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

NK603 × MON 810 Maize

A. GENERAL INFORMATION

1. Details of notification

(a)	***Member State of notification:*** Spain
(b)	***Notification number:*** C/ES/04/01
(c)	***Name of the product (commercial and other names):*** The Monsanto development code for this product is NK603 × MON 810 maize. The commercial name is yet to be decided.
(d)	***Date of acknowledgement of notification:*** Not available at time of submission

2. Notifier

(a)	***Name of notifier:*** Monsanto Company, represented by Monsanto Europe S.A.	
(b)	***Address of notifier:*** Monsanto Europe S.A. Avenue de Tervuren 270-272 B-1150 Brussels BELGIUM	Monsanto 800 N. Lindbergh Boulevard St. Louis, Missouri 63167 U.S.A
(c)	***Is the notifier domestic manufacturer: [X]***	***importer: [ ]***
(d)	***In case of an import the name and address of the manufacturer shall be given*** Not applicable.	

3. General description of the product

(a)	***Name of the recipient or parental plant and the intended function of the genetic modification*** NK603 × MON 810 maize consists of hybrid maize varieties, produced using conventional methods of maize breeding by crossing parental inbred lines of NK603 and MON 810 maize. Although genetic modification was used in the development of NK603 and MON 810 maize, no additional genetic modifications were involved for the production of NK603 × MON 810 hybrids.

Like parental NK603 maize, NK603 × MON 810 maize expresses CP4 EPSPS proteins derived from *Agrobacterium* sp. strain CP4, which confer tolerance to Roundup®[1] herbicide (containing glyphosate). Like its second parental maize line derived from event MON 810, NK603 × MON 810 maize also expresses the Cry1A(b) protein, derived from *Bacillus thuringiensis* subsp. *kurstaki,* which confers protection from predation by certain Lepidopteran insect pests, including the European Corn Borer (*Ostrinia nubilalis)* and pink borers (*Sesamia* spp).

The use of NK603 × MON 810 maize plants enables the farmer to utilise Roundup herbicide for effective control of weeds during the growing season and to take advantage of the favourable environmental and safety characteristics of Roundup herbicide. The use of NK603 × MON 810 maize also enables the farmer to effectively control the targeted Lepidopteran insect pests in maize, ensuring maximum realization of yield potential, while removing the environmental burden of the production, packaging and transport of insecticides, previously used to control *Ostrinia nubilalis* and *Sesamia* spp.

(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 is for import and use in the European Union (E.U.) of NK603 × MON 810 maize. The proposed uses of this maize are the same as for any other maize, *including* the cultivation of NK603 × MON 810 maize varieties and the use in animal feed.

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

The proposed uses of this maize are the same as for any other maize, including the cultivation of NK603 × MON 810 maize varieties in the E.U. The primary use of maize is for animal feed. Maize is also processed into valuable food and industrial products.

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

NK603 × MON 810 maize has been demonstrated to be substantially equivalent to its parental maize lines, NK603 and MON 810 maize, and to traditional maize varieties (except for its tolerance to Roundup herbicide and its protection from targeted Lepidopteran insect pests). As such, comprehensive information will be provided on seed bags and in accompanying documents of grain shipments in order for purchasers to be fully informed about the use of NK603 × MON 810 maize varieties (for labelling, please see question ***3.*(h)**).
The grain, forage and derived products of this maize will be used and handled in the same manner as current commercial maize varieties.

[1] Roundup® is a registered trademark of Monsanto Technology LLC.

(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*

NK603 × MON 810 maize is intended for import, cultivation and use in any geographical area currently producing or processing maize.

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

NK603 × MON 810 maize varieties may be cultivated or used in any environment currently suitable for the production or processing of maize.

(g) *Any proposed packaging requirements*

NK603 × MON 810 maize is substantially equivalent to its parental maize lines NK603 and MON 810 maize, and to traditional maize varieties (except for its tolerance to Roundup herbicide and its protection from targeted Lepidopteran insect pests). Therefore, NK603 × MON 810 maize grain or derived products will be used in the same manner as other maize and no specific packaging is foreseen (for the labelling, see question ***3.*(h)**).

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

In accordance with the requirements of Directive 2001/18/EC, Monsanto will undertake a number of measures to ensure that farmers and international traders are provided with the necessary information to comply with statutory requirements relating to the Placing on the Market of NK603 × MON 810 maize. In particular, Monsanto will:

a) Inform European and international traders, growers and users of maize of the approval of NK603 × MON 810 maize for import and use as any other maize, including the cultivation of these varieties in the European Union.

b) Bags containing NK603 × MON 810 maize seeds will be labelled as genetically modified maize and will bear an indication of the introduced characteristics to allow farmers to know they are purchasing a maize variety that is tolerant to Roundup® herbicide and protected from specific Lepidopteran insect pests. Seed bags will be clearly marked using the combination of the unique identifiers MON-ØØ6Ø3-6 and MON-ØØ81Ø-6 (see question ***3.*(j)**) and the procedures for accessing the publicly accessible part of the European Commission's registers of GM organisms. As for any other variety, all the usual information including variety name, seed quality, seed treatment, manufacturer's name and full address, will be given on the seed package.

