Application for authorisation of MZIR098 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 MZIR098 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)

MZIR098 maize (OECD code SYN-ØØØ98-3).

(d) Date of acknowledgement of valid application

Not available at time of submission.

1.2. Applicant

(a) Name of applicant

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

(b) Address of applicant

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

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

Not applicable.

1.3. Scope of the application

(a) GM food

☒ Food containing or consisting of GM plants

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

(b) GM feed

☒ Feed containing or consisting of GM plants

☒ Feed produced from GM plants

(c) GM plants for food or feed use

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

☐ Seeds and plant propagating material for cultivation in the Union

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

No ☒

Yes ☐ (in that case, specify)

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

Yes ☐

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

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

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

No ☒

Yes ☐ (in that case, specify)

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

No ☐

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

Submissions covering MZIR098 maize have been made in third countries around the world and are at different stages in the approval process. MZIR098 maize is currently authorized for cultivation in the US and Canada, and is authorized for import in Australia/New Zealand.

1.8. General description of the product

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

The recipient plant is maize (*Zea mays* L., corn). Syngenta transformed maize to produce Event MZIR098 maize, which provides dual modes of

action for control of corn rootworm (*Diabrotica* spp.). MZIR098 maize plants contain the transgenes *ecry3.1Ab* and *mcry3A*, which encode the insecticidal proteins eCry3.1Ab and mCry3A, and the transgene *pat-08*, which encodes the enzyme phosphinothricin acetyltransferase (PAT). The native Cry3A from the soil bacterium *Bacillus thuringiensis* subsp. *tenebrionis* is active against certain coleopteran pests. The modified protein mCry3A produced by MZIR098 maize has enhanced activity against western corn rootworm (*Diabrotica virgifera virgifera*) and other related coleopteran pests of maize. The engineered protein eCry3.1Ab is a chimera of mCry3A and Cry1Ab that is also active against *D. virgifera virgifera* and other related pests of maize. The native Cry1Ab from *B. thuringiensis* subsp. *kurstaki* is active against certain lepidopteran pests; however, the portion of Cry1Ab included in eCry3.1Ab has not preserved the activity of Cry1Ab against lepidopterans. The transgene *pat-08* was derived from the soil bacterium *Streptomyces viridochromogenes*. PAT acetylates glufosinate-ammonium, thus inactivating it and conferring tolerance to glufosinate-ammonium in herbicide products. PAT was used as a selectable marker in the development of MZIR098 maize.

(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 MZIR098 maize. It does not cover cultivation. The scope of the application includes all food and feed products containing, consisting or produced from MZIR098 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 MZIR098 maize for all potential uses as any other maize.

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

It is intended that MZIR098 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 handling, including mandatory restrictions proposed as a condition of the authorisation applied for

The characteristics of MZIR098 maize and products derived from it are not different from those of its conventional counterpart, apart from the introduced traits. MZIR098 maize has been shown to be as safe and as wholesome as existing varieties of miaze. Therefore, there are no specific instructions or recommendations for use, storage and handling of MZIR098 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 MZIR098 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 MZIR098 maize. It does not cover cultivation.

(g) Any proposed packaging requirements

The characteristics of MZIR098 maize and products derived from it are not different from those of its conventional counterpart. MZIR098 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 (refer to Part IV). This includes the labelling requirements outlined by Regulation (EC) No 1829/2003 and Annex IV of Directive 2001/18/EC. MZIR098 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 MZIR098 maize and derived products are not different from those of its conventional counterpart, no additional labelling is required.

(i) Estimated potential demand

(i) In the EU

There are no anticipated changes to the intake/extent of use of maize as a result of the introduction of MZIR098 maize to the maize supply. It is anticipated that the introduction of MZIR098 maize will replace some of the maize in existing food and feed products.

(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 MZIR098 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-ØØØ98-3 (also referred to as MZIR098 maize).

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 MZIR098 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 MZIR098 maize in the EU.

In the unlikely event that small amounts of seed from MZIR098 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 glufosinate-ammonium.

Exposure to the environment will be limited to unintended release of MZIR098 maize, which could occur for example via substantial losses during loading/unloading of the viable commodity including MZIR098 maize destined for processing into animal feed or human food products. In the event that small amounts of MZIR098 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 glufosinate herbicides). In addition, volunteers could be easily controlled using any of the current agronomic measures taken to control other commercially available maize.

