Report

Supplementary Risk Assessment for GM Maize MON 810 with regard to the conclusions of the WTO-Panel in the case „EC Biotech“ on Austrian safeguard measures for GM maize

Forschungsberichte der Sektion IV

Band 4/2007

umweltbundesamt

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Impressum:

Herausgeber, Medieninhaber und Hersteller:
Bundesministerium für Gesundheit, Familie und Jugend, Sektion IV
Radetzkystraße 2, 1031 Wien

Für den Inhalt verantwortlich:
BL Mag. Ulrich Herzog

Erscheinungstermin: Dezember 2007

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ISBN 978-3-902611-07-9

Diese Studie/Broschüre ist kostenlos beim Bundesministerium für Gesundheit, Familie und Jugend, Radetzkystraße 2, 1031 Wien, erhältlich.

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REPORT

SUPPLEMENTARY RISK ASSESSMENT FOR GM MAIZE MON 810 WITH REGARD TO THE CONCLUSIONS OF THE WTO-PANEL IN THE CASE „EC BIOTECH" ON AUSTRIAN SAFEGUARD MEASURES FOR GM MAIZE

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Vienna, 20 November 2007

Content

Summary

This report aims to summarize the Austrian arguments as a reaction to the ruling of the WTO Panel established to examine the dispute case "European Communities - Measures Affecting the Approval and Marketing of Biotech Products". Part of the alleged measures were the Austrian safeguard clauses which prohibit the import and use of the genetically modified maize lines MON810 and T25. This report therefore fulfils the WTO requirements to base any measures on a risk assessment in line with SPS provisions and according to guidance by international standard setting bodies.

The report is structured in two main parts:

1) Evidence that the available data were insufficient and did not allow a comprehensive risk-assessment.
2) A risk assessment in order to supplement the Austrian argumentation and to fulfil the requirements of the SPS agreement.

This report shows that the opinion of Austria with respect to the lack of data was supported at least partly by the Scientific Committee on Plants, the European Commission and one of the experts chosen by the WTO Panel to provide them with scientific information regarding the dispute case.

The risk assessment for maize MON810 included in this report examines possible effects on target and non-target organisms as well as the potential for gene transfer and other relevant risk assessment parameters.

With regard to GM maize MON810 the results of the assessment of information provided by the notifier for MON810 and recent scientific information were as follows:

- The conclusions drawn by the notifier with regard to out-crossing and gene-transfer are based on a "best case" scenario, rather than taking realistic data and the highly variable results from different scientific publications into account.

- The insect resistance management plan is insufficient because there is no information on baseline data, a lack of information regarding the implementation and a questionable assumption with regard to the adoption speed of GM maize MON810 in the European Union, which was estimated to be unrealistically low.

- It is clearly shown that there is a risk to non-target organisms. This conclusion is based on the scientific literature and data relevant for the Austrian situation, like population densities of lepidoptera in agricultural environments, including maize fields, and their classification as "endangered species". As it has been shown that Bt-toxins also affect non-target lepidopteran species, it is likely that the use of Bt-plants will negatively affect populations of lepidoptera living in agricultural environments. Aquatic non-target organisms, like trichoptera are also likely to be negatively affected, according to new scientific results.

- The assumptions made by the applicant concerning toxicological and allergenic properties of MON810 maize are based on acute toxicity studies using isolated, bacterial derived proteins, as well as homology and in-vitro digestibility studies. This cannot be considered sufficient as there may be structural differences between plant- and bacteria-derived proteins; any chronic ad sub-chronic effects cannot be assessed by the approach used.

- The set of parameters assessed for compositional analysis is very narrow and does not follow international guidelines. Even the results showing significant differences to non-GM-plants did not lead to further investigation.

The risk assessment for GM maize T25 is also addressed, but in a less detailed manner. Nevertheless it can be concluded that the risk assessment provided by the applicant does not take in to account all relevant issues according to the state-of-the-art of scientific knowledge.

In addition to the standard risk assessment parameters an estimation on the possible economic consequences for organic and conventional farmers is given. This assessment is in line with the ISPM-guidance by the standard setting body IPPC which is recognized by the WTO. A likely decrease in the income of organic and conventional farmers is caused by out-crossing from GM-maize fields and the consequentially decreased value of their harvest.

Zusammenfassung

Das Ziel dieses Berichts ist, die österreichischen Argumente im WTO-Fall "European Communities - Measures Affecting the Approval and Marketing of Biotech Products" zusammen zu fassen. Die österreichischen Schutzklauseln, mit denen der Import und die Anwendung der gentechnisch veränderten Maislinien MON810 und T25 verboten wird, waren Teil der beklagten EU-Maßnahmen im genannten Streitfall. Dieser Bericht erfüllt die WTO Kriterien hinsichtlich der Forderung, dass diese Maßnahmen auf einer Risikoabschätzung basieren müssen, die dem SPS Abkommen entspricht und nach Richtlinien von internationalen Standardisierungsorganisationen durchgeführt wurde.

Dieser Bericht ist in zwei thematische Bereiche geteilt:

1. Eine Argumentation, dass die zur Verfügung stehenden Daten nicht ausreichend waren, um eine umfassende Risikoabschätzung durchführen zu können.
2. Eine ergänzende Risikoabschätzung um die österreichischen Argumente zu vervollständigen und die Anforderungen nach dem SPS Abkommen zu erfüllen.

Dieser Bericht zeigt, dass die Meinung Österreichs in Bezug auf das Fehlen von Daten zur Risikoabschätzung zumindest teilweise vom Wissenschaftlichen Komitee für Pflanzen der EU, der Europäischen Kommission und einem der wissenschaftlichen Experten, die vom WTO-Panel zu dessen Unterstützung herangezogen wurden, geteilt wird.

Die in diesem Bericht vorgelegte Risikoabschätzung für MON810 Mais behandelt mögliche Effekte auf Ziel- und Nicht-Zielorganismen sowie möglichen Gentransfer und andere relevante Parameter der Risikoabschätzung.

Für MON810 kann mit Bezug auf die vom Antragsteller zur Verfügung gestellten Informationen und neuere wissenschaftliche Erkenntnisse folgendes festgestellt werden:

- Die Schlussfolgerungen des Antragstellers in Bezug auf Auskreuzung und Gentransfer beruhen auf einem „Best case"-Szenario, und basieren nicht auf realistischen Daten und den sehr variablen Resultaten aus den verfügbaren wissenschaftlichen Publikationen.

- Der Resistenzmanagementplan für den Maiszünsler ist unzureichend da keine Angabe von Basisdaten erfolgte, die Information bezüglich der Umsetzung dieses Plans unzureichend ist und eine unrealistische, d.h. viel zu niedrige, Annahme bezüglich der Geschwindigkeit der Einführung von MON810 in der EU getroffen wurde.

- Es konnte klar gezeigt werden, dass ein Risiko für Nicht-Zielorganismen besteht. Dieses Ergebnis beruht auf wissenschaftlicher Literatur und für Österreich relevante Daten, wie z.B. Populationsdichten von Lepidopteren (Schmetterlingen) in landwirtschaftlichen Ökosystemen und Maisfeldern sowie deren Gefährdungs-Klassifizierung. Da gezeigt wurde, dass Bt-Toxine auch Effekte auf Nicht-Ziellepidopteren haben, ist es wahrscheinlich, dass Lepidopterenpopulationen in landwirtschaftlichen Ökosystemen negativ beeinflusst werden. Nach neuesten wissenschaftlichen Erkenntnissen können auch aquatische Nicht-Zielorganismen, wie Trichopteren (Köcherfliegen) durch Bt-Toxine geschädigt werden.

- Die Schlussfolgerungen des Antragstellers hinsichtlich der toxischen und allergenen Eigenschaften von MON810 Mais basieren auf akut-Toxizitätstests, die mit aus Bakterien gewonnenem isolierten Protein durchgeführt wurden, sowie auf Homologiestudien und in-vitro Abbaustudien. Dies kann nicht als ausreichend angesehen werden, da sich das bakterielle Protein möglicherweise vom pflanzlichen unterscheidet und durch den Versuchsansatz chronische oder sub-chronische Effekte nicht erfasst werden.

