PART II

SUMMARY OF THE APPLICATION FOR RENEWAL OF AUTHORISATION OF EXISTING PRODUCTS ACCORDING TO ARTICLE 23 OF REGULATION (EC) No 1829/2003

FEED PRODUCED FROM GENETICALLY MODIFIED 1507 MAIZE (DAS-Ø15Ø7-1)

A. GENERAL INFORMATION

1. Details of application

(a) Member State of application:

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(b) Application number:

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

Feed produced from genetically modified 1507 maize. The commercial name assigned to 1507 maize seed in the US market is Herculex I *Insect Protection*.

(d) Date of acknowledgment of valid application:

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2. Applicant

(a) Name of applicant

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

(b) Address of applicant

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(c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii))

Same as applicant.

3. Scope of the application

This application is for renewal of authorisation of feed produced from genetically modified 1507 maize (feed materials and feed additives) according to Article 23 of Regulation (EC) No 1829/2003.

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

With regard to all other categories, see the three positive safety opinions adopted and published by the EFSA GMO Panel: *The EFSA Journal* (2004) 124, pp. 1-18; *The EFSA Journal* (2005) 181, pp. 1-33; and, *The EFSA Journal* (2005) 182, pp. 1-22.

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

Feed produced from 1507 maize is not being simultaneously notified within the framework of another regulation.

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

Yes, please refer to **Point E.1.** below.

If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC

Not applicable.

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

Yes, notification C/NL/00/10 for the placing on the market of 1507 maize for import, feed and processing was submitted in November 2000 under Part C of Directive 90/220/EEC and complemented in accordance with Directive 2001/18/EC. It received a positive opinion from EFSA on 24 September 2004 and was granted consent to placing on the market by the Competent Authority of The Netherlands on 16 March 2006 in accordance with Commission Decision 2005/772/EC of 3 November 2005.

A separate notification (Ref. C/ES/01/01) for the placing on the market of 1507 maize, including cultivation of 1507 maize seed products, was submitted in July 2001 under Part C of Directive 2001/18/EC. The authorisation is currently pending following a positive opinion from EFSA on 19 January 2005.

An application for authorisation of the use of 1507 maize for food purposes was submitted in February 2001 in accordance with Regulation (EC) No 258/97 and transformed (Application No EFSA-GMO-NL-2004-02) in accordance with Regulation (EC) No 1829/2003. It received an overall positive opinion from EFSA on 3 March 2005 and was authorised by Commission Decision 2006/197/EC of 3 March 2006.

Food and feed produced from 1507 maize were notified to the European Commission on 19 August 2004 as existing products under Articles 8 and 20 of Regulation (EC) No 1829/2003 and Articles 9 to 17 of Regulation (EC) No 641/2004.

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

Yes, 1507 maize has been authorised for food and feed use in the following countries: Argentina (2005); Australia (2003); Canada (2002); China (2004); Colombia (2006); Japan (2002); Mexico (2003); New Zealand (2003); Philippines (2003); South Africa (2002); South Korea (2002); Taiwan (2003) and the USA (2001).

In addition, cultivation of 1507 maize seed products has been authorised in Argentina (2005); Canada (2002); Colombia (2007); Japan (2002) and the USA (2001).

8. General description of the product

(a) Name of the recipient or parental plant and the intended function of the genetic modification

The recipient plant is maize (*Zea mays* L.), which is extensively cultivated and has a long history of safe use. The 1507 maize has been genetically modified to express CRY1F protein, conferring resistance to certain lepidopteran insect pests, such as the European corn borer and *Sesamia* spp., and PAT protein, conferring tolerance to glufosinate-ammonium herbicide.

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

See **Point A.3.** above.

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

Feed produced from 1507 maize is being used as any other feed produced from commercial maize.

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

There are no specific instructions or recommendations for use, storage and handling of feed produced from 1507 maize. Labelling of feed produced from 1507 maize must be carried out in accordance with Community law. See **Point A.8.f)** below for labelling of feed produced from 1507 maize.

(e) Any proposed packaging requirements

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

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

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 produced from 1507 maize should be labelled as follows:

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 feed produced from 1507 maize as 1507 maize has been shown to be equivalent to non-GM maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 1507 maize does not give rise to any ethical or religious concerns.

(g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants)

In accordance with Commission Regulation (EC) 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identifier assigned to 1507 maize is DAS-Ø15Ø7-1.

(h) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for. Any type of environment to which the product is unsuited

Not applicable.

9. Measures suggested by the applicant to take in case of unintended release or misuse as well as measures for disposal and treatment

Not applicable.

