Part VII - Summary

Request for Authorization of genetically modified soybean cyst nematode resistant and herbicide tolerant

GMB151 soybean

for food and feed uses, and import and processing, in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003

EFSA-GMO-NL-2018-XXX

Version CC1

Submitted on
04 October 2018

PART VII – SUMMARY

EFSA-GMO-NL-2018-XXX (GMB151 SOYBEAN)

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

The Netherlands

(b) Application number

EFSA-GMO-NL-2018-XXX

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

GMB151 soybean (no commercial name available at the time of submission)

(d) Date of acknowledgement of valid application

Not available at the time of submission

1.2. Applicant

(a) Name of applicant

BASF Agricultural Solutions Seed US LLC

(b) Address of applicant

BASF Agricultural Solutions
Seed US LLC
100 Park Avenue
Florham Park, NJ 07932
USA

Represented by:
BASF SE
Carl-Bosch-Str. 38
D-67063 Ludwigshafen
Germany

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

BASF Agricultural Solutions Belgium NV is the contact for this submission and all correspondence shall be directed to:

BASF Agricultural Solutions Belgium NV,
Rue Marie de Bourgogne 58,
1000 Brussels
Belgium

1.3. Scope of the application

(a) Genetically modified food

☑ Food containing or consisting of genetically modified plants

☑ Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

☑ Feed containing or consisting of genetically modified plants

☑ Feed produced from genetically modified plants

(c) Genetically modified plants for food or feed uses

☑ Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation

☐ Seeds and plant propagating material for cultivation in the Union

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation within the Union?

No ☑

Yes ☐ (in that case, specify)

1.5. Has the genetically modified plant been notified under Part B of Directive 2001/18/EC?

Yes ☐

No ☑ (in that case, provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

This application requests authorization for food and feed uses, and for import and processing and does not include cultivation in the EU.

1.6. Has the genetically modified plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC?

No ☑

Yes ☐ (in that case, specify)

1.7. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

No ☑

Yes ☐ in that case, specify the third country, the date of application and, where available, a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application

1.8. General description of the product

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

GMB151 soybean has been developed through *Agrobacterium*-mediated transformation using the vector pSZ8832 containing the *cry14Ab-1.b* and *hppdPf-4Pa* gene cassettes. GMB151 soybean produces the Cry14Ab-1 protein, a crystal protein derived from Bacillus thuringiensis, which confers resistance to soybean cyst nematode. GMB151 also produces a modified 4-hydroxyphenylpyruvate dioxygenase (HPPD-4), derived from *Pseudomonas fluorescens*, which confers tolerance to HPPD inhibitor herbicides, such as isoxaflutole.

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

The scope of the current application is for authorisation of GMB151 soybean for import, processing and all uses as any other soybean in the EU, according to Art 3(1) and 15(1) of Regulation (EC) No 1829/2003, with the exception of cultivation. The range of uses of this soybean will be identical to the full range of equivalent uses of conventional soybean.

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

GMB151 soybean will be traded and used in the EU in the same manner as current conventional commercial soybean (excluding cultivation) and by the same operators currently involved in the trade and use of soybean.

(d) Any specific instructions and recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for.

With the exception of herbicide tolerance and resistance to soybean cyst nematode, which only have agronomic relevance, the characteristics of GMB151 soybean and products derived from it are comparable to those of its conventional counterpart and the commercial reference varieties with a history of safe use. Therefore, GMB151 soybean and its derived products will be stored, packaged, transported, handled and used in the same manner as current commercial soybean products. No specific instructions and/or recommendations are warranted or required for the placing on the market of GMB151 soybean for import, processing and all uses, excluding cultivation, in the EU.

(e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for.

GMB151 soybean is suitable for use throughout the EU as any other soybean. The scope of this application covers the import, processing and all uses of GMB151 soybean, excluding cultivation.

(f) Any type of environment to which the product is unsuited.

GMB151 soybean is suitable for use throughout the EU as any other soybean. The scope of this application covers the import, processing and all uses of GMB151 soybean, excluding cultivation.

(g) Any proposed packaging requirements.

With the exception of herbicide tolerance and resistance to soybean cyst nematodes, which only have agronomic relevance, the characteristics of GMB151 soybean are not different from those of its conventional counterpart. Therefore, GMB151 soybean and derived products will be used in the same manner as other soybean and no specific packaging is required.

(h) Any proposed labelling requirements in addition to those required by other applicable EU legislation then (EC) No 1829/2003 and when necessary a proposal for specific labelling in accordance with Article 13(2) and (3), Article 25(2)(c) and (d) and Article 25(3) of Regulation (EC) No 1829/2003.

In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

In accordance with Regulations (EC) No 1829/2003 and 1830/2003, a labelling threshold of 0.9% is applied for the placing on the market of GMB151 soybean and derived products.

Operators shall be required to label products containing or consisting of GMB151 soybean with the words “genetically modified soybean” or “contains genetically modified soybean” and shall be required to declare the unique identifier in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Operators shall be required to label foods and feeds derived from GMB151 soybean with the words “produced from genetically modified soybean”. In the case of products for which no list of ingredients exists, operators shall ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

Operators handling or using GMB151 soybean and derived foods and feeds in the EU shall be required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003 and that authorised foods and feeds shall be entered in the EU Register for genetically modified food and feed, operators in the food/feed chain will be fully aware of the traceability and labelling requirements for GMB151 soybean. Therefore, no further specific measures are to be taken by the applicant.

(i) Estimated potential demand

- **In the EU**

There are no anticipated changes to the demand as a result of the introduction of GMB151 soybean into the soybean as the changes have only an agronomic benefit. It is anticipated that the introduction of GMB151 soybean will replace some of the soybean in existing food and feed products.

- **In EU export markets**

There are no anticipated changes to the extent of soybean production in export markets as a result of the introduction of GMB151 soybean. It is anticipated that the introduction of GMB151 soybean may replace some of the existing soybean products.

