Application for renewal of authorization of Bt11 maize and derived products notified according to Articles 11 and 23 of Regulation (EC) No 1829/2003 on genetically modified food and feed.

Part II Summary

APPENDIX 11

Summary of applications for genetically modified plants and/or derived food and feed

Application for renewal of authorization of Bt11 maize and derived products notified according to Article 8 and 20 of Regulation (EC) No 1829/2003 on genetically modified food and feed

Summary of applications for genetically modified plants and/or derived food and feed

A. GENERAL INFORMATION

1. Details of application

a) Member State of application	
b) Application number	
c) Name of the product (commercial and other names)	Bt11 maize; SYN-BTØ11-1
d) Date of acknowledgement of valid application	Not available at the time of submission

2. Applicant

a) Name of applicant Syngenta Seeds S.A.S. on behalf of Syngenta Crop Protection AG, Basel Switzerland
b) Address of applicant Syngenta Seeds S.A.S. 12, chemin de l'Hobit BP 27 F-31790 Saint-Sauveur France On behalf of Syngenta Crop Protection AG Schwarzwaldallee 215 CH-4058 Basel - SWITZERLAND
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)) Bt11 maize and derived products will be imported and used as any other maize in the EU by operators currently involved in these processes.

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)?

Yes ☐	No ☒
If *yes*, specify	

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

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

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 ☐

If *yes*, specify

C/GB/96/M4/1: notification for import and use of grain of Bt11 maize in the European Union according to Directive 90/220/EEC. Approved by Commission Decision 98/292/EC.

Notification pursuant to article 5 of regulation (EC) n° 258/97 of Food and food ingredient products derived from the original transformant Bt11 crossed with the Northrup King Company inbred line #2044 (maize), as well as from any inbred and hybrid lines derived from it and containing the introduced gene. (Date 06/02/98)

C(2004) 1865: notification for the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97. Approved by Commission Decision 2004/657/EC.

C/F/96.05.10 notification submitted under Directive 2001/18/EC for the placing on the market of insect resistant genetically modified maize Bt11, for cultivation, feed and industrial processing. Dossier still under evaluation. EFSA opinion http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/922.html

Additionally, Bt11 maize has been entered on the community register of GM Food and Feed as an Existing product under Article 8 and 20 of Regulation (EC) No 1829/2003. .

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

Yes ☒	No ☐

If *yes*, specify

Bt11 maize is approved for cultivation and food/feed uses in the USA, Canada, Argentina, South Africa, Uruguay, Japan and the Philippines.

It is approved for human food and animal feed use in Switzerland, Russia, Korea and China, and for food use in Australia, New Zealand and Taiwan.

8. General description of the product

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

Genetically modified maize, that is progeny from traditional crosses of traditionally bred maize with genetically modified maize line Bt11 that contains:

a synthetic version of the *cryIAb* gene derived from *Bacillus thuringiensis* subsp. *kurstaki* strain HD1 under the control of a 35S promoter from Cauliflower Mosaic Virus, and IVS 6 intron from the maize alcohol dehydrogenase gene and the nopaline synthase terminator sequence of *Agrobacterium tumefaciens*, and

a synthetic version of the *pat* gene derived from *Streptomyces viridochromogenes* under the control of a 35S promoter from Cauliflower Mosaic Virus, an IVS intron from the maize alcohol dehydrogenase gene and the nopaline synthase terminator sequence of *Agrobacterium tumefaciens*.

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

1.) Food and food ingredient products derived from the original transformant Bt11 crossed with the Northrup King Company inbred line #2044 (maize), as well as from any inbred and hybrid lines derived from it and containing the introduced genes

notified as existing food falling within the scope of Article 8(1)(a) of Regulation (EC) No 1829/2003, which is produced from a genetically modified organism (GMO) and which has been placed on the market in accordance with Art. 5 of Regulation (EC) No 258/97, notification forwarded to Member States on 06/02/1998, opinion on substantial equivalence by the UK Advisory Committee on Novel Foods and Processes from 14/02/1997

2.) Food additives produced from Bt11 maize

notified as existing food additives within the meaning of Article 8 (1)(b) of Regulation (EC) 1829/2003, authorised under Directive 89/107/EEC and complying with the relevant specifications laid down under this legislation.

3.) Feed consisting of and/or containing Bt11 maize to be used as any other maize grain but not for cultivation

notified as existing feed falling within the scope of Article 20(1)(a) of Regulation (EC) No 1829/2003, which consists of and/or contains a genetically modified organism (GMO) and which has been placed on the market in accordance with Part C to the Directives 90/220/EEC, Decision to grant consent: 98/292/EEC, Official Journal L 131, p. 28 - 29 - 05/05/1998, URL: http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31998D0292:EN:HTML

4.) Feed materials produced from Bt11 maize

notified as existing feed falling within the scope of Article 20(1)(b) of Regulation (EC) No 1829/2003, namely as feed materials which are produced from a genetically modified organism (GMO).

5.) Feed additives produced from Bt11 maize

notified as existing feed falling within the scope of Article 20(1)(b) of Regulation (EC) No 1829/2003, namely as feed additives subject to Directive 70/524/EEC which are produced from a genetically modified organism (GMO).

6) Food and food ingredients produced from Bt11 sweet maize.

Notified under document number C(2004) 1865, as Novel Food or as a Novel Food Ingredient under Regulation (EC) No 258/97, Article 7. Authorised by Commission Decision of 19 May 2004

The application also covers the import and industrial processing of Bt11 maize for all potential uses as any other maize.

