

**Application for authorization to place on the market  
MON 87427 × MON 89034 × 1507 × MON 88017 × 59122  
maize in the European Union, according to  
Regulation (EC) No 1829/2003  
on genetically modified food and feed**

**Part VII**

**Summary**

**Data protection.**

This application contains scientific data and other information which are protected in accordance with Art. 31 of Regulation (EC) No 1829/2003.

## 1. GENERAL INFORMATION

### 1.1. Details of application

- (a) **Member State of application**  
Belgium
- (b) **Application number**  
Not available at the time of submission.
- (c) **Name of the product (commercial and other names)**  
The Monsanto development code for this genetically modified maize is MON 87427  
× MON 89034 × 1507 × MON 88017 × 59122.
- (d) **Date of acknowledgement of valid application**  
Not available at the time of submission.

### 1.2. Applicant

- (a) **Name of applicant**  
Monsanto Company, represented by Monsanto Europe S.A.
- (b) **Address of applicant**

Monsanto Europe S.A.	Monsanto Company
Avenue de Tervuren 270-272	800 N. Lindbergh Boulevard
B-1150 Brussels	St. Louis, Missouri 63167
BELGIUM	U S
- (c) **Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)**  
*See above.*

### 1.3. Scope of the application

- (a) **GM food**
  - ☒ Food containing or consisting of GM plants
  - ☒ Food produced from GM plants or containing ingredients produced from GM plants
- (b) **GM feed**
  - ☒ Feed containing or consisting of GM plants
  - ☒ Feed produced from GM plants
- (c) **GM plants for food or feed use**
  - ☒ Products other than food and feed containing or consisting of GM plants with the exception of cultivation
  - ☐ Seeds and plant propagating material for cultivation in the EU

The scope of the current application is for all uses of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize as any other maize. Since maize is a segregating crop, the MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 grain imported in EU will contain a mixture of all possible combinations of the single GM events constituting it. Therefore, the risk assessment of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 should cover all combinations of the constituent events.

**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)

The protein expression, the composition, the safety, the agronomic and the phenotypic characteristics of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 have been studied at multiple locations in the US that cover a range of environmental conditions. The risk assessment presented in this application includes data collected from these field trials. A summary of the conclusions of the risk analysis that demonstrates the safety of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 to humans, animals and to the environment, has been presented in the respective sections throughout this summary.

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

No ☒

Yes ☐ (in that case, specify)

**1.7. Has the product been notified/authorised in a third country either previously or simultaneously?**

No ☐

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

Applications for the full range of uses have been made in Canada, Japan, Mexico, Taiwan, U.S. and are planned for Argentina. Applications for import approvals have been submitted to countries that import significant quantities of maize or food and feed products derived from maize and have regulatory review processes in place. The countries where applications were already submitted are: Singapore and Colombia. Also, as appropriate, notifications will be made to countries that import significant quantities of maize and maize products and do not have a formal regulatory review process for biotechnology derived crops.

**1.8. General description of the product**

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

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is produced by crossing MON 87427 and MON 89034 × 1507 × MON 88017 × 59122 parental lines using conventional breeding methods.

Like MON 89034 × 1507 × MON 88017 × 59122 parental maize, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 produces:

- Cry1A.105 and Cry2Ab2 proteins which provide a dual effective dose against feeding damage caused by the key lepidopteran pest complex in maize: European corn borer (ECB, *Ostrinia nubilalis*), southwestern corn borer (SWCB, *Diatraea grandiosella*), and corn earworm (CEW, *Helicoverpa zea*) and other lepidopteran insect pests, such as the fall armyworm (FAW, *Spodoptera frugiperda*) sugarcane borer (SCB, *Diatraea saccharalis*). Cry1A.105 is a modified *Bacillus thuringiensis* (Bt) Cry1A-type protein with overall amino acid sequence identity of 93.4%, 90%, and 76.7% to the Cry1Ac (subsp. *kurstaki*), Cry1Ab (subsp. *kurstaki*) and Cry1F (subsp. *aizawai*). Cry2Ab2 is a *Bacillus thuringiensis* subsp. *kurstaki* protein.
- Cry1F insecticidal protein, derived from *Bacillus thuringiensis* subsp. *aizawai* which provides a third activity against the lepidopteran pest complex, and further expands the spectrum of activity in the combined trait product to control the black cutworm (BCW, *Agrotis ipsilon*) and western bean cutworm (WBCW, *Richia albicosta*).
- Cry3Bb1 protein, derived from *Bacillus thuringiensis* subsp. *kumamotoensis* that provides protection against corn rootworm (*Diabrotica* spp.) larval feeding.
- Cry34/35Ab1 binary insecticidal protein, derived from *Bacillus thuringiensis* that provides a second mode of activity against corn rootworm (*Diabrotica* spp.) larval feeding.
- CP4 EPSPS protein, derived from *Agrobacterium* sp. strain CP4 which provides tolerance to glyphosate.
- Phosphinothricin acetyl transferase (PAT) protein from *Streptomyces viridochromogenes* which provides tolerance to glufosinate-ammonium,

While MON 87427 contains the *e35s-hsp70* promoter intron combination that allows for full vegetative and female reproductive glyphosate tolerance and also results in limited or no production of CP4 EPSPS protein in two key male reproductive tissues: pollen microspores, which develop into pollen grains, and tapetum cells that supply nutrients to the pollen, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 F1 seed has full vegetative and male reproductive tolerance to glyphosate as CP4 EPSPS expressed in MON 88017 on the male parent during hybrid seed production of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 resets full glyphosate tolerance in the MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 seed.

**(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**

The scope of the current application is for authorisation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU for all uses according to Art 3(1) and 15(1) of Regulation (EC) No 1829/2003, with the exception of cultivation. The

range of uses of this maize will be identical to the full range of equivalent uses of conventional maize.

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

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 will be traded and used in the EU in the same manner as current conventional commercial maize and by the same operators currently involved in the trade and use of maize.

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

With the exception of the lepidopteran and coleopteran (corn rootworm) protection traits and glufosinate and glyphosate tolerance traits that only have agronomical relevance, the characteristics of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize and products derived from it are comparable to those of its conventional counterpart and the conventional commercial reference varieties with a history of safe use. Therefore, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and its derived products will be stored, packaged, transported, handled and used in the same manner as current commercial maize products. No specific instructions and/or recommendations are warranted or required for the placing on the market of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 for import, processing and all uses in the EU as specified in Section 1.8(b) above.

(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**

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is suitable for use throughout the EU as any other maize. The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, excluding cultivation.

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

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is suitable for use throughout the EU as any other maize. The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, excluding cultivation.

(g) **Any proposed packaging requirements**

Except for the lepidopteran and coleopteran (corn rootworm) protection traits and herbicide tolerance traits, that only have agronomical relevance, the characteristics of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 are not different from those of its conventional counterpart. Therefore, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and derived products will be used in the same manner as other maize and no specific packaging is required.

- (h) **Any proposed labelling requirements in addition to those required by law and when necessary a proposal for specific labelling in accordance with Articles 13(2), (3) and 25(2)(c), (d) and 25(3) of Regulation (EC) No 1829/2003. In the case of GMO plants, food and/or feed containing or consisting of GMO plants, a proposal for labelling has to be included complying with the requirements of Annex IV, A(8) of Directive 2001/18/EC.**

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, a labelling threshold of 0.9 % is applied for the placing on the market of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and derived products.