- Die Anzahl der Parameter die zur Untersuchung der Inhaltsstoffe herangezogen wurden ist nicht ausreichend und entspricht nicht den internationalen Richtlinien. Außerdem wurden selbst bei Resultaten die signifikante Unterschiede zu konventionellen Pflanzen zeigten, keine weiteren Untersuchungen durchgeführt.

Der gentechnisch veränderte Mais T25 wird ebenfalls, aber weniger detailliert, behandelt. Trotzdem kann festgestellt werden, dass die vom Antragsteller vorgelegte Risikoabschätzung nicht dem Stand der Wissenschaft und Technik entspricht.

Zusätzlich zu den Standardparametern der Risikoabschätzung wurden auch mögliche ökonomische Auswirkungen auf die biologische und konventionelle Landwirtschaft abgeschätzt. Diese Abschätzung entspricht den ISPM Richtlinien der IPPC, einem von der WTO anerkannten Standard. Sehr wahrscheinlich würde das Einkommen von biologischen und konventionell wirtschaftenden Landwirten aufgrund von Auskreuzung und der damit verbundenen Wertminderung ihrer Ernte sinken.

Introduction

In September 2006 the WTO-Panel, which was established to settle the dispute case "European Communities - Measures Affecting the Approval and Marketing of Biotech Products" based on a complaint by the USA, Canada and Argentina concerning the authorization of GMOs and several national safeguard measures by EU-Member States, published a final report (WTO 2006). In this report it was stated that some of the alleged measures, like the "de facto moratorium" do no longer exist, whereas other measures, like the national safeguard clauses, are not in line with the requirements laid down in the SPS agreement.

After changes in EU authorization procedure and the withdrawal of several product notifications as well as national bans, the Austrian safeguard clauses regarding the genetically modified maize lines MON810 and T25 are the only alleged measures still in place.

Concerning the national safeguard measures the WTO Panel recommended that these measures are also to be brought into consistency with WTO agreements either by lifting them (as national measures or through involvement of the European Communities), or by providing revised risk assessments for these products that are in line with the SPS provisions.

In October 2006 the Federal Ministry for Health and Women (now Federal Ministry for Health, Family and Youth) already published an analysis of the WTO report (Eckerstorfer et al. 2006), which addressed a number of open questions regarding the reasoning of the WTO Panel, such as

- inadequacies of the final report of the WTO Panel in addressing the substantive justification of the concerns leading to the adoption of the Austrian safeguard measures,
- the failure of the WTO Panel to consider inadequacies in the risk assessments by the Scientific Committee on Plants (SCP), while regarding the opinions of the SCP as formal evidence that sufficient scientific information was available,
- not considering uncertainties with regard to the long-term environmental effects of herbicide-tolerant crops, the effects of GMOs on non-target organisms and the inadequacies of Bt-resistance management and monitoring designs,
- the failure of the WTO Panel to take into account that regional aspects were not considered sufficiently.

This report aims to present more detail and – where possible - new scientific data on some of these open questions and to support the Austrian argumentation by

1) summarizing the Austrian argumentation regarding insufficient information for carrying out a satisfactory risk assessment (according to Article 5.7. of the SPS agreement), and
2) supplementing the risk assessment carried out by Austria with additional information in order to fulfil the requirements of the SPS agreement (as reflected in Art. 5.1. of the SPS agreement).

Historical Overview

In May 2003 the USA, Canada and Argentina launched a dispute with the European Communities on complaints that certain regulatory measures of the European Communities concerning biotech products are not in conformity with WTO rules. As consultations between the Complaining Parties and the EC could not resolve these issues, the three Complaining Parties requested the establishment of a WTO Panel to further examine the matters. Following those requests the WTO Dispute Settlement Body (DSB)

established a Panel to deal with the requests of USA, Canada and Argentina in August 2003.
After several meetings and hearings the Panel distributed the final Report to WTO Member States in September 2006. The main results of this report are briefly summarized as follows:

Measure at Issue	**WTO Panel ruling**
General suspension of the EC approval processes; **"general de facto moratorium"** on the approval of biotech products.	• A general *de facto* moratorium has been applied by the EC between June 1999 and August 2003. • The moratorium itself is not an SPS measure. • It affected the operation and application of the EC approval procedures. • Currently no indications that repercussions are pending for EC.
Product-specific measures; Failure to advance and conclude the existing approval procedures of the EC without undue delay according to SPS in 27 cases (according to Dir. 90/220/EEC or Dir. 2001/18/EC and Reg. 258/97).	• The EC has breached its obligations on 24 (out of 27) specific approval procedures. • Inconsistencies only according to Annex C(1)(a) and Art.8 SPS ("Undue delay"). • When approval procedures are advanced without further undue delay, no repercussions pending.
National Safeguard Measures by EU Member States; marketing or import bans on 9 GM-products by 6 EU countries (Austria, France, Germany, Greece, Italy, Luxembourg).	• All safeguard measures are not based on a risk assessment as required under Art. 5.1 SPS and not consistent with the requirements of Art. 5.7. SPS. • By maintaining these measures, the EC has acted inconsistently with its obligations under Art. 2.2 SPS. • Existent measures need to be brought in conformity with SPS, otherwise repercussions are pending.

The first two alleged measures are no longer valid, as the de-facto moratorium has been terminated in September 2004 and action against any "undue delay" has been taken by the EU by establishing a more streamlined and centralized authorization procedure according to Regulation (EC) 1829/03.

Regarding the national safeguard measures the Austrian bans of GM maize MON810 and T25 are the only bans, which have been challenged by the complaining parties and which are still in place. Therefore these bans remain the only unsolved issue in the WTO-dispute "EC-Biotech".

The European Commission tried twice to force Austria to lift its ban by proposing such a measure to the European Council (24 June 2005 and 18 December 2006), but failed because these proposals were rejected by the Council with a qualified majority.
A third attempt by the European Commission to partly lift the Austrian bans, restricting them to bans for cultivation, could neither reach a qualified majority in favour or against the proposal at the Council on 30 October 2007. Therefore it is now up to the European Commission to decide whether the bans should be partly lifted.

Arguments to support the Austrian position

Insufficient scientific data

One of the crucial questions which was discussed during the Panel meetings and the meetings with the complaining parties and the EC was:

Is the scientific evidence insufficient to conduct a risk assessment according to Art. 5.1. of the SPS Agreement?

Austria based its bans on the lack of scientific information regarding environmental risk assessment, which was backed by scientific studies showing that adverse effects have not been correctly assessed in the initial risk assessment. In the course of the following years Austria provided even more arguments and scientific evidence covering also health aspects as requested by the European Commission. However, the WTO-Panel concluded that there was sufficient information, based on the fact, that otherwise the EC would not have approved the respective GMOs and that the scientific bodies involved in the process, namely the Scientific Committee on Plants (SCP) and the EFSA, would not have issued a positive opinion.

The following chapter identifies the contradictions in this argumentation and will summarize the arguments, why there is still insufficient scientific information available to conduct a proper risk assessment.

The Austrian Arguments

After consent was given to the notification of GM maize MON810 in April 1998 (Commission Decision 98/294/EC), the Austrian Competent Authority decided to prohibit the placing on the market of GM maize line MON810 on 10 June 1999 as a safeguard measure according to Article 16 of Directive 90/220/EEC. The objection of Austria was based on the fact that the information provided by the applicant was not deemed sufficient with regard to the following points of concern:

a. Possible unintended effects of the Bt toxin on **non-target insects**
b. Uncertainty about the **effectiveness of the refuge strategy** in order to prevent the development of Bt resistance in the European Corn Borer.
c. Effects of other Bt plants such as the increase of **secondary pests** and consequently additional use of synthetic plant protection products.
d. Uncertainty about the **specificity** of Bt plants

In a subsequent communication to the Commission dated January 2004 (BMGF 2004a) Austria reiterated its objections and raised additional concerns with respect to allergenic properties of Bt proteins relevant for GM maize MON810. Furthermore, general shortcomings in allergenicity and toxicity assessment under Directive 2001/18/EC and under the Novel Food Regulation were emphasised. Especially, digestibility studies using microbial test proteins were not considered appropriate because post translational modification could possibly affect protein properties or function (Dolezel et al. 2007). In addition it was pointed out that the nutritional analysis presented in the original dossier of MON810 does not fulfil the requirements of the OECD (OECD 2002), as several compounds, like minerals or vitamins were not assessed.

