Application for authorisation in the European Union of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain and sub-combinations independently of their origin for all uses as for any other maize, excluding cultivation, according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-NL-2017-145

Part VII

Summary

Part VII - Summary

1. GENERAL INFORMATION

1.1 Details of application

a)	**Member State of application** The Netherlands.
b)	**Application number** EFSA-GMO-NL-2017-XX.
c)	**Name of the product (commercial and other names)** The development code for this genetically modified maize is: MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9. In countries where MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 will be cultivated, packages of this maize will be marketed under the name of the variety, in association with the trademark (to be defined).
d)	**Date of acknowledgement of valid application** By EFSA: XXth XXXX 20XX.

1.2 Applicant

a)	**Name of applicant** Dow AgroSciences LLC represented by Dow AgroSciences Europe.
b)	**Address of applicant** Focal Point: Dow AgroSciences Europe European Development Centre 2nd Floor, 3B Park Square Milton Park, Abingdon Oxon OX14 4RN Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, Indiana 46268-1054
c)	**Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)** Dow AgroSciences Europe European Development Centre 2nd Floor, 3B Park Square Milton Park, Abingdon Oxon OX14 4RN

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 or containing ingredients produced from GM plants

c) GM plants for food or feed use

☒ Products other than food and feed containing of consisting of GM plants with the exception of cultivation
☐ Seeds and plant propagating material for cultivation in the EU

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?

Yes ☐	**No** ☒
If *yes*, specify	

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

Yes ☐	**No** ☒

If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC

The composition, expression, agronomic performance and environmental impact trials with MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize have been performed at several locations in the US, in 2012, where maize is commercially grown in order to gather data for the risk assessment.

A summary of the conclusions of the risk analysis that demonstrate the safety of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize 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?

Yes ☐	**No** ☒
If *yes*, specify	

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

Yes ☒	**No** ☐

If *yes*, specify the third country and provide a copy of the risk assessment conclusions, the date of the authorisation and the scope

Notification of intent to commercialize MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 has been sent to the US, Colombia, Mexico, Korea, Taiwan. Additional applications for food and feed use are being prepared for, South Africa and Philippines, and will be submitted throughout 2017.

1.8 General description of the product

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

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 was produced by crossing plants containing MON87427, MON89034, 1507, MON87411, 59122 and DAS-40278-9 using conventional breeding methods.

Expression of the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins confer resistance against certain insect pests and tolerance to application of 2,4-D, glufosinate-ammonium and glyphosate herbicides, respectively.

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 this application according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed includes all uses of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain equivalent to the uses of any other maize grain.

c) Intended use of the product and types of users

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain will be traded and used in the E.U. in the same manner as current commercial maize varieties and by the same operators currently involved in the trade and use of conventional maize.

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

No specific conditions or instructions are warranted or required for the placing on the market of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain, for all uses as any other maize grain. MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is substantially equivalent to other maize varieties except for its resistance against certain insect pests and tolerance to application of 2,4-D, glufosinate,-ammonium and glyphosate herbicides, which are traits of agronomic interest. MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 was shown to be as safe and as nutritious as conventional maize. Therefore MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 and derived products will be stored, packaged, transported, handled and used in the same manner as the

commercial maize products.

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

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain, are suitable for import, processing and food and feed uses throughout the E.U.

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

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain, are suitable for import, processing and food and feed uses throughout the E.U.

g) Any proposed packaging requirements

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is substantially equivalent to conventional maize varieties (except for its resistance against certain insect pests and tolerance to application of 2,4-D, glufosinate-ammonium and glyphosate herbicides). Therefore, MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 and derived products will be used in the same manner as other maize and no specific packaging is foreseen.

h) Any proposed labelling requirements in addition to those required by other applicable EU legislation than Regulation (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Articles 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003

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 MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 grain and derived products.