c) Inform traders that NK603 × MON 810 maize is a genetically modified organism and that NK603 × MON 810 grain may be present in bulk shipments of maize grain. For bulk shipments, the words "Contains genetically modified organisms: <*list of unique identifiers*>", which is to appear either on a label or in an accompanying document to the maize grain shipment, shall include the unique identifier for NK603 × MON 810 maize.

d) Advise traders and operators using the product that NK603 × MON 810 maize is subject to the traceability and labelling requirements of Directive 2001/18/EC and the Regulation (EC) N° 1830/2003 of the European Parliament and of the Council, concerning traceability and labelling of genetically modified organisms and traceability and labelling of food and feed products produced from genetically modified organisms.

(i) Estimated potential demand

(i) in the Community

For marketing year 2000, the maize grain demand and supply in the European Union ('000 hectares, '000 metric tons), including internal trade, are summarised in the table below.

	France	Italy	Spain	Germ.	Greece	Austria	Port.
Area harvested	1766	1064	425	361	215	188	153
Stock change	(68)	39	(169)	(21)	-	282	-
Production	16073	10138	3898	3324	2038	1852	891
Market year imports (total)	432	570	3538	1133	461	155	1116
Market year exports (total)	8212	578	189	715	13	154	28
Total dom. supply	8226	10168	7078	3721	2485	2135	1979

(continued)	Belux	Neth.	Swed.	U.K.	Irel.	Denm.	Finl.	**E.U.15**
Area harvested	36	20	-	-	-	-	-	**4228**
Stock change	(14)	250	3.4	142	-	13	-	**458**
Production	399	162	-	-	-	-	-	**38774**
Market year imports (total)	592	1423	29	1427	146	82	20	**11123**
Market year exports (total)	52	312	0.4	75	2.5	1.5	0	**10332**
Total dom. supply	926	1522	32	1494	143	94	20	**40022**

Source: FAOSTAT Database, 2002.

(ii) in export markets for EC supplies

The EU is not a major exporter of maize, exporting about half a million tonnes each year. This includes an element of food aid, which usually accounts for about three-quarters of the total export volume.

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

The code NK603 × MON 810 will uniquely identify hybrid seed and grain of this maize until replaced by an internationally recognised unique identifier. It is proposed that NK603 × MON 810 maize is identified by the combination of the unique identifiers MON-ØØ6Ø3-6 and MON-ØØ81Ø-6.

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 [X]	**No [ ]**

NK603 × MON 810 hybrids have been field-tested in the E.U. since the year 2000 (*see* B/FR/00.02.06).

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

Not applicable

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

Yes [ ]	No [X]

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

Please see questions ***9 - 11***, ***14 – 27***, ***29*** and ***31 – 33***, for risk assessment data, including experience from experiments conducted under 90/220/EEC Part B approvals.

or

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

Yes [X]	No [ ]

If yes, specify

See Part C, Information Relating to Previous Releases, for information on releases notified or carried out inside and outside of the E.U.

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

Yes [X]	No [ ]

If yes, give notification number and Member States

Notification (C/GB/02/M3/3) for import of NK603 × MON 810 maize and use thereof as any other maize, *excluding* the marketing of varieties in the E.U., has previously been submitted to the Competent Authorities of the *Rapporteur* Member State UK in 2002.

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. In the event that any grain were disseminated outside the agronomic environment, therefore, it would be highly unlikely to pose any threat to the environment. In the unlikely event of establishment, volunteer plants could easily be controlled by currently available selective herbicides or by mechanical means. Since NK603 × MON 810 maize was established to be equivalent to traditional maize with respect to its persistence, invasiveness, dissemination and survival characteristics, the potential for unintended release of NK603 × MON 810 maize is no different from any other maize. Therefore no specific measures are recommended in case of unintended release of NK603 × MON 810 maize.

Misuse of NK603 × MON 810 maize is unlikely, as the proposed uses for this maize include all the current uses of traditional maize.

The measures for waste disposal and treatment for NK603 × 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   NK603 × MON 810 maize, derived from a single conventional cross of Roundup Ready® maize (event NK603) and insect-protected maize (event MON 810).
(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.

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

Out-crossing with cultivated *Zea* varieties

In Europe, the potential for genetic transfer and exchange with other organisms is limited to other maize plants. 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

Wild *Zea* species are not present in Europe.

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.A. “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. Sixteen species of *Tripsacum* have been described. *Tripsacum floridanum* is native to southern tip of Florida, U.S.A. Twelve of sixteen *Tripsacum* species are native to Mexico and Guatemala. *Tripsacum australe* and two other species are native to South America. The centre of variation for *Tripsacum* is the western slopes of Mexico, the same area where teosinte is frequently found. In contrast to maize and teosinte, which can be easily hybridised both in the wild and by controlled pollination, 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. Modern maize cannot survive as a weed. Volunteer maize is not found growing in fencerows, ditches, and roadsides as a weed. Although maize from the previous crop year can over-winter in mild winter conditions and germinate the following year, it cannot persist as a weed. The appearance of maize in rotational fields following the maize crop from the previous year is usually 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.

