Application for authorisation in the European Union of MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain 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-2012-XX

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** The Netherlands
b)	**Application number** EFSA-GMO-NL-2012-XX
c)	**Name of the product (commercial and other names)** The development code for this genetically modified maize is: MON 89034 × 1507 × NK603 × DAS-40278-9. In countries where MON 89034 × 1507 × NK603 × DAS-40278-9 will be cultivated, packages of this maize will be marketed under the name of the hybrid variety, in association with the trademark (to be defined).
d)	**Date of acknowledgement of valid application** By EFSA: not available at the time of submission

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 Center 2nd Floor, 3 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 Center 2nd Floor, 3 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	

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) Applications have been submitted in the U.S.A. - TBC	

1.8 General description of the product

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

MON 89034 × 1507 × NK603 × DAS-40278-9 was produced by crossing plants containing MON 89034, 1507, NK603 and DAS-40278-9 using conventional breeding methods.

MON 89034 × 1507 × NK603 × DAS-40278-9 will combine multiple effective doses in multiple traits and provides season-long yield protection in two areas:

- Above-ground insect control (lepidopteran protection): combining MON 89034 with 1507, MON 89034 × 1507 × NK603 × DAS-40278-9 will provide the most comprehensive protection against corn borers as well as established and emerging insects including corn earworm, fall armyworm, western bean cutworm, and black cutworm;
- Weed control: MON 89034 × 1507 × NK603 × DAS-40278-9 also provides herbicide tolerance to glufosinate-ammonium, glyphosate, 2,4-D and to certain aryloxyphenoxypropionate (AOPP) herbicides, supporting broad spectrum weed and grass control within a single field.

By combining these proven technologies in hybrids developed across diverse breeding platforms, MON 89034 × 1507 × NK603 × DAS-40278-9 maximises grower choice, production efficiency, *Bt* maize durability, and grower profit potential while at the same time reducing the risk from insecticide and herbicide use to humans and the environment.

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 MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain[1] equivalent to the uses of any other maize grain.

c) Intended use of the product and types of users

MON 89034 × 1507 × NK603 × 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

1 Maize grain is the product of genetic segregation of the seed from which it is produced. Consequently MON 89034 × 1507 × NK603 × DAS-40278-9 grain includes a mixture of the combined event product, any combination of these events and the single events..

applied for

No specific conditions or instructions are warranted or required for the placing on the market of MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain, for all uses as any other maize grain. MON 89034 × 1507 × NK603 × DAS-40278-9 is substantially equivalent to other maize varieties except for its protection against target lepidopteran pests and its tolerance to glufosinate-ammonium, glyphosate, 2,4-D and to certain aryloxyphenoxypropionate (AOPP) herbicides, which are traits of agronomic interest. MON 89034 × 1507 × NK603 × DAS-40278-9 was shown to be as safe and as nutritious as conventional maize. Therefore MON 89034 × 1507 × NK603 × 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

MON 89034 × 1507 × NK603 × 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

MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain, are suitable for import, processing and food and feed uses throughout the E.U.

g) Any proposed packaging requirements

MON 89034 × 1507 × NK603 × DAS-40278-9 is substantially equivalent to conventional maize varieties (except for its protection from target lepidopteran insect pests and its tolerance to glufosinate-ammonium, glyphosate, 2,4-D and to certain aryloxyphenoxypropionate (AOPP) herbicides). Therefore, MON 89034 × 1507 × NK603 × 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 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 89034 × 1507 × NK603 × DAS-40278-9 grain and derived products.

