

Application EFSA-GMO-BE-2004-07 (MON863 x MON810 x NK603 maize)				ANNEX G
Comments and opinions submitted by Member States during the three-month consultation period				Revised version
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Comments from National Competent Authority under Directive 2001/18/EC				
AT	Ministry of Health and Women	General comments	<p>The dossier can be regarded as extremely voluminous.</p> <p>1) It is suggested to limit the information given to actual studies that guarantee a comprehensive risk assessment and to reduce the amount of copies of general literature on corn, which is present in all scientific libraries. Additionally studies are attached, that cannot be regarded as appropriate for a state-of-the-art risk assessment, based on actual data.</p> <p>2) Concerning MON863 a lot of member states voted against the placing on the market during the last regulatory committee under Directive 2001/18/EC on 29th November 2004. Concerning maize line NK603 - for which Monsanto got approval for placing on the market according to Regulation 258/97 and Directive 2001/18/EC last year – Austria is still of the opinion that the environmental risk assessment as well as allergological and toxicological risk assessment can be regarded as insufficient.</p> <p>3) In 1999 Austria raised a national ban against the putting on the market of genetically modified maize line MON810 and a regulation has been set into force in this respect.</p>	<p>1) See EFSA guidance document p 67 “each technical dossier should be a stand-alone document containing all of the information required for a full risk assessment of the product(s) in question”.</p> <p>2) Authorisation decision is outside the remit of the GMO Panel</p> <p>3) Not a scientific issue</p>
AT	Ministry of Health and Women	General comments	<p><u>Detection method and reference material:</u> Under part VI – Additional Information of GMOs it is quoted that “because MON863xMON810xNK603 contains multiple DNA inserts, there is no single PCR detection method available for MON863xMON810xNK603 which permits differentiation of this product from its single-trait parents. [...] However, as for all plants in which inserts are combined by traditional breeding, the unambiguous detection of MON863xMON810xNK603 in mixed consignments of grain will require single kernels to be subjected to detection methods for MON863, MON810 and NK603, and to test positive for all three the methods.” This will cause problems with these products containing stacked-genes: If MON863 and MON863xMON810xNK603 will get an approval for putting on the market (NK603 and MON810 got already approval), also a labelling threshold of 0,9% per ingredient will apply according to Regulation 1829/2003. Therefore it remains unclear how analytical results of</p>	Outside the remit of the GMO Panel

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			quantitative analysis of products – containing all four commercialised maize-lines - have to be interpreted. A validated event-specific detection method according to Art. 5 (3) i) of Regulation 1829/2003 for the stacked gene MON863xMON810xNK603 has to be published before deciding about the placing on the market of this product.	
AT	Ministry of Health and Women	General comments	<u>Labelling:</u> Though Monsanto is only notifier and not operator (according to part IV of the dossier), Monsanto should be obliged to transmit also all legal obligations on traceability and labelling to the first operator within the EU.	Outside the remit of the GMO Panel
AT	Ministry of Health and Women	General comments	<u>Post-market monitoring:</u> According to Art. 5 (3) k) of Regulation 1829/2003 a post-market monitoring plan regarding the use of food for human consumption should be added to the dossier.	<p>The Panel has assessed the maize both from a nutritional and safety point of view. See the summary of the scientific opinion: <i>In conclusion, the Panel considers... that it will not have adverse effects on human and animal health or the environment in the context of its proposed use.</i></p> <p>See also section 4.2.7 of the scientific opinion: <i>MON863 x MON810 x NK603 maize is, from a nutritional point of view, equivalent to conventional maize and will be used as any other maize. The GMO Panel is of the opinion that a post-market monitoring of the GM food/feed is not regarded necessary.</i></p> <p>The panel is of the opinion that PMM should be required only in specific cases where there is no traditional comparator. Those cases could include GM (functional) foods with altered nutritional composition and modified nutritional value and/or with specific health claims. See also section 7.11 of the GMO Panel Guidance Document (2006a).</p>
AT	Ministry of Health and Women	C. Information relating to the genetic modification	1) Molecular characterisation of the single maize-events MON863, MON810 and NK603 has been done. This information has been already provided in the former dossiers of these events. In this notification detailed information on the hybrid-line MON863xMON810xNK603 is missing. 2) The statement of the notifier “It is not considered necessary to repeat the laboratory analyses of copy number and insert integrity for MON863xMON810xNK603.” and “... the molecular structure of the inserts has likely been conserved in the combined-trait	As traditional breeding methods were used in the production of MON863 x MON810 x NK603 maize, no genetic modification was involved and thus the molecular structures of the DNA inserts in MON863, NK603 and MON810 were expected to remain unchanged in MON863 x MON810 x NK603. This was shown by the preservation of the phenotypes. Moreover, the molecular structures of the DNA inserts present in MON863 x MON810 x NK603 maize were investigated using Southern analyses. These were conducted to test for the presence of the MON863, MON810

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			product...” (answer concerning expression of potential fusion protein) can not be regarded as appropriate. In this case a postulate is made based on assumptions because all data, that could confirm the statement of the notifier are missing: Molecular characterization of the stacked gene including flanking regions, sequence information, localisation and distance in the genome for critical examination of a possible mutual influence.	<p>and NK603 events in the MON863 x MON810 x NK603 maize. The Southern blot data indicated that gross insert structures and the loci of insertion were retained in the MON863 x MON810 x NK603 maize. There is therefore no reason to assume any risk from structural modifications to the inserts in the maize. The GMO Panel is of the opinion that the stability of the trait phenotypes also provides evidence that the transgenes are combined as described in the dossier.</p> <p>See section 2.2.3 of the scientific opinion and see also the draft guidance “Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing” that has been under public consultation. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_consultations/gmo_hybrids_publcons.Par.0001.File.tmp/GMO_hybrids_publconsul.pdf)</p>
AT	Ministry of Health and Women	D, 07 Information on any toxic, allergenic or other harmful effects on human or...	The assessment of any potential toxic effects of MON863xMON810xNK603 is reduced to the risk assessment of the single traits. Only a broiler chicken study is carried out with MON863xMON810xNK603. The point of view that studies for each of the single products have been carried out and therefore additional subchronic toxicity studies with MON863xMON810xNK603-maize is not considered as necessary cannot be regarded as appropriate. The broiler chicken study is limited to 42 days and cannot be regarded as a suitable instrument for a comprehensive toxicological risk assessment – it is only one component thereof. The assessment of any potential allergenic effects of MON863xMON810xNK603 is reduced to assessment of the allergenicity of the isolated proteins produced from the newly inserted genes. This is done primarily through literature review and research into databases for comparison of the introduced sequence with known allergens. No experimental tests with the GMO itself have been conducted. The risk of an unintended enhancement of allergenic potential is therefore not thoroughly assessed. Secondary effects resulting from the event of insertion, which might lead to new/unexpected allergenic qualities should be studied in depth. It can be stated that the information given by the company is not sufficient to exclude with certainty a potential	<p>See section 4.2.4.3 of the scientific opinion: <i>A 90-days oral toxicity study with MON 863 x MON810 x NK603 maize in rats, which was submitted at a later date, has been assessed by the GMO Panel.</i></p> <p>See section 7.9 of the GMO Panel Guidance Document (2006a): <i>The specific allergy risk of GMOs is associated with i) exposure to newly expressed protein(s) that can be present in edible parts of the plants or in the pollen... and ii) with alterations to the allergenicity of the whole plant and derived products e.g. due to over-expression of natural endogenous allergens as an unintended effect of the genetic modification.</i></p> <p>i) Given this lack of complete predictability of allergenicity of a newly expressed protein, it is necessary to obtain, from several steps in the risk assessment process, a cumulative body of evidence which minimises any uncertainty with regard to the protein(s) in question.</p> <p>This approach is internationally accepted and has been conducted as described in section 4.2.5 of the scientific opinion.</p>

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			<p>allergenic risk of the product in quest: Neither allergenicity nor lack of allergenicity of a protein can be unambiguously proven by comparing its sequence with known allergen sequences for at least two reasons: a) The DNA and/or amino acid sequences of many allergens have been elucidated but the list of allergen sequences is still incomplete and continuously growing. On the other hand it has been shown that isoforms of allergens without allergenic activity exist, which differ from the allergen in only few amino acids. The latter would be wrongly classified as allergens by sequence comparisons. b) Even if a given protein per se does not represent an allergen, its expression in another host organism may indirectly upregulate the expression of potential allergens. It is therefore recommended to compare the engineered plant/plant product with that of the parent/wildtype plant/plant product regarding IgE reactivity to establish whether the transgenic organism represents a more potent allergen source than the parent/wildtype organism for already sensitised patients. The potentially increased ability of the transgenic organism versus the parent/wildtype organism to induce de novo IgE responses (i.e., allergic sensitization) needs to be compared by immunization experiments [Prof. Rudolf Valenta, Head of Department of Pathophysiology, University of Vienna, personal communication to the CA.]. Concerning the results of the above mentioned risk assessment of the company, it must be stated again, that comprehensive risk assessment as described in Spök et.al. [Spök A, Hofer H, Valenta R, Kienzl-Plochberger K, Lehner P, Gaugitsch H: Toxikologie und Allergologie von GVO Produkten, Monographie M-109, Umweltbundesamt, Wien, 2002] should be carried out. The recommendations given for a standardized and harmonized approach to the generation, presentation and interpretation of data concerning allergenicity of GM products are based on in depth scientific studies, performed by experienced scientists in the field. The proposed tests should be performed by the notifier and the resulting data provided in order to guarantee a high level of safety and public confidence in the approach taken.</p>	<p>ii) The issue is to demonstrate that the GM crop will not be more allergenic than the non GM comparator because of an unintended effect of the insertion of the transgene. If the host of the introduced gene is known to be allergenic, any potential change in the allergenicity of the whole GM food should be tested by comparison of the allergen repertoire with that of the conventional non-GM variety. It should be pointed out that these approaches should be applied on a case-by-case basis depending on the available information on the allergenic potential of the host.</p> <p>Furthermore see section 4.2.5.2 of the scientific opinion: <i>However, this issue does not appear relevant to the Panel since maize is not considered a common allergenic food. Food allergies to maize are of low frequency and mainly occur in populations of specific geographic areas. Rare cases of occupational allergy to corn dust have been reported. There is no reason to expect that the use of GM maize will significantly increase the intake and exposure to maize. Therefore a possible overexpression of any endogenous protein, which is not known to be allergenic, would be unlikely to alter the overall allergenicity of the whole plant or the allergy risk for consumers.</i></p>

