PART II

SUMMARY

SUMMARY OF THE APPLICATION FOR THE AUTHORISATION OF GENETICALLY MODIFIED 356043 SOYBEAN AND DERIVED FOOD AND FEED IN ACCORDANCE WITH REGULATION (EC) 1829/2003

A. GENERAL INFORMATION

1. Details of application

(a) Member State of application:

United Kingdom

(b) Application number:

EFSA-GMO-UK-2007-XX

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

The commercial name assigned to genetically modified 356043 soybean in the US market is Optimum™ GAT™ Soybean[1].

In accordance with Commission Regulation (EC) 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identification code assigned to 356043 soybean is DP-356Ø43-5.

(d) Date of acknowledgment of valid application:

[To be provided]

2. Applicant

(a) Name of applicant

Pioneer Hi-Bred International, Inc., as represented by Pioneer Overseas Corporation.

[1] Optimum™ and GAT™ are trademarks of Pioneer Hi-Bred International, Inc.

(b) Address of applicant

Pioneer Hi-Bred International, Inc.
7100 NW 62nd Avenue
P.O. Box 1014B-1040
Johnston, IA 50131-1014 (U.S.A.)

Pioneer Overseas Corporation
Avenue des Arts, 44
Brussels
Belgium

(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))

Same as applicant

3. Scope of the application

√ **GM plants for food use**
√ **Food containing or consisting of GM plants**
√ **Food produced from GM plants or containing ingredients produced from GM plants**
√ **GM plants for feed use**
√ **Feed containing or consisting of GM plants**
√ **Feed produced from GM plants**
√ **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)?

No

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

No

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

The scope of this application does not include authorisation for the cultivation of 356043 soybean seed products.

A detailed environmental risk assessment (e.r.a.) for this application has been carried out in accordance with Annex II of Directive 2001/18/EC and Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The overall conclusion obtained from the e.r.a. confirms that there are no identified adverse effects to human and animal health or the

environment arising from the proposed uses of 356043 soybean. Please refer to **Points D.7., D.8., D.9.** and **D.10.** below.

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?

No

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

Yes, notifications concerning all uses of 356043 soybean, including cultivation of 356043 soybean seed products, have been submitted in the US and Canada. Applications for authorisation to import for all uses of 356043 soybean have also been submitted in Mexico and are being prepared for other countries around the world.

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* (L.) Merill) which is extensively cultivated and has a long history of safe use. The 356043 soybean has been genetically modified to express the GAT4601 and GM-HRA proteins[2]. The GAT4601 protein is a glyphosate acetyltransferase (GAT), encoded by an optimized form of the *gat* gene from *Bacillus licheniformis*, that confers tolerance to the herbicide glyphosate. The GM-HRA protein is an acetolactate synthase (ALS), encoded by an optimized form of the endogenous *als* gene from *Glycine max*, that confers tolerance to ALS-inhibiting herbicides such as chlorimuron and thifensulfuron.

(b) Types of products planned to be placed on the market according to the authorisation applied for

The product described in this application is 356043 soybean for all food and feed uses, and for all food, feed and processed products derived from 356043 soybean.

(c) Intended use of the product and types of users

The intended use of 356043 soybean will be consistent with current uses of commercial soybean products and 356043 soybean will be used in the EU as any other soybean. Therefore, there are multiple categories of users of 356043 soybean, including the animal feed and milling industry, skilled trades and consumer use by public at large. The scope of this application does not include authorisation for the cultivation of 356043 soybean seed products.

[2] Please note that *gm-hra* stands for *Glycine max hra* gene and GM-HRA stands for *Glycine max* HRA protein.

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

The 356043 soybean is nutritionally equivalent to any other commercial soybean and use of 356043 soybean products will be consistent with current uses of other commercial soybean products. Labelling of 356043 soybean products will be carried out in accordance with Community law. See **Point A.8.f)** below for a proposal for labelling 356043 soybean.

(e) Any proposed packaging requirements

The packaging, handling, and storage systems that are currently used for soybean will apply. The 356043 soybean products will be packaged in the same manner as other commercial soybean products. See **Point A.8.f)** below for a proposal for labelling 356043 soybean.

