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Sent: Tuesday, December 23, 2003 4:36 PM
To: fdadockets@oc.fda.gov
Cc: Stein, Donald
Subject: Dockets Nos. 02N-0276 and 02N-0278

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[Docket No. 02N-0278]

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December 23, 2003

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Attention: Mr. Joseph Levitt
Director, Center for Food Safety and Applied Nutrition

RE: [Docket No. 02N-0278] - - Comments of SAGARPA On Interim-Final Rule Relating To Prior Notice of Imported Food

Dear Mr. Levitt:

These comments are submitted on behalf of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimentacion ("SAGARPA"), pursuant to the notice appearing in the *Federal Register* on October 10, 2003 (68 Fed. Reg. 58974) in response to the request for public comment on the interim-final rule promulgated to implement the prior notice provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act").

Initially, SAGARPA would like to commend the FDA for taking into consideration the numerous public comments - - including those submitted by SAGARPA - - received in response to the publication of the proposed prior notice rule. It is apparent from the interim-final rule that the FDA gave careful consideration to these comments, and published an interim-final rule that addresses many of the concerns expressed about the proposed prior notice rule.

SAGARPA also wishes to commend the FDA for its decision to phase in its implementation of this rule. This should minimize disruptions in the flow of trade across the border.

While appreciative of the fact that the FDA has significantly reduced the prior notice period from noon the day before the day of arrival, as was originally proposed, to two hours before arrival for goods crossing the border by truck (and four hours for goods crossing the border by rail and air, and eight hours for goods arriving by sea), SAGARPA would ask the FDA to consider harmonizing its prior notice time periods with those recently announced by the

[Docket No. 02N-0278]

December 23, 2003

Page 2

Bureau of Customs and Border Protection ("CBP") - - particularly for land shipments by truck, but also for rail and air shipments. *See* CBP Final Rule: Required Advanced Electronic Presentation of Cargo Information, 68 *Fed. Reg.* 68140 (December 5, 2003). Customs prior notification rule provides for only thirty minutes prior notice for goods arriving by truck, if the goods being are entered using the FAST program. For goods not using the FAST program which are crossing the border by truck, one hour prior notification is required by Customs. The FDA interim-final prior notification rule, which requires two hour advance notification for goods covered by its bioterrorism regulations, effectively preempts the Customs rule. SAGARPA urges that the FDA further consider reducing the prior notification period - - at least for goods arriving by truck - - to match the rules promulgated by Customs.

In its comments on the proposed prior notification rule, SAGARPA suggested that the special status of Mexico (and Canada), the Untied States' NAFTA trading partners, be recognized, and that it would not be inappropriate for special, preferential prior notice rules to be promulgated for NAFTA goods. We would suggest that if the FDA does not want to adopt the Customs prior notice time frames for goods arriving by truck (and by other means) for goods from all countries, it at least should do so for NAFTA originating goods arriving at the border. As all NAFTA originating goods must have NAFTA certificates of origin in order to obtain preferential NAFTA treatment, it would be easy to identify such goods, and this special treatment would not pose any administrative or enforcement difficulties for the FDA.

Finally, we would request that there be a Spanish language version of the prior notice module online.

Your consideration of these comments is greatly appreciated. We would hope that any further revision of the prior notice rule will take these suggestions into account.

Sincerely,

Donald S. Stein