

### III. PREPARATION FOR A RECALL -- GENERAL PRACTICES

Companies can take a number of steps to both prevent problems that might necessitate a recall and to prepare for the possibility of a recall. Having procedures in place in advance may prevent a crisis and save your company.

#### A. cGMPs, HACCP, QA/QC, and Food Defense Plans

All companies that manufacture, pack, or hold human food are required to comply with FDA's current Good Manufacturing Practices (cGMPs) regulations (21 C.F.R. Part 110). As required by FSMA, the cGMP regulations will soon be amended by FDA to require a hazard analysis and preventive controls plan. FDA regulations also include specialized, detailed cGMPs for acidified foods and low-acid canned foods (21 C.F.R. Parts 113, 114). These products, if not processed properly, can be a breeding ground for *Clostridium botulinum*, the bacterium that causes botulism. Infant formula, bottled water, dietary supplements, and shell eggs are also products subject to their own special cGMP requirements (21 C.F.R. Parts 106, 129, 111, and 118, respectively).

Certain food products are subject to Hazard Analysis and Critical Control Points (HACCP) requirements. Essentially, this means that each facility that manufactures or processes that product must implement a written food safety plan individually tailored to its specific product and process. FDA has HACCP regulations for seafood (21 C.F.R. Part 123) and for fruit and vegetable juices (21 C.F.R. Part 120). All companies that slaughter or process meat or poultry are required to comply with FSIS' sanitation and HACCP regulations (9 C.F.R. Parts 416 and 417). The FSIS regulations for meat and poultry establishments also require microbial testing of certain raw products.

Retailers must comply with their state or local health codes. If a retailer is located in a state or other jurisdiction that has adopted FDA's model *Food Code*, the retailer must comply with its requirements, many of which are designed to prevent adulteration of food.

In addition to these measures required by law, there are other measures a firm may consider adopting to prevent adulteration and quality problems, and thereby avoid recalls. A firm may adopt and implement a quality assurance and quality control (QA/QC) program. A QA/QC program should take into consideration those steps necessary to ensure product safety and quality. In addition, a firm not required to have a HACCP plan may nevertheless decide to implement HACCP. (For an explanation of HACCP, see the Food Institute's *HACCP and U.S. Food Safety Guide*.) A retailer may decide to comply with the requirements of FDA's model *Food Code*, even though it is located in a jurisdiction that has not adopted the *Food Code*.

Finally, a firm can develop and implement a food defense plan to protect its products from the risk of intentional adulteration. FDA has issued food security preventive measures guidance that can help companies protect against intentional contamination of food under their control. The FDA guidance documents include the following: