Genetically Modified (GM) Crops:

molecular and regulatory details

Version 2

BATS
Zentrum für Biosicherheit und Nachhaltigkeit

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SCOPE

This publication is the second version of the BATS-report 2003 on genetically modified crops. It provides comprehensive and up-to-date molecular and regulatory information on genetically modified (GM) crops approved worldwide and is to support authorities responsible for regulating gene technology, safety assessment personnel and analytical laboratories.

The report starts with an introduction in plant transformation methods and a survey of genes, promoters and terminators used for the development of GM crops. The majority of the publication consists of fact sheets with a molecular characterization and description of the regulatory status of all approved GM plants. Most key terms occurred in the molecular section, are defined in a glossary. In addition, information on the US and Argentinean GM crop regulatory system is provided in the annex.

The report is freely distributed on the Internet and molecular as well as regulatory information will be updated regularly.

Table of contents

Introduction

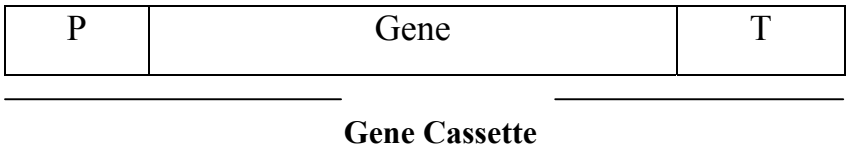
Plant Transformation Method

The currently approved transgenic crop plants have been genetically modified to improve product quality (fatty acid metabolism, fruit ripening delay), pest resistance (insect and viral resistance), and agronomic traits (herbicide tolerance, hybrid system).

The specific genes conferring the traits of interest can be introduced into the plant genome using transformation. The genetic modifications can also be produced by altering existing codes without insertion of a foreign DNA (e.g. chemical mutagenesis), which will not be discussed in this report.

The transformation involves insertion of a piece of DNA (the insert), a synthetic combination of several small pieces of DNA, into the genome of the target organism. The inserted genes are usually taken from other naturally occurring organisms, and have to undergo several modifications before they can be effectively inserted into a plant genome and successfully expressed. A promoter sequence must be added at the upstream side of the coding sequence of the gene in order to have a correct expression in the plant. A terminator sequence (involved in transcription termination and polyadenylation) at the end of the coding region of the gene is also necessary. This construction of a "promoter-gene-terminator" is called a gene cassette (Figure 1a). Frequently, two or more foreign gene cassettes are introduced in a gene construct (Figure 1b).

1a)



1b)

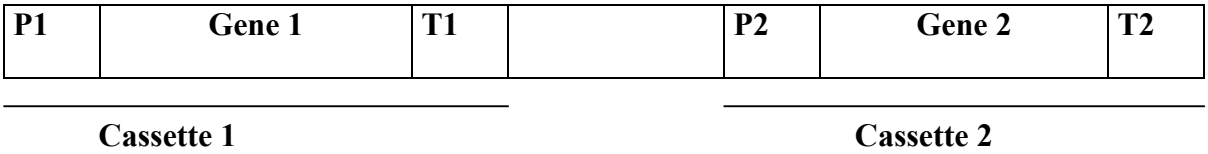


Figure 1: a) Simplified representation of a typical insert (gene construct), containing necessary components for a successful integration and expression. (P: promoter, T: terminator).
b) Presence of two gene cassettes with corresponding regulatory elements (promoter and terminator) in an insert.

In addition to gene cassettes, several other elements may be present in a gene construct, and their function is usually to control and stabilize the function of the gene, or facilitate combination of the various elements in a gene construct.
In order to transform a plant's phenotype, here following are three common forms of transformation.

(1) A. tumefaciens method

Perhaps the most successful method involves the pathogenic bacterium Agrobacterium tumefaciens, which has the innate ability to transfer DNA to plant cells. In nature, this transfer results in the formation of plant tumors (crown galls) at the infection site. Whereas in the laboratory, the tumor causing genes of Agrobacterium tumerfaciens have been removed. This allows the bacteria to transfer the gene of interest into the plant cells without causing tumor formation. The only disadvantage of the highly efficient Agrobacterium system is that it does not work with all plant species, most notably the cereals. This system has been widely used for transformation of several crops like canola, tomato, cotton and potato. More than 37 currently approved GM crops are transformed using this method.

(2) Direct DNA transfer methods

These techniques use physical or chemical agents to transfer DNA into plant cells. Transgenic corn and rice have been produced using these techniques, especially electroporation (for example Bt11, MS3, MS6, T14 & T25 corn, LLRICE06 & LLRICE62 rice). In order to ensure successful DNA transfer using physical or chemical agents, the plant cells must be stripped of their protective cell walls. The resulting cell is called a protoplast. Protoplast have the advantage of high DNA uptake when treated with physical or chemical agents (D'Halluin et al, 1992; Lindsey et al, 1989; Lindsey et al., 1990; Dekeyser et al, 1989). Once inside the protoplast, the DNA is integrated into the genome. The only disadvantage is the generation of a protoplast, which often leads to a lower success rate of generating viable plants.

(3) Microparticle bombardment method (biolistics or particle gun)

It involves accelerating very small particles of tungsten or gold coated with DNA into cells using an electrostatic pulse, air pressure, or gunpowder percussion. As the particles pass through the cell, the DNA dissolves and becomes free to integrate into the plant-cell genome (Becker et al, 1994; Vasil et al, 1992; Walters et al, 1992; Nahra et al 1994). Unlike chemical and physical methods, microparticle bombardment (MB) does not require the generation of protoplasts. With MB one may use whole

cells or plant tissue sections. Using MB, transgenic corn and soybean plants have been produced. More than 22 currently approved GM crops are transformed using this method[1].

With all the aforementioned transformation techniques, the insertion of genes into the plant genome occurs randomly. In some cases the foreign gene cassettes are inserted in single copy or tandem repeats, in truncated or rearranged forms, in one or more sites. In the case of many GM crops, the junctions between plant and insert DNA have not been characterized in detail. The random insertion of foreign DNA into the plant genome may cause unpredictable position or pleiotropic effects (see glossary) (van Leeuwen et al, 2001; Thiele et al, 1999).

In order to eliminate non-transformed cells, the gene of interest is cotransferred with a selectable marker gene. This marker gives transformed cells resistance to a certain antibiotic or herbicide. When the marker antibiotic or herbicide is applied to a cell population, only the transformed cells will survive. This process of using antibiotic or herbicides to eliminate non-transformed cells is called selection. After selection, new methods allow for the removal of the marker, thus yielding a marker-free transgenic plant.

The above mentioned transformation methods have been used to introduce or alter the traits which are associated with expression of single genes. But many important agronomic traits are not well understood and are controlled by many genes. Manipulating such polygenic traits by genetic engineering will require further research, and the development of techniques for isolating, reconstructing, and transferring is complex.

Survey of the genetic components introduced into GM crops approved worldwide

An analysis of the genetic elements of all approved GM crops represents a comprehensive basis for the development of DNA based detection methods. The elements which appear frequently in GM crops can be used for screening methods that can detect a wide range of GM crops without identifying it precisely. But one should be aware that there might be sequence divergence between different genetic elements of the same type. The genetic elements which have been used in particular cases may allow specific detection for the given transformation event.

[1] the relative lines deriving from the same transformation event are treated as a single product

The genes and corresponding regulatory sequences (promoters and terminators), which have been introduced into currently approved genetically modified crops are summarized in this section.

Since the source of introduced genetic material is an important factor in safety assessment, the donor organism for each genetic material is indicated in this section. This information can be used by safety assessment groups to better evaluate the possible risk of environmental and human health damage by the presence of sequences derived from plant pathogens.

The most present material in transgenic plants comes from *Agrobacterium tumefaciens* (*A. tumefaciens*) and Cauliflower Mosaic Virus (CaMV). Out of 66 surveyed transgenic crops, 62 of them contained at least one genetic sequence that was derived from these two organisms.[2]

Survey of the promoters used

One of the most important factors for achieving the desired expression levels of a transgene is the choice of the promoter that regulates transcription of the transgene. As shown in Table 1, many of the approved transgenic crops contain a copy of the constitutive 35s promoter (P-35s) from the CaMV or one of the derivatives of this promoter. The P-35s has been widely used in the screening detection methods. A comparison of P-35s sequences available from public sources (for example: patents, gene bank or petitions) shows that they are not identical and there are different sequence mutants of P-35s fragments in different GM crops. Out of 29 promoters, 20 have been employed only in a single product**.** No data were available on the promoters of one transgenic canola line: PHY23.

[2] Crops approved in Japan and China as well as all transgenic flowers (carnations) are not taken into account in the statistics, because there is no reliable molecular information available.

Used promoters	Donor organisms (origin)	Number of occurences of each promoter
An anther specifc promoter		2
Bacterial		22
dP-35s	Cauliflower Mosaic Virus	1
E-OCS	Agrobacterium tumefaciens	1
Nda		1
P-35s	Cauliflower Mosaic Virus	43
P-4AS1	Cauliflower Mosaic Virus	1
P-5126del	Zea mays	1
P-ALS	Nicotiana tabacum	1
P-Als	Arabidopsis thaliana	1
P-CDPK	Zea mays	1
P-E35s	Cauliflower Mosaic Virus	12
P-E8	Lycoperiscon esculentum (Tomato)	1
P-FMV	Figworth Mosaic Virus	8
P-HelSsu	Helianthus annus	1
P-Kti3	Glycine max (soybean)	1
P-mac	A. tumefaciens and Cauliflower Mosaic Virus	1
P-mas	Agrobacterium tumefaciens	1
P-napin	Brassica rapa	1
P-nos & 2xP-nos	Agrobacterium tumefaciens	11
P-NtQPT1	Nicotiana tabacum	1
P-OCS,35s	Cauliflower Mosaic Virus & A. tumefaciens	1
P-PCA55	Zea mays	1
P-PEPC	Zea mays	1
P-Ptac	Bacterial	1
P-ract	Oryza sativa (rice)	2
P-Ssu	Arabidopsis thaliana	9
P-TA29	Nicotiana tabacum	6
P-ubiZM1(2)	Zea mays	1
P-β-Conglycinin	Glycine max (soybean)	1

Table 1: The frequency of occurrence of introduced promoters into approved GM crops. The donor organisms of promoters are indicated. Some promoters may be present in more than one copy in a single product, since a regulatory sequence may have been used for more than one transgene and since several copies of a transgene may be present in the same product. This frequency of appearance is not taken into account in the table.

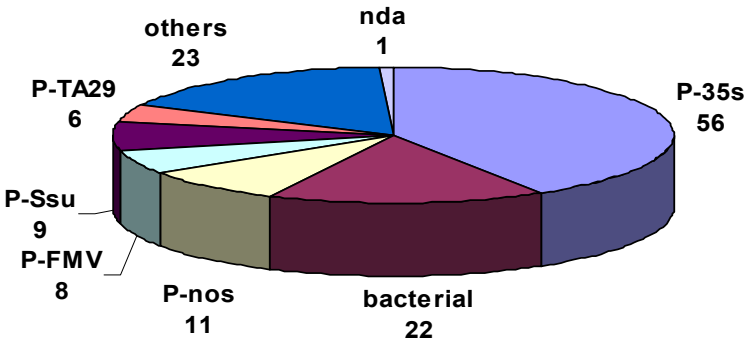


Figure 2: Frequency of occurrence of the most often used promoters in the currently approved genetically engineered crop plants. P-35s includes P-35s, P-E35s and dP-35s.

Survey of the genes used

More than 40 distinct genes have been used for the generation of currently approved transgenic crops (Table 2). The most frequently used transgene is nptII, originating from the E. coli transposon 5. This gene confers resistance to selected aminoglycoside antibiotics. In some cases nptII is under the control of bacterial regulatory elements, which does not allow expression in plants. Whereas when nptII is under the control of a eucaryotic promoter, its gene product will be expressed in plants.

In 1996, nptII was found to be present in 61% of the surveyed GM crops. Now seven years later, it was found in about 44% of the surveyed GM crops. Comparing these two studies, about an 17% decrease in use was observed (Figure 4).

The variants of δ endotoxin gene from *Bacillus thuringiensis* are most frequently used genes in the transgenic crops after nptII. The *cry* genes are all synthetic and modified and in some cases truncated forms of the native genes, in order to optimise gene expression in the host organism. They are found in 20 transgenic products. The most frequently used *cry* genes are cry1Ab and cry3A present in 6 out of 20 products containing *cry* genes. The sequence alignment of cry1Ab genes introduced into Bt11, 176 and both Mon809 and Mon810 corns shows that they have different sequences. CP4EPSPS and bar genes are found in 12 and 15 transgenic crops, respectively.

Introduced genes	Donor organisms (origin)	Number of occurences of each gene
aad	E. coli	7
accd	Pseudomonas chlororaphis	1
AccS	Lycopericon esculentum (Tomato)	1
ALS	Arabidopsis thaliana	1
bar	Streptomyces hygroscopicus	15
barnase	Bacillus amyloquefaciens	8
barstar	Bacillus amyloquefaciens	6
Bay TE	Umbellularia californica (California bay)	1
bla	E. coli	6 (+ 7 part.*)
Chimeric S4-HrA	Nicotiana tabacum	1
CMV cp	Cucumber Mosaic Virus strain C	1
CMV/PRV cp	Papaya Ringspot Virus & Cucumber Mosaic Virus	1
CMV/WMV2 cp	Watermelon Mosaic Virus 2 strain FL& Cucumber Mosaic Virus	2
CMV/ZYMV cp	Zucchini Yellow Mosaic Virus strain FL& Cucumber Mosaic Virus	2
CP4EPSPS	Agrobacterium tumefaciens sp. strain CP4	12
cry1Ab	B. thuringiensis subsp. kurstaki	6
cry1Ac	B. thuringiensis subsp. Kurstaki HD-73	5
cry1F	B. thuringiensis var. aizawai	1
cry2Ab	B. thuringiensis subsp. kurstaki	1
cry3A	B. thuringiensis subsp. Tenebrionis	6
cry3Bb1	B. thuringiensis subsp. kumamotoensis	1
cry9C	B. thuringiensis subsp. Tolworthi	1
dam	E. coli	1
dapA	Corynebacterium	1
gentR	E. coli	1
GmFAD2-1	Glycine max (soybean)	1
gox	Achromobacter sp. Strain LBAA	7
GUS	E. coli	5
mEPSPS	Zea mays	1
nitrilase	Klebsiella ozaenae	5
nos	Agrobacterium tumefaciens	1
nptII	E. coli	29 (+1 part.*)
NtQPT1	Nicotiana tabacum	1
pat	Streptomyces viridochromogenes	11
PG	Lycopericon esculentum (Tomato)	2
pinII	Selanum tuberosum	1
PLRVrep	Potato Leaf Roll Virus (PLRV)	2
PVYcp	Potato Virus Y (PVY) strain O	1
sam-k	E. coli bacteriophage T3	1
tetR	E. coli	1

Table 2: Frequency of occurrence of introduced genes in approved GM crop plants with the corresponding donor organisms. Multiple insertions of a gene into a genome were counted as one event.* denotes the number of GM crops containing only partial copies of the corresponding genes. It should be noted that plants containing only partial genes were not counted towards the total.

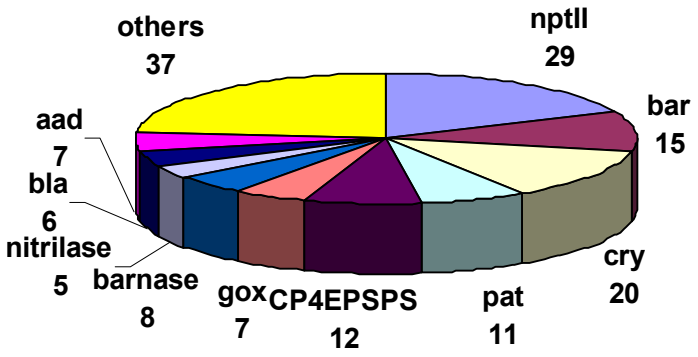


Figure 3: Frequency of occurrence of the most often used genes in the currently approved genetically engineered crop plants. The *cry* family was grouped as a whole and includes: cry1Ab, cry1Ac, cry3A, cry9C, cry1F, cry3Bb1, cry2Ab

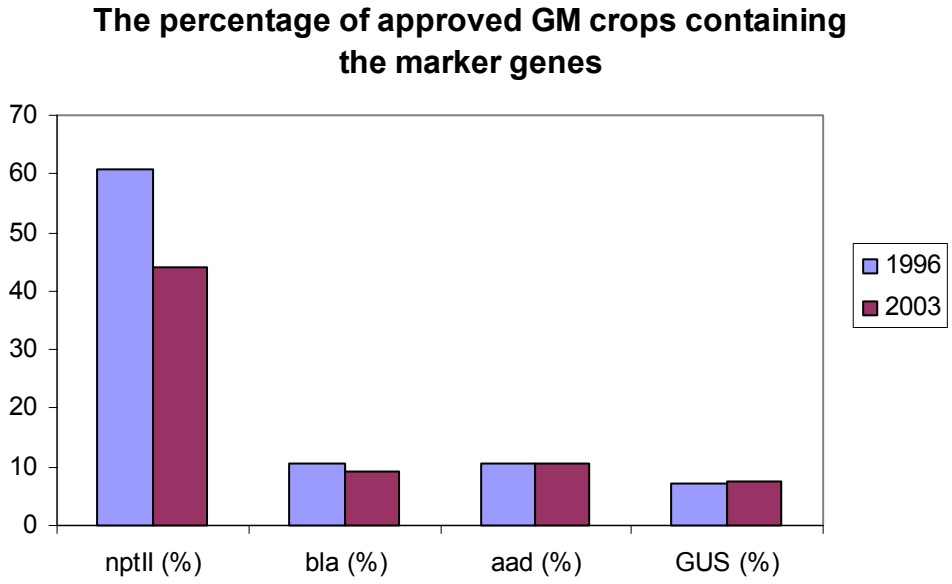


Figure 4: Represents the change in the number of GM crops containing marker genes from 1996 to 2003. The presence of nptII drops from about 61% of GM crops (1996) to about 44% (2003). It means that the nptII marker gene is less frequently present in the new GM crops. There is a very slight percentage decrease of GM crops carrying bla gene (10.7% versus 9.1%). When comparing GUS gene, a slight percentage increase of GM crops was observed. Only the GM crops containing complete copies of a marker gene are taken into account.

Survey of the terminators used

Another important component of a gene construct is terminator. The most frequently used terminator in approved GM crops is T-nos, isolated from the nopaline synthase gene of *A. tumefaciens*. It is found in 37 products. In the table below, other terminator sequences are listed, along with their origin, and how many times they are used in current GM crops. No data were available on the terminators of 3 transgenic canola products: PHY23, PHY14 and PHY35, PHY36.

Used Terminators	Donor organisms (origin)	Number of occurrences of each terminator
bacterial		**22**
nda		**3**
T-35s	**Cauliflower Mosaic Virus**	**17**
T-7S	**Glycine max (soybean)**	**2**
T-ALS	**Nicotiana tabacum**	**1**
T-Als	**Arabidopsis thaliana**	**1**
T-E9	**Pea**	**12**
T-g7	**Agrobacterium tumefaciens**	**3**
T-Kti3	**Glycine max (soybean)**	**1**
T-mas	**Agrobacterium tumefaciens**	**2**
T-napin	**Brassica rapa**	**1**
T-nos	**Agrobacterium tumefaciens**	**37**
T-ocs	**Agrobacterium tumefaciens**	**5**
T-ORF25	**Agrobacterium tumefaciens**	**1**
T-phaseolin	**Phaseolus vulgaris (green bean)**	**1**
T-pinII	**Selanum tuberosum**	**2**
T-SSU	**Glycine max (soybean)**	**1**
T-tahsp 17	**Triticum aestivum (Wheat)**	**1**
T-tml	**Agrobacterium tumefaciens**	**4**
T-Tr7	**Agrobacterium tumefaciens**	**2**

Table 3: Lists all terminators, the organism from which they originated, and how often they are found in current GM crops. Some terminators may be present in more than one copy in a single product, since a regulatory sequence may have been used for more than one transgene and since several copies of a transgene may be present in the same product. This frequency of appearance is not taken into account in the table.

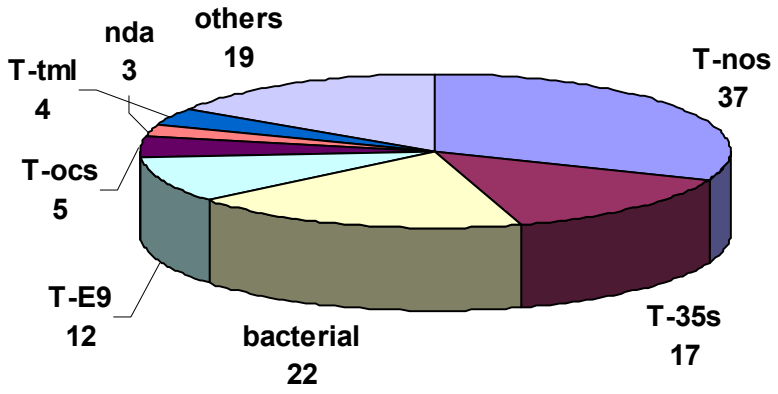


Figure 5: Frequency of occurrence of the most often used terminators introduced into the currently approved genetically engineered crop plants.

Approved GM crops worldwide – Fact-Sheets

Sources and definitions used in the fact-sheets

Information source for the molecular data are the US petitions (APHIS/USDA) except where other indicated (FSANZ, Health Canada, Japanese Regulatory authorities or EU Scientific Committee on Plants. (See References S. 181). Patent numbers are taken from the United States Patent and Trademark Office (see References S. 181). Authorities in charge of gene technology regulation have provided information about worldwide GM crop approvals. Other sources are indicated in the fact sheets.

In the figures in section "Event Characterisation" genes, promoters and terminators are marked in the following colours:

Promoter:

Gene:

Terminator:

Definitions used in the section "Approvals".

APHIS Petition	The Animal and Plant Health Inspection Service (APHIS) publishes after determining non-regulated status for a GM crop the petitions received from the applicants.
Approval type	legal forms of usage of GM crops
Environment	Environmental release is legal, can be large scale, but not for commercial purpose.
Feed	Feed use is legal.
Field production	Planting for commercial purpose and seed production is legal.
Food	Food use is legal.
Food/ Feed	Food and feed use is legal.
Import	Import, transport within the country, and processing is legal, but not necessarily implies that food and feed use is legal
Other	Other types of approval, for instance breeding activities for field testing
Plant pesticide	Plant pesticide approval by the Environmental Protection Agency (EPA) in the US
SM	Selection Marker, e.g. herbicide tolerance, antibiotic resistance marker

adzuki bean

Event: AR-9

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Insect resistance	unspecified		alpha-amylase inhibiter		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1999	Nat'l Agr. Res. Ctr.
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1999	Nat'l Agr. Res. Ctr.

broccoli

Event: BR891

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Herbicide tolerance	glufosinate		phosphinothricin acetyltransferase (PAT)		
Male sterility			unknown		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	2001	Takii Shubyo
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	2001	Takii Shubyo

canola

Event: 23-198, 23-18-17

The canola lines 23-18-17 and 23-198 were genetically engineered to express modified seed fatty acid content, specifically high levels of lauric acid. The increased levels of lauric acid in oil from the modified canola lines allow its use as a replacement for other lauric acid oils, such as coconut and palm kernel oil, in products such as confectionery coatings and fillings, margarines, spreads, shortenings and commercial frying oils.

The events are also named pCGN3828-212/86-18 and pCGN3828-212/86-23.

Brandname(s): Laurical

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pCGN3828

US-Patent-N°: 5,807,893

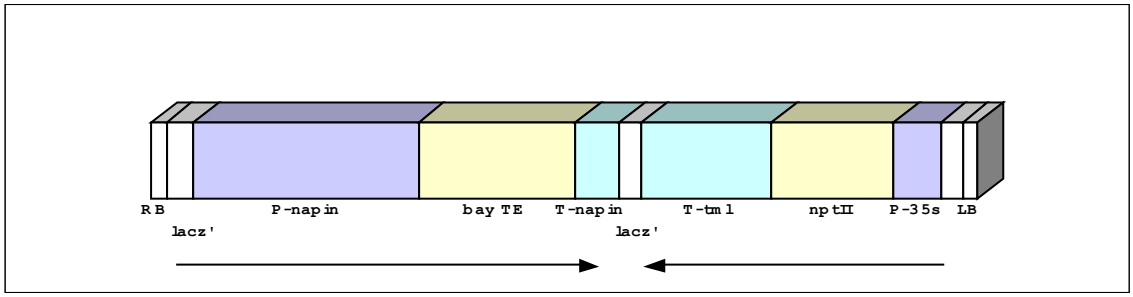


Figure 6: T-DNA region of construct pCGN3828

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
lacZ'	lacZ'	-
P-napin	P-napin	1.74
BayTE	thioesterase	1.22
T-napin	T-napin	0.34
lacZ'	lacZ'	-
T-tml	T-tml	-
nptII	neomycin phosphotransferase	-
P-35s	P-35s	-
LB	Left border	-

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses show that event 23-18-17 contains most likely 3 copies and event 23-198 approximately 15 copies of the T-DNA in their genome. The laurate canola may also contain the pRi origin of replication from A.rhizogenes which is beyond the left and right borders.

Approvals

Canada

Approval Type	Date	Applicant
environment	02/1996	Calgene
interim variety registration terminated, therefore commercial seed and field production is not legal		
feed	02/1996	Calgene
food	04/1996	Calgene

USA

Approval Type	Date	Applicant	Aphis Petition
field production	10/1994	Calgene	94-090-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	04/1995	Calgene	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: Falcon GS/40/90

Falcon GS/40/90 is a herbicide protected oilseed rape expressing a synthetic pat gene and conferring tolerance to glufosinate-ammonium containing herbicides. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

According to EU Scientific Committee on Plants:

Falcon GS 40/90 was produced with plasmid pHoe6/Ac.This plasmid contained between the left and right border T-DNA a partial sequence of Ti-plasmid pTiT37, P-35s, the coding sequence of a synthetic pat gene, T-35s, T-DNA partial sequence of the Ti-plasmid pTiAch5. Sequence outside the borders contained: the streptomycin/spectinomycin adenyltransferase gene from E. coli plasmid R538-1, ColE1 replication region from E. coli, a portion derived from *Agrobacterium tumefaciens* Ti plasmid, oriV and oriT regions from E. coli RK2 plasmid and a portion derived from *Agrobacterium tumefaciens* Ti plasmid Ach5.

Map: Linear map of DNA construct used for transformation - T-DNA region of the construct pHoe6/Ac (Falcon)

Abbreviation	Element-Name	Size [KB]
LB	Left border	-
P-35s	P-35s	-
	phosphinothricin acetyltransferase (PAT)	-
T-35s	T-35s	-
RB	Right Border	-

Molecular analyses demonstrate that Falcon GS 40/90 has integrated the sequence at two independent loci. The vector sequences outside of the borders have not been integrated into the oilseed rape genome.

Approvals

European Union

Approval Type	Date	Applicant
food	10/1999	AgrEvo
Reg. 258/97, authorization for processed oil from GM oilseed rape derived from Falcon GS/40/90		

Event: GT200

GT200 has been genetically engineered to be tolerant to glyphosate, the active ingredient of Roundup® herbicide, expressed by the gox and CP4 EPSPS genes. Glyphosate, the active ingredient in Roundup®, is a post emergent, systemic herbicide that is used worldwide for the non-selective control of a wide variety of annual and perennial weeds.

The event is also named RT200.

Brandname(s): Roundup Ready

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct PV-BNGT03

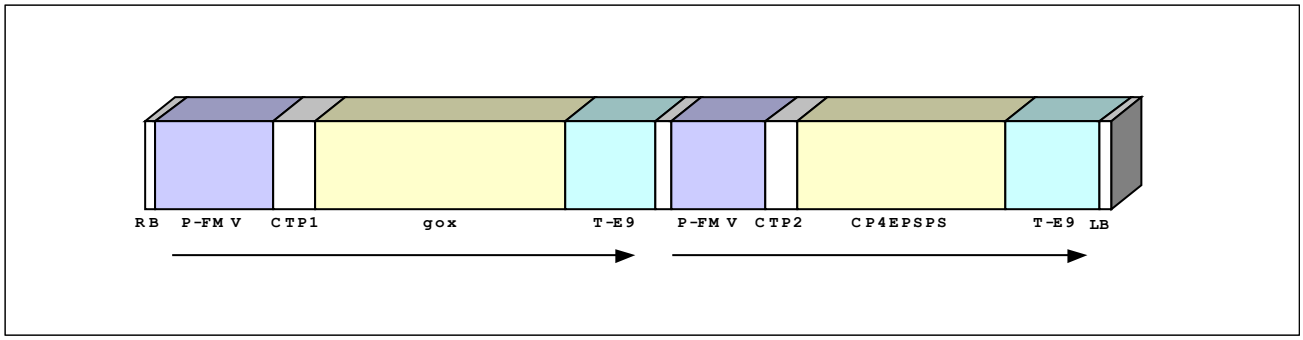


Figure 7: T-DNA region of construct PV-BNGT03

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
P-FMV	P-FMV	-
CTP1	Chloroplast Transit Peptide 1	-
gox	glyphosate oxidoreductase	-
T-E9	T-E9	-
P-FMV	P-FMV	-
CTP2	Chloroplast Transit Peptide 2	-
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	-
T-E9	T-E9	-
LB	Left border	-

Molecular analyses of the transformed plant show that GT200 contains a single insert, consisting of single copies of gox & CP4EPSPS cassettes. No genetic elements from outside of the right and left borders of the T-DNA were transferred into the genome of event GT200.

Approvals

Canada

Approval Type	Date	Applicant
environment	03/1996	Monsanto
no application for variety registration by Monsanto, therefore commercial seed and field production is not legal		
feed	10/1997	Monsanto
food	09/1997	Monsanto

Japan

Approval Type	Date	Applicant
feed	2001	Monsanto
food	2001	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	01/2003	Monsanto	01-324-01p
approval extension of 98-216-01p, for more information on GM crop regulation in the US see Annex			
food/ feed	09/2002	Monsanto	

no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)

Event: GT73

Canola GT73 has been genetically engineered to be tolerant to the herbicide glyphosate. Glyphosate, the active ingredient in Roundup®, is a post emergent, systemic herbicide that is used worldwide for the non-selective control of a wide variety of annual and perennial weeds. Herbicide tolerance is conferred by two genes, CP4 EPSPS and goxv247.

The event is also named RT73.

Brandname(s): Roundup Ready

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct PV-BNGT04

US-Patent-N°: 6 248 876

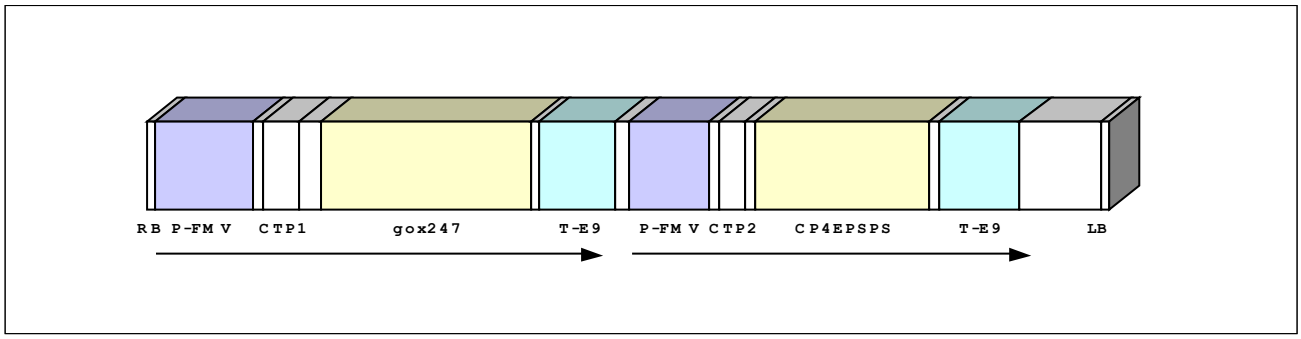


Figure 8: T-DNA region of construct PV-BNGT04

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
P-FMV	P-FMV	-
CTP1	Chloroplast Transit Peptide 1	-
gox247	glyphosate oxidoreductase 247	-
T-E9	T-E9	-
P-FMV	P-FMV	-
CTP2	Chloroplast Transit Peptide 2	-
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	-
T-E9	T-E9	-
LB	Left border	-

Molecular analyses of the transformed plant show that only a single copy of the T-DNA is inserted at a single location into the genome of the plant. According to the data published by FSANZ, T-DNA contains one complete copy of the CP4 EPSPS gene and a complete copy of the gox247 gene and their respective regulatory sequences in the plant genome.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	11/2000	Monsanto

Canada

Approval Type	Date	Applicant
feed	03/1995	Monsanto
field production	03/1995	Monsanto
food	11/1994	Monsanto

European Union

Approval Type	Date	Applicant
food	11/1997	Monsanto
Reg. 258/97, authorization only for refined oil		

Japan

Approval Type	Date	Applicant
feed	09/1996	Monsanto
field production	03/1996	Monsanto
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
food	2001	Monsanto
food approval renewal 2001, first approval in 09/96		
import	1996	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	01/1999	Monsanto	98-216-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	04/1995	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: HCN10, HCN92

HCN92 (Innovator) and HCN10 (Independence) are open pollinated canola lines, which are tolerant to the glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation

control on land not used for cultivation.Tolerance to glufosinate-ammonium is conferred in these lines by inserting pat gene.

HCN10 and HCN92 are lines derived from transformation event 19/2, also named Topas 19/2.

Brandname(s): Independence, LibertyLink

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The construct pOCA/AC has been used for transformation of event Topas 19/2. HCN92 and HCN10 are two lines derived from Topas 19/2.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pOCA/AC

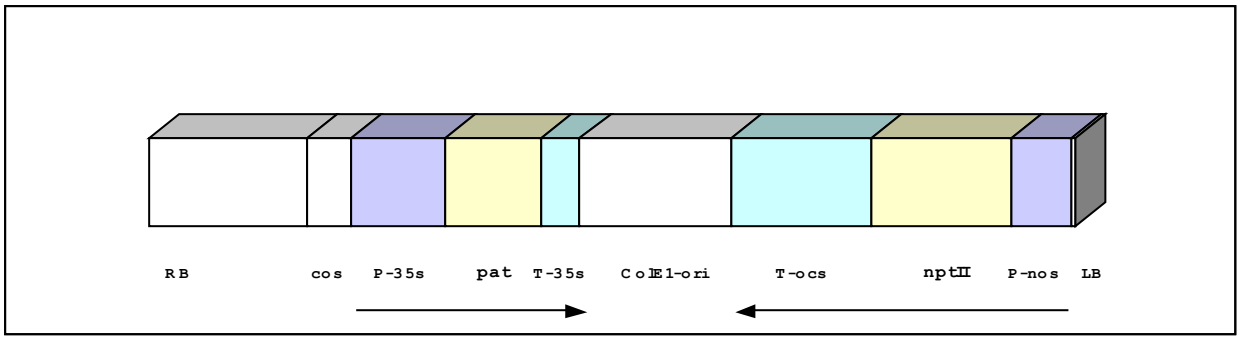


Figure 9: T-DNA region of construct pOCA/AC

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.9
cos	cos	0.25
P-35s	P-35s	0.53
	phosphinothricin acetyltransferase (PAT)	0.55
T-35s	T-35s	0.22
ColE1-ori	ColE1-ori	0.86
T-ocs	T-ocs	0.79
nptII	neomycin phosphotransferase	0.8
P-nos	P-nos	0.34
LB	Left border	0.025

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

The event Topas 19/2 contains the same genetic elements as event T45, with the exception that T45 does not contain nptII marker gene.

Molecular analyses of the transformed plants show that the incorporated DNA is limited to the T-DNA region. No additional coding sequences from the vector, other than the pat gene and the selectable marker, have been incorporated into the genome of these two lines.
Event HCN92 may contain 2 linked copies of the pat gene (from EU Scientific Committee on plants).

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Aventis CropScience

Canada

Approval Type	Date	Applicant
feed	03/1995	AgrEvo
original approval for line HCN92 (approval document DD95-01), lines HCN10 and HCN05, derived from the same transformation event (19/2), are also covered by DD95-01		
field production	03/1995	AgrEvo
original approval for line HCN92 (approval document DD95-01), lines HCN10 and HCN05, derived from the same transformation event (19/2), are also covered by DD95-01		
food	02/1995	AgrEvo

European Union

Approval Type	Date	Applicant
food	06/1997	AgrEvo
Reg. 258/97, authorization for processed oil from event Topas 19/2 and all conventional crosses		
food/ feed	04/1998	AgrEvo
Reg. 220/90/EEC, authorization for commercial release, restriction - uses: import and processing		

Japan

Approval Type	Date	Applicant
feed	09/1996	AgrEvo
authorization only for HCN92		
feed	01/1998	AgrEvo
authorization only for HCN10		
food	2001	Aventis CropScience
food approval renewal 2001, first approval in 11/97 for HCN10, first approval in 09/96 for HCN92, second applicant Shionogi Ltd.		
import	1996	AgrEvo
authorization only for HCN92		
import	1997	AgrEvo
authorization only for HCN10		

USA

Approval Type	Date	Applicant	Aphis Petition
food/ feed	03/1995	AgrEvo	

no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review), only line HCN92 is covered by the FDA Memo, for more information on GM crop regulation in the US see Annex

Event: Liberator L62

Transformant Liberator L62 contains a synthetic pat gene, coding for phosphinotricin acetyltransferase conferring tolerance to glufosinate-ammonium containing herbicides. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation.

The event is also named pHoe6/Ac.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of the construct pHoe6/Ac

Abbreviation	Element-Name	Size [KB]
LB	Left border	-
P-35s	P-35s	-
	phosphinothricin acetyltransferase (PAT)	-
T-35s	T-35s	-
RB	Right Border	-

According to EU Scientific Committee on plants:
Plasmid pHoe6/Ac was used to transform Liberator L62. The plasmid contains between the left and right border T-DNA partial sequence from Ti-plasmid pTiT37, P-35s, the coding sequence of a synthetic pat gene, T-35s, T-DNA partial sequence of the Ti-plasmid pTiAch5. Sequences outside the borders contain: the streptomycin/spectinomycin adenyltransferase gene from E.coli plasmid R538-1, ColE1 replication region from E.coli, a portion derived from *Agrobacterium tumefaciens* Ti plasmid, oriV and oriT regions from E. coli RK2 plasmid.

Molecular analyses demonstrate that Liberator L62 has integrated the sequence at one locus. Vector sequences outside of the borders have not been integrated into the oilseed rape genome.

Approvals

European Union

Approval Type	Date	Applicant
food	10/1999	AgrEvo
Reg. 258/97, authorization for processed oil only		

Event: MPS961, 962, 963, 964, 965

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Antibiotic resistance			neomycin phosphotransferase (nptII)		
Degradation of phytate			phytase		

Maps

No Map Information available.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
feed	03/1999	BASF	
no formal authorisation for feed use, consultation process between FDA and developer (pre-market review), for more information on GM crop regulation in the US see Annex			

Event: MS1, RF1, RF2, MS1xRF1, MS1xRF2

The MS and RF lines are pollinaton controlled parental breeding lines used for hybrid production. MS1 expresses the bacterial gene barnase, RF1 and RF2 lines express the bacteria-derived barstar gene. Expression of barnase in specific part of the flowers at a particular developmental stage gives rise to plants that are male sterile (MS). Conversely, expression of barstar does not produce any change in phenotype in the plant unless it is expressed at the same time and place as barnase. It means that its effect is only evident when an RF line is crossed with one of the MS lines to produce hybrid plants in which both genes are expressed at the same developmental stage.

These plants exhibit greater vigour than either of the parental lines and are fully fertile yielding greater amounts of seed.
These lines are also tolerant to the glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Hebicide tolerance is conferred by the bar gene and is used for selection of transformats.

MS1xRF1 is named PGS1 and Line MS1xRF2 is named PGS2. MS1 is derived from transformation event B91-4, RF1 is derived from transformation event B93-101 and line RF2 is dervied from transformation event B94-2.