The MZIR098 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 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 MZIR098 maize. Therefore, any outcrossing between MZIR098 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 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 MZIR098 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 natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts (for environmental safety aspects)

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

2.9. Other potential interactions, relevant to the GM plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms (for environmental safety aspects)

Maize is known to interact with other organisms in the environment including insects, birds, and mammals. It is susceptible to a range of fungal diseases, and insect and nematode pests, as well as to competition from surrounding weeds. Maize is extensively cultivated and has a history of safety for environmental safety aspects.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

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

The MZIR098 maize is a GM maize that is produced by *Agrobacterium*-mediated transformation.

(b) Nature and source of the vector used

The MZIR098 maize was produced through *A. tumefaciens*-mediated transformation with the binary plasmid vector, pSYN17629.

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

The genetic elements within the right and left borders of the T-DNA of the transformation plasmid pSYN17629 constitute the region intended for integration into the genome of the maize plant cell. The T-DNA contains

three gene cassettes – *ecry3.1Ab*, *mcry3A* and *pat* gene cassettes.

The *ecry3.1Ab* gene cassette contains the *ecry3.1Ab* coding sequence under the regulation of the NOS-02 enhancer and CMP-04 promoter, and the NOS-05-01 terminator. The *mcry3A* gene cassette contains the *mcry3A* coding sequence under the regulation of the Ubi1-18 promoter which contains the first intron, and the NOS-20 terminator. The *pat* gene cassette contains the *pat-08* coding sequence under the regulation of the 35S-04 promoter and NOS-05-01 terminator.

The source of each genetic element contained in the *ecry3.1Ab* gene cassette is as follows: the NOS-02 enhancer from the nopaline synthase gene of *A. tumefaciens*; the CMP-04 promoter from the Cestrum yellow leaf curling virus promoter region; the *ecry3.1Ab* coding sequence from a combination of the native genes *cry3A* of *B. thuringiensis* subsp. *tenebrionis* and *cry1Ab* of B*. thuringiensis* subsp. *kurstaki* strain HD-1; the NOS-05-01 terminator sequence from the nopaline synthase gene of *A. tumefaciens*.

The source of each genetic element contained in the *mcry3A* gene cassette is as follows: the Ubi1-18 promoter and first intron from the polyubiquitin 3 gene of *Zea mays*; the *mcry3A* coding sequence from the native *cry3A* gene of *B. thuringiensis* subsp. *tenebrionis*; the NOS-20 terminator sequence from the nopaline synthase gene of *A. tumefaciens*.

The source of each genetic element contained in the *pat* gene cassette is as follows: the 35S-04 promoter from the cauliflower mosaic virus; the *pat-08* coding sequence from the *S. viridochromogenes* strain Tü494; the NOS-05-01 terminator sequence from the nopaline synthase gene of *A. tumefaciens*.

Plasmid pSYN17629 contains right and left border sequences that are necessary for the transfer of T-DNA into the plant cell. These border sequences, each 25 bp long, flank the T-DNA allowing for the transfer and integration of the T-DNA into the plant genome during transformation. The right and left border regions in pSYN17629 was originally derived from the Ti plasmid of an *A. tumefaciens* nopaline strain.

The individual genetic elements intended for insertion into MZIR098 maize are provided in Table 1.

Table 1. Genetic elements of the T-DNA region of plasmid pSYN17629 intended for insertion in MZIR098 maize.

