SUMMARY NOTIFICATION INFORMATION FORMAT (SNIF) FOR PRODUCTS CONTAINING GENETICALLY MODIFIED HIGHER PLANTS (GMHP)

Table of contents

List of Tables

List of Figures

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A. GENERAL INFORMATION

1. Details of notification

(a) Member State of notification : Germany

(b) Notification number : C/DE/02/9

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

This application under Directive 90/220/EEC and anticipating Directive 2001/18/EC is for import into the European Union, and use therein, of grain and grain products from MON 863 and MON 863 x MON 810 maize. The proposed uses of this maize will be the same as for any other maize, but do not include the cultivation of varieties in the E.U.

(d) Date of acknowledgement of notification:

2. Notifier

(a) Name of notifier : Monsanto Company represented by Monsanto Europe S.A.

(b) Address of notifier :

Monsanto Europe S.A.
270-272 Avenue de Tervuren
B-1150 Brussels
BELGIUM

Monsanto
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
USA

(c) Is the notifier : domestic manufacturer : [X]
importer : [ ]

(d) In case of import the name and address of the manufacturer should be given

Not relevant

3. General description of the product

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

To produce MON 863 maize, a DNA sequence encoding i) a Cry3Bb1 protein variant, MON 863 Cry3Bb1 protein, which confers protection to certain coleopteran insects and ii) the NPTII protein (neomycin phosphotransferase II) which provides resistance towards kanamycin for maize plant cell selection purposes, was inserted into maize cells by particle bombardment.

For MON 863 x MON 810 maize, conventional maize breeding methods have been used to cross the progeny of MON 810 maize (obtained by the introduction of a DNA sequence encoding a Cry1Ab protein, which confers protection to certain lepidopteran insects into maize cells) with the progeny of MON 863 maize.

(b) Any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for

This application includes the importation in the European Union and use therein of grain and grain products from MON 863 and MON 863 x MON 810 maize and excludes maize varieties and forage derived from MON 863 and MON 863 x MON 810 maize. Therefore, varieties from MON 863 and MON 863 x MON 810 maize must not be placed on the market.

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

There are no specific differences when MON 863 and MON 863 x MON 810 maize are compared to conventional maize except for their protection, respectively, against certain Coleoptera and Coleoptera/Lepidoptera. MON 863 and MON 863 x MON 810 maize have been shown to be substantially equivalent, with exception of the introduced traits, to maize currently in commerce and therefore, the proposed uses and the types of users for grain and maize products derived from MON 863 and MON 863 x MON 810 maize are identical to those for grain and maize products derived from conventional maize.

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

MON 863 and MON 863 x MON 810 maize have been demonstrated to be substantially equivalent to other maize, apart from their protection against certain coleopteran and coleopteran/lepidopteran insect pests. No specific instructions or recommendations for use, storage or handling of grain or derived products from this maize are envisaged.

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

Grain and derived products of MON 863 and MON 863 x MON 810 maize are intended for use throughout the E.U. for the purposes specified in the application.

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

This application is for import into the E.U., and use therein, of grain and grain products from MON 863 and MON 863 x MON 810 maize and is for use as any other maize grain.

(g) Any proposed packaging requirements

MON 863 and MON 863 x MON 810 maize have been shown to be substantially equivalent to other maize varieties. Therefore, MON 863 and MON 863 x MON 810 maize grain or derived products will be used in the same manner as with other maize and no specific packaging is foreseen.

(h) Any proposed labelling requirements in addition to those required by law

The grain and derived products of MON 863 and MON 863 x MON 810 maize could be imported into the European Union from a number of world areas, including Africa, The Americas, Asia and Central and Eastern Europe. In accordance with the requirements of Directive 2001/18/EC, repealing Directive 90/220/EEC on 17 October 2002, Monsanto will undertake a number of measures to ensure that international traders are provided with the necessary information to comply with statutory requirements relating to the placing on the market of MON 863 and MON 863 x MON 810 maize grain.

In particular, Monsanto will:

a) Inform European and International traders of the approval for import into the European Union of MON 863 and MON 863 x MON 810 maize grain that this product is a genetically modified organism and that MON 863and MON 863 x MON 810 maize grain may be present in bulk shipments of maize grain. To that effect the words "Contains genetically modified organisms" shall appear either on a label or in an accompanying document to the maize grain shipment

b) Provide all traders with the commercial name of the product, any agreed European and/or international unique identifier (see question **3.(j)**) replacing the current unique code (MON 863, MON 863 x MON 810) and any other relevant product information, including procedures for accessing the European public registers of GM organisms

c) Advise all traders, and other operators using the product, that MON 863and MON 863 x MON 810 maize grain is subject to the traceability and labelling requirements of Directive 2001/18/EC and to the requirements of any Community legislation adopted to regulate the traceability and labelling of GM organisms.

It should be noted that other genetically modified maize products have been approved for import into the European Union and that MON 863 and MON 863 x MON 810 maize may be marketed in the European Union in mixture with these previously approved maize products.

(i) Estimated potential demand

(i) in the Community

In 2001, total production of maize within the fifteen countries comprising the E.U. was estimated at 38.86 million tonnes. The largest producers being France and Italy. However, the production of MON 863 and MON 863 x MON 810 maize is not intended in the E.U.

Imports of maize from outside the E.U. including maize grain is about 2.5 million tonnes.

