

June 27, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0275

Dear Sir or Madam:

Founded in 1919, the National Restaurant Association is the leading trade association for the restaurant industry. Representing more than 60,000 members and over 300,000 restaurant outlets in 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands, the National Restaurant Association has always supported government security enhancement of the nation's food supply. The restaurant industry has invested billions of dollars in the last two years to improve food security and food safety around the world. Our efforts have clearly made a difference in protecting our nation's food supply and in improving the safety of the national food supply.

We have a direct and vested interest in the proposed rules regarding the administrative detention requirements which were released in May 2003 and wish to submit formal written comments for the record concerning the Docket No. 02N-0275, Federal Registrar, Volume 61, Number 1 and 16. We appreciate the opportunity to comment on the newly released FDA administrative detention guidance and are encouraged that the Agency has requested input from the restaurant industry and others regarding their food security recommendations for the food industry from farm-to-table.

The restaurant industry has a long standing commitment to food safety and food security to protect our customers and our industry. The safety and security of the food supply, our customers and our employees is a top priority, and has been underscored by the industry response to the September 11th attacks. We fully support the need and intent of the 2002 Bioterrorism Act, and we commend the Agency for attempting the very difficult task of developing these guidelines for the multiple diverse food industry segments in such a short period of time. However, at this time the full impact on the nation's economy, business and trade must be fully understood and considered. We are concerned that the proposed FDA administrative detention rules lack real world business input and may inadvertently negatively impact the nation's economy. If even a small percentage of foods are delayed or removed from trade because of these new regulations, the cost implications for restaurants could be immediate and overwhelming.

Background

The proposed rule provides procedures for the detention of an article of food if an officer or qualified employee of 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 regulations establishing procedures for instituting—on an expedited basis—certain enforcement actions against perishable food subject to a detention order.

Detention authority clarification:

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, the level of evidence or information necessary to rise to the level of “credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death in humans or animals.” If FDA incorporates such procedural safeguards, trade can have some protection against the arbitrary or unsupported detention.

The Agency should consider special provisions for “perishable” foods:

Most fresh produce, seafood and food commodities in commerce are items that are perishable. Some ingredients may be unusable within a very short time, such as a day or less, while others might still be usable after being detained for several days. The conditions in which goods are held, however, will often have a significant influence on the time in which such ingredients can still be utilized. For example, eggs and egg products are perishable foods that must be kept under 45 degrees F refrigeration by federal statute (21 USC 104.1). Detained foods must continue to be kept under refrigeration at federally mandated temperatures until such times 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 its normal flow in the distribution and marketing channels. As such, providing appropriate storage facilities would extend the time in which some

perishable commodities can be maintained in usable condition. Therefore, The National Restaurant Association recommends that the procedures regarding administrative detention under this section for perishable foods include a specific process that would ensure the preservation of such foods until the detention is resolved. By not clearly providing a clear process for how perishable commodities will be held, the regulation can have a potentially negative impact, thus increasing the cost of goods for consumers.

In an attempt to regulate Bioterrorism vulnerabilities, the FDA may be creating increased vulnerabilities:

The National Restaurant Association is troubled about the newly created vulnerabilities this rule and others may create. Most fresh food products today are stored for only short periods of time and therefore move quickly from farm to table, often in just a matter of days. We feel that the quick movement of fresh products actually reduces the vulnerability of the fresh products to tampering or bioterrorism. This means that the current infrastructure minimizes storage times and rewards efficient, quick transport and border crossings. A horror story may unfold with numerous unguarded store rooms, garage sheds, waiting for the administrative detention of product to be resolved so goods can transit. All of these responses to the complexities and times in the proposed rule would not increase security but introduce very real points of risk that do not currently exist today. Even the construction of larger holding and storage areas would increase the risk of those facilities as potential targets of intentional contamination.

Therefore, any increase in storage or truck holding times due to these requirements must be fully contemplated and evaluated. We submit that the requirements in the final FDA rule must not be so absolute as to put the nation's fresh food supply at risk by creating new and real vulnerabilities in trucks and storage facilities both inside and outside our borders. Any increase in holding times when the product is not in motion towards its final destination significantly increases the statistical probability of an attack.

In closing, the National Restaurant Association strongly believes that sharing information and expertise with all food industry partners is crucial to the food industry's preparedness for potential food-contamination events. While we have carefully evaluated the proposed rules, we are not yet confident that we fully understand the myriad of logistical implications the new requirements and the impact on the flow of foods through commerce.

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Adjusting the requirements for detention as we have suggested may enable the FDA and industry to comply with Congressional directives without wasting or misdirecting scarce national resources. As such, The National Restaurant Association would like to offer our assistance in helping the FDA determine the true impact of these rules and develop appropriate alternatives.

Thank you for the opportunity to submit these comments. Please feel free to call our Health and Safety Regulatory Affairs Department with any questions you may have regarding this issue, at (202) 331-5900.

Sincerely,

A handwritten signature in cursive script that reads "Steven F. Grover, R.G.H.S." The signature is written in black ink and is positioned to the left of the typed name.

Steven F. Grover

Vice President

Health and Safety Regulatory Affairs

Cc: Steven C. Anderson, President and Chief Executive Officer
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