Application for authorisation of stacked Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize under Regulation (EC) No 1829/2003

PART VII: SUMMARY

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PART VII

SUMMARY

SUMMARY OF THE APPLICATION FOR AUTHORISATION OF STACKED Bt11 X MIR162 X MIR604 X 1507 X 5307 X GA21 MAIZE IN ACCORDANCE WITH REGULATION (EC) 1829/2003

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Germany

(b) Application Number

EFSA-GMO-DE-2011-103

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

Bt11 x MIR162 x MIR604 x TC1507 x 5307 x GA21 maize (hereafter referred to as Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize[1]).

(d) Date of acknowledgement of valid application

Not available at time of submission

1.2. Applicant

(a) Name of applicant

Syngenta Crop Protection AG, Basel Switzerland acting on its behalf and through its affiliated companies.

(b) Address of applicant

Syngenta Crop Protection AG
Schwarzwaldallee 215
CH- 4058 Basle
Switzerland

[1] Event TC1507 may be referred to as maize line 1507 in the European Union. It is normally referred to as Event TC1507 in applications submitted by Dow AgroSciences LLC to most countries other than the European Union. This applies also to the Detection Method published by the Community Reference Laboratory for Food and Feed in the EU.

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

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

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 EU

Please note that the scope of this application has been described in detail in Section 4. of Part I of the application.

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 2011/18/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 notified/authorised in a third country either previously or simultaneously?

No ☒

Yes ☐ (in that case, specify the third country and provide a copy of the risk assessment conclusions, the date of the authorisation and the scope)

1.8. General description of the product

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

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is a genetically modified maize (GM) that is produced by conventional breeding crosses of the following GM maize events: Bt11, MIR162, MIR604, 1507, 5307 and GA21.

- Event Bt11 maize (hereafter referred to as '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.
- Event MIR162 maize (hereafter referred to as 'MIR162 maize') which expresses a Vip3Aa protein for control of certain lepidopteran pests and a phosphomannose isomerase (PMI) protein, that acts as a selectable marker trait enabling transformed plant cells to utilize mannose as the only primary carbon source.
- Event MIR604 maize (hereafter referred to as 'MIR604 maize') which expresses a modified Cry3A (mCry3A) protein for control of certain coleopteran pests and a phosphomannose isomerase (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 phosphinothricin acetyltransferase (PAT) protein for weed control by providing tolerance to herbicide products containing glufosinate ammonium.

- Event 5307 maize (hereafter referred to as '5307 maize') which expresses a Cry protein, designated eCry3.1Ab, for control of certain coleopteran pests like *Diabrotica virgifera virgifera* (WCRW) and related *Diabrotica* species; and, a phosphomannose isomerase (PMI) protein that acts as a selectable marker trait enabling transformed plant cells to utilize mannose as the only primary carbon source.
- Event GA21 maize (GA21 maize) which produces a modified maize 5-enolpyruvylshikimate-3-phosphate synthase enzyme (mEPSPS) for weed control by providing tolerance to herbicide products containing glyphosate.

(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) 1829/2003 covers the import, food and feed use and processing of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize. It does not cover cultivation.

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

It is intended that Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize will be used as any other conventional maize which is cultivated or imported 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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and products derived from it are not different from those of its conventional counterpart. Bt11 x MIR162 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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

(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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and derived products is 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) 1829/2003 covers the import,

food and feed use and processing of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize. It does not cover cultivation.

(g) Any proposed packaging requirements

The characteristics of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and products derived from it are not different from those of its conventional counterpart. Bt11 x MIR162 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 law and when necessary a proposal for specific labelling in accordance with Articles 13(2), (3) and 25(2)(c), (d) and 25(3) of Regulation (EC) No 1829/2003. In the case of GMO plants, food and/or feed containing or consisting of GMO plants, a proposal for labelling has to be included complying with the requirements of Annex IV, A(8) of Directive 2001/18/EC

A proposal for labelling has been included in the application following the guidance provided by EFSA. This includes the labelling requirements outlined by Regulation (EC) No 1829/2003 and Annex IV of Directive 2001/18/EC. Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize grain 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 Bt11 x MIR162 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 Union

There are no anticipated changes to the intake/extent of use of maize as a result of the introduction of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize to the conventional maize supply. It is anticipated that the introduction of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize will replace some of the maize in existing food and feed products.

(ii) In export markets for EU supplies

There are no anticipated changes to the extent of maize production in export markets for EU supplies as a result of the introduction of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize seed products. It is anticipated that the introduction of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize seed will replace some of the existing maize seed 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-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9.