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AT	Ministry of Health and Women	D, 10 Potential changes in the interactions of the GM plant with the biotic...	Some of the conclusions within the ERA are drawn only on the basis of theoretical argumentation. That means that an ERA - as is the case within this notification - is often reduced to identifying any potential differences between the conventional plant and its GM counterpart or to conclusions drawn from the results obtained with the parental, i.e. the single-trait hybrids maize lines. This approach cannot be regarded as satisfying. Aim of a sound environmental risk assessment has to be the assessment of the GMO itself and its potential effects on the receiving environment.	<p>The scope of the application is for all food and feed uses and does not include cultivation. Therefore, there was no requirement for scientific information, including ecotoxicity studies, on possible environmental effects associated with the cultivation.</p> <p>See section 5.2.2.1 of the scientific opinion: <i>The Panel is of the opinion that the likelihood of unintended environmental effects due to the establishment and spread of this maize will be no different to that of MON863, MON810 or NK603 maize and traditionally maize varieties.</i></p> <p>The GMO Panel evaluated other routes of exposure of MON863 x MON810 x NK603 maize to the environment e.g. through animal faeces. See sections 5.2.2.2 and 5.2.2.3 of the scientific opinion.</p> <p>A draft guidance “Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing” has been under public consultation. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_consultations/gmo_hybrids_publcons.Par.0001.File.tmp/GMO_hybrids_publconsul.pdf)</p> <p>See section 2.b in the draft guidance: <i>Where the substantial equivalence of parental material containing genetically modified events has been fully tested in replicated field trials over at least 2 seasons, one years field trialling of events combined by crossing is acceptable where geographical localities are representative of the climatic conditions to which such crops will be exposed.</i></p>
AT	Ministry of Health and Women	D, 12 Environmental Monitoring Plan	Although the company is of the opinion that the genetically modified maize poses no or negligible risk for potential adverse effects on human health and the receiving environment resulting from the import and use of this GMO in the EU and therefore the overall environmental risk posed by this genetically modified higher plant is negligible and no specific strategies for risk management are required, Austria is nevertheless of the opinion that a monitoring plan according to the provisions of annex VII of directive	<p>See section 5.2.3 of the scientific opinion: <i>The scope of the monitoring plan provided by the applicant is in line with the intended uses for the GMO since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental impacts. Since the main use of MON863 x MON810 x NK603 maize will be animal feeds, the applicant proposed that general surveillance should concentrate on monitoring the health of those exposed to the processing of the</i></p>

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			<p>2001/18/EC that takes into account the accidental release has to be added to the dossier. Import of grains of MON863xMON810xNK603 does not necessarily mean that there is no environmental impact. Experience as well as results of surveys and inspections in Austria [Heissenberger et al., 2003, Research Report 4/03, Federal Ministry of Social Security and Generations (now Federal Ministry of Health and Women), Vienna.] have shown unintended or technically unavoidable contamination (e.g. through transport and processing respectively) leading to the unintended release of seed or grains. Although maize has a weak capability of surviving outside cultivation and of overwintering, consequences concerning implementation of any future potential co-existence of different agricultural systems (with or without GMO) are possible. Generally speaking, the monitoring plan lacks details of the arrangement for carrying out the general surveillance. The rather superficial description of the intended measures does not take into account or describe specific criteria, routes of observance, procedures etc. connected with the notified product and its intended uses.</p>	<p><i>animal feed as well as the animals fed on this maize. The Panel agrees to this proposed generic approach to general surveillance.</i></p> <p>See section 11.4.1.2 of the GMO Panel Guidance Document (EFSA, 2006a): <i>The establishment, persistence and spread of a GM plant is not an environmental hazard in itself. Similarly, dispersal of pollen and seeds and gene flow per se are not environmental hazards and thus the focus of general surveillance should be on recording any unanticipated consequences of the cultivation of the GM plant (...).</i></p> <p>and section 11.4.1.1: <i>In the case of imported GM products containing viable propagating material, general surveillance plans should consider that if substantial loss, spillage or establishment is possible, appropriate management systems should be in place to restrict environmental exposure.</i></p> <p>In this case of import and processing of MON863 x MON810 x NK603 maize, the GMO Panel agreed that environmental exposure will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment and the GMO Panel concluded that case-specific monitoring was not necessary.</p>
AT	Ministry of Health and Women	D, 12 Environmental Monitoring Plan	<p>A lot of questions related to the proposed monitoring plan remain unanswered, e.g.: -Detailed description of the “networks” to be involved; within the notification only general descriptions are to be found -Who is responsible for choosing relevant persons? -Which criteria do these people have to fulfill? What kind of knowledge or expertise is required? -How are traders or processors of maize grains supposed to assess any potential adverse effects on the environment or human health? -How can potential adverse effects on the environment be detected? Especially when it comes to effects concerning non-target organisms, soil microbiology etc. The notifier states that “technical information [...] and relevant legislation will be available for the relevant networks [...]”. Will information about ecosystems and relevant details in connection with the tasks to be carried out also be submitted? -How are cooperation and information</p>	<p>The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a, b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance.</p> <p>See section 5.2.3 of the scientific opinion: <i>The scope of the monitoring plan provided by the applicant is in line with the intended uses for the GMO since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental impacts. Since the main use of MON863 x MON810 x NK603 maize will be animal feeds, the applicant proposed that general surveillance should concentrate on monitoring the health of those exposed to the processing of the</i></p>

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			<p>flow as well as communication between involved people/institutions organized? -How is cooperation as well as quality of reporting ensured? -Which procedures will be in place in case that one or several networks do not report? -Which locations should be monitored particularly? -The environmental monitoring plan further states: „In many cases it may not be possible to establish a causal link between a potential adverse effect and use of a particular GM crop.” It is suggested that the monitoring plan contains a description of further procedure in such cases. As well known, to establish scientific evidence needs time. If any adverse effects can be detected they have to be reported immediately to the competent authority and the European Commission and not only after having considered where they might come from. To ensure comparability of any data, observations or any kind of information processes as well as reporting tools etc. should be standardized for the general surveillance. As the responsibility should remain with the notifier appropriate suggestions should be submitted. No information is provided by the notifier on what data will be collected. From an environmental point of view this should include for example (taking into account the differences relating to regional ecosystems): which parameters are looked for, methods to be applied, detailed timetable, description of baseline etc. These reports should contain all data available (raw data).</p>	<p><i>animal feed as well as the animals fed on this maize. The Panel agrees to this proposed generic approach to general surveillance.</i></p> <p>See section 5.2 of the PMEM opinion (EFSA, 2006b): <i>Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. (...) Thus detailed local arrangements will be developed by the applicant after the application has been accepted (...).</i></p> <p>See section 11.4.2 of the GMO Panel Guidance Document (EFSA, 2006a): <i>Knowing the limitations of existing monitoring systems, it is important for the applicant to describe the processes and criteria that will be used for selecting and evaluating existing monitoring systems for supplying data related to the unanticipated adverse effects of GM plants in the general surveillance.</i></p>
DK	Danish Forest and Nature Agency, Ministry of Environment	General comments	The PCR-method should be validated by the Joint Research Centre of the European Commission, before placing the product on the market.	Outside the remit of the GMO Panel
FR	DGAL (Ministère de l'Agriculture, de l'Alimentation, de la Pêche et de la Rurali	General comments	L'évaluation des risques pour l'environnement liés à la mise sur le marché du maïs MON863xMON810xNK603, telle que décrite dans le dossier EFSA/GMO/BE/2004/07, n'a pas mis en évidence de risques pour l'environnement. La réponse française ne couvre que les risques concernant l'environnement, sachant que les risques pour la santé humaine et animale sont traités par l'évaluation centralisée effectuée par l'AESA.	
DE	Federal Office of Consumer	General comments	Comments of the German Federal Agency for Nature Conservation (BfN):	1) As all parental lines have been assessed in detail by the GMO Panel, the Panel accepts that data for comparative assessment are

