Application for authorisation of DAS-68416-4 soybean grain for all uses as for any other soybean, excluding cultivation, according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-NL-2011-XX

Part II
Summary

A. GENERAL INFORMATION

1. Details of application

a) Member State of application

The Netherlands

b) Notification number

EFSA-GMO-NL-2011-XX

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

The development code for this genetically modified soybean is: DAS-68416-4. In countries where DAS-68416-4 will be cultivated, packages of this soybean 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

9330 Zionsville Road
Indianapolis, Indiana 46268-1054
U.S.A.

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-68416-4 soybean grain will be traded and used in the E.U. in the same manner as current commercial soybean varieties and by the same operators currently involved in the trade and use of conventional soybean.

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.

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 soybean (*Glycine max*), which is extensively cultivated and has a long history of safe use. The DAS-68416-4 soybean 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 aryloxyalkanoate herbicides (such as 2,4-D) and glufosinate-ammonium.

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-68416-4 soybean grain equivalent to the uses of any other soybean grain.

c) Intended use of the product and types of users

DAS-68416-4 soybean grain, will be traded and used in the E.U. in the same manner as current commercial soybean varieties and by the same operators currently involved in the trade and use of conventional soybean.

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-68416-4 soybean grain, for import, processing, and use as such or in food and feed. DAS-68416-4 is substantially equivalent to other soybean varieties except for its tolerance to application of aryloxyalkanoate herbicides (such as 2,4-D) and glufosinate-ammonium, which is a trait of agronomic interest. DAS-68416-4 was shown to be as safe and as nutritious as conventional soybean. Therefore DAS-68416-4 and derived products will be stored, packaged, transported, handled and used in the same manner as the commercial soybean products.

e) Any proposed packaging requirements

DAS-68416-4 is substantially equivalent to conventional soybean varieties (except for its tolerance to application of aryloxyalkanoate herbicides (such as 2,4-D) and glufosinate-ammonium. Therefore, DAS-68416-4 and derived products will be

used in the same manner as other soybean 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-68416-4 grain and derived products.

Operators shall be required to label products containing or consisting of DAS-68416-4 soybean grain with the words "genetically modified soybean" or "contains genetically modified soybean", 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-68416-4 soybean grain with the words "produced from genetically modified soybean". 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-68416-4 soybean 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-68416-4 soybean grain. Therefore, no further specific measures are to be taken by the applicant for DAS-68416-4 soybean 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-68416-4.

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-68416-4 soybean 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-68416-4 soybean grain, as any other soybean, not including the cultivation of DAS-68416-4 hybrids, environmental release would be more likely to occur during import, storage and processing of DAS-68416-4 soybean 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-68416-4 in the E.U. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since soybean cannot survive without human assistance and is not capable of surviving as a weed. Although soybean seed can over-winter in mild conditions and can germinate the following year, the appearance of soybean in rotational fields is rare under European conditions. Soybean 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-68416-4 is unlikely to be different from other soybean 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-68416-4 soybean 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** Leguminosae
b)	**Genus** *Glycine*
c)	**Species** *Glycine max*
d)	**Subspecies** N/A
e)	**Cultivar/breeding line** DAS-68416-4
f)	**Common name** Soybean

2. a) Information concerning reproduction

(i)	***Mode(s) of reproduction*** Soybean is considered a self-pollinated species, propogated commercially by seed.
(ii)	***Specific factors affecting reproduction*** The seed will germinate when the soil temperature reaches 10 ^{o}C and will emerge in a 5-7 day period under favourable conditions. In new areas of soybean production an inoculation with Bradyrhizobium japonicum is necessary, for optimum efficiency of the nodulated root system.
(iii)	***Generation time*** From seeding to maturity, soybean passes through various growth stages (e.g., germination — seedling stage, third true-leaf stage); the entire growing period is 120–140 days.

2 b) Sexual compatibility with other cultivated or wild plant species

Gene transfer between cultivated soybean and wild species of subgenus Soja may occur, but not in Europe, where the wild relatives of subgenus Soja are not present.

