PART II

SUMMARY

SUMMARY OF THE APPLICATION FOR THE AUTHORISATION OF GENETICALLY MODIFIED 1507xNK603 MAIZE AND DERIVED FOOD AND FEED IN ACCORDANCE WITH REGULATION (EC) 1829/2003 INCLUDING AUTHORISATION FOR CULTIVATION IN ACCORDANCE WITH DIRECTIVE 2001/18/EC

A. GENERAL INFORMATION

1. Details of application

(a) Member State of application:

United Kingdom

(b) Application number:

[To be provided]

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

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

(d) Date of acknowledgment of valid application:

[To be provided]

2. Applicant

(a) Name of applicant

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

(b) Address of applicant

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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

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

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

No

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

Yes, 1507xNK603 maize has been notified under Part B of Directive 2001/18/EC.

Year	Member State	Notification No
2003	France	B/FR/03.02.02
2003	Spain	B/ES/03/10
2004	France	B/FR/04.06.01
2004	Spain	B/ES/04/03
2005	France	B/FR/05.01.04

2005	Spain	B/ES/05/04
2005	Spain	B/ES/05/10
2005	Portugal	B/PT/05/02
2005	Hungary	B/HU/05/02/1

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

Not applicable.

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

No

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

Yes, a notification concerning foods derived from 1507xNK603 maize was submitted to the US Food and Drug Administration (FDA) in November of 2003. A notification letter was sent on 12th June of 2003 to the Canadian Food Inspection Agency and to Health Canada.

In addition, applications have been submitted to Japan, South Korea, Australia/ New Zealand, Mexico, Argentina and Taiwan. The necessary approvals in Japan for animal feed use, food safety and import of 1507xNK603 maize were obtained on 1st September 2003, 3rd March of 2004 and 25 March 2005, respectively. The approval for food and animal feed use of 1507xNK603 maize in Mexico was obtained on 14th December 2004.

8. General description of the product

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

The recipient plant is maize (*Zea mays* L.), which is extensively cultivated and has a long history of safe use. The 1507xNK603 maize has been obtained from traditional breeding methods from two GM maize, 1507 maize (expressing the CRY1F and PAT proteins), and NK603 maize (expressing the CP4 EPSPS protein). The CRY1F protein confers resistance to certain lepidopteran insect pests, such as the European corn borer and *Sesamia* spp. The PAT protein confers tolerance to glufosinate-ammonium herbicide and the CP4 EPSPS protein confers tolerance to glyphosate herbicide. No new genetic modification has been introduced in 1507xNK603 maize.

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

The product described in this application is 1507xNK603 maize, including 1507xNK603 maize seed products for cultivation, for all food and feed uses, and for all food, feed and processed products derived from 1507xNK603 maize.

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

The intended use of 1507xNK603 maize will be consistent with current uses of commercial maize products and 1507xNK603 maize will be used in the EU as any other maize. Therefore, there are multiple categories of users of 1507xNK603 maize, including agricultural growers, the animal feed and milling industry, skilled trades and consumer use by public at large.

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

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

(e) Any proposed packaging requirements

The packaging, handling, and storage systems that are currently used for maize will apply. The 1507xNK603 maize products will be packaged in the same manner as other commercial maize products. See **Point A.8.f)** below for labelling of 1507xNK603 maize.

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

1.- PROPOSAL FOR THE LABELLING OF 1507xNK603 MAIZE FOOD PRODUCTS ACCORDING TO ARTICLES 12 AND 13 OF REGULATION (EC) 1829/2003

Proposal for the labelling of 1507xNK603 maize food products

In accordance with Article 12(2) of Regulation No (EC) 1829/2003, labelling shall not apply to foods containing material which contains, consists of or is produced from 1507xNK603 maize in a proportion no higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient.

In accordance with Article 13 of Regulation (EC) 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of

foodstuffs, foods containing, consisting of, produced from, or containing ingredients produced from, 1507xNK603 maize should be labelled as follows:

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

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

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

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

(e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm^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 1507xNK603 maize food products as 1507xNK603 maize has been shown to be equivalent to non-GM maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 1507xNK603 maize does not give rise to any ethical or religious concerns.