The unique identifiers assigned to all the sub-combinations of this product are the following:

- Bt11 x MIR162: SYN-BTØ11-1 x SYN-IR162-4
- Bt11 x MIR604: SYN-BTØ11-1 x SYN-IR6Ø4-5
- Bt11 x 1507: SYN-BTØ11-1 x DAS-Ø15Ø7-1
- Bt11 x 5307: SYN-BTØ11-1 x SYN-Ø53Ø7-1
- Bt11 x GA21: SYN-BTØ11-1 x MON-ØØØ21-9
- MIR162 x MIR604: SYN-IR162-4 x SYN-IR6Ø4-5
- MIR162 x 1507: SYN-IR162-4 x DAS-Ø15Ø7-1
- MIR162 x 5307: SYN-IR162-4 x SYN-Ø53Ø7-1
- MIR162 x GA21: SYN-IR162-4 x MON-ØØØ21-9
- MIR604 x 1507: SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
- MIR604 x 5307: SYN-IR6Ø4-5 x SYN-Ø53Ø7-1
- MIR604 x GA21: SYN-IR6Ø4-5 x MON-ØØØ21-9
- 1507 x 5307: DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
- 1507 x GA21: DAS-Ø15Ø7-1 x MON-ØØØ21-9
- 5307 x GA21: SYN-Ø53Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR162 x MIR604: SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5
- Bt11 x MIR162 x 1507: SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1
- Bt11 x MIR162 x 5307: SYN-BTØ11-1 x SYN-IR162-4 x SYN-Ø53Ø7-1
- Bt11 x MIR162 x GA21: SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9
- Bt11 x MIR604 x 1507: SYN-BTØ11-1 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
- Bt11 x MIR604 x 5307: SYN-BTØ11-1 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1
- Bt11 x MIR604 x GA21: SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9
- Bt11 x 1507 x 5307: SYN-BTØ11-1 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
- Bt11 x 1507 x GA21: SYN-BTØ11-1 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
- Bt11 x 5307 x GA21: SYN-BTØ11-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- MIR162 x MIR604 x 1507: SYN-IR162-4 x SYN-IR6Ø4-5 x

DAS-Ø15Ø7-1
- MIR162 x MIR604 x 5307: SYN-IR162-4 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1
- MIR162 x MIR604 x GA21: SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9
- MIR162 x 1507 x 5307: SYN-IR162-4 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
- MIR162 x 1507 x GA21: SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
- MIR162 x 5307 x GA21: SYN-IR162-4 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- MIR604 x 1507 x 5307: SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
- MIR604 x 1507 x GA21: SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
- MIR604 x 5307 x GA21: SYN-IR6Ø4-5 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- 1507 x 5307 x GA21: DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR162 x MIR604 x 1507: SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
- Bt11 x MIR162 x MIR604 x 5307: SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
- Bt11 x MIR162 x MIR604 x GA21: SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9
- Bt11 x MIR604 x 1507 x 5307: SYN-BTØ11 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
- Bt11 x MIR604 x 1507 x GA21: SYN-BTØ11 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR162 x 1507 x 5307: SYN-BTØ11 x SYN-IR162-4 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
- Bt11 x MIR162 x 1507 x GA21: SYN-BTØ11 x SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR162 x 5307 x GA21: SYN- BTØ11 x SYN-IR162-4 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR604 x 5307 x GA21: SYN-BTØ11 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- Bt11 x 1507 x 5307 x GA21: SYN-BTØ11 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- MIR162 x MIR604 x 1507 x 5307: SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
- MIR162 x MIR604 x 1507 x GA21: SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
- MIR162 x MIR604 x 5307 x GA21: SYN-IR162-4 x SYN-

IR6Ø4-5 x SYN-Ø53Ø7-1 x MON-ØØØ21-9

- MIR162 x 1507 x 5307 x GA21: SYN-IR162-4 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- MIR604 x 1507 x 5307 x GA21: SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- MIR162 x MIR604 x 1507 x 5307 x GA21: SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR604 x 1507 x 5307 x GA21: SYN-BTØ11 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR162 x 1507 x 5307 x GA21: SYN-BTØ11 x SYN-IR162-4 x DAS- Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR162 x MIR604 x 5307 x GA21: SYN-BTØ11x SYN-IR162-4 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR162 x MIR604 x 1507 x GA21: SYN-BTØ11 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
- Bt11 x MIR162 x MIR604 x 1507 x 5307: SYN-BTØ11 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1

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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and derived products are not different from those of its conventional counterpart, apart from the intended effect of tolerance to certain lepidopteran and coleopteran insect pests and herbicide products containing glufosinate ammonium or glyphosate.

The scope of this application does not include cultivation of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize in the EU. In the unlikely event that small amounts of grain from Bt11 x MIR162 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 this grain 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.

The Bt11 x MIR162 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 (formerly Gramineae)

(b) Genus

Zea

(c) Species

Z. mays L.

(d) Subspecies

mays

(e) Cultivar/breeding line or strain

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21

(f) Common name

Maize; corn

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 159 million hectares worldwide (2009). 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 21º and 27º C and the freeze-free season lasts 120-180 days.

The EU is the fourth largest grain maize producer in the world, after the US, China and Brazil. In the EU-27, grain maize was cultivated on about 8.4 million hectares (2009) with a production of 57 million tonnes (2009). Another major maize product is silage maize produced on about 5.2 million hectares (2009).