(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. 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 naturally does not occur because of the structure of the ears of maize.

Maize grain survival is dependent upon temperature, moisture of seed, genotype, husk protection and stage of development. Freezing temperatures have an adverse effect on maize seed germination. Temperatures above 45°C have also been reported as injurious to maize seed viability.

11. Dissemination

(a) Ways and extent of dissemination

Maize is an annual crop and seeds are the only survival structures. Natural regeneration from vegetative tissue is not known to occur. Seed dissemination is impacted by mechanical harvesting and transport as well as insect or wind damage, which may cause some mature ears to fall to the ground and avoid harvest. Pollen dispersal is influenced by wind and weather conditions.

(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.

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. (See also question *31.*)

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 outcrossing 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

NK603 × MON 810 hybrid maize was created using conventional breeding techniques. No additional genetic modification is utilised in the production of NK603 × MON 810 maize hybrid varieties. Instead, NK603 × MON 810 hybrid maize is produced by a single traditional cross of NK603 and MON 810 inbred parental lines (homozygous for the respective introduced trait). F1 hybrid seed thereby inherits the introduced Roundup Ready trait from NK603 maize, as well as the insect-protection trait from MON 810 maize.

While NK603 × MON 810 hybrid maize results from traditional breeding, genetic modification was used in the development of the parental NK603 and MON 810 maize. These single trait parental maize lines were genetically modified using a particle acceleration method.

17. Nature and source of the vector used

No genetic modification was involved in the production of NK603 × MON 810 maize. NK603 × MON 810 maize was produced by conventional breeding of two genetically modified inbred parental maize lines, derived from transformation events NK603 and MON 810. As described in the respective application dossiers for these single-trait maize lines, NK603 maize was generated using a particle acceleration transformation system and a DNA fragment, containing *cp4 epsps* genes encoding glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzymes from *Agrobacterium* sp. strain CP4, and MON 810 maize was produced by the integration of a DNA sequence, which contains the *cry1A(b)* gene derived from *Bacillus thuringiensis* subsp. *kurstaki*, encoding the insecticidal Cry1A(b) polypeptide. The *cp4 epsps* and *cry1A(b)* genes are inherited in the nuclear genome of NK603 × MON 810 maize.

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

NK603 × MON 810 maize results from a single conventional cross of the inbred parental lines NK603 maize and MON 810 maize, homozygous in their respective inserted sequences.

By crossing NK603 and MON 810 maize, NK603 × MON 810 maize inherits the inserted DNA fragments from both its parental lines. The individual components and the function of the inherited sequences are given in Tables 1 and 2.

Table 1. Components of the inserted DNA fragment inherited from NK603 maize

Genetic Element	Source	Size (kb)	Function
First *cp4 epsps* gene cassette			
P-ract1/ ract1 intron	*Oryza sativa*	1.4	Contains promoter, transcription start site and first intron.
ctp 2	*Arabidopsis thaliana*	0.2	Encodes chloroplast transit peptide, which directs the CP4 EPSPS protein to the chloroplast
cp4 epsps	*Agrobacterium* sp. strain CP4	1.4	Encodes glyphosate-tolerant CP4 EPSPS protein
NOS 3'	*Agrobacterium tumefaciens*	0.3	Ends transcription and directs polyadenylation of the mRNA.
Second *cp4 epsps* gene cassette			
e35S	Cauliflower mosaic virus	0.6	Promoter
Zmhsp70	*Zea mays L.*	0.8	Stabilizes the level of gene transcription.
ctp 2	*Arabidopsis thaliana*	0.2	Encodes chloroplast transit peptide, which directs the CP4 EPSPS protein to the chloroplast
cp4 epsps l214p[1]	*Agrobacterium* sp. strain CP4	1.4	Encodes glyphosate-tolerant CP4 EPSPS L214P protein
NOS 3'	*Agrobacterium tumefaciens*	0.3	Ends transcription and directs polyadenylation of the mRNA.

Table 2. Components of the inserted DNA fragment inherited from MON 810 maize

Genetic Element	Source	Size (kb)	Function
e35S	Cauliflower mosaic virus	0.6	Promoter
Zmhsp70	*Zea mays* L.	0.8	Stabilizes level of gene transcription.
cry1A(b)	*Bacillus thuringiensis*	3.5	Encodes Cry1A(b) protein, which targets specific Lepidopteran insect pests

[1] The substitution of leucine by proline in the CP4 EPSPS encoded by the second *cp4 epsps* gene of the NK603 insert, is indicated by the suffix L214P.

INFORMATION RELATING THE GMHP

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

NK603 × MON 810 hybrid maize consists in the combination, by traditional breeding, of two genetically modified inbred parental lines, derived from maize transformation events NK603 and MON 810, respectively.