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

Proposal for the labelling of 1507xNK603 maize feed products

In accordance with Article 24(2) of Regulation No (EC) 1829/2003, labelling shall not apply to feed containing material which contains, consists of or is produced from 1507xNK603 maize in a proportion no higher than 0.9% of the feed and of each feed of which it is composed.

In accordance with Article 25 of Regulation (EC) 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) of Regulation (EC) 1829/2003, *i.e.* 1507xNK603 maize for feed use, and feed containing, consisting of or produced from 1507xNK603 maize, should be labelled as follows:

(a) where the feed contains or consists of 1507xNK603 maize, or where 1507xNK603 maize is used for the purpose of feed use, the words 'genetically modified maize' will appear in parentheses immediately following the specific name of the feed.

Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed;

(b) where the feed is produced from 1507xNK603 maize, the words 'produced from genetically modified maize' will appear in parentheses immediately following the specific name of the feed;

Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed;

No other particulars such as those referred to in Article 25(2)(c) and Article 25(3) of Regulation No (EC) 1829/2003 would need to be specified on the label of 1507xNK603 maize feed products as 1507xNK603 maize has been shown to be equivalent to non-GM maize in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 1507xNK603 maize does not give rise to any ethical or religious concerns.

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

In accordance with Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC, the information provided on a label or in an accompanying document for the purpose of satisfying the labelling requirements of products consisting of, or containing, 1507xNK603 maize will include the following:

i) Commercial name of the product;

ii) A statement that 'this product contains genetically modified maize';

iii) Name of the GMO;

iv) Name and full address of the person established in the Community who is responsible for the placing on the market; and,

v) An indication on how to access the information in the publicly accessible part of the register.

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

In accordance with Commission Regulation (EC) 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identifier assigned to 1507xNK603 maize is DAS-Ø15Ø7-1xMON-ØØ6Ø3-6.

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

Not applicable

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

Based on the conclusions from the environmental risk assessment for the placing on the market of 1507xNK603 maize, no specific measures need to be taken in case of unintended release or misuse or for disposal and treatment.

In case of unintended release, misuse, disposal or treatment of 1507xNK603 maize, current measures taken to control unintended release, misuse, disposal or treatment of non-GM maize can be applied, such as selective use of herbicides (with the exception of glufosinate-ammonium and glyphosate herbicides), and manual or mechanical removal.

B. INFORMATION RELATING TO THE RECIPIENT OR (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 or strain:	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 1507xNK603 maize has been obtained from traditional breeding methods between progeny of 1507 and NK603 maize. No new genetic modification has been introduced in 1507xNK603 maize.

The 1507 maize was obtained by insertion of a linear DNA fragment (insert PHI8999A) containing the *cry*1F and *pat* coding sequences and the necessary regulatory components into maize cells using the particle acceleration method.

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

2. Nature and source of the vector used

The 1507xNK603 maize has been obtained from traditional breeding methods between progeny of 1507 and NK603 maize. No new genetic modification has been introduced in 1507xNK603 maize.

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

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

The 1507xNK603 maize has been obtained from traditional breeding methods between progeny of 1507 and NK603 maize. No new genetic modification has been introduced in 1507xNK603 maize.

The intended insert used in the transformation of 1507 maize (insert PHI8999A) contained 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 (1.8 kb; origin: *Bacillus thuringiensis* subsp. *aizawai*) was under the control of the ubiquitin promoter *ubi*ZM1(2) (1.9 kb; origin: *Zea mays*) and the ORF25PolyA terminator (0.7 kb; origin: *Agrobacterium tumefaciens* pTi15995). The intended function of the *cry*1F gene was to confer resistance against certain lepidopteran insect pests such as the European corn borer and *Sesamia* spp. The *pat* gene (0.5 kb; origin: *Streptomyces viridochromogenes* strain Tü494) was under the control of the CaMV35S promoter and terminator (0.5 and 0.2 kb, respectively; origin: cauliflower mosaic virus). The intended function of the *pat* gene was to confer tolerance to the application of glufosinate-ammonium herbicide.