Operators shall be required to label products containing or consisting of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with the words “genetically modified maize” or “contains genetically modified maize” and shall be required to declare the unique identifier in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with the words “produced from genetically modified maize”. In the case of products for which no list of ingredients exists, operators shall ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003 and that authorised foods and feeds shall be entered in the EU Register for genetically modified food and feed, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. Therefore, no further specific measures are to be taken by the applicant.

(i) **Estimated potential demand**

(i) In the Union

There are no anticipated changes to the demand as a result of the introduction of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 into the maize supply. It is anticipated that the introduction of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize will replace some of the maize in existing food and feed products.

(ii) In export markets for EU supplies

There are no anticipated changes to the demand as a result of the introduction of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 into the maize supply. It is anticipated that the introduction of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize will replace some of the maize seed products.

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

The unique identifier for this genetically modified maize is MON-87427-7 × MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7.

The unique identifiers assigned to the sub-combinations of MON-87427-7 × MON-89034-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7, excluding the singles, are the following: DAS-Ø15Ø7-1 × DAS 59122-7, MON-87427-7 × DAS-Ø15Ø7-1, MON-87427-7 × DAS 59122-7, MON-87427-7 × MON-88Ø17-3, MON-87427-7 × MON-89Ø34-3, MON-89Ø34-3 × MON-88Ø17-3, MON-89Ø34-3 × DAS 59122-7, MON-89Ø34-3 × DAS-Ø15Ø7-1, MON-88Ø17-3 × DAS-Ø15Ø7-1, MON-88Ø17-3 × DAS 59122-7, MON-87427-7 × DAS-Ø15Ø7-1 × DAS 59122-7, MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3, MON-87427-7 × DAS-Ø15Ø7-1 × MON-89Ø34-3, MON-87427-7 × DAS 59122-7 × MON-88Ø17-3, MON-87427-7 × DAS 59122-7 × MON-89Ø34-3, MON-87427-7 × MON-88Ø17-3 × MON-89Ø34-3, DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS 59122-7, MON-89Ø34-3 × MON-88Ø17-3 × DAS 59122-7, MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3, MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS 59122-7, MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS 59122-7, MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS 59122-7, MON-87427-7 × DAS-Ø15Ø7-1 × MON-89Ø34-3 × DAS 59122-7, MON-87427-7 × DAS-Ø15Ø7-1 × MON-89Ø34-3 × MON-88Ø17-3 and MON-87427-7 × MON-88Ø17-3 × MON-89Ø34-3 × DAS 59122-7.

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

Because this application is for consent to import, process and all uses of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 as any other maize, not including the cultivation in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. However, modern methods of grain handling minimize losses of grain, so there is little chance of germination of spilt grain resulting in the development of mature plants of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since maize cannot survive without human assistance and is not capable of surviving as a weed. Although maize seed can over-winter in mild conditions and can germinate the following year, the appearance of maize in rotational fields is rare under European conditions. Maize volunteers, if they occurred, would be killed by frost or could be easily controlled by the use of selective herbicides or by mechanical means. Moreover, the information presented in this application established that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is not different in composition, nutritional and agronomic characteristics relative to the conventional counterpart, except for the lepidopteran and coleopteran (corn rootworm) protection and tolerance to glyphosate and glufosinate and, therefore, it is unlikely to pose any threat to the EU environment or to require special measures for its containment. Therefore, no special measures are considered to be required in case of misuse or unintended release.

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

### 2.1. Complete name

- |   |   |
|---|---|
| (a) <b>Family name</b>                      | Poaceae (formerly Gramineae)                                    |
| (b) <b>Genus</b>                            | <i>Zea</i>  |
| (c) <b>Species</b>                          | <i>mays</i> (2n = 20)   |
| (d) <b>Subspecies</b>                       | N/A   |
| (e) <b>Cultivar/breeding line or strain</b> | MON 87427, MON 89034 × 1507 ×<br>MON 88017 × 59122 <sup>1</sup> |
| (f) <b>Common name</b>                      | maize or corn   |

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

The bulk of the maize is produced between latitudes 30° and 55°, with relatively little grown at latitudes higher than 47° latitude anywhere in the world. The greatest maize production occurs where the warmest month isotherms range between 21 and 27 °C and the freeze-free season lasts 120 to 180 days. A summer rainfall of 15 cm is approximately the lower limit for maize production without irrigation with no upper limit of rainfall for growing maize, although excess rainfall will decrease yields and increase the chance of fungal infection.

Significant areas of maize production in Europe include the Danube Basin from southwest Germany to the Black Sea along with southern France through the Po Valley of northern Italy.

### 2.3. Information concerning reproduction (for environmental safety aspects)

#### (a) Mode(s) of reproduction

Maize (*Zea mays* L.) reproduces sexually. It is an annual, wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers which encourages the natural outcrossing between maize plants. Wind movement across maize fields causes pollen from the tassel to fall on the silks of the same or adjoining plants. Self-pollination leads to homogeneity of the genetic characteristics within a single plant while cross-pollination combines the genetic traits of many plants.

#### (b) Specific factors affecting reproduction

Tasselling, silking and pollination are the most critical stages of maize development and, consequently, grain yield may ultimately be greatly impacted by moisture and fertility stress. Under conditions of high temperature and desiccation maize pollen viability is measured in minutes; these conditions may even destroy the tassel before any viable pollen is shed.

#### (c) Generation time

Maize is an annual crop with cultural cycle ranging from as short as 60 to 70 days to as long as 43 to 48 weeks from grainling emergence to maturity. The different

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<sup>1</sup> Also referred to as MON 89034 × TC 1507 × MON 88017 × DAS 59122.

relative maturities occurring depend on prevailing weather patterns, topography, large bodies of water, and soil types.

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

### *Outcrossing with cultivated Zea varieties*

Maize is wind pollinated, and the distance that viable pollen can travel depends on prevailing wind patterns, humidity, and temperature. Once in the atmosphere, pollen grains must remain viable long enough to be able to reach a viable silk to complete the pollination process. On average maize pollen loses 100% viability after two hours of atmospheric exposure.

All maize will inter-pollinate, except for certain popcorn varieties and varieties that have one of the gametophyte factors (*GaS*, *Ga*, and *ga* allelic series on chromosome 4). Pollen of a specific variety can be carried by wind to pollinate other dent maize varieties, sweet maize and popcorn, if the popcorn does not carry the dent-sterile gametophyte factor (Hallauer, 1995). Maize pollen, therefore, moves freely within an area, lands on silks of the same variety or different varieties, germinates almost immediately after pollination, and within 24 hours completes fertilisation.

However, that the scope of the current application does not include cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU therefore any outcrossing between MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and cultivated *Zea* varieties is highly unlikely.

### *Outcrossing with wild Zea species*

Gene flow in maize (*Zea mays* L.) is closely associated with the biology of the staminate and pistillate inflorescences. Gene flow between maize and its closest relative, teosinte (*Zea* spp.) is specific to Mexico and Central America. In the Central Plateau and Valley of Mexico, maize can grow sympatrically with teosinte (*Zea* spp.) providing the opportunity for hybridization.

There are no compatible wild relatives of maize in Europe.

