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Analyse des WTO Berichts zum Streitfall „EC – Biotech"

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1 Executive summary

Analysis of the WTO Panel report concerning the EC-Biotech dispute and **Open Questions concerning the ruling of the WTO Panel**

The first part of the report (see Chapter 3) gives an overview of the results of the WTO dispute case "European Communities - Measures Affecting the Approval and Marketing of Biotech Products", published in the final report of the WTO Panel on 29th September 2006. Specifically, issues of the dispute which involve Austrian measures are discussed. With regard to the large number of complaints submitted by the USA, Canada and Argentina the Panel found that the European Communities only in some procedural aspects acted inconsistently with the WTO obligations under the SPS agreement. Such issues were on the one hand delays in the processing of certain applications by the EC, regarded as "undue" by the Panel and on the other hand certain safeguard measures concerning GMOs by a number of EC Member States including Austria. Since these Austrian safeguard measures are still in force the recommendation by the Panel that these measures need to be brought into consistency with SPS rules has to be taken into account.
Regarding these Austrian safeguard measures the presented analysis identifies a number of open questions concerning the findings 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.

The analysis of the WTO report thus shows that substantive arguments in support of the Austrian safeguard measures have not been taken into account by the WTO Panel. Since the European Communities support these Austrian arguments explicitly in their submissions and some of the arguments are furthermore supported by experts selected by the WTO Panel, it is reasonable for the EC to appeal against the WTO Panel decision.

An appeal should furthermore address the following general issues which are central for the arguments of the WTO Panel and the recommendations in the report, namely

- the different interpretations about precautionary measures given in the final report and preceding WTO decisions,
- the narrow definition of what is considered a risk assessment based upon a strict interpretation of Art. 5.1 and Annex A (4) of the SPS Agreement only and not taking into account the level of protection deemed necessary, is unduly limiting the possibilities to implement the precautionary principle in comparison with preceding interpretations,
- the open questions regarding the interplay between WTO agreements and other Multilateral Environment Agreements such as the Cartagena Protocol, which should be mutually supportive, but were not taken into account in the interpretation of the relevant SPS provisions by the Panel.

The European Commission's acknowledgement of scientific uncertainty and controversy in GMO risk assessment

The European Commission's scientific advisory committees on market authorisation of GMOs very rarely explicitly acknowledged scientific uncertainty in their statements despite such requirements in EU GMO legislation and in the EFSA's Guidance Document on GMO risk assessment. The Commission in turn very rarely communicated on

substantive scientific issues but always followed the scientific advice of EFSA indicating a similar or shared view on these issues. A different picture emerged, though, from an analysis of the European Commission's submissions in the course of the WTO dispute on GMOs which is presented in the second part of this report. Here the European Commission explicitly acknowledged uncertainties and controversy in the science, approaches, concepts and methods of GMO risk assessment. Evidence is presented by contrasting statements from these submissions to those of EFSA suggesting different views hold by EFSA and the Commission. This conclusion is supported by recent criticism and calls on EFSA of EU Commissioners to improve its risk assessment approaches. It remains, however, to be seen whether this in fact indicates a policy change of the Commission towards a more precautionary stance. Whatever the interpretation, it is quite likely that these acknowledgements set a measure for further policy development and communications. Given the nature and extend of uncertainties acknowledged it is highly unlikely that the Commission would get away by labelling its statements as mere historical descriptions of uncertainties in the past that have meanwhile be resolved by scientific progress and consensus building.

2 Zusammenfassung

Analyse des Berichts des WTO Schiedsgerichts im Streitfall "EC Biotech" und Identifizierung von offenen Fragen im Hinblick auf ein Berufungsverfahren

Der erste Teil der Studie (Kapitel 3) gibt einen Überblick über die Ergebnisse des WTO Schiedsgerichts im Fall "European Communities - Measures Affecting the Approval and Marketing of Biotech Products". In der Analyse des Berichts des WTO Schiedsgerichts, der am 29. September 2006 von der WTO publiziert wurde, wird speziell auf Aspekte eingegangen, die österreichische Maßnahmen betreffen.
Aus der Liste an Beschwerden welche von USA, Canada und Argentinien vorgebracht worden waren, urteilte das WTO Schiedsgericht nur in einigen wenigen hauptsächlich prozeduralen Fällen, dass seitens der Europäischen Union eine Verletzung von Pflichten, die sich aus dem SPS Abkommen ergeben, festgestellt werden konnte. Als nicht SPS-konform beurteilte das Schiedsgericht Verzögerungen im Verlauf der Genehmigungsverfahren von mehreren GVO-Produkten und die Verhängung von Importverboten gegenüber bestimmten GVOs. Darunter fallen auch die weiterhin aufrechten Österreichischen Importverbote in Bezug auf 3 gentechnisch veränderte Maisprodukten. Die Empfehlung des WTO Schiedsgerichts, dass diese nicht-konformen Maßnahmen zu sanieren sind, ist speziell für die aufrechten Importverbote relevant.
In Bezug auf die österreichischen Importverbote zeigt die Analyse folgende Schwächen des vorliegenden Berichts auf:

- Schwächen bei der inhaltlichen Analyse der fachlichen Begründungen für das Verhängen der österreichischen Importverbote.
- Den Umstand, dass das WTO Schiedsgericht das Vorliegen von wissenschaftlichen Risikoabschätzungen des Scientific Committee on Plants (SCP) als formalen Beweis dafür wertet, dass eine geeignete Beurteilung der betreffenden GVO möglich war, ohne die Schwächen dieser Risikobewertungen zu berücksichtigen.
- In Bezug auf langfristige Umweltauswirkungen von herbizidtoleranten GVO, die ungenügend erforschten Auswirkungen von GVO auf Nicht-Zielorganismen und die Schwächen bei Bt-Resistenzmanagement-Plänen und Monitoring-Plänen der betreffenden GVO, wurden die dokumentierten Unsicherheiten nicht entsprechend berücksichtigt.
- Ebenso wurde die Bedeutung von lokalen Besonderheiten, die Einfluss auf die Bewertung des Risikos von GVO haben können, nicht gewürdigt.

Die durchgeführte Analyse zeigt, dass das WTO-Schiedsgericht eine Reihe von Sachargumenten, die zur Begründung der österreichischen Importverbote vorgelegt wurden, nicht berücksichtigt hat. Da die Europäische Kommission in ihrer Verteidigung diese von Österreich vorgebrachten Argumente für die Beurteilung der Maßnahmen als relevant ansieht und einige dieser Argumente auch von den FachexpertInnen, welche das Schiedsgericht beraten haben, unterstützt werden, erscheint es ratsam zur Überprüfung des Schiedsspruches Berufung einzulegen.

In dem Berufungsverfahren sollten außerdem andere wesentliche Entscheidungen des Schiedsgerichts, welche von allgemeiner Bedeutung sind, überprüft werden.

- So sollte die Interpretation zur Anwendung des Vorsorgeprinzips, die das Schiedsgericht in seinem Bericht gibt, im Hinblick auf frühere Interpretationen, die einen größeren Spielraum bei der Anwendung des Vorsorgeprinzips einräumen, überprüft werden.
- Speziell die Entscheidungen des Schiedsgerichts, welche Anforderungen für die wissenschaftliche Risikoabschätzung bei GVO durch die WTO Regeln gestellt werden, sollte überprüft werden. Die vom Schiedsgericht herangezogene Interpretation stützt sich vor allem auf eine strikte Auslegung des Art. 5.1 und Annex A (4) des SPS Abkommens. Eine solche Interpretation nimmt nicht auf das spezifische Schutzbedürfnis eines Landes Bezug und engt die Möglichkeiten für vorsorgeorientierte Maßnahmen im Vergleich mit früheren Auslegungen unverhältnismäßig stark ein.

- In diesem Zusammenhang sollte auch die Auslegung des Schiedsgerichts über das Zusammenspiel der WTO Regeln und anderer internationaler Verträge, die im Anlassfall von Bedeutung sind, wie beispielsweise das Cartagena Protokoll über Biologische Sicherheit, überprüft werden.

Anerkennung von Unsicherheit und Kontroverse in den wissenschaftlichen Grundlagen der GVO-Risikoabschätzung durch die Europäische Kommission

Trotz anders lautender Erfordernisse im EU Gentechnikrecht und in den EFSA Leitlinien zur GVO Risikoabschätzung haben sich die wissenschaftlichen Komitees der Europäischen Kommission bislang kaum zu wissenschaftlichen Unsicherheiten und Kontroversen geäußert. Nachdem die Kommission nahezu immer den Empfehlungen der EFSA gefolgt ist, sich selbst aber kaum zu wissenschaftlichen Fragen geäußert hat, konnte man bisher davon ausgehen, dass ähnliche oder gleiche Sichtweisen auf dieses Thema vorliegen. Ein etwas anderes Bild ergibt sich aber aus der Untersuchung der Dokumente der Europäischen Kommission im Rahmen des WTO Streitverfahrens, die im zweiten Teil dieser Studie zusammengefasst ist. Dieses Kapitel stellt Aussagen der EFSA und der Kommission einander gegenüber, aus denen unterschiedliche Sichtweisen erkennbar werden. Darin anerkennt die Kommission explizit das Vorliegen von Unsicherheiten und begründeten Kontroversen im Zusammenhang mit den wissenschaftlichen Grundlagen, den Zugängen und Konzepten sowie den Methoden der GVO-Risikoabschätzung. Das Vorliegen unterschiedlicher Sichtweisen wird auch durch die jüngste Kritik von EU Kommissaren an der Arbeitsweise der EFSA und Anregungen zu Verbesserungen unterstützt. Ob dies allerdings als Indikator für einen Politikwechsel der Kommission interpretiert werden kann, hin zu einer mehr vorsorgeorientierten Gentechnikpolitik, bleibt abzuwarten. Unabhängig von der jeweiligen Interpretation ist es zu erwarten, dass die künftige Politik und Kommunikation der Kommission an diesen Stellungnahmen gemessen werden. Aufgrund der Charakteristika und des Ausmaßes der anerkannten Unsicherheiten ist es jedenfalls sehr schwierig, die Stellungnahmen der Kommission als bloße historische Beschreibungen anzusehen, die infolge von wissenschaftlichem Forschritts und Konsensbildung nicht mehr länger bestehen.

3 Analysis of the WTO Panel report concerning the EC-Biotech dispute

3.1 Introduction

The following chapter of this report gives an overview on the WTO dispute case "European Communities - Measures Affecting the Approval and Marketing of Biotech Products". Specifically an analysis of the findings included in the Report by the WTO Panel is presented. The analysis is focusing primarily on issues of the dispute, which involve Austrian measures. In conclusion the implications of the ruling are summarised in a general way.
In the next chapter open questions according to the Austrian measures addressed in the Panel report are considered. It is suggested that the identified issues are addressed in case of appeal.

3.2 General aspects of the WTO dispute

In May 2003 the USA, Canada and Argentina launched a dispute with the EU on complaints that certain regulatory measures of the European Communities concerning biotech products allegedly were at odds with WTO rules. The following consultations between the Complaining Parties and the EC could not resolve these issues. All three Complaining Parties requested the establishment of a WTO Panel to further examine the matters. Following those requests the WTO Dispute Settlement Body (DSB) on August 29th 2003 established a single Panel with standard terms of reference to deal with the requests of USA (WT/DS291/23), Canada (WT/DS292/17) and Argentina (WT/293/17) in accordance with the Dispute Settlement Understanding (DSU Art 6+9), pursuant to DSU (Art 4) SPS agreement (Art 11), Agreement on Agriculture (Art 19), TBT agreement (Art 14) and GATT 1994 (Art XXII). The complaints as such were treated individually; however the involved parties agreed that they were processed by the same Panel, with involvement of a common group of selected experts commenting on technical questions and that a single report will be issued.
The report covers all three complaints in separate chapters with individual findings for each complaint. The findings are based largely on a common factual base, compiled in the various Annexes to the report.
The Director-general of the WTO on February 23rd 2004 appointed: Christian Häberli as Panel Chair, with Mohan Kumar and Prof. Akio Schimizu elected as additional Panel members. On April 8th 2004 the Panel formally acknowledged the complaints in a " Ruling by the Panel on the consistency of the Complaining Parties Panel requests with Art. 6.2 of the DSU".
From June 2004 to February 2005 the Panel met with parties and the selected group of scientific experts discussing the matter. On February 7th 2005 the Panel released an Interim report and on May 10th 2006 after receiving comments from the Parties the Panel released its final report to the parties. On September 29 2006 the final Report was distributed to WTO Member States. A timeline for the course of events of the dispute and other relevant developments concerning biotech products in the European Communities is provided as Annex 1.

The deliberations address three categories of European Communities' (EC) and EC Member states' measures affecting the approval and marketing of Biotech products in the EU.

The **alleged measures** were

1) an alleged EU moratorium on approvals of biotech products
2) product-specific measures related to the approval of biotech products, and
3) the so called safeguard measures (marketing and import bans) by EC Member states relating to the import and marketing of specific biotech products.

The Complaining Parties alleged that these measures imposed barriers to trade in contradiction to the obligations according to several WTO agreements, specifically

- The GATT agreement of 1994
- The agreement on Technical Barriers to Trade (TBT)
- The Agreement on Agriculture
- The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

In general the ruling of the WTO Panel addressed only the SPS claims of the Complaining Parties, pursuant to its finding that the addressed EU measures fall into the scope of the SPS agreement. The claims were therefore judged according to the SPS rules, which are more specific in their requirements for risk assessments and the scientific base for decisions.
The WTO Panel found no need to issue rulings according to the alternative claims under the other WTO agreements, since it did not rule on claims relating to "like" product discrimination (for details see following list of issues considered or not considered by the WTO Panel). A summary on positions and rulings is given in Annex 2.

The **ruling** offers judgements:

- Whether the EC measures were to be considered measures in line with the SPS agreement.
- Whether their application was consistent with the SPS rules.
- Whether the Complaining Parties could establish that those measures were inconsistent with EC obligations under SPS.

The WTO Panel however did not examine some issues concerning the dispute case and consequently did not address them in the ruling.

The ruling does not address:

- Whether biotech products in general are "safe" or "not safe".
- Whether biotech products are "like" their conventional counterparts and regulating them differently must be considered discriminatory as such.
- Whether the EC has the right to require pre-marketing approval of biotech products, a point which was not raised by the Complaining Parties.
- Whether the EC approval procedures calling for case-by-case assessment of biotech products according to Directives 90/220/EEC and 2001/18/EC and Regulation (EC) 258/97 are consistent with WTO obligations in a general way (this again was not raised by the Complaining Parties)
- Whether the EC rules on labelling and traceability are consistent with WTO obligations, as such EU rules were not implemented prior to the complaints examined by the Panel
- The conclusions of the relevant EC scientific committees concerning the safety evaluation of specific products, because these conclusions were not challenged by the Complaining Parties.
  It did however examine the scientific basis for questions and objections towards certain biotech products from various EU Member States, because the Complaining Parties did challenge their legitimacy according to SPS rules.
- Whether the propositions of the Cartagena Protocol on Biosafety and the concept of precautionary approach as put forward in the Cartagena Biosafety Protocol support the arguments by the European Communities in this case. The Panel did not take the Cartagena Protocol on Biosafety into account when interpreting the relevant WTO rules. Only when all WTO Members involved would have been parties to another multilateral agreement like the Cartagena Biosafety Protocol it would be up to the WTO Panel to decide whether such an agreement is taken into account.

Despite the deliberations on substantive issues involving scientific experts the legal arguments were largely procedural, reflecting on the three types of challenged measures mentioned above.

Whereas the EC denied the existence of a formal "Moratorium" and tried to justify any delays in the process of the examined product-specific measures, the defence on the national safeguard measures was drawn from the Articles of the SPS agreement (e.g. Art. 5.7), which can be invoked to justify provisional measures based on the available pertinent information when the scientific evidence is insufficient to conduct a comprehensive risk assessment. This definition is interpreted by the WTO Panel to be a reflection of the precautionary principle (WTO 1998).
The question whether the Cartagena Biosafety Protocol could be invoked to defend the precautionary approach in defence to the alleged inconsistencies with SPS provisions was a crucial point to the arguments of the EC.

The ruling is based on the input of the parties and the selected experts only. It is disregarding three *amicus curiae* briefs that have been submitted for consideration from different groups. Their main arguments support the positions taken by the EC, but their arguments are not followed in the course of the deliberations.
[1]

3.3 Overview on the findings and recommendations by the WTO Panel

In the following a general overview is given in regard to the three main issues of the case, which were addressed by the Panel in detail in the "Findings" section of the report. These findings by the Panel were the basis for specific recommendations by the Panel concerning the

- **alleged "de facto moratorium"** on authorisations of biotech products,
- **product-specific measures** in processing individual biotech applications
- **national safeguard measures** by EC Member States including Austria.

A summary of the legal issues, their relevance and the recommendations by the panel is presented in Annex 3.

3.3.1 Recommendations concerning the alleged "de facto" moratorium

The Panel did not make specific recommendations concerning the issue of the moratorium itself if and to the extent that the measure has already ceased to exist. This recommendation leaves more room to interpretation than the language in the Interim Report. There the Panel refrained from making recommendations pursuant to Article 19.1 of the DSU, stating that the approval by the European Communities of a relevant biotech product subsequent to the establishment of this Panel brought to an end the general moratorium on approvals, which was found to have existed at the time of establishment of the Panel. On the other hand there is no evidence to conclude that any moratorium that had been was not effectively terminated September 2004. This suggests that the substance of the Panel´s rulings remained unchanged.
The relevant details concerning this issue together with an indication whether Austria is implicated are summarised in Table 1.

Table 1: Summary on issues and rulings in the WTO-EC-Biotech case concerning a general *de facto* moratorium

Measure at Issue	**European Communities**	**WTO Panel ruling** (final report)	**Implications for Austria**
General suspension of the EC approval processes; **"general de facto moratorium"** on the approval of biotech products.	• Deny the existence of "moratoria" or a unjustified "suspension" of approval of procedures • Claim that a moratorium is no "measure" according to SPS agreement.	• A general *de facto* moratorium has been applied by the EC between June 1999 and August 2003. • The moratorium itself is not in a SPS measure. • It affected the operation and application of the EC approval procedures. • Currently no indications that repercussions are pending for EC.	• Austrian action is not directly implicated in the ruling. • Declaration of precautionary action by Austria not tantamount to the moratorium. • .No need for action

3.3.2 Recommendations concerning the challenged product-specific measures

Concerning the product-specific measures the Panel recommended that the Dispute Settlement Body requests the EC to bring measures that were found to be inconsistent to SPS "into conformity with its obligations under the SPS agreement". This would mean that the approval procedures should be completed without further delays in the timeframes set forth in the respective regulations.
The relevant details concerning this issue together with an indication whether Austria is implicated are summarised in Table 2.

Table 2: Summary on issues and rulings in the WTO-EC-Biotech case concerning product specific measures

Measure at Issue	**European Communities**	**WTO Panel ruling** (final report)	**Implications for Austria**
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).	• Measures justified by discussion of case histories and context. • Delays not due to unjustified "suspension" of approval of procedures (but due to valid requests for further information).	• 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.	• Austrian objections to product applications are not directly implicated in the ruling. • Further action only necessary when the Panel´s ruling in respect to primary causes of delays is revised.

3.3.3 Recommendations concerning the challenged national safeguard measures

Concerning the national safeguard measures the Panel recommended that these measures are also brought into conformity with WTO agreements: Either by lifting them (as national measures or through involvement of EC), or by providing revised risk assessments for these products that are in line with the SPS provisions.

The relevant details concerning this issue together with an indication whether Austria is implicated are summarised in Table 3.

Table 3: Summary on issues and rulings in the WTO-EC-Biotech case concerning National safeguard measures

Measure at Issue	**European Communities**	**WTO Panel ruling** (final report)	**Implications for Austria**
National Safeguard Measures by EU Member States; marketing or import bans on 9 GM-products by 6 EU countries (Austria, France, Germany, Greece, Italy, Luxem-bourg).	• National measures are temporary and provisional, and based on the precautionary principle • EC Member states took precautionary approach to individual applications in line with Art.5.7 SPS agree-ment.	• 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.	• Austrian safeguard measures concerning GM-Maize lines Bt176, MON810, T25 are directly implicated in the ruling. • Austrian measures are regarded as not being based on risk assessment as required by Art. 5.1 SPS and not consistent with the requirements of Art. 5.7 SPS. • Obligation to bring into conformity

3.4 Analysis of the WTO Panel rulings and recommendations

An analysis of the findings focusing on some general aspects of the rulings and recommendations set forth in the report of the WTO Panel is presented in the following. The Panel´s rulings indicate how the WTO agreements are interpreted currently with regard to the dispute case and specifically to the Austrian safeguard measures. However the presented aspects are also relevant with respect to how the WTO agreements could be interpreted in future WTO dispute cases.

3.4.1 Basis for the WTO Panel´s conclusions

In summary only the **WTO agreements** and other **international obligations for WTO-Members** (or at least for all parties of the dispute) were taken into consideration for the Panel deliberations together with findings by relevant WTO bodies, e.g. Appellate Body decisions in comparable cases. Specifically considered was the consistency of the EC measures according to the SPS agreement.
Relevant for the conclusions were the claims submitted to the Panel as well as the **submissions by the parties** and the opinions **submitted by the scientific experts** consulted by the Panel.

