



ON THE FRONT BURNER

Since September, companies have been required to immediately report safety problems with food and animal feed in the supply chain to FDA's Reportable Food Registry. Though FDA recently declared its own web-based portal a stroke of brilliance, suggesting it will be useful in helping to track trends and food problems (see FCN Aug. 2, Page 1), the RFR has been the source of consternation for many food manufacturers and retailers. But here, just in the nick of time with his rolled up sleeves and some power equipment, is the other attorney from Seattle – the one who most frequently provides his outstanding representation and counsel to the food industry.

The Reportable Food Registry Toolkit

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In its first year, the FDA's Reportable Food Registry has proven itself to be a high-stakes game changer. The ticking of the RFR's 24-hour reporting deadline forces a company to make snap decisions that might affect its entire business (not to mention the health of its customers). Once a report is submitted, FDA will promptly alert your customers of the "reasonable probability" that your product will result in "adverse health consequences or death." While RFR reports can be amended or withdrawn based on new information, in the world of food products, the bell can almost never be unrung.

On the other hand, the civil and criminal consequences of failing to report when obligated to do so can be devastating. Companies that fail to comply with RFR requirements (even without intention not to comply) can be charged with felonies, and subject to fines and jail time for their executives. Those violating the RFR with intent are subject to greater penalties.

Assuming your company is a "responsible party" (meaning an "owner, operator, or agent in charge of a domestic or foreign facility" required to register under 415(a) of the FD&C Act) and already follows a HACCP plan, a GMP, GAPs, etc., what else can it do to prepare for and, if possible, prevent an RFR report? The answer is a lot.

At minimum, here's what should be in any food company's RFR toolkit/standard operating procedures (SOPs):

1. Identify the right personnel authorized to report before the event occurs

The first thing a food company that is a "responsible party" needs to do is to identify the personnel

responsible for reporting under the RFR. FDA permits a responsible party to authorize an employee or agent "to report an instance of reportable food on their behalf through the Reportable Food electronic portal." [www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm212793.htm].

Best practices dictate that personnel authorized should be:

- **Trained food scientists and/or epidemiologists.** All food companies should have competent and experienced food scientists in house or consultants on retainer who are food safety experts. Without proper food safety staff, compliance with a HACCP, a GMP or GAPs is impossible. Without the right staff, problems from foodborne illness, foreign objects and allergens are inevitable rather than avoidable. Without the right staff, unavoidable foodborne illness and other problems may easily destroy a company.
- **Intimately familiar with the company, its products and its quality and with supply chain personnel and practices.** More than well-trained and competent, food safety personnel authorized to report should be as familiar as possible with the company, its products, personnel, SOPs, suppliers, etc. Food products are often complex, involving multiple ingredients, suppliers, customers, formulations, etc. As with any crisis concerning the company's products, no one can fully grasp the scope of the problem, formulate a response or provide regulators with required information without all the information. The time of crisis is not the time to familiarize your experts with your company and your products.

For companies with multiple facilities required to register under the FD&C Act, clear identification of personnel responsible for reporting is critical to avoid multiple and inconsistent reports concerning the same product.

2. Train personnel to understand the RFR, the portal and legal requirements

The web-based RFR Portal [www.safetyreporting.hhs.gov/fpsr/WorkflowLoginIO.aspx?metinstance=AEA592606669DEEA39930BABD84B3E6DAD81AC3F] is relatively straightforward and user friendly. The easy part is learning to use the software. More challenging is understanding when a report is required.

For example, personnel must be able to determine what constitutes a “reportable food” under the law and what does not. Section 417 of the FD&C Act defines “reportable food” as “an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.” FDA in its guidance documents says that “reportable food” includes “those foods that would meet the definition of a Class I recall situation. A Class I recall situation is one in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.”

But what would FDA consider a “reasonable probability”? What if one lot of product tests positive for a foodborne illness but other lots do not? The nuances are significant.

Another example of a nuance-laced provision of the RFR that personnel need to understand in advance of a crisis relates to product transfer. The RFR might not require your company to report if your product is still in the field or in the possession of a third party. On the other hand, product not yet owned by your company but located on your company’s premises might be reportable.

An exception in the RFR states that a responsible party is not required to submit a report for a reportable food if all of the following conditions apply:

The adulteration “originated” within the responsible party; The responsible party detected the “adulteration” prior to any “transfer” to another person of such article of food; and the responsible party either corrected such adulteration, or destroyed or caused the destruction of such article of food.