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

The OECD unique identifier for GMB151 soybean is BCS-GM151-6.

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

Because this application is for consent to import, process and all uses of GMB151 soybean as any other soybean, not including the cultivation of varieties of GMB151 soybean in the EU, the only potential means of environmental release would be more likely to occur during import, storage and processing of GMB151 soybean. However, modern methods of soybean handling minimize losses of seed, so there is little chance of germination of spilled soybean resulting in the development of mature GMB151 soybean plants in the EU. Moreover, in the event of incidental spillage, the establishment of volunteer plants would be unlikely, since GMB151 soybean, like any other soybean, is unlikely to effectively compete with perennial vegetation outside agricultural fields. The likelihood for spilled seed to survive and establish is negligible. Soybean plants outside agricultural fields can produce seed but this is often prevented because most plants do not survive to reach maturity. This is due to competition from other vegetation, management operations such as roadside mowing, the use of broadleaf herbicides, animal predation, diseases and environmental conditions.

GMB151 soybean is not different in composition, nutritional and agronomic characteristics relative to conventional soybean, except for the introduced SCN resistance and tolerance to HPPD inhibitors, and therefore, it is unlikely to pose any threat to the EU environment or to require special measures for its containment. Furthermore, soybean volunteers can be easily controlled using currently available selective herbicides (other than HPPD inhibitors) or by mechanical means. Therefore, no special measures are considered to be required in case of misuse or unintended release.

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

2.1. Complete name

(a) Family name
Leguminosae

(b) Genus
Glycine

(c) Species
max

(d) Subspecies
none designated

(e) Cultivar/breeding line
various

(f) Common name
soybean

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

Historical and geographical evidence suggests that soybeans were first domesticated in eastern China, between the 17th and 11th century B.C. Today soybeans are grown as a commercial crop in more than 90 countries, including Europe, throughout the world. *Glycine max* is not found as a wild species in Europe. The USA and Brazil dominated world soybean exports in 2016, accounting for about 43% and 38%, respectively, of the world's soybean exports. The other main exporting countries are Argentina, Paraguay, and Canada. Meanwhile, the top five importing countries, i.e., China (mainland), the Netherlands, Mexico, Spain, and Germany, accounted for about 74.2% of the entire world's imports in 2016.

The major soybean producers in the EU Member States during 2016 were Italy, France and Romania.

2.3. Information concerning reproduction (for environmental safety aspects)

(a) Mode(s) of reproduction

Soybean is considered a self-pollinated species, propagated commercially by 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 level of self-fertilisation and cross pollination is usually less than one percent.

(b) Specific factors affecting reproduction

Soybeans are quantitative short day plants and thus flower more quickly under short days. As a result, photoperiodism and temperature response are important in determining areas of cultivar adaptation. Seed will germinate when the soil temperature reaches 10ºC and will emerge in a 5-7 day period under favourable conditions. In new areas of soybean production an inoculation with *Bradyrhizobium japonicum* is necessary for optimum efficiency of the nodulated root system. Soybeans do not yield well on acid soils.

(c) Generation time

Soybean is an annual crop. Generation time is 3 to 5 months in the primary areas of cultivation.

2.4. Sexual compatibility with other cultivated or wild plant species (for environmental safety aspects)

The subgenus *Soja*, to which *G. max* belongs, also includes *G. soja* Sieb. and Zucc. (2n=40) and *G. gracilis* Skvortz. (2n=40), wild and semi-wild annual soybean relatives from Asia. *Glycine soja* (2n=40) is a wild, viny annual with small and narrow trifoliate leaves, purple flowers and small round brown-black seeds. It grows wild in Korea, Taiwan, Japan, Yangtze Valley, N.E. China and areas around its western border. *Glycine gracilis*, an intermediate in form between *G. soja* and *G. max*, has been observed in Northeast China. Interspecific, fertile hybrids between *G. max*. and *G. soja*, and between *G. max* and *G. gracilis* have been easily obtained.

In addition to the subgenus *Soja*, the genus *Glycine* contains also the subgenus *Glycine*. The subgenus *Glycine* consists of sixteen wild perennial species, including *G. clandestina* Wendl., *G. falcata* Benth, *G. latifolia* Benth., *G. latrobeana* Meissn. Benth., *G. canescens*

F.J. Herm., *G. tabacina* Labill. Benth., and *G. tomentella* Hayata. These species are indigenous to Australia, South Pacific Islands, China, Papua New Guinea, Philippines, and Taiwan. Species of the subgenus *Glycine* have chromosome complements of 2n=40 or 2n=80.

Early attempts to hybridise annual (subgenus *Soja*) and perennial (subgenus *Glycine*) species were unsuccessful. Although pod development was initiated, these eventually aborted and abscised. Intersubgeneric hybrids were later obtained *in vitro* through embryo rescue, between *G. max* and *G. clandestina* Wendl; *G. max* and *G. tomentella* Hayata; and *G. max* and *G. canescens*, using transplanted endosperm as a nurse layer. In all cases, the progeny of such intersubgeneric hybrids was sterile and obtained with great difficulty.

In Europe, the cultivated soybean is *Glycine max*. No wild relatives have been reported and *G. max* itself is not a wild species.

2.5. Survivability (for environmental safety aspects)

(a) Ability to form structures for survival or dormancy

Soybean, *Glycine max*, is a cultivated, self-pollinating annual species, propagated commercially by seed. Soybean seeds rarely display any dormancy characteristics and only under certain environmental conditions will soybean emerge as a volunteer in the year following cultivation. The soybean plant is not weedy in character and is not found outside of cultivation. Weedy soybean has not been reported growing naturally outside its centre of origin in other parts of the world such as the Americas and Europe where only the cultivated soybean is commercially grown. Even in the agroecosystem soybean seeds usually do not survive due to predation, rotting, germination resulting in death during the winter, or due to management practices prior to planting the subsequent crop.