It is however not clear to what extent the **submissions of third parties** (Australia, Chile, China, New Zealand and Norway) were taken into account.
For those third party countries who declared themselves concerned by the measures taken by the European communities (Australia, Chile, New Zealand) the main concerns were:

- The process of deliberation needs to be transparent for third parties and taking into account their interests.
- Any conclusions should be taken only on grounds of WTO agreements based on submissions by parties to the dispute.

- Conclusions on factual issues should be taken in accordance with scientific principles
- The relevance of the Biosafety Protocol and the concept of the precautionary principle reflected in legal texts other than the WTO agreements should be closely scrutinised.

China called for clarifications of the interpretation of the terms "insufficient scientific evidence" and "available pertinent information" according to Art.5.7 of the SPS agreement:

- More factors for a risk assessment should be considered than listed in Art.5.2 SPS, including traceability of products.
- Additional information requested at steps of the approval procedure must be crucial to conducting a more objective risk assessment, however the difficulties and delays for obtaining additional information for complex issues must be considered in a reasonable way.

Norway with regard to own safeguard measures (Bt176, MS1xRF1, Topas 19/2) submitted considerations backing the EC submissions:

- A proven safety record for GMOs does not exist, whereas risk hypothesis have been debated in the scientific literature and some have been verified for some species and environments.
- The safeguard measures challenged need to be assessed under Art.5.7 (based upon available pertinent information until a proper risk assessment can be established) and according to the circumstances that relevant scientific evidence is difficult to obtain (research is time-consuming and needs to resolve complex issues), a prudent approach is justified.

According to the raised issues it seems that only the concerns of Australia, Chile, New Zealand are addressed positively in the ruling by the WTO Panel.

The ***Amicus Curiae* submissions** were accepted, but the substantive arguments in these Briefs, which supported positions taken by the European Communities were not taken into account further on by the Panel. According to the Panel there was no obligation to regard them in the Panels conclusions, because they were not submitted by official parties to the dispute.
The main issues reviewed in the *Amicus Curiae* Briefs are the differences and difficulties in establishing scientific risk assessments and how to relate to scientific uncertainty. Specifically addressed were:

- Issues related to science, risk assessment and precaution, stressing the complexities inherent in risk assessment, including levels of certainty and consensus – both of them low for GM technologies. It is pointed out that risk assessment is not a singular concept, but rather varies with context and decision-making cultures. In light of the developing status of risk assessment delays should be seen as a "reasonable" time to collect additional information.
- The de facto moratorium is not a "measure" subject to WTO rules, but rather an "expression of political intent", based on the precautionary principle and consequently on international standards. According to this argument the actions of the European Communities were regarded as based on risk assessment, non-discriminatory, transparent and fair. Specifically addressed were the following supporting arguments: Firstly a proven safety record for GMOs does not exist; secondly risk hypothesis on GMOs have been debated in the scientific literature and thirdly some of these risk hypotheses have been verified for certain species and environments.
- The prevailing scientific uncertainty surrounding the risks of GMOs. This uncertainty impedes an adequate consideration of those risks, thus allowing for the application of precautionary decision-making pursuant to SPS Article 5.7

Another important issue in defining the legal basis was the **relevance of Multilateral Environmental Agreements** for the deliberations of the Panel. Important legal matters

implicated were the applicability of precautionary principle and the underlying definition of risk assessment for GMOs, as based upon the Cartagena Protocol on Biosafety as the comprehensive international agreement on Biosafety concerning transboundary movement of GMOs.
The Panel took into consideration the obligation to interpret the issues of the dispute in accordance with the rules of interpretation of international law as given by Art.31 of the Vienna Convention on the Law of Treaties.
However a very strict interpretation was put forward, finding that neither the Convention on Biological Diversity nor the Cartagena Protocol on Biosafety needed to be taken into account because several WTO-Members with the Complaining Parties of the dispute among them had not ratified these agreements.

3.4.2 Applicability of the Cartagena Protocol on Biosafety and other international guidance

As mentioned the WTO Panel decided in disagreement with the European Communities not to consider the **Cartagena Protocol on Biosafety**. The European Communities had stated that it was necessary to consider the Cartagena Protocol on Biosafety as a mutually supportive international agreement to the WTO on the issues in question. It further submitted that the Cartagena Biosafety Protocol is closely related and complementary to WTO agreements and therefore gives additional information on how the provisions of SPS should be interpreted.

In addition the European Communities argued that the Protocol was negotiated subsequently to the WTO agreements. The EC concluded that therefore the rules of the Cartagena Protocol on Biosafety must be compatible with preceding WTO agreements, like the SPS agreement. Furthermore the EC stated that the Cartagena Protocol on Biosafety was signed by Canada and Argentina and supported by the US through participation in the BCH mechanism.

However the WTO Panel interpreted the Art.31(c) of the Vienna Convention - only relevant rules of international law applicable in the relations between the parties – in its most stringent way to exclude the Cartagena Protocol on Biosafety from consideration. The notion that some of the disputing parties had signed the mentioned agreements was ruled irrelevant unless they did not explicitly demand that these agreements should be considered.

The Panel confirmed that international treaties can act as a guideline in interpreting the scope and meaning of terms of a WTO agreement in question even in case not all parties of a dispute are parties to these particular agreements. However, they need not to be taken into account in the same way as the relevant WTO agreements itself.

However **other international guidance**, like Codex Alimentarius Guidelines or other Guidelines issued by international organisations, was deemed informative in interpreting what is acceptable as scientific risk assessment. The Panel explicitly referred to such international guidance documents, when examining the acceptability of the justifications submitted and their qualifications as a valid risk assessment.

The Panel also disagreed with the European Communities that the **precautionary principle** was a general and fully applicable principle of international law. This decision followed the reasoning of the Appellate Body in the EC-Hormones case that it was unclear whether the concept of the precautionary principle was generally accepted by all WTO Members. Based on this reasoning it did not accept the interpretation of the precautionary principle as submitted by the European Communities.

Instead it ruled that the meaning of Art.5.7 did embody the precautionary principle within the SPS agreement. The Panel argued that by examining the safeguard measures according to Art.5.7 the precautionary principle was adequately taken into consideration on a WTO level.

However it is important to note that by invoking very strict requirements for the Art.5.7, the possibility for consistent application of the precautionary principle in determining the appropriate level of sanitary and phytosanitary protection in defence of the safeguard measures was prevented.

3.4.3 Alleged general *de facto* moratorium for applications

In the deliberations the WTO Panel concluded that a general de facto Moratorium on the approval of biotech products had been applied by the EC between June 1999 and August 2003. It found this Moratorium to be existent as claimed in the submissions of the Complaining Parties. With regard to these claims the Panel ruled that the de facto Moratorium itself cannot be considered to be in an SPS measure. In consequence the arguments of the European Communities to this respect were supported by the Panel.

However the Panel further ruled that the Moratorium affected the operation and application of the EC approval procedures, which were considered SPS measures according to the meaning of the SPS agreement. Therefore with regard to the authorization of Biotech products the WTO-Panel ruled in agreement with the claims of the Complaining Parties, that the Moratorium had influence on the approval procedures of GMOs, lending evidence to the claim that they had been unduly delayed.
Upon examination of the histories of all individual applications cited in the submissions of the Complaining Parties certain delays could be identified, that were consistent with a general moratorium being in effect and that in the end were found to be inconsistent with the EU obligations according to Annex C(1)(a) and Art.8 of the SPS agreement.

With regard to the recommendations put forth following these conclusions the finding translates not to action because the moratorium was already terminated by approving GMO products from 2004 onwards.

Nevertheless the European Communities' argument that no moratorium was implemented as an official or legal measure was effectively dismissed.
Of crucial importance for the deliberations was a political declaration made by a group of 5 European Community Member states (Denmark, Greece, France, Italy, Luxembourg) in June 1999. In this declaration the group stated that they would exercise their powers to take steps to have any new authorizations for growing and placing on the market suspended.
The European Communities noted in their defence that political statements such as the mentioned declaration have no legal significance or effect in the European Communities and that this notion was confirmed by a ruling of the European Court of Justice. Member States were said to be aware of this position and did issue the declaration for political reasons.
The Panel nevertheless concluded that this declaration is evidence for a coordinated action from the side of this group to actively suspend any authorizations. The Panel furthermore notes that this declaration was reiterated afterwards on 9.12.1999 and again on 15.2.2001 with Austria joining the group. The Panel inferred from the way the declaration was worded and published that it accurately expressed the intentions of the governments of the mentioned Member States and such was reflecting their official position regarding their involvement in processing applications for the authorization of GMOs. The inferred intent of the group of Member States actions was identified in the exertion of pressure on the European Commission to put forth rules on labelling and traceability (which were adopted with Regulation (EC) 1830/2003 in September 2003).

The argumentation included that due to the actions of the Member States the road to authorisation routinely was leading to the European Commission having to take decisions. When the Regulatory Committee and the European Council do not adopt a decision with qualified majority the European Commission has the final right to decide on applications. The Panel alleged that this deadlock situation in the Regulatory Committee and the European Council was achieved through a systematic and wilful opposition of Member

States in voting against the authorization of GMOs on the basis of the Group of Five-declaration. Such display of lack of political support and opposition led the Panel to presume that the European Commission did not make use of the relevant procedures ensuring authorization of new products, and thus in effect final approvals of a number of applications were "unduly delayed".
The joining of the group by Austria could have been regarded to be relevant. However the arguments in the report do not explicitly implicate the joining of the Group of Five Declaration by Austria.

The Panel noted that a number of European Communities' documents of official EC and National bodies additionally gave indications to the existence of a moratorium or suspension of approval processes. This was seen as further evidence to the finding that the history of applications was consistent with a moratorium in place. The list of cited documents does not include statements of Austrian officials.
In disagreement to the European Communities the Panel considered that those documents were lending evidence to the alleged suspension of approvals.

Austria was also part of a group of seven Member States (Austria, Belgium, Finland, Germany, Netherlands, Spain, Sweden) adopting a different declaration in June 1999 stressing the need for a more transparent and strict framework for risk assessment concerning ecological impacts, monitoring of GMOs and labelling. Furthermore these so called Group of Seven countries would take a thoroughly precautionary approach in dealing with any applications and not to authorize the respective GMOs until it is demonstrated that there is no adverse effect on environment and human health.
Other than the Group of Five declaration the declaration by the latter group was not interpreted by the Panel as evidence that Member States were intending to systematically and unduly delay the authorization of GMOs.

Despite the conclusion of the Panel that the Moratorium led to inconsistent behaviour of the European Communities with SPS obligations, the ruling does not translate into economic sanctions, because the EC does not maintain a moratorium as such any more. However it is important to note that the findings indicate that the WTO is ready to challenge delays in the authorization procedure, which are not supported by valid justifications according to the SPS agreement. When based on a convincing justification the length of a delay in itself is not a decisive factor.

Furthermore political declarations were taken into account in the Panel´s deliberations, even in spite they do not have the formal status of Community Law or Regulations.
The Panel did not accept that the delays encountered were due to other reasons than conforming to the political declaration.

3.4.4 The implications of the Panel´s recommendations

The implications of the WTO Panel´s recommendations with respect to the issues of a general moratorium and towards the finding of undue delay in approval procedures of specific products are limited yet informative.

Since the "***de facto* moratorium**" had effectively ended with approvals on GMO products taking place from 2004 onwards, no open questions are pending on this issue. Caution with regards to the wording of political declarations is warranted however, as demonstrated by the effects of the Group of Five declaration. It is apparent that comparable declarations will be treated the same way and closely scrutinised for any effects on regulatory processes. It is likely that in this context any action taken will be challenged for its motive, i.e. if it was taken for reasons other than conforming to the political declaration.
It must be noted that it is very challenging or impossible to present substantive evidence which clearly disproves the reasoning followed by the Panel. In their submissions the EC tried to present evidence reflecting the actual behaviour of the European Member States

to support their position. However the Panel did not accept these arguments as convincing.

The same is true for **delays in the regulatory process**. The Panel´s recommendations show that the WTO is ready to challenge such delays unless an adequate justification can be supplied.
It is worthwhile to note that in some respects the arguments used by the Panel with regard to the reasons for unduly delaying specific applications and the deliberations regarding the general moratorium are contradictory.
With regard to the moratorium the Panel assumed that the declaration of the Group of Five was truly followed by the respective EU Member States, even though it was not part of the legal framework. This behaviour was interpreted as an indication of their intent in the regulatory process. Yet in respect to examining the European Commissions involvement in specific approval procedure (e.g. GA21, EC-78; Par.7.2138) the Panel did point out that there is "no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries vis-à-vis other member states or the Commission". However, the material evidence seems to support neither conclusion unequivocally. In the course of an appeal this inconsistency of the argumentation could be challenged.

Another completely different matter is the issue of the **existing safeguard measures** prohibiting the use and import of certain GMO in some Member States of the European Union.
The Panel ruled that these national safeguard measures were not based on a risk assessment as required by Art.5.1 of the SPS agreement, that they are not consistent with the requirements of Art.5.7 of the SPS Agreement, and that by maintaining these measures, the EC has acted inconsistently with its obligations under Art.2.2 of the SPS Agreement.
As the safeguard measures are still upheld the European Communities need to take steps to avoid trade sanctions authorised by the WTO:

- One possibility would be to supply a justification for the safeguard measures. To do so the EC needs to submit additional material to the Panel to rebut the current argumentation and demand that the Panel will revise its ruling accordingly.
- In case the ruling will not be revised or successfully challenged the other possibility is taking action to lift the safeguard measures. In any case, such an action can not be taken on the basis of the SPS agreement, but according to the rules laid down in the relevant European Directives and Regulations.

3.5 Austrian measures on GMOs concerned by the WTO Panel report

Austria is primarily involved in regard to objections to Biotech products within European Community approval procedures and in regard to safeguard measures implemented to prevent the import of Biotech products into Austria.
An overview on the issues of the WTO dispute involving Austrian actions is given in Annex 3.

3.5.1 Austrian involvement with approval procedures for biotech applications

The Complaining Parties in their submissions to the WTO Panel claimed that a number of individual applications according to Dir. 90/220/EEC and Dir. 2001/18/EC and Reg. (EC) 258/97 were unduly delayed in their processing. A finding of "undue delay" in the completion of an individual application due to failures of the involved authorities of the European Communities constituted the basis of a ruling of the WTO Panel that the European Communities breached their obligations according to Annex C(1)(a) and Art.8 of the SPS agreement. In the final report the WTO Panel examined all individual

applications according to the claims by the Complaining Parties and according to the explanations provided by the European Communities to the Panel in defence. An analysis of the findings is presented below with regard to the involvement of Austrian authorities. The analysis comprehends all applications where Austrian actions were implicated in the respective claims by the Complaining Parties.

In summary 27 approval procedures for individual applications were examined by the WTO Panel. For 3 of them the findings of the WTO Panel indicate that the claim of "undue delay" could not be established by the Complaining Parties. In all other 24 cases the WTO Panel concluded that the claim of "undue delay" could be established in the course of the examination. In 9 of those cases an Austrian involvement was mentioned by the Complaining Parties in their submissions. The rulings in these cases are analysed below.

It is noteworthy that the WTO Panel did not analyze all claims in the submissions by the Complaining Parties in full detail. In case the Panel ruled that the decision of "undue delay" was warranted by concluding that a single issue could be established, all additional arguments in those submissions were not examined further. Only in the cases where all arguments of the Complaining Parties were found to be inconclusive for establishing a decision of "undue delay", the claims were examined in full by the Panel. For most of the cases the claimed Austrian involvement was not examined in detail by the WTO Panel, because the findings established that other European Authorities were responsible for causing "undue delay" in these application processes.

A summary of the analysis is presented in table 4, listing the respective cases, the claim involving Austria, the ruling by the WTO Panel and the implications for Austria. Implications can be twofold: Further action towards rebutting a claim in the current dispute at WTO level could be necessary (WTO). Secondly some findings of the panel point towards general deficiencies of the EU approval procedures that need close attention and indicate that improvements should be made as soon as possible (EU).

The analysis indicates that in all of the cases as of now there is no immediate need for further explanations by Austria regarding the objections being made at the respective approval procedures. In a first step the European Communities need to refute the relevant claims leading to the ruling of the WTO-Panel. Only when convincing arguments can be presented to refute those claims the WTO (WTO Panel and Appellate Body) will have to further examine the additional claims of the Complaining Parties.

A clarification regarding the involvement of Austria in the Group of Five Declaration which was implicated as a reason for "undue delay" in the GA21 Maize case (EC-78) could be warranted. Austria was not part of the group of member countries (Denmark, Italy, Greece, Luxembourg, France) making the initial declaration in June 1999. However it joined the group in a statement made on February 15th 2001 reiterating the June 1999 declaration in stating that they will use the powers conferred upon them to ensure that new authorizations for cultivation and marketing of GMOs are suspended pending on the adoption of effective provisions for traceability and labelling of GMOs. The European Council decided to make public this statement, which was submitted as evidence by Canada (WTO 2006, see Exhibit CDA-114). The WTO panel concluded that this declaration lent proof that a general de facto moratorium existed and that consistent with this general moratorium EC authorities unduly delayed the approval processes of individual products.
The WTO Panel however did not find that the Group of Seven Declaration also of June 1999 (involving Austria together with Belgium, Finland, Germany, Netherlands, Spain, Sweden) calling for a thorough precautionary approach towards the safety assessment of Biotech products was circumstantial in causing "undue delay" in individual approval processes.

Table 4: **Summary of product-specific measures inconsistent with Annex C(1)(a) and Art.8 SPS involving secondary claims on Austrian actions**

Notification examined	Claim involving Austria	Ruling by WTO Panel based primarily on	Implications for Austria
Bt-531 Cotton (EC-65), **RR-1445 Cotton** (EC-66) (Dir. 90/220/EEC, Dir. 2001/18/EC)	Austrian objection implicated as one of the reasons for undue delay, Austrian objection regarded scientifically unjustified	"Undue delay" due to failure of the European Commission to propose a draft measure to the European Council	• WTO: No immediate need for further explanations by Austria; justification of scientific validity of objection by Austria in case that the European Commission submits evidence that further information was requested by the Commission • EU: Improvements on processing Member State concerns necessary
RR-Oilseed Rape (EC-70), **Bt-1507 Maize** (EC-74)¸ **Bt-1507 Maize** cultivation (EC-75) (Dir. 90/220/EEC, Dir. 2001/18/EC), **MON810xGA21** Maize (EC-94), (Reg. 258/97)	Austrian objection regarded irrelevant	"Undue delay" caused by lead CA at Member State level	• WTO: Austrian objections not implicated; validity of the Austrian concerns not evaluated no immediate need for further explanations
GA21 Maize (EC-78), (Dir. 90/220/EEC, Dir. 2001/18/EC)	Suspension of process due to Group of Five Declaration	"Undue delay" due to failure of the European Commission to propose a draft measure to the Regulatory committee	• WTO: Clarification on Group of Five Declaration regarding involvement of Austria; Group of Seven Declaration (involving Austria) not implicated in WTO panel decision • EU: Legal Status and implications of political declarations (Commission, Member States) need attention
RR-Sugar Beet (EC-88), (Dir. 90/220/EEC, Dir. 2001/18/EC)	Objection concerning possible allergenicity not regarded as a valid justification for delays	"Undue delay" caused by lead CA at Member State level	• WTO: Austria not directly implicated, no immediate need for further explanations • EU: Guidance for safety assessment with regard to allergenicity needs further consideration at Community Level
BT-11 for food use (EC-92), (Reg. 258/97)	Austrian objection regarded short of being a competing Risk assessment	"Undue delay" due to failure of the European Commission to propose a draft measure to the Regulatory committee	• WTO: Austrian objections not implicated; validity of the Austrian concerns not evaluated; no immediate need for further explanations

3.5.1.1 Case histories of deliberations on individual product applications

Bt-531 Cotton (EC-65), Dir. 90/220/EEC and Dir. 2001/18/EC
(WTO 2006, see Par. 7.1860ff)

Summary of case history:
The Complaining Parties (USA, Argentina) claim that the application was unduly delayed by the European Community. Additionally they claim that several objections were raised by Member States (Austria, United Kingdom) at the vote of the Regulatory Committee supported by written explanations. These are claimed to be considered by the SCP in their opinion.
The European Communities however state that the concerns raised by the objecting Member States were legitimate and scientifically sound and had to be considered further, causing delays in waiting for additional information from the applicant.
WTO Panel ruled that the failure of the European Commission to timely propose a draft measure to the European Council unduly delayed the application from being completed. It furthermore found that the time necessary to consider the scientific concerns was long enough to justify the time of delay. In this respect the Panel misses information that and how the voiced concerns have been followed up by the Commission to fully consider the comments and to ask for additional information.

Analysis of the implications for Austria:
No responsibility on the side of Austria is found relating to the ruling that the European Communities unduly delayed the processing of the application.
It is noteworthy, that the Panel points to discrepancies how the scientific concerns of Member States have been transposed into regulatory action by the European Commission. This is pointing to a need for improvement regarding these procedures.

