Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
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O./ref.: WIV-ISP/15/BAC/2009_01365

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/UK/2005/11 from Syngenta under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/UK/2005/11 was submitted by Syngenta on 12 January 2005 for the marketing (import and processing) of the insect-resistant genetically modified maize MIR604 for food and feed uses under Regulation (EC) No. 1829/2003[1][2].

The application was officially acknowledged by EFSA on 16 September 2005. 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).

At the time of this consultation, the Belgian Biosafety Advisory Council did not have the needed resources and did not participate to the consultation. However in February 2006, 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). Four experts answered positively to this request, and formulated a number of comments to the dossier. See Annexe I for an overview of all the comments.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 2 July 2009 (The EFSA Journal, 2009, 1193, 1-26)[3], and published together with the responses from the EFSA GMO Panel to comments submitted by the other member states during the three-month consultation period.

On 24 August 2009 the opinion of EFSA was forwarded to the Belgian experts. They were invited to give comments and to react, in particular in case the comments formulated in their initial assessment of the dossier were not addressed in the opinion of EFSA.

[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] The same GM maize is the object of application GMO/CZ/2008/54 for authorisation of cultivation. The full environmental risk assessment is ongoing at the Biosafety Advisory Council and will be the subject of a separate advice.
[3] See: <http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902691168.htm>

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

Scientific evaluation

1. Environmental risk assessment

According to the Biosafety Advisory Council no major risks were identified concerning the environment[4].

2. Molecular characterisation

According to the Biosafety Advisory Council the molecular characterisation data are considered as sufficient.

3. Food/feed safety assessment

3.1. Assessment of compositional analysis
Following the comments submitted by the Belgian experts, the Biosafety Advisory Council considers that even if the compositional analysis of the GM food/feed was performed according to the OECD consensus document[5], it lacks the analysis on dietary fibre. The Biosafety Advisory Council recommends the analysis on dietary fibre since this concept is widely accepted in human food studies and recommends the adaptation of the OECD consensus documents accordingly.

3.2. Assessment of toxicity
According to the Biosafety Advisory Council no major risks were identified concerning toxicity.

3.3. Assessment of allergenicity
The Biosafety Advisory Council is concerned about the potential allergenicity of the transgene protein, according to a possible cross-reactivity with a moderately important latex allergen. The MIR604 PMI – Hev b13 homology is 29.6%. Conversely to what is stated in the guidelines of the Codex Alimentarius, claiming a minimal homology of 35%, a homology of 29.6% could be an issue, as this represents 29 identical aminoacids between the two proteins, enough to construct several cross-reactive epitopes. Therefore, it is required that the reactivity of PMI be evaluated by using specific tests in vivo .

4. Monitoring

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

[4] 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.
[5] OECD, 2002. Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea Mays*): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites. ENV/JM/MONO(2002)25. http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)5

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 notifier 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 animal health were identified.

Disagrees with the GMO panel of EFSA when it says that no risks for human health were identified, since identified potential allergenicity of the transgene protein has not been tested in vivo.

The BAC therefore gives a negative advice for the placing on the market of the insect-resistant genetically modified maize MIR604.

In addition, the Biosafety Advisory Council recommends:

1) To include the analysis of dietary fibre in the compositional analysis of food and to adapt the OECD consensus documents accordingly;
2) 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 I: Full comments of experts in charge of evaluating application EFSA/GMO/UK/2005/11 *(ref: BAC_2006_PT_357)*

Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
Secrétariat

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Expertise report for the EFSA dossier EFSA/GMO/UK/2005/11 - Compilation of all the comments received from the experts

Mandate for the Group of Experts: mandate of the Biosafety Advisory Council (BAC) of 12 December 2005
Coordinator: Prof. dr. ir. Dirk Reheul (UGent)
Experts: Yann Devos (UGent), Michel Paquot (FUSAGx), Frank Van Breusegem (VIB), Hadewijch Vanhooren (KUL)
Domains of expertise of experts involved: ecology, nature conservation, biodiversity, sustainable development, biosafety research, risk analysis, biochemistry of food/feed, industrial processing, novel food, toxicology, immunology, consumer info, genome analysis, genetic engineering, maize
Secretariat: Adinda De Schrijver, Martine Goossens

INTRODUCTION

Dossier **EFSA/GMO/UK/2005/11** concerns a notification of the company **Syngenta seeds** for the marketing of the genetically modified **maize MIR604** for food and feed applications under Regulation (EC) 1829/2003.
The notification has been officially acknowledged by EFSA on 16 September 2005.
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 notification on its 1) molecular, 2) environmental, 3) allergenicity, 4) toxicity and/or 5) food and feed aspects. Its was expected that the expert should evaluate if the information provided in the notification 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.