3. Survivability

a) Ability to form structures for survival or dormancy

Cultivated soybean seed rarely displays any dormancy characteristics and only under certain environmental conditions grows as a volunteer in the year following cultivation.

b) Specific factors affecting survivability

Soybean is a quantitative short day plant and hence flowers more quickly under short days. As a result, photoperiodism and temperature response are important in determining areas of cultivar adaptation.

4. Dissemination

a) Ways and extent of dissemination

In general, dissemination of soybean may occur by means of seed dispersal and pollen dispersal. Dispersal of the soybean grain is highly restricted in domesticated soybean due to the ear structure including husk enclosure. For soybean 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 DAS-68416-4 hybrids in the E.U.

b) Specific factors affecting dissemination

In theory, soybean dissemination may occur by means of seed dispersal or pollen dispersal. However, during soybean harvesting, there are few seed lost due to the relatively large seed size. Furthermore, neither the soybean seedpod, nor the seed have morphological characteristics that would facilitate animal transportation.

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

Soybean can only cross with other members of Glycine subgenus Soja. The potential for such gene flow is limited by geographic isolation and by the fact that they are highly self-pollinating species. Wild soybean species are endemic in China, Korea, Japan, Taiwan and the former USSR, and do not exist naturally in the EU.

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

Soybeans are grown in the EU commercially.

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 soybean plant to humans, animals or livestock; it has a history of safe use for human food and animal feed. However, soybean 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

Transgenic soybean (*Glycine max*) DAS-68416-4 was generated through *Agrobacterium*-mediated transformation, using the disarmed *Agrobacterium tumefaciens* strain EHA101 carrying the binary vector pDAB4468 that lead to the transfer and insertion of its TDNA into the genome of cells from soybean cotyledonary node explants.

2. Nature and source of the vector used

The vector pDAB4468 is a binary one derived from *Agrobacterium tumefasciens*.

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

Location on T-DNA insert of pDAB4468[1]	***Genetic Element***	***Size (base pairs)***	***Description***
1−24	T-DNA Border B	24	Transferring DNA sequences
25−160	Intervening sequence	136	Sequence from Ti plasmid pTi15955 (Barker et al., 1983)
161−1326	RB7-MAR	1166	Matrix attachment region (MAR) from *Nicotiana tabacum* (Hall et al., 1991)
1327−1421	Intervening sequence	95	Sequence from plasmid pENTR/D-TOPO (Invitrogen Cat. No. A10465) and multiple cloning sites
1422−2743	AtUbi10	1322	*Arabidopsis thaliana* polyubiquitin UBQ10 comprising the promoter, 5' untranslated region and intron (Norris et al., 1993)
2744−2751	Intervening sequence	8	Sequence used for DNA cloning
2752−3633	aad-12	882	Synthetic, plant-optimized version of an aryloxyalkanoate dioxygenase gene from *Delftia acidovorans* (Wright et al., 2007)
3634−3735	Intervening sequence	102	Sequence used for DNA cloning
3736−4192	AtuORF23	457	3' untranslated region (UTR) comprising the transcriptional terminator and polyadenylation site of open reading frame 23 (ORF23) of *Agrobacterium tumefaciens* pTi15955 (Barker et al., 1983)
4193−4306	Intervening sequence	114	Sequence from plasmid pENTR/D-TOPO (Invitrogen Cat. No. A10465) and multiple cloning sites
4307−4819	CsVMV	513	Promoter and 5' untranslated region derived from the cassava vein mosaic virus (Verdaguer et al., 1996)

4820−5371	pat	552	Synthetic, plant-optimized version of phosphinothricin N-acetyl transferase (PAT) gene, isolated from *Streptomyces viridochromogenes* (Wohlleben et al., 1988)
5372−5484	Intervening sequence	113	Sequence from plasmid pCRI2.1(Invitrogen Cat. No. K205001) and multiple cloning sites

D. INFORMATION RELATING TO THE GM PLANT

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

DAS-68416-4 soybean expresses the AAD-12 and PAT proteins, derived from *Delftia acidovorans* and *Streptomyces viridochromogenes*, providing tolerance to application of aryloxyalkanoate herbicides (such as 2,4-D) and glufosinate-ammonium, respectively.