The scope covers any progeny derived from crosses of the product with any traditionally bred maize imported into the European Community

c) Intended use of the product and types of users

There are no differences when Bt11 maize is compared to conventional maize except for its protection against certain Lepidoptera and the tolerance to glufosinate ammonium herbicides. Bt11 maize has been shown to be substantially equivalent, with the exception of the introduced traits, to maize currently in commerce and, therefore, the proposed uses and type of users for grain and maize products derived from Bt11 maize are identical to those for grain and maize products derived from conventional maize.

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

Bt11 maize has been shown to be substantially equivalent, with the exception of the introduced traits, to maize currently in commerce and, therefore, no specific instructions and/or recommendations for use, storage and handling are proposed.

e) Any proposed packaging requirements

Bt11 maize has been shown to be substantially equivalent, with the exception of the introduced traits, to maize currently in commerce and, therefore, it will be used in the same manner as other maize and no specific packaging is required.

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

Bt11 maize grain will be labelled as “genetically modified maize” and products derived from it will be labelled as “containing (or produced from) genetically modified maize”. Since Bt11 maize and products derived from it are not different from those of its conventional counterpart, no additional labelling is required.

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)

A unique identifier for Bt11 maize has been assigned in accordance with Commission Regulation (EC) 65/2004: SYN-BTØ11-1

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

Not applicable. Bt11 maize is suitable for use as any other maize under the terms of the authorisation applied for.

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

The characteristics of Bt11 maize and products derived from it are not different from those of its conventional counterpart. Bt11 maize has been shown to be as safe and as wholesome as conventional varieties of maize. Any unintended releases or misuse can be managed in the same way as any conventional maize and, therefore, the measures for waste disposal and treatment of Bt11 maize and derived products are the same as those for other maize products.

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

1. Complete name

a) Family name	Poaceae (formally Gramineae)
b) Genus	*Zea*
c) Species	*mays* (2n=20)
d) Subspecies	*mays*
e) Cultivar/breeding line or strain	A Syngenta proprietary line of maize
f) Common name:	Maize; Corn.

2 a. Information concerning reproduction

(i) Mode(s) of reproduction

Sexual reproduction:
Zea mays is an allogamous plant that propagates through seed produced predominantly by cross-pollination and depends mainly on wind borne cross-fertilisation. *Z. mays* is a plant with protandrous inflorescence; however, decades of conventional selection and improvement have produced varieties of maize with protogynous traits. *Z. mays* has staminate flowers in the tassels and pistillate flowers on the ear shoots.

Asexual reproduction:

There is no asexually reproductive maize.

(ii) Specific factors affecting reproduction

The key critical stages of maize reproduction are tasselling, silking, pollination and fertilization and, consequently, temperature, moisture and fertility will affect reproduction.

Most maize varieties are protoandrous so pollen shedding precedes silk emergence by up to five days within a given variety. Pollen dispersal is limited by several factors, including large size (0.1 mm diameter), rapid settling rate and short viability. Greater than 98% of the pollen settles to the ground within a maximum distance of 25-50 meters of its source. Shed pollen typically remains viable for 10 to 30 minutes, but may remain viable longer under refrigerated and humid conditions.

(iii) Generation time

Maize is an annual crop. The generation time from sowing to harvesting varies according to the genetic background and the climate; it can range 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

Other cultivated plant species: the sexual compatibility of maize with other cultivated plant species is limited to *Zea* species.

Wild plant species: no wild relatives of maize are present in Europe. Therefore, maize cannot exchange genes with any other species in the EU.

3. Survivability

a) Ability to form structures for survival or dormancy

Maize is an annual crop. Seeds are the only survival structures; they cannot be dispersed without mechanical disruption of the cobs, and show little or no dormancy. Natural regeneration from vegetative tissue is not known to occur.

b) Specific factors affecting survivability

Survival of maize is dependent upon temperature, seed moisture, genotype, husk protection and stage of development. Maize cannot persist as a weed. Maize seed can only survive under a narrow range of climatic conditions. Volunteers are killed by frost or easily controlled by current agronomic practices including cultivation and the use of selective herbicides. Maize is incapable of sustained reproduction outside domestic cultivation and is non-invasive of natural habitats

4. Dissemination

a) Ways and extent of dissemination

Maize dissemination can only be accomplished through seed dispersal. Seed dispersal does not occur naturally due to the structure of the ear

b) Specific factors affecting dissemination

Maize has a polystichous (arranged in many rows) female inflorescence (flower), called the ear, on a stiff central spike (cob) enclosed in husks (modified leaves). Because of the structure of the ears, seed dispersal of individual kernels does not occur naturally. Maize is non-invasive of natural habitats

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

Maize, which has very diverse morphological and physiological traits, is grown on approximately 147 million hectares worldwide. It is distributed over a wide range of conditions: from 56º N Lat to 40º S Lat, below sea level of the Caspian plains up to 3000m in the Andes Mountains and from semi-arid regions to arid regions. The greatest maize production occurs where the warmest month isotherms range between 21º and 27º C and the freeze-free season lasts 120-180 days. 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 believed to have been introduced into Europe in the 15th century by Columbus and is widely grown in the European Union.

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 to competition from surrounding weeds. Maize is extensively cultivated and has a history of safe use for human food and animal feed. No significant native toxins are reported to be associated with the genus *Zea.*

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

Bt11 maize was generated by transformation of *Zea mays* protoplasts. The protoplasts were transformed with the larger DNA fragment obtained by a restriction digest of the plasmid pZO1502 with the enzyme *Not*I. Regenerated plants were backcrossed to a selected line resulting in a plant line called Bt11 maize.

2. Nature and source of the vector used

The vector used for transformation was pZO1502. This is a derivative of pUC18. The bacterium *Escherichia coli* is the common host of the pUC18 plasmid.

