Biosafety Advisory Council

01-02-2006

Secretariat

O./ref.: WIV-ISP/BAC/2006_SC_309
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Title: Advice of the Belgian Biosafety Advisory Council on the application **EFSA/GMO/BE/2004/07** of Monsanto under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/BE/2004/07 was submitted by Monsanto in November 2004 for the marketing (import and processing) of the insect-protected glyphosate-tolerant genetically modified hybrid maize MON863 x MON810 x NK603 for food and feed applications under Regulation (EC) No. 1829/2003[1]. It has been officially acknowledged by EFSA on 14 January 2005.

On the same date EFSA started the 3 months formal consultation of the Member States, in accordance with Articles 6.4 and 18.4 of Regulation (EC) No. 1829/2003 (consultation of national Competent Authorities within the meaning of Directive 2001/18/EC designated by each Member State in the case of genetically modified organisms (GMOs) being part of the products).

In the frame of this consultation, the Belgian Biosafety Advisory Council, under the supervision of a coordinator and with the assistance of its Secretariat contacted experts to evaluate the dossier, chosen from the common list of experts drawn up by the Biosafety Advisory Council and the Division of Biosafety and Biotechnology. Five experts answered positively to this request.

The comments received from the Belgian experts (see Annex I for an overview of all the comments) were synthesised by the coordinator and put on the EFSAnet on 14 April 2005 (see Annex II for comments actually placed on EFSAnet).

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. (OJ L 268, 18.10.2003, p.1)

The opinion of EFSA's scientific panel on GMOs was adopted on 6 July 2005 (The EFSA Journal, 2005, 256, 1-25)[2]

On 21 December 2005 the opinion of EFSA was forwarded to the Belgian experts and they were given access to the additional data received from the applicant on request of EFSA. The experts were invited to give comments and to react in case the comments formulated in their initial assessment of the dossier were not taken into account in the opinion of EFSA.

Scientific evaluation

The critical points raised by the Belgian experts can be summarised as follows (for the scientific evaluation we refer to annex I):

1. Molecular characterisation

No issues raised during the consultation period. However it should be noted that we didn't have any specialised expert in this field.

2. Food/feed safety assessment

2.1 Toxicological assessment of the whole GM food/feed

Two experts noted during the consultation period that there was a need for additional data to confirm the safety assessment of the hybrid MON863 x MON810 x NK603. In particular, an additional 90-day rat feeding study, including complete endpoints (biochemical, haematological, histological), with the hybrid MON863 x MON810 x NK603 to exclude any adverse effect on human health was asked for.

This concern was relayed by EFSA to the applicant. A 90-days toxicity study with rats fed with MON863 x MON810 x NK603 maize, was provided and assessed by the GMO Panel of EFSA. It was concluded that a 90-day sub-chronic rodent study with MON863 x MON810 x NK603 maize indicated that there are no adverse effects from its consumption.

The Biosafety Advisory Council did not receive reactions on this point from the Belgian experts.

2.2. Nutritional assessment of GM food/feed

During the consultation period it was stated that the feeding trials should have included more animals per treatment to increase the power of the statistical analysis or sensitivity of the trials.

This comment has not been retained by the EFSA GMO panel nor forwarded to the applicant as a request.

[2] see: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/720_en.html

The opinion of the Belgian experts that it is difficult to detect an effect on mortality when the background noise (i.e. the overall mortality) is too high is nevertheless maintained.

3. Environmental risk assessment and monitoring plan

No major issues were raised during the consultation period.

