PART II

SUMMARY

SUMMARY OF THE APPLICATION FOR AUTHORISATION OF GENETICALLY MODIFIED 305423 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

Netherlands

b) Application number

EFSA-GMO-NL-2007-XX

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

The product described in this application is 305423 soybean for all food and feed uses, and for all food, feed and processed products derived from 305423 soybean.

The 305423 soybean has been obtained by introducing the *gm-fad2-1* gene fragment and the *gm-hra* gene into the soybean genome.

The inserted *gm-fad2-1* gene fragment is part of the coding region of the soybean omega-6 desaturase gene 1 (*FAD2-1*) and does not code for a functional protein. Transcription of the *gm-fad2-1* gene fragment in 305423 soybean seeds acts to suppress transcription of endogenous omega-6 desaturase, resulting in the high oleic phenotype. The 305423 soybean will be commercialized for the production of TREUS™[1] brand high oleic soybean oil.

The *gm-hra* gene encodes the GM-HRA protein, an optimized version of the soybean acetolactate synthase (ALS). Expression of the GM-HRA protein in 305423 soybean, used as a selectable marker, confers tolerance to ALS-inhibiting herbicides.

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 305423 soybean is DP-3Ø5423-1.

[1] TREUS™ is a trademark of Pioneer Hi-Bred International, Inc.

d) Date of acknowledgement of valid application [To be provided]

2. Applicant

a) Name of applicant

This is an application submitted by:
Pioneer Hi-Bred International, Inc., as represented by Pioneer Overseas Corporation.

b) Address of applicant

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

Represented by:
Pioneer Overseas Corporation
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B-1040 Brussels
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c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant

Same as applicant

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
[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]

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.

The scope of this application does not include authorisation for the cultivation of 305423 soybean seed products in the EU.

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 305423 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?

Yes [ ]	**No** [x]

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

Yes [x]	**No** [ ]

Yes, notifications concerning all uses of 305423 soybean, including cultivation of 305423 soybean seed products, have been submitted in the US and Canada. Applications for authorisation to import for all uses of 305423 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.) Merr.), which is the world's leading oilseed crop with a long history of use.

The 305423 soybean has been obtained by introducing the *gm-fad2-1* gene fragment and the *gm-hra* gene into the soybean genome.

The inserted *gm-fad2-1* gene fragment is part of the coding region of the soybean omega-6 desaturase gene 1 (*FAD2-1*) and does not code for a functional protein. Transcription of the *gm-fad2-1* gene fragment in 305423 soybean seeds acts to suppress transcription of endogenous omega-6 desaturase resulting in the high oleic phenotype. The 305423 soybean will be commercialized for the production of TREUS™[2] brand high oleic soybean oil and it will be used by both the food and industrial oil sectors. The food service industry and food processors will benefit from the fact that high oleic soybean oil is a highly stable vegetable oil that is suitable for frying applications without the need for hydrogenation. In the industrial sector, high oleic soybean oil will offer an ingredient that is stable to oxidation for the formulation of cost effective, renewable, environmentally friendly industrial fluids.

The *gm-hra* gene encodes the GM-HRA protein, an optimized version of the soybean acetolactate synthase (ALS). Expression of the GM-HRA protein in 305423 soybean, used as a selectable marker, confers tolerance to ALS-inhibiting herbicides.

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

The product described in this application is 305423 soybean for all food and feed uses, and for all food, feed and processed products derived from 305423 soybean.

c) Intended use of the product and types of users

The 305423 soybean and all food, feed and processed products derived from 305423 soybean are expected to replace a portion of similar products from commercial soybean.

