

MONSANTO



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European Commission - DG Environment
attn. Hervé Martin
Rue de Genève 1
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Brussels, 21 December 2005

Dear Mr. Martin,

2005 annual general surveillance report for Roundup Ready® corn 2 (NK603) in accordance with Commission Decision 2004/643/EC

In accordance with Article 4(3) of Commission Decision 2004/643/EC of 19 July 2004 approving the placing on the market of NK603 according to Directive 2001/18/EC, the consent holder, Monsanto Europe S.A./N.V., is accountable for reporting of potential occurrence of unanticipated adverse environmental or health effects to the Commission and the competent authorities of the Member States in the E.U.

Therefore, please find herewith the first annual general surveillance report for NK603. To date, the general surveillance accompanying the placing on the market of NK603 in the E.U. indicates that there have been no adverse health or environmental effects associated with the importation and use of NK603. In the light of these results, no revisions to the general surveillance plan are considered warranted.

Please do not hesitate to contact us in case you have further questions on the annual general surveillance report for NK603.

Yours sincerely,

Ir. Annick Pleysier
Regulatory Affairs Manager
MONSANTO

cc: Jaime Alejandro (Ministerio de Medio Ambiente, Spain)
Jaime Costa (Monsanto Regulatory Affairs Manager, Spain)

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1. Background

On 19 July 2004, the European Commission issued Commission Decision 2004/643/EC approving the placing on the market of the genetically modified maize NK603 (MON-ØØ6Ø3-6) in accordance with Directive 2001/18/EC on the deliberate release of genetically modified organisms in the environment¹.

This approval under Directive 2001/18/EC resulted from the notification C/ES/00/01, submitted by Monsanto Europe S.A./N.V. to the Competent Authority of the Kingdom of Spain in 2000, and covers the import and use of NK603 as any other maize, excluding the use of NK603 for planting of varieties in the EU. In accordance with the provisions of Article 18(2) of the Directive, the Spanish Lead Member State informed the notifier, Monsanto Europe S.A./N.V., of the import approval decision on 18 October 2004.

According to the conditions laid down in Article 5 of the Decision, the approval entered into force on 3 March 2005, the date of application of the Community Decision to approve NK603 for human consumption under Regulation (EC) No 258/97 on Novel Foods and Novel Food Ingredients, as published in the Official Journal on 21 June 2005².

2. Outline of the General Surveillance conditions for NK603

In accordance with Directive 2001/18/EC and Article 4 of Commission Decision 2004/643/EC, the consent holder for NK603, Monsanto Europe S.A./N.V., is accountable for general surveillance of the placing on the market of NK603 whole-grain maize in the EU for the duration of the validity of the consent.

Article 4 specifies the following general surveillance requirements:

Art 4(1)

‘Throughout the period of validity of the consent, the consent holder is responsible for ensuring that the general surveillance plan, as contained in the notification, for any adverse effects on human health or the environment arising from the handling or use of the product is put in place and implemented.’

¹ Commission Decision. 2004. Commission Decision (2004/643/EC) of 19 July 2004 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and the Council, of a maize product (*Zea mays* L. line NK603) genetically modified for glyphosate tolerance. *Official Journal* L295/35, 18.9.2004.

² Commission Decision. 2005. Commission Decision (2005/448/EC) of 3 March 2005 authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Union and of the Council. *Official Journal* L158/20, 21.6.2005.

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Art 4(2)

‘The consent holder shall directly inform the operators and users concerning the safety and general characteristics of the product and of the conditions as to general surveillance.’

Art 4(3)

‘The consent holder shall, throughout the period of validity of the consent, without prejudice to Article 20 of Directive 2001/18/EC, submit to the Commission and to competent authorities of the Member States, annual reports on the results of the general surveillance and, in the lights of the results, proposals for a revised monitoring plan.’

Art 4(4)

‘The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States that:

- (a) the surveillance networks, particularly those specified in table 1 of the monitoring plan contained in the notification, collect the information relevant for the general surveillance of the product; and
- (b) that these surveillance networks have agreed to make available this information to the consent holder before the date of submission of the monitoring report to the Commission and competent authorities of the Member States in accordance with paragraph 3.’

In view of the obligation on Monsanto to submit annual monitoring reports for NK603 in accordance to Articles 4(1) and 4(3) of the Decision, Monsanto has undertaken a number of general surveillance activities accompanying the placing on the market of NK603 in the EU. In accordance with Article 4(3) and Article 4(4), a status update on these activities is given in this annual report.

