Application for authorisation of stacked 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the European Union under Regulation (EC) No 1829/2003

PART VII: SUMMARY

This document is complete as of May 2017. Since it is submitted as one part of a regulatory application, which is subject to an on-going regulatory review, it may be subject to later amendment or replacement. The information may also be supplemented with additional material requested by regulatory authorities. As such, it may only be considered properly with reference to those later amendments or supplementary materials and in the context of the dossier as a whole.

PART VII

SUMMARY

APPLICATION FOR AUTHORISATION OF 3272 X BT11 X MIR604 X 1507 X 5307 X GA21 MAIZE UNDER REGULATION (EC) 1829/2003

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Germany

(b) Application Number

EFSA-GMO-DE-2017-XXX (Not available at time of submission)

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

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize

(d) Date of acknowledgement of valid application

Not available at time of submission

1.2. Applicant

(a) Name of applicant

Syngenta Crop Protection NV/SA, acting on behalf of Syngenta Crop Protection AG

(b) Address of applicant

Syngenta Crop Protection NV/SA
Avenue Louise 489
1050 Brussels
Belgium

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

Not applicable.

1.3. Scope of the application

(a) GM food

☒ Food containing or consisting of GM plants

☒ Food produced from GM plants or containing ingredients produced from GM plants

(b) GM feed

☒ Feed containing or consisting of GM plants

☒ Feed produced from GM plants

(c) GM plants for food or feed use

☒ Products other than food and feed containing or consisting of GM plants with the exception of cultivation

☐ Seeds and plant propagating material for cultivation in the Union

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation procedure within the Union?

No ☒

Yes ☐ (in that case, specify)

1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?

Yes ☐

No ☒ (in that case provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

Risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC is provided in the application.

1.6. Has the GM plant or derived products been previously notified for marketing in the Union under Part C of Directive 2001/18/EC?

No ☒

Yes ☐ (in that case, specify)

1.7. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

No ☐

Yes ☒ (In that case, specify the third country, the date of application and where available, and provide a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application)

Submissions covering 3272 x Bt11 x MIR604 x TC1507 x 5307 x GA21 maize have been made in third countries around the world and are at different stages in the approval process. 3272 x Bt11 x MIR604 x TC1507 x 5307 x GA21 maize is currently authorized for cultivation in Canada, Japan and the United States of America (USA). This maize is authorized for import in Colombia, Japan, Korea, Mexico, South Africa and Taiwan.

1.8. General description of the product

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

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is a genetically modified (GM) maize that is produced by conventional breeding of the following GM maize events: 3272, Bt11, MIR604, 1507, 5307 and GA21.

- Event 3272 maize which expresses an alpha-amylase (AMY797E) protein for use in the production of fuel ethanol by maize dry-grind process and a phosphomannose isomerase (PMI) protein, which acts as a selectable marker enabling transformed plant cells to utilize mannose as the only primary carbon source.
- Bt11 maize which produces a truncated Cry1Ab protein for control of certain lepidopteran pests and a phosphinothricin acetyltransferase (PAT) protein for weed control by providing tolerance to herbicide products containing glufosinate ammonium.
- MIR604 maize which expresses a modified Cry3A (mCry3A) protein for control of certain coleopteran pests and a MIR604 PMI protein, which acts as a selectable marker enabling transformed plant cells to utilize mannose as the only primary carbon source.
- 1507 maize expressing the Cry1F protein which confers protection against certain lepidopteran pests and a PAT protein for weed control by providing tolerance to herbicide products containing glufosinate ammonium.
- 5307 maize which expresses a Cry protein, designated eCry3.1Ab, for control of certain coleopteran pests like *Diabrotica virgifera virgifera* (Western corn rootworm, WCRW) and related *Diabrotica* species; and, a PMI protein that acts as a selectable marker trait enabling transformed plant cells to utilize mannose as the only primary carbon source.
- GA21 maize which produces a double-mutated maize 5-enolpyruvylshikimate-3-phosphate synthase enzyme (mEPSPS) for weed control by providing tolerance to herbicide products containing glyphosate.

Where cultivated, the intended function of the genetic modification of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is to facilitate in the ethanol production and control certain insect pests and weeds.

(b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for

This application under Regulation (EC) No 1829/2003 covers the import, food and feed use, and industrial processing of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and relevant subcombinations. It does not cover cultivation.

The scope of the application includes all food and feed products containing, consisting of or produced from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and the subcombinations in the scope of the application, independently of their origin, including products from inbreds and hybrids obtained by conventional breeding of this maize product. The application also covers the import and industrial processing of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and relevant subcombinations for all potential uses as any other maize.

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

It is intended that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and relevant subcombinations will be used as any other conventional maize for all food, feed and industrial purposes.

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

The characteristics of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and products derived from it are not different from those of its conventional counterpart, apart from the introduced traits to enhance in the ethanol production and to control certain insect pests and weeds. 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize has been shown to be as safe and as wholesome as existing varieties of maize. Therefore, there are no specific instructions or recommendations for use, storage and handling of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize or its relevant subcombinations.

(e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for

The 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and derived products are suitable for use as any other maize under the terms of the authorisation applied for.

(f) Any type of environment to which the product is unsuited

This application under Regulation (EC) No 1829/2003 covers the import, food and feed use, and industrial processing of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and relevant subcombinations. It does not cover cultivation.

(g) Any proposed packaging requirements

The characteristics of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and products derived from it are not different from those of its conventional counterpart. 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize has been shown to be as safe and as wholesome as existing varieties of maize. Therefore, there are no specific instructions for packaging.

(h) Any proposed labelling requirements in addition to those required by other applicable EU legislation than regulation (EC) N° 1829/2003 and when necessary a proposal for specific labelling in accordance with Articles 13(2), and (3), Articles 25(2)(c), and (d) and Articles 25(3) of Regulation (EC) No 1829/2003.