The intended insert used in the transformation of NK603 maize (insert PV-ZMGT32L) contained two copies of the *cp4 epsps* gene (6.7 kb; origin: *Agrobacterium* sp. strain CP4). One of the copies of the *cp4 epsps* gene was under the control of the rice actin 1 gene intron (1.4 kb; origin: *Oryza sativa*); the chloroplast transit peptide of the *epsps* gene (0.2 kb, origin: *Arabidopsis thaliana*); and, the terminator of the nopaline synthase gene (0.4 kb; origin: *Agrobacterium tumefaciens*). The second copy of the *cp4 epsps* gene was under the control of the *e35S* promoter with a duplicated enhancer region (0.6 kb; origin: cauliflower mosaic virus); the *hsp70* gene intron (0.8 kb; origin: *Zea mays*); the chloroplast transit peptide of the *epsps* gene (0.2 kb, origin: *Arabidopsis thaliana*); and, the terminator of the nopaline synthase gene (0.4 kb; origin: *Agrobacterium tumefaciens*). The intended function of the *cp4 epsps* gene was to confer tolerance to the application of glyphosate herbicide.

D. INFORMATION RELATING TO THE GM PLANT

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

The 1507xNK603 maize has been obtained from traditional breeding methods between progeny of 1507 and NK603 maize. No new genetic modification has been introduced in 1507xNK603 maize.

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

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

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

2. Information on the sequences actually inserted or deleted

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

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

The Southern blot and sequence analyses demonstrate that the genetic material inserted in 1507 maize 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). In addition, the plant 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.

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. In addition, 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.

A detailed description of the copy number of all detectable inserts in NK603 maize has been included in the notification of NK603 maize pursuant to Directive 2001/18/EC (C/ES/00/01) and in the request for authorisation of NK603 maize pursuant to Regulation (EC) No. 258/97 submitted by Monsanto Europe S.A., which have been authorised by Commission Decisions of 19 July 2004 and 26 October 2004, respectively.

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

Not applicable

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

The inserts are integrated in the nuclear genome.

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

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

3. Information on the expression of the insert

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

The 1507xNK603 maize has been obtained from traditional breeding methods between progeny of 1507 and NK603 maize. As a result, 1507xNK603 maize expresses the proteins CRY1F, PAT and CP4 EPSPS during the life cycle of the plant. No new genetic modification has been introduced in 1507xNK603 maize.

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

The 1507xNK603 maize expresses the proteins CRY1F, PAT and CP4 EPSPS throughout the different parts of the maize plant. In particular, the proteins CRY1F and CP4 EPSPS were expressed at comparable levels regardless of the herbicide treatment in grain samples from 1507xNK603 maize. However, expression of the PAT protein in 1507xNK603 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 1507xNK603 maize.

(b) Dissemination

Cultivated maize has been domesticated to the extent that the seeds cannot be disseminated without human intervention. The 1507xNK603 maize plants show no difference in dissemination compared to non-GM maize.

(c) Survivability

Cultivated maize has been domesticated to the extent that it cannot survive outside managed agricultural environments. Lack of dormancy prevents maize seed from readily surviving from one growing season to the next. When cultivated, expression of the CRY1F protein in 1507xNK603 maize confers resistance to certain lepidopteran insect pests, expression of PAT confers tolerance to the herbicide glufosinate-ammonium and expression of CP4 EPSPS confers tolerance to the herbicide glyphosate. The survival characteristics of 1507xNK603 maize in the environment remain comparable to those of non-GM maize. Resistance against certain lepidopteran insect pests is not sufficient to allow survival of maize outside the agricultural habitat and, the broad-spectrum herbicides glufosinate-ammonium and glyphosate are not normally used outside agricultural habitats.

(d) Other differences

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

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

The 1507xNK603 maize has been shown to be genetically and phenotypically stable. Results from the Southern analysis, agronomic characteristics and protein expression analysis of 1507xNK603 maize plants have confirmed the stable

inheritance and expression of CRY1F, PAT and CP4 EPSPS proteins in 1507xNK603 maize.

