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**Regulating Carcinogens in Food: A Legislator's
Guide to the Food Safety Provisions of the
Federal Food, Drug, and Cosmetic Act**

Part I

by

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REGULATING CARCINOGENS IN FOOD: A LEGISLATOR'S GUIDE TO THE FOOD SAFETY PROVISIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Richard A. Merrill*†

I. INTRODUCTION

On March 9, 1977, the Food and Drug Administration (FDA) announced that a study in laboratory rats conducted by the Canadian government confirmed that saccharin is an animal carcinogen.¹ For this reason, the agency stated, the sweetener must be banned from human food.

The FDA's announcement triggered public incredulity and congressional demands for revision of the nation's legal framework for regulating food safety. Critics of the agency's action focused on the much publicized Delaney Clause of the Federal Food, Drug, and Cosmetic Act.² They characterized this provision, which forbids the approval of any "food additive" shown to induce cancer in man or in animals,³ as outdated and several critics also ridiculed the test methods used to evaluate the safety

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† © Copyright Richard A. Merrill 1979. The author was Chief Counsel of the United States Food and Drug Administration from 1975-1977. The views expressed in this Article are my own, and do not necessarily reflect those of the FDA or of any agency official. An earlier version of the Article appears as Appendix B to Food Safety in the United States, Part 2 of the Report of the Committee for a Study of Saccharin and Food Safety Policy of the Institute of Medicine and National Research Council, National Academy of Sciences (March 1979).

I wish to express my appreciation for the advice and helpful criticism of several colleagues, notably Peter Barton Hutt, Stuart Pape, Marshall Shapo, and Dr. Joseph Rodricks, and for the assistance of Mark Colley and James Davis of the Class of 1980 and the Class of 1979, respectively, at the University of Virginia School of Law.

1. Statement of Sherwin Gardner, Acting Commissioner of Food and Drugs (March 9, 1977) (copy on file with the *Michigan Law Review*).

2. 21 U.S.C. § 301-92 (1976)[hereinafter cited as "the Act"].

3. The original Delaney Clause appears in section 409(c) of the Act, 21 U.S.C. § 348(c)(3)(A) (1976), and reads as follows:

Provided, that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. . . .

As subsequently explained in more detail, functionally identical language appears in the provisions of the Act dealing with color additives and drugs administered to animals that are used to produce human food. See notes 44-45 *infra* and accompanying text.

of food ingredients.⁴ Reacting to these criticisms and to the public's apparent indignation at the imminent abolition of the only non-nutritive sweetener approved in this country for use in foods, Congress in late 1977 enacted the Saccharin Study and Labeling Act.⁵ This legislation forbade any FDA action against saccharin for eighteen months and directed the Secretary of Health, Education, and Welfare to arrange for separate studies of the safety and benefits of saccharin and of the current laws regulating food safety. The latter study and a major part of the former were subsequently undertaken by the Institute of Medicine of the National Academy of Sciences.

The studies which Congress mandated, to be accompanied by the recommendations of the Secretary of HEW,⁶ are likely to generate a fundamental reexamination of the nation's current food safety policies. This Article attempts to aid this inquiry by explaining the requirements of the present law. The Article describes the several statutory provisions that govern the regulation of food constituents and analyzes the FDA's implementation of them. Its primary objective is to provide a common starting place for discussion of the contours of future policy. A subsequent article will examine in detail various approaches to regulating risks posed by food and recommend specific reforms of the present law.

Readers should be advised that the Article starts from the premise that many features of the present law are outdated and require revision. In that sense, the Article may lack objectivity. I have conscientiously attempted, however, to reserve judgment about the directions of future policy and to assure that my description and analysis are historically accurate.

A continuing refrain in the furor over saccharin was the claim that the law dictates an overreaction to some trivial risks while allowing much graver hazards—cigarette smoking is the recurrent

4. For descriptions of the reaction, see, e.g., *The Great Saccharin Snafu*, CONSUMER REP., July 1977, at 410; Demkovich, *Saccharin's Dead, Dieters Are Blue, What Is Congress Going To Do?*, NATL. J., June 4, 1977, at 856; Wolff, *Of Rats and Men*, N.Y. TIMES, May 15, 1977, § 6 (Magazine), at 88; Hines & Randal, *Behind the Saccharin Uproar*, THE PROGRESSIVE, June 1977, at 13. Epitomizing the exaggerated reaction of many nonscientists was the proposal of Congressman Andrew Jacobs to amend the law to permit the continued sale of saccharin accompanied by the warning: "The Canadians have determined saccharin is dangerous to your rat's health." See *Cancer and Your Sweet Tooth*, NEW REPUBLIC, March 26, 1977, at 7, 8.

5. Pub. L. No. 95-203, 91 Stat. 1451 (codified in sections of 21 U.S.C.A. (West 1977)). For discussions of Congress's motives, see H.R. REP. No. 658, 95th Cong., 1st Sess. 6-11 (1977); S. REP. No. 353, 95th Cong., 1st Sess. 2-10 (1977).

6. Saccharin Study and Labeling Act, Pub. L. No. 95-203, § 2, 91 Stat. 1451 (1977) (codified at 21 U.S.C.A. § 343(n) (West Supp. 1978)).

example—to remain uncontrolled. As the Article demonstrates, the aggregation of statutory provisions governing food safety represents a patchwork of divergent, sometimes carefully considered but as often offhand, legislative policies which invite inconsistent treatment of comparable risks. The Delaney Clause illustrates this general characteristic, not because it produces controversial results, but because it applies inconsistently, without regard to the actual risks posed or the benefits provided by various classes of food constituents. The unequivocal instruction of the Delaney Clause magnifies the practical significance of the distinctions among categories of food constituents that the law now recognizes.⁷ These distinctions are the product of the sedimentary process by which the current law, the Federal Food, Drug, and Cosmetic Act, has been created. Beginning in 1938,⁸ Congress has on a half dozen occasions authorized the FDA (or its predecessors) to deal with specified categories of food hazards—addressing, first, pesticide residues; then food additives generally; later, color additives; and finally drugs used in the production of food animals.⁹ Typically, Congress has added new provisions without replacing, and often without modifying, those already in the law. Furthermore, it has often failed to explain how the new standards mesh with the old.