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

Safety and nutritional evaluations of 305423 soybean have shown that no specific instructions and/or recommendations for use, storage and handling of 305423 soybean are necessary. Therefore, 305423 soybean can be used, stored and handled in the same way as is currently done for commercial soybean. Labelling of 305423 soybean products will be carried out in

[2] TREUS™ is a trademark of Pioneer Hi-Bred International, Inc.

accordance with Community law. See Point **A.8.f)** below for labelling of 305423 soybean.

e) Any proposed packaging requirements

The packaging, handling, and storage systems that are currently used for commercial soybean will apply. The 305423 soybean products will be packaged in the same manner as other commercial soybean products. See Point **A.8.f)** below for labelling of 305423 soybean.

f) A proposal for labelling in accordance with Article 13 and Article 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 305423 SOYBEAN FOOD PRODUCTS ACCORDING TO ARTICLES 12 AND 13 OF REGULATION (EC) 1829/2003

In accordance with Article 12 of Regulation No (EC) 1829/2003, labelling will apply except to foods containing material which contains, consists of or is produced from 305423 soybean in a proportion no higher than 0.9 per cent of the food ingredients considered individually or food consisting of a single ingredient.

In accordance with Article 13(1) 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, 305423 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.

2. PROPOSAL FOR THE LABELLING OF 305423 SOYBEAN FEED PRODUCTS ACCORDING TO ARTICLES 24 AND 25 OF REGULATION (EC) 1829/2003

In accordance with Article 24 of Regulation No (EC) 1829/2003, labelling will apply except to feed containing material which contains, consists of or is produced from 305423 soybean in a proportion no higher than 0.9 per cent 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.* 305423 soybean for feed use, and feed containing, consisting of or produced from 305423 soybean, should be labelled as follows:

(a) where the feed contains or consists of 305423 soybean, or where 305423 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 305423 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.

3. PROPOSAL FOR THE LABELLING OF PRODUCTS CONSISTING OF, OR CONTAINING, 305423 SOYBEAN 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 1830/2003 and as specified in Point A.8 of 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 305423 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 or the unique identifier code;

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

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 identification code assigned to 305423 soybean is DP-3Ø5423-1.

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

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 305423 soybean, no specific measures need to be taken in case of unintended release or misuse or for disposal and treatment.

In the case of unintended release or misuse of 305423 soybean, current agronomic measures taken to control commercial soybean can be applied, such as use of mechanical means and selective use of herbicides (with the exception of ALS-inhibiting herbicides).

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.
d) Subspecies None
e) Cultivar/breeding line Jack
f) Common name Soybean, soya, soy

2 a. Information concerning reproduction

(i) Mode(s) of reproduction Soybean is a self-pollinated species and reproduces through seed. 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, soybeans 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 a self-pollinated species that exhibits a high percentage of self-fertilisation.

As a result, cross-pollination is usually less than one percent.

There are no wild plant species that are sexually compatible with soybean in the EU.

3. Survivability

a) Ability to form structures for survival or dormancy

Soybean is a self-pollinating, non-frost tolerant annual crop. Overwintering of soybeans is rare due to a lack of innate dormancy.

b) Specific factors affecting survivability

Soybean is a non-frost tolerant annual crop. The seed will only germinate when the soil temperature reaches 10°C.

The soybean plant has no weedy tendencies and is non-invasive in natural habitats. It does not grow in unmanaged habitats.

4. Dissemination

a) Ways and extent of dissemination

As discussed, soybean is a self-pollinating annual crop that reproduces by seed. Neither the seedpod, nor the seed, has morphological characteristics that would encourage animal transportation. Furthermore, 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 soybean seeds. Insect or 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 in the EU.

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 Europe and data for 2005 report soybean production in the following countries: Austria, Bulgaria, Germany, Greece, Latvia, Poland, Slovakia, Slovenia, Italy, France, Hungary, Czech Republic, Romania and Spain.

There are no wild plant species that are sexually compatible with soybean 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

Not applicable as soybean is normally grown 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 305423 soybean was produced by means of particle co-bombardment. Microscopic gold particles were coated with a mixture of two gel-purified linear DNA fragments, PHP19340A and PHP17752A that contain the *gm-fad2-1* gene[1] fragment and the *gm-hra* coding sequence together with the necessary regulatory components, and accelerated into embryogenic soybean cultures.

2. Nature and source of the vector used

No vector was used in the production of 305423 soybean. As described in Point **C.1.**, two linear DNA fragments containing the *gm-fad2-1* gene[1] fragment and the *gm-hra* coding sequence together with the necessary regulatory components were used to obtain 305423 soybean.

