
PART III**INFORMATION REQUIRED BY THE CARTAGENA PROTOCOL ON
BIOSAFETY, UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY****A. Name and contact details of the applicant for a decision for domestic use.**

Bayer CropScience GmbH
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B. Name and contact details of the authority responsible for the decision

European Commission
Rue de la Loi/Wetstraat 200
B-1049 Bruxelles/Brussel
Belgium

C. Name and identity of the LMO

Bayer CropScience has developed soybean varieties that are tolerant to the glufosinate ammonium-based herbicide, commercialized under the recognized trade name Liberty®. The commercial name of the planting seed product is LibertyLink® Soybean.

LibertyLink® Soybean varieties are based upon a well-characterized transgenic line, known as transformation event A2704-12, also designated by the OECD unique identifier code ACS-GM005-3.

D. Description of the gene modification, the technique used, and the resulting characteristics of the LMO

Tissue from the soybean cultivar A2704 was transformed with plasmid pB2/35SAcK by particle bombardment in order to incorporate the *pat* gene, coding for the enzyme phosphinothricin acetyl transferase (PAT). The *pat* gene product, PAT, metabolizes phosphinothricin to an inactive, acetylated derivative and consequently confers tolerance to the herbicide glufosinate ammonium (GA).

The plasmid pB2/35SAcK was first digested with restriction enzyme *PvuI* to disrupt the coding sequence of the β -lactamase gene (*bla*) and thereby remove the possibility of its expression, and the resulting restriction fragments were used in transformation.

The *pat* gene cassette contains a synthetic version of the *pat* gene from *Streptomyces viridochromogenes*, a common soil microbe. Two copies of the *pat* gene expression cassette, regulated by the 35S promoter, were introduced at one locus. The cassettes are joined by an inverted fragment from the transforming plasmid including a disrupted, non-expressing antibiotic resistance *bla* gene. No carrier DNA was used in the transformation process.

The insertion of the *pat* gene has been verified through a characterization of the insert by Southern blot and PCR analysis. Both the inserted DNA and the flanking DNA have been sequenced. The inserted DNA consists of two copies of the 35S-promoter sequence, the *pat* ORF and the 35S terminator sequence joined by an inverted *PvuI* fragment from the transforming plasmid including the disrupted *bla* gene the polilinker and ori sequences from the vector pUC19.

The inserted *pat* genes are inherited as a single dominant trait. Stability of the gene insertion has been demonstrated by Southern blot analyses and Mendelian crosses.

E. Any unique identification of the LMO

The OECD unique identifier code for soybean event A2704-12 is ACS-GM005-3.

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

Taxonomic status:

Family: *Leguminosae*
Genus: *Glycine*
Species: *max*
Sub-species: none designated
Breeding line: A2704

Common name: soybean

Point of collection or acquisition: commercial soybean variety A2704

Characteristics related to biosafety: not different from other soybean varieties

G. Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or 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 35 countries throughout the world.

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 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 twelve 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 $2n=80$.

FAO Agricultural Production Data 2004:

Country/Area	Production (metric ton)	% of total production	Surface harvested (ha)
World	206 million	100	91 million
USA	86 million	42	30 million
China	18 million	9	11 million
Brazil	49 million	24	22 million
Argentina	32 million	15.5	14 million
Canada	3 million	1.5	1.2 million
European Union*	760 000	0.36	269 000

* Soybean production in the following Member States: Austria (5%), Czech Republic, France (20%), Germany, Greece, Hungary (6.5%), Italy (64%), Slovakia, Slovenia and Spain.

FAO Agricultural Production Data indicates that during 2004, 206 million metric tons of soybeans were harvested from 91 million hectares world-wide. Of that, almost 760,000 metric tons were produced on about 269,000 hectares in the European Union. FAO data indicates soybean production in the following Member States during 2004: Austria, Czech Republic, France, Germany, Greece, Hungary, Italy, Slovakia, Slovenia and Spain. Approximately 64% of all the soybeans produced in the EU were grown in Italy during that time period. France's production represented 20%, Hungary's 6.5% and Austria's about 5%.

