



International Food Coalition

*Working to Make It Better*

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

**Prior Notice Regulations under the BioTerrorism Act**  
**Dockets Nos. 02N-0276 and 02N-0278**

Dear Sirs:

These comments to the Interim Final BioTerrorism Regulations (the "BTA Regulations") in large part echo and fully support those comments submitted to the FDA by the American Free Trade Association (AFTA). The International Food Coalition (IFC) similarly believes that conditioning importation of lawfully made and safe food products upon a direct relationship between the importer and the original food manufacturer is unreasonable and of no benefit to the Agency or the American consumer.

**Background on the IFC**

The IFC is a coalition of businesses involved in the international food industry, including Customs brokers, food importers, food carriers and others international traders concerned that overregulation of the global food industry threatens its very existence and imposes unnecessary impediments to free trade. IFC members depend upon the safety and integrity of imported food products. Accordingly, upon passage of the Bioterrorism Preparedness Act of 2002, IFC applauded and looked forward to implementing rules that would facilitate entry of unadulterated and otherwise compliant food articles without obstructing global food distribution or industry competition.

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## **General Comments and Discussion**

### **A. Requiring Manufacturers' Registration Numbers on Prior Notices Facilitates The Creation of Unlawful Monopolies**

Throughout the global food supply chain, food articles are purchased from wholesalers, food brokers and other legitimate third party distributors. Exporters who make such purchases have no means to verify original manufacturer FDA registration numbers. Even in the unlikely event that the wholesaler or broker provides this type of data at the time of the sale, there is no method for the purchaser to verify its accuracy. Accordingly, it is unreasonable for the FDA to insist upon these numbers as a condition of lawful import --- unless the intent is to eliminate this lawful and critical component of the international food business, which would be unreasonable and contrary to U.S. law (see AFTA's comments for more information on relevant legislative and judicial positions).

In addition to the fact that domestic manufacturers will most certainly not provide their registration numbers to unrelated parties --- especially those like most AFTA members who are in direct competition with them --- whether or not the food manufacturer resides in the United States, Prior Notice submissions may be made by traders purchasing products from a party other than that original food manufacturer. These legitimate third party food brokers are commonly utilized throughout Latin America and Europe in particular to consolidate shipments or as a means of purchasing originally manufactured food products at discounted prices.

IFC members, as a group, affirm that as purchasers of products from these wholesaler food consolidators there will be no means to obtain the original manufacturer's registration number because there is, more than likely, no relationship between the wholesaler and the manufacturer. Accordingly, not only will the food wholesale industry be decimated as a result of the BTA Regulations but all businesses relying upon these parties to facilitate competition within the global food industry will similarly be severely threatened. The only parties that benefit from such consequences are the food manufacturers themselves who, as a result of FDA rulemaking unreasonably elevates confidential manufacturer's numbers to a mandatory pre-condition for lawful US imports, as they will have been provided with the legal means to monopolistically control global food distribution and resale prices. Alternative means to accomplish the purposes of the statute, within the letter of the statute, should be found.

### **B. The Act Requires Registration of Facilities Processing Food For U.S. Consumption**

The BioTerrorism Act requires registration of food facilities that process, hold, manufacture, pack or store food for U.S. consumption and the FDA, in its interpretation of the BTA Regulations, has implied that this obligation also falls upon those facilities performing those actions in connection with food "intended" for U.S. consumption. However, in the case of foreign-manufactured food products purchased from food brokers outside of the United States, it is possible that these wholesalers are



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selling originally manufactured goods manufactured in facilities which, at the time of manufacture, had no knowledge that the articles would be sold for consumption in the U.S. Accordingly, pursuant to the BTA Regulations, which condition registration on the intended use of the food product for U.S. consumption, the manufacturer was under no obligation to register with the FDA at any time. Nevertheless, without a manufacturer's registration number on the Prior Notice, the product will be refused entry into the United States. This is true even if the food is perfectly safe, complies with all labeling and other FDA regulations and in no other way poses a threat to the safety or security of the American consumer.

In light of the foregoing, it is clear that requiring a manufacturer's registration number on a Prior Notice in all circumstances merely serves to eliminate much needed competition that provides American consumers with competitive prices and a greater variety of genuine food articles. As wholesale food suppliers, these parties offer competitively priced genuine and safe food articles that may not otherwise be available to American consumers. To deny distribution of these products in the domestic marketplace, is to favor business interests of certain manufacturers and their "authorized" distribution systems over the desires and needs of American purchasers, who look to the U.S. government and its agencies to provide competition and product variety - in addition to security and safety.

**C. Increase Inspections of Food Products Upon Arrival But Do Not Deny Admission for Lack of Manufacturer's Registration Number**

As suggested by AFTA in its comments, IFC members who import articles from parties other than the original food manufacturers are willing to bear the burden of increased inspections in the event that they are unable to provide a manufacturer's registration number on the Prior Notice. This is because these businesses appreciate that the intent of the BTA Regulations is to ensure the safety of America's food supply and they want to support the FDA in its efforts to meet that laudable objective. However, should those inspections prove that the article is safe for U.S. consumption and otherwise complies with U.S. admissibility requirements, then, respectfully, the only reason to deny admission would be to eliminate lawful competition within the American marketplace.

The lack of a manufacturer's registration number on the Prior Notice does not mean that the manufacturer is not registered. It may only indicate that the importer had no means to obtain that number and elected to leave the field blank rather than fraudulently creating a number only for purposes of completing all the data fields. Or, lack of a manufacturer's registration number on the Prior Notice may reflect the fact that the original manufacturer was not required to register with the FDA under the BTA Regulations because it had no intention or knowledge that the relevant food article would be consumed in the United States. If the Regulations themselves do not require registration of such a manufacturer, then refusal under those same rules cannot be premised solely upon the lack of such a registration number.



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### Conclusion

If every applicable facility in the supply chain is registered with the FDA as required and if the only deficiency with the Prior Notice is lack of a manufacturer's registration number, it is critical that the product not be automatically refused without further inquiry or examination. While the Prior Notice may be deficient because not all of its data fields are complete, it is not necessarily inaccurate or misleading. Accordingly, FDA must be called upon to use its available resources to facilitate entry of such products for the benefit of the competitive domestic marketplace and the ongoing operations of the critical global food industry. So long as the food article is safe and otherwise in compliance with U.S. laws as to admissibility, under the circumstances described herein, entry must be permitted. This is the only means of guaranteeing to the American consumer a competitive marketplace as well as lawful distribution of products that pose no threat to health or safety.

We urge that the BTA regulations be amended to permit the continuation of this legitimate trade, while adopting realistic and rationale standards to protect the nation's food supply from bioterrorism. Upon your review of this correspondence, please contact the undersigned or Lauren Perez of this office in order that we may facilitate ongoing dialogue between the IFC and the FDA on this issue. Considering the number of traders that are being severely threatened because of the existing requirement for manufacturers' registration numbers on prior notices and the IFC's (as well as AFTA's) commitment to work with the FDA to support its efforts to ensure food safety, it is hoped that the FDA will welcome continued feedback and discussions even after this present comment period closes. .

Respectfully submitted,  
**International Food Coalition**

By: 

Gilbert Lee Sander  
General Counsel

cc: IFC Members  
Lauren V. Perez

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