

PRONTO-Xi and the Bioterrorism Act

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Abstract



In this white paper, Michael Panosh, Pronto Software's Marketing Manager, details how PRONTO-Xi supports food companies in their need to comply with the U.S. Government Public Health and Bioterrorism Preparedness Act of 2002 requirements.

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Executive Summary

One of the more profound legislative changes related to food industry customers over the last few years would have to be the Public Health and Bioterrorism Preparedness Act of 2002 (Bioterrorism Act) requirements.

The Act is intended to protect the health and safety of the people of the United States from a potential terrorist attack on the nation's food supply, which is obviously a serious and laudable goal. And as with most legislation that is drafted to meet a general threat, the Act appears complex, complicated and onerous.

However, it is worth your effort to unraveling the Act, because irrespective of your view of the legislation, it lays down is an operational framework that *should* be in place in your business anyway.

Compliance – The Heart of the Bioterrorism Act

Before you expend any effort responding to the Act, it is important to answer two questions:

- Does the Act apply to your business?
- If it does, how do you implement compliance as a whole-of-business solution?

These questions may generate complicated answers, so be mindful that the Act is really about records keeping. It describes various records that you will be required to keep and the duration for which you keep them. Underpinning this is a reasonable assumption that you can access and present these records within 24 hours of the FDA's request for any particular set of records.

Fortunately, the Act is generally specific enough that there should be no doubt whether it applies to your business or not. And if you have any doubt there are numerous resources available to assist (refer to Table 3: Useful Web-based Bioterrorism Act Resources on page 9 for more information).

Excluded Businesses

There are a number of businesses that are exempt under the terms of the Act, including farms, foreign persons not transporting food into the USA (and the term 'person' is actually an inclusive one for individuals, partnerships, corporations, and associations), restaurants and others.

There are also levels of exclusions. For example, the exclusion for the term 'restaurant' describes a restaurant/retail facility where sales of food it prepares and sells to consumers for immediate consumption comprise more than 90 percent of its total food sales.

Finally, there are partial exclusions with regards records keeping as well as the usual vaguely worded clauses such as "Persons who operate retail food establishments that distribute food to persons who are not consumers must establish and maintain records to identify the immediate subsequent recipients only to the extent the information is reasonably available".

Unfortunately, due to the volume of Bioterrorism Act queries, the FDA is not in a position to respond to questions on a one-to-one basis, so don't expect them to tell you directly if you are compliant or not. However, they do maintain an excellent *Frequently Asked Questions* (FAQ) list on their web site (refer to Table 3 on page 9), and also issue regular updates that help to dispel any uncertainty that arises from the wording of the Act. These FAQ and updates are based on queries received by the FDA, so they do reflect both general concerns and specific lines of enquiries.

Transport of Food – a Key Activity in the Act

It is useful to consider your food transport activities as they pertain to the Act, as it clearly defines two types of activities, each of which has different records keeping rules associated with it.

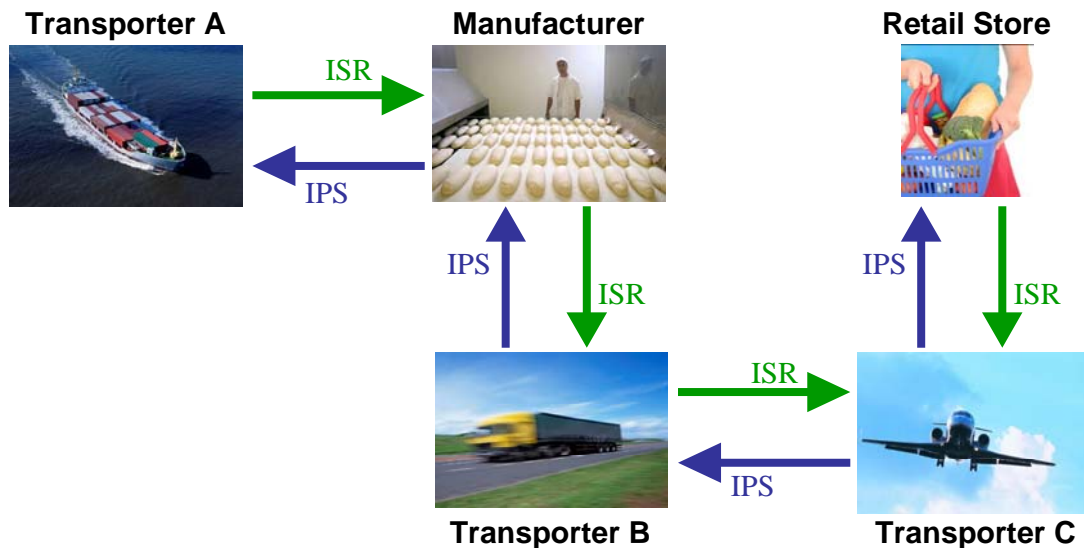
Table 1: Definition of Transporter and Non-transporter

