

Proposal Subject: Guidance on Equivalence Criteria for Food

Specific NSSP Guide Reference: N/A

Text of Proposal/ Requested Action: Under Article 4 of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) (the SPS Agreement), each member nation of the WTO, including the United States, is obligated to accept as equivalent a food regulatory system of another country if it provides the same level of health protection as is provided to consumers by its own system.

Equivalent regulatory systems need not be identical. Under the concept of equivalence, the “sanitary or phytosanitary measures” used by an exporting country may differ from the measures applied domestically by an importing country as long as these measures “achieve the importing Member’s appropriate level of sanitary or phytosanitary protection”.

Under the SPS Agreement, the burden of demonstrating that equivalence exist rest with the exporting country. The exporting country has the right to decide for itself whether the regulatory system of the exporting country is equivalent to its own or is inadequate to achieve “the importing Member’s appropriate level of sanitary or phytosanitary protection,” or that inadequate evidence has been provided to demonstrate equivalence.

One of the roles of the USFDA in the National Sanitation Shellfish Program (NSSP) is the evaluation of foreign programs and the establishment of MOU’s with countries that meet the requirements of the NSSP. This responsibility of FDA is outlined in IV. A. 4. of the ISSC/FDA Memorandum of Understanding, March 14, 1984. Article 4 of the WTO Agreement obligates the FDA to accept equivalency in foreign programs. The Agreement requires that the USFDA consider acceptance of foreign shellfish safety programs that, while having a system of sanitary measures that differ from those applied domestically, are recognized as providing an equivalent level of public health protection.

The FDA is seeking input from the ISSC for purposes of incorporating the concept of equivalency into the NSSP. Recognizing that FDA has a clear obligation under the WTO Agreement to take responsibility for equivalency determination, it is important to the Agency that this responsibility be recognized within the NSSP.

Public Health Significance: N/A

Cost Information (if available): N/A

Action by 2007 Task Force III Recommended referral of Proposal 07-303 to Executive Board for developing short term and long term approaches to incorporating equivalency into the NSSP and the ISSC.

Action by 2007 General Assembly Adopted recommendation of 2007 Task Force III.

Action by USFDA	December 20, 2007 Concurred with Conference action.
Action by 2009 Executive Board	Recommended the Executive Board continue discussions with FDA to address equivalency of food programs.
Action by 2009 Task Force III	Recommended adoption of the Executive Board recommendation on Proposal 07-303.
Action by 2009 General Assembly	Adopted recommendation of 2009 Task Force III on Proposal 07-303.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 07-303.
Action by 2011 Task Force III	Recommended adoption of Resolution 11-003 as a substitute for Proposal 07-303. Resolution No. 11-003 <i>Whereas</i> , the Interstate Shellfish Sanitation Conference, (ISSC), and the Food and Drug Administration, (FDA), agreed to a Memorandum of Understanding, (MOU), on March 14, 1984 which continues to present; and <i>Whereas</i> , The National Shellfish Sanitation Program (NSSP) and its associated documents, including the FDA/ISSC MOU, do not make provisions for equivalency determinations or recognition of other programs; and <i>Whereas</i> , under Article 4 of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), as a participating member, the U.S. is obligated to consider equivalent food safety measures of a participating country if those measures provide a level of public health protection equal to that provided by the U.S. system - the NSSP; and <i>Whereas</i> , FDA must address the concept of equivalence and related criteria afforded by non-NSSP shellfish regulatory systems; therefore <i>Be it Resolved</i> , that the ISSC recognizes that FDA, as a U.S. regulatory agency, is bound by the WTO to consider equivalency if requested by other countries and that the ISSC recognizes and accepts equivalency determinations by FDA; and <i>Be it Further Resolved</i> , that upon request from FDA, the ISSC will provide input on the criteria and evaluation processes that may be applied by FDA for such determinations.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 07-303.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 07-303.