Commercialisation of DAS-68416-4 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-68416-4 soybean contains a single, intact copy of the *aad-12* and *pat* expression cassette from plasmid pDAB4468. The event is stably integrated and inherited across and within breeding generations, and no plasmid backbone sequences are present in DAS-68416-4 soybean.

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-68416-4 is located in the nuclear genome as determined by Southern blot analyses and DNA sequencing.

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

The DAS-68416-4 insertion as well as the 5' and 3' flanking genomic regions of the DAS-68416-4 soybean insertion have been sequenced and characterised in detail. PCR analysis of the DNA flanking the DAS-68416-4 soybean insertion confirmed that both regions correspond to soybean 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-12 and PAT proteins has been determined in a range of DAS-68416-4 soybean tissues representing key developmental stages of a typical soybean plant. Expression was characterised using a specific Enzyme Linked Immunosorbent Assay (ELISA) system 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-68416-4 soybean and in all plant parts of the DAS-68416-4 soybean, including the DAS-68416-4 soybean

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-68416-4. 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-68416-4 have demonstrated that DAS-68416-4 has not been altered in survival, multiplication or dissemination characteristics when compared to conventional soybean varieties. The trait for herbicide tolerance has no influence on soybean reproductive morphology and hence no changes in seed dissemination would be expected.

b) Dissemination

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

c) Survivability

Soybean is known to be a weak competitor in the wild, which cannot survive outside cultivation without human intervention. Field observations have demonstrated that DAS-68416-4 has not been altered in its survivability when compared to conventional soybean.

d) Other differences

Comparative assessments in the field did not reveal any biologically significant differences between DAS-68416-4 and conventional soybean varieties, 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-68416-4 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 BC3S1 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 soybean genome from across five generations.

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-68416-4 has a genetic transfer function. Therefore, no changes are expected in the ability of these soybean 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-68416-4 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-68416-4 was compared with a conventional control soybean with similar genetic background, as well as with other commercially available soybean hybrids.

7.2 Production of material for comparative assessment

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

DAS-68416-4 and the conventional control soybean were grown at eight field sites in major soybean-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-68416-4 to the control. 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 ILSI ranges and ranges reported in literature.

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 soybean), in addition to other selected compounds.

Based on the positive results of these extensive, compositional analyses conducted for DAS-68416-4 compared to conventional soybean varieties, there is no indication to further analyze other selected compounds in this soybean.

7.4 Agronomic traits

Field trials with DAS-68416-4 were performed and the set of agronomic observations supports a conclusion that from an agronomic and phenotypic (morphological) point of view, DAS-68416-4 is equivalent to conventional soybean, except for tolerance to application of aryloxyalkanoate herbicides (such as 2,4-D) and glufosinate-ammonium.

7.5 Product specification

DAS-68416-4 soybean grain will be imported into the E.U. in mixed shipments of soybean grain and products, produced in other world areas, for use by operators

that have traditionally been involved in the commerce, processing and use of soybean and soybean derived products in the E.U.

7.6 Effect of processing

Soybean is converted into a diverse range of food and feed products and derivatives used as food and feed ingredients or additives. As DAS-68416-4 is substantially equivalent and as safe and as nutritious as conventional soybean, the use of DAS-68416-4 soybean grain for the production of foods and feeds is no different from that of conventional soybean. Consequently, any effects of the production and processing of DAS-68416-4 soybean grain are not expected to be any different from the production and processing of the equivalent foods and feeds, originating from conventional soybean.