While the importance of historical context in explaining the enactment and implementation of several provisions in the Act invites a chronological treatment, the practical implications of the Act's disparate treatment of different classes of food constituents can better be understood by considering the categories that constitute the FDA's jurisdiction. The legislator evaluating what kind of food-safety legislation should be enacted is probably more interested in how the law now operates than in how it came to

7. See R. Kingham, *Statutory and Administrative Theories by Which FDA Avoids Applying the Delaney Clause* (Nov. 10, 1977)(unpublished manuscript on file with author).

8. See Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 717, ch. 675, § 402(a), 52 Stat. 1046 (codified at 21 U.S.C. § 342(a) (1976)) [hereinafter cited as Federal Food, Drug, and Cosmetic Act of 1938].

9. See in historical sequence, Federal Food, Drug, and Cosmetic Act of 1938, *supra* note 8; Act of July 22, 1954, Pub. L. No. 518, ch. 559, 68 Stat. 511 (codified at 21 U.S.C. § 346a (1976)) [hereinafter cited as Pesticide Residues Amendment of 1954]; Food Additives Amendment of 1958, Pub. L. No. 85-929, § 4, 72 Stat. 1785 (codified at 21 U.S.C. § 348 (1976)) [hereinafter cited as Food Additives Amendment of 1958]; Color Additive Amendments of 1960, Pub. L. No. 86-618, tit. I, § 103(b), 74 Stat. 399 (codified at 21 U.S.C. § 376 (1976)) [hereinafter cited as Color Additives Amendments of 1960]; and Animal Drug Amendments of 1968, Pub. L. No. 90-399, § 101(b), 82 Stat. 343 (codified at 21 U.S.C. § 360b (1976)) [hereinafter cited as Animal Drug Amendments of 1968].

be. Accordingly, this Article follows legal categories in describing how the Act and the FDA regulate food safety. Most of these categories are defined by the origin of food constituents, *i.e.*, how the constituents become part of food.

The main part of the Article, Part III, analyzes the legal standards applicable to these several categories of food constituents. First, however, Part II surveys the Act's food-safety provisions and discusses the origin and interpretation of the Delaney Clause, the provision that triggered the FDA's action against saccharin and that is the focus of the current debate over food safety policy.

II. STATUTORY OVERVIEW

A. *The Food-Safety Provisions of the Act*

1. *The 1938 Act and Its Precursor*

The first federal statute governing food safety, the Food and Drugs Act of 1906, declared adulterated any food that contained "any added poisonous or other added deleterious ingredient which may render such article injurious to health."¹⁰ The early law did not mention hazards posed by constituents other than those "added" to food,¹¹ a term not defined in the statute but understood to embrace substances used as ingredients or intentionally applied during processing. When Congress wrote the present Act in 1938, it wanted to expand the 1906 law's controls over toxicants in food. Accordingly, without apparent limitation to "added" substances, section 402(a)(1) of the Act¹² declares adulterated any food that "bears or contains any poisonous or deleterious substance which may render it injurious to health." Almost as an afterthought, however, Congress qualified this standard as it applies to food constituents that are not added: "[B]ut 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."¹³ The 1938 Act thus retained the distinction between substances that are "added" and those that are not, but, like the 1906 law, neglected to define "added."

10. Federal Food and Drugs Act of 1906, ch. 3915, § 7, 34 Stat. 768 (repealed 1938).

11. *Id.* § 7.

12. Federal Food, Drug, and Cosmetic Act of 1938, *supra* note 8, § 402(a)(1) (codified at 21 U.S.C. § 342(a)(1) (1976)).

13. *Id.* For a discussion of the legislative history of this provision, see note 59 *infra*.

The statutory standard for non-added toxicants has remained unchanged since 1938; the "ordinarily injurious" test is still the legal measure of whether a substance that occurs naturally in foods, *e.g.*, nitrites in spinach, adulterates the food. Congress has, however, made several changes in the law governing added constituents of food. In the 1938 Act itself, Congress recognized that certain added toxicants in foods required special treatment. In section 406,¹⁴ it empowered the FDA to establish tolerances for added poisonous or deleterious substances whose occurrence in food "cannot be avoided" or whose use is "necessary" to produce the food. 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. Congress's primary objective apparently was to permit the continued use of pesticides on many agricultural commodities.

With the passage of the 1938 Act, therefore, federal law regulated toxicants in foods under three different standards: (1) section 402(a)(1)'s "ordinarily injurious" standard applied to constituents that were not added; (2) section 402(a)(1)'s "may render injurious" test applied to added constituents that were neither necessary or unavoidable; and (3) added constituents whose use was "necessary in the production of a food" or whose occurrence was "unavoidable by good manufacturing practice" were eligible for tolerance setting under section 406.

2. *Post-1938 Amendments to the Act*

The original triad of controls has been complicated by subsequent amendments to the 1938 Act. Each amendment deals with one category of the broad class of "added" food constituents and empowers the FDA to limit the use, or the occurrence, of potentially toxic substances in or on food. The first of these amendments was the Pesticide Residues Amendment of 1954, now section 408 of the Act.¹⁵ This provision was intended to complement the authority then residing in the United States Department of Agriculture (USDA) to register pesticides for use in the United States. The amendment provides, in substance, that a raw agricultural commodity shall be deemed adulterated if it bears any

14. 21 U.S.C. § 346 (1976).