3. Maize imports into the European Union

In the context of the general surveillance plan for imports of GM maize in the European Union, Monsanto has collected statistics on maize imports in the EU-25.

Spain and Portugal are the main EU markets for maize that is imported from outside the European Union. Bulk shipments of maize are likely to be a continual feature of imports into Portugal and Spain, since the EU has established a 2.5 million tonnes combined tariff rate quota for maize imports into these countries at reduced rates of import duty.

Table 1 summarises, by country, the total maize imports from outside the EU-25. Table 2 singles out those import flows that amount to over 50,000 tonnes (which is merely one Panamax bulk shipment³) during an entire year. All such flows originate in the Americas:

³ Panamax bulk carriers are of the maximum size able to pass through the Panama Canal. This is now the main vessel size used in bulk shipments of maize. Therefore annual imports of 50,000 tonnes would imply just one commercial-scale bulk shipment in a 12 month period. Annual imports below this threshold imply a reliance upon smaller shipments, quite possibly in containers.

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from Argentina, Brazil, the US and occasionally Paraguay, with Argentina being the largest exporter of maize grain to the European Union.

Table 1: Summary of Total Maize Imports into the EU-25 plus Bulgaria, Romania and Switzerland from Outside the EU-25, 1999 — Part of 2004 ('000 tonnes)

Imports into	1999	2000	2001	2002	2003	2004
Austria	2	3	4	4	8	4
Belgium	31	23	43	76	124	161
Bulgaria	-	-	-	-	-	-
Cyprus	154	179	160	161	231	77
Czech Republic	0	0	1	1	0	0
Denmark	4	3	4	4	3	1
Estonia	0	5	6	27	19	19
Finland	0	0	0	0	0	0
France	82	71	72	44	35	63
Germany	12	30	9	11	5	109
Greece	2	2	2	74	191	117
Hungary	-	-	-	-	-	-
Ireland	2	2	2	2	1	18
Italy	16	17	15	77	194	550
Latvia	5	16	7	6	14	8
Lithuania	16	20	22	35	49	24
Luxembourg	-	-	-	1	2	-
Malta	30	54	70	56	65	-
Netherlands	59	76	69	26	102	195
Poland	16	217	190	2	1	234
Portugal	368	445	496	470	696	642
Romania	-	19	379	8	65	271
Slovakia	2	0	27	1	1	1
Slovenia	6	9	18	4	42	96
Spain	1,400	1,503	1,412	1,083	2,240	1,115
Sweden	2	2	2	2	1	1
Switzerland	9	8	6	5	26	34
United Kingdom	285	276	242	213	218	157
Sum	2,505	2,981	3,258	2,392	4,333	3,897

Note: An entry of “-“ means zero; an entry of “0” means less than 500 tonnes. Source: National Trade Statistics

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Table 2: Maize Imports into the EU-25 from Outside the EU-25, Identifying Suppliers of Over 50,000 Tonnes, 1999 - Part of 2004 ('000 tonnes)

Importer	Exporter	1999	2000	2001	2002	2003	Part of 2004
Belgium	Argentina				75	61	64
	Brazil					63	97
Cyprus	Argentina				72	77	
	Brazil			69			
	United States	131	179	64		51	52
France	Argentina	61	56	54			
Germany	Brazil						106
Italy	Brazil					59	448
Netherlands	Argentina	52	70	63		86	70
	Brazil						118
Poland	Argentina		214				
	Brazil			155			211
Portugal	Argentina	287	376	399	381	555	433
	Brazil			60	86	140	200
Slovenia	Brazil						96
Spain	Argentina	1,319	1,433	560	718	1,041	655
	Brazil			774	291	980	402
	Paraguay			66		68	
United Kingdom	Argentina	277	268	233	205	192	107

Note: Suppliers are only listed if they supplied over 50,000 tonnes in a year. Entries are only made where shipments exceeded 50,000 tonnes; a blank cell means that imports from an exporter were below 50,000 tonnes that year.

