Bioveiligheidsraad
Conseil de Biosécurité

06-11-2009

Secretariaat
Secrétariat

O./ref.: WIV-ISP/BAC/2009_01492

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/NL/2007/38 from Monsanto under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/NL/2007/38 was submitted by Monsanto on 1 February 2007 for the marketing (import and processing) of the insect resistant and glyphosate-tolerant genetically modified MON89034 x NK603 maize for food and feed uses under Regulation (EC) No. 1829/2003[1].

The application was officially acknowledged by EFSA on 24 August 2007. On the same date EFSA started the formal three-month consultation period 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).

Within the framework 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 (SBB). Seven experts answered positively to this request, and formulated a number of comments to the dossier, which were edited by the coordinator. See Annex I for an overview of all the comments and for the list of comments actually placed on the EFSAnet on 20 November 2007.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 9 September 2009 (The EFSA Journal, 2009, 7 (9):1320)[2], and published together with the responses from the EFSA GMO Panel to comments submitted by the experts during the three-month consultation period.

On 30 September 2009 the opinion of EFSA was forwarded to the Belgian experts. They were invited to give comments and to react if needed to the answers given by the EFSA GMO Panel, in particular in case the comments formulated in their initial assessment of the dossier were not taken into account in the opinion of EFSA.

The comments formulated by the experts together with the opinion of EFSA including the answers of the EFSA GMO Panel form the basis of the advice of the Biosafety Advisory Council given below.

[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)
[2] See: <http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902910348.htm>

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In addition, the scientific evaluations of the single events, namely maize line MON89034 (EFSA/GMO/NL/2007/37) and maize line NK603 (EFSA/GMO/NL/2005/22), are taken into account in this advice. The Biosafety Advisory Council formulated a positive advice for each single event[3]. Maize NK603 is already authorised for food and feed uses[4] with the exception of cultivation.

Scientific evaluation

1. Environmental risk assessment

According to the Biosafety Advisory Council no major risks were identified concerning the environment[5].

2. Molecular characterisation

With regard to the molecular characterisation, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.

3. Assessment of food/feed safety and nutritional value

3.1. Assessment of compositional analysis
With regard to compositional analysis, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.

3.2. Assessment of toxicity
With regard to toxicity, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.

3.3. Assessment of allergenicity
With regard to allergenicity, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.

3.4. Nutritional value
The Biosafety Advisory Council is of the opinion that the information provided is sufficient and shows the nutritional equivalence of the GM maize with its non-GM counterpart and conventional maize varieties.

4. Monitoring

General surveillance is advised to follow-up unanticipated allergenicity aspects since the allergenicity of the whole GM maize has not been tested.

[3] Advice of BAC on maize line MON89034: BAC_2009_880; Advice of BAC on maize line NK603: BAC_2009_01367
[4] See Community Register <http://ec.europa.eu/food/dyna/gm_register/index_en.cfm>
[5] As the application doesn't imply a cultivation of the GM crop in the EU, a full environmental assessment is not required in EFSA procedure and was not achieved.

Conclusion

Based on the scientific assessment of the dossier done by the Belgian experts, taking into account the opinion of EFSA, the answers of the EFSA GMO Panel to the questions raised by the Belgian experts, the answers of the applicant to the EFSA GMO Panel questions and considering the data presently available, the Biosafety Advisory Council,

Agrees with the GMO panel of EFSA that
a) No major risks concerning the environment were identified.
b) No major risks for human and animal health were identified.

In addition, the Biosafety Advisory Council recommends general surveillance to follow up unanticipated allergenicity aspects since the allergenicity of the whole GM maize has not been tested;

p.o.