15. Pesticide Residues Amendment of 1954, *supra* note 9. Section 408 is codified at 21 U.S.C. § 346a (1976).

residue of a pesticide that does not conform to a tolerance established under section 408,¹⁶ and details an elaborate procedure for establishing tolerances.¹⁷

In 1958, Congress carved out for special treatment another category of added constituents of food. The Food Additives Amendment, section 409 of the Act,¹⁸ establishes a licensure scheme, similar in concept to that for pesticide residues, for substances intended to be used as ingredients in formulated foods. The amendment also applies to substances that, through use in articles such as packaging which contact food, become or can "reasonably be expected" to become components of food.¹⁹ A food that contains a food additive whose use the FDA has not approved as "safe," or that contains an approved food additive in a quantity exceeding limits specified by the agency, is adulterated under section 402(a)(2)(C) of the Act.²⁰ By congressional design, the Food Additives Amendment does not apply to all intentionally added ingredients in food or to all substances that may migrate to food. The two most important exceptions are substances whose use in food is "generally recognized as safe by qualified experts"—an exception embracing a large number of substances, such as sugar and salt—and substances that either the FDA or the USDA "sanctioned" for use in food prior to 1958.²¹

In 1960, Congress addressed the more limited problem of substances used to color foods, drugs, cosmetics, and medical devices.²² Colors derived from coal tar dyes had been regulated under a "harmless per se" standard,²³ which many could not meet, while other food colors had been regulated under the general safety provisions of the Act, notably section 402(a)(1). Unlike the Food Additives Amendment,²⁴ the Color Additive Amendments²⁵ apply to all substances used to impart color to food; the

16. 21 U.S.C. § 346a(a)-(b) (1976).

17. See 21 U.S.C. § 346a(b)-(h) (1976) and text accompanying notes 103-05 *infra*.

18. Food Additives Amendment of 1958, *supra* note 9. Section 409 is codified at 21 U.S.C. § 348 (1976).

19. Food Additives Amendment of 1958, *supra* note 9, § 2 (codified at 21 U.S.C. § 321(s) (1976)).

20. 21 U.S.C. § 342(a)(2)(C) (1976).

21. 21 U.S.C. § 321(s) (1976). For a detailed discussion of the Food Additives Amendment, see text accompanying notes 113-39 *infra*.

22. See Color Additive Amendments of 1960, *supra* note 9.

23. See Federal Food, Drug, and Cosmetic Act of 1938, *supra* note 8, § 406(b) (repealed 1960). For a detailed discussion of the FDA's implementation of this provision, see *Flemming v. Florida Citrus Exch.*, 358 U.S. 153 (1958).

24. See text at note 18 *supra*.

25. Color Additive Amendments of 1960, *supra* note 9, § 101 (codified at 21 U.S.C. § 321(t) (1976)).

amendments do not except colors that are recognized by experts as safe or that were approved for use prior to 1960. The amendments require FDA approval, or "listing," for any use of a color.²⁶ A food that bears or contains a color additive whose use in food the FDA has not approved, or whose use deviates from the terms of any approval, is adulterated under section 402(c) of the Act.²⁷

The most recent modification of the 1938 Act that is relevant in this context was part of the Animal Drug Amendments of 1968.²⁸ After 1958, drugs administered to food-producing animals were regulated under a combination of statutory provisions—under section 409 as well as section 505 for drugs that were administered directly to animals and that "could reasonably be expected" to leave residues in human food, and under section 409 alone for compounds incorporated in animal feeds.²⁹ In 1968, Congress sought to simplify the procedure for evaluating drugs used in food-producing animals by prescribing a unified licensure system under section 512.³⁰ Under the amended Act, no animal drug that is likely to leave residues in edible tissue of livestock may be used, nor may food containing residues be marketed, without prior FDA approval.³¹

Thus, by 1968 Congress had divided the broad class of added constituents of human food into several categories, each subject to special regulatory requirements. Broadly speaking, Congress required that individual substances be presented to the FDA for approval prior to use, and that the agency find a substance safe for human consumption when used as proposed. As will be evident, however, this general mandate has been expressed in different statutory terms, which have not only contributed to the appearance of inconsistency in the regulation of food safety, but have exaggerated the significance of the initial classification of substances.

An instructive illustration derives from the fact that the four categories of food constituents given special attention by Con-

26. Color Additive Amendments of 1960, *supra* note 9, § 706(b)(1) (codified at 21 U.S.C. § 376(b) (1976)).

27. Color Additive Amendments of 1960, *supra* note 9, § 102(a)(2) (codified at 21 U.S.C. § 342(c) (1976)).

28. Animal Drug Amendments of 1968, *supra* note 9 (codified principally at 21 U.S.C. § 360b (1976)).

29. See generally H.R. REP. No. 875, 90th Cong., 1st Sess. (1967); S. REP. No. 1308, 90th Cong., 2d Sess. (1968).

30. Animal Drug Amendments of 1968, *supra* note 9, § 101(b) (codified at 21 U.S.C. § 360b (1976)).

31. See 21 U.S.C. §§ 342(a)(2)(D), 360b(a)(1) (1976).

gress since 1938 do not, in the FDA's view, exhaust the class of added constituents. Neither in 1938 nor subsequently has Congress specifically addressed the problem of environmental contaminants, such as PCBs and mercury, whose occurrence in food is unintended and, to a large degree, uncontrollable. The agency could have regulated such contaminants under the "may render injurious" language of section 402(a)(1) or, indeed, under the "ordinarily injurious" language of section 402(a)(1), but neither provision authorizes it to determine what levels of such contaminants should be tolerated. Since the early 1970s, therefore, the FDA has classified environmental contaminants as unavoidable "added poisonous or deleterious substances" in order to trigger its tolerance-setting authority under section 406.³² The difficulty of controlling contaminants in food and the breadth of section 406's criteria, however, have led the agency to sanction levels of exposure to environmental contaminants that contrast sharply with its intolerance of potentially toxic, intentional ingredients, such as saccharin.³³ The relative difficulty of controlling human exposure in the two situations could explain this discrepant treatment of ostensibly similar hazards without reference to the statute. But a second explanation lies in the Delaney Clause, which codifies the Food Additives Amendment's basic "no risk" policy for intentional food constituents, thus precluding for saccharin the kind of inquiry that is permitted under section 406 or the pesticide residue section. Accordingly, it is appropriate at this point to examine the origins and interpretation of this controversial provision.

