



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

Official letter No. 030260 SPCIS/CE/IANC

Quito,

8 MAY 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 303 on Administrative Restrain and 306 on Maintenance for Food Records.

Section 303 on Administrative Restrain:

- Although the regulation sets forth that a restrain could be given when enough evidence has been gathered which shows that contaminated food can adversely affect human health or caused death to people or animals, these do not establish parameters for measuring and make decision objective when defining a contamination evidence as "credible"; thus, it is necessary to know exact procedures as well as parameters on which inspections are to be based when the section in question become in force.
- It is foreseen that retained food shall be moved to appropriate facilities during the detention period, therefore, it is necessary to know who is in charge of such transportation. Parallel to these procedures notifications of detention orders shall be addressed to the owner, operator or loading agent, where orders are issued; however, in order that food owners have access to motion for appeal communication mechanisms of retain orders shall be established, and more flexible periods: at present people that receive notifications has a 2-days-period for appealing to FDA decision.
- Administrative Detention of section 303 is already in force, therefore, logistic procedures shall be known immediately, because if a detention order is processed, people will know necessary steps to be given in order to solve any problem, specially when perishable products are traded and special care is necessary.

Section 306 on Maintenance of Food Records:

- This section sets forth that producers, processors, packers, transporters, distributors, people in charge of storehouses and importers of food to be consumed inside the U.S. shall keep a food record which allows to know their source on what is concerning with production, packing, transportation and storage aspects; i.e., all those process prior to arrival of food to U.S. ports of entry.



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However, precise mechanisms have not been established in order to accomplish this regulation nor where concerned people shall address to. Actually, according to FDA papers, there are provisory statutes in force which have the same aims this legislation has that are still subject to consultation; therefore, the FDA shall inform in detail such transitory dispositions because although they do not establish periods to be accomplished with this record, this information could be used when an administrative detention arises (according to what is established in section 303, subject to discussion also).

- It is also necessary to know the FDA and which other entity will have access to records, as the aforementioned information to be kept will be useful for food agents, producers, traders, transporters or importers. Moreover, mechanisms for keeping records updated have not been established, nor what people will have to do if a record's two years deadline expires, i.e., if it will be or not obligatory to open a new record.

The above mentioned points of view represent the official position of Ecuador according to what is established by the Food and Drug Administration, to be taken into account during next revision sessions of this legislation.

Sincerely yours,

Dr. Manuel Chiriboga
Undersecretary of Policy, Trade and Sector Information

Copy: Dr. Fernando Flores, General Director of Exports and Bilateral Investments
Ministry of Foreign Affairs of Ecuador

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