



Washington, D.C. July 8<sup>th</sup>, 2003

**Administrative Detention- Docket No. 02N-0275**

Rec'd 7/9/03  
/b

Joseph Levitt  
Director, Center for Food Safety and Applied Nutrition  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Comments of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca Y Alimentacion ("SAGARPA") On the Notice of Proposed Rule to Implement Provisions of the Bioterrorism Act of 2002 - - Administrative Detention of Food for Human or Animal Consumption (Section 303) - - **Docket No. 02N-0275**

Dear Mr. Levitt:

On behalf of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimentacion ("SAGARPA"), of the Government of Mexico, we are submitting these comments on the proposed regulations implementing sections in Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) regarding administrative detention.

Following September 11, 2001, the Food and Drug Administration ("FDA") proposed to the U.S. Congress that substantial new authorities be granted to FDA to protect against bioterrorism threats to the American food supply. As you are aware, these changes represent one of the the greatest expansions in food enforcement authorities in the history of regulating the safety of food in the United States. We respectfully submit that these new authorities are extensive and that the time frame for implementation is unusually quick for such a sweeping change. We would suggest that the United States not move too quickly to adopt ineffective or otherwise unnecessary regulatory requirements that burden the U.S., and also the Mexican economy, as this would not aid the fight against terrorism as intended.

We sincerely urge that FDA implement Title III authorities in a measured and appropriate manner within the intent of the law. We respectfully submit that the goal of FDA should be to improve protection against bioterrorism through the food supply, but without the economic burden of nonessential regulatory requirements, which will impact the Mexican economy as well as the U.S. economy.

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## **Administrative Detention**

We understand that, under the Bioterrorism Act, the FDA has the authority to “detain an article of food for which there is credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to human or animals.” FDA’s proposed regulations on administrative detention address procedures for instituting on an expedited basis certain enforcement actions against perishable foods subject to a detention order.

We respectfully submit that this new authority gives FDA much greater latitude to obtain food products than it had before. This new authority should be exercised with utmost care, and should be carefully monitored by the FDA, to avoid unnecessary detentions.

FDA states that the procedure for administrative detention was modeled on the regulation for medical devices. However, in this case, further consideration should be given: it is easy to recognize when a medical device comes with anomalies, but this is not the case for food.

We also see problems in the procedures for detention. Detention is based on a decision by the official of the FDA district where the product is located. We view that this procedure provides too much discretion. The order should be required to state the reasons for the detention and also the procedures for analysis of the product and the type of analysis and what will be considered. Also it is not clear who will do the sampling and guarantee there has not been contamination and who will pay for this process is also not clear.

Also, the administrative detention proposed rule incorporates a provision for accelerated review of detention of perishable products, as required by the Act. We note that the proposal defines “perishable” as a period that is much shorter than the length of the regular appeal procedure. We urge that perishable food be defined as food with a shelf life of 90 days or less so that products that may become unmarketable during the regular administrative procedure may be afforded access to the accelerated appeal procedure. Thereby, due process rights would be reasonably protected while providing for full use of this new public health protection.

We disagree that it is appropriate for FDA to require that detained goods may not be delivered to importers, owners or consignees subject to conditional recall. We suggest that conditional release remains the appropriate approach except where FDA believes there is an immediate threat of harm. We also believe that FDA must guarantee that they are going to have enough facilities to ensure the conservation of the merchandise that is detained.



Finally, what the FDA is proposing in this new regulation is already a part of FDA procedures. Reference IOM: Investigations Manual Operations 2003. In subchapter 750: Detention Activities describes the procedure that FDA officials must follow currently and these new bioterrorism regulations do not appear substantially different. We hope that the new regulations do not lead to even more discretion for imposing detentions. We are very concerned about the unfounded detentions that have occurred under existing regulations:

- Detention of avocado pulp due to *Listeria monocytogenes*: The vessel was returned to Mexico, the Mexican Ministry of Health made a representative sampling (200 samples of the vessel) and the load was found free of this microorganism
- Detention of tuna contaminated by *Histamina*: The company asked for the analysis results and these had been made by sensors, with no positive results.
- Cantaloupe detention halting: FDA closed the whole market because of only two producers that were involved in a salmonella outbreaks.

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We would welcome an opportunity to work cooperatively with FDA to enhance security in both Mexico and the United States. However, we believe that there are aspects of the proposed regulations that are over-reaching and which will cause economic harm without enhancing security. We request that you take these comments into account as you implement the final regulations.

Sincerely,

**Enrique Lobo**  
**Agriculture Minister**  
**Embassy of Mexico**