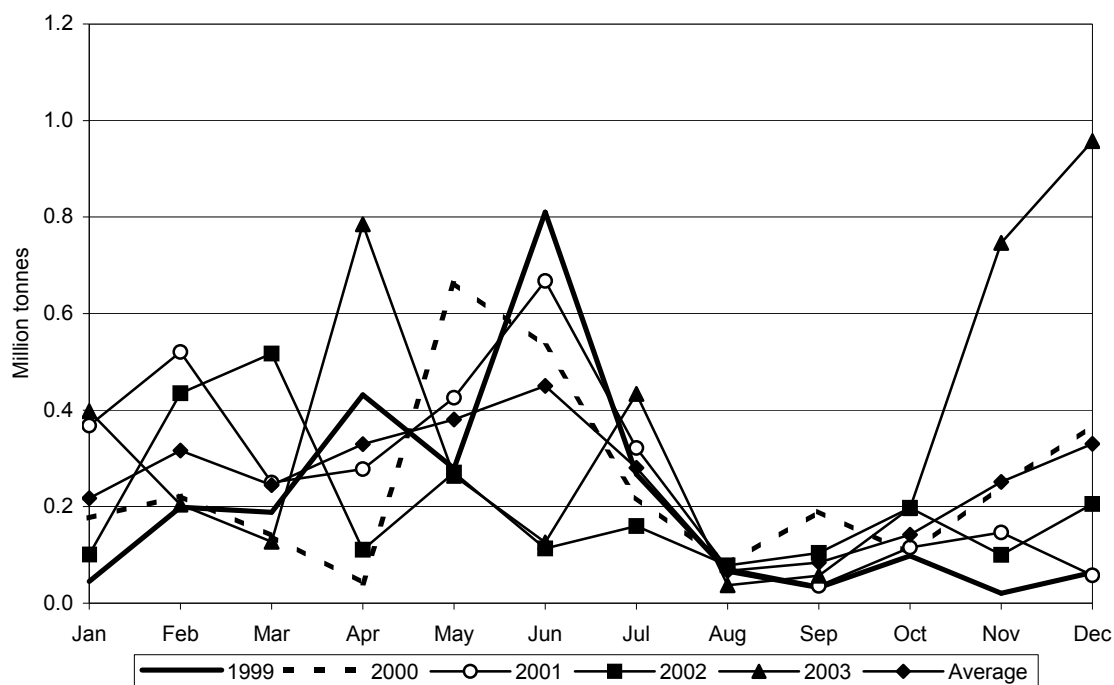
Source: National Trade Statistics

Within the group of leading supplier countries, the large shares for the South American suppliers are explained primarily by seasonal patterns of production. Since the EU-25 is close to being self-sufficient in maize, the need for imports tends to be greatest just before the arrival of the domestic harvest. This is depicted in Diagram 1, illustrating the monthly pattern of total extra-EU-25 maize imports from 1999 to 2003. It is evident that there is a clear seasonality to the monthly imports. They fall to a yearly low at the time of the start of the Community harvest in August; in a typical year, they pick up very slightly in September; they pick up a little more in October; and then move ahead in the last two months of the year. Imports remain at approximately 300,000 tonnes per month in the early months of the year, but then reach a yearly peak of an average of 450,000 tonnes in June, which is immediately before the earliest Community maize harvests reach the market in July.

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Diagram 1: Seasonality of EU-15 Maize Imports from Outside the EU, 1999-2003



Source: LMC, from National Trade Statistics

Most South American maize imports are shipped in Panamax vessels with a capacity of 50,000 tonnes. The only importers among the previous EU-15 countries that appear very regularly as importers of more than 50,000 tonnes a year of non-EU maize are Portugal, Spain and the UK (see Table 2).

- Portugal and Spain provide preferential tariff rate quotas (TRQ) for 0.5 and 2.0 million tonnes per annum, respectively, of maize; and their typical import volumes are close to these levels. These TRQs resulted from bilateral negotiations in 1992 between the US and EU at Blair House in Washington DC; they became part of the EU's commitments under the WTO Uruguay Round, and were incorporated into the basic EU Cereals Common Market Organisation legislation⁴. The TRQs were not reserved for any particular supplying country. Argentina and Brazil are the major sources of extra-EU-25 maize for import into Spain and Portugal. Spain and Portugal are the main importers of Argentine maize in the EU.
- In 2003, maize imports into the UK from within the EU-15 were slightly over 1.2 million tonnes, while those from outside the EU totalled 218,000 tonnes, nearly 90% from Argentina, but with 10% from Brazil.