Brandname(s): InVigor, SeedLink

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Constructs pTTM8RE and pTVE74RE were used to produce male sterility (MS) and restoration of fertility (RF), respectively.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pTTM8RE

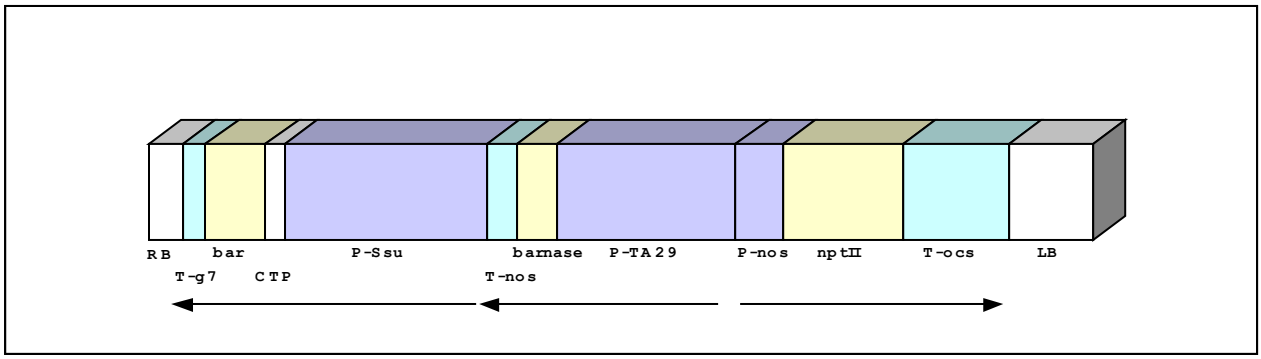


Figure 10: T-DNA region of construct pTTM8RE

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.28
T-g7	T-g7	0.2
	phosphinothricin acetyltransferase (bar)	0.5
P-Ssu	P-Ssu	2
T-nos	T-nos	0.25
	barnase	0.34
P-TA29	P-TA29	1.5
P-nos	P-nos	0.4
nptII	neomycin phosphotransferase	1
T-ocs	T-ocs	0.9
LB	Left border	0.7

***Map*: Linear map of DNA construct used for transformation - T-DNA region of construct pTVE74RE**

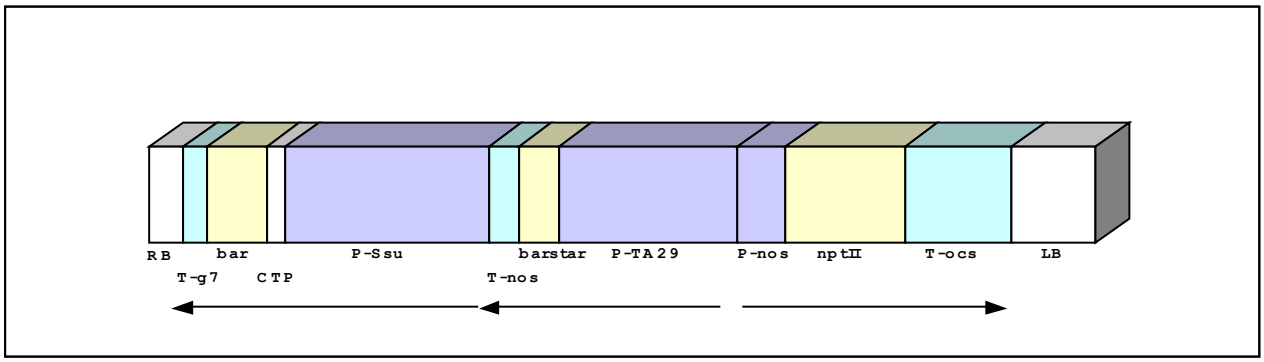


Figure 11: T-DNA region of construct pTVE74RE

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.28
T-g7	T-g7	0.2
	phosphinothricin acetyltransferase (bar)	0.5
P-Ssu	P-Ssu	2
T-nos	T-nos	0.25
	barstar	0.34
P-TA29	P-TA29	1.5
P-nos	P-nos	0.4
nptII	neomycin phosphotransferase	1
T-ocs	T-ocs	0.9
LB	Left border	0.7

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

In the lines MS1, RF1 and RF2 a single insertion event had occurred and only the DNA sequences within the T-DNA borders were transferred into the plant genome.
The MS1 contains bar, barnase and nptII cassettes.
The RF lines contain bar, barstar and nptII cassettes.
The hybrid system consists of crossing the MS line (female parent) with a specific RF line (MS1xRF1) or (MS1xRF2).

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Aventis CropScience

Canada

Approval Type	Date	Applicant
feed	04/1995	Plant Genetics Systems
authorization for MS1, RF1 and MS1xRF1		

feed	12/1995	Plant Genetics Systems
authorization for MS1, RF2 and MS1xRF2, RF2 is considered substantially equivalent to RF1		
field production	04/1995	Plant Genetics Systems
RF2 is considered substantially equivalent to RF1		
food	09/1994	Plant Genetics Systems
authorization for MS1, RF1 and MS1xRF1		
food	08/1995	Plant Genetics Systems
authorization for MS1, RF2 and MS1xRF2		

European Union

Approval Type	Date	Applicant
field production	06/1997	Plant Genetics Systems
Reg. 220/90/EEC, authorization for commercial seed and field production, not finally approved by France		
food	06/1997	Plant Genetics Systems
Reg. 258/97, authorization for processed oil of MS1Bn (B91-4) and all conventional crosses and RF1Bn (B93-101) and all conventional crosses and MS1xRF1 *Reg. 258/97, processed oil of MS1Bn (B91-4) and all conventional crosses and and RF2Bn (B94-2) and all conventional crosses and MS1xRF2*		
food/ feed	06/1997	Plant Genetics Systems
Reg. 220/90/EEC, authorization for commercial release, not finally approved by France		
other	02/1996	Plant Genetics Systems
Reg. 220/90/EEC, authorisation for breeding activities only (MS1, RF1)		

Japan

Approval Type	Date	Applicant
feed	09/1996	Plant Genetics Systems
authorization only for MS1xRF1		
feed	06/1997	Plant Genetics Systems
authorization only for MS1xRF2		
food	2001	Aventis CropScience
food approval renewal 2001, first approval in 09/96, second applicant Shionogi Ltd. (MS1x RF1) *food approval renewal 2001, first approval in 05/97, second applicant Shionogi Ltd. (MS1xRF2)*		
import	1996	Plant Genetics Systems
authorization only for MS1xRF1		
import	1997	Plant Genetics Systems
authorization only for MS1xRF2		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	12/2002	Aventis CropScience	01-206-01p
approval extension of 98-278-01p, authorization for MS1, RF1, MS1xRF1, for more information on GM crop regulation in the US see Annex			
field production	12/2002	Aventis CropScience	01-206-02p

	approval extension of 97-205-01p, authorization for MS1, RF2, MS1xRF2, for more information on GM crop regulation in the US see Annex		
food/ feed	03/1996	Plant Genetics Systems	
	no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)		

Event: MS8, RF3, MS8xRF3

The MS and RF lines are pollinaton controlled parental breeding lines used for hybrid production. MS8 contains the bacteria derived gene barnase, RF3 expresses the bacteria derived gene barstar. Expression of barnase in specific part of the flowers at a particular developmental stage gives rise to plants that are male sterile (MS). Conversely, expression of barstar does not produce any change in phenotype in the plant unless it is expressed at the same time and place as barnase. It means that its effect is only evident when an RF line is crossed with one of the MS lines to produce hybrid plants in which both genes are expressed at the same developmental stage. These plants exhibit greater vigour than either of the parental lines and are fully fertile yielding greater amounts of seed.
These lines are also tolerant to the glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. The tolerance to the glufosinate-ammonium is conferred by the bar gene and is used for selection of transformants.

Brandname(s): InVigor, SeedLink

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Plasmids pTHW107 and pTHW118 have been used to engineer male sterility (MS8) and restoration of fertility (RF3) lines, respectively.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct PTHW107

US-Patent-N°: 6, 344,602

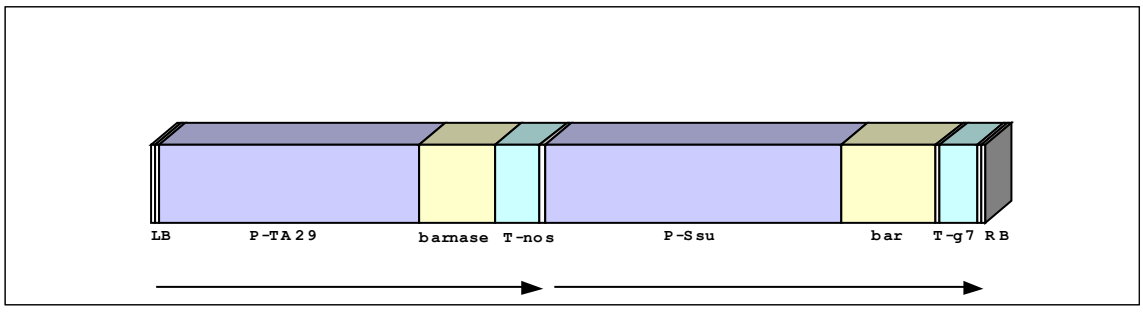


Figure 12: T-DNA region of construct PTHW107

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	-
P-TA29	P-TA29	1.509
	barnase	0.446
T-nos	T-nos	-
P-Ssu	P-Ssu	1.725
	phosphinothricin acetyltransferase (bar)	0.55
T-g7	T-g7	0.211
RB	Right Border	-

***Map*: Linear map of DNA construct used for transformation - T-DNA region of construct PTHW118**

US-Patent-N°: 6,372,960

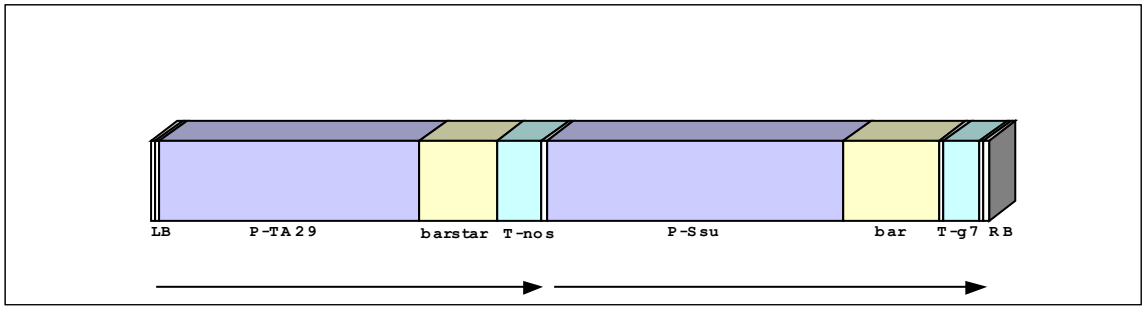


Figure 13: T-DNA region of construct PTHW118

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	-
P-TA29	P-TA29	1.509
	barstar	0.3
T-nos	T-nos	-
P-Ssu	P-Ssu	1.725
	phosphinothricin acetyltransferase (bar)	0.55
T-g7	T-g7	0.211
RB	Right Border	-

Molecular analyses of the transformed plant show that line MS8 contains one copy of T-DNA in a single locus (barnase and bar cassettes). According to the data published by FSANZ, only the DNA sequences within the T-DNA borders are transferred into the MS8 line.
RF3 elite locus carries one T-DNA (bar and barstar cassettes) arranged in an inverted repeat structure with a second, incomplete T-DNA copy. The second copy includes a functional part of the P-TA29, barstar gene, T-nos and a bar gene without the translation initiation codon. All the genes of the T-DNA are inserted at a single locus. According to the data published by FSANZ, in the line RF3, one full copy and one truncated copy of the T-DNA is present as one segment.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Aventis CropScience

Canada

Approval Type	Date	Applicant
feed	10/1996	Plant Genetics Systems
field production	10/1996	Plant Genetics Systems
food	03/1997	Plant Genetics Systems

European Union

Approval Type	Date	Applicant
food	10/1999	Plant Genetics Systems
Reg. 258/97, authorization for processed oil from GM oilseed rape derived from the male sterile MS8 (DBN 230-0028) line and all conventional crosses, the fertility restorer RF3 (DBN212-0005) and all conventional crosses, the hybrid combination MS8 x RF3		

Japan

Approval Type	Date	Applicant
feed	01/1998	Plant Genetics Systems
authorization only for MS8xRF3		
feed	02/1999	Plant Genetics Systems
authorization only for MS8 and RF3		
food	2001	Aventis CropScience
food approval renewal 2001, first approval 12/98 for MS8 and RF3, first approval 12/97 for MS8xRF3, second applicant Shionogi Ltd.		
import	1998	Plant Genetics Systems
authorization only for MS8xRF3		
import	2002	Aventis CropScience
authorization only for MS8xRF3		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	03/1999	AgrEvo	98-278-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	08/1998	AgrEvo	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: OXY235

Oxy-235 has been genetically engineered to be tolerant to bromoxynil and ioxynil herbicides. The oxynil family of herbicides is active against dicotyledenous plants by blocking electron flow during the light reaction of photosynthesis. One gene from the bacteria *Klebsiella pneumoniae ssp.ozanae* has been introduced into the canola variety Westar providing a field level of tolerance to oxynil herbicides. The gene

codes for a bacterial enzyme, nitrilase, which hydrolyses ioxynil and bromoxynil into non-phytotoxic compounds.

Brandname(s): Westar

Event Characterisation

Transformation Method: A. tumefaciens

Maps

According to the data published by the FSANZ:

T-DNA region of the construct pRPA-BL-150a:

Abbreviation	Element-Name	Size [KB]
P-35s	P-35s	-
RuBisCO	RuBisCO small subunit gene enhancer	-
	nitrilase	1.15
T-nos	T-nos	-

Southern blot analyses show that Oxy-235 contains a single genetic insert, consisting of a single copy of the nitrilase gene. No rearrangements of the T-DNA are apparent and no sequences residing outside the T-DNA region, including the gentamycin resistance gene, are transferred into the genome.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Aventis CropScience

Canada

Approval Type	Date	Applicant
feed	06/1997	Rhone Poulenc
field production	02/1997	Rhone Poulenc
food	07/1997	Rhone Poulenc

Japan

Approval Type	Date	Applicant
feed	12/1999	Rhone Poulenc
food	2001	Aventis CropScience
food approval renewal 2001, first approval in 11/99, second applicant Shionogi Ltd.		
import	1998	Rhone Poulenc

USA

Approval Type	Date	Applicant	Aphis Petition
food/ feed	10/1999	Rhone Poulenc	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review), for more information on GM crop regulation in the US see Annex			

Event: PHY14, PHY35

These lines are high yielding fertile hybrids and tolerant to the herbicide glufosinate-ammonium (also known as phosphinothricin), which is used for slection of the transformants.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

According to the Japanese regulatory authorities:
Introduced genes: bar with P-Ssu; barnase with P-TA29; barstar. No information about terminators is available.

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
feed	1997	Plant Genetics Systems
authorization only for PHY35		
feed	01/1998	Plant Genetics Systems
authorization only for PHY14		
food	2001	Aventis CropScience
food approval renewal 2001, first approval in 05/97, second applicant Shionogi Ltd.		
import	1997	Plant Genetics Systems

Event: PHY23

PHY23 is high yielding fertile hybrids and tolerant to the herbicide glufosinate-ammonium (also known as phosphinothricin), which is used for slection of the transformants.

Event Characterisation

Transformation Method: unknown

Maps

According to the Japanese regulatory organisation, the introduced genes are: bar, barnase and barstar.

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
feed	02/1999	Plant Genetics Systems
food	2001	Aventis CropScience
food approval renewal 2001, first approval in 11/99, second applicant Shionogi Ltd.		
import	1997	Plant Genetics Systems

Event: PHY36

These lines are high yielding fertile hybrids and tolerant to the herbicide glufosinate-ammonium (also known as phosphinothricin), which is used for slection of the transformants.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

According to the japanese regulatory organisation:
Introduced genes: bar with P-Ssu; barnase with P-TA29; barstar
No information about terminators is available.

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
feed	06/1997	Plant Genetics Systems
food	2001	Aventis CropScience
food approval renewal 2001, first approval in 05/97, second applicant Shionogi Ltd.		
import	1997	Plant Genetics Systems

Event: T45

T45 is an open pollinated canola line known commercially as LibertyLink® canola which is tolerant to the glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is

used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation. Tolerance to glufosinate-ammonium is conferred in these lines by the pat gene.

The event is also named HCN28.

Brandname(s): Excel, LibertyLink

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pHoe4/AC

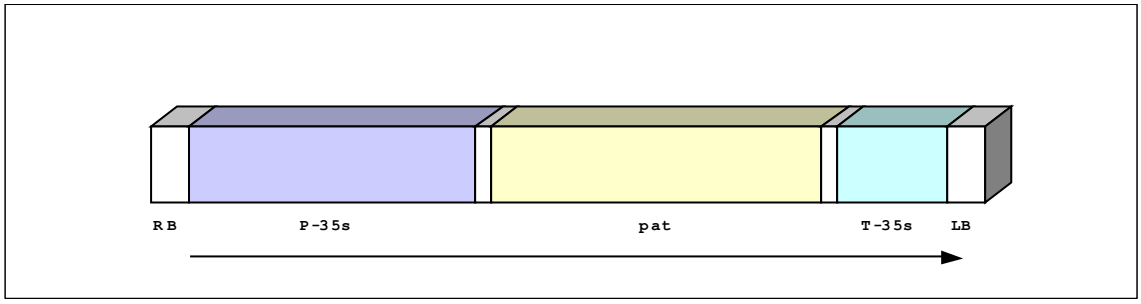


Figure 14: T-DNA region of construct pHoe4/AC

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
P-35s	P-35s	-
	phosphinothricin acetyltransferase (PAT)	0.55
T-35s	T-35s	-
LB	Left border	-

Molecular analyses of the transformed plant show that only one copy of the T-DNA from vector pHoe4/AC is transferred into the plant genome. It contains no sequence outside of the T-DNA.
The event T45 contains the same genetic elements as event Topas 19/2, with the exception that T45 does not contain nptII marker gene.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Aventis CropScience

Canada

Approval Type	Date	Applicant
feed	06/1996	AgrEvo
field production	05/1996	AgrEvo
food	02/1997	AgrEvo

Japan

Approval Type	Date	Applicant
feed	06/1997	AgrEvo
food	2001	Aventis CropScience
food approval renewal 2001, first approval in 05/97, second applicant Shionogi Ltd.		
import	1997	AgrEvo

USA

Approval Type	Date	Applicant	Aphis Petition
field production	01/1998	AgrEvo	97-205-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	05/1997	AgrEvo	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

cantaloupe

Event: A, B

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Antibiotic resistance		☑	neomycin phosphotransferase (nptII)		
Delayed fruit ripening	low ethylene production		S-adenosylmethionine hydrolase (sam-k)		

Maps

No Map Information available.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
food	10/1999	Agritope	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review), for more information on GM crop regulation in the US see Annex			

carnation

Event: 1.8.124, 16.0.66

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Delayed fruit ripening	low ethylene production		1-amino-cyclopropane-1-carboxylic acid synthase (AccS)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	2000	Florigene
import	2000	Florigene
second applicant Suntory		

Event: 121.2.7, 121.3.12, 123.1.36, 123.2.38

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered flower colour	unspecified		dihydroflavonol-4-reductase (DFR)		
Altered flower colour	unspecified		flavonoid-3',5'-hydroxydase (F3',5'H)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1999	Florigene
import	1999	Florigene
second applicant Suntory		

Event: 123.8.8

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered flower colour	unspecified		dihydroflavonol-4-reductase (DFR)		
Altered flower colour	unspecified		flavonoid-3',5'-hydroxydase (F3',5'H)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	2000	Florigene
import	2000	Florigene
second applicant Suntory		

Event: 1351, 1363

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered flower colour	unspecified		anthocyan synthesis enzymes (Ant)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1998	Florigene
import	1998	Florigene
second applicant Suntory		

Event: 4, 11 ,15, 16

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered flower colour	unspecified		unknown		
Herbicide tolerance	sulfonyl urea	☑	unknown		

Maps

No Map Information available.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
field production	09/1995	Florigene
General (Commercial) Release (GR), GR approvals are deemed licenses under the Gene Technology Act 2000, but general release is still legal, licenses need review by Gene Technology Regulator within first two years of operation of Gene Technology Act, deadline 21.6.03		

European Union

Approval Type	Date	Applicant
field production	12/1997	Florigene
Reg. 220/90/EEC, authorization for commercial seed and field production (by Member State consent)		

Event: 66

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Herbicide tolerance	sulfonyl urea	☑	unknown		
Increased shelf life	delayed softening		unknown		

Maps

No Map Information available.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
field production	09/1995	Florigene
General (Commercial) Release (GR), GR approvals are deemed licenses under the Gene Technology Act 2000, but general release is still legal, licenses need review by Gene Technology Regulator within first two years of operation of Gene Technology Act, deadline 21.6.03		

European Union

Approval Type	Date	Applicant
field production	10/1998	Florigene
Reg. 220/90/EEC, authorization for commercial seed and field production (by Member State consent)		

Event: 8.6.25, 12.1.8, 17.3.67, 18.3.33, 20.9.53

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Delayed fruit ripening	low ethylene production		1-amino-cyclopropane-1-carboxylic acid synthase (AccS)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1999	Florigene

import	1999	Florigene
second applicant Suntory		

Event: 959A, 988A, 1226A, 1351A, 1363A, 1400A

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered flower colour	unspecified		unknown		
Herbicide tolerance	sulfonyl urea	☑	unknown		

Maps

No Map Information available.

Approvals

European Union

Approval Type	Date	Applicant
field production	10/1998	Florigene
Reg. 220/90/EEC, authorization for commercial seed and field production (by Member State consent)		

Event: A-127

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Delayed fruit ripening	low ethylene production		1-amino-cyclopropane-1-carboxylic acid synthase (AccS)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1996	Suntory
import	1996	Suntory

Event: line-2, line-11

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered flower colour	unspecified		anthocyan synthesis enzymes (Ant)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1997	Florigene
import	1997	Florigene
second applicant Suntory		

cauliflower

Event: CF156

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Herbicide tolerance	glufosinate		phosphinothricin acetyltransferase (bar)		
Male sterility			unknown		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	2001	Takii Shubyo
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	2001	Takii Shubyo

chicory

Event: RM3-3, RM3-4, RM3-6

The chicory lines RM3-3, RM3-4, RM3-6 have been genetically engineered to generate hybrid male sterile seeds. The male sterility function is based on disruption of the tapetal cell layer development (pollen formation) in the anthers by introducing barnase gene construct. Two selectable marker genes linked to the barnase are: bar gene conferring phosphinothricin tolerance and nptII antibiotic resistance gene.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pTTM8RE (RM3-2, RM3-4, RM3-6)

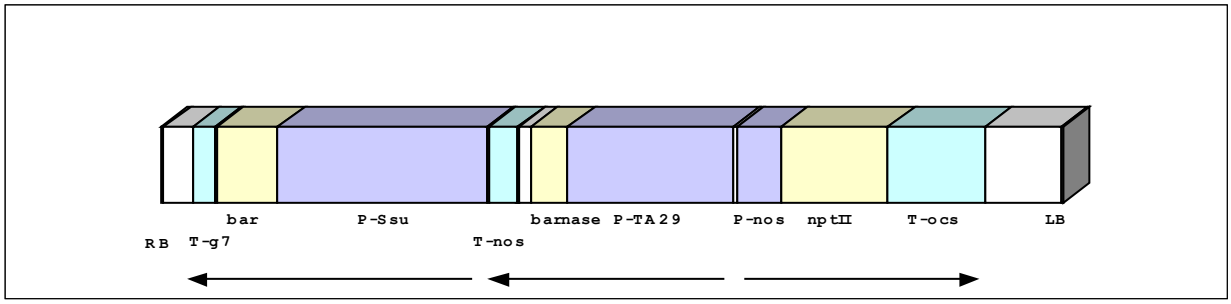


Figure 15: T-DNA region of construct pTTM8RE (RM3-2, RM3-4, RM3-6)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.025
Space	Space	0.26
T-g7	T-g7	0.21
Space	Space	0.02
	phosphinothricin acetyltransferase (bar)	0.55
P-Ssu	P-Ssu	1.9
Space	Space	0.028
T-nos	T-nos	0.26
Space	Space	0.015
	barnase	0.44
P-TA29	P-TA29	1.5
Space	Space	0.035
P-nos	P-nos	0.4
nptII	neomycin phosphotransferase	0.98
T-ocs	T-ocs	0.88
Space	Space	0.69
LB	Left border	0.024

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

The spaces between elements are synthetic polylinker derived sequences.
Molecular analyses of the transformed plant show that the RM3-6 line, used for ultimate seed production, contains one single copy of the T-DNA.

Approvals

European Union

Approval Type	Date	Applicant
other	05/1996	Bejo Zaden BV
Reg. 220/90/EEC, authorisation for breeding activities onl		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	11/1997	Bejo Zaden BV	97-148-01p
for more information on GM crop regulation in the US see Annex			
food	10/1997	Bejo Zaden BV	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review)			

chrysanthemum

Event: pac1 C2, C14-2, C29

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Viroid resistance	unspecified		pac1		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
other	2002	Kirin Brewery
planting is linited to breeding purpose (no authorization for commercial production)		

corn

Event: 176

176 has been engnineered to express the Cry1Ab delta-endotoxin insecticidal protein. This protein is known to be effective against certain lepidopteran insects, including European Corn Borer (ECB). ECB is a major corn pest that reduces yield by disrupting normal plant physiology and causing damage to the leaves, stalks, and ears.

The event is also named Bt176.

Brandname(s): Knockout, Maximizer, NatureGard

Event Characterisation

Transformation Method: microparticle bombardment

Maps

Two constructs pCIB4431and pCIB3064 have been used for transformation.

Map: Linear map of DNA construct used for transformation - Construct pCIB4431 (a pUC-derived plasmid)

US-Patent-N°: 6,121,014

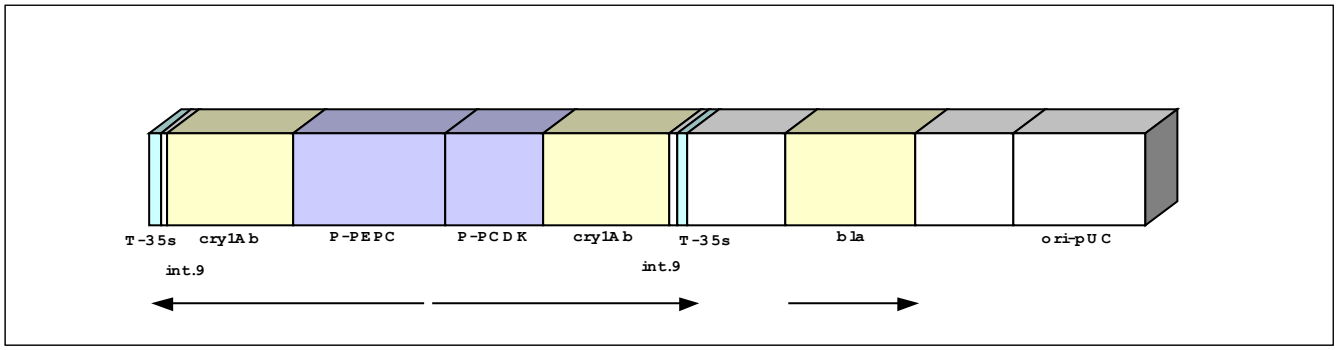


Figure 16: Construct pCIB4431 (a pUC-derived plasmid)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
T-35s	T-35s	0.16
int.9	intron 9	0.11
	cry1Ab delta-endotoxin	1.94
P-PEPC	P-PEPC	2.31
P-PCDK	P-PCDK	1.49
	cry1Ab delta-endotoxin	1.94
int.9	intron 9	0.11
T-35s	T-35s	0.16
Space	Space	-
bla	beta-lactamase	-

Space	Space	-
ori-pUC	ori-pUC	-

Map: Linear map of DNA construct used for transformation - Construct pCIB3064 (a pUC-derived plasmid)

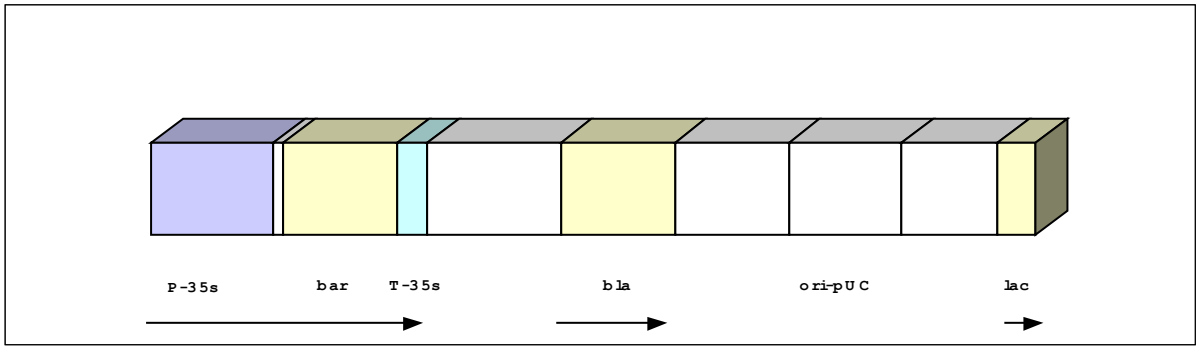


Figure 17: Construct pCIB3064 (a pUC-derived plasmid)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-35s	P-35s	0.64
	phosphinothricin acetyltransferase (bar)	0.6
T-35s	T-35s	0.16
Space	Space	-
bla	beta-lactamase	-
Space	Space	-
ori-pUC	ori-pUC	-
Space	Space	-
lac	beta-galactosidase	-

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla)

The space between P-PEPC and cry1Ab contains 12 nucleotides.
Molecular analyses of the transformed plant show that the genome of 176 contains at least 2 copies of plasmid pCIB4431 and two copies of the bar gene. The bla probing in the southern blot analysis shows multiple hybridization bands. All these genes are approximate to one another in the genome.
According to data published by FSANZ, in 176 there may be as many as six copies of the cry1Ab and bla genes (with its bacterial regulatory elements) and at least 2 copies of the bar gene (together with P-35s) present.

Approvals

Argentina

Approval Type	Date	Applicant
environment	08/1996	Ciba Seeds
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), for more information on GM crop regulation in Argentina see Annex		
field production	01/1998	Ciba Seeds

authorization for commercial seed and field production		
food/ feed	01/1998	Ciba Seeds
authorization for commercialization		

Australia/ New Zealand

Approval Type	Date	Applicant
food	07/2001	Syngenta

Canada

Approval Type	Date	Applicant
feed	01/1996	Ciba Seeds
feed	02/1996	Mycogen
field production	01/1996	Ciba Seeds
field production	02/1996	Mycogen
food	12/1995	Ciba Seeds

China

Approval Type	Date	Applicant
food/ feed	2002	Syngenta
temporary approval granted during application review		

European Union

Approval Type	Date	Applicant
field production	01/1997	Ciba Seeds
Reg. 220/90/EEC, authorization for commercial seed and field production, ban in some EU countries		
food/ feed	01/1997	Ciba Seeds
Reg. 220/90/EEC, authorization for commercial release, ban in some EU countries		

Japan

Approval Type	Date	Applicant
feed	09/1996	Ciba Seeds
food	2001	Syngenta
food approval renewal 2001, first approval in 09/96		
import	1996	Ciba Seeds

South Africa

Approval Type	Date	Applicant
food/ feed	08/2001	Syngenta

Switzerland

Approval Type	Date	Applicant
food/ feed	01/1998	Novartis
approval is limited to a five year period, without application for renewal it expires automatically		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	05/1995	Ciba Seeds	94-319-01p
for more information on GM crop regulation in the US see Annex			

food/ feed	07/1995	Ciba Seeds	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	08/1995	Mycogen	
registration of the cry1Ab delta-endotoxin gene, corn registration 176 phased out in 06/01, existing stocks for the seed must be used before or during the 2003 growing season			
plant pesticide	08/1995	Ciba Seeds	
registration of the cry1Ab delta-endotoxin gene, corn registration 176 phased out in 06/01, existing stocks for the seed must be used before or during the 2003 growing season			

Event: 676, 678, 680

The corn lines 676, 678, 680 have been genetically engineered for male sterility. The male sterile lines contain an adenine methylase gene (dam), derived from E.coli. It expresses a DNA adenine methylase enzyme in specific plant tissue. Its expression results in inability of the transformed plants to produce anthers or pollen. These lines also contain a pat selectable marker gene which confers tolerance to glufosinate.

Event Characterisation

Transformation Method: microparticle bombardment

Maps

A linear DNA fragment derived from plasmid PHP 6710 has been used to create these corn lines.

Map: Linear map of DNA construct used for transformation - DNA fragment of construct PHP 6710 used for transformation

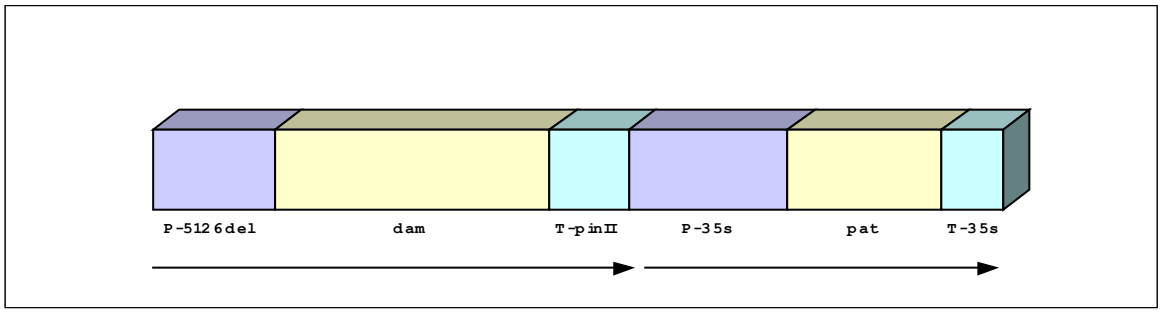


Figure 18: DNA fragment of construct PHP 6710 used for transformation

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-5126del	P-5126del	0.42
dam	DNA adenine methylase	0.95
T-pinII	T-pinII	0.27
P-35s	P-35s	0.55
	phosphinothricin acetyltransferase (PAT)	0.53
T-35s	T-35s	0.21

Molecular analyses show that the number of DNA inserts in male sterile events 676, 678 and 680 are different.
Event 676 contains one dam insert and two pat inserts. One of the pat and dam inserts are together.
Event 678 contains three dam and two pat inserts. One of the pat and dam inserts are together. The other pat insert appears to be a partial copy. There is at least one full copy of dam gene present in event 678 and a rearrangement has occurred at the 3' end of one of the dam inserts.
Event 680 contains four dam inserts and a single pat insert. One of the pat and dam inserts are together. The other three dam inserts appear to contain partial copies of dam. One intact dam and one intact pat gene are present in event 680.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
field production	05/1998	Pioneer Hi-Bred	97-342-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	12/1998	Pioneer Hi-Bred	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: B16

The line B16 has been genetically engineered to be tolerant of glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation. It is highly biodegradable, has no rsidual activity, and has a very low toxicity for humans and wild fauna. The availability of the glufosinate-ammonium tolerant corn line allows farmers to use the herbicides containing this compound as weed control option in the cultivation of maize. Glufosinate tolerance in this line is the result of introducing bar gene, encoding the enzyme phosphinothricin-N-acetyltransferase (PAT) that allows these plants to survive the otherwise lethal application of glufosinate.

The event is also named DLL25.

Event Characterisation

Transformation Method: microparticle bombardment

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pDPG165

US-Patent-N°: 6,395,966

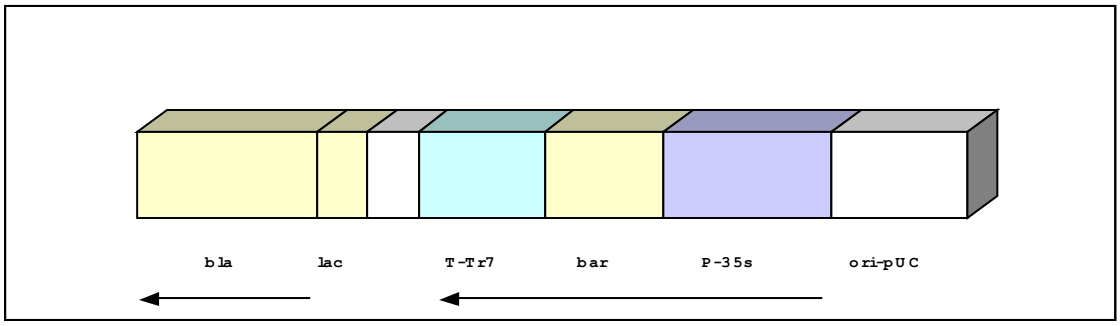


Figure 19: T-DNA region of construct pDPG165

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
bla	beta-lactamase	0.86
lac	beta-galactosidase	0.24
Space	Space	-
T-Tr7	T-Tr7	0.6
	phosphinothricin acetyltransferase (bar)	0.57
P-35s	P-35s	0.8
ori-pUC	ori-pUC	0.65

***Map*: Orientation of DNA construct integrated in the plant genome - B16 insertion**

Plant genome; bla (partial), lac, T-Tr7 (partial)/ P-35s (partial); bar (full); Tr7 (partial); **Plant genome**

Figure 20: B16 insertion

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla) partial.

Molecular analyses show that the insertion in the event B16 contains a single intact copy of the bar gene and a single incomplete copy of P-35s and the bla gene. Up to 100 bp of the 5' end of the 800 bp P-35s of the plasmid pDPG165 is not inserted in the event B16 genome. The bla gene is truncated at base pair 568 of the 858 bp of its coding sequence.

Approvals

Canada

Approval Type	Date	Applicant
feed	12/1996	DeKalb Genetics Corporation
field production	10/1996	DeKalb Genetics Corporation
food	12/1996	DeKalb Genetics Corporation

Japan

Approval Type	Date	Applicant
feed	03/2000	DeKalb Genetics Corporation
food	2001	Monsanto
food approval renewal 2001, first approval in 11/99		

import	1999	DeKalb Genetics Corporation

USA

Approval Type	Date	Applicant	Aphis Petition
field production	12/1995	DeKalb Genetics Corporation	95-145-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	01/1996	DeKalb Genetics Corporation	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: Bt11

Bt11 corn has been engnineered to express the Cry1Ab delta-endotoxin insecticidal protein. This protein is known to be effective against certain lepidopteran insects, including European Corn Borer (ECB). ECB is a major corn pest that reduces yield by disrupting normal plant physiology and causing damage to the leaves, stalks, and ears.

Brandname(s): Attribute, YieldGard

Event Characterisation

Transformation Method: direct DNA transfer

Maps

Construct pZO1502 derived from pUC18 has been used to engineer Bt11.

Map: Linear map of DNA construct used for transformation - Construct pZO1502

US-Patent-N°: 6,114,608

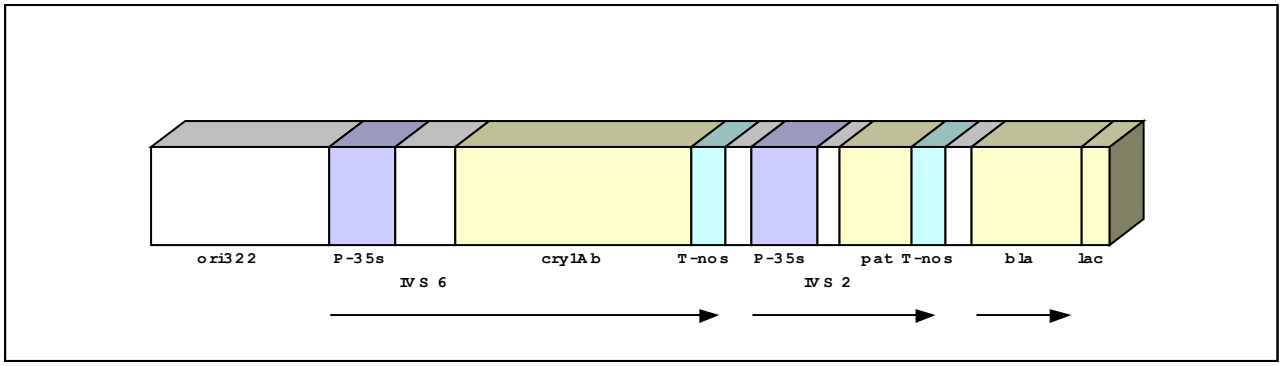


Figure 21: Construct pZO1502

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
ori322	ori322	-
P-35s	P-35s	0.514
IVS 6	intervening sequence 6	0.472
	cry1Ab delta-endotoxin	1.84

T-nos	T-nos	0.27
Space	Space	-
P-35s	P-35s	0.42
IVS 2	intervening sequence 2	0.178
	phosphinothricin acetyltransferase (PAT)	0.558
T-nos	T-nos	0.22
Space	Space	-
bla	beta-lactamase	-
lac	beta-galactosidase	-

In the construct pZO1502, there is a deletion (of about 150 bp) in the junction between two gene cassettes and just at the beginning of the P-35s of pat cassette (P. Brodmann, Kantonales Laboratorium Basel-Stadt).
According to data published by FSANZ, only one copy of cry1Ab and pat genes are transferred into the plant genome. Additionally, the insert in the genome of the Bt11 corn contains an approximately 1.4 kb DNA of the vector sequence, upstream of the cry1Ab cassette, including ori322. The bla gene is absent in the genome of event Bt11.

