Food GMPs for the 21st century

By David Joy, Contributing Editor

The FDA has announced plans to modernize its regulations governing good manufacturing practices (GMPs) for food. FDA’s food GMP regulations currently provide an umbrella set of requirements applicable to manufacturers, processors, packers and holders of human food.

In essence, GMPs are standard operating practices intended to guard against the contamination of food. The GMP regulations include recommendations and requirements on such aspects of food sanitation as personnel, plants and grounds, sanitary facilities, controls and operations, equipment and utensils, production and process controls, and warehousing and distribution. The focus is on the safety and sanitation of food up to the point when it reaches the retailer. FDA once planned to supplement the umbrella GMP regulations with detailed requirements for individual segments of the food industry, but that approach was dropped in 1977.

FDA last amended its food GMP regulations substantively in 1986. Those amendments phased out several proposed or existing GMPs specific to individual food types. They also abandoned a 1979 proposal to make lot coding mandatory throughout the food industry. Although not mandated for most foods, FDA encourages food producers to code their products to facilitate food recalls.

As with any regulatory regime, FDA has recognized that food GMPs should not increase the cost of food production beyond an amount that is reasonable in exchange for the associated benefit – a reduced risk of contamination.

An important aspect of FDA’s food GMP regulations is they may be applied in determining whether food is adulterated under the Federal Food, Drug and Cosmetic Act. Under the act, food may be deemed adulterated if, among other reasons, it has been prepared, packed or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Note that actual contamination need not have taken place; food can be deemed adulterated if it was merely held under unsanitary conditions likely to result in contamination. Arguably, this means that any violation of GMPs causes food to be adulterated and potentially subject to regulatory action without regard to whether anything is actually wrong with the food or whether any contamination has taken place as a result of the GMP violation.

FDA has not yet issued a formal proposal to modify the food GMP regulations. The process of developing amendments will probably last several years. As part of its preparatory work, the agency issued a report summarizing food recalls that occurred between 1999 and 2003 for GMP-related problems. By focusing on the types of food and types of incidents that most frequently lead to food recalls, FDA can, in theory, modify the GMP requirements in ways that addresses real hazards.

Of 1,307 food recalls reviewed, 88 percent occurred because of a GMP-related problem, including labeling errors. It has long been recognized that undeclared allergic ingredients account for a significant percentage of all food recalls. Other categories noted in FDA’s report include microbiological contamination, the presence of unapproved color additives, poisonous substances and foreign objects.

FDA’s report on recent food recalls does not include specific suggestions on how the GMP regulations might be modified to guard against these problems. However, the report indicates quite clearly that preventable human error is often to blame for food recalls, as in the case of undeclared food allergens.

On the one hand, it seems a reasonable amount of training and attention could prevent most labeling errors. On the other hand, it seems challenging to formulate a regulation that will bring about a significant reduction in labeling errors.

Because of its subject matter and broad applicability to the entire food industry, modernization of the food GMP regulations is one of the more important regulatory initiatives taking place at FDA right now. The food industry clearly needs to have effective GMPs in place. Without them, contamination incidents and other types of recalls would increase, and consumer confidence would suffer.

Indeed, without GMP regulations, the food industry would need to lobby Congress or FDA for their creation as the dietary supplement industry has done. However, there are limits to what the GMP regulations can be expected to accomplish. For this reason, self-policing on the part of the food industry will, as always, remain an important element of food safety.

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