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

(a) Plant to bacteria gene transfer

Transfer of genetic material originating from 1507xNK603 maize to bacteria is a negligible concern. There is no known mechanism for, or definitive demonstration of, DNA transfer from plants to microbes under natural conditions. Even if horizontal gene transfer were to take place, transfer of the *cry*1F, *pat* or *cp4 epsps* genes from 1507xNK603 maize does not represent a risk to human or animal health, nor is it of consequence as a plant pest risk. In addition, maize pollen grains are heavy, with a rapid settling rate, and show limited dispersal and viability capacities.

(b) Plant to plant gene transfer

The potential for transfer of genetic material from 1507xNK603 maize to other organisms has not been changed and it will be negligible, as there are no sexually compatible wild or weedy relatives of *Zea mays* known to exist in the EU.

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

7.1 Comparative assessment

Choice of the comparator

The comparator chosen for the safety evaluation of 1507xNK603 maize consists of non-GM maize with comparable genetic background. Wherever possible, publicly available data on commercial maize has also been used in the comparisons with 1507xNK603 maize.

7.2 Production of material for comparative assessment

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

A field study was conducted at several separate field locations in Europe during the 2003 growing season. Each location included a randomized block design containing three blocks (or replicates). Each block contained the 1507xNK603 maize and a non-GM control for comparison.

(b) The baseline used for consideration of natural variations

Publicly available data on commercial maize was compiled from the literature and was used as the baseline for consideration of natural variations in the comparisons

with 1507xNK603 maize. In addition, a comparative assessment with non-GM maize of comparable genetic background has been carried out.

7.3 Selection of material and compounds for analysis

As recommended by the OECD (1999), the compounds selected for analysis of grain from 1507xNK603 maize consisted of protein, fiber, carbohydrates, fat, ash, fatty acids, minerals, amino acids, vitamins, secondary metabolites and anti-nutrients. The results obtained confirmed that there are no statistically significant differences between 1507xNK603 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 1507xNK603 maize was tested in Europe during the 2003 growing season. The results obtained confirmed that there are no unexpected agronomic differences between 1507xNK603 maize and non-GM maize with comparable genetic background.

7.5 Product specification

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

7.6 Effect of processing

The 1507xNK603 maize will undergo existing methods of processing used for commercial maize. No novel methods of processing are envisaged.

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

7.7 Anticipated intake/extent of use

The 1507xNK603 maize and all food, feed and processed products derived from 1507xNK603 maize are expected to replace a portion of similar products from commercial maize with total consumption of maize products remaining unchanged. Therefore, the total anticipated intake/extent of use of maize and all food, feed and processed products derived from maize will remain the same. In any case, in the EU, the majority of maize products, either from imports or cultivation, are fed to livestock. In particular, human consumption of maize

products in the developed world is in the form of high fructose maize syrup, starches, and oil, *i.e.* products that contain only negligible amounts of protein.

According to GEMS/FOOD Dietary Tables (2003) maize consumption by the European population is estimated to be of 8.8 grams/person/day. The comparative and nutritional assessments of 1507xNK603 maize together with the absence of any adverse effects to human and animal health from CRY1F, PAT and CP4 EPSPS proteins confirm that there are no concerns related to the anticipated intake/extent of use of 1507xNK603 maize and all food, feed and processed products derived from 1507xNK603 maize.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

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

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

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

The safety in terms of toxicity for the CP4 EPSPS protein has already been determined in detail during the assessment of glyphosate tolerant maize. The *cp4 epsps* gene was originally obtained from *Agrobacterium* sp. strain CP4, which has no known toxic or pathogenic potential. Toxicity studies carried out on mice containing up to 5000 mg/kg body weight have confirmed the absence of any adverse treatment-related clinical signs.

In addition, a poultry feeding study has been carried out with diets containing grain from 1507xNK603 maize or from non-GM maize over a period of 42 days. The results obtained have confirmed that there are no statistically significant

differences on mortality, body weight gain or feed conversion between chickens fed a diet containing grain from 1507xNK603 maize or from non-GM maize.

7.8.2 Testing of new constituents other than proteins

Detailed compositional analyses of 1507xNK6032 maize demonstrated that the composition of 1507xNK603 maize grain is equivalent to that of non-GM maize with comparable genetic background. Therefore, no testing of any other constituent is necessary.

