Conference for Food Protection

Recall Evaluation Committee **Final report**

Council: **I**
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Committee Charges:

Clarify the system of classification for recalls established by USDA and FDA.

Create clarifying instructions and procedures that industry and consumers can easily understand and comply with.

Recommend enforceable and reasonable time frames for execution of recall communications and actions.

Clarify the information required to be included in supplier recall notifications.

Recommend expectations for the notification of end-users, including restaurant and retail customers as well as school and institutional food service.

Report back to the 2012 Biennial Meeting.

Committee Activities and Recommendations:

This document contains an overview of the discussions of the Recall Evaluation Committee of the past two years. Included are some suggestions and ideas that provide a background for the bullets provided in Committee Issue titled: Change in Definitions. These are not specific recommendations, but rather are intended to serve to provide a background into the concerns shared by many committee members.

Charge #1: Clarify the system of classification for recalls established by USDA and FDA.
For example, what is the difference between a "reasonable probability" (Class I) and a "remote probability" (Class II)? Many industry members believe the public does not distinguish between them; therefore, to the public, all recalls are "bad".

To address this issue, the committee felt that different terminology may be helpful. One set of terms under discussion was to use the word "recall" only for what is currently a Class I situation. Thus we defined "Food Recall" as *a health risk to the general public*, and generally agreed that a "food recall" should coincide with what the FDA generally defines as a "reportable food" or the USDA classifies as a Class I Recall.

The equivalent of what is currently a Class II recall was a bit more problematic

– many of us noted that historically, Class II's have been situations where a major allergen was not listed on the product label, and thought the term "Allergen Alert" would be appropriate. Other committee members felt the term was too narrow as not all Class II equivalents are caused by one of the big eight allergens. Their term of choice is "Food Alert". Either of these is defined as *a health risk to allergic/selected/sensitive populations*.

Finally, the term agreed upon for the equivalent of a Class III is "Food Notification", defined as *little or no health risk*.

A great deal of discussion centered on the difficulty on the part of industry and the public in distinguishing the differences between a Class I, II, and III Recall.

Regardless of the terminology used, the committee overwhelmingly agrees that recalls must be classified upon release. To better accomplish this goal, the committee recommends creation of a decision tree for classification of recalls, with the following stipulations:

- Tree should be transparent and readily available as a tool to industry and regulators
- The decision tree should be developed jointly with industry, regulators, and consumer representatives
- The tree is a guideline, not an absolute rule – regulators maintain final classification decision
- The same/ similar tree/ system should be followed by both FDA and USDA

Charge #2: Create clarifying instructions and procedures that industry and consumers can easily understand and comply with.

The committee's concern is that notifications do not clearly delineate the relative risks of the various categories of recalls. To correct this, the committee feels that:

- Recall announcements should clearly instruct public of severity of risk and tell them how to react accordingly
- Instructions should be different for each classification but standardized (public should always get same instructions for Class I, different for Class II, etc.)
- Affected, or potentially affected, industry sectors should be notified at the same time (or before) information is provided to the general public and media
- Announcements should be consistent and more specific consumer messages (for example, explaining the difference between recalls for pathogens that present a risk to the general public versus a recall for an allergen that only impacts a select portion of the population).

Furthermore:

- Guidelines established by the FDA and USDA, working jointly with

industry, should standardize industry best practices on what to do, and when, upon receiving notice of a recall.

- Expectations should differ by classification
- Expectations should be tailored to major industry segments – production, retail, foodservice – as each of these segments bears different responsibilities and reactions

Charge #3: Recommend enforceable and reasonable time frames for execution of recall communications and actions.

Currently, the recall initiating firm is the only entity in the distribution chain with written guidelines for recall actions. Our thoughts:

- Industry best practices should be established by the FDA/USDA and in place for secondary suppliers and distributors
- Expectations should be established for tracing one step forward and back within a defined time frame
- The government agency overseeing the recall should require that originating firm issues classified recall notice and contacts direct receivers
- FDA/USDA should establish expectations for timeliness in notifying next link in food chain
- Receivers should react immediately (defined as within 24 hours maximum – 4 hours for high-risk; or as defined by the FDA and USDA)
- Customers should be contacted/ notices posted as soon as possible (24 hours max- 4 hours for high-risk product recall) following the Food Safety Modernization Act (FSMA) guidelines
- Reports to Agency (product remaining, customers affected) should be submitted in a timely fashion

Note that the issue of retailers notifying consumers has already been addressed by FDA and the Food Marketing Institute (FMI) and therefore was not discussed here.