Genetic element	Size (bp)	Description
RB-01-01	25	Right border (RB) region of T-DNA. It is required for the transfer of the T-DNA into the plant cell.
NOS-02 enhancer	93	Enhancer sequence from the nopaline synthase gene. It enhances expression of *ecry3.1Ab*.
CMP-04 promoter	397	Promoter region from cestrum yellow leaf curling virus. It is required for the constitutive expression of *ecry3.1Ab* in maize.
ecry3.1Ab	1962	Sequence encoding the eCry3.1Ab protein. It confers resistance to certain coleopteran pests.
NOS-05-01 terminator	253	Terminator sequence from the nopaline synthase gene. Its function is to provide a polyadenylation site.
Ubi1-18 promoter	1993	Promoter region which contains the first intron from the maize ubiquitin gene. It is required for the constitutive expression of *mcry3A* in maize.
mcry3A	1797	Sequence encoding the mCry3A protein. It confers resistance to certain coleopteran pests.
NOS-20 terminator	277	Terminator sequence from the nopaline synthase gene. Its function is to provide a polyadenylation site.
35S-04 promoter	521	Promoter region of cauliflower mosaic virus. It is required for the constitutive expression of *pat-08* in maize.
pat-08	552	Sequence encoding the PAT protein. It confers tolerance to herbicides containing glufosinate-ammonium (phosphino-thricin).
NOS-05-01 terminator	253	Terminator sequence from the nopaline synthase gene. Its function is to provide a polyadenylation site.
LB-01-01	25	Left border (LB) region of T-DNA. It is required for the transfer of the T-DNA into the plant cell.

3.2. Information relating to the GM plant

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

MZIR098 maize is a genetically modified maize which provides dual modes of action for control of corn rootworm (*Diabrotica* spp.). MZIR098 maize plants contain the transgenes *ecry3.1Ab* and *mcry3A*, which encode the insecticidal proteins eCry3.1Ab and mCry3A, and the transgene *pat-08*, which encodes the enzyme phosphinothricin acetyltransferase (PAT). The PAT protein confers tolerance to herbicide products containing glufosinate-ammonium.

3.2.2. Information on the sequences actually inserted or deleted

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

Molecular characterisation of MZIR098 maize by Southern blot analyses confirmed that MZIR098 maize carries a single, intact copy of the pSYN17629 T-DNA. There are no extraneous T-DNA fragments of plasmid pSYN17629 inserted elsewhere in the maize genome and there is no backbone sequence from transformation plasmid pSYN17629 in MZIR098 maize.

The MZIR098 maize contains a single copy of each of the functional elements (NOS-02 enhancer, CMP-04 promoter, *ecry3.1Ab*, NOS-05-01 terminator, Ubi-18 promoter, *mcry3A*, NOS-20 terminator, 35S-04 promoter, *pat-08*, NOS-05-01 terminator).

In addition, sequencing data demonstrated that the insert is intact and that the contiguousness of the functional elements within the insert as intended in pSYN17629 has been maintained.

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

The maize genomic sequence at the point of integration of the MZIR098 insert was determined using PCR and sequencing. The DNA sequence of the non-transgenic maize genome at this location was sequenced and compared to the genomic sequences flanking the MZIR098 insert. This analysis was used to assess the changes in the maize genome that may have occurred at the genomic insertion site during integration of the MZIR098 insert.

Analysis of sequence data demonstrated that 24 base pairs from the maize genomic sequence were deleted during the integration of the MZIR098 insert.

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

Chi square analysis of the segregation data indicated that the MZIR098 maize insert segregated according to Mendelian principles and was consistent with a single site of insertion into the maize nuclear genome. Southern blot analyses demonstrated that MZIR098 maize has maintained the integrity number, structure and organization of the MZIR098 maize insert.

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

Southern blot data have demonstrated that MZIR098 maize contains a single insert that is intact with no rearrangements or base pair changes.

Sequencing data demonstrated that the insert is intact and that the contiguousness of the functional elements within the insert as intended in

pSYN17629 has been maintained. The sequences of NOS-02 enhancer, CMP-04 promoter, *ecry3.1Ab*, NOS-05-01 terminator, Ubi-18 promoter, *mcry3A*, NOS-20 terminator, 35S-04 promoter, *pat-08*, NOS-05-01 terminator in MZIR098 maize were identical to those in the transformation plasmid pSYN17629. Sequence analysis revealed that some truncation occurred at the right border and left border ends of the T-DNA during the transformation process that resulted in MZIR098 maize. The right border, along with 10 base pairs (bp) of non-coding sequence were truncated, and 10 bp from the left border were truncated. These deletions have no effect on the functionality of the T-DNA insert.

(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

MZIR098 maize produces three newly expressed proteins: eCry3.1Ab and mCry3A proteins, which exhibit insecticidal activity against certain coleopteran pests in particular *Diabrotica* species, and PAT protein, which confers tolerance to glufosinate-ammonium herbicides and was used as a selectable marker in the development of MZIR098 maize.

