WORLD TRADE ORGANIZATION

WT/DS291/R/Add.5
WT/DS292/R/Add.5
WT/DS293/R/Add.5
29 September 2006
(06-4236)

Original: English

EUROPEAN COMMUNITIES – MEASURES AFFECTING THE APPROVAL AND MARKETING OF BIOTECH PRODUCTS

Reports of the Panel

Addendum

This addendum contains Annex G to the Reports of the Panel to be found in document WT/DS291/R, WT/DS292/R, WT/DS293/R. The other annexes can be found in the following addenda:

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ANNEX G

REPLIES BY THIRD PARTIES TO QUESTIONS POSED BY THE PANEL AND THE PARTIES

ANNEX G-1

REPLIES BY AUSTRALIA TO QUESTIONS POSED BY THE PANEL AND THE PARTIES

QUESTIONS POSED BY THE PANEL

For all third parties:

1. With reference to pp. 27-36 of the EC first written submission, could the third parties please indicate whether the European Communities' description of their own regulatory systems is accurate?

From Australia's perspective, the accuracy of the European Communities' description of the Australian regulatory system does not appear to be of any relevance to the resolution of this dispute. Australia therefore does not wish to provide any response addressing the accuracy of this description.

For all complaining parties

50. With reference to Article 5.7 of the SPS Agreement, do the complaining parties agree with the European Communities that:

(a) Article 5.7 excludes the applicability of Article 5.1 and is not an exception (affirmative defence) to Article 5.1 (EC first written submission, para. 575)? In answering this question, please address the relevance of the Appellate Body reports on Japan-Apples (footnote 316), EC – Hormones (para. 104) and EC-Sardines (para. 275) and Japan-Agricultural Products II (paras. 86 et seq)?

In Australia's view, Article 5.7 operates as a *qualified* exemption from the obligation under Article 5.1. Article 5.7 is not, however, an exception (affirmative defence) and the burden of proof in establishing a claim of inconsistency with Article 5.7 rests with the complaining party.

Qualified exemption

In *Japan – Agricultural Products II*, the Appellate Body explained that:

> Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless.[1]

In light of the nexus between Articles 2.2 and 5.1[2], Australia considers that the same reasoning can be applied to the relationship between Article 5.1 and Article 5.7: Article 5.7 operates as a *qualified* exemption from the obligation under Article 5.1 requiring Members to ensure their SPS measures are based on an assessment of risk.

[1] *Japan – Agricultural Products II*, AB Report, para. 80.
[2] *EC – Hormones*, AB Report, para. 180.

Burden of proof

Article 5.7 establishes both a right and obligation of Members. It establishes a Member's right to take provisional sanitary or phytosanitary measures in "cases where relevant scientific evidence is insufficient", subject to that Member complying with the specific obligations as set out in the remainder of the paragraph. Australia considers that the burden of proof to establish a *prima facie* case of inconsistency with Article 5.7 rests with the complaining party. Australia notes that the Appellate Body has not explicitly addressed the issue of burden of proof under Article 5.7.[3]

Australia's position on the relationship between Article 5.1 and 5.7 is supported by Appellate Body findings in *EC – Hormones* and *EC – Sardines*.

In *EC – Hormones*, the Appellate Body discussed the existence of the "general-rule exception" in the relationship between Article 3.1 (the general obligation) and Article 3.3 (an exception) of the SPS Agreement. The Appellate Body found that "the general rule in a dispute settlement proceeding requiring a complaining party to establish a *prima facie* case of inconsistency with a provision of the *SPS Agreement* before the burden of showing consistency with that provision is taken on by the defending party, is *not* avoided by simply describing that same provision as an "exception".[4] The Appellate Body also found that the right of a Member under Article 3.3 was "an autonomous right and *not* an 'exception' from a 'general obligation' under Article 3.1.[5]

In *EC – Sardines*, the Appellate Body found that, as with Article 3.1 and 3.3 of the *SPS Agreement*, there is no "general-rule exception" relationship between the first and second parts of Article 2.4 of the TBT Agreement and therefore it is for "the complaining Member seeking a ruling on the inconsistency with Article 2.4 of the *TBT Agreement* of the measure applied by the European Communities – to bear the burden of proving its claim."[6]

Australia considers that the allocation of the burden of proof on the complaining party for claims under Article 5.7 is fully consistent with the above-mentioned findings of the Appellate Body in *EC – Hormones* and *EC – Sardines*.