Operators shall be required to label products containing or consisting of MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain. Therefore, no further specific measures are to be taken by the applicant for MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain.

i) Estimated potential demand

(i) In the Union
Comparable to that of conventional maize

(ii) In export markets for EU supplies
Not applicable

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

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6; MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-4Ø278-9; MON-89Ø34-3 × MON-ØØ6Ø3-6 × DAS-4Ø278-9; DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;

MON-89Ø34-3 × DAS-Ø15Ø7-1; MON-89Ø34-3 × MON-ØØ6Ø3-6; MON-89Ø34-3 × DAS-4Ø278-9; DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6; DAS-Ø15Ø7-1 × DAS-4Ø278-9; MON-ØØ6Ø3-6 × DAS-4Ø278-9;

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 MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain, as any other maize, not including the cultivation of MON 89034 × 1507 × NK603 × DAS-40278-9 in the E.U., environmental release would be more likely to occur during import, storage and processing of MON 89034 × 1507 × NK603 × DAS-40278-9. 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 MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × DAS-40278-9 grain for all uses as any other maize grain.

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** MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × 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

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

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 of MON 89034 × 1507 × NK603 × DAS-40278-9 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

Not Applicable.

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

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

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

MON 89034 × 1507 × NK603 × DAS-40278-9 was produced by crossing plants containing MON 89034, 1507, NK603 and DAS-40278-9 using conventional breeding methods.
While MON 89034 was developed through *Agrobacterium*-mediated transformation of maize, 1507 and NK603 were developed by the particle acceleration method and DAS-40278-9 was developed using direct Whiskers-mediated transformation.

b) Nature and source of the vector used

MON 89034 × 1507 × NK603 × DAS-40278-9 has been obtained by conventional breeding of MON 89034, 1507, NK603 and DAS-40278-9 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

By crossing MON 89034, 1507, NK603 and DAS-40278-9, by conventional breeding, MON 89034 × 1507 × NK603 × DAS-40278-9 inherits the inserted DNA from all three parental maize lines.

The individual components and the function of these inherited DNA sequences are given in Tables 1, 2, 3 and 4:

Table 1. Components of the inserted DNA inherited from MON 89034

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	Promotor
L-*Cab*	0.06	Wheat	Leader
I-*Ract1*	0.48	Rice actin gene	Intron
CS-*cry1A.105*	3.53	*Bacillus thuringiensis*	Coding sequence
T-*Hsp17*	0.21	Wheat heat shock protein	Transcript termination sequence
P-*FMV*	0.56	Figwort mosaic virus	Promotor
I-*Hsp70*	0.80	Maize heat shock protein	Intron
TS-*SSU-CTP*	0.40	Maize	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 2. Components of the inserted DNA inherited from 1507

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 3. Components of the inserted DNA inherited from NK603

Genetic element	Size (kb)	Source	Function
P-ract1/I-ract1	1.4	*Oryza sativa*	Promoter and Intron
TS-*CTP2*	0.2	*Arabidopsis thaliana*	Targeting sequence
CS-*cp4 epsps*	1.4	*Agrobacterium tumefaciens* sp. strain CP4	Coding sequence
T-*nos*	0.3	*Agrobacterium tumefaciens*	Transcript termination sequence
P-*e35S*	0.6	Cauliflower mosaic virus	Promoter
I-*Hsp70*	0.8	*Zea mays*	Intron
TS-*CTP2*	0.2	*Arabidopsis thaliana*	Targeting sequence
CS-*cp4 epsps l214p*	1.4	*Agrobacterium tumefaciens* sp. strain CP4	Coding sequence
T-*nos*	0.3	*Agrobacterium tumefaciens*	Transcript termination sequence

Table 4. Components of the inserted DNA inherited from DAS-40278-9

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

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 89034 × 1507 × NK603 × DAS-40278-9 is produced by crossing plants containing MON 89034, 1507, NK603 and DAS-40278-9 using conventional breeding methods and expresses :

- two distinct *Bacillus thuringiensis* proteins, Cry1A.105 and Cry2Ab2 which provide a dual effective dose against feeding damage caused by the key lepidopteran pest complex in maize,
- the *Bacillus thuringiensis* var *aizwai* Cry1F insecticidal protein which provides a third activity against the lepidopteran pest complex,
- the CP4 EPSPS protein, derived from *Agrobacterium tumefaciens* sp. strain CP4 which provides tolerance to glyphosate,
- the PAT protein, derived from *Streptomyces viridochromogenes*, which provides tolerance to glufosinate-ammonium, and,
- the AAD-1 protein, derived from *Sphingobium herbicidovorans* which provides tolerance to 2,4-D and to aryloxyphenoxypripionate (AOPP) herbicides (such as quizalofop).