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Sexual reproduction: *Zea 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.

Asexual reproduction: There is no asexual reproduction in maize.

(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. 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 and studies have indicated that most maize pollen falls within 5m of the field's edge. In general, such studies have shown that over 98% of maize pollen remains within a radius of 25-50m of the source, although some grains can travel several hundred meters. 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, it can range from as short as 60 to 70 days to as long as 43 to 48 weeks from seedling emergence to maturity.

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

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 wild species in the EU.

2.5. Survivability (for environmental safety aspects)

(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 of domestic cultivation and is non-invasive of natural habitats.

2.6. Dissemination (for environmental safety aspects)

(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

Compared to other wind-pollinated species, maize pollen grains are relatively large and therefore, settle to the ground rapidly and have usually a short flight range. Although vertical wind movements or gusts during pollen shedding can lift pollen up high in the atmosphere and distribute it over significant distances, concentrations of viable pollen considerably decrease with height and distance from the source. Hence, only low levels of cross-pollination could occur over longer distances under suitable climatic conditions.

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

There are no wild relatives of maize in Europe.

2.8. 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 (for environmental safety aspects)

Maize was introduced into Europe in the 15th century by Columbus and since

the 16th century it is widely grown in most of the EU Member States.

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 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.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

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

The Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is a GM maize that is produced by conventional breeding crosses of the GM maize events: Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize. No further genetic modification to produce this stack has taken place.

The Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize events maize were produced by genetic modification as follows:

- Bt11 maize was produced using protoplast transformation/regeneration.
- MIR162 maize was produced by transformation of immature maize embryos derived from a proprietary *Zea mays* line *via Agrobacterium tumefaciens*-mediated transformation.
- MIR604 maize was produced via *Agrobacterium*-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 *Zea mays* line *via Agrobacterium tumefaciens*-mediated transformation.
- GA21 maize was produced via microprojectile bombardment of maize suspension culture cells.

(b) Nature and source of the vector used

The Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: Bt11, MIR162, MIR604, 1507, 5307 and GA21 through conventional breeding techniques.

The vectors used to produce Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize are as follows:

- 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 pNOV1300 was used for the transformation of MIR162 maize.
- The Plasmid pZM26, a binary vector used for *Agrobacterium* 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 *Agrobacterium* 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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: Bt11, MIR162, 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:

Event Bt11 maize (transformation vector pZ01502)

Vector component	Size (bp)	Description
35S	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	253	Polyadenylation region from the nopaline synthase gene from *Agrobacterium tumefaciens*.
Selectable marker cassette		
35S	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	253	Polyadenylation region from the nopaline synthase gene from *Agrobacterium tumefaciens*.

Event MIR162 maize (transformation vector pNOV1300)

Vector component	Size (bp)	Description
ZmUbiInt promoter	1993	Promoter derived from the maize (*Zea mays*) polyubiquitin gene
vip3Aa19	2370	A modified version of the native *vip3Aa1* gene from *Bacillus thuringiensis* that confers resistance to certain lepidopteran pest species.
iPEPC9	108	Intron from the phosphoenolpyruvate carboxylase gene from maize *(Zea mays).*
35S 3' nontranslated region	70	3' nontranslated region sequence from the 35S DNA from the cauliflower mosaic virus (CaMV).
Selectable marker cassette		
ZmUbiInt promoter	1993	Promoter from the maize (*Zea mays*) polyubiquitin gene
pmi	1176	*E. coli pmi* gene encoding the enzyme phosphomannose isomerase (PMI). This gene is also known as *manA.*
NOS	253	Polyadenylation region from the nopaline synthase gene from *Agrobacterium tumefaciens.*

Event MIR604 maize (transformation vector pZM26)

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

Event 1507 maize (transformation vector PHP8999)

Vector component	Size (bp)	Description
*Ubi*1ZM	1986	Ubiquitin promoter derived from *Zea mays*
cry1F	1818	The *cry1F* gene was originally cloned from *Bacillus thuringiensis* subsp. *aizawai*. gene. It provides resistance against certain lepidopteran insect pests such as the European corn borer and *Sesamia* spp.
ORF25Poly A terminator	714	Terminator from *Agrobacterium tumefaciens* pTi15995
Selectable marker cassette		
CaMV35S	418	Promoter from the cauliflower mosaic virus.
pat	552	*Streptomyces viridochromogenes* gene encoding the selectable marker PAT (phosphinothricin acetyltransferase). PAT confers resistance to herbicides containing glufosinate
CaMV 35S terminator	204	35S terminator from the cauliflower mosaic virus

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.

Event GA21 maize (transformation vector pDPG434)

Vector component	Size (bp)	Description
Rice actin promoter, exon and intron	1.4	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	0.4	Optimised transit peptide sequence constructed based on transit peptide sequences from maize and sunflower ribulose-1,5-bis phosphate carboxylase oxygenase (RuBisCo) genes.
Modified maize EPSPS gene	1.3	Mutated *epsps* gene, which confers tolerance to herbicide products containing glyphosate.
NOS terminator	0.3	Polyadenylation region from the nopaline synthase gene from *Agrobacterium tumefaciens*.