NK603 × MON 810 maize expresses CP4 EPSPS proteins, which impart tolerance to glyphosate (N-phosphonomethyl-glycine), the active ingredient in the non-selective herbicide Roundup. EPSPS is an enzyme involved in the shikimic acid pathway for aromatic amino acid biosynthesis in plants and micro-organisms. CP4 EPSPS enzymes have been shown to have significantly reduced affinity for glyphosate herbicide when compared with the wild-type maize enzyme, and to retain catalytic activity in the presence of the inhibitor glyphosate. Therefore, when maize plants expressing the CP4 EPSPS proteins are treated with glyphosate, the plants are unaffected since the continued action of the tolerant CP4 EPSPS enzymes provides for the plant's need for aromatic amino acids.

NK603 × MON 810 maize also expresses the Cry1A(b) protein, which provides the maize plant of protection from certain Lepidopteran insect pests, including European Corn Borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp.). The insecticidal activity of the Cry1A(b) protein is specific to predation by the larvae of the targeted Lepidopterans.

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***

NK603 × MON 810 maize is produced by traditional breeding of two genetically modified inbred parental lines, one derived from maize transformation event NK603 and the other one derived from event MON 810. No additional genetic modification was applied.

Southern blot analysis using NK603 × MON 810 maize confirmed the presence of the NK603 and MON 810 events in NK603 × MON 810 maize. In addition, there are no indications for the presence of additional fragments of either of the insertions.

The size and structure of the sequences, actually inserted in the parental maize lines NK603 and MON 810, and inherited in NK603 × MON 810 hybrid maize are given in Tables 1 and 2 in question **18**.

(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, chloroplast, mitochondrion, or maintained in a non-integrated form), and methods for its determination***

NK603 × MON 810 contains a single insertion of each introduced (*i.e.*

inherited) DNA fragment. Both the NK603 and the MON 810 events are stably integrated into the plant nuclear genome (please see also question ***20.*(a)**).

(d) Copy number and genetic stability of the insert

NK603 × MON 810 hybrid seed (F1) is produced by a single cross of the NK603 and MON 810 parental inbred lines (made homozygous for event NK603 or MON 810, respectively) by traditional breeding. Thereby, each parental line passes on its inserted DNA sequence to the resulting NK603 × MON 810 F1 hybrid seed, which is sown by the grower.

The single-trait modified maize lines NK603 and MON 810 each contain one insert with a single copy of the respective transformed DNA, which is stably integrated into the nuclear maize genome. Each trait is inherited as a single dominant gene in a Mendelian fashion. This has been confirmed by Southern blot analyses and by studies of the inheritance pattern of these traits in maize.

The harvested (F2) grain of NK603 × MON 810 maize is marketed by the grower for food, feed or industrial use and is not used for further breeding. Therefore, since NK603 × MON 810 hybrid maize seed exists only for a single generation, there is no opportunity for its stability to be compromised.

(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

The levels of CP4 EPSPS and Cry1A(b) proteins measured in maize forage and grain samples for NK603 × MON 810 maize are summarised below. The values given for CP4 EPSPS represent the sum of both CP4 EPSPS and CP4 EPSPS L214P, as the ELISA analytical method recognizes both these proteins expressed in NK603 × MON 810 and NK603.

The mean levels of CP4 EPSPS across all sites was 36.3 µg/g fw in forage samples of NK603 × MON 810 maize and 12.7 µg/g fw in the grain. The mean level of the Cry1A(b) protein across all sites was 6.06 µg/g fw in the forage and 0.73 µg/g fw in grain samples.

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

The expression of the CP4 EPSPS and Cry1A(b) proteins is expected to occur throughout the whole plant since the rice actin and CaMV *e35S* promoters have been shown to drive constitutive expression of the encoded protein in genetically modified maize.

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

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

NK603 × MON 810 maize has been field tested in the E.U. since 2000. Agronomic data collected from these trials have demonstrated that NK603 × MON 810 maize has not been altered in survival, multiplication or dissemination characteristics when compared to its parental maize lines (NK603 and MON 810) or compared to traditional maize varieties. The introduced traits for herbicide tolerance and insect-protection have no influence on maize reproductive morphology and hence no changes in seed dissemination would be expected.

(b) Dissemination

Please see question ***22.*(a)**.

(c) Survivability

Please see question ***22.*(a)**.

(d) Other differences

Please see question ***22.*(a)**.

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

NK603 × MON 810 maize, like all other maize, is not sexually compatible with any indigenous or introduced wild plant species present in Europe. Therefore there is no potential for gene transfer from NK603 × MON 810 maize to wild plant species. In the event of plants of NK603 × MON 810 maize fertilising a neighbouring maize crop, the traits present in NK603 × MON 810 maize could be transferred to the recipient maize crop, including the introduced glyphosate-tolerance and insect-protection traits, and would be expressed in the progeny of the recipient crop. Since the majority of maize pollen is largely confined to short distances from the source plant, the likelihood of transfer of the glyphosate-tolerance trait to neighbouring maize crops through cross-pollination is low. Transfer of the glyphosate-tolerance gene to other maize, would, in any event, have negligible consequences for the environment. Therefore, the risk posed by this potential transfer, and hence by NK603 × MON 810 maize, is negligible.