The Austrian ban for GM maize MON810 was therefore based

- on lack of information on environmental issues, because they were not provided by the notifier or
- on scientific evidence, which was referred to by Austria, but was not taken into account when granting the consent, and
- on health issues, because the data provided in the dossier were either incomplete or not obtained by using adequate methods.

The SCP statements

In its first opinion, which was the basis for the decision to grant consent for the placing on the market of GM maize MON810, the SCP stated that there was neither a risk for the environment nor human or animal health. It considered the information provided by the applicant as sufficient. However, the Committee also pointed out that *"the often applied in vitro methodology used to study the survival of Btk toxin can be improved. In particular, the use of the isolated protein in toxicity studies does not adequately model degradation of the same protein when fed as an integral component of the diet*", but did not require further studies.

The second opinion of the SCP of 24 September 1999, which was published as a reaction to the Austrian ban, did not consider aspects of human health or substantial equivalence. This was in accordance with the scope of the Austrian submission of 1998, which only raised environmental concerns.

With regard to the environmental concerns raised by Austria the SCP did not consider them as justified but however stated that:

1. With respect to possible unintended effects on **non-target insects** results of laboratory studies would be difficult to interpret and extrapolate to field conditions and that such interpretation must be viewed against the comparative risk assessment of alternative spray applications of insecticides, and that **further work would be needed** to investigate and verify such effects in the field.
2. With respect to the **limited specificity of Bt plants** the Committee admitted that GM maize has the potential to be toxic to certain species of Lepidoptera and concluded that this issue **must be dealt with on a species-to-species basis**.

Even if the SCP could not see any risk linked to the placing on the market of MON810 in its first statement, it is highly important that it admitted in its reaction to the Austrian bans that there is a need for further investigation of negative effects on non-target organisms, admitting, in other words, that there is a lack of data with respect to the assessment of effects on non-target organisms.

The EFSA opinion

In 2004 the EFSA GMO Panel responded to a request from the European Commission and concluded that the evidence presented by Austria contained no new generic or local scientific information on the environmental impacts of the specified maize. In the review of the evidence provided by Austria EFSA only discussed evidence submitted to sustain Austria's environmental concerns. The Panel dismissed the evidence provided by Austria that critically reviews and assesses the validity of toxicity assessment, allergenicity assessment and the practice of substantial equivalence in a number of Directive 90/220/EEC and Novel Food dossiers, including GM maize MON810 and T25 maize (Spök et al. 2004).

In 2006 a second opinion of the EFSA GMO Panel, related to several GM crops subject to safeguard measures, was published, following a request by the Council of Ministers of Environment. EFSA explicitly stated that it did not reassess the dossiers of the original applications, whether they would comply with the most recent safety requirements laid down in Directive 2001/18/EC, Regulation (EC) 1829/03 and the EFSA Guidance Document, but focused on the arguments presented by the Member states to justify their safeguard measures.

In its opinion EFSA did neither mention any new evidence provided by Member States following its 2004 opinion, nor any new scientific literature in the public domain. The Panel however reaffirmed its conclusions for the previous 2004 opinion.

Arguments by the European Commission

Material provided by the European Commission in the course of the WTO dispute shows that the Commission is acknowledging in some cases the lack of sufficient scientific information in GMO risk assessment. In the following some examples of the Commission's arguments are presented (all taken from WTO 2006). A more detailed analysis is given in Eckerstorfer et al. (2006).

As a general observation the Commission states that:

- Scientific and technical knowledge is **incomplete** and that there is limited experience.
- There is "absence of agreed criteria on many issues (in scientific and regulatory circles), including with respect to the information necessary to perform a risk assessment and, also, the manner in which to interpret the relevant data."

With respect to the fundamental criticism of the reliance on acute toxicity testing the Commission, stated that

> *"[C]oncerning the results of the toxicological assessment of the companies, it must be stated that the comprehensive toxicological risk assessment as described in Spök et al. should be carried out. […] The proposed tests should be performed by the notifier and the resulting data provided in order to guarantee a high level of safety and public confidence in the approach taken."*

With regard to whole food studies:

> *"Whole food studies are necessary to complete the assessment of the safety of new feeds or foods for the following reasons: The determination of the nutrients-toxicants (substantial equivalence) can not detect all unintended effects (products); The level of proteins may be increasing significantly in successive products […]"*

And with regard to the used test substance:

> *"[T]oxicology of the newly expressed proteins in the GM products at stake, was often tested with "surrogate" proteins (i.e. isolated from heterologous systems, different from the GM plant, see review by Freese and Schubert (2004)), without proper demonstration of biochemical, structural, or functional equivalence of the surrogate protein to its counterpart (for instance as regards mutational changes, post translational modifications, or others), as recommended in Paragraph 40 of the Codex guidelines."*
> Remarkable here is the reference to the Codex Alimentarius Guidelines, as the Codex Alimentarius Commission is one of the standard setting bodies recognized in the SPS agreement.

Although this does not mean, that the European Commission is subscribing to all the arguments brought up by Austria, it supports in many ways the Austrian arguments to justify its safeguard measures, even if the European Commission by doing so contradicts the SCP and the EFSA Panel on GMOs.

Most important in this context is that the European Commission recognises that the available information is incomplete.

The opinion of an advisor to the WTO Panel

In the WTO report a small group of scientific experts were providing scientific input to questions posed by the Panel on various issues. The experts' advice was provided to assist the Panel in the scientific assessments, and should not cover general opinions on the safety of GMOs. Expert opinions should be limited to scientific and technical issues, whereas the task of any legal assessment remained with the Panel.

Dr. Dave Andow, one of the scientists from this group of experts, specifically provided valuable scientific evidence to be taken into account (WTO 2006, Annex h and j). Dr. Andow considered in depth the individual justifications provided by Austria in its prohibition of GM maize MON810. In particular he provided information, whether there was sufficient scientific evidence available to Austria in June 1999 and in August 2003 to undertake a more objective assessment of potential risks to the environment from GM maize MON810.

1. Dr. Andow stated that in 2003 Austria could reasonably maintain that there is still insufficient information to know which **non-target organisms** might be at risk and therefore an objective risk assessment was not possible. He emphasised that not all of the non-target species at risk caused by GM maize MON810 had been identified in Europe. Dr. Andow commented on the following points which were not reflected in the SCP opinion: First additional assessments should have been conducted on lacewings and monarch butterflies in order to determine the relevance in the field. The aim of a tiered risk assessment protocol is to expose organisms to concentrations higher than considered typical in the field. Therefore experimental positives from laboratory studies should undergo additional evaluations. Both lacewings and monarchs had been adversely affected by the Cry1Ab toxin in laboratory experiments. Secondly the specificity of the Cry1Ab toxin seemed to be broader than previously expected.
2. With respect to risks on **soil organisms** Dr. Andow discussed some scientific aspects that were left unconsidered by the SCP. First the actual rates and degradation processes for large proteins in soils are poorly understood. Second, the Bt toxin load in maize fields can be substantial which make large-scale effects possible. Third, it is known that the Bt toxin in the soil can have adverse effects on earthworms.
3. Referring to **resistance risk and management** Dr. Andow stated that the following points were not reflected in the SCP opinion. First the rate of market penetration of Bt maize had been faster than predicted in the US which contradicted the prediction of the SCP that market penetration would be slow. Secondly resistance would evolve locally and therefore refuges must be available wherever Bt maize is locally used and refuges are required from the beginning of Bt planting. Resistance management is the responsibility of each farmer who uses Bt maize and each farmer should be required to implement measures such as setting up of refuges.

In summary Dr. Andow, in his capacity as scientific advisor to the WTO Panel, supported the Austrian point of view, that there is insufficient information especially on possible negative effects on non-target organisms, soil organisms and the question of resistance risk and management.

Conclusions

Austria stated during the authorisation procedure that there was a lack of information in order to carry out an adequate risk assessment. Subsequently the concerns were reconfirmed when justifying its safeguard measures. Based on these arguments the import bans where issued. In the following procedure Austria extended its scientific reasoning also to possible negative effects on human health.

Though the SCP could not identify any risk linked to the placing on the market of GM maize MON810 it also stated (second opinion) that further work is needed to identify any possible effects on non target organisms.

