Application for authorisation to place on the market NK603 × T25 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-NL-2010-XX

Part II
Summary

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

The Netherlands.

b) Notification number

Not available at the time of submission.

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

The Monsanto development code for this genetically modified maize is NK603 × T25. Currently, no commercial name has been attributed to this product.

d) Date of acknowledgement of notification

Not available at the time of submission.

2. Applicant

a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

b) Address of applicant

Monsanto Europe S.A. Avenue de Tervuren 270-272 B-1150 Brussels BELGIUM	Monsanto Company 800 N. Lindbergh Boulevard St. Louis, Missouri 63167 US

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))

NK603 × T25 will be produced in other world areas and will be imported and used in the European Union by operators that have traditionally been involved in the commerce, transport, processing and use of maize and maize-derived products in the EU.

3. **Scope of the application**

   (X) GM plants for food use

   (X) Food containing or consisting of GM plants

   (X) Food produced from GM plants or containing ingredients produced from GM plants

   (X) GM plants for feed use

   (X) Feed containing or consisting of GM plants

   (X) Feed produced from GM plants

   (X) Import and processing (Part C of Directive 2001/18/EC)

   ( ) Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

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

Yes ( )	**No (X)**
If *ye*s, specify	

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

Yes ( )	**No (X)**
If *n*o, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC The protein expression, the composition, the safety, the agronomic and the phenotypic characteristics of NK603 × T25 have been studied at multiple locations in the US that cover a range of environmental conditions. The risk assessment presented in the NK603 × T25 application includes data collected from these field trials. A summary of the conclusions of the risk analysis that demonstrate the safety of NK603 × T25 to humans, animals and to the environment, have been presented in the respective sections throughout this summary.	

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

Yes ( )	**No (X)**
If *ye*s, specify	

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

Yes (X)	No ( )

If *yes*, specify

In the US, NK603 × T25 can be lawfully used for the full range of uses as traditional maize.

Regulatory submissions were made to countries that import significant quantities of maize from the US and that have regulatory approval processes in place. These include submissions to a number of countries and regulatory authorities, including Japan, Canada, The Philippines, Mexico, Columbia, Taiwan and Korea. The status of the pending regulatory reviews, which are currently in progress in numerous countries around the world, typically depend on the country and its local regulatory framework.

8. General description of the product

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

NK603 × T25 was obtained by traditional breeding of two parental lines, one derived from NK603 maize[1] and the other one derived from T25 maize[1].

NK603 was produced by means of the particle acceleration method and expresses the 5-enolpyruvylshikimate-3-phosphate synthase (*epsps*) derived from *Agrobacterium* sp. strain CP4 (*cp4 epsps*). Maize containing the NK603 insert expresses the CP4 EPSPS and CP4 EPSPS L214P[2] proteins conferring tolerance to glyphosate[3] to the plant.

T25 produces the phosphinothricin acetyltransferase protein from *Streptomyces viridochromogenes* (PAT), which confers tolerance to glufosinate-ammonium[4].

The ability to utilize glyphosate and glufosinate-ammonium in maize production offers farmers additional flexibility for broad-spectrum weed control.

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1 Hereafter referred to as NK603 and T25, respectively.

2 The CP4 EPSPS L214P protein is a form of CP4 EPSPS that contains a single amino acid substitution from leucine to proline at position 214. The CP4 EPSPS and CP4 EPSPS L214P proteins are structurally and functionally related to the EPSPS proteins that are present in all plants, including those used for human food.

3 Glyphosate is the active ingredient of Monsanto's Roundup® family of agricultural herbicides. Roundup is a registered trademark of Monsanto Technology LLC.

4 Glufosinate-ammonium is the active ingredient of Liberty® herbicide. Liberty is a registered trademark of Bayer CropScience.

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

The scope of the current application is for authorisation of NK603 × T25 in the EU for import, processing, and uses as any other maize, including food and feed use, according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed. The range of uses of this maize will be identical to the full range of equivalent uses of conventional maize. The scope of this application does not include the cultivation of NK603 × T25 in the EU.

c) Intended use of the product and types of users

NK603 × T25 will be used and traded in the EU in the same manner as current commercial maize and by the same operators currently involved in the trade and use of maize.

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

NK603 × T25 is substantially equivalent to conventional maize, except for its glyphosate and glufosinate-ammonium tolerance traits, which are traits of agronomic interest. This maize was shown to be as safe and nutritious as conventional maize. Therefore, NK603 × T25 and its derived products will be stored, packaged, transported, used and handled in the same manner as current commercial maize. No specific conditions or instructions are required for the placing on the market of NK603 × T25 for import, processing, and use as any other maize.

e) Any proposed packaging requirements

NK603 × T25 is substantially equivalent to conventional maize, except for its glyphosate and glufosinate-ammonium tolerance traits. Therefore, NK603 × T25 and derived products will be used in the same manner as other maize and no specific packaging is required (for labelling, please *see* question A.8.f).

f) A proposal for labelling in accordance with Articles 13 and 25 of Regulation (EC) 1829/2003. In the case of GMOs, food and/or feed containing, 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 Regulations (EC) No 1829/2003 and 1830/2003, the current labelling threshold of 0.9% will continue to be applied for the marketing of NK603 × T25 and derived products.