## **2.5. Survivability (for environmental safety aspects)**

### **(a) Ability to form structures for survival or dormancy**

Maize is an annual crop and seeds are the only survival structures. Natural regeneration from vegetative tissue is not known to occur.

### **(b) Specific factors affecting survivability**

Maize cannot survive without human assistance and is not capable of surviving as a weed due to past selection in its evolution. Volunteer maize is not found growing in fencerows, ditches or roadsides as a weed. Although maize seed from the previous crop year can over-winter in mild winter conditions and germinate the following year, it cannot persist as a weed. The appearance of “volunteer” maize in fields following a maize crop from the previous year is rare under European conditions.

Maize volunteers are killed by frost or, in the unlikely event of their occurrence, are easily controlled by current agronomic practices including cultivation and the use of selective herbicides.

Maize grain survival is dependent upon temperature, moisture of seed, genotype, husk protection and stage of development. Freezing temperatures have an adverse effect on maize seed germination and have been identified as being a major risk in

seed maize production. Temperatures above 45° C have also been reported as injurious to maize seed viability.

## **2.6. Dissemination (for environmental safety aspects)**

### **(a) Ways and extent of dissemination**

In general, dissemination of maize may occur by means of seed and pollen dispersal. Dispersal of the maize grain is highly restricted in domesticated maize due to the ear structure including husk enclosure. For maize pollen, the vast majority is deposited in the same field due to its large size (90 to 100 µm) with smaller amounts of pollen deposited usually in a downwind direction.

The current application does not include the environmental release of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU.

### **(b) Specific factors affecting dissemination**

Dispersal of maize seeds does not occur naturally because of the structure of the ears of maize. Dissemination of isolated seeds may result from mechanical harvesting and transport as well as insect or wind damage, but this form of dissemination is highly infrequent. Genetic material can be disseminated by pollen dispersal, which is influenced by wind and weather conditions. Maize pollen is the largest of any pollen normally disseminated by wind from a comparably low level of elevation. Dispersal of maize pollen is limited by its large size and rapid settling rate.

The current application does not include the environmental release of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU.

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

There are no sexually compatible wild relatives of maize in EU.

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

Not applicable, as maize is grown in Europe.

## **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)**

Like other plants, cultivated 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 nematode, insect and mite pests.

There are no known toxic effects of the maize plant to humans, animals or livestock; it has a history of safe use for human food and animal feed. Maize has been a staple of the human diet for centuries, and its processed fractions are consumed in a multitude of food and animal feed products.

### 3. MOLECULAR CHARACTERISATION

#### 3.1. Information relating to the genetic modification

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

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is produced by crossing maize plants of MON 87427 and MON 89034 × 1507 × MON 88017 × 59122 using conventional breeding methods.

MON 87427, was developed through *Agrobacterium*-mediated transformation of maize tissues. MON 89034 × 1507 × MON 88017 × 59122 was also produced through conventional breeding methods, however genetic modification was used to develop its constituent singles. MON 89034 was developed by *Agrobacterium*-mediated transformation of embryonic maize, 1507 was produced by biolistic (microprojectile bombardment) transformation, while MON 88017 and 59122 were produced by *Agrobacterium*-mediated transformation of embryonic maize cells.

(b) **Nature and source of the vector used**

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 has been obtained through conventional breeding by crossing MON 87427 and MON 89034 × 1507 × MON 88017 × 59122 and no vector has been used to produce this maize hybrid.

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

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 has been obtained through conventional breeding by crossing MON 87427 and MON 89034 × 1507 × MON 88017 × 59122 and therefore, the DNA fragments present in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 are inherited from MON 87427 and MON 89034 × 1507 × MON 88017 × 59122.

The individual components, location, source and function of these inherited sequences are given in Table 1 and Table 2.

**Table 1. Summary of the inserted DNA inherited from MON 87427 (Monsanto Company, 2010)**

Genetic Element	Size (~ kb)	Function (Reference)
T-DNA		
<b>B<sup>1</sup>-Left Border</b>	0.44	DNA region from <i>Agrobacterium tumefaciens</i> containing the Left Border sequence used for transfer of the T-DNA (Barker <i>et al.</i> , 1983)
<b>P<sup>2</sup>-e35S</b>	0.62	Promoter for the cauliflower mosaic virus (CaMV) 35S RNA (Odell <i>et al.</i> , 1985) containing the duplicated enhancer region (Kay <i>et al.</i> , 1987) that directs transcription in plant cells
<b>I<sup>3</sup>-hsp70</b>	0.80	First intron from the maize heat shock protein 70 gene (Brown and Santino, 1995)
<b>TS<sup>4</sup>-CTP2</b>	0.22	Targeting sequence from the <i>ShkG</i> gene encoding the chloroplast transit peptide (CTP) region of <i>Arabidopsis thaliana</i> EPSPS (Herrmann, 1995; Klee <i>et al.</i> , 1987) that directs transport of the CP4 EPSPS protein to the chloroplast
<b>CS<sup>5</sup>-cp4 epsps</b>	1.36	Codon-optimized coding sequence of the <i>aroA</i> gene from the <i>Agrobacterium</i> sp. strain CP4 encoding the CP4 EPSPS protein

		(Barry <i>et al.</i> , 2001; Padgett and Re, 1996)
<b>T<sup>6</sup>-nos</b>	0.25	3' non-translated region of the nopaline synthase ( <i>nos</i> ) gene from <i>Agrobacterium tumefaciens</i> that terminates transcription and directs polyadenylation (Bevan <i>et al.</i> , 1983)
<b>B-Right Border</b>	0.35	DNA region from <i>Agrobacterium tumefaciens</i> containing the Right Border sequence used for transfer of the T-DNA (Depicker <i>et al.</i> , 1982; Zambryski <i>et al.</i> , 1982)

<sup>1</sup>B, Border; <sup>2</sup>P, Promoter; <sup>3</sup>I, Intron; <sup>4</sup>TS, Targeting Sequence; <sup>5</sup>CS, Coding Sequence; <sup>6</sup>T, Transcription Termination Sequence.

