Application for authorisation of 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-2010-89

Part II
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.

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

Netherlands

b) Notification number

EFSA-GMO-NL-2010-89

c) Name of the product (commercial and other names)

The development code for this genetically modified maize is: DAS-40278-9. In countries where 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 notification

By EFSA: not available at the time of submission

2. Applicant

a) Name of applicant

Dow AgroSciences LLC represented by Dow AgroSciences Europe

b) Address of applicant

Dow AgroSciences Europe
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Oxon OX14 4RN
United Kingdom

Dow AgroSciences LLC
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Indianapolis, Indiana 46268-1054
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c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii))

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.

3. Scope of the application

(x) GM plants for food use
(x) Food containing or consisting of GM plants
(x) Food produced from GM plants or containing ingredients produced from GM plants
(x) GM plants for feed use
(x) Feed containing or consisting of GM plants

(x)	Feed produced from GM plants or containing ingredients produced from GM plants
(x)	Import and processing (Part C of Directive 2001/18/EC)
( )	Seeds and plant propagating material for cultivation in Europe (Part C of Directive 2001/18/EC)

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

Yes ( )	**No (x)**
If *yes*, specify	

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

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

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

Yes ( )	**No (x)**
If *yes*, specify	

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

Yes (x)	**No ( )**
If *yes*, specify Applications have been submitted in the U.S.A. Canada, Australia, Japan, Korea, Taiwan, and Mexico.	

8. General description of the product

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

The recipient plant is maize (*Zea mays* L.), which is extensively cultivated and has a long history of safe use. The DAS-40278-9 maize has been genetically modified to

express the AAD-1 protein.

Expression of the AAD-1 protein, confers tolerance to application of 2,4-D and to certain aryloxyphenoxypropionate (AOPP) herbicides.

b) Types of products planned to be placed on the market according to 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 DAS-40278-9 maize grain equivalent to the uses of any other maize grain.

c) Intended use of the product and types of users

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 DAS-40278-9 maize grain, for import, processing, and use as such or in food and feed. DAS-40278-9 is substantially equivalent to other maize varieties except for its tolerance to application of 2,4-D, which is a trait of agronomic interest. DAS-40278-9 was shown to be as safe and as nutritious as conventional maize. Therefore DAS-40278-9 and derived products will be stored, packaged, transported, handled and used in the same manner as the commercial maize products.

e) Any proposed packaging requirements

DAS-40278-9 is substantially equivalent to conventional maize varieties (except for its tolerance to application of 2,4-D and to certain aryloxyphenoxypropionate (AOPP) herbicides. Therefore, DAS-40278-9 and derived products will be used in the same manner as other maize and no specific packaging is foreseen. (For the labelling, *see* question A.8.(f)).

f) Any proposed labelling requirements in addition to those required by Community law (Annex IV of Directive 2001/18/EC; Regulation 1829/2003 art. 13 and 25)

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 DAS-40278-9 grain and derived products.

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

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

DAS-4Ø278-9.

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

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

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 DAS-40278-9 maize grain, as any other maize, not including the cultivation of DAS-40278-9 hybrids, environmental release would be more likely to occur during import, storage and processing of DAS-40278-9 maize grain. However, modern methods of grain handling minimize losses of grain, so there is little chance of germination of spilt grain resulting in the development of mature plants of 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 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 DAS-40278-9 maize grain, for import, processing, or use for food and feed.

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

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** DAS-40278-9
f)	**Common name** Maize; Corn

2. a) Information concerning reproduction

(i)	***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.
(ii)	***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.
(iii)	***Generation time*** Maize is an annual crop with a cultural cycle ranging from as short as 10 weeks to as long as 48 weeks covering the period of seedling emergence to maturity from seedling emergence to maturity.

2 b) 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 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.

3. Survivability

a) Ability to form structures for survival or dormancy

During the domestication of maize, many agronomically significant attributes for cultivation have been gained whilst maize has lost the ability to survive in the wild. Maize is a non-dormant annual crop and seeds are the only survival structures.

b) Specific factors affecting survivability

Survival of maize seed is dependent upon temperature, moisture of seed, genotype, husk protection and stage of development. Maize seed can only survive under favourable climatic conditions. Freezing temperatures have an adverse effect on germination of maize seed and it has been identified as a major risk in limiting production of maize seed.

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.

4. 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. Pollen shedding from the tassels takes place over a period of 10 to 15 days. Pollen grains are round, heavy and have high moisture content, characteristics that limit their dispersal and attachment to plant surfaces, such as leaves.. However, the current application does not include the environmental release of DAS-40278-9 hybrids in the E.U.

b) Specific factors affecting dissemination

Mechanical harvesting and transport are ways of disseminating grain and insect or wind damage may cause mature ears to fall to the ground and avoid harvest. Regardless of these routes of dissemination, maize cannot survive without human assistance in nonagricultural habitats in the EU.. 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.