Operators shall be required to label products containing or consisting of NK603 × T25 with the words "genetically modified maize" or "contains genetically modified maize" and shall continue to declare the unique

identifier MON-ØØ6Ø3-6 × ACS-ZMØØ3-2 in the list of GMOs that have been used to constitute a mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from NK603 × T25 with the words "produced from genetically modified maize". In the case of products for which no list of ingredients exists, operators shall continue to ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using NK603 × T25 and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003, and that authorized foods and feeds shall be entered in the Community Register, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for NK603 × T25. Therefore, no further specific measures are to be taken by the applicant.

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)

The unique identifier for this genetically modified maize is MON-ØØ6Ø3-6 × ACS-ZMØØ3-2

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

NK603 × T25 is suitable for use throughout the EU.

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

Because this application is for consent to import and use NK603 × T25 as any other maize, not including the cultivation of NK603 × T25 in the EU, environmental release would more likely occur during import, storage and processing of NK603 × T25. However, modern methods of maize handling minimize losses of grain, so there is little chance of germination of spilt maize resulting in the development of mature NK603 × T25 plants in the EU. Moreover, in the case of incidental spillage, the establishment of volunteer plants would be unlikely, since maize cannot survive without human assistance and is not capable of surviving as a weed due to selection over centuries of cultivation. Maize is not documented as a source of volunteer plants in rotational crops, which results from the combination of absence of seed dormancy, poor seed survivability in soils, frost sensitivity of maize seedlings and soil

preparations prior to the planting of a subsequent crop (which includes destruction of any existing vegetation and soil cultivation). NK603 × T25 is shown to be substantially equivalent to conventional maize, except for the inherited glyphosate and glufosinate-ammonium tolerance and, therefore, is unlikely to pose any threat to the EU environment or to require special measures for its containment. Furthermore, maize volunteers can be easily controlled using currently available selective herbicides or by mechanical means. Therefore, no specific conditions are warranted or required for the placing on the market of NK603 × T25 for import, processing and use as any other maize.

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

1. Complete name

a) Family name Poaceae (formerly Gramineae)
b) Genus *Zea*
c) Species *Mays* (2n=20)
d) Subspecies Not applicable
e) Cultivar/breeding line NK603 × T25
f) Common name Maize; Corn

2. a) Information concerning reproduction

(i) Mode(s) of reproduction

Maize (Zea mays L.) is an annual, wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers. Self- and cross-pollination are generally possible, with frequencies of each normally determined by proximity and other physical influences on pollen transfer.

(ii) Specific factors affecting reproduction

Tasselling, silking, and pollination are the most critical stages of maize development and, consequently, grain yield may ultimately be greatly impacted by moisture and fertility stress.

(iii) Generation time

Maize is an annual crop with a cultural cycle ranging from as short as 60 to 70 days to as long as 43 to 48 weeks from seedling emergence to maturity.

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

Outcrossing with cultivated *Zea* varieties

In Europe, the potential for genetic transfer and exchange with other organisms is limited to other maize plants. Maize is wind pollinated, and the distance that viable pollen can travel depends on prevailing wind patterns, humidity, and temperature. All maize will interpollinate, except for certain popcorn varieties and hybrids that have one of the gametophyte factors (GaS, Ga, and ga allelic series on chromosome 4). Maize pollen, therefore, moves freely within an area, lands on silks of the same variety or different varieties, germinates almost immediately after pollination, and within 24 hours completes fertilisation. It has to be noted, however, that the scope of the current application does not include the cultivation of NK603 × T25 in the EU. Therefore, any outcrossing between NK603 × T25 and cultivated maize is highly unlikely.

Outcrossing with wild *Zea* species

Wild relatives of maize do not exist in Europe.

3. Survivability

a) Ability to form structures for survival or dormancy

Maize is an annual crop and seeds are the only survival structures. Natural regeneration from vegetative tissue is not known to occur.

b) Specific factors affecting survivability

Maize cannot survive without human assistance and is not capable of surviving as a weed due to past selection in its evolution. Volunteer maize is not found growing in fencerows, ditches or roadsides as a weed. Although maize seed from the previous crop year can over-winter in mild winter conditions and germinate the following year, it cannot persist as a weed. The appearance of "volunteer" maize in fields following a maize crop from the previous year is rare under European conditions. Maize volunteers are killed by frost or, in the unlikely event of their occurrence, are easily controlled by current agronomic practices including cultivation and the use of selective herbicides. Maize grain survival is dependent upon temperature, moisture of seed, genotype, husk protection and stage of development. Freezing temperatures have an adverse effect on maize seed germination and have been identified as being a major risk in seed maize production. Temperatures above 45 °C have also been reported as injurious to maize seed viability.

4. Dissemination

a) Ways and extent of dissemination

Dissemination of maize may occur by means of seed dispersal and pollen dispersal. Dispersal of the maize grain is highly restricted in domesticated maize due to the ear structure including husk enclosure. For maize pollen, the vast majority is deposited in the same field due to its large size (90 to 100 Mm) with smaller amounts of pollen deposited usually in a downwind direction.

b) Specific factors affecting dissemination

Dispersal of maize seeds does not occur naturally because of the structure of the ears of maize. Dissemination of isolated seeds may result from mechanical harvesting and transport as well as insect or wind damage, but this form of dissemination is highly infrequent. Genetic material can be disseminated by pollen dispersal, which is influenced by wind and weather conditions. Maize pollen is the largest of any pollen normally disseminated by wind from a comparably low level of elevation. Dispersal of maize pollen is limited by its large size and rapid settling rate.