RR-1445 Cotton (EC-66), Dir. 90/220/EEC and Dir. 2001/18/EC
(WTO 2006, see Par. 7.1888ff)

Summary of case history:
The Complaining Parties (USA, Argentina) claim that the application was unduly delayed by EC regulators. Additionally they claim that several objections raised by Member States (Austria, Sweden, United Kingdom) were considered by the SCP and found not to contain a competing risk assessment or scientific evidence for the objections.
The European Communities however state that the concerns raised by the objecting Member States were legitimate and scientifically sound. The European Commission concluded that they had to be taken into account in adapting the proposal for a draft measure to the Council and that there is no specified timeframe for these considerations. Additionally the Commission claims that information on a post-market-monitoring plan was not provided by the applicant.
The WTO Panel ruled that the failure to timely propose a draft measure to the European Council unduly delayed the application from being completed. It furthermore ruled that the concerns by Austria regarding antibiotic resistance marker genes had been dealt with explicitly by the SCP and the claim of the European Commission that it had been waiting for additional information from the side of the applicant regarding these objections was not justified. Moreover according to expert Dr. Andow additional concerns regarding long-term effects could be best addressed with a monitoring plan; but that the necessity for a specific monitoring plan was not expressed in the objections.

Analysis of the implications for Austria:
Apart from the notion of the WTO Panel that the European Commission was responsible for causing undue delay of the application, it is noted in the report that consideration should be given to the question how objections (e.g. from Austria) are dealt with at Community level.
This substantiates the necessity that the current system for processing Member States comments needs to be improved. In case the objections are not supported by the SCP the

Commission needs to address the issue more explicitly, and inform the applicant that issues are unresolved and need additional scrutiny.
Furthermore more attention must be paid to comments by Member States to specify how specific concerns should be dealt with. The example of the WTO deliberation shows that otherwise comments will not be interpreted as demand for a specific action from the side of the applicant, like the request to submit a detailed monitoring plan specifically addressing certain risks identified in the comment.

RR-Oilseed Rape (EC-70), Dir. 90/220/EEC and Dir. 2001/18/EC
(WTO 2006, see Par. 7.1965ff)

Summary of case history:
Complaining Parties (USA, Canada) note that additionally to delay allegedly caused by the Netherlands as lead CA, Austria (together with Germany, France, Denmark, Italy, Belgium) objected to the favourable initial assessment on the grounds that support to any application could only be granted in case that new EC rules concerning traceability and labelling were put forth and implemented in the EU. This in the view of the USA shows opposition to the application without consideration of its merits. Additionally issues for objecting were the unresolved questions concerning liability and coexistence. The USA notes that these are issues that do not justify delays for processing the application. Canada referred to an objection on grounds of danger of seed spillage which allegedly is irrelevant for the scope of the application (import and processing). The longer than 105 day period used for processing at member state level is also criticised.
The European Communities provided as explanation that additionally, scientifically sound concerns have been issued together with the ones mentioned above that are concerning regulatory requirements outside the scope of the dispute.
The WTO Panel ruled that the actions by the lead CA constituted undue delay, without referring to the effects of the objections by other Member States and Austria.

Analysis of the implications for Austria:
Taken together the involvement of Austria was not found to be responsible for the Panels conclusion that the application was unduly delayed. Therefore no immediate need for further explanations is ascertained. In case the European Communities are successfully presenting evidence that the finding with regard to the causes of "undue delay" have to be revised, it may be necessary to demonstrate that the Austrian objections were in line with the relevant SPS provisions and cannot be disregarded.

Bt-1507 Maize (EC-74), Dir. 90/220/EEC and Dir. 2001/18/EC
(WTO 2006, see Par. 7.2064ff)

Summary of case history:
The complaint by the USA states that the completion of the approval procedure has been unduly delayed and Spain as the lead CA has delayed consideration longer than necessary. Furthermore a number of objections by other Member States (including Austria) are claimed to be without justification.
The European Communities noted that the time was necessary in order to prepare a valid safety assessment with delays on the side of the applicant for necessary clarifications to be submitted.
The WTO Panel ruled that the actions by the lead CA constituted undue delay, without referring to the effects of the objections by other Member States and Austria.

Analysis of the implications for Austria:
The Panel found no responsibility of Austria in the ruling that the application was unduly delayed. Therefore no need for further explanations is ascertained. In case the European Communities are successfully presenting evidence that the finding with regard to the causes of "undue delay" have to be revised, it may be necessary to demonstrate that the Austrian objections were in line with the relevant SPS provisions and cannot be disregarded.

Bt-1507 Maize for cultivation (EC-75), Dir. 90/220/EEC and Dir. 2001/18/EC
(WTO 2006, see Par. 7.2085ff)

Summary of case history:
The complaint by the USA states that the completion of the approval procedure has been unduly delayed by the lead CA and a number of objections by other Member States are claimed to be without justification.
The European Communities argued that the time was necessary in order to prepare a valid safety assessment according to Dir 90/220/EEC and adapting it according to Dir 2001/18/EC. It noted that there were an extensive number of objections and requests for further information to be dealt with.
The WTO Panel ruled that the actions by the lead CA constituted undue delay, without referring to the effects of the objections by other Member States and Austria.

Analysis of the implications for Austria:
The Panel found no responsibility of Austria in the ruling that the application was unduly delayed. Therefore no immediate need for further explanations is ascertained. In case the European Communities are successfully presenting evidence that the finding with regard to the causes of "undue delay" have to be revised, it may be necessary to demonstrate that the Austrian objections were in line with the relevant SPS provisions and cannot be disregarded.

GA21 Maize (EC-78), Dir. 90/220/EEC and Dir. 2001/18/EC
(WTO 2006, see Par. 7.2125ff)

Summary of case history:
The Complaining Parties (USA, Argentina) claimed that the application was unduly delayed by the European Commission although processing by the lead CA and the Member States was completed. No consideration took place until the application was withdrawn.
The European Communities argued that the application was withdrawn by the applicant on reasons accountable to the applicant.
The WTO Panel ruled that the failure of the European Commission to submit a draft measure to the Regulatory Committee constituted undue delay.
It is noteworthy that the ruling contains the argumentation that the European Commission was not justified to assume that the Group of Five Declaration was transmitted into respective voting behaviour and that the draft measure was therefore not going to be approved by the Regulatory Committee. This is exactly contrary to the interpretation of the Declaration put forth by the Panel to rule that there had been a moratorium on Biotech products in the EU, assuming that the Declaration of the Group of Five was predicting the opposition of the involved Member States in decisions of the Regulatory Committee and the Council.

Analysis of the implications for Austria:
The Panel found no responsibility of Austria in the ruling that the application was unduly delayed. Therefore no immediate need for further explanations is ascertained. In case the European Communities are successfully presenting evidence that the finding with regard to the causes of "undue delay" have to be revised, it may be necessary to demonstrate that the Austrian objections were in line with the relevant SPS provisions and cannot be disregarded.

RR-Sugar Beet (EC-88), Dir. 90/220/EEC and Dir. 2001/18/EC
(WTO 2006, see Par. 7.2166ff)

Summary of case history:
The complaint by the USA claims that the completion of the approval procedure has been unduly delayed by the lead CA in its initial stages.
The European Communities argued that the application was withdrawn by the applicants on his own initiative after discussions with the lead CA.

The WTO Panel ruled that the time taken by the lead CA to complete its assessment was considerably longer than 90 days and therefore constituted undue delay. Furthermore based on the expert opinion by Dr. Nutti the requested further information on allergenicity of the product was not prerequisite to commencing the safety assessment.

Analysis of the implications for Austria:
The Panel found no responsibility of Austria in the ruling that the application was unduly delayed.
The question concerning safety assessment with regard to allergenicity needs further consideration at Community level.

BT-11 (EC-92), Reg. (EC) 258/97
(WTO 2006, see Par. 7.2247)

Summary of case history:
The Complaining Party (USA) claims that the completion of the application is unduly delayed by the European Communities. It is claimed that the European commission failed to submit a draft measure to the Regulatory committee on the grounds that the positive evaluation of the SCF was confronted by objections from three Member State (one of them being Austria).
The European Communities argued that the risk assessment by the SCF was contradicted by 3 risk assessments by Member States. It argued that the contradicting positions needed to be resolved before a draft measure could successfully pass the Regulatory committee.
The WTO Panel ruled that the failure of the European Commission to submit a draft measure constituted undue delay. The ruling was taken without examining the issues concerning the contradicting risk assessments by SCF and Member States in detail. Without the Commission directly addressing these concerns in a formal way the objections provided no grounds for justification of the delay in approval. The justification presented by the Commission on the other hand was dismissed by the Panel.

Due to the fact that only actions taken by the Commission were examined to establish a ruling, the validity of the Austrian concerns was not evaluated. This however highlights that consideration of objections by Member States at the Community level need to be improved.
In case the European Communities are successfully presenting evidence that the finding with regard to the causes of "undue delay" have to be revised, it may be necessary to demonstrate that the Austrian objections were in line with the relevant SPS provisions and cannot be disregarded

MON810xGA21 Maize (for food use) (EC-94), Reg. (EC) 258/97
(WTO 2006, see Par. 7.2347ff)

Summary of case history:
The Complaining Party (USA) claims that the completion of the application was unduly delayed at the Member State level and has been pending at the Community level far longer than the average for applications according to Re. 258/97. The claim further mentions that at the Community level the application was objected by Austria on the grounds that the toxicological evaluation was insufficient, demanding further information regarding sub-chronic testing of EPSPS-Protein. This request is demanded unfounded and unreasonable and exceeding relevant guidelines (Codex Alimentarius Guidelines and EC Guidance Document for the Risk assessment of Genetically Modified Plants and Derived Food and Feed).
The European Communities argued that the time was spent duly to establish a valid safety assessment and for dealing with the concerns identified. Furthermore validation of a detection method was a pre-condition for market-approval on the basis of a voluntary agreement with the notifier.
The WTO Panel ruled that the lead CA was delaying the application by slow processing at the initial stages, constituting undue delay. The Panel was not convinced by the

information from the side of the European Communities that this was due to a prudent precautionary approach.

Analysis of the implications for Austria:
Due to the fact that only actions taken by the Commission were examined to establish a ruling, the validity of the Austrian concerns was not evaluated.
In case the European Communities are successfully presenting evidence that the finding with regard to the causes of "undue delay" have to be revised, it may be necessary to demonstrate that the Austrian objections were in line with the relevant SPS provisions and cannot be disregarded.

3.5.1.2 Summary and Implications

In general the WTO Panel did not rule on the **SPS-consistency of the EC regulations** concerning biotech applications as such. Therefore the Panel´s conclusions do not point to general inconsistencies of the EC regulatory process with the WTO agreements, specifically the SPS agreement. This is true for all challenged issues, the alleged moratorium as well as the product-specific measures.
Due to the decision of the Panel to reject all complains targeted in this direction, the scientific justification of the product-specific measures was not examined in detail, and was not found crucial to the ruling and the recommendations of the Panel.

Nevertheless the Panel stated that in the process of handling the applications **procedural aspects amounted to a violation of the SPS agreement**, namely the obligations according to Art.8 and Annex C(1)(a). Because the European Communities could not adequately explain certain delays during the authorization processes for specific products, the Panel decided that they were not warranted and such constitute "undue delays" inconsistent with the obligations according to the SPS agreement.

The findings give an indication that unwarranted delays and the failure to conclude the regulatory processes in time will be regarded as violation of the WTO obligation and certainly be challenged in any similar cases further on. The European Commission therefore needs to be prepared to justify any valid delays in regulatory processes in an adequate way.

Objections raised by EC Member States need to be justifiable as well, because it cannot be ruled out that the validity of these objections will be scrutinised in any further disputes. The current case does not give indications in this matter, because the Panel did not examine these issues in detail.

It can be assumed that **no economic consequences** due to the inconsistencies regarding product-specific measures are pending. Due to the commencing of authorisations of biotech products from 2004 onwards the findings will not translate into economic repercussions against the EC, given that no further violations of the SPS obligations are evident.

3.5.2 Austrian safeguard measures on the use of biotech products

The Complaining Parties in their submissions to the WTO Panel claimed that all safeguard measures by Member States including the Austrian safeguard measures according to Art.16 Dir. 90/220/EEC were SPS measures and that implementing and maintaining these measures was inconsistent with the obligations of the European Communities.
The questions examined during the WTO panel proceedings therefore were

- Are the mentioned safeguard measures SPS measures as far as purpose, form and nature of the measures are concerned?
- Are the safeguard measures affecting international trade?
- Are the safeguard measures consistent with relevant propositions of the SPS agreement

3.5.2.1 Austrian safeguard measures and the SPS agreement

The first question which was necessary to answer was to establish whether the safeguard measures qualify as SPS measures according to Annex A(1) and Art.1.1 of the SPS agreement. To this extent the safeguard measures were analysed according to their purpose, form and nature. This was done by evaluating the relevant articles of Dir.90/220/EEC or 2001/18/EC and Reg. (EC) 258/97 respectively and by analysing the documents provided by Member States when implementing and justifying the safeguard measures. In respect to the Austrian safeguard measures for T25 Maize, Bt-176 Maize and MON810 Maize these were Art.16 of Dir.90/220/EEC and documents by the Austrian Competent Authorities to the European Communities upon notification of the safeguard measure and for justifying them. The Panel in its deliberation then examined each single safeguard measure and concluded that the Austrian safeguard measures, as well as the ones by the other European Member States, in purpose, form and nature were SPS measures.

This was a crucial decision concerning the evaluation of the WTO compatibility of the safeguard measures, because the SPS agreement defines specific requirements for the scientific justification of measures, which are not set forth by the TBT agreement or the GATT 1994 agreement. In summary the Panel decided to apply a broad interpretation of the definitions given for SPS measures in Annex A(1) SPS agreement, and ruled that the measures based on relevant EC-Directives and Regulations – including the safeguard measures – listed in the complaints amount to SPS measures.
The decision thus confirmed the stance of WTO to implement a strict science-based approach imposing a high burden to justify prohibitive measures. The outcome of all preceding Appellate Body decisions by until 2006 in dispute cases based on the SPS agreement emphasises the determination of the WTO to apply this interpretation as a general policy (CIEL 2006).

Additionally the WTO Panel established that the safeguard measures, which were targeted to prohibiting import of the respective GMO products into Austria, may have affected international trade with these products. (WTO-Final Report Par. 7.2561- 7.2702)

3.5.2.2 The safeguard measures and risk assessment according to SPS

To answer the third question the WTO Panel analysed in depth the relevant provisions of the SPS agreement namely Art.2.2, Art.5.1 and Art.5.7.
The examination aimed to clarify under which legal regimen the safeguard measures have to be treated:
According to the "standard" regimen specified by Art.5.1 and Art.2.2 of the SPS agreement; or according to Art.5.7 SPS, allowing for provisional safeguard measures to

be adopted on available pertinent information given that the relevant scientific information is insufficient to perform a risk assessment according to Art.5.1 SPS.
The regimen under Art.5.7 was found to be no exception to Art.5.1 but a right in its own that could be invoked given all specific requirements of Art.5.7 were met.

The analysis was based on the interpretation of the relevant provisions itself, on other articles of the SPS agreement providing clarification in analogy, and on the interpretation by WTO Appellate Bodies of the respective articles and decisions taken in applying them in other dispute cases. For the analysis the Panel examined each safeguard measures whether it conformed to Art.5.1 SPS first of all. Only when a safeguard measure did not comply with the requirements of Art.5.1 SPS, the Panel in a second step analyzed whether the safeguard measures met the requirements for invoking a "precautionary approach" according to Art.5.7.

The European Communities argued in this occasion, that the provisions of the Cartagena Biosafety Protocol were to be taken into account to inform on the meaning and effect of the relevant SPS provisions as well as to give guidance how to the apply Art.5.7 SPS in general. Contrary to this notion the Panel ruled not to take the Protocol into consideration, but to base the legal analysis on the relevant SPS provisions itself and their former application in other dispute cases.
The obligation enshrined in Art.2.2 SPS to "… ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, …" was interpreted in a way that measures which were based or could have been based on a risk assessment according to SPS requirements, need to be addressed under Art.5.1 SPS agreement.

The Austrian safeguard measures in the eyes of the WTO Panel failed the test to demonstrate, that a Risk assessment was supporting the measure. This finding was based on reasoning addressing the following 2 questions:

1) Did the Austrian authorities submit a risk assessment according to Art.5.1 upon notification of the measure, or until the establishment of the WTO Panel?
2) Did any other risk assessment on these products indicate serious risks that needed to be countered by an adequate safety measure?

Based upon the Austrian documents supporting the safeguard measure the Panel decided that this information did not amount to a risk assessment according to Art.5.1.
It furthermore concluded that the concerns raised by Austria when notifying the safeguard measures were not based on acknowledged risks in the initial favourable risk assessments by the EC Scientific Committee on Plants. When examining these risk assessments the Panel did not find expressions of uncertainty that would justify other conclusions than those put forward in the documents.

It has to be noted that in this respect a crucial difference in obligations is encountered in the SPS agreement as interpreted by the Panel and the relevant EC legislation. According to the EC Dir. 90/220/EEC Art.16 under which the Austrian safeguard measures have been filed the acting Member State must notify " …justifiable reasons to consider that a product … constitutes a risk to human health or the environment". The Member State such is not obliged to establish a comprehensive risk assessment according to Art.5.1 to fulfil its obligations according to the EC legislation.

Because it concluded that the safeguard measures did not meet the requirements of Art.5.1, the Panel went on to scrutinise in a subsequent examination, whether all the requirements for invoking of Art.5.7 were met:

1) Is the scientific evidence insufficient to conduct a risk assessment according to Art.5.1?
2) Is the measure based on the available pertinent information?
3) Did the Member State try to obtain addition scientific information to conclude a more objective risk assessment?

4) Was the measure reviewed according to new information within a reasonable time?

In respect to the Austrian safeguard measures the examination to the first point proved to be crucial. In the interpretation of the Panel the available information was sufficient evidence for a risk assessment to be conducted.
In the view of the Panel this was demonstrated by Scientific Committees of the European Communities issuing risk assessments for all products in question at the time of adoption of the safeguard measures. The Panel considered this point of time relevant for the determination, whether the relevant scientific evidence was insufficient for an assessment to be made. It nevertheless examined all documents that had been submitted by Austria until establishment of the WTO Panel. That the Scientific Committees did reiterate their opinions when reviewing the information supplementing the safeguard measures was interpreted by the Panel as additional evidence for the ruling.

The argument that Austria on the basis of the concerns stated had justifiably demonstrated that these risk assessments were not appropriate to the circumstances in relation to the level of protection deemed necessary by Austria, was dismissed by the Panel in disagreement with the EC.
Contrary to submissions by the EC the Panel would not accept that a demonstration that the information for a scientific risk assessment might be insufficient in a case be dependent on the level of acceptable risk, which the decisions of regulators are based on. Furthermore the contextual framing of risk assessments as outlined in the Amicus Curiae brief by scientific scholars[2], which was underlying the different positions of the Scientific Committee evaluation and Austria was not taken in consideration.
The issue of insufficiency of the information itself was not directly addressed by the Panel stating "we need not determine whether relevant scientific evidence was or is insufficient for Austria, and if so, whether this would be a relevant circumstance. Even if this were the case, the flexibility which the phrase 'as appropriate to the circumstances' may in some situations provide does not relieve Austria from the requirement in Article 5.1 to base its safeguard measure on a risk assessment which meets the definition of Annex A(4)" (WTO 2006, Par. 7.3050).

The Panel decided that the level of protection defined by a country can only influence the initial scope of a risk assessment and the strictness of the measure adopted, but not the task of assessing the existence and magnitude of risks.
This definition of risk assessment seems to ignore the relevant current debates concerning risk assessment of risks accompanying modern technologies, e.g. biotechnology. Specifically the Panel seems to leave aside results of scientific research on current developments of how to prepare risk assessments on GMOs and GM-products as reflected in the mentioned *Amicus Curiae* Brief. The results summarized in this Brief indicate that any scientific risk assessment has to be conducted with respect to the context of the decision-making culture, reflecting the specific needs of the regulators as well as the level of protection deemed appropriate.

Furthermore the Panel´s conclusions on risk assessments do not address the quality of the scientific evidence and the uncertainties accompanying such assessments. This reasoning does not acknowledge situations, where there is a great deal of scientific data, but nevertheless little adequate evidence to inform decisions. Therefore it additionally disregards the wealth of scientific research in respect to the precautionary principle.

This interpretation of the Panel seems furthermore to deprive Members of the right to establish the level of protection they deem appropriate for their territory in case of scientific uncertainty. Even when a risk assessment does not provide enough conclusive or reliable information to determine on measures aimed at a certain high level of protection, the formal existence of such a risk assessment in effect prohibits the country from invoking Art.5.7 of the SPS agreement, which is meant to reflect the precautionary principle.

The outcome of the deliberations of the panel is that the right of Member States to invoke Art. 5.7 is subject to conditions, which must be regarded as very hard to satisfy and therefore prohibitive. Thus the respective country would in effect be denied the possibility to adopt provisional safeguard measures based on the precautionary principle. Furthermore this interpretation by the Panel of the precautionary principle does not consider the notion that the precautionary principle is meant to prevent harm and is therefore applied to avoid the necessity for emergency measures on a provisional basis (Shaw & Schwartz 2005).