In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

A proposal for labelling has been included in the application. This includes the labelling requirements outlined by Regulation (EC) No 1829/2003 and Annex IV of Directive 2001/18/EC. 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize will therefore, be labelled as “genetically modified maize” and products derived from it will be labelled as “containing (or produced from) genetically modified maize”. Since 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and derived products are not different from those of its conventional counterpart, no additional labelling is required.

(i) Estimated potential demand

(i) In the EU

There are no anticipated changes to the intake/extent of use of maize in the European Union (EU) as a result of the introduction of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize or its subcombinations to the maize supply.

(ii) In EU export markets

There are no anticipated changes to the extent of maize production in export markets for EU supplies as a result of the introduction of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize products.

(j) Unique identifier in accordance with Regulation (EC) No 65/2004

The unique identifier assigned to this product in accordance with Regulation (EC) No 65/2004 is (SYN-E3272-5 x SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9) (also referred to as 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize).

The unique identifiers asigned to the subcombinations in the scope of the application are determined by combining SYN-E3272-5 and/or SYN-BTØ11-1 and/or SYN-IR6Ø4-5 and/or DAS-Ø15Ø7-1 and/or SYN-Ø53Ø7-1 and/or MON-ØØØ21-9 in any perceiveable way, excluding each separate single.

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

Maize is incapable of sustained reproduction outside domestic cultivation and is non-invasive of natural habitats. The characteristics of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and products derived from it are not different from those of its conventional counterpart, apart from the intended traits.

The scope of this application does not include cultivation of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize or its subcombinations in the EU.

In the unlikely event that small amounts of seed from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize accidentally found their way into the environment, this would represent extremely low levels of exposure and the survival of these seeds to produce flowering plants would be very unlikely. In addition, volunteers could be easily controlled using any of the current agronomic measures taken to control other commercially available maize, with the exception of herbicide products containing glyphosate and glufosinate-ammonium.

Exposure to the environment will be limited to unintended release of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize, which could occur for example via substantial losses during loading/unloading of the viable commodity including 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize destined for processing into animal feed or human food products. In the event that small amounts of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 grain accidentally found their way into the environment, this would represent extremely low levels of exposure and the survival of this grain to produce flowering plants would be very unlikely. Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious maize plants, such as manual or mechanical removal and the application of herbicides. In addition, volunteers could be easily controlled using any of the current agronomic measures taken to control other commercially available maize.

The 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and derived products have been shown to be as safe and as wholesome as existing varieties of maize. Any unintended releases or misuse can be dealt with in the same way as any other conventional maize.

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

2.1. Complete name

(a) Family name

Poaceae (formally Gramineae)

(b) Genus

Zea

(c) Species

Zea mays L

(d) Subspecies

mays

(e) Cultivar/breeding line

A proprietary Syngenta line

(f) Common name

Maize

2.2. Geographical distribution and cultivation of the plant, including the distribution within the Union

Maize is the world's most widespread cereal with very diverse morphological and physiological traits; it is grown on approximately 185 million hectares worldwide. Maize is distributed over a wide range of conditions: from latitudes 50º North to 50º South, 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 21ºC and 27ºC and the freeze-free season lasts 120-180 days.

In the EU, between 60 and 78 million tonnes of maize are produced annually. Another major maize product is silage maize produced on about 5.2 million hectares.

This application requests authorization for food and feed uses, and for import and processing and does not include cultivation in the EU.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Zea mays (*Z. mays*) is an allogamous plant that propagates through seed produced predominantly by wind-borne cross-pollination. Self-pollination of up to 5% may be observed. Male and female flowers are separated on the plant by about 1 – 1.3m. *Z. mays* has staminate flowers in the tassels and pistillate flowers on the ear shoots. *Z. mays* is a plant with protoandrous inflorescence; however, decades of conventional selection and breeding have produced varieties of maize with protogyny.

(b) Specific factors affecting reproduction

The key critical stages of maize reproduction are tasselling, silking, pollination and fertilization. Climatic and drought stress affect pollen viability and silk longevity; thus potentially limiting the period of possible cross-pollination. Maize pollen is very sensitive to dehydration as it loses water rapidly. Other factors like rainfall or irrigation inhibit pollen emission because the anther dehiscence is limited by the mechanical layer. Climatic conditions also affect grain and seed production, especially under drought conditions during flowering, tasseling and silking. If severe drought occurs during these phenological stages, the grain yield is reduced.

(c) Generation time

Maize is an annual crop. The generation time from sowing to harvesting varies according to the genetic background and the climate; cultivars can range in maturity from 50 days to over a year from seedling emergence to maturity.

2.4. Sexual compatibility with other cultivated or wild plant species (for environmental safety aspects)

The scope of this application does not cover the cultivation of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize. Therefore, any outcrossing between 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and cultivated *Z. mays* varieties is highly unlikely.

Cultivated species: The sexual compatibility of maize with other cultivated plant species is limited to *Zea* species. However cross-pollination between maize volunteers and other maize crops, although possible, would only occur at very low levels.

Wild plant species: Species that are sexually compatible with maize are not native to the EU and steps are already in place to control them, therefore, cross-hybridisation and introgression with these is highly unlikely. Therefore, any vertical gene transfer will be limited to other maize plants where cross-pollination

between maize varieties under European cultivation conditions could occur. There have been some recent reports of occurrence of teosinte, a new invasive weed in EU maize fields, and teosinte is indeed a sexually compatible wild relative of maize. However, the potential risks associated with the hybridisation of sporadic teosinte plants and GM maize was recently evaluated by EFSA. The conclusion was that in the EU, teosinte is a weed that is subject to eradication measures and hybridization with GM maize is unlikely to result in adverse environmental effects.