3.2. Information relating to the GM plant

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

The Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: Bt11, MIR162, MIR604, 1507, 5307 and GA21 through conventional breeding techniques and produces the following proteins:

1. 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*).
2. A PAT protein that confers tolerance to herbicide products containing glufosinate ammonium.
3. A Vip3Aa20 protein for control of certain lepidopteran pests like corn earworm (*Heliothis zea.*), black cutworm (*Agrotis ipsilon*), fall armyworm (*Spodoptera frugiperda*), and western bean cutworm (*Striacosta albicosta*) or other lepidopteran pests of the order Noctuidae.
4. A modified Cry3A (mCry3A) protein for control of certain coleopteran pests (Western corn rootworm; 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 (*Ostrinia nubilalis*) and *Sesamia* spp.
7. An eCry3.1Ab protein for control of certain coleopteran pests like *Diabrotica virgifera virgifera* (Western corn rootworm) and related *Diabrotica* species.
8. A modified mEPSPS enzyme that confers tolerance to herbicide products containing glyphosate.

3.2.2. Information on the sequences actually inserted or deleted

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

The Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: Bt11, MIR162, MIR604, 1507, 5307 and GA21 through conventional breeding techniques.

The inserts in Bt11, MIR162, MIR604, 1507 and 5307 maize are present at a single locus and inherited as a single gene in a Mendelian fashion.

The insert integrated in 1507 maize contains one copy of the almost full-length linear fragment (6186 bp from the 6235 bp of insert PHI8999A)

used in the transformation, which includes one functional copy of the complete *cry*1F gene and one functional copy of the complete *pat* gene, together with the regulatory sequences necessary for their expression. In addition, the 1507 maize insert contains the following non-functional fragments: one fragment (335 bp) of the *cry*1F gene, with no *ubi*ZM1(2) promoter sequence; one fragment (15 bp) of the *cry*1F gene, both located at the 5' end of the almost full-length insert; two fragments (201 bp and 138 bp long, respectively) of the *pat* gene, without regulatory sequences associated, located at the 5' border and, one fragment (188 bp) of the *pat* gene, located at the 3' border; one fragment (118 bp) of the polylinker region and *ubi*ZM1(2) promoter sequence located at the 5' border; one fragment (550 bp) of the ORF25PolyA terminator sequence in inverted position located immediately at the 3' end of the almost full-length insert.

The insert in GA21 maize is comprised of six contiguous regions derived from the 3.49 kb *Not*I restriction fragment from pDPG434 employed in the generation of GA21 maize (copies 1-6). Copy 1 contains the rice actin promoter that has a 5' deletion of 696 bp, the actin first exon and intron, the optimized transit peptide, the *mepsps* gene and the NOS terminator. Copies 2, 3 and 4 are intact versions of the 3.49 kb *Not*I restriction fragment from pDPG434. Copy 5 contains a complete rice actin promoter, the actin first exon and intron, the optimized transit peptide and the first 288 bp of the *mepsps* gene which ends in a stop codon and does not contain the NOS terminator. Copy 6 contains the rice actin promoter and a truncated actin first exon only and contains no other elements from pDPG434.

In addition to sequencing, Southern analysis performed on each of the single events demonstrate the absence of further copies of the insert or vector sequence elsewhere in the genome. In order to assess the integrity of the insert from each individual event during conventional breeding to produce Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize, additional Southern analysis was performed. The predicted DNA hybridization patterns from each individual event were confirmed in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize, demonstrating preservation of the integrity of the transgenic fragment from each individual event to Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

(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

The inheritance pattern of the inserts in Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize were analysed and the results showed that insertions had taken place in the nucleus.

The Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: Bt11, MIR162, MIR604, 1507, 5307 and GA21 through conventional breeding techniques. It therefore, contains the inserts derived from the single events. The presence of the inserts from Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize in the stacked product was confirmed by Southern blot analyses.

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

The Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize described in this application has been produced by combining the GM maize events: Bt11, MIR162, MIR604, 1507, 5307 and GA21 through conventional breeding techniques. The organisation of the inserted genetic material in Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize is as follows:

Bt11 maize

Sequencing and Southern data have demonstrated that Bt11 maize contains a single DNA insertion with one copy of both the *cry1Ab* and the *pat* genes.

MIR162 maize

Sequencing and Southern data have demonstrated that MIR162 maize contains a single DNA insertion with one copy of both the *vip3Aa20* and *pmi* genes.

MIR604

Sequencing and Southern data have demonstrated that MIR604 maize contains a single DNA insertion with one copy of both the *mcry3A* and the *pmi* genes.

