

Recall Q&A

1. What is the difference between a Class I, II or III recall, a market withdrawal and a stock recovery?
 - a. Generally speaking, a Class I recall occurs when the public health impact is most severe. The exact differentiations depend on the regulatory agency. See the following links for each agency's definition:
FDA <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129337.htm>
USDA <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1.pdf>
CFIA <http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/distributors-guide/eng/1376400892829/1376401519986#a4.2>
2. How do we know how serious a hazard is?
 - a. A health hazard evaluation can be used to help determine the public health impact of an issue. Generally speaking, the presence of bacterial pathogens in ready to eat products including *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7 as well as the presence of undeclared allergens would result in a class I recall. Contact GMA for additional assistance.
3. How long does a company have to alert the government of a potential issue?
 - a. Companies have to alert FDA within 24 hours if they have received or shipped a product with a hazard known to cause a serious adverse health consequence or death to humans or animals (a SAHCODHA hazard). A report with the Reportable Food Registry can be filed here: <http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>
 - b. USDA also requires notification as stated in 9 CFR 418.2 "Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product."
4. When does the 24 hour clock begin?
 - a. The clock begins when the company confirms the presence of a hazard. For unlabeled allergens, this is immediate; for pathogens, this can be upon confirmation of a presumptive positive test result.
5. Does filing a report with the RFR automatically mean that you need to recall a product?
 - a. No. There are instances where you may need to file an RFR report but you do not need to recall a product. While these are related issues, they need to be handled and evaluated independently.
6. If a company receives an ingredient, tests it, and finds a problem, what should they do?
 - a. GMA recommends that the receiving company alert the supplier. Depending on the nature of the hazard, a report may need to be filed with the Reportable Food Registry

(see above). This needs to be done by both the supplier AND the recipient, *even if the recipient does not use the ingredient.*

7. When a product is manufactured by a co-packer, who is responsible for the recall?
 - a. Although brand owners generally issue recalls, if there is a dispute, companies should be aware that it is ultimately the responsibility of the manufacturing facility to recall the product. Brands and co-mans generally have contracts that govern the communication and execution processes and financial responsibilities associated with recalls and withdrawals.
8. Can product testing be used to determine the scope of an issue?
 - a. While each circumstance is different, generally speaking, testing is not a reliable way to determine the scope of an issue. First, a firm should understand the root cause of how the issue occurred; from there, various types of records and other information can be used to determine an appropriate scope of a recall. Contact GMA for assistance.
9. Where can I get more information?
 - a. GMA recommends the recently revised GMA recall handbook, [Successfully Handling Product Recalls and Withdrawals](#). GMA members also have access to GMA's in-house experts. Find the right contact at:
<http://www.gmaonline.org/about/contact/emergency-contacts/>
 - b. If you have product recall insurance, your insurer may also have resources and information to help you through an issue.