3. Revamp recordkeeping policies

In addition to the reporting provision itself, the RFR imposes new recordkeeping requirements and FDA inspection authority. FDA instructs that “the responsible party shall maintain records related to

each report received, notification made, and report submitted to the FDA under section 417 of the FD&C Act for two years.”

In addition to revamping document destruction/retention, companies should consider SOPs that define and segregate documents “related to” an RFR report. Both the document maintenance provision and the FDA’s current authority to demand documents are limited to those “related to” an RFR report.

For those documents that are provided to FDA, companies should take precautions to prevent disclosure of confidential and proprietary business information and trade secrets. Documents turned over to the FDA will be subject to the Freedom of Information Act (FOIA). However, a FOIA exception exists for “certain information, including but not limited to trade secrets and confidential commercial or financial information.” One SOP a food company should consider is including a standard cover letter with any documents provided to FDA explaining that the company considers some or all of the information exempt from FOIA disclosure.

4. Revisit supply contracts and reconsider timing/location of product testing

As discussed above, in the context of the RFR, possession is more than 9/10, it is everything when it comes to reporting responsibilities. A supply contract that does not transfer ownership of the product until after sampling does not relieve the purchaser from reporting if the product is held in a truck on the purchaser’s premises. A company might be required to report product owned by another party if the product happens to be located at the non-owner’s facility.

FDA describes this scenario in a Q and A format in its draft industry guidance:

QUESTION: *Our manufacturing facility receives bulk trailer shipments of ingredients from our suppliers. A truck driver brings a trailer full of bulk ingredients onto our property, drops off the trailer, and drives away. However, as company policy, we do not off-load the trailers that are delivered to our facility or take ownership of the food in the trailers until after we test a sample of the food and determine that the food is acceptable. If we “reject” a shipment, i.e., return the food to the supplier, because the sample results indicate that the food is a reportable food, are we required to submit a reportable food report?*

FDA’s ANSWER: *Yes, provided that you are a facility required to register with FDA under*

section 415(a) of the FD&C Act, you must submit a report for the food you determined to be a reportable food, even though you returned the food to your supplier. FDA considers that your facility “held” the reportable food because the trailers were no longer in transit once they were dropped off on your property. Thus, you are a responsible party with regard to the reportable food. Provided that the adulteration did not originate with you, you do not meet the criteria for the exemption from reporting in section 417(d)(2).

One solution to prevent the potentially awkward situation of having to report product not yet purchased is to require product testing prior to arrival on premises. Aside from requiring test results before shipment or arrival, supplier agreements should be amended to require at minimum that the supplier provide its food safety SOPs, plant inspection reports and, if possible, identities of other parties supplied. Personnel authorized or involved with the RFR reporting should make regular inspections and be familiar with the supplier’s facilities.

5. What to do when FDA inspectors arrive

A report submitted to the registry will likely result in a visit and inspection from the FDA. While FDA’s current statutory inspection powers are technically limited under current law, the reality is that companies should almost always cooperate with FDA’s request. The more difficult a company makes it for the FDA, the more difficult FDA will make it for the company. FDA has both the bully-pulpit and enforcement powers available if it feels that it’s not getting the cooperation it needs and public health is at risk.

Any FDA inspection should be shadowed by company personnel. Photos taken by FDA officials also should be taken by company personnel. The company should request from the FDA split samples if it decides to

swab the plant or test product. As discussed above, the company should segregate in advance records related to the reportable food and those unrelated. Records unrelated to the reportable food need not be provided for inspection. The company also should provide a letter to the FDA indicating that all photos and documents are confidential and proprietary, and should be exempted from FOIA disclosure.

6. Attorney-client privilege will not protect plant records from disclosure

The company’s records and communications (including emails) do not necessarily become privileged (and therefore protected from disclosure to FDA or other parties) because they are transmitted to or “through” the company’s lawyer. Company personnel should not assume that emails to counsel will be shielded unless they clearly relate directly to the provision of confidential legal advice provided to the company.

Even when provided for the explicit purpose of legal advice, “facts” or “business records” will still not be shielded from discovery. Many courts appreciate that in-house counsel provide both legal and business advice and presume that communications are not privileged unless it is very clear that the communication was strictly in the nature of legal counsel.

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