EFSA never examined the original application. It is highly doubtful, that the information included in the original application would be sufficient to fulfil the criteria of the new authorisation procedure according to Regulation (EC) 1829/03 and the requirements of the EFSA Guidance document on Risk assessment (EFSA 2006).

Most arguments of Austria were acknowledged by the European Commission, supporting the view that the scientific information is incomplete. Some of the statements by the European Commission are in clear contradiction to SCP and EFSA opinions.

Some of the arguments are even supported, and backed by additional scientific arguments by at least one of the scientific advisors to the WTO Panel.

Reviewing all the statements/opinions delivered by the different scientists and the European Commission, it is clearly shown, that all of them, except the EFSA Panel, which did not examine the original application, confirm the Austrian view that the available information is "insufficient" or "incomplete" or that further work is needed, and a proper risk assessment could not have been carried out.

This backs the Austrian position that the risk assessment carried out based on the information provided in the original application does not fulfil the criteria of the current European legislation and the SPS agreement.

Remarks with regard to maize T25

This report focuses on the genetically modified (GM) maize MON810 because of its higher relevance concerning cultivation in Austria compared to GM maize T25. MON810 varieties have been authorized for planting in the EU and GM maize MON810 is already used by farmers in several European countries.

Although many issues which were discussed above for GM maize MON810 are also valid for GM maize T25, like the improper assessment of toxicological and allergenic effects, the main environmental concerns of Austria are summarized in the following paragraphs. More details are given in Dolezel et al. (2007)

Specific environmental risks of GM maize T25which were identified are

- Risks for weed communities
- Lack of a monitoring plan
- Regional aspects in combination with coexistence issues

In summary the risk assessment data available for genetically modified herbicide tolerant (GMHT) maize T25 do not fulfil the requirements for an assessment of how these new herbicide/GM plant regimes could affect weed communities. As changes in weed management are to be expected with introduction of GM maize T25, a proper assessment of the effects on weed communities is required, based on an in-depth analysis of weeds and interactions between the GMO and target organisms of GM maize T25 as required both under Directive 90/220/EEC (Annex II, IV. C.3 and C.4) and Directive 2001/18/EC (Annex IIIB, D.). The insufficient control of certain weeds provided by glufosinate-ammonium and the resulting shift in weed communities has to be considered adequately.

The lack of a post-market monitoring plan conflicts with the current obligations for products such as GM maize T25. Annex VII of Directive 2001/18/EC is an agreed minimum standard for this issue. Furthermore, long term effects of the herbicide tolerant plant cannot be evaluated independently from the respective herbicide use and effects of

glufosinate-ammonium in combination with GM maize T25 on weed communities need to be addressed by such a monitoring plan.
Additionally there are open questions concerning regional aspects in connection with coexistence issues. EU-wide provisions regarding coexistence measures (including liability) of genetically modified maize and conventional or organic maize are still missing. Therefore economic consequences for organic or conventional farmers can not be excluded (see also below).

Competing Risk Assessment

This chapter examines and assesses the potential risks of the GM maize MON810. The assessment is based on the current scientific evidence concerning these risks and is aimed to fulfil the recommendation by the WTO Panel to bring the risk assessment in line with the requirements of the SPS agreement.

The structure follows the most recent guidance for such assessments as given by the EFSA "Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of Genetically Modified Plants and derived food and feed" (EFSA 2006). Furthermore reference is made to the respective issues for risk assessment as specified by Dir. 2001/18/EC Annex II.

1. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

This chapter covers issues which are listed in the EFSA Guidance Document, Annex III, chapter D.7. These issues for risk assessment correspond to the Guidance on risk assessment for genetically modified higher plants as detailed in Dir. 2001/18/EC, Annex II, D.2.6 (Possible immediate and/or delayed effects on human health). Individual reference for the issues relevant to the presented assessment is given below and indicated in parenthesis with regard to the structure outlined by EFSA (EFSA 2006).

1.1 Comparative assessment (D.7.1)

The results for substantial equivalence for MON810 are based on a compositional analysis that has several shortcomings:
The range of parameters measured is very narrow. Only proximates, amino acids and fatty acids are included in the comparative analysis. Micronutrients and other important ingredients are not considered. Furthermore, even these data do not always include fibres, ADF and NDF (in the case of 1994 field trials). This investigated set of assessed components must be considered as too narrow when compared to the OECD (2002) and to the EUROPABIO (2001) consensus documents.

Differences are detected between MON810 and the control, e.g. for glutamine, leucin, proline, ADF, NDF, C18:1 and C18:2 fatty acids, starch, protein. These differences are not considered relevant, as still within literature ranges. In one case the literature range used was exceeded (protein, US trials). The applicant used an older literature range (1976) in order to "normalise" the deviation. None of the differences were considered a reason to repeat or extend the comparative analysis.

Last not least it appears that no isogenic control line was used.

If compositional analysis is used as an indicator for unintended effects, the number of substances, for which data are presented, is too small. If used for nutritional assessment, certain proximates and micronutrients are missing.

1.2 Toxicology (D.7.8)

Toxicity assessment in the original dossier basically relies on an acute toxicity test and on in-vitro digestibility studies using a bacterial CryIA(b) Protein. In addition, the applicant provided homology comparisons with known toxic proteins and argued with the safe history of Bt toxins.
Results obtained from acute toxicity tests of the CryIA(b) protein on rodents cannot be extrapolated for sub-chronic and chronic effects. The assumption that proteins can only act via acute mechanisms is not backed up by a solid empirical basis. This has meanwhile been acknowledged by recent guidance documents, which ask for 28-day repeated-dose sub-acute test (EFSA 2006 and NL Biosafety Council 2003).

For conducting studies on toxic as well as allergenic properties of novel proteins test proteins were produced from bacteria. Using test proteins from microbes would in principle be acceptable if the proteins produced in the GM crop and the microbe would be identical or at least equivalent with respect to properties investigated in the test. However, several differences that might occur to the protein in cases the same gene is expressed in plants and microbes have been pointed out (Gurian-Sherman 2003b, Freese and Schubert 2004). Differences might occur at the level of DNA sequence during transformation and in RNA splicing, eventually resulting in an altered amino acid sequence. Posttranslational processing including proteolytic processing, glycosylation, acetylation, phosphorylation, methylation and folding might also differ between plants and microbes.

Bacterial proteins were also used for in vitro digestibility studies. Whole plant feeding studies were not performed.

It has to be concluded that the assessment of toxic properties of MON810 and the produced Bt-toxin is based on only a few results, which sometimes are obtained by methods which have been questioned in the scientific literature recently. Therefore we believe that the data provided do not support the safety-assumption for MON810 maize sufficiently.

1.3. Allergenicity (D.7.9)

Allergenicity testing in case of the MON810 dossiers is limited to the introduced CryIA(b) protein and consists of in-vitro-digestibility tests and homology comparisons to known allergens. History of safe use of Bt proteins in general and low expression levels are also mentioned to support the safety claim.

As discussed in detail in Spök et al. (2005) these methods do not provide any direct evidence of allergic properties and not at all on sensitizing properties. Furthermore, the methods and evidence used cannot be considered as reliable indicators of allergenic properties. A detailed review of the shortcomings of the allergenicity assessment provided by the applicant with regard to MON810 maize is given in Dolezel et al. (2007). The following punctuation lists the main points of criticism:

- Scientific studies investigating allergenic properties of proteins in connection with their digestibility/stability could not find a correlation at all (Kenna & Evans 2000, Fu et al. 2002). Therefore, if allergenic properties are only concluded from the stability of possible allergens, which is investigated using in-vitro digestibility studies, false positive and false negative results in safety testing might be possible. Furthermore, the differences in the design of in-vitro studies cast considerable doubt whether these experiments provide meaningful data at all.

- Routinely used sequence comparison technologies such as FASTA and BLAST (Pearson 2000, Altschul et al. 1990a, b) as well as new methods developed more specifically for predicting the allergenic potential of a given protein would provide false positive and false negative results in many cases as results of the comparisons might differ depending on the parameters set (e.g. substitution matrix and gap penalties) (Börklund et. al. 2005).

- The homology comparison referred to in the MON810 dossier dates back to 1990 and 1995 respectively. Given the pace of immunological research a more recent comparative analysis would have included five times more sequences from allergenic proteins (Mari 2005).

