

## ***The “Reasonably Available” Information Loophole for FDA Record-Keeping***

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By William R. Pape, Mark Armentrout, and Lee Curkendall, AgInfoLink Global, Inc.

We continue to receive substantial feedback on our two previous articles regarding the new FDA bio-terrorism record-keeping requirements. In July we provided a broad overview of the law which went into effect June 2006 for agri-food companies with eleven or more employees. Last month we reviewed who's exempt and who's not. This month we'll close the series by taking a look at the loophole many companies think they can use to avoid any additional record-keeping – their lack of available traceability information.

The law says that agri-food companies and the transporters who carry food must keep records about product movements in and out of their company. The farm and ranch of origin do not have to provide records as to who purchases their product. Neither do retail establishments who sell to the public. Every other transaction generally has a record keeping responsibility, and records must be provided to the FDA within 24 hours if FDA believes there is a credible threat to the health of people or animals.

In the enabling legislation language for this Act, the FDA's "Guidance for Industry" (<http://www.cfsan.fda.gov/~dms/recguid3.html>), and discussions with FDA officials the phrase "information reasonably available" crops up repeatedly. A casual reader may conclude that this means that if a company doesn't currently keep records, they're exempt from any record keeping requirement. Many companies have concluded that if they provide the FDA with a list of all of their customers and a list of all their suppliers, they are in compliance. Unfortunately, nothing could be further from the truth.

### **What is Reasonably Available Information?**

In Section 29.6 of the "Guidance for Industry", the FDA poses the question, "A manufacturing firm has multiple suppliers...Is it sufficient to simply record all the potential suppliers than an ingredient or packaging material might have come from?", and then answers with a resounding "No". In its answer to this question, the FDA makes it clear that "...it is not sufficient to record all potential suppliers that an ingredient or packaging material might have come from if there is no expectation that that supplier's product would be in the finished product."

This same theme is echoed in the FDA's response to a question about whether a company needs to keep track of the exact lot number of bottle caps that come into contact with the food. The FDA responds by saying that "...what is reasonably available depends on the particular circumstances...It is not acceptable, however, to simply identify all caps received by the facility if it is possible to determine more specific information...". So, what more specific information is required?

The FDA in Section 29.3 specifically zeroes in on the information that should be reasonably available in the answer to a question about the specific recordkeeping requirements of a firm using raw agricultural commodities from multiple sources that co-mingles them in on-site storage bins. In the answer to this question, the FDA provides the following direction: "...if a lot of a product incorporated an ingredient from a particular bin and that bin was filled with commodity derived from five immediate previous sources, then those five sources would be the reasonably available information for that ingredient. If the bin was refilled before being emptied and now may contain ingredients from up to ten immediate previous sources, then this is the information that is reasonably available."

### **What If the Process Is Complex or Continuous?**

The FDA also makes it clear that the recordkeeping requirement exists regardless of the complexity of the agri-food company. In Section 29.4, the FDA poses the question, “A manufacturing firm may handle over a thousand different ingredients on the same day, and three or four lot codes of the same ingredient from the same supplier...Assuming the ingredients arrive at the manufacturing facility with lot codes, does the manufacturer have to track each lot code and link it to a finished product?” The FDA response again is an unambiguous “Yes”.

The FDA goes on to speak about what they expect as reasonably available information for a manufacturer with a continuous flow process. The FDA asks, “A feed mill receives ingredients and commingles individual shipments into bins which are never completely empty...Would the feed mill have to provide all these lot numbers for food it releases?”, and answers again with a “Yes”. In these example, the FDA does say that a manufacturer may not be able to have a 1:1 association between incoming ingredients and outgoing food product, but “...the record created for every lot of food released by the manufacturer that incorporates material from the bin would include all possible sources of the material placed in that bin.”

An agri-food company or transporter, though, doesn't need to keep the upstream product pedigree information according to FDA officials. If upstream ingredient processor company A produces an ingredient lot that contains commodity from many different commodity suppliers, the downstream food manufacturer receiving that specific ingredient lot only is required to keep track of the single outgoing lot number from the ingredient supplier. For example, if a flour manufacturer produces a single flour lot and knows it came from wheat provided from three different grain elevators, the flour manufacturer must keep track of the lot numbers of the incoming wheat from the three different grain elevators. This flour lot is shipped via a third-party shipper to a baker who receives it. Both the shipping company and the receiving baker only have to record the single flour lot number established by the flour manufacturer. The baker and the shipping company do **not** have to maintain records about the lot numbers from the grain elevators that made up the single flour lot.

### **My Supplier Doesn't Tell Me their Lot Number?**

What if your supplier doesn't tell you the lot number of the incoming ingredient? In Section 32.2 the FDA asks this question and responds that a manufacturer is responsible for obtaining lot numbers from suppliers and plainly states this fact by saying, “The manufacturer must obtain the lot numbers for each ingredient received from the ingredient supplier.” There's no ambiguity here in their answer.

In Section 32.8 the FDA goes on to state “... that If a lot or code number or other identifier exists, but is not being used by a manufacturer, processor, or packer as part of current business practice, ..(the) business (is) required to include that identifier in the records it establishes and maintains.” “These persons must ensure that they meet the requirement regardless of whether the information is provided by their nontransporter immediate previous source.”

So, it appears that downstream companies in the agri-food chain must insist their suppliers provide a lot number or other unique identifier for each incoming ingredient shipment.

The FDA does say that it is sufficient to record the lot codes on pallets of incoming ingredients and handle receiving via the pallet rather than the individual cartons on that pallet as long as the processor can link each pallet to the cartons when the cartons may each contain different lots (Section 32.1). The key here is to connect the pallet to the different incoming lots.

### **It's my Brand but it's Produced by a Franchisee**

In Section 17.4, the FDA asks the question, “A supermarket receives direct store deliveries from various companies. For some of these companies, the actual product is manufactured by a franchisee or contractor. From a recordkeeping standpoint, is the nontransporter immediate

previous source the brand company or the contractor?” The answer is both companies are responsible for recordkeeping. “...both the brand company and the actual manufacturer are nontransporters subject to the final rule. Both are responsible for complying with the rule...legal responsibility for establishment and maintenance of records and for meeting the records access timeframes...remains with both parties.” Such a rule will require much greater communication between the brand owner and contract manufacturers.

There are many more points that could be discussed about this rule including the recordkeeping requirements for both the packaging material that comes into contact with the food, the recordkeeping requirements for packaging material that doesn't directly contact food, the recordkeeping requirements of producers of inputs into farms such as hay, and many other areas. The reader is directed to the previously referenced FDA document which can be obtained through the Internet.

Our primary conclusion from reviewing this document is that all companies in the agri-food chain, including their shippers, must look carefully at how these new laws may affect them. It appears the FDA is very serious about the law's enforcement. The government is very focused on eliminating bio-terrorism as a weapon in a terrorist's arsenal, or if it is used, to be able to limit the potential damage caused. The same rules will also help contain the adverse impacts of a non-intentional event which could impact the health of animals or humans. The challenge agri-food companies have is to implement this new level of security with minimal disruption to their operations.

Further information can be found at [www.aginfo.com](http://www.aginfo.com) or other organizations working to disseminate information about the FDA recordkeeping rules for the Bioterrorism Act.

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