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

The assessment of the human and animal health safety of NK603 × MON 810 maize was conducted based upon an extensive characterisation of the introduced traits and based upon comparison of this maize and its parental lines with traditional, nontransgenic counterparts.

Neither the host plant, maize, nor the donor organisms of the introduced sequences, are known to be harmful for human or animal health or the environment. NK603 × MON 810 maize has been shown to be equivalent to other maize varieties, apart from tolerance to the herbicide Roundup by expression of CP4 EPSPS proteins and protection from predation by certain Lepidopteran insect species by expression of Cry1A(b) protein.

The introduced traits

CP4 EPSPS proteins belong to a family of EPSPS enzymes that are commonly found in a wide variety of food sources, which have a long history of safe use. Moreover, there were no indications of acute toxicity in mice administered CP4 EPSPS protein by oral gavage, which is consistent with the rapid degradation of the CP4 EPSPS proteins and loss of enzymatic activity in simulated human gastric and intestinal fluids; the CP4 EPSPS proteins are not homologous to known protein toxins or allergens; the proteins are present at very low levels in NK603 × MON 810 maize, and finally, these proteins are from a family of proteins with a long history of safe consumption, including the CP4 EPSPS protein present in Roundup Ready soybean.

Similarly, the human and animal health safety of the Cry1A(b) protein has been established based upon the following considerations: (1) no indications of acute toxicity in mice administered Cry1A(b) protein by oral gavage, (2) rapid degradation and loss of insecticidal activity under conditions which simulate mammalian digestion, (3) no amino acid sequence similarity to known toxins, other than *B.t.* proteins, and no immunologically relevant sequence similarity with known allergens, (4) very low dietary exposure, and (5) a history of safe use as MON 810 maize varieties expressing the same protein have been approved, marketed and consumed since 1996 in several world areas including the E.U. Finally, the Cry1A(b) protein was demonstrated to be highly selective for certain insects, with no toxicity to other types of living organisms such as mammals, fish, birds or invertebrates.

Compositional analysis/ Feeding studies

The compositional and nutritional equivalence of grain and forage from NK603 × MON 810 maize and traditional maize have been established by compositional analysis. Finally, the wholesomeness of NK603 × MON 810 maize grain has been confirmed in a highly sensitive feeding study using broiler chickens.

Conclusion

In conclusion, on the basis of the extensive characterisation of the introduced traits, the history of safe use of the introduced proteins and the host plant, maize, the compositional and nutritional equivalence of NK603 × MON 810 maize versus traditional maize, and the absence of growth performance effects in a broiler feeding study, it is concluded that NK603 × MON 810 maize grain, containing the NK603 and MON 810 inserts, is as safe and nutritious as traditional maize hybrids.

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 event NK603 × MON 810 maize and the recipient organism (traditional maize) in terms of safety to animals (see question *24*).

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

The CP4 EPSPS proteins expressed in NK603 × MON 810 maize are glyphosate-tolerant EPSPS enzymes involved in the shikimate pathway of the plant, thereby conferring tolerance to Roundup herbicide. This introduced trait is of agronomic relevance and does not have any target organisms.

Unlike unmodified maize plants, NK603 × MON 810 maize expresses the Cry1A(b) protein protecting this maize from the European Corn Borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp.). Non-target organisms are not affected, since the insecticidal action of the Cry1A(b) protein is limited to the larvae of targeted Lepidopteran insect pests.

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

Cultivated maize is known to interact with a range of organisms in the environment, including micro-organisms, wildlife and numerous soil dwelling and foliar dwelling invertebrates. In addition, maize is known to be susceptible to a range of fungal diseases and nematode, insect and mite pests, which the grower traditionally has attempted to control by the application of plant protection products or by means of other agricultural practices such as crop rotation. Because maize is a good source of nutrition, interactions with vertebrate wildlife are well known, including birds and mammals that reside or forage in the agricultural habitat and its field edges, hedgerows or ditches. As NK603 × MON 810 maize was shown to be equivalent to traditional maize, except for the introduced glyphosate-tolerance and insect-protection traits, its baseline interaction with other organisms in the environment is not different from traditional nontransgenic maize, except for the additional direct exposure of herbivorous pests of maize to the CP4 EPSPS and Cry1A(b) proteins that are newly expressed in the plant. Through trophic transfer and decomposition processes, additional organisms such as predators and prey of the pests of maize could be exposed to some very low levels of these proteins. (See also question *31.*)

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

Southern blot or polymerase chain reaction (PCR) techniques may be employed for the detection and identification of the inserted sequences. NK603 × MON 810 maize will be detectable using either of the event-specific PCR methods for detection of the introduced DNA also present in the respective parental lines derived from the NK603 and MON 810 modification events. Specific ELISA methods have been developed and could be used to detect expression of CP4 EPSPS or Cry1A(b) proteins in individual plants and their grains. Alternatively, plants can also be sprayed with Roundup herbicide for the detection of the glyphosate tolerance and an insect bioassay using sensitive Lepidopteran insect species such as tobacco hornworm (*Manduca sexta*), cabbage looper (*Trichoplusia ni*) or European Corn Borer (*Ostrinia nubilalis*) may be used to identify plants expressing the Cry1A(b) protein or trait.