List of comments received from the experts

A. GENERAL INFORMATION

Comments/Questions of the expert(s)

Comment 1

The scope of the application includes all feed and food products containing, consisting or produced from the genetically modified maize Event MIR604 including products from inbreds and hybrids obtained by conventional breeding of Event MIR604.
The application also covers the import and industrial processing of Event MIR604 for all potential uses, as any other maize.
Event MIR604 is a genetically modified (GM) maize expressing two transgenes:

1. A modified *cry3A (mcry3A)* gene encoding the mCry3A protein that confers resistance to the Western Corn rootworm (WCRW) *(Diabrotica virgifera virgifera)* and other related coleopteran pests of maize like the Northern Corn rootworm (NCRW) (*Diabrotica longicornis barberi,* Smith and Lawrence*)* (Chen and Stacy, 2003).
2. The *pmi* (*manA*) gene from *Escherichia coli,* which encodes the enzyme PMI as a selectable marker. PMI allows transformed corn cells to utilize mannose as a sole carbon source, while maize cells lacking the *pmi* gene fail to grow.

Comment 2

The intended used of the product is similar to other conventional maizes. By consequence, food used are concerned. Among these uses, the whole grains can be considered but also cracking of the grains in order to obtain mainly starch.
Native starch is a food ingredient but other important products are derivatives of starch : pregelified, modified or hydrolysed.

Comment 3

The general information is sufficient / no questions.

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

Comments/Questions of the expert(s)

Sufficient information / no questions.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1

Sufficient information / no questions.

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

Sufficient information / no questions.

D.2. Information on the sequences actually inserted or deleted

Comments/Questions of the expert(s)

Comment 1

How were the 5' and 3' flanking regions of the insert obtained (p.16 Technical dossier-main text)?

D.3. Information on the expression of the insert

Comments/Questions of the expert

Comment 1

All the products derived from the genetically modified maize may content the proteins mCRY3A and PMI.
Even if the content is low (magnitude of 1ng ; 10ng/mg grain dry weight), it is useful to check the risk of accumulation into specific derivatives products especially those obtained by cracking of the raw materials. In other word, can the content in mCRY3A and PMI increase in a product of cracking for the food chain. Where does these proteins partition (starch fraction, oil,….)?

The extraction efficiency of mCRY3A is calculated by comparison with two other extractions after the first one. How can we have the certitude that an other part, important or not, of the proteins does not remain in the residual solid.

Comment 2

Sufficient information / No questions.

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

Sufficient information / No questions.

D5. Genetic stability of the insert and phenotypic stability of the GM plant

Comments/Questions of the expert(s)

Comment 1

Sufficient information / No questions.

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

Comments/Questions of the expert(s)

Comment 1

Chances of genetic material transfer to other organisms is negligible.

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)

To confirm that Event MIR604-derived maize plants are substantially equivalent to the non-transgenic isolines, replicate trials of transgenic and corresponding isogenic controls were planted in 12 locations over two growing seasons. The locations of the trial sites were selected to be representative of the range of environmental conditions under which the hybrid varieties are expected to be grown. At each location, three replicate plots of each genotype were planted.

The levels of multiple nutritive components were compared in maize kernels (grain) or whole plants (forage) produced from Event MIR604-derived maize plants and simultaneously grown isogenic control plants. The mean values were also compared with the range of data published in the literature.

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

Grain from transgenic MIR604-derived maize plants and isogenic non-transgenic control plants were analysed for proximates (including starch), minerals, amino acids and selected fatty acids, vitamins, anti-nutrients and secondary metabolites. Forage (whole plants) from transgenic MIR604-derived maize plants and isogenic non transgenic control plants were analysed for proximates and minerals.
Annex IV presents the compositional analysis of grain and whole plants from transgenic maize event MIR604. Sporadic statically significant differences (ex. Phytosterols, proteins) were observed for some parameters between the MIR604 transgenic and near-isogenic controls. All components evaluated were within the range of reported literature values for maize.