2.5. Survivability (for environmental safety aspects)

(a) Ability to form structures for survival or dormancy

Maize is a highly domesticated plant and cannot survive without human intervention. Maize is an annual crop and 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, and stage of development. Maize is not a persistent 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.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

Maize is a cross-pollinated plant, relying on wind for the dispersal of its pollen. The rate of cross-fertilisation between fields depends on pollen viability, flowering synchrony and the relative concentration of pollen in the donor and receptor plots. Effective pollen transport (gene flow) depends on viable pollen reaching and fertilising the ovules on target plants. A meta-analysis of existing cross-fertilisation studies concluded that most cross-pollination events occur within 50 m of the pollen source.

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

(b) Specific factors affecting dissemination

In general, maize pollen is only viable for a few hours after emission. As maize pollen is large and heavy it tends to be deposited close to the source plant. Most maize pollen falls within 5m of the field’s edge. In general,

these studies have shown that over 98% of maize pollen remains within a radius of 25 – 50m of the source, although some pollen grains can travel several hundred meters.

2.7. Geographical distribution within the Union of the sexually compatible species (for environmental safety aspects)

Species that are sexually compatible with maize are not native to the EU. The only sexually compatible species in the EU is other cultivated maize. There have been some recent reports of occurrence of teosinte, a new invasive weed in EU maize fields, and teosinte is indeed a sexually compatible wild relative of maize. However, the potential risks associated with the hybridisation of sporadic teosinte plants and GM maize was recently evaluated by EFSA. The conclusion was that in the EU, teosinte is a weed that is subject to eradication measures and hybridization with GM maize is unlikely to result in adverse environmental effects.

2.8. In the case of plant species not normally grown in the Union, description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts (for environmental safety aspects)

Not applicable, as maize is commercially cultivated in the EU.

2.9. 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 (for environmental safety aspects)

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 and nematode pests, as well as to competition from surrounding weeds. Maize is extensively cultivated and has a history of safety for environmental safety aspects.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

(a) Description of the methods used for the genetic modification

The 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is a GM maize that is produced by conventional breeding techniqueof the GM maize events: 3272, Bt11, MIR604, 1507, 5307 and GA21 maize. No further genetic modification to produce this stack has taken place.

The 3272, Bt11, MIR604, 1507, 5307 and GA21 maize events maize were

produced by genetic modification as follows:

- 3272 maize was produced via *Agrobacterium tumefaciens* -mediated transformation.
- Bt11 maize was produced using protoplast transformation/regeneration.
- MIR604 maize was produced via *A. tumefaciens*-mediated transformation.
- 1507 maize was produced by insertion of a DNA fragment into the maize genome using microprojectile bombardment.
- 5307 maize was produced by transformation of immature maize embryos derived from a proprietary *Z. mays* line *via A.tumefaciens*-mediated transformation.
- GA21 maize was produced via microprojectile bombardment of maize suspension culture cells.

(b) Nature and source of the vector used

The 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: 3272, Bt11, MIR604, 1507, 5307 and GA21 through conventional breeding techniques.

The vectors used to produce 3272, Bt11, MIR604, 1507, 5307 and GA21 maize are as follows:

- The Plasmid pNOV7013 was used for the transformation of 3272 maize.
- The Plasmid pZO1502, cut with a *Not*I restriction enzyme, was used to produce Bt11 maize. The plasmid is a derivative of the commercially available plasmid pUC18.
- The Plasmid pZM26, a binary vector used for *A. tumefaciens* mediated plant transformation, was used to generate MIR604 maize.
- No vector was used for the transformation of 1507 maize.
- Plasmid pSYN12274, a vector used for *A. tumefaciens* mediated plant transformation, was used to generate 5307 maize
- A *Not*I restriction fragment from the Plasmid pDPG434, was used to transform GA21 maize via microprojectile bombardment transformation. The plasmid is derived from a pSK- vector which is commonly used in molecular biology and is derived from pUC19.

(c) Source of donor DNA used for transformation, size and intended function of each constituent fragment of the region intended for insertion

The 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: 3272, Bt11, MIR604, 1507, 5307 and GA21 through conventional breeding techniques. There was no further genetic modification to produce the stacked product. The size, source and intended function of each constituent fragment of the regions intended for insertion in each of the single events is described below:

Table 1. Event 3272 maize (transformation vector pNOV7013)

Vector component	Size (bp)	Description
GZein promoter	677	Promoter region from the *Z. mays* 27-kDa storage protein (*zein*) gene. Provides endosperm-specific expression in *Z. mays*.
amy797E	1383	The gene includes the fusion of the 797GL3 alpha-amylase gene, derived from alpha-amylase genes from microorganisms of the archael order *Thermococcales* with the sequences encoding the maize gamma-zein signal sequence and the endoplasmic reticulum (ER) retention signal. The alpha-amylase enzyme catalyses the hydrolysis of starch by cleaving the internal α-1,4-glucosidic bonds into dextrins, maltose and glucose. The maize gamma-zein signal sequence and the ER retention signal provide signals for protein targeting to and retention in the endoplasmic reticulum of the cell, respectively.
iPEPC9	108	Intron #9 from the phosphoenolpyruvate carboxylase gene from *Z. mays*.
35S Terminator	70	Terminator sequence from the 35S RNA from the cauliflower mosaic virus genome.
Selectable marker cassette		
ZmUbiInt promoter	1993	Promoter region from *Zea mays* polyubiquitin gene, contains the first intron. Provides constitutive expression in monocots.
pmi	1176	*E. coli manA* gene encoding phosphomannose isomerase. Catalyzes the isomerization of mannose-6-phosphate to fructose-6-phosphate. Serves as a plant selectable marker.
NOS terminator	253	Terminator sequence from the nopaline synthase gene of *A. tumefaciens*.