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

Because of its many divergent types, maize is grown over a wide range of climatic conditions. The bulk of the maize is produced between latitudes 30° and 55°, with relatively little grown at latitudes higher than 47° latitude anywhere in the world. The greatest maize production occurs where the warmest month isotherms range between 21° and 27° C and the freeze-free season lasts 120 to 180 days. A summer rainfall of 15 cm

is approximately the lower limit for maize production without irrigation with no upper limit of rainfall for growing maize, although excess rainfall will decrease yields.

There are no wild relatives of 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

Maize is widely grown in the European Union. The most important areas of maize production in Europe include the Danube Basin, from southwest Germany to the Black Sea, along with southern France through the Po Valley of northern Italy.

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 nematode, insect and mite pests. Maize has a history of safe use for human food and animal feed.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

NK603 × T25 is produced by crossing maize plants of NK603 and T25 using traditional breeding methods. NK603 parental line was developed through particle acceleration method using a fragment of plasmid vector PV-ZMGT32. T25 parental line was developed through polyethylene-glycol mediated protoplasts transformation with purified plasmid vector pUC/Ac.

2. Nature and source of the vector used

NK603 × T25 results from traditional breeding of NK603 and T25 and no vector has been used to produce this maize.

NK603 was produced by a particle acceleration transformation method using a gel-isolated *Mlu* I fragment of plasmid vector PV-ZMGT32, containing a *5 enolpyruvylshikimate-3-phosphate synthase* (*epsps*) gene that was derived from the common soil bacterium *Agrobacterium sp.* strain CP4 (*cp4 epsps*).

T25 parental line was developed through polyethylene-glycol mediated protoplasts transformation with purified plasmid vector pUC/Ac. The pUC/Ac plasmid contains the *pat* gene isolated from *S. viridochromogenes*.

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

NK603 × T25 results from traditional breeding of NK603 and T25 and therefore, NK603 × T25 inherits the inserted DNA fragments from both parental maize lines.

The individual components and the function of the DNA sequences in NK603 and T25 are given in Tables 1 and 2.

Table 1. Summary of genetic elements inherited from NK603

Genetic Element[1]	Source	Size (kb)	Function (Reference)
		***CP4 EPSPS* gene cassette (1)**	
P-Ract1 / I-Ract1	*Oryza sativa*	1.4	5' region of the *rice actin* 1 gene containing the promoter, transcription start site and first intron.
TS-CTP2	*Arabidopsis thaliana*	0.2	DNA sequence for chloroplast transit peptide, isolated from *Arabidopsis thaliana* EPSPS, present to direct the CP4 EPSPS protein to the chloroplast, the site of aromatic amino acid synthesis.
CS-CP4 EPS PS	*Agrobacterium* sp. strain CP4	1.4	The DNA sequence for CP4 EPSPS, isolated from *Agrobacterium* sp. strain CP4 which imparts tolerance to glyphosate.
T-nos 3'	*Agrobacterium tumefaciens*	0.3	A 3' nontranslated region of the nopaline synthase gene from *Agrobacterium tumefaciens* T-DNA which ends transcription and directs polyadenylation of the mRNA.
		***CP4 EPSPS* gene cassette (2)**	
P-e35S	*Cauliflower mosaic virus*	0.6	The cauliflower mosaic virus (CaMV) promoter with the duplicated enhancer region.
I-Hsp70	*Zea mays L.*	0.8	Intron from the maize *hsp70* gene (heat-shock protein) present to stabilize the level of gene transcription.
TS-CTP 2	*Arabidopsis thaliana*	0.2	DNA sequence for chloroplast transit peptide, isolated from *Arabidopsis thaliana* EPSPS, present to direct the CP4 EPSPS protein to the chloroplast, the site of aromatic amino acid synthesis.
CS-CP4 EPS PS l214p	*Agrobacterium* sp. strain CP4	1.4	The DNA sequence for CP4 EPSPS L214P[2], isolated from *Agrobacterium* sp. Strain CP4 which imparts tolerance to glyphosate.
T-nos 3'	*Agrobacterium tumefaciens*	0.3	A 3' nontranslated region of the nopaline synthase gene from *Agrobacterium tumefaciens* T-DNA which ends transcription and directs polyadenylation of the mRNA.

[1] CS - Coding sequence; I - Intron; P - Promoter; T – Terminator; TS - Target sequence.

Table 2. Summary of genetic elements inherited from T25			
Genetic element[1]	**Source**	**Size (bp)**	**Function (Reference)**
BG-*bla*	pDH51	5	Part of the 5' sequence of the *β-lactamase* (*bla*) gene.
CVS	pDH51	611	Part of the cloning vector sequence needed for the maintenance in the *E. coli* host from the pUC/Ac plasmid.
T-*35S*	*Cauliflower mosaic virus*	206	Transcription stop signal (terminator) from the cauliflower mosaic virus (CaMV).
CS-*pat*	*Streptomyces viridochromogenes*	551	Synthetic[2] *pat* gene for herbicide tolerance and selectable marker. Source of the sequence is *Streptomyces viridochromogenes*.
P-*35S*	*Cauliflower mosaic virus*	529	35S high level constitutive expression promoter from the cauliflower mosaic virus (CaMV).
CVS	pDH51	1176	Part of the cloning vector sequence needed for the maintenance in the *E. coli* host from the pUC/Ac plasmid including the origin of replication (ori).
BG-*bla*	pDH51	665	Part of the 3' sequence of the *β-lactamase* (*bla*) gene sequence.
P-*35S*	*Cauliflower mosaic virus*	346	Nucleotide 80 until nucleotide 433 from the 35S high level constitutive expression promoter from the cauliflower mosaic virus (CaMV).

