Bioveiligheidsraad
Conseil de Biosécurité

02-10-2009

Secretariaat
Secrétariat

O./ref.: WIV-ISP/BAC/2009_01367

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/NL/2005/22 and EFSA/GMO/RX/NK603 from Monsanto under Regulation (EC) No. 1829/2003

Context

Application EFSA/GMO/UK/2005/22

The application EFSA/GMO/UK/2005/22 was submitted by Monsanto on 5 October 2005 for the marketing of the glyphosate tolerant genetically modified NK603 maize for cultivation, food and feed uses and import and processing under Regulation (EC) No. 1829/2003[1].

The application was officially acknowledged by EFSA on 12 May 2006. 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, chosen from the common list of experts drawn up by the Biosafety Advisory Council and the Division of Biosafety and Biotechnology (SBB), to evaluate the dossier. Eight 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 4 August 2006.

In addition, EFSA requested the Spanish Competent authority to conduct the initial environmental risk assessment of this application concerning the placing on the market of maize NK603 for cultivation.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 27 May 2009 (The EFSA Journal, 2009, 1137, 1-50)[2], and published together with the responses from the EFSA GMO Panel to comments submitted by the experts during the three-month consultation period and the environmental risk assessment report from the Spanish Competent Authority and its Biosafety Commission.

[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_1211902572982.htm>

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On 19 June 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.

Application EFSA/GMO/RX/NK603

The application EFSA/GMO/RX/NK603 was submitted by Monsanto on 5 October 2005 for renewal of the authorisation of GM maize NK603 as existing products (food additives and feed materials/additives produced from NK603 maize) within the framework of Regulation (EC) No. 1829/2003. It was officially acknowledged by EFSA on 12 May 2006.

All data required for the risk assessment of this application have also been provided in application EFSA/GMO/NL/2005/22. In consequence, the Biosafety Advisory Council issues a single comprehensive advice covering both applications.

Scientific evaluation

1. Environmental risk assessment

According to the Biosafety Advisory Council no major risks were identified concerning the environment. However, there are concerns that more effective weed control based on the GMHT maize cultivation may eventually lead to declining weed seed banks and have an impact on invertebrate and vertebrate biodiversity in the long run.
In addition, the lack of a good resistance management in GMHT maize may lead to glyphosate resistance in weed species, therefore reintroducing the need to use selective herbicides.

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[3], 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 Assesment of toxicity
According to the Biosafety Advisory Council no major risks were identified concerning toxicity.

[3] 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

3.3. Nutritional value
According to the Biosafety Advisory Council maize NK603 is as nutritious as 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.

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:

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;
3) To promote the application of resistance management to prevent the emergence of glyphosate resistant weeds;
4) To pay attention to floristic and faunistic biodiversity in monitoring plans.

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

Annex: Full comments of experts in charge of evaluating application EFSA/GMO/NL/2005/22 *and comments submitted on the EFSAnet (ref. BAC_2006_PT_401)*

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Conseil de Biosécurité

4/08/2006

Secretariaat
Secrétariat

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Comments of experts in charge of evaluating the application EFSA/GMO/NL/2005/22
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 19 June 2006
Coordinator: Prof. dr. ir. Dirk Reheul
Experts: Pascal Cadot (KUL), François Chaumont (UCL), Patrick De Clerq (UGent), Rony Geers (KUL), Jean-Pierre Maelfait (Instituut voor Natuurbehoud), Peter Smet (Consultant), Frank Van Breusegem (VIB), Johan Van Waes (CLO)
Domains of expertise of experts involved: Molecular biology, biochemistry, genetics, genome analysis, genetic engineering, immunology, alimentary allergology, animal feed, labelling of food/feed, consumer information, ecology, plant-insect relations, nature conservation, agronomy, crop protection, crop production management, herbicide tolerance, biosafety research, effect on non-target species, impact on bio-diversity, risk analysis, maize
Secretariat: Adinda De Schrijver, Martine Goossens

INTRODUCTION

Dossier **EFSA/GMO/NL2005/22** concerns a notification of the company **Monsanto** for the marketing of the genetically modified **maize NK603** for food and feed applications under Regulation (EC) 1829/2003.
The notification has been officially acknowledged by EFSA on 07 April 2006.
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 containing or consisting of GM plants
☒ 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 – including the impact of its cultivation in Europe, 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.

