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## **Impact of the 2002 Bioterrorism Act on the New Jersey Food Industry**

By

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## **Impact of the 2002 Bioterrorism Act on the New Jersey Food Industry**

### **Abstract**

This paper provides an overview of the four key sections of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, with regard to Administrative Detention (Section 303), Facilities Registration (Section 305), Records and Maintenance (Section 306), and Prior Notice of Food Imports (Section 307). The potential impacts of the Bioterrorism Act on the food industry are examined through qualitative analysis of industry submissions to the Food and Drug Administration (FDA) docket for each provision, and quantitatively through survey results, which were administered online by the Food Institute (FI) of Woodbridge, NJ and analyzed by Rutgers, Food Policy Institute (FPI).

Of the four key sections from the Bioterrorism Act that most affect the food industry, stakeholders were surveyed on two sections, Prior notice of Food Imports and Facilities Registration. While survey responses reveal that many food firms are aware of pending Bioterrorism Act policies, few however, have taken action towards compliance. Facilities registration is touted as the least cumbersome in terms of compliance. Results indicate that 50 percent of food industry professionals surveyed were not aware that many food firms must register with the FDA by the 12 December 2003 deadline; and, 20 percent, while aware of the facilities registration deadline, have done nothing to prepare.

Being unprepared for and subsequently complying with Bioterrorism Act rules is an overarching concern, which is apparent in both the survey results and docket summaries. Moreover, upon review of docket submissions to the FDA, it seems that food firms are generally sympathetic towards the need for increased food system security; however, the impact of the Bioterrorism Act can be both daunting and costly. Many perceive that significant changes to capital costs will be required to meet FDA standards.

# **Impact of the 2002 Bioterrorism Act on the New Jersey Food Industry**

## **Introduction**

The events of 11 September 2001 reinforced the need to enhance the security of the United States food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). President Bush signed the Act into law on 12 June 2002. Since then, outreach efforts on the part of the Food and Drug Administration have been made to inform the public about pending Bioterrorism Act regulations. For instance, on 7 May 2003, the Food and Drug Administration (FDA) held a public meeting about the Bioterrorism Act with respect to proposed regulations for Administrative Detention (Section 303) and Records and Maintenance (Section 306). The public meeting on Facility Registration (Section 305) and Prior Notice of Food Imports (Section 307) was on 29 January 2003. Both meetings were broadcasted, via satellite to locations across the country, including Rutgers University.

This paper first provides an overview of the Bioterrorism Act, then a summary of food industry perceptions regarding the Bioterrorism Act. The latter was accomplished by using two approaches; in that way, qualitatively reviewing industry submissions to the FDA docket on four sections of the act, commingled with reflections on issues and responses from industry representatives in attendance at the FDA telecasts, and by reporting on quantitative results from the, Food Policy Institute (FPI) and Food Institute (FI) survey, comprising two separate, electronic surveys administered by the Food Institute, Wood bridge, NJ listserve and results analyzed by Rutgers, Food Policy Institute.

The following section provides an overview of the Bioterrorism Act, and the second section offers a synopsis of stakeholder submissions to the FDA dockets. The third section of the paper summarizes the FPI/FI electronic survey results; and, the paper is then concluded.

## **Background**

FDA regulations to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, take effect in December 2003. The Act requires most regulations pertaining to drugs to be promulgated by 31 December 2002, and those related to foods to be promulgated by 12 December 2003. Final decisions for the Bioterrorism Act rules are expected

in October 2003. Of specific interest to the food industry is Title III of the Act (Protecting Safety and Security of Food and Drug Supply), Subtitle A (Protection of the Food Supply).