7.7 Anticipated intake/extent of use

There are no anticipated changes in the intake and/or extent of use of soybean or derived products for use as such or in food or feed as a result of the addition of DAS-68416-4 soybean grain to the conventional soybean supply. DAS-68416-4 soybean grain are expected to replace a portion of current soybean hybrids such that their intake or use will represent some fraction of the total products derived from soybean.

7.8 Toxicology

DAS-68416-4 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.

7.8.2 Testing of new constituents other than proteins

Since soybean 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-68416-4 was shown to be substantially equivalent to conventional soybean, no testing of any constituent other than the inherited proteins are indicated.

7.8.3 Information on natural food and feed constituents

Soybean 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 soybean 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-68416-4 and conventional soybean have been established by compositional analysis. Additionally, the wholesomeness of DAS-68416-4 grain has been confirmed by a repeat-dose animal feeding study in broiler chickens using diets containing grain from DAS-68416-4 soybean.

7.9 Allergenicity

7.9.1 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 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-68416-4. Taken together, these data lead to the conclusion that the AAD-12 and PAT proteins are unlikely to have any allergenic potential; hence, DAS-68416-4 is as safe as conventional soybean regarding the risk for allergenicity.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Compositional analyses, comparative phenotypic assessments and animal feeding studies have demonstrated that DAS-68416-4 is substantially equivalent to traditional soybean, with the exception of the introduced *aad-12* and *pat* genes (which are unlikely to have any allergenic potential).

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The introduced traits in DAS-68416-4 are of agronomic interest, and are not intended to change any nutritional aspects of this soybean. Hence this soybean 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 soybean-derived foods and feeds is not expected to be altered upon commercialisation of DAS-68416-4 soybean grain, and no nutritional imbalances are expected as a result of the use of DAS-68416-4 soybean 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-68416-4 grain and conventional control grain as well as commercial soybean hybrids, and to provide confirmation of the safety of this soybean. The results of this study show that there were no biologically relevant differences in the parameters tested between broiler chickens fed the DAS-68416-4 diet and the conventional control diet. The DAS-68416-4 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-68416-4, which showed that there were no biologically relevant differences in nutritional and compositional properties relative to control and reference soybean hybrids. These data confirm and support the conclusion that the DAS-68416-4 is as safe and nutritious as conventional soybean.

7.11 Post-market monitoring of GM food/feed

The assessment of the human and animal safety of DAS-68416-4 was conducted on the basis of its substantial equivalence to conventional soybean (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 protein.

There are no intrinsic hazards related to DAS-68416-4 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-68416-4 demonstrates that the risks of consumption of DAS-68416-4 or its derived products are consistently negligible and no different from the risks associated with the consumption of conventional soybean and soybean-derived products.

As a consequence, specific risk management measures are not indicated, and post-market monitoring of the use of this soybean 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-68416-4 expresses the AAD-12 and PAT proteins, which confer tolerance to application of aryloxyalkanoate herbicides (such as 2,4-D) and glufosinate-ammonium - there are no target organisms for the AAD-12 and PAT 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 soybean.

9.1 Persistence and invasiveness

Like for conventional soybean, the likelihood of DAS-68416-4 spreading in the environment is negligible, as soybean is neither persistent nor invasive and these parameters are unaltered in DAS-68416-4 when compared to conventional soybean. In the unlikely event of the establishment of DAS-68416-4 plants in the environment, the introduced traits would confer only a limited selective advantage tolerance to application of aryloxyalkanoate herbicides (such as 2,4-D) and glufosinate-ammonium) of short duration, narrow spatial context and with negligible consequences for the environment. Hence, the risk of establishment and

spreading of DAS-68416-4 soybean grain.

9.2 Selective advantage or disadvantage

Compared with conventional soybean, the presence of the introduced traits in DAS-68416-4 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 soybean fields) and is short in duration. The risk of 2,4-D and glufosinate-ammonium -tolerance traits in DAS-68416-4 to be the cause of any adverse effects resulting from a competitive advantage or disadvantage is negligible, as soybean 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 soybean, these advantages present negligible risk to the agricultural environment.