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

Maize is grown over a wide range of climatic conditions because of its many divergent types. However, survival and reproduction in maize is limited by cool conditions. Practically no maize can be grown where the mean mid-summer temperature is <19°C or where average night temperatures fall below ~13°C. The majority of maize is produced between latitudes 30 and 55 degrees, with relatively little grown at latitudes higher than 47 degrees anywhere in the world. Summer rainfall of 15 cm is the lower limit for maize production without irrigation. There is no upper limit of rainfall for growing maize, although excess rainfall will decrease yields. Maize has been cultivated in Europe starting in Spain since the 16th century

There are no wild relatives of maize in Europe.

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

Maize 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.

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

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.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

DAS-40278-9 maize was developed using direct Whiskers-mediated transformation to stably incorporate the *aad-1* gene from the soil bacterium, *Sphingobium herbicidovorans*, into maize. The *aad-1* gene encodes the aryloxyalkanoate dioxygenase (AAD-1) enzyme, which, when expressed in plants, degrades the herbicide 2,4-dichlorophenoxyacetic acid (2,4-D) into herbicidally-inactive 2,4-dichlorophenol (DCP). Additionally, plants expressing AAD-1 have been demonstrated to convert certain aryloxyphenoxypripionate (AOPP) herbicides (such as quizalofop) into their corresponding inactive phenols.

2. Nature and source of the vector used

The recipient maize line Hi-II was transformed using direct insertion of the DNA *Fsp* I fragment, carrying the *aad-1* expression cassette for insertion into the plant genome, from plasmid pDAS1740.

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

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

RB7 MAR v4	1166 bp	Matrix attachment region (MAR) from *Nicotiana tobacum*

D. INFORMATION RELATING TO THE GM PLANT

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

DAS-40278-9 maize expresses 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 DAS-40278-9 will therefore provide substantial benefits to growers by limiting yield losses from weed pressure.

2. Information on the sequences actually inserted or deleted

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

The genome of DAS-40278-9 maize contains a single, intact copy of the *aad-1* expression cassette from plasmid pDAS1740. The event is stably integrated and inherited across and within breeding generations, and no plasmid backbone sequences are present in DAS-40278-9 maize.

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

Not applicable.

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

The insert from DAS-40278-9 is located in the nuclear genome. Southern analyses further demonstrated the presence of the *Fsp* I fragment carrying the *aad-1* expression cassette from plasmid pDAS1740.

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

The DAS-40278-9 insertion as well as the 5' and 3' flanking genomic regions of the DAS-40278-9 maize insertion have been sequenced and characterised in detail. PCR analysis of the DNA flanking the DAS-40278-9 maize insertion confirmed that both regions correspond to maize genomic DNA.

3. Information on the expression of the insert

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

The expression level of the AAD-1 protein has been determined in a range of DAS-40278-9 maize tissues representing key developmental stages of a typical maize plant. Expression was characterised using a specific Enzyme Linked Immunosorbent Assay (ELISA) system developed for the AAD-1 protein. Results of these tests confirm expression of the AAD-1 protein throughout key developmental stages of DAS-40278-9 maize and in all plant parts of the DAS-

40278-9 maize, including the DAS-40278-9 maize grain.

b) Parts of the plant where the insert is expressed

Results of the analyses confirm expression of AAD-1 protein throughout key development stages of DAS-40278-9. Expression levels in grain are the most relevant tissue to food and feed safety.

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

a) Reproduction

Agronomic data collected from trials performed with DAS-40278-9 have demonstrated that 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 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 DAS-40278-9 and conventional maize hybrids, except for the introduced traits that are of agronomic interest.

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

The results from this characterization study indicate that the inheritance of the inserted DNA of event DAS-40278-9 is stable within a segregating generation (BC3S1). All individual plants analyzed indicated the insertion is equivalent in all individuals within the generation and the ratio in the BC3S1 generation fit the expected 3 to 1 based on a single locus. The Southern blot results indicated an intact copy of the *aad*-1 gene inserted into the maize genome and was stably inherited across the five generations tested.

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 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 DAS-40278-9 varieties in the E.U.

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

7.1 Comparative assessment

Choice of the comparator

DAS-40278-9 was compared with conventional control maize with similar genetic background, as well as with other commercially available maize hybrids.

7.2 Production of material for comparative assessment

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

DAS-40278-9 and the conventional control maize were grown at eight field sites (including 4 replicates) in major maize-growing areas of the U.S.A. during the 2009 field season.

b) the baseline used for consideration of natural variations

The compositional study compared 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 historical ranges.