Approvals

Argentina

Approval Type	Date	Applicant
environment	08/2000	Novartis
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), for more information on GM crop regulation in Argentina see Annex		
field production	07/2001	Novartis
authorization for commercial seed and field production		
food/ feed	07/2001	Novartis
authorization for commercialization		

Australia/ New Zealand

Approval Type	Date	Applicant
food	07/2001	Syngenta

Canada

Approval Type	Date	Applicant
feed	06/1996	Northrup King
regulated lines: 4334 CBR and 4374 CBR		
field production	05/1996	Northrup King
regulated lines: 4334 CBR and 4374 CBR		
food	08/1996	Northrup King
regulated lines: 4334 CBR and 4374 CBR		

China

Approval Type	Date	Applicant
food/ feed	2002	Syngenta
temprorary approval granted during application review		

European Union

Approval Type	Date	Applicant
food	01/1998	Novartis
Reg. 258/97, authorization for food and food ingredient products derived from Bt11 crossed with the NK company inbred line #2044 as well as from any inbred and hybrid lines derived from it		
food/ feed	04/1998	Novartis
Reg. 220/90/EEC, authorization for commercial release, restriciton - uses: import and processing		

Japan

Approval Type	Date	Applicant
feed	09/1996	Northrup King
authorization not for sweet corn		
field production	06/2002	Syngenta
authorization for field and sweet corn		
food	2001	Syngenta
food approval renewal 2001, first approval for field corn in 09/96 (applicant Northrup King), approval of sweet corn in 2001		
import	2002	Syngenta

South Africa

Approval Type	Date	Applicant
food/ feed	02/2002	Syngenta

Switzerland

Approval Type	Date	Applicant
food/ feed	10/1998	Novartis
authorization is limited to a five year period, without application for renewal it expires automatically		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	01/1996	Northrup King	95-195-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	05/1996	Northrup King	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	08/1996	Northrup King	
registration of the CryIA(b) delta-endotoxin gene, registration renewal in 10/01, expires in 10/08			
plant pesticide	02/1998	Syngenta	
sweet corn registration, registration renewal in 10/01, expires in 10/08			

Event: CBH-351

This event has been genetically engineered to express a Cry9C insecticidal protein which is effective in controlling the larvae of the European Corn Borer during the complete growing season.

Brandname(s): Starlink

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The constructs pRVA9909 containing cry9C and pDE110, containing bar, have been used for transformation.

Map: Linear map of DNA construct used for transformation - Construct pRVA9909

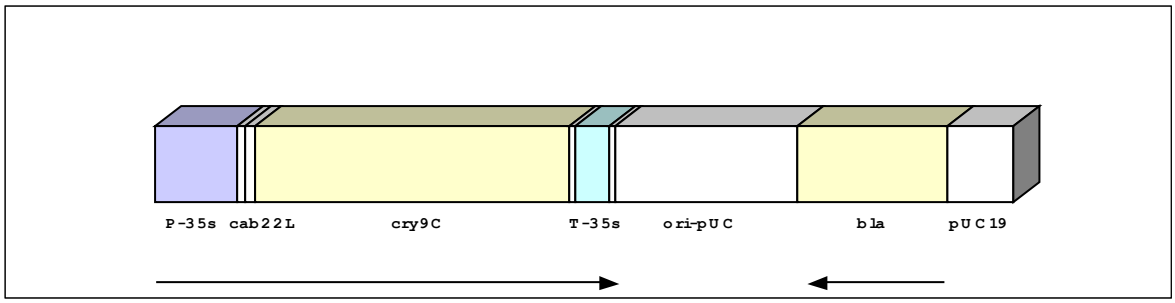


Figure 22: Construct pRVA9909

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-35s	P-35s	0.5
cab22L	cab22L	0.059
	cry9C delta-endotoxin	1.9
T-35s	T-35s	0.2
ori-pUC	ori-pUC	1.1
bla	beta-lactamase	0.9
pUC19	pUC19	0.4

Map: Linear map of DNA construct used for transformation - Construct pDE110

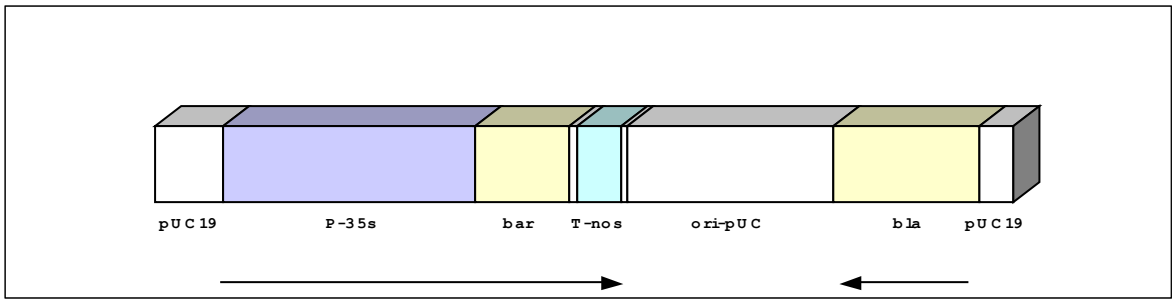


Figure 23: Construct pDE110

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
pUC19	pUC19	0.4

P-35s	P-35s	1.482
	phosphinothricin acetyltransferase (bar)	0.55
T-nos	T-nos	0.26
ori-pUC	ori-pUC	1.2
bla	beta-lactamase	0.86
pUC19	pUC19	0.2

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla)

Molecular analyses of the transformed plant show that there is a single DNA insertion in the genome of event CBH-351. This DNA insertion comprises of three fragments which include a single copy of the pDE110 plasmid, a head to tail linked double copy of the pDE110 plasmid and a combined copy of a truncated pDE110 plasmid linked to the pRVA9909 plasmid. At least one copy of the cry9C gene and four copies of the bar gene are present. All gene copies, except one, are flanked by the P-35s.

Approvals

Japan

Approval Type	Date	Applicant
import	1999	Plant Genetics Systems

USA

Approval Type	Date	Applicant	Aphis Petition
environment	05/1998	AgrEvo	97-265-01p
with the expiration of the plant pesticide registration in 2001, seed and commercial field production are not legal, although CBH-351 is still deregulated by USDA/APHIS, for more information on GM crop regulation in the US see Annex			
feed	05/1998	AgrEvo	
no formal authorisation for feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	1998	Plant Genetics Systems	
registration of the Cry9C delta-endotoxin gene, registration was limited to animal feed or industrial use only with a maximum of 120,000 acres, first registration in 05/98, Aventis requested voluntary cancellation of their corn registration, it became effective on 02/01			

Event: DBT418

DBT418 is resistant to European Corn Borer (ECB), a major insect pest of maize. The plant produces a truncated version of the insecticidal protein, Cry1Ac delta-endotoxin, derived from *Bacillus thuringiensis subp. kurstaki strain HD-73.* It is also tolerant to glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium tolerance is conferred by the bar gene, encoding the enzyme phosphinothricin-N-acetyltransferase (PAT).

Brandname(s): Bt-Xtra, DeKalBt

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The plasmids pDPG699, pDPG165, and pDPG320 have been used to create DBT418.

Map: Linear map of DNA construct used for transformation - Construct pDPG165

US-Patent-N°: 6,395,966

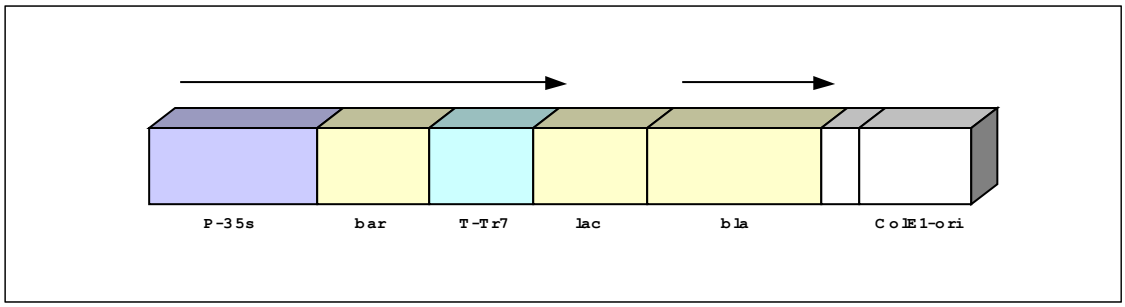


Figure 24: Construct pDPG165

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-35s	P-35s	0.83
	phosphinothricin acetyltransferase (bar)	0.55
T-Tr7	T-Tr7	0.52
lac	beta-galactosidase	0.56
bla	beta-lactamase	0.86
Space	Space	-
ColE1-ori	ColE1-ori	0.55

Map: Linear map of DNA construct used for transformation - Construct pDPG320

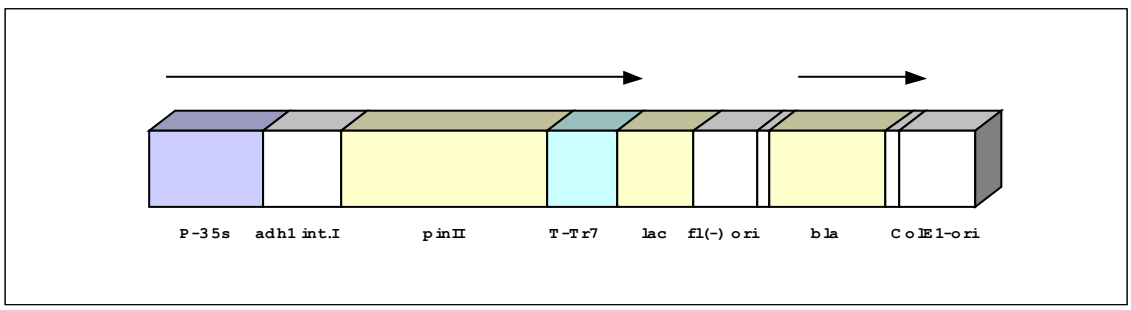


Figure 25: Construct pDPG320

Sequence-Details:

Abbreviation	Element-Name	Size [KB]

P-35s	P-35s	0.83
adh1 int.I	alcohol dehydrogenase –1 intron I	0.57
pinII	potato genomic DNA fragment	1.51
T-Tr7	T-Tr7	0.52
lac	beta-galactosidase	0.56
Fl(-) ori	fl bacteriophage origin of replication	0.46
Space	Space	-
bla	beta-lactamase	0.86
Space	Space	-
ColE1-ori	ColE1-ori	0.55

Map: Linear map of DNA construct used for transformation - Construct pDPG699

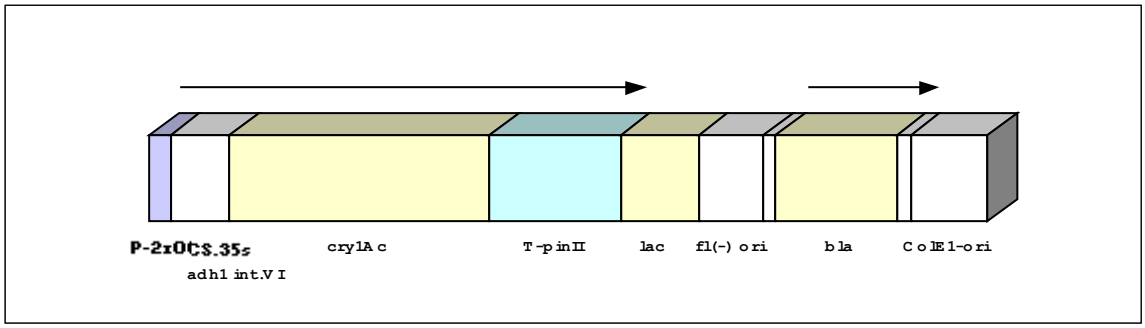


Figure 26: Construct pDPG699

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-2xOCS,35s	P-2xOCS,35s	0.15
adh1 int.VI	alcohol dehydrogenase –1 intron IV	0.42
	cry1Ac delta-endotoxin	1.85
T-pinII	T-pinII	0.93
lac	beta-galactosidase	0.56
Fl(-) ori	fl bacteriophage origin of replication	0.46
Space	Space	-
bla	beta-lactamase	0.86
Space	Space	-
ColE1-ori	ColE1-ori	0.55

Map: Orientation of DNA construct integrated in the plant genome - Inserted elements in event DBT418 (22.3 kb)

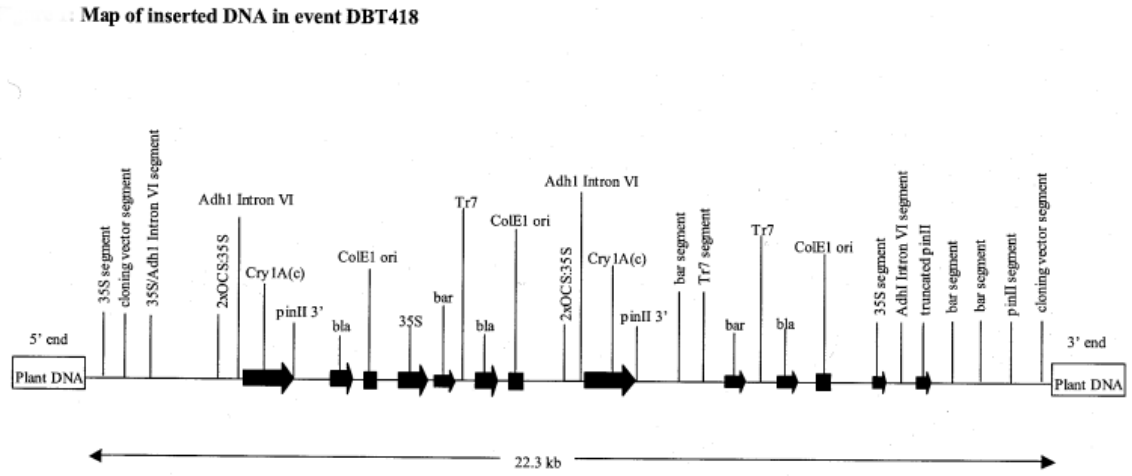


Figure 27: Inserted elements in event DBT418 (22.3 kb)

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla)

Southern analyses show that DBT418 contains approximately two intact copies of the cry1Ac gene, approximately one intact copy of bar, rearranged bar DNA, one partial rearranged copy of pinII gene, four intact copies and one partial copy of bla gene and approximately four intact copies of ColE1-ori, all at one insertion site.
The results of the Southern blot analyses are summarised in the following table:

Elements	**Approximate copy number**	
	intact	**rearranged**
cry1Ac	2	0
bar	1	1
pinII	0	0.5
Adh1 int. I	0	0.5
bla	4	0.5
ColE1-ori	4	0

According to the report published by FSANZ, the PCR and sequencing analysis confirmed the estimation of the gene copy number by southern blot analysis (the table above), although the more detailed information indicated that there were three, rather than four copies of the bla gene and ColE1-ori, plus several non-functional partial fragments of the bar and pinII gene, all at the one insertion site.

Approvals

Argentina

Approval Type	Date	Applicant

environment	02/1998	DeKalb Genetics Corporation
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), for more information on GM crop regulation in Argentina see Annex		

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Monsanto

Canada

Approval Type	Date	Applicant
feed	03/1997	DeKalb Genetics Corporation
field production	03/1997	DeKalb Genetics Corporation
food	04/1997	DeKalb Genetics Corporation

Japan

Approval Type	Date	Applicant
feed	2000	DeKalb Genetics Corporation
food	2001	Monsanto
food approval renewal 2001, first approval in 11/99		
import	1999	DeKalb Genetics Corporation

USA

Approval Type	Date	Applicant	Aphis Petition
environment	03/1997	DeKalb Genetics Corporation	96-291-01p
with the expiration of the plant pesticide registration in 2000, seed and commercial field production is not legal, although crop still deregulated by USDA/APHIS, for more information on GM crop regulation in the US see Annex			
food/ feed	03/1997	DeKalb Genetics Corporation	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	1997	DeKalb Genetics Corporation	
registration of the CryIA(c) delta endotoxin gene, field production not legal, because plant pesticide registration has been voluntariliy cancelled in 12/00			

Event: DBT418-DK566

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Herbicide tolerance	glufosinate		phosphinothricin acetyltransferase (PAT)		
Insect resistance	lepidoptera		cry1Ab delta-endotoxin		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1997	DeKalb Genetics Corporation
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1997	DeKalb Genetics Corporation

Event: DLL25-DK566

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Herbicide tolerance	glufosinate		phosphinothricin acetyltransferase (PAT)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1997	DeKalb Genetics Corporation
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1997	DeKalb Genetics Corporation

Event: GA21

GA21 is a Roundup Ready® maize, tolerant to the herbicide glyphosate. Glyphosate is a post emergent, systemic herbicide that is used worldwide for the non-selective control of a wide variety of annual and perennial weeds.
The herbicide tolerance was conferred in the line GA21 by introducing an endogenous maize EPSPS, modified through site-directed mutagenesis, such that its encoded enzyme was insensitive to inactivation by glyphosate.

Brandname(s): Roundup Ready

Event Characterisation

Transformation Method: microparticle bombardment

Maps

A linear NotI restriction fragment of construct pDPG434 has been used for transformation.

Map: Linear map of DNA construct used for transformation - NotI restriction fragment of construct pDPG434

US-Patent-N°: 6,040,497

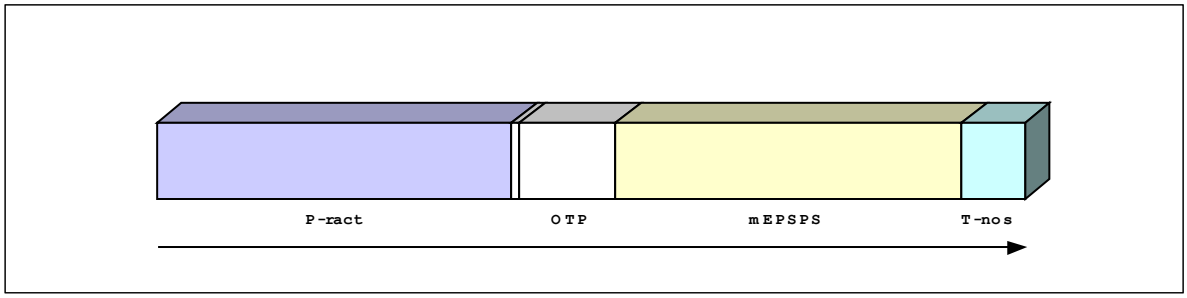


Figure 28: NotI restriction fragment of construct pDPG434

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-ract	P-ract	1.37
OTP	OTP	0.37
mEPSPS	maize 5-enolpyruvylshikimate-3-phosphate synthase	1.34
T-nos	T-nos	0.24

Molecular analyses of the transformed plant show that the GA21 corn genome contains one DNA insert. This insert consists of two copies of complete mEPSPS gene cassettes, and a third copy without T-nos.
According to data published by FSANZ, the single insert in the genome of the GA21 contains four functional mEPSPS gene cassettes plus a truncated mEPSPS cassette that does not produce a detectable RNA transcript.

Approvals

Argentina

Approval Type	Date	Applicant
environment	10/1998	DeKalb Genetics Corporation
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), for more information on GM crop regulation in Argentina see Annex		

Australia/ New Zealand

Approval Type	Date	Applicant
food	11/2000	Monsanto

Bulgaria

Approval Type	Date	Applicant
field production	1999	Monsanto
food/ feed	1999	Monsanto

Canada

Approval Type	Date	Applicant
feed	07/1998	Monsanto
field production	04/1998	Monsanto
food	05/1999	Monsanto

Japan

Approval Type	Date	Applicant
feed	12/1999	Monsanto
field production	12/1998	Monsanto
food	2001	Monsanto
food approval renewal 2001, first approval in 11/99		
import	1998	Monsanto

Russia

Approval Type	Date	Applicant
food	2000	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	11/1997	Monsanto	97-099-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	02/1998	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: Mon80100

Mon 80100 contains a cry1Ab delta-endotoxin gene encoding for an insect control protein. The protein is a member of a class of insecticidal proteins, also known as delta-endotoxins, that are produced in nature as parasporal crystals by *B. thuringiensis subsp. Kurstaki*. They are known to be quite selective in their toxicity against certain lepidopteran insects, including European corn borer (ECB). Corn producing the Cry1Ab protein are protected throughout the growing season from leave and stalk damage caused by ECB.

The event is also named MON801.

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The plasmid vectors PV-ZMBK07 and PV-ZMGT10 were used to produce the corn line MON80100.
These two vectors have been also used to engineer Mon809 and Mon810 and Mon832.

Map: Linear map of DNA construct used for transformation - Construct PV-ZMBK07

US-Patent-N°: 5,689,052

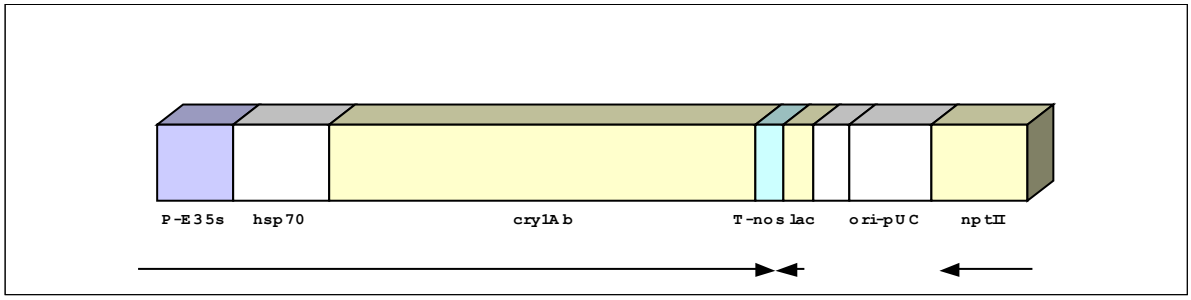


Figure 29: Construct PV-ZMBK07

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.62
hsp70	heat-shock protein 70	0.8
	cry1Ab delta-endotoxin	3.5
T-nos	T-nos	0.24
lac	beta-galactosidase	0.24
Space	Space	-
ori-pUC	ori-pUC	0.67
nptII	neomycin phosphotransferase	0.79

Map: Linear map of DNA construct used for transformation - Construct PV-ZMGT10

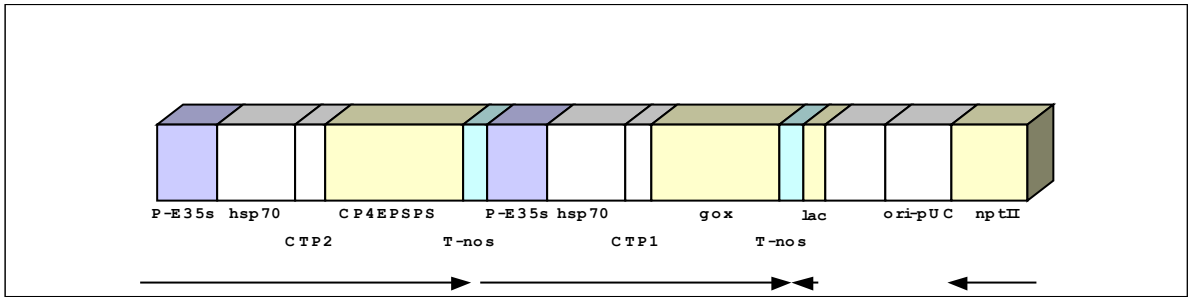


Figure 30: Construct PV-ZMGT10

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.62
hsp70	heat-shock protein 70	0.8
CTP2	Chloroplast Transit Peptide 2	0.31
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.4
T-nos	T-nos	0.24
P-E35s	P-E35s	0.62
hsp70	heat-shock protein 70	0.8
CTP1	Chloroplast Transit Peptide 1	0.26
gox	glyphosate oxidoreductase	1.3
T-nos	T-nos	0.24
lac	beta-galactosidase	0.24
Space	Space	-
ori-pUC	ori-pUC	0.67
nptII	neomycin phosphotransferase	0.79

Map: Orientation of DNA construct integrated in the plant genome - Inserted elements from PV-ZMBK07 and PV-ZMBK10 (insert 1)

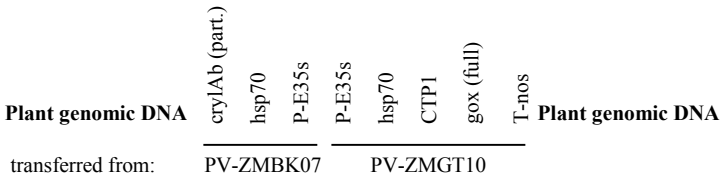


Figure 31: Inserted elements from PV-ZMBK07 and PV-ZMBK10 (insert 1)

Map: Orientation of DNA construct integrated in the plant genome - Inserted elements from PV-ZMBK07, PV-ZMBK10, PV-ZMBK10, PV-ZMBK10 (insert 2)

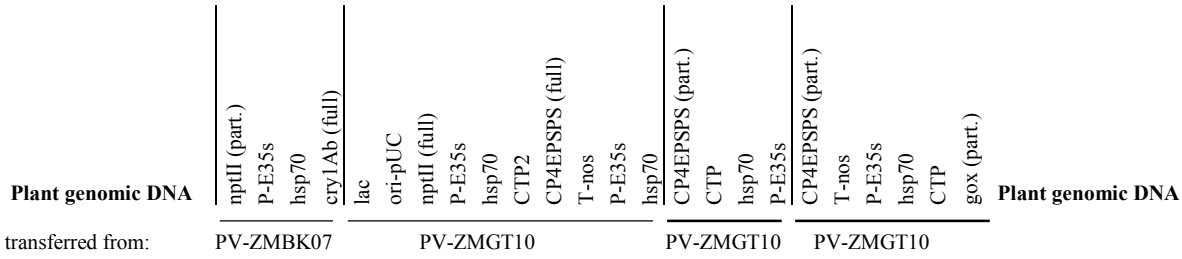


Figure 32: Inserted elements from PV-ZMBK07, PV-ZMBK10, PV-ZMBK10, PV-ZMBK10 (insert 2)

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses of the transformed plant show that two inserted DNA sequences are present in the genome of the plant. One insert contains a partial cry1Ab gene linked to a full-length gox gene. The second insert contains a full-length cry1Ab, one

partial gox gene, two partial and one full-length CP4EPSPS genes, a partial and a full-length nptII gene.The schematic presentation of inserts 1 and 2 can be seen above.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
environment	08/1995	Monsanto	95-093-01p
with the expiration of the plant pesticide registration in 1998, seed and commercial field production are not legal, although crop is still deregulated for environmental release by USDA/APHIS, for more information on GM crop regulation in the US see Annex			
food/ feed	03/1996	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	05/1996	Monsanto	
registration of the CryIA(b) delta-endotoxin gene, field production not legal, because plant pesticide registration has been voluntariliy cancelled in 05/98			

Event: Mon802

Mon802 has been genetically engineered to express a cry1Ab insect control protein derived from *B. thuringiensis subsp. Kurstaki.* and a CP4EPSPS and GOX protein conferring herbicide tolerance to glyphosate to the corn. The Cry1Ab delta-endotoxin protein protects the corn from leave and stalk feeding damage caused by the ECB throughout the growing season.

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The corn Mon802 was produced using vectors PV-ZMGT03 and PV-ZMBK15.

***Map*: Linear map of DNA construct used for transformation - Construct PV-ZMGT03, also named pMON19643**

US-Patent-N°: 5,859,347

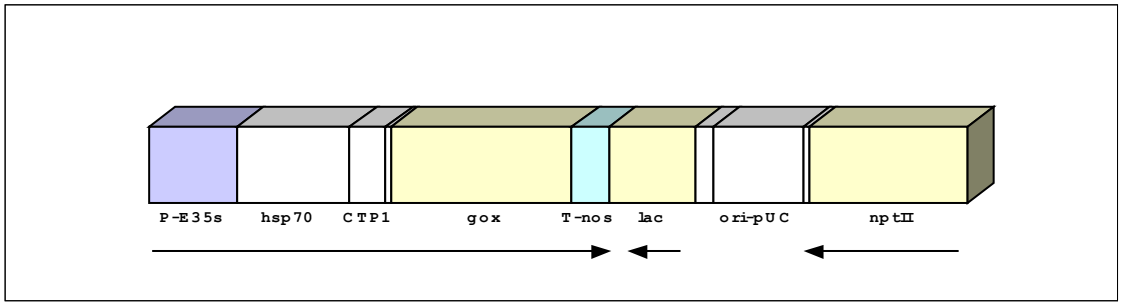


Figure 33: Construct PV-ZMGT03, also named pMON19643

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.64
hsp70	heat-shock protein 70	0.81
CTP1	Chloroplast Transit Peptide 1	0.26
gox	glyphosate oxidoreductase	1.3
T-nos	T-nos	0.27
lac	beta-galactosidase	0.62
ori-pUC	ori-pUC	0.65
nptII	neomycin phosphotransferase	1.14

Map: Linear map of DNA construct used for transformation - Construct PV-ZMBK15

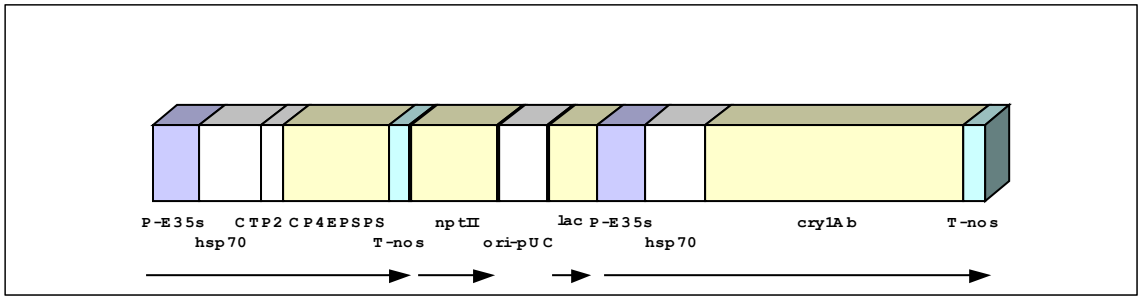


Figure 34: Construct PV-ZMBK15

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.64
hsp70	heat-shock protein 70	0.81
CTP2	Chloroplast Transit Peptide 2	0.31
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.4
T-nos	T-nos	0.27
nptII	neomycin phosphotransferase	1.14
ori-pUC	ori-pUC	0.65
lac	beta-galactosidase	0.62
P-E35s	P-E35s	0.64
hsp70	heat-shock protein 70	0.81
	cry1Ab delta-endotoxin	3.47
T-nos	T-nos	0.27

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses of the transformed plant show that the corn line Mon802 contains two closely linked inserts. The 23 kb insert contains the cry1Ab, CP4EPSPS and gox genes and the nptII/ori-pUC backbone. The 8 kb insert contains the gox gene and the nptII/ori-pUC backbone.

Approvals

Canada

Approval Type	Date	Applicant
feed	03/1997	Monsanto
field production	03/1997	Monsanto
food	09/1997	Monsanto

Japan

Approval Type	Date	Applicant
import	1997	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
environment	05/1997	Monsanto	96-317-01p
no plant pesticide registration, for more information on GM crop regulation in the US see Annex			
food/ feed	09/1996	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review), Mon805, Mon830 and Mon831 are also covered by the FDA Memo			

Event: Mon809

Mon809 contains a cry1Ab gene that encodes for a Cry1Ab delta-endotoxin insect control protein. Ddelta-endotoxins are produced in nature as parasporal crystals by *B. thuringiensis subsp. Kurstaki*. They are known to be quite selective in their toxicity against certain lepidopteran insects, including European Corn Borer (ECB). Corn producing the Cry1Ab protein are protected throughout the growing season from leave and stalk damage caused by ECB. Herbicide tolerance conferred by CP4EPSPS and gox has been used for selection.

Event Characterisation

Transformation Method: microparticle bombardment

Maps

Two constructs, PV-ZMBK07 and PV-ZMGT10, were used for transformation. These are the same constructs which have been used for transformation of events Mon80100, Mon810 and Mon832.

Map: Linear map of DNA construct used for transformation - Construct PV-ZMGT10

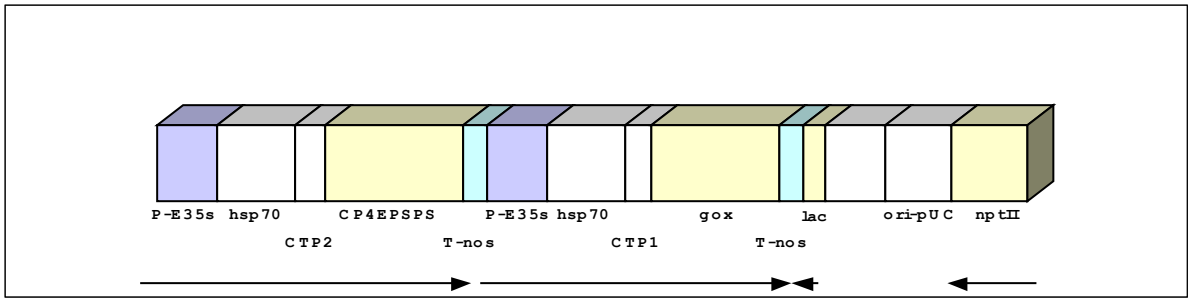


Figure 35: Construct PV-ZMGT10

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.62
hsp70	heat-shock protein 70	0.8
CTP2	Chloroplast Transit Peptide 2	0.31
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.4
T-nos	T-nos	0.24
P-E35s	P-E35s	0.62
hsp70	heat-shock protein 70	0.8
CTP1	Chloroplast Transit Peptide 1	0.26
gox	glyphosate oxidoreductase	1.3
T-nos	T-nos	0.24
lac	beta-galactosidase	0.24
Space	Space	-
ori-pUC	ori-pUC	0.67
nptII	neomycin phosphotransferase	0.79

***Map*: Linear map of DNA construct used for transformation - Construct PV-ZMBK07 (Mon809)**

US-Patent-N°: 5,689,052

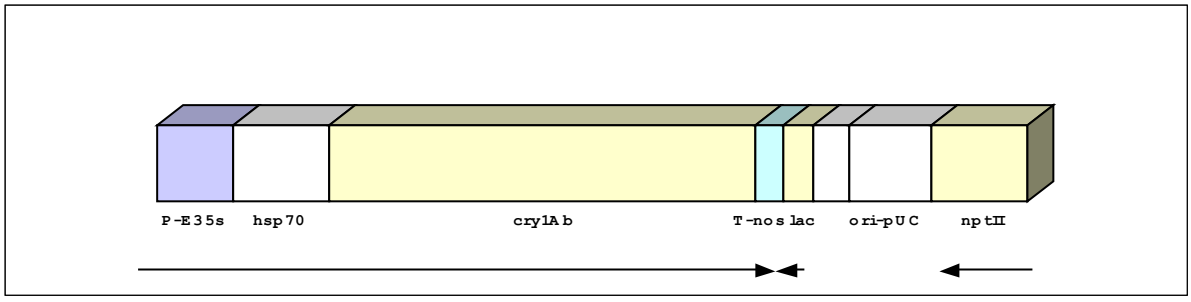


Figure 36: Construct PV-ZMBK07 (Mon809)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.61
hsp70	heat-shock protein 70	0.8
	cry1Ab delta-endotoxin	3.46
T-nos	T-nos	0.26
lac	beta-galactosidase	0.24
Space	Space	-
ori-pUC	ori-pUC	0.65
nptII	neomycin phosphotransferase	0.79

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses of the transformed plant show that corn line Mon809 contains one integrated DNA of approximately 23 Kb which includes: 2X cry1Ab (one complete, one partial); 2X CP4EPSPS both of expected size; 1X gox (partial size). nptII/Ori-pUC is also present in the insert but not the predicted size.

Approvals

Canada

Approval Type	Date	Applicant
feed	11/1996	Pioneer Hi-Bred
field production	11/1996	Pioneer Hi-Bred
food	12/1996	Pioneer Hi-Bred

European Union

Approval Type	Date	Applicant
food	10/1998	Pioneer Hi-Bred
Reg. 258/97, authorization for food and food ingredients produced from GM maize line Mon809		

Japan

Approval Type	Date	Applicant
feed	1998	Monsanto
import	1997	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
environment	03/1996	Monsanto	96-017-01p
approval extension of 95-093-01p, no plant pesticide registration, for more information on GM crop regulation in the US see Annex			
food/ feed	09/1996	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: Mon810

Mon810 contains a cry1Ab delta-endotoxin gene ecoding for an insect control protein. The protein is a member of a class of insecticidal proteins, also known as delta-endotoxins, that are produced in nature as parasporal crystals by *B. thuringiensis subsp. Kurstaki*. They are known to be quite selective in their toxicity against certain lepidopteran insects, including European corn borer (ECB). Corn producing the Cry1Ab protein are protected throughout the growing season from leave and stalk damage caused by ECB.

Brandname(s): YieldGard

Event Characterisation

Transformation Method: microparticle bombardment

Maps

Two constructs PV-ZMBK07 and PV-ZMGT10 have been used for transformation (the same constructs used to transform Mon809, Mon80100 and Mon832), but only the elements from construct PV-ZMBK07 have been integrated into the genome of line Mon810.

Map: Linear map of DNA construct used for transformation - Construct PV-ZMBK07 (Mon810)

US-Patent-N°: 5,689,052

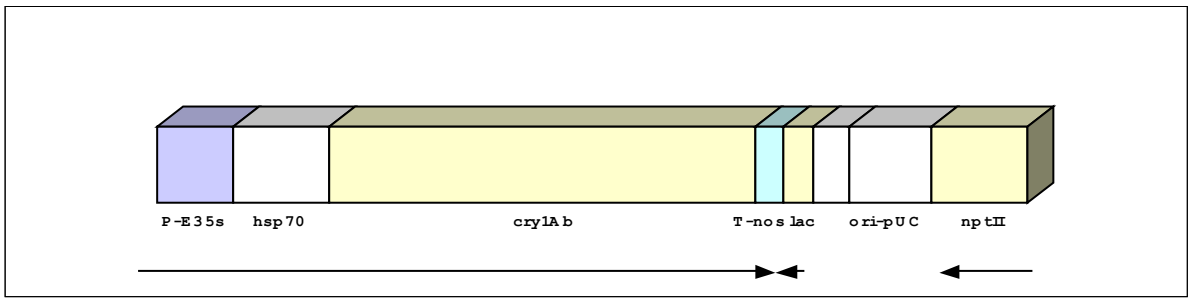


Figure 37: Construct PV-ZMBK07 (Mon810)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.61
hsp70	heat-shock protein 70	0.8
	cry1Ab delta-endotoxin	3.46
T-nos	T-nos	0.26
lac	beta-galactosidase	0.24
Space	Space	-
ori-pUC	ori-pUC	0.65
nptII	neomycin phosphotransferase	0.79

Molecular analyses of the transformed plant show that corn line Mon810 does not contain any element from PV-ZMGT10 construct. It contains one integrated DNA consisting of P-E35s, intron hsp70 and cry1Ab from construct PV-ZMBK07 (T-nos is absent). According to Pietsch K., *et al* 1997, T-nos is not transferred into the plant genome.

According to data published by FSANZ, corn line Mon810 contains only cry1Ab gene. No other genes were transferred during transformation. The DNA has been transferred into the corn genome as a single and stable DNA insert.

Approvals

Argentina

Approval Type	Date	Applicant

environment	05/1998	Monsanto
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), for more information on GM crop regulation in Argentina see Annex		
field production	07/1998	Monsanto
authorization for commercial seed and field production		
food/ feed	07/1998	Monsanto
authorization for commercialization		

Australia/ New Zealand

Approval Type	Date	Applicant
food	11/2000	Monsanto

Canada

Approval Type	Date	Applicant
feed	01/1997	Monsanto
field production	01/1997	Monsanto
food	02/1997	Monsanto

European Union

Approval Type	Date	Applicant
field production	04/1998	Monsanto
Reg. 220/90/EEC, authorization for commercial seed and field production		
food	1997	Monsanto
Reg. 258/97, authorization for food and food ingredients produced from maize flour, maize gluten, maize semolina, maize starch, maize glucose and maize oil derived from the progeny of maize line Mon810		
food/ feed	04/1998	Monsanto
Reg. 220/90/EEC, authorisation for commercial release		

Japan

Approval Type	Date	Applicant
feed	06/1997	Monsanto
food	2001	Monsanto
food approval renewal 2001, first approval in 05/97		
import	1996	Monsanto

South Africa

Approval Type	Date	Applicant
field production	1998	Monsanto
food/ feed	1998	Monsanto

Switzerland

Approval Type	Date	Applicant
food/ feed	07/2000	Monsanto
approval is limited to a five year period, without application for renewal it expires automatically		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	03/1996	Monsanto	96-017-01p

	approval extension of 95-093-01p, for more information on GM crop regulation in the US see Annex		
food/ feed	09/1996	Monsanto	
	no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)		
plant pesticide	12/1996	Monsanto	
	registration of the CryIA(b) delta-endotoxin gene, as extension of Mon80100 plant pesticide approval (07/96), registration renewal in 10/01, expires in 10/08		

Event: Mon832

The herbicide tolerant corn line Mon832 was genetically engineered to allow for the use of glyphosate, as a weed control option. Glyphosate, the active ingredient in Roundup®, is a post emergent, systemic herbicide that is used worldwide for the non-selective control of a wide variety of annual and perennial weeds. In order to obtain field tolerance to glyphosate herbicide, two genes, CP4 EPSPS and gox, were introduced into the genome of the plant.