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

The PHP19340A fragment contains the soybean *gm-fad2-1* gene fragment with transcription directed by the soybean Kunitz trypsin inhibitor gene 3 (KTi3) promoter and terminator. The *gm-fad2-1* gene fragment is a 597 bp fragment of the coding region of the microsomal omega-6 desaturase gene 1 from *Glycine max* (*FAD2-1* gene) and does not code for a functional protein. Transcription of the *gm-fad2-1* gene fragment is regulated by the 2084 bp long promoter region of the soybean Kunitz trypsin inhibitor gene 3 (KTi3 promoter). Termination of transcription of the *gm-fad2-1* gene fragment is controlled by the 196 bp long terminator sequence from the Kunitz trypsin inhibitor gene 3 (KTi3 terminator) from soybean.

The PHP17752A contains the *gm-hra* gene (1971 bp), which is an optimized form of the endogenous *als* gene from soybean, with transcription regulated by the S-adenosyl-L-methionine synthetase (SAMS) constitutive promoter (1.3 kb) from soybean and with transcription terminated by the endogenous *als* gene terminator (0.6 kb) from soybean.

D. INFORMATION RELATING TO THE GM PLANT

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

The 305423 soybean has been obtained by introducing the *gm-fad2-1* gene fragment and the *gm-hra* gene into the soybean genome.

The *gm-fad2-1* gene fragment that is inserted in 305423 soybean is part of the coding region of the soybean endogenous *FAD2-1* gene and does not code for a functional protein. Transcription of the *gm-fad2-1* gene fragment in 305423 soybean seeds acts to suppress transcription of endogenous omega-6 desaturase, resulting in the high oleic phenotype.

The *gm-hra* gene, an optimized version of the soybean acetolactate synthase (*als*) gene, encodes the GM-HRA protein. The GM-HRA protein in 305423 soybean, used as a selectable marker, confers tolerance to ALS-inhibiting herbicides.

No other traits have been introduced or modified in 305423 soybean.

2. Information on the sequences actually inserted or deleted

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

Molecular characterisation of 305423 soybean to evaluate insert copy number, insert integrity and presence of plasmid backbone sequences was conducted by Southern blot analysis in combination with sequencing of the inserted DNA in 305423 soybean.

Extensive Southern analyses demonstrate that multiple intact and truncated copies of fragment PHP19340A have been inserted into 305423 soybean that contain, in total, eight copies of the KTi3 promoter, seven copies of the *gm-fad2-1* gene fragment and five copies of the KTi3 terminator. A single intact copy of fragment PHP17752A has been inserted into 305423 soybean. In addition, Southern blot analyses confirm the absence of all functional elements from the plasmid backbone in 305423 soybean, despite the presence of a small non-functional fragment of the plasmid backbone DNA.

The genetic material that is inserted in 305423 soybean is genetically linked and segregates following a typical pattern of Mendelian inheritance expected for a single, genetically-linked insertion locus.

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 genetic material inserted in 305423 is integrated in the soybean nuclear genome as confirmed by the molecular characterisation of 305423 soybean by Southern blot and sequence analysis.

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

Sequence characterisation of the inserted DNA in 305423 soybean confirms that 305423 soybean contains four insertions that comprise:

- Insertion 1: one truncated PHP19340A fragment with a truncated KTi3 terminator and intact *gm-fad2-1* gene fragment and intact KTi3 promoter, one intact PHP19340A fragment, one intact PHP17752A fragment, one truncated PHP19340A fragment with an intact KTi3 promoter and a truncated *gm-fad2-1* gene fragment, and one truncated PHP19340A fragment with a truncated KTi3 promoter and truncated *gm-fad2-1* gene fragment
- Insertion 2: one truncated PHP19340A fragment with a truncated KTi3 promoter and with intact *gm-fad2-1* gene fragment and intact KTi3 terminator
- Insertion 3: one truncated copy of the KTi3 promoter with a non-functional 495 bp fragment of the plasmid backbone; and
- Insertion 4: two truncated PHP19340A fragments in an inverted repeat configuration, both with a truncated KTi3 promoter and intact *gm-fad2-1* gene fragment and KTi3 terminator.