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)

Analysis of the characteristics of NK603 × MON 810 maize has shown that the likelihood of potential adverse effects on human health and the environment in the European Union, resulting from its cultivation and use as any other maize, is consistently negligible. Therefore, the overall environmental risk posed by the GMHP is also negligible, and strategies for risk management for NK603 × MON 810 maize would be the same as for traditional maize.

It is actually expected that the production of NK603 × MON 810 maize will positively impact current agronomic practices in maize and provide benefits to farmers and the environment.

The use of Roundup in maize enables the farmer to take advantage of the herbicide's favourable environmental and safety properties (*see* Annex I listing of glyphosate under Council Directive 91/414/EEC). Roundup-tolerant maize benefits the farmer by providing (1) an additional broad-spectrum weed control option in maize, (2) a new herbicidal mode of action for in-season maize weed control, (3) increased flexibility to treat weeds on an "as needed" basis, (4) cost-effective weed control and (5) an excellent fit with reduced-tillage systems. In turn, a number of environmental benefits arise from the use of conservation tillage including improved soil quality, improved water infiltration, reductions in erosion and sedimentation of water resources, reduced runoff of nutrients and pesticides to surface water, improved wildlife habitat, increased carbon retention in the soil, reduced fuel use and encouragement of sustainable agricultural practices.

Moreover, cultivated NK603 × MON 810 maize is also protected against predation by certain economically damaging Lepidopteran insect pests, of wich the European Corn Borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp.) are prevalent in parts of Europe. The benefits of planting insect-protected maize include: 1) a reliable means to control the target Lepidopteran maize pests; 2) control of target insects while maintaining beneficial species; 3) reduced use of chemical insecticides; 4) reduced applicator exposure to chemical pesticides; 5) fit with integrated pest management (IPM) and sustainable agricultural systems; 6) reduced fumonisin mycotoxin levels in maize kernels; and 7) no additional labour or machinery requirements, allowing both large and small growers to maximize hybrid yields.

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)

Through the expression of Cry1A(b) in NK603 × MON 810 maize, this maize is protected from predation by certain targeted Lepidopteran insect pests. MON 810 maize contains the same insect-protection trait and affects the same target organisms as its NK603 × MON 810 hybrid progeny, produced from a single conventional cross with an inbred NK603 maize line. No additional, potentially harmful characteristics could be identified, as the other introduced trait in NK603 × MON 810 maize, glyphosate-tolerance, does not have any target organisms.

As the introduced insect-protection trait in NK603 × MON 810 maize only has activity toward the larvae of particular Lepidopterans, the effect of NK603 × MON 810 maize on target organisms is limited to specific conditions in the field which are predictable, spatially limited and short in duration. As the target insects represent important insect pests in the agronomic environment, the direct control of their population levels in maize fields is justified on an agronomic basis and is not considered a direct adverse environmental effect in itself.

As for parental MON 810 maize, NK603 × MON 810 maize poses negligible risk for adverse environmental effects through its interaction with target organisms.

Important environmental benefits of the planting of this insect-protected maize include: 1) a reliable means to control specific Lepidopteran maize pests while maintaining beneficial species; 2) potential for reduced use of hazardous chemical insecticides; 3) excellent fit with integrated pest management (IPM) and sustainable agricultural systems; 4) potentially reduced levels of fungal mycotoxins such as fumonisins in maize kernels.

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

(a) Effects on biodiversity in the area of cultivation

Cultivated maize interacts with a range of organisms in the area of cultivation, including pathogens, micro-organisms, vertebrate wildlife and numerous soil dwelling and foliar dwelling invertebrates. As NK603 × MON 810 maize was shown to be equivalent to traditional maize and to its well-characterised parental maize lines, the baseline interaction of NK603 × MON 810 maize with non-target organisms in the environment is considered no different from that of traditional maize, except for the additional exposure of herbivorous pests of maize to the CP4 EPSPS and Cry1A(b) proteins. Through trophic transfer and decomposition processes, additional organisms in the field such as predators and prey of the pests of maize could theoretically be exposed to some very low levels of these proteins.

CP4 EPSPS proteins expressed in NK603 × MON 810 maize belong to the larger family of EPSPS enzymes, which are ubiquitous in bacteria, fungi, algae and plants. Therefore, there is no *a priori* reason to suspect that *any* EPSPS protein, including the CP4 EPSPS protein derived from the soil-borne bacterium *Agrobacterium* sp. strain CP4, would possess biological activity towards non-target organisms. Any non-target organisms interacting with the crop have co-evolved in close interaction with a wide spectrum of green plants and micro-organisms, and therefore have *historically* been exposed to members of this safe class of proteins.