(b) Specific factors affecting survivability

Soybeans are adapted to agricultural regions from equatorial to temperate zones. They grow most rapidly when air temperatures are between 25 and 30^{o}C. They are very susceptible to frost damage and somewhat susceptible to excessive drought and extended flooding. Seeds of cultivated soybean survive poorly in soil, normally less than one year, and generally do not overwinter.

2.6. Dissemination (for environmental safety aspects)

(a) Ways and extent of dissemination

Soybean is considered a self-pollinated species, propagated commercially by seed. It exhibits a high percentage of self-fertilisation and cross pollination is usually less than one percent.

Natural cross-pollination in soybean was found to be rare across distances greater than 4.6 m from the pollen source.

Seed may be dispersed during transport, at sowing or during harvest. Pods may also shatter under some climatic conditions if harvest is delayed, resulting in seed dispersal.

(b) Specific factors affecting dissemination

No special factors affect dissemination. Dissemination is due primarily to human activity.

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

Historical and geographical evidence suggests that soybeans were first domesticated in eastern China, between the 17th and 11th century B.C. Today soybeans are grown as a commercial crop in more than 90 countries, including Europe, throughout the world. *Glycine max* is not found as a wild species in Europe.

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

Not relevant as soybean is normally cultivated as a crop in the EU.

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

The scope of this application does not include cultivation of GMB151 soybean seeds in the EU and therefore no potential interactions with organisms in the ecosystem in the EU are expected. However (and in regions where GMB151 soybean seed products will be cultivated) (*e.g.* North America), numerous insects, fungi, mycoplasmas and viruses are pathogenic to *G. max* and attack the crop during the growing season.

Soybean has no major interactions with the environment other than as a crop. It is known to interact with other organisms including pollinators, fungi, animal browsers, birds, soil microbes and soil insects. As soybean is a legume, it can fix atmospheric nitrogen as a source of nitrogen for growth and development in a symbiotic relationship with *Bradyrhizobium japonicum*.

Soybean is widely cultivated and has a history of safe use. It is not considered harmful or pathogenic to humans. However, there are a few compounds in legumes, and therefore also in soybeans, which are not favourable for human or animal nutrition.

3. MOLECULAR CHARACTERISATION

3.1. Information relating to the genetic modification

(a) Description of the methods used for the genetic modification

The event has been developed through *Agrobacterium tumefaciens* mediated transformation of conventional soybean variety Thorne.

(b) Nature and source of the vector used

The recipient plant material is soybean (*G. max*).

(c) Source of donor nucleic acid(s) used for the transformation, size and intended function of each constituent fragment of the region intended for insertion

Table1. Description of the genetic elements of pSZ8832

Nt Positions	Orientation	Origin and Function
1 - 184		ftiR: Ti-plasmid sequence of pTiAch5 flanking the T-DNA right border region
185 - 189		Polylinker sequences: sequence used in cloning
190 - 214		RB: right border region of the T-DNA of *Agrobacterium tumefaciens*
215 - 344		Polylinker sequences: sequence used in cloning
345 - 614	Counter clockwise	T35S: sequence including the 3´ untranslated region of the 35S transcript of the Cauliflower Mosaic Virus
615 - 625		Polylinker sequences: sequence used in cloning
626 - 4183	Counter clockwise	*cry14Ab-1.b:* coding sequence of the delta-endotoxin gene of *Bacillus thuringiensis* (GenBank accession number: AGU13817.1)
4184 - 5490	Counter clockwise	Pubi10At: sequence including the promoter region of ubiquitin-10 gene of *Arabidopsis thaliana*
5491 - 5595		Polylinker sequences: sequence used in cloning
5596 - 5790	Counter clockwise	T35S: sequence including the 3´ untranslated region of the 35S transcript of the Cauliflower Mosaic Virus
5791 - 5802		Polylinker sequences: sequence used in cloning
5803 - 6879	Counter clockwise	*hppdPf-4Pa:* coding sequence of a variant 4-hydroxyphenylpyruvate dioxygenase gene of *Pseudomonas fluorescens*
6880 - 7251	Counter clockwise	*TPotpY-1Pf*: coding sequence of an optimized transit peptide derivative (position 55 changed into Tyr), containing sequence of the RuBisCO small subunit genes of *Zea mays* and *Helianthus annuus*
7252 - 7272		Polylinker sequences: sequence used in cloning
7273 - 7399	Counter clockwise	Ltev: sequence including the leader sequence of the Tobacco Etch Virus genomic RNA
7400 - 7405		Polylinker sequences: sequence used in cloning
7406 - 8155	Counter clockwise	P2x35S: sequence including the double enhanced promoter region of the Cauliflower Mosaic Virus 35S genome transcript
8156 - 8282		Polylinker sequences: sequence used in cloning
8283 - 8307		LB: left border region of the T-DNA of *Agrobacterium tumefaciens*
8308 - 8612		ftiL: Ti-plasmid sequence of pTiAch5 flanking the T-DNA left border region
8613 - 8864	Counter clockwise	TaadA: sequence including the 3´termination region of the aminoglycoside adenyltransferase gene of transposon Tn7 of *Escherchia coli*
8865 - 9656	Counter clockwise	*aadA*: the coding sequence of the aminoglycoside adenyltransferase gene (aadA) of transposon Tn7 of *Escherichia coli*
9657 - 10394	Counter clockwise	PaadA**:** sequence including the promoter region of the aminoglycoside adenyltransferase gene of transposon Tn7 of *Escherchia coli*
10395 - 10400		Polylinker sequences: sequence used in cloning
10401 - 13187		ORIpVS1: fragment including the origin of replication of the plasmid pVS1 of *Pseudomonas aeruginosa*
13188 - 14251		ORI_ColE1: fragment including the origin of replication of the plasmid pBR322 for replication in *Escherichia coli*
14252 - 14361		Polylinker sequences: sequence used in cloning

3.2. Information relating to the genetically modified plant

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

Resistance to Soybean Cyst Nematodes

GMB 151 soybean produces the Cry14Ab-1 protein, a crystal protein derived from *Bacillus thuringiensis*, which confers resistance to the plant parasitic nematode Soybean Cyst Nematode (SCN), *Heterodera glycines.* The SCN nematode is of high agricultural importance in soybean, with SCN causing highest losses to growers in the US Midwest, and significant crop loss in Brazil.