3. Information on the expression of the insert

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

The 305423 soybean has been obtained by introducing the *gm-fad2-1* gene fragment and the *gm-hra* gene into the soybean genome.

The *gm-fad2-1* gene fragment is part of the coding region of the soybean omega-6 desaturase gene 1 (*FAD2-1*) and does not code for a functional protein. Transcription of the *gm-fad2-1* gene fragment in 305423 soybean seeds acts to suppress transcription of endogenous omega-6 desaturase, resulting in the high oleic phenotype.

The *gm-hra* gene encodes the GM-HRA protein, an optimized version of the soybean acetolactate synthase (ALS). Expression of the GM-HRA protein in 305423 soybean, used as a selectable marker, confers tolerance to ALS-inhibiting herbicides.

Northern analyses demonstrate that transcription of the endogenous *FAD2-1* gene is effectively silenced in 305423 soybean seed as intended by the genetic modification.

The expression level of the GM-HRA protein in 305423 soybean grain ranged from below the lower limit of quantitation of the ELISA up to 4.9 ng/mg tissue dry weight. The lower limit of quantitation of the ELISA was 0.54 ng/mg tissue dry weight.

b) Parts of the plant where the insert is expressed

Expression of the GM-HRA protein was detected in leaf, forage, root and grain from 305423 soybean.

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

a) Reproduction

Agronomic data for 305423 soybean were collected at six locations in the USA and Canada (2005 growing season) and at six locations in Chile and Argentina (2005/2006 growing season).

The 305423 soybean plants show no biologically significant difference in reproduction, dissemination and survivability compared to non-GM control soybean with comparable genetic background.

b) Dissemination

Please refer to Point **D.4.a)**

c) Survivability

Please refer to Point **D.4.a)**

d) Other differences

Please refer to Point **D.4.a)**

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

Genetic stability of 305423 soybean could be demonstrated by studying the pattern of inheritance and segregation of the introduced genetic material in different generations of 305423 soybean. These studies confirm that the 305423 soybean is genetically stable, following a typical pattern of Mendelian inheritance expected for a single, genetically-linked insertion locus.

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

a) Plant to bacteria gene transfer

The genetic modification in 305423 soybean does not enable soybean to transfer genetic material to bacteria. In particular, there are no sequences present in the inserted DNA in 305423 soybean that could potentially be involved in transfer of genetic material between soybean and bacteria.

b) Plant to plant gene transfer

As discussed in Point **B.2(b)**, soybean is a self-pollinated species and there are no other cultivated or wild plant species that are sexually compatible with soybean in the EU.

Additionally, this application is for authorisation of 305423 soybean for all food and feed uses, and for all food, feed and processed products derived from 305423 soybean, and not for cultivation of 305423 soybean seed products in the EU.

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

The comparator chosen for the safety evaluation of 305423 soybean consists of non-GM control soybean with comparable genetic background. In addition, composition data derived from four commercial soybean varieties as well as publicly available literature references have been used in the comparison with 305423 soybean.

7.2 Field trials

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

Field trials were conducted at six location in the USA and Canada during the 2005 growing season and at six locations in Chile and Argentina during the 2005/2006 growing season. Each location included a randomised block design containing 4 blocks (or replicates). Each block contained 305423 soybean and non-GM control soybean for comparison.

b) the baseline used for consideration of natural variations

The baseline for expected and natural variations consisted of composition data derived from four commercial soybean varieties and publicly available literature references.

In addition, the comparative assessment included non-GM control soybean of comparable genetic background as comparator.

7.3 Selection of materials and compounds for analysis

The compositional 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.

Comparative assessment of 305423 soybean grain confirmed that it is comparable to grain from commercial soybean except for the fatty acid profile which reflects the high oleic phenotype that was intended by the genetic modification in 305423 soybean.