(f) A proposal for labelling in accordance with Articles 13 and Articles 25 of Regulation (EC) 1829/2003. In the case of GMOs, food and/or feed containing or consisting of GMOs, a proposal for labelling has to be included complying with the requirements of Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC

1.- PROPOSAL FOR THE LABELLING OF 356043 SOYBEAN FOOD PRODUCTS ACCORDING TO ARTICLES 12 AND 13 OF REGULATION (EC) 1829/2003

Proposal for the labelling of 356043 soybean food products

In accordance with Article 12(2) of Regulation No (EC) 1829/2003, labelling shall apply except to foods containing material which contains, consists of or is produced from 356043 soybean in a proportion no higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient.

In accordance with Article 13 of Regulation (EC) 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods containing, consisting of, produced from, or containing ingredients produced from 356043 soybean, should be labelled as follows:

(a) where the food consists of more than one ingredient, the words ‘genetically modified’ or ‘produced from genetically modified soybean’ will appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned;

(b) where the ingredient is designated by the name of a category, the words ‘contains genetically modified soybean’ or ‘contains (name of ingredient) produced from genetically modified soybean’ will appear in the list of ingredients;

(c) where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified soybean' will appear clearly on the labelling;

(d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they will appear clearly on the labelling;

(e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm^2, the information referred to above will be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

No other particulars such as those referred to in Article 13(2)(a) and (b) and Article 13(3) of Regulation No (EC) 1829/2003 would need to be specified on the label of 356043 soybean food products as 356043 soybean has been shown to be equivalent to commercially available soybean in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 356043 soybean does not give rise to any ethical or religious concerns.

2.- PROPOSAL FOR THE LABELLING OF 356043 SOYBEAN FEED PRODUCTS ACCORDING TO ARTICLES 24 AND 25 OF REGULATION (EC) 1829/2003

Proposal for the labelling of 356043 soybean feed products

In accordance with Article 24(2) of Regulation No (EC) 1829/2003, labelling shall apply except to feed containing material which contains, consists of or is produced from 356043 soybean in a proportion no higher than 0.9% of the feed and of each feed of which it is composed.

In accordance with Article 25 of Regulation (EC) 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) of Regulation (EC) 1829/2003, *i.e.* 356043 soybean for feed use, and feed containing, consisting of or produced from 356043 soybean, should be labelled as follows:

(a) where the feed contains or consists of 356043 soybean, or where 356043 soybean is used for the purpose of feed use, the words 'genetically modified soybean' will appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed;

(b) where the feed is produced from 356043 soybean, the words 'produced from genetically modified soybean' will appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed;

No other particulars such as those referred to in Article 25(2)(c) and Article 25(3) of Regulation No (EC) 1829/2003 would need to be specified on the label of 356043 soybean feed products as 356043 soybean has been shown to be equivalent to commercially available soybean in composition; nutritional value and nutritional effects; intended use; health characteristics; and, the genetic modification in 356043 soybean does not give rise to any ethical or religious concerns.

3.- PROPOSAL FOR THE LABELLING OF PRODUCTS CONSISTING OF, OR CONTAINING, 356043 SOYBEAN ACCORDING TO ARTICLE 4, B(6) OF REGULATION (EC) 1830/2003 AND ANNEX IV OF DIRECTIVE 2001/18/EC

In accordance with Article 4, B(6) of Regulation (EC) 1830/2003 and Annex IV of Directive 2001/18/EC, the information provided on a label or in an accompanying document for the purpose of satisfying the labelling requirements of products consisting of, or containing, 356043 soybean will include the following:

i) Commercial name of the product;

ii) A statement that 'this product contains genetically modified soybean';

iii) Name of the GMO;

iv) Name and full address of the person established in the Community who is responsible for the placing on the market; and,

v) An indication on how to access the information in the publicly accessible part of the register.

(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)

In accordance with Commission Regulation (EC) 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identifier assigned to 356043 soybean is DP-356Ø43-5.

(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

Not applicable. The scope of this application does not include authorisation for the cultivation of 356043 soybean seed products.

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

Based on the conclusions from the environmental risk assessment for the placing on the market of 356043 soybean, no specific measures need to be taken in case of unintended release or misuse or for disposal and treatment.