Conclusion

Based on the scientific assessment of the dossier done by the Belgian experts,
taking into account the opinion of EFSA's GMO scientific panel,
the Biosafety Advisory Council concludes that:

1) EFSA did take into account some (but not all) remarks of the Belgian experts. As a result, the notifier was asked to deliver complementary information (e.g. additional information on an extra 90-day sub-chronic feeding trial with rats – topic D.7.8.4). The delivered information underpinned and consolidated the EFSA advice that there were no adverse effects of the consumption of the genetically modified maize hybrid MON863 x MON810 x NK603.
2) The Belgian Biosafety Advisory Biosafety council continues to disagree with EFSA on topic D.7.10: Nutritional assessement of GM food/feed. The feeding trials presented by the notifier, included a small number of animals (all trials). Trials reported in file 18175 – rats- and in file 18163 –broilers- show high threshold differences between the different treatments. Trials with broilers, reported in files 17243 and 18163 show an overall high animal mortality; mean values and variation were not reported in file 17243. As a result of these weaknesses, the power of the statistical analysis or the sensitivity of the trials is too low to draw scientifically sound conclusions. In addition it is difficult to detect an effect on mortality when the background noise, i.e. the overall mortality, is too high.

In absence of correct data concerning the nutritional assessment of this GM maize, the Belgian Biosafety Advisory Council can not support the positive advice of EFSA for the application EFSA/GMO/BE/2004/07.

p.o.

Prof. D. Reheul
President of the Biosafety Advisory Council.

Annex I : Comments of experts in charge of evaluating application EFSA/GMO/BE/2004/07 (ref: BAC_2005_PT_234)

Annex II: Belgian comments submitted on the EFSAnet on mandate of the Biosafety Council (print-out of EFSAnet pages)

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Bioveiligheidsraad
Conseil de Biosécurité

April, 14th, 2005

Secretariaat
Secrétariat

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Comments of experts in charge of evaluating application EFSA/GMO/BE/2004/07
and
Comments submitted on the EFSAnet on mandate of the Biosafety Council

Mandate for the Group of Experts: mandate of the Biosafety Advisory Council of February 2th, 2005
Coordinator: Dirk Reheul (UGent)
Experts: Philippe Baret (UCL), Rony Geers (KUL), Jean-Pierre Maelfait (Instituut voor Natuurbehoud), Hadewijch Vanhooren (KUL), Michel Van Koninckxloo (Haute Ecole Provinciale du Hainaut Occidental)
Domains of expertise of experts involved: genetics, population genetics, horizontal gene transfer, GMO traceability, biosafety research, ecology, plant-insect relations, nature conservation, sustainable development, agronomy, animal feed, toxicology and immunology
Secretariat: Martine Goossens, Adinda De Schrijver

INTRODUCTION

Dossier **EFSA/GMO/BE/2004/07** concerns a notification of Monsanto for the marketing (import and processing) of the genetically modified hybrid maize MON863xMON810xNK603 for food and feed applications under Regulation (EC) No. 1829/2003.
The notification has been officially acknowledged by EFSA on 14 January 2005. The deadline for posting comments on the EFSAnet by the Member States is 14 April 2005.

This document gives an overview of all the comments received by the experts involved in the safety evaluation of application EFSA/GMO/UK/2004/07. The experts were asked to structure their comments according to the guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed (EFSA Journal (2004), 99, 1-94; see attachment). Comments placed on the EFSAnet are indicated in grey.

LIST OF COMMENTS

A. GENERAL INFORMATION

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

Comment 1

The non-modified parental organism is a current maize hybrid variety.
This kind of maize are currently cultivated, processed and used for food and feed in E.U.
There is no risk for the human health and the environment related to the release in the environment of the non-modified maize.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

D. INFORMATION RELATING TO THE GM PLANT

D.1 DESCRIPTION OF THE TRAIT(S) AND CHARACTERISTICS WHICH HAVE BEEN INTRODUCED OR MODIFIED

Comment 1

MON 863 x MON 810 x NK603 comprises traditionally bred maize varieties, produced
by the combination of three genetically modified maize lines. MON 863 x MON 810 x NK603 thereby inherits and effectively combines the three introduced traits of agronomic interest, which were individually contained in the following genetically modified maize lines:

- YieldGard Rootworm maize (MON 863 maize3) expresses a modified Cry3Bb1 protein (MON 863 Cry3Bb1 protein4), derived from *Bacillus thuringiensis* subsp. *kumamotoensis*, which provides protection against certain coleopteran insect pests, including members of the corn rootworm (CRW) complex (*Diabrotica* spp.).
- YieldGard® Corn Borer maize (MON 810 maize5) produces the protein Cry1A(b), derived from *Bacillus thuringiensis* subsp. *kurstaki* (strain HD-1), which confers protection against certain lepidopteran insect pests, including the European corn borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp.).
- Roundup Ready® corn 2 (NK603 maize6) expresses the glyphosate-tolerant CP4 EPSPS and CP4 EPSPS L214P proteins7, derived from *Agrobacterium* sp. strain CP4. Maize containing the insert that is present in NK603 is tolerant to Roundup® agricultural herbicide (containing the active ingredient glyphosate8).

MON 863 × MON 810 × NK603 and its parental lines were developed by the Monsanto
Company.

MON 863:
On 2 April 2004, EFSA issued a favourable opinion on the safety of MON 863. The approval of MON 863 maize under Regulation (EC) N° 258/97 and Directive 2001/18/EC is pending.

MON 810:
The product was authorized for cultivation and use in the EU in 1998 (Commission Decision, 1998).

NK603
On 25 November 2003, EFSA issued a favourable opinion on the safety of NK603 which resulted in the approval of this maize for import, processing and feed use in the EU on 19 July 2004. The approval of NK 603 under Regulation (EC) N° 258/97 is pending.

The application (dossier and appendix) gives a complete description of the result of the genetic modification (methods used for the genetic modification, copy number of inserts in MON 86 x MON 810 x NK603, information on the expression and the stability of the insert …)

Composition :
I agree with the conclusion that MON 863 x MON 810 x NK603 is compositionally equivalent to traditional maize.

Agronomic traits:
Observations from field trials (Carringer et al., 2004), breeding trials and from commercial cultivation show that, except for the introduced traits, MON 863 x MON 810 x NK603 hybrids are agronomically, phenotypically and morphologically equivalent to parental single-trait hybrids and to traditional maize.

Processing:
I agree with this conclusion: Using both wet and dry milling processes, maize is converted into a diverse range of food and feed products and derivatives used as food and feed ingredients or additives. MON 863 x MON 810 x NK603 was shown to be substantially equivalent to commercially available non-transgenic maize, except for the introduced sequences and the expressed Cry3Bb1, NPTII, Cry1Ab and CP4 EPSPS proteins, which were shown to be safe for human and animal health. Therefore, when MON 863 x MON 810 x NK603 is used on a commercial scale as a source of food or feed, then these products are not expected to be different from the equivalent foods and feeds originating from traditional maize.

D.2. INFORMATION ON THE SEQUENCES ACTUALLY INSERTED OR DELETED

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

D.4. INFORMATION ON HOW THE GM PLANT DIFFERS FROM THE RECIPIENT PLANT IN: REPRODUCTION, DISSEMINATION, SURVIVABILITY

Comment 1

MON 863 x MON 810 x NK603 is unchanged compared to traditional maize in terms of invasiveness of natural environments and persistence in the environment. There is no information to indicate that there is a potential for MON 863 x MON 810 x NK603 to establish, persist and disperse to a greater extent than traditional maize. In cases where incidental release occurs and a MON 863 x MON 810 x NK603 plant would establish, these plants will be easily controlled by currently available selective herbicides (except glyphosate) and by mechanical means.

Comment 2

No reasons to expect that MON 863 x MON 810 x NK 603 maize would spread and survive more likely in the environment than traditional maize. Not to be expected that the GMHP is a less poor competitor than the parental plant in natural conditions in our region.