7.4 Agronomic traits

As discussed in Point **D.7.2**, 305423 soybean has been tested at different locations and during different growing seasons across key soybean growing regions of the USA, Canada, Chile and Argentina. The agronomic data obtained, support the conclusion that there are no unexpected agronomic differences between 305423 soybean and non-GM control soybean with comparable genetic background.

7.5 Product specification

As discussed throughout this application, 305423 soybean is as safe as and as nutritious as commercial soybean.

7.6 Effect of processing

The methods of production and manufacturing applied to soybean are well known and have a long history of safe use. The 305423 soybean will undergo existing methods of production and processing used for commercial soybean. No novel method of production and processing is envisaged.

7.7 Anticipated intake/extent of use

The 305423 soybean and all food, feed and processed products derived from 305423 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 is expected to remain the same.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

As discussed in Point **D.3.**, the only newly expressed protein in 305423 soybean is the GM-HRA protein.

The human food and animal feed safety of the GM-HRA protein expressed in 305423 soybean has been thoroughly characterised and evaluated. Based on a very broad body of evidence, which includes previous use of the protein; absence of toxicity to mammals; absence of adverse effects on fast growing species; a biochemical characterisation of the

protein; lack of sequence homology to known protein allergens or toxins; lack of resistance to proteolysis; and, lack of stability when heated, the GM-HRA protein can be regarded as safe for human food and animal feed use.

7.8.2 Testing of new constituents other than proteins

Not applicable

7.8.3 Information on natural food and feed constituents

As described in Point **D.7.3**, comparative assessment demonstrated that 305423 soybean grain is comparable to grain from commercial soybean except for the fatty acid profile which reflects the high oleic phenotype that was intended in 305423 soybean.

Although the oleic acid content of 305423 soybean has been increased beyond the natural variation that is typically expected for commercial soybeans, there is no concern for adverse effects. Oleic acid is a typical constituent of the human diet and is safely consumed and readily metabolised by humans and animals. Furthermore, several vegetable oils that have a long history of safe use for human consumption, such as olive oil, safflower oil, arachis oil, low erucic acid rapeseed oil and high oleic sunflower oil have a comparable oleic acid content as observed for 305423 soybean.

Furthermore, a 42-day poultry feeding study with diets containing 305423 soybean and a detailed nutritional assessment taking account of the changed fatty acid profile of 305423 soybean have been carried out (Point **D.7.10)** and confirm that the human food and animal feed products derived from 305423 soybean are comparable in nutritional value to human food and animal feed products derived from commercial soybean.

7.8.4 Testing of the whole GM food/feed

A poultry feeding study over a period of 42 days has been carried out with diets containing 305423 soybean, non-GM control soybean with comparable genetic background and three commercial non-GM soybeans. The mortality, body weight gain, feed efficiency, organ yield, carcass yield, breast, thigh, wing and leg yield and abdominal fat of the chickens fed with 305423 soybean were compared to chickens fed non-GM control soybean diets. The results from this 42-day poultry study confirm the safety of 305423 soybean and that 305423 soybean is nutritionally equivalent to non-GM control soybean with a comparable genetic background and to commercial soybeans.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

As discussed in Point **D.3.**, the only newly expressed protein in 305423 soybean is the GM-HRA protein.

In accordance with a weight-of-evidence approach, which accounts for a variety of factors and experimental approaches for an overall assessment of the allergenic potential of a protein,

the GM-HRA protein was assessed for its allergenic potential through: (i) assessing the allergenicity potential of the source of the gene, (ii) homology searches with known protein allergens, (iii) *in vitro* simulated digestibility studies, (iv) evaluation of protein glycosylation and (v) assessment of heat stability. The results obtained confirm that GM-HRA protein does 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 GM-HRA protein expressed in 305423 soybean.

