

April 4, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852  
ATTN: Docket No. 02N-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 February 2003 and wish to submit formal written comments for the record concerning the Docket No. 02N-0278, Federal Registrar, Volume 68, Number 22, February 03, 2003, pages 5428 -5468. We appreciate the opportunity to comment on the newly released 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 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.

The importer (or his designated agent) must submit prior notice information no later than noon on the calendar day preceding entry at the border crossing for all modes of transportation. Notice may not be provided more than five days in advance. A separate notification is provided on each article of food in each shipment. FDA proposes to allow an amendment once up to two hours prior to entry only to change the description of the food and quantity. If the location or time of entry is changed, that information may be updated up to two hours prior to entry. 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.

### **FDA may be attempting to replicate an existing program or not considering the advantages of using existing data collection opportunities:**

One of the most troublesome aspects of the new FDA prior notice proposal is that the agency is not planning to integrate the new information collection system with the existing system used by the U. S. Customs Service. Instead of cooperation and moving forward with the timeline for FDA to receive entry information from the Customs/FDA OASIS system, the agency is proposing to establish an entirely separate "prior notice" data collection system. Under this FDA proposal, an importer would have to feed data to the new prior notice system, but would also have to continue to send data independently

to the existing Customs/FDA OASIS system, and incidentally pass through two potential inspection points rather than one.

National Restaurant Association

Page 3

Docket No. [02N-0278]

The entire need for this new FDA pre-import notification system may be called into question. The FDA should seriously look into working with the Customs/FDA OASIS system to obtain the same data and not reproduce a duplicate system.

**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.

**The requirements of prior notice should be more flexible and provide less restrictive time periods and required data:**

The proposed limited time periods for prior notice are overly restrictive. What basis did FDA use when developing such restrictive time periods and has the Agency considered which data elements are even generally available to the importer the day before entry? The complexity of the current time lines required for the proposed prior notice system could result in depreciation or loss of products. The FDA stipulated in the proposed rule a minimum submission time of noon the day before the shipment arrives. In the fresh fish business, the harvest of fish may be occurring the day before the shipment arrives,

which will make precise product identification prior entry notification impossible under the proposed system. The problem is both one of time, and the degree of accuracy and complexity the FDA will require in the pre-import notification.

National Restaurant Association

Page 4

Docket No. [02N-0278]

The greater the amount of advance notice time required, the greater the possibility that the required prior notice information will need significant revision. We believe this will increase the possibility of perishable food shipments being held for erroneous data elements. Delays as little as 24 hours can substantially affect value, marketability and disrupt day to day trade business worldwide. Any disruption in the flow of food to the nation's restaurants could have a significant and long lasting negative impact on the entire U. S. economy.

Finally, the estimated time to complete, constantly track and modify the pre-import notification for each article has not been fully considered by FDA. As an alternative, a rolling notice period should be considered and implemented. This type of system could prevent delays that would otherwise occur due to the inevitable bombardment of prior notice submissions to the FDA. The rolling system could be designed so the FDA could receive notice at noon every day for shipments expected to arrive at the border crossing the next day. Moreover, a shorter prior notice period would reduce the need for importers to submit advanced notices, numerous updates, amendments, and cancellations to prior notice submissions. A rolling system would clearly save both FDA and industry time and resources and be far less likely to break down for extended periods of time and disrupt the food supply.

**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.

National Restaurant Association  
Page 5  
Docket No. [02N-0278]

**FDA estimates of the number of notices appear to be extremely low:**

The FDA has estimated that an average of 20,000 prior notices concerning imported food will be submitted daily. By looking at our membership alone, we believe that a number of 20,000 is a very low estimate and would expect this number to be three times that size when discussing all of the food, drink and food contact items which would fall under this regulation. With such a large number of users tapping into the system, we are concerned that FDA has not fully addressed the potential for internet or website failure or disruption. FDA has never tested nor verified that the new system to process incoming prior notice forms will be able to function at such a demanding rate. If normal interruption of the server occurs due to the overflow of large amounts of information being sent, it is highly possible that this could completely shut down international trade and disrupt the U.S. economy for an extended period of time.