Herbicide tolerance

The HPPD enzyme is involved in aerobic tyrosine catabolism. The L-tyrosine is first transformed into 4-HPP by tyrosine aminotransferase followed by the formation of HGA by the HPPD enzyme. The biosynthesis of HGA from 4-HPP involves three steps: decarboxylation of the pyruvate side chain, the incorporation of molecular oxygen and rearrangement of the resulting side chain. This reaction is iron-dependent since the enzyme activity requires a non-heme Fe^{2+} atom.

HPPD-4 and HPPD*Pf* were purified from *E. coli* and the kinetic properties of the proteins were determined. The introduced amino acid variations induce a decreased affinity.

HPPD inhibition

4-Hydroxyphenylpyruvate dioxygenase (HPPD) is an Fe(II)-dependent, non-heme oxygenase. HPPD is a key enzyme involved in the catabolism of tyrosine which catalyzes the conversion of 4-hydroxyphenylpyruvate (4-HPP) to homogentisate. In plants, HPPD enzyme is also involved in several anabolic pathways; its reaction product homogentisate (2,5-dihydroxyohenylacetate) being the aromatic precursor of tocopherol and plastoquinone, which are essential to the photosynthetic transport chain and antioxidative systems.

HPPD enzymes require a α-keto acid and molecular oxygen to oxidize or oxygenate a third molecule. The activity of HPPD is suppressed by HPPD-inhibiting herbicides. HPPD enzyme inhibition results in the disruption of the biosynthesis of carotenoids. Plants lacking carotenoids cannot protect themselves from the radicals generated by the light activation of chlorophyll, causing bleaching, necrosis, and death.

3.2.2. Information on the nuleic acid(s) sequences actually inserted or deleted

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

The molecular characterization demonstrated that GMB151 soybean consists of a single insert integrated at a single chromosomal locus within the soybean genome that is stably inherited over generations.

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

In the GMB151 soybean insertion locus sequence, 63 bp of genomic DNA were observed which are not present the GMB151 transgenic locus sequence. These base pairs were deleted during the transformation process and are referred to as the target site deletion.

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

The molecular characterization demonstrated that GMB151 soybean consists of a single insert integrated at a single chromosomal locus within the soybean genome that is stably inherited over generations.

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

The absence of vector backbone sequences was investigated and confirmed by next generation sequencing and junction sequence analysis. Blast searches performed to identify the host genomic sequences in the flanking regions identified 39 bp of filler DNA between the T-DNA sequence and the 3' flanking sequence. Part of this filler DNA shows sequence identity to the ORIpVS1 of the transforming plasmid and another part shows sequence identity to the 3' flanking genomic sequence. Based on the data presented in the application it can be concluded that there is no evidence that the genetic modification of GMB151 soybean resulted in unintended changes or raises any safety concerns.

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

Not applicable

3.2.3. Information on the expression of the insert

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

The expression levels of Cry14Ab-1 and HPPD-4 proteins in grain were similar between GMB151 soybean treated with the trait-specific herbicide and the conventional herbicide.

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

The expression levels of the Cry14Ab-1 and HPPD-4 proteins have been identified in whole plants, leaves, roots, flowers, forage and grain samples of GMB151 soybean.

3.2.4. Genetic stability of the insert and phenotypic stability of the genetically modified plant

The genetic stability of the GMB151 soybean transgenic locus was demonstrated by assessing individual GMB151 soybean plants from five generations by means of Next Generation Sequencing and Junction Sequence Analysis (NGS/JSA).

3.2.5. Information (for environmental safety aspects) on how the genetically modified plant differs from the recipient plant in

(a) Mode(s) and /or rate of reproduction

Phenotypic and agronomic data were collected from trials conducted with GMB151 soybean at multiple sites in the USA during 2017 growing season. These eleven field sites provided a range of environmental and agronomic conditions representative of commercial soybean production. The experiments were arranged as a randomized complete block design with four replicates at each field site. In each of these assessments, GMB151 soybean was compared to an appropriate conventional control, Thorne, with the same genetic

background as GMB151 soybean. In addition, conventional commercial reference varieties were included to provide a range of comparative values that are representative of existing commercial soybean varieties for each measured phenotypic and agronomic characteristic.

Results of these field trials showed that there are no unexpected biologically relevant changes in the agronomic and phenotypic characteristics of GMB151 soybean compared to the conventional counterpart, taking into account natural variation. On the basis of these studies, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in GMB151 soybean and that GMB151 soybean is not different in its phenotypic and agronomic behaviour relative to conventional soybean, except for the introduced traits.

(b) Dissemination

No differences in the dissemination compared to the conventional counterpart have been observed in agronomic and phenotypic assessments conducted with GMB151 soybean.

(c) Survivability

No differences in the survivability compared to the conventional counterpart have been observed in agronomic assessments conducted with GMB151 soybean.

(d) Other differences

Except for the introduced traits that are of agronomic interest, the agronomic assessments in the field did not reveal any biologically relevant differences between GMB151 soybean and its conventional counterpart.

3.2.6. Any change to the ability of the genetically modified plant to transfer genetic material to other organisms (for environmental safety aspects)

(a) Plant to bacteria gene transfer

None of the genetic elements in GMB151 soybean have a genetic transfer function. Therefore, no changes are expected in the ability of GMB151 soybean to transfer genetic material to bacteria.

