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: Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act **Docket No. 02N - 0275**

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: Administrative Detention of Food for Human or Animal Consumption 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* 25241).

We have previously submitted comments to the Office of Management and Budget and the FDA dealing with proposed regulations on facility registration and prior notice of imported food shipments proposed regulations.

PAI supports FDA efforts to ensure a secure food supply. However, we believe that the administrative detention proposal has the potential to cause harm to a facility if the information gathered by the FDA is not credible or is incomplete. The FDA must establish high standards for what constitutes "credible evidence or information." Also, every effort should be made to ensure that information regarding detainment of a product is accurate, publicized only when necessary to protect public health and such publicity is transmitted in a clear, unemotional and factual manner without unduly or inaccurately raising public concern. The Agency also needs to recognize if the public is told a product has been detained but is then subsequently found to be non-violative, the company will likely be damaged due to the perception by the public that the product was somehow unsafe because it had been detained. Information that detained product has been released seldom reaches the public.

Proposed section 1.378 states that government employees commissioned or deputized by FDA may order a detention. PAI believes that only employees of the FDA should be allowed to order a detention.

02N-0275 C31

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Proposed section 1.391 requires an authorized FDA representative to approve the detention order. The authorized representative is defined as an FDA District Director or in whose district the detained article of food is located or an FDA official senior to such director. PAI supports the FDA District Director or senior official approval of the detention order and is opposed to granting authority beyond those not included in the definition of "authorized representative."

According to proposed section 1.391, the approval for the detention order may be obtained from an authorized FDA representative, either in writing or orally, followed by written confirmation. The owner of the article of food should have access to the written approval granted by the authorized FDA representative, in addition to the detention order.

Proposed section 1.392(a) "requires FDA to issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the location of the food, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily." PAI believes that it is imperative that the FDA provide a copy of the detention order to the owner of the article of food. The owner must be made aware of the detention in order to be aware of the stated reason for the detention, determine a corrective course of action or to determine if an appeal will be filed. With the proposed recordkeeping regulations, identifying the owner of the article of food should not be a difficult task. These comments also apply to proposed section 1.392(b) regarding detention of food located in a vehicle or other carrier.

Proposed section 1.406 indicates that in those instances where credible evidence or information supporting a detention order consists of "classified information," the FDA will not release the classified information. It is stated that the presiding officer would provide notice of the "general nature" of the information. PAI believes that the owner/claimant of the article of food should have access to all information or credible evidence, which caused the FDA representative to conclude the article being detained, posed a threat to human or animal health. PAI is concerned that "general nature" information will be insufficient for owner/claimant to respond.

Attached are PAI's comments submitted to the Office of Management and Budget (OMB) regarding the data used to develop the estimated costs for implementing the proposal.

We appreciate your consideration of these comments.

Sincerely,

Andrew G. Ebert
President

Enclosure

Processed Apples Institute

June 6, 2003

Mr. Stuart Shapiro
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Office of Management and Budget
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RE: Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act **Docket No. 02N - 0275**

Dear Mr. Shapiro:

The Processed Apples Institute (PAI) is a trade association composed of companies producing apple products: juices, sauces, flavors, essences, etc. Our members produce a major portion of the apple juice and applesauce manufactured annually in the United States. PAI submits the following comments on the cost estimates outlined in Section V of the Food and Drug Administration's proposed regulation: Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

In the proposed regulation, the FDA has calculated the loss of value of the product during the detention period based on the product being found by the FDA not to be violative and subsequently being released. However, the proposal does not estimate the additional loss of sales that a company might incur if the product was detained and the detention was made known to the public. If the detention order becomes a part of the public record and the brand name is associated with the detention order, the company could well experience losses during the detention period due to consumer perception of the product being unsafe, even if the product was later found not to be violative and released by the FDA. In order to minimize these losses, the detention order should become a part of the public record only if the FDA determines that the product presents a threat of serious adverse health consequences or death to humans or animals.

We appreciate your consideration of these comments.

Sincerely,

Andrew G. Ebert

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President

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