There are 15 sections under this subtitle:

- Section 301 addresses threat assessment, including technologies and procedures for securing processing and manufacturing facilities and modes of transportation, response and notification procedures, and risk communication to the public.
- Section 302 deals with the issue of food adulteration. Under this section the Secretary of Health and Senior Services shall give “high priority” to the inspection of food offered for import at ports of entry with increased emphasis on detecting intentional adulteration of food.
- Section 303 deals with administration detention and provides an expanded authority to the FDA for detaining food products if there is “credible evidence or information indicating the article presents a threat of serious adverse health consequences or death to humans or animals.” Although the Act calls for expedited assessment of detained perishable products, an article of food could potentially be detained for up to 30 days.
- Section 304 establishes procedures for debarment for persons convicted of conduct related to the adulteration of imported food.
- Section 305 requires the registration of firms that manufactures, processes, packs, or holds food. Information required includes the name and location of facilities, product trade names, and general food categories. While section 305 excuses foreign firms that ship under-processed or unpackaged goods to the United States for further processing and packaging for export outside of the United States, the section will apply to firms that provide any food product to the United States for further processing or packaging of goods to be consumed domestically. A foreign firm cannot avoid registration and other obligations under the act by simply labeling a product in the United States or adding further processing of a de minimis nature. In addition, a foreign food company will not be able to export to the United States without registering, and failure to register will result in a hold being put on the product at the port of entry until registration requirements are satisfied.
- Section 306 amends the Federal Food, Drug and Cosmetics Act to require enhanced record keeping (FDA regulations will establish specific requirements for identifying the immediate, previous and subsequent recipients -- "one up and one down".) Record keeping applies to all records pertaining to the manufacture, processing, packaging, distribution, receipt, holding or importation of an article, and all records must be available including records in both paper and electronic formats. At the discretion of the Secretary, records could be made available for a period of two years.
- Section 307 deals with prior notification of all imported food shipments into the United States. Proposed guidelines require that notification be provided prior to entry into the United States with a possibility of up to 5 days for the notification to be reviewed. Specific information includes the article itself, the manufacturer and shipper (if known), the grower of the article, the country from which the article originates and the country from which it is shipped. Failure to notify will result in a refusal of shipments to enter the United States, and failure to disclose relevant information could also result in a refusal of permission to advance to a port of entry.

- Section 308 allows the marking of food posing a credible threat of serious adverse health consequences or death to humans or animals.
- Section 309 designates food as adulterated if it has been previously been denied entry into the U.S. (unless the person re-offering the food item can establish the article is in compliance).
- Section 310 requires the Secretary to notify States when there is credible evidence of information that a food shipment (or part of a shipment) poses a credible threat of serious adverse health consequences or death to humans or animals.
- Section 311 authorizes the Secretary to provide grants to States to assist with the costs of taking action in instances where a credible threat of adulterated food is present.
- Section 312 authorizes the Secretary to provide grants to States to assist with the costs of enhancing food safety efforts through expanded food safety surveillance and technical capacity.
- Section 313 directs the Secretary to, in conjunction with the FDA Commissioner, CDC Director, and Secretary of Agriculture, coordinate surveillance of zoonotic diseases.
- Section 314 authorizes the Secretary to commission other federal employees to conduct inspections and examinations of food shipments (under the appropriate memoranda of understanding between participating federal agencies).
- Section 315 establishes that the Title III of the Act does not alter jurisdictional boundaries between the Departments of Health and Senior Services and Agriculture.

Subtitle B of Title III deals with the requirements established for drug manufacturers including (1) annual electronic registration of foreign drug manufacturers, and (2) submission of statements regarding the import of components of a drug that are ready for use for health-related purposes and are imported for the purpose of further processing or incorporating into an article to be exported from the U.S. ("import for export").

For purposes of the Bioterrorism Act, and indeed the Federal Food Drug and Cosmetic Act, relevance of this subtitle with respect to the food industry deals with food additives, food colouring and dietary supplements. In regard to the registration of foreign drug manufacturers, the statute is not a new or separate registration requirement; rather, it merely reinforces the

existing regulatory requirement for foreign drug establishments to register with the FDA. There are, however, two issues that the Bioterrorism Act added to this requirement.

- a) U.S. agent and each importer of the drug also must be listed.
- b) Annual registration must be done electronically.

Subtitle C of Title III of the Bioterrorism Act deals with agricultural security. Of importance in this section is the right of the FDA to increase inspection capacity at points of origin, to improve surveillance at ports of entry, and to enhance methods of protecting against bioterrorism.

### **The FDA Dockets**

The FDA required that industry comments on Sections 303, 305, 306 and 307 be submitted within sixty days of their publication in the Federal Register. This report summarizes key issues arising from docket submissions on these sections and reflections on issues and responses from industry representatives at the FDA telecasts.

