A. GENERAL INFORMATION

1. Details of application

a) Member State of application Germany
b) Application number Not available at the time of submission
c) Name of the product (commercial and other names) Event 5307 maize (5307 maize)
d) Date of acknowledgement of valid application Not available at time of submission

2. Applicant

a) Name of applicant Syngenta Crop Protection AG, Basel Switzerland acting on its behalf and through its affiliated companies
b) Address of applicant Syngenta Crop Protection AG Schwarzwaldallee 215 CH 4058 Basle Switzerland
c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii)) 5307 maize will be imported and used as any other maize in the European Union Member States (EU) by operators currently involved in these processes.

3. Scope of the application

☒ GM plants for food use

☒ Food containing or consisting of GM plants

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

☒ GM plants for feed use

☒ Feed containing or consisting of GM plants

☒ Feed produced from GM plants

☒ Import and processing (Part C of Directive 2001/18/EC)

☐ Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

4. Is the product being simultaneously notified within the framework of another regulation (e.g. Seed legislation?)?

Yes ☐	No ☒
If *yes*, specify	

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

Yes ☐	No☒
A risk assessment has been performed according to the Directive 2001/18/EC and forms part of this application.	

6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC or Regulation (EC) 258/97?

Yes ☐	No ☒
If *yes*, specify	

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

Yes ☒	No ☐
If *yes*, specify Submissions covering 5307 maize have been made in third countries around the world and these are at different stages in the approval process.	

8. General description of the product

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

5307 maize is a genetically modified maize which expresses two transgenes:

1. An engineered *ecry3.1Ab* gene encoding the eCry3.1Ab protein for control of certain coleopteran pests like *Diabrotica virgifera virgifera* (Western corn rootworm) and related *Diabrotica* species.
2. A phosphomannose isomerase (*pmi*, also known as *manA*) gene encoding the PMI protein as a selectable marker that allows the plants to utilise mannose as a carbon source.

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

The scope of the application includes all food and feed products containing, consisting or produced from 5307 maize including products from inbreds and hybrids obtained by conventional breeding of this maize product. The application also covers the import and industrial processing of 5307 maize for all potential uses as any other maize.

c) Intended use of the product and types of users

It is intended that 5307 maize will be used as any other conventional maize which is cultivated or imported for all food, feed and industrial purposes.

d) 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 5307 maize and products derived from it are not different from those of its conventional counterpart, apart from the introduced trait of insect tolerance and expression of PMI. 5307 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 5307 maize.

e) Any proposed packaging requirements

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

f) A proposal for labelling in accordance with Articles 13 and Articles 25 of Regulation (EC) 1829/2003. In the case of GMOs, food and/or feed containing or consisting of GMOs, a proposal for labelling has to be included complying with the requirements of Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC

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

g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants)

A unique identifier for 5307 maize has been assigned in accordance with Commission Regulation (EC) 65/2004: SYN-Ø53Ø7-1

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

The 5307 maize is suitable for use as any other maize under the terms of the authorisation applied for.

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

Maize is incapable of sustained reproduction outside domestic cultivation and is non-invasive of natural habitats. The characteristics of 5307 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 is the authorisation of 5307 maize for import, processing, food and feed uses. The scope of the application does not include authorisation for the cultivation of 5307 maize seed products in the EU.

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

5307 maize has 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.

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

1. Complete name

a) Family name Poaceae (formerly Gramineae)
b) Genus *Zea*
c) Species *mays*
d) Subspecies *mays*
e) Cultivar/breeding line or strain 5307 maize
f) Common name Maize; corn

2 a. Information concerning reproduction

(i) Mode(s) of reproduction Sexual reproduction: *Zea mays* is an allogamous plant that propagates through seed produced predominantly by wind-borne cross-pollination. Self pollination of up to 5% may be observed. Male and female flowers are separated on the plant by about 1–1.3m. *Z. mays* has staminate flowers in the tassels and pistillate flowers on the ear shoots. *Z. mays* is a plant with protoandrous inflorescence; however, decades of conventional selection and breeding have produced varieties of maize with protogyny. Asexual reproduction: There is no asexual reproduction in maize.
(ii) Specific factors affecting reproduction The key critical stages of maize reproduction are tasselling, silking, pollination and fertilization. Climatic and drought stress affect pollen viability and silk longevity thus potentially limiting the period of possible cross-pollination. Maize pollen is very sensitive to dehydration as it loses water rapidly. Other factors like rainfall or irrigation inhibit pollen emission because the anther dehiscence is limited by the mechanical layer. In general, maize pollen is only viable for a few hours after