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	Protection and Food Safety (BVL)		<p>1) The Federal Agency for Nature Conservation considers that more data are needed to come to a final risk assessment of MON863xMON810xNK603 maize. In particular thoroughly analysed and more detailed data on the phenotypic equivalence and on the expression of the new proteins are recommended. With respect to this, it is our opinion that the number of field seasons and locations is not adequate for a commercial use of the GMO. Moreover data indicate an unexpected increase of Cry3Bb1 levels in the hybrids compared to MON863. Similar results were found when comparing MON863 with MON863xMON810 (Ledesma et al. 2004).</p> <p>2) The risk assessment of the applicant is not sufficient, because it is based on the assumption of the substantial equivalence. We do not share the opinion of the applicant that the provided data prove the substantial equivalence of MON863xMON810xNK603 to the parental lines MON863, MON810 and NK603, respectively.</p> <p>3) Furthermore, we raise objections concerning the placing on the market of maize MON863xMON810xNK603 because of the antibiotic resistance marker (ARM) gene nptII. The gene not only provides a resistance for kanamycin but also for neomycin, geneticin (G418), gentamicin A/B, paromomycin and framycetin. As a consequence of the above mentioned deficits the GMO should not be approved at present.</p>	<p>obtained from one growing season of maize MON863 x MON810 x NK603. See section 3.2.2. of the opinion and see also the draft guidance “Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing” that has been under public consultation. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_consultations/gmo_hybrids_publcons.Par.0001.File.tmp/GMO_hybrids_publconsul.pdf).</p> <p>In addition, the risk assessment performed by the GMO Panel is based on a case by case basis and using a weight of evidence approach. In this specific case, the Panel concluded that within these comparable ranges, the differences in expression of the transgenes in maize MON863 x MON810 x NK603 and the single parental lines are of no significance for safety assessment (see also section 2.2.4 of the scientific opinion).</p> <p>As the parental lines and the resulting hybrids have different genetic backgrounds it is not expected that the transgene proteins are expressed at exactly the same level.</p> <p>The risk assessment was carried out according to the principles in the EFSA guidance document which uses a weight of evidence approach. Taking this into account, there is no evidence from comparative analysis or from animal feeding trials of any adverse effects of MON863 x MON810 x NK603 to human and animal health or to the environment with regard to the proposed uses of MON863 x MON810 x NK603.</p> <p>2) See section 3.3 of the scientific opinion: <i>The Panel therefore concludes that MON863 x MON810 x NK603 maize is compositionally and phenotypically equivalent to its parental single-trait GM lines and non-genetically modified maize, except for the introduced traits.</i></p>

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				<p>3) See section 5.2.2.2 of the scientific opinion: <i>The EFSA GMO Panel recently formulated an Opinion (...) on the use of antibiotic resistance genes in GM plants and concluded that the use of nptII as a selection marker did not pose a risk to the environment or to human and animal health. This conclusion was based on the limited use of kanamycin and neomycin in human and veterinary medicine, the already widespread presence of this gene in bacterial populations and the low risk of trans-kingdom gene transfer from plants to bacteria (...). The nptII is a well-established selection marker with a history of safe use (...). This conclusion is consistent with earlier safety evaluations of nptII (...).</i></p>
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 02 Information on the sequences actually inserted or deleted	There is a discrepancy between the sizes given for EcoRV-fragment of the NK603 event in Fig.4, p.2w (the HSP-70, ctp2 and CP4-epsps comprise 2.8 Kb here) and the size of the respective fragments in Tab 4, p.19 (the fragments sum up to 2.4 Kb here). The respective Southern (Fig. 5, p.25) shows an EcoRV-fragment at a size of 2.8-3.0 Kb.	<p>See section 2.2.3 of the scientific opinion: <i>A fragment size inconsistency in the dossier was resolved by reference to the insert DNA sequence for event NK603. This represents part of the insert DNA and one of the flanks that are characteristic of in event MON810. The presence of the NK603 insert was confirmed by EcoRV digestion and hybridisation with a ctp2-cp4-epsps probe. The expected 2.8kb and 3.8kb restriction fragments were detected. This represents the majority of the insert DNA that is present in event NK603. This additional analysis confirmed that the insert structures were retained in this maize.</i></p>
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 03 Information on the expression of the insert	Comments of the German Federal Agency for Nature Conservation (BfN): Overall the expression of Bt-proteins in MON863 and MON863xMON810xNK603 must be considered high in comparison to other Bt-corn. Nevertheless the expression is not well characterized. The analysis of expression levels in MON863xMON810xNK603 maize is limited to four field sites during the 2002/2003 field season in Argentina (Carringer et al. 2004; Ledesma et al. 2004). Due to technical problems the number of locations and the sample size was further reduced. Since expression can be affected by climatic conditions, soil fertility, agricultural practice or unknown gene-environment interactions, the data presented give only a crude estimate of the expression levels and cannot be regarded as sufficient for a market release. The limited data set (one field season in two Argentinean locations with a total of four field sites) does not allow to test for unintended adverse	<p>As all parental lines have been assessed in detail by the GMO Panel, the Panel accepts that data for comparative assessment are obtained from one growing season of maize MON863 x MON810 x NK603.</p> <p>See section 3.2.2. of the opinion and see also the draft guidance “Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing” that has been under public consultation. http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_consultations/gmo_hybrids_publcons.Par.0001.File.tmp/GMO_hybrids_publconsul.pdf.</p> <p>In addition, the risk assessment performed by the GMO Panel is based on a case by case basis and using a weight of evidence</p>

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			effects on the expression due to gene-environment interactions as different climatic and environmental conditions.	<p>approach .In this specific case, the Panel concluded that within these comparable ranges, the differences in expression of the transgenes in maize MON863 x MON810 x NK603 and the single parental lines are of no significance for safety assessment (see also section 2.2.4 of the scientific opinion).</p> <p>As the parental lines and the resulting hybrids have different genetic backgrounds it is not expected that the transgene proteins are expressed at exactly the same level.</p> <p>The risk assessment was carried out according to the principles in the EFSA guidance document which uses a weight of evidence approach. Taking this into account, there is no evidence from comparative analysis or from animal feeding trials of any adverse effects of MON863 x MON810 x NK603 to human and animal health or to the environment with regard to the proposed uses of MON863 x MON810 x NK603.</p> <p>A draft guidance “Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing” has been under public consultation. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_consultations/gmo_hybrids_publcons.Par.0001.File.tmp/GMO_hybrids_publconsul.pdf)</p> <p>See section 2.b in the draft: <i>Where the substantial equivalence of parental material containing genetically modified events has been fully tested in replicated field trials over at least 2 seasons, one years field trialling of events combined by crossing is acceptable where geographical localities are representative of the climatic conditions to which such crops will be exposed.</i></p>
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 04 Information on how the GM plant differs from	Comments of the German Federal Agency for Nature Conservation (BfN): With regard to a final assessment further information is required. Information including parameters, methods and proper statistical tests should be given to establish the phenotypic and ecologic equivalence of MON863xMON810xNK603 with	<p>See section 3.2.2 of the scientific opinion: <i>In this case, where all parental lines have been assessed in detail by the GMO Panel or are authorised in the EU, the Panel accepts that data for comparative assessment are obtained from one growing season of MON863 x MON810 x NK603 maize .</i></p>

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		the recipient plant in: ...	conventional maize (isolines) and maize with the two single traits. The applicant assumes that the single traits or the combination of the traits by conventional breeding will not alter the plant properties in any unexpected way simply because this was not intended. This is clearly not acceptable. Because unexpected adverse effects should be given special attention in GMO, results from field trials before the market release play an important role in the risk assessment. The data provided to show the agronomic equivalence of MON863xMON810xNK603 (Carringer et al. 2004) are restricted to data from one year and four locations in Argentina. Moreover, variability between the experimental sites were not analyzed and parameters observed allow no assessment of any potential change in ecological characteristics.	<p>A draft guidance “Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing” has been under public consultation. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_consultations/gmo_hybrids_publcons.Par.0001.File.tmp/GMO_hybrids_publconsul.pdf)</p> <p>See section 2.b of the draft guidance: <i>Where the substantial equivalence of parental material containing genetically modified events has been fully tested in replicated field trials over at least 2 seasons, one years field trialling of events combined by crossing is acceptable where geographical localities are representative of the climatic conditions to which such crops will be exposed.</i></p>
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.01 Comparative assessment	Comments of the German Federal Agency for Nature Conservation (BfN): As the analysis of Bt-expression levels, the compositional analysis relies solely on the 2000/2001 Argentinean field trials. The comparative assessment of MON863xMON810xNK603 maize is limited to four field sites during the 2002/2003 field season in Argentina (Carringer et al. 2004). Since nutrients can be affected by climatic conditions, soil fertility, agricultural practice or unknown gene-environment interactions, the data presented give only a crude estimate of the nutrient levels and cannot be regarded as sufficient for a market release. The limited data set does not allow to test for unintended adverse effects due to different climatic and environmental conditions.	<p>See section 3.3.2 of the scientific opinion: <i>In this case, where all parental lines have been assessed in detail by the GMO Panel or are authorised in the EU, the Panel accepts that data for comparative assessment are obtained from one growing season of MON863 x MON810 x NK603 maize .</i></p> <p>A draft guidance “Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing” has been under public consultation. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_consultations/gmo_hybrids_publcons.Par.0001.File.tmp/GMO_hybrids_publconsul.pdf)</p> <p>See section 2.b of the draft guidance: <i>Where the substantial equivalence of parental material containing genetically modified events has been fully tested in replicated field trials over at least 2 seasons, one years field trialling of events combined by crossing is acceptable where geographical localities are representative of the climatic conditions to which such crops will be exposed.</i></p>
DE	Federal Office	D, 07.04	Comments of the German Federal Agency for Nature Conservation	A draft guidance “Risk Assessment of Plants Containing Genetic