Table 2. Event Bt11 maize (transformation vector pZ01502)

Vector component	Size (bp)	Description
35S promoter	509	Promoter from the cauliflower mosaic virus.
IVS6-ADH1	471	Maize intron sequence from the maize alcohol dehydrogenase gene used to enhance gene expression in maize.
cry1Ab	1848	*cry1Ab* gene, which encodes a Cry1Ab protein that confers resistance to certain lepidopteran insect pests. The *cry1Ab* gene was originally cloned from *Bacillus thuringiensis* var. *kurstaki* HD-1
NOS terminator	253	Polyadenylation region from the nopaline synthase gene from *A. tumefaciens*.
Selectable marker cassette		
35S promoter	418	Promoter from the cauliflower mosaic virus.
IVS2-ADH1	180	Maize intron sequence from the maize alcohol dehydrogenase gene used to enhance gene expression in maize.
pat	552	*Streptomyces viridochromogenes* gene encoding the selectable marker PAT. PAT confers resistance to herbicides containing glufosinate
NOS terminator	253	Polyadenylation region from the nopaline synthase gene from *A. tumefaciens*.

Table 3. Event MIR604 maize (transformation vector pZM26)

Vector component	Size (bp)	Description
MTL promoter	2556	Promoter derived from the *Z. mays* (maize) metallothionein-like gene.
mcry3A	1797	A modified *cry3A* gene that confers tolerance to WCRW *(D.virgifera virgifera)* and related *Diabrotica* species.
NOS terminator	253	Polyadenylation region from the nopaline synthase gene from *A. tumefaciens.*
Selectable marker cassette		
ZmUbiInt promoter	1993	Promoter from *Z. mays* polyubiquitin genes
pmi	1176	*E. coli pmi* gene encoding the enzyme PMI
NOS terminator	253	Polyadenylation region from the nopaline synthase gene from *A. tumefaciens.*

Table 4. Event 1507 maize (transformation vector PHP8999)

Vector component	Size (kb)	Description
*Ubi*1ZM promoter	1.98	Ubiquitin promoter derived from *Z. mays*
cry1F	1.82	The *cry1F* gene was originally cloned from *B. thuringiensis* subsp. *aizawai*. gene. It provides resistance against certain lepidopteran insect pests such as the European corn borer and *Sesamia* spp.
ORF25Poly A terminator	0.72	Terminator from *A. tumefaciens* pTi15995
Selectable marker cassette		
CaMV35S promoter	0.55	Promoter from the cauliflower mosaic virus.
pat	0.55	*S. viridochromogenes* gene encoding the selectable marker PAT. PAT confers resistance to herbicides containing glufosinate
CaMV 35S terminator	0.81	35S terminator from the cauliflower mosaic virus

Table 5. Event 5307 (transformation vector pSYN12274)

Vector component	Size (bp)	Description
CMP promoter	346	Cestrum Yellow Leaf Curling Virus promoter region. Provides constitutive expression in maize.
ecry3.1Ab	1962	An engineered *cry* gene active against certain corn rootworm (*Diabrotica*) species. The gene *ecry3.1Ab* consists of a fusion between the 5′ end of a modified *cry3A* gene and the 3′ end of the *cry1Ab* gene.
NOS terminator	253	Terminator sequence from the nopaline synthase gene of *A. tumefaciens*. Provides a polyadenylation site.
Selectable marker cassette		
Genetic element	**Size (bp)**	**Description**
ZmUbiInt promoter	1993	Promoter region from the maize polyubiquitin gene which contains the first intron. Provides constitutive expression in monocots
pmi	1176	*E. coli* gene *pmi* encoding the enzyme PMI; this gene is also known as *manA*. Catalyzes the isomerization of mannose-6-phosphate to fructose-6-phosphate.
NOS terminator	253	Terminator sequence from the nopaline synthase gene of *A. tumefaciens*. Provides a polyadenylation site.

Table 6. Event GA21 maize (transformation vector pDPG434)

Vector component	Size (bp)	Description
Actin promoter complex	1424	5' region of the rice actin 1 gene containing the promoter and first exon and intron provides constitutive expression of the *mepsps* gene in maize.
Optimised transit peptide	393	Optimised transit peptide sequence construct based on transit peptide sequences from maize and sunflower ribulose-1,5-bis phosphate carboxylase oxygenase (RuBisCo) genes.
mepsps gene	1338	Doube-mutated *epsps* gene, which confers tolerance to herbicide products containing glyphosate.
NOS terminator	272	Polyadenylation region from the nopaline synthase gene from *A. tumefaciens*.

3.2 Information relating to the GM plant

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

The 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: 3272, Bt11, MIR604, 1507, 5307 and GA21 through conventional breeding techniques and produces the following proteins:

1. An alpha-amylase (AMY797E) for use in the production of fuel ethanol by maize dry-grind process.
2. A truncated Cry1Ab protein for control of certain lepidopteran pests like the common European maize pests: ECB (*Ostrinia nubilalis*) and Mediterranean corn borer; MCB (*Sesamia nonagrioides*).
3. A PAT protein that confers tolerance to herbicide products containing glufosinate ammonium.
4. A modified Cry3A (mCry3A) protein for control of certain coleopteran pests such as *D. virgifera virgifera* (WCRW).
5. Two forms of the PMI protein, designated as PMI and MIR604 PMI, that act as a selectable marker trait enabling transformed plant cells to utilize mannose as the only primary carbon source.
6. A Cry1F insecticidal protein, which confers protection against certain lepidopteran pests such as European corn borer (*O. nubilalis*) and *Sesamia* spp.
7. An eCry3.1Ab protein for control of certain coleopteran pests such as WCRW and related *Diabrotica* species and
8. The mEPSPS protein that confers tolerance to herbicide products containing glyphosate.

3.1.2. Information on the sequences actually inserted or deleted

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

The 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: 3272, Bt11, MIR604, 1507, 5307 and GA21 through conventional breeding techniques.