emission. As maize pollen is large and heavy it tends to be deposited close to the source plant and studies have indicated that most maize pollen falls within 5m of the field's edge. In general, such studies have shown that over 98% of maize pollen remains within a radius of 25-50 m of the source, although some grains can travel several hundred meters. Climatic conditions also affect grain and seed production, especially under drought conditions during flowering, tasseling and silking. If severe drought occurs during these phenological stages, the grain yield is reduced.

(iii) Generation time

Maize is an annual crop. The generation time from sowing to harvesting varies according to the genetic background and the climate, it can range from as short as 60 to 70 days to as long as 43 to 48 weeks from seedling emergence to maturity.

2 b. Sexual compatibility with other cultivated or wild plant species

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

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

3. Survivability

a) Ability to form structures for survival or dormancy

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

b) Specific factors affecting survivability

The survival of maize is limited by a combination of low competitiveness, absence of a dormancy phase, susceptibility to plant pathogens, herbivores and to low moisture and cold climate conditions.

4. Dissemination

a) Ways and extent of dissemination

Maize seed dissemination can only be accomplished through seed dispersal. Seed dispersal does not occur naturally due to the structure of the ear. Maize is a cross-pollinated plant, relying on wind for the dispersal of its pollen. The rate of cross-fertilization between fields depends on pollen viability, flowering synchrony and the relative concentration of pollen in the donor and receptor plots. Most cross-pollination events occur within 40 m of the pollen source.

b) Specific factors affecting dissemination

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

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

Maize is the world's most widespread cereal with very diverse morphological and physiological traits; it is grown on approximately 160 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 21º and 27º C and the freeze-free season lasts 120-180 days.

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

There are no wild relatives of maize in Europe.

6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

Maize was introduced into Europe in the 15th century by Columbus and is widely grown in the EU since the 16th century.

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

Maize is known to interact with other organisms in the environment including insects, birds, and mammals. It is susceptible to a range of fungal diseases and insect pests, as well as to competition from surrounding weeds. Maize is extensively cultivated and has a history of safe use for human food and animal feed. No significant native toxins are reported to be associated with the genus *Zea*.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

5307 maize was produced by transformation of immature maize embryos derived from a proprietary *Z. mays* line *via Agrobacterium tumefaciens*-mediated transformation.

2. Nature and source of the vector used

Plasmid pSYN12274, was used to generate 5307 maize *via A. tumefaciens*-mediated transformation.

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

5307 maize is a genetically modified maize that controls certain coleopteran pests. The region intended for insertion contains the engineered *ecry3.1Ab* gene, based on the *cry1Ab* and the *mcry3A* genes from *Bacillus thuringiensis*; the *ecry3.1Ab* gene is under the control of the CMP promoter from Cestrum Yellow Leaf Curling Virus and the nopaline synthase (NOS) terminator from *A. tumefaciens* (ingredient cassette). It also contains the *pmi* gene from *Escherichia coli* encoding the enzyme phosphomannose isomerase (PMI); this gene is under the control of the maize polyubiquitin promoter and the NOS terminator from *A. tumefaciens* (selectable marker cassette).

Active ingredient cassette		
Genetic element	**Size (bp)**	**Description**
CMP promoter	346	Cestrum Yellow Leaf Curling Virus promoter region. Provides constitutive expression in maize.
ecry3.1Ab	1962	An engineered *cry* gene active against certain corn rootworm (*Diabrotica*) species. The gene *ecry3.1Ab* consists of a fusion between the 5′ end of a modified *cry3A* gene and the 3′ end of the *cry1Ab* gene.
NOS terminator	253	Terminator sequence from the nopaline synthase gene of *A. tumefaciens*. Provides a polyadenylation site.