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

Annex:
- Full comments of experts in charge of evaluating application EFSA/GMO/CZ/2006/33 *and Comments submitted on the EFSAnet (ref. BAC_2007_PT_604)*

Bioveiligheidsraad
Conseil de Biosécurité

20 November 2007

Secretariaat
Secrétariat

N./réf. : WIV-ISP/BAC/2007_PT_604
Email. : bac@sbb.ihe.be

Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2007/38
and
Comments submitted on the EFSAnet on mandate of the Biosafety Council

Mandate for the Group of Experts: mandate of the Biosafety Advisory Council (BAC) of 5 September 2007
Coordinator: Prof. dr. ir. Dirk Reheul
Experts: Dr. Pascal Cadot (Consultant), Prof. Dr. ir. François Chaumont (UCL), Prof. Dr. Jacques Dommes (ULg), Prof. Jean-Pierre Maelfait (UGent), Prof. Robert Renaville (FUSAGx), Dr. Peter Smet (Consultant), Prof. Wim Stevens (UIA)
Domains of expertise of experts involved: Biochemistry, genetics, genetic engineering, , improvement of plants, genome analysis, GMO traceability, transgene integration pattern, transgene expression, toxicology, immunology, alimentary allergology, animal nutrition, ecology, plant-insect relations, nature conservation, biosafety research.
Secretariat: Didier Breyer, Adinda De Schrijver, Martine Goossens, Philippe Herman

INTRODUCTION

Dossier **EFSA/GMO/NL/2007/38** concerns an application of the company **Monsanto** for the marketing of the genetically modified **maize MON 89034 x NK603** for food and feed applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 24 August 2007.
The scope of the application is:
☒ GM plants for food use
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
☒ GM plants for feed use
☒ Feed produced from GM plants
☒ Import and processing (Part C of Directive 2001/18/EC)
☐ Seeds and plant propagating material for cultivation in European Union (Part C of Directive 2001/18/EC)

Depending on their expertise, the experts were asked to evaluate the genetically modified plant considered in the application on its 1) molecular, 2) environmental, 3) allergenicity, 4) toxicity and/or

5) food and feed aspects. It was expected that the expert should evaluate if the information provided in the application is sufficient in order to state that the marketing of the genetically modified plant for its intended uses, will not raise any problems for the environment or human or animal health. If information is lacking, the expert was asked to indicate which information should be provided and what the scientifically reasoning is behind this demand.

The comments are structured as in 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). Items are left blank when no comments have been received either because the expert(s) focused on other related aspects, or because for this dossier the panel of experts who accepted to evaluate the dossier didn't have the needed expertise to review this part of the dossier. Comments placed on the EFSAnet are indicated in grey.

List of comments received from the experts

A. GENERAL INFORMATION

Comments/Questions of the expert(s)

Comment 1

The notification concerns the authorization of MON 89034 x NK603 maize for import, processing, and food and feed use and not for cultivation.

Comment 2

Because the modified maize is presented as more resistant to glyphosate, toxicity studies have to be realized to determine the residues level of this herbicide in MON 89034 × NK603, indeed more herbicides will be applied on MON 89034 × NK603 than on normal maize.

As this GMO is more resistant it allows higher amounts of herbicides to be used on crops, what about the persistence in the environment and/or contamination of groundwater.

In this dossier, MON 89034 × NK603 was often declared to be safe as it was obtained from normal breeding of two GMOs but some controversies has emerged about the safety of one of these (NK603).

As MON 89034 × NK603 will enter in the food chain as normal maize it'll probably also enter in the diet of mothers and kids. Therefore toxicity studies are lacking on gravid animals to assess possible teratogenic effects as well as effects on neonates.

Maize is usually consumed all over the year and doesn't present a seasonal ingestion so that humans and animals will be exposed to MON 89034 × NK603 for long periods of time even all life long. The duration of toxicity assays are therefore too limited and should be prolonged for more that 90 days to assess chronic effects.

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

Comments/Questions of the expert(s)

Comment 1

The recipient plant is maize (Zea mays L.) that has been widely and extensively cultivated worldwide.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1

MON 89034 x NK603 was produced by crossing inbred plants of MON 89034 and NK603 using traditional breeding. The maize plants contain the genetic modifications already present in the parents. No new specific genetic modification has been introduced.

D. INFORMATION RELATING TO THE GM PLANT

D.1 DESCRIPTION OF THE TRAITS AND CHARACTERISTICS WHICH HAVE BEEN INTRODUCED OR MODIFIED

Comments/Questions of the expert(s)

Comment 1

MON 89034 x NK603 produces two insecticidal proteins (Cry1A.105 and Cry2Ab2) that protect the plants against different lepidopteran insect pests. It expresses also two CP4 EPSPS proteins conferring tolerance to the herbicide glyphosate.