List of comments received from the experts

A. GENERAL INFORMATION

Comments/Questions of the expert(s)

Comment 1

None

Comment 2

The range of uses of this maize for food and feed will be identical to the full range of equivalent uses of traditional maize. So also the judging of this type of GMO-maize has to be as for classical bred hybrids.

Comment 3

The application concerns (i) the renewal of the authorization of the existing feed materials and food and feed additives produced from NK603 maize and (ii) the authorization of NK603 for all food and feed use as any other maize including the use for the cultivation in the E.U.

Comment 4

General information is complete. No questions.

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.

Comment 2

No questions.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1

The NK603 maize has been genetically modified to become resistant to the herbicide glyphosate. It results from the insertion of a DNA fragment containing two copies of the cDNA encoding the 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. strain CP4 (CP4 EPSPS). The *CP4 EPSPS* cDNAs have been fused to a DNA fragment encoding the transit peptide of *Arabidopsis thaliana* EPSPS to target the proteins into the chloroplasts, and placed under the control of rice actin-1 and CaMV 35S promoters, respectively. The EPSPS activity is essential for the biosynthesis of aromatic amino acids in plants. The plant enzyme is inhibited by glyphosate. The molecular characterization of NK603 maize is described in detail in the current application and annexes.

Comment 2

The information relating to the genetic modification is adequately provided. 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

See above.

Comment 2

No questions.

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

Comments/Questions of the expert(s)

Comment 1

Why does the insert contain two cp4 epsps cassettes which differ from each other by two nucleotides? According to the data provided, this results in two proteins differing by one amino acid.

- Why, what is the purpose of this?
- At a molecular level, do these proteins behave differently?

Comment 2

Molecular analysis (Southern blot, PCR amplification, sequencing, RT-PCR) showed that NK603 contains a single insertion containing one copy of the DNA fragment. The two CP4 EPSPS cassettes are intact. However, the second gene differs by 2 nucleotides, one of them resulting in one amino acid change in the expressed protein (L214P). The DNA insertion includes some molecular rearrangements at 3' of the fragment: (i) an inversely linked 217 bp fragment of the enhancer region of the rice actin promoter (this fragment does not act as a promoter) and (ii) a 305 bp fragment showing homology to chloroplast DNA. RT-PCR was used to determine if these rearrangements result in the production of new transcripts encompassing the 3'end of the insert and the genome-flanking region. A transcript produced from one of the promoters present in the insert and extending through the NOS3'sequence into the adjacent flanking DNA was detected. This transcript was not detected by Northern blot analysis suggesting that the RNA transcript is rare or instable. In addition no aberrant protein was detected by Western blot analysis. In conclusion, these modifications at 3' of the insert do not lead to new traits and are not considered to pose a safety risk.
It is of my opinion that the dossier contains fully documented molecular data of the genetic insertion and that the conclusions raised are in full agreement with the molecular results.

Comment 3

A detailed analysis (Southern blot analysis + PCRs) provides a clear picture on the structural organisation of the inserted sequences. In addition, the absence of vector backbone sequence was assessed and demonstrated to be absent.

In D.2.d (p.51) the sequence data of the flanking 5' and 3' regions is not provided. In contrast with the DNA sequence of the NK603, there is no reference towards the CBI. There is only a statement that the flanking regions were confirmed to be native to the maize genome. The methodology on how the flanking sequences originally were identified is not presented.

D.3. Information on the expression of the insert

Comments/Questions of the expert(s)

Comment 1

The expression of the insert was estimated using an enzyme-liked immunosorbent assay (ELISA) in various plant tissues of NK603 produced in 1999 in the EU and 2002 in the US. The expression of potential fusion proteins has been excluded from bio-informatics analysis and molecular characterization (RT-PCR, western blots, …).

Comment 2

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

Remarks concerning the survivability of seeds of maize: In the dossier it is mentioned that seed can only survive under favourable climatic conditions. Maize volunteers are killed by frost or, in the unlikely event of their occurrence, are easily controlled by current agronomic practices, including soil cultivation practices and the use of selective herbicides. This is correct but from our experience maize seeds can survive in the soil during a not so severe winter. It can happen that out of full ears, fallen on the ground at harvest and after labouring of the land, covered with soil, some seeds survive and give plantlets during the next season. So here in the case of GMO-plants it will be necessary to have a follow up of the fields in the next year to detect for surviving plants, especially when the next culture is again maize.