A study was also conducted using the sera from clinically reactive soy allergic patients (both children and adults) to assess whether 305423 soybean exhibits an altered endogenous allergen content compared to non-GM control soybean. This study involved comparing the 305423 soybean to its non-transgenic counterpart (Jack) by one dimensional (1D) IgE immunoblot (a visual, qualitative comparison) and ELISA inhibition (a quantitative comparison). The results of this study demonstrate that 305423 soybean and non-GM control soybean are similar in protein/allergen profiles without any significant changes in total protein concentrations or individual protein/allergen profiles, thereby confirming that the genetic modification in 305423 soybean did not change the characteristics of soybean with regard to allergenic potential.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

As described in Point **D.7.3**, compositional analysis of 305423 soybean grain demonstrates that it is comparable to grain from non-GM control soybean with comparable genetic background and to commercial soybean grain except for the fatty acid profile which reflects the high oleic phenotype that was intended by the genetic modification in 305423 soybean..

305423 soybean varieties are intended to be used for the production of TREUS™[3] brand high oleic soybean oil. The food service industry and food processors will benefit from the fact that high oleic soybean oil is a highly stable vegetable oil that is suitable for frying applications without the need for hydrogenation. Therefore, oil derived from 305423 soybean will be used primarily to replace commercial frying oils used with french fries, potato chips, tortilla chips and other maize based snacks, commercially fried fish and commercially fried chicken as well as oils used as a spray treatment on crackers, pretzels and other grain snacks.

A study was conducted to evaluate the changes in dietary fatty acids provided in the diet when commercial soybean frying oils as they exist in the marketplace today (*i.e.* baseline scenario) are substituted with oil from 305423 soybean (*i.e.* high oleic scenario) and to consider the nutritional implications of these changes.

[3] TREUS™ is a trademark of Pioneer Hi-Bred International, Inc.

Based on this assessment it was concluded that no changes are made in the overall quality of the fatty acid composition of the diet that are nutritionally or biologically meaningful when using oil from 305423 soybean.

7.10.2 Nutritional assessment of GM feed

Nutritional equivalence between 305423 soybean and commercial soybean has been demonstrated in a poultry feeding study over a period of 42 days. Broilers were fed diets containing 305423 soybean, non-GM control soybean with comparable genetic background or one of three commercial non-GM soybeans. The mortality, body weight gain, feed efficiency, organ yield, carcass yield, breast, thigh, wing and leg yield and abdominal fat of the chickens fed with 305423 soybean were compared to chickens fed non-GM control soybean diets.

The results from this 42-day poultry study confirm the safety of 305423 soybean and that 305423 soybean is nutritionally equivalent to non-GM control soybean with a comparable genetic background and to commercial soybeans.

In conclusion, feed products from 305423 soybean are nutritionally equivalent to, and as safe as feed products derived from commercial soybean.

7.11 Post-market monitoring of GM food/feed

Based on the safety assessment discussed throughout Point **D.7.**, no risks to human and animal health and the environment have been identified from the food or feed use of 305423 soybean as compared to food or feed use of commercial soybean. In addition, the nutritional characteristics and use of food, feed and processed products derived from 305423 soybean are no different from those of food, feed and processed products derived from commercial soybean (Point **D.7.10**).

Therefore, post-market monitoring of GM food and GM feed products containing, consisting of or derived from 305423 soybean is not necessary.

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

Not applicable since the GM-HRA protein has no target organism.

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

9.1 Persistence and invasiveness

It is generally recognised that domestication of crop plants over thousands of generations has resulted in modern crop cultivars that have lost common distinctive attributes of weeds. Modern soybean cultivars do not exhibit weedy characteristics and are therefore non-invasive in natural ecosystems. Furthermore, soybean is a non-frost tolerant crop and soybean volunteers do not compete well with succeeding crops. In any case, soybean volunteers can

easily be controlled mechanically or by selective use of herbicides (with the exception of ALS-inhibiting herbicides).

The 305423 soybean has been field tested in different locations worldwide, such as Chile, Argentina, the USA and Canada (Point **D.4.**), and analysis of field data collected from these trials established that the introduced traits in 305423 soybean do not result in differences regarding soybean reproductive morphology and persistence or invasiveness compared to commercial soybean.