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

The *Not*I restriction fragment intended for insertion contains the *cry1ab* and the *pat* genes, including the necessary regulatory components to drive their expression in maize but does not contain the ampicilline resistance gene.

The source, size and function of each constituent are listed below.

Vector component	Approx Size (kb)	Source	Intended function
35Spromo ter	0.514	*cauliflower mosaic virus 35S* gene	Promoter of high level constitutive gene expression in plant tissues
IVS6 enhancer	0.472	intron from maize *alcohol dehydrogenase 1S* gene	regulatory sequence that enhances *cryIAb* gene expression in the plant
cry1ab gene	1.845	*Bacillus thuringiensis* subsp. *kurstaki* strain HD-1	encodes a truncated version of the full-length *cryIAb* gene which confers tolerance to certain lepidopteran species
Nos 3' terminator	0.27	*A. tumefaciens* nopaline synthase gene	Contains the signal for the termination of transcription and directs polyadenylation

35S promoter	0.425	*cauliflower mosaic virus 35S* gene	Promoter of high level constitutive gene expression in plant tissues
IVS2 enhancer	0.472	intron from maize *alcoholdehydrogenase 1S* gene	regulatory sequence that enhances *pat* gene expression in the plant
pat gene	0.558	Phosphinothricin acetyl-transferase gene from *Streptomyces viridochromogenes*	encodes a phosphinothricin acetyl transferase enzyme which confers tolerance to glufosinate ammonium herbicides
Nos3' terminator	0.22	*A. tumefaciens* nopaline synthase gene	Contains the signal for the termination of transcription and directs polyadenylation

D. INFORMATION RELATING TO THE GM PLANT

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

Bt11 maize plants are protected from damage from certain Lepidopteran insect pests (including *Ostrinia nubilalis* (European Corn Borer) and *Sesamia spp*.) and show tolerance to glufosinate ammonium herbicides.

Protection from feeding damage by pest larvae is provided by expression in the tissues of Bt11 maize of a truncated form of a Cry1Ab protein encoded by a modified *crylAb* gene derived from the soil microorganism *Bacillus thuringiensis* subsp *kurstaki* HD-1

The tolerance to glufosinate ammonium herbicides is accomplished by expression of a *pat* gene that encodes an enzyme: phosphinothricin acetyl transferase (PAT), capable of detoxifying the herbicide.

2. Information on the sequences actually inserted or deleted

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

Bt11 maize was subjected to molecular analysis to determine the number of integration sites within the maize genome and the copy number (the number of copies of the DNA fragment used for transformation that were inserted in the GM plant), the integrity of the inserted cassettes and the absence of backbone sequences. Southern blot analyses were undertaken using a variety of DNA probes including the *pat* and *cry1Ab* genes, *amp* sequence and the entire plasmid to search for unintended insertions in the maize genome.

The data demonstrated that the Bt11 event contains a single DNA insertion with one copy of both the *cry1Ab* and the *pat* cassettes. The elements integrated into the Bt11 maize event as the single copies of the gene cassettes for the *cry1Ab* gene and *pat* gene are: 35S promoter; IVS6 intron sequence; *cry1Ab* gene; nos terminator; 35S promoter; IVS2 intron sequence; *pat* gene; nos terminator.

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 inserted DNA is located on the short arm of chromosome 8. The insert is stably integrated into the plant chromosome and is inherited as a single dominant gene in a Mendelian inheritance ratio.

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

The entire T-DNA insert and the 5’ and 3’ flanking regions in Bt11 maize have been sequenced. The sequence data demonstrated the overall integrity of the insert and that contiguousness of the functional elements within the insert have been maintained.

3. Information on the expression of the insert

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

Expression analysis of the Cry1Ab and the PAT proteins was carried out by ELISA using leaf, pollen, silk, stalk, root, grain (kernels) and the whole plant .
The Cry1Ab protein was found in all tissues examined, with a decrease in concentration at the time of plant maturation and senescence, although the level in the kernel remains relatively constant. The highest Cry1Ab concentration is found in the leaf tissue, especially at the younger stages of tissue development. The measured concentration of Cry1Ab protein in grain and leaves is respectively 1.4 and 3.26 µg Cry1Ab protein/g fresh weight.

With regard to PAT protein, measurable levels (nanogram quantities per gram) were only found in leaves, silk and tassel. For kernels, pollen, root and stalk concentrations were below the limits of detection. The PAT protein is present at less than 0.000008% fresh weight and 0.00016% of the total maize grain protein.

b) Parts of the plant where the insert is expressed

Cry1Ab protein can be detected in all plant tissues from Bt11 maize.

PAT protein can be detected in the leaf and tassel samples. Some PAT protein was detected in silk extracts but the levels of PAT protein found in the root, pollen and kernel were less than the limits of detection.

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

a) Reproduction

Maize reproduces sexually through the production of seed. As the intended effect of the modification is to enhance tolerance to insects, there is no evidence or reason to believe that the modification will affect the mode of reproduction. Results from previous field trials conducted with Bt11 maize suggest that the genetically modified varieties do not differ from the recipient plant in mode or rate of reproduction

b) Dissemination

The most likely routes of dissemination are through the seed and pollen. As the intended effect of the modification is to enhance tolerance to insects, there is no evidence or reason to believe that the modification will affect the mode of dissemination. Results from previous field trials conducted with Bt11 maize suggest that the genetically modified varieties do not differ from the recipient plant in mode or rate of dissemination.

c) Survivability

The survival structure and dispersal agent of maize is the seed. Plants of the genetically modified event Bt11 maize have been grown to maturity in the glasshouse over several generations. They flowered normally and produced seed. There is no evidence from previous field trials conducted with Bt11 maize to suggest that the modification affects the survivability of the plant.

d) Other differences

No other differences observed.