Comment 2

No conclusive differences between NK603 and traditional maize have been detected.

Comment 3

No questions.

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

Comments/Questions of the expert(s)

Comment 1

Are the GMO-plants already tested in more northern countries, with a cold spring and in many cases with bad conditions in autumn? Will the variety behaviour under such conditions be phenotypic the same? What will be the reaction after a herbicide control on plants grown in spring under not optimal conditions?

Comment 2

The stability of the insert has been demonstrated through six generations of crossing and three generations of self-pollination (segregation data and Southern blot analysis).

Comment 3

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)

No questions.

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)

The information given by the applicant is sufficient to conclude that there are no biological differences between NK 603 and traditional maize in agronomic and phenotypic characteristics with the exception for the tolerance of NK 603 plants to glyphosate.
A supplementary question: What is the agronomical value of the GMO-maize compared to the best actual varieties in the market?

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)

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Since it concerns a renewal, toxicology has already been reviewed. Still I have two questions.

- The acute oral toxicity study in mice with the CP4 EPSPS protein is provided by means of an article (Harrison et al, 1996). This – of course – contains no raw data. Why aren't these presented by means of the original study as it is done for the acute oral toxicity study in mice with the CP4 EPSPS L214P protein?
- Acute oral toxicity study in mice with
  - the CP4 EPSPS L214P protein:
    - Highest dose tested : 817 mg/kg of body weight
    - Target dose : 1000 mg/kg of body weight
  - the CP4 EPSPS protein:
    - Highest dose tested : 572 mg/kg of body weight
    - Target dose : 400 mg/kg of body weight
  - Why are these target doses different from each other? Why weren't the same doses chosen?

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

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)

In the experiment with rats 10 groups of 40 animals (20 females, 20 males) were used. A first remark is, that the authors mentioned that at week 5 half of the animals were sacrificed in order to study clinical parameters, however the initial number of animals is mentioned at the end of the trial. The number of animals is sufficient in order to find a difference in mean body weight of 5% at week 5, but at week 14 that number should have been 45 within each group to find a difference of 5% between treatments. Another remark is that the body weights of the males are far more heterogeneous at the end of the trial than is the case for the females, as being indicated by the value of the standard deviation.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

In section 7.9.1, it is said that CPA EPSPS protein shows no sequence similarity with known allergens. The reviewer agrees with this statement.
Although not a formal proof for the absence of allergenicity, the applicant performed a test for the resistance to digestion of CP4 EPSPS, where it is shown that the protein is readily degraded in a simulated gastric digestion assay.
In addition, eleven maize allergens have recently been determined (Weichel et al. 2006a), but none seems to correspond to the native EPSPS protein, or to belong to the EPSPS family.
As a conclusion, the reviewer agrees when it is said that CP4 EPSPS is unlikely to be allergenic.

Section 7.9.2
The potential allergenicity of the whole crop has not been evaluated. Although maize allergy is not well-documented, some reports exist (Pasini et al. 2002; Pastorello et al. 2003; Weichel et al. 2006a; Weichel et al. 2006b) and maize, therefore, can be considered as an allergenic source. Given that the introduction and expression of the new trait (under the influence of a different promoter than naturally occurring EPSPS proteins) might influence, by cascade reactions, the expression of other proteins

(including allergens), it is recommended to assess, by using patient's serum for example, whether there is no increase in the expression of known maize allergens, or no induction of new maize allergens not yet known. This can be achieved by comparing IgE-binding patterns of native and NK603 corn protein extracts.

