Application for authorisation of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize import in the European Union under Regulation (EC) No 1829/2003

PART VII: SUMMARY

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PART VII

SUMMARY

APPLICATION FOR AUTHORISATION OF BT11 X MIR162 X MIR604 X MON 89034 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

Not available at time of submission.

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

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize (OECD code SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-89Ø34-3 x SYN-Ø53Ø7-1 x MON-ØØØ21-9).

(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

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(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, a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application)

Submissions covering Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize have been made in third countries around the world and are at different stages in the approval process. Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is currently authorised for cultivation in Canada, Japan and the US, and import only in Mexico and South Korea.

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 MON 89034 x 5307 x GA21 maize is a genetically modified (GM) maize that was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. No further genetic modification to produce this stack has taken place.

- Event Bt11 maize expresses the insecticidal protein Cry1Ab that protects against feeding damage caused by certain lepidopteran pests and the

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phosphinothricin acetyltransferase (PAT) protein for weed control by providing tolerance to herbicide products containing glufosinate ammonium.

- Event MIR162 maize expresses the insecticidal protein Vip3Aa20 that protects against feeding damage caused by certain lepidopteran pests and the PMI protein which enables transformed plant cells to utilise mannose as a primary carbon source and therefore used as a selectable marker in the development of the MIR162 maize.
- Event MIR604 maize expresses the insecticidal protein mCry3A that protects against feeding damage caused by certain coleopteran pests and the MIR604 PMI protein which enables transformed plant cells to utilise mannose as a primary carbon source and therefore used as a selectable marker in the development of the MIR604 maize.
- Event MON 89034 maize expresses the insecticidal proteins Cry1A.105 and Cry2Ab2 that protect against feeding damage caused by certain lepidopteran pests.
- Event 5307 maize expresses the insecticidal protein eCry3.1Ab that protects against feeding damage caused by certain coleopteran pests and the PMI protein which enables transformed plant cells to utilise mannose as a primary carbon source and therefore used as a selectable marker in the development of the 5307 maize.
- Event GA21 expresses the double-mutated 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 each event contained in the maize stack Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 is to control 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 processing of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and relevant sub-combinations in the scope of the application, independently of their origin. It does not cover cultivation. The scope of the application includes all food and feed products containing, consisting or produced from Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize including products from inbreds and hybrids obtained by conventional breeding of the maize product. The application also covers the import and industrial processing of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize for all potential uses as any other maize.

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

It is intended that Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize 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

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handling, including mandatory restrictions proposed as a condition of the authorisation applied for

The characteristics of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and products derived from it are not different from those of its conventional counterpart, apart from the introduced traits. Bt11 x MIR162 x MIR604 x MON 89034 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 MON 89034 x 5307 x GA21 maize or its relevant sub-combinations.

(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 MON 89034 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 processing of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and relevant sub-combinations. It does not cover cultivation.

(g) Any proposed packaging requirements

The characteristics of Bt11 x MIR162 x MIR604 x MON 89034 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 MON 89034 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. Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and derived products are not different from those of its conventional counterpart, no additional labelling is required.

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(i) Estimated potential demand

(i) In the EU

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 MON 89034 x 5307 x GA21 maize or its sub-combinations 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 Bt11 x MIR162 x MIR604 x MON 89034 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-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-89Ø34-3 x SYN-Ø53Ø7-1 x MON-ØØØ21-9 (also referred to as Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize). The unique identifiers assigned to the sub-combinations in the scope of the application are determined by combining SYN-BTØ11-1 and/or SYN-IR162-4 and/or SYN-IR6Ø4-5 and/or MON-89Ø34-3 and/or SYN-Ø53Ø7-1 and/or MON-ØØØ21-9 in any peceivable 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 Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize or its sub-combinations in the EU.