**Table 2. Summary of the inherited DNA from MON 89034 × 1507 × MON 88017 × 59122 (Monsanto Company, 2006)**

<b>MON 89034</b>		
<b>Genetic Element</b>	<b>Size(~kb)</b>	<b>Function (Reference)</b>
<b>B<sup>1</sup>-Left Border</b>	0.24	239bp DNA region from the B-left Border region remaining after integration.
<b>P<sup>2</sup>-e35S</b>	0.30	Modified <i>e35s</i> promoter and 9 bp leader resulting from a recombination between the P- <i>e35s</i> and P-35s promoters. Differing from <i>e35S</i> in that it does not contain the duplicated enhancer element
<b>L<sup>3</sup>-Cab</b>	0.06	5' untranslated leader of the wheat chlorophyll a/b-binding protein (Lamppa <i>et al.</i> , 1985)
<b>I<sup>4</sup>-Ract1</b>	0.48	Intron from the rice actin gene (McElroy <i>et al.</i> , 1991)
<b>CS<sup>5</sup>-cry1A.105</b>	3.53	Coding sequence for the <i>Bacillus thuringiensis</i> Cry1A.105 protein (Monsanto unpublished data)
<b>T<sup>6</sup>-Hsp17</b>	0.21	3' nontranslated region of the coding sequence for wheat heat shock protein 17.3, which ends transcription and directs polyadenylation (McElwain and Spiker, 1989)
<b>P-FMV</b>	0.56	Figwort Mosaic Virus 35S promoter (Rogers, 2000)
<b>I-Hsp70</b>	0.80	The first intron from the maize heat shock protein 70 gene (Brown and Santino, 1995)
<b>TS<sup>7</sup>-SSU-CTP</b>	0.40	DNA region containing the targeting sequence for the transit peptide region of maize ribulose 1,5-bisphosphate carboxylase small subunit and the first intron (Matsuoka <i>et al.</i> , 1987)
<b>CS-cry2Ab2</b>	1.91	Coding sequence for a Cry2Ab2 protein from <i>Bacillus thuringiensis</i> (Donovan, 1991; Widner and Whiteley, 1989). This coding sequence uses a modified codon usage
<b>T-nos</b>	0.25	3' termination sequence of the nopaline synthase ( <i>nos</i> ) coding sequence from <i>Agrobacterium tumefaciens</i> which terminates transcription and directs polyadenylation (Bevan <i>et al.</i> , 1983)
<b>B-Left Border</b>	0.23	230 bp DNA region from the B-Left Border region remaining after integration
<b>1507</b>		
<b>Genetic Element</b>	<b>Size (~kb)</b>	<b>Function (Reference)</b>

<b>ubiZM1 PRO</b>	1.98	The ubiquitin promoter (plus 5' untranslated region) from <i>Zea mays</i> (Christensen <i>et al.</i> , 1992)
<b>cry1F</b>	1.82	A synthetic version of truncated cry1F from <i>Bacillus thuringiensis</i> sbsp. <i>aizawai</i> (plant optimized)
<b>ORF25 TERM</b>	0.72	A terminator from <i>Agrobacterium tumefaciens</i> pTi15955
<b>35S PRO</b>	0.55	35S promoter from CaMV (Odell <i>et al.</i> , 1985)
<b>pat</b>	0.55	The synthetic glufosinate-ammonium tolerance gene (plant optimized), based on a phosphinothricin acetyltransferase gene sequence from <i>Streptomyces viridochromogenes</i> (Eckes <i>et al.</i> , 1989; Wohlleben <i>et al.</i> , 1988)
<b>35S TERM</b>	0.20	35S terminator from CaMV (Pietrzak <i>et al.</i> , 1986)
<b>MON 88017</b>		
<b>Genetic element</b>	<b>Size (~kb)</b>	<b>Function (Reference)</b>
<b>B-Left Border</b>	0.29	292 bp DNA region from the B-Left Border region remaining after integration (Barker <i>et al.</i> , 1983)
<b>P-Ract1</b>	0.93	Promoter from the rice actin gene (McElroy <i>et al.</i> , 1990)
<b>I-Ract1</b>	0.48	Intron from the rice actin gene (McElroy <i>et al.</i> , 1991)
<b>TS-CTP2</b>	0.23	DNA sequence from <i>Arabidopsis thaliana</i> coding for the N-terminal CTP (Klee <i>et al.</i> , 1987).
<b>CS-cp4 epsps</b>	1.37	Coding sequence for the <i>Agrobacterium</i> CP4 EPSPS protein (Padgett <i>et al.</i> , 1996).
<b>T-nos</b>	0.25	3' transcript termination sequence of the nopaline synthase ( <i>nos</i> ) coding sequence from <i>Agrobacterium tumefaciens</i> which terminates transcription and directs polyadenylation (Bevan <i>et al.</i> , 1983)
<b>P-e35S</b>	0.61	Promoter with the duplicated enhancer region (Kay <i>et al.</i> , 1987; Odell <i>et al.</i> , 1985)
<b>L-Cab</b>	0.06	5' untranslated leader of the wheat chlorophyll a/b-binding protein (Lamppa <i>et al.</i> , 1985)
<b>I-Ract1</b>	0.48	Intron from the rice actin gene (McElroy <i>et al.</i> , 1991)
<b>CS-cry3Bb1</b>	1.96	Coding sequence for a synthetic variant of Cry3Bb1 protein (Romano, 2002).
<b>T-Hsp17</b>	0.21	3' transcript termination sequence for wheat heat shock protein 17.3, which ends transcription and directs polyadenylation (McElwain and Spiker, 1989)
<b>B-Right Border</b>	0.03	30 bp DNA region from the B-Right Border region remaining after integration (Depicker <i>et al.</i> , 1982)

59122		
Genetic element	Size (~kb)	Function (Reference)
Right Border	0.18	Right T-DNA border region from Ti plasmid of <i>Agrobacterium tumefaciens</i> . T-DNA right border 25 bp repeat region located from bp 1 to bp 25.
Ubiquitin promoter	1.99	Ubiquitin promoter from <i>Zea mays</i> including 5'UTR (bp 1149 to bp 1231) and intron (bp 1232 to bp 2241) (Christensen <i>et al.</i> , 1992).
<i>cry34Ab1</i>	0.37	Maize-optimised <i>cry34Ab1</i> gene encoding the 14 kDa delta-endotoxin parasporal crystal protein from <i>Bacillus thuringiensis</i> strain PS149B1 (Ellis <i>et al.</i> , 2002). Coding region from start codon through stop codon.
Pin II Term	0.31	Terminator sequence from <i>Solanum tuberosum</i> proteinase inhibitor II gene (An <i>et al.</i> , 1989).
Wheat Peroxidase	1.30	<i>Triticum aestivum</i> peroxidase promoter (wheat peroxidase); (Hertig <i>et al.</i> , 1991).
<i>cry35Ab1</i>	1.15	Maize-optimised <i>cry35Ab1</i> gene encoding the 44 kDa delta-endotoxin parasporal crystal protein from <i>Bacillus thuringiensis</i> strain PS149B1 (Ellis <i>et al.</i> , 2002). Coding region from start codon through stop codon.
Pin II Term	0.32	Terminator sequence from <i>Solanum tuberosum</i> proteinase inhibitor II gene (An <i>et al.</i> , 1989).
35S Promoter	0.53	35S promoter from CaMV, Strasbourg strain (Hohn <i>et al.</i> , 1982; Pietrzak <i>et al.</i> , 1986).
<i>pat</i>	0.55	Plant-optimised phosphinothricin acetyltransferase coding sequence from <i>Streptomyces viridochromogenes</i> . Coding region from start codon through stop codon (Wohlleben <i>et al.</i> , 1988).
35S Term	0.19	35S terminator from CaMV (Hohn <i>et al.</i> , 1982).
Left Border	0.08	Left T-DNA border region from Ti plasmid of <i>Agrobacterium tumefaciens</i> . T-DNA Left Border 25 bp repeat region located from bp 7366 to bp 7390.

<sup>1</sup>B, Border; <sup>2</sup>P, Promoter; <sup>3</sup>L, Leader; <sup>4</sup>I, Intron; <sup>5</sup>CS, Coding Sequence; <sup>6</sup>T, Transcription Termination Sequence; <sup>7</sup>TS, Targeting Sequence;

### 3.2. Information relating to the GM plant

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

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is produced by crossing maize plants of MON 87427 and MON 89034 × 1507 × MON 88017 × 59122 using conventional breeding methods.