1507 maize

Sequencing and Southern data have demonstrated that 1507 maize contains a single DNA insertion with one copy of the almost full-length linear fragment used in the transformation, which includes one functional copy of the complete *cry*1F gene and one functional copy of the complete *pat* gene, together with the regulatory sequences necessary for their expression. The insert also contains two non-

functional fragments of the *cry*1F gene, three non-functional fragments of the *pat* gene, one non-functional fragment of the polylinker region and *ubi*ZM1(2) promoter, and one non-functional fragment of the ORF25PolyA terminator sequence. See section D.2.a for further detail. The sequence analysis confirmed that the insert is intact and that the contiguousness of the functional elements within the insert as intended in PHI8999A has been maintained.

5307 maize

The molecular analyses confirmed that 5307 maize contains a single intact insert with one copy of the *ecry3.1Ab* and *pmi* genes.

GA21 maize

Sequence analysis of the GA21 maize insert demonstrates that the insert is comprised of six contiguous regions derived from the 3.49 kb *Not*I restriction fragment from pDPG434 employed in the generation of Event GA21 (copies 1-6).

Molecular comparisons of the Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize with the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize have shown that the inserts are preserved in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

(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.

3.2.3. Information on the expression of the insert

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

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is produced by combining Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize through conventional breeding techniques. Therefore, these maize plants produce the transgenic proteins inherited from these single GM maize events: Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS.

Tissues from maize plants derived from Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize and a breeding stack containing these events (Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21) were analyzed by enzyme-linked immunosorbent assay (ELISA) to compare the concentrations of Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, total PMI (PMI

and MIR604 PMI) and mEPSPS.

The analyses were performed on key plant tissues collected from transgenic hybrid plants at different sampling times across the growing season. To control for background effects, the corresponding tissues from a conventional counterpart were also analyzed.

The concentrations of Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab and mEPSPS were, in general, statistically similar in the Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize hybrid and the corresponding individual event hybrids. Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize, however, contains two functional copies of the *pat* gene and three copies of the *pmi* genes and is therefore, not expected to contain the same PAT and PMI concentrations as the single event parents.

The results obtained confirm that, as expected, transgenic protein expression in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is not substantially different from that of the Bt11, MIR162, MIR604, 1507, 5307 or GA21 single maize events.

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

As summarised above, studies to evaluate the range of expression of the proteins Cry1Ab, PAT, Vip3Aa20, total PMI (PMI together with MIR604 PMI), mCry3A, Cry1F, eCry3.1Ab and mEPSPS in different tissues of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize have been conducted.

These results obtained confirm that, as expected, transgenic protein expression in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize tissues is not substantially different from that of the Bt11, MIR162, MIR604, 1507, 5307 and GA21 single maize events.

3.2.4. 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 Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize.

In addition, the genetic and phenotypic stability of each of the single maize inserts in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize has been assessed by Southern blot and protein expression analyses. The results confirmed that the single events are present and that the structure of each insert is retained in the stacked product.

3.2.5. 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 Bt11 x MIR162 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 Bt11 x MIR162 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 Bt11 x MIR162 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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

In summary, the results of these studies indicate that the combination of Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize using conventional breeding techniques does not result in any biologically relevant agronomic or phenotypic differences related to reproduction, dissemination or survivability of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

3.2.6. 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 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. No changes in the ability of the Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize to transfer genetic material to other organism are expected compared to conventional maize since no sequences have been introduced to allow this to occur. An assessment was conducted on the hypothetical risk that horizontal gene transfer (HGT) between Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize, or any of the sub-combinations of the single events independently of their origin, and

micro-organisms could lead to harm to human or animal health or to the environment The likelihood that the import, processing and food and feed use of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize, or any of the sub-combinations independently of their origin, in the EU will result in harmful effects in human or animal health or the environment as a consequence of HGT is negligible.

(b) Plant to plant gene transfer

The genetic modification in the single maize events (Bt11, MIR162, MIR604, 1507, 5307 and GA21) is not intended to change any of the typical crop characteristics of maize (except for the tolerance to insect and herbicide products). Observations from field trials have confirmed that the agronomic and phenotypic characteristics of Bt11, MIR162, MIR604, 1507, 5307 and GA21 and Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize have not changed in comparison with the conventional counterpart, and therefore, there is no increase or decrease in the potential for plant-to-plant gene transfer of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize compared to traditional maize. Gene transfer from Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize to other sexually compatible plant species is not possible since maize has no 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

Stacked maize plants containing Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize 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

To evaluate whether biologically significant changes in composition occurred in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize plants compared to the conventional counterpart, trials were planted at eight locations in the US in 2012. The locations of the trial sites were selected to be representative of the range of environmental conditions under which the hybrid varieties are expected to be grown. At each location, four replicate plots per entry were planted.

The levels of multiple nutritive components were compared in maize kernels (grain) or whole plants (forage) from Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and conventional counterpart plants grown simultaneously. The mean values were also compared with the range of data published in the literature, where data was available.

4.3. Selection of materials and compounds for analysis

Based on guidance of the OECD, grain from transgenic plants and conventional counterpart plants were analysed for proximates (including starch), minerals, amino acids and selected fatty acids, vitamins, anti-nutrients and secondary metabolites. Forage (whole plants) from transgenic maize plants and conventional counterpartplants were analysed for proximates and minerals.