In the unlikely event that small amounts of seed from Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize, which could occur for example via substantial losses during loading/unloading of the viable commodity including Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize destined for processing into animal feed or human food products. In the event that small amounts of Bt11 x MIR162 x MIR604 x MON 89034 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 (with the exception of glyphosate and glufosinate

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herbicides). 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 MON 89034 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 L.

(c) Species

Zea mays L.

(d) Subspecies

Zea mays L. subsp. *mays*

(e) Cultivar/breeding line

A propriety Syngenta line

(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 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 3000 m 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 in the EU 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

Z. mays is an allogamous plant that propagates through seed produced predominantly by wind-borne cross-pollination. Self- pollination of up to 5% may

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be observed. Male and female flowers are separated on the plant by about 1 – 1.3 m. *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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize. Therefore, any outcrossing between Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and cultivated *Zea 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

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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 seeds is dependent upon temperature, seed moisture, genotype, husk protection, 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.

The current application excludes cultivation of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize in the EU.

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 5 m of the field's edge. In general, these studies have shown that over 98% of maize pollen remains within a radius of 25-50 m 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

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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

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is a GM maize that was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. No further genetic modification to produce this stack has taken place.

(b) Nature and source of the vector used

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is a GM maize that was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. No further genetic modification to produce this stack has taken place.

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

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is a GM maize that was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. No further genetic modification to produce this stack has taken place.

3.2. Information relating to the GM plant

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

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is a GM maize that was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. No further genetic modification to produce this stack has taken place. Therefore, the Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize produces the following transgenic proteins inherited from the single GM maize events: Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI.

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- Event Bt11 maize expresses the insecticidal protein Cry1Ab that protects against feeding damage caused by certain lepidopteran pests and the phosphinothricin acetyltransferase (PAT) protein for weed control by providing tolerance to herbicide products containing glufosinate ammonium.
- Event MIR162 maize expresses the insecticidal protein Vip3Aa20 that protects against feeding damage caused by certain lepidopteran pests and the PMI protein which enables transformed plant cells to utilise mannose as a primary carbon source and therefore used as a selectable marker in the development of the MIR162 maize.
- Event MIR604 maize expresses the insecticidal protein mCry3A that protects against feeding damage caused by certain coleopteran pests and the MIR604 PMI protein which enables transformed plant cells to utilise mannose as a primary carbon source and therefore used as a selectable marker in the development of the MIR604 maize.
- Event MON 89034 maize expresses the insecticidal proteins Cry1A.105 and Cry2Ab2 that protect against feeding damage caused by certain lepidopteran pests.
- Event 5307 maize expresses the insecticidal protein eCry3.1Ab that protects against feeding damage caused by certain coleopteran pests and the PMI protein which enables transformed plant cells to utilise mannose as a primary carbon source and therefore used as a selectable marker in the development of the 5307 maize.
- Event GA21 expresses the double-mutated 5-enolpyruvylshikimate-3-phosphate synthase enzyme (mEPSPS) for weed control by providing 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

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is a GM maize that was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. No further genetic modification to produce this stack has taken place.

(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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize has been assessed by comparative Southern blot analyses, concluding that each transformation event

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in the stacked event has the same molecular properties as the single transformation event.

Furthermore, sequence comparisons of Bt11, MIR162, MIR604, MON 89034, 5307 and GA21 inserts in Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize 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.

3.2.3. 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 MON 89034 x 5307 x GA21 maize is a GM maize that was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. No further genetic modification to produce this stack has taken place. Therefore, the Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize produces the following transgenic proteins inherited from the single GM maize events: Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI.

The levels of expression of the newly expressed proteins in Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and single event maize hybrids were determined by ELISA in various tissue types and across several developmental stages (at three locations in the USA in 2015), namely, in the leaves, roots, whole plants (consisting of forage and root ball), pollen, and kernels at V6, R1, R6 and senescence growth stages.