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

1. Complete name

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

2 a. Information concerning reproduction

(i) Mode(s) of reproduction

As a wind-pollinated, monoecious grass species, self-pollination and fertilisation, and cross-pollination and fertilisation, are usually possible and

frequencies of each are normally determined by proximity and other physical influences on pollen dispersal.

(ii) Specific factors affecting reproduction

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

(iii) Generation time

Maize is an annual crop with a cultural cycle ranging from as short as 10 weeks to as long as 48 weeks covering the period of seedling emergence to maturity. This variance in maturity allows maize to be grown over a range of climatic conditions.

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

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

3. Survivability

(a) Ability to form structures for survival or dormancy

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

(b) Specific factors affecting survivability

Survival of maize seed is dependent upon temperature, moisture of seed, genotype, husk protection and stage of development. Maize seed can only survive under favourable climatic conditions. Freezing temperatures have an adverse effect on germination of maize seed and it has been identified as a major risk in limiting production of maize seed.

4. Dissemination

(a) Ways and extent of dissemination

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

(b) Specific factors affecting dissemination

Mechanical harvesting and transport are ways of disseminating grain and insect or wind damage may cause mature ears to fall to the ground and avoid harvest. Regardless of these routes of dissemination, maize cannot survive without human assistance.

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

Maize is grown throughout Europe over a wide range of climatic conditions because of its many divergent types. However, survival and reproduction in maize is limited by cool conditions. The greatest maize production occurs where the warmest month isotherms range between 21 and 27°C and the freeze-free season lasts 120 to 180 days. Maize has been cultivated in Europe starting in Southern Europe since the 16th century. There are no other species compatible with maize in Europe.

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

Not applicable as maize has been cultivated in Europe since the 16th century.

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

Maize is known to interact with other organisms in the environment including insects, birds, and mammals. It is susceptible to a range of fungal diseases and insect pests, as well as competition from surrounding weeds. Maize is extensively cultivated and has a history of safe use. Maize or derived products of maize are not considered to have harmful characteristics. Maize has no toxic or pathogenic characteristics.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

The particle acceleration method was used to introduce into maize cells a linear DNA fragment containing the *cry*1F and *pat* coding sequences and the necessary regulatory components (insert PHI8999A). Maize event 1507 expressing the CRY1F protein and the PAT protein was produced, referred to as 1507 maize.

2. Nature and source of the vector used

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

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

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

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

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

D. INFORMATION RELATING TO THE GM PLANT

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

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

The *cry*1F gene is expressed constitutively by the *ubi*ZM1(2) promoter. Expression of CRY1F protein provides control against lepidopteran insect pest

damage to the above-ground parts of the maize plant including those parts which are beyond the reach of chemical insecticides. Specifically, the CRY1F protein confers season-long resistance against the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests such as the pink borer (*Sesamia* spp.). It is also highly effective against fall armyworm (*Spodoptera frugiperda*), black cutworm (*Agrotis ipsilon*) and southwestern corn borer (*Diatraea grandiosella*).

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

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

2. Information on the sequences actually inserted or deleted

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

The genetic modification in 1507 maize has been characterised in detail by Southern blot and DNA sequence analyses. The analyses have confirmed that the inserted genetic material is integrated into the nuclear genome of the maize plant and consists of an almost full-length copy of the linear fragment used in the transformation (*i.e.*, 6186 bp from the 6235 bp of insert PHI8999A, containing the *cry*1F and *pat* genes together with the regulatory sequences necessary for their expression). The insert integrated in 1507 maize contains one copy of the almost full-length linear fragment used in the transformation, which includes one functional copy of the complete *cry*1F gene and one functional copy of the complete *pat* gene, together with the regulatory sequences necessary for their expression. The insert also contains two non-functional fragments of the *cry*1F gene; three non-functional fragments of the *pat* gene; one non-functional fragment of the polylinker region and *ubi*ZM1(2) promoter; and, one non-functional fragment of the ORF25PolyA terminator sequence.

The 1507 maize does not contain the *nptII* gene nor any other detectable fragments from the portion of plasmid PHP8999 that was not intended for transformation of 1507 maize. Maize genomic DNA flanking regions at both the 5’ and 3’ borders of the 1507 maize insert have been sequenced and characterised in detail. Analysis by PCR amplification has confirmed the presence of both maize genomic flanking regions in non-GM Hi-II maize used in the transformation of 1507 maize.

(b) In case of deletion(s), size and function of the deleted region(s)

Not applicable.

(c) Chromosomal location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination

The insert is integrated into the maize plant genome as confirmed in the molecular characterisation of 1507 maize by detailed Southern blot analysis and DNA sequencing.