⁴ Council Regulation (EC) No 1784/2003 of 29 September 2003 on the Common Organisation of the Market in Cereals (Official Journal of the European Union L 270/81, 21/10/2003 P. 0078 – 0095)

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- Among the other EU-15 member states, the ones that feature in Table 2 in at least three years as importers of at least 50,000 tonnes of maize from outside the EU-25 per year are the Netherlands, France and Belgium.
- The new accession states include Cyprus, which regularly imported over 50,000 tonnes of maize from outside the EU-25. Poland was the only other new member that imported this quantity as many as three years in the past six.

Most of the US whole kernel maize export to the EU has been destined for Cyprus and Malta. Apart from 2000, the combined exports to the other 23 current member states plus Bulgaria, Romania and Switzerland totalled not more than 25,000 tonnes in a year (source: US International Trade Commission). Discussions with US maize exporters suggest that, since the 2004 EU enlargement, importers in Cyprus and Malta have turned to other sources of supply for most of their maize requirements.

In overall export volumes, the main category of US maize exports to the EU comprised yellow dent maize, nearly all of which was destined for processed feed uses, apart from small amounts processed into breakfast cereals. The average export volumes from 1999 to 2002 were 180,000 tonnes, but fell sharply in 2003 and again in 2004, when they stood at an annualised rate of about 45,000 tonnes.

Typically for large maize importing harbours in the EU, bulk imports of maize are unloaded at the port of importation into silos. They are then transported by road, rail or barge to feed processors. Imported maize from outside the EU is not normally fed directly as whole kernel maize, but is milled to be used as a compound feed ingredient⁵. This applies to the major bulk importers in Spain and Portugal, as well as to the smaller Northern European importer countries such as Belgium, the Netherlands and the UK. In Spain, where there is significant production of GM maize, this locally produced maize is added to bulk imports of maize in which GM may be present in the distribution circuit supplying feed compounders.

The operational rules and standards that are most relevant to port procedures for all maize imports into the EU are the ISO 9000 procedures about hygiene, unloading procedures, traceability, etc., as part of Good Manufacturing Practice (GMP). Under the ISO 9000 rules, a comprehensive annual review is undertaken of the port operations in order to ensure that preventive actions are taken, where necessary. Once unloaded, the hazard risk control practices prescribed within the HACCP (Hazard Analysis and Critical Control Point) system apply to grain storage and processing.

4. Imports of NK603 into the European Union

NK603 is approved for cultivation and/or import in many countries around the world. An updated list of the global regulatory approvals for NK603 is given in Table 3.

⁵ Note that foods and feeds produced from genetically modified organisms are not within the scope of the monitoring plan under Directive 2001/18/EC.

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Although Monsanto is the consent holder for NK603 in the EU and sells some but not all of the NK603 seed to growers outside the EU, Monsanto is not an operator directly involved in the import of maize grain into the EU. Therefore, Monsanto is not in a position to report directly on globally traded volumes of NK603 grain.

However, as there is an increasing number of regulatory approvals of NK603 for cultivation around the world, the presence of NK603 in a significant portion of the imported maize may be assumed, especially for commodity maize imported from the EU's key maize suppliers that grow NK603.

NK603 maize varieties have been planted commercially in the US and Canada since 2001. In 2003, the product was launched in South Africa and since 2004, NK603 has been commercially grown in Argentina. Since 2005, growers in the Philippines and Honduras are planting NK603 commercially as well, bringing the total number of countries where NK603 is cultivated to six.

Table 3. Approval status of NK603 worldwide (December 2005)

Country	Approval
EU	import, food/feed, processing
USA	Cultivation
Canada	Cultivation
S. Africa	Cultivation
Honduras	Cultivation
Argentina	Cultivation
Philippines	Cultivation
Japan	Import (environm. approval)
Australia	Import
Korea	Import
Mexico	Import
Singapore	Import
Russia	Import
Taiwan	Import
Colombia	Import

In 2004 and 2005, plantings of NK603 totalled between 3.8 and 4 million hectares annually globally. No adverse effects of the cultivation, handling or consumption of NK603 on either human or animal health or the environment have been reported.

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As discussed previously, Argentina typically exports some 0.5 to 1.4 million tonnes of whole-grain maize to Spain and some 0.3 to 0.6 million tonnes to Portugal annually, and smaller quantities to other EU-25 Member States. As of 2005, some portion of the Argentine bulk maize imports into the EU is expected to contain or consist of NK603 grain, given that the first Argentine plantings of NK603 have been harvested in February 2005. Also bulk maize of US origin, that is imported in much smaller quantities into the EU, may contain NK603.