Operators shall be required to label products containing or consisting of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain 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 MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain 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 MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain and derived foods and feeds in the E.U. are 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 Community Register, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain. Therefore, no further specific measures are to be taken by the applicant for MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain.

i)	**Estimated potential demand** **(i) In the EU** Comparable to that of conventional maize. **(ii) In EU export markets** Not applicable.
j)	**Unique identifier in accordance with Regulation (EC) No 65/2004** MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9.

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 and use MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain, as any other maize, not including the cultivation of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 varieties, environmental release would be more likely to occur during import, storage and processing of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain. However, modern methods of grain handling minimise losses of grain, so there is little chance of germination of spilt grain resulting in the development of mature plants of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 in the E.U. 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. Moreover, the information presented in this application established that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is unlikely to be different from other maize and, therefore, is unlikely to pose any threat to the environment or to require special measures for its containment.

No specific conditions are warranted or required for the placing on the market of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain, for import, processing, or use for food and feed.

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

2.1. Complete name

a)	**Family name** Poaceae (formerly Gramineae).
b)	**Genus** *Zea.*
c)	**Species** *mays* (2n=20).
d)	**Subspecies** N/A.
e)	**Cultivar/breeding line or strain** MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9.
f)	**Common name** Maize, Corn.

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

Because of its many divergent types, maize is grown over a wide range of climatic conditions. 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. There are no wild relatives of maize in Europe.

2.3 Information concerning reproduction

a)	**Mode(s) of reproduction** Maize (Zea mays) is an annual, wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers, self- and cross-pollination are generally possible, with frequencies of each normally determined by proximity and other physical influences on pollen transfer.
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.

c) Generation time

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

2.4 Sexual compatibility with other cultivated or wild plant species

Out-crossing with cultivated *Zea* varieties

The scope of the current application does not include cultivation of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 hybrids in the E.U. Outcrossing with cultivated *Zea* varieties is therefore not expected.

Out-crossing with wild *Zea* species

Wild relatives of maize do not exist 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 dispersal 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. However, the current application does not include the environmental release in the E.U.

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.

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

Not Applicable.

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

Maize is widely grown in the E.U. and represents a significant portion of global maize production. The most important 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.

2.9 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)

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. However, 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.

3. MOLECULAR CHARACTERISATION

3.1 Information relating to the genetic modification

a) Description of the methods used for the genetic modification

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 was produced by crossing plants containing MON87427, MON89034, 1507, MON87411, 59122 and DAS-40278-9 using conventional breeding methods.

b) Nature and source of the vector used

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 has been obtained by conventional breeding of MON87427, MON89034, 1507, MON87411, 59122 and DAS-40278-9 and no vector has been used to produce this maize stack.

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

By crossing MON87427, MON89034, 1507, MON87411, 59122 and DAS-40278-9, by conventional breeding, MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 inherits the inserted DNA from each parental maize lines.

The individual components and the function of these inherited DNA sequences are given in Tables 1 - 6.

Table 1 Source of donor DNA used for transformation of MON87427, size and intended function of each constituent fragment of the region intended for insertion

Genetic Element	Size(~kb)	Source	Function
B[1]-Left Border	0.44	*Agrobacterium tumefaciens*	DNA region from the B-left Border region remaining after integration.
P2 -e35S	0.62	Cauliflower mosaic virus	Promoter
I3 -hsp70	0.8	*Zea mays*	First intron
TS4 -CTP2	0.22	*Arabidopsis thaliana*	Chloroplast transit peptide (CTP)
CS5 -cp4 epsps	1.36	*Agrobacterium sp.*	Gene encoding the CP4 EPSPS protein.
T6 -nos	0.25	*Agrobacterium tumefaciens*	Terminator
B-Right Border Region	0.35	*Agrobacterium tumefaciens*	Right Border sequence used for transfer of the T-DNA.