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

Genetic stability

Molecular analysis indicates that the insert has been stably integrated into the plant's genome in Bt11 maize.

Phenotypic stability:
The stability of Cry1ab and PAT protein expression over multiple generations was evaluated. Segregation data of Bt11 maize for glufosinate ammonium tolerance and European corn borer resistance were collected at different points in a backcrossing experiment. BC3 and BC6 plants, identified as containing the *cry1Ab* and *pat* genes, were subjected to self-fertilisation experiments. This demonstrated the heritability and the stability of the two transgenes in Bt11 maize. Data support the presence of a single insertion that segregates according to Mendelian laws of genetics.

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

a) Plant to bacteria gene transfer

The horizontal gene transfer from GM plants to bacteria with subsequent expression of the transgene is regarded as a highly unlikely event under natural conditions, especially in the absence of selective pressure as discussed in detail by EFSA (2004)[1].
The transformation event that generated Bt11 maize did not involve the use of a bacterial antibiotic resistance gene. The two bacterially derived genes present in Bt11 maize have been modified to optimise expression in plants rather than bacteria.
There is no evidence to suggest that the presence of the inserted sequences in Bt11 maize could enhance the potential of intact horizontal gene transfer from GM plants to bacteria.
Therefore no change in the ability of the Bt11 maize to transfer genetic material to other organisms is expected compared to conventional maize.

b) Plant to plant gene transfer

[1] EFSA, 2004. Opinion of the Scientific Panel on Genetically Modified Organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants, The EFSA Journal 48, 1-18 http://www.efsa.eu.int/science/gmo/gmo_opinions/384_en.html

Pollen dispersal is the only potential route for the transfer of genetic material to other plants. In Europe there are no records of sexually compatible wild relatives of maize growing in the continent, therefore only cross-pollination with conventional maize crops could occur.

Pollen production and pollen viability, measured by yield and germination of progeny, are unchanged in Bt11 maize plants when compared with the conventional isogenic varieties. Therefore no change in the ability of Bt11 maize to transfer genetic material to other plants is expected compared to conventional maize. In addition, since the scope of this application does not include authorisation for the cultivation of Bt11 maize, the likelihood of dissemination of pollen to other plants (including cultivated maize) is considered to be negligible.

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

Studies compared the composition of maize grain and plant forage obtained from Bt11 maize plants with isogenic non-transgenic comparators.

7.2 Production of material for comparative assessment

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

To confirm that Bt11 maize composition is substantially equivalent to the composition of non-transgenic isogenic maize varieties, replicate trials of transgenic and corresponding isogenic controls were conducted in the EU and the US in 1995, each involving 3-6 sites and field trials at two locations in France in 1998.
In addition, data on silage composition were available from feeding study reports in the US in 1998.

b) The baseline used for consideration of natural variations

The levels of multiple nutritive components were compared in maize kernels (grain) or whole plants (forage) produced from Bt11 maize plants and concurrently grown isogenic control plants. The mean values were also compared with the range of data published in the literature, where data was available.

7.3 Selection of material and compounds for analysis

The selection of compounds analysed was generally similar to that recommended by OECD.

The analysis of kernels from maize plants grown in European greenhouses included nitrogen, ash, starch, cellulose, xanthophyll, fatty acids and amino acids. Kernels from maize plants grown during parallel US field studies were analysed for protein, oil, starch, fibre, fatty acid- and amino acid- profiles, as well as copper, magnesium, manganese, zinc, folic acid, niacin, and vitamins B1 and B2.

Data for the kernels harvested from field trials at two locations in France included carbohydrate, protein, fat, fibre, fatty acid- and amino acid- composition, as well as trypsin inhibitor and phytic acid. In addition, data on silage composition were available from feeding study reports.

Experimentally produced silage from Bt11 maize and non-transgenic controls, which were grown in the US in 1998 and used for a feeding study with beef- and dairy- cattle, was analysed for composition, including dry matter, nitrogen (protein and non-protein), ash, fibre, starch, and lignin.

Forage samples from Bt11 maize and non-GM isogenic control maize cultivated at several locations in the USA (1995) were analysed for proximates :dry matter, crude protein, available crude protein, acid detergent fibre, neutral detergent fibre, total digestible nutrients), and four minerals (calcium, phosphorus, potassium, and magnesium).
Silage from maize grown at one location in the USA (1996) and prepared for feeding studies with Bt11and non-transgenic control was analysed for protein, acid detergent fibre, neutral detergent fibre (NDF), total digestible nutrients, 12 minerals (calcium, phosphorus, potassium, magnesium, sulphur, sodium, zinc, manganese, copper, iron, cobalt, and aluminium), and energy (metabolisable energy, net energy lactation, net energy growth, and net energy maintenance).

7.4 Agronomic traits

Agronomic data (anthocyanin coloration at the level of the ear, tassel, leaf, internodes and glumes; plant and tassel length, grain type, resistance to pests and diseases, number of primary lateral branches, height of insertion of ears, length of peduncle, shape/length of ears, number of rows of grain) were collected and confirmed the phenotypic equivalence of Bt11 maize to its non-transgenic counterpart.

Furthermore, no differences in agronomic or phenotypic characteristics were found between Bt11 maize and its non-transgenic counterpart during field trials at different locations (Spain, France, Italy and Portugal) conducted between 1994 and 2006. This supports a conclusion that there were no unexpected pleiotropic effects of the genetic modification in Bt11 maize.

7.5 Product specification

Maize as a product has a history of safe use for human food and animal feed. No significant native toxins are reported to be associated with the genus *Zea*. The characteristics of Bt11 maize and products derived from it are not different from those of its conventional counterpart. This supports a conclusion that Bt maize and the corresponding isogenic non-transgenic maize are substantially equivalent.