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

The plasmid pB2/35SAck, used for the transformation after digestion with the restriction enzyme *PvuI* to disrupt the coding sequence of the β -lactamase gene, contains the right border fragment of the octopine plasmid TiAch5 from *Agrobacterium tumefaciens*, the synthetic *pat* gene, regulated by the 35S promoter and 35S terminator from Cauliflower Mosaic Virus and the sequence of the vector pUC19, including polylinker, ori and the *bla* gene.

The right border fragment of the octopine plasmid TiAch5 from *Agrobacterium tumefaciens*.

Taxonomic status:	<i>Agrobacterium tumefaciens</i>
Common name:	<i>Agrobacterium tumefaciens</i>
Point of collection or acquisition	Gielen <i>et al.</i> , 1984.
Characteristics related to biosafety	Risk Class 1 (lowest risk class)

The *pat* gene cassette contains a synthetic version of the *pat* gene from *Streptomyces viridochromogenes*, a common soil microbe, not known to be a human, animal or plant pathogen.

Taxonomic status: *Streptomyces viridochromogenes*
 Common name: *Streptomyces viridochromogenes*
 Point of collection or acquisition Strauch *et al.*, 1993.
 Characteristics related to biosafety Risk Class 1 (lowest risk class)

The 35S promoter and 35S terminator from Cauliflower Mosaic Virus, derived from vector PDH51, direct the expression of the *pat* gene.

Taxonomic status: Cauliflower Mosaic Virus
 Common name: Cauliflower Mosaic Virus
 Point of collection or acquisition Pietrzak *et al.*, 1986.
 Characteristics related to biosafety Risk Class 2

The *bla* gene, polylinker and ori sequences of the vector pUC19 from *Escherichia coli*

Taxonomic status: *Escherichia coli*
 Common name: *Escherichia coli*
 Point of collection or acquisition Yanish -Perron *et al.*, 1986.
 Characteristics related to biosafety Risk Class 1 (lowest risk class)

I. Approved uses of the LMO

Current Food and Feed Use, Environment and Cultivation Approvals for Soybean Event A2704-12

Country	Type and Date of Approval – Event A2704-12			
	Food	Feed	Environment	Cultivation
Argentina			7 May 2001	
Australia/ New Zealand	29 April 2004			
Canada	22 Nov. 2000	18 Dec. 2000	26 April 1999	26 April 1999
Japan	11 June 2002	27 March 2003	13 May 1999	
Mexico	13 Aug. 2001	10 March 2000		
South Africa	12 Dec. 2001	12 Dec. 2001		
Russia	19 July 2002			
United States	15 May 1998	15 May 1998	31 July 1996	31 July 1996

For future information please refer to the BCH website at the following address:
<http://bch.biodiv.org/decisions/uniqueidentifications.aspx>

J. A risk assessment report consistent with Annex II to Directive 2001/18/EC

A risk assessment consistent with Annex II to Directive 2001/18/EC has been included in the

request for placing on the market in accordance with Regulation (EC) No 1829/2003 on GM Food and GM Feed.

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

As the risk analysis for the request for placing on the market in accordance with Regulation (EC) No 1829/2003 indicates, any unintended release or misuse will not have any detrimental effects on the environment or on human and animal health. Therefore, there are no specific instructions or recommendations for storage and handling. The GM soybean will be handled in the same way as other conventional soybean.

The soybean transformation event A2704-12 is tolerant to herbicide products having glufosinate-ammonium as the active substance. However, it remains susceptible to other herbicides and can in this way, as well as mechanically, easily be destroyed. Soybean event A2704-12 behaves in the same manner in the environment as a conventional soybean.

It is the responsibility of the importer to follow the documentation requirements of the Cartagena Protocol on Biosafety and Regulation (EC) 1946/2003. Operators commercializing materials containing or derived from LL Soybean need to label the products in accordance with regulation (EC) 1830/2003.