(b) Article 5.6 is not "relevant" where Article 5.7 applies (EC first written submission, para. 612)?

Australia does not agree that Article 5.6 is not "relevant" where Article 5.7 applies. In Australia's view, a measure adopted under Article 5.7 of the SPS Agreement is subject to all relevant disciplines contained in other provisions of Article 5, including those set forth in Article 5.6.

Article 5.6 applies to *all* sanitary or phytosanitary measures, including any measures "provisionally adopted" under Article 5.7. An interpretation of Article 5.7 which excluded application of Article 5.6 to measures provisionally adopted pursuant to Article 5.7 can not be supported by the text of Articles 5.6 and 5.7, and is not supported by either the context of these provisions, or their object and purpose.

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[3] *Japan – Apples*, AB Report, para. 175, footnote 316. Panels have taken apparently conflicting approaches to this issue. See *Japan – Agricultural Products II*, Panel Report, para. 8.58 (indicating that the burden was on the complaining party) and *Japan – Apples*, Panel Report, paras. 8.4 and 8.212 (indicating that the burden was on the party invoking Article 5.7)

[4] *EC – Hormones*, AB Report, para. 104.

[5] *EC – Hormones*, AB Report, para. 172

[6] *EC – Sardines*, AB Report, para. 275.

(c) Article 5.7 "effectively excludes Article 5.5 (EC first written submission, para. 618)?

Australia does not agree that Article 5.7 "effectively" excludes Article 5.5. In Australia's view, a measure adopted under Article 5.7 of the SPS Agreement is subject to all relevant disciplines contained in other provisions of Article 5, including those set forth in Article 5.5.

Article 5.5 applies to *all* sanitary or phytosanitary measures, including any measures "provisionally adopted" under Article 5.7. An interpretation of Article 5.7 which excluded application of Article 5.5 to measures provisionally adopted pursuant to Article 5.7 can not be supported by the text of Articles 5.5 and 5.7, and is not supported by either the context of these provisions, or their object and purpose.

(d) the sufficiency of relevant scientific evidence depends, inter alia, on a country's level of protection and the nature of the risks (e.g., reversibility of damage)? (see EC first written submission, paras. 605-606)

Australia wishes to make some general points on the issue of sufficiency of scientific evidence.

As a threshold requirement, Article 5.7 applies "[i]n cases where relevant scientific information is insufficient". This threshold requirement is clearly linked to the obligation under Article 5.1 for a measure to be based on an adequate assessment of risk. As explained by the Appellate Body in *Japan – Apples*:

> "… 'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*." [7]

It is therefore clear that a critical question in determining the insufficiency of scientific evidence under Article 5.7 is whether the available relevant scientific evidence is sufficient to permit an assessment of risk which is adequate for the purposes of Article 5.1. If there is sufficient scientific evidence, then the measure must be based on an adequate assessment of risks which takes into account that evidence. If the scientific evidence is insufficient, then the measure may be adopted provisionally on the basis of "available pertinent information" (which will include, at a minimum, all of the available relevant scientific evidence).

52. Do the complainants agree with the definition of "an adequate risk assessment" put forward by the European Communities in the last sentence of para. 604 of its first written submission?