Commercialisation of MON 89034 × 1507 × NK603 × DAS-40278-9 will therefore provide substantial benefits to growers by reducing the risk from insecticide and herbicide use to humans and the environment and by limiting yield losses from insects feeding damage while at the same time limiting weed pressure.

3.2.2 Information on the sequences actually inserted or deleted

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

MON 89034, 1507, NK603 and DAS-40278-9 each contains a single DNA insert with a single functional copy of the introduced DNA fragment.

The genome of MON 89034 × 1507 × NK603 × DAS-40278-9 contains four different inserts, one derived from MON 89034, one derived from 1507, one derived from NK603 and one derived from DAS-40278-9. The presence of these inserts in the hybrid was confirmed through Southern blot analysis.

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

Not applicable.

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

The conventionally bred F_1 MON 89034 × 1507 × NK603 × DAS-40278-9 contains the single product inserts in the nuclear genome, as they were present in the single product MON 89034, 1507, NK603 and DAS-40278-9, respectively.

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

Since the inserts present in MON 89034 × 1507 × NK603 × 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 hybrid.

(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, PAT, CP4 EPSPS and AAD-1 proteins in various tissues of MON 89034 × 1507 × NK603 × DAS-40278-9 were assessed by validated enzyme-linked immunosorbent assays (ELISA).

Tissue samples for analysis were collected from ten field trials conducted in the U.S.A. in 2010. The locations of these trials represent the major maize growing region of the U.S.A. and provide a variety of environmental conditions.

The data show that the levels of Cry1A.105, Cry2Ab2, Cry1F, PAT, CP4 EPSPS and AAD-1 proteins in grain of MON 89034 × 1507 × NK603 × DAS-40278-9 are comparable to protein levels in the positive controls substances, MON 89034, 1507, NK603 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, PAT, CP EPSPS and AAD-1 proteins throughout key development stages of MON 89034 × 1507 × NK603 × DAS-40278-9. Expression levels in grain are the most relevant tissue to food and feed safety.

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

Based on the molecular characterisation of MON 89034 × 1507 × NK603 × DAS-40278-9, it is highly likely that the insert sequences of MON 89034 × 1507 × NK603 × DAS-40278-9 are conserved with their inherent properties. In addition, the harvested (F_2) grain of MON 89034 × 1507 × NK603 × DAS-40278-9 is marketed by the grower for food, feed or industrial use and is not used for further breeding. Therefore, since MON 89034 × 1507 × NK603 × DAS-40278-9 hybrid maize seed exists only for a single generation, there is no opportunity for its stability to be compromised.

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 MON 89034 × 1507 × NK603 × DAS-40278-9 have demonstrated that MON 89034 × 1507 × NK603 × DAS-40278-9 has not been altered in survival, multiplication or dissemination characteristics when compared to conventional maize varieties. The traits for insect-protection and herbicide tolerance have 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

MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × DAS-40278-9 and conventional maize hybrids, except for the introduced traits that are of agronomic interest.

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

a) Plant to bacteria gene transfer

None of the genetic elements inserted in MON 89034 × 1507 × NK603 × DAS-40278-9 has 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

Not applicable. The scope of the current application does not include the cultivation of MON 89034 × 1507 × NK603 × DAS-40278-9 in the E.U.