The decision as outlined in the Panel´s ruling narrows the degree of flexibility the Appellate Body in EC-Hormones deemed appropriate in meeting the requirements to the obligation of basing measures on scientific risk assessments. This Appellate Body decision in summary also stated that the Art. 5.7 does not exhaust the possible application of the precautionary principle in the interpretation of other provisions of the SPS agreement. According to this reasoning the assessment of risks under Art. 5.1 needs to consider "the actual potential for adverse effects on human health in the real world" and thus may legitimate a high level of (precautionary) protection on condition that scientific research addressing the risks is ongoing and the precautionary measures is reviewed appropriately (Shaw & Schwartz 2005)

3.6 Conclusions

The following conclusions address first of all the implications of the ruling presented in the WTO Panel report in regard to any further deliberations at the WTO level. Secondly the implications concerning biotech products on the EC level are considered.

3.6.1 Implications for further WTO dispute settlement cases:

Regarding **submissions to WTO Panels** it is necessary that all submissions be made by Parties. This is suggested from the example how the *Amicus Curiae* Briefs have been treated. Information as such will be accepted by the Panel, but nevertheless not taken into closer account in the following proceedings. However the arguments provided in the *Amicus Curiae* Briefs were touching on crucial issues of the dispute and seem to be well worth considering. Disregarding such relevant information may lead to reasoning and decisions of a lower quality. Additionally this very situation may be viewed by the public as intentional disregard and is certainly not evidence for open deliberations on important subjects like public health and risks to the environment.

Regarding the significant issues of the **role of science and precaution** it needs to be said that the conclusions of the Panel effectively limit the room for basing decisions on the precautionary principle. The definition of the Panel what constitutes a scientific risk assessment has severe consequences for the confirmed right of WTO Members to adopt and maintain a level of protection they deem adequate. The decision obviously reflects the Panel´s opinion that whenever a risk assessment has been conducted, measures according to Art.5.7 SPS agreement are not feasible, regardless of the conclusiveness of results, the uncertainties encountered and of any further information indicating substantive limitations of these risk assessments.
This is contrary to the findings of the Panel that a declaration to pursue such a precautionary approach by Austria as stated in the cited Group of Seven Declaration from June 1999 is not challenged as illegitimate. And it is contrary to the notion that the possibility to take measures based on the precautionary principle is embedded in the language of Art.5.7 of the SPS agreement.

The decisions in the final report with regard to the science-based approach are thus relevant for other dispute cases. The interpretation followed is seemingly running against current scientific and regulatory developments concerning improvements for risk assessments and the efforts towards the implementation of the precautionary principle.

Instead the broader scope for risk assessments acknowledged in the preceding WTO "EC-Hormones" dispute should be followed in regard to complex issues involving uncertainties, e.g. in biotechnology.

Regarding the consideration of **other Multilateral Environmental agreements**, like the Cartagena Protocol on Biosafety, this ruling of the WTO Panel indicates the notion that other relevant Multilateral Environmental Agreements are not readily considered by WTO bodies.
This is in spite of the fact that the aim of those agreements is to be mutually supportive with other international agreements such as the WTO/SPS agreement. These Multilateral Environmental Agreements may offer substantive clarifications on issues touched upon in WTO disputes.

3.6.2 Implications on the EC Level:

The report identifies issues for a necessary **review of the EC risk assessment procedures**. This review is in fact already ongoing.
In regard to the WTO implications it is necessary to explicitly include any objections to and limitations of the risk assessment in risk assessment and decision documents at the EC level. The Panel in this respect notes that risk assessments may justifiably include diverging scientific opinions from respected and qualified resources and need not inform unequivocally about the risk given that there are diverging opinions. Additionally such risk assessments should address the "degree of precision" with which the relevant risks were assessed and address explicitly any uncertainties encountered. Given that the circumstances are mentioned in a risk assessment under which this assessment may need to be revised, any further measures according to new scientific information on these matters can be "based upon" such a risk assessment in a way consistent to SPS obligations.

The WTO Report also rules that the **safeguard measures** were found inconsistent with SPS obligations and have to be brought in conformity with the SPS agreement.
This could be achieved through lifting of the measure. If the EC Member States however are convinced that the measures are necessary to achieve the level of protection deemed necessary, the Panel concludes that the measures have to be brought in line with the requirements according to Art.5.1 SPS agreement.
For other safeguard measures to be adopted it would be necessary to demonstrate that the requirements of Art.5.7 SPS are satisfied. This encompasses the demonstration of insufficient information to conduct a risk assessment as appropriate to the circumstances. It is noteworthy that the current interpretation given by the Panel on what is "appropriate to the circumstances" in effect relates to requirements on risk assessments according to Annex A(4) SPS, which were deemed applicable to measures regarding the risks of GMOs for human health and the environment (Annex A(4): "risk assessment - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.").

In this respect the conflicting **relationship between the WTO obligations and the current EC regulations** has to be stressed.
Currently any EC Member State when adopting a safeguard measure need to submit "new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge" (EC-Directive 2001/18/EC, Art.23). This is not necessarily the same as submitting a competing risk assessment indicating relevant risks that are addressed by the adopted measure.
According to the WTO Panel decision it is necessary to base any safeguard measure on a risk assessment in line with the respective SPS definitions for such a risk assessment.

The above mentioned conflict between the EC and WTO/SPS obligations concerning risk assessments needs to be addressed and clarified as a prerequisite to further steps. Without addressing the resulting conflict in obligations with regard to the community level risk assessment for GMO products the European Communities will not be in a position to defend any safeguard measures based on the sole obligations of current EC legislation.

4 Open Questions concerning the ruling of the WTO Panel

This chapter provides a short assessment of options for the European Communities and Austria with regard to issues that offer substantive grounds for an appeal against the final ruling of the WTO Panel. The discussion is focused on the arguments of the Panel concerning the ruling on Austrian safeguard measures towards a number of GM-maize varieties.

The Austrian safeguard measures, which are the only issues in the WTO findings where Austria is directly concerned, are addressed here, with regard to the following issues:

- Discrepancies in obligations concerning safeguard measures according to WTO Agreements and the regulatory framework of the European Union
- Disregarded evidence for shortcomings in risk assessments, invoked as national concerns when enforcing safeguard measures.
- Regional aspects that need to be considered for a deliberation on the adequacy of a risk assessment.

4.1 WTO obligations versus the European regulatory framework

In summary the Panel decided that the Austrian safeguard measures were inconsistent with the requirements according to Art.5.1 of the SPS agreement stating that each safeguard measure has to be based on a scientific risk assessment satisfying the respective requirements of the SPS agreement.
The European Communities claimed that these safeguard measures have to be assessed according to Art.5.7 of the SPS agreement, allowing for provisional measures based upon a precautionary approach. With regard to this claim the Panel concluded that Art.5.7 could not be invoked by the European Communities, based on a ruling that the safeguard measures did not comply with the requirements for Art.5.7. In this respect the Panel deliberated that the European Communities did not adequately demonstrate that the scientific evidence was insufficient for conducting a risk assessment according to the provisions of the SPS Agreement.

According to the relevant European Directives and Regulations the obligations for European Member States to introduce safeguard measures are somewhat different. It needs to be stressed that the respective requirements of Art.16 of EC-Directive 90/220/EEC as the legal basis of the Austrian safeguard measures do not in any respect correspond to the interpretation of the WTO obligations as given by the Panel. The crucial difference is that EC-Directive 90/220/EEC as well as EC-Directive 2001/18/EC (amending Dir. 90/220/EEC) does not oblige the Member State to establish a comprehensive scientific risk assessment or base the measure on an opinion explicitly included in the risk assessments of the Scientific Committee on Plants[3], when enforcing safeguard measures.

Dir.90/220/EEC obliges the Member States to present *"justifiable reasons to consider that a product constitutes a risk to human health or the environment"* and Dir.2001/18/EC

states that "*new and additional information affecting the environmental risk assessment or the reassessment of existing information on the basis of additional knowledge*" has to be submitted. Austria accordingly submitted concerns regarding a number of scientific aspects as well as other issues, when enforcing the safeguard measures. In response to requests from the European Commission for further relevant information, additional scientific evidence in support of the safeguard measures was submitted.
Thus the formal requirements of Dir.90/220/EEC and Dir.2001/18/EC have been fulfilled by Austria.
Concerning the scientific validity of these concerns the European Food Safety Authority did review the submissions only in a general way. It did not reassess the submissions according to the safety requirement laid down in Dir.2001/18/EC or any other guidance reflecting the state of the art in risk assessment at the time of reviewing the submissions. Based upon this reasoning the initial assessments, favourable for giving consent to marketing of the respective GMO, were reiterated by EFSA.
The European Communities in their submissions to the WTO Panel however did acknowledge the scientific uncertainty and the concerns regarding environmental and health effects, as well as the risk assessment approach in the case of the three banned maize varieties. This acknowledgment is also reflected in the ongoing process of reconsidering the GMO risk assessment procedures and role of Member State concerns at EFSA (EFSA 2006, EC 2006)

The ruling of the WTO Panel is in conflict with the factual situation according to the following points:

- The EC-Directives 90/220/EEC or 2001/18/EC do not call for a risk assessment to be provided by the Member State, when enforcing safeguard measures. The notification of concerns based upon the risk assessment of the respective scientific bodies is sufficient as long as the requirements of Art.16 or Art.23, respectively, are satisfied.
- The Scientific Committee on Plants as well as the lead CAs in their assessment reports did not usually state uncertainties or diverging opinions in their reports. The Member State concerns – legitimate or not - therefore could not be based upon such statements or opinions in the initial assessment reports explicitly. Nevertheless they were clearly based on shortcomings or inadequacies of these risk assessments.
- There is no mechanism to formally consider by the Scientific Committees the views of Member States including Austria in the assessment or re-assessment of GM crops. The final favourable risk assessment therefore does not reflect the submitted concerns in the cases of the Austrian safeguard measures. Consequently Austria maintained the measures on the grounds that the Austrian concerns were not addressed adequately.
  The European Communities support these concerns as legitimate according to the circumstances in submissions to the current dispute case. This indicates that these concerns were justified and cannot be rejected as a whole, but need to be reassessed in an improved way.
- Since the Austrian concerns were not addressed in the current risk assessments in an adequate manner their conclusions need to be evaluated critically. If the inadequacies described for the risk assessments of the banned products cannot be addressed by proper scientific evidence, conclusions are that considerable uncertainties persist. Such risk assessments cannot be regarded as based on sufficient evidence according to scientific principles. Because these uncertainties are not taken into account and addressed in a sufficient way, the conclusions by the Scientific Committees that possible risks are negligible and safeguard measures therefore unwarranted are tangible in their substance. Given that the European Communities in their submissions support this view in acknowledging the Austrian concerns towards the risk assessments, these do not stand the test of being an adequate scientific evaluation according to provisions of the SPS agreement.
  Taking into account only the formal aspect of the conducted risk assessments does

not appreciate the call for a scientifically sound risk assessment as contained in the SPS agreement.

4.2 Identified shortcomings in risk assessments

The WTO Panel in all cases of safeguard measures reasoned that the initial risk assessments for those products were favourable and not changed upon assessment of the scientific evidence submitted by Austria.

Some of the material submitted (Spök et al. 2002; Spök et al. 2003) was considered to evaluate risk assessment procedures only and therefore not directly addressing the potential for adverse effects on human and animal health arising from the consumption of foods containing or consisting of specific GMOs, namely the ones which had been banned by the safeguard measures.

Nevertheless, the mentioned studies were addressing differences and shortcomings of the risk assessment by analysis and comparison of a large number of individual applications in the European Communities.
The studies consequently identify deficiencies in certain individual applications, including the applications for GM-Maize lines MON810 and T25, which are subject to challenged safeguard measures. The same arguments apply to Bt-176 in comparison with the risk assessment of this product by the Scientific Committee on Plants.
The studies were aimed to identify whether the risk assessments for the respective GMOs are addressing the potential for toxic effects and of allergenic properties in a scientifically sound way. An assessment of these properties is crucial for a risk assessment, and addressing them adequately is widely considered being very important for justifying a favourable opinion. The study is therefore wrongfully dismissed as relevant scientific evidence concerning supporting the Austrian safeguard measures.

The WTO Report is rightly addressing that the studies are showing ways to improve the risk assessment process as such. It is however necessary to note that this is only an additional merit, which is not devaluating the significance concerning insufficiencies of the risk assessments.

Besides this evidence, which is central for the judgement on the Austrian safeguard measures, there is **further evidence for relevant uncertainties** available to the WTO Panel, which needs to be taken into account. Such evidence relevant to a decision towards the Austrian safeguard measures is compiled in the submissions by the European Communities to the WTO Panel (WTO 2006, ANNEX I-4) concerning other important issues of the risk assessment.
The submissions demonstrate that additional issues invoked by countries enforcing safeguard measures were not considered by the Scientific Committees at all or not properly. For example these were:

- The **long-term environmental effects of herbicide-tolerant crops**, like T25 maize, on soil composition and the spread of herbicide-tolerance genes.
  This issue was not recognised as environmental risk, despite evidence demonstrating such effects for glyphosate-tolerant crops (Kremer et al. 2000, cited in WTO 2006, ANNEX I-4, Par.246). On the whole the issue was described as very complex, with no simple straightforward conclusions to be drawn (WTO 2006, ANNEX I-4, Par.208).
- The **effects on non-target organisms**, including indirect effects, of Bt-toxins expressed in GMOs like Bt176 and MON810 and conflicting evidence on development of resistance to Bt-toxins.
  It should be noted that the European Communities stated in respect to this question that the risk assessment by the Scientific Committee on Plants has to be interpreted as given the expressed need that further information concerning this risk should be collected through post-marketing monitoring (WTO 2006, ANNEX I-4, Par. 714). The European Communities furthermore criticised the risk

assessment by the Scientific Committee on Plants because it did not deal with multi-trophic interactions leading to effects on non target organisms and therefore did not adequately reflect the concerns of the regulators (WTO 2006, ANNEX I-4, Par.692) and the rejection of hypotheses concerning effects on certain non-target organisms in view of inconclusive results (WTO 2006, ANNEX I-4, Par.709).

- The **adequacy of Bt-resistance management and monitoring designs**. The consequences of poor monitoring plans in regards to these risks are also stressed in the submissions by the European Communities and underline the initial concerns submitted by Austrian in support of the safeguard measures.

In summary the evidence listed above suggests that the data on which the risk assessments by the Scientific Committees are based were insufficient for a conclusive assessment of the respective GMOs. The favourable opinions expressed as outcome of these risk assessments need to be re-evaluated with respect to the identified areas of uncertainty.
The European Commission backed this viewpoint of the Austrian authorities twofold: in their submissions to the WTO Panel (as referenced above), and by their commitment to improve the risk assessment procedures in a process which is currently underway and which reviews how opinions and risk assessments are prepared by EFSA and the respective Scientific Committees.

The ruling of the Panel that the safeguard measures were not in accordance with Art.5.7 was based on the argument that risk assessments by the Scientific Committees have been conducted.
In its ruling however no reference was made to the quality of these risk assessments with regard to their comprehensiveness, reference to the uncertainties encountered and the judgements adopted in view of inconclusive results. These substantive issues should be at the core of determining whether the scientific evidence was sufficient for a conclusive risk assessment, at least in cases of an unequivocally favourable opinion.

The Panel therefore overstressed the risk assessments by the Scientific Committees in their formal power, not reflecting on doubts on their substance.
In contrast the Austrian submissions were evaluated for their substance, without reflecting on the formal background as reasoned objections according to Art.16 of Dir. 90/220/EEC to the consents for certain GMOs based upon questionable opinions by the respective Scientific Committees.

4.3 Regional aspects to be considered

An important point in considerations towards the Austrian safeguard measures are references made to the insufficient information for an assessment of the risks according to regional ecological conditions.
Regional differences had not been reflected adequately in the risk assessments by the Scientific Committees that led to authorization of certain GMOs in the European Union. Nevertheless there are strong scientific indications that regional conditions are of crucial importance. References addressing such indications can be found in the WTO Panel expert opinions as well as in submissions by the European Communities to the Panel.

Some important issues given in the reasons by Austria for establishing safeguard measures in the case of Bt-176, MON810, and T25-Maize varieties touch upon open questions that are influenced by regional conditions to a great extent. The information necessary for such an assessment was - and in some cases is still - insufficient and therefore an assessment sufficiently addressing them could not been done. These issues need to be considered before arriving at a final ruling on the safeguard measures from the side of the European authorities as well as the WTO bodies.

The following list is summarising some of the issues, which warrant an assessment according to regional conditions.

- In a general analysis of the answers by the scientific experts to questions of the Panel the European Communities, based upon a consultation of scientists and experts in the respective fields, concluded:
  The **extrapolation and translation of limited risk assessment results** from the USA, Australia and other Non-European Countries is regarded as scientifically not reasonable (WTO 2006, ANNEX I-4, Par.139).
  Specifically the assessment of toxic effects of Bt-maize needs to be done with respect to regional characteristics of the growing environments, the scale of fields, crop management practices, regional target and non-target species of a specific region, and with regard to interactions with other crops and regional biodiversity. Regarding the Austrian safeguard measures these aspects have not been addressed adequately in the risk assessments prepared by the Scientific Committees, giving weight to the Austrian concerns.
- As submitted and acknowledged by the European Communities a **regional assessment of Bt crops under realistic ecological conditions** with appropriate testing methods and scales for assessment had not been conducted (WTO 2006, ANNEX I-4, Par.145). In accordance with that opinion the WTO Panel´s expert Dr. Andow stated that the progressive determination of such risks is recommended and a tiered approach necessary to sensibly approach the open questions. According to Dr. Andow such an approach has only been begun recently in Spain, China and the US. Conclusive results were therefore not available at the time when the safeguard measures were enforced by Austria.
  A scientifically sound approach to address regional conditions needs adequate baseline data for comparison. The submissions by the European Communities specifically indicated these prerequisites for an adequate assessment of GMO-crops under conditions which vary regionally (WTO 2006, ANNEX I-4, Par.706). Efforts to establish relevant baseline data are currently underway in Austria and were thus not available when enforcing the safeguard measures.
- Especially **specific information on non-target organisms**, which might be at risk in specific regions is insufficient according to Dr. Andows expert opinion. In accordance the submissions by the European Communities addressed the point made by Dr. Andow that the requests of the Spanish CA concerning region-specific information on which non-target organisms would be exposed to Bt crops were valid. The same argument applies to safeguard measures enforced by Austria and other EU Member countries: Without appropriate scientific information addressing the open questions regarding non-target organisms an objective assessment of related risks was not possible.
- Additionally the Panel´s expert Dr. Andows noted that there is considerate **uncertainty about information on target pest populations for specific regions**. Without a region-specific characterisation of the populations, which would be affected by Bt-crops, differences in Bt-sensitivities cannot be addressed. Therefore he acknowledged that on a case-by-case basis environmental concerns by Member States were scientifically justified (WTO 2006, ANNEX I-4, Par.448). According to this issue the risk assessment by the Scientific Committee on Plants did not address indications from laboratory studies in a region specific manner, leading to concerns from Austria, which seem to be justifiable according to submissions by the Panel´s scientific expert and the European Communities.
- Another issue subject to open questions regarding a region-specific assessment is the **regional risk for development and spread of resistance** (Bt-resistant herbivores in case of Bt-Maize varieties and herbicide-tolerant volunteer plants and weeds in case of HT crops).
  The European Communities again acknowledged the respective concerns relevant for the Austrian safeguard measures that these risks needs to be assessed according to the regional flora and fauna and in relation to the specific agronomical conditions of a region (WTO 2006, ANNEX I-4, Par.168, 198). The European Communities find that position supported by the WTO Panel´s expert Dr. Andow emphasising that relevant scientific questions concerning the proposed risk management strategies in relation to regional conditions for particular Bt-varieties were not answered (WTO 2006, ANNEX I-4, Par.168, 448).

This is in line with the Austrian concerns against Bt-176 and MON810. The safeguard measures reflect that these concerns were not addressed with respect to regional aspects in the risk assessments of these products.
Concerning the assessment of an increase of Bt-resistant herbivores the European Communities furthermore noted that the indirect effects on crop management (with possible negative environmental effects) needed to be considered on a regional scale (WTO 2006, ANNEX I-4, Par.693).
Again, this acknowledges concerns by Austria that have not been addressed in a specific risk assessment previously.

In summary the safeguard measures reflect the difficulties to address the effects of a particular GMO in a general risk assessment without addressing specifically regional aspects.

4.4 Conclusion

This review of the WTO Panel´s ruling shows that a number of substantive arguments in support of the Austrian safeguard measures have not been taken into account by the WTO Panel.
Since the European Communities support these arguments explicitly in their submissions and some of the arguments are supported by experts selected by the WTO Panel, it is reasonable to appeal against the WTO Panel decision.

With regard to the safeguard measures the appeal should address the open questions concerning

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

In general terms an appeal should address

- the different interpretations about precautionary measures given in the final report and preceding WTO decisions.
- the narrow definition of what is considered a risk assessment is severely limiting the possibilities to implement the precautionary principle
- the open questions regarding the interplay between WTO agreements and other Multilateral Environment Agreements such as the Cartagena Protocol, which should be mutually supportive, but were not taken into account in the interpretation of the relevant SPS provisions by the Panel.