The concentrations of eCry3.1Ab, mCry3A and PAT proteins were measured in various tissue types and developmental stages of MZIR098 maize plants grown at four locations in USA in 2013. The levels of expression of the eCry3.1Ab, mCry3A, and PAT proteins in MZIR098 maize hybrid plants were determined by ELISA in the leaves, roots, whole plants (consisting of forage and root ball), pollen, and kernels at four growth stages, namely, V6, R1, R6, and senescence. As a control, non-transgenic, near-isogenic hybrid maize was also grown, and samples were collected and analysed concurrently with the samples of the MZIR098 hybrid maize.

For glufosinate-treated MZIR098 maize, the eCry3.1Ab protein concentrations ranged from below limit of detection in pollen to 45.94 µg/g fresh weight in leaves (V6 stage). The arithmetic mean expression value for eCry3.1Ab protein in kernels (senescence) is 1.42 ± 0.56 µg/g fresh weight. The mCry3A protein concentrations ranged from 0.72 µg/g fresh weight in roots (senescence) to 236.71 µg/g fresh weight in pollen. The arithmetic mean expression value for mCry3A protein in kernels (senescence) is 7.55 ± 1.58 µg/g fresh weight. The PAT protein concentrations ranged from below limit of detection in pollen, roots and kernels (R6 and senescence), leaves (senescence), and whole plants (R6) to 1.75 µg/g fresh weight in leaves (V6).

For untreated MZIR098 maize, the eCry3.1Ab protein concentrations ranged from below limit of detection in pollen to 46.68 µg/g fresh weight in

leaves (V6 stage). The arithmetic mean expression value for eCry3.1Ab protein in kernels (senescence) is 1.50 ± 0.79 µg/g fresh weight. The mCry3A protein concentrations ranged from 0.53 µg/g fresh weight in roots (senescence) to 246.96 µg/g fresh weight in pollen. The arithmetic mean expression value for mCry3A protein in kernels (senescence) is 8.30 ± 2.02 µg/g fresh weight. The PAT protein concentrations ranged from below limit of detection in pollen, leaves and roots and kernels (R6 and senescence), and whole plants (R6) to 1.85 µg/g fresh weight in leaves (V6).

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

MZIR098 maize produces three newly expressed proteins: eCry3.1Ab, mCry3A, and PAT proteins. Expression of these proteins are driven by constitutive promoters. Taking the scope of this application into consideration, the main route of exposure to the newly expressed proteins is via MZIR098 maize grain. However, in order to assess the expression profile of the newly expressed proteins during the life cycle of the plant, a broad range of tissues, including grain (kernels), were collected and analysed from plants at various stages of development. The parts of the plant where eCry3.1Ab, mCry3A and PAT proteins are expressed is provided in Section 3.2.3 (a) above.

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

Southern blot and Chi square analyses showed that the insert is stably inherited as a single locus in the maize nuclear genome across multiple generations. The protein expression levels of eCry3.1Ab, mCry3A and PAT proteins were similar across multiple generations.

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 MZIR098 maize.

(b) Dissemination

No changes in the dissemination compared to the conventional counterpart have been observed in agronomic assessments conducted with MZIR098 maize.

(c) Survivability

No changes in the survivability compared to the conventional counterpart have been observed in agronomic assessments conducted with MZIR098 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 MZIR098 maize.

In summary, the results of these studies indicate that the genetic modification to produce MZIR098 maize does not result in any biologically relevant agronomic or phenotypic differences related to reproduction, dissemination or survivability of MZIR098 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 MZIR098 maize insert and microorganisms 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 MZIR098 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.

(b) Plant to plant gene transfer

The genetic modification in MZIR098 maize is not intended to change any of the typical crop characteristics of maize (except for resistance to certain coleopteran insects and tolerance to certain herbicide products). Observations from field trials have confirmed that the agronomic and phenotypic characteristics of MZIR098 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 MZIR098 maize compared to traditional maize. Gene transfer from MZIR098 maize to other sexually compatible plant species is not possible since there are no indigenous populations of sexually compatible wild relatives in the EU. In addition, since the scope of this application does not include authorisation for the cultivation, the likelihood of dissemination of pollen to other plants (including cultivated maize plants) is considered to be negligible.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

MZIR098 maize was compared with the conventional counterpart with a genetic background similar to MZIR098, 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 MZIR098 maize plants compared to the conventional counterpart, trials were planted at eight locations in the USA in 2013. The locations of the trial sites were selected to be representative of the agricultural regions suitable for the cultivation of the selected maize hybrids. At each location, plants were grown in a randomized complete block design where four 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 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 MZIR098 maize are equivalent to those in the reference lines, and are not significantly different from those in the conventional counterpart maize.