Table 2 Source of donor DNA used for transformation of MON89034, size and intended function of each constituent fragment of the region intended for insertion

Genetic element	Size (kb)	Source	Function
B-Left Border^{r1}	0.24	*Agrobacterium tumefaciens*	Portion of the border region remaining after integration
P-*e35S^{89}*	0.30	Cauliflower mosaic virus	Promoter
L-*Cab*	0.06	*Triticum sp*	Leader
I-*Ract1*	0.48	*Oryza sativa*	Intron
CS-*cry1A.105*	3.53	*Bacillus thuringiensis*	Coding sequence
T-*Hsp17*	0.21	*Triticum sp*	Transcript termination sequence
P-*FMV*	0.56	Figwort mosaic virus	Promoter
I-*Hsp70*	0.80	*Zea mays*	Intron
TS-*SSU-CTP*	0.40	*Zea mays*	Targeting sequence
CS-*cry2Ab2*	1.91	*Bacillus thuringiensis*	Coding sequence
T-*nos*	0.25	*Agrobacterium tumefaciens*	Transcript termination sequence
B-Left Border ^{r2}	0.23	*Agrobacterium tumefaciens*	Portion of the border region remaining after integration

Table 3 Source of donor DNA used for transformation of 1507, size and intended function of each constituent fragment of the region intended for insertion

Genetic element	Size (kb)	Source	Function
***ubi*ZM1 PRO**	1.98	Maize	Promotor
***cry*1F**	1.82	*Bacillus thuringiensis* sbsp. *aizawai*	Coding sequence
ORF25PolyA	0.72	*Agrobacterium tumefaciens*	Transcript termination sequence
35S PRO	0.55	Cauliflower mosaic virus	Promotor
pat	0.55	*Streptomyces viridochromogenes*	Coding sequence
35S TERM	0.20	Cauliflower mosaic virus	Transcript termination sequence

Table 4 Source of donor DNA used for transformation of MON87411, size and intended function of each constituent fragment of the region intended for insertion

Genetic Element	Size(~kb)	Source	Function Reference
B1 -Left Border Region	400	*Agrobacterium tumefaciens*	Left border sequence used for transfer of the T-DNA.
T2 -E9	600	*Pisum sativum*	Promoter
DvSnf7p	200	*Diabrotica virgifera virgifera*	Partial coding sequence of the Snf7 gene
DvSnf7p	200	*Diabrotica virgifera virgifera*	Partial coding sequence of the Snf7 gene
I3 -Hsp70	900	*Zea mays*	Intron and flanking exon sequence
P4 -e35S	600	Cauliflower mosaic virus	Promoter.
P-pIIG	900	*Zea mays*.	Promoter
L5 -Cab	100	*Triticum aestivum*	5' UTR leader
I-Ract1	500	*Oryza sativa*	Intron and flanking UTR sequence
CS6 -cry3Bb1	2000	*Bacillus thuringiensis*.	Codon optimized coding sequence from Cry3Bb1 protein.
T-Hsp17	200	*Triticum aestivum*.	3' UTR sequence.
P-TubA	2200	*Oryza sativa*	Promoter.
TS7 -CTP2	200	*Arabidopsis thaliana*	Targeting sequence of the ShkG gene.
CS-cp4 epsps	1300	*Agrobacterium* sp.	Coding sequence of the aroA gene.
T-TubA	600	*Oryza sativa*	3' UTR sequence.
B-Right Border Region	300	*Agrobacterium tumefaciens*	Right border sequence used for transfer of the T-DNA.

Table 5 Source of donor DNA used for transformation of 59122, size and intended function of each constituent fragment of the region intended for insertion

Genetic element	Size (~kb)	Source	Function
RB	0.177	*Agrobacterium tumefaciens*	Right T-DNA border region
*Ubi*1ZM	1.993	*Zea mays*	Promoter
*cry*34Ab1	0.372	*Bacillus thuringiensis*	*Cry*34Ab1 gene
PINII	0.315	*Solanum tuberosum*	Terminator
TA peroxidase	1.298	*Triticum aestivum*	Promoter
*cry*35Ab1	1.152	*Bacillus thuringiensis*	*cry*35Ab1 gene
PINII	315	*Solanum tuberosum*	Terminator
CaMV 35S	530	Cauliflower Mosaic Virus	Promoter
Pat	552	*Streptomyces viridochromogenes*	Plant-optimised phosphinothricin acetyltransferase
CaMV 35S	194	35S terminator from Cauliflower Mosaic Virus.	Terminator
LB	82	*Agrobacterium tumefaciens*	Left T-DNA border

able 6 Source of donor DNA used for transformation of DAS-40278-9, size and intended function of each constituent fragment of the region intended for insertion