In case of unintended release, misuse, disposal or treatment of 356043 soybean, current measures taken to control unintended release, misuse, disposal or treatment of commercially available soybean can be applied, such as selective use of herbicides (with the exception of glyphosate and ALS-inhibiting herbicides), and manual or mechanical removal.

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

1. Complete name

(a) Family name:	Leguminosae
(b) Genus:	*Glycine*
(c) Species:	*G. max* (L.) Merill
(d) Subspecies:	None
(e) Cultivar/breeding line or strain:	Jack
(f) Common name:	Soybean, soy

2 a. Information concerning reproduction

(i) Mode(s) of reproduction

Soybean is a self-pollinated species and reproduces through seeds. The soybean flower stigma is receptive to pollen approximately 24 hours before anthesis and remains receptive 48 hours after anthesis. The anthers mature in the bud and directly pollinate the stigma of the same flower. As a result, soybean exhibit a high percentage of self-fertilisation and cross-pollination is usually less than one percent.

(ii) Specific factors affecting reproduction

Soybean is not frost tolerant and does not survive freezing winter conditions. The seed will germinate when the soil temperature reaches 10°C and will emerge in a 5-7 day period under favourable conditions.

(iii) Generation time

Soybean is an annual crop with a cultural cycle ranging from 3 to 5 months depending on the variety and the area of production.

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

Soybean is sexually compatible only with other members of the *Glycine* subgenus *Soja*, including *G. soja* and *G. gracilis*. However, the potential for such gene flow is limited by geographic isolation. There are no wild plant species that are sexually compatible with soybean in the EU.

Soybean is a self-pollinated species that exhibits a high percentage of self-fertilisation. As a result, cross-pollination is usually less than one percent.

3. Survivability

(a) Ability to form structures for survival or dormancy

Soybean is not dormant and it is a not frost tolerant annual crop. Seeds are its only survival structures. Natural regeneration of soybean from vegetative tissue is not known to occur.

(b) Specific factors affecting survivability

Survival of soybean seed is dependent upon temperature, moisture of seed, genotype and stage of development. Soybean seed can only survive under favourable climatic conditions. Freezing temperatures have an adverse effect on germination of soybean seed and it has been identified as a major risk in limiting production of soybean seed. Also, soybean does not yield well on acid soils.

4. Dissemination

(a) Ways and extent of dissemination

Commercial soybean is propagated by seed and it presents very limited dissemination under natural conditions in non-agricultural environments. Dissemination by pollen is also unlikely since soybean is a self-pollinating crop.

(b) Specific factors affecting dissemination

Mechanical harvesting and transport are ways of disseminating grain. Insect and wind damage may also cause soybean seeds to fall to the ground and avoid harvest. However and regardless of these routes of dissemination, soybean seeds cannot survive without human assistance in non-agricultural environments.

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

Soybean is grown as a commercial crop in over 35 countries worldwide. The major producers are the USA, Argentina, Brazil and China. Soybean is also cultivated in the EU, mainly in Italy and Romania. There are no wild plant species sexually compatible with soybean 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

Not applicable. Soybean is cultivated in the EU.

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

Soybean has a long history of safe use and it is known to interact with other organisms in the environment including insects, birds, and mammals. It is also susceptible to a range of fungal diseases and insect pests, as well as to competition from surrounding weeds.

There is no food use for unprocessed soybean because it contains antinutrients such as trypsin inhibitors and lectins. However, the processing methods applied to soybean are well known and have a long history of safety. In fact, soybean is one of the oldest cultivated crops.

Soybean contains a number of protein allergens that have been isolated and characterized in detail.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification

The 356043 soybean was produced by the particle acceleration method. A linear DNA fragment (insert PHP20163A) containing the *gat4601* and *gm-hra* coding sequences and the necessary regulatory components was inserted into soybean plant cells.

2. Nature and source of the vector used

No vector was used in the production of 356043 soybean.

