Representing, Educating and Promoting the Restaurant/Hospitality Industry

1200 SEVENTEENTH STREET NW, WASHINGTON DC 20036-3097 202/331-5900 FAX: 202/973-3952

NATIONAL RESTAURANT ASSOCIATION

June 27, 2003

Rec'd 7/1/03
r6

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0277

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-0277, Federal Registrar, Volume 68, Number 90, pages 25187-25240. We appreciate the opportunity to comment on the newly released FDA Records Maintenance 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. Although we understand that restaurants are clearly exempt from this regulation, we are very concerned with how implementation of these requirements will disrupt international food trade.

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 international trade must be fully understood and considered. We are concerned that the proposed FDA Records Maintenance rules lack real world international business input and may inadvertently negatively impact international trade and the nation's economy. If even a small percentage of imported foods are delayed or removed from international trade because of these new regulations, the cost implications for restaurants could be immediate and overwhelming.

02N-0277

C55

Background

The proposed rule would require the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States. In addition, these requirements apply to certain foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. The FDA expects that the requirements the agency is proposing in these regulations, if finalized as proposed, would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

The need for FDA to have access to records:

The proposed rule indicates that the purpose of records maintenance and access is to allow FDA to improve their ability to respond to threats which could cause serious health consequences to humans or from contamination of food deliberately or accidental. As such, FDA has incorporated language to move toward having access to these records in a quick manner to respond to such a threat. However, the information required by FDA is too specific and does not consider what may already be available based on what particular system a specific company may already have in place. By not considering what is already available, the proposed regulations are seeking tracking details that will not be cost effective, but more so unnecessary to achieve to meet the purpose of the regulation.

To meet FDA's expectations, the proposed rule should concentrate on the procedures and operational structures to expedite the handling of suspicious food product and a means to retrieve information about a specific product and implement a recall if necessary. We would suggest that there may be acceptable alternatives that are less burdensome on the industry that can meet the intention of the rule. Due to the impractical burden that would be placed on the distribution products, we encourage FDA to not focus on lot-level tracking, but rather on the company's ability to provide source information on ingredients. We believe that the current system in place to recall products through written notification to all possible retailers receiving product is the most practical way to remove and identify the product from the distribution system. To require information that is too prescriptive may go beyond the capability of the current systems in place.

FDA's four hour access requirement:

The National Restaurant Association believes that proposing a four hour requirement on companies to make records available is totally unworkable. The agency has not considered the difficulties of compliance in the real world, where there are different time zones and communications difficulties? Mandating an unattainable compliance level of four hours may cause great confusion globally and may actually impede the process even more. The Agency should focus on what information they can obtain in an expeditious manner and not the actual records themselves. With millions of foods transported annually, many firms utilize various data systems and have implemented records maintenance procedures to meet their specific company needs. Compliance with this new rule would require establishing new protocols and developing new database systems, which would require a substantial capital investment. As such, we recommend FDA clarify that records should be available in a timely manner, not to exceed 24 hours.

Updating contact information:

The information FDA is requiring is too specific and would need to be updated due to the frequent changes in the "responsible individual" during operations. Currently, the proposed rules would require updates be made in the event changes to personnel, titles, and locations. It is not necessary for FDA to have the "responsible individual" by name, but rather the emergency contact information needed to meet the intent of the regulation. This type information is less likely to change and is a more realistic approach, in our opinion, to make certain the correct individual is contacted in a suitable timeframe. As such, we believe the information provided during the registration process when all other pertinent information is being requested by FDA. By having this information in the registration process, FDA will not need to search for this information after the fact and if an incident occurs, the information can be retrieved readily and the impact on the free flow of food can be minimized.

Business impact in the restaurant industry:

Lastly, the restaurant industry has concerns regarding the economical impact the proposed regulations may incur if finalized as written. We do not believe that the FDA has fully considered the complex and numerous factors facing international trade today when developing the proposed regulation. For example, many companies as previously mentioned do not currently have the technology, manpower, or capital to accommodate the additional records establishment and maintenance requirement. There is a strong possibility that the resultant complications and costly implementations of these regulations would place imported commodities at a cost disadvantage due to increased

regulatory costs and reliability concerns. This disadvantage may raise food costs across the board and be a basis for companies to see many international food products as impractical and too costly. As such, we recommend that FDA look closely at such scenarios as they develop the final rule.

In the end, specifications and business decisions will be made on the basis of cost, reliability and regulatory complexity associated with the food products at the restaurant level. It is necessary for FDA to acknowledge this and help limit the economic burden on the food industry as a whole during the implementation of the final rule. 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. Adjusting the information collection requirements for food imports as we have suggested may enable FDA and food 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,

Steven F. Grover
Vice President
Health and Safety Regulatory Affairs

Cc: Steven C. Anderson, President and Chief Executive Officer
Lee Culpepper, Senior Vice President of Government Affairs and Public Policy
Peter Kilgore, Senior Vice President & General Counsel
Mary Adolf, Chief Operating Officer, NRAEF
Allison Whitesides, Legislative Representative