Food Contact Notification System Survives Budget Cuts

by Jerome H. Heckman

Have you ever wondered how your milk carton keeps milk fresh? Or how your egg carton manages to be so effective at protecting its cargo? If so, then you have an interest in food contact substances (FCSs). Also known as indirect additives, FCSs are "substances intended for use as components of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food."[1]

FCSs cover everything from the plastic bottle holding your soda to the conveyor belt transporting potato chips at the manufacturer's plant. The federal government began regulating such substances in 1958 with the Food Additives Amendment. In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), thereby authorizing the Food and Drug Administration (FDA) to develop an improved and much more efficient system for clearing food contact substances. The history of food contact regulation provides a useful perspective on recently proposed changes to the Food Contact Notification (FCN) process that could have resulted in losses of the efficiency gained since 2000.

Food Additive Amendment

The passage of the Food Additive Amendment in 1958 marked the first effort to formally regulate food packaging. Prior to 1958, food packaging materials were informally regulated by FDA and the Department of Agriculture (USDA) under the Food, Drug, and Cosmetic Act (FDCA), which required the food industry to protect the public from adulterated foods.[2] As plastics began to replace more traditional glass, paper, and metal food containers, packaging manufacturers sought informal guidance from FDA on how to assess the suitability of their materials.[3] FDA evolved an ad hoc system by which an expert at FDA, Dr. Arnold Lehman, and an expert at USDA, Mr. Robert Philbeck, compiled toxicology data on and assessed the safety of various packaging materials. If materials were determined to be safe, the manufacturer would receive a "no objection" letter from the appropriate agency, which the company could share with its customers as an assurance of safety.[4]

As the public interest in food safety increased in the 1950s, Congress began to consider legislation to regulate food additives. Congressman James J. Delaney of New York called hearings on food additives that lasted from 1952 to 1956, and led to the passage of the Food Additives Amendment to the FDCA. The amendment required that FDA approve food additives before they reached the market. Unfortunately, it painted food additives with broad brush strokes, grouping together direct and indirect additives under the same regulatory scheme. Although the Society of the Plastics Industry proposed a piece of legislation, H.R. 8112, suggesting that FDA regulate direct and indirect food additives under different procedures, that bill was rejected in favor of grouping all additives under one approach. However, when it passed FDAMA 39 years later in 1997, Congress adopted an approach analogous to H.R. 8112, which had proposed a food contact notification program for indirect additives or FCSs.

Under the Food Additive Amendment, FDA would establish regulatory clearance for the use of food additives based on the filing of Food Additive Petitions (FAPs); alternatively, substances that did not meet the definition of a "food additive" under the FDCA were not required to be the subject of a food additive regulation and could be used without petitioning FDA. The FAP process required the

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submission of a petition detailing the proponent's safety investigation, the intended use of the substance, and the chemical composition.[5] Upon filing an FAP, in theory the agency had ninety days (with a possible ninety day extension) to review and make a decision on the petition; however, in reality the agency was known to take between two and five years, sometimes more, to make a decision and publish a final rule in response to a petition.[6] All in all, the petition process was a cumbersome one both for petitioners and the government.

FDAMA updated and greatly improved the regulation of food contact substances.[7] For the most part FDAMA replaced the petition process for establishing regulatory clearance for food contact with the FCN. Under this program, the manufacturer of a food contact substance files a notification with FDA indicating its intention to manufacture a substance for use in food contact applications and includes data demonstrating that the substance will be safe for its intended use. If the agency takes no action after receiving the FCN, the manufacturer may bring the food contact substance to market 120 days after filing.[8]

FDA maintains an inventory of effective FCNs on its website, which includes the notifier and manufacturer of the substance, the chemical identity of the substance, its intended use, and relevant use specifications.[9] The inventory includes every substance approved since the system went into effect in 2000. Unlike the petition system, however, FCNs are proprietary in nature.[10] Each supplier or manufacturer must file a separate notification with FDA to be in compliance; however, in the case of Manufacturer A using a food contact substance produced by Manufacturer B, A may rely on B's FCN if A is using the substance under the conditions that are the subject of B's FCN.

The FCN system is a great improvement over Food Additive Petitions in that it has reduced the administrative burden on FDA, which no longer needs to issue formal rules on each FCS, and has increased the efficiency of processing for manufacturers, which are better able to forecast when these products can be marketed. FCNs lessened the administrative burden for FDA by changing the approval process from formal to a more informal and time-efficient process. As a result, the delay between notifying FDA and going to market has decreased from years to only four months. Much of this increased time-efficiency has been due to budgeting for staff at FDA's Center for Food Safety and Applied Nutrition (CFSAN) to administer the program, which FDAMA required as a precondition of the FCN system. Nevertheless, FDA still carefully reviews filings and uses the same safety analysis as the FAP system.

The increase in efficiency without a sacrifice in safety analysis has facilitated innovation in the marketplace, effectively reducing the interval between product developments and arrival at market and allowing manufacturers to better forecast the development timeline for their products.

Recent Threat to FCN System

Recent budget proposals have threatened to end the FCN system, which depends on annual budget appropriations. The President's FY 2007 Budget Proposal reallocated funds for the FCN program to emergency programs on avian flu preparedness and food bioterrorism.[11] The cut in funding would have required a reversion to the former FAP process. On May 23, 2006, the House of Representatives voted to restore funding to the FCN program for FY 2007.[12] Provided that the Senate also includes funding for the program and that the President signs the appropriations bill later this year, the FCN program will continue. This funding would mean that manufacturers and suppliers of FCSs would avoid returning to the FAP process and years of waiting to get food contact substances to market. To consumers it means finding that new and improved milk carton at our grocery stores a lot sooner.

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1 An FCS is "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." 21 U.S.C. § 348(h)(6).

2 21 U.S.C. § 342(a).

3 Keller and Heckman LLP, *Food Contact Legislation for U.S. Markets*, Pira Regulatory Series 1-2 (2005).

4 *Id.* at 2.

5 Pub. L. No. 85-929, 72 Stat. 1784, 1785 (1958) (section "Petition to Establish Safety").

6 Keller and Heckman LLP, The Food Contact Notification Story (Feb. 16, 2006), http://www.khlaw.com/index.cfm?fuseaction=publications.showPubDetail&pubID=1330.

7 21 U.S.C.A. § 348(h)(1).

8 If FDA finds that the substance is not safe or that the manufacturer has failed to demonstrate safety, it may formally object, thereby preventing the notification from becoming effective after the 120-day review period. 21 U.S.C.A. § 348(h)(2)(A).

9 Food & Drug Admin./Center for Food Safety and Applied Nutrition: Inventory of Effective Food Contact Substances, http://www.cfsan.fda.gov/~dms/opa-fcn.html (last visited May 24, 2006).

10 21 U.S.C.A. § 348(h)(2)(C).

11 Food & Drug Admin., FY 2007 Budget: Consolidated Narrative, *available at* http://www.fda.gov/oc/oms/ofm/budget/2007/PDF/3ConsolidatedNarrative.pdf, at 4 (last visited June 5, 2006).

12 H.R. 5384 (2006), *available at* http://thomas.loc.gov/cgi-bin/bdquery/z?d109:H.R.5384: (last visited May 26, 2006).