Processed Apples Institute

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
E-mail: www.fda.gov/dockets/ecomments

RE: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act
Docket No. 02N - 0277

The Processed Apples Institute (PAI) is a trade association composed of companies producing apple products: juices, sauces, flavors, essences, etc. Our members produce or import a major portion of the apple juice and applesauce manufactured annually in the United States. PAI submits the following comments on the Food and Drug Administration's (FDA) proposed regulation: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which was published in the May 9, 2003, *Federal Register* (68 *Federal Register* 25187).

PAI previously submitted comments to the Office of Management and Budget and the FDA covering proposed regulations on facility registration and prior notice of imported food shipments.

According to the proposed regulation, "the Bioterrorism Act directs the Secretary to take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary under the new regulations." The FDA has outlined the information that it would not have access to, including quantitative information used in a formula. However, the FDA would have access to other confidential information that, if made public, could have a negative impact on the company. PAI comments that the FDA must take steps to ensure that information either viewed or copied remains confidential.

PAI agrees with FDA's efforts in proposed section 1.337(a) not to require the segregation of an ingredient in those instances where the ingredient is received from multiple sources and commingled prior to being incorporated into finished product (e.g., allowing one silo to contain flour from multiple suppliers). The financial costs to dedicate a tank/silo to each supplier for each ingredient would clearly create an undue burden on the industry.

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Proposed section 1.337(a)(5) requires that records be kept on the quantity of the food and how it is packaged. All products are not packaged in neat containers. For some products (e.g., liquids), the raw material may be received in bulk, such as tanker loads; therefore, recording the type of packaging would not be applicable. PAI recommends requiring that records be kept on the quantity **or** how the product is received (e.g., 5,000 gallons or 5 – 1,000 gallon totes) depending on the product.

In proposed section 1.352(a)(6), the FDA seeks comment on whether the "individual responsible" for the transported food item should be the operator of the conveyance or whether it can be someone within the transportation corporation who has overall responsibility for the vehicle and the food being transported. PAI recommends that the "individual responsible" should be someone within the transportation corporation who has overall responsibility for the vehicle and the food being transported. We believe the transportation company should maintain records that link the operator to a shipment, but knowing who has overall responsibility for the shipment and the food being transported would be crucial if a food security violation occurred.

Proposed section 1.360 indicates that the FDA proposes to exempt electronic records from the requirement to comply with 21 CFR Part 11 "Electronic Records; Electronic Signatures." PAI agrees with this recommendation and believes that this exemption would help to minimize the cost to implement this regulation, as companies that use electronic records would not have to reconfigure their systems to comply with part 11.

We appreciate your consideration of these comments.

Sincerely,

Andrew G. Ebert

Andrew G. Ebert
President