(b) Plant to plant gene transfer

Based on the observation that reproductive morphology in GMB151 soybean is unchanged compared to conventional soybean, the out-crossing frequency to other soybean varieties or to wild relatives would be unlikely to be different for GMB151 soybean, when compared to conventional soybean varieties. Furthermore, the scope of the current application does not include the cultivation of GMB151 soybean varieties in the EU.

4. COMPARATIVE ANALYSIS

4.1. Choice of the conventional counterpart and additional comparators

The conventional counterpart, Thorne, was included for comparative purposes because it was the original background selected for transformation of the GMB151 event. The GMB151 soybean and its conventional counterpart have the same genetic background. Thorne has a history of safe commercial use.

Nine non-GM commercial reference soybean varieties used in this study were selected to represent a range of genetic backgrounds and phenotypic characteristics. They also reflect a range natural variability within commercial varieties and therefore can provide context for interpreting experimental results. The varieties were included to provide reference ranges for the comparative assessment of the agronomic and composition data. The conventional soybean varieties were selected to represent the breadth and representativeness of commercial germplasm. Their placements within the field study were intended to represent their presumed adaptation.

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

Field trials were conducted with soybean entries at multiple sites in 2017 to allow a comparative assessment of agronomic and phenotypic parameters as well as composition analytes of GMB151 soybean and its conventional counterpart. In addition, nine non-GM commercial reference soybean varieties (reference varieties) representing existing variability in commercial soybean varieties were included (three reference varieties at each site).

An analysis of variance (ANOVA) was conducted in a combined-site analysis in which the data was pooled across all sites. ANOVA models were used to perform difference and equivalence tests according to the 2010 EFSA Scientific opinion on statistical considerations for the safety evaluation of GMOs.

4.3. Selection of material and compounds for analysis

The key nutrients and other nutritionally important components that were selected for analysis of GMB151 soybean in the compositional study were chosen on the basis of internationally accepted guidance provided by the OECD consensus document on compositional considerations for new varieties of soybean.

4.4. Comparative analysis of agronomic and phenotypic characteristics

An assessment of the phenotypic and agronomic characteristics of GMB151 soybean compared to conventional soybean expected and biologically relevant changes in the agronomic or phenotypic characteristics of GMB151 soybean compared to the soybean conventional counterpart, taking into account natural variation.

4.5. Effect of processing

Composition Analysis of the forage and grain, and processed fraction samples and the analysis of protein content in processed fractions demonstrated that the processing of GMB151 soybean has no expected differences from that of conventional soybean.

5. TOXICOLOGY

(a) Toxicological testing of the newly expressed proteins

The available information for the assessment of the newly expressed proteins present in GMB151 soybean indicates that no adverse effects on human or animal health are expected. The outcome of heat stability studies and data concerning stability to proteolytic

enzymes demonstrate that the Cry14Ab-1 and HPPD-4 proteins are quickly degraded under heat treatment, have extremely short structural and functional stabilities under simulated gastric conditions. The Cry14Ab-1 and HPPD-4 proteins are also quickly degraded under simulated intestinal conditions. These results indicate a minimal likelihood that the protein could survive and be absorbed through the gastrointestinal system and consequently that the newly expressed Cry14Ab-1 and HPPD-4 proteins is unlikely to be toxic.

(b) Testing of new constituents other than proteins

Not applicable as the genetic modification in GMB151 soybean does not give rise to the expression of any new constituents other than the Cry14Ab-1 and HPPD-4 proteins.

(c) Information on natural food and feed constituents

No new constituents other than the Cry14Ab-1 and HPPD-4 proteins are expressed in GMB151 soybean. The comparative assessment of GMB151 soybean showed no biologically relevant differences between GMB151 soybean and its conventional counterpart, taking into account natural variation. Therefore, there is no need for further assessment.

(d) Testing of the whole genetically modified food and feed

There are no indications of possible toxicity of GMB151 soybean and whole food and/or feed testing with GMB151 soybean is not deemed necessary. From the results of the 90-day feeding study in rats it was concluded that the GMB151 soybean meal incorporated up to 30% (w/w) in the diet had no adverse effects on the growth or health of Sprague Dawley rats.

6. ALLERGENICITY

(a) Assessment of allergenicity of the newly expressed protein

The bioinformatics analysis demonstrated that there are no biologically relevant sequence similarities to allergens when Cry14Ab-1 and HPPD-4 protein sequences were used as query sequences for a FASTA search against the allergen database.

Based on the weight of evidence approach it can be concluded that the newly expressed Cry14Ab-1 and HPPD-4 are unlikely to be allergenic.

(b) Assessment of allergenicity of the whole genetically modified plant

There is no evidence to suggest that the food derived from GMB151 soybean is likely to be more allergenic than the food derived from the conventional soybean varieties.

7. NUTRITIONAL ASSESSMENT

(a) Nutritional assessment of the genetically modified food

The newly expressed proteins in GMB151 soybean have been assessed and confirmed safe for humans. All dietary exposure estimates were based on a worst-case scenario as it was assumed that 100% of raw soybean and soybean food products would have been harvested or produced from the GMB151 soybean. Additional worst-case assumptions considered that maximum percentages of soybean commodities would be used to prepare animal feed. However, all dietary exposure and intake estimates were minor, due to the low trait-specific protein expression. Therefore, no nutritional impact is expected and the risk to European consumers from GMB151 soybean is considered negligible.

(b) Nutritional assessment of the genetically modified feed

Chronic dietary exposure estimates were minor, due to the low trait-specific protein expression levels in GMB151 soybean seeds and whole plants. In addition, Therefore, the food and feed derived from GMB151 soybean is assumed to be nutritionally equivalent to food and feed derived from conventional soybean varieties.