Overall, the concentrations of Cry1Ab, PAT, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab and mEPSPS in tissues of the Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize hybrid were similar to those of the corresponding single-event maize hybrids, Bt11, MIR162, MIR604, MON 89034, 5307, and GA21. As expected, concentrations of PMI in tissues of the Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize hybrid were higher than those of the single-event hybrids, MIR162, MIR604, and 5307. The higher PMI concentrations in tissues of the Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 hybrid can be attributed to the presence of three copies of the gene *pmi* (including *mir604pmi*) in the stacked maize hybrid, while the MIR162, MIR604, and 5307 maize hybrids each contain one copy of the gene *pmi* or *mir604pmi*.

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

Concentrations of most newly expressed proteins were quantifiable in most Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize tissue types analysed (leaves, roots, whole plants, pollen and kernels).

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

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Molecular analyses showed that the inserts have been stably integrated into the plant's genome in Bt11, MIR162, MIR604, MON 89034, 5307 and GA21 maize.

In addition, the genetic and phenotypic stability of each of the inserts in Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize has been assessed by comparative 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 Bt11, MIR162, MIR604, MON 89034, 5307 and GA21 single maize events.

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 MON 89034 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 MON 89034 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 MON 89034 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 MON 89034 x 5307 x GA21 maize.

In summary, the results of these studies indicate that the genetic modification to produce Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize does not result in any biologically relevant agronomic or phenotypic differences related to reproduction, dissemination or survivability of Bt11 x MIR162 x MIR604 x MON 89034 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 probability of horizontal gene transfer (HGT) between the single event inserts in Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and micro-organisms was investigated *in silico*, and no sequences were identified as being able to promote homologous recombination.

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 MON 89034 x 5307 x GA21 maize to transfer genetic material to other organisms are expected

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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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize are not intended to change any of the typical crop characteristics of maize (except for resistance to certain lepidopteran and coleopteran insects and tolerance to certain herbicide products). Observations from field trials have confirmed that the agronomic and phenotypic characteristics of Bt11 x MIR162 x MIR604 x MON 89034 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 MON 89034 x 5307 x GA21 maize compared to traditional maize. Gene transfer from Bt11 x MIR162 x MIR604 x MON 89034 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. 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. 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

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize was compared with the conventional counterpart with a genetic background similar to Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize, as well as with commercially available maize varieties.

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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize plants compared to the conventional counterpart, trials were planted at ten locations in the USA in 2015. The locations of the trial sites were selected to be representative of the agricultural regions suitable for the cultivation of the selected maize hybrids. At each location, plants were grown in a randomized complete block design where five replicate plots per entry were planted.

4.3. Selection of materials and compounds for analysis

The selected materials for analysis were forage and grain (raw material). Maize grain

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from transgenic plants and conventional counterpart plants were analysed for proximates and starch, minerals, vitamins, amino acids, selected fatty acids, anti-nutrients and secondary metabolites. 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize are equivalent to those in the non-transgenic reference hybrids and/or not significantly different from those in the non-transgenic, near-isogenic control maize. Where the results indicate non-equivalence or statistically significant difference, component levels are within ranges considered normal for conventional maize.

These data support the conclusion that Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is compositionally equivalent to conventional maize.

4.4. Comparative analysis of agronomic and phenotypic characteristics

An assessment of the agronomic and phenotypic characteristics of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize compared to conventional maize has been performed. Data were collected for multiple agronomic characteristics: early stand count, days to 50% pollen shed, days to 50% silking, plant height, days to maturity, final stand count, total lodging, grain moisture, grain yield and grain test weight. The results of these trials showed that Bt11 x MIR162 x MIR604 x MON 89034 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 MON 89034 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, Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI, produced by Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize will influence this processing in any way.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is a GM maize that was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. Therefore, the Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize expresses the following transgenic proteins inherited from the single GM maize events: Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI. All of the newly expressed proteins have been assessed previously by EFSA where a lack of toxic potential was demonstrated. There is no evidence of potential interactions between the different newly expressed proteins that would affect the safety of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize or any of its sub-combinations.