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

The insert PHP20163A used in the transformation of 356043 soybean consisted of:

i) The *gat4601* gene (0.4 kb), an optimized form of the *gat* gene from *Bacillus licheniformis*, with transcription regulated by a synthetic constitutive promoter (0.4 kb) comprising a portion of the Cauliflower Mosaic Virus 35S promoter and the Rsyn7-Syn II Core consensus promoter, with transcription enhanced by omega 5' untranslated region translational enhancer element (0.1 kb) from the Tobacco Mosaic Virus, and with transcription terminated by the proteinase inhibitor II terminator (0.3 kb) from *Solanum tuberosum*; and,

ii) The *gm-hra* gene (1.9 kb), an optimized form of the endogenous *als* gene from *Glycine max*, with transcription regulated by the S-adenosyl-L-methionine synthetase constitutive promoter (1.3 kb) from *Glycine max*, and with transcription terminated by the endogenous *als* gene terminator (0.6 kb) from *Glycine max.*

D. INFORMATION RELATING TO THE GM PLANT

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

The 356043 soybean has been genetically modified to express the GAT4601 and GM-HRA proteins. The GAT4601 protein is a glyphosate acetyltransferase (GAT), encoded by an optimized form of the *gat* gene from *Bacillus licheniformis*, that confers tolerance to the herbicide glyphosate. The GM-HRA protein is an acetolactate synthase (ALS), encoded by the *gm-hra* gene which is an optimized form of the endogenous *als* gene from *Glycine max* that confers tolerance to ALS-inhibiting herbicides.

2. Information on the sequences actually inserted or deleted

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

A detailed molecular characterization consisting of Southern blot analyses has been carried out to characterize the copy number, structure and organization of the insert found in 356043 soybean. The results obtained confirm that the 356043 soybean insert consists of a single and intact copy of insert PHP20163A integrated into the nuclear genome.

(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 results obtained from Southern blot analysis and sequencing of the genetic material inserted in 356043 soybean and of the flanking 5' and 3' regions have confirmed that the 356043 soybean insert is integrated into the nuclear genome.

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

The results obtained from Southern blot analysis and sequencing of the genetic material inserted in 356043 soybean have confirmed that the 356043 soybean insert consists of a single and intact copy of insert PHP20163A.

3. Information on the expression of the insert

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

The 356043 soybean expresses the proteins GAT4601 and GM-HRA throughout the different developmental stages of the soybean plant.

(b) Parts of the plant where the insert is expressed

The 356043 soybean expresses the proteins GAT4601 and GM-HRA throughout the different parts of the soybean plant.

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

(a) Reproduction

The 356043 soybean plants show no significant difference in reproduction, dissemination, and survivability compared to control soybean. No unexpected changes in reproductive parameters or ecological interactions compared to control soybean have been observed in field trials of 356043 soybean.

(b) Dissemination

See **Point D.4.a.**, above.

(c) Survivability

See **Point D.4.a.**, above.

(d) Other differences

See **Point D.4.a.**, above.

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

The 356043 soybean has been shown to be genetically and phenotypically stable. Results from Southern analysis, agronomic characteristics and protein expression analysis of 356043 soybean plants have confirmed the stable inheritance and expression of GAT4601 and GM-HRA proteins in 356043 soybean.

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

(a) Plant to bacteria gene transfer

Transfer of genetic material originating from 356043 soybean to bacteria is a negligible concern. There is no known mechanism for, or definitive demonstration of, DNA transfer from plants to microbes under natural conditions. Even if horizontal gene transfer were to take place, transfer of the *gat4601* or *gm-hra* genes from 356043 soybean does not represent a risk to human or animal health, nor is it of consequence as a plant pest risk.

(b) Plant to plant gene transfer

Soybean is a self-pollinated species, propagated commercially by seed and the extent of cross-pollination is generally less than one percent. There are no other cultivated or wild plant species sexually compatible with soybean in Europe.

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

7.1 Comparative assessment

Choice of the comparator

The comparator chosen for the safety evaluation of 356043 soybean consists of control soybean with comparable genetic background. Wherever possible, publicly available data on commercial soybean has also been used in the comparisons with 356043 soybean.

7.2 Production of material for comparative assessment

(a) Number of locations, growing seasons, geographical spreading and replicates

Field studies were conducted at six locations in North America in 2005 and at six locations in South America in 2005-2006. Each location included a randomized complete block design containing four blocks (or replicates). Each block contained 356043 soybean and control soybean for comparison.

