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Comments submitted by the Office of Agriculture, Fisheries and Food of the Embassy of Spain in Washington, D.C. to Docket No. 02N-0278, Prior Notice of Imported Food Shipments, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Washington, D.C., April 3, 2003

The Office of Agriculture, Fisheries and Food of the Embassy of Spain in Washington, D.C. has studied the Proposed Rule of Prior Notice of Imported Food Shipments (Department of Health and Human Services, Food and Drug Administration), and submits the following comments in order that they be considered during the redaction of the Final Rule.

We understand and share the Rule's goals of taking all necessary precautions to prevent and fight the possible terrorist attacks on the population through the food supply chain, and we acknowledge the legitimate right of United States food safety authorities to undertake all appropriate measures to protect the population. Nevertheless, we believe that these measures ought to avoid distortion of international trade, be adequate and proportionate, avoid discrimination, and not impose a greater burden on foreign producers, especially small-scale, than on domestic producers.

The information requested for the prior notification is too broad for the desired goal, constitutes an excessive bureaucratic burden and bears an excessive additional cost. Although the responsibility for notification falls on the importer, the additional cost will undoubtedly raise the product's final price, affecting therefore the exporter's results. The requested information needs to be reduced to the minimum necessary, in order to minimize costs. In some occasions it will be particularly difficult to supply all the FDA registry numbers of all the operators that have handled the product. Requiring exporters to maintain records from all previous processors would achieve the same goal and be less burdensome.

It should not be necessary to submit a separate notification for each product of a similar nature and same origin, even if its format or presentation are different. Similar products prepared in the same premises present the same risks relating to prevention and fight against bioterrorism, so it would not be necessary to submit separate notices just because they are marketed in different presentation (such as different container, kind, or preparation). For instance, we believe that if one single producer exports canned tuna in different size containers and/or different preparations (in water, in oil, in sauce), a single prior notice should be sufficient.

The Rule should allow for increase flexibility to amend or update the information. Commerce needs to be agile and dynamic, which implies changes in numerous aspects, beyond those unknown at the time of submission of the notice, including time, date and port of arrival. For instance, certain products, such as frozen fish, are subject to changes in orders by the importer, while the product is in route. In those cases, the exporter is forced to find a new buyer for all or part of the merchandise, since return it to its origin would have an adverse financial impact.

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Therefore, it should be allowed to amend the information on the recipients of food. Also, it does not make much sense that notification data can only be amended or updated once. It is obvious, for economic reasons, that the stakeholders will avoid any amendments, but they cannot be limited to a specific number because, in most cases, the exporter would be the one adversely affected. And, most of the time, the exporter is not responsible for the changes.

Much of the information required by the FDA on the prior notice is the same as the one required by Customs. It would be necessary to improve the communication between Customs and the FDA to avoid duplications.

It is necessary to take the necessary measures to ensure data confidentiality, commercial in nature and strictly confidential, that derives from prior notices of shipments.