These suggestions are supported by the results of analysis of the case by other authors and organisations (e.g. CIEL 2006; Shaw & Schwartz 2005).

4.5 References

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Endnotes Chapters 3 and 4

[1] Amicus Curiae Briefs:

Amicus Curiae Brief 1 (6.5.2004) by a group of academics: L. Busch (Michigan State Univ.), B. Wynne, R. Grove-White (both Lancaster Univ.), S. Jasanoff, D. Winickoff (both Harvard Univ.)
Amicus Curiae Brief 2 (27.45.2004) by a "Public Interest Amicus Coalition", comprising 15 public interest groups (represented by the Foundation for International Environmental Law and Development-FIELD)

Amicus Curiae Brief 3 (1.6.2004), by a group of five non-governmental groups (FOE-US, Defenders of Wildlife, IATP and OCA-USA, CIEL) represented by the Center for International Environmental Law-CIEL

[2] Amicus Curiae Brief 1 (6.5.2004) by a group of academics: L. Busch (Michigan State Univ.), B. Wynne, R. Grove-White (both Lancaster Univ.), S. Jasanoff, D. Winickoff (both Harvard Univ.)
[3] The Austrian safeguard measures were based on concerns in regard to the opinions by the Scientific Committee on Plants on risk assessment of the respective GMO-products according to Dir.90/220/EEC. The Scientific Committee on Plants subsequently published opinions in reply to the Austrian safeguard measures, before the WTO Panel was established.
In 2004 and 2006 the EFSA GMO Panel reviewed the Austrian safeguard measures according to Art.23 of Dir. 2001/18/EC.

5 The European Commission's acknowledgement of scientific uncertainty and controversy in GMO risk assessment

5.1 Preface

The analysis presented in this chapter does not attempt to provide insights to the WTO dispute nor does it draw conclusions that might inform possible options to act on the basis of the Dispute Panel's Report. Rather, it uses the material provided in the course of the WTO dispute to analyse to what extend the Commission is acknowledging scientific uncertainty in GMO risk assessment. Further EU policy measures including implementing decisions in the course of GM crop authorisations might be judged against this backdrop.

5.2 Introduction

The European Commission in its submissions to the WTO Panel has explicitly acknowledged scientific uncertainty and legitimate scientific controversies in many areas of possible environmental or health effects as well as for risk assessment approaches for GM crops. These acknowledgements stand in contrast to the advice provided by the European Commission's scientific committees, the SCP and the EFSA GMO Panel and the reassuring language of EU policymakers. The European Commission's arguments put into perspective the opinions of the SCP and EFSA on the Austrian import bans as well as its so far policy to lift the national bans.

This chapter provides and analyses examples that illustrate this contrast. Quotes from the WTO dispute are derived from the European Commission's submission to the WTO Panel commenting on the scientific advice given by external experts to the Panel (WTO 2006).

The quotes provided in this chapter are mainly derived from two contexts:

First, from cases of "undue delay" where an authorisation procedure of GM crops took much more time than foreseen in the timelines of the respective regulations because of questions from the European Commission's own scientific committees (Scientific Committee on Plants – SCP, Scientific Committee on Food – SCF) or from Member State CAs or from temporary suspension of the procedure. In this context the Commission explains the relevance of Member State's questions by drawing on the state of the art in the relevant sciences and on Codex and FAO/WHO Guidance documents.

Most of these quotes are taken from a submission of the European Commission to the WTO Dispute Panel in response to the statements made by the Panel's experts to questions posed by the Panel.

Second, from the reasoning for and subsequent statements of the SCP, SCF and EFSA on cases where Member States invoked national import bans for certain GM crops.

A general characteristic of both the Panel's expert's and the Commission's undertaking is that they are referring to the state of the art in the relevant sciences, i.e. the time period between June 1998 and August 2003. As a result, one could argue that the guidance documents referred to are already outdated and – on the basis of more recent scientific knowledge – have meanwhile been updated. Similarly, it could be argued that the associated scientific uncertainty has meanwhile be reduced and controversy resolved. If so, the endeavour of contrasting statements of the Commission and its Scientific Committees would be of historical interest only and would have no bearing on the presence.

This is, however, not the case.

[1] The European Commission is in fact referring to the most recent Codex Guidance and – in cases where there is only general guidance provided by Codex – also referring to FAO/WHO Guidance documents back to 2001 that are still of relevance in regulatory contexts. With respect to the state of the art, the Commission's statements are often referring to uncertainties and controversies that are still prevalent at present. This is partly implicit in the wording. The Commission is thereby referring to recent scientific evidence with a lot of references given from the years 2003 and 2004. This would generally leave little room for substantial improvements in knowledge. Furthermore,

many of the issues discussed are connected with more fundamental uncertainties and controversies that are still not resolved at present and are likely to persist.
It is beyond the scope of the project on which this chapter is based and would also occupy much more space to provide an investigation of timelines of evidence and events to more accurately single out the, as the author assumes on the basis of this analysis, few cases that are of historical importance only. The focus of this chapter lies on health risks and health risk assessment. Environmental aspects have already been dealt with in chapter 4.2 of this report.
The chapter is organised into three main sections, on toxicity assessment, allergenicity assessment and substantial equivalence (comparative analysis). A concluding section provides a brief analysis and conclusions.
Footnotes included in the quotes in the original document are provided in brackets within the quote. Some of the quotes have already been considered in a preceding report (DOLEZEL et al. 2006). Full quotes and/or full context of quotes is provided in the endnotes.

5.3 Highlighting scientific uncertainty and controversy

In an introductory section of it's WTO submission, the Commission explicitly acknowledged in areas of GM crop and food risks:

- Scientific and technical knowledge is incomplete and that there is limited experience.
- Risk issues are associated with new scientific issues that have not yet been studied remain at the forefront of scientific knowledge.
- There is a clear lack of consensus in the scientific circles and even extensive disagreement between experts.[2]
- Differences in data interpretation-disagreements on the science.[3]

Associated with this diagnosis the European Commission stated that

- It is not possible to "make definitive findings of fact in the face of such conflict of views or uncertainty, beyond indicating the existence of such differences or uncertainty." (par. 36)
- There is "absence of agreed criteria on many issues (in scientific and regulatory circles), including in respect of the information necessary to perform a risk assessment and, also, the manner in which to interpret the relevant data." (par. 37)
- "[T]here is no unique, absolute, scientific cut off threshold available to decide whether a GM product is safe or not (the risk assessment end point)." (par. 38)
- "In the face of uncertainty scientific subjectivity prevails."[4]

5.4 Toxicity assessment

A standard practice in GM crop toxicity assessment is to draw on acute toxicity tests of a bacterial protein, on in-vitro digestibility tests and homology comparison to known toxins, and on a history of safe use. No toxicity testing using the whole GM crop has been demanded until recently. This approach and how both testing and reasoning is done in practice and subsequently the availability of detailed guidance has frequently been criticised as not sufficient for a sound risk assessment (e.g. SPÖK et al. 2002, 2003b, 2004). This criticism has eventually led to changes in risk assessment requirements. Since 2003 the European Commission's scientific advisors are recommending 28-day repeated dose studies and explicitly disregarding acute toxicity tests as not providing meaningful information (SSC 2003, EFSA 2004a). The EFSA Guidance also asks for 90-day whole-plant/food studies in rodents.
EFSA, in general, does not propose toxicity data to be delivered as a kind of base set, i.e. required in any case. Rather, the studies required to investigate the toxicity of a newly expressed protein should be selected on a case-by-case basis, depending on the knowledge available with respect to the protein's source, function/activity and history of

human/animal consumption. In case of a history of safe consumption by humans and animals of both the plant and the new proteins toxicity testing might not be required (EFSA 2004a:27).For specific toxicity testing the Guidance says

> "[I]n the case of newly expressed proteins with an insufficient database and, in particular, if the available data suggest the existence of any cause for concern […] Repeated dose toxicity studies should be performed, unless reliable information can be provided which demonstrates the safety of the newly expressed protein (including its mode of action) and that the protein is not structurally and functionally related to proteins which have the potential to adversely affect human or animal health. Normally a 28-day oral toxicity study with the newly expressed protein in rodents should be performed according to OECD guideline 407 (OECD, 1995). Depending on the outcome of the 28-days toxicity study, additional targeted investigations may be required, including an analysis of immunotoxicity." (EFSA 2004a: 27)

Similarly, whole-food toxicity studies mentioned above are required if "the composition of the GM plant is modified substantially, or if there are any indications for the potential occurrence of unintended effects, based on the preceding molecular, compositional or phenotypic analysis" (ibid.: 29).
Neither what would constitute an "insufficient database" nor "the existence of any concern" in case of the novel proteins is detailed in the Guidance. Neither details are given what would be considered as a "substantial modification" of plant composition, nor what would be acknowledged as indication for unintended effects.
Only from practical examples of evaluating dossiers one can get some clues how these triggers are being interpreted by the Panel's scientists.
Most of the dossiers still include acute toxicity tests only (SPÖK et al. unpublished). In-vitro digestibility studies, homology comparisons and the reasoning for a history of safe use seem to be still very similar compared to routine practice in the early 1990ies.
Thus, the changes in requirements in the 2003 and 2004 Guidance are, so far, only reflected by an increase in 90-day whole-plant/food studies in most recent dossiers. EFSA only rarely seems to explicitly ask for this kind of studies. Applicants seem, however, to be explicitly willing to supply them whatsoever (see SPÖK et al., unpublished results).
In its recent submissions to the WTO Panel the European Commission did acknowledge, the validity of toxicological endpoints beyond acute toxicity testing, the need for whole-plant/food toxicity studies and the relevance of a history of safe use in the absence of both proper data on exposure and epidemiological studies.

5.4.1 Toxicity endpoints

In practice EFSA has so far in no case required a 28-day repeated dose study of the introduced protein (Spök et al., unpublished).
Repeated dose tests were only included for the PAT protein in the rape Ms8 x Rf3 dossiers, all other recent dossiers continued to include acute toxicity tests only.
EFSA did not explicitly state why these tests are assumed sufficient and whether toxicity tests would have been demanded at all, in each case.
Other toxicity relevant information on the novel protein of cause plays an important role, as does the history of dietary exposure and previous evaluation of the introduced protein in the context of other GM crops. This is however less obvious for proteins such as Cry1F, CryBb1, mCry3A, CryF1, Cry34Ab1, Cry35Ab1, GOXv247, Tn7 AAD 3' adenyltransferase, all of which are of bacterial origin.
In the case of maize NK603 the Panel stated that acute toxicity studies are generally not necessary for proteins with a "known history of safe human exposure" – which in this case refer to CP4 EPSPS (EFSA 2003a).
Nevertheless it still remains opaque what actually triggers a 28-day repeated dose study and from the above it appears that these proposals were established with something different in mind than the first generation of GM crops.
The European Commission, however, in its recent statements appears to put more emphasis on endpoints beyond acute toxicity:

> "[…] *chronic tests and other tests […] may often be necessary to assess acute and chronic and sub-chronic toxicity of new substances with no known history of safe*

> *food use*. Examples of relevant tests are mentioned in paragraph 39 of the mentioned Codex guidelines." (WTO 2006, par. 867)[5]

With respect to the fundamental criticism of the reliance on acute toxicity testing and the proposal of additional endpoints in SPÖK et al. (2002, 2003) the Commission, when discussing the justifications for the Austrian import bans, coincided 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." (WTO 2006, par. 718)[6]

However, the Commission also argued that Austrian (and other) regulators would be eligible to choose a level of protection appropriate to the public concern.

5.4.2 History of safe use

As described above the history of safe use and consumption of the introduced protein and of the plant used is considered an important requisite for risk assessment. It appears that a history of safe consumption (and perhaps not indications of concern from other protein safety relevant information) would even not require any toxicity testing. For the parental plants presently being used (maize rape, fodder beet, soybean, potato) a history of safe consumption is presumed and is underlying the principle of familiarity. If a GM crop is found substantially equivalent to its conventional counterpart, it is deemed as safe.
As has been criticised elsewhere, this concept of history of safe consumption relies on common and anecdotal knowledge. In the absence of epidemiological studies only very severe effects would have been detected (see also SPÖK et al. 2004). This is also true for proteins that have been used in food (e.g. Cry proteins as pesticide residues).
For proteins the issue is complicated by the fact that, e.g. in the case of Cry proteins there is a history of safe exposure of cell or protein suspensions including a variety of Cry proteins. It is difficult to verify if each of the Cry proteins presently used in GM crops have actually been included in the relevant tests. Furthermore, human and animal exposure is likely to differ with Bt biopesticides, as crystalline Bt proteins applied by spraying are susceptible to inactivation by UV light.
A second general problem is the absence of reliable data on human exposure of proteins or particular food products.
This calls for more caution when valuing a history of safe consumption and even replacing toxicity tests. The European Commission thus critically stated that

> "[S]tandard epidemiology says that, *in the absence of exposure data with respect to chronic conditions, there is simply no way of ascertaining any effect – or lack thereof – on human health"* (WTO 2006, par. 873).

The Commission further argued that

> "[A]s regards food safety, even if some GM products have been found to be safe and approved on a large scale […] *the lack of general surveillance and consequently of any exposure data and assessment, means that there is no data whatsoever available on the consumption of these products* – who has eaten what and when. Consequently, one can accept with a high degree of confidence that there is no acute toxicological risk posed by the relevant products, as this would probably not have gone undetected – even if one cannot rule out completely acute anaphylactic exceptional episodes. However, *in the absence of exposure data in respect of chronic conditions that are common, such as allergy and cancer, there simply is no way of ascertaining whether the introduction of GM products has had any other effect on human health." (*WTO 2006, *par. 45)*[7]

5.4.3 Whole food studies

In practice 90-day whole-plant toxicity studies were included in the majority of dossiers recently submitted to EFSA, e.g. in case of maize 1507, MON863 x MON810, MON863 x MON810 x NK603, MON863 x Nk603; MON863, MON863 x MON810, NK603. It appears that most of those studies have been included without being asked for by EFSA.
Conversely, EFSA did not consider whole food toxicity studies as necessary in case of maize Bt11, rape Ms8 x Rf3 and GT73 despite of such demands raised by Member States.

In case of rape GT73 the EFSA Panel concluded on the basis of absence of "relevant compositional differences", and on the basis of livestock feeding studies (three 28-day rat studies, two 10-week studies in salmons, two studies in quails, a 42-day broiler study, and a 21-day study in lambs) wholesomeness and the absence of toxicity (EFSA 2004b).
In case of Ms8 x Rf3 oilseed rape the Panel disregarded the need for 90-day whole food studies on the basis of the "extensive comparative assessment, showing the compositional and nutritional equivalence of Ms8 x Rf3 oilseed rape and its non GM counterpart" (EFSA 2005a).
In case of maize Bt11 the Panel concluded that no such studies are necessary because the compositional analysis, the molecular characterisation, and the phenotypic analysis did not reveal unintended differences, which was also confirmed by animal testing data from short term feeding studies: 14-day feeding study on laying hens, 42-day feeding study in broiler chickens, 14-day feeding study in high producing dairy cows (EFSA 2005b).
In case of stacked traits EFSA does not seem to require such studies on a routine basis. For instance, in case of maize MON 863 x MON 810 the Panel did not ask for a whole-food toxicity study since such studies had already been performed for the parental lines and did not show any evidence of unintended effects. Furthermore,

> "[G]iven the specific modes of action of the inserted Cry3Bb1 and Cry1Ab proteins, there is no expectation that the Cry proteins expressed in these plants would have pleiotropic effects either in isolation or in combination." (EFSA 2004c)

In contrast to EFSA, the European Commission emphasised the importance of whole-food toxicity studies:

> "[Whole feed/food studies should be performed in order to assess the potential health consequences of unintended effects, such as those may have been caused by the insertion of additional DNA fragments, beyond the intended modifications (e.g. transgenic proteins) that have been tested for toxicity." (WTO 2006, par. 557)[8]
>
> "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 […] As is well known, acute gavage with recombinant proteins and in vitro degradation of purified proteins have limited value; Alternatively, use of well established protocols for tolerance studies of pharmaceutical are available but sometimes difficult to follow; Whole food studies can and must be used to complement other safety testing approaches." (WTO 2006, par. 907-912)[9]

In certain cases where whole-food toxicity studies had been demanded by Member States the Commission acknowledged such requests as reasonable and providing "additional reassurance", e.g. in case of maize NK603

> "The US claims (3rd written rebuttal submission summary) that the request for chronic toxicity when acute studies show no effect are not warranted in the case of NK 603 […]. However, just to take one single example, in the case of maize NK603, there where two proteins were expressed (CP4EPSPS and CP4EPSPS L 214 P) and these acute toxicity tests were notably insufficient (See KÖNIG et al., 2004. Food Chem.Tox. 42-1047)." (WTO 2006, par. 907-912)[10]

Similarly the Commission in case of RR soybean states:

> "It was discovered in 2000 that unintended insertions of DNA fragments had occurred in these soybeans, which had already been approved as a GM food in a number of countries, including the EU. The applicant (Monsanto) itself argued that these additional fragments could not pose a risk, since, among others, no adverse effects had been observed in a previously published peer-reviewed animal feeding study with whole feed products derived from Roundup Ready soybeans (Monsanto (2000) Updated Molecular Characterization and Safety Assessment of Roundup Ready Soybean Event 40-3-2. Monsanto Co. St. Louis, 20 pp. http://archive.food.gov.uk/pdf_files/acnfp/summary.pdf).
>
> It is therefore justifiable of the lead CA that, in the absence of toxicity studies with whole foods, it sought additional reassurance for the innoxiousness of any

> unintended effects by asking for an additional animal toxicity experiment." (WTO 2006, par. 603-607)[11]

Animal feeding studies that are conducted for nutritional and agronomic purposes have long been criticised for being presented as if providing evidence for the absence of toxic properties (SPÖK et al. 2002). In a similar way the Commission pointed out that

> "[…] *the chicken broiler study is not a model for toxicology*, but for nutrition (for example, see the discussion on this issue in Chassy et al., 2004). During studies on broilers, the growth, bodyweight, feed consumption, and weight and composition of edible parts after slaughter are usually measured. Therefore, the toxicity animal studies had been limited to those on acute toxicity of purified Cry1F and PAT, and no toxicity studies with the whole food." (WTO 2006, par. 603-607)[12]

5.4.4 Test substance

The test protein for in-vitro digestibility and toxicity studies is in almost all cases derived from bacteria. It has been so far accepted by regulators that it is too burdensome and too expensive for applicants to produce these proteins from plants.
The EFSA Panel seems to prefer a microbial derived protein compared to plant derived material, for reasons of higher purity (referring to the examples of 92,6% and 53,9% respectively in case of Cry1Ab and Cry3Bb1, maize MON863 x MON810). The presence of a large amount of unknown concentrated extraction products would be a serious disadvantage for toxicological testing in case of plant derive proteins[13] (EFSA 2004c).
Another difficulty of this approach is the case if even the primary sequence of the proteins is not identical. For instance, in case of maize Bt11 the PAT protein was derived from E.coli but the dossiers did not include experimental evidences for the equivalence of recombinant PAT from Bt11 maize and E.coli, although it is stated by the applicant that they are identical. The dossier refers instead to previous studies conducted on the first Bt maize developed by Novartis where the PAT is encoded by the bar gene and not by the pat gene as in Bt11. However the two proteins were considered structurally and functionally equivalent based on their molecular weight, their rapid degradation and loss of enzymatic activity during in-vitro digestion with digestive stomach fluids from various species, their immuno cross reactivity and their characteristics in terms of enzymatic activity (EFSA 2005b).
In another case the NPTII protein expressed as a marker in potato was produced in E.coli. The applicant did not provide evidence of equivalence between the bacterial and the potato protein. Rather it was referred to E.coli NPTII and a protein from an entirely different potato line identified in earlier studies. This approach was accepted by the Panel despite the known differences between plants of protein processing (EFSA 2005c).
The Commission, in contrast to the EFSA Panel, highlighted the limitations of this approach by referring to the work of FREEZE & SCHUBERT (2004):

> "[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.[14]" (WTO 2006, par. 872)[15]

5.4.5 In-vitro digestibility studies

In-vitro digestibility studies used as evidence in toxicity as well as allergenicity studies have been criticised for methodological reasons and because of their limited relevance for what actually happens in-vivo (recently reviewed in DOLEZEL et al. 2006). The limited relevance of in-vitro studies has also been endorsed in several Opinions of the Scientific Committee on Plants (SCP 1998a,b, 2000) and the Scientific Steering Committee (SSC 2000).
EFSA, however, did not see any problems with the in-vitro digestibility tests and encouraged their use (EFSA 2004a). Evidence from the literature (e.g. CHOWDHURY et al. 2004, EINSPANIER et al. 2004) that novel proteins might pass through the intestinal tract

was evaluated by the GMO Panel but no explicit conclusions were drawn how this would impact the validity of digestibility studies (EFSA 2005b).
The European Commission, however, by explicitly drawing on CHOWDHURY et al. (2004) admitted that

> "[…] today we know that *when embedded within transgenic plant material Bt-proteins can pass even through the intestinal tract of cows.* The request made by the Italian authority was, therefore, well founded. *In reality, some experts consider that the data requested by the Italians on food chain should become routine information provided in approval documentation.*" (WTO 2006, par. 304)[16]