Selectable marker cassette		
Genetic element	**Size (bp)**	**Description**
ZmUbiInt promoter	1993	Promoter region from the maize polyubiquitin gene which contains the first intron. Provides constitutive expression in monocots
pmi	1176	*E. coli* gene *pmi* encoding the enzyme PMI; this gene is also known as *manA*. Catalyzes the isomerization of mannose-6-phosphate to fructose-6-phosphate.
NOS terminator	253	Terminator sequence from the nopaline synthase gene of *A. tumefaciens*. Provides a polyadenylation site.

D. INFORMATION RELATING TO THE GM PLANT

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

5307 maize is a genetically modified maize which expresses two transgenes:

1. An engineered *ecry3.1Ab* gene encoding the eCry3.1Ab protein for control of certain coleopteran pests like *Diabrotica virgifera virgifera* (Western corn rootworm) and related *Diabrotica* species.

2. A *pmi* gene encoding the PMI protein as a selectable marker.

Protection against coleopteran insect pests is provided through the expression of an engineered eCry3.1Ab protein based on mCry3A, a protein derived from the native Cry3A protein from *B. thuringiensis* subsp. *tenebrionis,* and on the Cry1Ab protein from *B. thuringiensis* subsp. *kurstaki* HD-1.

5307 maize also expresses a PMI enzyme encoded by the *pmi* gene from *E. coli*, which serves as a selectable marker. PMI allows transformed maize cells to utilize mannose as the only primary carbon source and therefore confers the ability to survive on media in which mannose is the sole source of carbon, whereas maize cells lacking PMI fail to grow.

2. Information on the sequences actually inserted or deleted

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

Southern blot analyses were used to determine the number of integration sites within the maize genome, the copy number of each functional element in the insert and the presence or absence of the plasmid backbone sequence. These analyses demonstrated that single copies of the e*cry3.1Ab* gene, *pmi* gene, CMP promoter and ZmUbiInt promoter are present in 5307 maize. As expected, two copies of the NOS terminator (one copy regulating the *ecry3.1Ab* gene and one copy regulating the *pmi* gene) are inserted. Results also indicated that there are no extraneous DNA fragments of the functional elements elsewhere in the 5307 maize genome, and that 5307 maize does not contain any of the backbone sequences from the transformation plasmid pSYN12274. In addition, sequence analysis of the entire insert present in 5307 maize confirmed that it was intact and that the organization of the functional elements within the insert, as present in pSYN12274, was maintained.

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

Not applicable

c) Chromosomal location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination The inheritance pattern of the insert in 5307 maize was analysed and the results showed that insertion has taken place within the nucleus.
d) The organisation of the inserted genetic material at the insertion site The molecular analyses confirmed that 5307 maize contains a single intact insert with one copy of the e*cry3.1Ab* and *pmi* genes.

3. Information on the expression of the insert

a) Information on developmental expression of the insert during the life cycle of the plant The levels of expression of the eCry3.1Ab and PMI proteins in maize plants derived from 5307 maize were determined by enzyme linked immunosorbent assay (ELISA). The analyses were performed on key plant tissues collected from transgenic hybrid plants at different sampling times across the growing season. To control for background effects, the corresponding tissues from a non-transgenic, near-isogenic control maize were also analyzed. The concentrations of the proteins eCry3.1Ab and PMI were detectable or quantifiable in the 5307 maize tissues analyzed.
b) Parts of the plant where the insert is expressed The concentrations of the proteins eCry3.1Ab and PMI were detectable or quantifiable in the 5307 maize tissues analyzed.

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

a) Reproduction No changes in the reproduction compared to near-isogenic conventional maize have been observed in agronomic assessments conducted with 5307 maize.
b) Dissemination No changes in the dissemination compared to near-isogenic conventional maize have been observed in agronomic assessments conducted with 5307 maize.
c) Survivability No changes in the survivability compared to near-isogenic conventional maize have been observed in agronomic assessments conducted with 5307 maize.
d) Other differences No changes in the reproduction, dissemination or survivability compared to non-transgenic, near-isogenic control maize have been observed in agronomic

assessments conducted with 5307 maize.

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

Molecular and protein expression analyses showed that the insert has been stably integrated into the plant's genome in 5307 maize.