(ii) in export markets for EC supplies

Not relevant

(j) **Unique identification code(s) of the GMO(s)**

This application under Directive 90/220/EEC, anticipating Directive 2001/18/EC is for import into the European Union and use therein MON 863 and MON 810 x MON 863 maize, the latter being produced by traditional breeding of two genetically modified inbred lines, one derived from MON 810 event and the other one derived from MON 863 event. The unique identifiers for MON 863, MON-ØØ863-5 and MON 810, MON-ØØ810-6 have been attributed based on the guidance for the designation of a unique identifier for transgenic plants developed by OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology. For MON 863 x MON 810, a combination of those two unique identifiers will be used.

4. ***Has the GMHP referred to in this product been notified under part B of Directive 2001/18/EC and/or Directive 90/220/EEC ?***

Yes [ ] No [X]

If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC

See following sections.

5. ***Is the product being simultaneously notified to another Member State ?***

Yes [ ] No [X]

If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC

See following sections.

OR

Has the product being notified in a third country either previously or simultaneously ?

Yes [X] No [ ]

If yes, please specify

Canada, Japan and USA

6. ***Has the same GMHP been previously notified for marketing in the Community ?***

Yes [ ] No [X]

7. ***Measures to take in case of unintended release or misuse as well as measures for disposal and treatment***

Maize is not an invasive plant because it is a weak competitor outside cultivation. For this reason, volunteer maize is not found in non-crop situations, for example, in fence or hedgerows, ditches, and roadsides. It is highly unlikely, therefore, that any grain disseminated into the environment would pose any threat to the environment. In the unlikely event of establishment, volunteer plants could be easily controlled by currently available selective herbicides (e.g. fluazifop-p-butyl) or by mechanical

means. Therefore no specific measures are recommended in case of unintended release of MON 863 and MON 863 x MON 810 maize.

Misuse of the imported grain as seed remains extremely unlikely since 1) only certified hybrid maize seed can be marketed in the E.U. and 2) the (F2) grain, coming from open-pollinated production fields, will not have the agronomic yield potential and homogeneity of true F1 hybrid seed.

The measures for waste disposal and treatment for MON 863 and MON 863 x MON 810 maize products are the same as those for other maize products.

B. NATURE OF THE GMHP CONTAINED IN THE PRODUCT

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

8. Complete name

(a) Family name : Gramineae

(b) Genus : *Zea*

(c) Species : *mays* (2n = 20)

(d) Subspecies : Not applicable

(e) Cultivar/breeding line : specifically, the maize plant tissue that was the recipient of the introduced DNA was a cell culture designated AT824, initiated from immature embryos of an inbred maize line (AT)

(f) Common name : Maize; Corn

9. **(a) Information concerning reproduction**

(i) Mode(s) of reproduction

Maize (*Zea mays)* reproduces sexually, is a wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers, which encourages natural pollination between maize plants. Wind movements across the maize field cause pollen from the tassel to fall on the silks of the same or adjoining plants. Self-pollination leads to homogeneity of the genetic characteristics within a single plant while cross-pollination combines the genetic traits of many plants.

(ii) Specific factors affecting reproduction, if any

Tasselling, silking, and pollination are the most critical stages of maize development and, consequently, grain yield may ultimately be greatly impacted by moisture and fertility stress. Under conditions of high temperature and desiccation, maize pollen viability is measured in minutes; these conditions may even destroy the tassel before any viable pollen is shed. More moderate conditions can extend the field life of pollen to hours.

(iii) Generation time

Maize is an annual crop with a cultural cycle ranging from as short as 60 to 70 days to as long as 43 to 48 weeks from seedling emergence to maturity.

(b) Sexual compatibility with other cultivated or wild plant species

Out-crossing with cultivated *Zea* varieties

Maize is wind pollinated, and the distance that viable pollen can travel depends on prevailing wind patterns, humidity, and temperature. All maize will inter-pollinate, except for certain popcorn varieties and hybrids that have one of the gametophyte factors (Ga^S, Ga, and ga allelic series on chromosome 4). Maize pollen, therefore, moves freely within an area, lands on silks of the same variety or different varieties, germinates almost immediately after pollination, and within 24 hours completes fertilisation.

Out-crossing with wild *Zea* species

Annual teosinte (*Zea mays* ssp. *Mexicana*, formerly *Euchlaena mexicana*) (2n = 20) and maize (*Zea mays L.*) (2n = 20) are wind pollinated, tend to out-cross, and are highly variable, interfertile subspecies. A frequency of one F1 hybrid (maize x teosinte) for every 500 maize plants or 20 to 50 teosinte plants in the Chalco region of the Valley of Mexico was reported. Out-crossing and gene exchange between teosinte and maize occur freely, and, accompanied by selection, teosinte had a significant role in the evolution of maize.

Teosinte, however, is not present in either Europe or the U.S. "Corn Belt". The natural distribution of teosinte is limited to the seasonally dry, subtropical zone with summer rain along the western escarpment of Mexico and Guatemala and the Central Plateau of Mexico.

Tripsacum species are perennials and seem to be more closely related to the genus *Manisuris* than to either maize or teosinte. Special techniques are required to hybridise maize and *Tripsacum*. Except for *Tripsacum floridanum*, it is difficult to cross *Tripsacum* with maize, and the offspring of the cross show varying levels of sterility.

Tripsacum-maize hybrids have not been observed in the field and *Tripsacum*-teosinte hybrids have not been produced.