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

Comments/Questions of the expert(s)

Comment 1

The EFSA guidance document for the risk assessment of genetically modified plants (GMP) containing stacked events specifies that the intactness and stability of the inserted events should be assessed. In this dossier, this was done by hybridisation on Southern blots and the results support the claim that all inserts are intact in this GMP. Analysis of the expression of the inserts at the protein level also supports this conclusion. The same EFSA guidance document also asks to check intactness of flanking genomic DNA. This was not done here, although it can be easily carried out by PCR. Nevertheless there is no scientific basis to support the fact that these sequences would be more unstable than any other region of plant genomic DNA.

Comment 2

Because it is considered that there is a low likelihood of molecular interactions between the inserts, the applicants did not start again a complete molecular analysis to demonstrate the size, copy number and integrity of the 2 inserts. Only two Southern blot analyses were performed and showed that the size of the inserts and flanking regions correspond to those of their respective parents. The size of the bands obtained in the control lanes including plasmid DNA cannot be understood from the technical dossier

itself, but a detailed description of the Southern blot experiments is found in Tian et al., 2006. On which generation of MON 89034 x NK603 hybrid/inbred has the genomic DNA been extracted? This is an important issue concerning the genetic stability (see D5).
It is also mentioned that both inserts are on separate chromosomes in the nuclear genome. A precise reference of the data showing on which chromosome the inserts are found in the parent lines should be given.

Comments summarized by the coordinator

1. On which generation of MON 89034 x NK603 hybrid/inbred has the genomic DNA been extracted? This is an important issue concerning the genetic stability (see D5).
2. It is mentioned that both inserts are on separate chromosomes in the nuclear genome. A precise reference of the data showing on which chromosome the inserts are found in the parent lines should be given.
3. Because it is considered that there is a low likelihood of molecular interactions between the inserts, the applicants did not start again a complete molecular analysis to demonstrate the size, copy number and integrity of the 2 inserts. Only two Southern blot analysis were performed and showed that the size of the inserts and flanking regions correspond to those of their respective parents. The size of the bands obtained in the control lanes including plasmid DNA cannot be understood from the technical dossier itself, but a detailed description of the Southern blot experiments is found in Tian et al., 2006. On which generation of MON 89034 x NK603 hybrid/inbred has the genomic DNA been extracted? This is an important issue concerning the genetic stability (see D5).

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert(s)

Comment 1

The expression of the Cry and CP4 EPSPS proteins was assessed using an enzyme-linked immunosorbent assay (ELISA) in various plant tissues of MON 89034 x NK603 and the parents produced in 2004 in Argentina. The ranges of protein expression are comparable in the 3 maize lines.

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

Comments/Questions of the expert(s)

Comment 1

Some minor differences were observed for some phenotypic and agronomic characteristics between MON 89034 x NK603 and the control maize but seemed to be in the range of responses expected for maize.

D5. GENETIC STABILITY OF THE INSERT AND PHENOTYPIC STABILITY OF THE GM PLANT

Comments/Questions of the expert(s)

Comment 1

The genetic stability of the insert was not tested. The applicants justified this by theoretical arguments based on previous studies on recombinations and concluded that it is appropriate to apply results of the characterisation performed on the parental lines MON 89034 and NK603. Even though all the data support very unlikely recombination events, it is of my opinion that it should be tested. Parts of the two T-DNA inserts contain homologous sequences, and *Hsp70* intron and TS-*SSSU-CTP* DNA are maize sequences that could potentially recombine with endogenous DNA. Demonstration of genetic stability of the inserts in F2 grains marketed by the applicant and other generations (even if not sold) would be useful and fit with the guidelines for the safety assessment of genetically modified crops for food and feed use.