5307 maize F_1 seed once planted by growers produces grain (F_2) which is harvested for food, feed or industrial use. Such grain or products entering the commodity chain are not kept for further sowing.

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

a) Plant to bacteria gene transfer

There is no change in the ability of 5307 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.

b) Plant to plant gene transfer

The genetic modification in 5307 maize is not intended to change any of the typical crop characteristics of maize, except to confer resistance against certain coleopteran pests. Observations from field trials have confirmed that the agronomic and phenotypic characteristics of 5307 maize have not changed in comparison with non-transgenic, near-isogenic controls, and therefore, there is no increase or decrease in the potential for plant-to-plant gene transfer compared to traditional maize. Gene transfer from 5307 maize to other sexually compatible plant species is not possible since maize has no wild relatives in the EU. In addition, since the scope of this application does not include authorisation for cultivation, the likelihood of dissemination of pollen to other plants (including cultivated maize plants) is considered to be negligible.

7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

7.1 Comparative assessment

Comparative assessments of composition, agronomic and phenotypic characteristics of 5307 maize and nontransgenic, near-isogenic control maize have been carried out. 5307 maize plants were compared with relevant control maize lines that had not been genetically modified. Commercial varieties were also included in the comparison where possible.

7.2 Production of material for comparative assessment

a) number of locations, growing seasons, geographical spreading and replicates

To evaluate whether biologically significant changes in composition occurred in 5307 maize plants compared to non-transgenic, near-isogenic conventional maize, replicate trials were planted at a range of locations in the US over two seasons. The locations of the trial sites were selected to be representative of the range of environmental conditions under which the hybrid varieties are expected to be grown.

b) the baseline used for consideration of natural variations

The levels of multiple nutritive components were compared in maize kernels (grain) and whole plants (forage) from 5307 maize and its non-transgenic, near-isogenic conventional counterpart grown concurrently. The mean values were compared with means and ranges for forage and grain composition published in the ILSI Crop Composition Database or from commercially available hybrid maize.

7.3 Selection of materials and compounds for analysis

Key nutritional components in maize grain and maize forage derived from the GM maize plants and their corresponding non-transgenic, near-isogenic control plants were compared. Based on guidance from the OECD the components measured in grain were proximates (including starch), minerals, amino acids and selected fatty acids, vitamins, anti-nutrients and secondary metabolites. Forage was analysed for proximates and minerals.

No consistent pattern has emerged to suggest that biologically relevant changes in composition or nutritive value of the grain or forage have occurred as an unintended result of transformation or expression of the transgenes in 5307 maize.

These findings support the conclusion that forage and grain from 5307 maize are compositionally equivalent to conventional maize varieties except for the presence of the intended traits.

7.4 Agronomic traits

To confirm that 5307 maize hybrids were no different in agronomic characteristics, apart from the introduced traits, from the corresponding non-transgenic, near-isogenic control hybrids grain yield and agronomic performance were evaluated in a series of trials across the US. Selected agronomic and morphologic traits were assessed and compared. The results of these trials showed that 5307 maize is agronomically and phenotypically equivalent to conventional maize, apart from the introduced traits.

7.5 Product specification

Maize as a product has a history of safe use for human food and animal feed. No significant native toxins are reported to be associated with the genus *Zea*. The information presented in this application confirms that 5307 maize and products derived from it are not different from those of its conventional counterpart.

7.6 Effect of processing

5307 maize will be produced and processed in the same way as any non-GM maize and there is no evidence to suggest that the expression of the newly expressed proteins produced by this maize (eCry3.1Ab and PMI) will influence this processing in any way.

7.7 Anticipated intake/extent of use

There are no anticipated changes to the intake/extent of use of maize as a result of the introduction of 5307 maize to the conventional maize supply. It is anticipated that the introduction of 5307 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.

The expected levels of intake of the proteins eCry3.1Ab and PMI through consumption of 5307 maize in the EU will be very low. Margins of exposure exceed a factor of at least 100,000, supporting the conclusion that the risk to consumers from 5307 maize is negligible.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

5307 maize expresses two proteins: the eCry3.1Ab protein that confers resistance to certain coleopteran pests, such as the Western corn rootworm, and the PMI protein, an enzyme that allows transformed maize cells to utilize mannose as a sole carbon source, acting as a selectable marker.