10. Survivability

(a) Ability to form structures for survival or dormancy

Maize is an annual crop and seeds are the only survival structures. Natural regeneration from vegetative tissue is not known to occur.

(b) Specific factors affecting survivability, if any

Maize cannot survive without human assistance and is not capable of surviving as a weed due to past selection in its evolution. The appearance of maize in rotational fields following the maize crop from the previous year is rare under European conditions. Maize volunteers are killed by frost or easily controlled by current agronomic practices including cultivation and the use of selective

herbicides. Temperatures above 45°C have also been reported as injurious to maize seed viability.

11. Dissemination

(a) Ways and extent of dissemination

Dissemination may occur by means of seed and pollen dispersal. Although pollen might be spread over long distances, maize pollen viability is highly dependent on temperature and desiccation.

(b) Specific factors affecting dissemination, if any

In contrast to weedy plants, maize has a polystichous female inflorescence (ear) on a stiff central spike (cob) enclosed in husks (modified leaves). Consequently, seed dispersal of individual kernels does not occur naturally because of the structure of the ears of maize. Seed dissemination is impacted by mechanical harvesting and transport as well as insect or wind damage, all of which may cause some mature ears to fall to the ground, where they could remain un-harvested.

Genetic material can be disseminated by pollen movement. Pollen dispersal is influenced by wind and weather conditions. Measuring about 0.1 mm in diameter, maize pollen is the largest of any pollen normally disseminated by wind from a comparably low level of elevation. Dispersal of maize pollen is influenced by its large size and rapid settling rate.

12. Geographical distribution of the plant

Maize, because of its many divergent types, is grown over a wide range of climatic conditions. The bulk of the maize is produced between latitudes 30° and 55°, with relatively little grown at latitudes higher than 47° latitude anywhere in the world. The greatest maize production occurs where the warmest month isotherms range between 21 and 27° C and the freeze-free season lasts 120 to 180 days. A summer rainfall of 15 cm is approximately the lower limit for maize production without irrigation with no upper limit of rainfall for growing maize, although excess rainfall will decrease yields and increase the chance of fungal infection.

13. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

Maize is widely grown in the European Union and represents a significant portion of global maize production. Significant areas of maize production in Europe include the Danube Basin from southwest Germany to the Black Sea along with southern France through the Po Valley of northern Italy.

14. Potentially significant interactions of the plant with other organisms in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms

There are no known toxic effects of the maize plant to humans, animals or livestock; it has a history of safe use for human food and animal feed. However, maize is known to interact with other organisms in the environment including insects, birds, and mammals. It is susceptible to a range of fungal diseases and nematode, insect and mite pests.

15. *Phenotypic and genetic traits*

Maize (*Zea mays)* is a wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers, which encourages the natural out-crossing between maize plants. Self-pollination leads to homogeneity of the genetic characteristics within a single plant while cross-pollination combines the genetic traits of many plants. This inbred-hybrid concept and resulting yield response is the basis of the modern seed maize industry.

INFORMATION RELATING TO THE GENETIC MODIFICATION

16. *Description of the methods used for the genetic modification*

MON 863 and MON 810 maize were modified by incorporation of a DNA fragment derived, respectively, from plasmid vectors PV-ZMIR13 and PV-ZMBK07 into the maize genome using a particle acceleration method.

MON 863 x MON 810 maize has been obtained by conventional breeding of MON 863 and MON 810 maize lines.

17. *Nature and source of the vector used*

The vector used to amplify the DNA fragment which was introduced in MON 863 is composed of a pUC plasmid replication origin associated with a selectable marker, *nptII*. The functions carried by the vector are required to allow its maintenance and amplification in *E.coli* bacterial cells. Like the original pUC vectors, this vector does not contain transfer origins, *i.e.*, sequences allowing transfer from bacteria to bacteria.

The vector used for the genetic modification of MON 810 maize was described in the application pursuant to Council Directive 90/220/EEC [Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (98/294/EC - Official Journal of the European Communities, L 131/32 of May 05, 1998)].

MON 863 x MON 810 maize has been obtained by conventional breeding of MON 810 and MON 863 maize lines and no vector has been used to produce this maize hybrid.

18. *Size, source [name of donor organism(s)] and intended function of each constituent fragment of the region intended for insertion*