Although Cry1A(b) is a newly expressed protein in maize (and other genetically modified crops), the protein does already have a long history of safe use. MON 810 maize was genetically modified to produce the insect-control protein Cry1A(b) derived from the common soil bacterium *Bacillus thuringiensis* subsp. *kurstaki*. The Cry1A(b) polypeptide produced by MON 810 is also present in microbial formulations used for crop-protection. There is extensive information on the absence of non-target effects from these microbial preparations of *Btk* strains containing the Cry1A(b) protein. *Btk* Cry1A proteins are known to be extremely selective for the Lepidopteran insects. They bind specifically to receptors on the mid-gut of Lepidopteran insects and have no deleterious effect on beneficial or other non-target insects, including predators and parasitoids of Lepidopteran insect pests or honeybees (*Apis mellifera*).

To confirm and expand on the results produced for the microbial products which contain the same Cry1A protein as produced in MON 810 and NK603 × MON 810 maize, the potential impact of the Cry1A(b) protein on non-target organisms was assessed on several representative organisms. These studies have previously been reported in dossier C/FR/95/12-02 for MON 810 maize, which was approved for cultivation and use in the E.U. The results of these non-target organism studies showed that the mortality of non-Lepidopteran insect species and three other representative organisms exposed to the Cry1A(b) protein did not significantly differ from control mortality.

In conclusion, there is negligible potential for adverse environmental effects of NK603 × MON 810 maize on non-target organisms through their direct or indirect ecological interactions with this maize or through contact with the expressed CP4 EPSPS and Cry1A(b) proteins. The wide range of species examined is considered representative of the spectrum of invertebrate life that can be observed in all compartments of the below- and above-ground ecosystems interacting with the crop.

(b) Effects on biodiversity in other habitats

Like traditional maize, NK603 × MON 810 maize is a poor competitor and is non-invasive of natural environments. Therefore, the potential of this maize to cause adverse effects to wild plants in surrounding habitats, *e.g.* through competition for natural resources, is negligible.

Maize can also interact with animals in habitats surrounding the crop. For instance, as maize is a good source of nutrition, interactions with vertebrate wildlife are well known. However, as NK603 × MON 810 maize is substantially equivalent to traditional maize, except for the introduced glyphosate-tolerance and insect-protection traits, its baseline interactions with these organisms will not be different from traditional maize, except for the potential additional exposure to the expressed CP4 EPSPS and Cry1A(b) proteins.

The CP4 EPSPS and Cry1A(b) proteins have previously been shown to pose negligible risk to animal health.

(c) Effects on pollinators

Please see questions ***31.*****(a)** and ***31.*****(b)**.

(d) Effects on endangered species

Please see questions ***31.*****(a)** and ***31.*****(b)**.

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*

NK603 × MON 810 maize has been planted in the European Union for field-testing (agronomic performance, plant morphology and development, yield assessment, substantial equivalence, glyphosate residue trials) and compositional analysis since 2000.

A Part B consent for field trials was obtained in France (*see* B/FR/00.02.06).

(b) *Conclusions of post-release monitoring*

The conclusions of the E.U. field trials with NK603 × MON 810 maize which were conducted to date, relate to the assessment of agronomic performance, morphological equivalence, yield potential, residues determination and compositional analysis. Trials were conducted in France, a principal growing area in the European Union. Post-release surveillance provided no significant evidence that this maize would likely cause any adverse effects to human or animal health or to the environment.

(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)*

Post-release general surveillance from environments inside and outside the E.U. provided no significant evidence that NK603 × MON 810 maize would likely pose any risk of adverse effects to human or animal health or to the environment.

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

(a) *Release country*

NK603 × MON 810 maize has been planted for field-testing purposes at several locations in the E.U. since 2000 (see question ***32***).

(b) *Authority overseeing the release*

France: Ministry of Agriculture

(c) *Release site*

In the European Union NK603 maize was released for field-testing at several locations in France since 2000(*see* B/FR/00.02.06).

The parental maize lines NK603 and MON 810, however, have already been field-tested in a wide range of geographic locations since 1997 and 1993, respectively. In the E.U. NK603 maize has been planted for field-testing at several locations since 1999, and MON 810 maize since 1994.

NK603 × MON 810 maize was first commercialised in North America in 2002. Currently, NK603 × MON 810 hybrids and parental maize NK603 and

MON 810 have been registered in several world areas. NK603 was approved for cultivation in the U.S.A., Japan, Canada, South-Africa and Bulgaria, and in Mexico, Australia and Russia for import of grain for food purposes. NK603 was first commercialized in the U.S.A. and Canada in the spring of 2001. MON 810 maize has received authorisation for commercialisation in many countries around the world including the U.S.A., the E.U., Canada, Argentina, South Africa and -for import- Japan.

(d) Aim of the release

In the E.U. NK603 × MON 810 maize has been released for field-testing of agronomic performance, residues determination, testing of morphological and agronomic equivalence and for compositional analysis. In addition to the above-mentioned purposes of experimental release, field tests in the U.S.A. were also carried out to study protein expression and for generating the necessary grain material for the conduct of feeding studies.

Since 2002, NK603 × MON 810 maize has been commercially grown in North America.