5. Technical and Safety Information on NK603

As requested in Article 4(2) of Commission Decision 2004/643/EC, Monsanto provided information on NK603 to stakeholders, operators and users of the product.

As soon as the Community decisions regarding the import and feed approval of NK603 under Directive 2001/18/EC and the Novel foods approval under Regulation (EC) No 258/97 were announced by the EU Commission on 19 July and 26 October 2004, respectively, Monsanto informed various stakeholders (including international maize traders, processing companies, North American maize growers and the general public) of the regulatory progress made in the EU. The information was spread most widely through company press releases. In these and other communications, Monsanto referred to the safety and general characteristics of the product as well as the scope of the EU approvals obtained, specifying that the approval does not include cultivation of varieties in the EU.

A summary of the safety assessment and general characteristics of NK603 was posted on Monsanto's internet website which is broadly accessible (<http://www.monsanto.com>). The information on NK603 made available by the company was in addition to the information already posted by the European Commission and the European Food Safety Authority, which included: the EFSA scientific opinion and press release of 4 December 2003, the summary of notification C/ES/00/01, the Initial Assessment Report issued by the Lead Member State Spain, the CRL validated detection method, the EU Commission press releases of 19 July and 26 October 2004 announcing the approvals for NK603, the publication of Commission Decisions 2004/643/EC and 2005/448/EC in the Official Journal of the European Union, and the entry of NK603 in the GM Register of Food and Feed.

As specified in section 7 of this report, a network of associations of traders and storers that handle unprocessed maize grain in the EU were provided with specific information concerning the safety, the general characteristics and the general surveillance conditions for NK603 grain. The information which Monsanto provided to those associations consisted of: the Commission Decision 2002/643/EC, a technical facts sheet regarding NK603, the summary of EFSA's safety assessment, and correspondence specifying the general surveillance requirements, an emergency contact number in Spain for the two main markets (Spain and Portugal) and internet links to further information.

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6. Hotline for adverse effect reporting

Operators in the food and feed supply chain in the two main import markets, Spain and Portugal, wishing to report a potential adverse effect associated with the import or use of NK603 whole-grain maize, can contact a Monsanto expert directly by phone. The Monsanto expert is located in Spain and will record any reports of potential adverse effects by means of a standardised adverse effect reporting form (Appendix I). The relevant phone number was made available to the selected industry associations discussed in section 7. Reports of adverse effects would be analysed in the annual general surveillance report. To date no adverse effects have been reported via the hotline.

7. Activities with selected surveillance networks

In accordance with Monsanto's general surveillance plan and according to Article 4(4)(a) of Commission Decision 2004/643/EC, Monsanto selected an external network of operators in the supply chain, that are considered to be best placed to participate in the general surveillance activities for NK603 in the EU.

A number of European industry associations representing the food and feed supply chain were selected as the most appropriate participants in the network, as they are in close contact with a large number of member companies and member associations, whose day-to-day activities in environments where NK603 is handled, stored, transported and/or processed makes them most suitable to observe and report on potential adverse effects linked to the uses mentioned. Monsanto requested confirmation of the participation of these networks in the general surveillance for NK603, in accordance to Article 4(4)(b).

In December 2004, Monsanto experts met with the European industry association COCERAL (<http://www.coceral.com/>), an important network representing maize traders throughout Europe. The members of COCERAL are the national trade organisations in the EU, who represent importing and merchanting companies of cereals and other commodities in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, the Netherlands, Poland, Portugal, Spain, Sweden, and the United Kingdom. Monsanto experts informed COCERAL that NK603 is approved for import in the EU and summarized the safety and technical information on NK603 as well as the conditions for general surveillance.

In follow-up meetings in 2005, Monsanto further discussed the implementation of general surveillance actions for NK603 and future GM products with representatives from COCERAL, UNISTOCK (European association of professional storekeepers of agribulk commodities, <http://www.unistock.be>), FEFAC (the European Feed Manufacturers' Federation, <http://www.fefac.org>) and FEDIOL (the Seed Crushers' and Oil Processors' Federation of the EU, <http://www.fediol.be>). Conditions for general surveillance were presented, as well as options to design processes to collect and guide surveillance information from these networks to consent holders, represented by EuropaBio's Plant Biotechnology Unit (PBU) (<http://www.europabio.org/>).