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 produces:

- Cry1A.105 and Cry2Ab2 proteins which provide a dual effective dose against feeding damage caused by the key lepidopteran pest complex in maize: European corn borer (ECB, *Ostrinia nubilalis*), southwestern corn borer (SWCB, *Diatraea grandiosella*), and corn earworm (CEW, *Helicoverpa zea*); and other lepidopteran insect pests, such as the fall armyworm (FAW, *Spodoptera frugiperda*) sugarcane

borer (SCB, *Diatraea saccharalis*). Cry1A.105 is a modified *Bacillus thuringiensis* (Bt) Cry1A-type protein with overall amino acid sequence identity of 93.4%, 90%, and 76.7% to the Cry1Ac (subsp. *kurstaki*), Cry1Ab (subsp. *kurstaki*) and Cry1F (subsp. *aizawai*). Cry2Ab2 is a *Bacillus thuringiensis* subsp. *kurstaki* protein.

- Cry1F insecticidal protein derived from *Bacillus thuringiensis* subsp. *aizawai* which provides a third activity against the lepidopteran pest complex, and further expands the spectrum of activity in the combined trait product to control the black cutworm (BCW, *Agrostis ipsilon*) and western bean cutworm (WBCW, *Richia albicosta*).
- Cry3Bb1 protein, derived from *Bacillus thuringiensis* subsp. *kumamotoensis* that provides protection against corn rootworm (*Diabrotica* spp.) larval feeding.
- Cry34/35Ab1 binary insecticidal protein, derived from *Bacillus thuringiensis* that provides a second mode of activity against corn rootworm (*Diabrotica* spp.) larval feeding.
- CP4 EPSPS protein, derived from *Agrobacterium* sp. strain CP4 which provides tolerance to glyphosate.
- Phosphinothricin acetyl transferase (PAT) protein from *Streptomyces viridochromogenes* which provides tolerance to glufosinate-amonium.

While MON 87427 contains the *e35s-hsp70* promoter intron combination that allows for full vegetative and female reproductive glyphosate tolerance and also results in limited or no production of CP4 EPSPS protein in two key male reproductive tissues: pollen microspores, which develop into pollen grains, and tapetum cells that supply nutrients to the pollen, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 F1 seed has full vegetative and male reproductive tolerance to glyphosate as CP4 EPSPS expressed in MON 88017 on the male parent during hybrid seed production of MON 87427 × MON 89034 × 1507 × MON 88018 × 59122 resets full glyphosate tolerance in the MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 seed.

### 3.2.2. Information on the sequences actually inserted or deleted

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

The genome of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 contains five different inserts, one inherited from MON 87427 and four inherited from MON 89034 × 1507 × MON 88017 × 59122. The results of Southern blot analyses on MON 87427 and MON 89034 × 1507 × MON 88017 × 59122 indicate that each of these parental lines contain a single copy of the T-DNA of interest at a single insertion site. The presence of these five inserts in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 was confirmed through Southern blot analysis.

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

Not applicable since MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 was obtained through conventional breeding techniques.

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

The conventionally bred MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 F<sub>1</sub> contains the inserts in the nuclear genome, as they were present in the parental lines. The fingerprints obtained by Southern blot analyses of the combined trait product MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 are consistent with the corresponding fingerprints obtained with MON 87427, MON 89034, 1507, MON 88017, and 59122. These results confirmed the presence of the inserted sequences of MON 87427, MON 89034, 1507, MON 88017 and 59122 and that no detectable rearrangements of these inserts occurred in the combined trait maize product MON 87427 × MON 89034 × 1507 × MON 88017 × 59122.

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

Since the inserts present in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in this combined trait product.

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

Not applicable.

3.2.3. *Information on the expression of the insert*

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

The expression levels of Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1, CP4 EPSPS and PAT proteins were determined by validated enzyme-linked immunosorbent assays (ELISAs) in tissues collected during the 2010 planting season at five representative maize-growing locations in the US from glufosinate and glyphosate treated MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and positive control plants MON 87427, MON 89034, 1507, MON 88017 and 59122.

The expression levels in grain and forage of Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1, CP4 EPSPS and PAT in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, indicate that the inserted transgenes are being expressed and are functioning properly when combined via conventional breeding methods. Based on the reported expression levels of CP4 EPSPS proteins in the combined trait MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 there is no evidence for interaction between the two copies of *cp4 epsps*. Similarly, based on the reported expression levels of PAT proteins in the combined trait MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 there is no evidence for interaction between the two copies of *pat* genes. The levels of CP4 EPSPS proteins were as expected for the combined expression in MON 87427 and MON 88017. Similarly, the levels of and PAT proteins were as expected for the combined expression in 1507 and 59122.

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

The expression of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1, CP4 EPSPS and PAT proteins occurs throughout the plant at appropriate times of plant development. In terms of food and feed safety assessment of

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 grain and forage are the most relevant tissues.

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

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is produced through conventional breeding by crossing MON 87427 and MON 89034 × 1507 × MON 88017 × 59122 parental lines. Thereby, each parental line passes on its inserted DNA sequence to the resulting MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 combined trait seed.

Based on the molecular characterisation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, the MON 87427, MON 89034, 1507, MON 88017 and 59122 inserts are retained with their inherent properties. Furthermore, Southern blot analyses, carried out on MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 plant materials, confirmed the presence of the inserted sequences of MON 87427, MON 89034, 1507, MON 88017 and 59122 and that no detectable rearrangements of these inserts occurred.

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**

Phenotypic and agronomic as well as environmental interaction data were collected from eight sites at field trials conducted in the 2010 growing season. The field sites provided a range of environmental and agronomic conditions representative of commercial maize production in the U.S. Randomized complete block design with four replicates at each field site was used. In each of the assessments MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, either treated or not with glyphosate and glufosinate, was compared to an appropriate maize conventional counterpart which has a genetic background similar to MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with the exception of the *cry1A105*, *cry2Ab2*, *cry1F*, *cry3Bb1*, *cry34Ab1*, *cry35Ab1*, *cp4 epsps* and *pat* expression cassettes, thus, the effect of these expression cassettes and the expressed Cry1A105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins could be assessed in an unbiased manner. In addition, multiple conventional reference maize hybrids (references; four per site; a total of at least 25 different hybrids) were employed to provide a range of baseline values that are common to the existing commercial maize varieties for each measured phenotypic, agronomic, and ecological interaction characteristic.

Results of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 compared to the conventional maize counterpart. These results concur with those obtained previously for the parental lines MON 87427 and MON 89034 × 1507 × MON 88017 × 59122.

On the basis of the studies described above, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is equivalent to conventional maize in its phenotypic and agronomic behaviour, except for the herbicide tolerance and insect resistance traits.

No differences in the mode or rate of reproduction compared to the conventional counterpart have been observed in agronomic assessments conducted with MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize.

(b) **Dissemination**

No differences in the dissemination compared to the conventional counterpart have been observed in agronomic assessments conducted with MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize.

(c) **Survivability**

No differences in the survivability compared to the conventional counterpart have been observed in agronomic assessments conducted with MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize.

(d) **Other differences**

Except for the introduced traits that are of agronomic interest, the agronomic assessments in the field did not reveal any biologically significant differences between MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize and its conventional counterpart.

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**

There is negligible potential for recombination between genetic material inherited in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and environmental prokaryotic microorganisms due to limited bacterially derived sequence content, the sequence source and the organization of those bacterially derived sequences in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122.