These data support the conclusion that MZIR098 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 MZIR098 maize compared to conventional maize has been performed. Data were collected for multiple agronomic characteristics: early stand count, thinned stand count, days to 50% pollen shed, days to 50% silking, plant height, final stand count, root-lodged plants, stalk-lodged plants, grain yield, grain moisture, and grain test weight. The results of these trials showed that MZIR098 maize is agronomically and phenotypically equivalent to conventional maize, apart from the introduced traits.

4.5. Effect of processing

MZIR098 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, eCry3.1Ab, mCry3A and PAT, produced by MZIR098 maize will influence this processing in any way.

5. TOXICOLOGY

(a) Toxicological testing of newly expressed proteins

MZIR098 maize plants contain the transgenes *ecry3.1Ab* and *mcry3A*, which encode the insecticidal proteins eCry3.1Ab and mCry3A, and the transgene *pat-08*, which encodes the enzyme phosphinothricin acetyltransferase (PAT). The PAT protein confers tolerance to herbicide products containing glufosinate-ammonium.

To demonstrate the safety of each newly expressed protein, a series of studies have been conducted. In addition, existing data on the history of safety of the eCry3.1Ab, mCry3A and PAT proteins have also been taken into account. The assessment confirms that the newly expressed proteins, eCry3.1Ab, mCry3A and PAT, are not structurally or functionally related to proteins which have the potential to adversely affect human or animal health; they are rapidly degraded in *in vitro* digestibility assays; eCry3.1Ab, mCry3A and PAT have no biologically relevant sequence simliarity to known or putative mammalian protein toxins; eCry3.1Ab, mCry3A and PAT are unlikely to be allergenic; eCry3.1Ab, mCry3A and PAT 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. MZIR098 maize has been modified to produce the eCry3.1Ab, mCry3A and PAT proteins. No other new constituents apart from these proteins are expected to be produced in MZIR098 maize and compositional analyses have confirmed the compositional equivalence of MZIR098 maize to conventional maize. Therefore, no testing of any other constituent is considered necessary.

(c) Information on natural food and feed constituents

MZIR098 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 MZIR098 maize.

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

Although MZIR098 maize have been found to be compositionally equivalent to conventional maize varieties except for the presence of the intended traits, a 90-day feeding study with MZIR098 maize grain in rodents was performed since it is a requirement under Article 12 of the Regulation (EU) No 503/2013.

The 90-day whole food safety study was conducted in line with OECD TG 408 guidelines on 10 animals/sex/treatment fed diets incorporating MZIR098 maize grain or conventional counterpart maize grain at two dose levels (10 or 41.5%). The incorporation of MZIR098 maize grain in diets fed to rats for at least 91 consecutive days produced no toxicological effects on body weight, food consumption, clinical condition (including neurotoxicity assessments), ophthalmoscopy, haematology, coagulation, chemical chemistry, organ weights, macroscopic or microscopic pathology at inclusion levels up to and including 41.5%.

It was concluded that grain from MZIR098 maize is safe for food and feed consumption and no differences in wholesomeness are expected with comparable conventional counterpart maize varieties.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The weight-of-evidence indicates that the newly expressed proteins produced by MZIR098 maize are not likely to be food allergens because:

1. the eCry3.1Ab, mCry3A and PAT proteins are not derived from allergenic sources,
2. eCry3.1Ab, mCry3A and PAT do not have biologically relevant amino acid sequence similarity to known or putative allergenic proteins,
3. eCry3.1Ab, mCry3A and PAT are readily degraded in *in vitro* digestibility assays.

From these data, it can be concluded that eCry3.1Ab, mCry3A and PAT produced by MZIR098 maize are highly unlikely to be allergenic.

