WORLD TRADE ORGANIZATION

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INFORMATION ON THE PROCESS FOR DEVELOPMENT OF US SPS MEASURES AND EXPLANATION FOR THE VOLUME OF RECENT US SPS NOTIFICATIONS

Submission by the United States

In response to the Chairman's request to Members to provide additional information to the Committee on their experiences with implementing the notification provisions of Article 7 and Annex B of the SPS Agreement, the United States is pleased to provide this paper for the Committee's information and consideration.

Introduction

1. During the Committee's October meeting, we noted the significant number of notifications made by the United States to the Committee over the last several years. During 2000 and 2001, for example, the United States provided 323 SPS notifications to WTO.

2. The purpose of this paper is: (1) to provide the Committee with an explanation of the general nature of the US notifications and the process by which the United States develops them; and (2) to explain that the recent increase in volume of US notifications is a direct result of legislative changes in our food safety/pesticide laws.

The United States Administrative Procedures Act and Federal Rulemaking Requirements

3. In the United States, federal laws are written by the United States Congress, the Legislative Branch of the US Government. Rules/regulations are the means by which the President and the Executive Branch, including various departments and agencies, implement the laws adopted by Congress. US laws and regulations are subject to review by the Judicial Branch of government, i.e., the court system.

4. Standards-setting and regulatory procedures in the United States are required by law to be transparent and nondiscriminatory. The Administrative Procedures Act of 1946 (APA) is the primary statute which establishes the basic framework for rulemaking. In general, the APA requires a federal agency desiring to issue a regulation, to publish the proposed rule in the United States government journal, the **Federal Register**. Publication is intended to provide all interested parties, including other national governments, industries, organizations and individuals, an opportunity to comment on any aspect of the proposal.

5. The notice generally includes the text and the intended purpose for the proposal and cites the statutory authority and provisions affected by the proposed rule. The explanation of the proposed rule must be sufficient to inform the public of the rule's purpose. The notice of the proposed rule also includes a request for comment and allows all interested persons a reasonable opportunity to submit

written data, views and/or concerns relating to the agency's proposed rule. Comments are typically submitted in writing. Generally, the public comment period begins as soon as the proposed rule is published in the **Federal Register** with a specific deadline to receive comments.

6. Federal law requires an agency to consider and respond to all significant comments submitted during the comment period. Frequently, agencies revise rules in response to comments received during the rulemaking process.

7. In its response, a federal agency adopting a rule will publish a reasoned justification of the rule, a summary of comments received from parties interested in the rule, the reasons why the agency agrees or disagrees with the stakeholders comments, a restatement of the rule's factual basis, and the statement of authority under which the rule is adopted.

8. Once these procedures have been completed, the agency forwards its final rule for publication in the **Federal Register**. The provisions of the final rule can be effective immediately, within a few weeks, e.g., in 30 days or, in the case of major new rules, substantially longer. In this manner, the APA provides a structured and systematic means for ensuring a uniform and transparent rulemaking process. Final rules are generally subject to judicial review.

9. In general, the rulemaking process outlined above, governs the work of all federal agencies, including the regulatory agencies whose measures are notified under the SPS Agreement. These SPS-related regulatory agencies include the United States Environmental Protection Agency (EPA), the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) and Food Safety and Inspection Service (FSIS), and the United States Food and Drug Administration (FDA). The US SPS Notification Authority submits notifications of proposals and final rules developed by these agencies to the WTO immediately after their publication in the **Federal Register**, usually within one or two days.

Recent Changes in United States Law Pertaining to Pesticides

10. In the United States, pesticide residue tolerances set by the EPA are then enforced by FDA. FDA monitors domestically produced and imported foods traveling in interstate commerce, with the exception of meat, poultry and some egg products which are enforced by FSIS. FDA is responsible for all bulk and processed foods not under the jurisdiction of FSIS. APHIS regulates products that pose a risk to animal or plant health and is responsible for writing and enforcing such regulations.

11. As previously stated, during the years 2000 and 2001, the United States notified 323 SPS proposals. The majority of the notifications (64 per cent) concerned EPA pesticide measures. The other 36 per cent were divided between the rest of the SPS-related regulatory agencies. APHIS 17 per cent, FDA 15 per cent; and FSIS 4 per cent. The large number of recent pesticide-related notifications is a result of EPA's implementation of changes in US pesticide laws enacted in 1996 and the development of new, lower risk pesticides.

12. In October 1996, the United States submitted document G/SPS/GN/4, detailing provisions of the recently adopted Food Quality Protection Act (FQPA). This law was unanimously passed by the United States Congress in August 1996**.** FQPA, which revised the appropriate level of protection for pesticide residues, requires a comprehensive, integrated, and transparent approach to risk assessment and risk management for pesticide residues in foods. It established an appropriate level of protection of a single health-based standard for EPA's decisions on maximum residue limits (MRLs) "a reasonable certainty of no harm" which includes consideration of all non-occupational sources of pesticide exposure. FQPA also established a level of protection that provides for an additional 10-fold safety factor to protect children from threshold effects unless there are data demonstrating that

using a different factor will be safe. This safety factor was intended to make sure US Government decisions on pesticide chemical residues will be more protective for children.

13. In terms of the number of SPS notifications to the WTO, FQPA not only required that all new residue limits be assessed under the new standards, it also required that all existing maximum residue limits be re-evaluated to ensure that they meet current safety standards. In addition, FQPA requires the government to consider aggregate exposures to pesticide chemical residues. Specifically EPA must aggregate the potential exposures from all foods, drinking water, household use and any other non-occupational exposure. The law also requires the government to consider cumulative effects of any pesticides and other chemicals that share a common mechanism of toxicity.

14. Nearly 10,000 existing tolerances are now undergoing review by EPA. These reassessments have led to a substantial increase in the number and frequency of changes to US pesticide residue limits. Since such changes may have a direct and substantial impact on food producers in other countries who are required to comply with the MRLs if they wish to export food to the United States, our government notifies all relevant changes in its pesticide residue limits to the WTO at as early a stage as possible. In addition, EPA has, and will continue, to host technical workshops in foreign capitals to familiarize other countries with US levels of protection.

The Merits of a Strong Notification System:

15. Interested stakeholders which includes all interested parties - domestic and international - play a vital role in shaping US regulatory policies. Through extensive public involvement, the United States is able to ensure that regulations are based on the latest information and scientific principles. In the WTO context, a review of and comment on any member's proposal, though optional, can be effective in minimizing potential trade disruptions. By providing comments on the notifications of the other members, The United States has successfully encouraged changes to provisions of other members' proposals that would have had unintended or negative trade consequences.

16. In January 2001, in an effort to enhance transparency under the SPS Agreement, the United States began, with guidance from the WTO Secretariat, to notify the Committee of final rules by way of addenda to the original proposal. We believe it is very important to notify members of changes in the final rule and to alert other Members when these rules come into effect. Since January 2001, the United States has notified 67 final rules published by SPS related regulatory agencies.

17. This information is provided to Members to assist in understanding both the US process for development of SPS measures and the nature of many of its recent notifications to the WTO. Transparency, particularly timely and effective notification of all relevant SPS measures, should be a high priority for all Members.

18. The US Government is committed to ensuring full implementation of SPS Agreement. In our opinion, transparency, as outlined in the Agreement, can only be achieved when countries notify other Members of all significant changes to sanitary or phytosanitary measures on a timely basis. Equally important is that these measures be based on scientific principles and scientific evidence and involve all interested stakeholders. We encourage all members to take full advantage of the notification process to enhance our understanding of each other's regulatory systems.

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