Therefore, no changes are expected in the ability of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 to transfer genetic material to bacteria.

(b) **Plant to plant gene transfer**

Based on the observation that reproductive morphology in MON 87427, MON 89034 × 1507 × MON 88017 × 59122 and MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is unchanged compared to conventional maize, the outcrossing frequency to other maize varieties or to wild relatives (which are not present in the EU) would be unlikely to be different for MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 when compared to MON 87427 and MON 89034 × 1507 × MON 88017 × 59122, or when compared to other conventional maize varieties. Moreover, the scope of the current application does not include the cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize hybrids in the EU.

## 4. COMPARATIVE ANALYSIS

### 4.1. Choice of the conventional counterpart and additional comparators

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 was compared to a conventional maize variety with background genetics similar to MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, as well as with other commercially available maize hybrids.

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

Data were collected from eight sites within the U.S. in the 2010 season. MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, the conventional control and conventional commercial reference maize hybrids were evaluated at each site. The eight field sites provided a range of environmental and agronomic conditions representative of commercial maize production in the U.S.

At each field site, the test, the conventional counterpart and reference seed were planted in a randomized complete block design with four replicates per block. Field locations were acceptable environments for maize growth and are distributed across a wide geographical area to provide a variety of agronomic practices, soils and climatic factors. All the plants were grown under normal agronomic field conditions for their respective geographic regions.

An analysis of variance (ANOVA) was conducted in a combined-site analysis in which the data was pooled across all sites. ANOVA models were used to perform difference and equivalence tests according to the 2010 EFSA Scientific opinion<sup>2</sup> on statistical considerations for the safety evaluation of GMOs.

## **4.3. Selection of material and compounds for analysis**

The key nutrients and other nutritionally important components that were selected for analysis in the compositional study were chosen on the basis of internationally accepted guidance provided by the OECD on compositional considerations for maize.

## **4.4. Comparative analysis of agronomic and phenotypic characteristics**

An assessment of the phenotypic, agronomic and environmental interactions of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 compared to conventional maize has been performed in the field. It was guided by the OECD concept of familiarity by scientists who are familiar with the production and evaluation of maize.

Results of this field study showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 compared to the maize conventional counterpart.

## **4.5. Effect of processing**

With the exception of the lepidopteran and coleopteran (corn rootworm) protection traits and herbicide tolerance traits, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is not different from the conventional counterpart. Therefore, the processing of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is not expected to be any different from that of conventional maize.

# **5. TOXICOLOGY**

## **(a) Toxicological testing of newly expressed proteins**

The assessment of the potential toxicity of an introduced protein is based on comparing the biochemical characteristics of the introduced protein to characteristics of known toxins, based on the premise that a protein is not likely to have a toxic effect if:

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<sup>2</sup> <http://www.efsa.europa.eu/fr/efsajournal/pub/1250.htm> - Accessed on 31 October 2013.

- The protein has a demonstrated history of safe use;
- The protein has no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- The protein does not exert any acute toxic effects to mammals;
- If the protein is rapidly digested in mammalian gastrointestinal systems.

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is produced by conventional breeding of MON 87427 and MON 89034 × 1507 × MON 88017 × 59122. All the introduced traits from the parental lines are inherited by the MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 progeny resulting in the expression of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins in the same plant.

Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins have a demonstrated history of safe use, have no structural similarity to known toxins or other biologically active proteins, do not exert any acute toxic effects to mammals and are proven to be rapidly digested in mammalian gastrointestinal systems.

Moreover, all these proteins have been assessed by the EFSA on several occasions and deemed to be safe for humans and animals (EFSA, 2005<sup>3</sup>; 2008<sup>4</sup>; 2010<sup>5,6</sup>, 2011<sup>7</sup>, 2013<sup>8</sup>).

On the basis of knowledge concerning the molecular characteristics and biochemistry of these proteins, including their high degree of substrate specificity, it can be concluded that there are no potential interactions between these three traits and other plant constituents that would impact safety.

**(b) Testing of new constituents other than proteins**

Since maize is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world and as MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 was shown to be substantially equivalent to conventional maize, no testing of any constituent other than the introduced protein is warranted.

**(c) Information on natural food and feed constituents**

Maize is known as a common source of food and feed with a centuries-long history of safe use and consumption around the world. No particular natural constituents of maize are considered to be of significant concern to require additional information or further risk assessment.

**(d) Testing of the whole GM food/feed**

The compositional and nutritional equivalence of grain from MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and conventional maize have been established by compositional analysis. In addition, the transgenic proteins

<sup>3</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/181.htm> - Accessed on 31 October 2013.

<sup>4</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/909.htm> - Accessed on 31 October 2013.

<sup>5</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/1564.htm> - Accessed on 31 October 2013.

<sup>6</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/1781.htm> - Accessed on 31 October 2013.

<sup>7</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/2428.htm> - Accessed on 31 October 2013.

<sup>8</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/3135.htm> - Accessed on 31 October 2013.

produced in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize are digested rapidly, show a lack of acute toxicity and show no significant homology to known protein toxins. Also, the respective function and mode of action of these newly expressed proteins are known and there is no evidence of interaction of safety concern between the proteins expressed in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize. Based on this weight of evidence, no more data is required to demonstrate that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is as safe as conventional maize from a food and feed perspective.

## 6. ALLERGENICITY

### (a) Assessment of allergenicity of the newly expressed protein

A protein is not likely to be allergenic if: (1) the protein is from a non-allergenic source, (2) the protein represents only a very small portion of the total protein in the seed, (3) the protein does not share structural similarities with known allergens based on the amino acid sequence, and (4) the protein does not demonstrate resistance to digestion by pepsin or other digestive enzymes.

The lack of allergenic potential of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins expressed in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 has previously been established by the EFSA<sup>9,10,11,12,13,14</sup>.

Taken together, these data lead to the conclusion that the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins are unlikely to have any allergenic potential and MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is as safe as conventional maize with regards to allergenicity risk.

### (b) Assessment of allergenicity of the whole GM plant

Maize is not considered a common allergenic food. Food allergies to maize are rare, of low frequency and mainly occur in populations of specific geographic areas. Rare cases of occupational allergy to maize dust have been reported. There is no reason to expect that the use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 will significantly increase the intake and exposure to maize. Therefore a possible overexpression of any endogenous protein, which is not known to be allergenic, would be unlikely to alter the overall allergenicity of the whole plant or the allergy risk for consumers.

As MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is comparable and as safe as conventional maize, there is no reason to expect that the use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 will significantly increase the potential for allergenicity. Further, as the introduced proteins in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 do not have any allergenic potential, it was concluded that the use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 for food or feed does not lead to an increased risk for allergenic reactions compared to the equivalent range of food and feed uses of

<sup>9</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/909.htm> - Accessed on 12 November 2013.

<sup>10</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/181.htm> - Accessed on 12 November 2013.

<sup>11</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/1564.htm> - Accessed on 12 November 2013.

<sup>12</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/1781.htm> - Accessed on 12 November 2013.

<sup>13</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/2428.htm> - Accessed on 12 November 2013.

<sup>14</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/3135.htm> - Accessed on 12 November 2013.

conventional maize. Therefore, an assessment of the allergenicity of the whole MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 plant is not considered necessary.

