Application for authorisation of DAS-8191Ø-7 cotton grain for all uses as for any other cotton, excluding cultivation, according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-NL-2016-136

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-2016-136
c)	**Name of the product (commercial and other names)** The development code for this genetically modified cotton is: DAS-8191Ø-7. In countries where DAS-8191Ø-7 will be cultivated, packages of this cotton will be marketed under the name of the variety, in association with the trademark (to be defined).
d)	**Date of acknowledgement of valid application** By EFSA: 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., Canada, Mexico, ANZ, Japan, Korea and Brazil.

1.8 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 cotton (*Gossypium hirsutum*), which is extensively cultivated and has a long history of safe use. The DAS-8191Ø-7 cotton has been genetically modified to express the AAD-12 and PAT proteins.

Expression of the AAD-12 and PAT proteins confer tolerance to application of 2,4-D and glufosinate-ammonium herbicides, respectively.

b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for

The scope of this application according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed includes all uses of DAS-8191Ø-7 cotton grain equivalent to the uses of any other cotton grain.

c) Intended use of the product and types of users

DAS-8191Ø-7 cotton grain will be traded and used in the E.U. in the same manner as current commercial cotton varieties and by the same operators currently involved in the trade and use of conventional cotton.

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-8191Ø-7 cotton grain, for import, processing, and use as such or in food and feed. DAS-8191Ø-7 is substantially equivalent to other cotton varieties except for its tolerance to application of 2,4-D and glufosinate-ammonium herbicides, which is a trait of agronomic interest. DAS-8191Ø-7 was shown to be as safe and as nutritious as conventional cotton. Therefore DAS-8191Ø-7 and derived products will be stored, packaged, transported, handled and used in the same manner as the commercial cotton 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

DAS-8191Ø-7 cotton 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

DAS-8191Ø-7 cotton grain, are suitable for import, processing and food and feed

uses throughout the E.U.

g) Any proposed packaging requirements

DAS-8191Ø-7 is substantially equivalent to conventional cotton varieties (except for its tolerance to application of 2,4-D and glufosinate-ammonium herbicides. Therefore, DAS-8191Ø-7 and derived products will be used in the same manner as other cotton and no specific packaging is foreseen. (For the labelling, *see* question A.1.8.(h)).

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 DAS-8191Ø-7 grain and derived products.

Operators shall be required to label products containing or consisting of DAS-8191Ø-7 cotton grain with the words "genetically modified cotton" or "contains genetically modified cotton", 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-8191Ø-7 cotton grain with the words "produced from genetically modified cotton". 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-8191Ø-7 cotton 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-8191Ø-7 cotton grain. Therefore, no further specific measures are to be taken by the applicant for DAS-8191Ø-7 cotton grain.

i) Estimated potential demand

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

(ii) In export markets for EU supplies
Not applicable

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

DAS-8191Ø-7

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

Because this application is for consent to import and use DAS-8191Ø-7 cotton grain, as any other cotton, not including the cultivation of DAS-8191Ø-7 varieties, environmental release would be more likely to occur during import, storage and processing of DAS-

8191Ø-7 cotton 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-8191Ø-7 in the E.U. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since cotton cannot survive without human assistance and is not capable of surviving as a weed. Although cotton seed can over-winter in mild conditions and can germinate the following year, the appearance of cotton in rotational fields is rare under European conditions. Cotton 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-8191Ø-7 is unlikely to be different from other cotton 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-8191Ø-7 cotton grain, for import, processing, or use for food and feed.

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

2.1. Complete name

a)	**Family name** Malvaceae
b)	**Genus** *Gossypium*
c)	**Species** *Gossypium hirsutum*
d)	**Subspecies** N/A
e)	**Cultivar/breeding line or strain** DAS-8191Ø-7
f)	**Common name** Cotton

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

Plants of the Gossypium genus originated in different areas of the world, with centers of diversity in Australia, Southern Asia, Africa and the New World. There are four cultivated species, two diploids from the Old World, *G. arboreum* and *G. herbaceum,* and two tetraploids from the New World, *G. hirsutum* and *G. barbadense*, and do not exist naturally in the EU.