Comment rephrased and completed by the coordinator

The genetic stability of the insert was not tested. The applicants justified this by theoretical arguments based on previous studies on recombinations and concluded that it is appropriate to apply results of the characterisation performed on the parental lines MON 89034 and NK603. Even though all the data support very unlikely recombination events the demonstration of genetic stability of the inserts in the marketed grains and in subsequent generations (which will be consumed as food or feed) would be useful and fit with the guidelines for the safety assessment of genetically modified crops for food and feed use.
Parts of the two T-DNA inserts contain homologous sequences, and *Hsp70* intron and TS-*SSSU-CTP* DNA are maize sequences that could potentially recombine with endogenous DNA. The applicant is invited to comment on possible co-silencing effects in this context. This is in line with the EFSA guidance document on stacked events (EFSA Journal, 2007, 512, 1-5).

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

Comments/Questions of the expert(s)

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

Comments/Questions of the expert(s)

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert(s)

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

D.7.5 Product specification

Comments/Questions of the expert(s)

D.7.6 Effect of processing

Comments/Questions of the expert(s)

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

D.7.8 Toxicology

Comments/Questions of the expert(s)

Comment 1

The proteins inserted were tested separately and not together which doesn't give the opportunity to have data of possible interactions between these proteins.
Only acute studies were done, some effects can only be seen after a long period of exposure so chronic studies are needed. Moreover these studies were done with the two GMO used to made MON 89034xNK603 but not with the GMO under application, these acute and chronic studies are needed.
The GMO is considered as safe as both its components are but NK603 was not considered as safe by an independent committee of experts (Crii-Gen).

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1

No new genetic modification has been introduced in MON 89034 x NK603. This maize has been obtained from traditional breeding methods between progeny of genetically modified 89034 and NK603 maize.
Cry1A.105, Cry2Ab2 (both MON 89034) and CP4 EPSPS (NK603) proteins were tested in earlier studies. These studies showed no evidence of acute toxicity. Further testing of these proteins for acute toxicity is not required.

Comment 2

It is well-known that the pesticides are endocrinal disruptors. In clinical investigations, endocrine measures are considered routine measures in assessing patient health. In this dossier there are no mentions of any endocrine tests! Endocrine axis is the first to be disrupted in illness so that they can not be removed from a toxicity study.

Comments for D.7.8 till D.7.8.1 summarized by the coordinator

1. Cry1A.105, Cry2Ab2 (both MON 89034) and CP4 EPSPS (NK603) proteins were tested in earlier studies. These studies showed no evidence of acute toxicity. Further testing of these proteins for acute toxicity is not required.

2. But the proteins made by the inserted genes were tested (in chronic studies) separately and not together: this does not offer the opportunity to have data of possible interactions between these proteins.
3. See dossier 2007/37 for a remark on potential endocrinal disruption of substances with a pesticide action.

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

Comment 1

As more herbicides will be spread on cultures it is likely that more residues would be present on crops, what about glyphosate residues?
What's the impact of these high glyphosate quantities on hormonal status of animals and humans?

Additional comment from the SBB
The metabolism and residues of the herbicides in genetically modified herbicide-tolerant plants are already considered in the regulatory process for herbicide registration or extension of existing registrations which is covered by Directive 91/414/EEC[1].

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert(s)

D.7.8.4 Testing of the whole GM food/feed

Comments/Questions of the expert(s)

Comment 1

Comparison of broiler performance and carcass parameters when fed diets containing MON89034, control or commercial corn (Davis *et al.*, 2006).
There were no biologically relevant differences in the parameters measured between broilers fed the MON89034 diet and the control diet.

According to tables 4, and 5 the Cry1A.105 and Cry2A2 protein content is similar in MON 89034 and MON 89034 x NK603 grain.
According to table 6 the CP4 EPSPS protein content is similar in MON 89034 x NK603 and NK603 grain.

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market

13-Week feeding study in rats.
This study **should be performed** since synergistic effects of the proteins under investigation cannot be excluded beforehand. Furthermore, these results could have helped in deciding whether the problems, which arose during the 13-week feeding study in rats with MON 89034 (see comment for dossier EFSA/GMO/NL/2007/37), were of importance or simply due to chance.

Comment 2

The broiler study was not done on 960 broilers but only 100 broiler received the MON 89034xNK603, the other animals being fed with other GMOs. Moreover the toxicity study should report the weights of organs like kidneys and liver that are the first to be affected by toxins. Consumer usually consume corn for long period of time so there's a need of acute toxicity study.