(b) The baseline used for consideration of natural variations

Publicly available data on commercial soybean was compiled from the literature and was used as the baseline for consideration of natural variations in the comparisons with 356043 soybean. In addition, a comparative assessment with control soybean of comparable genetic background has been carried out.

7.3 Selection of material and compounds for analysis

The nutritional analysis was undertaken on a broad range of compounds such as protein, fiber, carbohydrates, fat, ash, minerals, fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients in accordance with OECD guidelines for assessment of genetically modified soybean.

7.4 Agronomic traits

The evaluation of the agronomic traits of 356043 soybean confirmed that 356043 soybean is comparable to control soybean.

7.5 Product specification

The 356043 soybean is nutritionally equivalent to commercial soybean. Therefore, the specification of 356043 soybean and all food, feed and processed products derived from 356043 soybean is the same as that of commercial soybean and all food, feed and processed products derived from commercial soybean.

7.6 Effect of processing

The 356043 soybean will undergo existing methods of processing used for commercial soybean. No novel methods of processing are envisaged.

The proteins GAT4601 and GM-HRA expressed in 356043 soybean degrade rapidly under conditions used in the processing of soybean. In particular, heating of soybean derived products will lead to the rapid denaturation and degradation of the GAT4601 and GM-HRA proteins expressed in 356043 soybean.

7.7 Anticipated intake/extent of use

The 356043 soybean and all food, feed and processed products derived from 356043 soybean are expected to replace a portion of similar products from commercial soybean with total consumption of soybean products remaining unchanged. Therefore, the total anticipated intake/extent of use of soybean and all food, feed and processed products derived from soybean will remain the same.

7.8 Toxicology

7.8.1 Safety assessment of newly expressed proteins

The safety assessment of the GAT4601 and GM-HRA proteins expressed in 356043 soybean has been based on a very broad body of evidence. It includes

history of safety of the GNAT (GCN5-related N-acetyltransferases) and ALS (acetolactate synthase) families of proteins to which the GAT4601 and GM-HRA proteins expressed in 356043 soybean respectively belong; detailed knowledge of their mode of action; and, absence of toxicity to mammals.

As a result, the safety assessment of the GAT4601 and GM-HRA proteins has concluded that expression of these proteins in 356043 soybean is safe to human and animal health.

7.8.2 Testing of new constituents other than proteins

Not applicable.

7.8.3 Information on natural food and feed constituents

Detailed compositional analyses of 356043 soybean have demonstrated that the composition of natural food and feed constituents of 356043 soybean is comparable and nutritionally equivalent to that of control soybean.

In addition, the results obtained from a 42-day poultry feeding study provide further confirmation of the safety of the natural food and feed constituents of 356043 soybean and nutritional equivalence between 356043 soybean and commercial soybean.

7.8.4 Testing of the whole GM food/feed

As described throughout this application, detailed compositional analyses and nutritional assessment of 356043 soybean have confirmed that whole food and feed consisting of or derived from 356043 soybean is equivalent to whole food and feed consisting of or derived from commercial soybean.

In addition, a poultry feeding study has been conducted over a 42-day period with diets containing 356043 soybean. For comparison, diets containing control soybean with a comparable genetic background and diets containing commercial soybean were also fed to the broiler chickens. The OECD considers that poultry studies are very useful because they utilize a fast growing organism that consumes a relatively high percentage of soybean in the diet, and that is very sensitive to potentially toxic effects of dietary components.

No statistically significant differences were observed in mortality, weight gain, feed efficiency and carcass yields between broilers consuming diets produced with 356043 soybean and those consuming diets produced with control or commercial soybean.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The assessment of the potential allergenicity of the GAT4601 and GM-HRA proteins expressed in 356043 soybean consisted on the evaluation of the

allergenicity of the relevant source organisms; amino acid sequence comparison with known allergens; rapid degradation in simulated gastric and intestinal fluids; relatively low level of expression; lack of glycosylation and, lack of thermal stability of the newly expressed proteins. The results obtained have confirmed that the GAT4601 and GM-HRA proteins expressed in 356043 soybean do not pose any significant risk of being a potential allergen.