2.3 Information concerning reproduction

a)	**Mode(s) of reproduction** Cotton is considered a self-pollinated species, propagated commercially by seed.
b)	**Specific factors affecting reproduction** Cotton plants will grow and be productive on a wide variety of soils. They are most productive on fertile soil under hot weather and irrigated conditions if rainfall is deficient. Cotton is generally self-pollinating, but in the presence of suitable insect pollinators allows for a limited cross-pollination. Bumble bees (Bombus spp.), Melissodes bees, and honey bees (*Apis mellifera*) are the primary pollinators. The presence of suitable pollinators varies from location to location and by season, and is considerably suppressed by insecticide use. If suitable bee pollinators are present, distribution of pollen decreases considerably with increasing distance..
c)	**Generation time** From seeding to maturity, cotton passes through various growth stages; the entire

growing period is 120–200 days.

2.4 Sexual compatibility with other cultivated or wild plant species

Fertility between different cotton species is highly variable, and only 2/3 of hybrids produced have fertile F1. Physiological barriers and genetic instability are the major causes preventing the development of fertile hybrids from widely related species. In addition to the partial sexual incompatibility, there is no availability of wild relatives with which to cross with since no genera in Gossypieae occurs naturally in Spain, Greece or other countries of the European union

2.5 Survivability (for environmental safety aspects)

a) Ability to form structures for survival or dormancy

Cottonseeds are not considered to be able to survive in the environment over long periods because they lack dormancy ability and are not able to germinate under diverse climatic conditions..

b) Specific factors affecting survivability

The main factors affecting survivability are the ability to form structures for survival along with the capacity of survival over long time periods over different generations. Cotton may persist as a perennial or may survive as seed. Neither plants or seed persist where over-wintering mean monthly temperature are below 18 °C.

2.6 Dissemination (for environmental safety aspects)

a) Ways and extent of dissemination

Cotton is considered a self-pollinated species, propogated commercially by seed.

b) Specific factors affecting dissemination

Cotton plants will grow and be productive on a wide variety of soils. They are most productive on fertile soil under hot weather and irrigated conditions if rainfall is deficient. Gossypium hirsutum is generally self-pollinating, but in the presence of suitable insect pollinators allows for a limited cross-pollination.

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

There is no availability of wild relatives with which to cross with since no genera in *Gossypieae* occurs naturally in Spain, Greece or other countries of the European union.

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

Cotton is grown in the EU commercially.

2.9 Other potential interactions, relevant to the GM plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms (for environmental safety aspects)

Cotton has a history of safe use for human food and animal feed. However, cotton 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 Transgenic cotton (*Gossypium hirsutum*) DAS-8191Ø-7 was generated through *Agrobacterium*-mediated transformation, using the disarmed *Agrobacterium tumefaciens* carrying the binary vector with the genes of interest (*aad-12*, and *pat*) within the T-DNA region.
b) Nature and source of the vector used The plasmid pDAB4468 is the transformation vector used with *Agrobacterium tumefaciens* to generate DAS-8191Ø-7.
c) Source of donor DNA used for transformation, size and intended function of each constituent fragment of the region intended for insertion

Feature Name	Feature Start	Feature Stop	Feature Size	Description
T-DNA Region				
T-DNA Border B	1	24	24	Transferring DNA sequences
Intervening sequence	25	160	136	Sequence from Ti plasmid pTi15955
RB7-MAR	161	1326	1166	Matrix attachment region (MAR) from *Nicotiana tobacum*
Intervening sequence	1327	1421	95	Sequence from plasmid pENTR/D-TOPO (Invitrogen Cat. No. A10465) and multiple cloning sites
AtUbi10	1422	2743	1322	*Arabidopsis thaliana* polyubiquitin UBQ10 gene comprising the promoter, 5′ untranslated region and intron
Intervening sequence	2744	2751	8	Sequence used for DNA cloning
aad-12	2752	3633	882	Synthetic, plant-optimized version of an aryloxyalkanoate dioxygenase from *Delftia acidovorans*
Intervening sequence	3634	3735	102	Sequence used for DNA cloning
AtuORF23	3736	4192	457	3′ untranslated region (UTR) comprising the transcriptional terminator and polyadenylation site of open reading frame 23 (ORF23) of *Agrobacterium tumefaciens* pTi15955
Intervening sequence	4193	4306	114	Sequence from plasmid pENTR/D-TOPO (Invitrogen Cat. No. A10465) and multiple cloning sites
CsVMV	4307	4823	517	Promoter and 5′ untranslated region derived from the cassava vein mosaic virus
Intervening sequence	4824	4830	7	Sequence used for DNA cloning
pat	4831	5382	552	Synthetic, plant-optimized version of phosphinothricin *N*-acetyl transferase (PAT) gene, isolated from *Streptomyces viridochromogenes*
Intervening sequence	5383	5484	102	Sequence from plasmid pCRI2.1(Invitrogen Cat. No. K205001) and multiple cloning sites
AtuORF1	5485	6188	704	3′ untranslated region (UTR) comprising the transcriptional terminator and polyadenylation site of open reading frame 1 (ORF1) of *Agrobacterium tumefaciens* pTi15955