7.3 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 DAS-40278-9 compared to conventional maize hybrids, there is no indication to further analyze other selected compounds in this maize.

7.4 Agronomic traits

Field trials with DAS-40278-9 were performed and the set of agronomic observations supports a conclusion that from an agronomic and phenotypic (morphological) point of view, DAS-40278-9 is equivalent to conventional maize, except for tolerance to 2,4-D and to certain aryloxyphenoxypropionate (AOPP) herbicides.

7.5 Product specification

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.

7.6 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 DAS-40278-9 is substantially equivalent and as safe and as nutritious as conventional maize, the use of 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 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.

7.7 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 DAS-40278-9 maize grain to the conventional maize supply. 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.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

DAS-40278-9 expresses the AAD-1 protein, the conclusion of safety to humans of this protein was based upon the following considerations:

- The protein has a history of safe use;
- It has no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- It does not exert acute or chronic toxicity to mammals.

In addition, its 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 AAD-1 protein would cause any toxic effects on human or animal health.

7.8.2 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 DAS-40278-9 was shown to be substantially equivalent to conventional maize, no testing of any constituent other than the inherited protein is indicated.

7.8.3 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.

7.8.4 Testing of the whole GM food/feed

The compositional and nutritional equivalence of grain from DAS-40278-9 and conventional maize have been established by compositional analysis. Additionally, the wholesomeness of DAS-40278-9 grain has been confirmed by a repeat-dose animal feeding study in broiler chickens using diets containing grain from DAS-40278-9 maize.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The AAD-1 protein has been assessed for their potential allergenicity according to the recommendations of Codex Alimentarius Commission. The protein is from a non-allergenic source, lacks structural similarity to known allergens, is rapidly digested in simulated gastric fluid, and constitutes a very small portion of the total protein present in the grain of DAS-40278-9. Taken together, these data lead to the conclusion that the AAD-1 protein is unlikely to have any allergenic potential; hence, DAS-40278-9 is as safe as conventional maize regarding the risk for allergenicity.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

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

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The introduced traits in 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 DAS-40278-9 maize grain, and no nutritional imbalances are expected as a result of the use of DAS-40278-9 maize grain.

7.10.2 Nutritional assessment of GM feed

A confirmatory feeding study in broiler chicken was conducted to compare the nutritional value of DAS-40278-9 grain and conventional control grain as well as commercial maize hybrids, and to provide confirmation of the safety of this maize. The results of this study show that there were no biologically relevant differences in the parameters tested between broiler chickens fed the DAS-40278-9 diet and the conventional control diet. The DAS-40278-9 diet was as wholesome as its corresponding conventional control diet and commercially available reference diets regarding its ability to support the growth of broiler chickens. This conclusion was consistent with the evaluation of the composition of the DAS-40278-9, which showed that there were no biologically relevant differences in nutritional and compositional properties relative to control and reference maize hybrids. These data confirm and support the conclusion that the DAS-40278-9 is as safe and nutritious as conventional maize.

7.11 Post-market monitoring of GM food/feed

The assessment of the human and animal safety of 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 AAD-1 protein.

There are no intrinsic hazards related to DAS-40278-9 as no signs of adverse or unanticipated effects have been observed in a number of safety studies, including an animal feeding study using doses of administration that are orders of magnitude above expected consumption levels. The pre-market risk characterisation for food and feed use of DAS-40278-9 demonstrates that the risks of consumption of 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.

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

Not applicable since DAS-40278-9 expresses the AAD-1 protein, which confers tolerance to 2,4-D and to certain aryloxyphenoxypropionate (AOPP) herbicides - there are no target organisms for the AAD-1 protein.

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

This application is limited to import for direct food or feed use or for processing. As such, exposure to the environment will be rare, occurring only through incidental release during shipment and handling. The conditions where incidental release will occur are not conducive to establishment of maize.

9.1 Persistence and invasiveness

Like for conventional maize, the likelihood of DAS-40278-9 spreading in the environment is negligible, as maize is neither persistent nor invasive and these parameters are unaltered in DAS-40278-9 when compared to conventional maize. In the unlikely event of the establishment of DAS-40278-9 plants in the environment, the introduced traits would confer only a limited selective advantage (tolerance to 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 DAS-40278-9 maize grain is negligible.

9.2 Selective advantage or disadvantage

Compared with conventional maize, the presence of the introduced traits in DAS-40278-9 would only confer a meaningful advantage under specific conditions, *i.e.* where plants would be treated with 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 2,4-D and AOPP-tolerance traits in 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 D.9.1). 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.

9.3 Potential for gene transfer

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

9.4 Interactions between the GM plant and target organisms

Since the likelihood is negligible that the import, processing and food and feed use of DAS-40278-9 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 AAD-1.