To demonstrate the safety of each protein a series of studies have been conducted. In addition, existing data on the safety of the Cry and PMI proteins have also been taken into account. The assessment confirms that both of the newly expressed proteins, eCry3.1Ab and PMI, are not structurally or functionally related to proteins which have the potential to adversely affect human or animal health. They are rapidly degraded in simulated gastric fluid. Neither of the proteins showed any sequence homology with known mammalian toxins. The acute oral toxicity studies conducted with eCry3.1Ab and PMI, confirmed that these proteins are not acutely toxic to mice at the highest dose tested and there is no evidence to suggest that protein digestion is altered as a result of repeated exposure to the protein or to expect accumulation of protein with repeated exposure.

7.8.2 Testing of new constituents other than proteins

Maize is a common source of food and feed and has a long history of safe use. 5307 maize has been modified to express the proteins eCry3.1Ab and PMI. No other new constituents apart from these two proteins are expected to be produced in 5307 maize and compositional analyses have confirmed the substantial equivalence of 5307 maize and conventional maize. Therefore, no testing of any other constituent is considered necessary.

7.8.3 Information on natural food and feed constituents

The presence and levels of natural food and feed constituents such as macro- and micronutrients, secondary plant metabolites as well as natural toxins and antinutritional factors have been analysed and compared with non-GM isolines and data from the literature.

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

7.8.4 Testing of the whole GM food/feed

In addition to the compositional analysis, the wholesomeness and safety of 5307 maize was confirmed in a poultry feeding study.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The weight-of-evidence indicates that the transgenic proteins produced by 5307 maize are not likely to be a food allergen because:

1. None of the transgenic proteins produced by 5307 maize (eCry3.1Ab and PMI) are derived from a known source of allergenic proteins,
2. eCry3.1Ab and PMI do not have biologically relevant amino acid sequence similarity to known or putative allergenic proteins,
3. eCry3.1Ab and PMI are rapidly degraded in simulated mammalian gastric fluid,

7.9.2 Assessment of allergenicity of the whole GM plant or crop

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

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

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

7.10.2 Nutritional assessment of GM feed

5307 maize is not intended to change the nutritional status of livestock animals. Compositional analysis and whole food and feed safety tests have demonstrated that no unexpected alterations in nutrients and other food or feed components have occurred and that no nutritional imbalances were introduced.

7.11 Post-market monitoring of GM food/feed

As described in sections 7.1 to 7.10 above, the presence of 5307 maize in food and feed will not result in any nutritional changes, therefore post-market monitoring of GM food/feed is not considered necessary.

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

5307 maize is a genetically modified maize which expresses two transgenes:

1. an engineered *ecry3.1Ab* gene encoding the eCry3.1Ab protein for control of certain coleopteran pests like *Diabrotica virgifera virgifera* (Western corn rootworm) and related *Diabrotica* species. The eCry3.1Ab protein is based on mCry3A, a protein derived from the native Cry3A protein from *B. thuringiensis* subsp. *tenebrionis,* and on the Cry1Ab protein from *B. thuringiensis* subsp. *kurstaki* HD-1.
2. a *pmi* gene from *E. coli* encoding the PMI protein which serves as a selectable marker that allows transformed maize cells to utilize mannose as the only primary carbon source. There are no toxic effects of PMI on any organism.

The mechanism of interaction and mode of action of the protein eCry3.1Ab with the target organisms has been characterised and found to be similar to that of other coleopteran-active toxins.

In any case, the scope of this application does not include cultivation of 5307 maize in the EU. Therefore, any direct or indirect interactions between plants of 5307 maize and target organisms are highly unlikely.

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

9.1 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 5307 maize, which means that environmental exposure in the EU would be very low and localised, it can be concluded that: The genetic modification introduced in 5307 maize has not altered agronomic and phenotypic characters of 5307 maize associated with persistence or invasiveness potential compared to conventional maize. In addition, the genes introduced in 5307 maize will not confer any selective advantage or disadvantage to this maize compared to conventional maize.