[1] BG – bacterial gene; CS - Coding sequence; CVS - Cloning vector sequence; P - Promoter; T - Terminator.

[2] Since the native *pat* gene has a high G:C content, which is atypical for plants, a modified nucleotide sequence was synthesized using codons preferred by plants. The nucleotide sequences of the native and synthetic gene share 70 % homology. The amino acid sequence of the enzyme encoded remains unchanged.

D. INFORMATION RELATING TO THE GM PLANT

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

NK603 × T25 is produced by crossing NK603 and T25 using traditional breeding methods and expresses:

- the CP4 EPSPS proteins which impart tolerance to glyphosate herbicide.
- the PAT protein which imparts tolerance to glufosinate-ammonium herbicide.

The use of NK603 × T25 would provide substantial benefits to growers by offering an easier weed management, increasing health of the plant and, subsequently yield, while at the same time reducing the risk from herbicide use to humans and the environment.

2. Information on the sequences actually inserted or deleted

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

The genome of NK603 × T25 contains two different inserts, one derived from NK603 and one derived from T25. The results of Southern blot analyses on NK603 and T25 indicate that each of these parental lines contain a single copy of the DNA of interest at a single insertion site.

The presence of these two inserts in NK603 × T25 was confirmed through Southern blot analyses.

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

NK603 × T25 is produced by crossing NK603 and T25. Since the inserts present in NK603 × T25 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in NK603 × T25. No deletion was intended in the development of the single parental lines. The analysis of the molecular structure at the insertion site of NK603 identified a 3 bp deletion and the analysis of the genomic organization of the T25 insertion site identified a 20 bp deletion. Further analyses revealed that there is no known function associated with the deleted regions.

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

The respective analyses of the segregation results for NK603 and T25 are consistent with single active sites of integration of the inserts into the nuclear genomic DNA. Southern blot analyses further demonstrate the stability of the inserted sequences of NK603 and T25, respectively, and their progeny. The traditionally bred NK603 × T25 contains both of the parental inserts and Southern analyses confirm that no detectable rearrangements of these inserts occurred.

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

Since the inserts present in NK603 × T25 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in NK603 × T25.

3. Information on the expression of the insert

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

NK603 × T25 produces three functional proteins, CP4 EPSPS, CP4 EPSPS L214P and PAT, providing tolerance to glyphosate and glufosinate-ammonium.

The levels of the CP4 EPSPS and PAT proteins in various tissues of NK603 × T25 collected from a field trial conducted in the US during 2008 were assessed by validated enzyme-linked immunosorbent assay (ELISA). Over-season leaf, root, forage grain and pollen tissues were collected from each replicated plot at five field sites.

ELISA results determined that the mean CP4 EPSPS[5] protein levels in NK603 × T25 across all US sites were 190 µg/g dwt in leaf, 48 µg/g dwt in root, 160 µg/g dwt in whole plant, 25 µg/g dwt in forage root, 53 µg/g dwt in forage, 8.1 µg/g dwt in grain, and 200 µg/g dwt in pollen. The CP4 EPSPS protein levels in NK603 × T25 tissues are comparable to the levels determined in NK603 tissues collected from the same trial.

ELISA results determined that the mean PAT protein levels in NK603 × T25 across all US sites were 48 µg/g dwt in leaf, 23 µg/g dwt in root, 63 µg/g dwt in OSWP-3, 21 µg/g dwt in forage root, 14 µg/g dwt in forage, and 0.59 µg/g dwt in grain. Pollen tissues were analyzed at levels below assay LOD, as expected. The PAT protein levels in NK603 × T25 tissues are comparable to the levels determined in the same tissues from the T25 tissues collected from the same trial.

b) Parts of the plant where the insert is expressed

The expression of the CP4 EPSPS and the PAT proteins occurs throughout the plant at appropriate times of plant development, as described in 3(a). The PAT protein was, however, not detected in pollen tissues analysed. In terms of food and feed safety assessment of NK603 × T25, grain and forage are the most relevant tissues.

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

a) Reproduction

Agronomic data collected from eight sites at field trials conducted in major US maize growing regions. In each of these assessments NK603 × T25 was compared to an appropriate conventional maize (control) which has a genetic background similar to NK603 × T25 but does not possess the *cp4 epsps* or the *pat* expression cassettes. In addition, multiple commercial maize varieties (reference) were employed to provide a range of baseline values that are common to the existing commercial maize varieties for each measured phenotypic, agronomic, and ecological interaction characteristic.

Results of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of NK603 × T25 compared to the conventional maize control. These results concur with those obtained previously for NK603 and T25.

[5] The values given represent the sum of both CP4 EPSPS and CP4 EPSPS L214P, as the ELISA analytical method recognizes both these proteins.

On the basis of the studies described above, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in NK603 × T25 and that NK603 × T25 is equivalent to conventional maize in its phenotypic and agronomic behaviour, except for the glyphosate and glufosinate-ammonium tolerance traits.

b) Dissemination

See Section D.4.a.

c) Survivability

See Section D.4.a.

d) Other differences

See Section D.4.a.

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

NK603 × T25 is produced by crossing NK603 and T25 parental lines using traditional breeding techniques. Thereby, each parental line passes on its inserted DNA sequence to the resulting NK603 × T25.

