

**Conference for Food Protection  
2012 Issue Form**

**Internal Number: 018  
Issue: 2012 I-020**

<b>Council Recommendation:</b>	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
<b>Delegate Action:</b>	Accepted _____	Rejected _____	

*All information above the line is for conference use only.*

---

**Title:**

Recall Definitions and Decision Tree

**Issue you would like the Conference to consider:**

The Recall Evaluation Committee requests that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing new terminology for Class I, II, and III recalls that is easier for industry, regulators, and the public to understand. Additionally, that a decision tree be developed that creates more transparency into how a recall should be classified.

**Public Health Significance:**

Food recalls are the last line of defense when a dangerous or violative food product has entered the marketplace. When a firm is unable to determine proper classification, the process slows down, causing potentially dangerous delays in public notification and distribution chain removal of the product from the marketplace.

Additionally, many suppliers and the general public do not understand the difference in the significance and danger associated with the various classes of recalls. The result is either apathy, where the public pays little attention because of the sheer volume of "noise", or they over-react and needlessly throw out and stop buying perfectly good products. The net result is an unnecessary loss of public confidence in our food supply, as well as a tremendous waste of food.

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

The equivalent of what is currently a Class II recall was a bit more problematic - many Committee members 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*.

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:

- Decision tree should be transparent and readily available as a tool to industry and regulators.
- Decision tree should be developed jointly with industry, regulators, and consumer representatives.
- Decision 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.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA and USDA recommending the following:

a. Change in definitions:

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

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

**Submitter Information:**

Name: Greg Pallaske, Co-Chair  
Organization: Recall Evaluation Committee  
Address: US Foods 6133 N River Rd Suite 300  
City/State/Zip: Rosemont, IL 60018  
Telephone: 847.232.5884 Fax:  
E-mail: greg.pallaske@usfood.com

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*