



**Ministerio de Agricultura y Ganadería**  
Subsecretaría de Política, Comercio e  
Información Sectorial

Oficio No. **030143** SPCIS/CE/IANC

Quito, **3rd April 2003**

Señores

**Dockets Management Branch  
Food and Drug Administration  
Rockville, USA**

Dear Sirs,

According to procedures established for public consultation of Act on Public Health Security and Preparedness and Response to Bioterrorism 2002, hereby I am pleased to expose the following criterion specifically on sections 305 on Registry of Food Installations, and 307 on Previous Notification of Imported Food Headings.

Section 305 on Food Installations Registry:

- Provisions for those who will register their business after December 12, 2003 are not specified. At present just few exporting companies trade their food products with the United States, and probably many other will do it in a near future, although not necessarily within the December 12, 2003 deadline. Therefore, the chance for other firms to access the U.S. food market is impossible.
- If this is an installation registry, it is not clear if the FDA will refuse one of them, and under which circumstances it will be done. On the other hand, in order to facilitate procedures installations registries shall be done just via e-mail and a reception communication (via e-mail too) will be the solely confirmation of total acceptance of such registry; however, otherwise is not foreseen, nor possible steps to be taken after refusal is explained.
- Within the Proposed Normative no extra costs shall be applied to exporters; however, the FDA is empowered to refuse exports of those foods from installations that did not accomplished such registry, resulting in losses to be covered by exporters. Therefore, additional time for registering installations is necessary.

Section 307 on Previous Notifications of Imported Food Headings:

- According to the national exporting sector presentation periods are appropriate; however, these could not be accomplished due to means used for transporting food, because depending on this situation, exporters somehow control variables to be notified. Finally, exceptional exports non foreseen which need aerial transportation instead of sea transportation, for instance, are not contemplated in the aforementioned Normative.



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- The Ecuadorian exporting sector is concerned on the notification's operational process as different notifications are foreseen for different kind of presentations for the same product (i.e., canned or cut heart of palm), that could seem unnecessary and bothersome. Moreover, classified information managed via internet could be misused to prejudice those exporters that are sending notifications. Therefore, a security systems for exporters shall be implemented.
- Although this notification neither represents additional costs for food exporting companies, chances are that the FDA refuses food access to those that have not accomplish with the notification in question. It is not clear if this notification could be done untimely while merchandise is kept in U.S. territory, which could be released once all requirements are fulfilled.

The above mentioned points of view represent the official position of Ecuador, as well as the Agricultural Sanity Ecuadorian Service (SESA) letter sent to Dr. Fernando Flores, General Director of Bilateral Exports and Investment of the Ministry of Foreign Affairs of Ecuador.

Sincerely yours,

(the original signed)  
Dr. Manuel Chiriboga  
Undersecretary of Policy, Trade and Sector Information

Copy: Dr. Fernando Flores

TRANSLATED BY

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