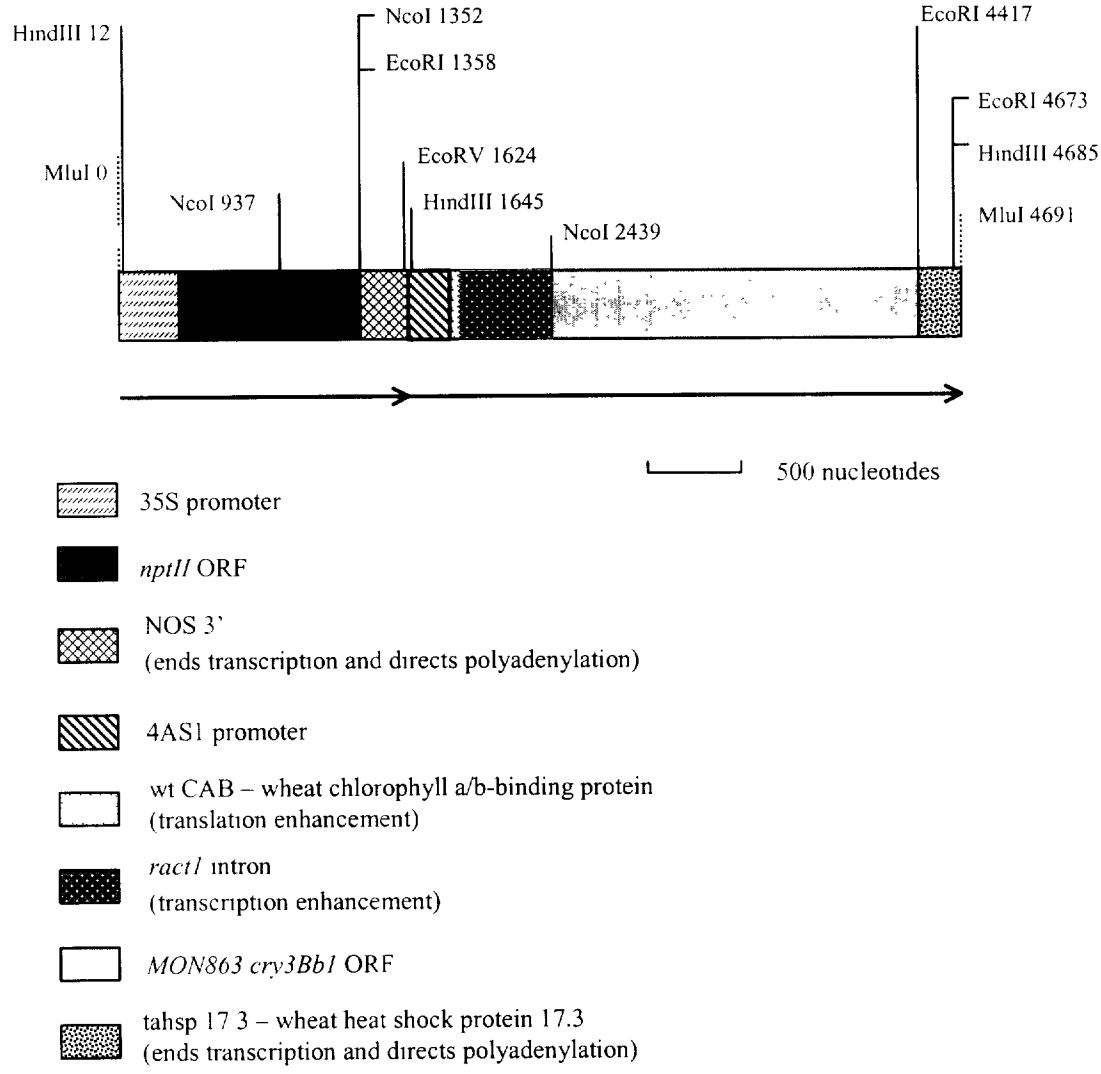
The transformation fragment PV-ZMIR13L contained the two genes to be introduced in the plant cells, *i.e.*, the chimeric *cry3Bb1* gene (encoding the agronomic trait) and the *nptII* gene (selectable marker) designed to be expressed in the maize cells.

The expression cassettes (see Table 18.1. and Figure 18.1.) corresponding to these two genes consist of respectively:
i) the *nptII* ORF regulated by the 35S promoter, and the NOS 3' polyadenylation sequence and ii) a *cry3Bb1* open reading frame (ORF) regulated by the 4-AS1 plant promoter and the wtCAB leader, rice actin intron and tahsp17 3' polyadenylation sequence.

Table 18.1. : Elements of the transformation fragment PV-ZMIR13L

Sequence	Size (Kb)	Source	Function
MON 863 cry3Bb1 gene cassette			
4AS1	0.22	Cauliflower Mosaic Virus (CMV)	Promoter
wt CAB	0.06	Wheat (*Triticum aestivum*)	Enhances translation
ract1 intron	0.49	Rice (*Oryza sativa*)	Enhances transcription
MON 863 cry3Bb1	1.96	*Bacillus thuringiensis* subsp. *kumamotoensis*	ORF encoding resistance to corn rootworm
tahsp 17 3'	0.23	Wheat (*Triticum aestivum*)	Ends transcription and directs polyadenylation
Selectable marker elements			
35 S	0.32	Cauliflower Mosaic Virus (CMV)	Promoter
nptII	0.82	*E. coli*	ORF allowing plant cell selection
NOS 3'	0.26	*Agrobacterium tumefaciens*	Ends transcription and directs polyadenylation

Figure 18.1. : Map of the transformation fragment PV-ZMIR13L



Information related to MON 810 maize is summarised in the Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (98/294/EC- Official Journal of the European Communities, L 131/32 of May 05, 1998).

MON 863 x MON 810 maize has been obtained by conventional breeding of MON 810 and MON 863 maize lines and no additional vector has been used to produce this maize hybrid (see transformation of parental lines).

INFORMATION RELATING THE GMHP

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

MON 863 maize plants are protected from damage due to feeding by CRW larvae. The tissues of MON 863 maize contain a modified *cry3Bb1* gene, derived from *Bacillus thuringiensis*, which encodes a modified *B.t.* Cry3Bb1 protein for CRW control.

MON 863 maize that expresses the modified Cry3Bb1 protein from *B.t.* offers an entirely new means to control CRW that is safe for humans and the environment. As the leading pest of U.S. maize, based on insecticide use, there is an ongoing need for efficacious CRW control measures. CRW-protected maize will offer growers a unique new management tool for CRW, which will reduce or eliminate the risks associated with chemical transportation, storage, application, disposal, and stewardship. Agro-ecosystems will benefit from the specificity of the product to CRW and the lack of harmful effects on beneficial insects or wildlife. CRW-protected maize is fully compatible with current management protocols for CRW, including integrated pest management (IPM).