3.2 Information relating to the GM plant

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

DAS-8191Ø-7 cotton expresses the AAD-12 and PAT proteins, derived from *Delftia acidovorans* and *Streptomyces viridochromogenes*, providing tolerance to application of 2,4-D and glufosinate-ammonium herbicides, respectively.

Commercialisation of DAS-8191Ø-7 will therefore provide substantial benefits to growers by limiting yield losses from 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

The genome of DAS-8191Ø-7 cotton contains a single, intact copy of the *aad-12* and *pat* expression cassette from plasmid pDAB4468. The insert is stably integrated and inherited across and within breeding generations. No plasmid backbone sequences are present in DAS-8191Ø-7 cotton.

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

Sequence analysis confirmed that DAS-81910-7 cotton contains a single transgene insert, including an intact copy of each of the aad-12 and pat PTUs along with a RB7 MAR element at the 5' end of the insert.

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

The insert from DAS-8191Ø-7 is located in the nuclear genome as determined by Southern blot analyses, DNA sequencing, and segregation analysis.

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

The DAS-8191Ø-7 insertion as well as the 5 prime and 3 prime flanking genomic regions of the DAS-8191Ø-7 cotton insertion have been sequenced and characterised in detail. PCR analysis and BLASTn searches of the DNA flanking the DAS-8191Ø-7 cotton insertion confirmed that both regions correspond to cotton genomic DNA.

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

Not Applicable

3.2.3 Information on the expression of the insert

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

The expression levels of the AAD-12 and PAT proteins have been determined in a range of DAS-8191Ø-7 cotton tissues representing key developmental stages of a typical cotton plant. Expression was characterised using specific Enzyme Linked Immunosorbent Assay (ELISA) systems developed for the AAD-12 and PAT proteins. Results of these tests confirm expression of the AAD-12 and PAT proteins throughout key developmental stages of DAS-8191Ø-7 cotton and in all plant parts of the DAS-8191Ø-7 cotton, including the DAS-8191Ø-7 cotton grain.

b) Parts of the plant where the insert is expressed

Results of the analyses confirm expression of AAD-12 and PAT proteins throughout key development stages of DAS-8191Ø-7. Expression levels in grain are most relevant for food and feed safety evaluation.

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

The results from this characterisation study indicated that the inheritance of the inserted DNA of event DAS-8191Ø-7 is stable within a segregating generation. All individual plants analyzed indicated the insertion is equivalent in all individuals within the generation and the ratio in the BC1F2 generation fit the expected 3 to 1 based on a single locus. The Southern blot results indicated an intact copy of the *aad*-12 and *pat* genes has been stably inserted into the cotton genome from across five generations.

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 DAS-8191Ø-7 have demonstrated that DAS-8191Ø-7 has not been altered in survival, multiplication or dissemination characteristics when compared to conventional cotton varieties. The trait for herbicide tolerance has no influence on cotton reproductive morphology and hence no changes in seed dissemination would be expected.

b) Dissemination

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

c) Survivability

Cotton is known to be a weak competitor in the wild, which cannot survive outside cultivation without human intervention. Field observations have demonstrated that DAS-8191Ø-7 has not been altered in its survivability when compared to conventional cotton.

d) Other differences

Comparative assessments in the field did not reveal any biologically significant differences between DAS-8191Ø-7 and conventional cotton varieties, 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 DAS-8191Ø-7 has a genetic transfer function. Therefore, no changes are expected in the ability of these cotton 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-8191Ø-7 varieties in the E.U.

4 COMPARATIVE ANALYSIS

4.1 Choice of the conventional counterpart and additional comparators

DAS-8191Ø-7 was compared with a conventional control cotton with similar genetic background, as well as with other commercially available cotton varieties.

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

DAS-8191Ø-7 and the conventional control cotton were grown at ten field sites in major cotton-growing areas of the U.S.A. during the 2010 field season.