The respective analyses of the segregation results for NK603 and T25 are consistent with single active sites of integration of the inserts into the nuclear genomic DNA. Southern blot analyses further demonstrate the stability of the inserted sequences of NK603 and T25, respectively, and their progeny.

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

a) Plant to bacteria gene transfer

None of the genetic elements in NK603 and T25 has a genetic transfer function. Therefore, no changes are expected in the ability of these maize or NK603 × T25 to transfer genetic material to bacteria

b) Plant to plant gene transfer

Based on the observation that reproductive morphology in NK603, T25 and NK603 × T25 is unchanged compared to conventional maize, the out-crossing frequency to other maize or to wild relatives (which are not present in the EU) would be unlikely to be different for NK603 × T25 when compared to NK603 and T25, or when compared to other conventional maize.

However, the scope of the current application does not include the cultivation of NK603 × T25 varieties in the EU.

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

7.1 Comparative assessment

Choice of the comparator

NK603 × T25 was compared to a conventional maize variety with background genetics similar to NK603 × T25, as well as with other commercially available maize.

7.2 Production of material for comparative assessment

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

Compositional analyses were conducted on NK603 × T25 and conventional control maize grain and forage grown at five field sites in major maize-growing areas of the US during the 2008 field season. Three to four commercially available maize varieties were grown also at each of the same field sites to provide a total of 19 different reference substances representative for their respective growing regions. At each field site, the test, control and reference were planted in a randomized complete block design with three replicates per block. All the plants were grown under normal agronomic field conditions for their respective geographic regions. The test substance NK603 × T25 was treated with glyphosate and glufosinate-ammonium herbicides.

NK603 × T25 was found to be compositionally equivalent to conventional maize and thus as safe as conventional maize for uses in food and feed applications.

b) the baseline used for consideration of natural variations

Levels of the components in grain and forage of NK603 × T25 were compared to the corresponding levels in the control conventional comparator, which has similar genetic background to NK603 × T25. Reference were grown in the same field locations and under the same conditions as the test and control to provide data for the development of a 99% tolerance interval for each analyte analyzed. Where statistical differences occurred, the measured analyte was compared to a confidence interval developed from these references. Finally differences were also compared to ILSI ranges and ranges reported in literature.

7.3 Selection of material and compounds for analysis

The key nutrients and other nutritionally important components that were selected for analysis in the compositional studies were chosen on the basis of internationally accepted guidance provided by the OECD on compositional considerations for new varieties of maize.

7.4 Agronomic traits

Field trials with NK603 × T25 were conducted and the set of agronomic observations supports the conclusion that from an agronomic and phenotypic (morphological) point of view, NK603 × T25 is equivalent to traditional maize, except for the inherited glyphosate and glufosinate-ammonium tolerance traits (*see* Section D.4.).

7.5 Product specification

NK603 × T25 will be imported into the EU in mixed shipments of maize products, produced in other world areas, for use by operators that have traditionally been involved in the commerce, processing and use of maize and maize derived products in the EU.

NK603 × T25 is developed by traditional breeding of NK603 and T25 and contains both inserts in combination. Therefore, NK603 × T25 is detectable using either the event-specific PCR method for detecting the introduced DNA present in NK603 or the equivalent method for T25. As for all plants in which one or more events are combined by traditional breeding, the unambiguous detection of NK603 × T25 in mixed consignments of seed will require single seeds to be subjected to detection methods for both NK603 and T25, and to test positive for both.

7.6 Effect of processing

NK603 × T25 has been shown to be substantially equivalent to conventional maize, except for the expressed CP4 EPSPS and PAT proteins. Therefore, it is highly likely that NK603 × T25 and its derived food and feed products are not different from the equivalent foods and feeds originating from conventional maize.

7.7 Anticipated intake/extent of use

There are no anticipated changes in the intake and/or extent of use of maize or derived products for use as or in food or feed as a result of the addition of NK603 × T25 to the maize supply.

NK603 × T25 is not expected to affect current usage patterns of maize, but to replace a portion of the commodity seed from current maize varieties such that their intake or use will represent some fraction of the total products derived from maize.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

NK603 × T25 is produced by traditional breeding of NK603 and T25. Both of the introduced traits from the parental lines are inherited by the NK603 × T25. This results in the combined expression of the CP4 EPSPS and PAT proteins in the same plant.

The conclusion of safety to humans of the CP4 EPSPS and PAT proteins was based upon the following considerations:

- Those proteins have a demonstrated history of safe use;
- They have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- They do not exert any acute toxicity to mammals.

In addition, their low concentration in tissues that are consumed and their rapid digestibility in simulated digestive fluids provide additional assurance for their safety.

It is therefore possible to conclude that the CP4 EPSPS and PAT proteins are safe and pose no concerns for humans, animals and the environment.

7.8.2 Testing of new constituents other than proteins

Maize has a long history of safe use and consumption around the world. Compositional analysis confirmed that NK603 × T25 is compositionally equivalent to conventional maize. Therefore, no testing of any constituent other than the introduced protein is required.

7.8.3 Information on natural food and feed constituents

Maize is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world. No particular natural constituents of maize are considered to be of significant concern to require additional information or further risk assessment.

NK603 × T25 was shown to be substantially equivalent to conventional maize, except for the introduced herbicide tolerance traits, and as safe and as nutritious as any other, commercially available maize.