Given that the application also refers to the cultivation of NK603 maize, inhalant allergy to maize pollen should also be taken into account, as experienced by allergic people living near maize fields. Maize pollen allergy is not well-documented. It is known, however, that grass pollen allergic patients frequently react to maize pollen by cross-reactivity. Such cross-reactivity between grass and corn pollen allergens has been documented for the first time in 1978 (Kalveram and Forck. 1978). Different reports emphasize the potential role of maize pollen as an allergenic source (Turcich et al. 1993; Astwood et al. 1995; Guneser et al. 1996). For that reason, it should be determined whether the presence and the expression of CP4 EPSPS in pollen do not influence the levels of known allergens, or whether the allergenic potential of NK 603 maize pollen is not increased. This could be achieved by using maize-allergic patient's sera as probe on natural and NK 603 maize pollen protein extracts.
The level of CP4 EPSPS in pollen has been determined by the applicant, and was shown to be 340 microg/g fw in mean (see section 3(a) (b)). The applicant should determine the levels of expression of the naturally occurring EPSPS in pollen, as a comparison. If the level of CP4 EPSPS in pollen is much higher than that of the naturally occurring EPSPS (which might be the case under the influence of an actin promoter), then additional surveillance should be carried out. Although proteins of the family of CP4 EPSPS have never been described as allergens, contact through the respiratory tract in higher amounts than usually might represent a new way of exposure, with unknown outcome, and a possible way of sensitization not existing previously.

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

The experiment with broilers is well designed with a sufficient number of replicates to detect potential statistically significant differences.

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)

None

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

Given the absence of wild relatives of maize in our regions and the fact that maize cannot persist without human assistance, I agree that dissemination of the transgene in the environment is unlikely and invasiveness of the GM plant is negligible.

Comment 2

Provided information: sufficient.

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert(s)

Comment 1

None

Comment 2

Provided information: sufficient.

D.9.3 Potential for gene transfer

Comments/Questions of the expert(s)

Comment 1

See D.9.1

Comment 2

"Maize is a wind-pollinated species. Self- and cross-pollination are generally possible. All maize will interpollinate" (pg 13)
"On average, almost all maize pollen travel no further than 100 metres, although a cut-off distance is not clear." (pg 119)
Personally, I believe it will be very hard to create the conditions needed to prevent contamination of non-GM maize fields, in small countries like Belgium, with its patchwork-like fields.
What measures – case specific for Belgium/Flanders – are foreseen to prevent contamination?

Comment 2

Provided information: sufficient.

D.9.4 Interactions between the GM plant and target organism

Comments/Questions of the expert(s)

None

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

Comments/Questions of the expert(s)

Comment 1

Here the results obtained for maize in the British Farm Scale Experiments (FSEs) should have been summarized and discussed.
These were at the time of making and updating the technical dossier (respectively August 2005, April 2006) already available for a relatively long time (Brook et al., 2005; DEFRA, 2005). They were used by the Advisory Committee for Releases into the Environment (ACRE, 2004) to provide advice on the likely benefits for within-field biodiversity if GM maize was adopted. This led to the conditional approval for this crop by UK government (DEFRA, 2004).
ACRE summarised the advice on GM maize as follows (my italics): "Maize: Based on the evidence provided by the FSE results published in October 2003, ***if*** GMHT maize were ***to be grown and managed as in the FSEs*** this would not result in adverse effects, as defined and assessed by criteria specified in Directive 2001/18/EC, ***compared with*** conventionally managed maize".

Comment 2

The technical dossier prepared by the applicant mainly addresses direct effects of the expressed CP4 EPSPS protein on non-target organisms, but information on indirect effects are scarce. Mention of indirect effects in section 9.5 (and 9.8) mainly relates to trophic chain effects of the expressed CP4 EPSPS protein. I agree that the likelihood of adverse effects of the expressed protein on a series of non-target organisms in or around the genetically modified herbicide tolerant (GMHT) crop (invertebrate natural enemies, pollinators and indifferent organisms, vertebrate organisms; invertebrate decomposers) is low, as has been demonstrated in several scientific papers. However, I feel that attention needs to be given to possible indirect effects on the longer term of the *practice of cultivating* GMHT maize, rather than of the expressed transgene itself.

In the United Kingdom, the Farm Scale Evaluation (FSE) has revealed no negative effects on biodiversity of invertebrate and vertebrate animals (e.g., granivorous birds) that depend on weeds for food in fields planted with GMHT fodder maize (ACRE, 2004). Indeed, the FSE even showed that dicot weed abundance was greater in GMTH maize than in conventional maize (where atrazine was used as a herbicide). However, little information was available on long term effects of the GMHT

crop. As the FSE indicated, effects of cultivating GMHT crops on biodiversity in and around the crop, may differ depending on the crop (maize versus spring oilseed rape and sugar beet). Table 11 in the technical dossier presents an overview of some field studies done with GMHT (Roundup Ready) crops assessing effects on pest and beneficial organisms. However, most of the references cited refer to studies on Roundup Ready soybean crops, and only one study on Roundup Ready maize is given (Rosca, 2004). Latter study, demonstrating no negative effects of GMHT maize NK603 on invertebrate biodiversity, is a medium scale field study done in Romania during a single season; its results have not been subjected to peer review (i.e., are not published in a peer reviewed journal), so should be interpreted with caution.