Event Characterisation

Transformation Method: microparticle bombardment

Maps

Two constructs PV-ZMBK07 and PV-ZMGT10 have been used for transformation. (These constructs have also been used to create Mon80100, Mon809 and Mon810).

Map: Linear map of DNA construct used for transformation - Construct PV-ZMBK07 (Mon832)

US-Patent-N°: 5,689,052

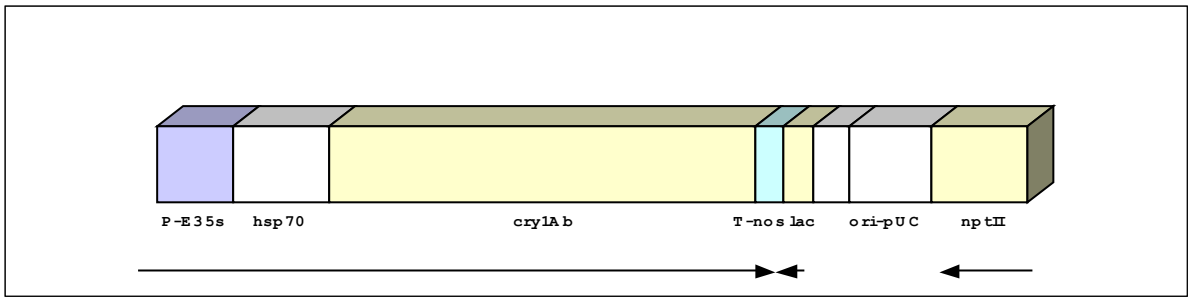


Figure 38: Construct PV-ZMBK07 (Mon832)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.62
hsp70	heat-shock protein 70	0.8
	cry1Ab delta-endotoxin	3.5
T-nos	T-nos	0.24
lac	beta-galactosidase	0.24
Space	Space	-
ori-pUC	ori-pUC	0.67

nptII	neomycin phosphotransferase	0.79

Map: Linear map of DNA construct used for transformation - Construct PV-ZMGT10 (Mon832)

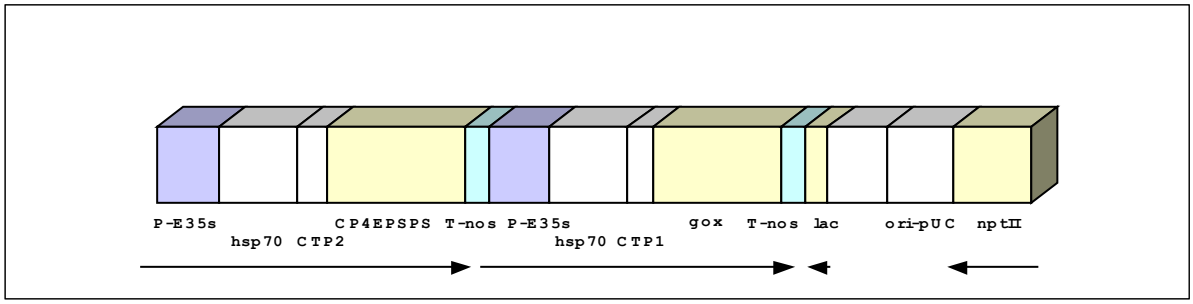


Figure 39: Construct PV-ZMGT10 (Mon832)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.62
hsp70	heat-shock protein 70	0.8
CTP2	Chloroplast Transit Peptide 2	0.31
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.4
T-nos	T-nos	0.24
P-E35s	P-E35s	0.62
hsp70	heat-shock protein 70	0.8
CTP1	Chloroplast Transit Peptide 1	0.26
gox	glyphosate oxidoreductase	1.3
T-nos	T-nos	0.24
lac	beta-galactosidase	0.24
Space	Space	-
ori-pUC	ori-pUC	0.67
nptII	neomycin phosphotransferase	0.79

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses show that event Mon832 contains one inserted DNA of ≈16 Kb, which contains CP4EPSPS, gox gene, two larger fragments which contain gox genes, backbone sequences (nptII/ori-pUC) plus rearranged backbone sequences. The cry1Ab gene was not integrated into the genome.

Approvals

Canada

Approval Type	Date	Applicant
food	09/1997	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
food/ feed	09/1996	Monsanto	

no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review), Mon805, Mon830 and Mon831 are also covered by the FDA memo, for more information on GM crop regulation in the US see Annex

Event: Mon863

Mon863 has been genetically engineered to express a Cry3Bb1 insecticidal protein derived from the *B. thuringiensis subsp. Kumamotoensis.* The protein is effective in controlling the larvae of corn rootworm (CRW) pests *(coleoptera, Diabrotica spp.).*

Brandname(s): MaxGuard, YieldGard Rootworm

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The linear *Mlu I* DNA fragment, PV-ZMIR13L (4691 bp), from vector PV-ZMIR13 has been used for transformation.

Map: Linear map of DNA construct used for transformation - Mlu I DNA fragment PV-ZMIR13L

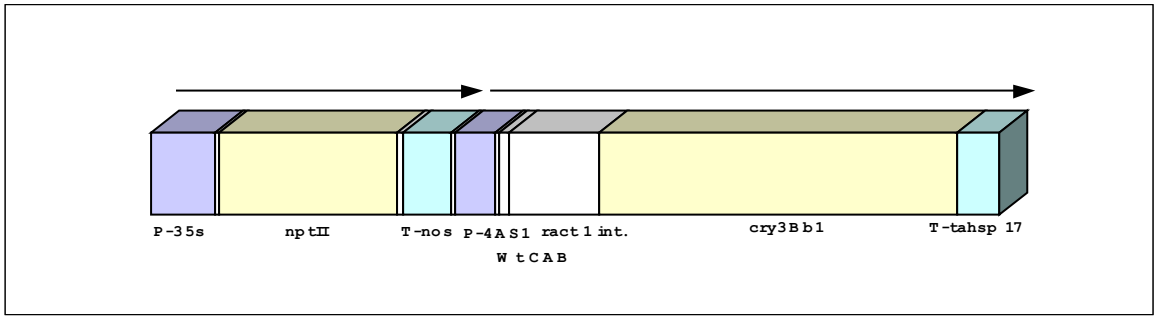


Figure 40: Mlu I DNA fragment PV-ZMIR13L

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-35s	P-35s	0.35
nptII	neomycin phosphotransferase	0.97
T-nos	T-nos	0.26
P-4AS1	P-4AS1	0.22
Wt CAB	Wt CAB	0.06
ract 1 int	ract 1 int	0.49
	cry3Bb1 delta-endotoxin	1.96
T-tahsp 17	T-tahsp 17	0.23

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Due to the use of a unique restriction site for the excision of nptII from Tn5, this gene cassette also contains a 153 bp of the 378 bp bleomycin binding protein gene (ble).This segment of ble is located 20 nucleotides downstream of the nptII stop codon, and it is joined to the T-nos.
Molecular analyses of the transformed plant show that one DNA insert has been transferred to the genome of Mon863. This insert contains one copy of the *Mlu I* plasmid fragment used in transformation. Both cassettes are intact and no DNA from plasmid backbone was detected.
The mRNA that is transcribed from the nptII cassette contains tandem open reading frames (ORF). The proximal ORF is the complete nptII coding sequence while the distal ORF encodes approximately 40% of the bleomycin binding sequence. Due to differences in the mechanism of initiation of translation between procaryotic and eucaryotic organisms, it is highly unlikely that the partial ble ORF will be translated into protein in Mon863. This means that nptII will be expressed in Mon863, but the ble fragment will not. According to the FDA, if the partial ble gene were translated into protein, the truncated peptide would not dimerize because it lacks the necessary amino acids to dimerize, and also lacks approximately 50% of the residues that are involved in bleomycin binding.

Approvals

Canada

Approval Type	Date	Applicant
field production	03/2003	Monsanto
food/ feed	03/2003	Monsanto

Japan

Approval Type	Date	Applicant
feed	2002	Monsanto
food	2002	Monsanto
import	2001	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	10/2002	Monsanto	01-137-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	12/2001	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	02/2003	Monsanto	
registration of the cry3Bb1 delta-endotoxin gene, expires in 05/04			

Event: MS3

The SeedLink system has been used to develop this pollination control system. In corn, SeedLink comprises two linked components: the dominant nuclear male sterility function and an efficient field selection marker. The nuclear male sterility function is based on disruption of the tapetal cell layer development (pollen formation) in the anthers by introducing barnase gene construct. The linked field selection system, is based on glufosinate-ammonium tolerance by introducing bar gene construct. The

maintenance and multiplication of the male sterile line is accomplished by crossing the male sterile plants with a fertile counterpart.

Event Characterisation

Transformation Method: direct DNA transfer

Maps

The linearized plasmid pVE108 (by HindIII digestion) was used to transform the event MS3. The plasmid pVE108 was isolated from E.coli WK6, which contains also the plasmid pMc5barstar. The molecules of pMc5barstar might be present in the pVE108 preparation used for transformation.

Map: Linear map of DNA construct used for transformation - Construct pVE108 (5616 bp)

US-Patent-N°: 6,002,070

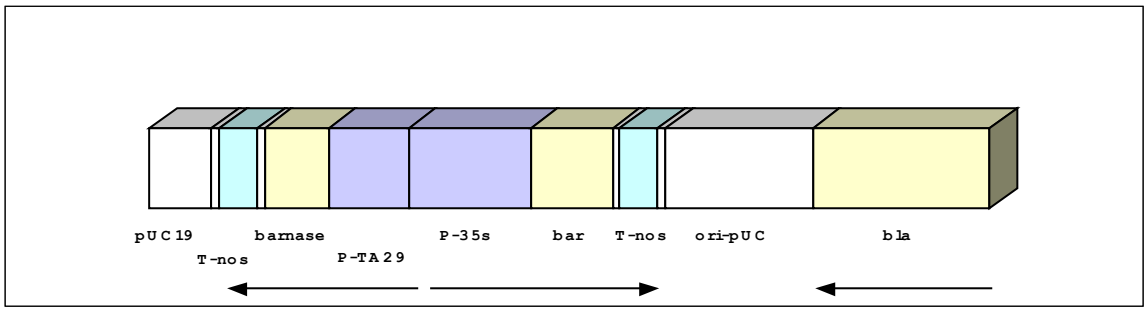


Figure 41: Construct pVE108 (5616 bp)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
pUC19	pUC19	0.421
T-nos	T-nos	0.26
	barnase	0.431
P-TA29	P-TA29	0.542
P-35s	P-35s	0.832
	phosphinothricin acetyltransferase (bar)	0.551
T-nos	T-nos	0.26
ori-pUC	ori-pUC	1
bla	beta-lactamase	1.2

Map: Linear map of DNA construct used for transformation - pMc5barstar (helper plasmid: 4219 bp)

Figure 42: pMc5barstar (helper plasmid: 4219 bp)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
PMc5-8	PMc5-8	3.7
P-Ptac	P-Ptac	0.272
	barstar	0.3
T-barstar	T-barstar	0.041

Map: Orientation of DNA construct integrated in the plant genome - Inserted elements of MS3

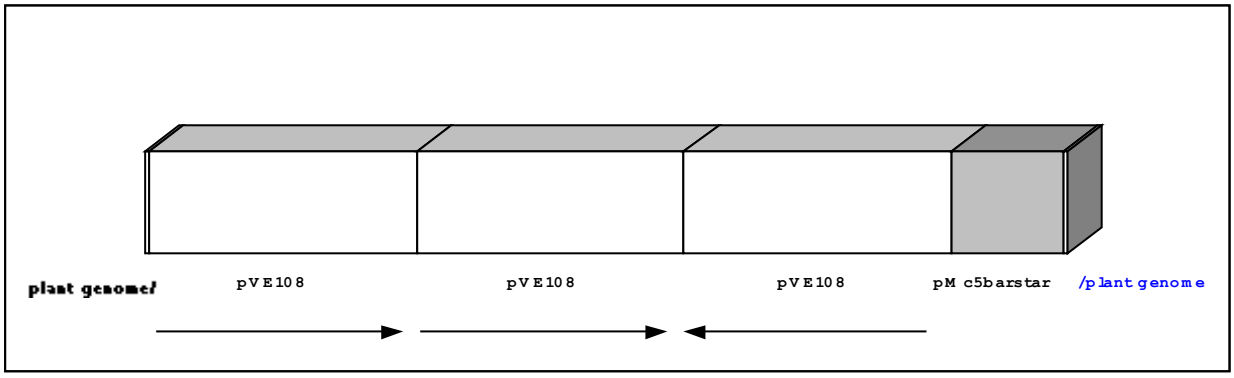


Figure 43: Inserted elements of MS3

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla)

Molecular analyses of the transformed plant show that the transferred elements are integrated at one site in the corn genome and are inherited as a single locus. The inserted DNA resides on 2 adjacent fragments. One ~12 kb fragment consisting of a head-to-tail dimer of pVE108 and a ~9kb fragment consisting of one pVE108 copy and a rearranged piece of pMc5barstar. Thus the insert of the MS3 contains a part of pMc5barstar plasmid. There is no clear indication about the completeness of pVE108 copies. The schematic presentation of insert can be seen above.

In the petition submitted by the same company for MS6 (Petition Nr.: 98-349-01p), it is mentioned that the event MS3 contains 3 copies of the barnase gene, one copy of bar gene and 2 copies of bla gene.

Approvals

Canada

Approval Type	Date	Applicant
feed	03/1998	Plant Genetics Systems
field production	10/1996	Plant Genetics Systems
food	07/1997	Plant Genetics Systems

USA

Approval Type	Date	Applicant	Aphis Petition
field production	02/1996	Plant Genetics Systems	95-228-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	03/1996	Plant Genetics Systems	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: MS6

The SeedLink system has been used to develop this pollination control system. In corn, SeedLink comprises two linked components: the dominant nuclear male sterility function and an efficient field selection marker. The nuclear male sterility function is based on disruption of the tapetal cell layer development (pollen formation) in the anthers by introducing barnase gene construct. The linked field selection system, is based on glufosinate-ammonium tolerance by introducing bar gene construct. The maintenance and multiplication of the male sterile line is accomplished by crossing the male sterile plants with a fertile counterpart.

Event Characterisation

Transformation Method: direct DNA transfer

Maps

Map: Linear map of DNA construct used for transformation - Construct pVE136

US-Patent-N°: 6,025,546

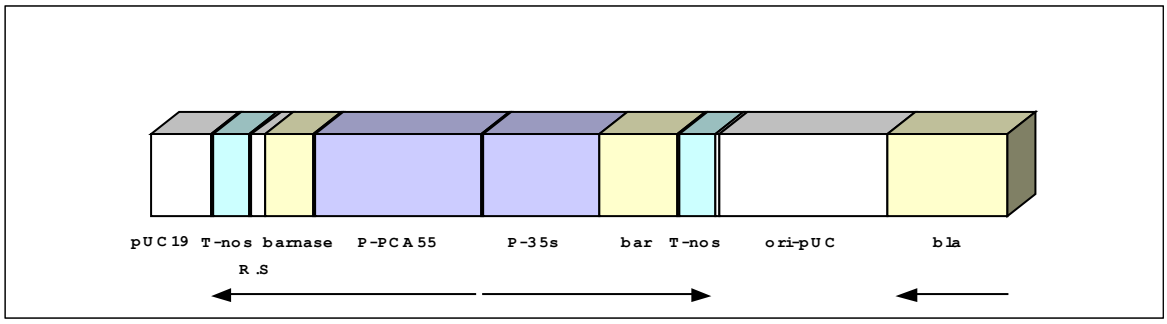


Figure 44: Construct pVE136

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
pUC19	pUC19	0.42
T-nos	T-nos	0.26
R.S.	Residual sequence	0.095
	barnase	0.34
P-PCA55	P-PCA55	1.18
P-35s	P-35s	0.83
	phosphinothricin acetyltransferase (bar)	0.55
T-nos	T-nos	0.26
ori-pUC	ori-pUC	1.2
bla	beta-lactamase	0.85

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla) partial.

Molecular analyses of the transformed plant show that one copy of the P-PCA55-barnase-T-nos cassette and two copies (complete and or partial) of P-35s-bar-T-nos cassette are integrated into the MS6 plant genome. Only small parts of the ori-pUC and bla sequences are inserted in the genome of event MS6.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
field production	04/1999	AgrEvo	98-349-01p
approval extension of 95-228-01p, for more information on GM crop regulation in the US see Annex			
food/ feed	04/2000	Aventis CropScience	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: NK603

NK603 has been genetically engineered to express tolerance to the herbicide glyphosate, allowing its use as a weed control option. Glyphosate, the active ingredient in Roundup®, is a post emergent, systemic herbicide that is used worldwide for the non-selective control of a wide variety of annual and perennial weeds. The CP4EPSPS gene, encoding a glyphosate-tolerant form of the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) confers the herbicide tolerance to the corn.

Brandname(s): Roundup Ready

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The DNA fragment PV-ZMGT32L from construct PV-ZMGT32 has been used to generate NK603.

Map: Linear map of DNA construct used for transformation - DNA fragment PV-ZMGT32L

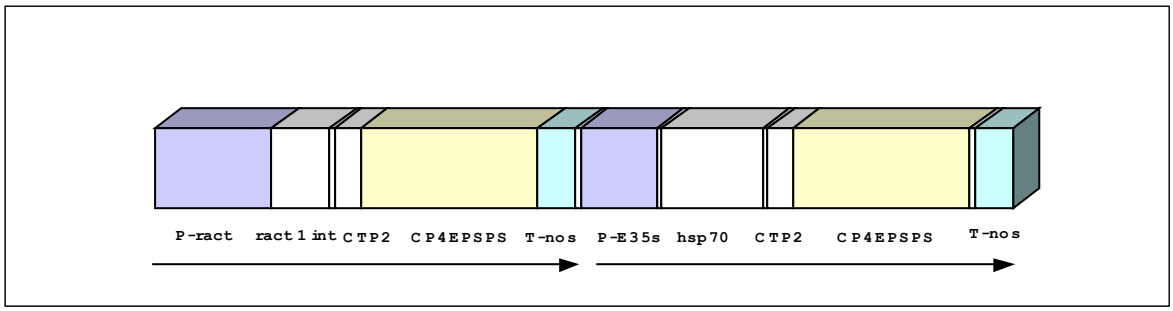


Figure 45: DNA fragment PV-ZMGT32L

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-ract	P-ract	0.8
ract 1 int	ract 1 int	0.6
CTP2	Chloroplast Transit Peptide 2	0.2
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.4
T-nos	T-nos	0.3
P-E35s	P-E35s	0.6
hsp70	heat-shock protein 70	0.8
CTP2	Chloroplast Transit Peptide 2	0.2
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.4
T-nos	T-nos	0.3

Molecular analyses of the transformed plant show that the genome of NK603 contains a single insert consisting of a single complete copy of PV-ZMGT32L. Both CP4EPSPS gene cassettes within the insert are intact. The insertion also includes a non-functional, inversely linked 217-bp fragment of the enhancer region of the rice actin promoter at the 3' end of the introduced DNA. The genome of event NK603 does not contain any detectable plasmid backbone DNA. FSANZ confirms this molecular characterisation of NK603.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Monsanto

Canada

Approval Type	Date	Applicant
feed	03/2001	Monsanto
field production	03/2001	Monsanto
food	02/2001	Monsanto

Japan

Approval Type	Date	Applicant
feed	2001	Monsanto
field production	2001	Monsanto
food	2001	Monsanto
import	2001	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	09/2000	Monsanto	00-011-01p
approval extension of 97-099-01p, for more information on GM crop regulation in the US see Annex			
food/ feed	10/2000	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: T14, T25

T14 and T25 have been genetically engineered to be tolerant to glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation. Tolerance to glufosinate-ammonium is conferred by the pat gene.

Event Characterisation

Transformation Method: direct DNA transfer

Maps

In order to construct the transformation Plasmid p35S/Ac, the pUC derived vector pDH51 has been used.

Map: Linear map of DNA construct used for transformation - Construct p35S/Ac

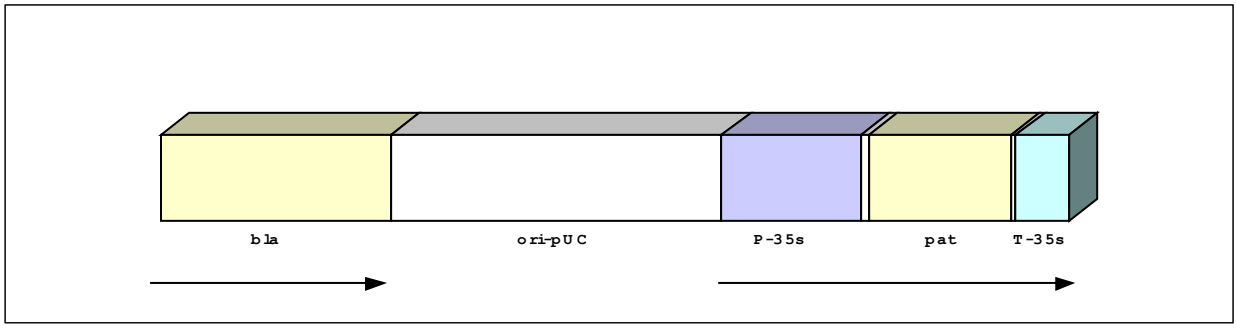


Figure 46: Construct p35S/Ac

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
bla	beta-lactamase	0.86

ori-pUC	ori-pUC	2.63
P-35s	P-35s	0.52
Space	Space	0.029
	phosphinothricin acetyltransferase (PAT)	0.53
Space	Space	0.019
T-35s	T-35s	0.2

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla) partial

Molecular analyses of the transformed plant show that the event T25 contains only one copy of p35S/Ac vector. It does not have an intact copy of bla gene (25% of bla gene at its 5' end is not integrated ino the T25 genome). An intact ori-pUC and pat cassette are present. In the report of the FSANZ, nothing is mentioned about ori-pUC. Molecular analyses of the transformed plant show that the event T14 contains 3 disrupted copies of the vector. All of these copies appear to contain an intact pat cassette and ori-pUC. None of these copies have an intact bla gene. In one of these copies bla gene appears to contain an insert and in two others it is truncated.

Approvals

Argentina

Approval Type	Date	Applicant
environment	02/1998	AgrEvo
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), for more information on GM crop regulation in Argentina see Annex		
field production	06/1998	AgrEvo
authorization for commercial seed and field production, authorisation only for T25		
food/ feed	06/1998	AgrEvo
authorization for commercialization (only for T25)		

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Aventis CropScience
authorization only for T25		

Canada

Approval Type	Date	Applicant
feed	03/1997	AgrEvo
field production	05/1996	AgrEvo
food	04/1997	AgrEvo

European Union

Approval Type	Date	Applicant
field production	04/1998	AgrEvo
Reg. 220/90/EEC, authorization for commercial seed and field production (only for T25)		
food	01/1998	AgrEvo

Reg. 258/97, authorization for starch and its derivatives, crude and refined oil, all heat-processed and fermented products of T25 and all varieties derived from the progeny of the line		
food/ feed	04/1998	AgrEvo
Reg. 220/90/EEC, authorization for commercial release (only for T25)		

Japan

Approval Type	Date	Applicant
feed	03/1997	AgrEvo
food	2001	Aventis CropScience
food approval renewal 2001, first approval in 05/97, second applicant Shionogi Ltd.		
import	1997	AgrEvo

USA

Approval Type	Date	Applicant	Aphis Petition
field production	06/1995	AgrEvo	94-357-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	12/1995	AgrEvo	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: TC1507

TC1507 has been genetically engineered for insect resistance and glufosinate tolerance. It contains cry1F gene which expresses a Cry1F insecticidal protein derived from *B. thuringiensis var. aizawai.* This insect control protein is effective in controlling the larvae of such common pests of corn as European Corn Borer, southwestern corn borer, black cutworm and fall armyworm. Tolerance to glufosinate-ammonium is conferred in this line by inserting pat gene.

Brandname(s): Herculex

Event Characterisation

Transformation Method: microparticle bombardment

Maps

A linear DNA portion (insert PHI8999A) of plasmid PHP8999 has been used for the transformation process.

Map: Linear map of DNA construct used for transformation - DNA fragment PHI8999A

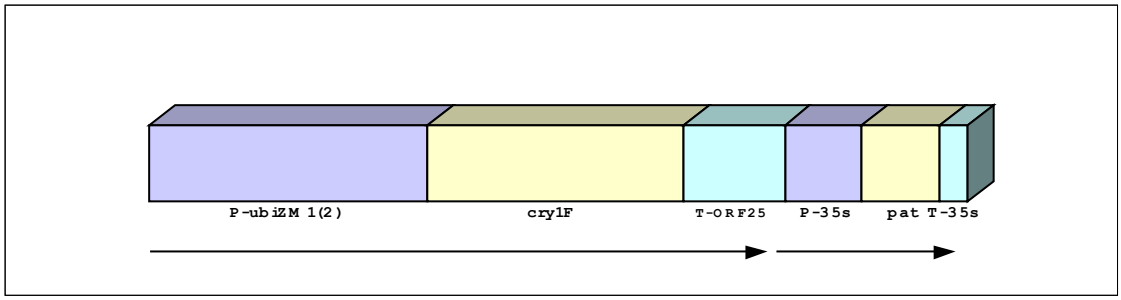


Figure 47: DNA fragment PHI8999A

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-ubiZM1(2)	P-ubiZM1(2)	1.98
	cry1F delta-endotoxin	1.82
T-ORF25	T-ORF25	0.72
P-35s	P-35s	0.55
	phosphinothricin acetyltransferase (PAT)	0.55
T-35s	T-35s	0.2

Molecular analyses of the transformed plant show that the event TC1507 contains a full-length of the DNA fragment used for transformation (i.e. the ~6235 bp of fragment PHI8999A containing the cry1F and pat genes) and an additional copy of the cry1F gene.

Approvals

Canada

Approval Type	Date	Applicant
field production	10/2002	Dow Agrosciences
applicants are Dow AgroSciences and Pioneer Hi-Bred		
food/ feed	10/2002	Dow Agrosciences
applicants are Dow AgroSciences and Pioneer Hi-Bred		

Japan

Approval Type	Date	Applicant
feed	2002	Dow Agrosciences
food	2002	Dow Agrosciences
further applicants Pioneer Hibred Inc.and Mycogen Seeds		
import	2002	Dow Agrosciences

USA

Approval Type	Date	Applicant	Aphis Petition
field production	06/2001	Dow Agrosciences	00-136-01p
second applicant Pioneer Hi-Bred, for more information on GM crop regulation in the US see Annex			
food/ feed	06/2001	Dow Agrosciences	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review), second applicant Pioneer Hi-Bred			
plant pesticide	05/2001	Pioneer Hi-Bred	

registration of the Cry1F delta-endotoxin gene, registration renewal in 10/01, expires in 10/08			
plant pesticide	05/2001	Mycogen	
registration of the Cry1F delta-endotoxin gene, registration renewal in 10/01, expires in 10/08			

cotton

Event: 1445, 1698

1445 and 1698 were genetically engineered to express resistance to glyphosate, allowing its use as a weed control option. Glyphosate, the active ingredient in Roundup®, is a post emergent, systemic herbicide that is used worldwide for the non-selective control of a wide variety of annual and perennial weeds. The CP4EPSPS gene, encoding a glyphosate-tolerant form of the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) was introduced into the cotton genome.

Brandname(s): Roundup Ready

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The constructs PV-GHGT07 and PV-GHGT06 have been used for transformation of 1445 and 1698 respectively.

Map: Linear map of DNA construct used for transformation - Construct PV-GHGT07

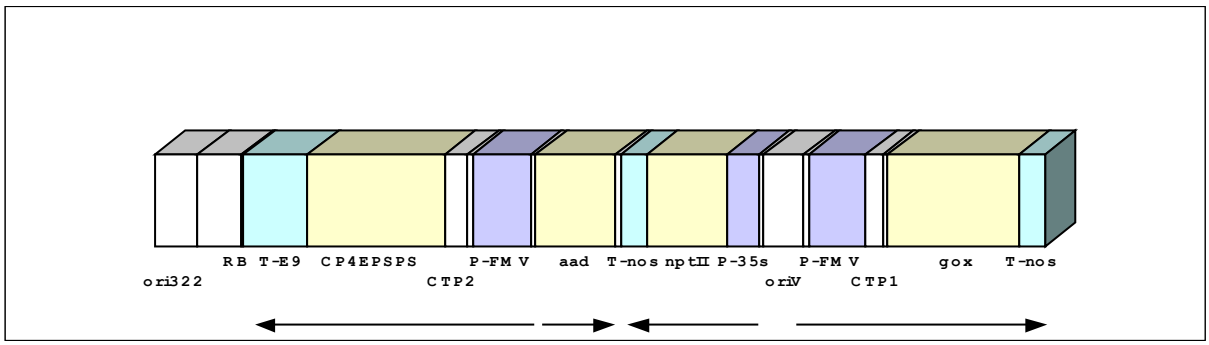


Figure 48: Construct PV-GHGT07

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
ori322	ori322	0.43
Space	Space	-
RB	Right Border	0.025

T-E9	T-E9	0.63
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.36
CTP2	Chloroplast Transit Peptide 2	0.23
P-FMV	P-FMV	0.57
aad	3"(9)-O-aminoglycoside adenylyltransferase	0.79
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-35s	P-35s	0.32
oriV	oriV	0.39
P-FMV	P-FMV	0.57
CTP1	Chloroplast Transit Peptide 1	0.16
gox	glyphosate oxidoreductase	1.3
T-nos	T-nos	0.26

***Map*: Linear map of DNA construct used for transformation - Construct PV-GHGT06**

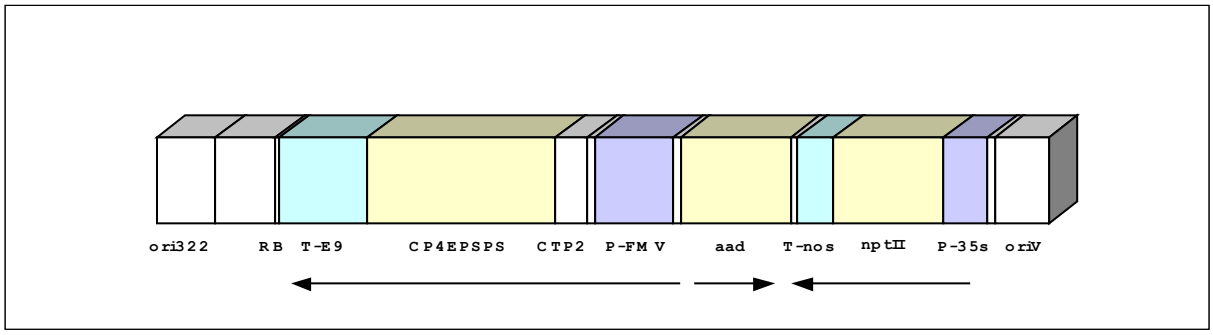


Figure 49: Construct PV-GHGT06

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
ori322	ori322	0.43
Space	Space	-
RB	Right Border	0.025
T-E9	T-E9	0.63
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.36
CTP2	Chloroplast Transit Peptide 2	0.23
P-FMV	P-FMV	0.57
aad	3"(9)-O-aminoglycoside adenylyltransferase	0.79
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-35s	P-35s	0.32
oriV	oriV	-

The following antibiotic genes have been incorporated in the genome: neomycin phosphotransferase (nptII), 3"(9)-O-aminoglycoside adenylyltransferase (aad)

Molecular analyses show that **1445** has a single locus containing DNA elements from PV-GHGT07.
In this locus P-FMV is present. However, the gox gene was shown not to be present.

CP4EPSPS, aad, nptII and a portion of the oriV are integreated into the genome, but ori322 is absent.
According to the data published by the FSANZ, a segment of DNA of approximately 6.1 Kb, comprised of the region of PV-GHGT07 from the right border to oriV is integrated into the genome of 1445. This fragment contains CP4EPSPS, aad, and nptII. All of the DNA required for expression of CP4EPSPS and nptII has been integrated into the plant genome. The gox gene is absent and only a truncated form of oriV is present in the genome of 1445.
Molecular analyses show that **1698** has a single locus containing DNA from PV-GHGT06 (P-FMV, CP4EPSPS, aad, nptII, oriV, ori322). An additional copy of the CP4EPSPS gene is incorporated as extension of the plasmid DNA at the same location (2 copies of CP4EPSPS).

Approvals

Argentina

Approval Type	Date	Applicant
environment	11/1999	Monsanto
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), authorization only for 1445, for more information on GM crop regulation in Argentina see Annex		
field production	04/2001	Monsanto
authorization for commercial seed and field production, authorization only for 1445		
food/ feed	04/2001	Monsanto
authorization for commercialization (only for 1445)		

Australia/ New Zealand

Approval Type	Date	Applicant
field production	09/2000	Monsanto
General (Commercial) Release (GR), GR approvals are deemed licenses under the Gene Technology Act 2000, but general release is still legal, licenses need review by Gene Technology Regulator within first two years of operation of Gene Technology Act, deadline 21.6.03		
food	11/2000	Monsanto
authorization only for 1445		

Canada

Approval Type	Date	Applicant
feed	03/1997	Monsanto
food	12/1996	Monsanto
authorization only for 1445		

European Union

Approval Type	Date	Applicant
food	07/2002	Monsanto
Reg.258/97, cottonseed oil from 1445		

Japan

Approval Type	Date	Applicant

feed	01/1998	Monsanto
authorization only for 1445		
food	2001	Monsanto
food approval renewal 2001, first approval in 12/97, authorization only for 1445		
import	1997	Monsanto
authorization only for 1445		

Mexico

Approval Type	Date	Applicant
field production	2002	Monsanto
actual approval date is not available, the GM cotton has been already approved in 2002		

South Africa

Approval Type	Date	Applicant
field production	2000	Monsanto
food/ feed	2000	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	07/1995	Monsanto	95-045-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	06/1995	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: 15985

15985 contains two genes, cry1Ac and cry2Ab delta-endotoxins, coding for insecticidal proteins. These confer insect resistance to lepidopteran caterpillar insect pests. Bollgard II has not been commercialized yet. In the US, APHIS approved the GM cotton in 2002, but it is still under review of the EPA.

Brandname(s): Bollgard II

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The cotton cultivar 50B (DP50B) derived from Bollgard cotton 531, was used for transformation which contains already cry1Ac, nptII and aad genes (see Bollgard cotton 531). The *KpnI* linear fragment of the plasmid PV-GHBK11, called PV-GHBK11L, has been used to transform 50 B (DP50B), and to produce the event 15985.

Map: Linear map of DNA construct used for transformation - Fragment PV-GHBK11L

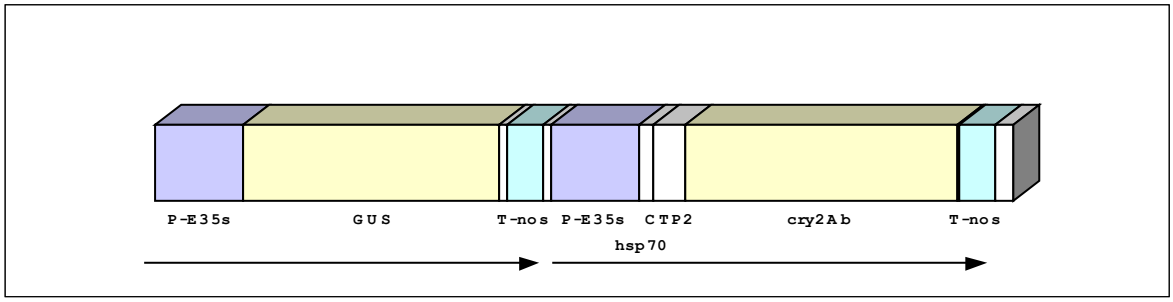


Figure 50: Fragment PV-GHBK11L

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.614
Space	Space	0.03
GUS	beta-glucuronidase	1.808
Space	Space	0.054
T-nos	T-nos	0.255
Space	Space	0.064
P-E35s	P-E35s	0.613
hsp70	heat-shock protein 70	0.099
CTP2	Chloroplast Transit Peptide 2	0.23
Space	Space	0.005
	cry2Ab delta-endotoxin	1.907
Space	Space	0.022
T-nos	T-nos	0.255
Space	Space	0.124

Map: Linear map of DNA construct used for transformation - Construct PV-GHBK04 (see event 531)

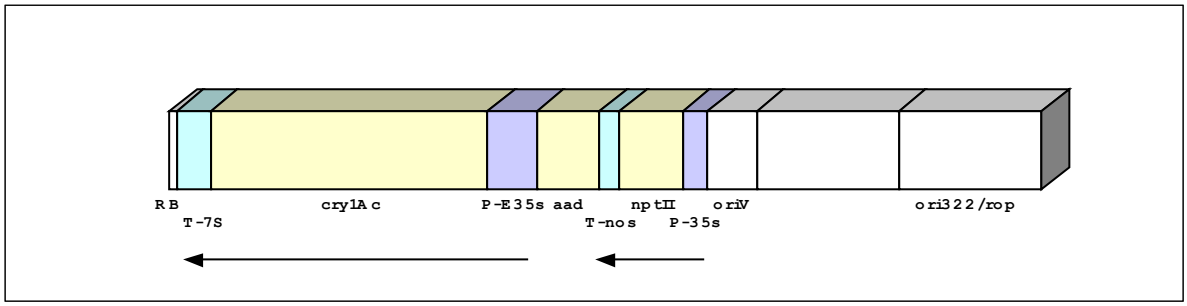


Figure 51: Construct PV-GHBK04 (see event 531)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.09
T-7S	T-7S	0.43
	cry1Ac delta-endotoxin	3.5
P-E35s	P-E35s	0.62
aad	3"(9)-O-aminoglycoside adenylyltransferase	0.79
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79

P-35s	P-35s	0.32
oriV	oriV	0.62
Space	Space	-
ori322/rop	ori322/rop	1.8

The following antibiotic genes have been incorporated in the genome: neomycin phosphotransferase (nptII), 3"(9)-O-aminoglycoside adenylyltransferase (aad)

15985 contains in addition to cry1Ac, nptII and aad genes (see Bollgard cotton 531), one new DNA insert. This insert is integrated into the genome as one complete copy of the cry2Ab cassette linked to one copy of the GUS cassette, which is missing approximately 260 bp at the 5' end of the P-E35s. 15985 does not contain any detectable plasmid backbone sequence of vector PV-GHBK11.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Monsanto

Japan

Approval Type	Date	Applicant
food	2002	Monsanto
import	2001	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	11/2002	Monsanto	00-342-01p
food/ feed	07/2002	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	12/2002	Monsanto	
plant pesticide registration of the Cry2Ab2 delta-endotoxin gene, expires in 05/04			

Event: 19-51A

The 19-51a line of cotton was genetically engineered, to be tolerant to sulfonyl urea herbicides. Sulfonyl urea are a group of compounds inhibiting acetolactate synthase (ALS), the enzyme that catalyzes the first common step in the biosynthesis of the essential amino acids isoleucine, leucine, and valine and thereby inhibit plant growth. The chimeric *S4-HrA* gene expresses a sulfonyl urea tolerant ALS which allows the cotton plant to produce the essential amino acids in the presence of the herbicide.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pMH26

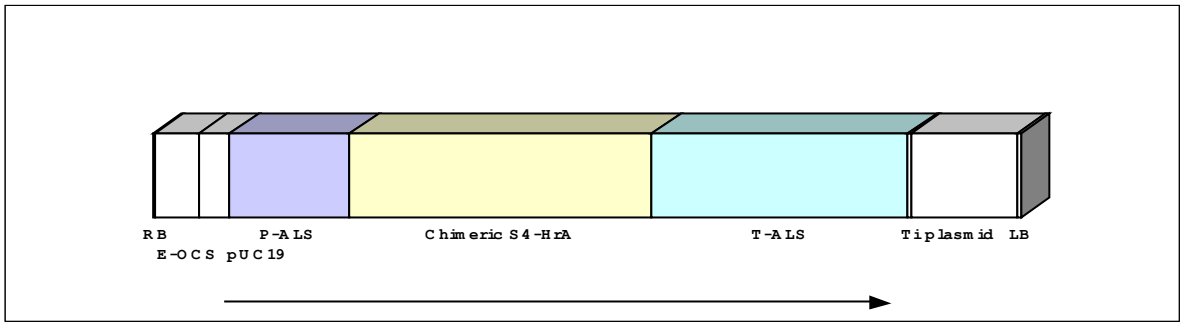


Figure 52: T-DNA region of construct pMH26

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
E-OCS	Enhancer Octopine Synthase	0.3
pUC19	pUC19	0.2
P-ALS	P-ALS	0.8
	chimeric S4-HrA	2
T-ALS	T-ALS	1.7
pUC19	pUC19	0.02
Ti Plasmid DNA	Ti Plasmid DNA	0.7
LB	Left border	0.03

Molecular analyses of the transformed plant show that 19-51a contains two copies of the T-DNA arranged as an inverted repeat at one locus. It contains no sequence beyond the left and right borders.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
field production	01/1996	DuPont Agricultural Products	95-256-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	04/1996	DuPont Agricultural Products	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: 31807, 31808

31807 and 31808 have been genetically engineered to express first, nitrilase degrading the herbicide bromoxynil, thus conferring tolerance to the herbicide and second, a Cry1Ac insect control protein, which is highly selective in controlling lepidopteran-induced cotton pests such as cotton bollworm, tobacco budworm, and pink bollworm.