7.8.4 Testing of the whole GM food/feed

The compositional equivalence of NK603 × T25 grain and forage to that of conventional maize has been established by compositional analysis. Additionally, the wholesomeness of NK603 × T25 grain has been confirmed by a repeat-dose animal feeding study in broiler chickens fed diets containing maize meal produced from NK603 × T25. These studies confirm the absence of any toxic effects associated to the inherited proteins and the absence of any unanticipated or pleiotropic effects linked to the genetic modification. There was no evidence of any adverse effects on human or animal health.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The assessment of the allergenic potential of the CP4 EPSPS and PAT proteins compares the biochemical characteristics of these proteins to characteristics of known allergens, according to the recommendations of Codex Alimentarius Commission.

It is unlikely that the CP4 EPSPS and the PAT proteins will cause allergenic concerns due to the following considerations:

- They were obtained from non-allergenic sources (*Agrobacterium* for CP4 EPSPS and *Streptomyces viridochromogenes* for PAT)
- They lack structural similarity to known allergens, as demonstrated by bioinformatics analyses
- They are rapidly digested in simulated gastric fluid
- They constitute a very small portion of the total protein present in NK603 × T25 grain.

Taken together, it can be concluded that the allergenic potential of the CP4 EPSPS and PAT proteins is negligible and therefore, these proteins do not pose a significant allergenic risk.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

NK603 × T25 is produced by traditional breeding of NK603 and T25. Both of the introduced traits from the parental lines are inherited by NK603 × T25. The assessment of a potential allergenicity of each of the parental lines against a conventional maize has been previously performed. Results of these assessments support the conclusion that both NK603 and T25 are comparable to conventional maize in terms of allergenicity potential.

As the CP4 EPSPS and PAT proteins expressed in NK603 × T25 are not allergenic and as there are no new genetic modifications in NK603 × T25, there are no reasons to believe that the expression of these proteins in NK603 × T25 would alter its endogenous allergen content compared to commercial maize.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The inherited traits in NK603 × T25 are of agronomic interest, and are not intended to change any nutritional aspects of this maize. The presence of these traits is not expected to alter patterns or volumes of maize consumption.

In addition to the extensive compositional analyses which demonstrated the substantial equivalence of NK603 × T25 to conventional maize (except for the inherited traits), a confirmatory feed performance study was conducted in rapidly growing broiler chickens which were fed

NK603 × T25 grain.

Therefore, no nutritional imbalances are expected as a result of the use of NK603 × T25 for food or feed or processing.

7.10.2 Nutritional assessment of GM feed

The dietary safety of the respective proteins within the maize matrix was further confirmed by an animal feeding study in broiler chickens using diets containing NK603 × T25 grain. This study confirms the absence of any toxic effects associated to the introduced proteins and the absence of any unanticipated or pleiotropic effects linked to the genetic modification. There was no evidence of any adverse effects on human or animal health.

7.11 Post-market monitoring of GM food/feed

There are no intrinsic hazards related to NK603 × T25 as no signs of adverse or unanticipated effects have been observed in a number of safety assessment studies.

The pre-market risk characterization for food and feed use of NK603 × T25 demonstrates that the risks of consumption of NK603 × T25 or its derived products are consistently negligible and no different from the risks associated with the consumption of conventional maize. As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of maize for food and feed is not considered appropriate.

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

Not applicable since NK603 × T25 inherited two traits, which confer tolerance to glyphosate and glufosinate-ammonium herbicides. There are no target organisms for the CP4 EPSPS and PAT proteins.

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

This application under Regulation (EC) No 1829/2003 is for the authorisation of NK603 × T25 for import and all uses as for any other maize but excluding the cultivation of NK603 × T25 in the EU. As the scope of this application under Regulation (EC) No 1829/2003 includes the import and use of the viable GMO, an environmental risk assessment in accordance with the principles of Annex II to Directive 2001/18/EC is included in this section.

9.1 Persistence and invasiveness

Based on centuries of experience with conventional, domesticated maize in Europe, there is no potential for maize to be invasive of natural habitats or persist in the environment without human intervention.

NK603 × T25 is substantially equivalent to conventional maize, except for the inherited tolerance to glyphosate and glufosinate-ammonium traits. Field trial data demonstrated that this maize has not been altered in its phenotypic, agronomic, reproductive, survival and dissemination characteristics when compared to conventional maize. In the event NK603 × T25 grain was spilt in the environment, its introduced trait would have negligible consequences for the environment.

Therefore, the risk to the environment from NK603 × T25 through increased persistence and invasiveness of this maize is negligible.

9.2 Selective advantage or disadvantage

NK603 × T25 is substantially equivalent to conventional maize, except for the inherited tolerance to glyphosate and glufosinate-ammonium traits.

Compared with conventional maize, the presence of the herbicide-tolerance traits would only confer a selective advantage where weed control was performed using only glyphosate and/or glufosinate-ammonium, and if no other, more important factors limiting the survival of maize in the receiving environment were present. In practice, however, this advantage would be of short duration and of limited consequence because of the poor survival characteristics of maize under most European conditions

Therefore, the likelihood is negligible for the inherited traits in NK603 × T25 to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

9.3 Potential for gene transfer

There is no potential for gene transfer from NK603 × T25 to wild plant species in the EU (as not present) while there is negligible likelihood for gene transfer from NK603 × T25 to other maize crops since this application is not for consent to cultivate NK603 × T25 in the EU.

In the case that an introduced gene outcrossed to other maize, its transfer would only confer a selective advantage under specific conditions (*i.e.* applications of glyphosate- and/or glufosinate-ammonium herbicide), as discussed in Section 9.2.