4 COMPARATIVE ANALYSIS

4.1 Choice of the conventional counterpart and additional comparators

MON 89034 × 1507 × NK603 × DAS-40278-9 was compared with a conventional control maize with similar genetic background, as well as with other commercially available maize hybrids.

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

MON 89034 × 1507 × NK603 × DAS-40278-9 and the conventional control maize were grown at ten field sites in major maize-growing areas of the U.S.A. during the 2010 field season.

The compositional study compared MON 89034 × 1507 × NK603 × DAS-40278-9 to the control. Reference hybrids 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 ILSI ranges and ranges reported in literature.

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 MON 89034 × 1507 × NK603 × DAS-40278-9 compared to conventional maize hybrids, 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 MON 89034 × 1507 × NK603 × DAS-40278-9 were performed and the

set of agronomic observations supports a conclusion that from an agronomic and phenotypic (morphological) point of view, MON 89034 × 1507 × NK603 × DAS-40278-9 is equivalent to conventional maize, except for the inherited lepidopteran protection and tolerance to glufosinate-ammonium, glyphosate, 2,4-D and to certain aryloxyphenoxypropionate (AOPP) herbicides.

4.5 Effect of processing

Using both wet and dry milling processes, maize is converted into a diverse range of food and feed products and derivatives used as food and feed ingredients or additives. As MON 89034 × 1507 × NK603 × DAS-40278-9 is substantially equivalent and as safe and as nutritious as conventional maize, the use of MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × 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

MON 89034 × 1507 × NK603 × DAS-40278-9 is produced by conventional breeding of MON 89034, 1507, NK603 and DAS-40278-9. The introduced traits from the parental lines inherited by MON 89034 × 1507 × NK603 × DAS-40278-9, resulted in the combined expression of the Cry1A.105, Cry2Ab2, Cry1F, PAT, CP4 EPSPS and AAD-1 proteins in the same plant.

The conclusion of safety to humans of those proteins was based upon the following considerations:

- Those proteins have a demonstrated 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 Cry1A.105, Cry2Ab2, Cry1F, PAT, CP4 EPSPS and AAD-1 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 MON 89034 × 1507 × NK603 × DAS-40278-9 was shown to be substantially equivalent to conventional maize, no testing of any constituent other than the inherited proteins is 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

The compositional and nutritional equivalence of grain from MON 89034 × 1507 × NK603 × DAS-40278-9 and conventional maize have been established by compositional analysis.

6. ALLERGENICITY

a) Assessment of allergenicity of the newly expressed protein

The Cry1A.105, Cry2Ab2, Cry1F, PAT, CP4 EPSPS and AAD-1 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, and constitute a very small portion of the total protein present in the grain of MON 89034 × 1507 × NK603 × DAS-40278-9. Taken together these data lead to the conclusion that the Cry1A.105, Cry2Ab2, Cry1F, PAT, CP4 EPSPS and AAD-1 proteins are unlikely to have any allergenic potential, and MON 89034 × 1507 × NK603 × DAS-40278-9 is as safe as conventional maize regarding the risk for allergenicity.

b) Assessment of allergenicity of the whole GM plant

Maize is not considered a common allergenic food. Food allergies to maize are of low frequency and mainly occur in populations of specific geographic areas. Rare cases of occupational allergy to maize dust have been reported.

As MON 89034 × 1507 × NK603 × DAS-40278-9 is substantially equivalent and as safe as conventional maize, there is no reason to expect that the use of MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain will increase the potential for allergenicity. Further, as the introduced proteins in MON 89034 × 1507 × NK603 × DAS-40278-9 do not have any allergenic potential, it was concluded that the use of MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain 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 conventional maize.