Type	Definition
Transporter	Person who has possession, custody, or control of an article of food in the U.S. for the sole purpose of transporting the food, whether by road, rail, water, or air. This includes a foreign person that transports food in the U.S., regardless of whether that foreign person has possession, custody or control of that food for the sole purpose of transporting that food.
Non-transporter	Person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Typically a transporter is as it suggests – a person who physically moves food between separate locations. The converse, a non-transporter, would typically be a Manufacturer, Wholesaler or Retailer who handles food but does not transport it.

A consequence of these definitions is that the Act has essentially two parties in the food transport supply chain – an *Immediate Previous Source* (IPS) and *Immediate Subsequent Recipient* (ISR). In terms of records keeping, a good rule of thumb is that you need to know as much as possible about these parties and track what goods you have issued to them. An example of this requirement is illustrated in Figure 1 below, which show the IPS and IRS relationships in a simple food distribution supply chain. In this diagram all the parties are independent and obviously not all parties are shown for the sake of clarity (for example, the farm and flour mill are not included).

Figure 1: Example of IPS and ISR relationships in the food manufacturing supply chain



The Whole of Business Aspect

Legislative compliancy typically has a whole of business impact, and the Bioterrorism Act is no exception. The extent of information that needs to be captured ranges from your inwards good receipting, through your warehouse and manufacturing process, and then to your outward bound shipping processes. You need to know what ingredients made up what products, where the ingredients came from, and be able to indicate where the products were sent. And you need to be able to extract this information accurately and rapidly when required.

Given that the Act is mainly about records keeping, a fully integrated *Enterprise Resource Planning* (ERP) system is mandatory for any but the smallest businesses. Manual techniques introduce too much scope for error and inaccuracy and the consequences of these can be onerous.

For example, Title III, Subtitle A, Section 306 Maintenance and Inspection of Records for Foods, requires that information of the following kind be maintained by Non-Transporters:

“Identify the immediate non-transporter previous sources, whether foreign or domestic, of all foods received, including the name of the firm; address; telephone number; fax number and e-mail address, if available; type of food, including brand name and specific variety (e.g., Brand X Cheddar Cheese, not just cheese; romaine lettuce, not just lettuce); date received; quantity and type of packaging (e.g., 12 oz. bottles); and identify the immediate transporter previous sources including the name, address, telephone number--and, if available, fax number and e-mail address. Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.”

We recommend that automated process techniques such as Warehouse RF scanning, Quality Management and EDI messaging be implemented wherever possible to reduce the likelihood – and impact – of manual errors.

Having made this recommendation, there are aspects of the Act where manual methods are appropriate. Section 305 (Registration of Food Facilities) requires that the owner, operator, or agent in charge of a domestic or foreign facility has to register their details with the FDA (refer to Figure 2, Form 3537).

"PRONTO-Xi's real-time Radio Frequency scanning capabilities have dramatically improved Graceland's inventory accuracy and tracking abilities."

Gary L. Michalek, IT Manager
Graceland Fruit, Inc

Much of this information can be stored on your computer, but since the FDA support an online submission process, the effort of submission is generally best handled manually because the time it would take to configure your system for this occasional task is not cost or process effective.

Figure 2: A small sample of information required for Form 3537 (10/03)

Section 11a - GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION	
To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37.	
<input checked="" type="checkbox"/> 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]	<input type="checkbox"/> 7. CHEESE AND CHEESE PRODUCTS [21 CFR 170.3 (n) (5)]
<input type="checkbox"/> 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula (Optional Selection)	<input type="checkbox"/> 8. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (38), (43)]
<input type="checkbox"/> 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]	<input checked="" type="checkbox"/> 9. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]
<input type="checkbox"/> 4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (16), (35)]	<input type="checkbox"/> 10. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]
<input type="checkbox"/> 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALITIES & CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]	<input type="checkbox"/> 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (includes Medical Foods) [21 CFR 170.3 (n) (31)]
<input type="checkbox"/> 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS [21 CFR 170.3 (n) (4)]	

