

I am exempt from the New FDA Regulations, aren't I?

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

Last month we wrote about the new Industry Guidance document FDA released in June which provides fifty-four pages of Q&A clarification regarding the recordkeeping responsibilities for agri-food companies and their transportation providers in the Bioterrorism Preparedness and Response Act of 2002 (<http://www.cfsan.fda.gov/~dms/recguid3.html>). These regulations just went into effect for companies with 11 or more employees this past June 9th. They will become law for everyone with one or more employee this coming December.

The nearly universal feedback to us on this article was “Yes, that’s all nice, but my company is exempt from these record keeping requirements. We don’t need to do anything.” Or “we already have all the records we need.” As we go back and re-read the 54 page guidance document, we wonder if all of these companies are correct in their interpretation of the new law.

Before jumping into why people think they don’t need to do anything, let’s review once again the Act’s essence. Section 306 of the Act indicates that any U.S. company must create and maintain records of food movements into and out of their operations if they “manufacture, process, pack, transport, distribute, receive, hold, or import food into the United States”. These records must be provided within a maximum of 24 hours after they are requested by the FDA or else the FDA can impose a series of criminal penalties on the company and its officers. The farm or ranch of origin is exempt but once it leaves the farm or ranch of origin it’s fair game. Retail establishments selling directly to consumers are also exempt. Everyone else in-between has some level of recordkeeping responsibility.

From our perspective, about the only one not required to keep and produce records under this Act are farms/ranches of origin who exclusively use their trucks and their own staff to sell directly from their farm or ranch to consumers at farmer’s markets. Everyone else has a reporting duty.

Let’s look at the common responses we’ve heard from agri-food and transportation companies about why the person thinks their company isn’t subject to this Act:

I’m just a transporter. I don’t manufacture food

Even though a transport company doesn’t process or manufacture food, it still has a recordkeeping responsibility under the Act. The Act specifies that any company that transports food must maintain records of the immediate previous non-transporter or transporter (in the event of trans-shipment) **and** the immediate subsequent non-transporter or transporter. There’s only one exception to this rule – when either of the immediate previous and/or the immediate subsequent recipient is under the same **exact** legal ownership (see below for the virtual integration requirements).

For third-party transporters, the type of information stored will likely be different that what is currently being recorded. The large national transport companies such as UPS and Fedex are realizing that they have to add additional information fields to capture needed data such as a more complete product description and lot information.

I only broker transportation for food haulers

In Section 1.1 of the FDA Industry Guidance document, the question is posed, “A brokerage division of a shipping company handles nationwide shipping needs for several other shippers. The brokerage division does not physically take custody of the food but negotiates the freight rates and assigns the contracts to independent carriers. Does the brokerage division have record

keeping obligations...?” FDA answers “Yes. ...a person...who enters into a contract to transport an article of food and has control of the food is considered a transporter, even if the actual transport is subsequently subcontracted to another entity.” However, the guidance does provide a way that a broker might be able to become exempt.

We're vertically integrated

Several companies responded that they were vertically integrated from the farm or ranch or origin so they felt they had no recordkeeping responsibility. Typical examples were companies that were grower-packer-shippers in the fruit and vegetable industry. Are these companies exempt? Maybe.

Comment 13 of the Final Rule preamble states that “a vertically integrated company does not have to establish and maintain records of internal transactions.” However, Section 1.5 of the Industry Guidance document states that for this exemption to come into force, all parts of the company must be under “identical ownership”.

Identical ownership is defined in Section 35.1 as well as comments 13 and 71 in the Final Rule preamble as “continuous possession of an article of food. Once a covered person receives food and keeps information on its immediate previous source, that person does not need to keep additional records until it releases the food to another person. .. In Section 35.3, it states “Person” as defined in 21 CFR 1.328 includes individuals, partnerships, corporations and associations. The exemption for vertically integrated companies only applies to distinct legal persons.” Therefore, if the vertical integration involves more than one distinct legal entity (e.g., a holding company has one distinct legal entity for farming, one for shipping, one for warehousing, etc.), then in the eyes of this Act, these are distinct companies, the holding company is not vertically integrated, and recordkeeping must be done at the hand-off to each distinct legal entity (e.g., growing company hands off to packing company which hands off to trucking company if all three were distinct legal entities).

