Summary of the conclusions and recommendations of the WTO Dispute Panel interim report on GMOs

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HIGHLIGHTS OF THE CONCLUSIONS AND SOME IMPLICATIONS OF THE INTERIM REPORT

It is clear that this interim ruling does not question the soverign right of any country to put into place strict biosafety legislation to regulate GMOs, including a decision to reject an application related to a GMO. In this case, the EC was merely taken to task for not applying its own rules properly.

EC general "de facto" moratorium

* The Panel found that the EC applied a general "de facto" moratorium on approvals of biotech products between June 1999 and 29 August 2003, the date of the establishment of the Panel.
* The Panel found that the EC had acted inconsistently with its obligations in **only one** matter, in that it did not ensure that procedures are undertaken and completed without "undue delay".
* **All other claims** by the US, Canada and Argentina that the "de facto" moratorium resulted in various inconsistencies with obligations under the SPS Agreement were **dismissed**.
* As the EC had approved a relevant biotech product subsequent to the Panel establishment, the Panel refrained from making any recommendations (hence **no action to be taken**) on this issue.
** While the Panel found inconsistency in the EC's obligations to ensure no "undue delay", this does not necessarily mean that a moratorium on GMOs is WTO inconsistent. Specific and general moratoria on GMOs may be justifiable under some circumstances.*

Product-specific EC measures

* With respect to the complaint that the EC had failed to consider for final approval, applications for specific biotech products, the Panel found that the EC had breached its obligations in **only one** matter, in that there was "undue delay" in the completion of the approval procedures with respect to 24 of 27 products.
* **All other claims** by the US, Canada and Argentina that the relevant product-specific measures were inconsistent with the SPS Agreement were **dismissed**.
* The Panel recommended that the EC be requested to bring the relevant product-specific measures into conformity with its obligations. These recommendations do not apply to those measures that were withdrawn after the Panel was established or to that affecting the approval of Bt11 sweet maize (food), since that application was approved during the Panel's proceedings.
* *Presumably, the recommendations also do not apply to other GM events that have since been approved in the EC. Many of the products in question have since been withdrawn or approved.*
* *This does not mean that the EC will have to approve the products in question, but simply that it has to ensure that the applications procedure for the relevant products are undertaken and completed without "undue delay".*

EC member States safeguard measures

* On the safeguard measures (in the form of prohibitions on a particular biotech product that has been approved within the EC) taken by Austria, Belgium, France, Germany, Italy and Luxembourg, the Panel concluded that these are not based on a "risk assessment" as required under the SPS Agreement, and by implication the EC had acted inconsistently with the requirements that SPS measures are based on scientific principles and not maintained without sufficient scientific evidence.
* The Panel considered that there was sufficient scientific evidence for a "risk assessment" to be conducted, thus the safeguard measures were inconsistent with the SPS clause that allows provisional measures to be maintained only where "relevant scientific evidence is insufficient".
* Some EC member States provided some scientific studies to support their product-specific bans, but the Panel considered that this was not a "risk assessment" that meets the requirements of the SPS Agreement.
* *The relevant member States will have to ensure that if they apply safeguard measures, such as product-specific bans, they must provide a "risk assessment" of such products that meets the requirements of the SPS Agreement.*
**Product-specific bans are allowed under the EC biosafety law, and this law has not been challenged by the complainants, thus the right of countries to introduce strict regulations for GMOs, including product-specific bans,*

has not been questioned.

BACKGROUND

On 7 February 2006, the interim report of the WTO Panel considering the case "European Communities - Measures Affecting the Approval and Marketing of Biotech Products" was made available to the parties in the dispute (US, Canada and Argentina as complaining parties, the European Communities (EC) as defendant).

This is a preliminary report and parties may ask for a review, after which a final report will be issued and made public. Unless a consensus at the WTO's Dispute Settlement Body (DSB) rejects the final report, it becomes the Body's ruling or recommendation. Both sides can appeal the ruling, which would be heard by members of the Appellate Body. The appeal can uphold, modify or reverse the Panel's legal findings and conclusions. The DSB has to accept or reject the appeals report, and rejection is only possible by consensus.