The major constituents of maize grain and forage are carbohydrates, protein, fat and ash. A statistically significant difference was observed in protein levels in the 2003 grain, with average % dry weight of protein in the transgenic grain only 4-7% higher than in the non-transgenic control. Fibre is the predominant form of carbohydrate present in forage, and starch is the major carbohydrate in corn grain. Fibre is measured by the neutral detergent fibre method (NDF), which measures the insoluble fibre : lignin, cellulose and hemicellulose. This method has replaced the crude fibre method, which underestimates the cell wall content due to hydrolysis of hemicellulose and cellulose. Total dietary fibre (TDF) consists of the insoluble and soluble fibre (pectin). The soluble fibre fraction in maize is negligible, so the NDF value in maize grain is comparable to that of TDF. The acid detergent fibre (ADF) method makes soluble hemicellulose, measuring only cellulose and lignin.
Considering food application, the evaluation of total dietary fibre, soluble and insoluble is more obvious than ADF and NDF (appendix 4, part 2). It is recommended to measure the soluble and insoluble dietary fibre after enzymatic extraction of starch and proteins.

Some questions arise also from the results.
The carbohydrate content is obtained by difference. In some trials, starch is measured.
The sum of the starch content plus the NDF-ADF (+raffinose, acid feluric, acid coumaric, phytic acid,…) is lower than the carbohydrate content (eg : table 2, appendix IV, part3).
Are they some components missing?

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

D.7.5 Product specification

Comments/Questions of the expert(s)

Comment 1

Even if significant differences between Event MIR604 near-isogenic non transgenic control plants are not numerous and quantitatively important, a rigorous equivalence is not proved from the analysis. Toxicological studies seem necessary.
Comparison with reported literature ranges is not valid because of the too high reported variability.

D.7.6 Effect of processing

Comments/Questions of the expert(s)

Comment 1

Maize from Event MIR604 will be produced and processed in the same way as any non-GM maize and there is no evidence to suggest that the expression of the mCry3A and PMI proteins will influence this processing in any way.

Presence of modified Cry3A protein was quantitatively analyzed in standard wet-milled and dry-milled processing fractions, corn oil and corn chips from maize grain derived from Event MIR604. Control grain was obtained from non-transgenic hybrid field corn plants that were derived from similar germplasm as the MIR604-derived plants. The analysis of different samples derived from Event MIR604 plants showed mCry3A protein could be found in some of the fractions in both wet and dry-milling processes, but no quantifiable levels were found in corn chips or corn oil.

Comment 2

The cracking of maize in order to produce different food ingredients may concentrate some secondary metabolites or anti-nutrients and allergens.
Some of these compounds will be denatured during food process, especially by heat treatment.
Nevertheless, the chemical composition of a raw material is not sufficient to predict the repartition of the minor components during a food process or the cracking.
The used technology is of course important but also the locations and the interactions between the different components in the raw materials.

Considering the risk, even weak, to concentrate a secondary metabolite in an other way than the traditional sources, recommendations of a post-market monitoring seem necessary.

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

Comment 1

It is expected that the introduction of Event MIR604 will replace some of the maize in existing food and feed products.
The estimated consumption of products of cracking is missing. A estimation of the 95th percentile of derived maize products consumption is necessary.

D.7.8 Toxicology

Comments/Questions of the expert(s)

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1

Screening for structure-activity relationship, *in vitro* digestibility assays, and acute toxicity testing.
A battery of tests showed that the newly expressed proteins, mCry3A and PMI, are structurally and functionally not related to known toxins (App. XI and XVII) and food allergens (App. XII and XVIII). The mCry3A and PMI proteins were found sensitive to processing and heat (App. V and XIV; App. XX) and are rapidly degraded under simulated mammalian gastric and intestinal conditions (App. XIII and XIX). In the acute oral toxicity studies of the mCry3A protein (2377 mg/kg bw) and PMI protein (5050 mg/kg bw) in the mouse, no signs of systemic toxicity were found. There were no test-substance related effects on bodyweight, food consumption, organ weight or macroscopic or microscopic pathology (App. VI and VIII). The proteins were found not acutely toxic to mice.
The proteins used for the *in vitro* digestibility studies and the acute oral toxicity studies were produced by recombinant E. coli. The test substances PMI-0198 (App. II) and MCRY3A-0102 (App. VII, XV, XVI) were compared by various structural, functional and biochemical parameters to the PMI protein and the mCry3A protein produced in the transgenic maize event MIR604. The proteins from recombinant E. coli and the MIR604-derived maize are found substantially equivalent and the microbial test substances can be accepted as a suitable surrogate.
Repeated dose toxicity testing.
No 28-day oral toxicity test has been performed with either proteins. It was motivated by the applicant that since no safety concerns have been raised by the acute toxicity studies, digestibility