In addition, within the context of this application which is for authorisation of 305423 soybean for all food and feed uses, and for all food, feed and processed products derived from 305423 soybean, and not for cultivation of 305423 soybean seed products in the EU, release of 305423 soybean will be strictly confined to unintended grain spillage during import, storage and processing of the 305423 soybean.

Taking into account all the above, there is negligible likelihood for 305423 soybean to become environmentally persistent or invasive giving rise to any weediness.

9.2 Selective advantage or disadvantage

Within the context of this application which is for authorisation of 305423 soybean for all food and feed uses, and for all food, feed and processed products derived from 305423 soybean, and not for cultivation of 305423 soybean seed products in the EU, release of 305423 soybean will be strictly confined to unintended grain spillage during import, storage and processing of the 305423 soybean.

Furthermore and as discussed in Point **D.9.1**, soybean is highly domesticated to the extent that it cannot become established as a feral species outside the agricultural environment. The specific advantages introduced by the genetic modification in 305423 soybean do not confer any selective advantage to the plants in the natural environment, *i.e.* outside the agricultural environment.

Therefore, there is negligible likelihood for increased survival of 305423 soybean in the agricultural or natural environment within the context of this application.

9.3 Potential for gene transfer

There are no sexually compatible wild or weedy relatives of *Glycine max* known to exist in the EU, which eliminates any potential for gene transfer to such species. In addition, soybean exhibits a high percentage of self-fertilization. Natural outcrossing levels in soybean range from less than 0.5% to about 1%.

Furthermore and as discussed in Points **D.9.1** and **D.9.2**, there is negligible likelihood for 305423 soybean to become environmentally persistent or invasive giving rise to any weediness, nor does the introduced traits in 305423 soybean result in any selective advantage to soybean plants outside the agricultural environment.

The genetic modification in 305423 soybean does not change the inability of soybean to transfer genetic material to bacteria. In particular, there are no sequences present on the inserted DNA in 305423 soybean that could potentially be involved in transfer of genetic material between soybean and bacteria.

In conclusion, within the context of this application which is for authorisation of 305423 soybean for all food and feed uses, and for all food, feed and processed products derived from 305423 soybean, and not for cultivation of 305423 soybean seed products in the EU, the potential for gene transfer is considered negligible.

9.4 Interactions between the GM plant and target organisms

The GM-HRA protein that is expressed in 305423 soybean has no target organisms.

9.5 Interactions of the GM plant with non-target organisms

There is no potential toxicity in the interaction of 305423 soybean with non-target organisms resulting from the genetic modification.

Within the context of this application which is for authorisation of 305423 soybean for all food and feed uses, and for all food, feed and processed products derived from 305423 soybean, and not for cultivation of 305423 soybean seed products in the EU, there is negligible likelihood that the import of 305423 soybean will lead to an adverse effect on non-target organisms.

9.6 Effects on human health

Soybean is the world's leading oilseed crop with a long history of use in human food and animal feed.

As discussed in Points **D.7.8** and **D.7.9**, a very detailed evaluation of the potential toxicity and allergenicity of the GM-HRA protein has been carried out, confirming that 305423 soybean does not express any known toxic or allergenic proteins.

Furthermore and as discussed in Point **D.7.3**, compositional analysis has demonstrated that 305423 soybean grain is comparable to commercial soybean grain except for the fatty acid composition. As discussed in Point **D.7.10**, a detailed nutritional assessment confirmed that the intended high oleic phenotype of 305423 soybean does not result in changes in the overall quality of the fatty acid composition of the diet that would be nutritionally or biologically meaningful when using 305423 soybean.

Therefore and in conclusion, consumption of 305423 soybean or derived food products will result in no adverse consequences to human health.

9.7 Effects on animal health

The genetic modification in 305423 soybean does not introduce any new compounds known

to cause, or expected to cause, any possible immediate and/or delayed effects on animal health. Use of 305423 soybean and any animal feed products derived from it will result in no adverse consequences for the feed/food chain.

This conclusion is based on a detailed safety evaluation concerning 305423 soybean. As discussed in Points **D.7.3**, **D.7.8.** and **D.7.10.2**, safety evaluation of 305423 soybean included compositional analyses, toxicological assessment and a nutritional assessment. In summary, feed products from 305423 soybean are as safe as and as nutritious as feed products derived from commercial soybean.