The *B.t.* protein, MON 863 Cry3Bb1 has shown high levels of activity against the CRW complex. MON 863 maize demontrates levels of control that are superior to those of commercial soil-applied insecticides.

MON 863 x MON 810 maize consists of varieties developed using conventional methods of maize breeding which express:

1. the Cry1Ab protein, derived from *Bacillus thuringiensis* subsp. *kurstaki*, which provides protection from certain Lepidopteran insect pests (including *Ostrinia nubilalis* (European corn borer) and *Sesamia* spp),
2. the modified Cry3Bb1 protein, derived from *Bacillus thuringiensis* subsp. *kumamotoensis*, which provides protection from certain Coleopteran pests (corn rootworm).

20. Information on the sequences actually inserted/deleted/modified

(a) Size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP

MON 863 maize was produced by particle acceleration technology using a *Mlu*I DNA restriction fragment from plasmid PV-ZMIR13 containing the *nptII* and *MON 863 cry3Bb1* cassettes. The MON 863 event contains one DNA insert located on a 5.0 Kb *Nde*I fragment. This insert contains one copy of the fragment used in transformation. No additional elements from the DNA fragment used in transformation, linked or unlinked to intact cassettes, were detected in the genome. PCR and DNA sequencing were used to verify the 5' and 3' junction sequences of the insert with the plant genome, as well as the intactness of the 5' and 3' ends of the insert. Approximately 10 bp from the 3' end of PV-ZMIR13L, including the *Hind*III restriction site, is missing; however, the tahsp17 3' polyadeylation sequence is intact. Additionally, event MON 863 does not contain any detectable plasmid backbone sequence including *ori*-pUC or the *nptII* coding region regulated by a bacterial promoter. These data support the conclusion that only the two expected full length proteins, MON 863 Cry3Bb1 and NPTII, should be encoded by the insert in event MON 863.

Molecular analysis related to MON 810 maize is summarise in the Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (98/294/EC- Official Journal of the European Communities, L 131/32 of May 05, 1998).

The genome of MON 863 x MON 810 maize contains two different inserts, one derived from MON 810 maize and one derived from MON 863 maize. Southern blot analyses demonstrated that the size and structure of each insert are identical to those of their respective parents and therefore that their molecular structure has been preserved during the breeding process .

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

Not applicable

(c) Location of the insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination

Southern blot analysis was conducted to confirm the location and stability of the inserted DNA in MON 863 maize. One single copy of the transformation fragment has been inserted at one site of the plant nuclear genome. This copy contains two ORFs, *MON 863 cry3Bb1* and *nptII*, which are expressed. Segregation of the traits occurs according to Mendelian genetics.

The integration of MON 810 insert in the nuclear genome has been previously established [Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (98/294/EC- Official Journal of the European Communities, L 131/32 of May 05, 1998)].

MON 863 x MON 810 maize results from the conventional breeding of MON 810 and MON 863 maize and thus location of inserts has not been altered during the breeding process.

(d) Copy number and genetic stability of the insert

MON 810 maize and MON 863 maize each contain a single insert at one locus in the maize genome. Therefore, the MON 863 x MON 810 product contains two distinct simple inserts.

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

Not applicable

21. Information on the expression of the insert

(a) Information on the expression of the insert and methods used for its characterisation

Levels of MON 863 Cry3Bb1, NPTII and Cry1Ab proteins were determined in tissues collected from MON 863 and MON 863 x MON 810 maize plants grown under field conditions at multiple sites, representative of regions where corn rootworm protected maize would be grown as commercial products.

Direct double antibody sandwich enzyme-linked immunosorbent assay (ELISA) methods were developed and validated to quantify the levels of MON 863 Cry3Bb1, NPTII and Cry1Ab proteins in tissue extracts of MON 863 and MON 863 x MON 810 maize and control plants. MON 863 Cry3Bb1, NPTII

and Cry1Ab levels were below the limit of detection in control plant tissues and thus, are not reported.

(b) Parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc.)

This application being restricted to import of grain and derived products from MON 863 and MON 863 x MON 810 maize, the only relevant part of the plant for protein expression levels is the grain.

Table 21.1. summarizes the level of proteins in grain samples.

Table 21.1. : Summary of MON 863 Cry3Bb1, NPTII and Cry1Ab protein levels measured in MON 863 and MON 863 x MON 810 maize grains [average (range) in µg/g fw]

MON 863 maize		MON 863 x MON 810 maize		
MON 863 Cry3Bb1	NPTII	MON 863 Cry3Bb1	NPTII	Cry1Ab
70 (49-86)	< LOD•			
42.7 (<LOD♦-84.1)	< LOD•	61.1 (38.5-83.1)	< LOD•	0.84 (0.63-1.2)

• Below the limit of detection : 0.076 µg/g fw

♦ Below the limit of detection : 0.096 µg/g fw

First and second lanes correspond to field trials in the US (1999) and Argentina (1999-2000), respectively.