Brandname(s): BXN - Bollgard

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pCGN4084

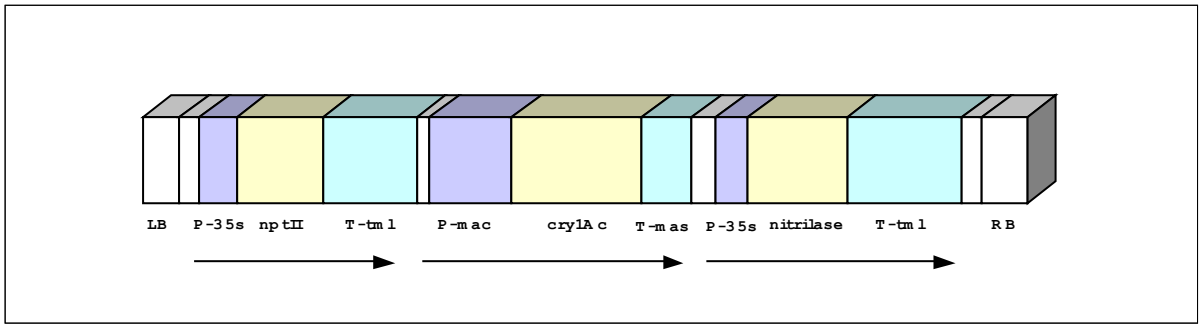


Figure 53: T-DNA region of construct pCGN4084

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	-
P-35s	P-35s	-
nptII	neomycin phosphotransferase	-
T-tml	T-tml	-
P-mac	P-mac	-
	cry1Ac delta-endotoxin	-
T-mas	T-mas	-
P-35s	P-35s	-
	nitrilase	-
T-tml	T-tml	-
RB	Right Border	-

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

The size of synthetic cry1Ac is 1770 bp which is approximately half of the native gene size.
The southern blot analyses show that events 31807, 31808 and BXN/ Bt cotton lines derived from them, contain a single insert of T-DNA. Line 31808 might contain a second copy of the nptII gene. No beyond the border transfer of DNA had occurred.

Approvals

Canada

Approval Type	Date	Applicant
food	12/1998	Monsanto

Japan

Approval Type	Date	Applicant
feed	12/1999	Monsanto
authorization only for 31807		
import	1998	Monsanto
authorization only for 31807		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	04/1997	Calgene	97-013-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	12/1997	Calgene	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review), lines 31707, 31803 and 42317 are also covered by FDA memo			
plant pesticide	10/1995	Monsanto	
registration of the CryIA(c) delta-endotoxin gene, registration renewal in 10/01, expires in 09/06			

Event: 531, 757, 1076

531, 757, 1076 were genetically engineered to produce Cry1Ac delta-endotoxin, an insect control protein. The protein is highly selective in controlling lepidopteran-induced cotton pests such as cotton bollworm, budworm, and pink bollworm and is expressed at a consistent level in the cotton plant throughout the growing season.

Brandname(s): Bollgard

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The plasmid vector PV-GHBK04 (a single border binary transformation vector) has been used to transform the lines 531 and 757 and the plasmid vector PV-GHBK03 (a single border binary transformation vector) has been used to transform the line 1076. In the vector PV-GHBK03, the promoter region of the cassette cry1Ac is considered as confidential business information (P-CBI).

Map: Linear map of DNA construct used for transformation - Construct PV-GHBK04 (531, 757)

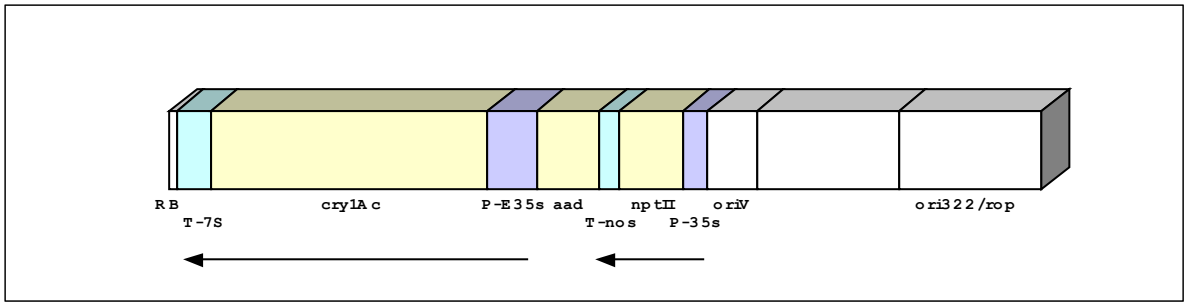


Figure 54: Construct PV-GHBK04 (531, 757)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.09
T-7S	T-7S	0.43
	cry1Ac delta-endotoxin	3.5
P-E35s	P-E35s	0.62
aad	3"(9)-O-aminoglycoside adenylyltransferase	0.79
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-35s	P-35s	0.32
oriV	oriV	0.62
Space	Space	-
ori322/rop	ori322/rop	1.8

***Map*: Linear map of DNA construct used for transformation - Construct PV-GHBK03 (1076)**

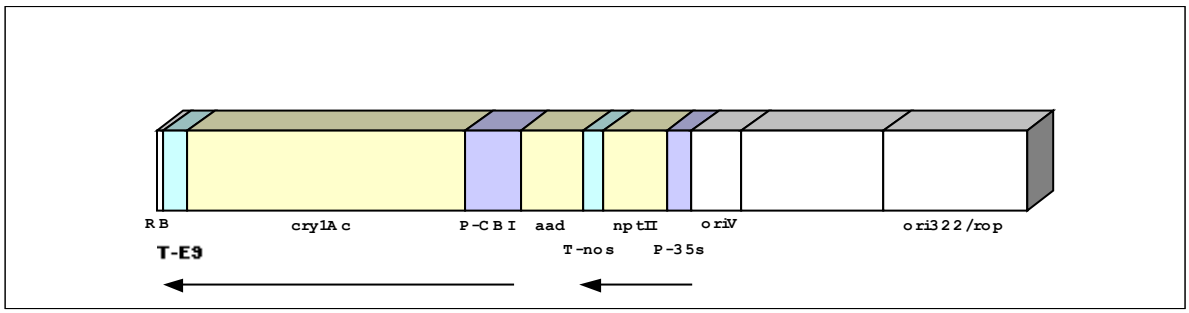


Figure 55: Construct PV-GHBK03 (1076)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.09
T-E9	T-E9	0.63
	cry1Ac delta-endotoxin	3.5
P-CBI	P-CBI	-
aad	3"(9)-O-aminoglycoside adenylyltransferase	0.79
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-35s	P-35s	0.32
oriV	oriV	0.62
Space	Space	-
ori322/rop	ori322/rop	1.8

The following antibiotic genes have been incorporated in the genome: neomycin phosphotransferase (nptII), 3"(9)-O-aminoglycoside adenylyltransferase (aad)

Molecular analyses show that in the **event 531** cry1Ac, nptII, aad genes and part or all of the oriV region are present but the ori322 region is absent.
There are two DNA inserts in the genome of event 531.The primary functional insert consists of a T-DNA (8.2 Kb) containing a full-length cry1Ac, nptII, aad. This insert also contains a 892 bp portion of the 3' end of the cry1Ac gene fused to the T-7S (inactive gene). This segment of DNA is at the 5' end of the insert, is contiguous and in the reverse orientation with the full-length cry1Ac gene cassette and does not have a promoter. The second insert contains a 242 bp portion of the T-7S from the terminus of the cry1Ac gene and is not functionally active in the plant genome (EU scientific committee on plants).
The **event 757** has a complete copy of the T-DNA as well as an incomplete copy of the T-DNA inserted at separate sites within the genome. The complete copy consists of almost the entire plasmid. The incomplete copy consists of T-7S and a part of cry1Ac gene (inactive gene).
Molecular analyses show that the **event 1076** contains a complete copy of the T-DNA (almost the entire plasmid PV-GHBK03) and an incomplete copy consisting of a T-E9 and a portion of cry1Ac gene (inactive gene).

Approvals

Argentina

Approval Type	Date	Applicant
environment	05/1998	Monsanto
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), authorization only for 531, for more information on GM crop regulation in Argentina see Annex		
field production	07/1998	Monsanto
authorization for commercial seed and field production, authorization only for 531		
food/ feed	07/1998	Monsanto
authorization for commercialization (only for 531)		

Australia/ New Zealand

Approval Type	Date	Applicant
field production	01/1996	Monsanto
General (Commercial) Release (GR), GR approvals are deemed licenses under the Gene Technology Act 2000, but general release is still legal, licenses need review by Gene Technology Regulator within first two years of operation of Gene Technology Act, deadline 21.6.03		
food	07/2000	Monsanto

Canada

Approval Type	Date	Applicant
feed	05/1996	Monsanto
food	04/1996	Monsanto
authorization of 757 (1076 was not approved) and authorization of 531(1076 was not approved)		

food	11/1996	Monsanto
authorization of 757 (1076 was not approved)		

China

Approval Type	Date	Applicant
field production	1997	Monsanto
food/ feed	1997	Monsanto

European Union

Approval Type	Date	Applicant
food	07/2002	Monsanto
Reg.258/97, authorization for cottonseed oil from 531		

India

Approval Type	Date	Applicant
environment	2002	Monsanto
commercial field trial, no edible biotechnology crops are legally grown for consumption in India		

Indonesia

Approval Type	Date	Applicant
field production	2001	Monsanto
food/ feed	2001	Monsanto

Japan

Approval Type	Date	Applicant
feed	06/1997	Monsanto
authorization only for 531 and 757		
food	2001	Monsanto
food approval renewal 2001, first approval in 05/97, authorization only for 531 and 757		
import	1997	Monsanto
authorization only for 531		
import	1999	Monsanto
authorization only for 757		

Mexico

Approval Type	Date	Applicant
field production	1997	Monsanto
authorization only for 531		
food/ feed	1997	Monsanto

South Africa

Approval Type	Date	Applicant
field production	1997	Monsanto
food/ feed	1997	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	06/1995	Monsanto	94-308-01p

for more information on GM crop regulation in the US see Annex			
food/ feed	04/1995	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	10/1995	Monsanto	
registration of the CryIA(c) delta-endotoxin gene, registration renewal in 10/01, expires in 09/06			

Event: BG4740

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Herbicide tolerance	bromoxynil		nitrilase		
Insect resistance	lepidoptera		cry1Ac delta-endotoxin		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1998	Monsanto
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1998	Monsanto
second applicant Calgene		

Event: BXN

BXN lines express a nitrilase gene. The gene isolated from *Klebsiella pneumoniae ssp. ozaenae* encodes the enzyme nitrilase, that degrades the herbicide bromoxynil, thus conferring herbicide tolerance to the cotton.

Brandname(s): BXN

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The constructs pBrx74 and pBrx75 were used to produce a number of BXN lines: 10103, 10109, 10206, 10208, 10209, 10211, 10215, 10222, 10224.

Map: Linear map of DNA construct used for transformation - T-DNA region (line 10103)

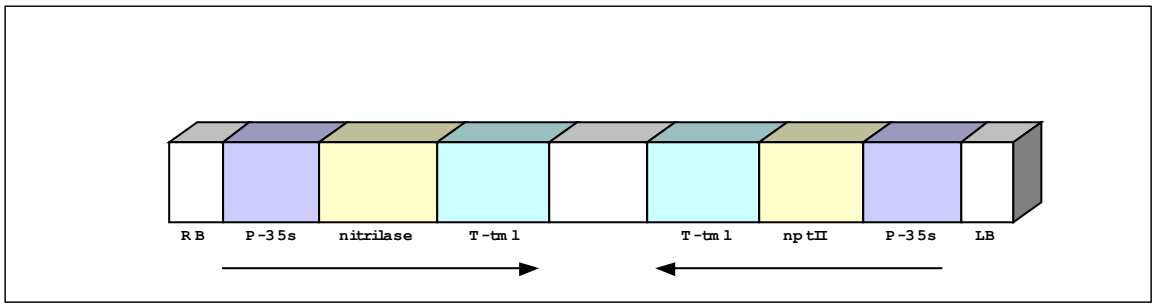


Figure 56: T-DNA region (line 10103)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
P-35s	P-35s	-
	nitrilase	-
T-tml	T-tml	-
Space	Space	-
T-tml	T-tml	-
nptII	neomycin phosphotransferase	-
P-35s	P-35s	-
LB	Left border	-

Map: Linear map of DNA construct used for transformation - Line 10109

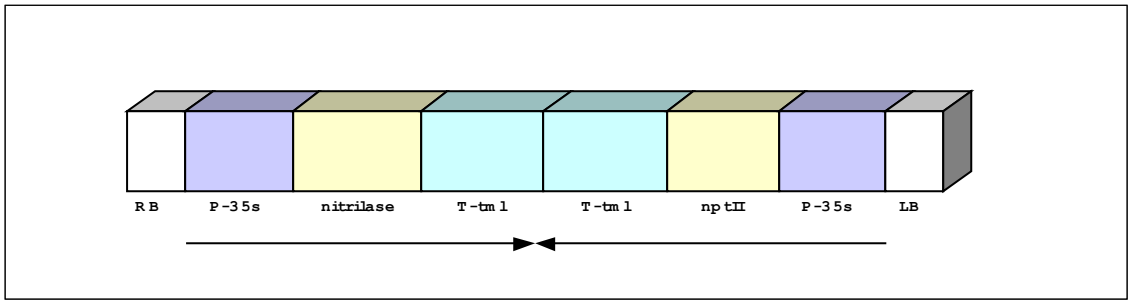


Figure 57: Line 10109

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
P-35s	P-35s	-
	nitrilase	-
T-tml	T-tml	-
T-tml	T-tml	-
nptII	neomycin phosphotransferase	-
P-35s	P-35s	-
LB	Left border	-

Map: Linear map of DNA construct used for transformation - Lines 10206, 10208, 10211, 10222, 10224

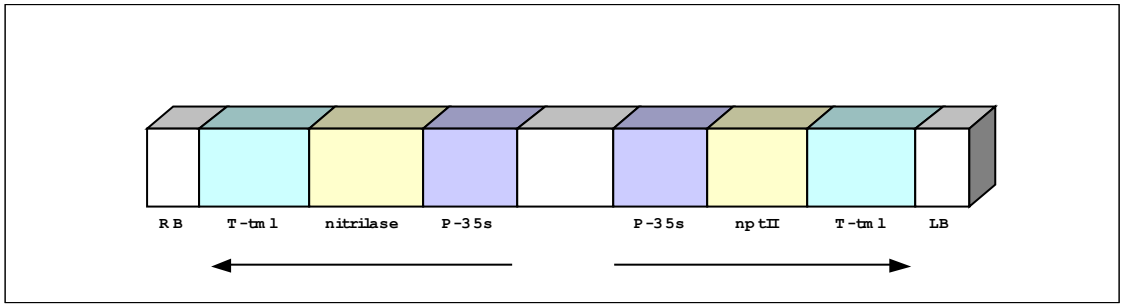


Figure 58: Lines 10206, 10208, 10211, 10222, 10224

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
T-tml	T-tml	-
	nitrilase	-
P-35s	P-35s	-
Space	Space	-
P-35s	P-35s	-
nptII	neomycin phosphotransferase	-
T-tml	T-tml	-
LB	Left border	-

Map: Linear map of DNA construct used for transformation - Lines 10209 and 10215

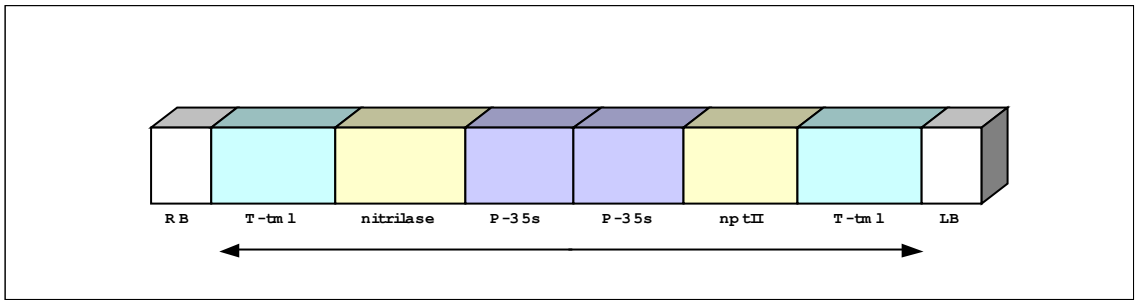


Figure 59: Lines 10209 and 10215

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
T-tml	T-tml	-
	nitrilase	-
P-35s	P-35s	-
P-35s	P-35s	-
nptII	neomycin phosphotransferase	-
T-tml	T-tml	-
LB	Left border	-

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

In the report published by FSANZ, there is a description of the genetic analysis of two lines: 10222 and 10211. According to these data, a single copy of T-DNA, containing nitrilase (also called BXN or oxy gene) and nptII gene cassettes, have been integrated at a single site in transformation events 10222 and 10211 and no rearrangements of the T-DNA were detected.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	2002	Stoneville Pedigreed Seed
second applicant Aventis CropScience		

Canada

Approval Type	Date	Applicant
feed	10/1997	Calgene
regulated lines: 10215, 10222 and 10224		
food	08/1996	Calgene
regulated lines: 10215, 10222 and 10224		

Japan

Approval Type	Date	Applicant
feed	01/1998	Monsanto
authorization only for 10215, 10222 and 10224		
food	2001	Monsanto
food approval renewal 2001, first approval in 12/97, regulated lines: 10211, 10215, 10222		
import	1997	Monsanto
regulated lines: 10211, 10215, 10222, 10224		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	02/1994	Calgene	93-196-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	09/1994	Calgene	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: China cotton 1

Brandname(s): Guokang

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Insect resistance	lepidoptera		unknown		
Virus resistance	unspecified		unknown		

Maps

No Map Information available.

Approvals

China

Approval Type	Date	Applicant
field production	1997	Chinese Academy of Agricultural Sciences (CAAS)
food/ feed	1997	Chinese Academy of Agricultural Sciences (CAAS)

Event: China cotton 2

Brandname(s): Zhongmian

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Insect resistance	lepidoptera		unknown		

Maps

No Map Information available.

Approvals

China

Approval Type	Date	Applicant
field production	2001	Unknown
actual approval date is not available, it has already been approved in 2001		
food/ feed	2001	Unknown
actual approval date is not available, it has already been approved in 2001		

Event: China cotton 3

Brandname(s): American DPL

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Insect resistance	unspecified		unknown		

Maps

No Map Information available.

Approvals

China

Approval Type	Date	Applicant
field production	2001	Unknown
actual approval date is not available, it has already been approved in 2001		
food/ feed	2001	Unknown
actual approval date is not available, it has already been approved in 2001		

Event: LLcotton25

The event LLCotton25 has been genetically engineered for tolerance to the hebicide glufosinate-ammonium. The herbicide tolerance is conferred by insertion of bar gene.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The construct pGSV71 (9555 bp) has been used for transformation. It has been derived from plasmid pGSV1, which is essentially derived from pGSC1700

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pGSV71

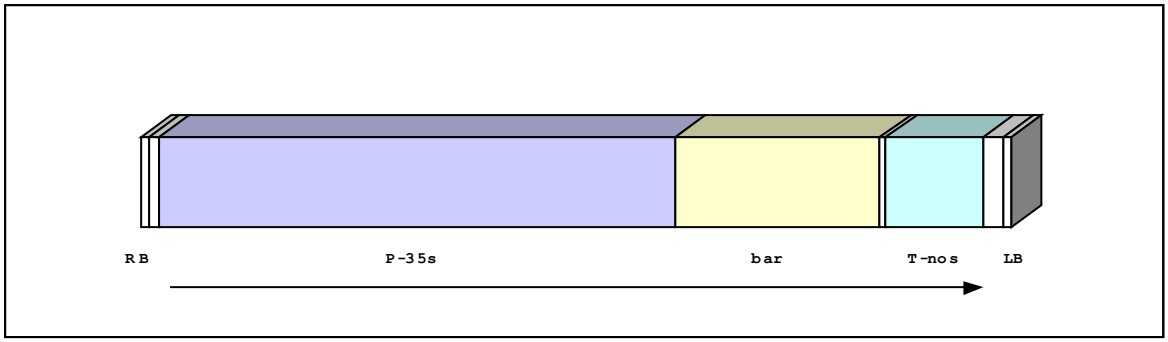


Figure 60: T-DNA region of construct pGSV71

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.024
Space	Space	0.026
P-35s	P-35s	1.384
	phosphinothricin acetyltransferase (bar)	0.551
Space	Space	0.018
T-nos	T-nos	0.259
Space	Space	0.053
LB	Left border	0.024

Space: synthetic polylinker sequence
The southern blot analyses show that one intact copy of the bar gene cassette has been integrated into the genome of event LLCotton25. It contains no vector backbone sequences outside of the right and left borders (including strR/strR, pVS1ori and ColE1-ori).
PVS1ori: the origin of replication from the *Pseudomonas* plasmid pVS1 for replication in *Agrobacterium tumefaciens.*

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
field production	03/2003	Aventis CropScience	02-042-01p

cucumber

Event: CR29, CR32, CR33

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Fungus resistance	gray mold		chitinase		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1999	Nat'l Agr. Res. Ctr.
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1999	Nat'l Agr. Res. Ctr.

flax

Event: FP967

FP967 was genetically engineered to be tolerant to soil residues of triasulfuron and metsulfuron-methyl which may result from a previous year's application of the products at labelled rates. The sulfonylurea resistant flax can be therefore cultivated the year following the use of triasulfuron or metsulfuron-methyl (sulfonylurea herbicides), which provides an alternative to both the continuous cropping of wheat and barley on these soils and to summer-fallowing during this time. Sulfonylurea tolerance is conferred by an altered acetolactate synthase (ALS) gene from *Arabidopsis thaliana*.

The event is also named CDC Triffid.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Agrobactrium tumefaciens strain C58 was the parental bacterium, containing a disabled Ti plasmid pGV3850. A co-integrating vector plasmid, pGH6, containing the genes of interest was inserted into this Ti plasmid.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct FP967

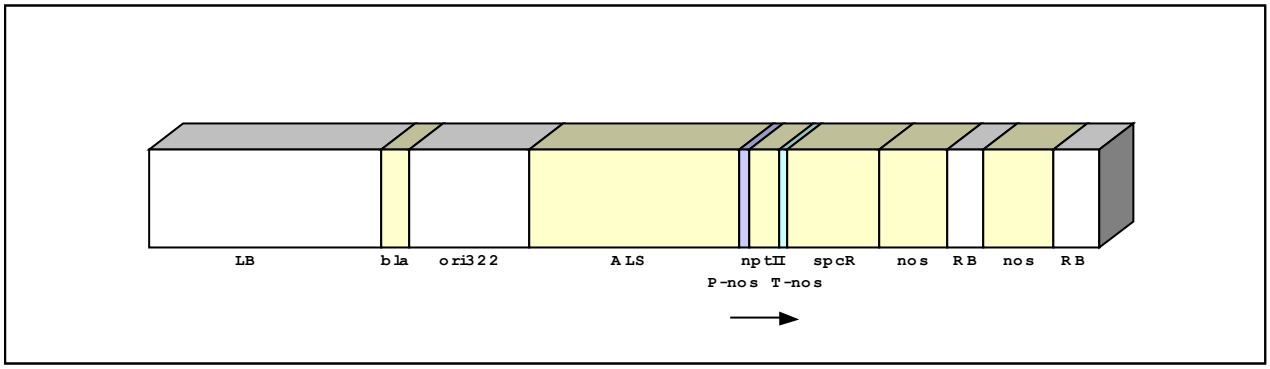


Figure 61: T-DNA region of construct FP967

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	6.4
bla	beta-lactamase	0.8
ori322	ori322	3.3
ALS	acetolactat synthase	5.8
P-nos	P-nos	-

nptII	neomycin phosphotransferase	-
T-nos	T-nos	-
spcR/strR	spectinomycin/streptomycin	2.5
nos	nopaline synthase	-
RB	Right Border	-
nos	nopaline synthase	-
RB	Right Border	-

The following antibiotic genes have been incorporated in the genome: beta-lactamase (bla), neomycin phosphotransferase (nptII), spectinomycin/streptomycin (spcR/strR)

Molecular analyses show that there are two insertions of T-DNA in different loci of the plant genome.The transferred DNA does not include bacterial DNA outside the T-DNA.

Approvals

Canada

Approval Type	Date	Applicant
environment	05/1996	University of Saskatchewan
cancellation of variety registration in 04/01, therefore commercial seed and field production is not legal		
feed	05/1996	University of Saskatchewan
food	02/1998	University of Saskatchewan

USA

Approval Type	Date	Applicant	Aphis Petition
field production	05/1999	University of Saskatchewan	98-335-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	03/1998	University of Saskatchewan	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

melon

Event: Prince Melon

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	cucumber mosaic virus (CMV)		coat protein - Cucumber Mosaic Virus (CMV cp)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1996	Nat'l Agr.Ctr.
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1996	Nat'l Agr.Ctr.
second applicant NIAR		

papaya

Event: 55-1, 63-1

55-1 and 63-1 were genetically engineered to resist infection by PRV, by inserting virus-derived sequences that encode the PRSV coat protein (CP).

Brandname(s): Rainbow, Sunup

Event Characterisation

Transformation Method: microparticle bombardment

Maps

Map: Linear map of DNA construct used for transformation - Construct pGA482GG/cpPRV-4

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
P-nos	P-nos	-
nptII	neomycin phosphotransferase	-
T-nos	T-nos	-
P-35s	P-35s	-
5'UT	5' untranslated region	-
CMV/PRV cp	coat protein - Papaya Ringspot & Cucumber Mosaic Virus	-
T-35s	T-35s	-
P-35s	P-35s	-
GUS	beta-glucuronidase	-
T-35s	T-35s	-
ColE1-ori	ColE1-ori	-
cos	cos	-
LB	Left border	-
gentR	gentamycin	-
oriT	oriT	-
tetR	tetracyclin	-
oriV	oriV	-

The following table shows which antibiotic resistance marker genes have been incorporated in the plant genome of 55-1 and 63-1.

	Marker genes
55-1	nptII, tetR (partial)
63-1	nptII, tetR, gentR

There is no consistent information about terminators used in the nptII and GUS marker gene cassettes. However, it has been mentioned in the US-petition that T-nos

and T-35s have been used for the transformation. gentR and tetR marker genes are under the control of their bacterial regulatory sequences.
Molecular analyses of the transformed plants show that **in 55-1** CMV/PRV cp, GUS, nptII, oriT/tetR are present. According to the FDA, only a part of tetR gene is incorporated in the genome of 55-1.
In 63-1 CMV/PRV cp, nptII, gentR, oriV,tetR, oriT are present (GUS gene is absent).

Approvals

Japan

Approval Type	Date	Applicant
import	2000	Cornell University
authorization only for 55-1, further applicants are Hawai University and Upjohn		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	09/1996	Cornell University	96-051-01p
for more information on GM crop regulation in the US see Annex			
food	09/1997	University of Hawai	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review), only 55-1 covered by FDA Memo			

petunia

Event: China petunia 1

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered flower colour	unspecified		unknown		

Maps

No Map Information available.

Approvals

China

Approval Type	Date	Applicant
field production	2000	Peking University
actual approval date is not available, it has already been approved in 2000		

Event: Japan petunia 1

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	tobacco mosaic virus (TMV)		coat protein - Tobacco Mosaic Virus (cpTMV)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1994	Suntory
import	1994	Suntory

potato

Event: ATBT04-6, ATBT04-27, ATBT04-30, ATBT04-31, ATBT04-36

ATBT04-6, ATBT04-27, ATBT04-30, ATBT04-31, ATBT04-36 have been genetically engineered to express the insecticidal protein Cry3A delta-endotoxin. The protein is highly selective in controlling Colorado potato beetle (CPB) and is expressed at a consistently effective level in the potato foliage throughout the growing season.

Brandname(s): Atlantic lines, New Leaf

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The plasmid vector PV-STBT04 has been used to create ATBT04-6, ATBT04-27, ATBT04-30, ATBT04-31, ATBT04-36.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct PV-STBT04

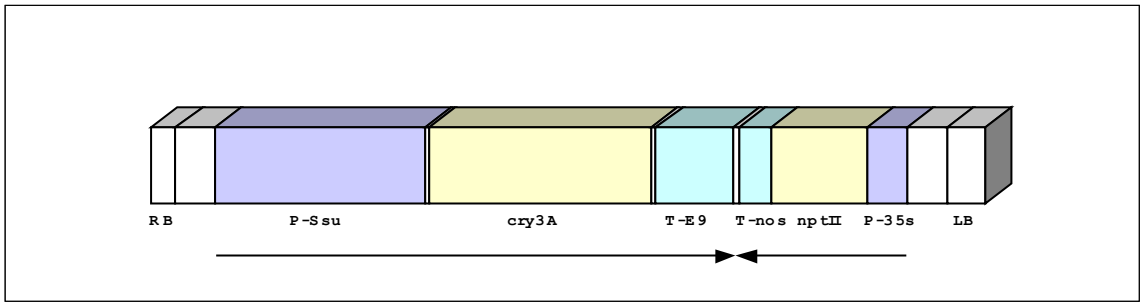


Figure 62: T-DNA region of construct PV-STBT04

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
P-Ssu	P-Ssu	1.7
	cry3A delta-endotoxin	1.8
T-E9	T-E9	0.63
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-35s	P-35s	0.32
LB	Left border	-

The following table shows which antibiotic resistance marker genes have been incorporated in the plant genome of ATBT04-6, ATBT04-27, ATBT04-30, ATBT04-31 and ATBT04-36.

Events	Marker genes
ATBT04-6	nptII
ATBT04-27	nptII+ aad
ATBT04-30	nptII
ATBT04-31	nptII
ATBT04-36	nptII+ aad

The genetic elements beyond right and left borders are: oriV, ori322/rop, and aad gene (with its bacterial regulatory elements).
Molecular analyses of the transformed plants show that :
ATBT04-6 contains 3 copies of T-DNA at 3 insertion sites.
ATBT04-27 contains 2 complete copies of T-DNA inserted at 2 sites.The second insert contains one T-DNA plus an aad and a part of cry3A gene.
ATBT04-30, ATBT04-31 contain a single copy of T-DNA.
ATBT04-36 contains inserts at 3 loci. One insert contains the whole plasmid PV-STBT04. The second contains T-DNA plus the oriV. The third one contains only the cry3A gene. All genetic elements present in plasmid PV-STBT04, including oriV, ori322 and aad, were detected in the line ATBT04-36.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	07/2001	Monsanto
authorization only for ATBT04-31 and ATBT04-36		

Canada

Approval Type	Date	Applicant
feed	02/1997	Monsanto
field production	02/1997	Monsanto
interim variety registration for ATBT04-6, ATBT04-31, ATBT04-36 expired in 05/01, therefore commercial field and seed production of these lines is not legal		
food	11/1996	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	05/1996	Monsanto	95-338-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	03/1996	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	05/1995	Monsanto	
registration of the Cry3A delta-endotoxin gene (no expiration date)			

Event: BT6, BT10, BT12, BT16, BT17, BT18, BT23

BT6, BT10, BT12, BT16, BT17, BT18 and BT23 have been genetically engineered to express the insecticidal protein Cry3A delta-endotoxin. The protein is highly selective in controlling Colorado potato beetle (CPB) and is expressed at a consistently effective level in the potato foliage throughout the growing season.

Brandname(s): New Leaf, Russet Burbank lines

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The plasmid vector PV-STBT02 has been used to create BT6, BT10, BT12, BT16, BT17, BT18 and BT23.

Map: Linear map of DNA construct used for transformation - T-DNA region of vector PV-STBT02 (BT6, BT10, BT12, BT16, BT17, BT18, BT23)

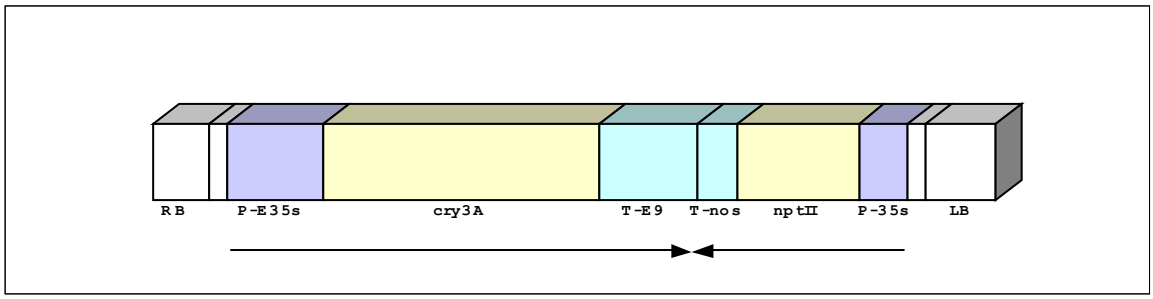


Figure 63: T-DNA region of vector PV-STBT02 (BT6, BT10, BT12, BT16, BT17, BT18, BT23)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.36
P-E35s	P-E35s	0.62
	cry3A delta-endotoxin	1.8
T-E9	T-E9	0.63
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-35s	P-35s	0.32
LB	Left border	0.45

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses show that in BT6, BT12, BT17, BT18 and BT23 a single T-DNA is inserted into one genetic locus of the plant genome. Two lines BT10 and BT16 contain

two inserted T-DNA copies. In BT10, two T-DNA copies are integrated in-tandem at a single site and in BT16, two single T-DNA copies are inserted at separate genetic loci.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	07/2001	Monsanto
authorization only for BT6		

Canada

Approval Type	Date	Applicant
feed	01/1996	Monsanto
field production	12/1995	Monsanto
variety registration for BT6, BT10, BT12 and BT17 only, therefore commercial field and seed production of BT18 and BT23 is not legal		
food	09/1995	Monsanto

Japan

Approval Type	Date	Applicant
food	2001	Monsanto
environment and import approval are not needed, because potatoes are imported only as processed food to Japan, feed approval is not available, authorization only for BT6		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	03/1995	Monsanto	94-257-01p
food/ feed	09/1994	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	05/1995	Monsanto	
registration of the Cry3A delta-endotoxin gene (no expiration date)			

Event: RBMT15-101, SEMT15-02, SEMT15-15, HLMT15-46

RBMT15-101, SEMT15-02, SEMT15-15 and HLMT15-46 have been genetically engineered for resistance to Colorado Potato Beetle and for resistance to infection by PVY-O.

Brandname(s): Hi-Lite lines, New Leaf, Russet Burbank lines, Shepody lines, Y lines

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The construct PV-STMT15 has been used to create RBMT15-101, SEMT15-02 and SEMT15-15.

Map: Linear map of DNA construct used for transformation - Construct PV-STMT15

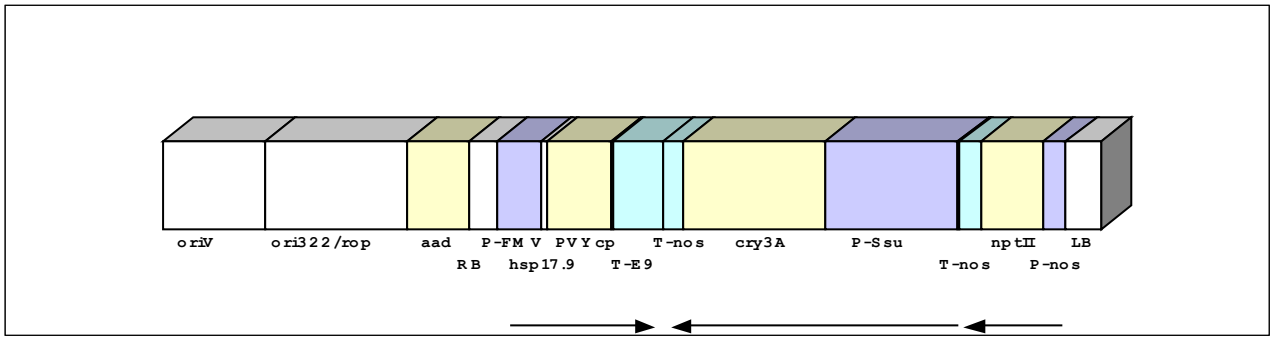


Figure 64: Construct PV-STMT15

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
oriV	oriV	1.3
ori322/rop	ori322/rop	1.8
aad	3"(9)-O-aminoglycoside adenylyltransferase	0.79
RB	Right Border	0.36
P-FMV	P-FMV	0.57
hsp17.9	heat-shock protein 17.9 kD leader sequence	0.08
PVYcp	coat protein - Potato Virus Y	0.81
T-E9	T-E9	0.63
T-nos	T-nos	0.26
	cry3A delta-endotoxin	1.8
P-Ssu	P-Ssu	1.7
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-nos	P-nos	0.3
LB	Left border	0.45

The following table shows which antibiotic resistance marker genes have been incorporated in the plant genome of RBMT15-101, SEMT15-02, SEMT15-15.

Events	genes
RBMT15-101	nptII
SEMT15-02	nptII+ aad
SEMT15-15	nptII+ aad

Molecular analyses of the transformed plants show that:
The PVYcp, cry3A and nptII genes were inserted in the genome of RBMT15-101, SEMT15-02, SEMT15-15 and the integrity of the linkage between these genetic elements are maintained during the transfer process. The elements beyond the left

and right borders which include the aad, oriV and ori322 plasmid elements were inserted only into the line SEMT15-02 and SEMT15-15.
In the line RBMT15-101 , insertion of the T-DNA occurred at three to four loci. In the line SEMT15-15, insertion of the T-DNA occurred at four to five loci. In both lines at least one locus contains 2 copies of the T-DNA in inverted orientations. For two copies of the T-DNA, P-FMV is incomplete. One of the T-DNAs in both lines has an incomplete P-nos region associated with the nptII coding region. The coding regions of all other genetic elements are intact.

FSANZ published a report with a more precise description of RBMT15-101, SEMT15-02, SEMT15-15:

(i) **In RBMT15-101** - insertion of the T-DNA occurred at three to four loci. At least one locus contains two copies of the T-DNA organised in inverted orientations. For two copies of the T-DNA, transfer was incomplete at the right border resulting in an incomplete copy of P-FMV associated with the PVYcp gene. One of the cry3A genes also lacks P-Ssu and a portion of the 5' end of the gene. T-nos of this gene cassette is intact. One of the T-DNAs also has an incomplete P-nos associated with an intact nptII coding region. The coding regions of all the other genetic elements are intact. The analyses also showed that no plasmid sequences beyond the left and right borders were transferred;

(ii) **In SEMT15-02** - insertion of the T-DNA occurred at four to five loci. At least one locus contains two copies of the T-DNA organised in inverted orientations and one locus contains two T-DNAs linked by a complete copy of the plasmid backbone. For seven copies of the T-DNA, transfer of the T-DNA resulted in incomplete resolution of the right border leaving incomplete copies of P-FMV associated with the PVYcp coding region. One of the T-DNAs in this line has an incomplete P-nos associated with an intact nptII coding region. One of the nptII genes has a truncation within the coding region. All full-length and less than full-length copies of the nptII gene are associated with T-nos. The coding regions of all other genetic elements are intact. Plasmid sequences beyond the left and right borders, which include the aad gene and oriV and ori322 plasmid elements, were inserted in SEMT15-02. Integration of complete backbone elements occurred in two different ways: at one locus two T-DNAs are linked by a complete copy of the backbone; at two other loci, backbone integration is not associated with the left border, flanking the P-nos of the nptII gene.