How PRONTO-Xi supports the Act

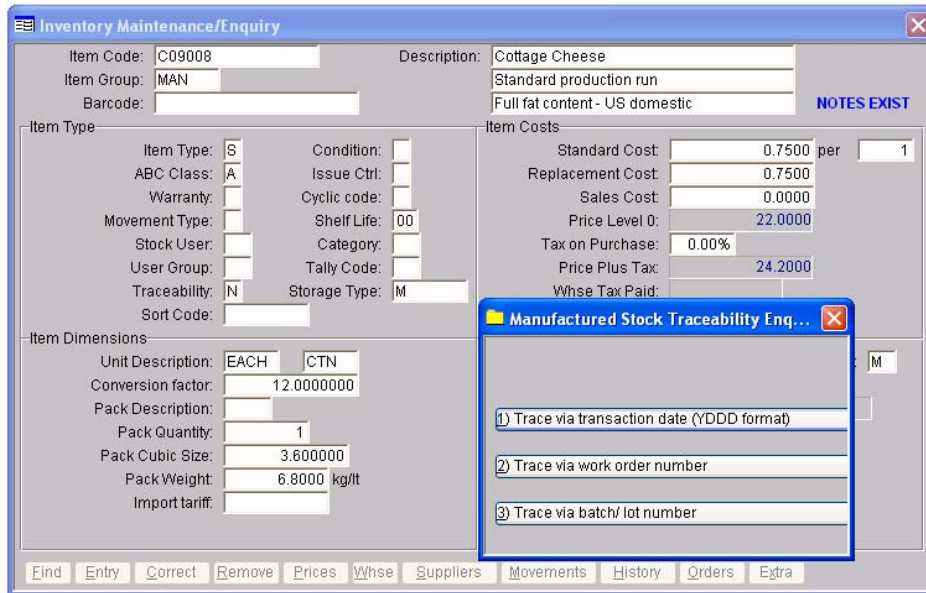
The Act requires that records must include information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product. As Table 2 illustrates, PRONTO-Xi v650 supports the capture and storage of the mandatory information in various processes within your manufacturing and/or distribution operations. These records need to be kept for specific periods of time, ranging from 6 months to 2 years, which is supported within PRONTO-Xi (typically customers retain records for up to 7 years).

Table 2: Mapping of Bioterrorism Act Information within PRONTO-Xi v650

Information Required	Stored in PRONTO-Xi
The name, address, phone number, fax number and e-mail of the Company's plant who had the product or ingredient immediately before you (the Transporter's IPS), and the date you received it from that Company	<input type="checkbox"/> Supplier Records <input type="checkbox"/> Purchase Orders
The name, address, phone number, fax number and e-mail of the Transportation Company who delivered the product or ingredient to your Company including the Bill Of Lading Number and mode of transportation	<input type="checkbox"/> Goods Inward Records <input type="checkbox"/> Bill of Lading <input type="checkbox"/> Localization for some Carrier components as no industry standard record definitions
The name, address, phone number, fax number and e-mail of the Company's plant who had the product or ingredient immediately after you (the Transporter's ISR), and the date it was delivered it to that Company	<input type="checkbox"/> Delivery Address Records
The name, address, phone number, fax number and e-mail of the Transportation Company who picked up the product or ingredient from your Company including the Bill Of Lading Number and mode of transportation	<input type="checkbox"/> Despatch Records <input type="checkbox"/> Carrier Code Records <input type="checkbox"/> Localization for some Carrier components as no industry standard record definitions
The type of product or ingredient, brand name and specific variety	<input type="checkbox"/> Bill of Material (BOM) <input type="checkbox"/> Inventory Stock Keeping Unit (SKU)
The lot number or other identifier of the product or ingredient if available	<input type="checkbox"/> Lot Tracking Item
The type of packaging and quantity per lot	<input type="checkbox"/> Localization as dependent on manufacturing/distribution requirements

Once data is captured, there is an obvious need to be able to access it, and PRONTO-Xi includes a number of ways to trace products. These methods support both forward and backward tracking to ensure visibility across all inventory movements. The resulting information is presented in a data grid that supports data filtering, one-button export to Excel and a straightforward way to email the information to other people.