9.2 Selective advantage or disadvantage

The comparative assessment of phenotypic and agronomic traits conducted for 5307 and near-isogenic conventional maize has shown that the genetic modification introduced in 5307 maize has not altered the agronomic characteristics of 5307 maize compared to conventional maize, apart from the intended modification, which is tolerance to certain coleopteran pests and expression of the selectable marker PMI.

Expression of eCry3.1Ab could be considered to give 5307 maize an advantage over conventional maize in areas of Europe where Western corn rootworm is an important pest. However maize is a highly domesticated plant and cannot survive

without human intervention, even in areas without pressure from these target pests. Therefore, expression of eCry3.1Ab will not increase the chances of maize survival under European conditions and would not confer any selective advantage.

Expression of PMI could confer an advantage to 5307 maize plants growing under conditions where mannose was the only source of carbon. However, these conditions are highly unlikely in normal soils. Therefore, expression of PMI cannot be considered a factor that would confer selective advantage to 5307 maize plants.

In summary, the likelihood that the expression of the coleopteran pest protection trait, or the selectable marker in 5307 maize will result in a selective advantage or disadvantage compared with conventional maize, under the scope of this application, can be considered negligible.

9.3 Potential for gene transfer

There is no change in the ability of 5307 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 5307 maize to other sexually compatible plant species is not possible since there are no wild relatives of maize in the EU.

The genetic modification in 5307 maize is not intended to change any of the typical crop characteristics of maize (except for the intended traits). Observations from field trials have confirmed that the agronomic and phenotypic characteristics of 5307 maize have not changed in comparison with near-isogenic controls, and therefore, there is no increase or decrease in the potential for plant-to-plant gene transfer compared to traditional maize. In addition, since the scope of this application does not include authorisation for cultivation, the likelihood of dissemination of pollen to other maize plants is considered to be negligible.

Given the exposure to micro-organism that could arise from the import and food and feed use of 5307 maize in the EU and the characteristics of the transgenes, it can be concluded that it is very unlikely that genes from 5307 maize would become established in the genome of microorganisms in the environment or human and animal digestive tract.

9.4 Interactions between the GM plant and target organisms

The intended effect of the genetic modification in 5307 maize is the protection of maize from pests such as the Western corn rootworm and related *Diabrotica* species through the expression of eCry3.1Ab in the plant.

The scope of this application does not include cultivation of 5307 maize in the EU, therefore potential immediate or delayed effects in the environment due to direct or indirect interactions between 5307 maize plants and target organisms as a result of the import of 5307 grain or products for food and feed use in the EU are highly unlikely.

9.5 Interactions of the GM plant with non-target organisms

Exposure to non-target organisms as a result of import or food and feed use of 5307 maize in the EU will be low, localised and limited in time. This combined with the fact that the insecticidal activity of eCry1.Ab is limited to Western corn rootworm and related species, allows the conclusion that harmful effects on populations of non-target organisms are highly unlikely.

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

9.6 Effects on human health

Compositional analysis and broiler feeding studies with 5307 maize have confirmed that the 5307 maize is equivalent in composition to conventional maize and as safe and nutritious as conventional maize.

There is no reason to anticipate that 5307 maize would result in a product that differs in toxicity or allergenic potential to humans. None of the proteins produced by 5307 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.

In summary, no adverse effects on human health are expected following consumption of food products consisting or containing 5307 maize.

9.7 Effects on animal health

Compositional analysis and broiler feeding studies with 5307 maize have confirmed that the 5307 maize is equivalent in composition to conventional maize and as safe and nutritious as conventional maize.

There is no reason to anticipate that 5307 maize would result in a product that differs in toxicity or allergenic potential to humans or animals. None of the proteins produced by 5307 maize are known to be toxic or allergenic to humans or animals and there are no known precedents where interactions between non-toxic proteins lead to toxic effects.

In summary, no adverse effects on animal health or adverse consequences for the feed chain are expected following consumption of animal feed products consisting or containing 5307 maize.

9.8 Effects on biogeochemical processes

The scope of this application does not include cultivation of 5307 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 event that small amounts of grain of 5307 maize accidentally found their way into the EU environment, their survival would be very unlikely, as maize is a highly domesticated plant and cannot survive without human intervention, especially under normal European climatic conditions. Moreover, these plants could be easily controlled using any of the current agronomic measures taken to control other commercially available maize.