(b) Testing of new constituents other than proteins

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

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use. Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize has been modified to produce the Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI proteins. No other new constituents apart from these proteins are expected to be produced in Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and compositional analyses have confirmed the compositional equivalence of Bt11 x MIR162 x MIR604 x MON 89034 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

Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11, MIR162, MIR604, MON 89034, 5307 and GA21 maize would lead to any toxicity as a result of unintended effects, 90-day feeding studies with Bt11, MIR162, MIR604, MON 89034, 5307 and GA21 maize grain in rodents have been performed. Studies for MIR162, MIR604, MON 89034 and GA21 have been submitted and reviewed in the context of previous applications and reviewed by EFSA. Studies for 5307 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

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is a GM maize that was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. Therefore, the Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize expresses the following transgenic proteins inherited from the single GM maize events: Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI. All of the newly expressed proteins have been assessed previously by EFSA where a lack of allergenic potential was demonstrated. There is no evidence of potential interactions between the different newly expressed proteins that would affect the safety of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize or any of its sub-combinations.

(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

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of maize allergy is exceedingly low amongst the human population. Equivalence of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize (with the exception of the introduced traits) to the conventional comparator was demonstrated on the basis of compositional analysis. Therefore, no increased allergenicity is anticipated for Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize.

There is no evidence to suggest that Bt11 x MIR162 x MIR604 x MON 89034 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

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is not intended to change the nutritional status of individuals or populations or to be processed 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 MON 89034 x 5307 x GA21 maize, and derived food products.

(b) Nutritional assessment of the genetically modified feed

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is not intended to change the nutritional status of livestock animals or to be processed in products with enhanced functionality. Compositional analysis has 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 MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize to the conventional maize supply. It is anticipated that the introduction of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize will replace some of the maize in existing food and feed products. However, the genetic modifications in Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and its sub-combinations were 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, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI, through maximum consumption and exposure assumptions considered in Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is negligible. The dietary exposure assessment supports the conclusion that the risk to consumers from Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is negligible.

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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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and derived food and feed products are not different from those of its conventional counterpart. The molecular characterisation of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize did not raise any safety concerns nor identify any unintended changes as a result of the genetic modification. Compositional analysis concluded that the levels of the vast majority of nutritional components in Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize are equivalent to those in the non-transgenic reference lines, and are not significantly different from those in the non-transgenic, conventional counterpart maize. The agronomic and phenotypic characteristics of Bt11 x MIR162 x MIR604 x MON 89034 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 Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI proteins, and evidence of history of safe use, 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is not intended to improve the nutritional status of individuals or populations or to be processed in products with enhanced functionality. The exposure assessment in humans and animals did not indicate any safety concerns, and dietary role of Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 MON 89034 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 MON 89034 x 5307 x GA21 maize has been developed to confer resistance to certain lepidopteran and coleopteran pests and tolerance to certain herbicides. However, the scope of this application covers the food and feed, import and processing in the EU. Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize cultivation in the EU is not included in the scope. Therefore, exposure of target organisms to Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize plants 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

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fact that the scope of this application does not include cultivation of Bt11 x MIR162 x MIR604 x MON 89034 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 each single event constituting the Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize has not altered agronomic and phenotypic characteristics of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize associated with persistence or invasiveness potential compared to conventional maize. In addition, the genes introduced in Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize will not confer any selective advantage or disadvantage to Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize compared to conventional maize, apart from the intended modifications. Therefore Bt11 x MIR162 x MIR604 x MON 89034 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 MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize (*cry1Ab, pat, vip3Aa20, pmi, mcry3A, mir604pmi, cry1A.105, cry2Ab2, ecry3.1Ab,* 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 (ERA), 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 MON 89034 x 5307 x GA21 maize in the EU, the conclusion from the assessment is that the expression of the newly introduced genes will not confer any selective advantage or disadvantage to Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and derived products in the EU. Cultivation of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize in the EU is not included in the scope. Therefore, it is highly unlikely that Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize plants will grow in the EU.