## **7. NUTRITIONAL ASSESSMENT**

### **(a) Nutritional assessment of GM food**

The introduced traits in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 are of agronomic interest, and are not intended to change any nutritional aspect of this maize. The presence of these traits is not expected to alter patterns or volumes of maize consumption. Results of the extensive compositional analyses indicate that observed differences fell within the range of natural variability for maize with a history of safe usage, and the grain and forage composition of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is not different to the grain and forage composition of the conventional counterpart.

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 reveals comparable nutritional characteristics to the conventional counterpart maize, as well as to maize varieties in commerce. Hence this maize is not expected to be more or less attractive for use as food (or feed), for processing or as a food (or feed) ingredient. Therefore, anticipated dietary intake of maize-derived foods (and feeds) is not expected to be altered and no nutritional imbalances are expected as a result of the presence of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the maize supply.

### **(b) Nutritional assessment of GM feed**

*See Section 7 (a).*

## **8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE**

The exposure assessment in humans and animals indicates that there is minimal dietary exposure to Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins from consumption of foods and feed derived from MON 87427 × MON 89034 × 1507 × MON 88017 × 59122.

There are no anticipated changes in the intake and/or extent of use of maize or derived products for use as or in food or feed as a result of the addition of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 to the maize supply. MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is expected to replace a portion of current maize such that its intake or use will represent some fraction of the total products derived from maize.

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

Based on the information provided in this application, it can be concluded that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is as safe as conventional maize. The molecular characterization of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 did not raise any safety concern and did not show any evidence of unintended changes in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. Detailed compositional comparisons of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, its conventional counterpart and conventional commercial reference varieties demonstrated that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is

compositionally similar to the conventional maize counterpart and that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is not a contributor to compositional variability in maize. The assessed phenotypic and agronomic characteristics of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 were within the range expected for maize and did not show any phenotypic changes indicative of increased plant weed/pest potential of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 compared to conventional maize. An extensive characterisation of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins expressed in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 confirmed that the protein is safe for human and animal consumption. Additionally, the exposure assessment in humans and animals did not indicate any safety concerns.

In summary, there are no signs of adverse or unanticipated effects observed in a number of safety studies and the pre-market risk characterisation for food and feed use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. The consumption of food and feed derived from MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 plants is as safe as the consumption of its respective comparators. It can be concluded that the food derived from a MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 plant is not nutritionally disadvantageous for the consumer compared to the food which is intended to replace. Finally, it can be also concluded that the feed derived from a MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 plant does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed. Based on the molecular characterisation, expression of the inherited genes, outcomes of the comparative analysis of compositional, phenotypic and agronomic characteristics of maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, the known functional characteristics and modes of action of the newly expressed proteins, it is unlikely that the sub-combinations of its constituent single events have an adverse effect on human and animal health and the environment, in the context of their intended uses, which cover food and feed uses, import and processing

## **10. POST-MARKET MONITORING ON GM FOOD/FEED**

Based on the information provided in this application, it is reasonable to conclude that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is as safe as conventional maize. There are no intrinsic hazards related to MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 which would indicate that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is less safe than its conventional counterpart. The pre-market risk characterisation for food and feed use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 demonstrates that the risks of consumption of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 or its derived products are not different from the risks associated with the consumption of conventional maize or its derived products. As a consequence, specific risk management measures are not warranted and post-market monitoring of the use of this maize for food and feed is not considered necessary.

## 11. ENVIRONMENTAL ASSESSMENT

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

According to the EFSA ERA Guidance<sup>15</sup>, the primary focus for the assessment on target organisms is the development of resistance to the insect or pathogen tolerance traits expressed by the GM plant.

The scope of his application covers the import, processing and all uses as any other maize, but excludes the cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU. Hence, no deliberate release of viable plant material in the EU environment is expected and no target organisms are associated with this event. Therefore an assessment of the potential resistance development in target organisms resulting from import, processing and all uses as any other maize, but excluding the cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU is not relevant for this submission.

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

#### (a) Persistence and invasiveness including plant to plant gene flow

Results from the assessment support a conclusion that the abilities of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 to persist in agricultural fields or invade non-agricultural habitats, are comparable to those of conventional maize in the EU. Thus, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is not more likely to represent an agronomic problem in agricultural fields or become more invasive in natural habitats and no adverse effects on ecological functions within agricultural production fields or on biodiversity is expected as a result of the import, processing and all uses as any other maize. Given the negligible hazard and the low levels of environmental exposure that could arise from the import, processing and all uses as any other maize of this product and the fact that any exposure would be limited spatially and temporally, the uncertainties associated with this risk characterization and the probability of long-term adverse environmental effects are negligible.

#### (b) Selective advantage or disadvantage

It was previously demonstrated that the inherited genetic sequences in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 did not lead to any biologically meaningful alterations of the phenotypic characteristics, such as plant growth and development, morphology, agronomic performance, composition, nutritional value or safety characteristics, when compared to conventional maize. Therefore, it was concluded that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is not meaningfully different from conventional maize, with the exception of the intentionally introduced agronomically beneficial traits.

Compared with conventional maize, the introduced insect protection and herbicide tolerance traits in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 confer a selective advantage only under specific conditions (i.e. upon attack by the target insects or following treatment with glufosinate or glyphosate), which are short in duration. The advantage is of purely agronomic interest and presents negligible risk to the non-agricultural environments, because of the poor survival characteristics of maize under most European conditions.

<sup>15</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/1879.htm> - Accessed on 31 October 2013.

Therefore, the likelihood is negligible for the inherited traits in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

**(c) Potential for gene transfer**

The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 as any other maize in the EU, excluding cultivation. Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with the biotic environment will be limited. Given the low likelihood of occurrence of horizontal gene transfer and lack of adverse consequences if it were to occur, the import, processing and food and feed use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU is not likely to pose any risk to human and animal health or the environment.

Considering the low exposure and lack of hazard from horizontal gene transfer of the *cp4 epsps*, *cry1A.105*, *cry2Ab2*, *cry1F*, *cry3Bb1*, *cry34Ab1*, *cry35Ab1* and *pat* genes from MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 to micro-organisms, resulting from the import, processing and all uses of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, the risk that this would result in adverse effects on human or animal health or the environment is negligible.

**(d) Interactions between the GM plant and target organisms**

The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 as any other maize, but excludes the cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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 all uses as any other maize of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU is not relevant for this submission.

**(e) Interactions of the GM plant with non-target organisms (NTO's)**

The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 as any other maize, but excludes the cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with the biotic environment will be limited. Importantly, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins are heat inactivated during processing for feed and Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins can also be inactivated in the digestive tract of animals. Given the low levels of environmental exposure combined with low hazard from exposure of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 to NTOs, the likelihood of adverse effects from the import of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 to NTO communities that perform in-field ecological functions and NTO communities outside of the field from import of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, is negligible.

The conclusion from the risk characterization is that the probability that direct or indirect interactions between MON 87427 × MON 89034 × 1507 × MON 88017 ×

59122 and NTOs that could lead to direct or indirect, immediate or delayed environmental harm as a result of import, processing and use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU (excluding cultivation) is negligible.

**(f) Effects on human and animal health**

This application is for the import, processing and all uses as any other maize, but excludes the cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with humans and animal health will be limited to the occupational hazards associated with the cultivation, storage, handling and processing of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact with MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 grain, The likelihood for any adverse effects, occurring in humans and animals as a result of their contact with this maize, is no different from conventional maize. MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 contains the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT, which have negligible potential to cause any toxic or allergenic effects in humans and animals.

