

July 8, 2003

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 02N-0275. Proposed Regulation for Administrative Detention under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (Federal Register Volume 61, Number 1 and 16; May 9, 2003); Submission of comments.

Dear Sir or Madam:

The United Fresh Fruit & Vegetable Association (United) is pleased to provide comments on the proposed rule for the provisions of Title III, Subtitle A, Section 303 (Administrative Detention) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") contained in Docket Number 02N-0275.

The proposed rule provides procedures for the detention of an article of food if an officer or qualified employee of U.S. Food and Drug Administration (FDA) has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. The proposed regulation implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which authorizes the use of administrative detentions and requires the development of regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order.

Introduction

United is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United members provide the leadership to shape business, trade and public policies that drive our industry. Working with thousands of industry members, United provides a fair and balanced forum to promote business solutions; helps build strong partnerships among all segments of the industry, promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace.

The dramatic impact of the terrorism attacks of September 11, 2001 has led to a new focus in public policy aimed at promoting greater safety and security and preventing terrorist action. As our members provide over 1,000 different fresh fruits and vegetables to American

consumers from both domestic growers and around the world, we take seriously our responsibility for prevention, detection, and all necessary actions to protect consumers from intentional contamination of our products.

We commend the FDA for its leadership in working with the private sector, including our industry, to ensure that appropriate steps are in place to minimize the potential of terrorist action to contaminate foods. However, let us keep in mind the American food supply continues to be the safest in the world. Continuing to ensure the safety and security of fresh fruits and vegetables whether produced domestically or abroad is a top priority of the entire produce industry. With this in mind, we have serious reservations about certain provisions of the proposed rule for Administrative Detention.

“Perishable” foods

We commend the decision of the Agency in developing of expedited procedures for detention actions and appeals for perishable foods, such as fresh produce. The Bioterrorism Act does not define perishable food. FDA’s proposal provides a definition, modeled after the current Regulatory Procedures Manual definition of “perishable commodity.” Under the proposal, perishable food means food that is not heat-treated, not frozen, and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than seven days under normal shipping and storage conditions.

Highly perishable fresh produce commodities may be unusable within a very short time, such as a few days or less, while others might still be usable after being detained for several weeks. The conditions under which produce is held, however, will often have a significant impact quality and marketability of these items. Under the proposal, the person receiving the detention order, or that person’s representative, must hold the detained article of food in the location and under the conditions specified in the detention order. Such conditions may include those necessary to protect the safety and wholesomeness of the detained article of food, such as temperature, humidity, and segregation from other products stored in the same facility. It is essential that the detention of perishable foods must continue under appropriate conditions until such time as the threat of serious adverse health consequences or death to humans or animals no longer exists and the food can be released to resume the distribution through the supply chain. Therefore, we recommend that the agency develop internal procedural guidance for employees regarding the preservation of perishable foods during an administrative detention action. By not clearly providing a process for the handling of perishable commodities, the regulation can have a severe impact on the cost of these goods for consumers. The produce industry produces and markets highly perishable items and time is a very valuable commodity. Thus, a prolonged detention period of more than 7 days could result in significant economic losses. Timely decision-making in determinations of detention actions is critical to the viability of our industry.

Evidence for issuing and appealing a detention order

In section 303 of the Bioterrorism Act, FDA is given the authority to detain an article of food in limited circumstances where FDA possesses “substantial information to support a conclusion that the food to be detained presents a serious threat of adverse health consequences or death to humans or animals (serious threat).” However, there is a possibility that the expanded authority for administrative detention defined in this section of the Act could be interpreted more broadly than the Congressional intent in providing this authority. In order to protect against such possibility, rulemaking should define, as nearly as possible without diminishing the usefulness of this authority in protecting the public health

by preventing, preparing for and responding to bioterrorism. If FDA incorporates such procedural safeguards, trade can have some protection against the arbitrary or unsupported detention.

FDA proposes that it may order the detention of an article of food if the article is found during an inspection, examination, or investigation conducted pursuant to the FDC Act, and the officer ordering the detention has credible evidence or information indicating that the article of food poses a threat of serious adverse health consequences or death to humans or animals. This criterion is derived directly from the Bioterrorism Act. Relying upon a dictionary definition, FDA interprets the “credible evidence or information” standard as “worthy of belief or confidence; trustworthy.” The agency plans to measure fulfillment of this standard on a case-by-case basis. Among the factors that FDA would consider when assessing the credibility of evidence are its reliability, reasonableness, and the totality of the facts and circumstances.