8. EXPOSURE ASSESSMENT – ANTICIPATED INTAKE/EXTENT OF USE

All dietary exposure estimates were based on a worst-case scenario as it was assumed that 100% of raw soybean and soybean food products would have been harvested or produced from the GMB151 soybean. Additional worst-case assumptions considered that maximum percentages of soybean commodities would be used to prepare animal feed. However, all dietary exposure and intake estimates were minor, due to the low trait-specific protein expression.

9. RISK CHARACTERISATION

A comprehensive risk characterization of GMB151 soybean has been carried out by considering all available evidence from the analyses discussed through this application. The following conclusions from molecular characterization, phenotypic and agronomic analyses, compositional analyses, toxicology assessment, allergenicity assessment and exposure assessment have been considered:

- The molecular characterization demonstrated that GMB151 soybean consists of a single insert integrated at a single chromosomal locus within the soybean genome that is stably inherited over generations. The absence of vector backbone sequences has been confirmed, with the exception of a 21bp fragment near the 3' end of the T-DNA.

  Bioinformatics analysis of the full DNA sequence of GMB151 soybean revealed no evidence supporting cryptic gene expression or unintended effects resulting from the genetic modification.

  The expression levels of Cry14Ab-1 and HPPD-4 proteins in grain were similar between GMB151 soybean treated with the trait-specific herbicide and the conventional herbicide.

  Altogether, the data presented in this section show no evidence that the genetic modification of GMB151 soybean resulted in unintended changes or raises any safety concerns.

- The results of the comparative assessment (seed composition data and agronomics and phenotypic characteristics) conducted on GMB151 soybean identified no biological relevant differences and/or lack of equivalence between GMB151 soybean and its comparators, taking into account natural variation.

  The comparative assessment of GMB151 soybean, the conventional counterpart and the non-GM reference varieties showed no differences that would require further assessment of the agronomic and phenotypic parameters or the soybean forage and grain composition analytes with respect to their possible impact on food and feed safety and nutritional properties.

  The comparative assessment established the comparability of GMB151 soybean to its conventional counterpart and equivalency of GMB151 soybean to the reference varieties. In conclusion, based on the comparative assessment, there are no

unexpected or unintended effects and no impact on either the agronomic performance of the plants or the nutritional value of the forage and grain from GMB151 soybean plants as a result of the genetic modification of the soybean plants.

- The available information for the assessment of the newly expressed proteins present in GMB151 soybean indicates that no adverse effects on human or animal health are expected. The outcome of heat stability studies and data concerning stability to proteolytic enzymes demonstrate that the Cry14Ab-1 and HPPD-4 proteins are quickly degraded under heat treatment and have extremely short structural and functional stabilities under simulated gastric and intestinal conditions. These results indicate a minimal likelihood that the proteins could survive and be absorbed through the gastrointestinal system and consequently that the newly expressed Cry14Ab-1 and HPPD-4 are unlikely to be toxic.

  The results of the comparative assessment conducted on GMB151 soybean supports a conclusion that no biologically relevant differences, except for the introduced traits, were identified in the composition data obtained from GMB151 soybean or in its agronomic and phenotypic characteristics that would require further assessment with respect to their possible impact on food and feed safety and nutritional properties. Therefore, there are no indications of any potential adverse effect that could arise from natural constituents' changes.

  The outcome of the 28-day toxicity studies demonstrates the lack of toxicity of the newly expressed Cry14Ab-1 and HPPD-4 proteins.

  From the results of the 90-day feeding study in rats it can be concluded that the GMB151 soybean meal incorporated up to 30% in the diet of Sprague Dawley rats did not cause any adverse effects.

  Overall, the results of the toxicological assessment indicate that consumption of GMB151 soybean food and feed products will be as safe as consumption of equivalent products from conventional soybean, regardless of the anticipated intake level.

- Bioinformatics analysis demonstrated that there are no biologically relevant sequence similarities to allergens when Cry14Ab-1 and HPPD-4 protein sequences were used as query sequences for a FASTA search against the allergen database. There is also no evidence of possible adjuvanticity of both individual proteins.

  Based on the weight of evidence approach it can be concluded that the newly expressed Cry14Ab-1 and HPPD-4 proteins are unlikely to be allergenic.

  The comparative analysis of GMB151 soybean identified no biologically and nutritionally relevant differences (except for introduced traits) between GMB151 soybean and its conventional counterpart, taking into account natural variation. The newly expressed proteins are unlikely to be allergenic. Therefore, no increased allergenicity is anticipated for GMB151 soybean or for the food derived from GMB151 soybean in comparison to the food derived from the conventional soybean varieties.

- As expected, in the comparative assessment of GMB151 soybean no indications of unintended changes in nutritional value due to the genetic modification have been observed. Therefore, the food and feed derived from GMB151 soybean is assumed to be nutritionally equivalent to food and feed derived from conventional soybean varieties. In addition, the outcome of the 90-day feeding study revealed no toxicological findings associated with the consumption of the whole feed derived from GMB151

soybean in comparison with the conventional counterpart.

All dietary exposure estimates were based on a worst-case scenario as it was assumed that 100% of raw soybean and soybean food products would have been harvested or produced from the GMB151 soybean. Additional worst-case assumptions considered that maximum percentages of soybean commodities would be used to prepare animal feed. However, all dietary exposure and intake estimates were minor, due to the low trait-specific protein expression. Therefore, it may be assumed that the food and feed derived from GMB151 soybean is nutritionally equivalent to food and feed derived from the conventional soybean varieties.

The evidence presented throughout this application and summarized above demonstrate that:

- The consumption of food and feed derived from GMB151 soybean is as safe as the respective comparators;
- The food derived from GMB151 soybean is not nutritionally disadvantageous for the consumer compared to the food which is intended to replace;
- The feed derived from GMB151 soybean is not nutritionally disadvantageous for animals compared to the feed which is intended to replace;
- The feed derived from GMB151 soybean does not harm or mislead the consumer by impairing distinctive features of the animal products compared to conventionally produced feed.