#### ***Docket Summary of Section 303: Administrative Detention***

Upon reviewing submissions to the FDA dockets, the most common concern identified by four separate submissions and put forth primarily by foreign governments are:

- (1) A fear that the FDA implementation of detention may not be transparent, and
- (2) What are the exact criteria for a judgment of detention?

In regard to (1) the primary concern with transparency is in articulating the exact criteria for detention and the flow of information between the shipper and the FDA. The rationale for a detention order must be disclosed to the shipper since this information is essential for any appeal procedure. Point (2), takes into account that administrative detention might be used as a barrier to trade or add restrictions on the activities of private businesses. It is recommended that once detention is ordered at the port of unloading, the FDA should publish the facts of detention through the Import Refusal Report. Cases where safe consignments have been temporarily detained for import checks and have thus (due to the elapsed time) become unfit for consumption

should be governed by rules oriented towards general trade law in accordance with the relevant WTO provisions. It would be helpful to clarify whether the overall burden of requirements on companies exporting to the U.S., are more or less onerous, than on firms within the U.S. producing for the domestic market.

While point (2) is perceived to be an issue by countries and businesses exporting to the U.S., at the telecast, the FDA acknowledges that the greatest implication of administrative detention would not be on importing firms but on domestic firms. The FDA already has the authority to detain shipments at ports of entry, but what they lack is the rule to detain foods shipped domestically within and between states. Other concerns identified by at least three submissions to the dockets were:

- Fear of delays
- Clear rules for indemnification and compensation respectively in accordance with the customary trade law should be foreseen.
- The time frame for detention might not fit all products (e.g. perishables with shorter shelf life)
- Who will assume the costs related to detention, especially in the case when the merchandise is wrongly detained?
- Time frame for release of food test should be indicated in the proposed Act

Businesses expressed concern about disruptions and uncertainty in business plans pertaining to the negative impact to the normal flow of trade of FDA regulated products, especially perishables, and possible losses due to unusable produce after detention or imposed import-checking procedures.

Recommendations made by submitters include, for perishable products, a maximum period of detention of 24 hours is advisable. There should also be a notification procedure, whereby exporters are informed directly by the FDA in the case of detained shipments. For notification purposes, the creation of a central FDA-contact point is suggested.

Other issues addressed in the May 7<sup>th</sup> FDA telecast for example, suggest a rapid appeals process and demand that jurisdiction is in the state or region in which detention occurred. Also, as indicated above, the FDA stated in terms of food offered for import into the United States, Section 303 does not expand FDA power beyond what already exists at border points, but does



increase power within the United States. From a trade point of view Section 303 appears to equalize the powers of detention between domestic and foreign shipments of food.

Other concerns raised in the dockets include:

- a) Detained equipment cannot be used to haul other loads, and drivers of that equipment could run out of their available “hours of service” as mandated by the Department of Transportation;
- b) Documenting any breaking of seals and re-sealing on tank truck or dry bulk trailers transporting food products and;
- c) The likelihood that that the detention requirement demands are not proportional in relation to the pursued objective.

Issue (a) is in response to the fear of delays due to detention, which can cause significant equipment and manpower problems for the carrier (opportunity cost). Issue (b) deals with the quality of the shipment upon delivery to its destination. In many instances receivers will not accept a shipment if a container seal is broken. Issue (c) is simply a statement about whether the societal benefits of the proposed regulation outweigh the costs to industry within the contexts of the overall objectives of the Bioterrorism Act.

### ***Docket Summary of Section 305: Facility Registration***

Section 305 of the Bioterrorism Act outlines the rules for registration of companies involved in the food system. The section requires domestic or foreign facilities that manufacture, process, pack or hold food for consumption in the U.S. to register with the FDA no later than 12 December 2003. Registration will consist of providing information, such as the firm name, address, product brands and categories, etc. Farms, restaurants, retail food establishments, non-profit establishments that prepare or serve food, and fishing vessels not engaged in processing are exempt from this requirement. Also exempt are foreign facilities, if the food from the facility is to undergo further processing or packaging by another facility before it is exported to the U.S. or if the facility performs a minimal activity such as putting on a label.