Australia does not agree with the definition of "an adequate risk assessment" put forward by the European Communities. In Australia's view, the expansive definition proposed by the EC goes well beyond a proper interpretation made in accordance with the principles of treaty interpretation applicable to panel proceedings as set out in Article 3.2 of the DSU. As indicated by the Appellate Body in *India-Patents*:

[7] *Japan – Apples*, AB Report, para. 179

> "these principles of interpretation neither require nor condone the imputation into a treaty of words that are not there or the importation into a treaty of concepts that were not intended" [8]

By way of example, Australia notes the reference to an assessment being "delivered by a reputable source". Apart from the absence of any textual support for this elaboration of the definition of an adequate risk assessment; it is not clear what the EC means by "reputable source". Although a WTO Member would no doubt seek to ensure its risk assessments are conducted by a competent body, the SPS Agreement does not impose a particular organisational approach on Members in this regard.

Another example of the extent to which the EC's definition goes beyond a proper interpretation of the SPS Agreement is the reference to an adequate risk assessment "that unequivocally informs the legislator". Once again, there is no textual support for this interpretation. Moreover, in scientific matters there is often some degree of equivocation.

Australia also notes that the EC considers a risk assessment must be "unlikely to be revised". Again it is unclear what the EC means by "unlikely to be revised". A risk assessment can only take account of the scientific evidence available at the time it is undertaken. However, to suggest that a risk assessment which does so will "withstand the passage of time" and "be unlikely to be revised" ignores the possibility of further relevant scientific information emerging which may require a Member to adjust its measure in order to comply with obligations in Articles 2 and 5 of the SPS Agreement.

For the European Communities:

110. With reference to the European Communities' interpretation of Article 5.7 of the SPS Agreement:

(a) Please elaborate further upon why Article 5.6 is not "relevant" where Article 5.7 applies? (EC first written submission, para. 612)

(b) Please elaborate further on why Article 5.7 "effectively" excludes Article 5.5? (EC first written submission, para. 618)

(c) The European Communities argues that the member State safeguard measures fall to be assessed under Article 5.7 and not, as the complaining parties argue, Article 2.2 and 5.1 of the SPS Agreement. Article 5.7 appears to apply only in circumstances where relevant scientific evidence is insufficient. Is this an issue of fact? If so, which side bears the burden of proof in respect of this issue?

Please refer to Australia's responses to question 50 posed by the Panel.

In addition, we would note that the threshold question for invocation of Article 5.7 is whether the relevant scientific evidence is insufficient, and not whether the measure has been characterised under a Member's legislative system as provisional, or provisionally adopted.

[8] *India – Patents*, AB report, at para. 94.

QUESTIONS POSED BY THE EUROPEAN COMMUNITIES

For Australia:

3. Would Australia agree with the view that Article 5.7 of the SPSP Agreement is to be interpreted like any other provision of the SPS Agreement, and in particular in the context of the burden of proof?

Please refer to Australia's responses to question 50 posed by the Panel.

For New Zealand:

3. In New Zealand's view, if a moratorium has been formally adopted, explicitly based on the justification that there is scientific uncertainty on the risks associated with GMOs, and properly notified to the WTO under Article 7, would such a moratorium be compatible with WTO law?

The compatibility of any such moratorium with WTO law would depend upon whether relevant WTO obligations had been met. In this context, of particular relevance are the obligations set forth in Articles 2 and 5 of the SPS Agreement. In Australia's view, these obligations would not necessarily be satisfied by the formal adoption of a measure based on the existence of scientific uncertainty and the notification of that measure under Article 7.

For Argentina and Canada:

1. Do you agree with the United States' position as stated at DSB meeting of 10 December 2003 and again implied in its oral statement of last week (para. 56) that the burden of proof for Article 5.7 of the SPS agreement is on the Complainants and not on the European Communities as the defendant?

Please refer to Australia responses to question 50 posed by the Panel.

ANNEX G-2

REPLIES BY THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU TO QUESTIONS POSED BY THE PANEL AND THE PARTIES

QUESTIONS POSED BY THE PANEL

For all third parties:

With reference to pp. 27-36 of the EC first written submission, could the third parties please indicate whether the European Communities' description of their own regulatory systems is accurate?