(iii) **In SEMT15-15** - insertion of the T-DNA occurred at four to five loci. At least one locus contains copies of the T-DNA organised in inverted orientations. For two copies of the T-DNA, transfer of the T-DNA resulted in incomplete resolution of the right border leaving incomplete copies of P-FMV associated with the PVYcp coding region. One of the T-DNAs contains an incomplete P-nos associated with an intact nptII coding region. The coding regions of all the genetic elements are intact. Plasmid sequences beyond the left and right borders contain the aad gene and the oriV and ori322 plasmid elements.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	07/2001	Monsanto

authorization only for RBMT15-101, SEMT15-02 and SEMT15-15

Canada

Approval Type	Date	Applicant
feed	04/1999	Monsanto
authorization only for RBMT15-101, SEMT15-02 and SEMT15-15		
field production	08/2001	Monsanto
authorization only for RBMT15-101, SEMT15-02, SEMT15-15, plant variety registration for SEMT 15-02 and SEMT15-15 only *plant variety interim registration for RBMT15-101 expired in 05/01, therefore commercial field and seed production of RBMT15-101 is not legal anymore*		
food	05/1999	Monsanto
authorization only for RBMT15-101, SEMT15-02 and SEMT15-15		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	02/1999	Monsanto	97-339-01p
authorization only for RBMT15-101, SEMT15-02 and SEMT15-15 (HLMT15-46 witdrawn from consideration of the subject petition on Monsanto's request			
food/ feed	01/1998	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review), SEMT15-07, HLMT15-3 and HLMT15-15 are also covered by the FDA Memo			
plant pesticide	05/1995	Monsanto	
registration of the Cry3A delta-endotoxin gene (no expiration date)			

Event: RBMT21-129, RBMT21-152, RBMT21-350

RBMT21-129, RBMT21-152, RBMT21-350 have been genetically engineered for resistance to Colorado Potato Beetle by introducing the cry3A delta-endotoxin gene and for virus resistance to leaf roll disease by introducing PLRVrep gene (also called PLRV ORF1 and ORF2).

Brandname(s): New Leaf, Plus lines, Russet Burbank lines

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Construct PV-STMT21 has been used to create RBMT21-129, RBMT21-152 and RBMT21-350.

<u>Map</u>: Linear map of DNA construct used for transformation - T-DNA region of construct PV-STMT21

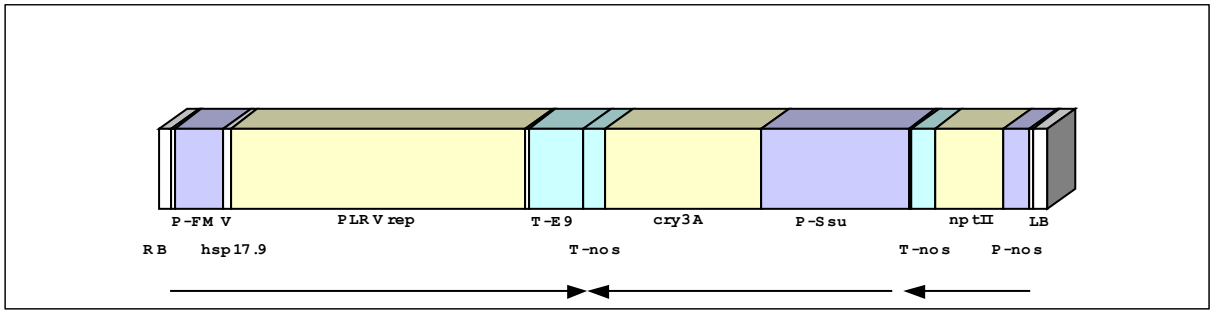


Figure 65: T-DNA region of construct PV-STMT21

<u>Sequence-Details:</u>

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
P-FMV	P-FMV	0.57
hsp17.9	heat-shock protein 17.9 kD leader sequence	0.077
PLRVrep	potato leaf roll virus replicase	3.4
T-E9	T-E9	0.63
T-nos	T-nos	0.26
	cry3A delta-endotoxin	1.8
P-Ssu	P-Ssu	1.7
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-nos	P-nos	0.3
LB	Left border	-

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses show that the transferred gene cassettes are all intact and functional.

According to the data published by FSANZ:
In RBMT21-129, insertion of the T-DNA occurred at two sites. One of the insertions starts at the right border of the T-DNA, continues through the PLRVrep gene cassette, the cry3A gene cassette, the nptII coding region, and terminates within the P-nos. This T-DNA insertion has a partial deletion of the 5' end of the P-nos used to express the nptII gene. The second insert consists of the PLRVrep gene and a partially deleted cry3A gene cassette. The P-Ssu of the cry3A gene, as well as a portion of the 5' coding region of the cry3A gene, are deleted. The partial cry3A gene is still associated with its T-nos. This T-DNA insertion has a deletion in P-FMV as well as a portion of the 5' end of the PLRVrep gene.
In RBMT21-350, insertion of the T-DNA occurred at two sites. At one site, intact copies of all three genes have been inserted. At the second site, a less than full-length copy of the T-DNA has been inserted resulting in a truncated copy of the PLRVrep gene, lacking the P-FMV.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	08/2001	Monsanto
authorization only for RBMT21-350 and RBMT21-129		

Canada

Approval Type	Date	Applicant
environment	08/2001	Monsanto
interim plant variety registration for RBMT21-350 expired October 2001, therefore commercial field and seed production of this line is not legal, authorization only for RBMT21-350		
feed	04/1999	Monsanto
authorization only for RBMT21-350		
feed	09/1999	Monsanto
authorization only for RBMT21-129		
field production	09/1999	Monsanto
no variety registration, therefore commercial seed and field production is not legal, authorization only for RBMT21-129,		
food	05/1999	Monsanto
authorization only for RBMT21-350 and RBMT21-129		

Japan

Approval Type	Date	Applicant
food	2001	Monsanto
authorization only for RBMT21-350, RBMT21-129, environment and import approval are not needed, because potatoes are imported only as processed food to Japan		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	12/1998	Monsanto	97-204-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	01/1998	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	05/1995	Monsanto	
registration of the Cry3A delta-endotoxin gene (no expiration date)			
plant pesticide	11/1998	Monsanto	
registration of the PLRV replicase gene (no expiration date)			

Event: RBMT22-082, RBMT22-186, RBMT22-238, RBMT22-262

RBMT22-082, RBMT22-186, RBMT22-238 and RBMT22-262 have been genetically engineered for resistance to Colorado Potato Beetle by introducing the cry3A delta-

endotoxin gene and for virus resistance to leaf roll disease by introducing PLRVrep gene (also called PLRV ORF1 and ORF2).

Brandname(s): New Leaf, Plus lines, Russet Burbank lines

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Vector PV-STMT22 has be used to create RBMT22-82, RBMT22-186, RBMT22-238 and RBMT22-262.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct PV-STMT22

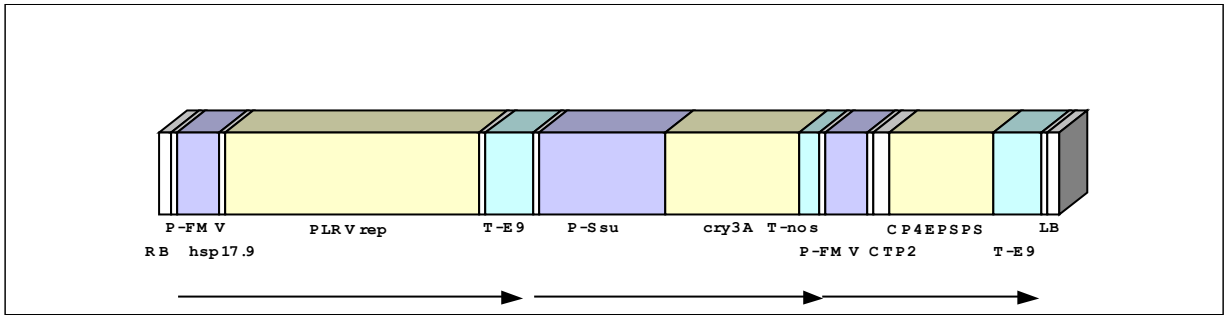


Figure 66: T-DNA region of construct PV-STMT22

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	-
P-FMV	P-FMV	0.57
hsp17.9	heat-shock protein 17.9 kD leader sequence	0.077
PLRVrep	potato leaf roll virus replicase	3.4
T-E9	T-E9	0.63
P-Ssu	P-Ssu	1.7
	cry3A delta-endotoxin	1.8
T-nos	T-nos	0.26
P-FMV	P-FMV	0.57
CTP2	Chloroplast Transit Peptide 2	0.23
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.4
T-E9	T-E9	0.63
LB	Left border	-

Molecular analyses show that the transferred gene cassettes are all intact and functional.

Petition 99-173-01p contains the complementary information about RBMT22-082:

The T-DNA from Vector PV-STMT22 is transferred into the plant genome at 3 loci. Two of these insertions contain the intact coding regions of PLRVrep, cry3A and CP4EPSPS genes. One of these 2 insertions contain also the sequences outside of right and left borders (aad with its bacterial regulatory elements: 0.8kb and ori322: 1.8kb).
The third insertion contains a truncated copy of CP4EPSPS gene and intact coding regions of PLRVrep and cry3A genes.

According to the data published by FSANZ:
In RBMT22-082, insertion of the T-DNA occurred at three sites. All three copies of the T-DNA contain intact coding regions for the PLRVrep gene and the cry3A gene. Two copies of the T-DNA contain an intact coding region of the CP4EPSPS gene. At one site, however, a less than full-length copy of the CP4EPSPS gene has been inserted. For another T-DNA, DNA sequence beyond the RB has also been integrated into the genome. This DNA is adjoined to the RB of the T-DNA and contains the aad gene and the ori322 region. This result conflicts with that of the PCR analyses, which were unable to detect the aad gene. The failure to detect the aad gene by PCR suggests that the gene is probably not intact.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	07/2001	Monsanto
authorization only for RBMT22-082		

Canada

Approval Type	Date	Applicant
feed	04/1999	Monsanto
authorization only for RBMT22-082		
field production	08/2001	Monsanto
authorization only for RBMT22-082		
food	05/1999	Monsanto
authorization only for RBMT22-082		

Japan

Approval Type	Date	Applicant
food	2001	Monsanto
authorization only for RBMT22-082, environment and import approval are not needed, because potatoes are imported only as processed food to Japan		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	07/2000	Monsanto	99-173-01p
approval extension of 97-204-01p, for more information on GM crop regulation in the US see Annex			
food/ feed	01/1998	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	05/1995	Monsanto	

	registration of the Cry3A delta-endotoxin gene (no expiration date), authorization only for RBMT22-082		
plant pesticide	11/1998	Monsanto	
	registration of the PLRV replicase gene (no expiration date), authorization only for RBMT22-082		

Event: SPBT02-5, SPBT02-7

These lines has been genetically engineered to express an insecticidal protein Cry3A. This insect control protein is identical in amino acid sequence to one of the proteins (band 3 protein encoded by cry3A gene) from *B. thuringiensis subsp. Tenebrionis*. The protein is highly selective in controlling Colorado potato beetle (CPB) and is expressed at a consistently effective level in the potato foliage throughout the growing season.

Brandname(s): New Leaf, Superior lines

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Vector PV-STBT02 has been used to create SPBT02-5 and SPBT02-7.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct PV-STBT02

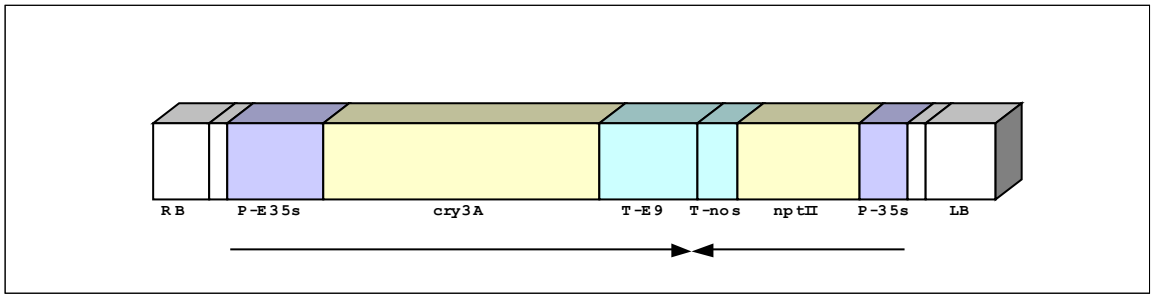


Figure 67: T-DNA region of construct PV-STBT02

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.36
P-E35s	P-E35s	0.62
	cry3A delta-endotoxin	1.8
T-E9	T-E9	0.63
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-35s	P-35s	0.32
LB	Left border	0.45

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

The genetic elements beyond right and left borders are: oriV, Ori322/rop, and aad gene (with its bacterial regulatory elements).
Molecular analyses of the transformed plants show that a single copy of the T-DNA containing cry3A and nptII genes were inserted at a single site of the SPBT02-7 genome. No region outside the borders were inserted.
In the case of SPBT02-5, the cry3A and a region outside of the borders containing the oriV and ori322 were inserted.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	07/2001	Monsanto
authorization only for SPBT02-5		

Canada

Approval Type	Date	Applicant
feed	02/1997	Monsanto
field production	02/1997	Monsanto
variety registration only for SPBT02-5		
food	11/1996	Monsanto

Japan

Approval Type	Date	Applicant
food	2001	Monsanto
authorization only for SPBT02-5, food approval renewal 2001, first approval in 05/97, environment and import approvals are not needed, because potatoes are imported only as processed food to Japan		

Romania

Approval Type	Date	Applicant
field production	2002	Monsanto
expiration of approval in 2003		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	05/1996	Monsanto	95-338-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	03/1996	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			
plant pesticide	05/1995	Monsanto	
registration of the Cry3A delta-endotoxin gene (no expiration date)			

rice

Event: 730, 1107, 1316, 1702, 1708, 1763

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Herbicide tolerance	glyphosate		maize 5-enolpyruvylshikimate-3-phosphate synthase (mEPSPS)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	2000	Monsanto
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	2000	Monsanto

Event: G2-59, G2-70, G2-138

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Herbicide tolerance	glyphosate		maize 5-enolpyruvylshikimate-3-phosphate synthase (mEPSPS)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	2001	Monsanto
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	2001	Monsanto

Event: KA130

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered gluterin content	low gluterin		antisense gluterin (AS gluterin)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	2000	Orynova
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	2000	Orynova

Event: Kinuhikari 1

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	rice stripe virus		coat protein - Rice Stripe Virus (RSVcp)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1994	NIAES Planttech Research Institute
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1994	NIAES Planttech Research Institute
second applicant Mitsubishi Chemical Corporation		

Event: Kinuhikari 2

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Reduced allergenicity			antisense albumin (AS albumin)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1995	Mitsui Chemicals
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1995	Mitsui Chemicals

Event: LLRICE06, LLRICE62

The rice lines LLRICE06, -62 are genetically engineered to be tolerant of glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation. Tolerance to glufosinate-ammonium is conferred by the bar gene**.**

Brandname(s): LibertyLink

Event Characterisation

Transformation Method: direct DNA transfer

Maps

Plasmid pB5/35Sbar derived from pUC 19 has been used to create rice events LLRICE06, and LLRICE62.

Map: Linear map of DNA construct used for transformation - Construct pB5/35Sbar

US-Patent-N°: 6,333,449

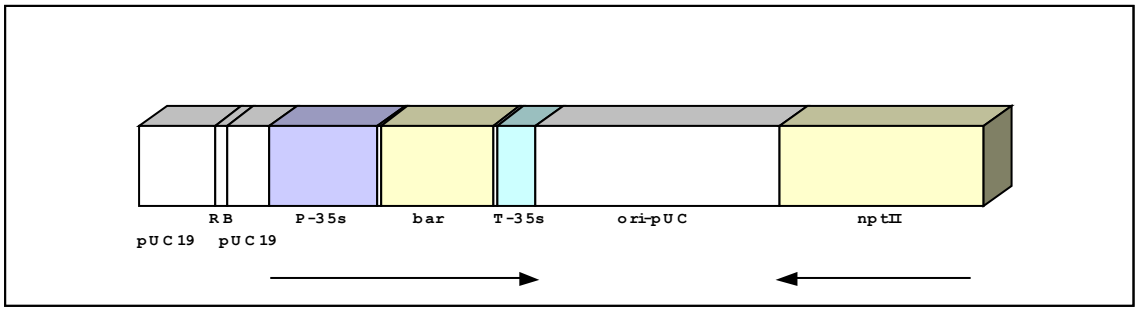


Figure 68: Construct pB5/35Sbar

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
pUC19	pUC19	0.37
RB	Right Border	0.06
pUC19	pUC19	0.21
P-35s	P-35s	0.53
Space	Space	0.015
	phosphinothricin acetyltransferase (bar)	0.55
Space	Space	0.018
T-35s	T-35s	0.193
ori-pUC	ori-pUC	1.2
nptII	neomycin phosphotransferase	1

Molecular analyses of the transformed plants show that the event LLRICE62 contains one intact copy of the complete bar gene cassette. No pB5/35Sbar vector backbone sequences (including nptII) are present.
In the event LLRICE06, at least one intact copy of the bar gene cassette is integrated into the plant genome. It contains no vector backbone sequences (including nptII). The insert is complex and certainly carries incomplete transgenic gene cassettes.

Approvals

Japan

Approval Type	Date	Applicant
import	2000	AgrEvo
authorization only for LLRICE62		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	04/1999	AgrEvo	98-329-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	08/2000	Aventis CropScience	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: Nihonbare 16-2

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	rice stripe virus		coat protein - Rice Stripe Virus (RSVcp)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1994	Nat'l Agr.Ctr.
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1994	Nat'l Agr.Ctr.
second applicant NIAR		

Event: Nihonbare 20-2, 21-3

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	rice stripe virus		coat protein - Rice Stripe Virus (RSVcp)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1997	Nat'l Agr. Res. Ctr.
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1997	Nat'l Agr. Res. Ctr.
second applicant NIAR		

Event: Tsuki-no-hikari H39, H75

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered gluterin content	low gluterin		antisense gluterin (AS gluterin)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1998	Japan Tobacco
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1998	Japan Tobacco

soybean

Event: A2704-12, A2704-21, A5547-35

A2704-12, A2704-21, and A5547-35 are genetically engineered to be tolerant of glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation.Herbicide tolerance is conferred by introducing pat gene in the plant genome.

Brandname(s): LibertyLink

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The plasmid pB2/35SacK has been used to create A2704-12, A2704-21, A5547-35 (the same as used for development of A5547-127 and GU262).

Map: Linear map of DNA construct used for transformation - Construct pB2/35SacK (A2704-12, A2704-21, A5547-35)

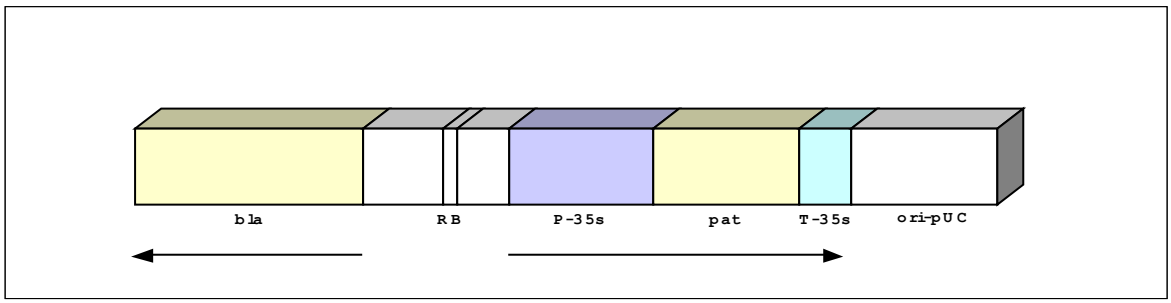


Figure 69: Construct pB2/35SacK (A2704-12, A2704-21, A5547-35)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
bla	beta-lactamase	0.86
Space	Space	-
RB	Right Border	0.054
Space	Space	-
P-35s	P-35s	0.54
	phosphinothricin acetyltransferase (PAT)	0.55

T-35s	T-35s	0.2
ori-pUC	ori-pUC	0.55

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla) partial.

A2704-12, A2704-21 and A5547-35 contain approximately 4, 5, and 1 intact copies or fragments of the pat gene and 4, 2, and 0 fragments of the bla gene, respectively. The transferred bla gene fragments are not intact and functional.

Approvals

Argentina

Approval Type	Date	Applicant
environment	05/2001	AgrEvo
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), authorization only for A2704-12, for more information on GM crop regulation in Argentina see Annex		

Canada

Approval Type	Date	Applicant
environment	04/1999	AgrEvo
no variety registration, therefore commercial seed and field production is not legal, authorization only for A2704-12		
feed	12/2000	AgrEvo
authorization only for A2704-12		
food	11/2000	AgrEvo
authorization only for A2704-12		

Japan

Approval Type	Date	Applicant
food	2002	Aventis CropScience
authorization only for A2704-12, second applicant Shionogi Ltd.		
import	01/1999	AgrEvo
authorization only for A2704-12		

Russia

Approval Type	Date	Applicant
food	2003	Bayer CropScience
authorization only for A2704-12, actual approval date is not available, A2704-12 has already been approved in 2003		

South Africa

Approval Type	Date	Applicant
food	2003	Bayer CropScience
authorization only for A2704-12, actual approval date unknown, A2704-12 has already been approved in 2003		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	07/1996	AgrEvo	96-068-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	04/1998	AgrEvo	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review), only A2704-12 is covered by the FDA Memo			

Event: A5547-127

A5547-127 is genetically engineered to be tolerant to glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation.Tolerance to glufosinate-ammonium is conferred by the pat gene.

Brandname(s): LibertyLink

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The plasmid pB2/35SacK has been used to create A5547-127 (the same as used for development of A2704-12, A2704-21, A5547-35 and GU262).

Map: Linear map of DNA construct used for transformation - Construct pB2/35SacK

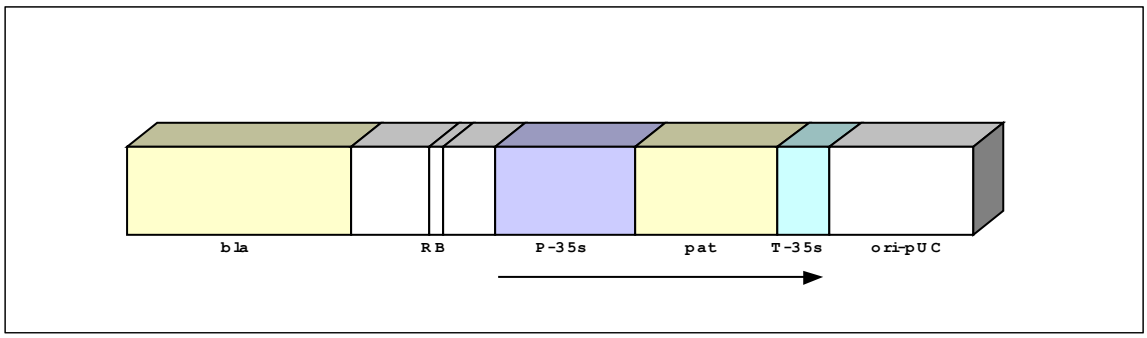


Figure 70: Construct pB2/35SacK

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
bla	beta-lactamase	0.86
Space	Space	-
RB	Right Border	0.054

Space	Space	-
P-35s	P-35s	0.54
	phosphinothricin acetyltransferase (PAT)	0.55
T-35s	T-35s	0.2
ori-pUC	ori-pUC	0.55

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla) partial.

Molecular analyses of the transformed plant show that only one copy of the pat gene cassette is integrated into the plant genome. One copy of the 5' bla sequence is integrated upstream of the pat gene, and one copy of the 3' bla sequence is integrated downstream of the pat gene. Therefore, it does not constitute an intact bla gene.

Approvals

Argentina

Approval Type	Date	Applicant
environment	05/2001	AgrEvo
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), for more information on GM crop regulation in Argentina see Annex		

Canada

Approval Type	Date	Applicant
feed	12/2000	AgrEvo
food	11/2000	AgrEvo

Japan

Approval Type	Date	Applicant
food	2002	Aventis CropScience
second applicant Shionogi Ltd.		
import	2001	AgrEvo

USA

Approval Type	Date	Applicant	Aphis Petition
field production	04/1998	AgrEvo	98-014-01p
approval extension of 96-068-01p, for more information on GM crop regulation in the US see Annex			
food/ feed	04/1998	AgrEvo	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: G94-1, G94-19, G-168

G94-1, G94-19 and G-168, have been genetically engineered to produce a soybean oil with a high level of oleic acid (a monounsaturated fatty acid), exceeding 80%, versus 23% found in typical conventional soybean oil. These high oleic soybeans contain an inserted soybean fatty acid desaturase gene (GmFAD2-1), under the control of a seed

specific promoter, which suppresses the addition of a second double bond to oleic acid resulting in greatly increased oleic acid in the seed only. The result is a superior, more heat stable soybean oil, which may be used in food applications such as frying without the need for an additional processing step, chemical hydrogenation.

G94-1, G94-19, G-168 are lines derived from event 260-05.

Brandname(s): Optimum

Event Characterisation

Transformation Method: microparticle bombardment

Maps

Two constructs pBS43 and pML102 have been used for transformation.

Map: Linear map of DNA construct used for transformation - Construct pBS43

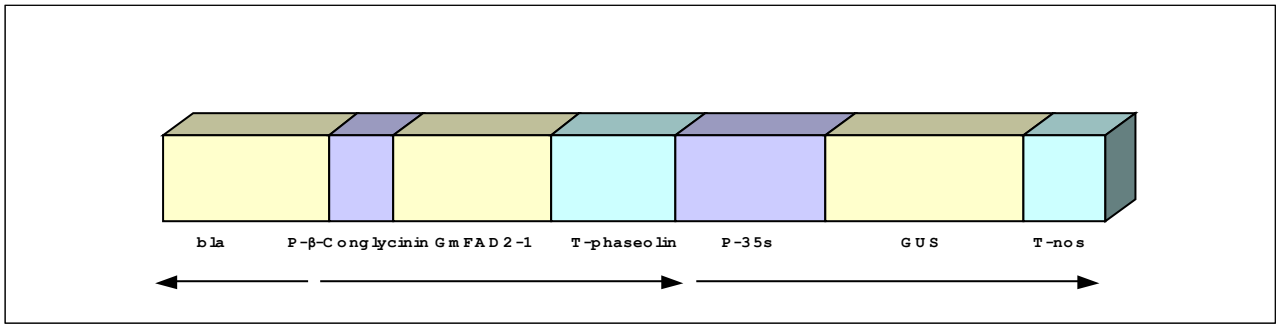


Figure 71: Construct pBS43

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
bla	beta-lactamase	-
P-β-Conglycinin	P-β-Conglycinin	0.606
GmFAD2-1	delta-12 desaturase	1.462
T-phaseolin	T-phaseolin	1.174
P-35s	P-35s	1.4
GUS	beta-glucuronidase	1.85
T-nos	T-nos	0.77

Map: Linear map of DNA construct used for transformation - The linear map of the introduced elements in construct pML102

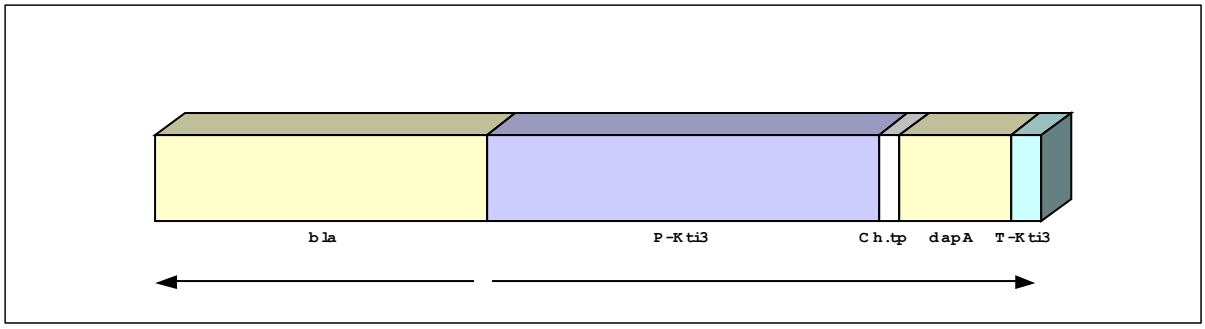


Figure 72: The linear map of the introduced elements in construct pML102

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
bla	beta-lactamase	-
P-Kti3	P-Kti3	3.2
ch.tp	chloroplast transit peptide	0.17
dapA	dihydrodipicolinic acid synthase	0.91
T-Kti3	T-Kti3	0.25

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla)

Molecular analyses show that the original transformant (event 260-05) contains inserts at three loci (A, B and C). The selected sublines G94-1, G94-19, G168 contain locus A with two copies of GmFAD2-1 gene (2 copies of whole pBS43 construct), and locus C which contains an inactive, truncated dapA gene (not functional). The GUS and bla genes are not expressed.

According to the data published by FSANZ:
The GUS expression cassette in the construct pBS43, contains a cab22L non-translated leader between P-35s and GUS coding region.
In addition to the elements shown in map1 and 2, other genetic elements present in the constructs pBS43 and pML102 are: lac, ori-pUC, FL(-) ori.
In the report of the FSANZ, there is also more precise information about the inserts in the genome of lines G94-1, G94-19, G168: the insertion at locus A consists of two intact copies of the GmFAD2-1 expression cassette, one intact and one truncated copy of the GUS expression cassette, and at least two intact copies plus one truncated copy of the bla gene. Additional southern blots, using a dapA probe, indicated that a truncated dapA gene expression cassette is integrated at another locus in the genome (locus C). This locus segregates independently of locus A. The truncated dapA gene is not functional.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	11/2000	DuPont Agricultural Products

Canada

Approval Type	Date	Applicant

environment	02/2000	Optimum Quality Grains L.L.C
no variety registration, therefore commercial seed and field production is not legal		
feed	02/2000	Optimum Quality Grains L.L.C
food	10/2000	Optimum Quality Grains L.L.C

Japan

Approval Type	Date	Applicant
feed	2000	DuPont Agricultural Products
food	2001	DuPont Agricultural Products
import	1999	DuPont Agricultural Products

USA

Approval Type	Date	Applicant	Aphis Petition
field production	05/1997	DuPont Agricultural Products	97-008-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	12/1996	DuPont Agricultural Products	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: GTS40-3-2

GTS 40-3-2 has been genetically engineered to allow the use of glyphosate, as a weed control option. Glyphosate, the active ingredient in Roundup®, is a post emergent, systemic herbicide that is used worldwide for the non-selective control of a wide variety of annual and perennial weeds. Herbicide tolerance is conferred by CP4EPSPS gene.

Brandname(s): Roundup Ready

Event Characterisation

Transformation Method: microparticle bombardment

Maps

Map: Linear map of DNA construct used for transformation - Construct PV-GMGT04

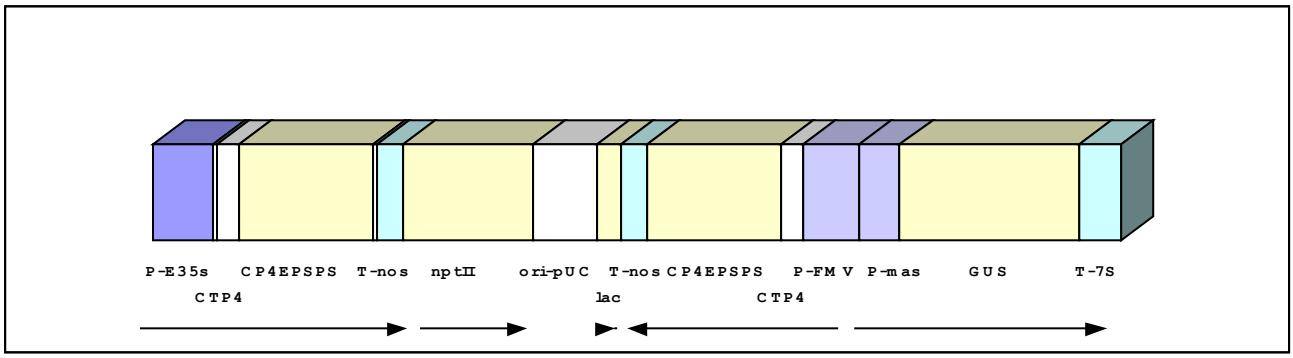


Figure 73: Construct PV-GMGT04

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
P-E35s	P-E35s	0.61
Space	Space	0.036
CTP4	Chloroplast Transit Peptide 4	0.23
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.36
Space	Space	0.032
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	1.32
ori-pUC	ori-pUC	0.65
lac	beta-galactosidase	-
T-nos	T-nos	0.26
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.36
CTP4	Chloroplast Transit Peptide 4	0.22
P-FMV	P-FMV	0.57
P-mas	P-mas	0.42
GUS	beta-glucuronidase	1.81
T-7S	T-7S	0.43

The original molecular characterization studies (mentioned in the US-petition) indicate that GTS40-3-2 contains a single functional insert. This insert contains P-E35s (or a portion), CTP4, CP4EPSPS, and T-nos (or a portion). The other elements present in construct PV-GMGT04 have not been transferred into the genome of GTS40-3-2.
Additional more detailed molecular studies performed by Monsanto confirm a deletion in the P-E35s enhancer region which does not disturb the transcription of the CP4EPSPS gene. These studies show that the T-nos is intact, and not a partial element, as previously reported. An additional unobserved 250 bp segment of the CP4EPSPS element adjacent to the 3' end of the T-nos element was shown to be present. The event GTS40-3-2 contains a second insert consisting of 72 bp of CP4EPSPS sequence. These newly detected CP4EPSPS segments are non-functional. (Updated molecular characterisation and safety assessment of the soybean GTS40-3-2, Monsanto report, Product Safety Centre)

Approvals

Argentina

Approval Type	Date	Applicant
environment	03/1996	Nidera S.A.
authorization for unconfined field trials, called flexibilization (commercialization within the country illegal), for more information on GM crop regulation in Argentina see Annex		
field production	03/1996	Nidera S.A.
authorization for commercial seed and field production		
food/ feed	03/1996	Nidera S.A.
authorization for commercialization		

Australia/ New Zealand

Approval Type	Date	Applicant
food	07/2000	Monsanto

Brazil

Approval Type	Date	Applicant
environment	1999	Monsanto
decision reversed - approval is pending		
food/ feed	1999	Monsanto
decision reversed - approval is pending		

Canada

Approval Type	Date	Applicant
feed	06/1995	Monsanto
field production	11/1995	Monsanto
food	04/1996	Monsanto

European Union

Approval Type	Date	Applicant
food/ feed	04/1996	Monsanto
Reg. 220/90/EEC, authorization for commercial release, restriciton - uses: import and processing		

Japan

Approval Type	Date	Applicant
feed	09/1996	Monsanto
field production	03/1996	Monsanto
food	2001	Monsanto
food approval renewal 2001, first approval in 09/96		
import	1996	Monsanto

Korea, Democratic People's Republic of

Approval Type	Date	Applicant
field production	2000	Monsanto
food/ feed	2000	Monsanto

Mexico

Approval Type	Date	Applicant
environment	1998	Monsanto
according to Monsanto, GTS40-3-2 were grown on a "semi-commercial" basis in 2001		
food/ feed	1998	Monsanto

Poland

Approval Type	Date	Applicant
field production	2000	Monsanto
food/ feed	2000	Monsanto

Romania

Approval Type	Date	Applicant
field production	1999	Monsanto
food/ feed	1999	Monsanto

Russia

Approval Type	Date	Applicant

field production	2000	Monsanto
food/ feed	1999	Monsanto

South Africa

Approval Type	Date	Applicant
field production	2001	Monsanto
food/ feed	2001	Monsanto

Switzerland

Approval Type	Date	Applicant
food/ feed	10/2002	Monsanto
first approval in 12/96, approval renewal in 2002, is limited to 12/06		

Thailand

Approval Type	Date	Applicant
food/ feed	2000	Monsanto

Uruguay

Approval Type	Date	Applicant
field production	1997	Monsanto
food/ feed	1997	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	05/1994	Monsanto	93-258-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	09/1994	Monsanto	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

Event: GU262

GU262 has been genetically engineered to be tolerant of glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation. The herbicide tolerance is conferred by the pat gene.

Brandname(s): LibertyLink

Event Characterisation

Transformation Method: microparticle bombardment

Maps

The plasmid pB2/35SacK has been used to create GU262 (the same as used for development of A5547-127 and A2704-12, A2704-21, A5547-35).

Map: Linear map of DNA construct used for transformation - Construct pB2/35SacK (GU262)

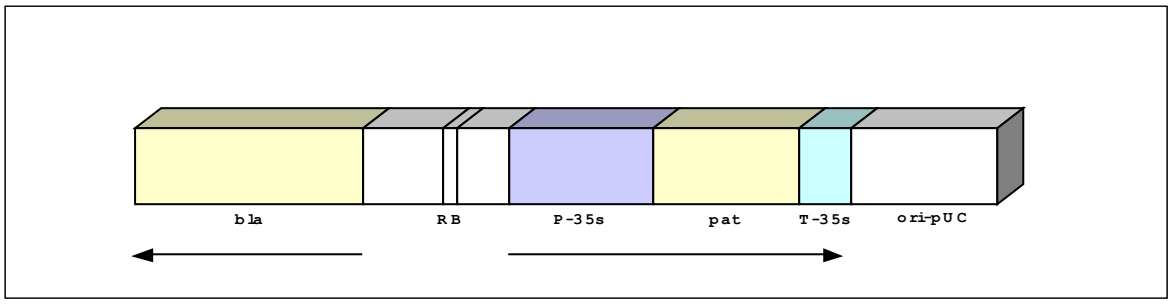


Figure 74: Construct pB2/35SacK (GU262)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
bla	beta-lactamase	0.86
Space	Space	-
RB	Right Border	0.054
Space	Space	-
P-35s	P-35s	0.54
	phosphinothricin acetyltransferase (PAT)	0.55
T-35s	T-35s	0.2
ori-pUC	ori-pUC	0.55

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla) partial.

Molecular analyses of the transformed plant show that the event GU262 contains a head-to-tail insertion of the DNA construct. It consists of 2 copies of pat gene cassette and ori sequences and two copies of only 5' part of bla marker gene.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
field production	10/1998	AgrEvo	98-238-01p
according to FDA, all developers of GM crops have gone through premarket review processs, but no FDA Memo is available, for this reason no food/ feed approval is indicated, for more information on GM crop regulation in the US see Annex			

Event: W62, W98

W62, W98 have been genetically engineered to be tolerant to glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides

Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation. Herbicide tolerance is conferred by the bar gene.

Brandname(s): LibertyLink

Event Characterisation

Transformation Method: microparticle bombardment

Maps

Map: Linear map of DNA construct used for transformation - Construct pWRG2114

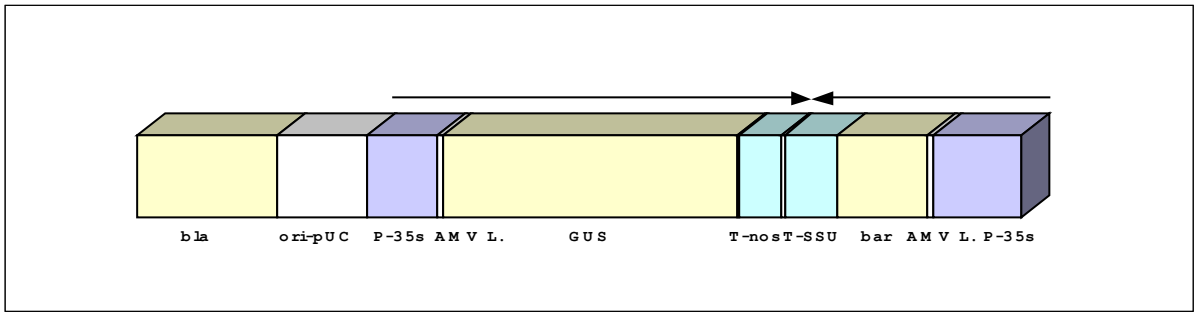


Figure 75: Construct pWRG2114

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
bla	beta-lactamase	0.86
ori-pUC	ori-pUC	0.55
P-35s	P-35s	0.43
AMV L.	Alfalfa Mosaic Virus Leader	0.035
GUS	beta-glucuronidase	1.81
T-nos	T-nos	0.26
T-SSU	T-SSU	0.32
	phosphinothricin acetyltransferase (bar)	0.55
AMV L.	Alfalfa Mosaic Virus Leader	0.035
P-35s	P-35s	0.43

The following antibiotic gene has been incorporated in the genome: beta-lactamase (bla)

Molecular analyses show that W62 and W98 contain approximately 2 and 12 intact copies of the bar, GUS and bla genes, respectively.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
field production	07/1996	AgrEvo	96-068-01p
according to FDA, all developers of GM crops have gone through the pre-market review process, but no FDA Memo is available, for this reason no food/ feed approval is indicated, for more information on GM crop regulation in the US see Annex			

squash

Event: CZW3

CZW3 has been genetically engineered for resistance to infection of CMV, ZYMV, and WMV2. Virus resistance is conferred by inserting virus-derived sequences encoding coat proteins (CPs) of these viruses.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The construct CMV73/ZYMV72/WNBN22 has been used for transformation. It is derived from ZYMV72/WMBN22, which has been used to develop ZW20.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct CMV73/ZYMV72/WNBN22

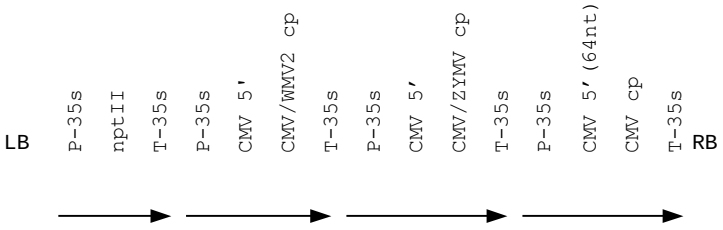


Figure 76: T-DNA region of construct CMV73/ZYMV72/WNBN22

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	-
P-35s	P-35s	-
nptII	neomycin phosphotransferase	-
T-35s	T-35s	-
P-35s	P-35s	-
CMV 5'	CMV 5'	-
CMV/WMV2 cp	coat protein - Watermelon Mosaic Virus 2& Cucumber Mosaic Virus	-
T-35s	T-35s	-
P-35s	P-35s	-
CMV 5'	CMV 5'	-
CMV/ZYMV cp	coat protein - Zucchini Yellow Mosaic Virus & Cucumber Mosaic Virus	-
T-35s	T-35s	-
P-35s	P-35s	-
CMV 5' (64nt)	CMV 5' (64nt)	-

CMV cp	coat protein - Cucumber Mosaic Virus	-
T-35s	T-35s	-
RB	Right Border	-

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses of the transformed plant show that the CZW-3 squash contains a single complete integrated T-DNA consisting of CMV, ZYMV, WMV2 and nptII gene cassettes. It does not contain any binary plasmid sequences outside the T-DNA border region.