5.5 Allergenicity assessment

Since about 2001 weaknesses in the so far used decision-tree approach to allergenicity assessment became more apparent (e.g. FAO/WHO 2001, Spök et al. 2003a), scientists have started to critically review the approach (see e.g. HASLBERGER & JANK 2003, HASLBERGER 2003, STADLER & STADLER 2002, SPÖK et al. 2002, 2003a, 2004, 2005).
As a matter of fact the language used in recent guidance documents has become more cautions about the validity of the presently used approach (SSC 2003, EFSA 2004a, CODEX ALIMENTARIUS 2003). However, by re-interpreting the decision-tree into a weight-of-evidence approach guidance has become more fuzzy about the particular tests required for allergenicity assessment (e.g. EFSA 2004a).
In practice, applicants have largely continued to provide the same type of data compared to the early 1990ies (SPÖK et al. 2004, unpublished). Still, the source of the gene, homology comparisons of the introduced protein to known allergens, and in-vitro digestibility studies are being accepted as sufficient scientific evidence for allergenicity assessment.
As a consequence of the controversy on reasonable and legitimate approaches in GMO allergenicity assessment EU Member States have raised doubts on the presently applied approach and started to ask for more and extended tests in the context of Directive 2001/18/EC and Regulation 1829/2003 authorisation procedures (e.g. in the case of maize NK603 authorisation procedure; EFSA 2003a,b). While EFSA in principle acknowledged that no single method of those so far used would yield "decisive evidence" for allergenicity, it did not see a reason to abandon the presently used strategy:

> "The Panel is not aware of any new information on allergenicity which requires a change of this opinion. Nor is the Panel aware of any new tests which produce more relevant or accurate information on possible allergenicity of the protein and which provide a higher guarantee of safety". (EFSA 2003a,b)

In dealing with these requests, EFSA has started in its opinions to explicitly consider the possibility that the allergenic potential of whole GM crop can be altered as a consequence of unintended effects of the genetic modification and inhalation as a relevant route for exposure by introducing subsections or paragraphs in their opinions. However, in no case this has led EFSA to ask for whole-plant/allergenicity testing.
In its recent submission to the WTO Panel the European Commission, in contrast, appears to consider more seriously the uncertainty and controversy associated with allergenicity assessment and the shortcomings in the presently applied approach:

> "There has also been discrepancy between experts in general about allergenicity testing schemes. Even the present strategy based on a sequence prediction model established by FAO/WHO was contradicted by important groups [reference to Stadler & Stadler 2003]. Difficulties raised by the current approach are summarised in Jank & Haslberger, 2003. Whereas a general decision tree is generally accepted many experts consider it often sufficient to do sequence homology search and stability testing, whereas some experts also in some of these cases ask for more testing. Also the ways to perform the sequence homology search is under dispute. This idea is not fully explained in CODEX but there are elements in it and the latest FAO/WHO expert consultations address it more clearly (CAC/ GL 45-2003 and its annex; Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology, 2001)." (WTO 2006, par. 868-870)[17]

5.5.1 Inhalation as a relevant route of exposure

Inhalation of pollen as well as dust or flour of plant material constitutes a very important route of sensitisation to plant proteins. Inhalation is also relevant for allergic respiratory diseases in both occupational settings (e.g. dust, flour) and for a broad range of individuals exposed to pollen. Beyond the limited relevance of digestibility (recently reviewed in Dolezel et al. 2006) in case of inhalation the protein is not subjected to digestive enzymes and hydrolytic cleavage or denaturation by low pH.
EFSA has so far not considered inhalation as a relevant route of exposure.
Allergy to maize is considered by the GMO Panel (both for exposure as food and via inhalation) as very rare. Thus, possible over-expression of any endogenous plant allergen is deemed unlikely to alter the overall allergenicity of the plant (e.g. EFSA 2005d).
The case of rape pollen was not considered an issue because the GM crop was not intended for cultivation. Allergy from rape dust or flour was in principle acknowledged as an issue because of evidence from the scientific literature.[18] Still, occupational risks were not considered relevant in the context of rape GT73, since the number of reported cases is considered low and "there is no information whether the genetic modification might alter the allergenicity of the GM oilseed rape" (EFSA 2004b).
Evidence on occupational allergy from Bt spores was also not considered relevant by the Scientific Committee on Food (SCF 2000) when brought up by the Italian CA as supportive evidence to suspend the marketing of four maize varieties (Bt11, MON810, MON809 and T25) under the Novel Food Regulation. The Commission, in contrast, seem to attach more importance to the same evidence of occupational risks:

> "The European Communities also notes that there are some important toxicological issues […] For instance, the recently published observation on occupational allergy to Bt bacterium spores in farmers using Bt pesticides mentioned by the SCF and by Italy[19]" (WTO 2006, par. 757)[20]

5.5.2 Allergenic risks of the whole-plant

In its comments to risk assessment dossiers under Directive 2001/18/EC and Regulation 1829/2003 Austria repeatedly pointed to the possibility of elevated allergenicity of the whole plant as a consequence of possible up-regulation of endogenous plant allergens.
Only recently (since 2004) the EFSA GMO Panel has explicitly acknowledged endogenous plant allergens as a risk source. Nevertheless, the Panel disregarded this kind of risks in case of maize because allergies against maize are only rarely occurring (see above).
Similarly, in case of rape the Panel considered the numbers of allergenic reactions as very small and – given the small number of available sera– as practically very difficult to comparatively assess such differences (EFSA 2004b).
The European Commission, however, used a more cautious language and put more emphasis on comparative allergenicity testing.

> "Even if a given protein per se does not represent an allergen, its expression in another host organism may indirectly upregulate the expression of potential allergens. It is therefore recommended to compare the engineered plant/plant product with that of the parent/wildtype plant/plant product regarding IgE reactivity to establish whether the transgenic organism represents a more potent allergen source than the parent/wildtype organism for already sensitized patients. The potentially increased ability of the transgenic organism versus the parent/wildtype organism to induce de novo IgE responses (i.e. allergic sensitization) needs to be compared by immunization experiments." (WTO 2006, par. 716)[21]

Moreover, in the view of the Commission endogenous plant allergens should be included in the comparative analysis:

> "[P]otential alterations of intrinsic allergens (which were already present in the GM organism before it became modified) should be considered during the comparative safety assessment (also called "substantial equivalence"). This is because the genetic modification might unintendedly have changed this intrinsic allergenicity of the plant. Intrinsic allergens are mentioned, for example, in the Codex guideline section dealing with compositional analysis of key components, as footnote 5 to paragraph 44: "Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic

potency and level may be significant to health (e.g. solanine in potatoes if the level is increased, selenium in wheat) and allergens." (WTO 2006, par. 473)[22]

5.5.3 Serum testing

The use of specific and targeted serum screening constitute important tests in the course of allergenicity assessment which are included in the FAO/WHO, Codex Alimentarius and EFSA Guidance (CODEX ALIMENTARIUS 2003,FAO/WHO 2001, EFSA 2004a). A positive homology screen or in case of a protein from an allergenic source a specific serum screen should be conducted, e.g. according to Codex. For targeted serum screening the situation is more complex. Whereas a negative homology search would be followed be a targeted serum screening according to FAO/WHO 2001, is not clarified what would trigger a targeted serum in the Codex and EFSA Guidance. As these experiments are normally not included in the EU risk assessment dossiers and are even not briefly mentioned in EFSA opinions the issue remained unresolved, so far.

The lack of clarity about possible triggers for serum screening is also emphasised by the Commission:

> "In the present case [maize GA21], thus, whereas some data on sequence analysis and stability were provided by the applicant, the request of the CA for further allergenicity tests reflected the scientific dispute for a need of improved assessment methods as reflected in turn in the above documents. It is to be noted that the Codex does not provide for a final harmonised and agreed guidance as regards the assessment of allergenicity that would restrict the analysis to the two tests [homology comparison, digestibility studies] […]." (WTO 2006, par. 515)[23]

The language of the Commission on these issues is ambiguous, though. On one hand the Commission seems to interpret the Codex Guidance along the lines of the FAO/WHO 2001 Consultation and to describe serum testing as if it would be an almost standard requirement if the homology search does not reveal any positive results:

> "If no significant sequence homology is identified, then targeted serum screening is conducted with serum samples that contain high levels of IgE antibodies with a specificity that is broadly related to the gene source. If the targeted serum screening is positive, then the protein is considered likely allergenic. If the targeted serum screening is negative, then pepsin resistance of the expressed protein and the immunogenicity of the expressed protein in suitable animal models.
>
> The latest FAO/WHO consultation on GM foods of 2003 agrees that it has been recognized that there is no single parameter that can predict the allergenic potential of a substance. A strategy to assess allergenicity of biotechnology products has been formulated (FAO/WHO, 2001; CODEX ALIMENTARIUS COMMISSION, 2003), which relies on the parameters: source of the gene, sequence homology, serum testing of patients known to be allergenic to the source organism or to sources distantly related, pepsin resistance, the prevalence of the trait and assessment using animal models." (WTO 2006, par. 395-396)[24]

Related, elsewhere in the text:

> "The first step is a database search for an allergen with a homologous amino acid sequence, according to the principles described in Section 6.1. If this search reveals a level of homology with a known allergen that suggests a potential for cross-reactivity, the expressed protein is considered to be an allergenic risk. No further evaluation for allergenicity would typically be necessary. The second step is conducted if no such homologous protein is found. In such cases, cross-reactivity is tested with a panel of serum samples that contain high levels of IgE antibodies with a specificity that is broadly related to the gene source (Section 6.3)." (WTO 2006, par. 511-515)[25]

The Commission also stated that Austria in asking for such tests in the case of the authorisation procedure of maize NK603 had been following the recommendations of an FAO/WHO Expert Consultation on the Allergenicity of Genetically Modified Foods which in turn provided input to a Codex Consultation (FAO/WHO 2001, Codex Alimentarius 2003 quoted from WTO 2006, par. 469).[26]

> "The FAO/WHO Expert Consultation devised a decision tree approach for the testing of potential allergenicity of GM foods, in which serum screening was one of the steps that had to be followed. Serum screening could be either specific (if the foreign gene was from an allergenic source, and therefore sera directed against this allergen should be used) or targeted (if the gene was from a source unknown to be allergenic, and therefore sera against broadly related allergens should be used). […] Austria's question for the serum binding tests was therefore relevant at that time." (WTO 2006, par. 472)[27]

On the other hand, the Commission's statements ("at that time") seem to imply that the FAO/WHO 2001 view is no longer relevant. Elsewhere in the text, the Commission provides examples what might serve as particular triggers for serum studies:

> "The requirement of tests including antibodies/sera is widely accepted in unclear situations nowadays. The assessment of the consequences of a new ORF with a potential protein with no history in risk assessment or food safety is certainly a case where additional testing is required according to the Codex Guideline." (WTO 2006, par. 398)[28]

A targeted serum screen of the introduced protein would be triggered in case of maize NK603 which harbours two slightly different versions of the CP4 EPSPS protein.

> "Within this approach, a targeted serum screening should have been carried out with the transgenic EPSPS proteins from maize NK603." (WTO 2006, par. 472)[29]

5.5.4 Level of expression

Low level of expression of the heterologous protein in plants has frequently being used by applicants as a safety argument. This has repeatedly been criticised (e.g. FAO/WHO 2001, SPÖK et al. 2005). Expression levels of allergens can vary depending on the particular variety, on plant growth, developmental stages, tissue-specific expression and environmental stress.

The level of expression has neither been explicitly endorsed nor disregarded as an valid indicator for allergenicity by the EFSA Guidance (EFSA 2004a) nor was if mentioned in EFSA Opinions. It has, however, frequently been found when investigating Risk Assessment compiled between 1995 and 2001.[30] EFSA, when evaluating more recent applications, is still partly drawing on the risk assessments conducted in these and even older dossiers, e.g. in case of GMO hybrids the single traits of which had been evaluated before.

The European Commission, however, recently reiterated this criticism by explicitly acknowledging that level of expression does not provide meaningful information for allergenicity assessment:

> "A report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology, 2001, concluded that: 5.6.1. Level of expression Highly allergenic proteins are often expressed at relatively high levels. However, allergens can sensitize susceptible individuals at less than milligram levels, possibly at less than microgram levels (SORVA et al., 1994; JARVINEN et al., 1999). ….Thus, level of expression cannot yet be incorporated into the assessment of the allergenicity of genetically modified foods." (WTO 2006, par. 395)[31]

5.5.5 Homology comparisons

Homology comparison of the introduced protein sequence to known allergens is a standard requirement included in all relevant risk assessment guidance documents. Homology comparisons have been criticised for several reasons including possible differences in outcomes depending on the search algorithm applied. These shortcomings may lead to false negative and false positive results (SPÖK et al. 2002, 2005).

However, this criticism has never been reflected in EFSA Opinions nor does the EFSA Guidance (EFSA 2004b) in its most recent update include any details to avoid problems with homology comparisons.

The European Commission, general more critical with respect to the present approach of allergenicity assessment, is referring to an FAO/WHO consultation that points to the limitation of the sequence databases for not being up to date:

> "6.1. Sequence Homology as Derived from Allergen Databases: The commonly used protein databases (PIR, SwissProt and TrEMBL) contain the amino acid

> sequences of most allergens for which this information is known. However, these databases are currently not fully up-to-date." (FAO/WHO 2001 cf WTO 2006, par. 395)[32]

EFSA is frequently drawing on homology comparisons conducted in the first half of the 1990ies (e.g. in case of hybrid events and of proteins that have already been evaluated before).
Furthermore, the Commission was emphasising methodological limitations by pointing to the work of STADLER & STADLER (2003) highlighting the inaccuracy of the presently used methods for sequence comparisons:

> "Even the present strategy based on a sequence prediction model established by FAO/WHO was contradicted by important groups. (Stadler and Stadler, Allergenicity prediction by protein sequence, FASEB, J 2003, 17, 9, 1141-3. Difficulties in the concept are summarised in Jank and Haslberger, Improved evaluation of potential allergens in GM food, Trends Biotechnol., 2003, 21, 6, 249-250)." (WTO 2006, par. 395-398)[33]

5.5.6 In-vitro digestibility testing

See Section "In-vitro digestibility studies", p.40.

5.5.7 Test substance

See Section "Test substance", p. 40.

5.6 Substantial equivalence

Since its inception in the early 1990ies, the concept of substantial equivalence has been at the heart of risk assessment by establishing a normative baseline (conventional crops with a known history of safe use/consumption) and by guiding risk assessment.
From its outset the concept has attracted a lot of criticism for conceptual reasons and how it is put into practice. Substantial equivalence has also undergone several changes in interpretation and role in risk assessment (reviewed in e.g. SPÖK et al. 2003b, LEVIDOW et al. 2007, LEVIDOW & SPÖK, manuscript submitted).
A key aspect of the concept of substantial equivalence is to detect any unintended effects of the genetic modification by comparative analysis .
EFSA has recently more humbly reinterpreted the concept as "comparative analysis" (EFSA 2004a), i.e. a strategy searching for differences which avoids the difficulty of its interpretation as an endpoint, considering two plants as substantially equivalent.
EFSA has so far not acknowledged any difficulties or problems with the concept. In contrast, the European Commission acknowledged:

> "The difficulties with substantial equivalence is at least three fold: (i) it may largely overlook significant and numerous differences in composition that may remain undetected, (ii) it is often used as an endpoint, rather than a starting point of the risk assessment, and (iii) it is a essentially only a series of chemical tests, which establish gross differences or similarities (but within the broad range of values for that species, including the less safe ones as regards toxicants or antinutrients), but by no means able to test or demonstrate biological effects (The brain from a mad cow showing advanced spongiform encephalopathy would pass a test of substantial equivalence undetected!), which would be the most relevant criteria." (WTO 2006, par. 876)[34]

Furthermore, the Commission is pointing to the work of ROESSNER et al. (2001) who describe a large number of significant changes in metabolism following a genetic modification in potatoes.

> "Very large number of changes of endogenous metabolites may occur as a consequence of the genetic modification. Such unintended changes in GM crops could be detected by metabolic profiling, but would remain silent according to a standard substantial equivalence test, as proposed by the US. For instance, ROESSNER et al. (2001) have detected by metabolic profiling a very large amount of significant unintended changes in GM potato, many more than previously assumed. 9 novel compounds were detected in GM potato tubers not found in the control plants, and more than half of the 88 plant chemicals measured had been

altered (levels) as a consequence of the genetic modification." (WTO 2006, par. 877) [35]

Such results are difficult to interpret, according to the Commission. Nevertheless, such cases highlight the limitations of the concept of substantial equivalence to search for unintended effects.

There has also been a lot of methodological criticism (see also SPÖK et al. 2004). The European Commission mentions a number of items that had been brought up by Member States in the course of evaluating risk assessment dossiers, including

- statistical analysis (par. 424)[36]: e.g. to allow detection of effects independent from herbicide in herbicide tolerant crops (par. 530)[37]; could not be conducted because plot size too small (par. 305);[38]
- herbicides used in the experiments (par. 424)[39]: information on herbicide treatment of plant material for samples is relevant (par. 586)[40]; comparison of GM crop with both its treated and non-treated counterpart (par. 528-529);[41]
- size of samples taken for analysis (par. 424);[42]
- field trial design: e.g. number of seasons (par. 597-600); [43]
- potential cross-contamination (par. 424);[44]
- geographical representativeness of field trials: comparability of Canadian with European conditions (par. 424)[45]; field trials in France, Italy and Chile were not deemed representative for cultivar regions importing maize to the EU (WTO 2006, par. 439-442).[46]

5.7 Discussion and conclusions

The European Commission has only rarely made statements on the scientific and more substantive aspects of GMO risk assessment. Usually, EFSA and the preceding Scientific Committees have been communicating on these aspects. Therefore, the documents exchanged in the course of the WTO dispute provide a rare insight into the Commission's view on the science behind risk assessment.

EFSA and its preceding Scientific Committees frequently considered arguments from and questions raised by Member States and critical scientists as not relevant to the risk assessment. The final conclusions usually was that there is no safety concern associated with these GMO products and the Commission always followed their advice in the course of authorisation procedures. This is true for both drafting decisions for market authorisation and eventually deciding despite the failure to reach such a decision in the Standing Committee or in the Council of Ministers. It is also true for its policy on the import bans, where the Commission has based its demand for lifting the ban on advice from EFSA.

In contrast, the Commission appears to more seriously consider those arguments in its submissions to the WTO Panel. This is also true for the scientific reasoning provided from Member States to justify their import bans, including the case of Austria.

The EFSA Guidance (EFSA 2004a) describes the identification of attendant scientific uncertainties as being part of the risk assessment. According to EU environmental legislation, environmental risk assessments are required to identify areas of uncertainty. In none of its scientific opinions, however, did EFSA explicitly acknowledge scientific uncertainty or controversy, suggesting that there were/are no uncertainties or controversies perceived by EFSA. In contrast, the Commission, before the WTO Panel, explicitly acknowledged and highlighted, that there was and still is uncertainty and legitimate controversy.

The original motivation for the Commission to do so was perhaps to justify its own precautionary regulatory system as well as lengthy and suspended market authorisation procedures for GMO crops in the EU that have caused, as the Panel views it, "undue delay" as well as national import bans (LEVIDOW & MURPHY 2006, CIEL 2006).

In doing so, however, the Commission highlighted more fundamental uncertainties and controversies most of which are still prevalent at present. These uncertainties are identified in risk assessment approaches (e.g. allergenicity testing, concepts (e.g.

substantial equivalence), methods (e.g. test substances from microbial origin), scope of risk assessment (e.g. inhalation as exposure route) and validity of data and methods (e.g. statistical evaluation in comparative analysis).
The acknowledgement of uncertainty and controversy is important in a twofold respect. First, it renders the risk assessment conclusions of EFSA and preceding Scientific Committees less robust than they had been officially portrayed. Second, it emphasises the legitimacy of competing scientific views and pulls the trigger for precautionary risk management decisions. Third, it suggests that EFSA has not appropriately considered scientific uncertainty and controversy in the view of the Commission. This conclusion is also backed-up by the criticisms raised by Commission members and calls on improvement of the risk assessment procedure (EC 2006).
On a more substantive level, some of the uncertainties and controversies acknowledged are in line with the arguments raised by the Austrian CAs in the cause of GMO authorisation procedures and general criticism raised by Austrian scientists (SPÖK et al. 2002, 2003a, 2005). This does not mean though, that the Commission is bluntly subscribing to the arguments brought up by Austria. In fact the careful wording used by the Commission (e.g. "scientific evidence insufficient from the perspective of the Member State"; c.f. CIEL 2006) opens up room for manoeuvre in subsequent discussions.
Furthermore, the analysis provides insight into the Commission's interpretations of Codex Alimentarius and FAO/WHO Guidance. The Commission is frequently referring to and is thereby interpreting these Guidance documents.
As these aspects are at the heart of an intense EU policy controversy this preliminary conclusions would therefore warrant a more in-depth study of these apparently contradicting views from the EU administration and should especially include the environmental aspects.

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Endnotes Chapter 5

[1] The possible exception might be particular points where the Commission is pointing to that was knowledge available at that particular time of e.g. a request for further data of a Member State CA. This kind of explicit reference is rare but would, of course, deserve special attention in the analysis.

