



## Nacional Agricultural Council

**Fax Cover**

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<b>For:</b>	Dockets and Management Branch (HFA 305)
<b>Organization:</b>	Food and Drug Administration
<b>From:</b>	<b>Mr. Armando Paredes, President Nacional Agricultural Council</b>
<b>Subject:</b>	<b>The Bioterrorism Act Title III section 306 Recordkeeping Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002</b>
<b>Date:</b>	<b>July 8<sup>th</sup>, 2003</b>

***To whom it may concern:***

Attaach to this fax cover we send comments about The Bioterrorism Act Title III section 306 Recordkeeping Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

*Sincerely*

***Armando Paredes President  
Nacional Agricultural Council***

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02N-0277

EMC140

Mexico, D.F. July 8th, 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 Fisher Lane, Room 1061  
Rockville, MD 20852

Dear Mr. Levitt:

The National Agricultural Council (NAC thereafter) is conformed by near 150 Members; it's partners are Agricultural and Cattle Producer's Organizations of Mexico.

As associates has Farm Services Suppliers Organizations and Agricultural and Livestock industry enterprises, who enforces and compliment sectorial activities. Our organism is the most important at national level; its members contribute with 70% of Gross Domestic Agricultural Product, 85% of Gross Domestic Livestock, 70% of Gross Domestic Agricultural and Livestock Industry related Products and 75% of Total Agricultural Exports.

On behalf of the NAC we are submitting these comments on the proposed regulation implementing a section 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 for foods.**

- The requirement of registering the lot or code numbers of the food products produced and distributed is neither feasible nor necessary and should be deleted from the final regulation. In the case of "direct store delivery" this requirement would require substantial technological innovation and redesigning of this delivery system for it to be possible to capture the lot number of each product as it was delivered to each retail location.
- Some ingredients lots cannot be defined properly. This is the case of ingredients that arrive to the plants in bulk, such as flour, shortening, vegetable oil, fructose syrup, etc. sometimes from different suppliers. The identification of lot should be reviewed in order to be flexible enough to take in account this cases.

- It is not clear from the proposal whether the "responsible individual" is the same as the "emergency contact person" for purposes of facility registration. It is equally unclear whether the term refers to the person who loaded a pallet of product onto a loading dock, the person who loaded it onto a truck, the driver of the truck and so forth.
- FDA's definition of food includes food contact materials, including food packaging. This expanded definition overreaches the traditional definition for food and expands FDA's authority too broadly and in a manner unjustified by the risks presented by these materials. This might at least, quadruple the number of products that would be captured in the new requirements and would burden companies with an unmanageable database.
- The definition of perishable food should be reviewed and extended to cover foods with longer shelf life. This would affect the Record Retention Time Requirements. We are proposing to increase the definition to include products up to 120 days of shelf life.
- Since an infrastructure for long term record retention does not exist to the extent FDA seeks, and it would be quite burdensome for the industry, We recommend amending the record retention time requirements to the following:
  - For Perishable foods: To retain the records a time equal the product shelf life plus 4 months. (by this means, the maximum record retention time would be 7 months for a perishable product of 120 days of shelf life)
  - For Non-Perishable foods - To retain the records a time equal the product shelf life plus 12 months, up to a maximum of 24 months.
- The time to provide records must be reasonable. We strongly recommend that FDA establish a record longer retrieval time deadline, rather than the 4hour/8 hours timeframe that was proposed. We ask for the increase a term of 72 hours in labor days.
- The proposal should be revised to provide that, whenever FDA exercises the records access authority under sections 414 or 704(a), it will provide a written statement which contains a summary of the evidence on which FDA relied in concluding that the standard for records access ("reasonable belief that an article of food is adulterated and presents a serious risk of adverse health consequences or death to humans or animals") has been met to the person from whom the records are sought.
- To establish the type of record keeping system that FDA proposes it might require much more than the 6 months required, since it does not allow individual companies adequate time to institute a system and educate staff on its use. We believe that this time frame should be reviewed and increased substantially.

The NAC strongly believes that enhanced security of the U.S. food supply is crucial for the continued safety of U.S. consumers and their confidence in the food imports.

Mexico, D.F. July 8th, 2003.

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The NAC wishes to reiterate that we fully support measures to ensure that we can deliver food safe, secure produce to American consumers. However, we do not feel that the current Establishment and Maintenance of Records proposal will be an effective mechanism to accomplish the desired objectives of the FDA.

Our members stands ready to work with the FDA in implementing a system that would fully take advantage of existing resources and in sharing our first hand knowledge of current exporting procedures to help the FDA to develop an efficient system that could enhance security of the U.S. Food supply system.

Sincerely,

**Armando Paredes Arroyo Loza**  
**President**

**Alfredo Moises Ceja**  
**Vicepresident, Foreign Trade**