Bt11 maize has been shown to be as safe and as wholesome as conventional varieties of maize. Any intended use can be managed in the same way as any other conventional maize and, therefore, no particular product specification is considered.

7.6 Effect of processing

Bt11 maize has been shown to be as safe and as wholesome as conventional varieties of maize. The characteristics of Bt11 maize and products derived from it are not different from those of its conventional counterpart and have been demonstrated to be substantially equivalent to the non-transgenic isolines. In particular, heating of Bt11 maize-derived products will lead to the denaturing and degradation of the Cry1Ab and PAT proteins.

Bt11 maize products will be produced and processed in the same way as any non-GM maize and there are no reasons to assume that the stability of the processed products derived from Bt11 maize would be different from the non-GM processed products.

7.7 Anticipated intake/extent of use

There are no anticipated changes to the intake/extent of use of maize as a result of the introduction of Bt11 maize to the conventional maize supply.
The introduction of Bt11 maize has resulted in the replacement of some of the conventional maize in existing food and feed products. However, the genetic modification was not intended to change any of the compositional parameters in food and feed and this been shown to be the case through extensive compositional assessment.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

Cry1Ab and PAT proteins are expressed in Bt11 maize plant tissues.
An assessment of the safety of the Cry1Ab and PAT proteins was conducted based upon the extensive characterization of those proteins.
The safety of Cry1Ab and PAT proteins has been established upon the following considerations:

(1) Searches for amino acid sequence homology showed no homologies with known toxins for both proteins (other than with *B.t.* proteins in the case of Cry1Ab)
(2) Rapid degradation under conditions which simulate mammalian digestive systems
(3) No indications of acute toxicity in mice at the highest dose tested.

In addition, an extensive published scientific literature is available, including feeding/toxicity studies of Cry1Ab protein on poultry, pigs, calves and cattle and official safety assessments for both proteins showing the safety of both proteins.

No recent scientific information has become available which would justify a reassessment of the safety of the Cry1Ab and PAT proteins.

7.8.2 Testing of new constituents other than proteins

Since no new constituents other than the above-mentioned proteins are expressed in Bt11 maize, nor were levels of endogenous compounds altered, a toxicological assessment of such compounds is not applicable.

7.8.3 Information on natural food and feed constituents

Maize is a common source of food and feed and has a long history of safe use.

Bt11 maize has been modified to express the Cry1Ab and PAT proteins. No other new constituents apart from these proteins are produced.
The comparisons carried out between the natural constituents of Bt11 maize and its non-GM comparator confirms that the composition of Bt11 maize and its nutritional value have not been altered by the genetic modification.

7.8.4 Testing of the whole GM food/feed

The results of the compositional analysis, the molecular characterisation, and the phenotypic analysis did not reveal unintended differences between Bt11 maize and non-transgenic maize. Further, animal testing data from feeding studies did not show any adverse effects and confirmed the equivalence of Bt11 maize when compared to non-transgenic maize.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

An allergy risk evaluation of Cry1Ab and PAT proteins has been completed using different approaches: The data obtained showed that both proteins:

- are not derived from a known allergenic source
- have no amino acid sequence homology to known or putative allergens
- are rapidly degraded in simulated gastric fluid
- are sensitive to heat and processing

From these data, it can be concluded that the Cry1Ab and PAT proteins expressed in Bt11 maize are unlikely to be allergenic.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Maize has been extensively cultivated and has a history of safe use for human food and animal feed. Maize is not considered to be an allergenic food crop and Bt11 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

Bt11 maize is not intended to change the nutritional status of individuals of populations or to be processed in products with enhanced functionality.
Compositional analysis and whole-food safety tests have demonstrated that no unexpected alterations in the levels of nutrients or other food components have occurred and that no nutritional imbalances were introduced.

7.10.2 Nutritional assessment of GM feed

Bt11 maize is not intended to change the nutritional status of livestock animals.
Compositional analysis, whole-food safety tests and nutritional studies in domestic animals have demonstrated that no unexpected alterations in the levels of nutrients or other food components have occurred and that no nutritional imbalances were introduced. In conclusion, results indicate nutritional equivalence between transgenic Bt11 maize and non-GM control maize.

7.11 Post-market monitoring of GM food/feed

As described in sections 7.1 to 7.10 above, the presence of Bt11 maize in food and feed does not result in any nutritional changes, therefore post- market monitoring is not considered necessary.

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

Bt11 maize does not interact with the environment in a different way than non-modified maize, except for the tolerance to the target insects.

As the introduced insect-protection trait in Bt11 maize only has activity toward the larvae of particular Lepidoptera, the effect of Bt11 maize on target organisms is limited to specific conditions in the field, which are predictable, spatially limited and transient. As the target insects represent important insect pests in the arable environment, the direct control of their population levels in maize fields is justified on an agronomic basis and is not considered a direct adverse environmental effect itself. The effects of this reduction are not likely to be different from reductions in those areas where corn borer control is achieved through the use of insecticides or microbial preparations of *Bacillus thuringiensis*.

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

9.1 Persistence and invasiveness

Cultivation of Bt11 maize in the EU is not within the scope of this application. Any release in the environment would mainly be the consequence of grain spillage, however, maize is a highly domesticated crop and cannot survive without human intervention, especially under normal European climatic conditions.
As shown in several field trials there are no indications of altered ecological fitness of Bt11 maize in comparison to conventionally bred maize hybrids of similar genetic background.