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Soybean, the host of the genetic modification and the source of the endogenous *als* gene used in the production of the *gm-hra* gene, has a history of causing food allergy. The allergenic proteins present in soybean have been isolated and they have been characterized in great detail. None of the allergenic proteins from soybean have any significant similarity to the GAT4601 and GM-HRA proteins expressed in 356043 soybean.

A study was also conducted using the sera from clinically reactive soybean allergic patients to assess whether the genetic modification used to generate the 356043 soybean altered the endogenous allergen content. The study involved comparing the 356043 soybean to control soybean with comparable genetic background using a one dimensional (1D) IgE immunoblot (a visual, qualitative comparison) and ELISA inhibition (a quantitative comparison). The results obtained with the sera indicated that the 356043 soybean and control soybean with comparable genetic background are very similar in protein/allergen profiles without any significant changes in concentrations of total protein or individual protein/allergen profiles. In conclusion, expression of the GAT4601 and GM-HRA proteins in 356043 soybean does not alter the allergenic characteristics of soybean.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

Composition analyses of the contents of protein, fiber, carbohydrates, fat, ash, minerals, fatty acids, amino acids, vitamins, secondary metabolites and anti-nutrients have shown that 356043 soybean is nutritionally equivalent to control soybean with comparable genetic background. Furthermore, nutritional equivalence between 356043 soybean and control soybean has also been shown in a poultry feeding study over a 42-day period.

In conclusion and taking into account the anticipated dietary intake of 356043 soybean products, consumption of 356043 soybean foods will not give rise to any adverse nutritional impact.

7.10.2 Nutritional assessment of GM feed

As summarised in **Point D.7.10.1** above, consumption of 356043 soybean feed will not give rise to any adverse nutritional impact.

7.11 Post-market monitoring of GM food/feed

As summarised in **Point D.7.10** above, the nutritional assessment has concluded that 356043 soybean is nutritionally equivalent to control soybean. In addition, the use of 356043 soybean food and feed will not be different from that of commercially available soybean food and feed.

Therefore, post-market monitoring of GM food/feed products derived from 356043 soybean is not necessary.

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

Not applicable as there are no target organisms for the GAT4601 and GM-HRA proteins expressed in 356043 soybean. The 356043 soybean is tolerant to the application of glyphosate and ALS-inhibiting herbicides.

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

9.1 Persistence and invasiveness

There is negligible likelihood for 356043 soybean to become environmentally persistent or invasive giving rise to weediness. Commercial soybean does not possess any trait for weediness and the expression of the GAT4601 and GM-HRA proteins in 356043 soybean does not introduce new traits for weediness.

9.2 Selective advantage or disadvantage

Commercial soybean is highly domesticated, to the extent that it cannot become established as a feral species outside the agricultural environment. Expression of the GAT4601 and GM-HRA proteins in 356043 soybean does not confer any selective advantage to the plants in the natural environment, *i.e.* outside the agricultural environment. In addition, application of broad spectrum herbicides, such as glyphosate and ALS-inhibiting herbicides, does not commonly occur in the natural environment.

In conclusion, expression of the GAT4601 and GM-HRA proteins in 356043 soybean does not confer any selective advantage outside the agricultural environment.

9.3 Potential for gene transfer

There are no sexually compatible wild or weedy relatives of soybean known to exist in the EU, which eliminates the possibility of potential gene transfer to such species. In addition, there is negligible likelihood for 356043 soybean plants to become environmentally persistent or invasive giving rise to weediness. Furthermore, expression of the GAT4601 and GM-HRA proteins in 356043 soybean does not present any selective advantage outside the agricultural environment.

9.4 Interactions between the GM plant and target organisms

Not applicable as there are no target organisms for the GAT4601 and GM-HRA proteins expressed in 356043 soybean. The 356043 soybean is tolerant to the application of glyphosate and ALS-inhibiting herbicides.