9.8 Effects on biogeochemical processes

This application is for authorisation of 305423 soybean for all food and feed uses, and for all food, feed and processed products derived from 305423 soybean, and not for cultivation of 305423 soybean seed products in the EU. Therefore, release to the environment of 305423 soybean would be strictly confined to unintended grain spillage during import, storage and processing of the 305423 soybean.

Furthermore and as discussed in Points **D.9.4** and **D.9.5**, the genetic modification in 305423 soybean will not cause any possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of 305423 soybean and target and non-target organisms.

9.9 Impacts of the specific cultivation, management and harvesting techniques

The scope of this application does not include authorisation for the cultivation of 305423 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 305423 soybean seed products in the EU. As a consequence, any exposure to the environment from the import of 305423 soybean will be limited to unintended release of 305423 soybean e.g. via spillage during transportation of the grain. Therefore, the likelihood of adverse interactions with the abiotic environment are negligible

11. Environmental monitoring plan

11.1 General (risk assessment, background information)

As discussed in Point **A.4.**, the scope of this application is for the authorisation of 305423 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 305423 soybean in accordance with Part C of Directive 2001/18/EC.

The scope of this application does not include authorisation for the cultivation of 305423

soybean seed products in the EU. Therefore, any exposure to the environment from the import of 305423 soybean will be limited to unintended release of 305423 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 ALS-inhibiting herbicides).

The proposal for an environmental monitoring plan for 305423 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.) for this application for authorisation of genetically modified 305423 soybean and derived food and feed in accordance with Regulation (EC) 1829/2003 (see Points **D.9.** and **D.10.**).

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 the product described in this application. Therefore, the risk to human and animal health or the environment from 305423 soybean and any derived products is as negligible as for any commercial soybean and any derived products.

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

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 305423 soybean and any derived products is as negligible as for any commercial soybean and any derived products. Therefore, case-specific monitoring is not applicable for the use of 305423 soybean for all food and feed purposes and the import and processing of 305423 soybean.

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

As discussed in Point **A.4.**, the scope of this application is for the authorisation of 305423

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 305423 soybean in accordance with Part C of Directive 2001/18/EC. The scope of this application does not include authorisation for the cultivation of 305423 soybean seed products in the EU.

As discussed in detail in the e.r.a. and in Points **D.11.1.** and **D.11.2.**, exposure to the environment will be limited to any unintended release of 305423 soybean, which could occur via accidental spillage during loading/unloading of the vessels, trains and trucks carrying the load of commodity grain including 305423 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 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 ALS-inhibiting herbicides) and manual or mechanical removal.

11.5 Reporting the results of monitoring

As confirmed in Points **11.1** to **11.4**, case-specific monitoring is not applicable for the use of 305423 soybean for all food and feed purposes and the import and processing of 305423 soybean. As a result, no case-specific monitoring is proposed for this application for authorisation of 305423 soybean for all food and feed uses.

The applicant will inform the European Commission, without delay, of any adverse effects arising from 305423 soybean reported to him. Furthermore, the applicant will investigate such reports and inform the outcome to the European Commission.

In accordance with Articles 9 and 21 of Regulation (EC) 1829/2003, the European Commission shall make the information supplied by the applicant available to EFSA and the Member States without delay.

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

A PCR-based quantitative event-specific detection method for 305423 soybean has been developed and is submitted to the EC Joint Research Centre (Community Reference Laboratory) in 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 305423 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
One season.
(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 305423 soybean performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.
(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
Three sites.

(d) Aim of the release
Regulatory trials and Research trials involving observation and yield testing and field breeding and product development.

(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 305423 soybean plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.

(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
Multiple sites.

(d) Aim of the release
Regulatory trials and Research trials involving breeding and seed increase.

(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 305423 soybean plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.

(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 and Research trials involving efficacy, yield testing, breeding and seed increase.

(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 305423 soybean plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics.

(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]