The question by the Panel refers to the EC's analysis of the wide variety of different approaches to national regulation on post–approval surveillance that appears to exist in a number of WTO Member countries. Paragraph 84 of the EC's First Written Submission mentions that, "...given the scientific uncertainty surrounding GMOs, many systems provide for labelling and post marketing surveillance, thus allowing for the monitoring of long-term environmental and health effects of GM products." In the footnote to this paragraph, the EC identifies labelling requirements that exist, for example, in Brazil, Japan, China, Indonesia, Korea, Saudi Arabia, Taiwan, Switzerland, Australia and New Zealand.

The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu confirms that such labelling requirements do exist in our national regulation, but only for a limited number of GM products. It would also be correct to state that such labelling requirements allow "... for the monitoring of long-term environmental and health effects of GM products."

QUESTION POSED BY THE UNITED STATES

For all third parties:

At the third-party session, a number of third parties noted that they had systemic interests in this dispute. The United States would ask whether any of these third parties would care to explain the nature of their systemic interests.

We note that a similar question was also raised by the Panel during the Third Party Session of the First Panel Meeting. While we thank the Panel and the United States for placing such importance on the views of the third parties, we wish to caution against over-emphasis of the role of the third parties in this dispute. The Panel is established to resolve disputes between the complainants and the respondent, and to examine the matter referred to it by the complainants. In addition, under Article 11 of the DSU, "a panel should make an objective assessment of *the matter before it*, including an objective assessment of *the facts of the case and the applicability of and conformity with the relevant covered agreements.*" [emphasis added]

To the extent that the views of the third parties can help the Panel determine the applicability of and conformity with the relevant covered agreements, the submissions and answers of the third parties should be taken into account. On the other hand, the reasons, expressly stated or otherwise, for the third parties deciding to participate in this dispute, as well as the domestic legislation of the third

parties, have little bearing on the legal and factual matter to be decided by the Panel. In addition, the views of the fourteen third parties in this dispute cannot be seen to represent the views of the entire WTO Membership in general. We therefore urge the Panel to take account of the views of the third parties only as they relate to the matter referred to the Panel.

This being said, the matter of substance in this dispute presents new issues not previously considered by the Panel or Appellate Body. Added to that, the general subject of biotech products in itself is highly controversial in the public eye. The outcome of this case may thus have wide-ranging effects. We are therefore particularly interested in monitoring the progress of this case in order to be fully aware of the possible consequences.

QUESTION POSED BY THE EUROPEAN COMMUNITIES

For all third parties:

Does the SPS or TBT Agreement apply to a single legal instrument that is simultaneously pursuing objectives both covered and not covered under the SPS or TBT Agreement? [paraphrase]

The answer to this question depends on whether the single legal instrument can be described as a sanitary and phytosanitary measure and/or a technical measure under the SPS or TBT Agreement. If this is the case, the SPS or TBT Agreements should not be deprived of their applicability, even if the legal instrument is pursuing objectives beyond the scope of these two Agreements. The role of the Panel, under this scenario, is to determine how and to what extent the SPS or TBT Agreements cover the legal instrument, not whether the SPS or TBT Agreement should apply.

ANNEX G-3

**REPLY BY EL SALVADOR
TO THE QUESTION POSED BY THE UNITED STATES**

QUESTION POSED BY THE UNITED STATES

To all third parties:

At the third party session, a number of third parties noted that they had systemic interests in this dispute. The United States would ask whether any of these third parties would care to explain the nature of their systemic interests.

El Salvador stated that it has a systemic interest in this dispute particularly when it comes to the Panel's interpretation of the various provisions of the Agreement on Technical Barriers to Trade and the Agreement on Sanitary and Phytosanitary Measures that have come under consideration.

This is particularly significant in view of the fact that El Salvador is currently working on a possible reform of its regulations as are other developing country Members – a fact mentioned by some of the third parties in the meeting with by the Panel.

Although El Salvador currently has transitional regulations governing biotech products, efforts are being made at the national level to define new conditions for these products in keeping with the country's WTO commitments.

