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Codex, Substantial Equivalence and WTO Threats to National GMO Labeling Schemes

by

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During 25-28 May, 1998 in Ottawa, the Codex Committee on Food Labeling will consider adoption of the "*substantial equivalence*" test as a Codex international standard for the labeling of products containing genetically modified organisms (GMOs). Under the *substantial equivalence* approach, a food product containing GMOs that exhibits sufficient resemblance to a traditional product can be treated in the same manner with respect to food safety. This approach has been widely criticized as inadequate method for addressing the risks and uncertainties arising from the genetic modification of food.

If adopted at Codex, the *substantial equivalence* approach may be imposed by the WTO on all WTO Member States, as the rules of international trade embody a strong preference for international standards such as those set by Codex. As explained in this brief, a Codex endorsement of *substantial equivalence* as an international GMO product labeling standard may thus affect the WTO-consistency of national labeling laws. At particular risk are national laws responding to widespread consumer demand for the labeling of *all* GMO products. These and other national GMO labeling laws may be vulnerable to challenge in the WTO's dispute settlement system.

Summary:

- *Substantial equivalence* provides an inadequate basis for testing the safety of products containing GMOs.
- Standards adopted at Codex will likely be considered "international standards" at the WTO.
- The WTO rules manifest a strong preference for domestic laws that are based on "international standards". As an international standard, *substantial equivalence* would be used by the WTO as a benchmark against which to test national laws regulating the labeling of GMO products.
- National laws that set standards higher than required by *substantial equivalence* will not qualify for a presumption of WTO consistency.
- If *substantial equivalence* is recognized at the WTO as an international standard, the WTO will limit Members' ability to impose more stringent national laws. National laws requiring the labeling of *all* GMO products risk being struck down by the WTO.
- Codex should therefore not endorse *substantial equivalence* as the international standard for the labeling of GMO products.

Substantial equivalence provides an inadequate basis for testing the safety of products containing GMOs.

The use of *substantial equivalence* for determining the safety of GMO products is receiving increasing criticism by the international scientific community. For example, it has been argued that *substantial equivalence*:

- permits rapid commercialization of GMO products without adequate testing for unintended side effects, including gene transfers occurring after GMO product are released;
- ignores the revolutionary nature of recombinant DNA techniques and their inherent risks; and
- ignores recent scientific evidence including the spread of antibiotic-resistance marker genes by horizontal transfer.

Standards adopted at Codex will likely be considered "international standards" at the WTO.

In this context, two WTO Agreements are relevant:

- ***Agreement on Sanitary and Phytosanitary Measures (SPS Agreement).*** The SPS Agreement applies to national laws for the protection of life and health from risks arising from, among other things, additives, contaminants, toxins, diseases and pests. It explicitly defines "international standards" to include food safety standards set by Codex.
- ***Agreement on Technical Barriers on Trade (TBT Agreement).*** The TBT Agreement applies to national laws regulating product characteristics, labeling and packaging. While not explicitly referencing Codex, it has been argued that the TBT Agreement would recognize Codex standards as "international standards".

It is unclear whether the SPS Agreement or the TBT Agreement would apply to GMO labels. Arguably the TBT Agreement is the more appropriate agreement as it permits consideration of the non-food safety factors (ethical, religious, dietary factors and consumer right-to-know) that underpin existing and proposed GMO labeling schemes. By contrast, the SPS Agreement, due to its preoccupation with science and risk assessment, should not be applied to labels based on these factors.

The WTO rules manifest a strong preference for domestic laws that are based on "international standards". As an international standard, substantial equivalence would be used by the WTO as a benchmark against which to test national laws regulating the labeling of GMO products.

The SPS Agreement requires WTO Members to "base their sanitary and phytosanitary measures on international standards". Similarly the TBT Agreement requires WTO Members to use international standards "as the basis for" national regulations and standards. Through these rules, the WTO encourages Members to use international standards as the basis for their laws. The purpose is to encourage the harmonization of the laws of different countries in order to reduce barriers to market access. However, WTO pressure to harmonize may restrict national capacity to regulate new technologies

such as genetic engineering. By encouraging low international standards, GMO-exporting nations position themselves to use the WTO to challenge sound laws (such as those responding to consumer demand for the labeling of all GMOs) in potential GMO importing nations.

Both the SPS and TBT Agreements limit WTO Members' ability to decide not to base domestic laws on international standards such as those set by Codex. Therefore, if countries were to adopt the *substantial equivalence* standard at Codex, WTO Members would have to base their GMO product labeling laws on the *substantial equivalence* approach or potentially face a WTO challenge.

National laws that set standards higher than required by substantial equivalence will not qualify for a presumption of WTO consistency.

Under the SPS Agreement, national laws that "conform to" international standards are presumed to comply with the SPS Agreement (and with the GATT). Similarly, under the TBT Agreement, national laws that are "in accordance" with international standards are presumed not to be "unnecessary obstacles to trade", thereby satisfying one of the TBT Agreement's main requirements. Laws that exceed international standards will not enjoy the benefit of these presumptions, and will, consequently, be more vulnerable to challenge at the WTO.

If substantial equivalence is recognized at the WTO as an international standard, the WTO will limit Members' ability to impose more stringent national laws. National laws requiring the labeling of all GMO products risk being struck down by the WTO.

Under the SPS Agreement, Members may exceed international standards only where there is a scientific justification for doing so, or, in the absence of adequate scientific evidence, where the Member continues to seek information necessary for an objective assessment of risk within a reasonable time. The SPS Agreement's preoccupation with risk assessment prevents adequate consideration of non-safety justifications for national law. This failure would be further compounded by adoption of the *substantial equivalence* test which, in the specific context of GMO labeling, ignores the non-safety (ethical, religious and dietary concerns, and consumers' right to know) factors that underpin GMO labeling. If *substantial equivalence* is adopted, labels responding to these concerns may be more easily challenged at the WTO as being "more trade restrictive than required", or as failing to "minimiz[e] negative trade effects" as required by the SPS Agreement.

Under the TBT Agreement, Members may exceed international standards only where, for reasons such as fundamental climatic or geographical factors, the standard is inappropriate or inapplicable to pursue a "legitimate objective". The parameters of these requirements, including what will be considered a "legitimate objective", is unclear. Governments should reject *substantial equivalence* for failing to consider non-safety factors to send a signal to the WTO to consider non-safety factors as "legitimate objectives" for the purposes of setting GMO standards.

Codex should not endorse substantial equivalence as the international standard for the labeling of GMO products.

Substantial equivalence is inadequate on both scientific and policy grounds. Scientifically, it is an inadequate method for assessing the risks associated with GMOs. And, *substantial equivalence* ignores important policy justifications for GMO product labeling – ethical, religious and dietary preferences and consumers' right-to-know. National governments should retain their ability to adopt flexible responses to the risks posed by genetic engineering, including the labeling, and if necessary, the banning of GMO products. Because of Codex's relation to the WTO, a Codex endorsement of *substantial equivalence* risks foreclosing these and many other options.