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The selected operator associations agreed to discuss the requirements and proposals for general surveillance for NK603 (and future products) with their respective member associations and/or member companies. Proposals for the collection of general surveillance information were discussed, which may still be adjusted in the future based on experience gained by the network or experience gained with other products.

To facilitate the notification of any observed adverse effects on human health or the environment by operators handling unprocessed GMOs, the associations COCERAL, UNISTOCK and FEDIOL agreed in their correspondence to

1. inform their member associations to ask their own member companies to monitor post market effects;
2. remind members on an annual basis;
3. request members to inform their association of any adverse effects reported to them by their members;
4. inform the consent holders via EuropaBio's PBU at least annually and otherwise in a timely fashion of any adverse effects reported.

Because maize grain that is imported from outside the EU is not normally used for direct animal feeding without it first having been processed, the participation of FEFAC members in the surveillance network for NK603 was not considered essential. Processed feed materials produced from a GMO are not within the scope of the general surveillance plan under Directive 2001/18/EC.

To date, no reports of adverse effects of NK603 on health or the environment were received from any operators in the surveillance network.

8. Other information sources

Based on an assessment of the potential risks of NK603 to human or animal health and to the environment, this maize has been approved by regulatory agencies around the world (Table 3). Based on the available information and guided by scientific risk assessment principles, NK603 was found to be as safe as traditional maize (e.g. *The EFSA Journal* (2003), 10, 1-13). Therefore, no adverse effects are to be expected from the use of NK603.

NK603 is currently grown on an annual area of around 4 million hectares worldwide. The harvest is often transported over thousands of kilometres by ship, barge, road and/or railroad without any noticeable adverse effects on the environment. Since the first commercial plantings of NK603 varieties in North America in 2001, tens of millions of tonnes of NK603 grain have been handled, imported/exported, used for animal feed, and processed into an array of foods, feeds and industrial products without any apparent adverse effects to humans, animals or the environment.

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Finally, recently published peer-reviewed scientific literature, relevant to the safety of NK603, is included in the list given in Appendix II. Expert analysis of the scientific findings reported in the literature does not indicate any adverse effects associated with the import or use of NK603 as any other maize.

Taking into account a) the favourable scientific evaluations by scientists and regulatory agencies around the world, b) our extensive commercial experience with this product and c) the conclusions from independent research available through the public literature, there is, to the best of our knowledge, no information available that questions the previous conclusion that NK603 does not pose any greater risk to health or the environment than traditional maize.

9. Conclusion: no indication of any adverse effects

To date, the general surveillance accompanying the placing on the market of NK603 in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of NK603.

In the light of these results, no revisions to the general surveillance plan are considered warranted.

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Appendix I

MONSANTO SURVEILLANCE FORM

Country: Office filing number (year/n°): 20.../.....
Date received in office: .../.../200.. via ___ phone ___ fax ___letter ___email.
Monsanto interface person:
Operator name and address (plus phone or email):.....
.....
Company or institution where operator is working:

Crop (fraction):(.....). Variety (if available):
Genetic modification (GM) involved: Unique identifier:
Previous experience of operator with the GM: ___ none, ___ one year, ___ 2 years
___ 3 years, ___ 4 to 6 years, ___ 7 to 10 years, ___ more than 10 years.
Origin of the crop (fraction) involved:
When did the incidence occur?: ___ planting, ___ cultivating, ___ harvesting,
___ loading, ___ transport ___ unloading, ___ processing.
Type of incidence reported (tick if applicable):
___ suspected adverse effect on human health
___ suspected adverse effect on cattle (..... species)
___ suspected adverse effect on wildlife
___ suspected adverse effect on the environment
___ suspected vandalism (by..... (if the action has been claimed).

Summary of the incidence:.....
.....
.....
.....

Recommendations by the Monsanto interface person:.....
.....
.....
.....

Report communicated via email to(Monsanto Europe) on .../.../20....
By

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Appendix II – list of references

- EFSA. 2003a. Opinion of the Scientific Panel on genetically modified organisms on a request from the Commission related to the safety of foods and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto. Question No EFSA-Q-2003-002. *The EFSA Journal* (2003). 9, 1-14.
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