The losing party will then have to bring its policy into line with the ruling or recommendations. If complying with the recommendation immediately proves impractical, the member is given a "reasonable period of time" to do so. If it fails to act within this period, it has to enter into negotiations with the complaining countries to determine mutually-acceptable compensation. If after a certain period, no satisfactory compensation is agreed, the complaining side may ask the DSB for permission to impose limited trade sanctions against the other side.

The 1050 page interim report is thus preliminary in nature. It is confidential and only made available to the parties in the dispute, but the conclusions and recommendations of the interim report have been made public at: www.tradeobservatory.org/library.cfm?refid=78475

Comment and analysis of the interim report and its implications is impossible without access to the full document. We have, however, had access to pages 1029-1050 of the interim report, which provide the interim conclusions and the recommendations of the Panel.

We highlight the facts of some of the conclusions and recommendations below, based only on a viewing of pages 1029-1050. A fuller TWN analysis will be made at a later date when the report is publicly available.

WHAT THE PANEL DID NOT EXAMINE

1) It is important to note that the Panel did not examine whether products of biotechnology in general are safe or not.

2) The Panel did not examine whether the biotech products (this is the term used by the Panel and it is understood to refer to genetically modified organisms and the products of such organisms) at issue in the dispute are "like" their conventional counterparts (within the notion of "like products" under WTO rules).

3) The Panel did not examine whether the EC has a right to require the pre-marketing approval of biotech products; this issue was not raised by the complainants.

In addition, the right of the EC to consider the possible risks prior to giving approval for the consumption or planting of biotech plants was not questioned by any of the complainants.

4) The Panel did not examine whether the EC's approval procedures under its biosafety regulations, which provide for a product-by-product assessment requiring scientific consideration of potential risks, are consistent with its obligations under the WTO agreements; this issue was not raised by the complainants.

5) The Panel did not examine the conclusions of the relevant EC scientific committees regarding the safety evaluation of specific biotech products.

EC GENERAL "DE FACTO" MORATORIUM

The Panel found that the EC applied a general "de facto" moratorium on approvals of biotech products between June 1999 and 29 August 2003, the date of the establishment of the Panel. It said that while the moratorium was not itself a sanitary and phytosanitary (SPS) measure, it affected the operation and application of the EC approval procedures, which were found to be SPS measures.

The complaining parties had alleged that the "de facto" moratorium had resulted in various breaches of the EC's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

However, the Panel agreed with the US and Canada that the EC had acted inconsistently with its obligations in **only one** matter. This was to do with obligations under Annex C(1)(a), first clause of the SPS Agreement, under which WTO members should ensure that procedures are undertaken and completed without "undue delay".

However, the Panel **refrained from making recommendations** for the EC to bring this into conformity with its obligations, as the general "de facto" moratorium has ended, given that the EC had approved a relevant biotech product subsequent to the Panel establishment.

All other claims by the US, Canada and Argentina that the "de facto" moratorium resulted in various inconsistencies with obligations under the SPS Agreement were **dismissed**.

The Panel concluded that it was **not established** that the EC had acted inconsistently with its obligations to ensure that

* the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly

examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained (this claim was only made by the US);
* any SPS 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;
* SPS measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members, and that they are not applied in a manner which would constitute a disguised restriction on international trade.

The Panel also concluded that, in applying the general "de facto" moratorium, the EC **has not acted inconsistently**, as claimed by the US, Canada and Argentina, with its obligations to
* notify changes in their SPS measures and provide information on them in accordance with the relevant Annex of the SPS Agreement;
* ensure that the SPS measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations;
* avoid arbitrary or unjustifiable distinctions in the levels of SPS protection against risks to human life or health it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade;
* ensure that SPS measures are not more trade-restrictive than required to achieve their appropriate level of SPS protection, taking into account technical and economic feasibility (this claim was only made by Canada).

While the Panel found inconsistency in the EC's obligations to ensure no "undue delay", this does not necessarily mean that a moratorium on GMOs is WTO inconsistent. Specific and general moratoria on GMOs may be justifiable under some circumstances.

PRODUCT-SPECIFIC EC MEASURES

The complaining parties had claimed that the EC had failed to consider for final approval, applications concerning certain specified biotech products for which the EC had commenced approval procedures. They alleged that these so-called product-specific measures resulted in various breaches in the EC's obligations.

