STARTING FROM SCRATCH?: REINVENTING THE FOOD ADDITIVE APPROVAL PROCESS

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INTRODUCTION

The safety of novel foods and food ingredients has been of intense public concern and periodic political interest at least since World War II, which inspired heroic efforts to expand, extend, and improve the products of nature. One need only recall controversies over diethylstilbestrol (DES) in beef cattle, the artificial sweeteners cyclamate and saccharin, nitrite-treated bacon, Alar on apples, and bovine growth hormone (rBST) to be impressed by the popular and journalistic salience of putative hazards created by modern food production methods. In more recent years, truly innovative technologies—such as Procter & Gamble's fat-substitute olestra and Calgene's bioengineered tomato—have attracted significant attention, and their regulation by the U.S. Food and Drug Administration (FDA) has become the focus of a complex debate. Some have criticized the FDA for its lengthy delays in reviewing these and other innovative substances added to food.[1] Others have argued that the Agency does not adequately ensure the safety of such substances. These latest controversies pose significant questions about how best to regulate substances added to food.

This Article explores the FDA's regulation of substances purposely added to food as it has evolved over the last several decades, and it concludes with a discussion of several possible avenues for reform. Debates about proposals to modify existing approaches must start with a proper appreciation of the difficulties encountered in the past. Moreover, the history of the food ingredient approval process illuminates recurring challenges faced in the design of regulatory programs. Past studies of other federal agencies have revealed valuable lessons about regulatory performance that transcend the particular program under study.[2]

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[1] *See, e.g.*, *Delays in the FDA's Food Additive Petition Process and GRAS Affirmation Process: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov't Reform and Oversight*, 104th Cong. (1995) [hereinafter *1995 Hearings*] (examining the reasons for, and consequences of, delays in the FDA's review of food additive petitions and the GRAS affirmation process); Peter Barton Hutt, *Approval of Food Additives in the United States: A Bankrupt System*, FOOD TECH., Mar. 1996, at 118, 122 (arguing that the FDA's regulation of food additives has failed because of the Agency's sluggish review process).

[2] *See, e.g.*, THOMAS O. MCGARITY & SIDNEY A. SHAPIRO, WORKERS AT RISK: THE FAILED PROMISE OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (1993) (suggesting improvements in the Occupational Safety and Health Administration's regulatory process); JERRY L. MASHAW & DAVID L. HARFST, THE STRUGGLE FOR AUTO SAFETY (1990) (evaluating the National Highway Traffic Safety Administration's regulatory efforts to promote automobile safety); GLEN O. ROBINSON, THE FOREST SERVICE: A STUDY IN

Part I describes the FDA's system for regulating food-use substances as it existed before the enactment of specific food additive legislation in 1958. The next three Parts explore, in turn, the definitional, procedural, and substantive provisions of this legislation as implemented over the last several decades. Part V offers three recent case studies that expose some of the special difficulties encountered in the regulation of food-use substances. Finally, Part VI identifies several problems experienced by the FDA in recent years and analyzes an accompanying range of possible reforms. The time is ripe for reinventing this country's food ingredient approval process.

I. HISTORY

The federal government asserted authority over the quality and safety of food products early this century. In 1906, reacting to widely publicized examples of filth and deception, Congress prohibited the introduction of adulterated or misbranded food and drugs into interstate commerce.[3] The 1906 Act provided that any food containing an "added poisonous or other added deleterious ingredient which may render such article injurious to health" would be deemed adulterated.[4] If federal officials suspected a safety problem, they could initiate enforcement action to remove the product from the market, but the government would shoulder the burden of proving that the food ingredient, as consumed, posed "a reasonable possibility of injury."[5] Congress replaced the original statute in 1938 with the Federal Food, Drug, and Cosmetic (FD&C) Act,[6] but the newer legislation retained the same basic system of after-the-fact policing for adulterants in food. It was not until

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PUBLIC LAND MANAGEMENT (1975) (analyzing the U.S. Forest Service's organizational and administrative process in the context of general public land management); JAMES Q. WILSON, THE POLITICS OF REGULATION (1980) (collecting essays describing how various regulatory agencies ordinarily operate).

[3] *See* Pure Food and Drugs Act, Pub. L. No. 59-384, ch. 3915, § 2, 34 Stat. 768 (1906) (superseded by the FD&C Act in 1938).

[4] *Id.* § 7.

[5] United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 411 (1914) ("If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such [product], though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act."); *see also* United States v. Coca Cola Co., 241 U.S. 265, 279-85 (1916) (holding that caffeine added to beverage syrup was an "added" ingredient and that the government's evidence that caffeine was poisonous or deleterious should have been submitted to the jury).

[6] Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 321-393 (1994)). The statute refers throughout to the Secretary of Health and Human Services (previously the Secretary of Health, Education and Welfare (HEW) and before that the Secretary of Agriculture (USDA)), *see* 21 U.S.C. § 321(d), but the Secretary has delegated most powers under the FD&C Act to the Commissioner of Food and Drugs, *see id.* § 393(b); 21 C.F.R. §§ 5.10(a)(1), 5.11(a) (1997).

the Food Additives Amendment of 1958[7] that Congress established a premarket approval system for food ingredients. The detailed requirements of these two enactments are discussed more fully below.