- Furthermore, expression levels of proven allergens may greatly vary in different strains, tissues and developmental stages, and can be influenced by a variety of factors. This has also been acknowledged by a Joint FAO/WHO expert consultation which concluded that it is not possible to link potential allergenicity of a given protein to its expression level (FAO/WHO 2001).

- Equally important, allergenicity assessment of the introduced protein should be complemented by an assessment of the whole-plant as described in Spök et al. 2005.

1.4. Maize T25 – Health aspects

The following paragraphs summarize the Austrian findings with regard to the application for placing on the market of the GM maize T25. More details and references to the scientific literature are given in Dolezel et al. (2007).

The assessment of the data provided by the applicant with regard to the authorization of the genetically modified maize T25 reveals a number of shortcomings and a lack of verifiability.
Toxicity assessment does not consider effects beyond a 14-day study of the introduced protein. All studies are carried out on isolated proteins. Possible toxic properties of the whole-plant are not considered at all.
The assessment of the allergenic potential is based on methods and evidence that cannot be considered sufficiently reliable. The approach used is even less appropriate to assess any de-novo sensitizing properties. The possibility of allergenic properties of the whole-plant is not considered at all.
Field trials and compositional analysis are not fully verifiable and it is not clear whether they have been properly conducted.
In light of the most recent guidance provided, the information included in the dossier would also not be sufficient for a market authorisation under Directive 2001/18/EC or Regulation (EC) 1829/2003.
In summary, from the data provided in the dossier of maize T25 and in the light of recent evidence from scientific literature, it is neither possible to fully verify all aspects of the risk assessment conducted by the applicant nor to conclude a sufficient degree of safety.

2. Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification

This chapter covers issues which are listed in the EFSA Guidance Document, Annex III, chapter D.9. These issues for risk assessment correspond to the Guidance on risk assessment for genetically modified higher plants as detailed in Dir. 2001/18/EC, Annex II, D.2. Individual reference for the issues relevant to the presented assessment is given below and indicated in parenthesis with regard to the structure outlined by EFSA (EFSA 2006).

2.1 Potential for gene transfer (D.9.3)

The assessment of the potential for gene transfer is presented according to the EFSA Guidance Document in Annex III, chapter D.9.3 corresponding to issue D.2.3 as listed in Dir. 2001/18/EC, Annex II.
Special consideration is given to the demand that the assessment should also consider the consequences of low frequencies of gene transfer to related and unrelated organisms (EFSA 2006). The assessment as presented in the following is relevant for both GM maize MON810 and GM maize T25.

With respect to gene transfer the notifier concluded that the risk of gene transfer will be limited by poor dispersal and the absence of wild-living sexually-compatible plants either of the same or different species. However the regional conditions for maize cultivation in Austria and the implication of these conditions for out-crossing and gene transfer were not considered.

Pollen production and viability were considered to be unchanged for GM maize MON810 (or GM maize T25) and therefore dispersal and out-crossing should not be different from other maize varieties. Therefore gene transfer from GM maize MON810 (or GM maize T25) to other maize could occur through pollen dispersal during the cultivation of the crop. Maize is predominantly wind pollinated. Maize plants produce pollen for 10-13 days and the shed pollen remains viable for a short time. Though it is known that viable pollen is transported over variable distances relating to the local meteorological conditions, the notifier concludes that the pollen from GM maize MON810 is only distributed over short distances. An approximation which is typically referred to is that 98% of pollen settles within 25-50 m of its source (EEA, 2002). However in experiments conducted to estimate the amount of pollen which is carried from a plot into neighbouring environments using pollen-mass-filters distances of up to 2 700 m were seen (Beismann & Kuhlmann 2006; Hofmann et al. 2005), with substantial quantities of pollen found at 2 400 m downwind of the pollen source (Hofmann et al. 2005).

Data on pollen transport however are not fully conclusive for assessing the potential for gene transfer through out-crossing. Empirical data from different sources on out-crossing frequencies show some variation. An evaluation under Austrian conditions and based on data from seed certification studies indicated at a distance of approximately 200 m the out-crossing rate is less than 0.9 %. At approximately 300 m distance the out-crossing rate is around 0.1 % (Pascher & Dolezel 2005). The effect of gene transfer can thus be relevant in a scenario of a limited amount of GMO-plots compared to non-GMO plots (10 % GM maize area). Higher rates of adoption of GM maize crops lead to even more pronounced effects. Data from the British Farm Scale Evaluations (Henry et al. 2003) show similar patterns and an isolation distance of approximately 260 m was deduced to limit out-crossing rates to approximately 0.1 %. Experiments to test for out-crossing effects of maize in Austria did even advise larger distances to minimise the risk for out-crossing (AGES 2006). An additional important conclusion is that other factors than distance between plots, like windfall and pollen concentration among others, influence out-crossing effects (AGES 2006).
Data from the evaluation of cultivation of GM maize MON810 showed results that are relevant with regard to comparable Austrian conditions. Specific data do indicate substantial out-crossing frequencies up to 10% in the vicinity of plots on which GM maize MON810 was grown (Eder 2006). Based upon these results it was concluded that a minimum of 100 m or 150 m is advised respectively in order not to surpass the 0.9 % threshold level (Eder 2006; Miller 2006).

In conclusion the data indicate that gene flow from GM maize MON810 (or GM maize T25 respectively) through out-crossing to neighbouring non-modified varieties is likely and has relevant environmental and agricultural consequences in Austria.
This fact is also important when assessing economic consequences of gene transfer (see Chapter 3).

2.2 Interactions between the GM plant and target organisms (D.9.4)

According to the EFSA Guidance Document in Annex III, chapter D.9.4 corresponding to issue D.2.4 as listed in Dir. 2001/18/EC, Annex II an assessment of the environmental impact resulting from direct and indirect interactions between the GMO and target organisms, specifically the herbivorous lepidopteran pest species, like the European Corn Borer, which are targeted by the heterologous Bt-Toxin produced by the GM maize MON810, is required. Development of resistance in the pest species against the Bt-Toxin needs to be considered within this assessment. This is exemplified by the EU Working Group on Bt, which has developed risk assessments protocols for evaluating the development of resistance in target insects to Bt toxins (SCP, 1999).

With respect to resistance and tolerance issues the resistance management strategy proposed by the notifier must be considered as inadequate. As the effectiveness of the refuge strategy cannot be deduced from the information submitted by the notifier, the SCP emphasized that it advised on the establishment of non-Bt refuges as an appropriate measure. However it was pointed out that due to the expected slow introduction in Europe, Bt crops would be surrounded by "natural refuges" for some time.

This assumption however cannot be justified for the following reasons: First the rate of market penetration of Bt maize as seen in the US was faster than predicted. For assessment of possible resistance development under European conditions it was assumed that market penetration would be slow. Secondly resistance would evolve locally and therefore refuges must be available, wherever Bt maize is locally used and refuges are required from the beginning of Bt planting onwards. Resistance management is the responsibility of each farmer who uses Bt maize and each farmer should be required to implement measures such as setting up of refuges (see e.g. Andow in WTO, 2006 for reference).

The insect resistance management (IRM) plan itself, which was provided by the notifier is very general and does not give detailed information on how it will be implemented. Although the notifier recommends a managed refuge approach and states that a surveillance program will be implemented, no exact information on the implementation details of this program is given.

Specifically with respect to susceptibility studies the notifier refers only to studies in the US and Italy. Without adequate information on baseline susceptibilities of pest species and information on initial resistance allele frequencies in these species the rate at which resistance will evolve can not be determined. Additionally it is not possible to deduce how this rate differs among different populations of this insect species (Huang et al. 1997). These issues should be investigated for each separate European corn borer population or even sub-population (Chaufaux et al. 2001).

The scientific facts thus do not convincingly support the hypotheses on which the proposed plan is based. Without demonstration by the notifier of the spatial distribution and total areas of GM maize MON810 plots in relation to other areas of maize cultivation the conclusions drawn by the notifier cannot be validated.
Furthermore the strategy does not take into account the different dispersal capacities of other pest species, including Sesamia species (Mediterranean Corn Stalk Borer). Resistance Management strategies designed for the European Corn Borer are less efficient for the less polyphagous and more sedentary Sesamia (Eizaguirre et al. 2006). Furthermore Sesamia for reasons of reduced susceptibility is less responsive to the proposed management strategy.

