

**Conference for Food Protection
2010 Issue Form**

**Internal Number: 013
Issue: 2010 I-010**

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	_____
Delegate Action:	Accepted	Rejected	_____	_____

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Title:

USFDA Recall Policy Revision

Issue you would like the Conference to consider:

Beyond question, the current system of recalling food products in the United States in case of real or purported health or quality issues is flawed. While part of the problem resides in the sheer complexity of the global food production and distribution system, the process of recalling a product is difficult for industry and incomprehensible to the general public. While new (pending) food safety legislation will address a few of the problems, there remains the need to overhaul and clarify the current recall classification and notification process.

Consider:

- >FDA is guided by Ch. 7 of their 2009 Regulatory Procedures Manual/ 21CFR
- >Recalling Firm is guided by "GUIDANCE FOR INDUSTRY" document by FDA
- >Firms affected by the recall throughout the complex food system (distributors, sub-producers, brokers) have no official FDA guidance
- >There is no time limit for executing a Class I Recall, or any other Class
- >There are no minimum requirements for the information required in a recall notice
- >There is no consideration of cost to benefit
- >Current Classification system is ambiguous and confusing:

Current Classification System from FDA web site for Industry:

Recall Classifications

- Class I recall: a situation 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.
- Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- Market withdrawal: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to

tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

These classifications are vague and difficult to understand. What is a "reasonable probability"? Furthermore both the FDA and the USDA, which uses the same definitions, are inconsistent with their application. A recall of chili with beans that was found to contain some pebbles was recalled as a Class I. Other than a chipped tooth, is there a problem of public health significance? A more recent recall for pieces of plastic in shaved steaks was a Class II. Last year, a slaughterhouse was found to be mistreating "downer" cows. This was an administrative violation, as there was no evidence that cattle with BSE entered the food supply. Nevertheless, millions of pounds of products containing beef from that plant were subjected to a Class II Recall at an extraordinary cost to industry in spite of virtually no health risk. Many more examples can be found, all pointing to a lack of clarity and understanding of how recalls should be classified.

Public Health Significance:

Rapidly removing adulterated products from commerce reduces the odds of consumption and subsequent illness. Clear concise guidelines will allow industry to focus efforts when food needs to be rapidly recalled. An understandable system will allow the public to gain confidence in the food supply and recall system, creating better cooperation and opportunities for clear communication. Administrative guidelines that tie the classification of a recall to the specific actions required of each layer of industry will greatly improve efficiency and enhance cooperation between industry and federal and state regulators

Recommended Solution: The Conference recommends...:

that a letter be written to the FDA urging creation of a committee/task force to redesign the administration of food recalls. The committee should include FDA, USDA, State Public Health, academia, and industry, including primary and secondary producers, brokers, and distributors.

The following model is offered as a starting point for the revised administrative guidelines to be developed by the committee/task force. There are only three categories, each with an expanded definition and actions required of industry:

Class I:

Definition: Consumption is likely to start, increase, or continue a FBI outbreak, or, a reportable FBI Agent is involved: C.Bot, HepA, Giardia, Listeria, Vibrio, Salmonella, Shiga+ E coli, Shigella, Campylobacter, or Vibrio.

Actions: Immediate response (within 24 hrs.), contact customers, public notification, destruction of product

Class II:

Definition: Consumption, at worst, may result in short illness treatable with over-the-counter meds - or - the consequences may be more serious (an allergic reaction) but few persons would be affected.

Actions: Next business day response, pull product from distribution and other suppliers, notify public.

Class III:

Definition: Administrative issues only - or - the consequences of consumption are minimal

Actions: no customer or public contact, pull product from distribution

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Attachments:

- "FDA 2009 Regulatory Procedures Manual, Chapter 7/21CFR"

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