Figure 3: Lot Traceability is accessed via Inventory Management

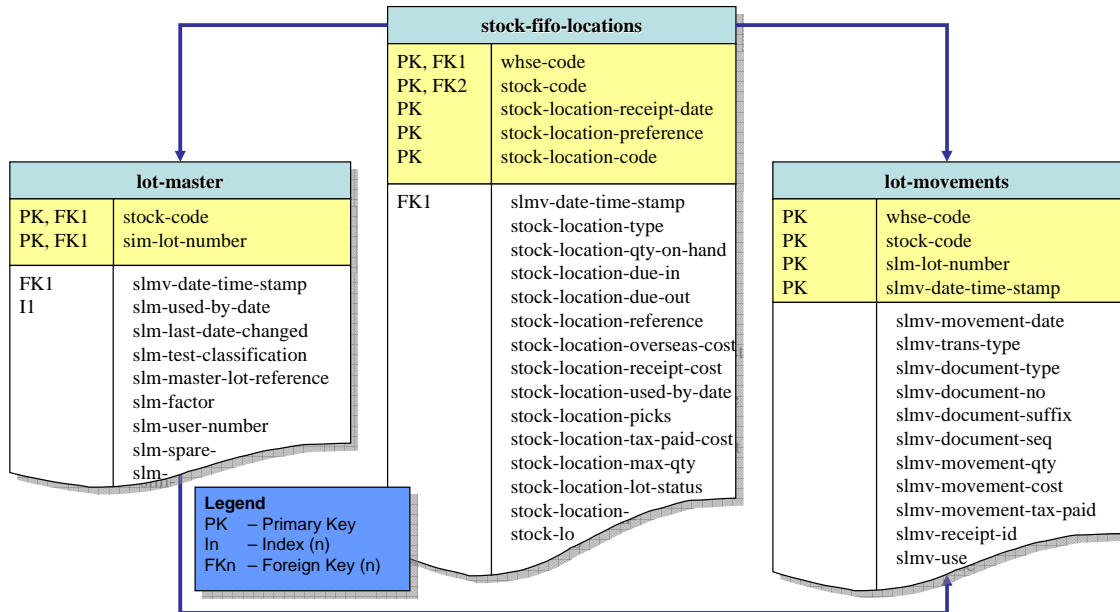


With specific regards for the Act, a review of the traceability functions associated with Lots and Serials was undertaken to examine the tracking and traceability of product data within PRONTO-Xi. This included an examination of the implications related to functions such as Location Control, FIFO Costing and Works Order Costing. Research and Development enhanced various aspects of the system, delivering a number of operational benefits for food processing customers:

- Enhanced capabilities of products requiring recall;
- Enhanced costing of lot items produced from work orders;
- Improvements in files structures:
 - Higher visibility of lot movements, which provides greater traceability;
 - More readily available auditing;
 - Clearer presentation of product information.
- Improved data integrity through consolidating storage of lot details within a central location;
- Location tracking and FIFO costing can work independently;
- Simplification of the picking process.

PRONTO-Xi maintains considerable lot tracking information in the major inventory control tables as shown in Figure 4. Also included are user defined fields and R&D expansion fields to ensure that localization requirements can be delivered without impacting on core code. First-rate lot tracking is critical to enable compliance with the Act, and PRONTO-Xi's real-time movement provides the necessary accuracy and timely access to records to support your compliance efforts. In particular, lot tracking is fully integrated across Lot Master, Picking, Receiving, Warehouse, Costing and Tally records to comprehensively track and trace inventory movements within your system.

Figure 4: Lot Tracking Tables



Conclusion

Pronto Software has invested considerable effort to ensure that PRONTO-Xi v650 meets the requirements of the Bioterrorism Act for our food processing customers. However, PRONTO-Xi still may require localization in terms of specific reports for each customer so they are confident that they can respond to the FDA as they see that they need to. As demonstrated, in this regard the underlying database objects and lot tracking data is available to enable this.

Of course, if you do not capture or keep all the information required by the Act then the business outcome is clear...you will not be compliant, no matter that you are using PRONTO-Xi.

Finally, as illustrated in Table 3 below, there is a large body of documentation for the Act, including the following web sites that we have found particularly accessible.

Table 3: Useful Web-based Bioterrorism Act Resources

Description	Web Site
FDA Overview of the Act	http://www.fda.gov/oc/bioterrorism/bioact.html
FDA Fact Sheet on the Establishment and Maintenance of Records	http://www.cfsan.fda.gov/~dms/fsbtac23.html
FDA Online form 3537 for registration of food processing facility	http://www.cfsan.fda.gov/~furls/frm3537.pdf
Detailed overview of Procedures for Implementation of Enforced Compliance and Penalties for the Bioterrorism Act	http://www.cbp.gov/linkhandler/cgov/import/commercial_enforcement/bioterrorism/external_bt_procedures.ctt/external_bta_procedures.doc
Food Safety and Security – Operational Risk Management presentation	http://foodsafety.cas.psu.edu/Food_Safety_and_Security.ppt#256,1
Produce Marketing Association/ Canadian Produce Marketing Association Best Practices documents regarding traceability	http://www.pma.com/Template.cfm?Section=Traceability&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=51&ContentID=4523
Just for Fun – Food Safety Music Website that features Dr. Carl Winter's musical parodies	http://foodsafety.ucdavis.edu/