Genetic Element	Size (base pairs)	Source	Description
Intervening sequence	164 bp	-	Sequence used for DNA cloning
RB7 MAR v3	1166 bp	*Nicotiana tobacum*	Matrix attachment region (MAR)
Intervening sequence	129 bp	-	Sequence used for DNA cloning
ZmUbi1 promoter	1991 bp	*Zea mays*	Ubiquitin promoter
Intervening sequence	22 bp	-	Sequences used for DNA cloning
aad-1	891 bp	*Sphingobium herbicidovorans*	Synthetic, plant-optimized version of an aryloxyalkanoate dioxygenase gene
Intervening sequence	34 bp	-	Sequence used for DNA cloning
ZmPer5 3' UTR	365 bp	*Zea mays*	Terminator
Intervening sequence	39 bp	-	Sequence used for DNA cloning
RB7 MAR v4	1166 bp	*Nicotiana tobacum*	Matrix attachment region (MAR)
Intervening sequence	269 bp	-	Sequence used for DNA cloning

3.2 Information relating to the GM plant

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

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize expresses the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins, derived from *Bacillus thuringiensis, Diabrotica virgifera virgifera, Delftia acidovorans*, *Streptomyces viridochromogenes* and *Agrobacterium tumefasciens*, providing tolerance to application of 2,4-D, glufosinate-ammonium and glyphosate herbicides, respectively.

Commercialisation of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 will therefore provide substantial benefits to growers by limiting yield losses from insect pests and weed pressure.

3.2.2 . Information on the nucleic acid(s) sequences actually inserted or deleted

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

MON87427, MON89034, 1507, MON87411, 59122 and DAS-40278-9 each contain a single DNA insert with a single functional copy of the introduced DNA fragment.

The genome of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 contains the inserts, one derived from each single line. The presence of these inserts in the hybrid was confirmed through Southern blot analysis.

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

Not applicable.

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

The conventionally bred MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 contains the single product inserts in the nuclear genome, as they were present in the single products MON87427, MON89034, 1507, MON87411, 59122 and DAS-40278-9, respectively.

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

Since the inserts present in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 correspond to those of the parental lines, the characteristics of the insertions and the 5' and 3' flanking sequences are likely to have been 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 levels of the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins in various tissues of MON87427

x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 were assessed by validated enzyme-linked immunosorbent assays (ELISA).

Tissue samples for analysis were collected from eight test sites during field trials conducted in the U.S.A. in 2015. The locations of these trials represent the major maize producing regions of the U.S.A. and provide a variety of environmental conditions.

The data show that the levels of cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins in grain of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 are comparable to protein levels in the positive controls substances, MON87427, MON89034, 1507, MON87411, 59122 and DAS-40278-9, as appropriate.

b) Parts of the plant where the insert is expressed

Results of the analyses confirm expression of cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins throughout key development stages of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9. Expression levels in grain are most relevant for food and feed safety evaluation.

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

Based on the molecular characterisation of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9, it is highly likely that the insert sequences of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 are conserved with their inherent properties.

3.2.5 Information on how the GM plant differs from the recipient plant in

a) Mode(s) and/or rate of reproduction

Agronomic data collected from trials performed with MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 have demonstrated that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 has not been altered in survival, multiplication or dissemination characteristics when compared to conventional maize varieties. The trait for herbicide tolerance has no influence on maize reproductive morphology and hence no changes in seed dissemination would be expected.

b) Dissemination

The inherited traits have no influence on maize reproductive morphology and hence no changes in seed dissemination are to be expected.

c) Survivability

Maize is known to be a weak competitor in the wild, which cannot survive outside cultivation without human intervention. Field observations have demonstrated that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 has not been altered in its survivability when compared to conventional maize.

d) Other differences

Comparative assessments in the field did not reveal any biologically significant differences between MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 and conventional maize varieties, except for the introduced trait that is of agronomic interest.