studies or toxin homology searches, both proteins can be considered non-toxic and unlikely to present a health risk to humans and animals.
We cannot completely agree with this motivation, but as whole-food toxicity testing has been performed consisting of a well-conducted and well-documented 90-days feeding study in rats (including biochemical, haematological and histological endpoints) and a 49-days broiler chicken study, we decide not to request for a 28-days oral toxicity study combining the 2 proteins.
Genotoxicity testing.
Genotoxicity testing, whether it is performed or not, should always be well motivated.

Comment 2

The effect of temperature on modified Cry3A (mCry3A) protein was determined by incubating test substance MCRY3A-0102 for 30 minutes at a range temperatures (4°C, 25°C, 37°C, 65°C and 95°C) followed by bioassay against western corn rootworm larvae (WCRW, Diabrotica virgifera virgifera). At 95°C mCry3A was completely inactivated. At 4°C, 25°C, and 37°C there was little or no effect on mCry3A bioactivity, whereas at 65°C there was some reduction in the bioactivity.

The thermo-denaturation could be different in a complex system and results could be different for pasteurised products (ex. 75°C, shorter time) ?

Proteins are not denatured in the same way when comparing high temperature short time treatments against lower temperature long time. Denaturing and cooking effects are more important for long treatments. It is the same for sterilization (eg. 120°C - 20 min) against UHT (140°C- few seconds).

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

Comment 1

No constituents other than the mCry3A protein and PMI enzyme are novel: Agreed.

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert(s)

The presence and levels of natural food and feed constituents have been analysed in grain and whole plants from Event MIR604 and compared with non-genetically modified isolines and data from literature (App. IV). Although sporadic statistically significant differences were observed between Event MIR604 transgenic plants and isogenic controls, these changes were not found biologically significant (no consistent patterns). All components evaluated were within the range of reported literature values of maize. It was concluded that based on these data there is strong evidence that the MIR604 hybrids are substantially equivalent in composition to the isogenic controls. 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

Comments/Questions of the expert(s)

Comment 1

The 90-days whole food study in rats. (App. IX)
In a well-conducted sub-chronic (90-days) toxicity study in rats fed MIR604 maize, no consistent differences in bodyweight, food consumption, clinical condition, clinical pathology, organ weights or histopathology were noted for rats fed on 10 or 41.5% non-GM isolines or MIR604 maize. It was concluded that Event MIR604 maize grain did not cause any treatment related effects and there were no differences with the non-GM isolines. Agreed.
The 49-days poultry feeding study. (App. X)
The 49-days poultry feeding study was conducted to evaluate the nutritional value of Event MIR604 grain compared with the non transgenic isoline control grain as well as an additional commercial source of corn. The results show that there were no biologically relevant differences in the parameters tested between broilers fed the Event MIR604 grain and the non-transgenic control diet. Agreed.
In conclusion, it was concluded by the applicant that no differences in wholesomeness are expected with comparable non-GM maize varieties.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

Comment 1

See D.7.5, D.7.6. and D.7.7.

A surveillance programme should accompany the marketing of the derived products from maize MIR604.

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

Comments/Questions of the expert(s)

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

- See 9.3.

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert(s)

Comment 1

- See 9.3.