Additionally IRM plans have to be carried out in combination with systematic monitoring in order to detect resistance at the very time of development. As baseline susceptibilities

and other ecological factors between different populations of the respective pests as well as agronomic practices might differ locally, the results of the experiences gained from Bt maize cultivation in Spain are not applicable without further consideration to other European agricultural systems. Therefore an adaptation of the IRM strategy must be envisaged. Again it has to be taken into account that several varieties of GM maize MON810 are already approved within the European Union for cultivation. Therefore it can be expected that further adoption rates of GM maize MON810 will be rather high in Europe. Indeed recent data on adoption trends in Europe, which confirm an increase in cultivation area of approximately 70% for the last season, support this notion. High adoption rates of Bt maize varieties have also been experienced in the US (Carpenter & Gianessi 2001), although a slow rate for introduction of this type of GM maize had been previously predicted.

Therefore the effectiveness of the strategy proposed by the notifier in order to prevent the development of resistance in target species, like the European corn borer, is doubtful. A refined strategy on resistance management needs to be proposed by the notifier and adequate baseline information on the pest biology and ecology and a workable IRM plan has to be submitted.

2.3 Interactions of the GM plant with non-target organisms (D.9.5)

According to the EFSA Guidance Document in Annex III, chapter D.9.5 corresponding to issue D.2.5 as listed in Dir. 2001/18/EC, Annex II an assessment of the environmental impact resulting from direct and indirect interactions between the GMO and non-target organisms is required. Any effects on organisms which interact with the target organisms need to be taken into account as well.

2.3.1 Effects on other non-target lepidopteran species

Possible risks for non target organisms were considered by the notifier and in all preceding assessments (e.g. SCP, 1998). The conclusion by the notifier was based on the information as submitted. This information is interpreted in a way that no relevant risk for non-target herbivores including vertebrates is identified.

However with regard to current assessments of the information available to judge possible unintended effects on non-target insects this conclusion cannot be supported. Marvier et al. (2007) recently identified a number of weaknesses in most of the available field studies on potential adverse effects of insect resistant GM crops, during an effort to set up a comprehensive repository of data for empirical assessments. In our opinion these weaknesses also severely limit the conclusiveness of the field test data submitted on GM maize MON810 (see chapter 1.3.2 for further discussion).

It is evident that GM maize MON810 has the potential to be toxic to certain species of Lepidoptera and that this issue must be dealt with on a species-by-species basis. The notifier assumes without reference to regional conditions that cultivated fields are not considered as important reproductive areas for lepidopteran species and exposure of non-target lepidopteran species would not be significant.
An assessment of risks to non-target butterflies especially relating to European and specifically the Austrian agricultural conditions has not been carried out in the risk assessment, in spite of information that many species of butterflies are present in agricultural areas (Felke & Langenbruch 2005).

Given the substantial transport of transgenic pollen containing Bt toxin from the growing areas into the field margins and to adjacent habitats, these species are very likely to be exposed to pollen from GM maize MON810 upon cultivation. Recent analyses based on data from studies in Germany (e.g. Hofmann et al. 2005) indicate that an average deposition of more than 5 pollen/cm^2 can be expected at a distance of 300 m from adjacent maize fields. In this context it is important to note that intake of small amounts

of pollen containing Bt toxin cause sub-lethal effects on native lepidoptera larvae such as the Peacock butterfly, Inachis io (Felke & Langenbruch 2005). In Austria this butterfly is commonly found in habitats next to cultivated areas of maize (Traxler et al. 2005).

Our assessment that other butterflies living in agricultural habitats would be seriously affected in case of cultivation is supported by recent research (Szekacs & Darvas 2006). Other scientific studies have recently indicated that certain non-target lepidoptera, like monarch butterfly larvae, show prolonged developmental time and reduced survival when exposed to pollen of Bt maize MON810 either for short or for prolonged time under field conditions, possibly resulting in up to 25% fewer surviving larvae (Dively et al. 2004). Also adverse effects on pupae and adults of the monarch butterfly were reported in this study. Possible adverse effects on non-target lepidoptera through the consumption of anthers from Bt maize plants (Anderson et al. 2004, Felke & Langenbruch 2005) and especially the combined effects of pollen and anthers of Bt maize containing the Bt toxin (Anderson et al. 2005) have so far not been taken into consideration. Also Lepidoptera other than the Monarch butterfly have been shown to suffer sublethal or lethal effects when exposed to Bt maize (Vojtech et al. 2005, Dutton et al. 2005). It is still uncertain which other non-target butterflies might be adversely affected by the consumption of Bt corn pollen or anthers.

Out of 215 butterfly species occurring in Austria, 152 species have been reported from agricultural areas and more than half of those species are already classified as either near threatened, vulnerable, endangered or critically endangered (Traxler et al. 2005). Traxler et al. (2005) further show that development of these butterflies does coincide with the time of pollen shed of cultivated maize for 75 – 100% of the time in case of 29 butterfly species. Shorter overlaps of respective timeframes are seen with the other butterfly species: 25% overlap for 51 species, up to 50% overlap for another 59 species and 50 – 75% for 5 species. Based on a number of characteristics (developmental overlap with flowering time of maize, ecological characteristics of butterflies, incidence of endangered species, biodiversity of butterfly species) a risk-index for butterflies was deduced and shows that areas in Austria, where insect resistant GM maize varieties are potentially grown, are in the vicinity of areas, which are characterised by high biodiversity of butterflies and a high number of endangered butterfly species (Traxler et al. 2005).

Therefore in conclusion we expect it to be likely that butterfly species which are already endangered would be additionally affected by cultivation of GM maize MON810. Since additional impacts on endangered species should be minimised the cultivation of GM maize MON810 is expected to have negative effects.

2.3.2. Effects on other non-target organisms

Concerning the important aspect of potential adverse effects on different classes of non-target organisms a study on the meta-analysis of available data on field trials from different sources was published recently (Marvier et al. 2007).
This work uses available data on effects of Bt toxins on different groups of arthropod insects. To analyse effects of Cry1A(b) toxin as contained in GM maize MON810 data on abundance of coleoptera, hemiptera, hymenoptera, aranae, neuroptera, diptera, thysanoptera and collembola in addition to lepidoptera were analysed.
For all kinds of Cry1A(b) expressing GM maize varieties the overall mean abundance of non-target invertebrates was significantly lower for the GM-varieties compared to control of non-GM maize varieties which were not treated with insecticides. This form of comparison is relevant to assess any differences of the potential cultivation of GM maize MON810 with conventional varieties grown under conditions of organic agriculture and reduced insect management by insecticides. These management practices are favoured by the Austrian national plans for implementation of eco-friendly agriculture. Specific additional funding to farmers in Austria is connected to application of such management practices.

Significant effects of Cry1A(b) toxin expressing GM maize are found specifically for hymenoptera and collembola.
Specific data for GM maize MON810 also show a lower average abundance of non-target invertebrate species on plots of GM maize MON810 compared with untreated plots of non-modified maize, but with a lower level of significance.

Another overview on results concerning the potential adverse effects of GM plants expressing Bt toxins like GM maize MON810 was published by Lövei & Arpaia (2005). They concluded that parameters connected to development, general biology, or fitness of predating insects, like survival/mortality, development time, body mass/size, prey consumption, reproduction, longevity, egg viability or behaviour, were negatively affected in 41 % of the feeding tests (in 30% of cases significantly negative). An analysis of the respective results for feeding tests with parasitoids showed comparable data (Lövei & Arpaia 2005). Even considering the fact that worst case scenario testing methods were not consistently applied and many important species have not been tested at all, this does constitute a clear indication that most likely negative effects have to be expected.

In the report by Marvier et al. (2007) the authors consistently found relevant deficiencies with regard to the original data. Specifically they reported that out of 64 studies analysed

- 40% of reports did not indicate the variance for the reported treatment means,
- 22% used the subsamples in an improper way to calculate measures of variance and
- for 20% of the reports the sample sizes were not clearly presented.