From the dockets, several firms expressed antipathy towards facility registration; many argue that it is not cost effective. Others complain that the registration requirements are duplicating existing FDA and USDA systems that already capture such information. For example, one submission noted:

*Responsible importers are already doing such things anyway, even from the point where produce is still growing in the field in foreign countries.... and USDA are also doing their part in such a process already... To request legitimate business to put up more paper work with FDA in this regard is only a redundant paper chase and should be discouraged. No guidance is provided as to how these rules will improve the current systems in place (Blackstone Co., Lytone Enterprise, Inc.)*

Foreign governments view registration as punitive to their exporting sector; it will require establishing new systems that call for appropriate expertise and technology. For example, the registration requirement does not recognize that some of the capital and administrative requirements are out of reach to many small businesses (e.g., Governments of Japan, Argentina, Mexico, Korea, Hong Kong). Consequently, some foreign firms, organizations and governments view registration requirements as a trade barrier that do not seem consistent with WTO provisions designed to safeguard the food supply system (e.g., Federal Republic of Germany, UK, Switzerland and EU).

The US food industry wishes to see more publicity on the registration requirements, especially pertaining to their foreign counterparts in effort to make sure that foreign food supply is not disrupted. Some have expressed, however, in docket submissions a concern that the registration requirement maybe giving foreign suppliers a competitive advantage over domestic suppliers. They feel that the foreign food supply chain is inadequately covered, for it is only the last stage manufacturer who is required to register. The stakeholders are asking for equal treatment for domestic and foreign facilities to allow for a level playing ground without undue advantages to foreign competitors.

### ***Docket Summary of Section 306: Record Keeping and Maintenance***

The greatest concerns raised in the docket submissions for Section 306 were:

- (1) Duplicative records;
- (2) Commingling of products; and
- (3) Confidentiality.

With respect to duplicative records, many firms are concerned that the FDA's trace-back and trace-forward initiatives may require an entirely new system of record keeping. Firms queried the possibility that the FDA could limit its record-keeping objectives to the protection of the food system and integrity of food products, rather than create new requirements.

Commingling refers to the use of many inputs, from numerous suppliers, to create multiple food products and to maintain the principle of identity preservation. The ability to link incoming products and ingredients with outgoing products and ingredients may almost be impossible, thus making compliance difficult. Examples such as Tolling Operations and Futures Exchanges will be difficult in such cases where product “ownership” and actual product possession are usually separate. In tolling, the processor does not know the titleholder’s identity and Manufacturing Site Record Specificity further complicates this. Some manufacturing operations are not conducive to linking incoming records to records of outgoing finished product; separating information on dedicated suppliers maybe costly and may discourage business. Dedicated supplier storage to facilitate supplier-specific one-back record keeping, would involve significant financial costs and logistical burdens for the entire food industry. The resource impact maybe large for small business especially such instances as, purchasing computer technologies and hiring and training dedicated personnel to match ingredient purchases with recipes, recipes to products, and products to customers.

The third concern relates to confidentiality; there is a fear of leaks or exposure of confidential business information such as recipes, know-how, product formulations, and trade secrets as well as, information such as pricing, sales, and research data. The FDA, however, has made it clear in its May 7<sup>th</sup> telecast that record keeping requirements are limited only to the physical product of ingredients and final products, and does not require food firms to divulge any information regarding recipes, processes, prices or trade secrets.

Additional concerns occurring with less frequency were:

- (4) Time frame for keeping records
- (5) Diversity in channels of trade
- (6) Definition of food firm not inclusive
- (7) Packaging
- (8) Congressional intent
- (9) Trade impacts

The issue of record keeping standards (4) is mentioned in multiple submissions; holding records for up to two years is seen as excessive and may increase storage costs. Issue (5) concerns narrowly defined record keeping requirements, which do not accommodate the diversity and complexity of the channels of trade within the food chain and differences in the

operational characteristics of individual food businesses. Concern (6) relates to the issue of which firms have to provide records and which firms do not.