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

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

- one fragment (335 bp) of the *cry*1F gene, with no *ubi*ZM1(2) promoter sequence, and one fragment (15 bp) of the *cry*1F gene, both located at the 5' end of the almost full-length insert;
- two fragments (201 bp and 138 bp long, respectively) of the *pat* gene, without regulatory sequences associated, located at the 5' border and, one fragment (188 bp) of the *pat* gene, located at the 3' border;
- one fragment (118 bp) of the polylinker region and *ubi*ZM1(2) promoter sequence located at the 5' border;
- one fragment (550 bp) of the ORF25PolyA terminator sequence in inverted position located immediately at the 3' end of the almost full-length insert.

3. Information on the expression of the insert

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

Leaf, pollen, silk, stalk, whole plant, grain and senescent whole plant tissue samples from 1507 maize and control maize with comparable genetic background were obtained from field studies conducted during the growing seasons of 1998/99 in Chile, 1999 in France and Italy, and 2000 in France, Italy and Bulgaria. Expression levels of CRY1F and PAT proteins in these tissues were measured using specific Enzyme Linked Immunosorbent Assay (ELISA) developed for each protein. Results show that the CRY1F protein is expressed in all tissues and throughout the development of maize, while the PAT protein was measurable at the V9 developmental stage only.

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

Expression of the proteins CRY1F and PAT occurs throughout the different parts of the 1507 maize plant. However, expression of the PAT protein in 1507 maize

grain was below the lower limit of quantitation of the assay, which was 0.075 ng/mg grain dry weight.

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

(a) Reproduction

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

(b) Dissemination

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

(c) Survivability

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

(d) Other differences

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

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

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

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

(a) Plant to bacteria gene transfer

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

(b) Plant to plant gene transfer

The potential for transfer of genetic material from 1507 maize to other organisms has not been altered. Maize does not transfer genetic material to other plant species in the EU.

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

7.1 Comparative assessment

The comparator chosen for the safety evaluation of 1507 maize consists of non-GM maize with comparable genetic background. Wherever possible, publicly available data on commercial maize has also been used in the comparisons with 1507 maize.

7.2 Production of material for comparative assessment

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

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

(b) The baseline used for consideration of natural variations

Publicly available data on commercial maize was compiled from the literature and was used as the baseline for consideration of natural variations in the comparisons with 1507 maize. In addition, a comparative assessment with non-GM maize of comparable genetic background has been carried out.

7.3 Selection of material and compounds for analysis

As recommended by the OECD (1999), the compounds selected for analysis of grain from 1507 maize consisted of protein, fiber, carbohydrates, fat, ash, fatty acids, minerals, amino acids, vitamins, secondary metabolites and anti-nutrients. The results obtained confirmed that there are no statistically significant differences between 1507 maize and non-GM control maize with comparable genetic background that would fall outside the normal ranges of natural variation for non-GM maize.

7.4 Agronomic traits

The 1507 maize was tested in the USA during the 1999 growing season in up to 15 locations and in 2000 at six locations in France (3 locations), Italy (2 locations) and Bulgaria (1 location). In addition, the results obtained from field trials carried out in 2002 in Spain further confirmed that there are no unexpected agronomic differences between 1507 maize and non-GM maize with comparable genetic background.

7.5 Product specification

As summarised in **Point A.5.**, 1507 maize is substantially and nutritionally equivalent to commercial maize. Therefore, the specification of feed produced from 1507 maize is the same as that of feed produced from commercial maize.

7.6 Effect of processing

Feed produced from 1507 maize undergoes existing processing methods used for non-GM maize. No novel production or processing methods are applied.

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

7.7 Anticipated intake/extent of use

Feed produced from 1507 maize represents a relatively small portion of existing maize feed production with total consumption of maize feed remaining unchanged.

The comparative and nutritional assessments of 1507 maize together with the absence of any adverse effects to animal health from CRY1F and PAT proteins confirm that there are no concerns related to the anticipated intake/extent of use of feed produced from 1507 maize.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

The genetic modification in 1507 maize results in expression of CRY1F and PAT proteins. The CRY1F protein has specific toxicity against certain lepidopteran insect pests (target organisms). An acute toxicity study with CRY1F protein in mice has confirmed the safety of the CRY1F protein to human and animal health. No mortality, toxicity or adverse clinical signs were observed at the highest dose tested of 5050 mg of test material per kg of body weight which was equivalent to 576 mg of pure CRY1F protein per kg of body weight. In addition, there is no evidence for CRY proteins originating from *Bacillus thuringiensis* to have harmful effects on the health of humans and animals.