There is also no change in the ability of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize to transfer genetic material to other organisms when compared to conventional maize. The horizontal gene transfer 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize to other sexually compatible plant species is not possible since there

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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. 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. Therefore, it is highly unlikely that the import, processing, and food and feed use of Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize in the EU and the characteristics of the transgenes, *cry1Ab, pat, vip3Aa20, pmi, mcry3A, mir604pmi, cry1A.105, cry2Ab2, ecry3.1Ab,* and *mepsps*, 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 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 MON 89034 x 5307 x GA21 maize 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 MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize in the EU. Therefore, potential immediate or delayed effects in the environment due to direct or indirect interactions between Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize in the EU can be considered highly unlikely.

(f) Effects on human health

Compositional analysis with Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize has confirmed that Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034

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x 5307 x GA21 maize would result in a product that differs in toxicity or allergenic potential to humans when compared to conventional maize. None of the proteins (Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI) produced by Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize.

(g) Effects on animal health

The potential adverse effects of importing Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize or derived products into the EU on animal health have been assessed. Studies conducted with Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI 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, Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab, mEPSPS, PAT, PMI and MIR604 PMI are unlikely to be allergenic.

The results obtained from the comparative analysis of composition of Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604

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x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 MON 89034 x 5307 x GA21 maize in the EU. Therefore, interactions of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize with the abiotic environment are highly unlikely. In the unlikely event that small amounts of Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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*. Results from the environmental risk assessment support the conclusion that the import, processing, and food and feed uses of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize in the EU represents negligible risk to human and animal health and the environment, and poses no greater risk than the import, processing, and food and feed uses of conventional maize.

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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 MON 89034 x 5307 x GA21 maize. Environmental exposure to Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize could only occur in the unlikely event that small amounts of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize accidentally found their way into the environment in the EU. However, the survival of this maize would be very unlikely as maize is a highly domesticated plant and cannot survive without human intervention, especially under normal European climatic conditions. If germinated, Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize could easily be controlled using any of the current agronomic measures taken to control other commercially available maize, except for the use of trait-specific herbicides.

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 a proposed Post-Market Environmental Monitoring (PMEM) plan for Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize has been conducted according to the principles laid down in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The PMEM plan also takes into account the approaches and conclusions provided in the 2011 Scientific Opinion on guidance on the PMEM of genetically modified plants.

(b) Interplay between environmental risk assessment and monitoring

The scope of this application does not include cultivation of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize. An ERA has been conducted for Bt11 x MIR162 x MIR604 x MON 89034 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 MON 89034 x 5307 x GA21 maize in the ERA has shown that the risk for potential adverse effects on human and animal health or to the environment is negligible in the context of the intended uses of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize in the EU.

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

The scientific evaluation of the characteristics of Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 ERA.

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The scope of this application does not include authorisation for the cultivation of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize. Therefore, exposure to the environment will be limited to unintended release of Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize.

(e) Reporting the results of monitoring

The authorisation holder is responsible, under Regulation (EC) No 1829/2003, to inform the European Commission of the results of the 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize.

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

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is detectable using the event-specific real-time quantitative PCR methods developed for Bt11, MIR162, MIR604, MON 89034, 5307 and GA21 maize events. 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.

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 MON 89034 x 5307 x GA21 maize have been carried out in the EU.

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

(a) Release country

United States (including United States Territory of Puerto Rico).

(b) Authority overseeing the release

Not applicable. Bt11, MIR162, MIR604, MON 89034, 5307 and GA21 are deregulated by the United States Department of Agriculture (USDA). Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize is not requested to be deregulated in the United States and is therefore not deregulated.

(c) Release site

Various sites across the United States.

(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 MON 89034 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.

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