Therefore, the risk of changes in the occupational health aspects of this maize is negligible.

**(g) Effects on biogeochemical processes**

The scope of this application covers the import, processing and all uses of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU as any other maize (excluding the cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122). Therefore, no deliberate release of viable plant material in the EU environment is expected, and interactions of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with the biotic environment will be very limited. Importantly, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins are rapidly inactivated (either during processing for feed, or in the digestive tract of animals) thereby limiting any exposure via faeces of animals fed processed or unprocessed MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 grain. Given the low level of environmental exposure combined with a lack of hazard, the import, processing, and food and feed use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU is not likely to adversely impact soil micro-organisms that perform ecological functions in-field or in non-agricultural habitats and therefore poses negligible environmental risk.

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

Cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU is not included in the scope of this application. An assessment of the impacts of specific cultivation, management and harvesting techniques of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is therefore not relevant for this application.

### 11.3. Potential interactions with the abiotic environment

Although the MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 proteins are introduced in maize, they already have a safe history of use and they have no known negative interactions with the abiotic environment.

Overall results of the comparative analysis of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with respect to its conventional counterpart indicate that observed differences in composition and agronomic and phenotypic characteristics fell within the range of natural variability for maize with a history of safe usage. Therefore, there is no evidence that this maize would be any different from conventional maize with regard to its baseline interactions with the abiotic environment.

In addition, because this application is for import, processing and all uses as any other maize in the EU, interactions of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with the environment will be limited. Moreover, no negative impact of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 on the abiotic environment is expected to result from the import, processing and all uses as any other maize in the EU.

### 11.4. Risk characterisation for the environmental risk assessment

Results from the environmental risk assessment which takes into consideration the risk characterization and includes results described above addressing risk hypotheses for the specific areas of assessment laid down in the EFSA ERA guidance<sup>15</sup>, support a conclusion that the import, processing and all uses (excluding cultivation) of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 as any other maize, in the EU represents negligible risk to human and animal health and the environment and poses no greater risk than the import and processing of conventional maize. Based on the conclusions formulated for MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, there is no reason to expect that any other sub-combination of the single events would represent a risk to human and animal health or the environment.

## 12. ENVIRONMENTAL MONITORING PLAN

### (a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003 the proposed monitoring plan for MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The monitoring plan also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants<sup>16</sup>.

### (b) Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 for import, processing and the use of food and feed produced from MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the European Union under Regulation (EC) No. 1829/2003. The scope of the application does not include authorisation for the cultivation of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 seed products in the EU.

<sup>16</sup> [www.efsa.europa.eu/en/efsajournal/doc/2316.pdf](http://www.efsa.europa.eu/en/efsajournal/doc/2316.pdf) - Accessed June 2012.

An environmental risk assessment (ERA) was carried out for MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 according to the principles laid down in Annex II to Directive 2001/18/EC, the Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC and the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed<sup>17</sup>. The scientific evaluation of the characteristics of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the ERA (*see* Section E of Part II of this application) 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 MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 relative to:

- Persistence and invasiveness including plant to plant gene flow,
- Plant to micro-organisms gene transfer,
- Interactions between the GM plant and target organisms,
- Interactions of the GM plant with non-target organisms,
- Impacts of the specific cultivation, management and harvesting techniques,
- Effects on biochemical processes,
- Effects on human and animal health.

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

As discussed in Section E.4.2 of Part II of this application, the scientific evaluation of the characteristics of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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 MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. It is therefore considered that there is no need for case-specific monitoring.

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

Any potential adverse effects of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 on human health and the environment, which were not anticipated in the ERA, can be addressed under the general surveillance. General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified crop in its receiving environment.

In order to allow detection of the broadest possible scope of unanticipated adverse effects, general surveillance is performed by either selected existing networks, by specific company stewardship programmes or by a combination of both. The consent holder will ensure that appropriate technical information on MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and relevant legislation will be available for the relevant networks, in addition to further relevant information from a number of sources, including industry and government websites, official registers and government publications.

Following the approval of this maize in the EU, the consent holder will approach key stakeholders and key networks of stakeholders of the product (including international

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<sup>17</sup> [www.efsa.europa.eu/en/scdocs/doc/1879.pdf](http://www.efsa.europa.eu/en/scdocs/doc/1879.pdf) -Accessed 31 October 2013

grain traders, maize processors and users of maize seed for animal feed) and inform them that the product has been authorised. The consent holder will request key stakeholders and networks for their participation in the general surveillance of the placing on the market of this maize, in accordance with the provisions of Directive 2001/18/EC and the consent. Key stakeholders and networks will be requested to be aware of their use of this maize and to inform the consent holder in case of potential occurrence of any unanticipated adverse effects to animal or human health or the environment, which they might attribute to the import or use of this product. Appropriate technical information on MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 will be provided to them.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, further evaluation of the consequence of that effect should be science-based and compared with available baseline information. Relevant baseline information will reflect prevalent use practices and the associated impact of these practices on the environment. Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

**(e) Reporting the results of monitoring**

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

If information that confirms an adverse effect of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorisation holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on any unanticipated adverse effects that have arisen from handling and use of viable MON 87427 × MON 89034 × 1507 × MON 88017 × 59122.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation 1829/2003.

### **13. DETECTION AND EVENT-SPECIFIC IDENTIFICATION TECHNIQUES FOR THE GM PLANT**

As MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 was produced by crossing plants containing MON 87427 and MON 89034 x 1507 x MON 88017 x 59122 using conventional breeding methods, it contains inserts in combination. Therefore, MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 is detectable using the combination of the individual event detection methods. For all plants in which two or more events are combined by conventional breeding, the events involved will segregate in the grain; therefore such detection methods when applied to individual grains from MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 will detect any combination of the four events.

A MON 87427-specific PCR-based assay allowing the identification and quantification of MON 87427 has been provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EURL). The detection method for MON 89034, 1507, MON 88017 and 59122 have already been validated by the European Union Reference Laboratory (EU-RL).

### **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**

(a) **Notification number**

There is no history of field release of MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 in EU.

(b) **Conclusions of post-release monitoring**

Not applicable

(c) **Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)**

Not applicable

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

(a) **Release country**

MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 has been field tested in the U.S. (2010), and Argentina (2008, 2012 and 2013).

(b) **Authority overseeing the release**

US and Puerto Rico: United States Department of Agriculture (USDA)

Argentina: Secretary of Agriculture, Livestock, Fisheries, and Food (SAGPyA)

(c) **Release site**

US: in multiple major maize growing states and Puerto Rico

Argentina: in multiple sites in major maize growing areas

- (d) **Aim of the release**  
US/Argentina: Regulatory trials, efficacy, yield, product development, and demonstration.
- (e) **Duration of the release**  
US / Argentina: One growing season.
- (f) **Aim of post-releases monitoring**  
US /Argentina: Assessment of volunteers.
- (g) **Duration of post-releases monitoring**  
US / Argentina: 12 months.
- (h) **Conclusions of post-release monitoring**  
In general, no volunteers have been observed since maize is an annual crop. 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**  
Field-testing provided no evidence that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 would be the cause of any adverse effects to human health or to the environment.

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