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

Not applicable.

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

Not applicable

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

The genetic stability of each of the single maize inserts in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize has been assessed by Southern blot analysis, concluding that each transformation event in the stacked event has the same molecular properties as the single transformation event.
Furthermore, sequence comparisons of 3272, Bt11, MIR604, 5307, GA21 and 1507 inserts in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 have been made and indicated that the organisation of the inserted genetic material remained the same in the stacked product.

(e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification as well as direct changes in expression of genes as a result of the modification

Not applicable.

3.1.3. Information on the expression of the insert

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

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize was produced by conventional breeding and express the genes *amy797E, cry1Ab, mcry3A, cry1F, ecry3.1Ab, pat, pmi, mir604 pmi and mepsps*. Therefore the 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 hybrid maize plants produce the transgenic proteins AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, total PMI (PMI and MIR604 PMI) and mEPSPS, respectively.

Several tissue types from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize plants were analyzed by enzyme-linked immunosorbent assay (ELISA) to compare the concentrations of AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, total PMI (PMI and MIR604 PMI) and mEPSPS. The concentrations of the proteins measured in tissues from plants of the

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize hybrid were then compared to those measured in the corresponding single-event maize hybrids. Samples from plants of a corresponding conventional counterpart grown concurrently were included with analyses as analytical controls.

Overall, the concentrations of AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, total PMI (PMI and MIR604 PMI) and mEPSPS in tissues of the 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize hybrid were similar to those of the corresponding single-event maize hybrids 3272, Bt11, MIR604, 1507, 5307 and GA21.

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

Concentrations of most newly expressed proteins were quantifiable in most 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize tissue types analysed (leaves, roots, whole plants, pollen and kernels).

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

Molecular analyses showed that the inserts have been stably integrated into the plant's genome in 3272, Bt11, MIR604, 1507, 5307 and GA21 maize.

In addition, the genetic and phenotypic stability of each of the inserts in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize has been assessed by Southern blot and protein expression analyses. The results concluded that each single event in the stacked event are present and that the structure of each insert is retained in the stacked product. The phenotypic stability was confirmed and demonstrated that expression of the transgenic proteins in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is similar to the expression in the 3272, Bt11, MIR604, 1507, 5307 and GA21 single maize events.

3.1.5. Information (for environmental safety aspects) on how the GM plant differs from the recipient plant in:

(a) Mode(s) and/or rate of reproduction

No changes in the reproduction compared to the conventional counterpart have been observed in agronomic assessments conducted with 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

(b) Dissemination

No changes in the dissemination compared to the conventional counterpart have been observed in agronomic assessments conducted with 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

(c) Survivability

No changes in the survivability compared to the conventional counterpart have been observed in agronomic assessments conducted with 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

(d) Other differences

No changes in the reproduction, dissemination or survivability compared to the conventional counterpart have been observed in agronomic assessments conducted with 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

In summary, the results of these studies indicate that the genetic modification to produce 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize does not result in any biologically relevant agronomic or phenotypic differences related to reproduction, dissemination or survivability of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

3.1.6. Any change to the ability of the GM plant to transfer genetic material to other organisms (for environmental safety aspects)

(a) Plant to bacteria gene transfer

The probability of horizontal gene transfer (HGT) between the 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 insert and micro-organisms was investigated *in silico*, and no sequences were identified as being able to promote homologous recombination.

The HGT 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. No changes in the ability of the 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize to transfer genetic material to other organisms are expected compared to conventional maize since no sequences have been introduced to allow this to occur.

(b) Plant to plant gene transfer

The genetic modifications in the single events present in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize are not intended to change any of the typical crop characteristics of maize (except for the enhancement of the ethanol production and control of certain insect pests and weeds). Observations from field trials have confirmed that the agronomic and phenotypic characteristics of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize have not changed in comparison with the conventional maize, and therefore, there is no increase or decrease in the potential for plant-to-plant gene transfer of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize compared to traditional maize. Gene transfer from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize to other sexually compatible plant species is not possible since there are no indigenous populations of sexually compatible wild relatives in the EU. In addition, since the scope of this application does not include authorisation for the cultivation, the likelihood of dissemination of pollen to other plants (including cultivated maize plants) is considered to be negligible.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize plants were compared with the conventional counterpart that had not been genetically modified. Commercial varieties were also included in the comparison.

4.2. Experimental design and statistical analysis of data from field trials for comparative analysis

The experimental design for comparative analysis was in accordance with EFSA guidance. To evaluate whether biologically significant changes occurred in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize plants compared to the conventional counterpart, trials were planted at eight locations in Artgentina in 2013. The locations of the trial sites were selected to be representative of the agricultural regions suitable for the cultivation of the selected maize hybrids. Entries within each trial were grown in a randomized complete block design with four replicates.

4.3. Selection of materials and compounds for analysis

The selected materials for analysis were forage and grain (raw material). Maize grain from transgenic plants and conventional counterpart plants were analysed for proximates and starch, minerals, vitamins, amino acids, selected fatty acids, anti-nutrients and secondary metabloites. Forage (above ground portion) from transgenic maize plants and conventional counterpart plants were analysed for proximates and minerals.

The vast majority of nutritional components in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize are equivalent or more likely than not to be equivalent to levels of those in the reference lines, and are overall not materially different from those in conventional maize. When differences did occur, levels were within ranges considered to be normal for conventional maize, and therefore are expected to have no impact on the health or nutrition of consumers.

These data support the conclusion that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is compositionally equivalent to conventional maize.