And if the product moves from the vertically integrated chain to an independent operator, at any point in the farm-to-consumer chain, then the vertical integration is broken and information is required from the vertically integrated chain to the independent operator (both transporter and non-transporter) and from the independent back to the vertical chain. All of Section 35 provide example after example of companies that thought they were vertically integrated, found out they weren't.

There's another limitation to this rule. In Section 5.2, the FDA makes it clear that even if a company was vertically integrated under the exact same legal structure and fed from the farm to a restaurant, the restaurant, because the business was distinct from the growing, packing, shipping activity, would constitute a break in the chain. “The restaurant exemption under 1.327(b) applies to the facility that prepares and sells food directly to consumers...(it) does not extend to the supplier/warehouse/distributor level even though they are all part of the same company.”

I'm too small, I'll fly under the radar

Of all the rationalizations about why a company didn't need to respond, this reaction is the most dangerous. Not only does this “head-in-the-sand” approach create potential gaps in the country's bioterrorism response, but it exposes the company, its managers and board members to a wide range of potential criminal penalties. It's possible lightning won't strike, and the FDA won't knock on your door, but if it does it could be catastrophic if you aren't able to “connect the dots” within the 24 hour time period. Not only are the criminal penalties onerous for the company, its management and board members, but the negative public relations can't help a company's marketing program.

So, will FDA come calling?

What Congress may have thought was a safeguard for industry may turn out to be a double-edged sword -- the Act specifically prohibits FDA from conducting compliance audits on this

record keeping requirement. Under the Act's authorizing language, the FDA can only request these records in the event FDA believes there is "...credible threats of serious adverse health consequences or death to humans or animals." While this language may sound great on the surface, what this means is that companies have no means to determine if they are in compliance until the company is compelled to produce the records with serious criminal penalties for the company and its officers if they are unable to respond within the statutory 24 hour period. Few teams want to go to the Super Bowl without any practice.

And if we didn't think recordkeeping was a big enough issue...

There's an added wrinkle to this FDA recordkeeping requirement – it appears that both attorneys and the Sarbanes-Oxley Act of 2002 may potentially become involved. We heard one major law firm with numerous agri-food clients started scrambling after reading our column. They asked us a number of questions about our interpretation, read the 54-page FDA document, and then sent us a copy of a page from a professional legal publication which explains Sarbanes-Oxley to attorneys. Under the section entitled "Attorney Professional Responsibility", they highlighted a relevant passage that indicated that if an attorney becomes aware of a material violation of "any other U.S. federal or state law by a company or any of its officers, directors, employees, or agents, that attorney has a reporting obligation". The obligation is to the company as an organization "rather than to the officers, directors or employees in question." The firm concluded they needed to inform all of their partners and associates about the FDA recordkeeping requirement, and to look into whether their client customers were in compliance.

So, even though the FDA may not be doing any compliance audits, a company's legal firm may be adding another question to their annual management questionnaire -- "To the best of your knowledge, is your company in compliance with the recordkeeping requirements of the Bioterrorism Act of 2002?" We again urge agri-food managers to carefully read the 54-page FDA industry guidance to ensure they are correctly answering this question. There are no simple answers to whether or not a company is in compliance.

Even though the fifty-four page Q&A Guidance to Industry document is clearly written for a government document, there are still quite a number of potential grey areas. We've covered a few last month, a few more this month, and next month we'll conclude the series. Regardless of what one thinks about this law (and remember it was approved by a near unanimous Congressional vote), it is the law of the land.

Further information can be found at www.aginfolink.com or other organizations working to disseminate information about the FDA recordkeeping rules for the Bioterrorism Act.