9.2 Selective advantage or disadvantage

The herbicide tolerance trait can only be regarded as providing a selective advantage where and when glufosinate-ammonium containing herbicides are applied, *i.e.* mainly on arable land.
Insect protection against lepidopteran pests is also not regarded as providing a selective advantage for maize in Europe, as survivability is mainly limited by the absence of a dormancy phase, susceptibility to fungi and susceptibility to cold climate conditions.
Therefore, as for any other maize cultivars, it is considered very unlikely that volunteers of Bt11 maize could survive until subsequent seasons or would establish undesirable populations under European environmental conditions.

9.3 Potential for gene transfer

Since there are not any maize wild relatives in the EU the only potential gene transfer is through cross-pollination to other cultivated maize varieties.
The extent of cross-pollination to conventionally bred hybrids will mainly depend on accidental grain spillage, however, it is considered very unlikely that plants from these seeds could survive and transfer the genes to neighbouring maize crops.

9.4 Interactions between the GM plant and target organisms

The insecticidal action of Cry1Ab protein is limited to the larvae of specific lepidopteran pests and has been introduced into maize to confer resistance to maize corn borers, European Corn Borer (ECB), *Ostrinia nubilalis*, and Mediterranean Corn Borer (MCB), *Sesamia nonagrioides*. The lack of activity against non-target species appears to be due to a number of factors including physical differences in the gut environment and an absence of Cry1Ab-specific gut receptors. Additionally, there is evidence that demonstrates that the mammalian gut contains receptors that are not comparable to those found in the gut of susceptible insects.

9.5 Interactions of the GM plant with non-target organisms

Cultivation of Bt11 maize in the EU is not within the scope of this application. Exposure of non-target organisms to Bt11 maize would mainly occur as a consequence of accidental spillage of grain and growth of the plant.

(a) Effects on predators and parasitoids of the target organisms
Most field studies confirm that predator and parasitoid abundances and biocontrol functions are very similar in Bt and non-Bt fields

(b) Effects on other non-target organisms
Exposure of any populations of Lepidoptera to Cry1Ab is restricted to those consuming the Bt11 maize plant or its products. Maize, a relatively recently introduced species into Europe, is not a significant food source for endemic Lepidoptera, and impacts due to pollen dispersal are likely to be transient and minor as demonstrated by studies on monarch butterflies in the USA. In addition, as cultivation is not within the scope of this application, it is considered very unlikely that plants resulting from grain spillage could survive and produce pollen.

Regarding animals higher in the food chain including both invertebrates and vertebrates (e.g., birds, fish, mammals), no indications of intoxication have been reported or are indicated from first-and second-tier exposure studies or from feeding studies with diets containing Cry1Ab protein. It should also be considered that under field conditions most animals higher in the food chain would be eating diets consisting of a range of food sources. No evidence of accumulation of Bt toxins in the food chain has been reported and is not expected as the toxin is an easily degradable protein.

9.6 Effects on human health

Human exposure to Bt11 maize could occur though food consumption. However the recipient organism, maize, has a history of safe use throughout the world.
The human health assessment of Bt11 maize is based upon the information provided on the molecular characteristics of the insertion and on the safety of the proteins expressed, including evaluation of potential toxicological and allergenic properties of Bt11 maize.

Analysis of the chemical composition of the maize and field trial data were also used to assess the potential for unintended changes in nutritional or agronomic parameters. Data have confirmed that Bt11 maize is as safe as its non-GM comparators. In addition there is a large background of experience and knowledge already available regarding the safety of the CryIAb and the PAT proteins.
9.7 Effects on animal health Animal exposure to Bt11 maize could occur though feed consumption. However the recipient organism, maize, has a history of safe use throughout the world. The animal health assessment of Bt11 maize is based upon the information provided on the molecular characteristics of the insertion and on the safety of the proteins expressed, including evaluation of potential toxicological properties of Bt11 maize. Analysis of the chemical composition of the maize and field trial data were also used to assess the potential for unintended changes in nutritional or agronomic parameters. Data have confirmed that Bt11 maize is as safe as its non-GM comparators. In addition there is a large background of experience and knowledge already available regarding the safety of the CryIAb and the PAT proteins, as well as a large number of studies published on animal feeding trials using Bt11 maize.
9.8 Effects on biogeochemical processes Cultivation of Bt11 maize in the EU is not within the scope of this application. Exposure of non-target organisms to Bt11 maize would mainly result from accidental spillage or grain and growth of the plant. Cry1 proteins are rapidly degraded in soil and have no apparent effect on earthworms or nematodes. The published results from laboratory and field trials showed that on short to medium time scales and under field conditions, the effects on soil functions and biodiversity of Bt11 maize cultivation does not exceed the range of the “natural” variability. There is not conclusive evidence that currently released GM maize crops expressing the Cry1Ab protein are causing significant direct effects on the soil environment. In addition, the available data do not indicate that there will be long term impacts on soil ecosystems. Therefore, it seems likely that the consequences of any effects on soil functions and soil organisms are negligible. Effects on biogeochemical processes resulting from *pat* expression in Bt11 maize are likely to be the same as effects resulting from cultivation of non-GM maize.
9.9 Impacts of the specific cultivation, management and harvesting techniques Cultivation of Bt11 maize in the EU is not within the scope of this application.

10. Potential interactions with the abiotic environment

Cultivation of Bt11 maize in the EU is not within the scope of this application. Exposure of non-target organisms to Bt11 maize will mainly depend on accidental grain spillage and

growth of the plant.

Cry1 proteins are rapidly degraded in soil and have no apparent effect on earthworms or nematodes. The published results from laboratory and field trials showed that in short to medium time scales and under field conditions, the effects on soil functions of Bt11 maize cultivation does not exceed the range of “natural” variability.