Approvals

Canada

Approval Type	Date	Applicant
food	04/1998	Seminis Vegetable Inc.

USA

Approval Type	Date	Applicant	Aphis Petition
field production	06/1996	Asgrow	95-352-01p
for more information on GM crop regulation in the US see Annex			
food	07/1997	Seminis Vegetable Inc.	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review)			

Event: ZW20

ZW20 has been genetically engineered for resistance to infection of ZYMV and WMV2. Virus resistance is conferred by inserting virus-derived sequences encoding coat proteins (CPs) of these viruses.

Brandname(s): Freedom II

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The vector ZYMV72/WMBN22 has been used for transformation. It has been designed by inserting the genes for WMV2 and ZYMV coat proteins into pPRBN. The vector pPRBN has been derived from pPRBoriGN.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct ZYMV72/WMBN22

US-Patent-N°: 6,337,431

LB, P-35s, nptII, T-35s; P-35s, CMV 5', CMV/WMV2 cp, T-35s, P-35s, CMV 5', CMV/ZYMV cp, T-35s, RB

Figure 77: T-DNA region of construct ZYMV72/WMBN22

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	-
P-35s	P-35s	-
nptII	neomycin phosphotransferase	-
T-35s	T-35s	-
P-35s	P-35s	-
CMV 5'	CMV 5'	-
CMV/WMV2 cp	coat protein - Watermelon Mosaic Virus 2 & Cucumber Mosaic Virus	-
T-35s	T-35s	-
P-35s	P-35s	-
CMV 5'	CMV 5'	-
CMV/ZYMV cp	coat protein - Zucchini Yellow Mosaic Virus & Cucumber Mosaic Virus	-
T-35s	T-35s	-
RB	Right Border	-

Molecular analyses show that only the T-DNA region has been transferred and integrated into the plant genome. The original regenerant plant was found to contain five inserts of the introduced genes. Four of these inserts had a truncation of the T-DNA in the region of left border, thus eliminating the nptII gene (and in one of these cases, the CMV/WMV2 cp gene as well). The fifth insert consists of one nptII gene and CMV/WMV2 cp gene only. ZW20 is the result of selection in the subsequent generations which contain the coat protein genes but lack the plant expressible nptII gene.

Approvals

Canada

Approval Type	Date	Applicant
food	04/1998	Seminis Vegetable Inc.

USA

Approval Type	Date	Applicant	Aphis Petition
field production	12/1994	Upjohn	92-204-01p
for more information on GM crop regulation in the US see Annex			
food	10/1994	Asgrow	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review)			

sugarbeet

Event: GTSB77

GTSB77 has been genetically engineered to express resistance to glyphosate, allowing its use as a weed control option. Glyphosate, the active ingredient in Roundup®, is a post emergent, systemic herbicide that is used worldwide for the non-selective control of a wide variety of annual and perennial weeds. Herbicide tolerance is conferred by the CP4EPSPS gene.

Brandname(s): Roundup Ready

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - Construct PV-BVGT03

US-Patent-N°: 6,204,436

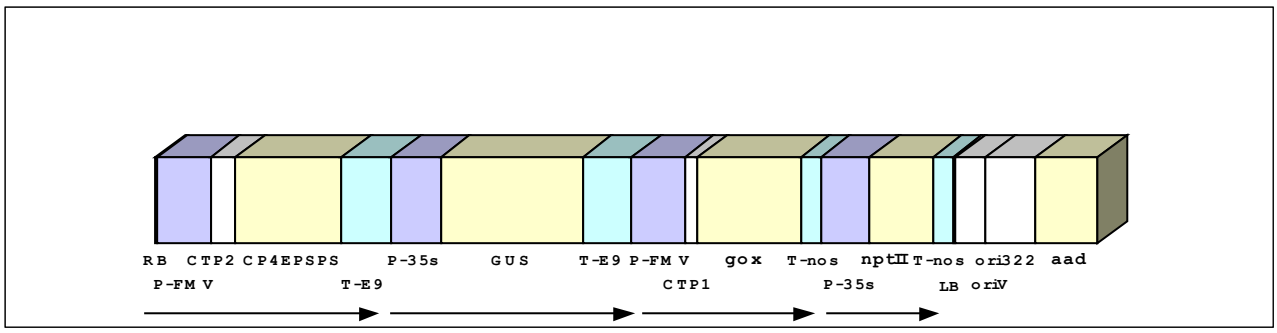


Figure 78: Construct PV-BVGT03

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.03
P-FMV	P-FMV	0.67
CTP2	Chloroplast Transit Peptide 2	0.31
CP4EPSPS	CP4 5-enolpyruvylshikimate-3-phosphate synthase	1.36
T-E9	T-E9	0.63
P-35s	P-35s	0.62
GUS	beta-glucuronidase	1.81
T-E9	T-E9	0.63
P-FMV	P-FMV	0.67
CTP1	Chloroplast Transit Peptide 1	0.17
gox	glyphosate oxidoreductase	1.3
T-nos	T-nos	0.26

P-35s	P-35s	0.62
nptII	neomycin phosphotransferase	0.8
T-nos	T-nos	0.26
LB	Left border	0.03
oriV	oriV	0.39
ori322	ori322	0.63
aad	3"(9)-O-aminoglycoside adenylyltransferase	0.79

Molecular analyses show that CP4EPSPS gene, GUS gene and a truncated form of gox have been integrated in one insertion site. The nptII gene and the sequences outside of the T-DNA borders are not present in the genome of GTSB77.

Approvals

Australia/ New Zealand

Approval Type	Date	Applicant
food	05/2002	Monsanto, Novartis Seeds

USA

Approval Type	Date	Applicant	Aphis Petition
field production	12/1998	Monsanto, Novartis Seeds	98-173-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	09/1998	Monsanto, Novartis Seeds	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review), second applicant Novartis Seeds			

Event: T-120-7

T120-7 has been genetically engineered to be tolerant to glufosinate-ammonium (also known as phosphinothricin), the active constituent of the proprietary herbicides Basta, Finale, Buster, Harvest and Liberty. Glufosinate-ammonium is a non-selective broad-spectrum herbicide which is used to control a wide range of weeds after the crop emerges or for total vegetation control on land not used for cultivation. It is highly biodegradable, has no rsidual activity, and has a very low toxicity for humans and wild fauna. The availability of glufosinate-ammonium tolerant sugar beet line allows farmers to use the herbicides containing this compound as weed control option in the cultivation of sugar beet. herbicide tolerance is conferred by the pat gene.

Brandname(s): LibertyLink

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pOCA18/Ac

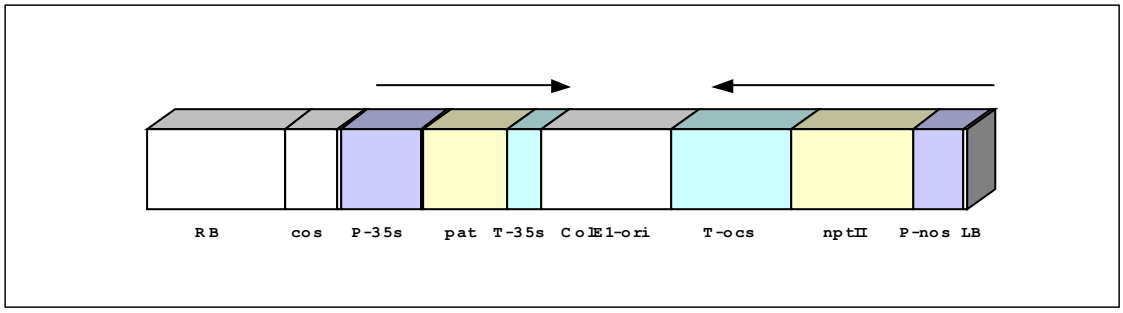


Figure 79: T-DNA region of construct pOCA18/Ac

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.903
cos	cos	0.346
P-35s	P-35s	0.531
	phosphinothricin acetyltransferase (PAT)	0.551
T-35s	T-35s	0.225
ColE1-ori	ColE1-ori	0.854
T-ocs	T-ocs	0.792
nptII	neomycin phosphotransferase	0.795
P-nos	P-nos	0.337
LB	Left border	0.024

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses show that the transformation event T-120-7 and its progeny contain one copy of the T-DNA from vector pOCA18/Ac.Therefore, one copy of the pat and nptII genes have been integrated into the genome. No DNA from outside the T-DNA borders is present.

Approvals

Canada

Approval Type	Date	Applicant
environment	01/2001	Aventis CropScience
no variety registration, therefore commercial seed and field production is not legal, regulated lines: 1022S, 1026S and 1031S		
feed	01/2001	Aventis CropScience
regulated lines: 1022S, 1026S and 1031S		
food	11/2000	Aventis CropScience
regulated lines: 1022S, 1026S and 1031S		

Japan

Approval Type	Date	Applicant
feed	12/1999	AgrEvo
environment and import approval are not needed, because sugarbeet is imported only as processed food to Japan		
food	2001	Aventis CropScience
food approval renewal 2001, first approval in 11/99, environment and import approvals are not required, second applicant Shionogi Ltd.		

Russia

Approval Type	Date	Applicant
food	2000	AgrEvo
actual approval date is not available, the GM sugar beet has been already approved in 2000		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	04/1998	AgrEvo	97-336-01p
for more information on GM crop regulation in the US see Annex			
food/ feed	09/1998	AgrEvo	
no formal authorisation for food/ feed use, consultation process between FDA and developer (pre-market review)			

sweet pepper

Event: China pepper 1

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	cucumber mosaic virus (CMV)		coat protein - Cucumber Mosaic Virus (CMV cp)		

Maps

No Map Information available.

Approvals

China

Approval Type	Date	Applicant
field production	2000	Peking University
actual approval date is not available, it has already been approved in 2000		
food/ feed	2000	Peking University
actual approval date is not available, it has already been approved in 2000		

tobacco

Event: PBD6-238-2

Brandname(s): ITB1000ox

Event Characterisation

Transformation Method: A. tumefaciens

Maps

According to EU scientific committee on plants:

Map: Elements of T-DNA region of PBD6-238-2

Abbreviation	Element-Name	Size [KB]
P-HelSsu	P-HelSsu	-
	nitrilase	-
T-nos	T-nos	-

Approvals

European Union

Approval Type	Date	Applicant
field production	06/1994	Seita
Reg. 220/90/EEC, authorization for commercial seed and field production		

Event: Vector 21-41

Vector 21-41 has been genetically engineered to produce a very low nicotine levels. In order to reduce nicotine levels, the NtQPT1 promoter has been used to direct antisense expression of NtQPT1 cDNA (NtQPT1 A).

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The construct pYTY32 (15.2 Kb), derived from pBin 19 has been used for transformation.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pYTY32

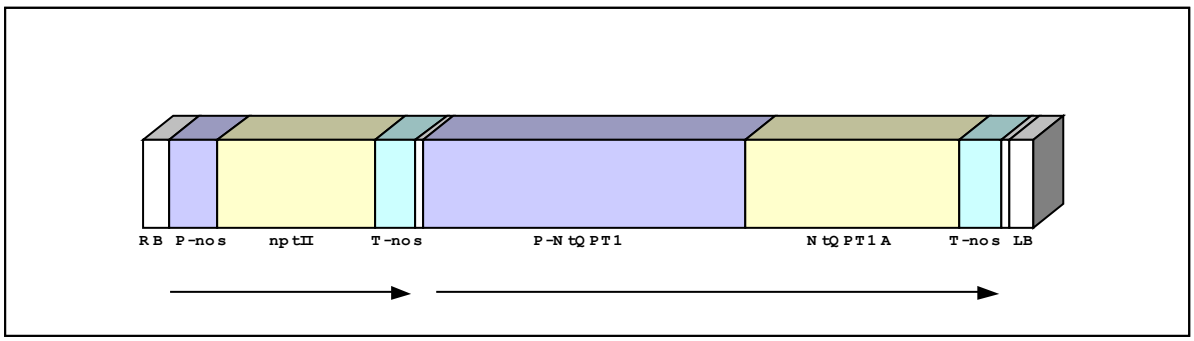


Figure 80: T-DNA region of construct pYTY32

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.16
P-nos	P-nos	0.31
nptII	neomycin phosphotransferase	0.98
T-nos	T-nos	0.26
P-NtQPT1	P-NtQPT1	2.01
NtQPT1-A	Antisense quinolinate phosphoribosyltransferase	1.35
T-nos	T-nos	0.26
LB	Left border	0.15

The other sequences from vector pBin 19 outside of T-DNA are as follows:
tetA (2.24 Kb): no fuction. The gene is disrupted by T-DNA; trfA (1.48): Plasmid transfer/ conjugation; nptII(2.11 Kb); oriV(0.62 Kb); traF (0.78 Kb): plasmid transfer/ conjugation; ColE1-ori (0.37).
Molecular analses show that event Vector 21-41 contains two copies of the T-DNA region of pYTY32. These copies ore arranged as inverted, tandem repeats. Approximately 2.1 Kb of pBin 19 sequences (that carry the 3' half of the tetA gene and about one half of the trfA gene) is located between the inverted T-DNA repeats.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
field production	09/2002	Vector Tobacco Ltd.	01-121-01p
for more information on GM crop regulation in the US see Annex			

tomato

Event: 117, 1046, 1204, 1208

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	cucumber mosaic virus (CMV)		coat protein - Cucumber Mosaic Virus (CMV cp)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1997	NIVOT
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1997	NIVOT

Event: 1345-4

Tomato line 1345-4 was genetically engineered to express the trait of delayed ripening of tomato fruit. The aminocyclopropane carboxylate (Acc) synthase gene was introduced into the tomato genome in the sense orientation, resulting in tomato plants which exhibit significantly reduced levels of ACC synthase and ethylene biosynthesis.

Brandname(s): Endless Summer

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pWTT2144/AccS

US-Patent-N°: 5,952,546

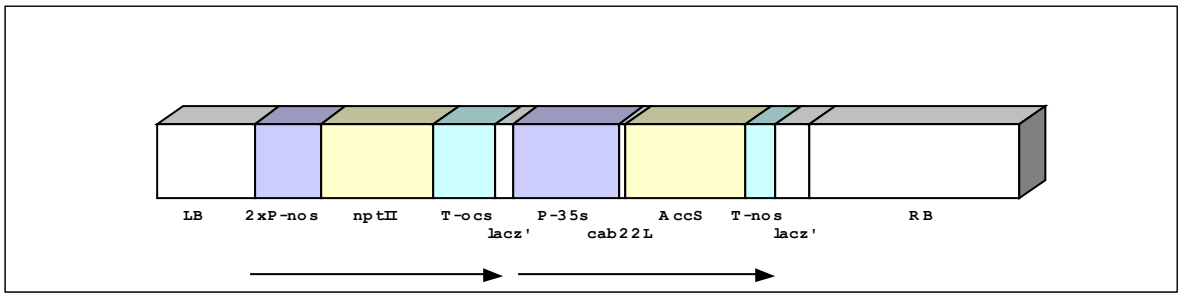


Figure 81: T-DNA region of construct pWTT2144/AccS

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	0.88
2xP-nos	2xP-nos	0.6
nptII	neomycin phosphotransferase	1.02
T-ocs	T-ocs	0.56
lacZ’	lacZ’	-
P-35s	P-35s	0.96
cab22L	cab22L	0.069
AccS	1-amino-cyclopropane-1-carboxylic acid synthase	1.09
T-nos	T-nos	0.27
lacZ’	lacZ’	-
RB	Right Border	1.9

Map: Orientation of DNA construct integrated in the plant genome - Inserted elements from construct pWTT2144/AccS

Plant genome-AccS-nptII **LB** nptII-AccS **RB** AccS-nptII-**Plant genome**

Figure 82: Inserted elements from construct pWTT2144/AccS

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses of the transformed plant show that 1345-4 contains 3 copies of the T-DNA in a single locus. As it is shown schematically above, the three T-DNAs are assembled in inverted repeats at the LB and RB.

Approvals

Canada

Approval Type	Date	Applicant
food	11/1995	DNA Plant Technology

		Corporation

USA

Approval Type	Date	Applicant	Aphis Petition
field production	01/1995	DNA Plant Technology Corporation	94-228-01p
food	10/1994	DNA Plant Technology Corporation	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review), for more information on GM crop regulation in the US see Annex			

Event: 35 1 N

35 1 N has been genetically engineered to delay fruit ripening. The sam-k gene encoding the enzyme S-adenosylmethionine hydrolase has been introduced in the tomato genome. The enzyme alters the ethylene biosynthetic pathway and delays ripening of the tomato on the vine. 35 1 N tomato ripens normally when exposed to exogenous ethylene.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pAG-5420

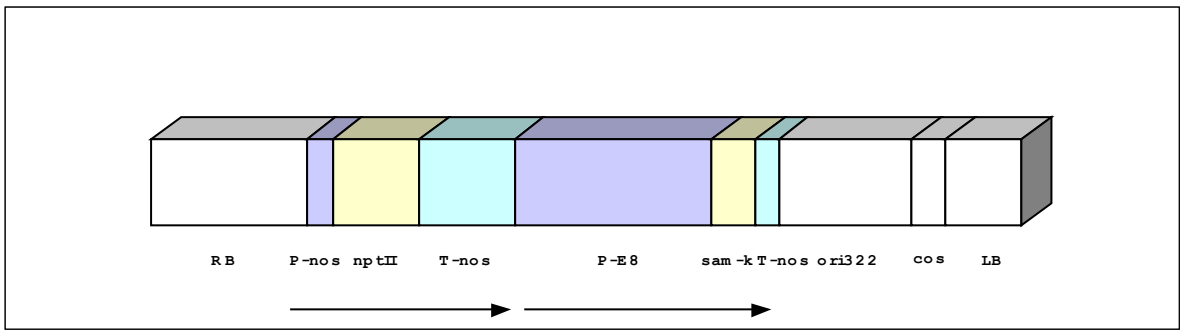


Figure 83: T-DNA region of construct pAG-5420

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	1.8
P-nos	P-nos	0.3
nptII	neomycin phosphotransferase	1.02
T-nos	T-nos	1.1
P-E8	P-E8	2.3
sam-k	S-adenosylmethionine hydrolase	0.51
T-nos	T-nos	0.27
ori322	ori322	1.54

cos	cos	0.4
LB	Left border	0.88

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses of the transformed plant show that there are two copies of T-DNA in a single locus within the genome of 35 1 N. The second copy of T-DNA is incomplete. However more than one copy of sam-k gene is present in this single locus.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
field production	03/1996	Agritope	95-324-01p
for more information on GM crop regulation in the US see Annex			
food	02/1996	Agritope	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review)			

Event: 405, 707

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	cucumber mosaic virus (CMV)		coat protein - Cucumber Mosaic Virus (CMV cp)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1996	NIVOT
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1996	NIVOT

Event: 5345

5345 has been genetically engineered to express Cry1Ac delta-endotoxin, an insect control protein.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Binary single border transformation vector PV-LEBK04 was used to develop 5345.

Map: Linear map of DNA construct used for transformation - Construct PV-LEBK04

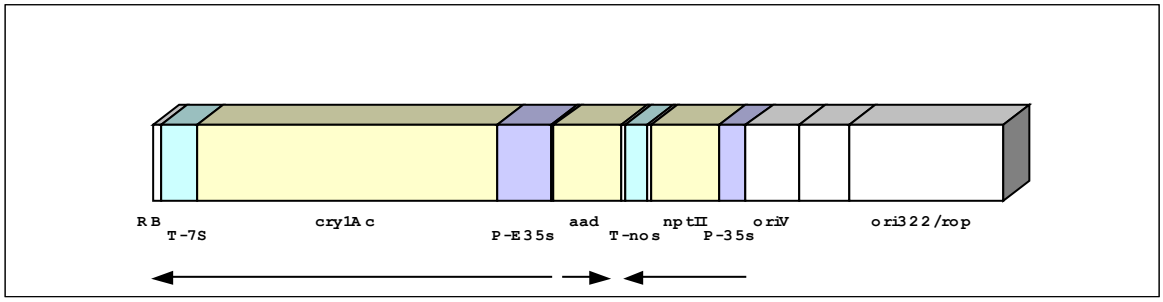


Figure 84: Construct PV- LEBK04

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.09
T-7S	T-7S	0.43
	cry1Ac delta-endotoxin	3.5
P-E35s	P-E35s	0.62
aad	3"(9)-O-aminoglycoside adenylyltransferase	0.79
T-nos	T-nos	0.26
nptII	neomycin phosphotransferase	0.79
P-35s	P-35s	0.32
oriV	oriV	0.62
Space	Space	-
ori322/rop	ori322/rop	1.8

The following antibiotic genes have been incorporated in the genome: neomycin phosphotransferase (nptII), 3"(9)-O-aminoglycoside adenylyltransferase (aad)

Molecular analyses of the transformed plant show that there is a single T-DNA insert in the plant genome. The T-DNA transfer includes the entire plasmid and continues through the right border into the 3' region of the cry1Ac gene (2 copies of cry1Ac).

Approvals

Canada

Approval Type	Date	Applicant
food	10/2000	Monsanto

USA

Approval Type	Date	Applicant	Aphis Petition
field production	03/1998	Monsanto	97-287-01p
for more information on GM crop regulation in the US see Annex			
food	02/1998	Calgene	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review)			

Event: 8338

The line 8338 has been genetically engineered ot contain (accd) that encodes the enzyme 1-aminocyclopropane-1-carboxylic acid deaminase (ACCd). In the plant, ACCd catalyzes metabolism of 1-aminocyclopropane-1-carboxylic acid (ACC), an essential precursor for the biosynthesis of the plant hormone ethylene. The activity of ACC is sufficiently reduced in detached fruits so that ethylene becomes limiting and the ripening process is delayed.

Event Characterisation

Transformation Method: A. tumefaciens

Maps

Map: Linear map of DNA construct used for transformation - T-DNA region of plasmid PV-LERP07 (pMON10117)

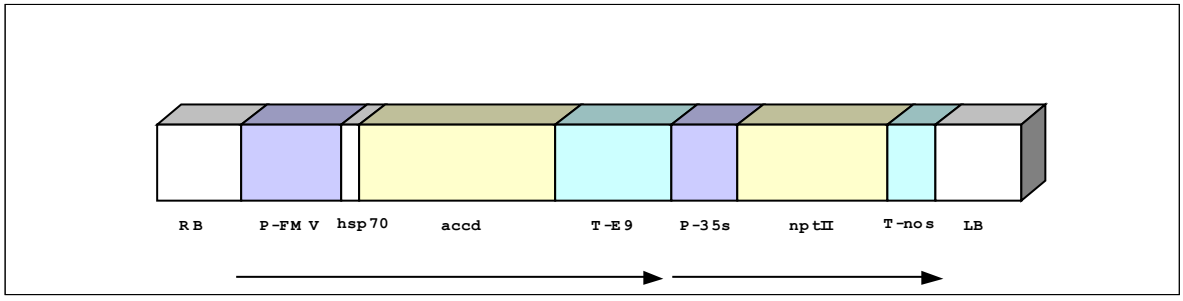


Figure 85: T-DNA region of plasmid PV-LERP07 (pMON10117)

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
RB	Right Border	0.48
P-FMV	P-FMV	0.57
hsp70	heat-shock protein 70	0.1
accd	1-amino-cyclopropane-1-carboxylic	1.1

	acid deaminase	
T-E9	T-E9	0.66
P-35s	P-35s	0.37
nptII	neomycin phosphotransferase	0.85
T-nos	T-nos	0.27
LB	Left border	0.48

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Molecular analyses of the transformed plant show that there is a single DNA insert in the genome of event 8338. This insert contains a single copy of the accd and the nptII gene.

Approvals

USA

Approval Type	Date	Applicant	Aphis Petition
field production	09/1995	Monsanto	95-053-01p
for more information on GM crop regulation in the US see Annex			
food	09/1994	Monsanto	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review)			

Event: B, Da, F

The tomato lines B, Da, and F have been genetically engineered for suppressed polygalacturonase enzyme activity.

Brandname(s): Vegadura, Vegaspeso

Event Characterisation

Transformation Method: A. tumefaciens

Maps

The lines differ slightly in that Da and F contain the partial PG gene in the sense orientation while line B contains a partial antisense PG gene, essentially a reverse copy.
The constructs used to generate these lines are binary vectors pJR16A and pJR16S derived from pBIN-19.

Map: Linear map of DNA construct used for transformation - T-DNA region in the construct pJR16s

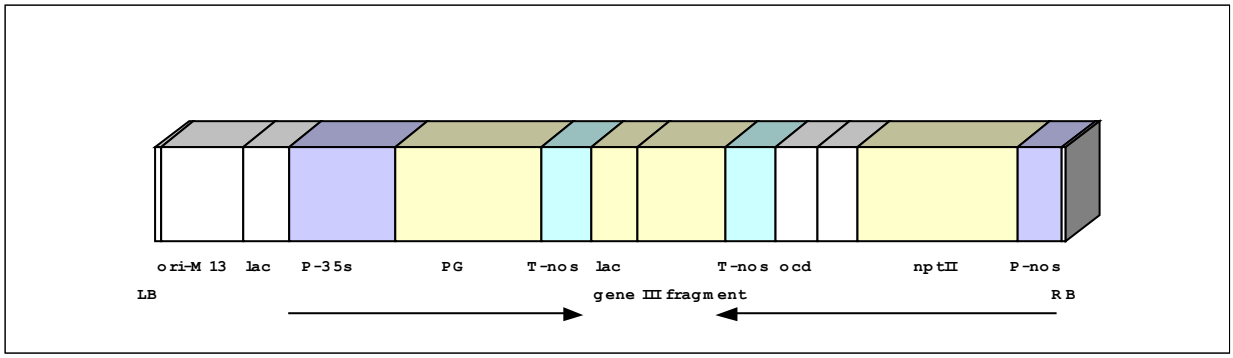


Figure 86: T-DNA region in the construct pJR16s

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	0.025
ori-M13	ori-M13	0.406
lac	beta-galactosidase	0.23
P-35s	P-35s	0.529
PG	polygalacturonase	0.731
T-nos	T-nos	0.247
lac	beta-galactosidase	0.23
gene III fragment	gene III fragment	-
T-nos	T-nos	0.247
ocd fragment	ornithine cyclodeaminase fragment	0.209
Space	Space	0.2
nptII	neomycin phosphotransferase	0.8
P-nos	P-nos	0.227
RB	Right Border	0.02

***Map*: Linear map of DNA construct used for transformation - T-DNA region in the construct pJR16A**

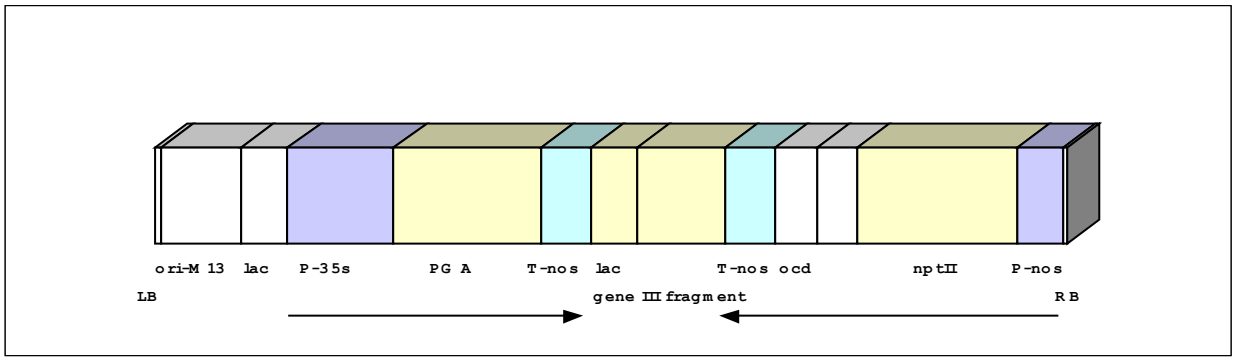


Figure 87: T-DNA region in the construct pJR16A

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	0.025
ori-M13	ori-M13	0.406
lac	beta-galactosidase	0.23
P-35s	P-35s	0.529
PG A	antisense polygalacturonase	0.731
T-nos	T-nos	0.247
lac	beta-galactosidase	0.23
gene III fragment	gene III fragment	-

T-nos	T-nos	0.247
ocd fragment	ornithine cyclodeaminase fragment	0.209
Space	Space	0.2
nptII	neomycin phosphotransferase	0.8
P-nos	P-nos	0.22
RB	Right Border	-

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Da and F contain the partial PG gene in the sense orientation while line B contains a partial antisense PG gene, essentially a reverse copy.
For the line B, all regions of T-DNA from pJR16A, except the left border region are present.
For the line Da, all T-DNA region of the pJR16S is present, probably not the left border.
For the line F, the insertion of the T-DNA region of pJR16S is not complete. The presence of the right border has not been shown - that indicates a possible deletion at the 5' end of the P-nos.

Approvals

Canada

Approval Type	Date	Applicant
food	06/1996	Zeneca
authorization only for 1401F, h382F, 11013F and 7913F		

USA

Approval Type	Date	Applicant	Aphis Petition
field production	06/1995	Zeneca	94-290-01p
second applicant Petoseed, for more information on GM crop regulation in the US see Annex			
food	09/1994	Zeneca	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review)			

Event: China tomato 1

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	cucumber mosaic virus (CMV)		coat protein - Cucumber Mosaic Virus (CMV cp)		

Maps

No Map Information available.

Approvals

China

Approval Type	Date	Applicant
field production	2000	Peking University
actual approval date is not available, it has already been approved in 2000		
food/ feed	200	Peking University
actual approval date is not available, it has already been approved in 2000		

Event: China tomato 2

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Increased shelf life	delayed softening		unknown		

Maps

No Map Information available.

Approvals

China

Approval Type	Date	Applicant
field production	2000	CCAU
actual approval date is not available, it has already been approved in 2000		
food/ feed	2000	CCAU
actual approval date is not available, it has already been approved in 2000		

Event: Flavr Savr

The Flavr Savr tomato lines have been genetically engineered to express delayed softening by insertion of an additional copy of the PG encoding gene in the "anti-sense" orientation, resulting in reduced translation of the endogenous PG messenger RNA (mRNA). Reduced PG expression decreases the breakdown of pectin and leads

to fruit with slowed cell wall breakdown, better viscosity characteristics and delayed softening.

Flavr Savr lines are also named CR3-613 and CR3-623.

Brandname(s): Flavr Savr, MacGregor's

Event Characterisation

Transformation Method: A. tumefaciens

Maps

In the original petition, different binary vectors have been used to transform the Flavr Savr lines.
The Flavr Savr lines which are created with one of the plasmids pCGN1436, pCGN1547, pCGN1548 or pCGN1549 have the mas regulatory signals driving the nptII gene.
The Flavr Savr lines which are created with one of the plasmids pCGN1557, pCGN1558, pCGN1559, pCGN1578, or pCGN4109, have the 35s promoter and tml terminator as regulatory elements for the nptII gene.

Map: Linear map of DNA construct used for transformation - T-DNA region of construct pCGN1436

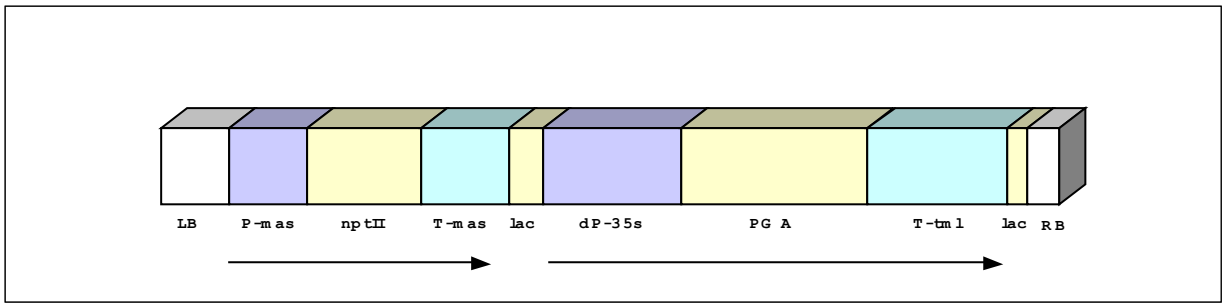


Figure 88: T-DNA region of construct pCGN1436

Sequence-Details:

Abbreviation	Element-Name	Size [KB]
LB	Left border	0.58
P-mas	P-mas	0.68
nptII	neomycin phosphotransferase	0.98
T-mas	T-mas	0.77
lac	beta-galactosidase	0.29
dP-35s	dP-35s	1.2
PG A	antisense polygalacturonase	1.6
Space	Space	0.012
T-tml	T-tml	1.2
lac	beta-galactosidase	0.17
RB	Right Border	0.28

Map: T-DNA region ofconstruct pCGN4109 contains

Abbreviation	Element-Name	Size [KB]
LB	Left border	-
T-tml	T-tml	-
nptII	neomycin phosphotransferase	-
P-35s	P-35s	-
T-tml	T-tml	-
PG A	antisense polygalacturonase	-
dP-35s	dP-35s	-
RB	Right Border	-

The following antibiotic gene has been incorporated in the genome: neomycin phosphotransferase (nptII)

Some Flavr Savr tomato lines transformed with vector pCGN1436 are as follows:
8 lines covered by US petition 92-196-01p: 501-1436-1001; 502-1436-2021; 7B-1436-92; 22B-1436-215; 28B-1436-419; 28B-1436-425; 28B-1436-498; 501-1436-1035 ;
3 lines covered by US petition 95-030-01p: 105F-1436-2018, 105F-1436-2035, and 105F-1436-2049;
1 line covered by US petition: 94-227-01p: N73-1436-111.

Some Flavr Savr tomato lines transformed with vector pCGN4109 are as follows:
17 lines covered by US petition 95-030-01p: 35F-4109a-3023, 84F-4109a-148, 88F-4109a-2797, 121F-4109a-333, 121F-4109a-1071, 121F-4109a-1120, 137F-4109a-71, 138F-4109a-164, , 519A-4109a-4527, 519A-4109a-4621, 519A-4109a-4676, 531A-4109a-2105, 531A-4109a-2270, 532A-4109a-5097, 585A-4109a-3604, 585A-4109a-3530, 540A-4109a-1739**;**
1 line covered by US petition 96-248-01p: 532A-4109a-5166;
2 lines covered by US petition 95-179-01p: 519A-4109a-4645, 540A-4109a-1823;
9 lines covered by US petition 94-230-01p: (7 unknown lines) plus 114F-4109a-26, 114F-4109a-81**.**

Approvals

Canada

Approval Type	Date	Applicant
food	02/1995	Calgene

Japan

Approval Type	Date	Applicant
field production	04/1996	Calgene
second applicant Kirin Brewery, a food approval had been granted in 12/97, which was not renewed in 2001		
import	1996	Calgene
second applicant Kirin Brewery		

Mexico

Approval Type	Date	Applicant
field production	1995	Calgene
food/ feed	1995	Calgene

USA

Approval Type	Date	Applicant	Aphis Petition
field production	10/1992	Calgene	92-196-01p
for more information on GM crop regulation in the US see Annex			
field production	10/1994	Calgene	94-227-01p
approval extension of 92-196-01p, line N73 1436-111			
field production	11/1994	Calgene	94-230-01p
approval extension of 92-196-01p			
field production	03/1995	Calgene	95-030-01p
approval extension of 92-196-01p			
field production	07/1995	Calgene	95-179-01p
approval extension of 92-196-01p			
field production	10/1996	Calgene	96-248-01p
approval extension of 92-196-01p			
food	05/1994	Calgene	
no formal authorisation for food use, consultation process between FDA and developer (pre-market review)			

Event: ICI9, ICI13

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Increased shelf life	delayed softening		antisense polygalacturonase (PG A)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1996	Zeneca
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1996	Zeneca
second applicant Kagome		

Event: Japan tomato 1

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	tobacco mosaic virus (TMV)		coat protein - Tobacco Mosaic Virus (cpTMV)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1992	NIAES Planttech Research Institute
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1992	NIAES Planttech Research Institute
further applicants NIA, NARC		

Event: N°4-7

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Virus resistance	cucumber mosaic virus (CMV)		satelite RNA		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	2000	Hokkaido Nat. Agr. Station
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	2000	Hokkaido Nat. Agr. Station

torenia

Event: 1165, 1382

Event Characterisation

Transformation Method: unknown

Traits

Trait	Sub-Trait	SM	Gene	Promoter	Terminator
Altered flower colour	unspecified		dihydroflavonol-4-reductase (DFR)		
Altered flower colour	unspecified		chalcone synthase (CHS)		

Maps

No Map Information available.

Approvals

Japan

Approval Type	Date	Applicant
field production	1998	Florigene
commercial seed and field production is legal, but no authorization for marketing (food approval is needed)		
import	1998	Florigene
second applicant Suntory		

Annex I

Regulation of GM crops in the United States

In 1986 the White House Office of Science and Technology Policy (OSTP) published the "Coordinated Framework for Regulation of Biotechnology (CFRB)". (OSTP, 1986) It is still the key document for regulating gene technology in the United States and provides the basis for the regulation of crop varieties produced by recombinant DNA techniques. The document establishes the Biotechnology Science Coordinating Committee, and proposes three government agencies, the US Department of Agriculture (USDA), the Department of Health and Human Services (DHHS) and the Environmental Protection Agency (EPA), as lead agencies for the implementation of the technology policy. This sectoral regulatory approach, established by the CFRB, uses existing statutes in order to regulate products of recombinant DNA technology by their characteristics and not by their method of production. (see also CAST, 2001; Vogt and Parish, 1999) The regulatory trigger of the US regulation on transgenic crops is the "plant pest risk".

Regulatory oversight

US Department of Agriculture (USDA)/ Animal and Plant Health Inspection Service (APHIS)

The USDA/ APHIS is entrusted with the mandate to ensure the environmental safety of transgenic crops, to assess their plant pest risk potential under the Federal Plant Pest Act (FPPA) and the National Environmental Policy Act (NEPA) and to control their movement into and through the United States.

Food and Drug Administration (FDA)

The FDA is a department within the DHHS and has the primary responsibility for food and animal feed safety of transgenic crops and their products under the Federal Food, Drug and Cosmetic Act (FFDC).

Environmental Protection Agency (EPA)

The EPA shares with the FDA the responsibility for the evaluation of the risks to human health of transgenic plants. The agency regulates pest and virus resistant crops

as plant pesticides[3] under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is responsible for one, assessing adverse effects of these crops to humans, non-target organisms and the environment and two, setting tolerance levels for pesticidal substances and registrating them.

Commercialization of GM crops: approval process

The USDA/ APHIS oversees confined and unconfined release of transgenic plants as well as importation and interstate movement under the FPPA. In addition to FPPA, the USDA issued rules in 1987 for the "introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests". (USDA, 1987) By these rules, the introduction of a crop produced by recombinant DNA techniques into the environment is only legal with an authorization of the APHIS. APHIS grants a release permit after preparing an environmental impact assessment and "Finding Of No Significant Impact" ("FONSI"). Exempt from these rules are experiments with plants produced by recombinant DNA technology in a contained environment (e.g. laboratory, green house).