The assumptions made during the risk assessment are very conservative and include the following:

- All soybean seeds consumed in the EU would be from GMB151 soybean plants
- No loss or degradation of protein would occur during processing and food preparation of GMB151 soybean products.

The labelling requirements specified in Articles 5(3)(f) and 17(3)(f) of Regulation (EC) No 1829/2003 are not applicable because the characteristics of the food and feed products from GMB151 soybean are not different from the characteristics of its conventional counterpart taking into account natural variation.

10. POST-MARKET MONITORING ON GENETICALLY MODIFIED FOOD/FEED

The risk characterization of GMB151 soybean has shown that the risk for potential adverse effects on human and animal health is negligible in the context of the intended uses of GMB151 soybean. It is therefore considered that there is no need for post marketing monitoring of food and feed derived from GMB151 soybean.

11. ENVIRONMENTAL ASSESSMENT

11.1. Mechanism of interaction between the genetically modified plant and target organisms

In this area of assessment, the main environmental concern, according to the EFSA ERA Guidance, is that target organisms develop resistance to the insect or pathogen tolerance traits expressed by the GM plant.

GMB151 soybean has been developed to confer resistance to soybean cyst nematodes and tolerance to HPPD inhibitors. No target organisms are associated with this product since no cultivation of GMB151 soybean in the EU is foreseen. Therefore, an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use GMB151 soybean is not relevant.

11.2. Potential changes in the interactions of the genetically modified plant with the biotic environment resulting from the genetic modification

(a) Persistence and invasiveness

An assessment has been conducted of whether the import, processing and food and feed use of GMB151 soybean in the EU could result in harm to sustainable agricultural production or to biodiversity. The assessment has considered whether:

- the persistence and invasiveness potential of GMB151 soybean differs from the conventional crop or not;
- cross-hybridisation and introgression with wild relatives can occur;
- the traits introduced could confer a selective advantage.

The conclusions from the comparative safety assessment conducted confirmed that no biologically relevant differences (*i.e.* consistent differences or differences outside the ranges for conventional varieties) in agronomic or phenotypic characteristics were observed between GMB151 soybean and a conventional counterpart, apart from the intended traits.

The potential that the introduced traits confer a selective advantage or disadvantage to the GM crop or to sexually compatible wild relatives has also been assessed. The main limiting factors preventing the spread of the crop outside agro-ecosystems are human dependence and frost tolerance; therefore, the herbicide tolerance and resistance to soybean cyst nematode are unlikely to confer selective advantage or disadvantage to the soybean. Since no sexually compatible wild relatives of the soybean are found in the EU, cross-hybridization and introgression is highly unlikely.

The conclusion is that risk that the import, processing or food and feed use of GMB151 soybean in the EU will result in harm to sustainable agricultural production or biodiversity is negligible.

(b) Selective advantage or disadvantage

It was previously demonstrated that the inherited genetic sequence in GMB151 soybean did not lead to any biologically meaningful alterations of the phenotypic characteristics, such as plant growth and development, morphology, agronomic performance, composition, nutritional value or safety characteristics, when compared to the conventional soybean, except for the inherited herbicide tolerance and resistance to soybean cyst nematodes. Therefore, it was concluded that GMB151 soybean is not meaningfully different from conventional soybean, with the exception of the intentionally introduced agronomically beneficial traits.

Compared with conventional soybean, the introduced herbicide tolerance and resistance to soybean cyst nematodes in GMB151 soybean confer a selective advantage only under specific conditions (i.e. following treatment with trait-specific herbicide). The advantage is of purely agronomic interest and presents negligible risk to the non-agricultural environments. Given the scope of this application, the likelihood is negligible for the inherited traits in GMB151 soybean to confer any meaningful competitive advantage or disadvantage of relevance to the environment.

(c) Potential for gene transfer

An assessment of whether the new genes present in GMB151 soybean, could be transferred into micro-organisms and become integrated into their genome leading to adverse effects in human and animal health or the environment has been conducted. The conclusion from this assessment is that it is very unlikely that these genes would become established in the genome of micro-organisms in the environment or human and animal digestive tract and the risk is negligible. In the very unlikely event that such a horizontal gene transfer would take place, no adverse effects on human and animal health or the environment are expected.

(d) Interactions between the genetically modified plant and target organisms

The scope of this application covers the import, processing and food and feed use of GMB151 soybean in the EU, no deliberate release of viable plant material in the EU environment is expected. Therefore, an assessment of the potential resistance development in target organisms resulting from the import, processing and food and feed use of GMB151 soybean is not relevant for this application. It can be concluded that the likelihood that import, processing and food and feed use of GMB151 Soybean in the EU will result in harmful effects in human or animal health or the environment as a consequence of development of resistance is negligible.

(e) Interactions of the genetically modified plant with non-target organisms

The risk that the import, processing or food and feed use of GMB151 soybean could harm sustainable agricultural production or biodiversity due to direct or indirect interactions between GMB151 soybean and NTO populations has been assessed. The conclusion of this risk characterisation is that the risk will be negligible. Given the scope of this application and considering the low levels of exposure (and hazard) and absence of identified unintended differences, the uncertainty associated with this risk characterisation can be considered low and the probability of long-term environmental effects occurring is also low.

(f) Effects on human health

This application is for the import, processing and all uses as any other soybean, but excludes the cultivation of GMB151 soybean in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of GMB151 soybean with human health will be limited to the occupational hazards associated with the storage, handling and processing of GMB151 soybean. Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact with GMB151 soybean seed, the likelihood for any adverse effects, occurring in humans as a result of their contact with this seed, is no different from conventional soybean. GMB151 soybean seed contains the Cry14Ab-1 and HPPD-4 proteins, which have negligible potential to cause any toxic or allergenic effects in humans. Therefore, the risk of changes in the occupational health aspects of this soybean is negligible.