Thus, any decisions reached by the Panel provide an important frame of reference for the work being conducted by the Salvadoran authorities.

ANNEX G-4

REPLY BY HONDURAS TO THE QUESTION POSED BY THE UNITED STATES

QUESTION POSED BY THE UNITED STATES

To all third parties:

At the third-party session, a number of third parties noted that they had systemic interests in this dispute. The United States would ask whether any of these third parties would care to explain the nature of their systemic interests.

At the third-party session, Honduras submitted that it had a systemic interest in this dispute because, like all WTO Members, it is interested in the interpretation and proper application of the rules negotiated by Members, in particular the interpretation and proper application of the provisions relating to the Agreement on Sanitary and Phytosanitary Measures, the Agreement on Technical Barriers to Trade, and the GATT 1994.

Specifically, it is of interest to Honduras that panels and, where appropriate, the Appellate Body, when examining sanitary and phytosanitary measures in the framework of dispute settlement proceedings, should do so in the light of scientific principles, and that they should ensure that there is scientific evidence for maintaining the measure, as stipulated in Article 2.2 of the Agreement on Sanitary and Phytosanitary Measures (*" … is based on scientific principles and is not maintained without sufficient scientific evidence … "*), and Article 5.1 (*" … 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 organisations"*).

Similarly, care must be taken to ensure that the approval procedures at issue in a given dispute are conducted without unjustified delay, as stipulated in Article 8 of the Agreement on Sanitary and Phytosanitary Measures (*"Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures … "*), and Annex C(i)(a) (*"Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products; … "*).

ANNEX G-5

**REPLIES BY NEW ZEALAND
TO QUESTIONS POSED BY THE PANEL AND THE PARTIES**

QUESTION POSED BY THE PANEL

For all third parties:[1]

1. With reference to pp. 27-36 of the EC first written submission, could the third parties please indicate whether the European Communities' description of their own regulatory systems is accurate?

Paragraph 73 of the First Written Submission of the EC variously refers to New Zealand putting in place a "temporary ban" and a "statutory moratorium" on commercial release of genetically modified organisms (GMOs) which "lasted several years". This is not an accurate description of the New Zealand situation. Before any new organism, including a GM organism, can be imported, developed or released in New Zealand, it must first undergo a safety assessment by the Environmental Risk Management Authority (ERMA), a regulatory agency established under the Hazardous Substances and New Organisms Act 1996 (HSNO).

In 2000 the Government established a Royal Commission of Inquiry on Genetic Modification to inquire into and report on the strategic options available to enable New Zealand to address genetic modification issues. During the period of the Royal Commission's inquiry, a voluntary moratorium on all applications for the release of genetically modified organisms, and for new field trials of GMOs was introduced by relevant industry and research groups in New Zealand. At the conclusion of its deliberations the Royal Commission was satisfied that New Zealand's basic regulatory framework was appropriate, but suggested a number of enhancements.

After considering the Royal Commission's Report, the Government decided there was a need to restrict the release of GM organisms into the New Zealand environment for a two-year period to give the Government a fixed period of time to implement regulatory changes and to undertake other work recommended by the Royal Commission. Approved human and veterinary GMO medicines and GM organisms approved under emergency provisions in the HSNO Act were exempt from the restricted period. New Zealand legislation enhancing the regulatory framework for GM organisms was passed by the New Zealand Parliament in late 2003 and the two-year restricted period ended as scheduled on 29 October 2003. Changes in the new legislation included the introduction of a new category of approvals that enables conditions to be attached to the release of new organisms, including GM organisms, into the environment. It also streamlined procedures for low risk GM organisms, particularly GMO medicines.