7.8.3 Information on natural food and feed constituents

The comparisons carried out between the natural constituents of 1507xNK603 maize and non-GM control maize with comparable genetic background confirm that there are no statistically significant differences that would fall outside the normal ranges of variation for commercial maize.

7.8.4 Testing of the whole GM food/feed

As described throughout this application, there is no new genetic modification in 1507xNK603 maize. In addition, the nutritional assessment of 1507xNK603 maize has confirmed that whole food and feed consisting of or derived from 1507xNK603 maize is equivalent to whole food and feed consisting of or derived from commercial maize.

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

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

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

The most important factor to consider in assessing allergenic potential is whether the source of the gene being introduced into plants is known to be allergenic. Neither *Bacillus thuringiensis* (the source of the *cry*1F gene), *Streptomyces viridochromogenes* (the source of the *pat* gene) nor *Agrobacterium* sp. strain CP4 (the source of the *cp4 epsps* gene) have a history of causing allergy.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Maize has a long history of use as food in the EU and constitutes a traditional counterpart to 1507xNK603 maize that can be used as a baseline to facilitate the assessment of potential toxicity and allergenicity of 1507xNK603 maize. Maize is not considered to be a common allergenic food crop and 1507xNK603 maize does not express any new proteins with allergenic characteristics.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

Composition analyses of grain from 1507xNK603 maize have shown that the contents of protein, fiber, carbohydrates, fat, ash, minerals, fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients are all equivalent to that found in non-GM maize with comparable genetic background and to the published range of values in the literature. In addition, nutritional equivalence between 1507xNK603 maize and non-GM control maize with comparable genetic background has also been shown in a poultry feeding study over a 42-day period.

Furthermore and taking into account the anticipated dietary intake of 1507xNK603 maize products, consumption of 1507xNK603 maize foods will not give rise to any adverse nutritional impact.

7.10.2 Nutritional assessment of GM feed

As summarised in **Point D.7.10.1** above, consumption of 1507xNK603 maize feed will not give rise to any adverse nutritional impact.

7.11 Post-market monitoring of GM food/feed

As summarised in **Point D.7.10** above, the nutritional assessment has concluded that 1507xNK603 maize is nutritionally equivalent to non-GM maize. In addition, the use of 1507xNK603 maize food and feed will not be different from that of non-GM maize food and feed.

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

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

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

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

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

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

9.1 Persistence and invasiveness

There is negligible likelihood for 1507xNK603 maize to become environmentally persistent or invasive giving rise to any weediness. First, because maize does not possess any traits for weediness and second, expression of CRY1F, PAT and CP4 EPSPS proteins in 1507xNK603 maize does not give rise to traits for weediness.

Maize plants are annuals that generally will not survive in Europe from one growing season to the next because of poor dormancy and sensitivity to low temperature. Despite its non-dormant nature, maize seed can occasionally persist from one growing season to the next under favourable climatic conditions. When the temperature and moisture are adequate, the seed will germinate. These volunteers are easily identified and controlled through current agronomic measures taken to control other commercially available maize can be applied, such as selective use of herbicides (with the exception of glufosinate-ammonium and glyphosate herbicides), and manual or mechanical removal.

9.2 Selective advantage or disadvantage

Maize is highly domesticated, to the extent that it cannot become established as a feral species outside the agricultural environment, and expression of CRY1F, PAT and CP4 EPSPS proteins in 1507xNK603 maize do not confer any selective advantage or disadvantage to the plants in the natural environment, *i.e.* outside the agricultural environment. Insect attack is only one of the multiple biotic and abiotic factors that prevent growth of maize outside heavily managed agricultural environments, and therefore, expression of the CRY1F protein conferring resistance to certain lepidopteran insect pests cannot be considered a selective advantage.

In addition, application of broad spectrum herbicides, such as glufosinate-ammonium and glyphosate, does not commonly occur in the natural environment, and therefore expression of PAT and CP4 EPSPS proteins in 1507xNK603 maize does not confer a selective advantage outside the agricultural environment.