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** None of the genetic elements inserted in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 have a genetic transfer function. Therefore, no changes are expected in the ability of these maize lines to transfer genetic material to bacteria.
b)	**Plant to plant gene transfer** There is a negligible probability for plant to plant gene transfer as the scope of the current application does not include the cultivation of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 varieties in the E.U.

4 COMPARATIVE ANALYSIS

4.1 Choice of the conventional counterpart and additional comparators

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 was compared with a conventional control maize with similar genetic background, as well as with other commercially available maize varieties.

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

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 and the conventional control maize were grown at nine field sites in major maize-growing areas of the U.S.A. during the 2012 field season.

The compositional study compared MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 to the non-transgenic near-isogenic control maize Maverick. Reference lines were grown in the same field locations and under the same conditions as the test and control. Where statistical differences occurred, the measured analyte was compared to reference ranges.

4.3 Selection of material and compounds for analysis

The numerous compounds that were selected for analysis in the compositional study were chosen on the basis of internationally accepted guidance provided by the OECD (*See* consensus document for compositional analysis of maize), in addition to other selected compounds.

Based on the positive results of these extensive, compositional analyses conducted for MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 compared to conventional maize varieties, there is no indication to further analyse other selected compounds in this maize.

4.4 Comparative analysis of agronomic and phenotypic characteristics

Field trials with MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 were performed and the set of agronomic observations supports a conclusion that from an agronomic and phenotypic (morphological) point of view, MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is equivalent to conventional maize, except for the resistance against certain insect pests and tolerance to application of 2,4-D, glufosinate,-ammonium and glyphosate herbicides.

4.5 Effect of processing

Maize is converted into a diverse range of food and feed products and derivatives used as food and feed ingredients or additives. As MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is substantially equivalent and as safe and as nutritious as conventional maize, the use of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain for the production of foods and feeds is no different from that of conventional maize. Consequently, any effects of the production and processing of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain are not expected to be any different from the production and processing of the equivalent foods and feeds, originating from conventional maize.

5 TOXICOLOGY

a) Toxicological testing of newly expressed proteins

With respect to the DvSnf7 suppression cassette, there is no evidence to suggest dietary consumption of RNA is associated with mammalian toxicity or allergenicity. Based on the ubiquitous nature of the RNA-based suppression mechanism utilizing dsRNA, the history of safe consumption of RNA and the apparent lack of proteins produced from the DvSnf7 suppression cassette, the RNA-based suppression technology used in MON 87411 poses no novel risks from a food or feed perspective. Therefore, the safety assessment of the newly expressed proteins is focused on the newly expressed proteins. MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 expresses the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins. The conclusion of safety to humans of these proteins was based upon the following considerations:

- The proteins have a history of safe use;
- They have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- They do not exert any acute toxicity to mammals.

In addition, their low concentration in tissues that are consumed and their rapid digestibility in simulated digestive fluids provide additional assurance for their safety.

It is therefore highly unlikely that the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins would cause any toxic effects on human or animal health.

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 MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 was shown to be substantially equivalent to conventional maize, no testing of any constituent other than the inherited proteins are indicated.

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

Evaluation of the nutrient composition of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize proved its equivalency to non-GM control maize with comparable genetic background and to representative commercial lines. In addition it's been shown that the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins expressed in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize are safe for humans, animal health and the environment. On that basis, no additional studies are required.