22. Information on how the GMHP differs from the recipient plant in

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

Agronomic equivalency (seedling vigour; early stand count; GDU[1] to 50% pollen shed; GDU to 50% silk emergence; ear height; plant height; final stand count; test weight; grain moisture; yield) has been evaluated in multiple field trials with six MON 863 hybrids. Statistically significant differences were observed for very few of the parameters evaluated. These differences were uniformly small, not consistently observed across locations or other MON 863 hybrids, and none would be considered to be of adverse agronomic consequence. The results of these trials support a conclusion of agronomic equivalence for MON 863 maize and their respective controls.

Information related to MON 810 maize was described in the application pursuant to Council Directive 90/220/EEC [Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (98/294/EC-Official Journal of the European Communities, L 131/32 of May 05, 1998)].

[1] *Growing degree units (GDU) = [(Tmax + Tmin)/2] - 50; where Tmax ≤ 31°C and Tmin ≥ 13°C*

Based on the conclusion established for each parent, no differences are anticipated in the reproductive capability of MON 863 x MON 810 maize when compared to the parental lines and therefore MON 863 x MON 810 maize should behave similarly to conventional lines.

(b) Dissemination

This application being restricted to import of maize grain, dissemination of flowering maize plants in Europe is likely to be limited.

For a cross pollination to occur between MON 863 derived plants and other maize plants, release would have to take place within proximity of other maize plants.

Based on the above-mentioned results, the mode of reproduction of MON 863 maize is equivalent to that of conventional maize and thus its dissemination capabilities (by seed or pollen) will also be equivalent.

Outcrossing with wild *Zea* species

Outcrossing to wild *Zea* species will not occur as there are no wild related species of maize in Europe (see Section B.2.).

Outcrossing to cultivated maize varieties

Gene exchange between MON 863 maize and cultivated conventional and genetically modified maize will be similar to natural crossing between conventional varieties (see Section B.2.). Wind blown pollen would move among plants within the same field and among plants in nearby fields at low frequencies. If outcrossing occurs, the production of MON 863 Cry3Bb1 protein in maize would not raise safety concerns due to the demonstrated safety of the protein to humans.

Information related to MON 810 maize was described in the application pursuant to Council Directive 90/220/EEC [Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (98/294/EC-Official Journal of the European Communities, L 131/32 of May 05, 1998)].

Based on the conclusion established for each parent, no differences are anticipated in dissemination of MON 863 x MON 810 maize when compared to the parental lines and therefore MON 863 x MON 810 maize should behave similarly to conventional lines.

(c) Survivability

This application being restricted to import of maize grain, release of viable seeds in Europe is likely to be limited.

Analysis of the agronomic parameters from MON 863 maize have shown no difference with non-transgenic control hybrids and thus MON 863 maize is not expected to behave differently from conventional maize with respect to survivability.

To assess whether MON 863 maize could have a selective advantage, with respect to pest infestation, a maize line containing the MON 863 event was compared to the non-transgenic control hybrid for susceptibility to a series of pests and diseases.

Apart from protection against CRW, no differences in disease severity or insect infestation were detected between MON 863 and non-transgenic control plants.

The only new genetic trait specific to the line containing MON 863 event is the insecticidal property carried by the inserted DNA sequence and directed against the coleopteran pest of maize corn rootworm (CRW, *Diabrotica* sp).

Weediness potential of MON 863 maize

Modern maize cannot survive as a weed because of the past selection for agronomic criteria which guided the evolution of maize. In contrast to weedy plants, the maize ear is enclosed within husks. Consequently, seed dispersal of individual kernels does not occur naturally because of this structure. Even if imported maize grain was to be more widely disseminated, volunteer maize is not found growing in fence rows, ditches, or road side as a weed. Maize is poorly suited to survive without human assistance and is not capable of surviving as a weed.

Maize lines derived from MON 863 event can be considered substantially equivalent to their non-transgenic counterparts except for the presence of the introduced traits. The presence of these genes is unlikely to increase the weediness potential of MON 863 maize. Maize lines derived from MON 863 event are thus expected to behave like their non-transgenic counterparts and thus not to be able to survive as weeds.

Information related to MON 810 maize was described in the application pursuant to Council Directive 90/220/EEC [Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (98/294/EC-Official Journal of the European Communities, L 131/32 of May 05, 1998)].

Based on the conclusion established for each parent, no differences are anticipated in survivability of MON 863 x MON 810 maize when compared to the parental lines and therefore MON 863 x MON 810 maize should behave similarly to conventional lines. The scope of the use of MON 863 x MON 810 maize in the European Union excludes cultivation of varieties.

(d) Other differences

No other differences observed.

23. Potential for transfer of genetic material from the GMHP to other organisms

Based on the fact that pollen production and pollen viability as measured by yield and germination of progeny are unchanged by the genetic modification, the outcrossing frequency to other maize varieties or to wild relatives (which are not present in the E.U.) is unlikely to be different for MON 863 and MON 863 x MON 810 maize when compared to other varieties. Also, none of the genetic elements introduced in the plant carries genetic transfer function. Furthermore neither MON 863 nor MON 863 x MON 810 cultivation is within the scope of this application.

24. *Information on any harmful effects on human health and the environment, arising from the genetic modification*

An assessment of the human safety of the MON 863 Cry3Bb1, NPTII and Cry1Ab proteins was conducted based upon the extensive characterization of those proteins.