7. NUTRITIONAL ASSESSMENT

a) Nutritional assessment of GM food

The introduced traits in MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × DAS-40278-9, and no nutritional imbalances are expected as a result of the use of MON 89034 × 1507 × NK603 × DAS-40278-9.

b) Nutritional assessment of GM feed

The evaluation of the composition of the MON 89034 × 1507 × NK603 × DAS-40278-9 showed that there were no biologically relevant differences in nutritional and compositional properties relative to control and reference maize hybrids. This data confirms and supports the conclusion that the MON 89034 × 1507 × NK603 × DAS-40278-9 is as safe and nutritious as conventional 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 MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain to the conventional maize supply. MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain are expected to replace a portion of current maize hybrids such that their 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

Assessments show that MON 89034 × 1507 × NK603 × 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, PAT, CP4 EPSPS and AAD-1 proteins will be toxic or allergenic making it negligible that MON 89034 × 1507 × NK603 × DAS-40278-9 will cause adverse effects in humans or animals.

10.POST-MARKET MONITORING ON GM FOOD/FEED

The assessment of the human and animal safety of MON 89034 × 1507 × NK603 × 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, PAT, CP4 EPSPS and AAD-1 proteins.

There are no intrinsic hazards related to MON 89034 × 1507 × NK603 × DAS-40278-9 as no signs of adverse or unanticipated effects have been observed in a number of safety studies. The pre-market risk characterisation for food and feed use of MON 89034 × 1507 × NK603 × DAS-40278-9 demonstrates that the risks of consumption of MON 89034 × 1507 × NK603 × 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

The Cry1A.105, Cry2Ab2 and Cry1F proteins produced in MON 89034 × 1507 × NK603 × DAS-40278-9 provide protection against lepidopteran pests. Those lepidopteran insects may be considered the target organisms which interact with MON 89034 × 1507 × NK603 × DAS-40278-9. The PAT, CP4 EPSPS and AAD-1 proteins, which also present in MON 89034 × 1507 × NK603 × DAS-40278-9, confer herbicide tolerance and hence do not have target organisms.

A generalised mode of action of Cry proteins includes the following steps: ingestion of the protoxin crystal by the insect, solubilisation 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 paralysed, which causes the insect to stop eating and die.

Any significant interactions of MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × DAS-40278-9 in the E.U. are not within the scope of this application. The likelihood that the import and use of MON 89034 × 1507 × NK603 × DAS-40278-9 maize 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 MON 89034 × 1507 × NK603 × DAS-40278-9 spreading in the environment is negligible, as maize is neither persistent nor invasive and these parameters are unaltered in MON 89034 × 1507 × NK603 × DAS-40278-9 when compared to conventional maize. In the unlikely event of the establishment of MON 89034 × 1507 × NK603 × DAS-40278-9 plants in the environment, the introduced traits would confer only a limited selective advantage (protection against lepidopteran pests, tolerance to glufosinate-ammonium, glyphosate, 2,4-D and to certain aryloxyphenoxypropionate (AOPP) herbicides) of short duration, narrow spatial context and with negligible consequences for the environment. Hence, the risk of establishment and spreading of MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain.

b) Selective advantage or disadvantage

Compared with conventional maize, the presence of the introduced traits in MON 89034 × 1507 × NK603 × DAS-40278-9 would only confer a meaningful advantage under specific conditions, *i.e.* where target lepidopteran pest species would be present in sufficiently high numbers or where plants would be treated with glufosinate-ammonium, glyphosate, 2,4-D and certain aryloxyphenoxypropionate (AOPP) herbicides and 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 the lepidopteran pest protection and the glufosinate-ammonium/glyphosate/2,4-D/aryloxyphenoxypropionate (AOPP)-tolerance traits in MON 89034 × 1507 × NK603 × 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

MON 89034 × 1507 × NK603 × DAS-40278-9 is unchanged in its potential for gene transfer compared to conventional maize. There is no potential for gene transfer from MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × DAS-40278-9 in the E.U. The environmental risk of potential gene transfer is negligible.

d) Interactions between the GM plant and target organisms

Since the likelihood is negligible that the import and uses of MON 89034 × 1507 × NK603 × DAS-40278-9 grain as any other maize grain will result in plants of this maize being present in the environment at meaningful levels, it is not expected that the target organisms will be exposed to Cry1A.105, Cry2Ab2 and Cry1F.