9.3 Potential for gene transfer

DAS-68416-4 is unchanged in its potential for gene transfer compared to conventional soybean. There is no potential for gene transfer from DAS-68416-4 to wild plant species in the E.U. and negligible likelihood for gene transfer to other soybean crops, as this application is not for consent to cultivate DAS-68416-4 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-68416-4 will result in plants of this soybean being present in the environment at meaningful levels, it is not expected that the target organisms will be exposed to the AAD-12 and PAT proteins.

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-68416-4 hybrids in the E.U., the likelihood for direct or indirect interactions of these soybean 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-68416-4 grain during import, storage, transport or use would lead to the short survival of DAS-68416-4 plants in the environment. As a consequence, there is negligible risk for harmful effects of DAS-68416-4 on non-target organisms, either through direct or indirect interactions with this soybean 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 soybean, is no different from conventional soybean. DAS-68416-4 expresses the AAD-12 and PAT protein, 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 soybean is negligible.

9.7 Effects on animal health

The likelihood of potential adverse effects in animals fed on DAS-68416-4 and in humans, consuming those animals, is negligible. Therefore, the risk of DAS-68416-4 for the feed/food chain is also negligible.

9.8 Effects on biogeochemical processes

There is no evidence that DAS-68416-4 plants would be any different from conventional soybean regarding their direct influence on biogeochemical processes or nutrient levels in the soil, as DAS-68416-4 is compositionally equivalent and has equivalent growth and development, conventional soybean. 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 AAD-12 and PAT proteins are subjected to rapid degradation in soil.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable. This application is for consent to import DAS-68416-4 soybean grain in the E.U. and for the use of these soybean lines as any other soybean, excluding the cultivation of hybrids in the E.U.

10. Potential interactions with the abiotic environment

No adverse impact of DAS-68416-4 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 soybean, they already have a safe history and have no known negative interactions with the abiotic environment. The *Delftia acidovorans* and *Streptomyces viridochromogenes* species from which the AAD-12 and PAT proteins are derived is a common soil microbe, 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. 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-68416-4 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).

11.2 Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) was carried out for DAS-68416-4

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-68416-4 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-68416-4 soybean grain.

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

The scientific evaluation of the characteristics of DAS-68416-4 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-68416-4 soybean 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-68416-4 soybean grain. They are exposed to the imported viable DAS-68416-4 soybean 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-68416-4 soybean grain can be established. If the investigation establishes that DAS-68416-4 soybean grain were present when the adverse effect was identified, and confirms that DAS-68416-4 soybean 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 methods to confirm the molecular identity of DAS-68416-4 soybean along with complementary information and samples of DAS-68416-4 soybean and non-GM soybean 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-68416-4 soybean. 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.

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-68416-4 has been field tested in the U.S.A. and Canada in 2008, 2009, and 2010. It has also been field tested in Japan in 2009, Argentina beginning in 2009 and in Brazil and Chile beginning in 2010.

b) Authority overseeing the release

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

Canada: Canadian Food Inspection Agency (CFIA)

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

Argentina: National Advisory Committee of Agricultural Biosafety (CONABIA)

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

c) Release site

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

Canada: Multiple sits in soybean producing provinces of Canada.

Japan: Dow AgroSciences Ogori Development Center.

Argentina: Multiple sites in soybean producing regions of Argentina.

Brazil: Multiple sites in soybean 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.

Canada: assess performance, efficacy, variety evaluation, yield, and collection of regulatory data.

Japan: collection of regulatory data.

Argentina: assess performance, efficacy, variety evaluation, yield, and collection of regulatory data.

Brazil: assess performance, efficacy, variety evaluation, yield, and collection of regulatory data.

Chile: assess performance, variety evaluation, yield.

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-68416-4 is likely to cause any adverse effects to human or animal health or 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[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-68416-4 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-68416-4, 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-68416-4. The EFSA website[4] does provide a link to this summary of the application for DAS-68416-4 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