There are concerns that more effective weed control based on the GMHT maize cultivation may eventually lead to declining weed seed banks and have an impact on invertebrate and vertebrate biodiversity in the long run. Dewar et al. (2003), Hough-Goldstein et al. (2004), and Wilson et al. (2004) have indicated that GMHT crops do not necessarily provide more complete weed control and that effects on non target fauna (herbivores, carnivores, decomposers) will largely depend on cultivation and weed control practices. In small scale experiments, delayed weed control by early band spraying of the herbicide followed only later by an overall spray application resulted in higher abundance of invertebrates without a significant reduction in yield (Dewar et al., 2003). Thus, allowing a certain degree of weediness in the field for a certain period of time is expected to increase diversity of vertebrate and invertebrate wildlife. In conclusion, the non target effects of GMHT maize cropping may greatly depend on how the herbicide (here glyphosate) will be used.
Herbicide regimes and application methods associated with the use of GMHT crops should be carefully evaluated and optimized to minimize possible adverse environmental effects in the longer term.

Predictions of the FSE and other field studies with respect to environmental effects are largely based on the assumption that cropping systems (e.g., crop rotations, tillage regimes) will not be substantially altered as a result of the widespread adoption of GMHT maize. All of the above implies that we still do not have a reliable long-term forecast of the possible indirect effects of GMHT maize cultivation on non-target organisms in and around the fields. I do recognize, however, that it would be a huge endeavour to perform such a long-term assessment and an almost impossible task to do so based on small to medium scale field trials.

D.9.6 Effects on human health

Comments/Questions of the expert(s)

None

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

None

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

The FSE trials in the UK showed an increase in invertebrate detritivores as a result of the more abundant dead weed matter available in summer in GMHT maize (ACRE, 2004). In general, no negative effects of GMTH maize are expected based on the FSE trials, again provided that cropping methods are not altered as a result of the adoption of the GM crop. If it would appear, for instance, that crop rotations are less used because of a reduced need for crop rotation as an alternative weed control strategy, negative effects on the long term may arise. Effective weed control based on the GM maize cultivation may eventually lead to declining weed seed banks and have an impact on biodiversity and abundance of decomposer organisms in the long run.

See also my general comments in D.9.5, which are also valid for invertebrate decomposers.

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

Comments/Questions of the expert(s)

Comment 1

The alleged usefulness of glyphosate (Roundup) as a tool for conservation tillage farming, as mentioned in the technical dossier in section 9.9, is scientifically not well substantiated. Of the different references given here (p. 144), only 2 treat the possible role of glyphosate for conservation tillage (Dies Jambrino & Fernandez-Anero, 1997; Ruiz et al., 2001). Both of these papers have not been subjected to peer review and have Monsanto collaborators as co-authors. This somehow puts the statement that "Roundup is well known to be a useful tool in conservation tillage farming" (p. 140) into a different perspective.

Comment 2

In the framework of the EU- regulation 2002/53 a new variety have to be submitted to DUS (Distinctness, Uniformity, Stability) and VCU (Value for Cultivation and Use) tests before the variety can be commercialised. The new variety has to be compared with the best existing standard varieties. So my question here is : can the GM- maize be incorporated in normal VCU trials, for example treated with specific herbicides for maize and will the agronomical value be the same as tested in trials, where herbicides for which the variety is tolerant were used?

Comment 3

Should be discussed in view of the remarks made in D.9.5.

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

Comment 1

None

Comment 2

Information provided: sufficient.

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

Comments/Questions of the expert(s)

None

D.11.2 Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert(s)

None

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert(s)

None

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

Comments/Questions of the expert(s)

In the example of the farmers questionnaire for general surveillance on p. 259 of the technical dossier (appendix VI), I recommend adding “pests” to question 12 (now saying “Plant diseases”).

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

None

References

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