However, the Panel found that the EC had breached its obligations in **only one** matter. The Panel considered that there was "undue delay" in the completion of the approval procedures with respect to 24 of 27 specified biotech products, and therefore the EC had breached its obligations to ensure that procedures are undertaken and completed without "undue delay", and consequently under Article 8 (dealing with control, inspection and approval procedures), of the SPS Agreement.

All other claims by the US, Canada and Argentina that the relevant product-specific measures were inconsistent with the SPS Agreement were **dismissed**.

The Panel concluded that it was **not established** that the EC had acted inconsistently with its obligations to ensure that
* procedures are undertaken and completed in no less favourable manner for imported products than for like domestic products (this was a claim made only by Argentina);
* the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained (this was a claim made by the US and Argentina);
* information requirements are limited to what is necessary for appropriate control, inspection and approval procedures (this was a claim made only by Argentina);
* any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary (this was a claim made only by Argentina);
* any SPS 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;
* SPS measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members, and that they are not applied in a manner which would constitute a disguised restriction on international trade (this was a claim made only by Canada).
The Panel also concluded that in respect of the relevant product-specific measures, the EC **has not acted inconsistently**, as claimed by the US, Canada and Argentina, with its obligations to
* notify changes in their SPS measures and provide information on them in accordance with the relevant Annex of the SPS Agreement (this was a claim made only by the US);
* ensure that the SPS measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations;
* avoid arbitrary or unjustifiable distinctions in the levels of

SPS protection against risks to human life or health it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade;
* ensure that SPS measures are not more trade-restrictive than required to achieve their appropriate level of SPS protection, taking into account technical and economic feasibility (this was a claim made by Canada and Argentina).

The Panel recommended that the EC be requested to bring the relevant product-specific measures into conformity with its obligations. However, these recommendations do not apply to those measures that were withdrawn after the Panel was established or to that affecting the approval of Bt11 sweet maize (food), since that application was approved during the course of the Panel's proceedings.

Presumably, the recommendations also do not apply to other GM events that have since been approved in the EC. Many of the products in question have since been withdrawn or approved.

If the recommendation is adopted, this does not mean that the EC will have to approve the products in question, but simply that it has to ensure that the applications procedure for the relevant products are undertaken and completed without "undue delay".

EC MEMBER STATE SAFEGUARD MEASURES

The safeguard measures (in the form of prohibitions on a particular biotech product that has been formally approved for use within the EC) taken by Austria, Belgium, France, Germany, Italy and Luxembourg, were deemed by the Panel as failing to meet the obligations of the EC under the SPS Agreement.

The Panel considered that there was sufficient scientific evidence for a "risk assessment" to be conducted. As such, it said that the safeguard measures were inconsistent with the clause in the SPS Agreement that allows provisional measures to be maintained only where "relevant scientific evidence is insufficient".

The Panel also considered that none of the EC member States provided any "risk assessment" that would reasonably support their product-specific bans. Although some of the EC member States did provide some scientific studies to support their national product-specific bans, the Panel considered that this was not a "risk assessment" that meets the requirements of the SPS Agreement.

Thus the Panel concluded that the safeguard measures are not based on a "risk assessment" as required under the SPS Agreement.

(Under the SPS Agreement, "risk assessment" is defined as "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".)

As such, by implication the EC was deemed to have acted inconsistently with the requirements that any SPS measure is based on scientific principles and is not maintained without sufficient scientific evidence.

The Panel recommended that the Dispute Settlement Body request the EC to bring the relevant member State safeguard measures into conformity with its obligations under the SPS Agreement.

This means that the relevant member States will have to ensure that if they apply safeguard measures, such as product-specific bans, they must provide a "risk assessment" of such products that meets the requirements of the SPS Agreement.

Product-specific bans are allowed under the EC biosafety law, and this law has not been challenged by the complainants, thus the right of countries to introduce strict regulations for GMOs, including product-specific bans, has not been questioned.

This part of the Panel's interim report will need to be examined fully when the entire report is publicly available. The gaps and lack of consensus in scientific knowledge, and the application of the precautionary principle/approach are fundamental issues in ensuring biosafety. Any interpretation by the Panel would need close analysis.