B. *History and Impact of the Delaney Clause*

The Delaney Clause is perhaps the most discussed, yet least used, provision of the Federal Food, Drug, and Cosmetic Act. It became law in 1958 as part of the Food Additives Amendment, in which Congress for the first time required premarket testing of

32. See *Poisonous or Deleterious Substance in Food*, 39 Fed. Reg. 42,743, 42,744 (1974).

33. For example, the FDA estimates that the consumption of one can each day of a soft drink sweetened with saccharin increases the risk of bladder cancer of between zero and four in 10,000. See *Saccharin and Its Salts*, 42 Fed. Reg. 19,995, 20,001 (1977). By contrast, the risk of cancer associated with average consumption of products bearing permitted levels of aflatoxin contamination is, by the agency's own estimate based on animal studies, somewhere between 240 and 1100 per 100,000 population. See *Assessment of Estimated Risk Resulting from Aflatoxins in Consumer Peanut Products and Other Food Commodities 2* (Food and Drug Administration Report, January 19, 1978).

most intentional food ingredients.³⁴ Prior to 1958, the Act controlled the safety of food constituents primarily through section 402(a)'s dual proscriptions against distribution of adulterated food.³⁵ These proscriptions were enforced through court action, usually seizures, instituted by the Department of Justice upon the FDA's recommendation. The agency could not require manufacturers to test the safety of food constituents,³⁶ and had never formally exercised its authority under the original section 406 to prescribe tolerances for potentially toxic chemicals in food.³⁷ The Food Additives Amendment thrust the FDA squarely into the business of licensing food ingredients by requiring the agency to determine whether any "food additive" was safe for its intended use.³⁸

Stimulated by hearings chaired by Congressman James Delaney of New York,³⁹ the Food Additives Amendment was the product of lengthy congressional consideration of proposals to regulate chemicals in food. The investigating subcommittee's work led first to the passage in 1954 of the amendment permitting the FDA to establish tolerances for pesticide residues on raw agricultural commodities.⁴⁰ The Food Additives Amendment, en-

34. 21 U.S.C. § 348(c)(3)(A) (1976). See C. DUNN, LEGISLATIVE RECORD OF 1958 FOOD ADDITIVES AMENDMENT TO FEDERAL FOOD, DRUG, AND COSMETIC ACT (CCH Food Law Institute Series 1958).

35. 21 U.S.C. § 342(a)(1)-(a)(2) (1976).

36. Pesticide residues on raw agricultural commodities were an exception to this general statement. In 1954, Congress had established a system for "licensing" pesticide residues that had been shown to be safe. Pesticide Residue Amendments of 1954, *supra* note 9 (codified at 21 U.S.C. § 346a (1976)). See note 15 *supra* and accompanying text.

37. See 21 U.S.C. § 346 (1976); Poisonous or Deleterious Substances in Food, 39 Fed. Reg. 42,743, 42,744 (1974).

38. Section 409(c) of the Food Additives Amendment of 1958, *supra* note 9, provides: (c)(1) The Secretary shall—

(A) by order establish a regulation . . . prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, that no additive shall be deemed to be safe if it is found . . . , after tests which are appropriate for the evaluation of the safety of good additives, to induce cancer in man or animal

39. *Hearings Before the House Select Comm. To Investigate the Use of Chemicals in Foods and Cosmetics*, 81st Cong., 2d Sess. and 82d Cong., 1st & 2d Sess. (1950-1952) (popularly known as the "Delaney Committee" hearings); see H.R. REP. NO. 2356, 82d Cong., 2d Sess. (1952).

40. Pesticide Residue Amendments of 1954, *supra* note 9.

acted four years later, was addressed mainly to intentional food ingredients. The clause that bears Congressman Delaney's name was not part of the legislation introduced in the House,⁴¹ but was an amendment from the House floor after the Department of Health, Education, and Welfare, on behalf of the FDA, withdrew its objection that the clause was redundant.⁴²

The Delaney Clause now appears in three provisions of the Act: the 1958 Food Additives Amendment (now Section 409(c)(3)(A)),⁴³ the Color Additive Amendments of 1960 (now section 706(b)(5)(B)),⁴⁴ and the Animal Drug Amendments of 1968 (now section 512(d)(1)(H)).⁴⁵ While the Clause's three versions differ slightly in language,⁴⁶ their basic thrust is similar—to prevent the addition to food of any substance that has been shown

41. H.R. 13254, 85th Cong., 2d Sess. (1958).

42. 104 CONG. REC. 17,412, 17,415 (1958). The letter from the Department withdrawing the agency's objection to the Delaney Clause stated in part:

The widespread interest in cancer led to suggestions that the food additives legislation should mention the disease by name and forbid the approval of any substance that is found upon test to cause cancer in test animals. This Department is in complete accord with the intent of these suggestions H.R. 13254, as approved by [the] committee, will accomplish this intent

To single out one class of diseases for special mention would be anomalous and could be misinterpreted. Hence, . . . we chose general language that would restrain any use of any additive that would have an adverse effect on the public health.

At the same time, if it would serve to allay any lingering apprehension on the part of those who desire an explicit statutory mandate on this point, the Department would interpose no objection to appropriate mention of cancer in food additives legislation.

Id.

43. 21 U.S.C. § 348(c)(3)(A) (1976).

44. 21 U.S.C. § 376(b)(5)(B) (1976).

45. 21 U.S.C. § 360b(d)(1)(H) (1976).

46. All three provisions prohibit the use of substances in products that may be swallowed if those substances are shown to induce cancer when ingested by man or animal or are shown to induce cancer by other appropriate tests. Thus, tests in which an additive is administered by a route other than ingestion must be determined, in the first instance by the FDA, to be "appropriate" before the Delaney Clause applies. The clause applicable to color additives bars the approval of a carcinogenic color for any use "which will or may result in ingestion of all or part of such additive." This language leaves open the possibility that a carcinogenic color additive could be used to enhance the appearance of certain parts of foods (*e.g.*, husks, rinds, shells) if it were certain the color would not contaminate edible portions of the food.