9.5 Interactions of the GM plant with non-target organisms

The natural ubiquity of the *gat* and *als* genes and of the GAT and ALS proteins in the environment, together with the absence of toxicity and the specific biochemical activity of the GAT4601 and GM-HRA proteins expressed in 356043 soybean confirms that there will be no adverse effects on non-target organisms arising from the proposed uses of 356043 soybean.

9.6 Effects on human health

Soybean has a long history of safe use in human food and animal feed. A very detailed safety assessment of the potential toxicity and allergenicity to humans of the GAT4601 and GM-HRA proteins expressed in 356043 soybean has been carried out. As a result and in conclusion, expression of the GAT4601 and GM-HRA proteins in 356043 soybean does not introduce any toxic or allergenic proteins into 356043 soybean. Furthermore, the nutritional assessment of 356043 soybean has confirmed that 356043 soybean is nutritionally equivalent to commercial soybean. Therefore, any consequences to human health arising from working with, coming into contact with, or in the vicinity of the 356043 soybean or any derived food and processed products will be no different from working with, coming into contact with, or in the vicinity of any other commercial soybean or any derived food and processed products.

9.7 Effects on animal health

As discussed in **Points D.7.8** and **D.7.9**,, consumption of 356043 soybean or any derived food, feed and processed products will result in no adverse consequences to human or animal health. Therefore, use of 356043 soybean as feed and consumption of any food, feed and processed products derived from 356043 soybean will result in no adverse consequences to animal health or the food/feed chain.

9.8 Effects on biogeochemical processes

The natural ubiquity of the *gat* and *als* genes and of the GAT and ALS proteins in the soil environment, and the specific biochemical activity of the GAT4601 and GM-HRA proteins confirm that expression of the GAT4601 and GM-HRA proteins in 356043 soybean will not cause any significant immediate and/or delayed effects on biogeochemical processes.

9.9 Impacts of the specific cultivation, management and harvesting techniques

Not applicable. The scope of this application does not include authorisation for the cultivation of 356043 soybean seed products in the EU.

10. Potential interactions with the abiotic environment

The scope of this application does not include authorisation for the cultivation of 356043 soybean seed products in the EU. Exposure to the environment from the import of 356043 soybean will be limited to unintended release of 356043 soybean e.g. via spillage during transportation of the grain, which can be controlled with current measures used to control spillage of commercially available soybean, such as use of mechanical means and selective use of herbicides (with the exception of glyphosate and ALS-inhibiting herbicides). Therefore, the likelihood of adverse interactions with the abiotic environment is negligible.

11. Environmental monitoring plan

11.1 General

The scope of this application does not include authorisation for the cultivation of 356043 soybean seed products in the EU. Exposure to the environment from the import of 356043 soybean will be limited to unintended release of 356043 soybean e.g. via spillage during transportation of the grain, which can be controlled with current measures used to control spillage of commercially available soybean, such as use of mechanical means and selective use of herbicides (with the exception of glyphosate and ALS-inhibiting herbicides).

The proposal for an environmental monitoring plan for 356043 soybean has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

11.2 Interplay between environmental risk assessment and monitoring

The design of the environmental monitoring plan is based on the conclusions of the environmental risk assessment (e.r.a.) carried out for this application for authorisation of genetically modified 356043 soybean and derived food and feed in accordance with Regulation (EC) 1829/2003.

The e.r.a. has been carried out in accordance with Annex II of Directive 2001/18/EC and Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The overall conclusion obtained from the e.r.a. confirms that there are no identified adverse effects to human and animal health or the environment arising from 356043 soybean. Therefore, the risk to human and animal health or the environment from 356043 soybean and any derived products is as negligible as for any other commercial soybean and any derived products.

11.3 Case-specific GM plant monitoring

In accordance with Annex VII of Directive 2001/18/EC and Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC, case-specific monitoring should only be carried out in those cases where potential adverse effects have been identified in the e.r.a.

The e.r.a. concluded that the risk to human and animal health or the environment from 356043 soybean and any derived products is as negligible as for any other commercial soybean and any derived products. Therefore, case-specific monitoring is not applicable for the use of 356043 soybean for all food and feed purposes and the import and processing of 356043 soybean.

11.4 General surveillance of the impact of the GM plant

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 unforeseen adverse effects of the GMO or its use for human health and the environment that were not predicted in the risk assessment.