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	of Consumer Protection and Food Safety (BVL)	Agronomic traits	(BfN): The data provided to show the agronomic equivalence of MON863xMON810xNK603 (Carringer et al. 2004) are restricted to data from one year and four locations in Argentina. Moreover, variability between the experimental sites were not analyzed and parameters observed allow no assessment of any potential change in ecological characteristics. With regard to a final assessment further information is required. Information including parameters, methods and proper statistical tests should be given to establish the phenotypic and ecologic equivalence of MON863xMON810xNK603 with conventional maize and maize with the two single traits. Because unexpected adverse effects should be given special attention in GMO, results from field trials before the market release play an important role in the risk assessment.	Modification Events Combined by Crossing” has been under public consultation. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_consultations/gmo_hybrids_publcons.Par.0001.File.tmp/GMO_hybrids_publconsul.pdf) See section 2.b in the draft: <i>Where the substantial equivalence of parental material containing genetically modified events has been fully tested in replicated field trials over at least 2 seasons, one years field trialling of events combined by crossing is acceptable where geographical localities are representative of the climatic conditions to which such crops will be exposed.</i>
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.06 Effect of the production and processing	Comments of the German Federal Agency for Nature Conservation (BfN): The applicant states that no effects of processing are expected when comparing MON863xMON810xNK603 maize with traditional maize. However, no data or studies are presented to show that this assumption is valid. The statement that any alteration in MON863xMON810xNK603 maize was not “intended” or only of agronomic nature cannot be sufficient to address any unintended effects.	See section 4.2.3 of the scientific opinion: <i>Since MON863 x MON810 x NK603 maize has been found to be substantially equivalent to conventional maize, except for the introduced traits, considerations of the stability of any altered nutritional components do not pertain to this in the Panel’s opinion.</i>
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.08 Toxicology	Comments of the German Federal Agency for Nature Conservation (BfN): The broiler feeding study was not designed to show possible adverse effects but to show the effect of the genetic modification on broiler performance. It does not prove that any adverse effects are unlikely to occur. The measured parameter are mainly of agricultural and economic relevance. Another criticism of the study is that the control and the conventional maize is not Bt-toxin free. Comments of the German Federal Agency for Nature Conservation (BfN): With regard to the large differences observed the expression studies and the non sufficient compositional analysis, testing of the whole GM food/feed is crucial to obtain the necessary information about any adverse unintended effects of MON863xMON810xNK603 maize on human or animal health. However, only one test with the GMO (broiler study MSL-18762) has been carried out. The broiler feeding study is a pure yield study with nearly no physiological data relating to the health status of the animals. As a consequence the safety of	See section 4.2.4.3 of the scientific opinion: <i>A 90-days oral toxicity study with MON863 x MON810 x NK603 maize in rats, which was submitted at a later date, has been assessed by the GMO Panel.</i> The panel considered that the level of contamination of the controls (with Bt Corn < 2 %) in the nutritional study does not impact the outcome of the assessment given the toxicological profile of the Bt protein. See section 4.3 of the scientific opinion: <i>MON863 x MON810 x NK603 maize has been studied in nutritional feeding studies with broilers and showed no adverse effects. The Panel concludes that the broiler study was adequate to establish nutritional equivalence and considers that the nutritional properties of maize MON863 x MON810 x NK603 would be no</i>

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			MON863xMON810xNK603 maize for human or animal health cannot be assessed from this study. To complete the risk assessment a 90-day-chronic rat study is necessary (see also application EFSA-GMO-DE-2004-03, letter of EFSA dated 27th August 2004). A final risk assessment is therefore not possible. The rat study, in our opinion, should be supplemented by other chronic studies with ruminants and swine which will be exposed to MON863xMON810xNK603 feed. The applicant states that Cry3Bb1 and Cry1Ab have different modes of action and the proteins functions under very different physiological conditions. The assumption seems not to be justified since both proteins are comparatively similar (gut toxins, receptor bound molecules induce pore formation and desintegration of the gut tissue). Additive or synergistic effects therefore can be rather expected and need to be addressed before a market release.	<p><i>different from those of conventional maize.</i></p> <p>The panel considers that additional ruminant and swine studies are not necessary, since the hybrid has been assessed by the panel to be substantial equivalent to conventional maize. This is further supported by the 90-day rat study. Although some differences exist on the efficiency and specificity of action of Cry 1Ab and Cry 3Bb1 on target organisms and explain why they are associated for a wider and more efficient effect, those two proteins may be regarded as having a similar mode of action which is specific of insect gut cells and no binding on receptors of mammalian cells. There are no indications that they have any adverse effect for humans and animals.</p>
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.09 Allergenicity	Comments of the German Federal Agency for Nature Conservation (BfN): The broiler feeding study was not designed to show possible adverse effects but to show the effect of the genetic modification on broiler performance. It does not prove that any adverse effects are unlikely to occur. The measured parameter are mainly of agricultural and economic relevance. Another criticism of the study is that the control and the conventional maize is not Bt-toxin free. Literature to D, 07.09.: FAO-WHO (2001) Evaluation of Allergenicity of Genetically Modified Foods. Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology, Jan. 22-25, 2001. http://www.fao.org/es/ESN/food/pdf/allergygm.pdf . Gaugitsch, Stirn, S. & Spök, A. (2003) Toxikologie und Allergologie von GVO-Produkten - Teil 2B. Untersuchung von Regelungen zur Sicherheitsbewertung von gentechnisch veränderten Lebensmitteln in der EU und den USA. Monographie 164B, Umweltbundesamt Wien. Gendel, S. (1998) The use of amino acid sequence alignments to assess potential allergenicity of proteins used in genetically modified foods. Advances in Food and Nutrition Research 42, 45-62. Metcalfe, D.D., Astwood, J.D., Townsend, R., Sampson, H.A., Taylor, S.L. and Fuchs, R.L. (1996) Assessment of the Allergenic Potential of Foods Derived from Genetically Engineered Crop	<p>See section 4.3 in the scientific opinion: <i>MON863 x MON810 x NK603 maize has been studied in nutritional feeding studies with broilers and showed no adverse effects. The Panel concludes that the broiler study was adequate to establish nutritional equivalence and considers that the nutritional properties of maize MON863 x MON810 x NK603 would be no different from those of conventional maize.</i></p> <p>The panel considered that the level of contamination of the controls (with Bt Corn < 2 %) in the nutritional study does not impact the outcome of the assessment given the toxicological profile of the Bt protein.</p>

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			Plants. Critical Reviews in Food Science and Nutrition 36(S), S165-186. Noteborn, H.P.J.M. (1998) Assessment of the Stability to Digestion and Bioavailability of the LYS Mutant Cry9C Protein from Bacillus thuringiensis serovar tolworthi." Unpublished study submitted to the EPA by AgrEvo, EPA MRID No. 447343-05. Spök, A., Hofer, H., Valenta, R., Kienzl-Plochberger, K., Lehner, P. & Gaugitsch, H. (2002) Toxikologie und Allergologie von GVO-Produkten. Monographie 109, Umweltbundesamt Wien. Spök, A., Hofer, H., Gaugitsch & Stirn, S. (2003) Toxikologie und Allergologie von GVO-Produkten - Teil 2A: Untersuchung zur Praxis und Empfehlungen zur Standardisierung der Sicherheitsbewertung von gentechnisch veränderten Lebensmitteln. Monographie 164A, Umweltbundesamt Wien.	
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.10 Nutritional assessment of GM food/feed	Comments of the German Federal Agency for Nature Conservation (BfN): The nutritional assessment of MON863xMON810xNK603 maize is limited to four field sites during the 2002/2003 field season in Argentina (Carringer et al. 2004). Since nutrients can be affected by climatic conditions, soil fertility, agricultural practice or unknown gene-environment interactions, the data presented give only a crude estimate of the nutrient levels and cannot be regarded as sufficient for a market release. The limited data set (one field season in two Argentinean locations with a total of four field sites) does not allow to test for unintended adverse effects due to different climatic and environmental conditions.	See section 3.2.2 of the scientific opinion: <i>In this case, where all parental lines have been assessed in detail by the GMO Panel or are authorised in the EU, the Panel accepts that data for comparative assessment are obtained from one growing season of MON863 x MON810 x NK603 maize .</i> A draft guidance "Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing" has been under public consultation. (http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_consultations/gmo_hybrids_publcons.Par.0001.File.tmp/GMO_hybrids_publconsul.pdf) See section 2.b in the draft: <i>Where the substantial equivalence of parental material containing genetically modified events has been fully tested in replicated field trials over at least 2 seasons, one years field trialling of events combined by crossing is acceptable where geographical localities are representative of the climatic conditions to which such crops will be exposed.</i>
DE	Federal Office of Consumer Protection and Food Safety	D, 08 Post-market monitoring of GM	Comments of the German Federal Agency for Nature Conservation (BfN): As stated in the application the safety of MON863xMON810xNK603 maize for human or animal health cannot be fully assessed by the provided documents. Therefore a	The Panel has assessed the maize both from a nutritional and safety point of view. See the summary of the scientific opinion: <i>In conclusion, the Panel considers... that it will not have adverse effects on human and animal health or the environment in the</i>