Comments summarized by the coordinator

1. Broiler performance
According to tables 4, and 5 the Cry1A.105 and Cry2A2 protein content is similar in MON 89034 and MON 89034 x NK603 grain. According to table 6 the CP4 EPSPS protein content is similar in MON 89034 x NK603 and NK603 grain.
The toxicity study should report the weights of organs like kidneys and liver that are the first to be affected by toxins. Consumers usually consume corn for a long period of time so there is a need of a chronic toxicity study.

2. 13-Week feeding study in rats.
This study **should be performed** since synergistic effects of the proteins under investigation cannot be excluded beforehand. Furthermore, these results could have helped in deciding whether the problems, which arose during the 13-week feeding study in rats with MON 89034 (see comment for dossier EFSA/GMO/NL/2007/37), were of importance or simply due to chance.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

Comment 1

This GM maize is a combination of the CP4 EPSPS protein, inducing resistance against glyphosate and de Cry1A.105 and Cry2Ab2 proteins, inducing insect resistance.
The CP4 EPSPS protein has already been evaluated in the EFSA dossier EFSA/GMO/CZ/2005/27 and the Cry1A.105 and Cry2Ab2 proteins in the EFSA dossier NL/2007/37 (maize MON 89034).

The conclusion of both dossiers is reproduced here:

To study the allergenicity of the Cry1A.105 and Cry2Ab2 proteins Monsanto has used the following criteria to test for allergenicity:

1. the protein is from a non-allergenic source: hitherto there are no reports on allergenic properties of Bt proteins.

2. the protein does not share structural similarities to known allergen based on the amino acid sequence: no relevant matches were found using the AD6 database for both proteins ore aminoacid sequences. There is no significant similarity between Cry1A.105 and a kiwi fruit protein. There were no alignments of at least 8 aminoacids found for Cry1A.105.
3. the protein is rapidly digested in simulated gastric fluid (SGF).
4. the protein represents only a very small portion of the total protein in the grain.

Nevertheless these rules are not absolute (Ebo and Stevens, 2001):

- a protein or polypeptide inserted in an other protein can end up with conformational changes of the original protein. Allergens are non only linear epitopes but can be formed by conformational epitopes.
- The rapid digestibility of a protein does not warrant non-allergenicity; some labile proteins are allergenic (eg. Mal d 1 form apple)
- The quantity of the protein in food is not absolutely related to allergenicity: allergic reactions can be induced by minute amounts of allergen

Post marketing surveillance remains necessary.

For the CP4 EPSPS protein, a 30 % homology was found with the *Dermatophagoides farinae* 2 protein (Der f 2). Although this homology is under the limit of 35 %, it would be interesting to compare the 3d structures of Der p 2 and CP4 EPSPS and to test some sera of patients allergic to Der p 2.

Comment 2

Assessment of allergenicity of the introduced traits.
For the allergenicity evaluation of Cry1A.105 and Cry2Ab2, the applicant refers to the application EFSA/GMO/NL/2007/37. Therefore, the same comments as for this application can be made:
The fact that Cry1A.105 shows 24.2% identity over 318 aa with actinidin, the major allergen of kiwi (Pastorello et al, 1998), might be a concern. Of course, this does not exceed the threshold of 35% over 80 aa, as recommended in the FAO/WHO guidelines, but this represents a sufficient number of aminoacids to form common conformational epitopes with actinidin when folded in the 3-D structure, which is not taken into account with single alignment searches. Kiwi allergy is not uncommon in Europe. It might be relevant and not difficult to perform skin tests with purified Cry1A.105 on kiwi-sensitized patients (the right kiwi-sensitized population must be chosen (Lucas et al, 2007)).
Likewise, potential cross-reactivity of Cry2Ab2 with Cop c 1 (Brander et al, 1999) should be further evaluated, though basidiomycetes-sensitized patients might be more difficult to find.
Testing the resistance to digestion is not useful in the assessment of allergenicity since there are multiple examples of labile allergens.