D.5. GENETIC STABILITY OF THE INSERT AND PHENOTYPIC STABILITY OF THE GM PLANT

D.6. ANY CHANGE TO THE ABILITY OF THE GM PLANT TO TRANSFER GENETIC MATERIAL TO OTHER ORGANISMS

D.7. INFORMATION ON ANY TOXIC, ALLERGENIC OR OTHER HARMFUL EFFECTS ON HUMAN OR ANIMAL HEALTH ARISING FROM THE GM FOOD/FEED

D.7.1 Comparative assessment

D.7.2 Production of material for comparative assessment

D.7.3 Selection of material and compounds for analysis

D.7.4 Agronomic traits

D.7.5 Product specification

D.7.6 Effect of processing

D.7.7 Anticipated intake/extent of use

D.7.8 Toxicology

Comment 1

MON 863 x MON 810 x NK603 is produced by crossing the parental single-trait maize lines MON 863, MON 810 and NK603 by means of traditional breeding methods. Each of the introduced traits from the parental lines are inherited in MON 863 x MON 810 x NK603 in a standard Mendelian fashion. This results in the combined expression of the Cry3Bb1, NPTII, Cry1Ab, and CP4 EPSPS proteins in the same plant.

D.7.8.1 Safety assessment of newly expressed proteins

Comment 1

Screening for structure-activity relationship, *in vitro* digestibility assays, and acute toxicity testing

The introduced proteins, the Cry3Bb1, NPTII, Cry1Ab, and CP4 EPSPS proteins, were demonstrated to be safe for animal and human health. These proteins were well characterised in accordance with the

applications for authorisation of MON 863, MON 810, and NK603. Substantial equivalence has been established for MON 863, MON 810, and NK603.
A battery of tests designed to evaluate the Cry3Bb1, NPTII, Cry1Ab, and CP4 EPSPS proteins for characteristics associated with food allergens and toxins raised no concern. The Cry3Bb1, NPTII, Cry1Ab, and CP4 EPSPS proteins shared no sequence homology with known toxins (other than B.t. proteins for Cry3Bb1 and Cry1Ab). There is a rapid digestion of the Cry3Bb1, NPTII, and CP4 EPSPS proteins in in vitro simulated gastric fluids and the Cry1Ab protein is rapidly degraded and its insecticidal activity lost under conditions simulating mammalian digestion. There is lack of acute toxicity for the Cry3Bb1, NPTII, Cry1Ab, and CP4 EPSPS proteins, as determined by a mouse acute oral toxicity study. The proteins used for the *in vitro* digestibility testing and the acute oral toxicity testing in mice have been produced by *E. coli* and are considered to be equivalent to the MON 863, MON 810, and NK603 proteins.

D.7.8.2 Testing of new constituents other than proteins

Comment 1

No constituents other than the Cry3Bb1, NPTII, Cry1Ab, and CP4 EPSPS proteins, are novel. MON 863 x MON 810 x NK603 was shown to be compositionally equivalent to traditional maize. Agreed.

D. 7.8.3 Information on natural food and feed constituents

Comment 1

Substantial equivalence was demonstrated. No particular natural constituents of maize are considered to be of significant concern to require additional information or further risk assessment. Agreed.

D.7.8.4 Testing of the whole GM food/feed

Comment 1

The applicant concluded that the safety assessment for the individual proteins is not changed when combined in MON 863 x MON 810 x NK603, since the proteins: 1° are unlikely to interact, 2° have very different and well-documented modes of action, 3° are localized to different subcellular compartments, 4° are produced in very low quantities in MON 863 x MON 810 x NK603, and 5° were shown to be safe in their individual safety assessments. Furthermore, a confirmatory animal feeding experiment was conduced using MON 863 x MON 810 x NK603 fed to broiler chickens.

Poultry broilers feeding study
The 42-day broiler chicken feeding study using whole grain MON 863 x MON 810 x NK603 (Taylor et al., 2004: Report No MSL-18762) was conducted to compare the nutritional value of MON 863 x MON 810 x NK603 and non-transgenic control as well as additional commercial maize hybrids. The results show that there were no biologically relevant differences in the parameters tested between broilers fed the MON 863 x MON 810 x NK603 diet and the non-transgenic control diet.
This conclusion was consistent with the evaluation of the composition of MON 863 x MON 810 x NK603, which showed that there were no biologically relevant differences in

nutritional and compositional properties relative to control and reference maize. Relevant reports: Ridley et al., 2004: Report No MSL-19157; Ledesma et al., 2004: Report No MSL-18946.