(e) Duration of the release

Please see question ***33.*(a)**.

(f) Aim of post-releases monitoring

No adverse effects of the GMHP have been identified (see question ***29***). This indicates that a requirement for case-specific post-release monitoring is not appropriate, which is consistent with approvals granted in other world areas.

NK603 × MON 810 maize will be commercialized alongside stewardship and surveillance programmes involving downstream stakeholders in the use of this maize, in order to ensure the implementation of good agricultural practice in its cultivation and to ensure a channel of communication in the unlikely event that unanticipated adverse effects might occur.

No such unanticipated effects have been observed since the commercialization of NK603 × MON 810 maize in other world areas, nor during the field-testing programmes inside and outside the E.U.

(g) Duration of post-releases monitoring

Please see question ***33.*(f)**.

(h) Conclusions of post-release monitoring

Please see question ***33.*(f)**.

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

Field-testing and post-marketing experience provided no significant evidence that grain and derived products from NK603 × MON 810 maize are likely to cause any adverse effects to human or animal health and the environment.

D. *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. Case-specific monitoring

An environmental risk assessment of NK603 × MON 810 maize was undertaken in the context of the scope of the notification, that is, for consent for import of NK603 × MON 810 maize and use of this maize in the E.U. as any other maize, including the cultivation of NK603 × MON 810 maize varieties and the use of this maize for animal feed.

Analysis of the characteristics of NK603 × MON 810 maize and comparison to the experience with cultivation of traditional maize in the E.U. has shown that the risk for potential adverse effects on human health and the receiving environment, resulting from the import and use of NK603 × MON 810 in the E.U., including the cultivation of NK603 × MON 810 maize varieties and use thereof as any other maize, is consistently negligible relative to:

- Persistence or invasiveness
- Selective advantage
- Potential for gene transfer
- Impact on target organisms
- Impact on non-target organisms
- Persons in proximity or contact with the GMHP
- Animal health and the consumption of the GMHP
- Effects on biogeochemical processes
- Changes in agricultural practice

Therefore, the overall environmental risk posed by this genetically modified higher plant is negligible, and no specific strategies for risk management are required. Since the conclusions of this environmental risk assessment are derived from the results of scientific studies, rather than major assumptions, no case-specific post-marketing monitoring actions, typically aimed at testing assumptions made in this assessment, would be warranted or required.

2. General surveillance

Any potential adverse effects of the GMO on human health and the environment which were not anticipated in the e.r.a., can be addressed under the general surveillance. General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified (GM) crop in its receiving environment. Areas of post-marketing surveillance for unanticipated effects are: the agronomic environment, the non-agronomic environment and human and livestock health.

In order to allow detection of the broadest possible scope of unanticipated adverse effects, general surveillance is performed by either selected, existing networks, or by specific company stewardship programmes, or by a combination of both. Such networks are already in place in the majority of E.U. countries and in many cases have been involved either in scientific studies and/or in field trials with GM crops. In addition, company stewardship programmes recognise that farmers are constantly present in the receiving environment and, therefore, are well placed to ensure good stewardship in the cultivation of GM crops as well as being a valuable source of surveillance information.

The notifier will ensure that awareness of good practice in the use of GM crops is made widely available by providing key information, for example by product briefings (*e.g.* farmer and distributor meetings, briefings for agricultural extension services) and technical literature (*e.g.* product leaflets, codes of practice, toll-free telephone number). In addition, further information on products and relevant legislation will be available from a number of sources, including industry and government websites, official registers and government publications.

The main sources of surveillance information are as follows:

- *The seed supply and distribution network.*
  A continuous supply and distribution network extends from the technology provider, via intermediate distribution, to the end-user. Through their sales and technical organisations, key participants, especially those companies involved in farm sales, would be regular visitors to fields where GM crops will be cultivated. Experience has shown that this network ensures a continuous and efficient communication link from the grower to the technology provider, especially in relation to complaints about product performance, and thus would provide a key surveillance network for possible adverse effects.
- *Key external networks*
  As discussed above, the use of existing networks to provide surveillance information is seen as a key aspect of ensuring that sufficient observers are available to identify and report possible unanticipated adverse effects, as well as ensuring methodological consistency and optimising the expenditure of resources. This would include existing observation programmes in the fields of agriculture, the non-agronomic environment, occupational health and livestock welfare.

Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with baseline information. Relevant baseline information will reflect prevalent agricultural practice and the associated impact of these practices on the environment. Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this would be investigated further to establish a correlation, if present, between the use of the GM crop and the observed effect. The evaluation should consider the consequence of the observed effect and remedial action, if necessary, should be proportionate to the significance of the observed effect.

Monsanto will submit a General Surveillance Report containing information obtained from participating networks, and/or in case of an effect that was confirmed. If information that confirms an adverse effect which alters the existing risk assessment becomes available, Monsanto will submit a Report, consisting of a scientific evaluation of the potential adverse effect and a conclusion on the safety of the product. The report will also include, where appropriate, the measures that were taken to ensure the safety of human or livestock health and/or the environment.