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	(BVL)	food/feed	post-market monitoring of the use of MON863xMON810xNK603 maize for food and feed is regarded obligatory and a post-market monitoring plan is required.	<p>context of its proposed use.</p> <p>See also section 4.2.7 of the scientific opinion: <i>MON863 x MON810 x NK603 maize is, from a nutritional point of view, equivalent to conventional maize and will be used as any other maize. The GMO Panel is of the opinion that a post-market monitoring of the GM food/feed is not regarded necessary.</i></p> <p>The panel is of the opinion that PMM should be required only in specific cases where there is no traditional comparator. Those cases could include GM (functional) foods with altered nutritional composition and modified nutritional value and/or with specific health claims. See also section 7.11 of the GMO Panel Guidance Document (2006a).</p>
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 10 Potential changes in the interactions of the GM plant with the biotic...	Comments of the German Federal Agency for Nature Conservation (BfN): Water and soil may be exposed to the toxins present in MON863xMON810xNK603 via organic waste material and litter or sewage, which occur during processing or through spillage. No data are provided about the concentration of Cry1Ab and Cry3Bb1 in organic waste material or litter and the possibility of an accumulation of the Cry-proteins in the environment. These data should be provided before a market release of MON863xMON810xNK603 maize. No risk assessment concerning this possible exposure of the environment was made by the applicant.	<p>The scope of the application is for all food and feed uses and does not include cultivation. Therefore, there was no requirement for scientific information, including ecotoxicity studies, on possible environmental effects associated with the cultivation.</p> <p>See section 5.2.2.1 of the scientific opinion: <i>The Panel is of the opinion that the likelihood of unintended environmental effects due to the establishment and spread of this maize will be no different to that of MON863, MON810 or NK603 maize and traditionally maize varieties.</i> The GMO Panel evaluated routes of exposure of MON863 x MON810 x NK603 maize to the environment e.g. through animal faeces. See section 5.2.2.3 of the scientific opinion.</p> <p>See section 4.2.5.2 of the scientific opinion: <i>Rare cases of occupational allergy to corn dust have been reported. There is no reason to expect that the use of GM maize will significantly increase the intake and exposure to maize. Therefore a possible overexpression of any endogenous protein, which is not known to be allergenic, would be unlikely to alter the overall allergenicity of the whole plant or the allergy risk for consumers.</i></p>

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DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 12.01 General	Comments of the German Federal Agency for Nature Conservation (BfN): As stated by the notifier, the scope of the application of MON863xMON810xNK603 maize is for import, processing and all uses for food and feed. The applicant provides an environmental monitoring plan. This post-market monitoring plan does not fully meet the objectives defined in Annex VII of Directive 2001/18/EC. A plan suitable to meet these objectives and the supplementing guidance notes (2002/811/EC) is requested.	<p>The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a, b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance.</p> <p>See section 5.2.3 of the scientific opinion: <i>The scope of the monitoring plan provided by the applicant is in line with the intended uses for the GMO since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental impacts. Since the main use of MON863 x MON810 x NK603 maize will be animal feeds, the applicant proposed that general surveillance should concentrate on monitoring the health of those exposed to the processing of the animal feed as well as the animals fed on this maize. The Panel agrees to this proposed generic approach to general surveillance.</i></p> <p>See section 5.2 of the PMEM opinion (EFSA, 2006b): <i>Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. (...) Thus detailed local arrangements will be developed by the applicant after the application has been accepted (...).</i></p> <p>See section 11.4.2 of the GMO Panel Guidance Document (EFSA, 2006a): <i>Knowing the limitations of existing monitoring systems, it is important for the applicant to describe the processes and criteria that will be used for selecting and evaluating existing monitoring systems for supplying data related to the unanticipated adverse effects of GM plants in the general surveillance.</i></p>

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DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 12.02 Case-specific GM plant monitoring	Comments of the German Federal Agency for Nature Conservation (BfN): We do not share the opinion of the applicant that a case specific monitoring is not necessary. During transport, storage, package or processing incidental spillage of MON863xMON810xNK603 maize can occur. Furthermore the exposure of MON863xMON810xNK603 maize and the corresponding Bt-proteins to the environment during or after the production process and during animal consumption is given. Therefore, case specific monitoring has to focus on pathways, how the MON863xMON810xNK603 maize can get into the environment. The notifier is requested to provide a case specific monitoring plan including information • how losses and spillage of MON863xMON810xNK603 maize during transport, storage, package, processing and use as feed will be monitored, • how the exposure of organic waste material or waste water containing MON863xMON810xNK603 maize and the corresponding Bt-protein to the environment during or after the production process or after animal consumption will be monitored. If spread, persistence and accumulation of MON863xMON810xNK603 maize and the corresponding Bt-protein in the receiving environment occur, further observations of possible impacts on organisms, food chains and habitats in the specific environment are required	See section 11.4.1.2 of the GMO Panel Guidance Document (EFSA, 2006a): <i>The establishment, persistence and spread of a GM plant is not an environmental hazard in itself. Similarly, dispersal of pollen and seeds and gene flow per se are not environmental hazards and thus the focus of general surveillance should be on recording any unanticipated consequences of the cultivation of the GM plant (...).</i> and section 11.4.1.1: <i>In the case of imported GM products containing viable propagating material, general surveillance plans should consider that if substantial loss, spillage or establishment is possible, appropriate management systems should be in place to restrict environmental exposure.</i> In this case of import and processing of MON863 x MON810 x NK603 maize, the GMO Panel agreed that environmental exposure will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment and the GMO Panel concluded that case-specific monitoring was not necessary.
DE	Federal Office of Consumer Protection and Food Safety (BVL)	D, 12.03 General Surveillance of the impact of the GM plant	Comments of the German Federal Agency for Nature Conservation (BfN): According to Directive 2001/18/EC general surveillance is a compulsory part of the monitoring. The objective of general surveillance is to monitor potential cumulative long-term impacts on human health and the environment and to identify the occurrence of adverse effects of the GMO on human health and the environment which were not anticipated in the E.R.A. The general surveillance plan, provided by the applicant isn't in line with the supplementing guidance notes (2002/811/EC). The applicant presents a plan that existing networks and internet information are going to be monitored and does not specify the monitoring parameters. Both parts of the monitoring plan – case-specific monitoring and general surveillance have to meet the following general requirements: • A fully specified list of monitoring parameters has to be defined. The applicant is requested to present for each parameter a detailed statement of the	The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a, b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance. See section 5.2.3 of the scientific opinion. <i>The scope of the monitoring plan provided by the applicant is in line with the intended uses for the GMO since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental impacts. Since the main use of MON863 x MON810 x NK603 maize will be animal feeds, the applicant proposed that general surveillance should concentrate on monitoring the health of those exposed to the processing of the animal feed as well as the animals fed on this maize. The Panel</i>

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			<p>parameter definition, the observation methods (collection and analysis of samples with references), the frequencies of observations (time and number of visits to collect data) and the monitoring locations including number and size. Furthermore an operating schedule giving full details of points in time is requested. • In case of monitoring data being collected by external persons or institutions other than the applicant binding agreements/contracts with third parties are requested which clearly determine what data are provided and how these data are made available. • The concept of sampling needs to be elaborated. Particularly, it must be explained how the necessary representativeness of the collected data in space and time has to be ascertained. The applicant is requested to indicate how the monitoring plan is adapted to different local conditions where appropriate. • The methods of data analysis including the statistical methods have to be elaborated in full detail. • The applicant is required to report on the results of the monitoring on an annual basis. All raw data have to be appended to the reports. • The applicant is requested to state how the condition of the environment before the placing on the market of the notified maize is described (determination of the baseline status of the receiving environment as a point of reference of the monitoring). • The time-period of monitoring needs to be sufficient to detect delayed or long-term adverse effects. Therefore, it may be necessary to extend the monitoring of certain parameters beyond the period of the consent. • The applicant is requested to state how the results of the monitoring will be published. Furthermore, the general surveillance plan has to focus on possible pathways how MON863xMON810xNK603 maize can get into the environment and how unforeseen adverse effects on human health and the environment can be linked to the dispersal of the GMO. Therefore, the applicant is requested to provide an appropriate monitoring plan to observe the spread, persistence and accumulation of the inserted genetic sequences and the corresponding proteins in organism and environmental media (soil, air, water).</p>	<p><i>agrees to this proposed generic approach to general surveillance.</i></p> <p>See section 5.2 of the PMEM opinion (EFSA, 2006b): <i>Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. (...) Thus detailed local arrangements will be developed by the applicant after the application has been accepted (...).</i></p> <p>See section 11.4.2 of the GMO Panel Guidance Document (EFSA, 2006a): <i>Knowing the limitations of existing monitoring systems, it is important for the applicant to describe the processes and criteria that will be used for selecting and evaluating existing monitoring systems for supplying data related to the unanticipated adverse effects of GM plants in the general surveillance.</i></p>

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GR	HELLENIC FOOD SAFETY AUTHORITY	A, 06 Where applicable, a detailed description of the method of production and...	Which is the so-called "traditional breeding method" that is used to produce the F1 from the hybrid MON863xMON810xNK603? Which are the parents in the final cross that will subject the F1 of the triple hybrid?	<p>See section. 2.2.1 of the scientific opinion: <i>Traditional breeding methods were used to produce MON863 × MON810 × NK603 maize and no new genetic manipulation was involved. The three transgenic inserts that are present in MON863 x MON810 x NK603 maize were derived from three independent single trait GM maize lines: MON863, MON810 and NK603. Each of these GM maize lines was the subject of an earlier safety evaluation and separate Opinions for each of them have been published (...). The maize MON863 × MON810 × NK603 combines the insect protection traits from MON863 and MON810 with the herbicide tolerance trait from NK603.</i></p> <p><i>The production of hybrid maize is a well established process in traditional maize breeding. It involves the production of separate elite inbred lines that are subsequently crossed in order to produce hybrid seed that is used in agriculture. This process allows the selection of desirable traits and the crossing of inbred lines results in heterosis and a superior agricultural performance.</i></p> <p><i>The use of GM maize in agriculture involves analogous traditional breeding methods for the production of hybrid seed and this is the case both for GM maize with a single transgenic insert and for multiple trait hybrids, including MON863 × MON810 × NK603.</i></p> <p><i>Where two GM traits are combined in a hybrid the individual inbred GM lines can be crossed as a final stage in the production of seed for agriculture. The breeding process is necessarily more complex in the case of MON863 × MON810 × NK603 maize where three independent transgenic traits are combined. The applicant uses three related breeding strategies to produce MON863 × MON810 × NK603 seed. Inbred lines are produced for each of the three single trait GM maize lines: MON863, MON810 and NK603. Inbred lines are produced for the three possible paired combinations of the independent transgenic inserts: MON863 × MON810, MON810 × NK603 and MON863 × NK603. The final stage in MON863 × MON810 × NK603 seed production involves a cross between appropriate inbred lines with</i></p>