6. ALLERGENICITY

a) Assessment of allergenicity of the newly expressed protein

With respect to the DvSnf7 suppression cassette, there is no evidence to suggest dietary consumption of RNA is associated with mammalian toxicity or allergenicity. Based on the ubiquitous nature of the RNA-based suppression mechanism utilizing dsRNA, the history of safe consumption of RNA and the apparent lack of proteins produced from the DvSnf7 suppression cassette, the RNA-based suppression technology used in MON 87411 poses no novel risks from a food or feed perspective. Therefore, the safety assessment of the newly expressed proteins is focused on the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, cp4-epsps, pat, and aad-1 genes proteins have been assessed for their potential allergenicity according to the recommendations of Codex Alimentarius Commission. The proteins are from non-allergenic sources, lack structural similarity to known allergens, are rapidly digested in simulated gastric fluid, constitute a very small portion of the total protein present in the grain of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9. Taken together, these data lead to the conclusion that the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, cp4-epsps, pat, and aad-1 genes proteins are unlikely to have any allergenic potential; hence, MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is as safe as conventional maize regarding the risk for allergenicity.

b) Assessment of allergenicity of the whole GM plant

Compositional analyses, comparative phenotypic assessments and animal feeding studies have demonstrated that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is substantially equivalent to traditional maize, with the exception of the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, cp4-epsps, pat, and aad-1 genes proteins (which are unlikely to have any allergenic potential). Moreover, the whole food derived from MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 shows no potential change in the overall allergenicity when compared to a nontransgenic control.

7. NUTRITIONAL ASSESSMENT

a) Nutritional assessment of GM food

The introduced traits in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 are of agronomic interest, and are not intended to change any nutritional aspects of this maize. 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 upon commercialisation of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain, and no nutritional imbalances are expected as a result of the use of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain.

b) Nutritional assessment of GM feed

As discussed throughout this application, animal feed products from MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize are substantially equivalent to, nutritionally equivalent to, and as safe as feed derived from commercial maize.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

There are no anticipated changes in the intake and/or extent of use of maize or derived products for use as such or in food or feed as a result of the addition of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain to the conventional maize supply. MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain is expected to replace a portion of current maize varieties such that their intake or use will represent some fraction of the total products derived from maize.

9. RISK CHARACTERISATION

Assessments show that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 demonstrates agronomic, phenotypic and compositional equivalence to non-transgenic maize. It has also been established that it is highly unlikely that cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 proteins will be toxic or allergenic making it negligible that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 will cause adverse effects in humans or animals.

10. POST-MARKET MONITORING ON GM FOOD OR FEED

The assessment of the human and animal safety of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 was conducted on the basis of its substantial equivalence to conventional maize (except for the introduced traits) and by extensive characterisation of the introduced traits, which are of agronomic interest, resulting in the expression of the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 proteins.

The pre-market risk characterisation for food and feed use of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 demonstrates that the risks of consumption of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 or its derived products are consistently negligible and no different from the risks associated with the consumption of conventional maize and maize-derived products.

As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of this maize for food, feed or processing is neither warranted, nor appropriate.

11. ENVIRONMENTAL ASSESSMENT

11.1 Mechanism of interaction between the GM plant and target organisms

Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, cry35Ab1, proteins produced in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 provide protection against pests. Those insects may be considered the target organisms which interact with MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9. The AAD-1, PAT and CP4-EPSPS proteins (conferring tolerance to application of 2,4-D, glufosinate-ammonium and glyphosate herbicides), also present in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9, do not have target organisms.

A generalized mode of action of Cry proteins includes the following steps: ingestion of the protoxin by the insect, solubilization of the crystal in the insect midgut, proteolytic processing of the released Cry protein by digestive enzymes to produce an active toxin termed delta-endotoxin, binding of the endotoxin to receptors on the surface of midgut epithelial cells of target organisms, formation of membrane ion channels or pores, and consequent disruption of cellular homeostasis. Electrolyte imbalance and pH changes render the gut paralyzed, which causes the insect to stop eating and die.

Partial coding sequence of the Snf7 gene designed to match that from *Diabrotica virgifera virgifera* encoding the SNF7 subunit of the ESCRT-III complex that forms part of the suppression cassette.

Any significant interactions of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 with its target pest organisms are, however, limited to those countries where the cultivation of this maize will be authorised. The cultivation of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 in the E.U. are not within the scope of this application. The likelihood that the import and use of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 grain for food, feed or processing will result in plants of these maize lines being present in the environment is negligible.