Rat feeding study

Maize lines MON 863, MON 810, and NK603 were separately tested.

In a sub-chronic (90-days) toxicity study in rats fed MON 863 maize, no consistent differences in the measured clinical, biological and histological parameters were noted for rats fed on non-GM or MON 863 maize except for some differences observed in haematological parameters, including total white blood cell, lymphocyte and basophil counts. White blood cell counts were slightly increased for the male 33% MON 863 group compared with control and reference groups. At study termination, statistically significant decreases for reticulocyte counts were observed in the female 33% MON 863 group compared with control and reference groups. Also a statistically significant decrease in individual kidney weights (males, 33% MON 863 group), and a statistically significant lower incidence of mineralized kidney tubules was noted in female 33% MON 863 fed animals. It was accepted by EFSA that the differences found were considered not to be of biological significance.

In a sub-chronic (90-days) toxicity study in rats fed MON 810 maize, no consistent differences in the measured clinical, biological and histological parameters were noted for rats fed on non-GM or MON 810 maize except for albumin/globulin count. For rats fed 33% MON 810 maize, a statistically significantly lower albumin/globulin count was observed compared with control and overall reference lines at study termination. In one reference line, similar values were shown as for those fed MON 810. The slightly lower values for these parameters are not considered to be related to MON 810 maize feeding, given the small magnitude of the observed changes. It was accepted by EFSA that the differences found were considered not to be of biological significance.

In a sub-chronic (90-days) toxicity study in rats fed NK603 maize, no consistent differences in the measured clinical, biological and histological parameters were noted for rats fed on non-GM or NK603 maize except for slightly elevated levels of average corpuscular volume and average corpuscular haemoglobin in female rats administered with a high dose. It was accepted by EFSA that these findings were concluded as of no biological significance.

According to the applicant, it was considered that it is scientifically valid to use data from the single GM lines MON 863, MON 810, and NK603 to support the safety assessment of the hybrid MON 863 x MON 810 x NK603. Outdoor experiments, a compositional study, and a broiler chicken feeding study performed with MON 863 x MON 810 x NK603 maize, support the conclusion that adverse effects are highly unlikely to occur following oral exposure to MON 863 x MON 810 x NK603 maize.

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 (see p14 of http://www.biosafety.be/NF/GuidanceNotes/Documents/Chapter3_Toxicology.pdf). In this rodent feeding study, experimental 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.

D.7.9 Allergenicity

D.7.10 Nutritional assessment of GM food/feed

Comment 1

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.

D.7.11 Post-market monitoring of GM food/feed

D.8. MECHANISM OF INTERACTION BETWEEN THE GM PLANT AND TARGET ORGANISMS (IF APPLICABLE)

D.9. POTENTIAL CHANGES IN THE INTERACTIONS BETWEEN THE GM PLANT WITH THE BIOTIC ENVIRONMENT RESULTING FROM THE GENETIC MODIFICATION

D.9.1. Persistence and invasiveness

Comment 1

MON 863 x MON 810 x NK603 will not be cultivated in EU, in case of unintended release we remind that:
There are no wild relatives of maize in Europe and the risk of genetic transfer to other species is negligible;
Maize cannot survive without human assistance and is not capable of surviving as a weed due to past selection in its evolution. Volunteer maize is not found growing in fencerows, ditches or roadsides as a weed. Although maize seed from the previous crop year can over-winter in mild winter conditions and germinate the following year, it cannot persist as a weed (Hallauer, 1995). The appearance of "volunteer" maize in fields following a maize crop from the previous year is rare under European

conditions. Maize volunteers are killed by frost or, in the unlikely event of their occurrence, are easily controlled by current agronomic practices including cultivation and the use of selective herbicides.
Maize grain survival is dependent upon temperature, moisture of seed, genotype, husk protection and stage of development (Rossman, 1949). Freezing temperatures have an adverse effect on maize seed germination and have been identified as being a major risk in seed maize production (Wych, 1988). Temperatures above 45° C have also been reported as injurious to maize seed viability (Craig, 1977).