In summary, the risk of adverse effects on biogeochemical processes resulting from interactions of 5307 maize and target or non-target organisms can be considered negligible under the scope of this application.

9.9 Impacts of the specific cultivation, management and harvesting techniques

The scope of this application does not include cultivation of 5307 maize plants in the EU. Therefore, there will be no impacts on the specific cultivation, management and harvesting techniques for 5307 maize.

10. Potential interactions with the abiotic environment

The scope of this application does not include cultivation of 5307 maize in the EU. Therefore interactions of 5307 maize with the abiotic environment are highly unlikely. In the event that small amounts of grain of 5307 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.

11. Environmental monitoring plan (not if application concerns only food and feed)

11.1 General (risk assessment, background information)

The scope of this application does not include cultivation of 5307 maize in the EU. Environmental exposure to 5307 maize could only occur in the event that small amounts of grain of 5307 maize accidentally found their way into the environment in the EU. However, the survival of this grain would be very unlikely as maize is a highly domesticated plant and cannot survive without human intervention, especially under normal European climatic conditions. This grain, if germinated, could be easily controlled using any of the current agronomic measures taken to control other commercially available maize.

An environmental risk assessment (ERA) has been carried out for 5307 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 conclusion of the ERA is that the effects to the environment arising from the import and use of 5307 maize can be considered as negligible as those from any other commercial maize.

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (ERA) for the import and use of 5307 maize in the EU has been conducted as required under Regulation (EC) No 1829/2003. The methodology used follows the recommendations outlined in the Guidance document of the Scientific Panel of Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed and the requirements described in Directive 2001/18/EC.

The scientific evaluation of the characteristics of 5307 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.

Therefore, a case-specific monitoring plan is not considered necessary.

However, a general surveillance plan based on Annex II of the Directive 2001/18/EC has been developed and is outlined below.

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

The conclusion of the ERA confirms that the potential risks to human and animal health or the environment arising from 5307 maize can be considered negligible under the scope of this application. Therefore, a case-specific monitoring plan is not considered necessary.

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

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

The scope of this application is the authorisation for import and food and feed use of 5307 maize, including processing of 5307 maize for all potential uses, as any other maize. However, the scope of the application does not include authorisation for the cultivation of 5307 maize seed products in the EU.

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

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 5307 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 5307 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 5307 maize. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable 5307 maize.

11.5 Reporting the results of monitoring

The applicant/consent holder is responsible, under Regulation (EC) No 1829/2003, to inform the European 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.

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

For specific detection of 5307 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 DG JRC-EURL as part of this application.

E. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT AND/OR DERIVED PRODUCTS

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

No trials of 5307 maize have been carried out in the EU

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

a) Release country US.
b) Authority overseeing the release EPA and USDA.
c) Release site Various sites across the US.
d) Aim of the release Research and development.
e) Duration of the release Varied depending on the aim of the trial.
f) Aim of post-releases monitoring Control of volunteers.
g) Duration of post-releases monitoring Varied depending on the aim of the trial, typically one year.

h) Conclusions of post-release monitoring The occurrence of volunteers after planting 5307 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.

3. Links (some of these links may be accessible only to the competent authorities of the Member States, to the Commission and to EFSA):

a) Status/process of approval The status and process of approval can be found on the EFSA website: http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOApplications.htm
b) Assessment Report of the Competent Authority (Directive 2001/18/EC) An application for approval of 5307 maize under Directive 2001/18/EC has not been made by Syngenta.
c) EFSA opinion EFSA opinions, once available, can be found at: http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOApplications.htm
d) Commission Register (Commission Decision 2004/204/EC) The Commission register of GM Food and Feed can be found at: http://ec.europa.eu/food/food/biotechnology/authorisation/index_en.htm
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre The Community Reference Laboratory webpage is http://gmo-crl.jrc.ec.europa.eu/
f) Biosafety Clearing-House (Council Decision 2002/628/EC) Information relating to the Biosafety Clearing-House can be found at: http://bch.biodiv.org/
g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC) An application for approval of 5307 maize under Directive 2001/18/EC has not been made by Syngenta, however a link to this Summary under Regulation (EC) No

1829/2003 may be found at:

http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOApplications.htm