The safety in terms of toxicity for the PAT protein has already been determined in detail during the assessment of glufosinate-ammonium tolerant maize. The *pat* gene was originally obtained from *Streptomyces viridochromogenes* strain Tü494 which has no known toxic or pathogenic potential. Toxicity studies carried out on rats and mice containing up to 50000 and 5000 mg/kg body weight respectively, have confirmed the absence of any adverse treatment-related clinical signs.

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

7.8.2 Testing of new constituents other than proteins

Not applicable.

7.8.3 Information on natural food and feed constituents

The comparisons carried out between the natural constituents of 1507 maize and non-GM control maize with comparable genetic background confirm that there are no statistically significant differences that would fall outside the normal ranges of variation for non-GM maize.

7.8.4 Testing of the whole GM food/feed

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

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

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

The results of the thirteen-week (90-day) oral toxicity feeding study in rats carried out with 1507 maize grain have been published in the peer-reviewed journal *Food and Chemical Toxicology* in 2007, Vol. 45, pp. 551-562.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The most important factor to consider in assessing allergenic potential is whether the source of the gene being introduced into plants is known to be allergenic. Neither *Bacillus thuringiensis* (the source of the *cry*1F gene) nor *Streptomyces viridochromogenes* (the source of the *pat* gene) have a history of causing allergy. Also, both donor organisms are common soil bacteria.

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

Two recent publications in the peer-reviewed journal *Regulatory Toxicology and Pharmacology* have provided further evidence confirming the absence of allergenicity of the CRY1F and PAT proteins expressed in 1507 maize. See Vol. 44, pp. 136-143 regarding the protein CRY1F; and, pp. 182-188 of the same volume with regard to the protein PAT.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Maize has a long history of use in the EU and constitutes a traditional counterpart to 1507 maize that can be used as a baseline to facilitate the assessment of potential toxicity and allergenicity of 1507 maize. In addition and as summarised in **Point D.7.9.1**, the CRY1F and PAT proteins expressed in 1507 maize are not allergenic; and therefore expression of these proteins in 1507 maize does not alter the inherent characteristics of maize regarding its allergenic potential.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

Not applicable.

7.10.2 Nutritional assessment of GM feed

Composition analyses of grain from 1507 maize have shown that the contents of protein, fiber, carbohydrates, fat, ash, minerals, fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients are all equivalent to that found in non-GM maize with comparable genetic background and to the published range of values in the literature. In addition, nutritional equivalence between 1507 maize and non-GM control maize with comparable genetic background has also been shown in a poultry feeding study over a 42-day period.

Therefore, the nutritional assessment of 1507 maize concluded that 1507 maize food/feed products are nutritionally equivalent to those from non-GM maize and consumption of 1507 maize food/feed products will not give rise to any adverse nutritional impact.

7.11 Post-market monitoring of GM food/feed

As summarised in **Point D.7.10** above, the nutritional assessment has concluded that 1507 maize food/feed products are nutritionally equivalent to those from non-GM maize. In addition, the use of feed produced from 1507 maize will not be different from that of feed produced from non-GM maize.

Therefore, post-market monitoring of feed produced from 1507 maize is not necessary.

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

Not applicable.

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

Not applicable.

10. Potential interactions with the abiotic environment

Not applicable.

11. Environmental monitoring plan

Not applicable.

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

A PCR detection method to confirm the molecular identity of 1507 maize has been validated by the JRC-CRL (Joint Research Centre-Community Reference Laboratory) and was published on 15 February 2005 (http://gmo-crl.jrc.it/statusofdoss.htm).

In addition, certified reference materials for 1507 maize are accessible from the EC JRC Institute of Reference Materials and Measurements in Geel (Belgium) (http://www.irmm.jrc.be/html/homepage.htm).

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 numbers
B/IT/98/19; B/FR/99/03/09; B/FR/01/03/02; B/ES/02/11; B/ES/03/11; B/ES/04/06; B/ES/04/11; B/FR/04/02/06; B/FR/04/03/04; B/ES/05/02; B/ES/05/07; B/FR/05/01/02; B/ES/06/16; B/FR/06/01/05.

(b) Conclusions of post-release monitoring
The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.

(c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)

No adverse effects on human health and the environment observed.

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

(a) Release country
Argentina.
(b) Authority overseeing the release
Secretary of Agriculture.
(c) Release site
Multiple sites.
(d) Aim of the release
Research and registration.
(e) Duration of the release
Multiple seasons.
(f) Aim of post-release monitoring
Control of potential volunteers.
(g) Duration of post-release monitoring
One season.
(h) Conclusions of post-release monitoring
The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed. Cultivation of 1507 maize seed products has been authorised.