The compositional study compared DAS-8191Ø-7 to the Non-transgenic near-isogenic control cotton . Reference lines were grown in the same field locations and under the same conditions as the test and control. Where statistical differences occurred, the measured analyte was compared to reference ranges 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 cotton), in addition to other selected compounds.

Based on the positive results of these extensive, compositional analyses conducted for DAS-8191Ø-7 compared to conventional cotton varieties, there is no indication to further analyze other selected compounds in this cotton.

4.4 Comparative analysis of agronomic and phenotypic characteristics

Field trials with DAS-8191Ø-7 were performed and the set of agronomic observations supports a conclusion that from an agronomic and phenotypic (morphological) point of view, DAS-8191Ø-7 is equivalent to conventional cotton, except for tolerance to application of 2,4-D and glufosinate-ammonium herbicides.

4.5 Effect of processing

Cotton is converted into a diverse range of food and feed products and derivatives used as food and feed ingredients or additives. As DAS-8191Ø-7 is substantially equivalent and as safe and as nutritious as conventional cotton, the use of DAS-8191Ø-7 cotton grain for the production of foods and feeds is no different from that of conventional cotton. Consequently, any effects of the production and processing of DAS-8191Ø-7 cotton grain are not expected to be any different from the production and processing of the equivalent foods and feeds, originating from conventional cotton.

5 TOXICOLOGY

a) Toxicological testing of newly expressed proteins

DAS-8191Ø-7 expresses the AAD-12 and PAT proteins. The conclusion of safety to humans of these proteins was based upon the following considerations:

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

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

It is therefore highly unlikely that the AAD-12 and PAT proteins would cause any toxic effects on human or animal health.

b) Testing of new constituents other than proteins

Since cotton 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-8191Ø-7 was shown to be substantially equivalent to conventional cotton, no testing of any constituent other than the inherited proteins are indicated.

c) Information on natural food and feed constituents

Cotton 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 cotton are considered to be of significant concern to require additional information or further risk assessment.

d) Testing of the whole GM food/feed

Evaluation of the nutrient composition of DAS-8191Ø-7 cotton proved its equivalency to non-GM control cotton with comparable genetic background and to representative commercial lines. In addition it's been shown that the AAD-12 and PAT proteins expressed in DAS-8191Ø-7 cotton are safe for humans, animal health and the environment. On that basis, no additional studies are required.

6. ALLERGENICITY

a) Assessment of allergenicity of the newly expressed protein

The AAD-12 and PAT 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 DAS-8191Ø-7. Taken together, these data lead to the conclusion that the AAD-12 and PAT proteins are unlikely to have any allergenic potential; hence, DAS-8191Ø-7 is as safe as conventional cotton regarding the risk for allergenicity.

b) Assessment of allergenicity of the whole GM plant

Compositional analyses, comparative phenotypic assessments and animal feeding studies have demonstrated that DAS-8191Ø-7 is substantially equivalent to traditional cotton, with the exception of the AAD-12 and PAT proteins (which are unlikely to have any allergenic potential).

7. NUTRITIONAL ASSESSMENT

a) Nutritional assessment of GM food

The introduced traits in DAS-8191Ø-7 are of agronomic interest, and are not intended to change any nutritional aspects of this cotton. Hence this cotton 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 cotton-derived foods and feeds is not expected to be altered upon commercialisation of DAS-8191Ø-7 cotton grain, and no nutritional imbalances are expected as a result of the

use of DAS-8191Ø-7 cotton grain.

b) Nutritional assessment of GM feed

As discussed throughout this application, animal feed products from DAS-8191Ø-7 cotton are substantially equivalent to, nutritionally equivalent to, and as safe as feed commercial cotton.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

There are no anticipated changes in the intake and/or extent of use of cotton or derived products for use as such or in food or feed as a result of the addition of DAS-8191Ø-7 cotton grain to the conventional cotton supply. DAS-8191Ø-7 cotton grain is expected to replace a portion of current cotton varieties such that their intake or use will represent some fraction of the total products derived from cotton.

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

Assessments show that DAS-8191Ø-7 demonstrates agronomic, phenotypic and compositional equivalence to non-transgenic cotton. It has also been established that it is highly unlikely that AAD-12 and PAT proteins will be toxic or allergenic making it negligible that DAS-8191Ø-7 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 DAS-8191Ø-7 was conducted on the basis of its substantial equivalence to conventional cotton (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-12 and PAT proteins.

