

DRAFT

Biotechnology in the Seattle Round

At the July meeting of the WTO General Council, the U.S. submitted a proposal to include biotechnology on the agenda for the Seattle Round. The proposal in its entirety reads: "That the *objectives* for the negotiations include addressing disciplines to ensure trade in agricultural biotechnology products is based on transparent, predictable and timely processes."

This paper outlines biotechnology-related objectives for the Seattle Round.

Objectives

The two parts of the WTO most relevant to trade in biotech products are the SPS Agreement and the Agreement on Technical Barriers to Trade (TBT). It is our position that the provisions of the SPS Agreement fully cover the regulatory approval processes for biotech products. Labeling requirements are covered by the TBT Agreement. Potential objectives for each of the agreements are discussed below.

SPS Agreement

Although the SPS Agreement does not specifically mention biotechnology, biotech regulatory approval procedures clearly fall within the scope of the Agreement. The Agreement establishes rules for approval procedures. The applicability of the Agreement is defined in terms of the risk addressed by a measure, not in terms of a "product" or a "production process".

The SPS Agreement requires approval procedures to be based solely on sound science; it requires risk assessments; and it encourages countries to rely on mutual recognition of equivalent standards. Within certain limitations, the SPS Agreement also requires measures to be based on international standards where they exist. Within the context of these rules, the two greatest risks to trade in biotech products are: 1) the lack of time limits for conducting risk assessments and granting approvals; and 2) the threat that countries will use non-scientific justifications (e.g., consumer concerns) to withhold approvals.

Proposed biotech objectives for the SPS Agreement:

1. Prevent the SPS Agreement from being re-opened: The SPS Agreement is fundamentally sound. It can be safely assumed that if the SPS Agreement is re-opened, the EU and others will push hard to include consumer and other non-scientific concerns as legitimate factors to be considered in adopting an SPS measure.
2. Engage the WTO in a dialogue on agricultural biotechnology: Biotech-related issues are being discussed in various fora – Codex, OECD, Convention on Biological Diversity, etc. In most cases, the trade complications arising from attempts to regulate biotechnology are not being adequately considered because trade officials are not participating. The WTO is the appropriate forum for discussing trade rules that have an affect on trade in biotech products and for reviewing the trade-related aspects of the activities in other fora.

3. Affirm the Applicability of the SPS Agreement to Biotech: Although the argument in favor of applicability is very persuasive, many countries simply have not focused on the question. The question of applicability can be resolved either through a dispute settlement case, or through the development of a consensus in either a negotiating group, a working party, or perhaps within the SPS committee.
4. Enforce Time limits on Risk Assessments: Paragraph 1(a) of Annex C of the SPS Agreement requires that risk assessment procedures shall be "undertaken and completed without undue delay". This provision could be clarified to impose specific time limits on biotech approvals.
5. Prevent the fundamental SPS principles from being undermined: Discussions on Trade and Environment could undermine the SPS Agreement. The precautionary principle and the consideration of non-scientific concerns are the two biggest threats to the fundamental SPS principles – sound science and risk assessments. Any discussions on Trade and Environment will almost certainly include the precautionary principle. If Trade and Environment is included in the negotiations, the outcome should not be inconsistent with the SPS Agreement.