9.3 Potential for gene transfer

There are no sexually compatible wild or weedy relatives of *Zea mays* known to exist in the EU, which eliminates any potential for gene transfer to other species.

In addition, there is negligible likelihood for 1507xNK603 maize plants to become environmentally persistent or invasive giving rise to any weediness. Furthermore, expression of the proteins CRY1F, PAT and CP4 EPSPS does not present any selective advantage outside the agricultural environment.

9.4 Interactions between the GM plant and target organisms

Expression of CRY1F protein in cultivated 1507xNK603 maize provides growers with a highly effective and environmentally beneficial tool to control certain lepidopteran pests that attack maize plants, such as European corn borer and *Sesamia* spp. The mechanism of interaction between CRY1F protein expressed in 1507xNK603 maize and target organisms is highly specific against target insect pests and it is similar to the well characterized interactions between *Bacillus thuringiensis* Cry proteins and target organisms.

9.5 Interactions of the GM plant with non-target organisms

The specificity of the biological activity and the absence of toxicity to non-target organisms of the proteins CRY1F, PAT and CP4 EPSPS confirms that there will be no adverse effects on non-target organisms arising from 1507xNK603 maize.

9.6 Effects on human health

Maize is not considered to have harmful effects on human health. Maize has a long history of safe use in human food and animal feed. A very detailed assessment of the potential toxicity and allergenicity to humans of CRY1F, PAT and CP4 EPSPS proteins expressed in 1507xNK603 maize has been carried out. The conclusion obtained is that 1507xNK603 maize does not express any known toxic or allergenic proteins.

Furthermore, the nutritional assessment of 1507xNK603 maize has confirmed that 1507xNK603 maize is nutritionally equivalent to commercial maize.

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

9.7 Effects on animal health

As discussed in **Point D.9.6**, consumption of 1507xNK603 maize or any derived food, feed and processed products will result in no adverse consequences to human or animal health. Therefore, use of 1507xNK603 maize as feed and consumption of any food, feed and processed products derived from 1507xNK603 maize will result in no adverse consequences to animal health or the food/feed chain.

9.8 Effects on biogeochemical processes

Expression of CRY1F, PAT, and CP4 EPSPS proteins in 1507xNK603 maize will not cause any possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of 1507xNK603 maize and non-target organisms in the vicinity of 1507xNK603 maize.

9.9 Impacts of the specific cultivation, management and harvesting techniques

The specific cultivation, management and harvesting techniques used for 1507xNK603 maize are comparable to those used for other commercially available maize, with the exception of the herbicide regime and environmental monitoring plan proposed specifically for the cultivation of 1507xNK603 maize seed products. As a result, we cannot expect the occurrence of any possible immediate and/or delayed, direct and indirect environmental impacts arising from cultivation, management or harvesting techniques.

10. Potential interactions with the abiotic environment

Expression of CRY1F, PAT and CP4 EPSPS proteins in 1507xNK603 maize does not alter the natural interactions of maize plants with the abiotic environment. The natural ubiquity of the CRY1F, PAT and CP4 EPSPS proteins in the soil environment and the absence of adverse effects on soil biota means negligible possibility for adverse interactions with the abiotic environment and no adverse effects on the biogeochemical cycles.

11. Environmental monitoring plan

11.1 General

The proposal for an environmental monitoring plan for the placing on the market of 1507xNK603 maize has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

11.2 Interplay between environmental risk assessment and monitoring

The design of the environmental monitoring plan is based on the conclusions of the environmental risk assessment (e.r.a.) for the placing on the market of 1507xNK603 maize.

The e.r.a. has been carried out in accordance with Annex II of Directive 2001/18/EC and Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The overall conclusion obtained from the e.r.a. confirms that there are no identified adverse effects to human and animal health or the environment arising from 1507xNK603 maize. Therefore, the risk to human and animal health or the environment from

1507xNK603 maize and any derived products is as negligible as for any commercial maize and any derived products.

11.3 Case-specific GM plant monitoring

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

The e.r.a. concluded that there are no identified adverse effects to human and animal health or the environment arising from 1507xNK603 maize and that therefore, the risk to human and animal health or the environment from 1507xNK603 maize is as negligible as for any commercial maize.