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

Given the scope of the current application, which does not include the cultivation of MON 89034 × 1507 × NK603 × DAS-40278-9 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 MON 89034 × 1507 × NK603 × DAS-40278-9 grain during import, storage, transport or use would lead to the short survival of MON 89034 × 1507 × NK603 × DAS-40278-9 plants in the environment. As a consequence, there is negligible risk for harmful effects of MON 89034 × 1507 × NK603 × DAS-40278-9 on non-target organisms, either through direct or indirect interactions with this maize or through contact with the newly expressed proteins.

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. MON 89034 × 1507 × NK603 × DAS-40278-9 contains the Cry1A.105, Cry2Ab2, Cry1F, PAT, CP4 EPSPS and AAD-1 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 MON 89034 × 1507 × NK603 × DAS-40278-9 and in humans, consuming those animals, is negligible. Therefore, the risk of MON 89034 × 1507 × NK603 × DAS-40278-9 for the feed/food chain is also negligible.

h) Effects on biogeochemical processes

There is no evidence that MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × DAS-40278-9 is compositionally equivalent and has equivalent growth and development, conventional maize. Furthermore, any indirect interactions of the GMO and target or non-target organisms in the vicinity of an incidental release of the grain are not likely to cause hazardous effects on the biogeochemical processes in the soil. The Cry1A.105, Cry2Ab2, Cry1F, PAT, CP4 EPSPS and AAD-1 proteins are subjected to rapid degradation in soil.

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

Not applicable. This application is for consent to import MON 89034 × 1507 × NK603 × 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 hybrids in the E.U.

11.3 Potential interactions with the abiotic environment

No adverse impact of MON 89034 × 1507 × NK603 × 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, PAT, CP4 EPSPS and AAD-1 are introduced proteins in maize, they already have a safe history of use and have no known negative interactions with the abiotic environment. The insecticidal proteins Cry1A.105, Cry2Ab2, Cry1F, are subjected to rapid degradation in soil and are therefore not expected to negatively affect soil or water. The *Streptomyces* and *Sphingobium herbicidovorans* species from which the PAT and AAD-1 proteins are derived are common soil microbes, widespread in nature and found all over the world. The CP4 EPSPS and AAD-1 proteins are innocuous and belong to a large class of enzymes that are ubiquitous in nature. The families of EPSPS and AAD-1 proteins have no known negative interactions with the abiotic environment.

11.4 Risk characterisation for the environmental risk assessment

The scope of this application is for import for food and feed uses of MON 89034 × 1507 × NK603 × DAS-40278-9 and that cultivation of MON 89034 × 1507 × NK603 × DAS-40278-9 maize varieties in the EU is not planned; any exposure to the environment from the import of MON 89034 × 1507 × NK603 × DAS-40278-9 maize will be limited to unintended release via spillage during transportation of the grain. Since the likelihood is negligible that the import and uses of MON 89034 × 1507 × NK603 × DAS-40278-9 grain as any other maize grain will result in plants of this maize being present in the environment at meaningful levels, it is not expected that the target organisms will be exposed to Cry1A.105, Cry2Ab2 and Cry1F. There are no target organisms for the CP4 EPSPS and AAD-1 proteins expressed in MON 89034 × 1507 × NK603 × DAS-40278-9, which confers tolerance to certain herbicides.

Therefore, the likelihood that the import and use of MON 89034 × 1507 × NK603 × DAS-40278-9 for food, feed or processing will result in plants of this soybean 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 MON 89034 × 1507 × NK603 × 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 (EFSA, 2006).

b) Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) was carried out for MON 89034 × 1507 × NK603 × 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 MON 89034 × 1507 × NK603 × DAS-40278-9 in the e.r.a.

