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Recall Readiness: Preparedness, Discovery, Action

Recalls in the food industry are a fact of life. If you have not had to deal with one, it is likely only a matter of time before you are part of a recall.

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Cottingham & Butler, in partnership with the leading food safety consultancy, The Acheson Group (TAG), provides companies with leading risk, safety and insurance advisory and brokerage services.

Preparedness, discovery, and action are the three key components of FDA's recently issued final guidance on Initiation of Voluntary Recalls – fundamentally the same elements on which TAG has focused its consultation and training. It also is little changed from the proposed guidance of April 2019, beyond editorial changes for clarity, deletion of the References section, and two Terminology additions (correction and market withdrawal) – except for one key update.

As FDA has made clear over the last few years, particularly since the publication of its New Era of Smarter Food Safety Blueprint, it is encouraging the use of technology, especially for product traceability. Its emphasis in the new guidance is no different, as the guidance specifically states, "FDA encourages the use of electronic communications for conveying voluntary recall communications about FDA-regulated products." The guidance provides little direction on electronic communication beyond that, and does include the allowance for calls, written/paper or electronic communication in various sections of the guidance. But the agency's continuing emphasis on technology and the guidance focus on "timely communications" for quick action all continue to push the industry to integrate technology for traceability – which is the foundation of an effective recall.

The recommendations for recall preparedness and initiation are fairly straightforward and in line with what TAG sees as best practices for such events. But the publication of the guidance takes these "best" practices up a level to "expected" practices – although, as with any guidance, it is considered to be "nonbinding recommendations." FDA further strengthens its expectation for industry preparedness in both the guidance itself ("It is critical for firms in a product distribution chain to be 'recall ready'") and in the title of its guidance announcement ("FDA Urges Companies to be 'Recall Ready' to Protect Public Health as Part of Final Guidance for Voluntary Recalls").

In addition to this guidance, it is critical to note that FSMA's Preventive Controls Rule requires that facilities establish "a written recall plan for food that requires a preventive control" that includes "procedures that describe the steps to be taken and assign responsibility for taking those steps." (See Chapter 14: Recall Plan guidance for more on this.)

The new guidance takes this a step further, providing recommendations for preparedness to ensure a firm is "recall ready" for a voluntary recall and the issuance of communication. Following is a synopsis of the guidance steps:

PREPAREDNESS

- Identify appropriate personnel. The assigning of specific person(s) to recall roles is essential for quick implementation when an event occurs. Best practice is to establish a recall team that includes alternates for critical roles.

- Train personnel on their responsibilities. Regular training, including mock recalls, help to ensure that team members have a thorough understanding of the recall procedures they are being asked to perform.

Establish a recall communications plan. Identify specific contacts and develop templates for internal, FDA, and direct account communications, as well as public communications if the recall is deemed necessary. Keep these updated.

- Identify any reporting requirements for distributed products. For foods, it is required that a report be submitted through the Reportable Food Registry any time there is a reasonable probability that use of/exposure to a food will cause serious adverse health consequences or death to humans or animals.

- Use adequate product coding. Products should include coding that enables lot identification and facilitates the effective recall of all violative lots.

- Maintain distribution records. Recalled product location records should be retained at least as long as the expected shelf life and use of the product and the time specified in other applicable regulations concerning records retention.

DISCOVERY

- Identify the problem. Procedures should be in place to enable identification of an adulterated product, including those for testing, deviation reporting, consumer complaints, etc.

- Investigate the problem. Specific personnel assignments for investigating a problem should be in place and a timely investigation conducted of any problem, with prompt evaluation and action taking place.*

- Make decisions and take action. Once it is decided that a recall is needed, the scope and depth of the recall needs to be determined, and production and distribution of affected product ceased.

- Consult with FDA about the problem. FDA encourages firms to consult with FDA while it conducts its investigation if the firm has any questions about it.*

*The guidance specifically notes that a recalling firm need not delay initiation of a voluntary recall pending completion of the investigation or FDA's review of its recall strategy or communications.

ACTION (THE RECALL)

Note: While guidance is nonbinding, steps in this section refer to various regulatory provisions of 21 CFR 7.42 on Recall Enforcement.

- Ceasing distribution, shipment, and/or sales of affected product(s). With no further elaboration, FDA apparently sees this as self-explanatory.

- Developing a recall strategy. This should consider various factors (e.g., potential risk, ease of product identification, etc.), address the depth of the recall as well as other factors of 21 CFR 7.42(b), and consider potential expansion should it be needed.

- Notifying direct accounts about the product being recalled, including what should be done with respect to the recalled product. To ensure prompt notification that enables direct accounts to act quickly and effectively to implement the recall, the guidance encourages the use of electronic communication, and recommends that any contact by phone be accompanied by written confirmation and documentation.

- Providing response instructions to notified direct accounts including contact information for and method by which the direct account should respond.

- Including instructions for appropriate disposition of recalled product to ensure the product does not remain a risk.

- When appropriate, notifying the public about a product that presents a health hazard. FDA simply references its guidance on Public Warning-Notification of Recalls which provides recommendations for when warnings should be issued, by whom, how, and the information to be contained.

Despite one's best efforts, things can go wrong through an unintentional contamination in processing or another link in the supply chain, or through the intentional and/or economic adulteration of a food. Regardless of the origination of the problem, it is essential that a facility act quickly to initiate a recall when public health is at risk, and the only way to ensure that is for the facility to have procedures in place that enable it to be prepared to take action.

Although being recall ready based on the specifics of the FDA guidance is "nonbinding," it is an FDA expectation – and having a written recall plan is a FSMA requirement – for the protection of consumers – and your brand. To ensure that your recall plan not only meets FDA expectations and requirements, but also protects your brand, give TAG a call. We can assess your plan, train your team, or work your facility through a mock recall or crisis scenario to ensure it is as protective as it can be.

Should you find yourself in a potential or actual recall situation, TAG has a great deal of experience in helping companies navigate the various challenges of getting a recall right. Being prepared is key, as noted above; but in the heat of the moment, TAG has supported many companies in making the best out of what is a very stressful situation.

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TAG and the dedicated Food & Agribusiness team at Cottingham & Butler work closely together to provide practical and cost-effective solutions and develop insurance programs based on customized needs and goals of food and agribusiness clients throughout the world. We work together to strategically develop risk transfer (contractual and insurance) programs built to retain and/or backstop risk per the tolerance of each company. Risk mitigation is a core competency of both organizations and drives resiliency in the individual businesses and broader portfolio.

The aforementioned article was an adaptation of an article published by TAG.