



Will the FDA or Bioterrorism Put You Out-of-Business?

10 micrograms of Ricin (about the size of a pin-head) can kill a person. Ricin can be made with readily available equipment from the waste products from converting castor beans into castor oil. A small vial introduced into a batch of food in any one of the hundreds of thousands of food processing plants in the USA could kill tens of thousands of people. To counter this Bioterrorism threat the FDA has been given sweeping new powers under the Bioterrorism Act of 2002. As of last December all food processing plants had to register with the FDA.

More importantly, food processors have to comply with the 4-hour one-step forward, one-step backward traceability rule. This rule says that anyone in the food supply chain has four hours to respond to a demand from an FDA, Homeland Security, or other designated government official for data about where all the foodstuffs they produced went and where all the materials, including where the food contact containers came from.

What this means is that, if people suddenly start getting sick or dying and you are a food processor and your products are suspected of having been ingested by some of these people, then the FDA and Homeland Security and the FBI and people from about another dozen agencies will arrive on your doorstep and demand to look at your traceability data. If they are able to go into your computer system and look for a common link and hopefully not find one then you will be allowed to proceed with your business. If all you have is a set of incomplete paper records stuffed in a filing cabinet, then government agents in black jump-suits, armed with assault rifles, will start wrapping your building in yellow tape and shut you down.

An FDA inspector, an agent from Homeland Security, or other designated agents can place your facility and presumably its management under administrative detention for up to five days, while they determine whether you are the cause of the problem.

If your plant is suspected of being the source of the contamination and you can identify the suspect batch, then the FDA will order you to recall all shipments from that batch. If you have good computer-based records, then you will be able to give the FDA the data they need to assist you in quickly quarantining any materials that came from that batch. If you cannot quickly identify the suspected batch, where the materials that went into that batch came from, as well as other possible suspect batches, then the FDA will probably order you to be shut down while you recall all the material you have made in the past 3 years. This will effectively put you out of business!

It used to be that correctly labeling products and making sure that proper traceability records were the responsibility of mid-level production and QC managers. Now, maintaining good traceability records has become a "bet-your-business" issue for senior management of food processors as well as manufacturers of containers and other supplies that come into contact with the food.

So, how do you go about maintaining good traceability records? The first thing to recognize is that you cannot realistically meet the 4 hour rule with a paper-based records system. If people are dying, the Government needs to have instant access to traceability data in a form that they can easily analyze. A filing cabinet full of paper records does not meet this need.

The second thing you need to recognize is that you need to put a unique “license plate” tracking barcode on each separately trackable container of materials that you make and that you use to make materials. In October 2003, the UCC/EAN council came out with new standards to be used for tracking barcodes in the USA and Europe. This standard specifies the format for the barcodes used to uniquely identify each container and pallet for identification purposes.

This does not supplant lot tracking but supplements it, to give the traceability data needed. When each box, bag, barrel or other container of raw material is received, it has a unique “license plate” tracking barcode applied, if one has not been previously applied by its vendor. This tracking barcode is scanned and associated with the vendor and vendor part and lot numbers.

When a container of raw material is used in making a batch of food, then the tracking barcode on the container is scanned to trace the raw material to the batch. All containers of finished goods have a unique license plate tracking barcode applied that is associated back to the batch from which it came. Note that packaging containers that come into immediate contact with the food also have to be tracked, just like the food itself.

When the container of finished materials is shipped, then the tracking barcode on the container has to be scanned and associated with the customer to whom it is shipped. This completes the chain of traceability from vendor materials to the mix batch to the finished goods to the customers. From this data, the Government can quickly work its way back from sick people to common batches of food to the contaminant source. Then they can quickly perform a “where used” analysis to implement a rapid, limited, and effective recall.

There is a question of what level of container to track. Most food processors are used to putting UPC barcodes on their products but these only identify the product and manufacturer. Most are now labeled with batch or lot information but typically only in human and not machine readable form. It is highly desirable to individually label the first level corrugated case containers and essential if these are picked for individual shipment to customers. If shipments are only made in whole pallets, where the whole of each pallet comes from a single mix batch, then it may be acceptable to simply label and track the pallet and not the boxes on the pallet. If individual containers are shipped to people, such as by mail or Internet order, then it may be desirable to uniquely identify individual containers of material.

This presents some new challenges:

1. Automated print-and-apply systems that are now used to put the same label on a run of boxes will now have to apply a uniquely serialized barcode to each box. This means that the data that used to be “fat-fingered” in, must now be accurate and correct and driven from a computer that is able to link the tracking barcode with the batch and source of the container.

2. An ever increasing number of distributors now want traceability data about each container sent to them electronically as an EDI Advanced Shipment Notice or as an XML packet over the Internet. This is so that they can integrate your food processing data into their traceability records.
3. Employees must be trained in traceability procedures that were previously limited to the domain of pharmaceutical manufacturing. This presents a challenge in that many workers in food processing plants do not read or write English very well and in many cases are semi-literate in their own languages. This is only possible with a high level of automation of the data collection process.
4. Most existing ERP systems are not designed to handle traceability data. They need to be supplemented by a data collection system such as BellHawk[®] from BellHawk Systems Corporation that complies with the FDA 21 CFR Part 11 requirements for the capture of electronic data related to human safety in Food and Drug production.

In summary: These new FDA regulations are not just another bureaucratic interference in our commercial world. They are designed to enable the US Government to respond quickly to a Bioterrorism attack to which we are all too vulnerable. As a food processor you can do your part by having the systems and data that can enable the Government agents to quickly identify the source of contamination and to quickly quarantine suspected materials before any more people get sick or die.

If you think that you can just ignore this issue and it will just go away, please think again. We have already been subjected to a number of Bioterrorism attacks and a bigger number of scares. You can kill a few thousand people by crashing an airplane or exploding a bomb but you can kill tens of thousands by contaminating the food chain. We will be subject to repeated Bioterrorism attacks, especially as our food supply chain is so vulnerable. This can cost you your business, even if you are not at fault, if you are not prepared to help deal with this threat.

This paper was written by Peter E. Green Ph.D. who is the chief systems architect for BellHawk Systems Corporation. He is an expert in computer based material tracking systems and led the team that developed the BellHawk tracking software. Dr Green holds a Ph.D. in computer science and a BSEE from Leeds University in England. He was previously on the research staff at MIT and was a full professor at WPI. He has spent most of his career of over 30 years developing tracking systems for Government, commercial, and industrial clients.