(Section E) 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 89034 × 1507 × NK603 × DAS-40278-9.

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

The scientific evaluation of the characteristics of MON 89034 × 1507 × NK603 × 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 holder is not involved in commodity trade with MON 89034 × 1507 × NK603 × DAS-40278-9. 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 MON 89034 × 1507 × NK603 × DAS-40278-9. They are exposed to the imported viable MON 89034 × 1507 × NK603 × DAS-40278-9 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 holder 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 MON 89034 × 1507 × NK603 × DAS-40278-9 can be established. If the investigation establishes that MON 89034 × 1507 × NK603 × DAS-40278-9 were present when the adverse effect was identified, and confirms that MON 89034 × 1507 × NK603 × DAS-40278-9 is the cause of the adverse effect, the authorisation holder will immediately inform the European Commission, as described in Section E.4.3.4.

e) Reporting the results of the monitoring

The authorisation holder 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 EVENT-SPECIFIC IDENTIFICATION TECHNIQUES FOR THE GM PLANT

As MON 89034 × 1507 × NK603 × DAS-40278-9 was produced by crossing plants containing MON 89034, 1507, NK603 and DAS-40278-9 using conventional breeding methods, it contains inserts in combination. Therefore, MON 89034 × 1507

× NK603 × DAS-40278-9 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 89034 × 1507 × NK603 × DAS-40278-9 will detect any combination of the four events.

14 INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT

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** 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 89034 × 1507 × NK603 × DAS-40278-9 has been field tested in the U.S.A. in 2010.
b)	**Authority overseeing the release** U.S.A: United States Department of Agriculture and Environmental Protection Agency (USDA & EPA).
c)	**Release site** Multiple sites in maize producing states of the U.S. corn belt and southern corn growing regions.
d)	**Aim of the release** Assess performance, efficacy, hybrid evaluation, seed production, yield, and collection of regulatory data and materials.
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.

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 MON 89034 × 1507 × NK603 × DAS-40278-9 is likely to cause any adverse effects to human or animal health and the environment.

7.5 Product specification

MON 89034 × 1507 × NK603 × DAS-40278-9 maize grain will be imported into the E.U. in mixed shipments of maize grain and products, produced in other world areas, for use by operators that have traditionally been involved in the commerce, processing and use of maize and maize derived products in the E.U.

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

a)	**Status/process of approval** The EFSA website[2] provides information related to the applications submitted under Regulation (EC) No 1829/2003 on genetically modified food and feed.
b)	**Assessment Report of the Competent Authority (Directive 2001/18/EC)** A notification for MON 89034 × 1507 × NK603 × DAS-40278-9 according to Part C of Directive 2001/18/EC has not been submitted by Dow AgroSciences Europe.
c)	**EFSA opinion** An EFSA opinion, specifically for MON 89034 × 1507 × NK603 × DAS-40278-9, was not available at the time of submission of this application.
d)	**Commission Register (Commission Decision 2004/204/EC)** Once authorised, food and feed products will be entered in the Community Register of GM food and feed[3].
e)	**Molecular Register of the Community Reference Laboratory/Joint Research Centre** Information on detection protocols can be found on the JRC website[4].
f)	**Biosafety Clearing-House (Council Decision 2002/628/EC)** The publicly accessible portal site of the Biosafety Clearing-House (BCH) can be found at http://bch.biodiv.org/.
g)	**Summary Notification Information Format (SNIF) (Council Decision**

[2] http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOApplications.htm
[3] http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm
[4] http://gmo-crl.jrc.it/statusofdoss.htm

2002/812/EC)

A notification and SNIF according to Directives 2001/18/EC and 2002/812/EC, respectively, have not been submitted for MON 89034 × 1507 × NK603 × DAS-40278-9. The EFSA website[5] does provide a link to this summary of the application for MON 89034 × 1507 × NK603 × DAS-40278-9 under Regulation (EC) No 1829/2003.

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