Considering the available information on potential effects of Bt plants on the soil environment, adverse effects are unlikely.

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)

The scope of this application does not include cultivation of Event Bt11 maize in the EU.

Environmental exposure to Event Bt11 maize could only occur in the unlikely event that small amounts of grain of Bt11 maize accidentally found their way into the environment in the EU. However, the survival of this grain would be very unlikely as maize is a highly domesticated plant and cannot survive without human intervention, especially under normal European climatic conditions. This grain, if germinated, could be easily controlled using any of the current agronomic measures taken to control other commercially available maize.

An environmental risk assessment (e.r.a.) has been conducted as recommended by the Guidance document of the EFSA Scientific Panel of Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed. According to this guidance the e.r.a. should follow the principles outlined in Directive 2001/18/EC (Annex II). The risk assessment is described as *”a process of evaluation, including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s)/event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s)”*. This risk assessment has been conducted taking into account the scope of this application, which covers the import of grain for use as any other conventional maize grain but does not include the cultivation of Bt11 maize. A sequential approach to the e.r.a., as recommended by Commission Decision 2002/623/EC has been followed, so the characteristics of Bt11 maize that may cause an adverse effect have been identified, their potential consequences evaluated, the likelihood of their occurrence assessed and the overall risk posed by each characteristic identified. Comparison of Bt11 maize with conventional maize has been used as a baseline.

The conclusions of this e.r.a. confirm that the effects to the environment arising from the use of Bt11 maize can be considered as negligible as those from any other commercial maize, under the scope of this application.

11.2 Interplay between environmental risk assessment and monitoring

In general two types of environmental monitoring can be described:

case-specific monitoring, designed to evaluate potential adverse effects linked to the genetic modification, identified in the e.r.a.

general surveillance, which is aimed to identify adverse unforeseen effects that were not anticipated in the environmental risk assessment.

An environmental risk assessment (e.r.a.) has been conducted in accordance with Annex II of Directive 2001/18/EC to evaluate potential adverse effects of Bt11 maize on human and animal health and the environment. The conclusions of this e.r.a. confirm that the potential risks to human and animal health or the environment arising from the placing on the market of Bt11 maize can be considered negligible, under the scope of this application. Therefore, a case-specific monitoring plan is not considered necessary under the scope of this application. However, a general surveillance plan based on Annex II of the Directive 2001/18/EC is outlined below.

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

An environmental risk assessment (e.r.a.) has been conducted in accordance with Annex II of Directive 2001/18/EC to evaluate potential adverse effects of Bt11 maize on human and animal health and the environment. The conclusions of this e.r.a. confirm that the potential risks to human and animal health or the environment arising from the placing on the market of Event GA21 maize can be considered negligible, under the scope of this application. The only adverse effect identified was the possibility that resistance to Cry1Ab protein might evolve in corn borer populations exposed over multiple generations to Bt11 maize following its cultivation. Since this notification does not cover cultivation no case-specific monitoring is proposed. However, a general surveillance plan based on Annex II of the Directive 2001/18/EC is outlined below.

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

The objective of general surveillance is to identify unforeseen adverse effects of the GM plant or its use, on human health and the environment, which were not predicted in the risk assessment. The scope of this application is limited to import of Event Bt11 maize and excludes cultivation practices. Cultivation outside the EU is accompanied by stewardship and surveillance programmes which include the provision of information to traders and processors of bulk mixtures of grain.

The provisions concerning traceability and labelling for placing on the market of Event Bt11 maize will allow the prompt identification of products containing or consisting of this maize, and thus enable any unanticipated adverse effects to be effectively traced.
The majority of imported Event Bt11 maize material will be used for feed purposes. Therefore, traders and processors as well as the European feed industry serve as a good focal point to address questions related to any unanticipated effects that might be associated with the use of Bt11 maize.

Syngenta is committed to inform traders, processors and the European feed and food industry of details on the safety of Bt11 maize and to establish a communication network wherein unforeseen effects can be reported. If unusual observations are reported, more focussed in-depth studies can be carried out in order to determine cause and relationship with the specific event. Final decisions on whether any identified effects are significant can only be made if causality is clear and endpoints are determined. Although not a formal part of the surveillance plan, it is appropriate to note that there is an extensive information network, with global reach, which will provide additional information on possible adverse effects arising from the use of GM crops. These include new and rapid means of access to information from across the globe through telecommunications, the media and Internet access. Through these means, many groups, including agronomists, ecologists, health professionals, and the general public now have unprecedented access to reports on the use world-wide of GM crops. In addition, electronic discussion sites, for example those of WHO, OECD, FAO, and consumer organisations, are valuable sources of information and communication for professionals and, in many cases, the general public.
11.5 Reporting the results of monitoring The notifier/consent holder is responsible, under Regulation (EC) No 1829/2003, to inform the Commission of the results of the surveillance. Consistent with the EFSA guidance, the notifier will submit a General Surveillance Report containing information related to the monitoring on an annual basis.