They indicated that some of these insufficiencies could be clarified by additional information submitted by the authors upon request. Their conclusion towards these deficiencies is that regulatory agencies should require submitting the data on field tests in an adequately structured way, to be able to spot any lacking information which is crucial for an adequate assessment. Any approvals should be postponed until complete sets of data have been submitted and assessed.
Since similar data were used for the preceding risk assessments of GM maize MON810, the conclusions drawn in these assessments should be regarded as tentative and subject to review based on assessment of adequate data.

Bt toxin exposition of non-target organisms of higher trophic levels like predators and parasitoids has been documented in recent studies (Harwood et al. 2005; Zwahlen & Andow 2005; Obrist et al. 2006). For some of these species a lower abundance on plots of Bt maize varieties has been reported (e.g. Pilcher et al. 2005; Bourguet et al. 2002). Any large-scale application of GM maize MON810 would thus lead to exacerbated effects on specific natural enemies of maize pest insects.

Effects on water dwelling organisms

The effect of the Bt-Toxin incorporated in GM maize MON810 on aquatic non-target species was not specifically considered by the notifier and during the preceding risk assessments (see e.g. SCP 1998). A recent publication (Rosi-Marshall et al. 2007) reports adverse effects on aquatic insect species and their data substantiate the previously hypothesised risk potential that material derived from GM maize MON810 containing the Cry1A(b) protein could affect the food chain in aquatic environments. Thus any comprehensive risk assessment needs to also take into account effects on water-dwelling insects.

The necessary assessment of specific effects of GM maize MON810 cannot be based on data concerning effects of insecticidal sprays produced from *Bacillus thuringiensis var. israelensis* (Bti) on aquatic environments. Due to differences in exposure and the nature of Bt proteins present in Bti the previous assessments of Bti cannot be regarded of high significance for assessing the risk of Bt-toxins derived from GM maize MON810 (Hershey

et al. 1998, Pont et al. 1999, and Jackson et al. 2002 as cited in Rosi-Marshall et al. 2007).
The risk assessment must be based on studies directly evaluating the specific effects of GM maize MON810 on aquatic non-target species. Recently a study addressing such adverse effects has been published for certain Trichoptera species, which can consume material derived from GM maize MON810 cultivated in the vicinity of aquatic ecosystems (Rosi-Marshall et al. 2007).

The results do demonstrate that material derived from GM maize MON810 in agricultural environments is deposited in neighbouring aquatic ecosystems and available to aquatic insects of different feeding behaviour, like certain water-dwelling trichoptera species (filter feeding and leaf-shredding trichopteran groups). These insects are feeding on material containing Bt-toxin and do ingest Bt-toxin from this source in detectable and relevant quantities. As a supporting line of evidence laboratory feeding tests with these trichoptera species demonstrate that ingested Bt-toxin does lead to adverse effects, like significantly reduced growth rates of leaf-shredding trichoptera species and elevated mortality rates of species feeding on algal biofilms, which contain pollen from GM maize MON810. The effects are plausible given the close relationship of target Lepidoptera and the trichoptera analysed in the study. Adverse effects on aquatic species like trichoptera will predictably reduce the biomass available for predating species and therefore have relevant effects on aquatic food-webs and biota in agricultural areas, where GM maize MON810 is cultivated.

Similar to the situation as encountered at the sites of sampling in Rosi-Marschall et al. (2007) maize is cultured in Austria in close vicinity to aquatic ecosystems as described in an assessment of habitats found in typical areas of maize cultivation, e.g. in Carinthia (Wutschein/Thon), Upper Austria (Mettensdorf), Burgenland (Kotezicken), and Lower Austria (Ebreichsdorf) (Heissenberger et al. 2004).
Additionally material containing Cry1Ab toxin from GM maize MON810 could be introduced into aquatic ecosystems from manure used as organic fertiliser and maize material from silage (Malitzky 2007).
Furthermore trichoptera species related to the ones analysed in the above mentioned study do also occur in Austria. Specifically 19 species of Hydropsychidae and four species of Lepidostomatidae were reported for Austria (Graf et al. 2002). Therefore similar adverse effects as demonstrated in the above mentioned research have to be expected in Austria resulting from any cultivation of GM maize MON810.

With regard to the data on trichoptera distribution in Austria it is evident that there is a twofold risk for this group of aquatic species by the Bt toxins as contained in GM maize MON810:

- A number of trichoptera species is currently endangered in Austria and additional adverse effects by GM maize MON810 on their population are relevant as explicitly mentioned by Malitzky (2007). Specifically more than half of the Hydropsychidae and Lepidostomidae species (the groups of trichoptera examined in Rosi-Marschall et al. (2007) for adverse effects) are listed as endangered in Austria. Three of those species are recognised as highly endangered or even critically endangered (Malitzky 2007). These endangered species are vulnerable against additional negative effects, like any adverse effects by GM maize MON810.
- Secondly some other trichoptera species are very abundant and therefore important sources of prey for aquatic predators, e.g. fish. Adverse effects of the cultivation of GM maize MON810 as described in Rosi-Marschall et al. (2007) would impact on this food web and thus negatively affect higher trophic levels of the exposed aquatic ecosystems.

Since any undesired impairment of aquatic habitats should be avoided, the potential effect of GM maize MON810 on these ecosystems has to be regarded as relevant, considering that it is unknown due to lacking data which additional effects the cultivation of GM maize MON810 might have on aquatic ecosystems.

2.3.3. Effects on non-target soil organisms

According to the notifier risks to soil organisms and soil function through degradation of GM plant material or risks through contamination of ground water are considered to be extremely low.

However a range of information was left unconsidered in previous assessments. The actual rates and degradation processes for large proteins in soils are poorly understood. There is evidence that Bt maize releases the Bt toxin in root exudates (Saxena et al. 2004).
Under the Austrian conditions the exposure of soil organisms towards Cry1Ab toxin from GM maize MON810 could be substantially higher as assumed by the notifier. Recent data indicate that Bt maize decomposes slower in the soil than non-Bt plants (Flores et al. 2005). Therefore the Bt toxin load in maize fields can be substantial, which makes large-scale effects possible.
Furthermore results show that the Bt toxin can persists in soil for months retaining its insecticidal activity (Saxena & Stotzky 2002, Stotzky 2004). This is relevant for the assessment of adverse effects of Bt toxins released into the soil. Adsorbed to soil minerals the Bt toxin in active form can be detected longer than 200 days and thus persists longer than the vegetation period of maize plants (Ceccio & Stotzky, 2001, Zwahlen et al. 2003a). The amounts of Bt toxins delivered to the soil are most pronounced with GM Plants like Bt-Cotton and Bt-maize (Clark et al. 2005). Cry1Ab toxin is released from the roots of GM Maize plants and can accumulate in the rhizosphere to relevant concentrations (Saxena & Stotzky 2005).

Adverse effects for soil living non-target organisms were discussed in a substantial number of recent publications (Andow & Hilbeck 2004, Dale et al. 2002, Hilbeck 2001, Liu et al. 2005, Marvier 2001, Zwahlen et al. 2003a and 2003b). Specifically herbivorous and detrivorous organisms would be exposed to Bt toxins from GM maize MON810, as well as predating species feeding on exposed organisms.

A direct impact is an inhibitory effect for the formation of symbiontic fungal communities in the roots of higher plants by the Mycorrhiza fungi (Castaldini et al. 2005).
Soil living arthropods are ingesting the Cry1Ab toxin and show various adverse effects:
Earthworms show a decrease in their weight after 200 days exposition (Zwahlen et al. 2003b) and developmental defects (reduced hatching rates) (Verecsi et al 2006). Additionally other soil organisms like nematodes and isopods do show negative effects (growth depression, lower food intake) upon exposition to Cry1Ab toxin from GM maize MON810 (Griffiths et al. 2006; Wandeler et al. 2002).
Another group which is possibly affected are insect larvae e.g. certain carabidae which would feed on material derived from GM maize MON810 (Langenbruch et al. 2006). Meissle et al. (2005) showed that carabid larvae showed elevated mortality when fed on Spodoptera reared with GM maize containing Cry toxins.

Taken together evidence is available to show that the risk for soil organisms is relevant under regional Austrian conditions. Since healthy soils are a prerequisite for low-input agriculture and organic agriculture, the potential effects of the cultivation of GM maize MON810 are likely leading to a negative impact on soil quality.