The Food Additives Amendment permits the approval of a carcinogenic additive for use in animal feed if the additive will neither adversely affect the animals nor leave any measurable residue in edible portions of slaughtered animals or in food yielded by living animals. A similar exception is made for carcinogenic animal drugs which neither harm animals nor leave residues in food products derived from treated animals. See 21 U.S.C. 348(c)(3)(A) (1976). This exception to the Delaney Clause is explored in detail in the text at notes 225-50, *infra*.

to induce cancer in man or laboratory animals. The language of section 409(c)(3)(A) is exemplary:

No such regulation [authorizing use of a food additive] shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. . . .⁴⁷

This language seems unequivocal, and certain consequences of the Clause are obvious. It accords the same—decisive—weight to evidence that a substance induces cancer in animals as to evidence of cancer in man. (Accordingly, when this Article refers to a carcinogen, or to a finding of carcinogenicity, it assumes, unless otherwise noted, that the characterization is based on one or more experiments in laboratory animals. Such experiments have become the primary mode for evaluating the safety of food constituents.) In addition, the Delaney Clause allows no room for consideration of dose; it presumes, as a matter of law, that no level of exposure to an animal carcinogen can be considered safe.⁴⁸ However, several critical terms in the Clause are undefined, including terms—such as “induce,” “cancer,” and “tests appropriate for the evaluation of the safety of food additives”⁴⁹—that are

47. 21 U.S.C. § 348(c)(3)(A) (1976).

48. During hearings on the Color Additive Amendments, Secretary of Health, Education and Welfare Arthur Flemming endorsed the conclusion of a National Cancer Institute report: “No one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop.” *Color Additives: Hearings on H.R. 7624 and S. 2197 Before the House Comm. on Interstate and Foreign Commerce*, 86th Cong., 2d Sess. 61 (1960). He went on to state,

We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substances.

Id. at 62. See Blank, *The Delaney Clause: Technical Naiveté and Scientific Advocacy in the Formulation of Public Health Policies*, 62 CALIF. L. REV. 1084 (1974); Turner, *The Delaney Anticancer Clause: A Model Environmental Protection Law*, 24 VAND. L. REV. 889 (1971).

49. “[T]he opposition to inclusion of an anticancer clause arises largely out of a misunderstanding of how this provision works. It allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to cause cancer” *Color Additives: Hearings on H.R. 7624 and S. 2197 Before the House Comm. on Interstate and Foreign Commerce*, 86th Cong., 2d Sess. 501 (1960) (statement of HEW Secretary Arthur S. Flemming).

said to permit the FDA to exercise scientific judgment in evaluating food additives. Thus, for example, the statute does not indicate whether in evaluating an animal experiment the FDA should consider both benign and malignant tumors, or whether an additive should be considered to "induce cancer" when it is associated with an increase in tumors, even though carcinogenesis is thought to result from some predisposing condition that the additive has simply exacerbated. These are issues about which scientists disagree and which the FDA has refrained from attempting to resolve by rules or administrative guidelines. Debate also often arises over the appropriateness of particular tests to determine whether a food additive induces cancer in laboratory animals.⁵⁰ Thus, although the policy of the Delaney Clause is clear, scientific judgment has played, and apparently was intended to play, an important role in the policy's application.

The current debate over the Delaney Clause, however, does not concern its interpretation but its basic premises and potentially dramatic consequences.⁵¹ My objective is not to document or to defend the judgments of the FDA scientists who assess the

50. Controversy continues to rage over the appropriateness of experiments in which laboratory animals are fed large doses of a substance to compensate for their short life span and for the relatively small number of animals that can practicably be included in a single experiment. Congressman James G. Martin (R.-N.C.) was extremely critical of the rodent studies on which the FDA relied in proposing a ban on saccharin:

[S]accharin causes no significant increase in cancer of the test rats if they were fed massive overdoses of it every day from the moment of birth, and . . . no significant increase in bladder cancer resulted from exposure where the rat and its pregnant mother were fed 2 percent of their diet, that is 1 gram of saccharin per kilogram of body weight, daily. Thus, only with the "double whammy," of 2.5 grams per kilogram daily for two generations, was there a significant effect.

That does not translate into much of a risk to humans.

123 CONG. REC. H11,066 (daily ed. Oct. 17, 1977). Mr. Martin went on to argue that [t]he carcinogenic effect [is] perhaps due to the action of that overdose of saccharin as being a physical irritant, one which would increase the raw sensitivity of the rat's bladder tissue. The mechanism may be a secondary effect in which this massive, extreme overdose would affect the rat's detoxification mechanism. Either way [cancer] only occurs at a near lethal overdose.

123 CONG. REC. H 6414 (daily ed. Oct. 18, 1977). See *Martin Criticizes Conclusions of MIT Study*, FOOD CHEMICAL NEWS Aug. 21, at 29.

51. In practice, the FDA has rarely relied solely on the Delaney Clause in attempting to ban or restrict exposure to carcinogenic food ingredients. Between the early 1950s and 1977, the agency forbade the use of 14 food constituents on the ground that they caused cancer in laboratory animals. (In only three instances—those involving Flectol H, Chronaline, and saccharin—did it expressly invoke the Delaney Clause.) This total does not include more recent FDA actions dealing with chloroform and acrylonitrile. See *Agriculture-Environmental and Consumer Protection Appropriations for 1975*, pt. 8, *Hearings Before a Subcomm. of the House Comm. on Appropriations*, 93d Cong., 2d Sess. 214-21 (1974).

carcinogenicity of food additives. For present purposes, it suffices to record that the agency exercises judgment in combining malignant and benign tumors, and is usually unpersuaded by attempts to explain that an increase in tumors was not "induced" by the test compound.⁵² It routinely insists that ingredients be tested according to current scientific standards, but it must nevertheless often make decisions on the basis of studies that fall short of this criterion.⁵³ On occasion it has discounted findings of carcinogenicity on the ground that the test procedures were not appropriate.⁵⁴ Ordinarily, the FDA would reject as inappropriate any test of a food additive administered by a route other than ingestion.⁵⁵