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

Maize grain has a history of safe use throughout the world and it is not considered to be a major allergenic food source. Although rare cases of occupational allergy to maize dust or maize pollen allergy have been

reported and IgE-binding proteins have been identified in maize flour, the prevalence of maize allergy is exceedingly low amongst the human population. Equivalence of MZIR098 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 MZIR098 maize.

There is no evidence to suggest that MZIR098 maize will have a greater allergenic potential compared to conventional counterpart maize varieties.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

MZIR098 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 MZIR098 maize, and derived food products.

(b) Nutritional assessment of the genetically modified feed

MZIR098 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 MZIR098 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 MZIR098 maize to the conventional maize supply. It is anticipated that the introduction of MZIR098 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 eCry3.1Ab, mCry3A and PAT, through maximum consumption and exposure assumptions considered in MZIR098 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 MZIR098 maize is negligible. The dietary exposure assessment supports the conclusion that the risk to consumers from MZIR098 maize is negligible.

9. RISK CHARACTERISATION

Maize food and feed products have a long history of safe use. No significant native toxins are reported to be associated with the genus *Zea*.
The information presented in the application confirms that MZIR098 maize and derived food and feed products are not different from those of its conventional counterpart. The molecular characterization of MZIR098 maize did not raise any safety concerns nor identified any unintended changes as a result of the genetic modification. Compositional analysis concluded that the levels of the vast majority of nutritional components in MZIR098 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 MZIR098 maize plants, except for the introduced traits, are not different to those of its conventional counterpart comparator, taking into account natural variation. Characterisation of eCry3.1Ab, mCry3A and PAT 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 MZIR098 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 MZIR098 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 MZIR098 maize or its derived products in food and feed will not result in any nutritional changes. Therefore, post-market monitoring of MZIR098 maize food/feed is not considered necessary.

11. ENVIRONMENTAL ASSESSMENT

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

MZIR098 maize has been developed to confer resistance to certain coleopteran insects and tolerance to certain herbicides. These coleopteran insects, in particular *Diabrotica* species, may be considered as target organisms which interact with the MZIR098 maize plants. However, the scope of this application covers the food and feed, import and processing in the EU. MZIR098 maize cultivation in the EU is not included in the scope. Therefore, exposure of target organisms to MZIR098 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 fact that the scope of this application does not include cultivation of MZIR098 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 MZIR098 maize has not altered agronomic and phenotypic characteristics of MZIR098 maize associated with persistence or invasiveness potential compared to conventional maize. In addition, the genes introduced in MZIR098 maize will not confer any selective advantage or disadvantage to MZIR098 maize compared to conventional maize, apart from the intended modifications. Therefore MZIR098 maize will not differ in persistence and invasiveness from conventional maize.

In summary, the likelihood that MZIR098 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 MZIR098 maize (*ecry3.1Ab*, *mcry3A* and *pat-08*) 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 MZIR098 maize in the EU, the conclusion from the assessment is that the expression of *ecry3.1Ab*, *mcry3A* and *pat-08* will not confer any selective advantage or disadvantage to MZIR098 maize.

(c) Potential for gene transfer

The scope of this application covers the import, processing, and food and feed use of MZIR098 maize and derived products in the EU. Cultivation of MZIR098 maize in the EU is not included in the scope. Therefore, it is highly unlikely that MZIR098 maize plants will grow in the EU.

There is also no change in the ability of MZIR098 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 MZIR098 maize to other sexually compatible plant species is not possible since there are no indigenous populations of sexually compatible wild relatives of maize in the EU and vertical gene transfer would be limited to other maize plants. Therefore, it is highly unlikely that the import, processing, and food and feed use of MZIR098 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 MZIR098 maize in the EU and the characteristics of the transgenes, *ecry3.1Ab*, *mcry3A* and *pat-08*, 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 MZIR098 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 MZIR098 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 MZIR098 maize in the EU. Therefore, potential immediate or delayed effects in the environment due to direct or indirect interactions between MZIR098 maize plants and non-target organisms as a result of the import, processing or products for food and feed use of MZIR098 maize in the EU can be considered highly unlikely.

(f) Effects on human health

Compositional analysis with MZIR098 maize has confirmed that MZIR098 maize is equivalent in composition to conventional maize and is as safe and nutritious as conventional maize.