No consistent pattern has emerged to suggest that biologically relevant changes in composition or nutritive value of the grain or forage have occurred as an unintended result of the combination of the single events or expression of the transgenes in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

These data support the conclusion that Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is compositionally equivalent to conventional maize, apart from the introduced traits of insect and herbicide tolerance.

4.4. Comparative analysis of agronomic and phenotypic characteristics

To confirm that the stack maize plants are equivalent in agronomic characteristics compared to the conventional counterpart, apart from the introduced traits, Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize plants were grown concurrently with conventional counterpart plants at eight US locations in 2012. Selected agronomic and phenotypic traits were assessed and compared. The results of these trials showed that Bt11 x MIR162 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

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize will be produced and processed in the same way as any non-GM maize and there is no evidence to

suggest that the expression of the proteins produced by Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize (Cry1Ab, Vip3Aa20, 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

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is produced by combining Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize through conventional breeding. No new genetic modification has therefore, taken place in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and, as intended, the Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize plants produce the proteins inherited from these single GM events: Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS.

Potential adverse effects to human and animal health arising from Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS have previously been assessed and it was concluded that the potential toxic effects to humans and animals of these proteins could be considered negligible. In summary:

- The recipient organism, maize, has a history of safe use throughout the world.
- None of the gene sequences or their donors are known to be pathogenic to humans and no pathogenic sequences have been introduced.
- Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS have no significant amino acid homology to known mammalian protein toxins.
- Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS are unlikely to be allergenic.
- Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS are readily degraded in *in vitro* digestibility assays.
- Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS 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. Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize has been modified to produce the Cry1Ab, Vip3Aa20, 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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and compositional analyses have confirmed the compositional equivalence of Bt11 x MIR162 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

Grain and forage from Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize have been found to be compositionally equivalent to conventional maize varieties except for the presence of the intended traits. In particular, the presence and levels of natural food and feed constituents such as macro- and micronutrients, secondary plant metabolites as well as natural toxins and antinutritional factors have been analysed and compared with non-GM isolines and data from the literature.

These analyses showed that the levels of the components measured had not changed beyond the natural variation in maize. No consistent patterns emerged to suggest that biologically relevant changes in composition or nutritive value of the grain or forage had occurred as an unintended result of the expression of the transgenes in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

(d) Testing of the whole GM food/feed

Grain and forage from Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize have been found to be compositionally equivalent to conventional maize varieties except for the presence of the intended traits. In addition, the transgenic proteins produced in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize are digested rapidly, show a lack of acute toxicity and show no significant homology to known protein toxins. Also, the respective function and mode of action of these newly expressed proteins are known and there is no evidence of interaction of safety concern between the newly expressed proteins expressed in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize. Therefore, no additional testing of the whole GM food/feed is considered necessary.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is produced by combining Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize through conventional breeding and therefore, expresses the proteins inherited from these three single GM maize events.

The allergenic potential arising from Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS have previously been assessed and it was concluded that the allergenic potential to humans and animals of these proteins could be considered negligible. In summary:

- None of the transgenic proteins produced by Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize (Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS) come from donors known to be a significant cause of food allergy.
- Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS have no biologically significant amino acid homology to known allergens
- Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS are readily degraded in *in vitro* digestibility assays.

From these data, it can be concluded that Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS produced by Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize are highly unlikely to be allergenic.

(b) Assessment of allergenicity of the whole GM plant

Maize has been extensively cultivated and has a history of safe use for human food and animal feed. Maize is not considered to be a food crop which causes significant food allergy and the newly expressed proteins in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize are very unlikely to be allergenic.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of GM food

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is not intended to change the nutritional status of individuals of populations or to result in products with enhanced functionality. Compositional analysis and whole food safety tests have demonstrated that no unexpected alterations in nutrients and other food components have occurred and that no nutritional imbalances were introduced in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

(b) Nutritional assessment of GM feed

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is not intended to change the nutritional status of livestock animals. Compositional

analysis and whole food and feed safety tests have demonstrated that no unexpected alterations in nutrients and other food or feed components have occurred and that no nutritional imbalances were introduced in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize to the conventional maize supply. It is anticipated that the introduction of Bt11 x MIR162 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 Cry1Ab, Vip3Aa20, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS through consumption of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize in the EU will be very low. Margins of exposure exceed a factor of at least 800, supporting the conclusion that the risk to consumers from Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is negligible and confirming the results previously obtained for the single events.

9. RISK CHARACTERISATION FOR THE SAFETY ASSESSMENT OF GM FOOD AND FEED

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 this application confirms that Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and derived food and feed products are not different from those of its conventional counterpart.