In summary, the Delaney Clause leaves the FDA room for scientific judgment in deciding whether its conditions are met by a food additive. But the clause affords no flexibility to determine ultimate regulatory consequences once FDA scientists determine that these conditions are satisfied. *A food additive that has been found in an appropriate test to induce cancer in laboratory animals may not be approved for use in food for any purpose, at any level, regardless of any "benefits" that it might provide.* And if an approved food additive whose benefits have become widely accepted is found to induce cancer in animals, the FDA must end its use.⁵⁶ Evidence that an additive causes other types of adverse

52. The FDA allowed the use of the nutrient selenium in animal feed although some studies indicated that it is a potential carcinogen. The agency's rationale was that at certain dosages the additive induced in test animals a pathologic change (*i.e.*, liver damage) which in turn led to cancer. The FDA maintained that the anticancer clause did not preclude approving the additive for use at levels safely below the dose at which pathologic changes occur. 38 Fed. Reg. 10,458, 10,459-60 (1973); 39 Fed. Reg. 1355 (1974).

53. 21 C.F.R. § 170.20(a) (1978) states:

In reaching a decision on any petition filed under section 409 of the act, the Commissioner will give full consideration to the specific biological properties of the compound and the adequacy of the methods employed to demonstrate safety for the proposed use, and the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council

See FDA Advisory Comm. on Protocols for Safety Evaluation, *Panel on Carcinogenesis Report on Cancer Testing in the Safety Evaluation of Food Additives and Pesticides*, 20 TOXICOL. & APP. PHARMACOL. 419 (1971).

54. This was the basis of the FDA's recent rejection of a petition by the Health Research Group to revoke approval for several color additives. 43 Fed. Reg. 54,990 (1978). See *Acrylonitrile Copolymers Used To Fabricate Beverage Containers; Final Decision*, 42 Fed. Reg. 48,528 (1977).

55. See note 53 *supra*; 21 C.F.R. § 500.80(b) (1978); *Color Additives: Provisional Regulations; Postponement of Closing Date*, 42 Fed. Reg. 6992, 6994 (1977).

56. See *Saccharin and Its Salts*, 42 Fed. Reg. 19,996 (1977). The Act does not specify how quickly the FDA must act to ban an approved additive that is later found to be carcinogenic. In this silence, the agency argued unsuccessfully in correspondence with the

effects, by contrast, does not automatically dictate disapproval if the FDA can conclude, under the general standards of the Food Additives Amendment, that the conditions of the additive's use pose no significant human risk.

The reader should not conclude from this summary, however, that Congress has unequivocally forbidden the introduction or presence of carcinogens in foods. As the previous section revealed, the Food, Drug, and Cosmetic Act incorporates several different, not always consistent provisions designed to assure that foods do not contain harmful constituents. Some of these provisions accord dispositive weight to a finding of carcinogenicity, *i.e.*, to a finding that a substance has induced cancer in laboratory animals, but others prescribe more general criteria that do not differentiate between the induction of cancer and other risks to health and that vary in the degree to which they permit the agency to consider factors offsetting such risks. The result is a patchwork of regulatory approaches that has produced seemingly irreconcilable decisions respecting the use or occurrence of specific food constituents.

Part III examines the regulatory standards applicable to each of the several classes of food constituents recognized by the Act. I have used "constituent" to embrace any substance that is or becomes a part of food. The term does not appear in the Act, which, as the reader is now aware, divides food constituents into numerous categories—such as "food additives" or "pesticide residues"—to which special rules apply. Except when "constituent" is used in an undifferentiated fashion to apply to any or all of these categories, the Article uses the Act's terminology.

III. STATUTORY STANDARDS FOR REGULATING CONSTITUENTS OF HUMAN FOOD

As we have seen, Congress's current food safety "policy" must be distilled from the several overlapping provisions of the Food, Drug, and Cosmetic Act enacted in or since 1938. These various provisions focus either on the way in which constituents

Department of Justice about the additive sodium nitrite that the ingredient's use could be phased out while efforts are made to find an alternative means of preventing botulism. See Culliton & Waterfall, *Nitrites—To Ban or Not To Ban?*, 1978 *BRIT. MED. J.* 1613; Smith, *Ever So Cautiously, the FDA Moves Toward a Ban on Nitrites*, 201 *SCIENCE* 887 (1978). See also Statement of Joseph A. Califano, Jr., Secretary of Health, Education, and Welfare, March 30, 1979 (announcing the Department of Justice's rejection of this argument). It is clear, however, that § 409(c)(3)(A) precludes the FDA from allowing any use whatever of a new additive that is shown to induce cancer, regardless of its utility.

become part of food, *e.g.*, as residues of pesticides, or on the functions they serve, *e.g.*, color additives, rather than on the risks to health they present or the benefits they provide. Each provision addresses these two elements—if at all—largely without regard to the treatment accorded other classes of food constituents.

For purposes of discussion, constituents of food can be divided into four general categories based upon their source or origin. Some of these categories in turn include subclasses of constituents that are themselves subject to distinct statutory standards. The following sections describe and analyze the FDA's current interpretation of specific statutory provisions, an interpretation that in some instances may be disputable. Where the agency's position remains untested or differs from an earlier interpretation, the Article notes this fact and discusses any significant differences.

The four broad categories are:

A. Natural constituents of agricultural commodities, *e.g.*, ascorbic acid in oranges, nitrates in spinach.

B. Environmental contaminants of food, which the FDA has characterized as "added" on the theory that they are not inherent even though they may in some measure be unavoidable in some foods, *e.g.*, PCBs in fish, mycotoxins in or on many grains.

C. Substances used intentionally as food ingredients, *e.g.*, salt, saccharin, Red Dye No. 2, sodium nitrite.

D. Substances that become constituents of human food through their intentional use for other purposes, which may or may not be food-related, *e.g.*, food-packaging materials, animal drugs, and pesticides.