Assessment of allergenicity of the whole GM plant.
This has not been evaluated in the application. As in the comments for application EFSA/GMO/NL/2007/37, the reviewer wishes to emphasize that the rationale of this section is to evaluate, due to the introduction of the new traits, possible changes in the allergenicity of the recipient plant when this plant is known as an allergenic source.
Although not frequent, food allergy to maize has been described and major allergens have been determined (Pastorello et al. 2003; Pasini et al. 2002). In addition, other potential allergens have been detected (Weichel et al. 2006). The introduction in the plant of Cry1A.105, Cry2Ab2, and CP4 EPSPS

proteins, even if not allergenic, might interfere with the expression levels of other maize proteins, including allergens. Care must be taken that food allergy to maize grain does not become more frequent due to the introduction of new traits and the interferences thereof. For that reason, it is relevant to analyze whether the expression levels of known major allergens is increased in genetically modified MON89034 x NK603 maize grains. Patient IgE binding to maize grain extract or titration of known major allergens of maize should be carried out.

Comments summarized by the coordinator

1. General comments: see dossier 2007/37.

2. For the allergenicity evaluation of Cry1A.105 and Cry2Ab2: see commnents of the Belgian experts in dossier 2007/37.

3. For the CP4 EPSPS protein, a 30 % homology was found with the *Dermatophagoides farinae* 2 protein (Der f 2). Although this homology is under the limit of 35 %, it would be interesting to compare the 3d structures of Der p 2 and CP4 EPSPS and to test some sera of patients allergic to Der p 2.

4. Assessment of allergenicity of the whole GM plant.
This has not been evaluated in the application. As in the comments for application EFSA/GMO/NL/2007/37, the reviewer wishes to emphasize that the rationale of this section is to evaluate, due to the introduction of the new traits, possible changes in the allergenicity of the recipient plant when this plant is known as an allergenic source.
Although not frequent, food allergy to maize has been described and major allergens have been determined (Pastorello et al. 2003; Pasini et al. 2002). In addition, other potential allergens have been detected (Weichel et al. 2006). The introduction in the plant of Cry1A.105, Cry2Ab2, and CP4 EPSPS proteins, even if not allergenic, might interfere with the expression levels of other maize proteins, including allergens. Care must be taken that food allergy to maize grain does not become more frequent due to the introduction of new traits and the interferences thereof. For that reason, it is relevant to analyze whether the expression levels of known major allergens is increased in genetically modified MON89034 x NK603 maize grains. Patient IgE binding to maize grain extract or titration of known major allergens of maize should be carried out.

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

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

Comments/Questions of the expert(s)

Comment 1

As no long term toxicity studies has been done, it is not possible to exclude long term effect of GMO consumption. That's why it is required to do a follow-up of the GM food post-market

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

Comments/Questions of the expert(s)

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

Comments/Questions of the expert(s)

Comment 1

Provided information: sufficient.

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert(s)

Comment 1

Provided information: sufficient.

D.9.3 Potential for gene transfer

Comments/Questions of the expert(s)

Comment 1

Provided information: sufficient.

D.9.4 Interactions between the GM plant and target organism

Comments/Questions of the expert(s)

Comment 1

Not applicable

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

Comments/Questions of the expert(s)

Comment 1

Provided information: sufficient.

D.9.6 Effects on human health

Comments/Questions of the expert(s)

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

Comment 1

Provided information: sufficient.

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

Comments/Questions of the expert(s)

Comment 1

Not applicable

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

Comment 1

Provided information: sufficient.

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

See comments for dossier 2007/37

Comments/Questions of the expert(s)

Comment 1

We support the recommendation of ACRE (2006) that provision of detailed arrangements for general surveillance post-market monitoring plans for the import and processing of grain from GM maize should be made a condition of any consent. These should include which and when information should be provided to EFSA and how the applicant can ensure this to happen.
Although resistance to insect attack is not the only factor preventing maize to grow outside the agricultural environment, the (indeed low) possibility of the establishment of maize protected against insect larvae in the wild in Europe should be a point of particular interest in a more detailed general surveillance plan.

D.11.2 Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert(s)

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert(s)

D.11.4 General surveillance of the impact of the GM plant

Comments/Questions of the expert(s)

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

References

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