As required by the WTO *SPS Agreement* and the WTO *TBT Agreement*, the two-year restricted period on the release of GM organisms into the environment was notified to both the WTO SPS Committee and the WTO TBT Committee. As no applications had been made under HSNO for the release of a GM organism into the New Zealand environment, no historic trade was affected by the restriction. Contained field tests of both GM plants and animals had been conducted for some years, and these continued during the restricted period. In addition the restriction did not affect processed GM foods and ingredients, which are permitted after safety assessment and approval by the Australia and

[1] New Zealand has not responded to questions not specifically addressed at New Zealand.

New Zealand Food Regulation Ministerial Council. There are at present over 20 GM food varieties approved for sale in New Zealand. Labelling of GM foods[2] is a separate regulatory process from the safety assessment and approval process and provides the consumer with choice after the safety of food has been assessed. It is not to allow for "the monitoring of long-term environmental and health effects of GM products" as implied by the EC in paragraphs 84 and 85 of its First Written Submission.

Paragraph 79 of the First Written Submission of the EC contains an inaccurate representation of Section 7 of the Hazardous Substances and New Organisms Act. Section 7 of that Act provides that "All persons exercising functions, powers and duties under the Act … shall take into account the need for caution in managing adverse effects where there is a scientific and technical uncertainty about those effects".

QUESTIONS POSED BY THE EUROPEAN COMMUNITIES

For New Zealand:

1. In para. 2.02 of your third party submission you state that

> **… the EC's regulatory approvals processes have been adopted by the EC for the purpose of providing protection from one or more of these risks. Both the moratorium and the product-specific marketing bans which affect the implementation of these processes are thus sanitary or phytosanitary measures within the meaning of the SPS Agreement.**

Do you consider that any measure that "affects the implementation" of an SPS approvals system is also an SPS measure?

Whether a measure is an SPS measure depends on whether the measure falls within the scope of the *SPS Agreement* as set out in Article 1 and Annex A of that Agreement. The statement reproduced above relates to the factual issue of what the purpose of the moratorium and product-specific marketing bans is. In this instance evidence provided by the Complainants shows that they have the same purpose as the approval processes that they affect and are thus SPS measures.

2. At para. 1.07 of your third party statement you state that

> **Insofar as the EC's product-specific marketing bans may not be subject to the provisions of the SPS Agreement, the Agreement on Technical Barriers to Trade (the TBT Agreement) would apply as argued in the alternative by Canada and Argentina.**

Do you accept the apparent view of the Complainants that a measure falling under the TBT Agreement will cease to do so as soon as the prevention of an SPS risk is added to the objectives of the measure?

New Zealand would refer the EC to Article 1.5 of the *TBT Agreement* which provides that the provisions of the *TBT Agreement* do not apply to sanitary and phytosanitary measures as defined in Annex A of the *SPS Agreement*.

[2] Labelling of GM foods is required where there is novel DNA or protein present in the final food. Exceptions are provided, inter alia, for unintended presence and food prepared at the point of sale.

3. In New Zealand's view, if a moratorium has been formally adopted, explicitly based on the justification that there is scientific uncertainty on the risks associated with GMOs, and properly notified to the WTO under Article 7, would such a moratorium be compatible with WTO law?

New Zealand does not consider that a view on the compatibility of a measure with the requirements of the WTO Agreements can be given in the abstract. Any measure would have to be examined in light of the substantive provisions of the *SPS Agreement* including Articles 2.2, 5.1, 5.5 and 5.6. As far as New Zealand is aware, the EC has not made the argument that its moratorium has been formally adopted, or that it is explicitly based on the justification of scientific uncertainty on the risks associated with GMOs, or that it has been properly notified under Article 7.

4. Does New Zealand think that delays should be notified to the WTO under Article 7 of the SPS Agreement?

That would depend on whether, as a matter of fact, what was being referred to as a 'delay' was in fact an SPS measure or a change to an SPS measure within the meaning of Article 7 and Annex B.

5. We note that New Zealand only concludes that the EC has failed to comply with Articles 7 and 8 of the SPS Agreement. Does that mean that New Zealand agrees that other provisions such as Articles 5.1, 5.5 and 5.6 are not applicable for addressing delays?

