

REGIONALIZATION

Communication by the United States

The following communication, dated 15 March 2004, is being circulated at the request of the Delegation of the United States.

1. The United States applies the concept of regionalization both in reaching import determinations and to facilitate exports with regard to animal and plant products. Application of regionalization actually predates the WTO SPS Agreement. In 1987, USDA-APHIS amended its regulations to establish criteria under which the importation of fruits and vegetables from “definite areas or districts” would be allowed. Since that time, USDA-APHIS has recognized numerous pest-free or low prevalence areas, facilitating plant or plant product imports as a result.

2. In 1997, APHIS published a statement setting out its policy regarding recognition of animal disease freedom on the basis of areas defined by factors other than national borders. The policy statement identified specific factors affecting the disease risk of a region that APHIS considers in its evaluation, such as livestock demographics, diagnostic laboratory capabilities, and the disease status of adjacent regions. These factors have been incorporated into APHIS regulations (http://www.access.gpo.gov/nara/cfr/waisidx_03/9cfr92_03.html).

1. Experience and Observations

3. Drawing on our experience in regionalization, the United States would like to share the following observations:

- Any regionalization decision must consider the strength and credibility of the veterinary or phytosanitary infrastructure of the exporting region(s). The veterinary or plant health authorities must demonstrate their ability to maintain freedom from specified pests or diseases to create the necessary confidence on the part of the importing country. A key element in this is credibility as well as timely, consistent and accurate disease and pest reporting, as called for under the OIE and the IPPC.
- Regionalization decisions must be based on science and a risk assessment that takes into account the biology of the particular pest or disease at issue and an evaluation of the veterinary or phytosanitary infrastructure in the exporting region. In addition, the availability of appropriate risk management options will influence the regionalization determination.

- The availability and quality of scientific information will dictate to a great extent the length of time and the complexity of the risk assessment. In some cases, it is necessary to gather appropriate surveillance or other information to support a regionalization request. The willingness of the exporting country to collect and share this information can significantly affect the time required.
- Regionalization decisions must be reached in an open and transparent manner, allowing relevant input from all interested parties.
- Disease or pest outbreaks may occur in areas that had attained freedom. The United States recently proposed amending its regionalization approach to address situations where an area, previously recognized as free, has had an outbreak but regained its free status (G/SPS/N/USA/763). While it is necessary to evaluate how the outbreak occurred and was subsequently eradicated, many elements such as the strength of the infrastructure, may already be known.

2. Activities of the International Standard Setting Bodies

4. The United States considers that the relevant international standard-setting bodies, the OIE and IPPC, are the appropriate bodies to undertake the task of developing guidelines for reaching regionalization decisions. The OIE and the IPPC possess the necessary technical expertise to consider the multitude of factors that must be examined, such as the biological nature of pests or diseases, inefficiencies in the exchange of relevant data, and the ability of the exporting country to demonstrate the effectiveness of its disease eradication and control programs.

5. The OIE does, upon request and in the context of OIE standards, evaluate members' status with respect to Foot and Mouth Disease, Rinderpest, and Bovine Spongiform Encephalopathy. The IPPC, however, does not conduct similar evaluations of plant pest status among its members. Changes to the functions performed by the OIE and IPPC must be decided upon through the appropriate mechanisms of these bodies.

6. For exporting countries: The relevant OIE and IPPC standards point out that the establishment of pest or disease free areas is an effort or procedure undertaken by an exporting country for the purposes of international trade. These standards are very helpful in showing exporting countries how to establish and maintain disease or pest free areas in a manner that will give importing countries the assurance they seek. Participation in the work of the OIE and IPPC, and timely reporting of disease or pest outbreaks, contribute significantly to building the credibility importing countries must rely upon in making regionalization decisions.

7. For importing countries: The United States considers that the existing standards of the OIE and IPPC related to risk assessment are the starting point for more specific guidance for importing countries evaluating requests for regionalization. This guidance could help Members improve the transparency and consistency of the scientific evaluations related to regionalization determinations. The OIE and the IPPC possess the necessary technical expertise to develop such guidelines, and provide the appropriate forum for this work.