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

a) Persistence and invasiveness

Like for conventional maize, the likelihood of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 spreading in the environment is negligible, as maize is neither persistent nor invasive and these parameters are unaltered in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 when compared to conventional maize. In the unlikely event of the establishment of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 plants in the environment, the introduced traits would confer only a limited selective advantage of: resistance against certain insect pests and tolerance to application of 2,4-D, glufosinate-ammonium and glyphosate herbicides of short duration, narrow spatial context and with negligible consequences for the environment. Hence, the risk of establishment and spreading of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain into the environment is negligible.

b) Selective advantage or disadvantage

Compared with conventional maize, the presence of the introduced traits in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 would only confer a

meaningful advantage under specific conditions, i.e. high insect pressure or where plants would be treated with 2,4-D, glufosinate-ammonium and glyphosate herbicides; if no other more important factors limiting its survival in the environment were present. This introduced "advantage" is only relevant in agricultural habitats (i.e. in maize fields) and is short in duration. The risk of 2,4-D, glufosinate-ammonium and glyphosate tolerance traits in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 to be the cause of any adverse effects resulting from a competitive advantage or disadvantage is negligible, as maize is unlikely to establish outside cultivation under European conditions (see Section E.3.1). When viewed in the context of today's baseline agronomic practices for the production of maize, these advantages present negligible risk to the agricultural environment.

c) Potential for gene transfer

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is unchanged in its potential for gene transfer compared to conventional maize. There is no potential for gene transfer from MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 to wild plant species in the E.U. and negligible likelihood for gene transfer to other maize crops, as this application is not for consent to cultivate MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 varieties in the E.U. The environmental risk of potential gene transfer is negligible. Further to this searches against microbial databases indicate it is highly unlikely a Homologous Recombination event can happen between MON87427, MON89034, 1507, MON87411, 59122 and DAS-40278-9 sequences, and any sequence present in the bacteria, plasmid and virus sequence databases, meaning the potential for horizontal gene transfer is negligible.

d) Interactions between the GM plant and target organisms

Since the likelihood is negligible that the import, processing and food and feed use of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 will result in plants of this maize being present in the environment at meaningful levels, it is not expected that organisms will be exposed to the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7 proteins.

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

Given the scope of the current application, which does not include the cultivation of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 varieties in the E.U., the likelihood for direct or indirect interactions of these maize lines with non-target organisms is considered to be negligible. In addition, the newly expressed proteins present a negligible hazard to non-target organisms, even if incidental spillage of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 grain during import, storage, transport or use would lead to the short survival of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 plants in the environment. As a consequence, there is negligible risk for harmful effects of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 on non-target organisms, either through direct or indirect interactions with this maize or through contact with the newly expressed protein.

Furthermore, no adverse effects were brought forward by the people handling these products during the field trials conducted in the U.S.A.

f) Effects on human health

The likelihood for any adverse effects occurring in humans as a result of their contact with this maize is no different from conventional maize. MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 expresses the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins, which have negligible potential to cause any toxic or allergenic effects in humans. Therefore, the risk of

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

g) Effects on animal health

The likelihood of potential adverse effects in animals fed on MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 and in humans, consuming those animals, is negligible. Therefore, the risk of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 for the feed/food chain is also negligible.

h) Effects on biogeochemical processes

There is no evidence that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 plants would be any different from conventional maize regarding their direct influence on biogeochemical processes or nutrient levels in the soil, as MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is compositionally equivalent and has equivalent growth and development as conventional maize.

i) Impacts of the specific cultivation, management and harvesting techniques

Not applicable. This application is for consent to import MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain in the E.U. and for the use of these maize lines as any other maize, excluding the cultivation of varieties in the E.U.

11.3 Potential interactions with the abiotic environment

No adverse impact of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 on the abiotic environment is expected to result from the import, processing or use of this product for food and feed in the E.U. Although the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins are introduced proteins in maize, they already have a safe history and have no known negative interactions with the abiotic environment. The *Bacillus huringiensis, Delftia acidovorans, Streptomyces viridochromogenes* and *Zea mais*. 2mfrom which the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins are derived are widespread in nature and found all over the world. The cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins are innocuous and are ubiquitous in nature. The families of the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins have no known negative interactions with the abiotic environment.