There is no reason to anticipate that MZIR098 maize would result in a product that differs in toxicity or allergenic potential to humans. None of the proteins (eCry3.1Ab, mCry3A and PAT) produced by MZIR098 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 MZIR098 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 MZIR098 maize.

(g) Effects on animal health

The potential adverse effects of importing MZIR098 maize or derived products into the EU on animal health have been assessed. Studies conducted with eCry3.1Ab, mCry3A and PAT 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, eCry3.1Ab, mCry3A and PAT are unlikely to be allergenic.

The results obtained from the comparative analysis of composition of MZIR098 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 MZIR098 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 MZIR098 maize.

(h) Effects on biogeochemical processes

The scope of this application does not include cultivation of MZIR098 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 MZIR098 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 MZIR098 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 MZIR098 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 MZIR098 maize in the EU.

11.3. Potential interactions with the abiotic environment

The scope of this application does not include cultivation of MZIR098 maize in the EU. Therefore, interactions of MZIR098 maize with the abiotic environment are highly unlikely. In the unlikely event that small amounts of MZIR098 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

MZIR098 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 MZIR098 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.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

The scope of this application does not include cultivation of MZIR098 maize. Environmental exposure to MZIR098 maize could only occur in the unlikely event that small amounts of MZIR098 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, MZIR098 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.

An ERA has been conducted for MZIR098 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 MZIR098 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 MZIR098 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 MZIR098 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 relative to:

- Persistence and invasiveness
- Selective advantage or disadvantage
- Potential for gene transfer
- Interactions between the GM plant and target organisms

- Interactions of the GM plant with non-target organisms
- Effects on human health
- Effects on animal health
- Effects on biogeochemical processes
- Impacts of the specific cultivation, management and harvesting techniques
- Potential interactions with the abiotic environment.

(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 MZIR098 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 MZIR098 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 GM plant 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 MZIR098 maize. Therefore, exposure to the environment will be limited to unintended release of MZIR098 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 MZIR098 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 MZIR098 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 MZIR098 maize. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable MZIR098 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

For specific detection of MZIR098 maize genomic DNA, a real-time quantitative TaqMan® PCR method has been developed by Syngenta. This detection method has been submitted for validation to the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) of the Joint Research Centre of the European Commission as part of this application.

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

14.1. History of previous releases of the GM plant notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier

No trials of MZIR098 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

Argentina: 2012-2013

Chile: 2012-2017

United States: 2009-2015

(b) Authority overseeing the release

Argentina: Secretariat of Agriculture Livestock and Fishery from the Ministry of Agriculture

Chile: SAG (Agricultural and Livestock Service) Ministry of Agriculture

United States: United States Department of Agriculture

(c) Release site

Argentina: Santa Fe; Buenos Aires

Chile: Arica; Granderos; Talca

United States: Hawaii; Illinois; Indiana; Iowa; Kansas; Minnesota; Missouri; Nebraska; North Carolina; Pennsylvania; Puerto Rico; South Dakota; Washington; Wisconsin

(d) Aim of the release

Argentina: Research and Development

Chile: Research and Development

United States: MZIR098 was released for the purpose of regulatory trials, efficacy testing, yield testing, product development, and/or demonstration.

(e) Duration of the release

Argentina: One summer season each year

Chile: The duration of each release was one growing season.

United States: The duration of each release was one growing season.

(f) Aim of post-releases monitoring

Argentina: Control of volunteers

Chile: Control of volunteers

United States: Post-release monitoring was conducted to assess volunteers.

(g) Duration of post-releases monitoring

Argentina: Depending of the aim of the release, but typically one year after harvest

Chile: 6 months

United States: 12 months

(h) Conclusions of post-release monitoring

Argentina: The occurrence of post-harvest volunteers on the regulated field sites was no different to other conventional material.

Chile: Since the field trial were conducted in Syngenta Sites, volunteers control was efficient and we didn't have problems in the subsequent crops.

United States: No volunteers typically observed. If volunteers occur, practice is to eliminate them manually or chemically to prevent occurrence in subsequent crops.

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

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

Chile: Out of the scope of the trial.

United States: Field-testing provided no evidence that MZIR098 would be the cause of any adverse effects to human health or to the environment.