10. POST-MARKET MONITORING ON GM FOOD/FEED

As described in sections 7.1 to 7.10 above, the presence of Bt11 x MIR162 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 Bt11 x MIR162 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

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize has been developed to

confer maize plants tolerance to some coleopteran and lepidopteran pests that typically cause economic damage in maize crops, feeding either on maize leaves or roots. However, the scope of this application covers the import and food and feed use of Bt11 x MIR162 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 Bt11 x MIR162 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

Potential changes in persistence and invasiveness due to the genetic modifications introduced in the Bt11, MIR162, MIR604, 1507, 5307 and GA21 single maize events have been previously conducted. The conclusions of these assessments were that the agronomic characteristics of these maize, including those which are indicative of persistence or invasiveness, are comparable to conventional maize. Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 is a stacked maize product produced by combining Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize using conventional breeding techniques. A comparison of the agronomic and phenotypic characteristics (including those which are indicative of persistence or invasiveness) of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize with conventional maize was conducted. The conclusions from this assessment were that the combination of Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize using conventional breeding has not altered the agronomic and phenotypic characteristics of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize that indicate persistence or invasiveness compared to conventional maize, apart from the intended modification, which is tolerance to some herbicides and resistance to certain insect pests. Therefore Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize will not differ in persistence and invasiveness from conventional maize.

In summary, the likelihood that Bt11 x MIR162 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 importing Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize in the EU can be considered negligible.

(b) Selective advantage or disadvantage

An assessment of whether the transfer of the newly introduced genes in the single maize events Bt11, MIR162, MIR604, 1507, 5307 and GA21

(Cry1Ab, Vip3Aa, 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 in previous ERAs conducted with the individual maize events and the results of the comparative safety assessment and the fact that the scope of this application does not include cultivation of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize in the EU, the conclusion from the assessment is that the expression of Cry1Ab, Vip3Aa, mCry3A, Cry1F, eCry3.1Ab, PAT, PMI, MIR604 PMI and mEPSPS will not confer any selective advantage or disadvantage to Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

(c) Potential for gene transfer

The scope of this application covers the import and food and feed use of Bt11 x MIR162 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 its is highly unlikely that Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize plants will grow in the EU. Since populations of sexually compatible wild relatives of maize are not known in the EU, any vertical gene transfer would be limited to other maize plants. Therefore, it is highly unlikely that the import and food and feed use of Bt11 x MIR162 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.

In terms of horizontal gene transfer, current scientific knowledge indicates that horizontal gene transfer of non-mobile DNA fragments between unrelated organisms (such as plants to microorganisms) is extremely unlikely to occur under natural conditions. However, since the *cry1Ab*, *vip3Aa20*, *pmi*, *cry1F*, *mcry3A*, *ecry3.1Ab* and *pat* genes expressed in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize have been derived from bacteria, an assessment of whether these genes could be transferred into micro-organisms and get integrated into their genome leading to adverse effects to humans, animal or the environment has been conducted.

Given the low levels of exposure to micro-organisms that could arise from the import and food and feed use of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize in the EU and the characteristics of the transgenes, it is highly unlikely that horizontal gene transfer will occur. If gene transfer did occur, it is unlikely that the transgenes would become established in the genome of microorganisms 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 microorganisms, no adverse

effects on human and animal health or the environment are expected

Further, the molecular characterization data establish that:

1. There are no presence of antibiotic resistance markers in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.
2. No changes in the genes were introduced to enhance recombination or gene transfer.
3. The *cry1Ab, vip3Aa20, pmi, cry1F, mcry3A, ecry3.1Ab* and *pat* genes expressed in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize are derived from bacteria. The *mepsps* gene comes from maize and therefore unrelated to bacteria.

A bioinformatics search was conducted in order to investigate any homology between Bt11, MIR162, MIR604, 1507, 5307, GA21 insert sequences and micro-organisms. The sequence homologies of the insert and genomic sequences flanking it were screened for similarity to microbial deoxyribonucleic acid (DNA) sequences found in public databases. Due to the origin and donor of the above mentioned newly inserted genes in Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize it was expected that the bioinformatic search outcome will indicate sufficient DNA similarity for homologous recombination with the respective original genes from bacteria. However no further homologies were detected. As the inserted gene sequences already exist in the environment they could be transferred by HGT between naturally occurring microorganisms. Therefore, a negligible increase in exposure to the aligned sequence and no new hazard indicate that risk to the environment as a consequence of HGT of these genes from Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize import, or any of the sub-combinations independently of their origin, is considered negligible.

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(d) Interactions between the GM plant and target organisms

The scope of this application does not include cultivation of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize in the EU. Therefore, interactions between Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize plants and target organisms are highly unlikely.

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

The scope of this application covers the import and food and feed use of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize and derived products in the EU. Cultivation of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize in the EU is not included in the scope. Therefore exposure of non-target organisms (NTOs) to this maize or derived products will be highly unlikely. However, an assessment has been conducted to take into account other routes of exposure like exposure to

faeces of animals fed with Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize derived grain or products. Previous ERAs conducted for the import and use in the EU of each of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize concluded that the potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between each of these GM maize events and NTOs could be considered negligible. There is no evidence to suggest that the hazard associated with each of the proteins present in the individual events has increased due to combination through conventional breeding with other proteins in the other events. Expression studies have also shown that the concentration of each of the proteins that can have effects in organisms in single events is comparable to those found in the stacked product. In addition, exposure of NTOs to Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize will be very unlikely given the scope of this application. Therefore, it can be concluded that stacked products derived from combinations of Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize are as safe as each of the individual events, which in turn have been considered as safe as conventional maize in previous assessments.