9.5 Interactions of the GM plant with non-target organisms

Given the scope of the current application, which does not include the cultivation of DAS-40278-9 hybrids 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 protein present a negligible hazard to non-target organisms, even if incidental spillage of DAS-40278-9 grain during import, storage, transport or use would lead to the short survival of DAS-40278-9 plants in the environment. As a consequence, there is negligible risk for harmful effects of 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.

9.6 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. DAS-40278-9 expresses the AAD-1 protein, which has 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.

9.7 Effects on animal health

No signs of adverse or unanticipated effects have been observed in a number of safety studies, including nutritional composition of the grain and an animal feeding study using doses of administration that are orders of magnitude above expected consumption levels. The likelihood of potential adverse effects in animals fed on DAS-40278-9 and in humans, consuming those animals, is negligible. Therefore, the risk of DAS-40278-9 for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

The scope of this application does not include cultivation uses of DAS-40278-9 hybrids in the E.U. Given that DAS-40278-9 is compositionally equivalent and has equivalent growth and development, conventional maize; DAS-40278-9 plants would be no different from conventional maize regarding their direct influence on biogeochemical processes or nutrient levels in the soil,.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable. This application is for consent to import 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.

10. Potential interactions with the abiotic environment

No adverse impact of 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 AAD-1 protein is an introduced protein in maize, it already has a safe history and has no known negative interactions with the abiotic environment. The *Sphingobium herbicidovorans* species from which the AAD-1 protein is derived is a common soil microbe. The AAD-1 protein is innocuous and belongs to a class of enzymes that are common in nature. The AAD-1 protein has no known negative interactions with the abiotic environment.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants)

11.1 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 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.

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) was carried out for 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 DAS-40278-9 in the e.r.a. (Section D.9) 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 DAS-40278-9 maize grain.

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

The scientific evaluation of the characteristics of 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.

11.4 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 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 DAS-40278-9 maize grain. They are exposed to the imported viable 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 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 DAS-40278-9 maize grain can be established. If the investigation establishes that DAS-40278-9 maize grain were present when the adverse effect was identified, and confirms that DAS-40278-9 maize grain is the cause of the adverse effect, the authorisation holder will immediately inform the European Commission, as described in Section D.11.5.

11.5 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.

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

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

The Institute for Reference Materials and Measurements (IRMM) is collaborating with Dow AgroSciences to develop certified reference materials for DAS-40278-9 maize. The sales conditions of certified reference materials are available from the IRMM website (http://irmm.jrc.ec.europa.eu/html/homepage.htm) or from the e-mail address jrc-irmm-gmo@ec.europa.eu. Detailed information on these materials is given in the IRMM certification reports and sample certificates, posted on the IRMM website.

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

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

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

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

a)	**Release country** DAS-40278-9 has been field tested in the U.S.A. and Canada in 2007, 2008, 2009, and 2010, and in Brazil and Argentina in 2009 and 2010.

b)	**Authority overseeing the release** U.S.A: United States Department of Agriculture (USDA) Canada: Canadian Food Inspection Agency (CFIA) Brazil: National Technical Biosafety Committee (CTNBio) Argentina: Secretary of Agriculture, Livestock, Fishery, and Food (SAGPyA)
c)	**Release site** U.S.A.: Multiple sites in maize producing states of the U.S. corn belt and southern corn growing regions Canada: Multiple sites in the maize growing regions Brazil: In the states of Minas Gerais, São Paulo and Parana Argentina: Several locations in the corn belt region of Argentina
d)	**Aim of the release** All locations: assess performance, hybrid evaluation, seed production, yield, breeding, and collection of regulatory data and materials

e)	**Duration of the release** All locations: 12 months or one planting season per release
f)	**Aim of post-releases monitoring** All locations: Removal of volunteers
g)	**Duration of post-releases monitoring** All locations: 12 months
h)	**Conclusions of post-release monitoring** All locations: 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** All locations: no evidence that DAS-40278-9 is likely to cause any adverse effects to human or animal health and the environment

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[5] 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 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 DAS-40278-9, was not available at the time of submission of this application.
d)	**Commission Register (Commission Decision 2004/204/EC)** Once authorized, food and feed products will be entered in the Community Register of GM food and feed[6].
e)	**Molecular Register of the Community Reference Laboratory/Joint Research Centre**

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

6 http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm

	Information on detection protocols can be found on the JRC website[7].
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 2002/812/EC)** A notification and SNIF according to Directives 2001/18/EC and 2002/812/EC, respectively, have not been submitted for DAS-40278-9. The EFSA website[8] does provide a link to this summary of the application for DAS-40278-9 under Regulation (EC) No 1829/2003.

7 http://gmo-crl.jrc.it/statusofdoss.htm

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