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

Reports of the Panel

Addendum

This addendum contains Annex K 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:

- Annex C: Add.1
- Annex D: Add.2
- Annex E: Add.3
- Annex F: Add.4
- Annex G: Add.5
- Annex H: Add.6
- Annex I: Add.7
- Annex J: Add.8

ANNEX K

LETTER OF THE PANEL TO THE PARTIES OF 8 MAY 2006

The Panel thanks the Parties for their comments on the interim reports and their comments on each others' comments. The Panel expects to be able to issue its final reports in accordance with the applicable timetable, *i.e.*, on 10 May 2006.

The Panel recalls its letters of 9 February and 2 March 2006 in which it expressed its grave concern about the leaks which occurred, first of the interim reports' confidential conclusions, then of the confidential interim reports in their entirety. In a series of letters (EC letters of 13 February and 7 March 2006; US letters of 13 February and 7 March 2006; Canada's letters of 13 February and 8 March 2006; and Argentina's letter of 3 March 2006), the Parties all shared the Panel's concern and deplored the failure to observe the confidentiality of the Panel's interim reports, but denied any involvement in, and responsibility for, the leaks.

The Panel appreciates the Parties' responses and continued cooperation in this matter. Indeed, as previously noted by the Panel, confidentiality at all stages of the panel process is an inherent part of the WTO dispute settlement mechanism the purpose of which is to secure a positive solution to a dispute, and the disclosure of any part of a confidential panel report is, therefore, unacceptable.

The Panel will issue to the Parties a **confidential** version of the Panel's final reports (which, in addition to being confidential as a whole, contains and discloses SCI). In order to prevent leaks from recurring, the Panel will issue to the Parties paper and electronic versions of the final reports which would allow it to trace back and attribute any leaked version of part or all of the confidential reports to the Party receiving it. Furthermore, the Panel reserves the right to revert to this issue in the reports which will be circulated to Members upon completion of the translation of the reports into the official WTO languages, or when it transmits the final reports to the DSB.

The above-mentioned regrettable situation of a complete disregard of the confidentiality of the Panel's interim reports has led to these reports of the Panel being discussed and analysed by groups and members of civil society already at the interim review stage of the proceedings. In this context, the Panel notes with concern that, whether inadvertently or on purpose, certain aspects of its confidential findings have been misconstrued. The Panel therefore considers it justified, and indeed necessary, given the sensitivity of certain matters at issue in this case, to state the following:

(a) The Panel's findings recognize that the notion of "insufficiency of relevant scientific evidence" as it appears in Article 5.7 of the *SPS Agreement* includes cases of qualitative insufficiency of relevant scientific evidence. Indeed, as the Panel has noted, the Appellate Body determined that "'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*".[1] However, after considering the evidence before it, the Panel was ultimately not persuaded that the scientific evidence available at the relevant time was qualitatively (or quantitatively) insufficient, such that a risk assessment as required under Article 5.1 and as defined in Annex A(4) of the *SPS Agreement* could not be performed in relation to the products subject to the member State safeguard measures challenged in this case. The Panel also recalls the Appellate Body's view

[1] Appellate Body Report, *Japan – Apples*, para. 178 (emphasis added).

that the concepts of "insufficiency of relevant scientific evidence" as it appears in Article 5.7 and "scientific uncertainty" are not interchangeable and that it would therefore be inappropriate to interpret Article 5.7 through the prism of "scientific uncertainty".[2]

(b) In applying the concept of "insufficiency of scientific evidence" as it appears in Article 5.7 of the *SPS Agreement*, the Panel has kept in mind the Appellate Body's statement that "the risk that is to be evaluated in a risk assessment under Article 5.1 of the *SPS Agreement* is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die".[3] Yet after considering the evidence before it, which includes the various risk assessments undertaken by lead CAs and by the relevant EC scientific committees, the Panel was ultimately not persuaded that in relation to the products subject to the member State safeguard measures challenged in this case, the scientific evidence available at the relevant time did not allow the performance of an assessment of the risk in human societies, or natural environments, as they actually exist, in accordance with the provisions of Article 5.1 and Annex A(4) of the *SPS Agreement*.

(c) The Panel's findings relating to Article 5.1 of the *SPS Agreement* preserve the freedom of Members to take prompt protective action in the event that new or additional scientific evidence becomes available which affects their risk assessments. Particularly if the new or additional scientific evidence provides grounds for considering that the use or consumption of a product might constitute a risk to human health and/or the environment, a Member might need expeditiously to re-assess the risks to human health and/or the environment. Initially at least, an expedited re-assessment of relevant risks might be "appropriate to the circumstances"[4] and might provide a basis for a different SPS measure or for an SPS measure where none has been applied before.[5] However, the same re-assessment of relevant risks might no longer be "appropriate to the circumstances" at some later point in time, *e.g.*, if and when further and more thorough and elaborate analysis of the new or additional scientific evidence, as such and together with other available evidence, was possible

[2] *Ibid*., para. 184. We also note in this connection that the Appellate Body in *EC – Hormones* stated that "Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty. Sometimes the divergence may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty". Appellate Body Report, *EC – Hormones*, para. 194. Thus, the Appellate Body was apparently of the view that this form of scientific uncertainty would not mean, *eo ipso*, that relevant scientific evidence is insufficient to perform a risk assessment as required under Article 5.1 and as defined in Annex A(4) of the *SPS Agreement*.

[3] Appellate Body Report, *EC – Hormones*, para. 187.

[4] We recall that Article 5.1 of the *SPS Agreement* requires that SPS measures be 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.

[5] It is useful to note in this context that the first type of risk assessment defined in Annex A(4) of the *SPS Agreement*, which envisages an evaluation of the likelihood of entry, establishment or spread of a pest or disease, and of the associated potential biological and economic consequences, "does not require that the evaluation of the likelihood needs to be done quantitatively. The likelihood may be expressed either quantitatively or qualitatively." Appellate Body Report, *Australia – Salmon*, para. 124.

and indicated, and such analysis would have shown that the conclusions of the initial, expedited re-assessment of relevant risks is no longer valid.

(d) The Panel's findings leave room for the possibility that even if at a given point in time relevant scientific evidence is sufficient to perform a risk assessment, a situation might subsequently arise where the relevant scientific evidence could be considered insufficient to perform a risk assessment as required under Article 5.1 and as defined in Annex A(4) of the *SPS Agreement*. It is conceivable, for instance, that relevant new scientific evidence would negate the validity of the scientific evidence on which an existing risk assessment relied, without, however, being sufficient, in quantitative and qualitative terms, to allow the performance of a new risk assessment.