The scope of this application is for the authorisation of 356043 soybean for all food and feed uses in accordance with Articles 3(1) and 15(1) of Regulation (EC) 1829/2003 and for import and processing of 356043 soybean in accordance with Part C of Directive 2001/18/EC. In this application we are not seeking approval for cultivation of 356043 soybean seed products in the EU.

As discussed in the e.r.a., exposure to the environment will be limited to any unintended release of 356043 soybean, which could occur via accidental spillage during loading/unloading of the vessels, trains and trucks carrying the load of commodity grain including 356043 soybean destined for processing into animal feed or human food products. However, such limited exposure is highly unlikely to give rise to any adverse effect and, if necessary, can be easily controlled by the application of current practices used for the control of spillage of commercial soybean, such as use of mechanical means and selective use of herbicides (with the exception of glyphosate and ALS-inhibiting herbicides).

Furthermore and taking into account that there is no food use for unprocessed soybean because it contains antinutrients such as trypsin inhibitors and lectins, general surveillance might assist in confirming the safety of animal feed use of 356043 soybean with a view of safeguarding against any unanticipated effects.

11.5 Reporting the results of monitoring

As discussed in **Points 11.1** to **11.4**, case-specific monitoring is not applicable for the use of 356043 soybean for all food and feed uses and the import and processing of 356043 soybean. As a result, no case-specific monitoring is proposed for this application for the authorisation of 356043 soybean and derived food and feed.

The applicant will inform the European Commission, without delay, of any adverse effects arising from 356043 soybean reported to him. Furthermore, the applicant will investigate such reports and inform the outcome to the European Commission.

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

A PCR-based quantitative event-specific detection method for 356043 soybean has been developed and submitted to the EC Joint Research Centre (Community Reference Laboratory) in Ispra for validation.

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
There have been no previous releases of 356043 soybean in the EU.
(b) Conclusions of post-release monitoring
Not applicable.
(c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)
Not applicable.

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

(a) Release country
Argentina
(b) Authority overseeing the release
Secretary of Agriculture.
(c) Release site
Two sites.
(d) Aim of the release
Regulatory trials.
(e) Duration of the release
Two seasons.
(f) Aim of post-releases monitoring

Control of potential volunteers.

(g) Duration of post-releases monitoring
One season.

(h) Conclusions of post-release monitoring
The 356043 soybean plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 356043 soybean.

(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
Canada.

(b) Authority overseeing the release
Canadian Food Inspection Agency.

(c) Release site
Two sites.

(d) Aim of the release
Regulatory trials.

(e) Duration of the release
Two seasons.

(f) Aim of post-releases monitoring
Control of potential volunteers.

(g) Duration of post-releases monitoring
One season.

(h) Conclusions of post-release monitoring
The 356043 soybean plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 356043 soybean.

(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
Chile.

(b) Authority overseeing the release
Ministry of Agriculture.

(c) Release site
Four sites.

(d) Aim of the release
Regulatory trials.

(e) Duration of the release
Two seasons.

(f) Aim of post-releases monitoring
Control of potential volunteers.

(g) Duration of post-releases monitoring
One season.

(h) Conclusions of post-release monitoring
The 356043 soybean plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 356043 soybean.

(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

(a) Release country
U.S.A.

(b) Authority overseeing the release
USDA.

(c) Release site
Multiple sites.

(d) Aim of the release
Regulatory trials.

(e) Duration of the release
Multiple seasons.

(f) Aim of post-releases monitoring
Control of potential volunteers.

(g) Duration of post-releases monitoring
One season.

(h) Conclusions of post-release monitoring
The 356043 soybean plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 356043 soybean.

(i) Results of the release in respect to any risk to human health and the environment
No adverse effects on human health and the environment observed.

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

[To be provided]

(b) Assessment report of the Competent Authority (Directive 2001/18/EC)

[To be provided]

(c) EFSA opinion

[To be provided]

(d) Commission Register (Commission Decision 2004/204/EC)

[To be provided]

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

[To be provided]

(f) Biosafety Clearing-House (Council Decision 2002/628/EC)

[To be provided]

(g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC)

[To be provided]