However, the e.r.a. has indicated that there is a limited potential for development of resistance within the target pest population to CRY1F protein as expressed in cultivated 1507xNK603 maize seed products. Therefore, a case-specific monitoring plan is considered appropriate as part of the risk management strategy. It will ensure that cultivation of 1507xNK603 maize seed products poses negligible risk and that the efficacy of the CRY1F protein expressed in 1507xNK603 maize will be maintained, thereby sustaining the environmental benefits of the *Bacillus thuringiensis* (Bt) technology.

The case-specific monitoring plan for cultivation of 1507xNK603 maize seed products will consist of an insect resistance management plan (IRM plan).

11.4 General surveillance of the impact of the GM plant

The overall conclusion obtained from the e.r.a. for the placing on the market of 1507xNK603 maize is that there are no identified adverse effects to human and animal health or the environment arising from 1507xNK603 maize. Therefore, the risk to human and animal health or the environment from 1507xNK603 maize is as negligible as for any commercial maize.

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

As a result and in order to safeguard against any adverse effect on human health and the environment that was not anticipated in the e.r.a., the applicants will undertake to have a general surveillance plan for 1507xNK603 maize throughout the period of validity of the consent.

11.5 Reporting the results of monitoring

The applicants will inform the European Commission of any adverse effects arising from 1507xNK603 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

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

The PCR detection methods for 1507 and NK603 maize have already been submitted to JRC-IHCP (Joint Research Centre-Institute of Health and Consumer Protection) and have been validated by the Community Reference Laboratory (CRL). In addition, complementary information and samples of 1507xNK603 maize and non-GM maize have also been made available to the CRL.

E. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT AND/OR DERIVED PRODUCTS

1. History of previous releases of the GM plant notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier

(a) Notification number
B/FR/03.02.02

(b) Conclusions of post-release monitoring
The 1507xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507xNK603 maize.

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

(a) Notification number
B/ES/03/10

(b) Conclusions of post-release monitoring
The 1507xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507xNK603 maize.

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

(a) Notification number
B/FR/04.06.01
(b) Conclusions of post-release monitoring
Not applicable as this field trial was not carried out.
(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)
Not applicable as this field trial was not carried out.

(a) Notification number
B/ES/04/03
(b) Conclusions of post-release monitoring
The 1507xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507xNK603 maize.
(c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)
No adverse effects on human health and the environment observed.

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

(a) Release country
Bulgaria
(b) Authority overseeing the release
Biosafety Committee
(c) Release site
Tchavdarzi and Letniza
(d) Aim of the release
Regulatory trials
(e) Duration of the release
One season.
(f) Aim of post-releases monitoring
Control of potential volunteers.
(g) Duration of post-releases monitoring
One season.
(h) Conclusions of post-release monitoring
The 1507xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507xNK603 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
Canada.
(b) Authority overseeing the release
Not regulated.
(c) Release site
Multiple sites.
(d) Aim of the release
Research.
(e) Duration of the release
Not applicable.
(f) Aim of post-releases monitoring
Not applicable.
(g) Duration of post-releases monitoring
Not applicable.
(h) Conclusions of post-release monitoring
Not applicable. In any case, the 1507xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507xNK603 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
Chile.
(b) Authority overseeing the release
Ministry of Agriculture.
(c) Release site
Six sites.
(d) Aim of the release
Research.
(e) Duration of the release
One season.
(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 1507xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507xNK603 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
U.S.A.
(b) Authority overseeing the release
Not regulated.
(c) Release site
Multiple sites.
(d) Aim of the release
Research.
(e) Duration of the release
Not applicable.
(f) Aim of post-releases monitoring
Not applicable.
(g) Duration of post-releases monitoring
Not applicable.
(h) Conclusions of post-release monitoring
Not applicable. In any case, the 1507xNK603 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507xNK603 maize.
(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

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

(a) Status/process of approval

[To be provided]

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

[To be provided]

(c) EFSA opinion

[To be provided]

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

[To be provided]

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

[To be provided]

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

[To be provided]

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

[To be provided]