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				<i>a single and a double transgenic insert. The resulting seed is used in agriculture.</i>
GR	HELLENIC FOOD SAFETY AUTHORITY	D, 07.01 Comparative assessment	The forage and compositional data of MON863xMON810xNK603 and the traditional maize control demonstrated statistically significant differences for folic acid. These differences were within the 99% tolerance interval for the commercial reference hybrids. Moreover, these differences were found only at one site and not consistently across all sites. We consider that further analysis in samples from different fields is necessary in order to ensure the equivalence of the GM food / feed with the traditional maize.	
GR	HELLENIC FOOD SAFETY AUTHORITY	D, 07.02 Field trials	Field trials in different climatic conditions provide useful information on the protein levels of cry1Ab, cry3Bb1 and cp4 epsps throughout the growth and development of the maize. The protein levels are relatively good quantitative markers of the competitive advantage of this maize against pest attacks and fields sprayed with herbicides. The file on the MON863xMON810xNK603 maize includes data on field trials that were conducted only in Argentina. Data on field trials that were conducted in other parts of the world with different climatic conditions should be provided.	
GR	HELLENIC FOOD SAFETY AUTHORITY	D, 07.08 Toxicology	We think that an additional 90-day feeding study in rats should be carried out to further complete their safety assessment.	
IT	Ministero dell'ambiente e della tutela del territorio	General comments	As a preliminary remark, we note that in the notification at least four general aspects are not clear or correct, in our view. 1) First of all, we note that the Unique Identifier proposed for the product it is clearly not in agreement with the Commission Regulation (CE) N. 65/2004, of January 2004. 2) Second, in the Summary of the notification we note that the applicant does not answer to the relevant question in Paragraph 2.c : as this question has been proposed according to Commission Decision n° 2004/204/EC, Art. 3(a)(ii), and considering the legal implication of the issue, we believe that an exact answer to such a question is needed, with the name and address of a single person which is responsible for the placing on the EU market of the product. 3) Third, the Scope of the notification (Paragraph 3 of the Summary), includes plants for food/feed production (which would be letter a) of paragraph 1 of	

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			Articles 3 (for food) and 15 (for feed) of Reg. (CE)/1829/2003. This is in contrast with the content of the notification, where several time the request for import of food/feed or for processing is stated. We recall that Reg. (CE)178/2002 clearly identifies as food/feed plant products after harvest: the current Scope in the summary seems to imply a request for authorisation for pre-harvest products (never covered in the notification itself). 4) Fourth, we note that one of the elements of this "stacked" GMO, i.e. event MON 863, has never been authorised in the EU, and contains an antibiotic resistance trait. As no final decision has been taken on issues related to Article 4, paragraph 2, of Dir. 2001/18/EC, this product should not be considered, so far, as suitable for placing in the EU market.	See section 5.2.2.2 of the scientific opinion: <i>The EFSA GMO Panel recently formulated an Opinion (...) on the use of antibiotic resistance genes in GM plants and concluded that the use of nptII as a selection marker did not pose a risk to the environment or to human and animal health. This conclusion was based on the limited use of kanamycin and neomycin in human and veterinary medicine, the already widespread presence of this gene in bacterial populations and the low risk of trans-kingdom gene transfer from plants to bacteria (...). The nptII is a well-established selection marker with a history of safe use (...). This conclusion is consistent with earlier safety evaluations of nptII (...).</i>
IT	Ministero dell'ambiente e della tutela del territorio	General comments	As more specific technical considerations for the product, we note the following: -from the description of the breeding process which has conducted to the product, it appears that the same product would be generated (at least) by three different breeding patterns. Since the production of the same product it is clearly not possible for living material generated by sexual processes, it is obvious that the request of authorisation does not concern a single product, but rather a process; 1) no information is provided by the notifier on the erbicide residuals in the product; -no measures to guarantee coexistence among this GMO product and its traditional and/or organic counterparts is present. There is no clear provisions for use and transport of the product, to prevent accidental dispersal and/or co-mingling with non GM maize, and provisions for the treatment of residuals of processing (including waste product which may contain living seeds) are also absent; -the objectives of traceability and labelling following Reg. CE/1830/2003 should be respected: this is not clear from the content of the notification; 2) post marketing monitoring should be more accurate and effective, with national details, including provision for information of ANC under Dir. 2001/18/EC in case of accidental spillage of living material, to be agreed by National Authorities. Moreover, we recall that, in previous evaluation of the GMO traits MON 863 and NK 603, we have made the following observations/objection, which still hold true in our opinion. For MON 863, our objections can be	1) and 3) Human and animal health issues related to plant-protection products are regulated by Directive 91/414/EEC and fall outside the remit of the GMO Panel. 2) and 4) See section 5.2.3 of the scientific opinion. <i>The scope of the monitoring plan provided by the applicant is in line with the intended uses for the GMO since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental impacts. Since the main use of MON863 x MON810 x NK603 maize will be animal feeds, the applicant proposed that general surveillance should concentrate on monitoring the health of those exposed to the processing of the animal feed as well as the animals fed on this maize. The Panel agrees to this proposed generic approach to general surveillance.</i>

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			summarised as follows: -the notifier did not extended, as required, the sequencing of all the insertion sites to identify and characterise all the unintended sequences effectively inserted; -not enough data have been provided to evaluate the presence of chloroplastic and/or mitochondrial DNA in plant genome (as a by product of the genetic manipulation); -feeding studies were criticised by this ANC, and others. Within the process of authorisation in the frame of Dir. 2001/18/EC, even the Reporting Country proposed to repeat the test. For the event NK 603 our objections can be summarised as follows: 3) no information was provided by the notifier on the erbicide residuals in the product; 4) for the monitoring plan, similar requirements as those requested for this product above were also requested for NK 603 Finally, we point the fact that, being unacceptable the authorisation for a "process" instead that for a "product", we strongly believe that the authorisation document must include, if necessary as an annex, a clear description of the transgenic genomic traits known to be present in the product.	
LV	Latvian Food centre	A. General information	Member State of application is Belgium, since Monsanto Europe S.A. is registered in Belgium. The Monsanto development code for this genetically modified maize is MON 863 x MON 810 x NK603. In countries where MON 863 x MON 810 x NK603 varieties are being cultivated, packages of hybrid seed of this maize are marketed under the name of the hybrid variety, in association with the trademarks YieldGard®1 Plus and Roundup Ready®1 corn 2, indicating clearly to growers that the hybrid is protected from certain coleopteran and lepidopteran insect pests and tolerant to Roundup®1 herbicide, containing the active ingredient glyphosate.	
LV	Latvian Food centre	A, 01 Name and address of the applicant (company or institute)	Monsanto company possesses unique experience in construction of genetically modified maize	
LV	Latvian Food centre	A, 04 Scope of the application	The GM plant is addressed for food and feed use, for import and processing, but not for seeds and plant propagating material for cultivation in Europe.	

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		as defined in Annex II		
LV	Latvian Food centre	A, 05 Designation and specification of the GM plant and/or derived product	MON 863 x MON 810 x NK603 is produced by the combination of genetically modified YieldGard® Rootworm maize (MON 863), YieldGard® Corn Borer maize (MON 810) and Roundup Ready® maize (NK603)3 using traditional breeding methods. No additional genetic modification is involved in the production of MON 863 x MON 810 x NK603.	
LV	Latvian Food centre	A, 06 Where applicable, a detailed description of the method of production and...	The method of plant construction is described in sufficient details	
LV	Latvian Food centre	A, 07 Where appropriate, the conditions for placing on the market the food(s) or...	The scope of the application is for import, processing and all uses of MON 863 x MON 810 x NK603 for food and feed. The range of uses of this maize for food and feed will be identical to the full range of equivalent uses of traditional maize. MON 863 x MON 810 x NK603 will be traded and used in the European Union in the same manner as current commercial maize varieties and by the same operators currently involved in the trade and use of traditional maize. No specific conditions or instructions are considered necessary for the placing on the market of MON 863 x MON 810 x NK603 for import, processing, and use as or in food and feed. As demonstrated in this application, MON 863 x MON 810 x NK603 is equivalent to traditional maize except for its protection against the corn rootworm pest, certain lepidopteran insect pests, and its tolerance to glyphosate, which are traits of agronomic interest. This maize was shown to be as safe and as nutritious as traditional maize. Therefore, MON 863 x MON 810 x NK603 and derived products from MON 863 x MON 810 x NK603 will be stored, packaged, transported, used, and handled in the same manner as for current commercial maize varieties, and the measures for waste disposal and treatment of	