In the two decades that elapsed between the passage of the FD&C Act and the Food Additives Amendment, a number of developments rendered the original statutory design outdated. Indeed, the 1938 legislation, based as it was on the 1906 Act, focused on the control of "adulterants" and did not fully anticipate the rapid progress in food processing technology and the growing utilization of intentional additives that would follow.[8] Technological advances spurred by World War II allowed processors to offer more nutritious, palatable, and convenient foods, and consumers increasingly demanded such improved products. Meanwhile, progress in the biomedical sciences increased the understanding of human nutritional needs and the causes of chronic diseases. These advances have not slowed, and, almost four decades later, Congress is being urged to consider once again updating—or overhauling—the statutory system governing food additives.[9]

A. *The Food, Drug, and Cosmetic Act of 1938*

Under the original FD&C Act, the FDA possessed broad responsibility but comparatively weak regulatory authority over substances added to food. Section 402(a) provided that a food shall be deemed to be adulterated under the following circumstances:

> (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or
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> (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406 . . . .[10]

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[7] Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified as amended in scattered sections of 21 U.S.C.).

[8] *See* 104 CONG. REC. 17,417 (1958) (statement of Hon. John B. Williams) ("The 1938 law gave no recognition to substances deliberately added to food for beneficial purposes, such as retarding natural spoilage or keeping food moist or tasty. There is a gap in our pure food law as a result of advancing technology.").

[9] *See, e.g.*, GENERAL ACCOUNTING OFFICE, FOOD SAFETY AND QUALITY: INNOVATIVE STRATEGIES MAY BE NEEDED TO REGULATE NEW FOOD TECHNOLOGIES, No. RCED-93-142 (1993), at 1-2, 5 [hereinafter GAO, NEW FOOD TECHNOLOGIES] (discussing new food technologies, various possible responses to these new technologies, and unresolved regulatory issues).

[10] FD&C Act § 402(a) (codified as amended at 21 U.S.C. § 342(a)). Section 406 of the Act provided:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufac-

> The authority to promulgate food standards of identity under Section 401 provided the FDA with another regulatory mechanism, though cumbersome, for restricting the use of added substances; it permitted the Agency to specify what ingredients could be used in standardized food.[11]

To enforce Section 402(a) of the FD&C Act, the FDA (through the Department of Justice) could initiate judicial proceedings to seize adulterated food or enjoin its continued marketing.[12] Unless the product exceeded one of the very few tolerances ever established under Section 406, however, the Agency had to shoulder the burden of proving that the substance (1) was poi-

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> turing practice[,] shall be deemed to be unsafe for purposes of the application of [the above-quoted clause]; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health . . . .

Id. § 406(a) (codified as amended at 21 U.S.C. § 346); *see also* H.R. REP. NO. 75-2139, at 6 (1938) (explaining that the tolerance setting provision would provide greater flexibility in dealing with pesticide residues); Richard A. Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 MICH. L. REV. 171, 175 (1978) ("In substance, Congress authorized the FDA to license the use of some potentially toxic substances in food, apparently in recognition of their utility or of the importance of foods from which they cannot practicably be eliminated.").

[11] FD&C Act § 401 (codified as amended at 21 U.S.C. § 341); *see also* Federal Sec. Admin. v. Quaker Oats Co., 318 U.S. 218, 227-31 (1943) (upholding "standards of identity" which were adopted in order to avoid consumer confusion); Atlas Powder Co. v. Ewing, 201 F.2d 347, 350-55 (3d Cir. 1952) (upholding FDA decision, after almost one decade of hearings, not to permit the use of certain emulsifiers in bread because of unresolved safety concerns and the risk of consumer deception); Richard A. Merrill & Earl M. Collier, Jr., *"Like Mother Used to Make": An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 600 (1974) (establishing a framework for analyzing the costs and benefits of food standards). The FDA did have limited premarket approval powers under the 1938 Act through the listing and batch certification provisions applicable to coal-tar colors used in food. *See* FD&C Act § 406(b), 52 Stat. 1040, 1049 (1938), *repealed and replaced by* Color Additive Amendments of 1960, Pub. L. No. 86-618, tit. I, 74 Stat. 397 (codified as amended at 21 U.S.C. § 379e).

[12] *See* 21 U.S.C. § 331(a)-(c) (designating the adulteration of food, or its delivery or receipt, in interstate commerce as prohibited acts); *id.* § 332(a) (authorizing injunctions to restrain violations of the Act); *id.* § 334(a) (authorizing seizure of products in violation of the Act); *see also id.* § 333(a) (authorizing the imposition of criminal penalties for violations of the Act); United States v. Park, 421 U.S. 658, 671-74 (1975) (affirming the imposition of strict criminal liability under the FD&C Act in a case involving food adulteration); Brenda A. Bachman & Lori Ludemann, Note, *Federal Food and Drug Act Violations*, 33 AM. CRIM. L. REV. 757 (1996) (examining the criminal provisions of the FD&C Act). In practice, the FDA typically sends a warning letter first, threatening to pursue formal enforcement action only if the company fails to bring itself into prompt compliance. *See* Warning Letters; Procedure Manual, Chapter 8-10; Availability, 56 Fed. Reg. 27,026 (1991).

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