Farmers, retailers, restaurants and other businesses dealing directly to consumers do not have to provide records, however, they are required to maintain records on where retail products were sourced. It is argued that there exists an unfair advantage to those not included in the regulatory fabric, since more regulation adds cost to business. It is recommended, however, that the definition of “farm” include typical post-harvest farming operations such as packing/packaging, washing, grading, waxing, sizing, cooling, application of inventory control items (e.g. price lookup stickers or universal product codes), conventional storage, controlled-atmosphere storage, transportation from the fields, transportation to storage or processing facilities, and transportation from the farm. It is also recommended that the definition of foodservice expand to operations in retail supermarkets, convenience stores, noncommercial foodservice operations (e.g. hospital/prison cafeterias), and worksite foodservice operations (e.g. company cafeterias). Nevertheless, the FDA has made it quite clear that foodservice firms do not have to maintain records on their customers.

Concern (7) relates to particular articles in the Bioterrorism Act that require firms to maintain records on packaging materials. The FDA announced in its May 7<sup>th</sup> telecast that records on packaging would not be required.

Congressional intent (8) concerns whether, the government’s most important investment in either food safety or food security is prevention and not tracking records after the fact. Part of this concern derives from the original wording in the act and the requirement to establish or maintain records related to immediate subsequent recipients of food. Trade organizations such as the American Herbal Products Association assert that it must be assumed that retailers do not have records that identify the immediate subsequent recipient of the food that they “hold” and then sell to consumers. The FDA, however, assures retailers that they do not have to track direct sales to consumers.

Concern (9) deals with trade impacts. Record-keeping measures will have potentially significant consequences for existing trade patterns. Unnecessary and needless expenses due to increased bureaucracy may inhibit trade. The European Commission for example believes that the combined system of controls by member states and the commission provide the best possible

safeguards for consumer safety and animal and plant health. Further, they assert, the provisions of the Bioterrorism Act do not appear to enhance those safeguards.

### ***Docket Summary of Section 307: Prior Notice of Food Imports***

This section requires that on or after 12 December 2003, the FDA must receive advance notice of each shipment of food into the U.S. The notice must include a description of the article, the manufacturer, shipper, grower (if known), country of origin, country from which the article is shipped, and the anticipated port of entry. The FDA must issue the final regulation by 12 December 2003. If the regulation is not final by that date, the act requires importers to provide notice to the FDA no less than 8 hours and no more than 5 days prior to shipment until the regulation takes effect.

From the dockets, a number of submissions show that grower information will largely not be available, and an insistence on including it in a prior notice will substantially raise direct and indirect costs. Concerns on commingling were articulated by a number of firms, for example, the cocoa and coffee importers particularly perceive that this requirement will have a negative impact on trade. What's more, cocoa and coffee, assembled for export are the products of thousands of farmers located all over a producing country. For example, one submission noted:

*Cocoa beans are grown on more than 2 million farms worldwide. In the Ivory Coast alone, over 600,000 farms produce cocoa beans for export. Between the farm on which they are grown and the exporter who ships the beans to the United States, cocoa beans typically change hands several times and undergo commingling, blending, sorting, cleaning, drying, grading, and re-bagging. (Chocolate Manufacturers Association (CMA) and National Coffee Association of USA (NCA)).*

The magnitude of the problem cannot be overlooked. Chocolate manufacturers say it is practically impossible to compile growers' names; hence it is not practical and should not be considered for inclusion on prior notice information, particularly if failure to identify all growers can lead to rejection or detention of the shipment.

Import Brokers have identified similar problems relating to the commingling of articles, in terms of shipment arriving from various sources and owners; they argue that additional manifests will be required to provide the information. Furthermore, processing and collating piecemeal information will raise the administrative costs of shipping, decrease economic efficiencies, and may lead to delays in transit. In addition to increased administrative costs,

delays in transit could also result in additional costs to business. Some submissions to the docket pointed out that the current Operational and Administrative System for Import Support (OASIS) system can be used to verify shipment information.

Fresh produce crossing the Canadian and Mexican borders via road transport may face compounded timing problems; truckers cannot generally be locked into the detailed requirements of prior notice in advance of departure. Furthermore, prior notice requires a timeline for arrival at a border point; there is significant concern that extraneous factors such as inclement weather conditions may result in violations of prior notice. Enactment of this provision can lead to excessive delays at the ports of entry, spoilage of produce, brokerage fees, as well as, increased transportation, labor and warehousing costs. There is also a grave concern that markets may be lost due to quality changes:

*...keep in mind that the produce industry produces and markets highly perishable items and time is a very valuable commodity. Timely decision-making is critical to the viability of our industry.* (Fresh Produce Association of the Americas).