This division of food constituents into discrete categories is potentially misleading, for some constituents fall into more than one category. Nitrate, for example, occurs naturally in many vegetables and has been intentionally added to some processed meats. Ascorbic acid is a natural constituent of oranges, but may also be added to processed foods to provide Vitamin C. Furthermore, it can be difficult to judge which category a given constituent of a specified food fits. DDT residues in fish may now be considered an unavoidable environmental contaminant, but their original occurrence can be attributed to human efforts to control agricultural pests. Before DDT was banned as a pesticide, tolerances had been established for its residues on agricultural commodities in accordance with section 408 of the Act, and some tolerances remain in effect because DDT's persistence in the envi-

ronment makes its presence in some foods unavoidable.

The following sections outline the current statutory criteria applicable to each of the four categories of food constituents and briefly describe the legal processes by which these criteria are applied. In each instance specific attention is given to the regulatory significance of a finding that a constituent induces cancer in experimental animals.

A. Natural Food Constituents

Section 402(a)(1) of the Act⁵⁷ sets forth the safety standard applicable to naturally occurring food constituents. Under this provision a food is adulterated

[i]f 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*⁵⁸

The legislative history of the 1938 Act, in which this language first appeared, does not aid its interpretation.⁵⁹ Congress evidently

57. 21 U.S.C. § 342(a)(1) (1976).

58. 21 U.S.C. § 342(a)(1) (emphasis added). The second clause of § 402(a)(1) concerns the manner in which a substance becomes part of food (*i.e.*, its natural occurrence), not its character. A substance is considered naturally occurring when it is an inherent constituent of a food marketed without processing, even though it may be identical to a compound synthesized in a laboratory. See *Poisonous or Deleterious Substances in Food*, 39 Fed. Reg. 42,743, 42,744 (1974). Similarly, the category of food additives is not confined to substances synthesized by man. An apple used in making applesauce would be a food additive if it were not generally recognized as safe, while a synthesized chemical preservative might be so well-tested that it would be so recognized.

59. The 1906 Act declared food adulterated "[i]f it contain any *added* poisonous or other *added* deleterious ingredients which may render such article injurious to health." Federal Food and Drugs Act of 1906, ch. 3915, § 7, 34 Stat. 768 (1906) (emphasis added). Most of the early bills to reform the law would have changed that language to define food as adulterated "[i]f it bears or contains any poisonous or deleterious substance which may render it dangerous to health." S. 2000, 73d Cong., 2d Sess. § 3(a)(1) (introduced Jan. 4, 1934); S. 2800, 73d Cong., 2d Sess. § 3(a)(1) (introduced Feb. 19, 1934 and as revised and reported from committee, *reprinted in* 78 CONG. REC. 4567-73 (1934)); S. 5, 74th Cong., 1st Sess. § 3(a)(1) (introduced Jan. 4, 1935); S. 5, 74th Cong., 1st Sess. § 301(a)(1) (reported in the House May 31, 1935); S. 5, 75th Cong., 1st Sess. § 11(a)(1) (introduced Jan. 6, 1937). The language Congress ultimately adopted to deal specifically with naturally occurring adulterants appeared unexplained in a bill prepared by a subcommittee of the House Interstate and Foreign Commerce Committee and reported to the House on August 14, 1938 as a substitute for the bill (S.5) passed by the Senate several months earlier. While the Committee's report, H.R. REP. No. 2139, 75th Cong., 3d Sess. (1938), does not indicate why this wording was added, the legislative record of the earlier bills may suggest an answer.

The earliest proposed bills had deleted the word "added" from the language of the 1906 Act to allow the FDA to regulate any food that might be dangerous, whether the

was aware that some foods naturally contain substances that, if consumed in excess, can be harmful, and quite clearly it wanted a demanding standard for FDA enforcement. The provision makes no specific mention of the risk of cancer, and not surprisingly, there is no evidence that Congress anticipated that a natural food might itself cause cancer or—a more common occurrence—be found to contain naturally a substance that induces cancer when fed to laboratory animals.

Judicial construction of the “ordinarily injurious” standard has been surprisingly rare. However, the few cases, as well as the sparse legislative history, indicate that the FDA must show that the amount of a naturally occurring poisonous substance is sufficient to render the food in which it occurs injurious when consumed in ordinary quantities by ordinary consumers. The leading case, *United States v. 1232 Cases of American Beauty Brand Oysters*,⁶⁰ involved an FDA seizure of oysters that contained shell

deleterious constituent occurred naturally or was put in food by artifice. *Federal Foods, Drugs, and Cosmetics: Hearing on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong., 2d Sess. (1934). The bills also substituted the word “dangerous” for “injurious.” FDA Chief Walter G. Campbell pointed out to both House and Senate committees that during the congressional consideration of the 1906 Act, language that would have prohibited interstate transportation of any food naturally containing an “injurious” substance had been deleted because of concern that it would outlaw foods such as coffee and tea. Thus, the 1906 Act had been limited to foods containing *added* adulterants. But, Mr. Campbell explained, the 1906 Act also left such foods as poisonous mushrooms and particularly toxic varieties of West Coast mussels, which acquire their injurious properties naturally, beyond federal control. The word “dangerous” was therefore applied to foods naturally containing poisonous or deleterious substances in order to differentiate “between those products which may be injurious to health in a mild way and those that are unquestionably dangerous to health in a very definite way.” *Foods, Drugs, and Cosmetics: Hearings on H.R. 6906, H.R. 8805, H.R. 8941, and S.5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong., 1st Sess. 58 (1935); *Food, Drugs, and Cosmetics: Hearings on S.5 Before a Subcomm. of the Senate on Commerce*, 74th Cong., 1st Sess. (1935).