4.4. Comparative analysis of agronomic and phenotypic characteristics

To confirm that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize plants are equivalent in agronomic characteristics compared to the conventional counterpart, apart from the introduced traits, selected agronomic and phenotypic characteristics were assessed and compared. Data were collected for multiple agronomic characteristics: early stand count, early growth rating, days to 50% pollen shed, days to 50% silking, ear height, plant height, stay green, root-lodged plants, stalk-lodged plants, final stand count, dropped ears, grain yield, grain moisture, grain test weight. The results of these trials showed that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is agronomically and phenotypically equivalent to conventional maize, apart from the introduced traits.

4.5. Effect of processing

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize will be produced and processed in the same way as any conventional counterpart maize and there is no evidence to suggest that the expression of the proteins produced by 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize (AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS) will influence this processing in any way.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 hybrid maize plants produce the proteins AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS. AMY797E catalyses the hydrolysis of starch by cleaving the internal α-1,4-glucosidic bonds into dextrins, maltose and glucose. Cry1Ab, mCry3A, Cry1F and eCry3.1Ab control certain lepidopteran and coleopteran pests. PAT and mEPSPS confer tolerance to herbicide products containing glufosinate-ammonium and glyphosate, respectively. The AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS proteins produced in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize are identical to the proteins produced in 3272, Bt11, MIR604, 1507, 5307 and GA21 maize. All of these proteins have been previously assessed by EFSA.

None of the newly expressed proteins, AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI, and mEPSPS, are structurally or functionally related to proteins which have the potential to adversely affect human or animal health; they are rapidly degraded in *in vitro* digestibility assays; have no biologically relevant sequence simliarity to known or putative mammalian protein toxins; and show no acute oral toxicity in mammalian studies.

(b) Testing of new constituents other than proteins

Maize is a common source of food and feed and has a long history of safe use. 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize has been modified to produce the AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS proteins. No other new constituents apart from these proteins are expected to be produced in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and compositional analyses have confirmed the compositional equivalence of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize to conventional maize. Therefore, no testing of any other constituent is considered necessary.

(c) Information on natural food and feed constituents

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize grain and forage have been found to be compositionally equivalent to conventional maize varieties.

These analyses showed that the levels of the components measured had not changed beyond the natural variation in maize. No significant differences emerged to suggest that biologically relevant changes in composition or nutritive value of the maize grain or forage had occurred as an unintended result of the expression of the novel proteins in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

(d) Testing of the whole genetically modified food or feed

Although there is no reason to believe that consumption of 3272, Bt11, MIR604, 1507, 5307 and GA21 maize would lead to any toxicity as a result of unintended effects, 90-day feeding studies with 3272, Bt11, MIR604, 1507, 5307 and GA21 maize grain in rodents have been performed. Studies for MIR604, 1507, 5307 and GA21 have been submitted and reviewed in the context of previous applications and reviewed by EFSA. Newly performed studies for 3272 and Bt11 maize have been submitted as part of this application to comply with the requirements of the Regulation (EU) No 503/2013.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The weight-of-evidence analysis performed by Syngenta indicates that the newly expressed proteins AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS produced by 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize are not likely to be food allergens because:

1. None of the transgenic proteins produced by 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize (AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS) come from donors known to be a significant cause of food allergy.
2. AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS have no biologically significant amino acid homology to known allergens.
3. AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS are readily degraded in *in vitro* digestibility assays.

From these data, we can conclude that AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS produced by 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize are highly unlikely to be allergenic.

(b) Assessment of allergenicity of the whole genetically modified plant

Maize grain has a history of safe use throughout the world and it is not considered to be a major allergenic food source. Although rare cases of occupational allergy to maize dust or maize pollen allergy have been reported and IgE-binding proteins have been identified in maize flour, the prevalence of maize allergy is exceedingly low amongst the human population. Equivalence of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize (with the exception of the introduced traits) to the conventional maize, was demonstrated on the basis of compositional analysis. Therefore, no increased allergenicity is anticipated for 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

There is no evidence to suggest that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize will have a greater allergenic potential compared to conventional counterpart maize varieties.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is not intended to change the nutritional status of individuals or populations. The product is enhancing the ethanol production and is intended to be commercialised accordingly. Data from the compositional analysis suggests that overall the 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is not materially different from conventional maize; therefore, it can be concluded that no nutritional imbalances were introduced in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and derived food products.

(b) Nutritional assessment of the genetically modified feed

Compositional analysis has demonstrated that no unexpected alterations in nutrients and other food or feed components have occurred. The product is enhancing the ethanol production and is intended to be commercialised accordingly. Data from the compositional analysis suggests that overall the 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is not materially different from conventional maize; therefore, it can be concluded that no nutritional imbalances were introduced in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and derived feed products.

8. EXPOSURE ASSESSMENT – 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 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize to the conventional maize supply. It is anticipated that the introduction of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize will replace some of the 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 as confirmed by the results obtained from the extensive compositional assessment.

Furthermore, the expected levels of intake of the proteins AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS through maximum consumption and exposure assumptions considered in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the EU, will be very low. The dietary exposure assessment performed took into consideration a maximum exposure assumption leading to margins of exposure that greatly exceed a factor of 100, supporting the conclusion that the risk to humans and animal livestock from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is negligible. The dietary exposure assessment supports the conclusion that the risk to consumers from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is negligible.

9. RISK CHARACTERISATION

Maize food and feed products have a long history of safe use. No significant native toxins are reported to be associated with the genus *Zea*.

The information presented in the application confirms that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and derived food and feed products are not materially different from those of its conventional maize. The molecular characterization of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize did not raise any safety concerns or identify any unintended changes as a result of the genetic modification. Data from the compositional analysis suggests that, overall, the 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and conventional maize are not materially different.The agronomic and phenotypic characteristics of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize plants, except for the introduced traits, are not different to those of its conventional counterpart comparator, taking into account natural variation. Characterisation of AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604PMI and mEPSPS proteins, and evidence of history of safe use of Bt proteins, mEPSPS and PAT, continue to confirm that these proteins are safe for human and animal consumption, and that no adverse effects on human and animal health can be expected. The genetic modification in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is not intended to improve the nutritional status of individuals or populations. The product is enhancing the ethanol production and is intended to be commercialised accordingly. The exposure assessment in humans and animals did not indicate any safety concerns, and dietary role of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is intended to be the same as the dietary role of conventional maize.