The human safety of the MON 863 Cry3Bb1, NPTII and Cry1Ab proteins has been established based upon the following considerations: (1) no amino acid sequence similarity to known toxins, other than *B.t.* proteins in the case of MON 863 Cry3Bb1 and Cry1Ab, and no immunologically relevant sequence similarity with known allergens, (2) rapid degradation under conditions which simulate mammalian digestive systems, (3) no indications of acute toxicity in mice administered MON 863 Cry3Bb1, NPTII or Cry1Ab protein by oral gavage, (4) very low dietary exposure, and (5) a history of safe use.

Finally, the nutritional equivalence of grain from MON 863 and MON 863 x MON 810 maize has been established by compositional analysis and the wholesomeness of MON 863 and MON 810 maize grain, confirmed by feeding to broiler chickens.

25. *Information on the safety of the GMHP to animal health, where the GMHP is intended to be used in animal feedstuffs, if different from that of the recipient/parental organism(s)*

There is no difference between MON 863, MON 863 x MON 810 maize and the recipient organism in terms of safety to animals.

An assessment of the safety of the MON 863 Cry3Bb1, NPTII and Cry1Ab proteins was conducted based upon the extensive characterization of those proteins.

The safety of the MON 863 Cry3Bb1, NPTII and Cry1Ab proteins has been established based upon the following considerations: (1) no amino acid sequence similarity to known toxins, other than *B.t.* proteins in the case of MON 863 Cry3Bb1 and Cry1Ab, and no immunologically relevant sequence similarity with known allergens, (2) rapid degradation under conditions which simulate mammalian digestive systems, (3) no indications of acute toxicity in mice administered MON 863 Cry3Bb1, NPTII or Cry1Ab protein by oral gavage, (4) very low dietary exposure, and (5) a history of safe use.

The Cry3Bb and Cry1Ab proteins are present in commercially available insecticides, which are considered environmentally acceptable, because they are specific for the target insect pest and are typically harmless to plants and other non-target organisms. Cry1Ab maize has been grown commercially on 20.5 million hectares since 1997 and has been widely used in the E.U. and other countries as a source of feed ingredients.

Finally, the nutritional equivalence of grain and forage from MON 863 and MON 863 x MON 810 maize has been established by compositional analysis and the wholesomeness of MON 863 and MON 810 maize grain, confirmed by feeding to broiler chickens.

26. Mechanism of interaction between the GMHP and target organisms (if applicable), if different from that of the recipient/parental organism(s)

Not relevant to the current application since this application is restricted to import of grain and grain derived products from MON 863 and MON 863 x MON 810 maize and excludes E.U. cultivation of maize varieties expressing MON 863 Cry3Bb1.

27. Potentially significant interactions with non-target organisms, if different from the recipient or parental organism(s)

Not relevant to the current application since this application is restricted to import of grain and grain derived products from MON 863 and MON 863 x MON 810 maize and excludes E.U. cultivation of MON 863 and MON 863 x MON 810 maize varieties.

28. Description of detection and identification techniques for the GMHP, to distinguish it from the recipient or parental organism(s)

Southern blot or PCR techniques may be employed for the detection and identification of the inserted nucleotide sequences. Specific ELISAs have been developed and could be used to detect MON 863 Cry3Bb1, NPTII or Cry1Ab proteins in individual plants and their grains.

A detection method specific for MON 863 transformation event was provided to the German Competent Authority in charge of the evaluation of this application.

In the case of MON 810 maize, which is authorised under Directive 90/220/EEC and Regulation 258/97, a validation process is currently being organised through a collaboration with AACC (American Association of Cereal Chemists), BgVV, GeneScan and JRC. The BgVV (Germany) has also developed an event-specific method for MON 810 ["Commission Recommendation of 25 January 2002 concerning a coordinated programme for the official control of foodstuffs for 2002" (2002/66/EC - Official Journal of the European Communities, L 26/8 of January 30, 2002)].

MON 810 x MON 863 maize will be detectable using either the event-specific PCR method for detecting the introduced DNA present in the parental lines, MON 810 maize or the equivalent method for MON 863 maize.

INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GMHP

29. Potential environmental impact from the release or the placing on the market of GMOs (Annex II, D2 of Directive 2001/18/EC), if different from a similar release or placing on the market of the recipient or parental organism(s)

Not relevant to the current application since this application is restricted to import of grain and grain derived products and excludes E.U. cultivation of MON 863 and MON 863 x MON 810 maize varieties.

30. ***Potential environmental impact of the interaction between the GMHP and target organisms (if applicable), if different from that of the recipient or parental organism(s)***

Not relevant to the current application since this application is restricted to import of grain and grain derived products and excludes E.U. cultivation of MON 863 and MON 863 x MON 810 maize varieties.

31. ***Possible environmental impact resulting from potential interactions with non-target organisms, if different from that of the recipient or parental organism(s)***

Not relevant to the current application since this application is restricted to import of grain and grain derived products and excludes E.U. cultivation of MON 863 and MON 863 x MON 810 maize varieties.

C. INFORMATION RELATED TO PREVIOUS RELEASES

32. ***History of previous releases notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier***

(a) Notification number

No release has been notified under Part B of the Directive 90/220/EEC and under Part B of Directive 2011/18/EC.

