WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures Original: English

EQUIVALENCE

Submission from the United States

1. In response to the Committee's agreement to discuss Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures at its November 2000 meeting, the United States submits this paper regarding Article 4. This paper describes the experiences of the United States regarding the practical implementation of the provisions of Article 4. It should be noted that the United States has few equivalence agreements in effect at this time. This is, in part, due to the resource commitments needed and the difficulty of pursuing these kinds of agreements. Nonetheless, the experience of the United States may be of interest to the Committee during the discussion of this issue.

Article 4 states:

> *1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.*
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> *2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.*

US Approach

2. The United States, in its approach towards implementing the concept of equivalence, recognizes that SPS measures of other Members may achieve the appropriate levels of protection (ALOP) of the United States. In the United States, several different agencies develop and administer SPS measures which achieve the ALOPs that are generally established by different statutes for food safety and animal and plant health. The responsible US agency will determine another Member's SPS measures equivalent if they achieve the relevant ALOP.

3. With regard to food safety measures, three different federal agencies have responsibility: (1) the Department of Health and Human Services' Food and Drug Administration (FDA); (2) the Department of Agriculture's Food Safety and Inspection Service (FSIS); and (3) the Environmental Protection Agency (EPA). FDA has primary responsibility for the safety of all foods, with the exception of meat, poultry, and certain egg products, which FSIS regulates. EPA regulates the use of pesticides and establishes maximum residue limits in foods that are enforced for domestically produced and imported foods by FDA and FSIS. US food safety laws are contained in several key statutes.[1] US laws pertaining to the safety of meat and poultry differ from those pertaining to the safety of other foods.

4. In regard to measures applied to protect plant and animal health, the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has regulatory responsibility for determining whether the exporting country's measures meet the ALOP of the United States.

Foods (except meat and poultry)

5. Under US law, most fresh and processed foods falling within FDA's regulatory authority may be exported to the United States without any prior FDA approval or authorization. There are a few exceptions, most notably infant formula and low-acid/acidified canned foods, which are subject to prior registration of both US and foreign production facilities and certain other requirements, as preconditions for distribution within the United States. All foods marketed in the United States, whether domestically produced or imported, are expected to meet FDA safety and labeling requirements. It is primarily the responsibility of food manufacturers to meet these requirements. If food products do not conform to these requirements, FDA takes the appropriate enforcement actions to remove these products from the market in accordance with the laws of the United States.

6. An FDA finding of equivalence is not a prerequisite for export of foods to the United States. Neither does FDA require consignment-specific "health" or "compliance" certificates be provided from governments of countries exporting foods to the United States. Nonetheless, some WTO Members have requested equivalence determinations from the FDA. Generally, however, these requests are not addressing an actual trade barrier.

7. FDA's equivalence determination process requires a review of relevant laws, regulations, directives and practices and on-site verification of the competent authority's administration of the program or product under consideration. The FDA procedures are similar to those of FSIS, described below.

Meat and Poultry

8. Laws of the United States governing meat and poultry inspection require an equivalence determination before these products can be imported into the United States. FSIS does not enter into equivalence agreements with countries, but rather, at the completion of the equivalence determination process, changes US regulations to list the country as eligible to export to the United States. FSIS has developed and published a process for evaluating whether a foreign country's meat and poultry regulatory system and individual sanitary measures are equivalent to the system and measures of the United States. Before implementing it in1999**,** the proposed process was notified to the public.

[1] The Federal Food, Drug, and Cosmetic Act; the Public Health Service Act; the Federal Meat Inspection Act; the Poultry Products Inspection Act; Egg Products Inspection Act; and the Federal Insecticide, Fungicide, and Rodenticide Act.

9. Applications from foreign countries for an initial determination of equivalence must contain sufficient technical and scientific evidence for FSIS to evaluate whether sanitary measures of the foreign food regulatory system are equivalent to the system of the United States. To facilitate this process, FSIS provides questionnaires to countries. Completed questionnaires, along with copies of laws, regulations and directives, provide the documentation needed by FSIS to make an equivalence determination. The document review is generally the lengthiest part of the equivalence process. Once the document review process is completed, FSIS conducts an on-site audit to verify the equivalence of the country's inspection system.

10. When a country becomes eligible to export meat and poultry to the United States, FSIS verifies its continued equivalence through random sampling of products for reinspection at the port of entry and through annual on-site system audits. Results of reinspections and audits are shared with the exporting country. There are currently 36 countries recognized as having meat and poultry inspections systems equivalent to the United States. All meat and poultry products, domestic and imported, marketed in the United States are expected to be in compliance with standards of the United States. If these food products are not to be in compliance, appropriate actions are taken to remove the products from the market in accordance with the laws of the United States.