D.9.3 Potential for gene transfer

Comments/Questions of the expert(s)

Comment 1

- Establishment of invasive feral MIR604 maize populations (vertical gene flow): unlikely.
During transport of imported F_2 maize grains some grains will inevitably be spilled accidentally. The probability that these spilled grains result in self-sustaining and/or invasive feral maize populations is *nihil*. Maize has been grown for many years in the EU and feral maize populations are rarely observed. Even in agricultural fields with ideal conditions, maize is not known to persist as a weed: volunteers are killed by frost. In Mediterranean countries, some volunteers occur but these are easily controlled by current agronomic practices. Although no information is provided on the germination and establishment potential of MIR604, it seems improbable that this potential was enhanced compared to the isogenic control. Due to its high level of domestication, the germination and establishment potential of maize outside the fields is expected to remain very low despite the acquisition of the new transgenic traits (that confer a selective advantage under field conditions with the appropriate selection pressure). It is important to bear in mind that the imported grains that can be spilled are from the F_2 generations and that these are expected to be less fit than F_1 grains. Moreover, the selection pressure of

corn rootworm is currently small in Belgium being limited to some major airports but may increase in the future. According to the notifier the expression of PMI cannot be considered a factor that would confer selective advantage to MIR604, since mannose is generally not the only source of carbon in normal soils. However, no data were provided in the notification allowing the confirmation of this statement.

- Acquisition of transgenic traits by wild/weedy maize relatives resulting in invasive progeny (vertical gene flow): unlikely.
There are no wild/weedy relatives of maize in the EU. However, cultivated maize occurring in the neighbourhood of the feral MIR604 maize could theoretically act as a recipient. This hypothesis seems improbable. First, feral maize populations resulting from spilled grains are rarely observed and it is even more doubtful that these plants will flower. Second, pollen flow would only occur locally. The pollen amount will be small compared to a field of commercial size. As maize pollen is heavy, pollen will be deposited within a few meters of the source. Third, it is not clear that feral maize plants will flower and release their pollen at the moment of silking of the recipients.

D.9.4 Interactions between the GM plant and target organism

Comments/Questions of the expert(s)

Comment 1

- Corn rootworm develops resistance requiring alternative pest control: unlikely.
- Other pests become abundant due to the efficient control of corn rootworm: unlikely.
The number of feral MIR604 plants will be extremely low and the selective pressure against the corn rootworm small.

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

Comments/Questions of the expert(s)

Comment 1

- Decline of non-target organisms resulting in the loss of biodiversity and/or ecological functions: unlikely.
The number of feral MIR604 plants will be extremely small as a result of what the environmental exposure of MIR604 will be *nihil*.

D.9.6 Effects on human health

Comments/Questions of the expert(s)

Comment 1

- Accidental consumption of maize plant parts leading to toxicological and/or allergenic reactions: unlikely.
See food and feed experts.

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

Comment 1

- Accidental consumption of maize plant parts leading to toxicological and/or allergenic reactions: unlikely.
See food and feed experts.

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

Comment 1

- Decline of non-target organisms resulting in the loss of biodiversity and/or ecological functions: unlikely.
- Impact on carbon and nitrogen recycling through changes in soil decomposition of organic material: unlikely.
The exposure to spilled MIR604 grains and feral MIR604 plants will be extremely low as a result of what the environmental exposure to toxins produced by MIR604 (*e.g.* through root exudates and decaying plant parts) will be extremely low.

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

Comments/Questions of the expert(s)

Comment 1

- Not of application.

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

Comments/Questions of the expert(s)

Comment 1

The general surveillance (GS) remains vague and only provides a general frame of principles, which is understandable at this stage of the authorisation procedure. However, it might be advisable to complete the GS with more details once a positive advice of EFSA is obtained (*e.g.* include the names and coordinates of the networks that will be involved in the GS, the countries/regions where the GS will be done and the information that will be asked in the questionnaires).

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)

Comment 1

Given that the risks identified in the environmental risk assessment were extremely small and not uncertain, there is no reason to demand a case-specific monitoring (CSM). CSM is not mandatory but required when uncertainty remains.

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

Comments/Questions of the expert(s)

Comment 1

On the opposite of the CSM, GS is mandatory for viable GM material. Non-viable GM material falls beyond the scope of the environmental monitoring provision. In case of imported viable grains, GS should consider that if substantial loss, spillage and establishment are possible, appropriate management systems should be in place to restrict environmental exposure. Given the increasing number of notifications covering import, unforeseen (cumulative) effects should be followed up in the GS.

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

References

Eastham K, Sweet J (2002) Genetically modified organisms (GMOs): the significance of gene flow through pollen transfer. Environmental Issue Report 28, EEA, http://reports.eea.eu.int/environmental_issue_report_2002_28/en/GMOs%20for%20www.pdf