ASOEX
ASOCIACION DE EXPORTADORES DE CHILE A.G.
"Juntos, nuestra fruta vale más"

1225 19th St., N.W.
Suite 500
Washington, D.C. 20036
Tel: 202.857.0242
Fax: 202.861.0610

November 6, 2003 3 8 0 '03 NOV 17 19:35

Docket No. 02N-0276
Docket No. 02N-0278
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Registration of Food Facilities (Docket No. 02N-0276);
Prior Notice of Imported Food (Docket No. 02N-0278)

Dear Sir or Madam:

These questions are being submitted by the Asociación de Exportadores de Chile, A.G. (ASOEX) on behalf of its members. They constitute a compilation of the most frequently asked questions arising among members who have reviewed the above referenced Federal Register notices. We realize that some of these questions may be addressed in whole or in part, but for one reason or another more specific information would facilitate a clearer understanding of the rules and steps necessary to comply with them

Registration of Food Facilities:

1. Fresh fruit is packed and graded in a facility located inside a farm in a foreign country. The facility also labels and palletizes the packages. The pallets are transported to another facility in the country for cold storage and/or fumigation before they are exported to the U.S. Should the first facility, which is part of a farm, register? Are the activities at the second facility, cold storage and fumigation, considered *de minimis* activities?

2. Fresh fruit is packed and classified into categories in a facility located inside a farm in a foreign country. The facility also labels and palletizes the packages. The pallets are then transported to another facility for cold storage and/or fumigation, where they also undergo quality control. Is the first facility, which is part of the farm, required to register? Are the activities at the second facility considered *de minimis* activities?

3. Fresh berries are packaged in clamshells on a farm in a foreign country. The packages are transported to a holding facility, where they are placed in boxes and the boxes are then labeled, palletized, cooled down and re-packaged. The boxes furthermore undergo quality control at the second facility. Is the first facility required to register, or is the first facility exempted from registering as it fits in the definition of a "farm"? Are the activities performed at the second facility considered *de minimis* activities"?

Cruz del Sur 133 • Piso 2 • Las Condes • Santiago de Chile • Teléfonos:(56-2) 4724700 • Fax (56-2) 2064163
e-mail: asoex@asoex.cl • www.asoex.cl • www.cffa.org

[redacted] 02N-0278 C235

4. What will happen if a facility accidentally registers or is registered by third parties two or more times? What action will the FDA take in such a case?

5. If a facility responsible for packaging and cold storage services is registered by a renderer of the services, is the service renderer required to inform a person who requests the services of the FDA registration number of the facility to the effect of the prior notice?

6. Is it required for joint U.S-Chile phytosanitary preclearance inspection sites in Chile to register? These are the inspection sites where USDA and Chilean Government officials conduct inspection of Chilean fresh fruit samples to be exported to the U.S.

7. Can a facility name more than one agent in the US? For instance, one for the US West coast and another one for the US East coast, or one agent in every US entry port.

8. Does FDA allow a person in the U.S. to be designated as a U.S. agent for all produce-related facilities in a foreign country?

9. Can a U.S. agent appointed by a foreign facility for purposes of FDA registration be a "transmitter" of a prior notice?

10. What is the legal responsibility of a U.S. agent?

11. Will a U.S. agent of a facility only be a contact person should a problem arise in the U.S. or will this agent have a permanent relationship with the FDA on a daily or weekly basis?

Prior Notice of Imported Food:

1. Will there be a trial period before the official implementation of the new prior notice rules on December 12th, in order to correct eventual mistakes or shortcomings in the actual implementation?

2. Is it possible to amend the information provided in a prior notice after the deadline for delivering the information to the FDA, for instance, 5 hours before the arrival of the subject shipment?

3. Fresh fruit is processed in one given facility in a foreign country. The processed fruit is later transported to one or several other facilities that are presumably registered with the FDA. Whose registration number should be included in the prior notice? The registration number of the first facility, the last facility, or the numbers of all facilities?

4. In a facility which "holds" fresh fruit to be exported to the U.S., packaged fresh fruit is frequently re-palletized. As a result, a finished pallet at the facility, which is ready to be exported to the U.S., contains boxes that have been packaged at several packing facilities. If all the holding and packing facilities are presumably registered with FDA, whose registration number should be provided on the prior notice? The registration number of the facility where the fruit is originally packaged, the facility where boxes of fruit are re-palletized, or all the facilities?

5. In the section relating to the US importer's or consignee's identification on the prior notice form, is it acceptable to state that the shipment goes "TO THE ORDER"?

6. If FDA decides to verify a shipment whose documentation fulfills all requirements and complies with regulations, who is to pay for the costs associated with the verification?

7. What legal responsibility does a submitter has?

8. Is it possible for a submitter to have his/her legal residence in the country of origin and for an authorized transmitter to have his/her legal residence in the USA?

Sincerely,

David A. Holzworth
U.S. General Counsel
ASOEX