The pre-market risk characterisation for food and feed use of DAS-8191Ø-7 demonstrates that the risks of consumption of DAS-8191Ø-7 or its derived products are consistently negligible and no different from the risks associated with the consumption of conventional cotton and cotton-derived products.

As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of this cotton 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

Not applicable since DAS-8191Ø-7 expresses the AAD-12 and PAT proteins, which confer tolerance to application of 2,4-D and glufosinate-ammonium herbicides - there are no target organisms for the AAD-12 and PAT protein.

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 cotton, the likelihood of DAS-8191Ø-7 spreading in the environment is negligible, as cotton is neither persistent nor invasive and these

parameters are unaltered in DAS-8191Ø-7 when compared to conventional cotton. In the unlikely event of the establishment of DAS-8191Ø-7 plants in the environment, the introduced traits would confer only a limited selective advantage of tolerance to application of 2,4-D and glufosinate-ammonium herbicides. of short duration, narrow spatial context and with negligible consequences for the environment. Hence, the risk of establishment and spreading of DAS-8191Ø-7 cotton grain into the environment is negigible.

b) Selective advantage or disadvantage

Compared with conventional cotton, the presence of the introduced traits in DAS-8191Ø-7 would only confer a meaningful advantage under specific conditions, i.e. where plants would be treated with 2,4-D and glufosinate-ammonium herbicides; if no other more important factors limiting its survival in the environment were present. This introduced "advantage" is only relevant in agricultural habitats (i.e. in cotton fields) and is short in duration. The risk of 2,4-D and glufosinate-ammonium tolerance traits in DAS-8191Ø-7 to be the cause of any adverse effects resulting from a competitive advantage or disadvantage is negligible, as cotton 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 cotton, these advantages present negligible risk to the agricultural environment.

c) Potential for gene transfer

DAS-8191Ø-7 is unchanged in its potential for gene transfer compared to conventional cotton. There is no potential for gene transfer from DAS-8191Ø-7 to wild plant species in the E.U. and negligible likelihood for gene transfer to other cotton crops, as this application is not for consent to cultivate DAS-8191Ø-7 varieties 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, processing and food and feed use of DAS-8191Ø-7 will result in plants of this cotton being present in the environment at meaningful levels, it is not expected that organisms will be exposed to the AAD-12 and PAT proteins. As this is a herbicide tolerance trait only, there are no specific target organisms.

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

Given the scope of the current application, which does not include the cultivation of DAS-8191Ø-7 varieties in the E.U., the likelihood for direct or indirect interactions of these cotton 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 DAS-8191Ø-7 grain during import, storage, transport or use would lead to the short survival of DAS-8191Ø-7 plants in the environment. As a consequence, there is negligible risk for harmful effects of DAS-8191Ø-7 on non-target organisms, either through direct or indirect interactions with this cotton or through contact with the newly expressed protein.

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

f) Effects on human health

The likelihood for any adverse effects, occurring in humans as a result of their contact with this cotton, is no different from conventional cotton. DAS-8191Ø-7 expresses the AAD-12 and PAT 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 cotton is negligible.

g) Effects on animal health

The likelihood of potential adverse effects in animals fed on DAS-8191Ø-7 and in humans, consuming those animals, is negligible. Therefore, the risk of DAS-8191Ø-7 for the feed/food chain is also negligible.

h) Effects on biogeochemical processes

There is no evidence that DAS-8191Ø-7 plants would be any different from conventional cotton regarding their direct influence on biogeochemical processes or nutrient levels in the soil, as DAS-8191Ø-7 is compositionally equivalent and has equivalent growth and development, conventional cotton.

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

Not applicable. This application is for consent to import DAS-8191Ø-7 cotton grain in the E.U. and for the use of these cotton lines as any other cotton, excluding the cultivation of varieties in the E.U.

11.3 Potential interactions with the abiotic environment

No adverse impact of DAS-8191Ø-7 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-12 and PAT proteins are introduced proteins in cotton, they already have a safe history and have no known negative interactions with the abiotic environment. The *Zea mays*, *Delftia acidovorans* and *Streptomyces viridochromogenes* from which the AAD-12 and PAT proteins are derived are either a domesticated crop or common soil microbes, widespread in nature and found all over the world. The AAD-12 and PAT proteins are innocuous and belong to a class of enzymes that are ubiquitous in nature. The family of AAD-12 and PAT 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 DAS-8191Ø-7 and that cultivation of DAS-8191Ø-7 cotton varieties in the EU is not planned; any exposure to the environment from the import of DAS-8191Ø-7 cotton will be limited to unintended release via spillage during transportation of the grain. There are no target organisms for the AAD-12 and PAT proteins expressed in DAS-8191Ø-7, which confers tolerance to certain herbicides