Some industry representatives recommend giving pro-forma or an estimated notice and that a final notice is given once it is known what is actually being shipped. They also argue that foods under the same category should use one prior notice. Moreover, such information already exists and can be shared with the FDA (National Tank Truck Carriers, Produce Marketing Association, Jacobs Farm, Ricardo Gonzalez Customs Broker Brownsville, Texas, Fresh Producers Association: Nogales, Arizona, Fresh Produce Association of the Americas)<sup>1</sup>.

The requirement of having an agent who resides in the U.S. was vehemently opposed by foreign governments; they explain that most of the firms exporting to the U.S. may not have resources to engage an agent. This requirement will alter the way business is conducted and may place undue pressure on small and medium scale businesses (Dutch Produce Association, Government of Argentina). In the docket, it is argued that the FDA should rely on existing systems to obtain such information. For example, Japanese food manufacturers, in many cases, export and sell foods via a trading company or a shipping company, rather than export articles by

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<sup>1</sup> The current FDA proposal requires a prior notice based on FDA food groups. Commingling food from two different groups would violate the prior notice and will render the shipment subject to detention. It is unclear if a single shipment will allow a number of prior notices for each food group contained in the shipment, or whether one shipment comprises a single prior notice. If the latter case occurs, shipping containers would not be allowed to include food items from two separate FDA food classes.

themselves. Some argue that the act will cause a considerable administration burden for both foreign and domestic firms, explaining that food facilities could be inspected by the competent local regulatory authority of the exporting countries under the existing set of FDA rules and guidelines. Food products would then only be shipped to the U.S. with the appropriate import permits.

In terms of timeliness and compliance, the 5 days maximum presented little or no problem. The problematic areas that respondents see as potential compliance problems are the noon hour provision (notice must be given by 12pm on the day prior to arrival at a port of entry) and the 2 hours provision (amendments to a prior notice must occur within 2 hours of arrival at a port of entry)<sup>2</sup>. Also quite revealing is the difference between the mode of transport and how this provision varies in impact. There are marked differences between air, water and land transportation, and hence varying degrees of difficulty or ease of compliance. For air and water transport, prior notice is not considered to be a big problem. However, cross border trucking by road across the Mexican and Canadian borders may pose a problem because of their peculiar way of doing business. Industry stakeholders, import brokers in particular, insist that food imports arriving by sea, and air shipping manifests, have all of the necessary information. Many are concerned with the possibility of unforeseen circumstances on compliance; for example, inclement weather often requires a change in the transportation route. Others worry that low awareness by shippers of sanitary and phytosanitary or other quality conditions could also be used to vitiate prior notice and result in detention and/ or border delays.

It is recommended, that a working relationship across U.S. departments (e.g. FDA and Customs) share information, rather than establish a parallel system.

Implementation of this legislation will affect the food industry. Direct and indirect costs may inadvertently be imposed on businesses. Industry participants, in particular the truckers and brokers have made cogent suggestions. They argue, that the existing system and its established methods is working therefore new requirements should be co-opted, so as not to disrupt business, moreover they call for more time and to allow for appropriate changes to the act to be made as

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<sup>2</sup> In case of amendments the dockets are more revealing in terms of foods that are considered under same category or different. Virtually all of the potential benefits that could arise from an 24 or 2 hour prior notice are already captured through the OASIS computer database that FDA uses to **monitor the ports** of entry and to target specific individual shipments for further inspection and testing.

they occur. They argue, however, that this has not and will not compromise food safety at the moment and should be viewed as positive.

### **Current Industry Awareness and Preparedness**

In partnership with the Food Institute of Woodbridge, New Jersey, the Food Policy Institute implemented two on-line questionnaires to assess current levels of food industry awareness and preparedness in terms of compliance with (1) Section 305 - Facility Registration and (2) Section 307 - Prior Notice of Food Imports. The Food Institute administered the questions electronically as part of their daily update service to three separate on-line memberships: a general Food Institute listserv [FI], National Association of Specialty Food Trade listserv [NASFT] and a National Food Processor Association listserv [NFPA].