(g) Effects on animal health

This application is for the import, processing and all uses as any other soybean, but excludes the cultivation of GMB151 soybean in the EU. Therefore, no deliberate release of viable plant material in the EU environment is expected and interactions of GMB151 soybean with animal health will be limited to the occupational hazards associated with the storage, handling and processing of GMB151 soybean. Given the low levels of environmental exposure combined with the negligible hazard occurring from the contact with GMB151 soybean seed, the likelihood for any adverse effects, occurring in animals as a result of their contact with this seed, is no different from conventional soybean. GMB151 soybean seed contains the Cry14Ab-1 and HPPD-4 proteins, which have negligible potential to

cause any toxic or allergenic effects in animals. Therefore, the risk of changes in the occupational health aspects of this soybean is negligible.

(h) Effects on biogeochemical processes

Cultivation of GMB151 soybean in the EU is not included in the scope of this application. An assessment of the impacts of GMB151 soybean on biogeochemical processes resulting from specific cultivation, management and harvesting techniques is not relevant given the scope of this application.

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

Cultivation of GMB151 soybean in the EU is not included in the scope of this application. An assessment of the impacts of specific cultivation, management and harvesting techniques of GMB151 soybean is therefore not relevant given the scope of this application.

11.3. Potential interactions with the abiotic environment

Overall results of the comparative analysis of GMB151 soybean with respect to its conventional counterpart indicate that observed differences in composition and agronomic and phenotypic characteristics fell within the range of natural variability for soybean with a history of safe use. Therefore, there is no evidence that this soybean would be any different from conventional soybean with regard to its baseline interactions with the abiotic environment.

In addition, because this application is for import, processing and all uses as any other soybean in the EU, but excluding cultivation, interactions of GMB151 soybean with the environment will be limited.

11.4. Risk characterisation

Results from the environmental risk assessment which takes into consideration the risk characterization and includes results described above addressing risk hypotheses for the specific areas of assessment laid down in 2010 EFSA guidance, support a conclusion that the import, processing and all uses of GMB151 soybean (excluding cultivation) as any other soybean, in the EU represents negligible risk to human and animal health and the environment and poses no greater risk than the import and processing of conventional soybean.

12. ENVIRONMENTAL MONITORING PLAN

(a) General (risk assessment, background information)

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 the proposed Post-Market Environmental Monitoring (PMEM) plan for GMB151 soybean has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The PMEM also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring of genetically modified plants

(b) Interplay between environmental risk assessment and monitoring

An environmental risk assessment (e.r.a.) was carried out for GMB151 soybean according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC

establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of GMB151 soybean in the e.r.a. has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of GMB151 soybean.

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

The scientific evaluation of the characteristics of GMB151 soybean in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of GMB151 soybean. It is therefore considered that there is no need for case-specific monitoring.

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

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

The scope of this application is the authorisation of GMB151 soybean for food and feed uses, import and processing. The scope of the application does not include authorisation for the cultivation of GMB151 soybean seed products. Therefore, exposure to the environment will be limited to unintended release of GMB151 soybean, which could occur for example via substantial losses during loading/unloading of the viable commodity including GMB151 soybean destined for processing into animal feed or human food products. Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious soybean plants, such as manual or mechanical removal and the application of herbicides (with the exception of HPPD inhibitors).

However, and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, general surveillance on GMB151 soybean will be undertaken for the duration of the authorisation. The general surveillance will take into consideration, and be proportionate to, the extent of imports of GMB151 soybean and use thereof in the Member States.

In order to increase the possibility of detecting any unanticipated adverse effects, a monitoring system will be used, which involves the authorisation holder and operators handling and using viable GMB151 soybean. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable GMB151 soybean.

(e) Reporting the results of monitoring

In accordance with Regulation (EC) No 1829/2003, the authorisation holder is responsible to inform the European Commission of the results of the general surveillance.

If information that confirms an adverse effect of GMB151 soybean and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the confirmed effect.

The authorisation holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on unanticipated adverse effects, if any, that have arisen from handling and use of viable GMB151 soybean.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of GMB151 soybean and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts of such report shall be submitted in separate documents.

13. DETECTION AND IDENTIFICATION TECHNIQUES FOR THE GENETICALLY MODIFIED PLANT

The detection method for GMB151 soybean was sent to the Community Reference Laboratory (CRL) of the Joint Research Centre of the European Commission (EC-JRC) for the purposes of experimental testing and validation in the frame of the food and feed application of GMB151 soybean. Appropriate control samples were also made available to the JRC-CRL.

14. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GENETICALLY MODIFIED PLANT (FOR ENVIRONMENTAL SAFETY ASPECTS)

14.1. History of previous releases of the genetically modified 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 is no history of field release of GMB151 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 in accordance with Article 10 of Directive 2001/18/EC)

Not applicable.

14.2. History of previous releases of the genetically modified plant carried out outside the Union by the same notifier

(a) Release country

GMB151 soybean has been tested in the USA, Brazil and Argentina.

(b) Authority overseeing the release

U.S.: U.S. Department of Agriculture and EPA; Brazil: CTNBio; Argentina: Conabia

(c) Release site

U.S.: multiple major soybean-growing provinces, states and regions respectively; Brazil and Argentina.

(d) Aim of the release

Regulatory trials, testing of efficacy, yield and product development.

(e) Duration of the release

The generation time for soybean from planting to harvest, is 3 to 5 months in the primary growing areas.

(f) Aim of post-releases monitoring

Volunteer assessment.

(g) Duration of post-releases monitoring

Generally, one season.

(h) Conclusions of post-release monitoring

Occurrence of volunteers is very infrequent and no different from soybean derived through conventional breeding practices.

(i) Results of the release in respect to any risk to human health and the environment

No risk to human health or the environment has been indicated by the field release experience.