New Zealand concluded in its written submission that "the [moratorium and product-specific marketing bans] are also more trade restrictive than necessary to achieve the appropriate level of protection from risks which may arise from biotech products".[3] New Zealand believes, therefore, that the EC has failed to comply with the obligations set out in Articles 2.2, 5.1, 5.5 and 5.6 of the *SPS Agreement*.

QUESTION POSED BY THE UNITED STATES

For all third parties:

1. At the third-party session, a number of third parties noted that they had systemic interests in this dispute. The United States would ask whether any of these third parties would care to explain the nature of their systemic interests.

As set out in its submission, "As both a significant producer and exporter of agricultural products, New Zealand has a strong interest in ensuring that the delicate balance of rights and obligations set out in the WTO Agreements, especially the *SPS Agreement*, is maintained".[4] New Zealand is pursuing this systemic interest through its participation as a third party in the current dispute (and has similarly participated in a number of other disputes that have sought to clarify the provisions of the *SPS Agreement*).

[3] Third Party Submission of New Zealand 24 May 2004, paragraph 3.02.
[4] Third Party Submission of New Zealand 24 May 2004, paragraph 1.04.

ANNEX G-6

REPLIES BY PERU
TO QUESTIONS POSED BY THE PANEL AND THE PARTIES

QUESTION POSED BY THE PANEL

For all third parties:

With reference to pp. 27 to 36 of the EC first submission, could the third parties please indicate whether the European Communities' description of their own regulatory system is accurate?

The legislation in force in Peru is Law No. 27104 of 12 May 1999 on the prevention of risks related to the use of biotechnology, the regulations of which were approved by Supreme Decree No. 108-2002-PCM of 28 October 2002.

By means of this Law, Peru lays down the rules governing biosafety with a view to protecting human health, the environment and biological diversity; promoting safety in biotechnology research and development and in its applications for the production and provision of services; regulating, managing and controlling the risks arising from the contained use and deliberate release of living modified organisms (LMOs); regulating trade in and the marketing of LMOs at both domestic and international level; and facilitating international technology transfer in accordance with the international agreements to which Peru is or will become a signatory.

QUESTION POSED BY THE UNITED STATES

For all third parties:

At the third-party session, a number of third parties noted that they had systemic interests in this dispute. The United States would ask whether any of these parties would care to explain the nature of their systemic interests.

Peru became a third party to this dispute owing to its interest in participating in the discussions warranted thereby on the issues specified in the requests by Argentina, Canada and the United States for the establishment of a panel.

Peru considers the development and application of biotechnology and genetic engineering and the resulting activities to be important in the light of their possible effects in areas such as health, agriculture, mining, environmental conservation and biodiversity, *inter alia*, particularly at the economic, commercial and administrative level.

Peru has an ongoing systemic interest in the proper implementation and interpretation of the WTO Agreements. Of interest in this particular case is the analysis by the Panel of the legal consistency of the implementation of European Community legislation with the provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, especially with regard to the following:

(1) The procedures for the deliberate release into the environment of agricultural biotechnology products (for purposes other than their being placed on the market);

(2) the procedures for the placing on the market of agricultural biotechnology products as products or ingredients in products;

(3) the procedures for novel foods and their ingredients.

ANNEX G-7

REPLY BY THAILAND TO THE QUESTION POSED BY THE PANEL

QUESTION POSED BY THE PANEL

For all third parties:

With reference to pp. 27 to 36 of the EC first submission, could the third parties please indicate whether the European Communities' description of their own regulatory system is accurate?

At present, Thailand bans a total of 89 types of biotech plants under the Plant Quarantine Act, B.E. 2507(1964). The first such ban was issued for 40 biotech plants on 4 March 2000, and the second was recently issued on 14 October 2003 for 49 additional biotech plants. However, the ban does not extend to imports of prepared food products which use these crops as ingredients. Furthermore, importation of soy beans and corn as raw materials for the processing of animal or human food, or for industrial purposes is allowed.