Charge #4: Clarify the information required to be included in supplier recall notifications.

- Identify the format of the communications downstream- start with existing models (USDA/FDA)
- All Recall Notices should follow the same format
- Identify minimum required information to properly identify the product - note that existing models exist with both government agencies but industry is not required to use them as a template
- Identify minimum best practices for notification, including times
- Classification of the recall should be determined by FDA/USDA and included upon release of the recall notification
- Standardized plain language assessment of risk should be included in the recall notice
- The recalling firm, including contact information, should be included
- Describe the recalled product in adequate detail so that it can be clearly identified and rapidly followed through distribution to the end user. This should

include:

- The product description or some surrogate—manufacturer and product name
- Producing establishment identification /plant numbers
- Brands/ sizes/ packaging/identifying information such as lot codes, manufacturing codes, "sell by" or "best by" dating, retail product UPC, shipping case UPC, etc.

- Provide instructions on how to return, destroy, get credit, or avoid a potential hazard
- Include the Distribution channel (retail, foodservice, etc.) including geographic information – this is especially important because firms and individuals want to know if they are NOT included in a recall.

Charge #5: Recommend expectations for the notification of end-users, including restaurant and retail customers as well as school and institutional food service.

- A Properly Classified recall notice should be publicized on FDA or USDA web site as well as the supplier web site – including instructions how to avoid or minimize harm
- All downstream recipients in the supply chain of a recall (including consumers when required) must be notified by verified phone, fax, or email (note that retail consumer notification is covered under a FSMA committee)
- Federal Agencies are urged to review best methods of communicating recalls to the general public, including use of modern technology.

Requested Action:

The Committee will submit three (3) Issues to the Conference.

1) To acknowledge the Committee report, thank the members, and disband the committee.

2) Requesting that a letter be sent to the FDA and USDA recommending the following

a. Change in definitions:

i. Replace Class I Recall with "Food Recall" defined as *a health risk to the general public*, and should coincide with what the FDA generally defines as a "reportable food" or the USDA Class I Recall

ii. Replace Class II Recall with "Allergen Alert" or "Food Alert" defined as *a health risk to allergic/selected/sensitive populations*.

iii. Replace Class III Recall with "Food Notification" defined as *little or no health risk.*

b. Creation of a decision tree for classification of recalls, with the following stipulations:

i. Tree should be transparent and readily available as a tool to

industry and regulators

ii. The decision tree should be developed jointly with industry, regulators, and consumer representatives

iii. The tree is a guideline, not an absolute rule – regulators maintain final classification decision

iv. The same/ similar tree/ system should be followed by both FDA and USDA

3) Requesting that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing a uniform food recall system. Examples of what should be considered in this initiative include:

- A mechanism for working with industry and other stakeholders to further identify the specific changes needed to enhance the current recall system
- A uniform recall process be used by all federal food regulatory agencies
- A revised classification system that is prompt, transparent and meaningful to industry, regulatory, and the general public using consistent definitions for recall classifications
- Consistent information provided with every recall, especially a decision on the classification
- Clarifying instructions and procedures for industry and the public
- A mechanism for engaging relevant private-sector expertise in recall investigations and recall decisions
- Reasonable "best practice" time frames for execution of recall communications and actions including verification of notification
- Clear and consistent information in recall notifications to each segment of the supply chain including information that clearly identifies the product being recalled in sufficient detail
- Consistent protocol for audits and/or effectiveness checks
- Consistent and more specific consumer messages (for example, explaining the difference between recalls for pathogens that present a risk to the general public versus a recall for an allergen that impacts a select portion of the population)
- A single website and database for all food recalls with a consumer-friendly format

Roster: (see attached)