11.4 Risk characterisation for the environmental risk assessment

Considering the scope of this application is for import for food and feed uses of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 and that cultivation of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize varieties in the EU is not planned; any exposure to the environment from the import of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize will be limited to unintended release via spillage during transportation of the grain. There are no target organisms for the cry1A.105, cry2Ab2, cry1F, cry3Bb1, cry34Ab1, cry35Ab1, DvSnf7, cp4-epsps, pat, and aad-1 genes proteins expressed in MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9, which confers tolerance to certain herbicides.

Therefore, the likelihood that the import and use of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 for food, feed or processing will result in plants of this maize being present in the environment is negligible.

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 MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 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 structure of the monitoring plan also takes into account the guidance on presentation of applications provided in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed.

b) Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) was carried out for MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 in the e.r.a. (Section E.3) 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 MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain.

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

The scientific evaluation of the characteristics of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 in the e.r.a. 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. 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)

In accordance with Council Decision 2002/811/EC, 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 e.r.a.

The authorisation holders are not involved in commodity trade with MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain. The monitoring methodology hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain. They are exposed to the imported viable MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use.

The general surveillance information reported to and collected by the authorisation holders from the European trade associations or other sources will be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder will immediately investigate to determine and confirm whether a significant correlation between the effect and MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain can be

established. If the investigation establishes that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain was present when the adverse effect was identified, and confirms that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize grain is the cause of the adverse effect, the authorisation holders will immediately inform the European Commission, as described in Section E.4.3.4.

e) Reporting the results of the monitoring

The authorisation holders will submit an annual monitoring report containing information obtained from participating networks, and/or in case of an effect that was confirmed. If information that confirms an adverse effect which alters the existing risk assessment becomes available, Dow AgroSciences LLC will submit a report, consisting of a scientific evaluation of the potential adverse effect and a conclusion on the safety of the product. The report will also include, where appropriate, the measures that were taken to ensure the safety of human or livestock health and/or the environment.

13. DETECTION AND IDENTIFICATION TECHNIQUES FOR THE GM PLANT

The PCR detection methods to confirm the molecular identity of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize along with complementary information and samples of MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 maize and non-GM maize that have been provided to the JRC-IHCP (Joint Research Centre-Institute of Health and Consumer Protection).

The Institute for Reference Materials and Measurements (IRMM) has collaborated with Dow AgroSciences, to develop certified reference materials for MON87427, MON89034, 1507, MON87411, 59122 and DAS-40278-9 maizes. The sales conditions of certified reference materials for DAS-68416-4 are available from the IRMM website (http://irmm.jrc.ec.europa.eu/html/homepage.htm). Detailed information on these materials is given in the IRMM reports and sample certificates, posted on the corresponding websites.

14 INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT (FOR ERA 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

None.

b) Conclusions of post-release monitoring

N/A.

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)

N/A.

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

a) Release country

MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 has been field tested in the U.S.A. in 2016 and 2016.

b) Authority overseeing the release

U.S.A: United States Department of Agriculture (USDA).

c) Release site

U.S.A.: Multiple sites in maize producing states of the U.S.A.

d)	**Aim of the release** U.S.A.: assess performance, efficacy, variety evaluation, seed production, yield, and collection of regulatory data. Argentina: Assess performance, efficacy, yield, and collection of regulatory data.
e)	**Duration of the release** 12 months per release.
f)	**Aim of post-releases monitoring** Assessment/removal of volunteers.
g)	**Duration of post-releases monitoring** 12 months per release.
h)	**Conclusions of post-release monitoring** Volunteers have been eliminated to prevent potential persistence in the environment.
i)	**Results of the release in respect to any risk to human health and the environment** No evidence that MON87427 x MON89034 x 1507 x MON87411 x 59122 x DAS-40278-9 is likely to cause any adverse effects to human or animal health or the environment.