For this reason alone, FDA should accept prior notice of imported foods by all means of communication from the outset. With electronic notice being the only specified option for prior notification, the potential of the system overloading is a real threat to international trade. FDA proposed rules would only allow alternative methods of communications once the system is down; however, the transition to other methods of communication is unclear and not well articulated in the proposed rules. If all international food shipments are held at the borders, for even a short period of time because of a system malfunction, severe economic disruption may follow. FDA needs to do a much better job of expanding reliable pre-notification alternatives and properly staffing those alternatives from the outset, if a viable alternative to internet pre-notification is really envisioned.

**The FDA should request only information necessary for oversight:**

The information FDA is requiring for registration and pre-notification is overly complex and precise, and may go beyond what is mandated by the statute. While the name and full address of the facility, emergency contact information, and trade names are indeed needed, much of the information beyond that can become inaccurate and may create unnecessary technical violations of the Act. Because of the massive international scope of the proposal, the amount of information required, translation and the need for timely information updates, the FDA database system may become clogged. The resulting adverse consequences for domestic commerce and international trade have been previously discussed.

We strongly recommend that the FDA review all requested data in this proposal and eliminate that which is not primary to the mission at hand. Those data items beyond the company name, location, contact information and trade names must be limited and fully

justified before inclusion in the final regulation. The collection of “like to have” information for compliance in this regulatory context is inappropriate.

National Restaurant Association  
Page 6  
Docket No. [02N-0278]

**The role of FDA in contacting importers of detained shipments:**

Once prior notice is received or a product is denied entry by FDA, it is unclear how a confirmation, if any will be received by the importer from FDA. This uncertainty does not provide the importer with any type of assurance that the articles of a shipment will be accepted into the country in a timely manner, if at all. It is also unclear how, when, and if FDA will communicate in a timely fashion the reason a product may be detained at entry. If not accepted, the rule clearly states the importer will be held responsible for related costs incurred during detention. Without developing a systematic approach to responding to prior notice submissions, delays as little as 24 hours can substantially affect the value of the product and cost the importer millions in a short period of time.

We suggest implementing a checks and balances system to assure the free flow of imports is not unnecessarily disrupted. It is necessary for FDA to establish clearly defined written procedures and communication protocols on how communication to all parties will take place. Furthermore, FDA must anticipate every foreseen circumstance under which timely and effective communication must take place to prevent the loss of safe food products and the disruption in the normal flow of food products shipped into the U.S.

**More flexibility to change prior notices and point of entry needed:**

Proposed section 1.294 would require that prior notice of a shipment be amended if the shipment is anticipated to be an hour earlier or three hours later than the anticipated time of arrival specified on the original prior import notice. It is unclear how many amendments a submitter can make to the estimated time of arrival information but we anticipate the need to allow multiple amendments to accommodate delays in transportation, manufacturing, harvest and border crossing tie-ups. Additionally, it is common practice for Canadian and Mexican importers to change the port of entry (and possibly border crossing point) regularly.

We recommend that FDA automatically allow for delays of up to twelve hours for time of arrival declarations and allow a reasonable change at points of arrival for Canadian and Mexican importers. This would greatly reduce the number of amendments that proposed section 1.294 would necessitate, and reduce the massive detention of food products from our close neighbors.

National Restaurant Association

Page 7

Docket No. [02N-0278]

**The FDA proposed “one-size-fits-all” risk approach to food security misses the point:**

We submit that FDA is doing itself and the American public a disservice by proposing prior notice rules premised on a “one-size-fits all approach” with regards to risk. Not all food products from all countries pose the same risk to the U.S. food supply chain. Many low risk foods imported from our close neighbors in Canada are manufactured under the same or tighter controls than in the U.S. In developing the final rule, FDA should consider how other bilateral initiatives are helping to reduce the risk of Bioterrorism. U.S. Customs initiatives such as the Customs-Trade Partnership Against Terrorism (C-TPAT) and the Free and Secure Trade (FAST) programs are bilateral arrangements available to low risk imports. Countries that enroll in these innovative risk reduction programs are today investing in preventive measures to reduce Bioterrorism risks. FDA should build on these initiatives which share FDA’s counter-Bioterrorism objective.

**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 borders. Any

National Restaurant Association

Page 8

Docket No. [02N-0278]

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 not yet confident that we fully understand the myriad of logistical implications of the new information gathering requirements in the new 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. Adjusting the information collection requirements for food imports as we have suggested will enable 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,

Steven C. Anderson  
President and Chief Executive Officer

Steven F. Grover  
Vice President  
Health and Safety Regulatory Affairs

Cc: 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