#### ***Facility Registration***

The following Facility Registration question was posted on May 21 and 22, 2003. A total of 1292 responses were received.

*Do you know that by Dec. 12, 2003, all food manufacturing facilities must register with FDA as part of its implementation of the Bioterrorism Act?*

- Yes, and I am actively preparing
- Yes, but I have done nothing to prepare
- No, but it may affect my business
- It doesn't apply to my business.

Overall, 413 respondents indicated that the Facility Registration regulation will not apply to their businesses. As shown in Table 1, among the remaining 879 respondents:

- 260 (30 percent) said that they are actively preparing for compliance.
- 181 (21 percent) indicated that they know of the pending requirement, but have not yet begun preparing.
- 438 (50 percent) were not aware of the registration requirement but feel it may affect their businesses.

The fact that more than half of respondents were unaware of the facility registration provision (due to go into effect on December 12, 2003) is disconcerting. It demonstrates greater need for communication of federal efforts to promote biosecurity within the food industry.



**Table 1: Survey Results: Facility Registration**

		Yes, I am Actively Preparing	Yes, But I have done nothing to prepare	No, But it may affect my business	Total
Total	Count	260	181	438	879
	Pct.	29.6	20.6	49.8	100.0

***Prior Notice of Food Imports***

The following Prior Notice of Food Imports question was posted on May 28, 2003 A total of 1292 responses were received.

*Do you know that by Dec. 12, 2003, FDA will have to be notified of all food entering the U.S. no later than the day before the article will arrive at the border and no more than 5 days before the anticipated date of arrival under the Bioterrorism Act?*

- Yes, and I am actively preparing
- Yes, but I have done nothing to prepare
- No, but it may affect my business
- It doesn't apply to my business.

A total of 401 respondents reported that the prior notice requirement will not affect their businesses. As shown in Table 2, of the remaining 890 respondents:

- 166 (19 percent) report that they are actively preparing for compliance.
- 510 (57 percent) are aware of the upcoming requirement, but have done nothing to prepare.
- 214 (24 percent) were not aware of the pending regulation, but believe it may affect their businesses.

A substantially higher percentage of respondents were aware of the import notice requirement vis-à-vis the facility registration provisions (only 16 percent report being unaware). However, nearly three-quarters (72 percent) report that they have not taken any measures to prepare for complying with the regulation.

**Table 2: Survey Results: Prior Notice**

		Yes, I am Actively Preparing	Yes, But I have done nothing to prepare	No, But it may affect my business	Total
Total	Count	166	510	214	890
	Pct.	18.7	57.3	24.0	100.0

## Conclusions

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 emerged as a response to the events of 11 September 2001 and a belief amongst politicians that the food system was susceptible to forms of chemical or biological adulteration. The Bioterrorism Act is comprised of several parts, but the most important sections for the food industry are sections 303 (Administrative Detention), 305 (Facility Registration), 306 (Records and Maintenance) and 307 (Prior Notice). This report reviewed the act in very general terms, and then reviewed the docket submissions on Sections 303, 305, 306 and 307. Among other concerns, it appears that the key concern related to administrative detention is the fear of perishable products being held for long periods of time. In regards to record keeping the greatest concern was in the ability of a diverse food system to adapt to a control process that required detailing the sources of all ingredients and mapping these ingredients to products in wholesale or retail markets. Industry concerns focused on the cost of compliance and the ability to preserve the identity of food products passing through the supply chain.

The Food Policy Institute also conducted two surveys to identify awareness by food industry firms about impending legislation, and to determine attitudes by industry stakeholders regarding the four key sections of the Act. The awareness survey was conducted in conjunction with the Food Institute and employed an on-line questionnaire. The results suggested that 50 percent of food firms were unaware of the registration requirements under the act, and of those that were aware, 20 percent were not yet preparing for compliance. In a second question about awareness of prior notice, only 15 percent were not aware of prior notice, while, over 72 percent of food businesses to whom the act applied were making preparations.

Reflections on attitudes towards the Bioterrorism Act from the FDA telecast commingled with docket summaries, suggest that Prior notice and record keeping were deemed costly to

many of the food firms. Nonetheless, many food firms were sympathetic towards a need for a Bioterrorism Act.