Therefore, gene transfer from NK603 × T25 to other maize crops is not considered to constitute an adverse environmental effect in itself and the environmental risk posed by this potential transfer to other maize crops, and hence by NK603 × T25, is negligible.

9.4 Interactions between the GM plant and target organisms

NK603 × T25 inherited the glyphosate and glufosinate-amonium-tolerance traits from NK603 and T25. As such, NK603 × T25 has no target organisms with which to interact either directly or indirectly. Thus, no characteristics could be identified which may case an adverse environmental effect.

9.5 Interactions of the GM plant with non-target organisms

Given the scope of the current application, which does not include the cultivation of NK603 × T25 in the EU, the likelihood for direct or indirect interactions of this maize with non-target organisms is considered to be negligible.

In addition, even if incidental spillage of NK603 × T25 grain during import, storage, transport or use would lead to the short survival of NK603 × T25 plants, the newly produced proteins in NK603 × T25, CP4 EPSPS and PAT present a negligible hazard to NTOs. As a consequence, there is negligible risk for harmful effects of NK603 × T25 on non-target organisms, either through direct or indirect interactions with this maize or through contact with the newly expressed protein.

Furthermore, no adverse effects were observed in field trials conducted since 2008 across a broad geographic range of environments involving NK603 × T25.

9.6 Effects on human health

The likelihood for any adverse effects occurring in humans as a result of their contact with NK603 × T25 is no different from that of conventional maize, as NK603 × T25 contains the CP4 EPSPS and PAT proteins, which have negligible potential to cause any toxic or allergenic effects in humans.

NK603 × T25 is substantially equivalent to conventional maize, except for the inherited glyphosate and glufosinate-ammonium tolerance traits. These traits of agronomical interest are imparted by the production of the CP4 EPSPS and the PAT proteins, for which safety has been extensively investigated. Furthermore, the potential for the CP4 EPSPS and PAT proteins to interact when expressed in combination in NK603 × T25 is negligible.

Therefore, the risk of changes in the occupational health aspects of this maize is negligible.

9.7 Effects on animal health

The likelihood for any adverse effects occurring in animals fed on NK603 × T25 is negligible. NK603 × T25 contains the CP4 EPSPS and PAT proteins which have negligible potential to cause any toxic or allergenic effects in animals.

NK603 × T25 is substantially equivalent to conventional maize as well as to maize varieties in commerce, except for the inherited glyphosate and glufosinate-ammonium tolerance traits imparted by the CP4 EPSPS and PAT proteins, respectively. As previously discussed, the CP4 EPSPS and PAT proteins have a history of safe use and its safety has been extensively investigated when assessed individually and in combination in NK603 × T25.

In conclusion, the NK603 × T25 is expected to pose no meaningful health risks to farm animals that would consume it. Therefore, the risk of NK603 × T25 for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

This application is limited to import of NK603 × T25 grain into the EU and use thereof as any other maize commodity grain. As such, exposure to the environment will be rare, occurring only through incidental release during shipment and handling. As for conventional maize, spillage of NK603 × T25 during transport or storage of grain could cause some grain to fall to the ground. Although such grain could eventually germinate if the local soil and environmental conditions are favourable, this maize is a poor competitor and cannot persist as a weed. Environmental conditions at the sites of handling are, however, unlikely to be conducive to germination, growth and reproduction of maize seed that is incidentally released.

Maize production in general is known to have indirect impacts on biogeochemical processes through tillage, fertilizer application, and establishment of a monoculture in a defined area. As NK603 × T25 was shown to be compositionally equivalent to conventional maize with no biologically meaningful differences in agronomic and phenotypic characteristics, except for the inherited traits, there is no evidence that this maize would be any different from conventional maize regarding its influence on biogeochemical processes and nutrient levels in the soil. Furthermore, any indirect interactions of the GMO with other organisms in the vicinity of an incidental release of the grain are not likely to cause hazardous effects on the biogeochemical processes in the soil. The CP4 EPSPS protein in NK603 × T25 belongs to the safe class of EPSP synthases which are ubiquitous in the environment. Therefore, decomposers and interacting detritivores have historically been exposed to a diversity of naturally occurring EPSPS proteins and there is no *a priori* reason to suspect that any EPSPS protein may have adverse effects on the decomposition function. Animals have been naturally exposed to the PAT protein, originally obtained from *Streptomyces viridochromogenes* strain Tü494, a common soil organism, which has no

known toxic or pathogenic potential.

In conclusion, as for conventional maize, it is highly unlikely that there would be any significant immediate or delayed adverse effects from NK603 × T25 on the biogeochemical processes in the soil.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable. This application is for consent to import NK603 × T25 in the EU and for the use of this maize as any other maize, excluding the cultivation of NK603 × T25 in the EU.

10. Potential interactions with the abiotic environment

NK603 × T25 carries two traits of agronomic interest: tolerance to glyphosate and glufosinate-ammonium. As NK603 × T25 was shown to be substantially equivalent to conventional maize (with the exception of the inherited traits, imparted by the expression of the CP4 EPSPS and PAT proteins), with respect to its composition, phenotypic and agronomic characteristics, there is no evidence that this maize would be any different from conventional maize with regard to its baseline interactions with the abiotic environment.

Although the CP4 EPSPS and PAT are introduced proteins in maize, they already have a safe history of use and have no known negative interactions with the abiotic environment. The CP4 EPSPS protein is innocuous and belongs to a large class of EPSPS enzymes that are ubiquitous in nature. The family of EPSPS proteins has no known negative interactions with the abiotic environment. The *Streptomyces* species from which the PAT protein is derived are common soil microbes, widespread in nature and found all over the world.

