

Part III – Cartagena Protocol

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-2018-153

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PART III – CARTAGENA PROTOCOL

Information required under Article 5(3)(c) and Article 17(3)(c) of Regulation (EC) No 1829/2003 for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

The provided information shall contain as a minimum the information specified in Annex II to Regulation (EC) No 1946/2003 of the European Parliament and of the Council:

(a) The name and contact details of the applicant for a decision for domestic use.

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
Tel: +32 471 98 36 44
E-mail: oksana.apanasetz@agro.basf-se.com

(b) The name and contact details of the authority responsible for the decision.

European Commission
Rue de la Loi 200
1049 Bruxelles
Belgium

(c) Name and identity of the GMO.

GMB151 is soybean cyst nematode resistant and herbicide tolerant soybean.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the GMO.

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.

(e) Any unique identification of the GMO.

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

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

Taxonomic status:

Family:	<i>Leguminosae</i>
Genus:	<i>Glycine</i>
Species:	<i>max</i>
Sub-species:	none designated
Cultivar/Breeding line:	various
Common name:	soybean

Point of collection or acquisition: North America and other countries

Characteristics related to biosafety: not different from any other commercial soybean varieties except for the intended traits

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

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.

Soybeans are quantitative short-day plants and thus flower quicker 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 10°C and will emerge in a 5-7 day period under favourable conditions. In new areas of soybean production an inoculation with *Bradyrhizobium japonicum* is necessary for optimum efficiency of the nodulated root system. Soybeans do not yield well on acid soils.

The subgenus *Soja*, to which *G. max* belongs, also includes *G. soja* Sieb. and Zucc. (2n=40) and *G. gracilis* Skvortz., 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 the border of the former USSR. *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 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.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

GMB151 soybean has been developed through *Agrobacterium*-mediated transformation using the vector pSZ8832 containing the *cry14Ab-1.b* and *hppdPf-4Pa* gene cassettes.

The *cry14Ab-1.b* gene originates from genomic DNA of *Bacillus thuringiensis*.

Taxonomic status:	<i>Bacillus thuringiensis</i>
Common name:	<i>Bacillus thuringiensis</i>
Point of collection or acquisition:	All genetic elements were isolated or obtained from internal research laboratories of the applicant.
Characteristics related to biosafety:	There is no evidence of any human or animal pathogenicity for any of the donor organisms of the DNA sequences that were used to develop GMB151 soybean.

The *hppdPf-4Pa* gene originates from genomic DNA of *Pseudomonas fluorescens*.

Taxonomic status:	<i>Pseudomonas fluorescens</i>
Common name:	<i>Pseudomonas fluorescens</i>
Point of collection or acquisition:	All genetic elements were isolated or obtained from internal research laboratories of the applicant.
Characteristics related to biosafety:	There is no evidence of any human or animal pathogenicity for any of the donor organisms of the DNA sequences that were used to develop GMB151 soybean.

(i) Approved uses of the GMO.

NA at the moment of submission.

(j) A risk assessment report consistent with Annex II to Directive 2001/18/EC.

A risk assessment report consistent with Annex II to Directive 2001/18/EC has been provided in Part II of this application.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

An extensive comparative safety assessment has been performed in the frame of the present application and GMB151 soybean has been found to be equivalent to its conventional counterpart except for the intended traits.

The interaction of GMB151 soybean with the biotic and the abiotic environment will be the same as for any other commercial soybean in the EU.

It is the responsibility of the importer to follow the documentation requirements of the Cartagena Protocol on Biosafety and Regulation (EC) No 1946/2003. Companies commercializing GMB151 soybean need to label the products in accordance with Regulation (EC) No 1830/2003.