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July 8, 2004

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852  
ATTN: Docket No. Comment EXT1 [2002N-0278]

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 Prior Notice requirements which were released in April 14, 2004 and wish to submit formal written comments for the record concerning the Docket No. 2002N-0278, Federal Register Volume 69, Number 19763. We appreciate the opportunity to comment again on the FDA prior notice 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 prior notice 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 Prior Notice 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

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from international trade because of these new regulations, the cost implications for restaurants could be immediate and overwhelming.

### **Background**

The proposed rule requires that FDA receives prior notice of all food offered for import into the U.S. beginning December 12, 2003. The notice is required to provide the article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry. The proposed rule also states that if notice is not provided, the article shall be refused admission. If an article of food is offered for import and prior notice has not been provided, the article shall be held at the port of entry until the importer, owner, or consignee complies.

Under the interim final rule, prior notice must be submitted to FDA and confirmed for FDA review no less than 2 hours before arrival by land via road, no less than 4 hours before arrival by air and land via rail, and no less than 8 hours before arrival by water. A separate notification is provided on each article of food in each shipment. Food that is imported for which prior notice is not provided or is inadequate will be refused entry. Refused entry products must be removed to a secure location and the importer will be held responsible for related costs incurred.

Prior notice will be required for transshipments and products shipped in bond. The rules are applicable to all FDA regulated food products as under the Food, Drug, and Cosmetic Act including dietary supplements, food additives, pet foods and food contact materials that may migrate into the food. The only exemptions are provided to food arriving with travelers and USDA regulated products.

### **The FDA should consider exemptions for small quantities of food offered for import through common carriers:**

In the proposed rule, FDA is making no exceptions for even the smallest quantities of food coming across US borders via common carriers such as United Parcel Service or FEDEX. A growing number of restaurants import very small quantities for their daily specials or dining events via package delivery. The current proposal makes no concession for low risk status importers, small quantities or very small businesses. The burden of prior notice for respondents could be minimized if FDA reduced the information collected to only that which is absolutely necessary for tracking and exempted small quantities of food shipped on common carriers. The FDA should consider a limited blanket exemption for our largest direct trading partners in Canada and Mexico which are under similar security controls. Small quantity shipments imported from these neighboring countries via package delivery, requiring complex pre-notifications will place a large burden on small business owners nationwide who rely on Mexican and Canadian producers for their fresh catch of the day menu items.

We recommend the FDA consider a limited exemption for very small quantities of food under 80lbs or 100 bottles of liquid or less and consider a general limited exemption to our trading partners in Canada and Mexico. Taking a large number of low risk imports out of the initial system of tracking could greatly improve the entire pre-import system and greatly reduce the economic impact and burden on small businesses.

**FDA has failed to consider the increased costs of compliance on products:**

FDA has not considered several factors facing the international food trade today when developing the proposed regulation. There is a strong possibility that the resultant complications and costly restrictions on imports will place imported food and drink at a cost disadvantage due to increased regulatory costs and reliability concerns. This disadvantage may provide a reason for companies to see international foods as impractical or unreliable. FDA must effectively address the ever growing popularity of internet food sales and how these relatively small transactions can be made in compliance with this new rule. FDA requires the importer to provide the specific information to FDA, but such information is not accepted from the exporter. This will drastically change how business is currently done via the internet and possibly make internet sales less feasible or cost prohibitive. We recommend that FDA look at such scenarios as they develop the final rule and expand the ability for various parties to make pre-import declarations.

Specifications and business decisions will be made based on the basis of cost, reliability and regulatory complexity associated with the food products at the restaurant level. Unnecessary complexity and restrictive rules may raise the costs of foods imported. The FDA should implement exemptions for small shipments as previously stated and allow both exporters and importers to make pre-import notifications as appropriate.

**While attempting to reduce Bioterrorism vulnerabilities, the FDA may be creating longer product holding times and increased vulnerabilities:**

Of concern to the National Restaurant Association are the newly created vulnerabilities this rule and others may create. Most fresh produce, seafood and food commodities imported from Mexico and Canada are items that are perishable. 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. Given the repetitive number, absolute time periods and complexity of mandatory declarations required under this proposal and those of Customs, we fear that significant increases in fresh product holding or storage times at the border will follow. A horror story may unfold with numerous unguarded store rooms, garage sheds, and trucks idling along the sides of the highways leading to the ports waiting for the absolute prior notice periods to expire 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 at the packing house level would increase the risk of those facilities as potential targets of intentional contamination.

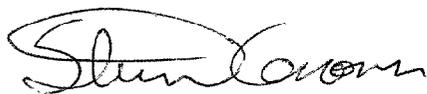
Therefore, any increase in storage or truck holding times due to these requirements must be fully contemplated and evaluated. We submit that the requirements in the final FDA rule must not be so absolute as to put the nations fresh food supply at risk by creating new and real vulnerabilities in trucks and storage facilities just outside our boarders. Any increase in holding times when the product is not in motion towards the border 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 especially concerned with trade across the Canadian and Mexican borders and the impact these very complex rules may have.

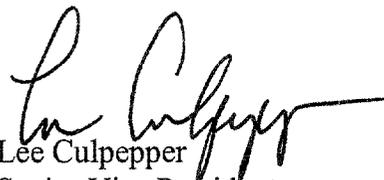
If the federal government and food industry are to work together in order to ensure the safety of the food supply deploying available resources effectively and efficiently is the critical first step. As such, The National Restaurant Association would like to offer our assistance in helping the FDA determine 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, REHS  
Vice President  
Health and Safety Regulatory Affairs



Lee Culpepper  
Senior Vice President  
Government Affairs and Public Policy