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

Syngenta has developed an event-specific, real-time quantitative PCR based method for genetically modified Bt11 maize, SYN-BTØ11-1. It is published in European Food Research and Technology, Vol. 216/2003, pages 347-354. The method is validated by the Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL). URL: http://gmo-crl.jrc.it/detectionmethods/Bt11-protocol.pdf

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 Spain: B/ES/96/07, B/ES/97/14, B/ES/98/02, B/ES/99/27, B/ES/00/04, B/ES/01/06, B/ES/02/04, B/ES/02/05, B/ES/02/14, B/ES/04/09, B/ES/05/21,B/ES/06/05,

B/ES/06/38, France: B/F/94 01.06, B/F/95 01.03, B/F/95 12.04, B/F/96 01.09, B/F/97 11.14, B/F/99 01.02, B/FR/99 02 09, B/FR/02 03 04, B/FR/03 01 01, B/FR/03 03 02 Italy: B/IT/95/16, B/IT/96/13, B/IT/96/53, B/IT/97/19, B/IT/98/39, B/IT/99/20 Portugal: B/PT/98/1
b) Conclusions of post-release monitoring No unexpected effects or observations have been detected. No negative impacts on the environment or human health have been observed or reported during these releases The results of these releases confirm the safety of the deliberate release in the environment of Bt11 maize in the E.U.
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 unexpected effects or observations have been detected. No negative impacts on the environment or human health have been observed or reported during these releases Final reports of the releases can be found at the JRC web page http://gmoinfo.jrc.it/

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

a) Release country Bt11 maize is approved for cultivation and food/feed uses in the USA, Canada, Argentina, South Africa, Uruguay, Japan and the Philippines. It is approved for human food and animal feed use in Switzerland, Russia and China, and for food use in Australia, New Zealand, Korea and Taiwan Bt11 maize has been planted commercially on hundreds of thousands of hectares worldwide, in the U.S.A. and Canada since 1997, in Argentina since 2002, in South Africa since 2003 and in the Philippines since 2005. Prior to its commercialisation, Bt11 maize was tested extensively at multiple locations in the field in a broad range of environments around the world.
b) Authority overseeing the release The authority overseeing the first field release was the United States Department of Agriculture (USDA). Bt11 maize was later deregulated in the U.S.A. and approved by the respective competent authorities in the countries mentioned in section 2-a.
c) Release site All major maize growing regions in North America and increasingly in other countries around the world, as described in Section E.2(a).
d) Aim of the release Commercial release for all uses as traditional maize in USA, Canada, Argentina, South Africa, Uruguay and the Philippines.
e) Duration of the release Please see Section E.2.(a)
f) Aim of post-releases monitoring Extensive pre-market risk assessment did not provide evidence of adverse effects potentially associated with the cultivation, handling or use of Bt11 maize, indicating that a requirement for post-release monitoring would not be appropriate. In addition, Bt11 maize has been commercialized concurrently with stewardship programmes, involving downstream stakeholders in the use of this maize, in order to ensure the implementation of good agricultural practice in its cultivation and to ensure a channel of communication in the unlikely event that unanticipated adverse effects might occur. However, no such unanticipated effects have been observed since the large-scale commercialization of Bt11 maize in North America and in Argentina, nor during the field-testing programmes inside and outside the E.U.

g) Duration of post-releases monitoring Please see Section E.2.(f)
h) Conclusions of post-release monitoring Please see Section E.2.(f)
i) Results of the release in respect to any risk to human health and the environment Field-testing and post-marketing experience provided no significant evidence that Bt11 maize or derived products would be the cause of any adverse effects to human or animal 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 status and process of approval of notifications under Directive 2001/18/EC and applications under Regulation (EC) No 1829/2003,can be found at: ❑ the JRC websites http://gmoinfo.jrc.it/gmc_browse.asp and http://gmocrl.jrc.it/statusofdoss.htm ❑ the EFSA website http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html
b) Assessment Report of the Competent Authority (Directive 2001/18/EC) The JRC website http://gmoinfo.jrc.it/gmc_browse.asp provides a link to publicly accessible Initial Assessment Reports (IAR) under Directive 2001/18/EC, including the IAR from the French Lead Member State for Syngenta's notification **C/F/96/05.10**
c) EFSA opinion EFSA opinion for the placing on the market of insect resistant genetically modified maize Bt11, for cultivation, feed and industrial processing. http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/922.html. Bt11 maize has been previously evaluated (SCP, 1998)[2] for import, processing and feed use under Directive 90/220/EEC: http://europe.eu.int/comm/food/fs/sc/scp/out86_gmo_en.html

[2] SCP, 1998. Opinion of the Scientific Committee on Plants on the Genetically Modified Maize Lines Notified by the Novartis Company (Notification C/GB/96/M4/1). http://europe.eu.int/comm/food/fs/sc/scp/out05_en.html

Bt11 maize has also been evaluated for cultivation under the same Directive (SCP, 2000)[3]. http://europe.eu.int/comm/food/fs/sc/scp/out86_gmo_en.html Bt11 sweet maize has also been evaluated (SCF, 2002)[4] for food consumption in the framework of Regulation (EC) 258/97 http://europe.eu.int/comm/food/fs/sc/scf/out129_en.pdf
d) Commission Register (Commission Decision 2004/204/EC[5]) http://ec.europa.eu/food/dyna/gm_register/gm_register.cfm?gm_id=17
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre The Community Reference Laboratory webpage is http://gmo-crl.jrc.it/
f) Biosafety Clearing-House (Council Decision 2002/628/EC[6]) Information relating to the Biosafety clearing house can be found at: http://bch.biodiv.org/
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.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

[3] SCP, 2000. Opinion of the Scientific Committee on Plants on the submission for placing on the market of genetically modified insect resistant and glufosinate ammonium tolerant (Bt-11) maize for cultivation. Notified by Novartis Seeds SA Company (notification C/F/96/05-10), 30 November 2000. http://europe.eu.int/comm/food/fs/sc/scp/out86_gmo_en.html

[4] SCF, 2002. Opinion on a request to place genetically modified sweet maize line Bt11 on the market (expressed on 17 April 2002). http://europe.eu.int/comm/food/fs/sc/scf/out129_en.pdf

[5] Commission Decision of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council. Official Journal of the European Communities L 65: 20 – 22.

[6] Council Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety. Official Journal of the European Communities L 201: 48 – 49.