Therefore, the likelihood that the import and use of DAS-8191Ø-7 for food, feed or processing will result in plants of this cotton 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 DAS-8191Ø-7 has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The structure of the monitoring plan also takes into account the guidance on presentation of applications provided in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment

of genetically modified plants and derived food and feed.

b) Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) was carried out for DAS-8191Ø-7 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-8191Ø-7 in the e.r.a. (Section E.3) has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of DAS-8191Ø-7 cotton grain.

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

The scientific evaluation of the characteristics of DAS-8191Ø-7 in the e.r.a. has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses. It is therefore considered that there is no need for case-specific monitoring.

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

In accordance with Council Decision 2002/811/EC, general surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the e.r.a.

The authorisation holders are not involved in commodity trade with DAS-8191Ø-7 cotton 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-8191Ø-7 cotton grain. They are exposed to the imported viable DAS-8191Ø-7 cotton grain and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use.

The general surveillance information reported to and collected by the authorisation holders from the European trade associations or other sources will be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder will immediately investigate to determine and confirm whether a significant correlation between the effect and DAS-8191Ø-7 cotton grain can be established. If the investigation establishes that DAS-8191Ø-7 cotton grain was present when the adverse effect was identified, and confirms that DAS-8191Ø-7 cotton grain is the cause of the adverse effect, the authorisation holders will immediately inform the European Commission, as described in Section E.4.3.4.

e) Reporting the results of the monitoring

The authorisation holders will submit an annual monitoring report containing information obtained from participating networks, and/or in case of an effect that was confirmed. If information that confirms an adverse effect which alters the existing risk assessment becomes available, Dow AgroSciences LLC and M.S. Technologies 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

The PCR detection methods to confirm the molecular identity of DAS-8191Ø-7 cotton along with complementary information and samples of DAS-8191Ø-7 cotton and non-GM cotton 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 and M.S. Technologies to develop certified reference materials for DAS-8191Ø-7 cotton. 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-irmmgmo@ec.europa.eu. Detailed information on these materials is given in the IRMM certification reports and sample certificates, posted on the IRMM website.

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

N/A

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

N/A

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

a) Release country

DAS-8191Ø-7 has been field tested in the U.S.A. in 2008, 2009, 2010 and 2011. It has also been field tested in Japan and Brazil In 2011.

b) Authority overseeing the release

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

Japan: Ministry of Agriculture, Foresty, and Fisheries (MAFF)

Brazil: Ministry of Science and Technology, National Technical Commission of Biosafety (CTNBio)

c) Release site

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

Canada: Multiple sits in cotton producing provinces of Canada.

Japan: Dow AgroSciences Ogori Development Center.

Argentina: Multiple sites in cotton producing regions of Argentina.

Brazil: Multiple sites in cotton producing regions of Brazil.

Chile: Multiple sites near Rancagua, south of Santiago.

d)	**Aim of the release** U.S.A.: assess performance, efficacy, variety evaluation, seed production, yield, and collection of regulatory data. Japan: collection of regulatory data. Brazil: assess performance, efficacy, variety evaluation, yield, and collection of regulatory data.
e)	**Duration of the release** 12 months per release
f)	**Aim of post-releases monitoring** Assessment/removal of volunteers
g)	**Duration of post-releases monitoring** 12 months per release.
h)	**Conclusions of post-release monitoring** Volunteers have been eliminated to prevent potential persistence in the environment.
i)	**Results of the release in respect to any risk to human health and the environment** No evidence that DAS-8191Ø-7 is likely to cause any adverse effects to human or animal health or the environment.

7.5 Product specification

DAS-8191Ø-7 cotton grain will be imported into the E.U. in mixed shipments of cotton grain and products, produced in other world areas, for use by operators that have traditionally been involved in the commerce, processing and use of cotton and cotton 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[1] 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-8191Ø-7 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-8191Ø-7, 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[2].

e) Molecular Register of the Community Reference Laboratory/Joint Research Centre

Information on detection protocols can be found on the JRC website[3].

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-8191Ø-7. The EFSA website[4] does provide a link to this summary of the application for DAS-8191Ø-7 under Regulation (EC) No 1829/2003.

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