10. POST-MARKET MONITORING ON THE GENETICALLY MODIFIED FOOD OR FEED

As described in Sections 4 to 9 above, the presence of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize or its derived products in food and feed will not result in any nutritional changes. Therefore, post-market monitoring of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize food/feed is not considered necessary.

11. ENVIRONMENTAL ASSESSMENT

11.1. Mechanism of interaction between the GM plant and target organisms

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize has been developed to enhance the ethanol production andto confer resistance against certain insect pests and to provide tolerance to certain herbicides. However, the scope of this application covers the import and food and feed use of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and derived products in the EU. Cultivation of these maize products in the EU is not included in the scope. Therefore, exposure of target organisms to maize leaves and roots of 3272 x Bt11 x MIR604 x 1507 x

5307 x GA21 maize will be highly unlikely.

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

(a) Persistence and invasiveness

Taking into account the results obtained in agronomic comparisons and the fact that the scope of this application does not include cultivation of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize, the growth of any maize plants outside cultivated areas is very unlikely, which means that environmental exposure in the EU would be very low and localised. It can be concluded that the genetic modification introduced in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize has not altered agronomic and phenotypic characteristics of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize associated with persistence or invasiveness potential compared to conventional maize. In addition, the genes introduced in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize will not confer any selective advantage or disadvantage to 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize compared to conventional maize, apart from the intended modifications. Therefore 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize will not differ in persistence and invasiveness from conventional maize.

In summary, the likelihood that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize will become more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats as a result of import, processing or food and feed use, in the EU can be considered negligible.

(b) Selective advantage or disadvantage

An assessment of whether the transfer of the newly introduced genes in 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize (*amy797E, cry1Ab, mcry3A, cry1F, ecry3.1Ab, pat, pmi, mir604 pmi* and *mepsps*) could confer any selective advantage or disadvantage to other maize plants or to sexually compatible wild relatives and the potential consequences of this transfer has been conducted. Taking into account the results obtained from the Environmental Risk Assessment (e.r.a.), the results of the comparative safety assessment and the fact that the scope of this application does not include cultivation of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the EU, the conclusion from the assessment is that the expression of AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604PMI and mEPSPS will not confer any selective advantage or disadvantage to 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

(c) Potential for gene transfer

The scope of this application covers the import, processing, and food and feed use of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and derived products in the EU. Cultivation of these maize products in the EU is not

included in the scope. Therefore, it is highly unlikely that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize plants will grow in the EU.

There is also no change in the ability of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize to transfer genetic material to other organisms when compared to conventional maize. The HGT from GM plants to bacteria with subsequent expression of the transgenes is regarded as highly unlikely under natural conditions, especially in the absence of selective pressure.

Gene transfer from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize to other sexually compatible plant species is not possible since there are no indigenous populations of sexually compatible wild relatives of maize in the EU and vertical gene transfer would be limited to other maize plants. Therefore, it is highly unlikely that the import, processing, and food and feed use of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and derived products in the EU would lead to any adverse environmental effects due to plant-to-plant gene transfer.

Given the low levels of exposure to micro-organisms that could arise from the import, processing, and food and feed use of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the EU and the characteristics of the transgenes, *amy797E, cry1Ab, mcry3A, cry1F, ecry3.1Ab, pat, pmi, mir604 pmi* and *mepsps*, it is highly unlikely that HGT will occur. If gene transfer did occur, it is unlikely that the transgenes would become established in the genome of micro-organisms in the environment or human and animal digestive tract.

In the very unlikely event that any of the genes were established in the genome of micro-organisms, no adverse effects on human and animal health or the environment are expected.

(d) Interactions between the GM plant and target organisms

The scope of this application covers the import, processing, and food and feed use of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and the subcombinations in the scope of the application in the EU; no deliberate release of viable plant material in the EU environment is expected. Therefore an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is not relevant for this application.

(e) Interactions of the GM plant with non-target organisms

The scope of this application does not include cultivation of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the EU. Therefore, potential immediate or delayed effects in the environment due to direct or indirect interactions between 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize plants and non-target organisms as a result of the import, processing or products for food and feed use of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the EU can be considered highly unlikely.

(f) Effects on human health

Compositional analysis with 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize have confirmed that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is equivalent in composition to conventional maize and is as safe and nutritious as conventional maize.

There is no reason to anticipate that 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize would result in a product that differs in toxicity or allergenic potential to humans. None of the proteins (AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS) produced by 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize are known to be toxic or allergenic to humans and there are no known precedents where interactions between non-toxic proteins lead to toxic effects. The results of the toxicological and allergenicity assessment indicate that consumption of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize food products will be as safe as consuming equivalent products from conventional maize, regardless of the anticipated intake level.

In summary, no adverse effects on human health or adverse consequences for the food chain are expected following consumption of food consisting, containing or derived from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

(g) Effects on animal health

The potential adverse effects of importing 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize or derived products into the EU on animal health have been assessed. Studies conducted with AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS show that these proteins are unlikely to be toxic to humans or animals. None of these proteins shows significant sequence identity to known protein toxins. In addition, AMY797E, Cry1Ab, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS are unlikely to be allergenic.

The results obtained from the comparative analysis of composition of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize with conventional maize have shown that the levels of natural food and feed constituents have not changed beyond the natural variation in maize and no evidence of unintended effects has been observed. The conclusion of this assessment is that feed derived from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is as safe for animal consumption as feed derived from conventional maize.