After gaining experience with the release of GM crops, the APHIS facilitated the approval process, in April 1993, by establishing an "expedited procedure" for **experimental release of GM crops** into the environment. (USDA, 1993) The procedure requests from organizations only the submission of a notification letter to APHIS, when the field tests involve, corn, cotton, potato, soybean, tobacco or tomato[4] and meet the following, summarized eligibility criteria:

- Crop must not be listed as noxious weed or weed in the testing region.
- Introduced genetic material must be stable and characterized.
- Introduced genetic materials
    - must not result in any plant disease
    - must not confer an infectious entity or encode toxic substances to non-target organisms,
    - must not encode products for intended pharmaceutical use.

[3] Confusion existed about the term „plant pesticide". Since EPA regulates only the pesticidal protein within the plant and not the plant itself, the term "plant incorporate protectant" is now used by the agency.

[4] Recently, additional crops have been added.

- Plant virus-derived sequences must not pose a significant risk for new plant virus creation.
- The GM crop must be free of known human and animal pathogens or allergens. (CAST, 2001)

Of all GM crop applications, 99%, made use of the notification process in 1998. (Vogt and Parish, 1999) The 1%, which do not meet the criteria of the process (mostly pharmaceutical-producing plants) need to go through an APHIS environmental assessment in order to obtain a release permit for one year.

In 1997, the USDA also simplified the procedure for **unconfined release of transgenic crops** into the environment by allowing the applicant to petition APHIS for a "determination of non-regulated status". (USDA, 1997). When receiving a petition, APHIS prepares an environmental impact assessment taking into account the eligibility criteria outlined above. After a complete petition is filed, it is being published in the Federal Register soliciting comments from the public. Thereafter APHIS reviews the data taking into account public comments and takes a final decision, which is announced in the Federal Register.

The issuance of a "non-regulated" status for a transgenic crop means that, it is deregulated and can be freely commercialized in the US (unconfined release, import, interstate movement) except if it contains a pesticidal substance. In that case, an additional "plant pesticide" approval by the EPA is required.

The responsibility of the EPA is to evaluate the risks of GM crops "producing their own pesticide" for **human consumption** under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The evaluation process is held to the same standards as for pesticides applied to plants. To be registered under FIFRA, a pesticide must not cause "unreasonable adverse effects" on the environment and on human health. (NRC, 2000) Transgenic insect and virus resistant plants fall under the jurisdiction of the EPA, whereby viral coat proteins are normally exempted from the requirements. The reason is, the EPA considers these proteins as "low risk applications" based on the principle of familiarity and their ubiquitous presence in the food supply. Today, Bt delta-endotoxins and one viral coat protein, the potato leaf roll virus protein, are registered as pesticides and supervised by the EPA. (CAST, 2001)

The agency evaluates the risks of these plant-incorporated protectants by taking into account the following criteria: toxicological effects, effects on non-target organisms, insect resistance management and persistence of the substance in the environment.

The evaluation process lasts approximately one year. If adverse effects of insect- or virus resistant plants are observed after commercialization, the EPA has the legal power to amend existing registrations. Moreover, the EPA may impose new measures such as new pest resistance schemes. (EPA, 2001a)

Besides the pesticide registration under FIFRA, Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) requires the EPA to determine tolerance limits for substances used as pesticides on and in food and feed. (EPA, 2001b; NRC, 2000) "Nucleic acids that are part of a plant-incorporated protectant" are exempted from this requirement, because the EPA considers them as "safe". (EPA, 2001b)

Once approvals from USDA/ APHIS and from EPA (when pesticidal substances are used) have been granted, it is legal to commercialize the genetically modified plant or product in the United States. However, applicants normally engage in a voluntary consultation process with the FDA, before marketing of the transgenic plant or plant products.

There is at the moment no legal obligation to consult with FDA on **food and feed safety** issues of transgenic crop, because first, the FDA views them as extension of conventional breeding methods and second, regulation on food commodities in the United States is based on the principle of "producer responsibility". That means, producers of novel foods have a legal duty to ensure that the foods they offer consumers are safe and in compliance with applicable legal requirements according to Section 402(a)(1) of the FFDC.

Nevertheless, developers of GM crops engage in a voluntary, but recommended consultation process with the FDA (voluntary pre-market review) to avoid food and feed safety risks. The FDA supports them in their safety assessment by providing the "Statement of Policy: Foods Derived From New Plant Varieties" guidelines and decision making outlines.

Product-derived risks, which the FDA discusses with developers of transgenic crops, are, beside others:

- Potential human toxicants in the host or donor species
- Potential food allergens
- Concentration and bioavailability of important nutrients
- Safety and nutritional value of the newly introduced protein

- Identity, composition and nutritional value of modified carbohydrates or fats/ oils. (DHHS, 1992)

Before commercializing a GM crop, producers normally submit a formal letter with a summary of data to FDA, and the agency will make its final recommendation in form of a memorandum.

Theoretically, the FDA could legally require a pre-market safety review from the producer prior to marketing of transgenic crops under the FFDC, but it is not practised because the agency views GM crops as "extensions at the molecular level of traditional [breeding] methods, which have a long history of safe use". (DHHS, 1992)

Only the Flavr Savr tomato had undergone a thorough safety assessment process under 21CFR 10.58 of the FFDC, because: one, it was the first GM crop, intended to be commercialised on large scale and two, the FDA guidelines on transgenic plants were not finalized at that time. (DHHS, 1992)

According to the FDA, today all developers of GM crops have voluntarily gone through the consultation process. However, the FDA seeks to strengthen its rules and announced in May 2000 that it is planning to introduce a mandatory pre-market notification procedure for all products. (FDA News, 2000) The agency might require to be notified by developers 120 days before the marketing of GM crops or products. In the 120 days, the FDA will review the notification, and then issue a letter on the regulatory status of the GM commodity. Moreover, the agency proposes to make the received information on the GM crop as well as FDA's conclusions on it available to the public. (DHHS, 2001)

Labelling

Labelling of food products also lies within the jurisdiction of the FDA. The FDA does notgenerally require labelling of genetically modified products, because as previously mentioned, the agency views transgenic plants as extension of conventional breeding methods. Thus, since the FDA has not considered labelling other methods of modern breeding, like enhanced mutagenisis or embryo rescue, it would not be consistent to label GM commodities.

Exceptions to this rule are crops transformed with genes from known allergens. These products need to be labelled to alert the population susceptible to the proteins in question.

Definition of genetically modified or transgenic crop

A simplified definition from regulation 7CFR340 on the regulated article is:
Crops altered or produced through genetic engineering which are plant pests or which there is a reason to believe are plants pests.

The full definition of the regulated article in 7CFR340 is:
"Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient micro-organisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions." (USDA, 1987)

Regulation of GM crops in Argentina

Argentina's legislative framework for regulating genetically modified organisms has been established in 1991. Like in the US, Argentine biosafety regulation follows a sectoral product-based approach. That means, several agencies are entrusted with the mandate to regulate GM crops and products and that the Argentine biosafety framework focuses on the characteristics of the novel product and not on the process of genetic engineering.
The GMO ordinance is based on the one hand on the existing agricultural regulatory system (e.g. for plant protection chemicals), on the other hand, GM crop specific regulation has been established to specify conditions for environmental release (Resolution N°289/97) or to assess food safety (Resolution N°511/98).
→ see also http://www.sagpya.mecon.gov.ar/12/ingles/Regulati.htm; http://www.sagpya.mecon.gov.ar/0-0/

Regulatory Oversight

The main body responsible for the assessment and approval of GM crops are the following the Agricultural Directorate of Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA) subordinated agencies:

- National Advisory Committee on Agricultural Biotechnology (CONABIA)
- National Service of Health and Quality Agrifood (SENASA)
- National Institute of Seeds (ex-INASE)

The National Directorate of AgriFood Markets (DNMA) assesses the potential impact that commercialisation of a GM crop might have on Argentina's export markets.

National Advisory Committee on Agricultural Biotechnology (CONABIA)
The National Advisory Committee on Agricultural Biotechnology (CONABIA) is the lead agency in charge of regulating GM crops. The Committee has been created in 1991 by Resolution N°124/91 of the Secretariat of Agriculture, Livestock and Fisheries (later expanded by Resolution N°669/93).
Jurisdiction and procedures of CONABIA are established in the following resolutions: N°s. 656/92, 837/93 and 289/97 (which is currently in force). (Burachik and Traynor, 2002)
→ see also http://www.sagpya.mecon.gov.ar/12/ingles/Regulati.htm, http://www.sagpya.mecon.gov.ar/0-0/
The Committee, comprising experts from the public and the private sector, is responsible for the assessment of confined and unconfined releases of GM crops into the environment and advises SAGPyA on the issuance of authorizations.

National Institute of Seeds (ex-INASE[5])
INASE is in charge of registering seeds and controlling their commercialization. GM seeds are treated similarly to seeds of new hybrids. Before a seed is registered, it must first undergo, two to three years of confined field releases. The role of INASE in the GM crop regulatory framework is to cooperate with CONABIA to ensure compliance with the Committee's rules concerning field releases.

National Service of Health and Quality Agrifood (SENASA)
SENASA, whose jurisdiction is established in Resolution N°289/87, is responsible for regulating the food safety and feed use of GM crops. The agency oversees the food safety process under Resolution N°511/98.

Commercialization of GM crops: approval process

When an organization intends to obtain an authorisation for commercialisation of a GM crop in Argentina, it has to pass a **3-step process**, which normally takes about two years.

[5] The National Seeds Institute (INASE) has been liquidated. (see http://www.biodiversidadla.org/noticias/noticias103.htm)

1. "Flexibilization" of testing conditions (in the responsibility of CONABIA), that means authorization for uncofined field trials
2. Food and feed safety review (in the responsibility of SENASA)
3. Market review (in the responsibility of DNMA)

(CONABIA, 2002a)

Prerequisites for entering the commercial evaluation process are: one, that "authorizations for experimentation and/or release into the environment of Genetically Modified Plant Organisms" have been granted (SAGPyA, 1997) and two biosafety has been adequately assessed by CONABIA. (Burachik and Traynor, 2002) When these conditions are met, as **first step** to commercialization, an authorisation for unconfined field trials, called "flexibilization", may be requested. (see Figure 89) "Flexibilized" conditions are for instance granted for the following purposes:

- For providing testing material
- for export
- for off–season seed multiplication (not for use in Argentina)
- for tests, which need to be presented at later stage (e.g.variety registration)
- for precommercial seed multiplication for a pending variety registration (Burachik and Traynor, 2002)

The deregulation of field testing conditions is dependent on the results of the biosafety assessment conducted by CONABIA with regard to the criteria laid down in resolution N°131/98, which include the characterization of the GMO (recipient organism, genetic modification, insert, donor organisms, phenotypic characterisation, potential environmental interactions of GMO) and the impacts expected from the production of the GM crop at commercial scale (environmental effects, impact on human health) (SAGPyA, 1998)
If SAGPyA (on the recommendation of CONABIA) authorizes "flexibilized" release conditions on the GM crop in question, the applicant only needs to submit information on the area to be sown, the date of sowing, the site of release and the harvest date. (SAGPyA, 1997) The flexibilization status of a GM crop allows large scale planting, but not planting for commercial purpose. Currently, maize DBT418, maize GA21, maize T14 and soybeans A2704-12/ A5547-127 have "flexibilization" status. (CONABIA, 2002a)

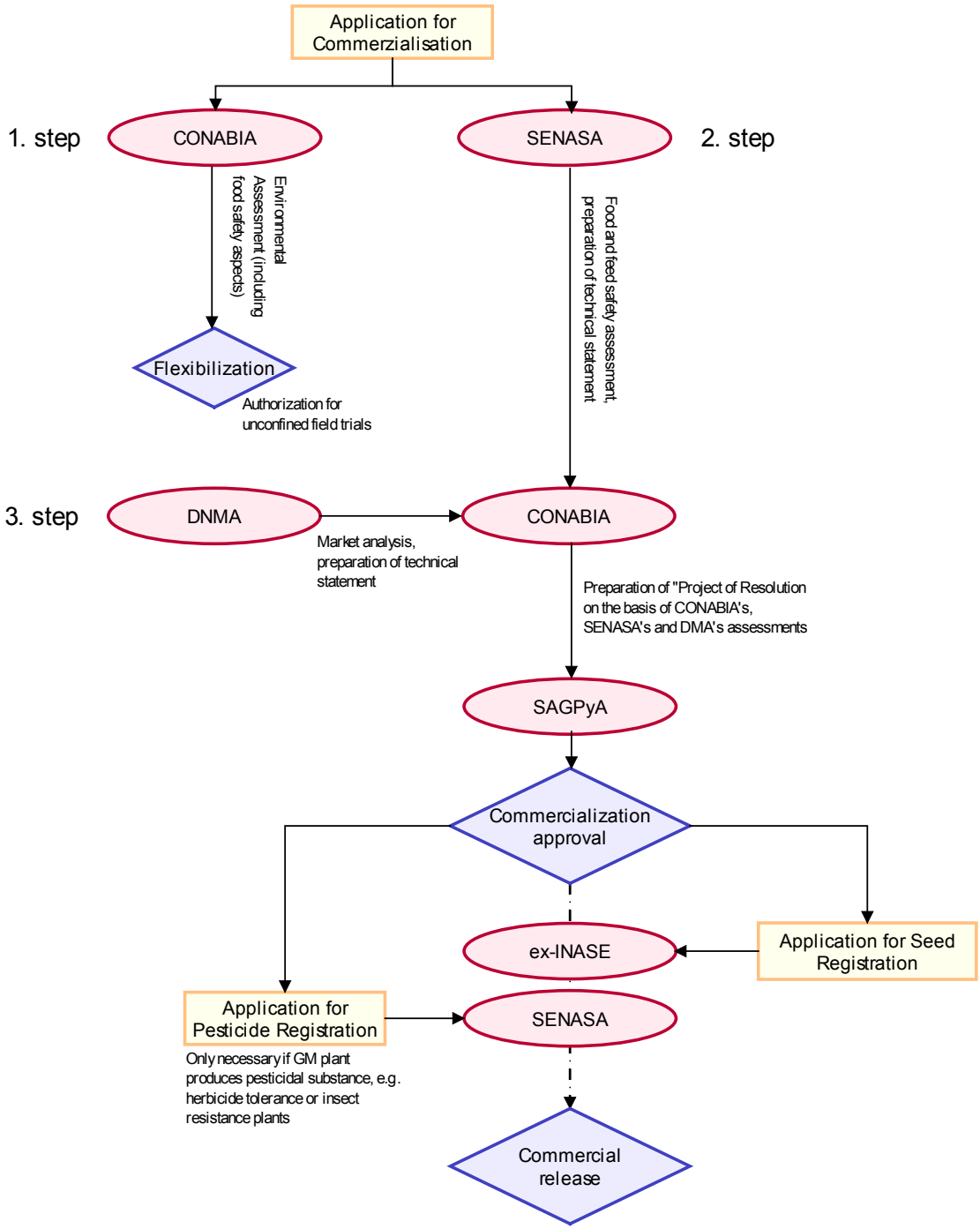


Figure 89: Steps to commerzialisation of genetically modified crops in Argentina

The first step is the flexibilization of testing conditions by CONABIA, the second a food and feed safety assessment by SENASA and the third a market assessment by DNMA. On the basis of the reviews of the agencies, COBABIA prepares a "Project of Resolution" serving SAGPyA as recommendation for issuing or denying authorization. Once a product has received a marketing permit, the applicant needs to apply for seed registration and if the crop contains pesticidal substances, a pesticide registration (as for conventionally bred plants). (Adapted from Commercial Release Approval Procedure, Burachik and Traynor, 2002)

The **second step** to commercialization is the evaluation of the safety of the GM crop for human consumption and feed. This evaluation is carried out by SENASA.
The grounds (laid down in Resolution N°511/98) requiring a food safety assessment are the following:

- Toxicity (of known toxicants and toxicants produced by protein expression)
- Allergenicity
- Nutritional modification and nutritional characterisation
- Modification of nutrients bio-availability

(CONABIA, 2002a)

In the **third step** of the commercialization process, the Directorate of Agri-Food Marketing (DMNA) assesses the impact of the GM crop in question on export market security.

After passing through these steps, CONABIA prepares a "Project of Resolution" on the basis of its own, SENASA's and DNMA's assessments and submits it to the SAGPyA, which takes the final decision on approval or denial of the commercialization request. (Burachik and Traynor, 2002)
The following GM crops have received commercialization status: maize 176, T25, Bt11 and Mon810, cotton 531 and 1445, and soybean GTS40-3-2. (CONABIA, 2002a)

Once a product is approved for marketing, requirements of the Department of Seeds (Ex-INASE) need to be met for registration of the GM seed in the National Cultivars Register and in the Taxation Scheme. (CONABIA, 2002a) GM crops expressing a herbicide tolerance or an insect resistance trait require a pesticide approval from SENASA for their commercial use. (Burachik and Traynor, 2002)

Labelling

No mandatory or voluntary labelling scheme has been established.

Definition of genetically modified organism

"Organisms in which any of the genes or other genetic material have been modified by means of the following techniques:

- the insertion by any method into a virus, bacterial plasmid or other vector system of a nucleic acid molecule, which has been produced by any method outside that virus, bacterial plasmid or other vector system, as to produce a

new combination of genetic material which is capable of being inserted into an organism in which that combination does not occur naturally and within which it will be heritable genetic material;

- the insertion into an organism, by micro-injection, macro-injection, micro-encapsulation or other direct means, of heritable genetic material prepared outside that organism; where they involve the use of recombinant DNA molecules in in vitro fertilisation that implies the genetic transformation of an eukaryotic cell."

(CONABIA, 2002b)

Annex II

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Glossary

1-amino-cyclopropane-1-carboxylic acid deaminase
1-aminocyclopropane-1-carboxylic acid deaminase,), an essential precursor for the biosynthesis of the plant hormone ethylene

1-amino-cyclopropane-1-carboxylic acid synthase
truncated coding region from the tomato Acc2 1-aminocyclopropane-1-carboxylate synthase gene. This endogenous enzyme is responsible for the conversion of s-adenosylmethionine to ACC, which is the immediate precursor of ethylene, a phytohormone known to play a key role in fruit ripening

2xP-nos
the tandem duplicate promoter region of the nopaline synthase gene

3"(9)-O-aminoglycoside adenylyltransferase
3"(9)-O-aminoglycoside adenylyltransferase; conveys (bacterial) resistance to streptomycin and spectinomycin

5' untranslated region
5' untranslated region from Cucumber Mosaic Virus RNA3

5'UT
see 5' untranslated region

aad
see 3"(9)-O-aminoglycoside adenylyltransferase

accd
see 1-amino-cyclopropane-1-carboxylic acid deaminase

AccS
see 1-amino-cyclopropane-1-carboxylic acid synthase

acetohydroxyacid synthase
also known as acetolactat synthase (ALS)

acetolactat synthase
a modified Acetolactate synthase gene from Arabidopsis thaliana

adh1 int.I
see alcohol dehydrogenase –1 intron I

adh1 int.VI
see alcohol dehydrogenase –1 intron IV

AHAS
see acetohydroxyacid synthase

alcohol dehydrogenase –1 intron I
the first intron from maize gene alcohol dehydrogenase –1

alcohol dehydrogenase –1 intron IV
the intron VI from the maize gene alcohol dehydrogenase –1

Alfalfa Mosaic Virus Leader
the Alfalfa Mosaic Virus leader

alpha-amylase inhibiter

ALS
see acetolactat synthase

AMV L.
see Alfalfa Mosaic Virus Leader

Ant
see anthocyan synthesis enzymes

antisense polygalacturonase
an antisense polygalacturonase gene (see PG), also called Flavr Savr gene

phosphoribosyltransferase
NtQPT1-A is the NtQPT1 gene in the antisense orientation. Its expression down-regulates the expression of endogenous NtQPT1 gene. NtQPT1 is Tobacco gene originally called TobRD2 which encodes QPTase (quinolinate phosphoribosyltransferase) a regulatory enzyme in the nicotine biosynthesis.

barnase
the barnase gene for male sterility, isolated from Bacillus amyloliquefaciens. The barnase gene encodes for a ribonuclease enzyme (RNAse) expressed only in the tapetum cells of the pollen sac during anther development. The RNAse affects RNA production, disrupting normal cell functioning and arresting early anther development, thus leading to male sterility.

barstar
the coding region of the barstar gene from B.amyloliquefaciens. The barstar gene encodes for a ribonuclease inhibitor (barstar enzyme) expressed only in the tapetum cells of the pollen sac during anther development. The ribonuclease inhibitor (barstar enzyme) specifically inhibits barnase RNAse. Together, the RNAse and the ribonuclease inhibitor form a very stable one-to-one complex, in which the RNAse is inactivated. As a result, when pollen from the restorer line is crossed to the male sterile line, the resultant progeny express the RNAse inhibitor in the tapetum cells of the anthers allowing hybrid plants to develop normal anthers and restore fertility.

BayTE
see thioesterase

beta-galactosidase
1) lacZ-alpha, the gene for the alpha region of beta-galactosidase under its bacterial promoter used for plasmid construction in E. coli. 2) lacZ: a partial lacI repressor coding sequence, the lac promoter and a partial coding sequence for β-galactosidase (lacZ) protein

beta-glucuronidase

gene encoding GUS (beta-glucuronidase) protein, a marker gene which is also called uidA

beta-lactamase
beta-lactamase gene; conveys resistance to beta-lactam antibiotics (e.g. penicillin, ampicillin);

bla
see beta-lactamase

ble
see bleomycin binding protein

bleomycin binding protein
Bleommycin binding protein from Tn5 forms homodimers that are capable of binding two molecules of bleomycin. It confers bleomycin resistance by binding the belomycin-iron complex, therby inhibiting the production of hydroxyl radicals that cause DNA and RNA cleavage. Bleomycin is a glycopeptide antibiotic that forms a complex with iron (Fe+2). In the presence of molecular oxygen, the bleomycin-iron complex causes nucleotide sequence specific DNA and RNA cleavage. It is this ability to cleave DNA and RNA which form the basis of bleomycin's antibiotic activity

cab22L
the gene leader sequence corresponding to the 5' untranslated region of the cab22R gene from Petunia

CDC
Centre of the University of Saskatchewan

ch.tp
see chloroplast transit peptide

chimeric S4-HrA
encodes an acetolactate synthase (ALS) enzyme from Nicotiana tabacum. This ALS enzyme is a resistant form of the similar enzyme present in all plants, bacteria and fungi, which allows the cotton plant to produce the essential amino acids in the presence of the sulfonylureas, and thereby confers resistance or tolerance to sulfonylurea herbicides.

chloroplast transit peptide
a chloroplast transit peptide sequence from small subunit of ribulose bisphosphate carboxylase of soybean

Chloroplast Transit Peptide 1
N-terminal chloroplast transit peptide sequence of the small subunit 1A ribulose-1,5-bisphosphate carboxylase gene from A. thaliana

Chloroplast Transit Peptide 2
N-terminal chloroplast transit peptide sequence derived from EPSPS gene of A. Thaliana

Chloroplast Transit Peptide 4
CHS
see chalcone synthase

CMV 5'
5' untranslated region from Cucumber Mosaic Virus coat protein gene (CMV cp) gene

CMV 5' (64nt)
64 nucleotides from the 5' untranslated region of the Cucumber Mosaic Virus coat protein gene (CMV cp) gene

CMV cp
see coat protein - Cucumber Mosaic Virus

CMV/PRV cp
see coat protein - Papaya Ringspot & Cucumber Mosaic Virus

CMV/WMV2 cp
see coat protein - Watermelon Mosaic Virus 2 & Cucumber Mosaic Virus

CMV/ZYMV cp
see coat protein - Zucchini Yellow Mosaic Virus & Cucumber Mosaic Virus

coat protein - Cucumber Mosaic Virus
Cucumber Mosaic Virus coat protein gene

coat protein - Papaya Ringspot & Cucumber Mosaic Virus
coat protein gene of Papaya Ringspot Virus (PRV) HA 5-1 which has codons specifying the first 16 amino acids of CMV coat protein at its N-terminus

coat protein - Potato Virus Y
coding region of the coat protein gene derived from Potato Virus Y strain O

coat protein - Watermelon Mosaic Virus 2 & Cucumber Mosaic Virus
coding region of the WMV2 cp gene fused to the 48 nucleotides from the 5' terminus of the CMV cp gene

coat protein - Zucchini Yellow Mosaic Virus & Cucumber Mosaic Virus
ZYMV cp coding region fused to the CMV cp translation initiation codon

ColE1-ori
the origin of DNA replication from E. coli high copy plasmid pUC19

CBI
confidential business information

cos
cos site of bacteriophage Lambda

CP4 5-enolpyruvylshikimate-3-phosphate synthase
5-enolpyruvylshikimate-3-phosphate synthase, isolated from Agrobacterium sp. (strain CP4)

CP4EPSPS
see CP4 5-enolpyruvylshikimate-3-phosphate synthase

CPB: Colorado Potato Beetle

cry1Ab delta-endotoxin
a synthetic version of the delta-endotoxin insecticidal protein, Cry1Ab, derived from

Bacillus thuringiensis subp. kurstaki strain HD-1. Delta-endotoxins, such as the cry1Ab, act by selectively binding to specific sites localized on the brush border midgut epithelium of susceptible insect species. Following binding, cation-specific pores are formed that disrupt midgut ion flow and thereby cause paralysis and death. Cry1Ab is insecticidal only to lepidopteran insects, and its specificity of action is directly attributable to the presence of specific binding sites in the target insects.

cry1Ac delta-endotoxin
a modified gene (cry1Ac) that encodes an insecticidal Cry1Ac delta-endotoxin protein, derived from the soil bacterium Bacillus thuringiensis subsp. kurstaki (B.t.k) strain HD-73. Insecticidal Delta-endotoxins, such as the Cry1Ac protein, exhibit highly selective insecticidal activity against a narrow range of lepidopteran insects such as cotton bollworm, tobacco budworm and pink bollworm. The specificity of action is directly attributable to the presence of specific receptors in the target insects.

cry1F delta-endotoxin
a synthetic version of truncated cry1F gene from Bacillus thuringiensis var.aizawai which produces a delta-endotoxin insect control protein Cry1F

cry2A delta-endotoxin
the modified cry2A gene (99.8% amino acid homology with B. thuringiensis kurstaki HD-1 gene referred to as cry2a gene)

cry2Ab delta-endotoxin
the synthtic cry2Ab gene based on sequence from B. thuringiensis subsp. Kurstaki. The cry2Ab protein provides protection against certain lepidopteran insects.

cry3A delta-endotoxin
cry3A gene, isolated from the common soil bacterium Bacillus thuringiensis subspecies tenebrionis (Btt). The delta-endotoxin Cry3A protein confers resistance to the larvae of coleopteran insects such as CPB, elm leaf beetle and yellow mealworm

cry3Ab delta-endotoxin
coding sequence for a synthetic variant of Cry3Bb1 Coleopteran-specific insecticidal protein from Bacillus thuringiensis subsp. Kumamotoensis. This delta-endotoxin protein confers resistance to the larvae of corn rootworm species

cry3Bb1 delta-endotoxin
coding sequence for a synthetic variant of Cry3Bb1 Coleopteran-specific insecticidal protein from Bacillus thuringiensis subsp. Kumamotoensis. This delta-endotoxin protein confers resistance to the larvae of corn rootworm species

cry9C delta-endotoxin
a chimeric modified insecticidal gene (cry9C.PGS2a). The chimeric gene cry9C.PGS2a encodes a protein which corresponds to insecticidal delta-endotoxin portion of the cry9C protein from Bacillus thuringiensis subsp. Tolworthi

CRW:
corn rootworm

CTP
DNA sequences from chloroplast transit peptides from A. thaliana

CTP1
see Chloroplast Transit Peptide 1

CTP2
see Chloroplast Transit Peptide 2

CTP4
see Chloroplast Transit Peptide 4

dam
see DNA adenine methylase

dapA
see dihydrodipicolinic acid synthase

delta-12 desaturase
codes for the enzyme, delta-12 desaturase, which is involved in fatty acid synthesis. Unlike conventional soybeans, the presence of a second copy of the GmFAD2-1 gene in the high oleic soybeans G94-1, G94-19 and G168 causes a phenomenon known as "gene silencing" which results in both copies of the fatty acid desaturase gene being "switched off". This blocks the fatty acid biosynthetic pathway and results in the accumulation of oleic acid. As a consequence, polyunsaturated fatty acids (linoleic acid and linolenic acid) are only produced in very small amounts

DFR
see dihydroflavonol-4-reductase

dihydrodipicolinic acid synthase
the Corynebacterium dap A gene encoding for the enzyme dihydrodipicolinic acid synthase (DHDPS)

dihydroflavonol-4-reductase
DNA adenine methylase
gene encoding DNA adenine methylase from E. coli

dP-35s
double 35s promoter, promoter region from Cauliflower Mosaic Virus. The double (d) represents a duplicated region in the promoter

Enhancer Octopine Synthase
octopine synthase enhancer from A. tumefaciens Ti plasmid, pTiACH5. The upstream region of the octopine synthase promoter which enhances gene expression from downstream promoters

E-OCS

see Enhancer Octopine Synthase

fl bacteriophage origin of replication
fl bacteriophage origin of replication from phagemid pBluescriptSK(-)

Fl(-) ori
see fl bacteriophage origin of replication

gene III fragment
M13 gene III fragment (component of the viral coat)

gentamycin
gentamycin resistance gene

gentR
see gentamycin

glyphosate oxidoreductase
it encodes the enzyme glyphosate oxidase (GOX) from the bacterium Ochrobactrum anthropi. The function of the glyphosate oxidase enzyme is to metabolise glyphosate (N-phosphonomethylglycine), the active ingredient in Roundup herbicide, to an inactive form. This degradation effectively inactivates the herbicide and enables the transgenic plant to grow when treated with Roundup herbicide.

glyphosate oxidoreductase 247
a variant of gox gene. It is isolated from Ochrobactrum anthropi strain LBAA. Protein Gox and the Gox247 of the same enzyme are 99% identical.

GmFAD2-1
see delta-12 desaturase

gox
see glyphosate oxidoreductase

gox247
see glyphosate oxidoreductase 247

GUS
see beta-glucuronidase

heat-shock protein 17.9 kD leader sequence
heat-shock protein 17.9 kD leader sequence from Glycine max

heat-shock protein 70
intron from the hsp70 gene (heat-shock protein) present to increase the levels of gene transcription

hsp17.9
see heat-shock protein 17.9 kD leader sequence

hsp70
see heat-shock protein 70

int.9
see intron 9

intervening sequence 2
intron derived from the maize gene adh1 (alcohol dehydrogenase-1S gene)

intervening sequence 6
intron derived from the maize gene adh1 (alcohol dehydrogenase-1S gene)

intron 9
sequence containing the number 9 intervening sequence from the corn phosphoenolpyruvate carboxylase gene

IVS 2
see intervening sequence 2

IVS 6
see intervening sequence 6

lac
see beta-galactosidase

lacZ'
the untranslated lacZ polylinker sequence

LB
see Left border

Left border
Left Border

maize 5-enolpyruvylshikimate-3-phosphate synthase
a modified form of wild type 5-enolpyruvyl-3-phosphoshikimate synthase gene from Zea mays which encodes an insensitive enzyme to inactivation by glyphosate

mEPSPS
see maize 5-enolpyruvylshikimate-3-phosphate synthase

neomycin phosphotransferase
aminoglycoside (3') phosphotransferase type II gene from E.coli transposon Tn5 (or Kanamycin resistance gene). The NPTII enzyme coded by this gene confers resistance to selected aminoglycoside antibiotics and is used as a plant selectable marker. It is also called kanamycin resistance gene

nitrilase
also called oxy or BXN: gene isolated from K. pneumoniae subspecies ozaenae encoding the enzyme nitrilase, which hydrolyses ioxynil and bromoxynil into non-phytotoxic compounds

nopaline synthase
nos is considered as obsolete marker (FDA Memo)

nos
see nopaline synthase

nptII
see neomycin phosphotransferase

NtQPT1-A
see Antisense quinolinate phosphoribosyltransferase

ocd fragment
see ornithine cyclodeaminase fragment

ori
see origin of replication

ori322
E.coli origin of replication which ensures replication in E. coli

ori322
see ori322

ori322/rop
a segment of pBR322 which provides the origin of replication, the replication of primer (rop) region and the bom site for the conjugational transfer into the A. tumefaciens cells

origin of replication
origin of replication

ori-M13
origin of replication of the M13 bacteriophage

ori-pUC
Sequence containing the origin of replication for the pUC plasmids that allows for plasmid replication in E. coli

oriT
pRK2 origin of conjugative transfer

oriV
origin of replication for ABI Agrobacterium derived from the broad-host range plasmid RK2

ornithine cyclodeaminase fragment
ocd gene fragment. A 209 bp internal fragment of the ornithine cyclodeaminase (ocd) gene of A. tumefaciens Ti plasmid, which is responsible for the catabolism of nopaline.

OTP
N-terminal chloroplast transit peptide (CTP) sequences based on the CTP sequences from the Helianthus annus and Zea mays RuBisCo genes (sssu CTP and mssu CTP)

P-2xOCS,35s
a chimeric promoter consisting of the OCS enhancer element derived from A. tumefaciens, in inverse orientation, coupled to a 90 bp fragment of 35s from CaMV

P-35s
a promoter derived from the Cauliflower Mosaic Virus

P-4AS1
promoter containing four tandem copies of AS1 (activating sequence 1) and a single portion of 35s promoter from cauliflower mosaic virus

P-5126del
a modified Z. mays anther specific promoter

P-ALS
tobacco ALS1 promoter

P-CBI
The promoter region in this cassette is considered as confidential business information

P-E35s
the 35s promoter from the cauliflower mosaic virus with the duplicated enhancer region

P-E8
ethylene responsive gene promoter

P-FMV
a promoter derived from Figwort Mosaic Virus (FMV)

PG
see polygalacturonase

PG A
see antisense polygalacturonase

P-HelSsu
the promoter RuBisCo SSU (ribulose-1,5-bisphosphate carboxylase small subunits1A) from Helianthus annuus

phosphinothricin acetyltransferase (bar)
gene from S.hygroscopicus encoding phosphinothricin acetyltransferase. It confers tolerance to the phosphinothricin herbicides (Liberty®). The bar gene encodes a phosphinothricin acetyl transferase (PAT) enzyme. The active ingredient in phosphinothricin herbicides is glufosinate ammounium which acts by inhibiting the plant enzyme glutamine synthase, leading to the accumulation of phytotoxic levels of ammonia killing the plant within hours of application. PAT detoxifies glufosinate ammonium by acetylation into an inactive compound, eliminating its herbicidal activity. The bar gene can be used as a selectable marker gene.

phosphinothricin acetyltransferase (PAT)
gene coding for a phosphinothricin acetyltransferase from Streptomyces viridochromogenes; homologue to bar

pinII
see potato genomic DNA fragment

P-Kti3
Kunitz trypsin inhibitor 3 (Kti 3) promoter

PL
synthetic polylinker sequence

Pleiotropic effects
or pleiotropy means that more than one change occurs in a plant as a result of the new gene expression, due to functional interactions of foreign gene with host genes

Plant Genome
plant genomic DNA

PLRVrep
see potato leaf roll virus replicase

P-mac
P-mas and P-35s hybrid

P-mas
promoter region of mannopine synthase gene of pTiA6

PMc5-8
sequence derived from pMc5-8

P-napin

the promoter of the nopamin gene from Brassica rapa which functions in developping seeds

P-nos
promoter region of the nopaline synthase gene

P-NtQPT1
NtQPT1 promoter

polygalacturonase
truncated PG gene.Transcription of PG gene fragment results in the inhibition of endogenous PG enzyme. it is derived from a tomato (Lycopersicon esculentum Mill. Variety Ailsa Craig) and encodes the enzyme polygalacturonase (PG) gene. PG is a key enzyme in fruit ripening. It accumulates only during ripening due to de novo synthesis of the enzyme. It is responsible for the breakdown of pectin molecules in the cell walls of tomato fruit. Pectin is a large polymer consisting of polygalacturonic acid residues to which rhamnose residues are attached at irregular intervals. Pectin is largely insoluble in green fruit. During ripening, the average size of pectin molecules significantly decreases with a coincident increase in soluble polygalacturonic acid molecules. The structure of pectin in tomatoes is a key determinant of tomato fruit texture and of the rheological characteristics of processed products. PG catalyses the cleavage of pectin chains by hydrolysis of bonds between adjacent galacturonic acid residues. Tomato fruit contains three related isoformes of endopolygalacturonase (PG1, PG2a, and PG2b), all products of a single PG gene. Purified PG isozymes were shown to degrade tomato cell walls in vitro and to reproduce cell wall softening changes that occur during natural ripening

Position effects
the influence of the location of a gene (particularly a transgene) on its expression

potato genomic DNA fragment
a potato DNA containing 18 bp untranslated leader, pinII protein coding region with intron and about 920 bp of 3' sequence (3' untranslated region of the RNA and putative transcription termination region), which encodes for a protease inhibitor.

potato leaf roll virus replicase
the full-length ORF1 and ORF2 from Potato Leaf Roll Virus (PLRV), which encode a fusion protein having both helicase and RNA-dependent RNA polymerase activity.

P-PCA55
the promoter region of the anther specific gene CA55 from Zea mays

P-PCDK
the promoter derived from a corn calcium-dependent protein kinase (CDPK) gene that is exclusively expressed in pollen

P-PEPC
green tissue-specific phosphoenolpyruvate carboxylase (PEPC) promoter from corn

P-Ptac
bacterial Ptac promoter

P-ract
5' region of the rice actin 1 gene containing the promoter and first intron

P-Ssu
(also called P-SsuAra): the A. thaliana ribulose-1,5-bisphosphate carboxylase small subunits1A promoter

P-TA29
the promoter region of anther-specific gene TA29 from Nicotiana tabacum

P-ubiZM1(2)
the ubiquitin promoter plus ubiquitin intron and a 5' untranslated region from Zea mays

pUC18
Sequence of high copy E.coli plasmid pUC18 used for cloning of DNA sequences

pUC19
DNA sequences from pUC19

PVYcp
see coat protein - Potato Virus Y

P-β-Conglycinin
seed-specific promoter derived from the ά-subunit of the Glycine max β-Conglycinin gene

R.S.
see Residual sequence

ract 1 int
the first intron from the rice actin 1 gene which enhances DNA transcription

RB
see Right Border

Residual sequence
residual sequence from B.amyloliquefaciens situated downstream of the barnase gene.

Right Border
Right Border

RuBisCO
see RuBisCO small subunit gene enhancer

RuBisCO small subunit gene enhancer
a non-translated leader of a RuBisCO small subunit gene derived from Maize

S-adenosylmethionine hydrolase
modified S-adenosylmethionine hydrolase gene derived from E. coli bacteriophage T3 that encodes an enzyme, S-adenosylmethionine hydrolase (SAMase)

sam-k
see S-adenosylmethionine hydrolase

satelite RNA

spcR/strR
see spectinomycin/streptomycin

spectinomycin/streptomycin
spectinomycin/streptomycin resistance marker gene (probably aad gene)

T-7S
the 3' untranslated region of the soybean alpha subunit of the beta-Conglycinin gene

T-ALS
tobacco ALS1 terminator

T-barstar
Bacillus amyloliquefaciens sequences following barstar coding region

T-E9
the 3' non-translated region of the pea ribulose-1,5-bisphosphate carboxylase small subunit E9 gene

tetR
see tetracyclin

tetracyclin
tetracycline resistance gene, a marker gene

T-g7
the 3' untranslated end of the TL-DNA gene 7

thioesterase
the 12:0 acyl carrier protein (ACP) thioesterase gene which codes for an enzyme in the fatty acid biosynthetic pathway found in developping seeds

Ti Plasmid DNA
a segment of DNA from the octopine Ti-plasmid, pTiA6. The DNA was isolated from a region upstream of the T-DNA gene 5. It contains no promoter signals for the gene 5 nor any portion of the coding region of the gene 5

T-Kti3
Kunitz trypsin inhibitor 3 (Kti 3) terminator

T-mas
polyadenylation region from mannopine synthase gene of pTiA6

T-napin
the terminator of the napin gene

T-nos
the 3' non-translated region of the nopaline synthase gene

T-ocs
terminator of the octopine synthase gene

T-ORF25
a terminator from A. tumefaciens

T-phaseolin
a 3' fragment from the phaseolin gene of green bean

T-pinII
terminator sequence from Selanum tuberosum proteinase inhibitor II gene

T-SSU
the 3' untranslated region from the G. max ribulose-1,5-bisphosphate carboxylase small subunit gene

T-tahsp 17
3' untranslated region of the coding sequence for wheat heat shock protein 17.3

T-tml
polyadenylation region of tml gene from pTiA6

T-Tr7
the 3' region from A. tumefaciens T-DNA transcript 7

T-tr7 (segment)
the 3' region from A. tumefaciens T-DNA transcript 7

Wt CAB
5' untranslated leader of the wheat chlorophyll a/b-binding protein that facilitates mRNA translation

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