11. A similar process - document review and on-site verification - is used when a country eligible to export to the United States requests an equivalence determination for an alternative sanitary measure. Alternative measures are raised independently by meat and poultry exporting countries in the form of proposed changes in their inspections systems or they may be offered in response to new inspection requirements of the United States.

Plants, Plant Products, Animals and Animal Products

12. APHIS applies the concept of equivalence in determining that an alternative measure or combination of measures, proposed by the exporting country, achieves APHIS' objective of reducing a given pest or disease risk to an acceptable level. Different measures can, under certain circumstances, achieve a comparable or identical level of protection against certain pest or disease risks. Generally, APHIS evaluates a number of risk mitigation measures in determining the conditions under which trade can be allowed. For example, APHIS may generally require fumigation of imported fruits in order to reduce the risk of introducing exotic fruit flies. However, the exporting country may be able to demonstrate that an alternative measure, such as cold treatment, or a combination of measures under a systems approach, is equally effective in reducing the pest risk.

13. In accordance with Article 4, it is the responsibility of the exporting country to supply data demonstrating the efficacy of the proposed measures to APHIS, and to permit APHIS to conduct appropriate testing, inspection and other relevant procedures to assure the effectiveness of these measures.

Practical Challenges with Article 4

14. In the experience of the United States, practical implementation of the concept of equivalence is dependent upon a variety of factors, including:

- the scope (single product or product sector);
- the formality of any agreement reached between the parties, i.e., ranging from a simple exchange of letters to a formal memorandum of understanding; and
- the number of parties involved, i.e., bilateral or multilateral.

15. Based on US experience, there are several practical problems that could limit the use of Article 4. Among these problems are: (1) where no trade barrier exists, should the request for equivalence be pursued; (2) whether the actual trade benefits justify the administrative burden of making a determination of equivalence and/or negotiating an agreement; (3) the inherent difficulty linking numerous and disparate measures to a country's ALOP; and (4) stakeholder acceptance of equivalence determinations and negotiated equivalence agreements.

16. Possibly the most important factor constraining the use of Article 4 is that the practical gains in product trade from an equivalence determination and any associated agreement may not be viewed as worth the costs of reaching such a determination or agreement. In the experience of the United States, conducting equivalence evaluations and negotiating equivalence agreements involves a substantial commitment of technical and trade specialists to review materials, exchange data and information, establish terms and conditions of discussions, meet with counterparts, and to conduct on-site visits and verification audits.

17. A second factor is the inherent difficulty associated with linking measures to a country's appropriate level of protection. This problem is magnified when the scope of the agreement is broadened to include multiple products and the concept of equivalence as applied to import and export control and inspection systems.

18. Another complicating factor is addressing stakeholder concerns. It is critical that Members take every appropriate opportunity to inform stakeholders about their on-going and intended equivalence discussions with other Members to ensure stakeholder acceptance. The use of an open, public forum, which respects the need for direct government-to-government negotiations, appears to be an excellent tool to facilitate consideration of the merit of seeking an equivalence determination or agreement for particular products.

Conclusions Based on the Experience of the United States

19. Members should not regard an equivalence agreement as a necessary condition to gain access to another member's market.

> *Over 85 percent of all food products imported into the United States do not require a prior determination of equivalence and/or an export certificate. Meat and poultry products are the primary exceptions and are based on legislative and regulatory requirements. A country must obtain an equivalence determination process before it can export meat or poultry to the United States.*

20. Utilization of other provisions of the SPS Agreement, specifically Article 5 (Risk Assessment), Article 7 and Annex B (Transparency), Article 8 and Annex C (Control, Inspection and Approval Procedures), and Article 9 (Technical Assistance), prior to a request for formal equivalence consultations may yield more immediate trade benefits.

> *WTO Members can request an explanation for the rationale for a specific measure in accordance with Article 5.8. Similarly, Members can request answers to all reasonable questions and the provision of documents regarding a country's existing and proposed measures under Article 7 and Annex B. Moreover, importing Members have additional obligations in accordance with Article 8 and Annex C to assure that their approval procedures are "undertaken and completed without undue delay" and that a procedure exists to review complaints and take corrective actions when a complaint is justified. Finally, developing countries may benefit more directly by requesting product-specific technical assistance in accordance with Article 9 in order "to adjust to, and comply with,*

sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets."

21. The "consultations" mentioned in Article 4.2 require a considerable investment in time and other resources from both technical and trade officials.

Equivalence determinations require a significant investment of technical and trade experts to address and resolve safety issues Even in instances where ALOPs and governmental institutions of two WTO Members may appear to be similar, determinations of equivalence have taken several years of negotiations and a great deal of the time of technical and trade experts and have not resulted in immediate new trade opportunities.