



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

**Recordkeeping-Docket No. 02N-0277**

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

1  
1  
2  
7  
03  
JUL  
-9  
10  
10  
6

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 - -- Establishment and Maintenance of Records (Section 306) - - **Docket No. 02N-0277**

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 two sections in Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) regarding maintenance and inspection of records.

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.

02N-0277

279



### **Establishment and maintenance of records.**

We have a very serious concern regarding FDA's new records authority. The purposes for the records authority are clearly specified in the Bioterrorism Preparedness Act: 1) to determine whether a suspect food product poses a threat of serious adverse health consequences; and 2) to trace the distribution and recovery of any foods that meet that standard. We understand that the purpose of the proposed record keeping system is to assist in product tracking in case of an emergency, when closing down the market is required; however, only record keeping or access requirements that accomplish those objectives are authorized by the act.

Under the proposed regulation, as a "foreign facility that manufactures, processes, packs or holds food intended for human or animal consumption in the United States," our company will have to keep records for at least two years that "are needed for the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food." If carriers are required to maintain registries of all of the carriers in the chain, including the immediate non carrier, the workload becomes excessive. It is our belief that the statute allows for the immediate previous and subsequent party, but that the proposed regulation may go beyond this.

Our exporters have reported to us serious problems with the practical effect of the proposed record keeping regulations. Of the greatest concern is that the proposal appears to require maintenance of lot-by-lot distribution and receipt records, which would require development of expensive new record keeping. We do not believe that our industry could establish such record keeping systems by December 2003.

We are also concerned about requirements for excessive and unnecessary record keeping. To require that every commercial transaction record identify the name of the "responsible individual" appears to be both burdensome and redundant of the "emergency contact information" to be identified through the facility registration requirement. Similarly, we question the need for both the manufacturer who ships a food and the third-party warehouse and wholesaler who receives it to retain detailed information about the transporter of a food.

We are extremely concerned about these new and burdensome requirements, and we believe that they will significantly impact the cost of business without improving security for the United States.



SECRETARÍA DE  
AGRICULTURA, GANADERÍA,  
DESARROLLO RURAL, PESCA Y ALIMENTACIÓN

**SAGARPA**

Consejería Agroalimentaria para EUA

---

\* \* \* \* \*

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**