3. Assessment of economic consequences due to outcrossing and adventitious presence

The EFSA Guidance Document on Risk Assessment of GMOs does not take into consideration the economic effects of cultivation of genetically modified plants and therefore offers no guidance for notifiers and assessors on these issues. However such an assessment is required with a view to the potential effects of the cultivation of GM plants and is in line with the ISPM-guidance by the international standard setting body IPPC, which is recognised by the WTO.

According to this internationally agreed guidance the economical consequences of the potential cultivation of GM maize MON810 (or GM maize T25 respectively) in Austria are assessed as follows:

Cultivation of GM maize MON810 (or GM maize T25) is expected to lead to cross-fertilisation of other varieties of maize grown on neighbouring plots specifically under the conditions of the Austrian agricultural environment (see Chapter 2.1 for reference). This effect is relevant specifically for the growers of non-modified varieties, specifically of organically grown maize.

In Austria an amount of 1.72 Mio tonnes (t) grain maize and 3.54 Mio t maize for silage were produced in 2005. As part of the overall amount 34 204 t grain maize was produced according to the provisions of organic agriculture (BMLFUW, 2007).
Maize for production of grains and cob-corn mix (CCM) was planted on 181 196 ha, maize for silage on 78 655 ha. For certified organic production 6 024 ha were planted to produce grain and CCM Maize, 1 664 ha for production of silage maize.

In Austria additionally 4 306 ha of the maize production area were dedicated to the production of maize seeds in 2006. In the same year organic maize seeds were produced on 165 ha. In some regions of Austria the production of seeds and the production of maize for consumption are situated in close neighbourhood.

Specific data for Upper Austria as an example of a region with a high proportion of maize production the total acreage for maize are supplied in the following:

- In 2006 maize was grown on 66 777 ha with 414 478 t grain and CCM maize and 1 111 085 t maize silage produced (BMLFUW, 2007).
- In 2004 an area of 21 379 ha was cultivated with field crops according to organic standards (at 2 386 farms). Most of the farms are quite small with less than 5 ha arable land/farm.
- Organic maize was cultivated at 142 farms on 551 ha (average acreage of 3.9 ha/farm).
- About 1 000 ha of maize were planted 2004 under specific contracts as certified GM-free produce for the production of 10 000 t maize for production of starch in Upper Austria. Production of speciality maize was also ongoing in the following years.

For the production of seeds as well as for the organically produced maize and GMO-free maize the threshold level for adventitious presence of GM maize is set to 0.1 %, being the technical limit for detection of GM presence (BMLFUW 2001; Codex Alimentarius Austriacus 1998).

The difference in prices for organically grown maize versus conventional maize is 157 Euro/t (395 Euro/t vs. 238 Euro/t) as of October 2007 (Raiffeisen Ware Austria). This difference in current prices is substantial for the producers: a 40 % loss of income on sales has to be expected in case the indicated thresholds for GM-free produce (including organic produce) are exceeded as a consequence of out-crossing from GM maize MON810. A comparable difference does exist between maize that can be sold as seed and maize sold for consumption purposes. Therefore any producers of seed, organically produced maize and producers of special produce, which is certified to be GMO-free will accrue severe losses of income in case the presence of GM maize in their produce exceeds a margin of 0.1 %.

With the cultivation of GM maize MON810 or GM maize T25 the feasibility for production of GM-free maize will certainly become increasingly difficult and costly. Additionally to any unexpected loss of income in case of contamination of produce through out-crossing from neighbouring fields the expenses for quality-control of organic farmers will certainly rise.
To give a representative example for the costs that have to be taken into account for the screening of produce for content of GM-maize including GM maize MON810 or GM maize

T25, respectively: such analyses for detection of GM maize currently cost 195 Euro/sample at the testing facility of the Austrian Federal Environment Agency (Umweltbundesamt 2007). Prices in other facilities are comparable by a margin of 20 %. Demand for analytical detection to certify that the produce is meeting the required standards is expected to increase substantially.

Furthermore it will be necessary to introduce additional procedures to avoid contamination of produce at harvest and afterwards once GM maize MON810 or GM maize T25 are cultivated:

- Cleaning procedures for harvesters and other necessary machinery involved in harvest and transport,
- Specific segregation systems for shipment and storage

For maize crops such additional measures will certainly lead to loss of production of GMO-free produce as well as additional relevant expenses for setup and maintaining such measures as shown by Mertens & Schimpf (2006).
Similar substantial costs have to be expected in the Austrian conditions.

In conclusion the cultivation of GM maize MON810 or GM maize T25 on plots distributed throughout Austria will have severe and dramatic economic consequences for the producers of GM-free maize and maize seed. In case contamination levels should approach the 0.9 % threshold, the produce would have to be labelled as GM-material leading to further economic consequences.
The assessment thus shows that adoption of cultivation of GM maize MON810 or GM maize T25 in Austria will very likely have severe economic consequences.

4. Environmental Monitoring Plan

This chapter covers issues related to an Environmental Monitoring Plan as outlined in the EFSA Guidance Document in Annex III, chapter D.10. These issues for risk assessment correspond to the guidance for monitoring of deliberate releases of GMOs and the placing on the market as detailed in Dir. 2001/18/EC, Annex VII. Individual reference for the issues relevant to the presented assessment is given below and indicated in parenthesis with regard to the structure outlined by EFSA.

4.1 General aspects (D 10.1)

According to Directive 2001/18/EC each notification of a GMO must contain a plan for monitoring in accordance with Annex VII with the aim to confirm the assumptions from the risk assessment and to identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the risk assessment.

However, a monitoring plan according to the mentioned standards has not been provided by the notifier.
Specifically the absence of effects on non-target organisms, which was stated by the notifier in the risk assessment, as well as the possible occurrence of secondary pests should be subject to a monitoring in line with the requirements laid down in Directive 2001/18/EC as well as the Guidance by the EFSA GMO Panel.

4.2 Case-specific GM plant monitoring (D.10.3)

The main objective of case-specific monitoring is to determine the significance of any adverse effects identified in the environmental risk assessment. In this respect the lack of a monitoring plan for cultivation of GM maize MON810 taking into account the conditions for use and cultivation in Austria are considered a main deficiency.

Firstly this conflicts with the current obligations for such products. Annex VII of Directive 2001/18/EC must be considered as agreed minimum standard for this issue. On the other hand, such a monitoring scheme would be necessary to address the issue of secondary pests, a question considered important by the Scientific Committee on Plants in their opinion on the safeguard measure for GM maize MON810, but not taken into account adequately in the preceding assessments.

The presented risk assessment identified two kinds of potentially adverse effects on the environment that have to be covered in an adequate case-specific monitoring strategy:

- potential resistance development of target insect species and
- effects on non-target organisms in different habitats.

Additionally recent investigations of Bt cotton cultivation in China have shown an extraordinary increase of other pest species such as leaf bugs (Wu et al. 2002) and consequently a rise in pesticide applications (Wang et al. 2006). However, secondary pests were neither considered in the risk assessment nor in a monitoring plan.
Therefore the effects of Bt crop cultivation on other pests and the development of secondary pests and consequently the additional use of synthetic plant protection products should be monitored for applications of Bt crops.

4.3 General Surveillance of the impact of the GM plant (D.10.4)

In addition to the case specific monitoring a general surveillance plan is necessary according to Dir. 2001/18/EC, Annex VII as well as according to guidance by the EFSA GMO Panel. The plan should be directed to identify any unexpected adverse effects of the application of GM maize MON810 in addition to effects covered by case specific monitoring.

The lack of a detailed and effective general surveillance plan must be regarded a major deficiency of the application and inadequate with a view to addressing the concerns that have been put forward against this application.

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Das Ziel dieses Berichts ist, die österreichischen Argumente im WTO-Fall “European Communities - Measures Affecting the Approval and Marketing of Biotech Products” zusammen zu fassen. Die österreichischen Schutzklauseln, mit denen der Import und die Anwendung der gentechnisch veränderten Maislinien MON810 und T25 verboten wird, waren Teil der beklagten EU-Maßnahmen im genannten Streitfall. Dieser Bericht erfüllt die WTO Kriterien hinsichtlich der Forderung, dass diese Maßnahmen auf einer Risikoabschätzung basieren müssen, die dem SPS Abkommen entspricht und nach Richtlinien von internationalen Standardisierungsorganisationen durchgeführt wurde.