry35Ab1 proteins to non-target and beneficial organisms through multiple studies.

Within the context of this application which is for authorisation of 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize, there is negligible likelihood that the import of 59122 maize will lead to an adverse effect on non-target organisms.

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 grain. As discussed in Points **D.7.8.1**, **D.7.8.4**, and **D.7.10.2**, safety evaluation of 59122 maize grain 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

The genetic modification 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 target and non-target organisms in the vicinity of 59122 maize. Furthermore, this application is for authorisation for 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize, and not for cultivation of 59122 maize. Therefore, release to the environment of 59122 maize would be strictly confined to grain spillage during import, storage and processing.

9.9 Impacts of the specific cultivation, management and harvesting techniques

The scope of this application does not include authorisation for the cultivation of 59122 maize. Therefore, any exposure to the environment from the import of 59122 maize will be limited to unintended release of 59122 maize e.g. via spillage during import, transportation and storage of the grain. As a consequence, it is concluded that there will be no impact on management and harvesting techniques

10. Potential interactions with the abiotic environment

The scope of this application does not include authorisation for the cultivation of 59122 maize seed products. As a consequence, any exposure to the environment from the import of 59122 maize will be limited to unintended release of 59122 maize e.g. via spillage during transportation of the grain. Therefore, the likelihood of adverse interactions with the abiotic

environment are negligible.

11. Environmental monitoring plan

11.1 General (risk assessment, background information)

The scope of this application does not include authorisation for the cultivation of 59122 maize seed products. Therefore, any exposure to the environment from the import of 59122 maize will be limited to unintended release of 59122 maize e.g. via spillage during transportation or storage of the grain.

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.) carried out for this application for authorisation of genetically modified 59122 maize and derived food and feed (Points **D.9** and **D.10**).

The e.r.a. for this application for authorisation of food and feed from 59122 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 product described in this application, which is 59122 maize for all food and feed uses, and for all food, feed and processed products derived 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 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. As a result, case-specific monitoring is not applicable for the use of 59122 maize for all food and feed purposes and the import and processing of 59122 maize.

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

As discussed in Point **A.4**, the scope of this application is for the authorisation of 59122 maize

for all food and feed uses in accordance with Articles 3(1) and 15(1) of Regulation (EC) 1829/2003 and for import and processing of 59122 maize in accordance with Part C of Directive 2001/18/EC. The food and feed uses of 59122 maize could arise from imports to the EU, processing and/or cultivation. However, in this application we are not seeking approval for cultivation of 59122 maize seed products.

As discussed in detail in the e.r.a. and in Points **11.1** and **11.2**, exposure to the environment will be limited to any unintended release of 59122 maize, which could occur via accidental spillage during loading/unloading of the vessels, trains and trucks carrying the load of commodity grain including 59122 maize destined for processing into animal feed or human food products. However, such limited exposure is highly unlikely to give rise to any adverse effect and, if necessary, can be easily controlled by the application of current practices used for the control of volunteer maize plants, such as the application of non-selective herbicides with the exception of glufosinate-ammonium and glyphosate herbicides.

Therefore, application of established routine surveillance practices (e.g. the monitoring of agricultural cultivars or plant protection products) is not necessary for the general surveillance of the occurrence of unanticipated adverse effects to commercial agricultural practice due to the use of 59122 maize for all food and feed purposes and the import and processing of 59122 maize.

However, since the majority of imported maize is used for animal feed purposes, general surveillance might assist in confirming the safety of animal feed use of 59122 maize and any derived feed products with a view to safeguarding against any unanticipated effects.

11.5 Reporting the results of monitoring

As confirmed in Points **11.1** to **11.4**, case-specific monitoring is not applicable for the use of 59122 maize for all food and feed purposes and the import and processing of 59122 maize. As a result, no case-specific monitoring is proposed for this application for authorisation of 59122 maize and derived food and feed.

The applicants will inform the European Commission, without delay, of any adverse effects arising from the handling and use of imported 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 DNA has been developed and is submitted to the EC Joint Research Centre (Community Reference Laboratory) in Ispra (Italy) for validation.

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]