(f) Effects on human health

The potential adverse effects of importing Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize grain or derived products into the EU on human or animal health have been assessed in Section D.7 following the recommendations of the EFSA "Guidance document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed". Studies conducted with Cry1Ab, Vip3Aa20, 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 (other than known Cry or Vip proteins in the case of Cry1Ab, Vip3Aa20, mCry3A, eCry3.1Ab and Cry1F). No adverse effects were observed in mice exposed to each of the proteins. In addition, Cry1Ab, Vip3Aa20, 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 Bt11 x MIR162 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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is as safe for use in food as conventional maize.

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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

(g) Effects on animal health

The potential adverse effects of importing Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize grain or derived products into the EU on human or animal health have been assessed in Section D.7 following the recommendations of the EFSA "Guidance document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed". Studies conducted with Cry1Ab, Vip3Aa20, 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 (other than known Cry or Vip proteins in the case of Cry1Ab, Vip3Aa20, mCry3A, eCry3.1Ab and Cry1F). No adverse effects were observed in mice exposed to each of the proteins. In addition, Cry1Ab, Vip3Aa20, 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 Bt11 x MIR162 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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is as safe for use in feed as conventional maize.

In summary, no adverse effects on animal health or adverse consequences for the food or feed chain are expected following consumption of feed consisting, containing or derived from Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

(h) Effects on biogeochemical processes

The scope of this application does not include cultivation of Bt11 x MIR162 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 grain of Bt11 x MIR162 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. In the unlikely event that some plants of Bt11 x MIR162 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 interactions of Bt11 x MIR162 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

The scope of this application does not include cultivation of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize in the EU. Therefore, there are no specific cultivation, management and harvesting techniques for the use of Bt11 x MIR162 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 Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize in the EU. Therefore, interactions of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize with the abiotic environment are highly unlikely. In the unlikely event that small amounts of grain of Bt11 x MIR162 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. In the unlikely event that some plants of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize survive, the potential effects on the abiotic environment are likely to be the same as those effects resulting from cultivation of non-modified maize.

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 Bt11 x MIR162 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)

The scope of this application does not include cultivation of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize. Environmental exposure to Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize could only occur in the unlikely event that small amounts of grain from Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 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 ERA has been conducted for Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize as recommended in the EFSA Guidance for risk assessment of food and feed from genetically modified plants and the EFSA Guidance on the ERA of GM plants, and taking into account the scope of this application. Risk assessment concepts described in recent scientific publications have also been used.

The overall conclusion of the ERA confirms that the import and food and feed use of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize will not result in harmful effects on human or animal health or to the environment in the EU.

(b) Interplay between environmental risk assessment and monitoring

An ERA has been conducted for Bt11 x MIR162 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 Bt11 x MIR162 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 this GM maize.

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

An ERA has been conducted in accordance with Annex II of Directive 2001/18/EC to evaluate potential adverse effects of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize on human and animal health and the environment. The conclusions of this ERA confirm that the potential risks to human and animal health or the environment arising from the placing on the market of Bt11 x MIR162 x MIR604 x 1507 x 5307 x

GA21 maize can be considered negligible, under the scope of this application. Therefore, a case-specific monitoring plan is not considered necessary.

(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 GMO or its use for human and animal health or the environment that were not predicted in the ERA.

The scope of this application does not include authorisation for the cultivation of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize. Therefore, exposure to the environment will be limited to unintended release of grain from Bt11 x MIR162 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 grain from Bt11 x MIR162 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 grain from Bt11 x MIR162 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 grain from Bt11 x MIR162 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 grain from Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

(e) Reporting the results of monitoring

The applicant/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 applicant will submit a General Surveillance Report containing information related to the monitoring on an annual basis.

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

The Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize described in this application, has been produced by combining the GM maize events: Bt11, MIR162, MIR604, 1507, 5307 and GA21 through conventional breeding techniques. There was no further genetic modification to produce the stack. As such the detection methods developed for the single events should be appropriate for use on Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

Methods for detection of Bt11, MIR162, MIR604, 5307 and GA21 maize have been developed by Syngenta and for 1507 by Dow AgroSciences LLC. The proposed methods are real-time quantitative TaqMan® PCR based on specific detection of the genomic DNA of these events. The methods for detection of Bt11, MIR162, MIR604, 1507, 5307 and GA21 maize have been validated by the DG-JRC-CRL. There is no reason to suspect that the detection methods developed for the single events should not work on Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize. In any case Syngenta has confirmed the applicability of these methods on Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize.

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 Bt11 x MIR162 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

US.

(b) Authority overseeing the release

EPA and USDA.

(c) Release site

Various sites across the US.

(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 Bt11 x MIR162 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.