In addition, FDA proposes that detention orders must specify “[a] brief, general statement of the reasons for the detention.” FDA notes that the purpose of the detention order is to serve notice of the detention and of the right to an informal hearing to appeal the detention. Since, however, the detention order need not specify the credible evidence or information that led FDA to conclude that the article of food poses a threat of serious adverse health consequences or death, individuals served with an order may be unable to prepare for or assess their likelihood of winning an appeal. Therefore, FDA should require that detention orders include a statement of the evidence or information upon which its order is based.

Qualifications of FDA officials in issuing and appealing an order

While we do not oppose the removal or detention of products when there is a reasonable and credible belief by the Secretary that a food is adulterated or presents a serious adverse health threat. We do, however, have reservations concerning qualifications and authorities given to an “officer or qualified FDA employee” in making such a determination. For an industry that has fallen victim to otherwise “qualified” federal and state employees who have wrongly accused commodities of potential contamination, we caution the Secretary to be absolutely certain that there is strong evidence to support adulteration claims because if the potential impact it could have on consumer confidence of our products. We recommend strict internal procedural requirements for FDA officers, employees, and its agents that would be involved in the determination of potential adulteration or intentional contamination.

The proposed rule provides that the presiding officer at an informal hearing on an appeal of a detention order must be senior to an FDA District Director. To avoid inadvertently have authorized officials at the same level to both approve detention orders and preside over appeals of such orders, the agency should specify that presiding officers shall be senior to the person who approved the detention order being appealed or a senior FDA officers from headquarters.

FDA authority in intrastate commerce

FDA is proposing to assert jurisdiction over food, whether or not it enters interstate commerce. This federal government’s assertion of power to regulate food in intrastate commerce may be unconstitutional. FDA’s interpretation that the Bioterrorism Act extends the agency’s jurisdiction over administrative detentions to food that does not enter interstate commerce is inconsistent with limitations imposed by the Commerce Clause of the U.S. Constitution. FDA asserts that Congress in the Act intended to give the agency authority over detention of food in purely intrastate commerce as

well. The Commerce Clause generally restricts Congress' power to regulate purely intrastate commerce. Congress cannot delegate power to FDA that which it does not possess. In fact, FDA should have assumed that Congress did not intend to violate the Constitution, and should amend the administrative detention provisions accordingly.

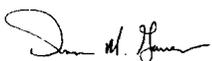
The cost of detention

FDA states that it cannot confidently estimate the percentage of times that it will wrongly order the administrative detention of an article of food. The agency does acknowledge, however, that during the first nine months of 2002, it released 48 percent of the import shipments of human and animal food that it detained. FDA claims that this represents the upper limit of that which in can be expected to erroneously detain pursuant to the administrative detention provisions at issue here. According to FDA, an administrative detention may impose numerous costs, including those associated with transportation, storage, security, loss of product, loss of product value, and appeals. The agency estimates that the average cost for small entities would be \$20,000 to \$330,000 per detention, the actual potential costs for a single detention would be much larger. FDA acknowledges that nearly half of its detentions may be erroneous, and that most of these costs will be borne by small businesses . With this in mind, if even a fraction of this percentage would constitute a substantial, unnecessary economic burden for the food industry.

Conclusion

In conclusion, FDA's administrative detention proposal has the potential for imposing considerable economic hardship on affected parties. Overreaching by FDA that threatens to unconstitutionally expand federal power also should be restrained. United's members strongly support the goal of the Bioterrorism Act to strengthen the safety of our food supply and the efforts by the FDA to implement rulemaking that is consistent with the intent of the law. The implementation of the regulation should not unnecessarily disrupt the flow of commerce. Perishable fruits and vegetables loose quality, therefore, market value very quickly. Delays as little as 24 hours can substantially affect value and marketability. The produce industry is committed to ensuring the security of its products. The industry is proud of the contribution it makes to the health of Americans by providing wholesome foods essential for good health. It is important to always consider that increasing the consumption of fresh fruits and vegetables is a critical component of public health, and that risk management steps are properly weighed with the public health impact on the cost and availability of fresh produce. It is important for the Secretary to keep in mind that the produce industry produces and markets highly perishable items and time is a very valuable commodity. Timely decision-making is critical to the viability of our industry. Thank you for the opportunity to comment. We look forward to continuing to work together with the FDA on these important matters.

Sincerely,



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Vice President, Scientific and Technical Affairs