(a) Release country
Brazil
(b) Authority overseeing the release
CTNBio
(c) Release site
One site.
(d) Aim of the release
Research.
(e) Duration of the release
One season.
(f) Aim of post-release monitoring
Control of potential volunteers.
(g) Duration of post-release monitoring
One season.
(h) Conclusions of post-release monitoring
The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
Chile.
(b) Authority overseeing the release
Ministry of Agriculture.
(c) Release site
Multiple sites.
(d) Aim of the release
Research.
(e) Duration of the release
Multiple seasons.
(f) Aim of post-release monitoring
Control of potential volunteers.
(g) Duration of post-release monitoring
One season.
(h) Conclusions of post-release monitoring
The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
China.
(b) Authority overseeing the release
Ministry of Agriculture
(c) Release site
Multiple sites.
(d) Aim of the release
Registration.
(e) Duration of the release
One season.
(f) Aim of post-release monitoring
Control of potential volunteers.
(g) Duration of post-release monitoring
One season.
(h) Conclusions of post-release monitoring
The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
Colombia.
(b) Authority overseeing the release
Colombian Agricultural Institute.

(c) Release site
Multiple sites.
(d) Aim of the release
Research.
(e) Duration of the release
One season.
(f) Aim of post-release monitoring
Control of potential volunteers.
(g) Duration of post-release monitoring
One season.
(h) Conclusions of post-release monitoring
The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed. Cultivation of 1507 maize seed products has been authorised.

(a) Release country
Honduras.
(b) Authority overseeing the release
Biosafety Committee.
(c) Release site
One site.
(d) Aim of the release
Registration.
(e) Duration of the release
One season.
(f) Aim of post-release monitoring
Control of potential volunteers.
(g) Duration of post-release monitoring
One season.
(h) Conclusions of post-release monitoring
The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
Japan.
(b) Authority overseeing the release
Ministry of Agriculture, Forestry and Fisheries.
(c) Release site
Multiple sites.
(d) Aim of the release
Registration.

(e) Duration of the release
Multiple seasons.
(f) Aim of post-release monitoring
Control of potential volunteers.
(g) Duration of post-release monitoring
One season.
(h) Conclusions of post-release monitoring
The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed. Cultivation of 1507 maize seed products has been authorised.

(a) Release country
South Africa.
(b) Authority overseeing the release
Ministry of Agriculture.
(c) Release site
One site.
(d) Aim of the release
Research.
(e) Duration of the release
One season.
(f) Aim of post-release monitoring
Control of potential volunteers.
(g) Duration of post-release monitoring
One season.
(h) Conclusions of post-release monitoring
The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
U.S.A.
(b) Authority overseeing the release
USDA and EPA.
(c) Release site
Multiple sites.
(d) Aim of the release
Research.
(e) Duration of the release
Multiple seasons.
(f) Aim of post-release monitoring
Control of potential volunteers.

(g) Duration of post-release monitoring

One season.

(h) Conclusions of post-release monitoring

The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.

(i) Results of the release in respect to any risk to human health and the environment

No adverse effects on human health and the environment observed. Cultivation of 1507 maize seed products has been authorised.

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

Commission Decision 2005/772/EEC of 3 November 2005, OJ L 291, 05/11/2005:

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_291/l_29120051105en00420044.pdf

Commission Decision 2006/197/EC of 3 March 2006, OJ L 070, 09/03/2006:

http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2006/l_070/l_07020060309en00820086.pdf

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

With regard to notification C/NL/00/10 for import, feed and processing under Directive 2001/18/EC:

http://gmoinfo.jrc.it/csnifs/C-NL-00-10_AssessmentReport.pdf

With regard to notification C/ES/01/01, including cultivation of 1507 maize, under Directive 2001/18/EC:

http://gmoinfo.jrc.it/csnifs/C-ES-01-01_AssessmentReport.pdf

(c) EFSA opinion

With regard to notification C/NL/00/10 for import, feed and processing under Directive 2001/18/EC:

http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/663.html

With regard to notification C/ES/01/01, including cultivation of 1507 maize, under Directive 2001/18/EC:

http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/827.html

With regard to application EFSA-GMO-NL-2004-02 for food use under Regulation 1829/2003:

http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/826.html

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

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

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

http://gmo-crl.jrc.it/summaries/TC1507-report_mm.pdf

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

http://bch.biodiv.org/database/record.shtml?id=12199

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

This summary can be accessed from the EFSA website:

http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications.html