It is concluded that MON 863 x MON 810 x NK603 does not differ from traditional maize with regard to reproduction, dissemination, survivability or other agronomic and phenotypic traits.

D.9.2 Selective advantage or disadvantage

Comment 1

The risk of the coleopteran and lepidopteran pest protection traits or the glyphosate-tolerance trait in MON 863 x MON 810 x NK603 to be the cause of any competitive advantage or disadvantage impacting the receiving environment is negligible.

Comment 2

GMHP will not be deliberately planted. If spilled seeds germinate nearby cultivated maize fields and produce pollen that arrives on the crop, a gene transfer might occur.
Because of the low competitive abilities of maize plants in our regions in general in F2 plants in particular a spread in the wild environment is not to be expected.

Comment 3

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> As the likelihood of incidentally spilt MON 863 × MON 810 × NK603 kernels to germinate, establish, mature and flower is very low and as the majority of maize pollen is largely confined to short distances from the source plant, the transfer of the introduced traits to neighbouring maize plants through cross-pollination is negligible. Furthermore, in the highly unlikely case where a trait would be transferred, the risk of the insect-protection and glyphosate-tolerance traits to be the cause of any meaningful competitive advantage or disadvantage that could impact the receiving environment is negligible (*see* Section D.9.2).

This paragraph is proposed without any references to the literature. I don't understand how a risk can be described as "negligible" in absence of quantitative information. What is the scope of "negligible" in terms of probability (below 0.1 %, 1 %; 10 %)? I agree that most of the effects may be small but a major issue is the range of variation of these "negligible" effects. Most of the environmental problems occurring during the last decades are due to high impact consequences of very improbable events. I suggest asking the notifier to provide quantitative data on the risk of transfer to neighbouring maize plants and on the competitive advantage of disadvantage of the plants occurring from this transfer on the basis on the literature. In absence of convincing answer to this point, I consider that the risk should be qualified on "uncertain" and not of "negligible".

D.9.3 Potential for gene transfer

Comment 1

see D.9.1

D.9.4 Interactions between the GM plant and target organism

D.9.5 Interactions of the GM plant with non-target organism

Comment 1

Irrelevant as MON 863 x MON 810 x NK603 will not be cultivated in EU.

Comment 2

Not to be expected because a release in the field is not intended.

D.9.6 Effects on human health

Comment 1

Irrelevant as MON 863 x MON 810 x NK603 will not be cultivated in EU.

D.9.7 Effects on animal health

Comment 1

MON 863 x MON 810 × NK603 inherits the inserts present in both the MON 863, MON 810 and NK603 parental lines. The introduced protection against certain coleopteran and lepidopteran insect pests and the introduced tolerance to glyphosate herbicide are traits of agronomic interest that are not intended to change the nutritional aspects of maize.

D.9.8 Effects on biogeochemical processes

Comment 1

Irrelevant as MON 863 x MON 810 x NK603 will not be cultivated in EU.

Comment 2

Not to be expected because a release in the field is not intended.

D.9.9 Impacts of the specific cultivation, management and harvesting techniques

Comment 1

Irrelevant as MON 863 x MON 810 x NK603 will not be cultivated in EU.

Comment 2

Not to be expected because a release in the field is not intended.

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

D.11.2 Interplay between environmental risk assessment and monitoring

Comment 1

Care should be taken that no feral populations develop from spillages during transit from import zones to mills.

D.11.3 Case-specific GM plant monitoring

D.11.3 General surveillance of the impact of the GM plant

D.11.5 Reporting the results of monitoring

Application GMO-BE-2004-07 - Comments from Belgium (extracted from EFSAnet)

Dirk Reheul	Belgian Biosafety Advisory Council	No	Belgium	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 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.
Dirk Reheul	Belgian Biosafety Advisory Council	No	Belgium	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.