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			MON 863 x MON 810 x NK603 products are the same as those for traditional maize.	
LV	Latvian Food centre	B. Information relating to (a) the recipient or (b) parental plants	Exhausting information is given by the Inventor on the description and characteristics of the recipient and parental plants	
LV	Latvian Food centre	C. Information relating to the genetic modification	The most important point consists in the fact that no novel method of genetic modification has been utilized in the production of MON 863 x MON 810 x NK603. Instead, traditional maize breeding methods are used to cross inbreds of MON 863, MON 810 and NK603. Whereas MON 863 x MON 810 x NK603 results from traditional breeding, genetic modification was used in the development of the single-trait parents. MON 863, MON 810 and NK603 were produced using the particle acceleration method.	
LV	Latvian Food centre	D. Information relating to the GM plant	Summarizing, MON 863 x MON 810 x NK603 has been produced by crossing the parental single-trait maize lines MON 863, MON 810 and NK603 by means of traditional breeding methods. The GM genes expressed by MON 863 x MON 810 x NK603 are therefore following: 1. The Cry3Bb1 protein from MON 863, which confers protection against certain coleopteran insect pests (<i>Diabrotica</i> spp.) 2. The NPTII protein from MON 863. The nptII gene is inserted into maize cells along with the MON 863 cry3Bb1 gene to have an effective method for selecting cells that contain the insecticidal gene and can be used in bacterial selection during construction of the plasmid. 3. The Cry1Ab protein from MON 810, which confers protection against certain lepidopteran insect pests, including the European Corn Borer (<i>Ostrinia nubilalis</i>) and pink borers (<i>Sesamia</i> spp). 4. The CP4 EPSPS proteins from NK603, which imparts tolerance to glyphosate (N-phosphonomethyl-glycine), the active ingredient of the non-selective broadspectrum herbicide Roundup. The structure of the GM plant is described in details, with all necessary explanations.	
LV	Latvian Food centre	D, 04 Information	The most important point is that the introduced insect-protection traits and the herbicide tolerance trait have no influence on maize	

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		on how the GM plant....	reproductive morphology and hence no changes in seed dissemination are to be expected.	
LV	Latvian Food centre	D, 05 Genetic stability of the insert and phenotypic stability of the GM plant	The harvested (F2) grain of MON 863 x MON 810 x NK603 is marketed by the grower for food, feed or industrial use and is not used for further breeding. Therefore, there is negligible opportunity for its genetic or phenotypic stability to be compromised.	
LV	Latvian Food centre	D, 06 Any change to the ability of the GM plant to ...	No elements known to be involved in DNA mobility are contained in either of the inserted DNA fragments. Therefore, in comparison to traditional maize, no changes are to be expected in the ability of the GM plant to exchange genetic material with bacteria.	
LV	Latvian Food centre	D, 07 Information on any toxic, allergenic or other harmful effects on human or...	Compositional analyses were performed on forage and grain samples from MON 863 x MON 810 x NK603, grown at four sites in Argentina during the 2002-2003 season. It has been concluded that MON 863 x MON 810 x NK603 is compositionally equivalent to traditional maize.	
LV	Latvian Food centre	D, 07.04 Agronomic traits	Take into account that this application does not include the cultivation of MON 863 x MON 810 x NK603 varieties in the E.U.	
LV	Latvian Food centre	D, 07.05 Product Specification	It is important for the EU that the MON 863 x MON 810 x NK603 will be imported into the EU in mixed shipments of maize products, produced in other world areas, for use by operators that have traditionally been involved in the commerce, processing and use of maize and maize derived products in the EU. MON 863 x MON 810 x NK603 comprises all traditionally bred maize, produced by the combination of MON 863, MON 810 and NK603, which have been approved by the EU earlier.	
LV	Latvian Food centre	D, 07.06 Effect of the	Using both wet and dry milling processes, maize is converted into a diverse range of food and feed products and derivatives used as food	

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		production and processing	and feed ingredients or additives. As MON 863 x MON 810 x NK603 is substantially equivalent and as safe and as nutritious as traditional maize, the use of MON 863 x MON 810 x NK603 for the production of foods and feeds is no different from that of traditional maize.	
LV	Latvian Food centre	D, 07.08 Toxicology	MON 863 x MON 810 x NK603 is produced by traditional breeding of MON 863, MON 810 and NK603 lines. Each of the introduced traits from the parental lines are inherited in MON 863 x MON 810 x NK603, which results in the combined expression of the Cry3Bb1, NPTII, Cry1Ab and CP4 EPSPS proteins in the same plant. These introduced proteins are present at low levels and were demonstrated to be safe for animal and human health. History of safety of the GM proteins is provided in details.	
LV	Latvian Food centre	D, 07.09 Allergenicity	Absence of any allergenic potential associated with the introduced Cry3Bb1, NPTII, Cry1Ab and CP4 EPSPS proteins expressed in MON 863 x MON 810 x NK603 has previously been demonstrated.	
LV	Latvian Food centre	D, 07.10 Nutritional assessment of GM food/feed	Feeding trials should have included more animals per treatment to increase the power of the statistical analysis or sensitivity of the trial in all three cases. File 18175: trial with rats The threshold difference between two treatments seems to be 7 to 10%, based on the observed coefficient of variation and the number of animals per treatment. Hence, more animals per treatment would have been more appropriate to increase the sensitivity of the test. File 17243: trial with broilers Reported mortality ranges from 3 to 7 % through treatments, which is rather high as being compared with standard practice on farms, i.e. <1%. Mean values with variation are not reported, so that it is difficult to calculate the power of the statistical analysis. File 18163: trial with broilers Again reported mortality is rather high within some treatments, up to 7%. Mean values and variation are reported, showing that differences from 10 to 15% on can be detected, which is much higher than in a farm environment. Hence, also in this case the sensitivity of the trial is too low.	
LV	Latvian Food centre	D, 08 Post-market monitoring	There are no intrinsic hazards related to MON 863 x MON 810 x NK603 as no signs of adverse or unanticipated effects have been observed in a number of safety studies, including animal feeding studies using doses of administration that are orders of magnitude above expected consumption levels.	

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LV	Latvian Food centre	D, 09 Mechanism of interaction between the GM plant and target org...	Any significant interactions of MON 863 x MON 810 x NK603 with its target pest organisms are, however, limited to those countries where the cultivation of this maize has been authorized. The cultivation of MON 863 x MON 810 x NK603 varieties in the E.U. is not within the scope of this application. The likelihood that the import and use of MON 863 x MON 810 x NK603 for food, feed or processing will result in plants of this maize being present in the environment is negligible.	
LV	Latvian Food centre	D, 10 Potential changes in the interactions of the GM plant with the biotic...	Like for traditional maize, the likelihood of MON 863 x MON 810 x NK603 spreading in the environment is negligible, as maize is neither persistent nor invasive and these parameters are unaltered in MON 863 x MON 810 x NK603 when compared to traditional maize. Hence the risk of establishment and spreading of MON 863 x MON 810 x NK603 in the environment is negligible.	
LV	Latvian Food centre	D, 10.03 Potential for gene transfer	There is no potential for gene transfer from MON 863 x MON 810 x NK603 to wild plant species in the E.U. and negligible likelihood for gene transfer to other maize crops, as this application is not for consent to cultivate MON 863 x MON 810 x NK603 varieties in the E.U. The environmental risk of potential gene transfer is negligible.	
LV	Latvian Food centre	D, 10.04 Interactions between the GM plant and target organ..	Since the likelihood is negligible that the import, processing and food and feed use of MON 863 x MON 810 x NK603 will result in plants of this maize establishing in the environment, any significant interactions with target organisms are unlikely.	
LV	Latvian Food centre	D, 10.06 Effects on human health	The likelihood for any adverse effects, occurring in humans as a result of their contact with this maize, is no different from traditional maize. MON 863 x MON 810 x NK603 contains the Cry3Bb1, NPTII, Cry1Ab and CP4 EPSPS proteins, which have negligible potential to cause any toxic or allergenic effects in man. Therefore, the risk of changes in the occupational health aspects of this maize is negligible.	

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LV	Latvian Food centre	D, 10.07 Effects on animal health	The likelihood of potential adverse effects in animals fed on MON 863 x MON 810 x NK603 and in humans, consuming those animals, is negligible. Therefore, the risk of MON 863 x MON 810 x NK603 for the feed/food chain is also negligible.	
LV	Latvian Food centre	D, 12 Environmental Monitoring Plan	The monitoring plan elaborated by company is well based and sufficiently detailed.	
MT	Malta Environment and Planning Authority	General comments	It is important to note that Malta has never reviewed the dossier of MON810, as it was notified and authorised prior to Malta's accession into the EU. All applications which contain this event refer to the MON810 dossier, which Malta never reviewed and therefore cannot approve.	Not within the remit of EFSA
MT	Malta Environment and Planning Authority	D, 05 Genetic stability of the insert and phenotypic stability of	1) Searches on information in the public domain showed that the stability of the inserted DNA in MON810 was not conclusive and so further information regarding this line is needed.	See section 2.2.2: <i>An apparent inconsistency in bioinformatic data for the 5' flanking DNA in MON810 was clarified as resulting from searching an updated database. In addition, a specific concern about possible secondary insertions of the nos terminator in the genome of MON810 was resolved (...).</i>
NO	Directorate for Nature Management	A. General information	The Notification lack information on possible benefit for the society, ethics and effects on sustainable development. This is a demand in accordance to the Norwegian Gene Technology Act which will be addressed in the evaluation of the notification in Norway.	
NO	Directorate for Nature Management	D, 10.05 Interactions of the GM plant with non-target organisms	D.10.05 We find that the selectivity of the Bt-toxin is not documented well enough for European conditions and request that EFSA ask for more information on this.	
NO	Directorate for Nature Management	D, 10.06 Effects on human health	The genetically modified maize MON 863 contains the intact resistance gene NPTII that confer resistance towards the antibiotics: kanamycin, neomycin, geneticin, gentamicin A & B, butirosin and paramomycin. In Norway there is a certain use of these antibiotics in	