[2] "[…] the scientific or technical knowledge is often not complete, due to the novel character of the GM products in dispute, or the fact that the empirical and limited experience gained in one type of system […]

some issues have not yet been studied at all, that the products in dispute have regularly given rise to many new questions in the last ten years, and that they remain at the forefront of scientific knowledge, both in terms of risks and benefits. […]

an absence of scientific evidence does not constitute evidence of an absence of impacts or risks. This is in particular important in the case of these novel products, when a

relevant new scientific issue, raised in the context of these GM products' assessments, has even not yet been studied, or not studied with proper scientific methodologies. […]

there is extensive disagreement between the experts or with independent scientists. This indicates a clear lack of consensus in the scientific circles on the issues at stake in these proceedings. This lack of consensus is partly explained by the questions addressed below. The European Communities considers that the Panel cannot make definitive findings of fact in the face of such conflict of views or uncertainty, beyond indicating the existence of such differences or uncertainty. […]

the absence of agreed criteria on many issues (in scientific and regulatory circles), including in respect of the information necessary to perform a risk assessment and, also, the manner in which to interpret the relevant data."(III. GENERAL AND METHODOLOGICAL ISSUES, par. 31-37)

[3] "Another source of the experts divergent conclusions derives from differences in data interpretation – disagreements on the science. Differences of individual experts' arguments and approaches leading to their scientific advice, which is sometimes conflicting despite being faced with the same sets of scientific facts and data, illustrates the subjective character of the Panel's experts' and other scientists' opinions in this field. This indicates that the scientific data at stake requires a substantial amount of scientific interpretation. It also confirms that the novel character of these GM products and the new issues they raise may require a different approach, and that any interpretation cannot be based on agreed criteria and methodologies or on a non-existent scientific consensus." (III. GENERAL AND METHODOLOGICAL ISSUES, par. 39)

[4] "[T]here is no unique, absolute, scientific cut off threshold available to decide whether a GM product is safe or not (the risk assessment end point).

[…] to decide when the available data is sufficient to conclude that an element of the risk assessment is adequate or not still involves the judgement of experts (ideally this should be expertise which is independent of the regulatory authorities and the legislator, as recommended by the Codex guidance on risk analysis).

[…] experts may disagree on whether there is a sufficiency of information (as they do in the present case very frequently) without necessarily disagreeing on the science. There may be a legitimate difference of view not on what is the state of scientific knowledge, but how it is to be applied to a particular set of facts. It is clear that, expert judgement and subjectivity are important elements of a science based risk assessment. In this regard, it appears rather clearly from Dr. Healy's considerations that she often believes that the information available for a specific dossier may have been sufficient to reach a positive conclusion; yet she may still agree remaining uncertainties exist and have been identified. In her approach these are of low significance – she may be less cautious (or precautionary) than another expert -, while other experts, on the same data, may have an equally valid judgement and reach a different conclusion as to the consequences to be drawn from such uncertainties. They may, for example, conclude that further information is necessary to try eliminate uncertainties to a greater extent." (III. GENERAL AND METHODOLOGICAL ISSUES, par. 38)

[5] VIII. THE PANEL'S ADDITIONAL QUESTIONS, Question 111. Please provide an assessment of the US statements regarding the evaluation of the safety of biotech products in paragraphs 128-133 of the US Supplementary Rebuttal Submission, and in particular of the statement in the last sentence of paragraph 133 that: ""... where all of the data consistently provide no indication of adverse effects, and there is no specific indication that the data submitted are inadequate, there is generally no reason to expect that any remaining risk as gone undetected, and that further studies are warranted".

What relevance does the foreseen end product use(s) have in the context of the evaluation of the safety of that product?

Codex: "Potential toxicity of non-protein substances that have not been safely consumed in food should be assessed on a case-by-case basis depending on the identity and biological function in the plant of the substance and dietary exposure. The type of studies to be performed may include studies on metabolism, toxicokinetics, sub-chronic toxicity, chronic toxicity/carcinogenicity, reproduction and development toxicity according to the traditional toxicological approach."

[6] VI. THE PANEL'S QUESTIONS ON ISSUE 2 ("SAFEGUARD MEASURES") (NOS 59 TO 95) E. MAIZE MON 810 (NOTIFICATION C/F/95/12-02) (AUSTRIA, ITALY) (QUESTIONS 78 TO 80).

[7] III. GENERAL AND METHODOLOGICAL ISSUES, M. SURVEILLANCE AND FOOD SAFETY.

[8] Monsanto Roundup Ready corn (GA 21) C/ES/98/01 (EC chronology 78), C/GB/97/M3/2 (EC chronology 85), Question 44. Given the information before the Panel, including the notification (EC-94/At.1-3), was the information requested by the Netherlands(EC-94/At.12) concerning molecular characterization, DNA sequence analysis of the insertion event, analysis of protein levels, effect of glyphosphate treatment, composition, toxicology and the request for a study on dairy cows necessary to ensure that conclusions of the safety assessment were valid?

[9] VIII. THE PANEL'S ADDITIONAL QUESTIONS, Question 113. Please provide an assessment of the statements regarding the purpose and use of whole food studies in paragraphs 142-144 of the US Supplemental Rebuttal Submission. What relevance does the foreseen end product use(s) have in the context of using whole food studies in the evaluation of the safety of that product?

[10] VIII. THE PANEL'S ADDITIONAL QUESTIONS, Question 113. Please provide an assessment of the statements regarding the purpose and use of whole food studies in paragraphs 142-144 of the US Supplemental Rebuttal Submission. What relevance does the foreseen end product use(s) have in the context of using whole food studies in the evaluation of the safety of that product?

[11] Question 51. Given the information before the Panel, including the application (EC-95/At.1-2) and the responses from Pioneer/Dow AgroSciences (EC-95/At.10-12), was information regarding molecular characterization, compositional analyses and toxicological analyses of the product requested by the Health Council of the Netherlands (EC-95/At.8 and 13) necessary to ensure that conclusions of the safety assessment were valid?

[12] Question 51. Given the information before the Panel, including the application (EC-95/At.1-2) and the responses from Pioneer/Dow AgroSciences (EC-95/At.10-12), was information regarding molecular characterization, compositional analyses and toxicological analyses of the product requested by the Health Council of the Netherlands (EC-95/At.8 and 13) necessary to ensure that conclusions of the safety assessment were valid?

[13] The latter point deserves critical attention. Even if in crude protein concentrates all kind of plant substances might be present it is difficult to consider this a disadvantage if on the on other hand bacterial protein concentrates are accepted that include 50% of other substances.

[14] This may require the isolation of the new substance from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case, the material should be shown to be biochemically, structurally, and functionally equivalent to that produced in the recombinant-DNA plant.

[15] VIII. THE PANEL'S ADDITIONAL QUESTIONS, Question 111.

[16] Bayer oilseed rape (Falcon GS40/90) C/DE/96/05 (EC chronology 62), Question 10. Given the information before the Panel, including the notification by AgrEvo (EC-62/At.1-30) EC SCP's opinion (EC-62/At.74), was the information to assess the long-term effect of expressed protein on the biogeochemical cycle and the food chain requested by the Italian (EC-62/At.95) necessary to ensure that conclusions of the safety assessment were valid?

[17] VIII. THE PANEL'S ADDITIONAL QUESTIONS, Question 111.

[18] Suh et al. (1998); Monsalve et al. (1997), cited from the EFSA Opinion.

[19] Presumably the paper of Bernstein et al. (1999).

[20] G. MAIZE MON 809 (NOTIFICATION C/F/95/12-01/B) (ITALY), (QUESTIONS 90 TO 92).

[21] VI. THE PANEL'S QUESTIONS ON ISSUE 2 ("SAFEGUARD MEASURES"), (NOS 59 TO 95), E. MAIZE MON 810 (NOTIFICATION C/F/95/12-02) (AUSTRIA, ITALY), (Questions 78 to 80).

[22] Monsanto Roundup Ready corn (NK603) C/ES/00/01 (EC chronology 76), Question 39bis. Given the information before the Panel, including the notification and additional letter from Monsanto providing additional information (previously referenced and EC-76/At.11-12), was additional information regarding allergenicity studies and PCR tests requested by Austria (EC-76/At.44) necessary or useful to ensure that conclusions of the safety assessment were valid?

[23] Monsanto Roundup Ready corn (GA 21) C/ES/98/01 (EC chronology 78), C/GB/97/M3/2 (EC chronology 85), Question 43. Given the information before the Panel, including the notification and additional information provided by the notifier (EC-88/At.10, 11, 13, 14, 15, 16, and 18-26), was the information regarding molecular characterisation and allergenicity of event '77' requested by the lead CA (EC-88/At.27-28) necessary to ensure that conclusions of the safety assessment were valid?

[24] Amylogene starch potato C/SE/96/3501 (EC chronology 67), Question 25. Given the information before the Panel, including the application (EC-67/At.13-44), and additional information provided by the notifier (EC-67/At.51, 57, 61-63, 75-83, 87, 92-93, 94-95, 101, and 103), was the information regarding molecular characterisation, toxicity, protein analysis, animal feed trials, effects on non-target organisms, bleomycin resistance, and substantial equivalence requested by the Scientific Committee for Food (SCF) (EC-67/At.84-86, 96, 98, 100, 102, 104, 105 and 106), necessary to support a valid safety assessment?

[25] Monsanto Roundup Ready corn (GA 21) C/ES/98/01 (EC chronology 78), C/GB/97/M3/2 (EC chronology 85), Question 43. Given the information before the Panel, including the notification and additional information provided by the notifier (EC-88/At.10, 11, 13, 14, 15, 16, and 18-26), was the information regarding molecular characterisation and allergenicity of event '77' requested by the lead CA (EC-88/At.27-28) necessary to ensure that conclusions of the safety assessment were valid?

[26] Monsanto Roundup Ready corn (NK603) C/ES/00/01 (EC chronology 76), Question 39bis. Given the information before the Panel, including the notification and additional letter from Monsanto providing additional information (previously referenced and EC-76/At.11-12), was additional information regarding allergenicity studies and PCR tests requested by Austria (EC-76/At.44) necessary or useful to ensure that conclusions of the safety assessment were valid?

[27] Monsanto Roundup Ready corn (NK603) C/ES/00/01 (EC chronology 76), Question 39bis. Given the information before the Panel, including the notification and additional letter from Monsanto providing additional information (previously referenced and EC-76/At.11-12), was additional information regarding allergenicity studies and PCR tests requested by Austria (EC-76/At.44) necessary or useful to ensure that conclusions of the safety assessment were valid?

[28] Amylogene starch potato C/SE/96/3501 (EC chronology 67), Question 25. Given the information before the Panel, including the application (EC-67/At.13-44), and additional information provided by the notifier (EC-67/At.51, 57, 61-63, 75-83, 87, 92-93, 94-95, 101, and 103), was the information regarding molecular characterisation, toxicity, protein analysis, animal feed trials, effects on non-target organisms, bleomycin resistance, and substantial equivalence requested by the Scientific Committee for Food (SCF) (EC-67/At.84-86, 96, 98, 100, 102, 104, 105 and 106), necessary to support a valid safety assessment?

[29] Monsanto Roundup Ready corn (NK603) C/ES/00/01 (EC chronology 76), Question 39bis. Given the information before the Panel, including the notification and additional letter from Monsanto providing additional information (previously referenced and EC-76/At.11-12), was additional information regarding allergenicity studies and PCR tests requested by Austria (EC-76/At.44) necessary or useful to ensure that conclusions of the safety assessment were valid?

[30] Unfortunately, data on more recent dossiers are not available. Thus, it is not clear whether applicants have continued to use a low level of expression as a safety argument.

[31] Amylogene starch potato C/SE/96/3501 (EC chronology 67), Question 25. Given the information before the Panel, including the application (EC-67/At.13-44), and additional information provided by the notifier (EC-67/At.51, 57, 61-63, 75-83, 87, 92-93, 94-95, 101, and 103), was the information regarding molecular characterisation, toxicity, protein analysis, animal feed trials, effects on non-target organisms, bleomycin resistance, and substantial equivalence requested by the Scientific Committee for Food (SCF) (EC-67/At.84-86, 96, 98, 100, 102, 104, 105 and 106), necessary to support a valid safety assessment?

[32] Amylogene starch potato C/SE/96/3501 (EC chronology 67), Question 25. Given the information before the Panel, including the application (EC-67/At.13-44), and additional information provided by the notifier (EC-67/At.51, 57, 61-63, 75-83, 87, 92-93, 94-95, 101, and 103), was the information regarding molecular characterisation, toxicity, protein analysis, animal feed trials, effects on non-target organisms, bleomycin resistance, and substantial equivalence requested by the Scientific Committee for Food (SCF) (EC-67/At.84-86, 96, 98, 100, 102, 104, 105 and 106), necessary to support a valid safety assessment?

[33] Amylogene starch potato C/SE/96/3501 (EC chronology 67), Question 25. Given the information before the Panel, including the application (EC-67/At.13-44), and additional information provided by the notifier (EC-67/At.51, 57, 61-63, 75-83, 87, 92-93, 94-95, 101, and 103), was the information regarding molecular characterisation, toxicity, protein analysis, animal feed trials, effects on non-target organisms, bleomycin resistance, and substantial equivalence requested by the Scientific Committee for Food (SCF) (EC-

67/At.84-86, 96, 98, 100, 102, 104, 105 and 106), necessary to support a valid safety assessment?

[34] VIII. THE PANEL'S ADDITIONAL QUESTIONS, Question 111.

[35] VIII. THE PANEL'S ADDITIONAL QUESTIONS, Question 111.

[36] Question 28.

[37] Monsanto Roundup Ready corn (GA 21),C/ES/98/01 (EC chronology 78), C/GB/97/M3/2 (EC chronology 85).

[38] "In paragraph 10.08 of his response, Dr. Andow concurs with the finding of the SCP at that time, that the provided information was 'not scientifically convincing that the environmental effects of Falcon GS 40/90 are in no way different from non-transgenic cultivars.' Plot sizes were apparently so small that no statistical analyses could be conducted by the notifier and, thus, could hardly detect differences anyway. The European Communities considers correct to conclude that the scientific value from such small studies is rather limited. Therefore, it is appropriate to request more data from the notifier which the notifier in turn did on relevant aspects of the risk assessment, 'dispersal of OSR pollen', the 'potential invasiveness' and 'a number of aspects related to fitness, weediness and outcrossing' – although the expert does note that neither the data nor the sources were provided which is crucial for an independent assessment." (WTO 2006, V. THE PANEL'S QUESTIONS ON ISSUE 1 ("DELAY") (NOS 10 TO 58), Bayer oilseed rape (Falcon GS40/90), C/DE/96/05 (EC chronology 62), par. 305).

[39] See endnote 36.

[40] Monsanto Roundup Ready corn (GA 21), C/ES/98/01 (EC chronology 78), C/GB/97/M3/2 (EC chronology 85).

[41] "This issue is also addressed by the Codex Guideline 2003 under the heading Compositional Analysis of Key Components, in which the comparison of a GM crop with both its sprayed and nonsprayed counterparts is recommended: Analyses of concentrations of key components of the recombinant-DNA plant and, especially those typical of food, should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. In some cases, a further comparison with the recombinant-DNA plant grown under its expected agronomic conditions may need to be considered (e.g. application of an herbicide). Treatment of a GM crop (MaisGard Roudup Ready using HT and Bt genes stacked) with applied herbicide (glyphosate) could trigger metabolic changes in the GM maize event. The effects on plant metabolism under regional conditions of the herbicide applied to this GM crop event were unknown at the time. Thus toxic effects on non target organisms likely to be exposed to the herbicide treated GM maize event (e.g. humans, dairy cows and a range of other herbivores consuming glyphosate-treated Maisgard Roundup Ready) were impossible to predict without testing. Therefore, comparative data on treated and untreated GM maize was required to assess such effects." (WTO 2006, Monsanto Roundup Ready corn (GA 21), C/ES/98/01 (EC chronology 78), C/GB/97/M3/2 (EC chronology 85), par. 528-529).

[42] See endnote 36.

[43] "Actually, the Codex guideline CAC/GL 45-2003 addresses this issue by stating that field trials for compositional analysis should be carried out during a sufficient number of generations, but does not mention a specific number of generations (or seasons): Similarly, trials should be conducted over a sufficient number of generations to allow

adequate exposure to the variety of conditions met in nature.220 597. At the time of the request, the applicant had provided data from the seasons 1998-1999 in Chile (Southern hemisphere) and 1999 in France and Italy (Northern hemisphere). The lead CA considered this to be one season (EC95, At.8). Given this opinion of the CA and the Codex guideline CAC/GL 45-2003 recommendation on this issue, it therefore appears justifiable that, at the time of the request, the Dutch CA asked for data from multiple (3) seasons. 598. In addition, the Dutch CA later (in reply to additional compositional data provided by the applicant) asked for an additional study from the US, as this would be representative for the commercial production of the new maize line.221 599. Furthermore, the lead CA's request is in line with Codex guideline CAC/GL 45-2003, paragraph 45, pertaining to compositional analysis of key components, which reads as follows: The location of field trials should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. 600. Therefore, the data requested by the lead CA on compositional analyses from multiple (3) seasons, as well as from regions representative of commercial maize cultivation (and export to the EU) are in line with Codex recommendations and relevant to the safety assessment." (WTO 2006, Monsanto Roundup Ready corn (GA 21), C/ES/98/01 (EC chronology 78), C/GB/97/M3/2 (EC chronology 85), par. 596-600).

[44] See endnote 36.

[45] See endnote 36.

[46] "Two Panel's experts, Dr. Andow and Dr. Nutti, replied to this question. Their conclusions diverge substantially. Dr. Nutti states that the compositional data on France, Italy, and Chile were supplementary to other previously provided data (which, in fact, they were not) and that therefore, they would not have been necessary. In so doing, she does not really address the question of the Panel. Dr. Andow, on the contrary, clearly concludes that "maize from France, Italy, and Chile would not provide compositional data on maize kernels that is relevant to evaluating cultivation areas exporting maize to the EC".

The European Communities concurs with Dr. Andow's above conclusion and will provide below some detailed comments on replies from both experts. […]

In paragraph 35.07, Dr. Andow discusses the point that no explicit scientific rationale has been provided for the lead CA's request mentioned above. Whereas the lead CA's request is not mentioned in question 35, it is in line with the Codex guideline, paragraph 45, pertaining to compositional analysis of key components, which reads as follows: The location of field trials should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of compositional characteristics over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. Therefore, while no explicit rationale is provided in the lead CA's request, this is in line with Codex recommendations.

Indeed, Dr. Nutti correctly notes that the compositional data should be in line with Codex recommendations, citing paragraph 45 of these guidelines with regard to the choice of field trial location being representative for the various environmental conditions for crop cultivation. However, Dr. Nutti assumes that the compositional data from France, Italy, and Chile has been provided as a supplement to previous data that would comply with Codex guidelines. Perhaps the answer by the applicant (EC-74/At.36, p.5), recapitulating what has previously been provided, might have created this confusion. However, the data from France, Italy, and Chile were the only compositional data provided by the applicant at that time (summarized on pp. 11-26 of EC74/At.7). Based upon the Codex paragraph cited by Dr. Nutti, and given that the application concerned import of maize 1507, the

question whether France, Italy, and Chile are relevant for areas exporting maize to the EU would therefore still be relevant. And, as discussed by Dr. Andow, as these countries are not among the major exporters of maize in the world, the answer to the question should be negative." (WTO 2006, Pioneer/Dow AgroSciences Bt corn Cry1F (1507) C/NL/00/10 (EC chronology 74), Question 35. In your view can EC field trials, in France, Italy, and Chile, provide compositional data on maize kernels that is relevant to evaluating cultivation areas exporting maize to the EC? par. 439-442).