Therefore, no deleterious impact of NK603 × T25 on the abiotic environment is expected to result from the import of NK603 × T25 grain into the EU and use thereof as any other maize grain.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants and if the applicant has clearly shown that environmental exposure is absent or will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment)

11.1 General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003, a environmental monitoring plan in accordance to Annex VII of Directive 2001/18/EC is included.

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (ERA) of NK603 × T25 was undertaken in the context of the scope of the application, that is, for import, processing and all uses of NK603 × T25 as any other maize, but not including the cultivation of NK603 × T25 in the EU. Analysis of the characteristics of NK603 × T25 has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the proposed use of NK603 × T25 in the EU is consistently negligible. Therefore, the overall environmental risk posed by this genetically modified higher plant is negligible, and no specific strategies for risk management and no case-specific post-market monitoring actions are considered required.

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

As the overall environmental risk posed by this genetically modified higher plant is negligible, and as the conclusions of the environmental risk assessment are derived from the results of scientific studies, rather than major assumptions, no case-specific post-market monitoring actions, typically aimed at testing assumptions made in this assessment, would be warranted or required.

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

Any potential adverse effects of NK603 × T25 on human health and the environment, which were not anticipated in the ERA, can be addressed under the general surveillance. General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified (GM) crop in its receiving environment.

In order to allow detection of the broadest possible scope of unanticipated adverse effects, general surveillance is performed by either selected, existing networks, or by specific company stewardship programmes, or by a combination of both. The consent holder will ensure that appropriate technical information on NK603 × T25 and relevant legislation will be available for the relevant networks, in addition to further relevant information from a number of sources, including industry and government websites, official registers and government publications.

Following the approval of this maize in the EU, the consent holder will approach key stakeholders and key networks of stakeholders of the product (including international grain traders, maize processors and users of maize for animal feed) and inform them that the product has been authorised. The consent holder will request key stakeholders and networks for their participation in the general surveillance of the placing

on the market of this maize, in accordance with the provisions of Directive 2001/18/EC and the consent. Key stakeholders and networks will be requested to be aware of their use of this maize and to inform the consent holder in case of potential occurrence of any unanticipated adverse effects to health or the environment, which they might attribute to the import or use of this product. Appropriate technical information on NK603 × T25 will be provided to them.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with available baseline information. Relevant baseline information will reflect prevalent use practices and the associated impact of these practices on the environment. Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of NK603 × T25 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

11.5 Reporting the results of monitoring

Monsanto will submit an annual General Surveillance Report containing information obtained from participating networks, and/or in case of an effect that was confirmed. If information that confirms an adverse effect which alters the existing risk assessment becomes available, Monsanto will submit a Report, consisting of a scientific evaluation of the potential adverse effect and a conclusion on the safety of the product. The report will also include, where appropriate, the measures that were taken to ensure the safety of human or livestock health and/or the environment.

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

As NK603 × T25 is the result of a traditional cross of NK603 and T25, it contains both inserts in combination. Therefore, NK603 × T25 is detectable using either the event-specific PCR method for detecting the introduced DNA present in NK603 or the equivalent method for T25. However, as for all plants in which one or more events are combined by traditional breeding, the unambiguous detection of NK603 × T25 in mixed consignments of grain will require single maize grain to be subjected to detection methods for both NK603 and T25, and to test positive for both.

A NK603 and T25-specific PCR-based assays allowing the identification and quantification of NK603 and T25, respectively, have been validated by the Joint Research Centre (JRC), acting as the Community Reference Laboratory (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 There is no history of release of NK603 × T25 in the EU.
b) Conclusions of post-release monitoring Not applicable.
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.

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

a) Release country NK603 × T25 has been field tested in the US since 2007.
b) Authority overseeing the release NK603 and T25 are USDA deregulated and were tested extensively at multiple locations in the field. NK603 x T25 maize is not regulated in the US.
c) Release site In the major US maize growing states (Iowa, Kansas, Illinois and Arkansas).
d) Aim of the release Regulatory trials, efficacy, yield, breeding, product development.
e) Duration of the release 6 months.
f) Aim of post-releases monitoring Post-release monitoring was not required and no unanticipated effects have been observed during field release of NK603 x T25.
g) Duration of post-releases monitoring See E.2.f.

h) Conclusions of post-release monitoring

See E.2.f.

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

Field-testing provided no evidence that NK603 × T25 or derived products would be the cause of any adverse effects to human health or to the environment.

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

The JRC websites (http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm) and the EFSA website (http://www.efsa.europa.eu/) provide publicly accessible links to up-to-date databases on the regulatory progress of applications under Regulation (EC) No 1829/2003, including the Monsanto application for NK603 × T25.

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

A notification for NK603 × T25 according to Directive 2001/18/EC has not been submitted by Monsanto Company.

c) EFSA opinion

No EFSA opinion is available at the time of submission of this application.

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

The Commission Register can be seen in the at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

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

Information on detection methods is posted at http://gmo-crl.jrc.ec.europa.eu/default.htm

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

The publicly accessible portal site of the Biosafety Clearing-House (BCH) can be found at http://bch.cbd.int/ /

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

EFSA provides a link to the publicly accessible summary of this application under Regulation (EC) No 1829/2003 at http://www.efsa.europa.eu/.