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			<p>veterinary medicine. (In Norway, the antibiotic neomycin, is in use in veterinary treatment. The Norwegian report "NORM/NORM-VET 2003. Usage of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Norway. Tromsø / Oslo 2004. ISSN:1502-2307" gives an overview of the annual consumption of antimicrobial agents and occurrence of resistance in Norway. The veterinary use of some relevant antibiotics (without the usage in aquaculture) is as follows: Tetracyclines 175 kg, Ampicillin 8 kg. Amoxicillin 192 kg, Neomycin 35 kg, Dihydrostreptomycin 139 kg. The total veterinary use of antibiotics (excluding aquaculture) in Norway in 2003 was 5787 kg.) The Norwegian opinion is that antibiotic resistance genes, including NPTII, should be phased out in accordance with article 4 (2) of directive 2001/18/EC. In accordance with the Norwegian Act regulating products for use in animal feed, it is prohibited to manufacture, import and offer for sale animal feed that contains resistance genes for antibiotics, when these genes are introduced through gene modification and is detectable in the end product. Due to the containment of intact NPTII genes in the notified maize (EFSA/GMO/BE/2004/07) will be prohibited for import and sale in Norway.</p>	
NO	Directorate for Nature Management	D, 10.06 Effects on human health	<p>The genetically modified maize MON 863 contains the intact resistance gene NPTII that confer resistance towards the antibiotics: kanamycin, neomycin, geneticin, gentamicin A & B, butirosin and paramomycin. In Norway there is a certain use of these antibiotics in veterinary medicine. (In Norway, the antibiotic neomycin, is in use in veterinary treatment. The Norwegian report "NORM/NORM-VET 2003. Usage of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Norway. Tromsø / Oslo 2004. ISSN:1502-2307" gives an overview of the annual consumption of antimicrobial agents and occurrence of resistance in Norway. The veterinary use of some relevant antibiotics (without the usage in aquaculture) is as follows: Tetracyclines 175 kg, Ampicillin 8 kg. Amoxicillin 192 kg, Neomycin 35 kg, Dihydrostreptomycin 139 kg. The total veterinary use of antibiotics (excluding aquaculture) in Norway in 2003 was 5787 kg.) The Norwegian opinion is that antibiotic resistance genes, including NPTII, should be phased out in accordance with article 4 (2) of directive 2001/18/EC. In accordance</p>	

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NO	Directorate for Nature Management	D, 12.01 General	D.12.01 In our opinion a more comprehensive post market monitoring plan is needed. The plan is very general without any concrete description of who shall do what, where and when. A description of the distribution of responsibilities within the networks they are describing is absent.	<p>The GMO Panel comments on the scientific quality of the monitoring plan. EFSA has published guidance and opinion on PMEM (EFSA, 2006a, b) following a broad consultation with stakeholders, including national competent authorities. The information supplied by the applicant is in line with this guidance.</p> <p>See section 5.2.3 of the scientific opinion. <i>The scope of the monitoring plan provided by the applicant is in line with the intended uses for the GMO since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental impacts. Since the main use of MON863 x MON810 x NK603 maize will be animal feeds, the applicant proposed that general surveillance should concentrate on monitoring the health of those exposed to the processing of the animal feed as well as the animals fed on this maize. The Panel agrees to this proposed generic approach to general surveillance.</i></p> <p>See section 5.2 of the PMEM opinion (EFSA, 2006b): <i>Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. (...) Thus detailed local arrangements will be developed by the applicant after the application has been accepted (...).</i></p>

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				See section 11.4.2 of the GMO Panel Guidance Document (EFSA, 2006a): <i>Knowing the limitations of existing monitoring systems, it is important for the applicant to describe the processes and criteria that will be used for selecting and evaluating existing monitoring systems for supplying data related to the unanticipated adverse effects of GM plants in the general surveillance.</i>
NO	Directorate for Nature Management	D, 12.03 General Surveillance of the impact ..	D.12.03 Norway opposes the opinion expressed by representatives of EFSA, that the MS shall be responsible for General Surveillance. This has come up during the work in the working group on surveillance and during the GMO EFSA net launch where EFSA consulted Member States. We urge the Commission to deal with this question, so that it can be clarified how the directive 2001/18/EC should be interpreted on the issue of responsibility related to monitoring.	
SE	Swedish Board of Agriculture	D, 12 Environmental Monitoring Plan	General conditions for environmental post market monitoring: In order to achieve consistency, it is important to ensure that the same conditions apply to GMOs that are approved under Regulation (EC) No 1829/2003, as to GMOs that are approved under Directive 2001/18/EC. Therefore, the conditions regarding post market monitoring, which are set out in the Commission decisions concerning placing on the market of GMOs, should also apply to this application. The most recent wording of this article is found in the draft Commission decision, document ENV/05/02. In Article 4.4 in the above mentioned draft decision, the competent authority (CA) of the Member State which received the original notification, has a central role in the revision of the monitoring plan. For applications under Regulation (EC) No 1829/2003, that CA does not necessarily make a full assessment of the application in contrast to the procedure under the Directive 2001/18/EC. Nevertheless, we suggest that the CA that received the application would have the same role in the revision of the environmental monitoring plan for GMOs that are approved under the Regulation as for GMOs approved under the Directive. For applications that include the scope of cultivation, EFSA shall ask a national CA to carry out the environmental risk assessment. In these cases, it would seem appropriate that it should be this CA that has the role described for the CA that received the	

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			original notification in Article 4.4 mentioned above.	
SE	Swedish Board of Agriculture	D, 12 Environmental Monitoring Plan D, 12.03 General Surveillance of the impact of the GM plant D, 12.05 Implementing General Surveillance	The general surveillance plan is too unspecific: The monitoring plan contained in the notification is very general. For example it is not clear who will be requested to provide information and how the company will ensure participation. The monitoring plan is similar to the one contained in the notification C/GB/02/M3/3 (MON810 x NK603). In order to achieve consistency, it would be appropriate to impose, also on this application, the following condition regarding the post market monitoring, set out by the lead CA on the notification C/GB/02/M3/3 (MON810 x NK603). "(...) the consent holder should be required to report on post-market monitoring as follows: - at least 30 days before (...) is placed on the market the consent holder should provide further details of the arrangements for carrying out general surveillance, including: (1) precisely who will be requested to provide information; (2) what type of information will be requested and the frequency of requests and (3) how the company will ensure participation to ensure a robust assessment." In addition, for the above-mentioned notification, Sweden has requested that the detailed monitoring plan should be approved by the UK before placing on the market. The detailed monitoring plan for the present application should also be approved before placing on the market. In the procedure under Directive 2001/18/EC it follows that the CA of the member state that received the notification is the appropriate authority to approve such an updated monitoring plan. In the procedure under Regulation (EC) No 1829/2003 it is not as clear, but we would like to suggest that that CA can take on the role as the authority to approve the detailed monitoring plan.	
Comments from other EFSAnet users				
BE	Belgian Biosafety Advisory Council	D, 07.08 Toxicology	Testing of the whole GM food/feed Although broiler chickens are the livestock animal of choice for confirming nutritional equivalence, confirmatory data for the safety assessment of the hybrid MON 863 x MON 810 x NK603 is needed, in particular, the need for an additional 90-day rat feeding study, including complete endpoints (biochemical, haematological, histological), with the hybrid MON863 x MON 810 x NK603 to exclude any adverse effect on human health. In this rodent feeding study, experimental	See section 4.2.4.3 of the scientific opinion: <i>A 90-days oral toxicity study with MON863 x MON810 x NK603 maize in rats, which was submitted at a later date, has been assessed by the GMO Panel.</i>

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			treatments should include the GM crop and a non-GM counterpart with comparable genetic background, and a range of commercial non-GM controls. Plants should be grown under conditions that represent normal practice for the crop plant.	
BE	Belgian Biosafety Advisory Council	D, 07.10 Nutritional assessment of GM food/feed	Feeding trials should have included more animals per treatment to increase the power of the statistical analysis or sensitivity of the trial in all three cases. File 18175: trial with rats The threshold difference between two treatments seems to be 7 to 10%, based on the observed coefficient of variation and the number of animals per treatment. Hence, more animals per treatment would have been more appropriate to increase the sensitivity of the test. File 17243: trial with broilers Reported mortality ranges from 3 to 7 % through treatments, which is rather high as being compared with standard practice on farms, i.e. <1%. Mean values with variation are not reported, so that it is difficult to calculate the power of the statistical analysis. File 18163: trial with broilers Again reported mortality is rather high within some treatments, up to 7%. Mean values and variation are reported, showing that differences from 10 to 15% on can be detected, which is much higher than in a farm environment. Hence, also in this case the sensitivity of the trial is too low.	<p>See section 4.2.4.3 of the scientific opinion: <i>A 90-day oral toxicity study on Sprague Dawley rats has been carried out with diets prepared with the whole food, .i.e. maize kernels. The experiment was carried out with three groups of 40 animals each (20 animals/sex/group)...The study design followed OECD guidelines 408 (OECD, 1998).</i></p> <p>OECD guidelines are internationally recognized guidelines that are considered adequate and sufficient by the GMO Panel.</p> <p>See section 4.2.6 of the scientific opinion: <i>Each diet was fed to a group of 100 animals divided into separate pens.</i></p> <p>The experimental design involves eight treatments of 100 animals per treatment with 5 pens of 10 animals/gender/treatment. According to AFSSA (AFSSA, 2002), using groups of 45 animals would provide 99% power for establishing a 2% difference (alpha 5%). The study design and statistical power of the broiler studies presented by the applicant is considered adequate, in line with recent publication and is accepted by the GMO Panel.</p> <p>The GMO Panel is of the opinion that mortality rate of 3-7% are not uncommon in chicken broiler studies. An average mortality rate up to 8% has already been reported (DEFRA, 2002).</p>
UK	FOOD STANDARDS AGENCY	General comments	The UK has no observations at this stage on the maize hybrid MON863 x MON810 x NK603. We have commented previously on the way that such hybrids are assessed and we are confident that those general comments will be taken into account in EFSA's evaluation of this dossier.	

List of References

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