Annex

Annex 1: **Timeline of events relevant to issues of the WTO EC-Biotech trade case** (adapted from Pew Initiative on Food and Biotechnology 2005; events relevant to the WTO dispute are indicated in bold)

1990–APRIL	The EU adopts Directive 90/220/EC, which establishes a process for the approval of agricultural biotechnology products.
1994–1998	The EU authorizes the commercial use of nine GM products and plants.
1995–MAY	The U.S. approves the first commercially significant biotech soybean, Monsanto's "Round-up Ready."
1996	Crop varieties developed by biotechnology are first introduced for commercial production in the U.S.
1996–MARCH 20	Scientific evidence reveals a link between some cases of a variant form of a brain wasting disease in humans and consumption of meat from cows with bovine spongiform encephalitis (BSE or "mad cow disease"). The British government downplays the link and argues that meat is safe to eat.
1997–FEBRUARY	Austria bans Novartis Bt176, a GM maize that has already been approved for use in the EU. The Commission does not challenge the action. Luxembourg also bans an EU-approved maize variety.
1997–MAY 15	The EU adopts the "Novel Foods Regulation", which requires that the person responsible for placing a novel food, including any food containing or produced from GM crops, on the market shall submit a request to the member state in which the product will first be marketed. Relevant authorities in that member state then decide either to allow the product on the market or to refer the application to the European Commission. In either case, the other member states have an opportunity to make their views known. The regulation also provides for special labelling of foods containing GM ingredients, provided that the GM content can be detected. The Novel Food Regulation included several exemptions for products that did not need to be labelled. It also did not define a standard for the percentage of a product that could contain GM ingredients before it had to carry the GM label.
1997–SEPTEMBER 19	EU regulation provides for labelling of foods processed from certain Bacillus thuringiensis (Bt) corn, or corn that has been genetically engineered to produce its own insecticide, and herbicide-tolerant soybeans. These products were already on the market when the May 1997 novel foods labelling directive went into effect.
1998	France bans two EU-approved rapeseed varieties; Greece bans one EU-approved rapeseed variety.
1998–OCTOBER	Approval of new agricultural biotechnology products in the EU comes to a halt. The EU Commission tells the U.S. that they will begin to approve products again if the companies submitting applications agree to follow newly proposed revisions before they become law. Despite applicant compliance, the EU approval processes does not continue.
1999	Austria bans two more EU-approved maize varieties.
1999–JUNE	EU members call for a moratorium on new approvals of GM products. The EU Environmental Council says traceability and labelling must be linked with a new approval process. Ministers from Denmark, France, Greece, Italy, and Luxembourg declare a refusal to approve new products until new rules are in place.
1999–DECEMBER	The Ministerial Conference of the World Trade Organization (WTO) in Seattle is disrupted by demonstrations by people concerned about continued globalization of trade, as well as issues of agriculture and trade in GM foods. The U.S. and Canada propose a working group on biotechnology.
2000	Italy bans four EU-approved maize varieties; Germany bans one EU-approved maize variety.
2000–JANUARY 11	The European Commission publishes a regulation providing a one percent labelling threshold for food for accidental commingling of corn and soy made

	by modern biotechnology. It is expected that the threshold will be adopted as the basis for labelling other foods containing ingredients made from GMOs.
2000–JANUARY 29	More than 130 countries adopt the Cartagena Protocol on Biosafety, aimed at providing a framework for assessing the environmental impact of bioengineered products that cross international borders. Fifty countries must ratify it before it goes into effect. The scope of the protocol does not directly cover food safety.
2000–MARCH	The Codex Ad Hoc Task Force on Foods Derived from Biotechnology has its first meeting in Japan.
2000–APRIL	The European Food Standards Agency (EFSA) is created in the EU to "protect public heath from risks which may arise in connection with the consumption of food, and otherwise to protect the interests of consumers in relation to food." This includes responsibility for issues relating to GM foods.
2000–JUNE	French Environmental Minister Dominique Voynet, speaking for the five states in favour of a moratorium on GMOs, insists on the inclusion of a liability scheme for biotechnology products.
2000–JULY	EU Environmental Ministers meet informally and decide to support the moratorium at least until the Commission prepares labelling and traceability proposals for biotech products. The Commission tells the U.S. that it will complete the proposals by the end of the year so that the approval process could start up again.
2000–SEPTEMBER	StarLink® corn—a GM corn variety approved only for animal consumption—is found in taco shells sold in the U.S.
2001–JANUARY 17	The U.S. Food and Drug Administration (FDA) issues a proposed rule and a "Guidance for Industry" document for labelling GM products. The proposed rule would require food developers to notify FDA at least four months before putting a new GM food on the market, and the scientific description of the product is posted on the Internet during this time. The guidance on labelling was meant for manufacturers who wish to voluntarily label their foods as being made with or without the use of GM ingredients.
2001–JUNE	At the G-8 Economic Summit in Italy, the U.S.-EU Summit includes a special session of World Trade Organization (WTO) agriculture negotiations.
2001–JULY 25	The European Commission proposes legislation on GM Food and Feed thereby amending Directive 2001/18/EC on labelling and traceability.
2001–OCTOBER	At an informal meeting of the Environmental Ministers Council, France, Austria, Finland, Luxembourg, Denmark, Italy, the Netherlands, and Sweden reject the Commission's plan to restart the GMO approval process before the new regulations are implemented.
2002	The European Food Safety Authority becomes operational.
2002–MARCH 21	The Economic and Social Committee issues its opinion on the Commission's 2001 proposal on labelling and traceability.
2002–MAY 16	The Committee of the Regions issues its opinion on the Commission's 2001 proposal on labelling and traceability.
2002–JUNE 3	The Environment Committee of the European Parliament narrowly voted to require all food products derived from biotech ingredients be labelled—even if no remnants of the genetic modification (DNA) are detectable in the final product on the shelves.
2002–AUGUST 27	The European Union ratifies the Cartagena Protocol on Biosafety.
2002–SUMMER	Mid-term report of the Codex Ad Hoc Task Force on Foods Derived From Biotechnology is made to the Codex Executive Committee.
2002–SEPTEMBER 15	The European Commission resubmits a revised proposal for GM Food and Feed and to amend Directive 2001/18/ EC based on the amendments requested by the Parliament's first reading in June
2002–OCTOBER 17	Directive 2001/18/EC is applicable and Directive 90/220/EEC is repealed. At this date the 15 member states should have all adopted national legislation to implement Directive 2001/18/EC, and should have notified the Commission of their action. Twelve of the 15 member states fail to meet this deadline.

2002–DECEMBER	The Council of Ministers on the Environment agrees to a common position on traceability and labelling. The Danish delegation declares the moratorium should remain in place until the EU has developed and implemented liability legislation for biotech products.
2003–MARCH 11–14	The Codex Ad Hoc Task Force on Foods Derived From Biotechnology meets in Yokohama, Japan.
2003–MARCH 17	The EU Council of Ministers concludes a Common Position on the Commission's September 2002 proposal for GM Food and Feed and amendments to its 2001 proposal. The Common Position is forwarded to the European Parliament.
2003–APRIL 10	The European Commission formally requests action to be taken in France, Luxembourg, Belgium, Netherlands, Germany, Italy, Ireland, Greece, Spain, Portugal, and Austria to adopt and notify the Commission of national legislation that implemented Directive 2001/18/EC.
2003–MAY 14	**The U.S., Canada and Argentina file complaints to the WTO to dispute the EU moratorium on GM imports.**
2003–MAY 20	The United States' President Bush accuses the EU of impeding the fight against famine in Africa, calling the ban on GM foods morally wrong and based on "unscientific fears." EU Commissioner on Trade Pascal Lamy answers back that the accusations are "unacceptable" and "should not be used in this kind of debate."
2003–JUNE 13	Palau becomes the 50th country to ratify the Cartagena Protocol on Biosafety, permitting it to enter into force in September 2003.
2003–JUNE 19	**The United States and EU begin consultation with regard to the WTO suit brought by the U.S. The consultations break down shortly after they begin, and the U.S. delegation announces their intent to ask for the empanelment of a WTO Dispute Settlement Body.**
2003–JUNE 30–JULY 7	The 26th Session of the Codex Alimentarius Commission, meets in Rome, Italy. The Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms from the Ad Hoc Committee on Foods Derived From Biotechnology is considered.
2003–JULY 2	The European Parliament passes the Commission's September version of the proposed GM Food and Feed Reglulation and amendments to Directive 2001/18/EC. The United States does not accept the action as "lifting the moratorium" and vows to continue its push for more favourable laws for its GM products.
2003–JULY 15	The European Commission refers Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands and Spain to the European Court of Justice for failing to adopt national legislation implementing Directive 2001/18/EC.
2003–JULY 22	The Council of Ministers adopts the Commission's proposal for GM Food and Feed and amendments to Directive 2001/18/EC on labelling and traceability.
2003–JULY 23	The European Commission publishes guidelines for the agricultural management of "co-existence" or growing GM crops alongside non-GM crop varieties.
2003–SEPTEMBER	**A WTO-Panel to address the complaints filed by U.S., Canada and Argentina is established.**
2004–APRIL	**Members of the WTO Panel elected.**
2004–APRIL 18	The labelling and traceability amendments of 2001/18/EC and the new GM Food and Feed Regulation are applicable in the EU market.
2004–APRIL	**A ruling of the WTO Panel acknowledges the validity of the complaints by the USA, Canada and Argentina.**
2004–MAY 19	The European Commission authorizes the marketing of canned sweet corn with the GM BT-11 trait for 10 years; this is the first GM authorization in the EU since 1998.
2004–MAY	Ten nations from eastern Europe are admitted into the European Union, bringing total membership to 25 countries.

2004–JUNE	**WTO Panel begins a series of meetings with parties and scientific experts.**
2004–JULY	The European Commission authorizes the marketing (but not cultivation) of NK603, a Roundup Ready maize.
2005–JANUARY	Hungary invokes the "safeguard clause" to ban MON810 despite EC approval.
2005–FEBRUARY	EU Commission announces that it will sponsor a broad debate on biotechnology with the purpose to clarify the position of the EU-25 on matters related to the deadlock on GMO, the WTO case filed against the EU for its moratorium on new GMO imports, and the issues relating to "coexistence".
2005–APRIL	EU Commission temporarily suspends import of corn and corn products, including corn gluten, after Syngenta announces that small quantities of an unapproved GM variety of maize (Bt10) had inadvertently been released into commercial distribution channels over a four-year period.
2005–APRIL	EC tells Austria, France, Germany, Greece, and Luxembourg that their invocation of the "safeguard" clause to ban approved GMOs is not legitimate and that the bans must be lifted, or they will face legal action by the Commission.
2005–JUNE 24	The Council rejects by a qualified majority the Commission's proposal to lift the bans or restrictions on authorized GMOs adopted by Austria, France, Germany, Greece and Luxembourg. This represents the first time the Council mustered a qualified majority either for or against a Commission proposal on GMOs.
2005–AUGUST	The Commission authorizes the import of GM maize MON 863 for use in animal feed (but not for cultivation of human food) following the failure of the Council to reach a position on the Commission's proposal in June.
2005–OCTOBER	The European Court of First Instance, the EU's second-highest court, rejected an appeal by Austria to the Commission's finding that the state-wide temporary ban of any GMOs for cultivation in Upper Austria was illegal.
2005–DECEMBER	The EU Council of Ministers again does not succeed in adopting a clear decision on or against a GM-Maize, leaving it up to the European Commission to adopt a final decision.
2006–JANUARY	European Commission decides to grant permission to a number of GM-Maize varieties for import and introduction into the market as a product but not for cultivation. Austrian Minister Pröll announces that questions related to applications of GMOs in agriculture and food productions are one of the priorities of the Austrian EU presidency.
2006–FEBRUARY	**WTO Panel interim report released to parties for review and comment.** A majority of European consumers voted against GM-foods according to the newest Eurobarometer EB 64.3 on biotechnology.
2006–MARCH 10	**Interim Report of the WTO Panel with findings and recommendations concerning the 3 complaints is released to parties and leaked to NGOs**
2006–MARCH	EU Commission grants consent according to Reg. 1829/2003 for the first application notified for a GMO for food use (Maize 1507)
2006–APRIL	Two international conferences held in Vienna on the topics: "Coexistence of GM, conventional and organic crops", and "The role of precaution in GMO politics". European Commissioner S. Dimas announces a review of the role of EFSA in regulation of GMOs and changes in their involvement in the regulatory process.
2006–APRIL 11	EFSA publishes an opinion on the safeguard measures and recommends lifting of the import bans.
2006–MAY	Additional safeguard measure directed towards modified MON810-Maize in Poland, similar safeguard measures in Greece and Hungary sustained.
2006–APRIL	Additional safeguard measure directed towards modified GT73-rapeseed is enacted by the Austrian government.
2006–SEPTEMBER	**Publication of the final report by the WTO Panel.**

Annex 2: **Summary on positions and rulings in the WTO-EC-Biotech case** (adapted from ICTSD, 2006)

	Complaining Parties (USA, Canada, Argentina)	**European Communities**	**WTO Panel ruling** (final report)
Context	• Biotech products proven to be safe • No inherent difference between GMOs and their conventional counterparts in terms of health and environmental risks • Need for a case-by case analysis (rather than general assertions about the risks of biotech products) • EU measures have hindered developing countries' agricultural and economic development by blocking exports of biotech products and by discouraging acceptance of food aid, and imports and cultivation of biotech seeds	• Highlight potential risks of modern bio-technology, including evidence of harm to bio-diversity from herbicide resistant crops • International community recognises differences in risks between GMOs and conventional organisms • Trade statistics show that mea-sures do not restrict exports of developing countries to the EC	• Request for consultations on 14 May 2003 • Panel established on 29 August 2003
	Complaining Parties (USA, Canada, Argentina)	**European Communities**	**WTO Panel ruling** (final report)
Measure at issue	(1) general suspension of the EC approval processes ("moratorium") (2) product-specific measures (failure to apply the EU's existing approval procedures) (3) Member states' "national measures" (marketing or import bans)	(1) Deny the existence of "moratoria" or "suspension" of approval of procedures (2) National measures are temporary and provisional, based on the precautionary principle	(1) A general de facto moratorium on the approval of biotech products has been applied by the EC between June 1999 and August 2003. The de facto moratorium is not in itself an SPS measure within the meaning of the SPS agreement, however it affected the operation and application of the EC approval procedures which the Panel have determined to be SPS measures within the meaning of the SPS agreement (2) The EC is found to have breached its obligations on 24 (out of 27) specific approval procedures. (3) The EC is found to have acted inconsistently with its obligations under the SPS agreement by maintaining the safeguard measures, as applied by the relevant EU

			members, which were not based on a risk assessment as required under the SPS agreement.
Relevant Agree-ments	(1) Moratorium: SPS agreement, including measures not based on risk assessment; more trade restrictive than required to achieve the EC's appropriate level of protection; not based on scientific principles; maintained without sufficient scientific evidence; not "necessary to protect human, animal or plant life or health"; inconsistencies in the levels of protection in comparable situations; discrimination between WTO member states; "undue delay" in its control, inspection and approval procedures; failure to "publish promptly" the general moratorium (SPS 2.2, 2.3, 5.1, 5.5, 5.6, 7, 8) (2) Product-specific marketing bans: • SPS agreement (similar to 1) (SPS 2.2, 2.3, 5.1, 5.5, 5.6, 8) • GATT 1994 ("like product" discrimination) (GATT III.4) • TBT agreement ("like product" discrimination; unnecessary obstacles to international; inadequate application of conformity assessment procedures) (TBT 2.1, 2.2, 5.1.2, 5.2.1 (3) SPS agreement (similar to 1); GATT 1994 ("like product" discrimination; restriction other than duties, taxes or other charges); TBT agreement ("like product" discrimination, failure to publish notice) (SPS 2.2, 2.3, 5.1, 5.5; GATT III:4, XI:1, TBT 2.1, 2.2, 2.9)	(1) SPS agreement (for certain kinds of risks as defined in the agreement); TBT agreement (environmental and related objectives not covered by the SPS agreement); GATT 1994 (including Article XX); Biosafety Protocol (including the norms of international law on the precautionary principle and risk assessment reflected in the Protocol) (2) SPS Agreement (Article 5.7 allowing for provisional measures in cases of insufficient scientific evidence)	(1) The EC is in breach of its WTO obligations under Annex C(1)(a), first clause, and consequently, Art. 8 of the SPS agreement. (2) The EC is in breach of its WTO obligations under Annex C(1)(a), first clause and, consequently, Art. 8 of the SPS agreement (3) The relevant EU member states are in breach of the EC's WTO obligations under the SPS agreement. The safeguard measures are found not to have been based on a risk assessment as required under Art. 5.1 of the SPS agreement and not to be consistent with the requirements of Art. 5.7. of the SPS agreement. Furthermore, by maintaining the measures, the EC has acted inconsistently with Art. 2.2 of the SPS agreement.

	Complaining Parties (USA, Canada, Argentina)	**European Communities**	**WTO Panel ruling** (final report)
Risk and pre-caution	• Measures not based on a risk assessment as defined by the SPS agreement (Annex A); • not based on scientific principles • maintained without sufficient scientific evidence • implementation of the Protocol does not mean that countries can disregard other international obligations	• Protocol's provisions on precaution and risk assessment inform meaning and effect of relevant WTO provisions; • Member states take precautionary approach to individual applications (n line with Article 5.7)	• In no case was there insufficient scientific evidence to perform an assessment of the risks to human health and / or the environment as required by Art. 5.1 of the SPS agreement • The relevant EU member states did not undertake a risk assessment as required by Art 5.1 of the SPS agreement • National safeguard measures were not based on risk assessment as required by Art. 5.1 of the SPS agreement and are not consistent with the requirements of Art. 5.7 of the SPS agreement. By maintaining these measures, the EC has acted inconsistently with its obligations under Art. 2.2 of the SPS agreement

Annex 3: **Issues addressed in the WTO Panel report and their relevance for Austria**

Legal issue (Source: Par.)	**GMO concerned** (Complaining Party)	**Reasoning by WTO Panel**	**Relevance for Austria**	**Recommendation by WTO panel**
Are the EC approval procedures SPS-measures in general? (8.1)	All GMOs notified under Directives 90/220/EEC and 2001/18/EC, and risk assessments according to Regulation (EC) 258/97 (USA, Can, Arg)	The risk assessment according to Dir. 90/220/EEC and 2001/18/EC is within scope of SPS, Reg. (EC) 258/97 are within scope of SPS regarding risk assessment procedures	Austrian measures according to Dir. 90/220/EEC 2001/18/EC, and Reg. (EC) 258/97 need to be in context of SPS	EC measures need conform to SPS
Was the general EU application moratorium 10/1998 to 08/2003 a SPS measure? (8.6)	All notified GMOs in the timeframe 10/1998 to 08/2003 (USA, Can, Arg)	The moratorium itself was no SPS measure, but it affected the application of respective procedures; the completion of applications was prolonged with "undue delay" in violation of obligations according to Annex C(1)(a) and Art.8 of SPS	Austrian objections concerning Bt-531 Cotton, RR-1445 Cotton, RR-Oilseed Rape, Bt-1507 Maize, Bt-1507 Maize for cultivation MON810xGA21 Maize, GA21 Maize, RR-Sugar Beet, Bt-11 Maize (food use) as implicated by claims	EC needs to bring moratorium in conformity to SPS obligations to the extent that it had not ceased to exist; (Recommendations do not implicate Austrian action directly)
Were product-specific procedures unduly delayed, consistent with a general Moratorium 10/1998 to 08/2003) (8.7)	27 product applications; 20 applications according to Dir.90/220/EEC, 7 applications according to Reg. (EC) 258/97	All records have been examined; there was "undue delay" with 24/27 applications. No inconsistency with Annex C(1)(b) , Annex B(1); Art.7, Art.5.1, Art.5.5, Art.2.2, Art.2.3, Art.10.1 of SPS No inconsistencies found for Transgenic Potato, LL Soybean, LL Rape	Austrian objections concerning Bt-531 Cotton, RR-1445 Cotton, RR-Oilseed Rape, Bt-1507 Maize, Bt-1507 Maize for cultivation MON810xGA21 Maize, GA21 Maize, RR-Sugar Beet, Bt-11 Maize (food use) as implicated by claims	EC needs to bring measures in conformity to SPS obligations to the extent that applications were not withdrawn, or already approved affecting (Bt11 Sweet Corn, Reg. 258/97). No recommendations concerning Transgenic Potato, LL Soybean, LL Rape

Annex 3 continued

Legal issue (Source: Par.)	**GMO concerned** (Complaining Party)	**Reasoning by WTO Panel**	**Relevance for Austria**	**Recommendation by WTO Panel**
Were safeguard measures by EC Member States SPS-Measures? (8.8)	T25 Maize, Bt-176 Maize, MON810 Maize, Bt-11 Maize, MON809 Maize, Topas 19/2 Rape, MS1/RF1 Rape	Objectives identified fall in scope of SPS, in no case there was insufficient information allowing to adopt provisional measures in accordance to Art. 5.7 of SPS	Austrian safeguard measures concerning Bt-176, T25, MON810 implicated	EC must bring measures in conformity to SPS obligations; (Austria is directly implicated by the recommendation)
Did a risk assessment support safeguard measures? (8.10)	All GMOs subject to safeguard measures (T25 Maize, Bt-176 Maize, MON810 Maize, Bt-11 Maize, MON809 Maize, Topas 19/2 Rape, MS1/RF1 Rape)	No separate RA was undertaken that is meeting the requirements of SPS; EC risk assessment did not support such bans; Requirements for invoking Art. 5.7 of SPS not satisfied	Austrian notification is not accompanied by an adequate risk assessment supporting safeguard measure	EC must bring measures in conformity to SPS obligations: lift measure or submit a risk assessment supporting measures
Were Austrian safeguard measures consistent with SPS? (8.22-8.24, 8.42, 8.57-8.59)	Bt-176, T25, MON810 (USA), T25 (Can), Bt-176, T25, MON810 (Arg)	Safeguard Measure was not based on RA as required by Art. 5.1 SPS and was not adopted consistent with Art. 5.7 SPS; No evidence for inconsistencies according to Art.2.3., Art.5.5, Art.5.6 SPS; no need to rule on alternative claims under Art.2.2, 2.2, 2.9 TBT and Art.III:4 GATT 1994	National measure leads to inconsistency of EC with obligations under SPS, maintaining it is inconsistent with 2nd and 3rd requirement of Art.2.2	EC must bring measures in conformity to SPS obligations; Austria is directly implicated by the recommendation: lift measure or enable EC to submit a risk assessment supporting the measures