(b) Conclusions of post-release monitoring

Not applicable

(c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)

Not applicable

33. ***History of previous releases carried out inside or outside the Community.***

(a) Release country

Table 33.1. : First year of experiment

Country	First year of experiment	
	MON 863	**MON 863 x MON 810**
USA	1998	2000
Argentina	1999	1999
Japan	2000	-
Canada	2000	-
Chile	2000	-

(b) Authority overseeing the release

USA : United States Department of Agriculture and Environmental Protection Agency

Argentina : Secretary of Agriculture (SAGPyA) - CONABIA

Japan : Ministry of Agriculture, Forestry and Fisheries (MAFF)

Canada : Canadian Food Inspection Agency

Chile : Ministry of Agriculture and Cattle (SAG : Servicio Agrícola y Ganadero) and CALT: Comité Asesor para la Liberación de Transgénicos

(c) Release site

USA :Mainly in the states of the corn belt and in Hawaii and Porto Rico

Argentina : Bragado, Salto, Rojas

Japan : Monsanto Japan Kawachi Research Farm in Ibaraki prefecture

Canada : Various sites in Southern Ontario/Quebec

Chile : Different site from the seeds Companies fields along Chile

(d) Aim of the release

USA : Assess the performances : efficacy, yield, breeding, ...

Argentina : Compare different hybrid phenotypes and yielding performance

Japan : Requirement for import approval

Canada : Assess agronomic performance

Chile : Requirement for import and re-export approval

(e) Duration of the release

USA : field releases - one year

Argentina : one year

Japan : May 2000 - March 2001

Canada : Typical growing season (May-October 00/01/02)

Chile : one year

(f) Aim of post-releases monitoring

USA : destroy volunteers to prevent persistence in the environment of the regulated material

Argentina : Assess for volunteers

Japan : Not required

Canada : Removal of volunteers

Chile : destroy volunteers to prevent persistence in the environment

(g) Duration of post-releases monitoring

USA: 12 months

Argentina : one year

Japan : not applicable

Canada : one year

Chile : one year

(h) Conclusions of post-release monitoring

USA : volunteers have been eliminated to prevent persistence in the environment

Argentina : nothing to report

Japan : not applicable

Canada : No conclusion required. Monitoring ensured containment of the novel genetic material

Chile : nothing to report

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

USDA : The reports of these field releases do not indicate any adverse effects on the environment and do not address human health.

Argentina : No risk to human health and environment.

Japan : MAFF granted the environmental safety approval for the grain import on May 8, 2001 and also granted the feed safety approval on February 28 in 2002. Ministry of Health, Labor and Welfare (MHLW) granted the food safety approval on February 21 in 2002.

Canada : Nothing special to report

Chile : Nothing special to report

E. INFORMATION RELATING TO THE MONITORING PLAN – IDENTIFIED TRAITS, CHARACTERISTICS AND UNCERTAINTIES RELATED TO THE GMO OR ITS INTERACTION WITH THE ENVIRONMENT THAT SHOULD BE ADDRESSED IN THE POST COMMERCIALISATION MONITORING PLAN

1. Confirmation that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use in the E.R.A. are correct.

The results of the environmental risk assessment (E.R.A.) of MON 863 and MON 863 x MON 810 maize (Annex II) show effectively zero overall risk arising from the placing on the market of this maize relating to:

- Persistence or invasiveness
- Selective advantage
- Potential for gene transfer
- Impact on target organisms
- Impact on non-target organisms
- Effects on biogeochemical processes due to direct or indirect interactions with target and non-target organisms
- Changes in agricultural practice

This assessment is reinforced by the fact that this application is restricted to import of grain and grain derived products from MON 863 and MON 863 x MON 810 maize.

Moreover, the risk assessment has demonstrated that MON 863 and MON 863 x MON 810 maize presents effectively zero risk to human and animal health relating to:

- Persons in proximity or contact with the release
- The consumption of grains and derived products

These conclusions having been reached on the basis of scientific data and analysis, rather than on the basis of assumptions, case-specific monitoring of MON 863 and MON 863 x MON 810 maize is not relevant.

2. Identification of the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the E.R.A.

The environmental and human health safety assessment for MON 863 and MON 863 x MON 810 maize did not identify any specific risks related to its placing on the market during import, storage, processing and other uses. Therefore the monitoring plan for MON 863 and MON 863 x MON 810 maize is focused on general surveillance for unanticipated, adverse effects.

Since the notification of MON 863 and MON 863 x MON 810 maize is for consent for import and use as any other maize, and since the majority of use of this maize will be for animal feed, it follows that any unanticipated effects are most likely to be manifested as a result of this use. Therefore, it is proposed:

- To provide traders and processors of bulk mixtures of maize grain, likely to contain MON 863 and MON 863 x MON 810 maize grain, with product information about MON 863 and MON 863 x MON 810 maize. Traders and processors will be requested to inform the relevant authorities of any adverse

effects on the environment or human health, which they consider to be attributable to MON 863 and MON 863 x MON 810 maize grain.

- To inform the European feed industry directly, by way of a public announcement, of the consent for placing on the market of MON 863 and MON 863 x MON 810 maize at such time as it appears in the Official Journal of the Rapporteur Member State. Monsanto will also offer to meet with interested operators to discuss the safety and general characteristics of the product. Operators in the feed chain will be requested to inform the relevant authorities of any adverse effects on animal health reported to them through farmers or national feed associations, which they consider to be attributable to the feed use of MON 863 and MON 863 x MON 810 maize grain.
- For the duration of the authorisation of MON 863 and MON 863 x MON 810 maize, to immediately inform the Commission and the Competent Authorities for Directive 90/220/EEC and, after 17 October 2001, for Directive 2001/18/EC, of any reports of adverse effects which come to the attention of Monsanto, so that any reports can be further investigated by the appropriate authorities.