In summary, no adverse effects on animal health or adverse consequences for the feed chain are expected following consumption of feed consisting, containing or derived from 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

(h) Effects on biogeochemical processes

The scope of this application does not include cultivation of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the EU. Interactions with target or non-target organisms that could lead to effects on biogeochemical processes are therefore highly unlikely.

In the unlikely event that small amounts of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize accidentally found their way into the EU environment, their survival would be very unlikely, as maize is a highly domesticated plant and cannot survive without human intervention, especially under normal European climatic conditions. Moreover, these plants could be easily controlled using any of the current agronomic measures taken to control other commercially available maize, except for the use of trait specific herbicides. In the unlikely event that some plants of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize survived, the potential effects on biogeochemical processes as a result of interactions with target and non-target organisms are likely to be the same as those effects resulting from cultivation of non-modified maize.

In summary, the risk of adverse effects on biogeochemical processes resulting from changes in management practises or interactions of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize and target or non-target organisms can be considered negligible under the scope of this application.

(i) Impacts of the specific cultivation, management and harvesting techniques

Not applicable since the scope of this application does not include cultivation of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the EU.

11.3. Potential interactions with the abiotic environment

The scope of this application does not include cultivation of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the EU. Therefore, interactions of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize with the abiotic environment are highly unlikely. In the unlikely event that small amounts of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize accidentally found their way into the EU environment, their survival would be very unlikely, as maize is a highly domesticated plant and cannot survive without human intervention, especially under normal European climatic conditions. Moreover, these plants could be easily controlled using any of the current agronomic measures taken to control other commercially available maize, except for the use of trait specific herbicides. In the unlikely event that some plants of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize survive, the potential effects on the abiotic environment will be negligible.

11.4. Risk characterisation for the environmental risk assessment

Cultivation of maize has a long history of environmental safety. Maize has no weedy characteristics and there are no significant native toxins associated with the genus *Zea*. The information presented in this application confirms that the environmental safety of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is not different from the conventional counterpart.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

Therefore, exposure to the environment will be limited to unintended release of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize, which could occur for example via substantial losses during loading/unloading of the viable commodity including 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize destined for processing into animal feed or human food products. Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious maize plants, such as manual or mechanical removal and the application of herbicides (except for the use of trait-specific herbicides).

An e.r.a.was carried out for 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC.The scientific evaluation of the characteristics of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the e.r.a. has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

(b) Interplay between environmental risk assessment and monitoring

An e.r.a. was carried out for 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21maize according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC.

The scientific evaluation of the characteristics of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21.

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

The scientific evaluation of the characteristics of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of 3272 x Bt11 x MIR604

x 1507 x 5307 x GA21 maize. It is therefore considered that there is no need for case-specific monitoring

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

General surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable GM plant or its use for human and animal health or the environment that were not predicted in the e.r.a..

The scope of this application does not include authorisation for the cultivation of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize. Therefore, exposure to the environment will be limited to unintended release of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize, which could occur for example via substantial losses during loading/unloading of the viable commodity destined for processing into animal feed or human food products. Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious maize plants, such as manual or mechanical removal and the application of herbicides.

However, and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, general surveillance on 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize will be undertaken for the duration of the authorisation. The general surveillance will take into consideration, and be proportionate to, the extent of imports of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize, and use thereof in the Member States.

In order to increase the possibility of detecting any unanticipated adverse effects, a monitoring system will be used, which involves the authorisation holder and operators handling and using viable 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

(e) Reporting the results of monitoring

In accordance with Regulation (EC) No 1829/2003, the authorisation holder is responsible to inform the European Commission of the results of the general surveillance.

The authorisation holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on unanticipated adverse effects, if any, that have arisen from handling and use of viable 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize.

13. DETECTION AND EVENT-SPECIFIC IDENTIFICACION TECHNIQUES FOR THE GM PLANT

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 hybrid maize is detectable using the event-specific real-time quantitative PCR methods for 3272, Bt11, MIR604, 1507, 5307 and GA21 maize events, respectively. These detection methods have been validated by the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) of the Joint Research Centre of the European Commission as part of this application.

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT (FOR ENVIRONMENTAL SAFETY ASPECTS)

14.1. 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

No trials of 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize have been carried out in the EU.

14.2. History of previous releases of the GM plant carried out outside the Union by the same notifier

(a) Release country (1)

U.S.A.

(b) Authority overseeing the release

Not applicable.

3272, Bt11, MIR604, 1507, 5307 and GA21 are deregulated by United States Department of Agriculture (USDA).

3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize is not regulated in the U.S.

(c) Release site

Various sites across the U.S.A.

(d) Aim of the release

Research and development.

(e) Duration of the release

Varied depending on the aim of the trial.

(f) Aim of post-releases monitoring

Control of volunteers.

(g) Duration of post-releases monitoring

Varied depending on the aim of the trial, typically one year.

(h) Conclusions of post-release monitoring

The occurrence of volunteers after planting 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize field trials was no different to other maize.

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

No evidence of adverse effects to human health or the environment has been found.

(j) Release country (2)

Argentina

(k) Authority overseeing the release

SAGyP: Secretariat of Agriculture, Livestock and Fisheries

(l) Release site

Various sites across Argentina.

(m) Aim of the release

Research and development.

(n) Duration of the release

5 months.

(o) Aim of post-releases monitoring

Control of volunteers.

(p) Duration of post-releases monitoring

Varied depending on the aim of the trial, typically one year.

(q) Conclusions of post-release monitoring

The occurrence of volunteers after planting 3272 x Bt11 x MIR604 x 1507 x 5307 x GA21 maize field trials was no different to other maize.

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

Out of the scope of the trial – however no differences were registered compared to conventional material.