The final wording of § 402(a)(1) returned to “injurious,” but omitted “added” from the second clause—in order to reach naturally occurring poisons. Although not spelled out in the legislative history, the rationale of the final language may be inferred. “Injurious” had been the standard for all FDA enforcement actions under the 1906 Act, and Congress was reluctant to change language that the courts had already interpreted. But to prevent draconian enforcement against foods that naturally contained a deleterious substance, the House committee added the proviso requiring the government to prove that a substance was harmful when consumed in ordinary quantities. In other words, the phrase appears to have been another means of differentiating between “mildly” disturbing and “unquestionably” dangerous nonadded substances without abandoning the familiar term, “injurious.” Statements during hearings indicate that foods such as coffee, tea, rhubarb (which naturally contain oxalic acid), and cocoa were not to be restricted. Congress wanted to reach only foods such as the poisonous mushrooms, mussels, and “Burma beans” that FDA witnesses had cited as examples of foods that are highly toxic in their natural state.

60. 43 F. Supp. 749 (W.D. Mo. 1942).

fragments which the government claimed were capable of lodging in the esophagus or injuring the mouth. The court observed that section 402(a)(1) contemplates that "there may be of necessity food products containing deleterious substances."⁶¹ It found that the shell fragments could not be entirely removed, even though the claimant used the most modern processing techniques, and that there were no more fragments than in the products of other processors. That the claimant had distributed over fifty million cans without receiving any complaints about the presence of shell fragments also influenced the court. Accordingly, it concluded, the government had not shown the oysters to be dangerous in ordinary use:

[Because] it is impossible to eliminate shell fragments in toto from the product, the use of oysters as a food must be entirely prohibited or it must be found that the presence of shell fragments is not a deleterious substance within the meaning of the law and must be tolerated[;] to reject oyster products as a food is unthinkable. It would be as reasonable to reject fish because of the presence of bones.⁶²

The court's statement assumes that notwithstanding the risk of choking or other injury from oyster shell fragments, Congress would regard oysters as sufficiently important to preclude a finding of adulteration. While the Act does not explicitly authorize such a rough weighing of risks and benefits, the court's assumption is consistent with the few illustrations contained in the legislative history of section 402(a)(1). The bill's proponents clearly did not want to ban coffee, although they acknowledged that excessive consumption of caffeine could be injurious to health. Their desire to control the marketing of mushrooms and mussels but not rhubarb suggests that the "ordinarily injurious" standard was meant to permit the FDA, or a district court, to weigh the relative dangers and importance of foods that naturally contain poisonous constituents.⁶³

This does not mean that the FDA could not restrict the marketing of a food that naturally contains a constituent shown to be an animal carcinogen. Given the current skepticism among scien-

61. 43 F. Supp. at 750.

62. 43 F. Supp. at 751.

63. See note 59 *supra*. In *Certified Color Indus. Comm. v. Folsom*, 236 F.2d 866 (2d Cir. 1956), the court discerned in the legislative history of § 402(a)(1) a rough balancing of risks and benefits. The court pointed out that in § 402(a)(1) Congress had differentiated between added and naturally occurring poisonous substances, precluding a finding of adulteration unless a naturally occurring substance was present in sufficient quantity to render the food injurious when ingested in the customary fashion.

tists about the existence of "safe" levels of any carcinogen, the agency could contend that any exposure poses a hazard for at least a small number of consumers. However, the FDA has never made this argument with respect to a natural constituent of food. The sparse case law suggests that the agency would have to demonstrate a probability of harm to some significant number of consumers. Thus, section 402(a)(1) would appear to allow, and perhaps require, the FDA to consider whether a naturally occurring carcinogen is present in amounts sufficient to present a serious risk. And the agency has assumed, without ever explicitly stating, that under 402(a)(1) its assessment of seriousness of such a risk may legitimately include some evaluation of the "benefits" of the food itself.⁶⁴

Section 402(a)(1) is enforced primarily through seizure or other court action. The Act does not require the distributor of a commodity to seek approval of the safety of its natural constituents, nor does it provide a procedure for administratively withdrawing permission to market a food that naturally contains an unsafe constituent. Theoretically, the FDA could promulgate a regulation declaring a particular natural constituent an adulterant—as it has done with some added food constituents which had never been "licensed."⁶⁵ But even in such a case, the agency would have to enforce its judgment through judicial action, and it is unclear what weight a court would accord to the agency's ruling. The FDA bears the burden of initiating any challenge to the safety of a natural constituent of food. Accordingly, the FDA's failure to initiate court action reflects, and probably places beyond executive review, its determination that a natural constituent is *not* present in amounts sufficient to cause harm, or that the importance of the food outweighs the risk.⁶⁶ The Act does not

64. There is no other satisfactory explanation for the agency's understandable silence on the subject of nitrates as natural constituents of many green vegetables. See generally Congressional Research Service, *Nitrate Food Contaminant: A Case Study* (Aug. 31, 1978) (working paper prepared for the Office of Technology Assessment).

65. See 21 C.F.R. pt. 189 (1978). It has attempted to impose similar limitations on the use of specific ingredients in drugs and cosmetics. One example is chloroform, which the agency banned from use in cosmetics because of a finding by the National Cancer Institute that the substance induces cancer in laboratory animals. The agency relied on § 601(a) of the Act, 21 U.S.C. 361(a) (1976), whose language parallels the first clause of § 402(a)(1). In so doing, however, the agency purported to evaluate whether the risk was outweighed by any benefit. See *Chloroform as an Ingredient of Human Drug and Cosmetic Products*, 41 Fed. Reg. 26,842 (1976)(codified in 21 C.F.R. §§ 310.513, 700.18 (1978)).

66. See *Public Citizen v. Schmidt*, [1977] *FOOD DRUG COS. L. REP.* (CCH) ¶ 70,171.13 (D.D.C. 1976).

impose, and the FDA has not assumed, any responsibility to announce or document such decisions.

B. "Unavoidable," "Added" Constituents of Food

An important and increasingly larger group of food constituents are those that, although not inherent in agricultural commodities, unintentionally contaminate foods such as grains, vegetables, meat, milk, and fish during harvesting or production. Such environmental contaminants are common; they include aflatoxins on peanuts and grains, polychlorinated biphenyls (PCBs) in fish and milk, and mercury in swordfish and other marine species. Most such contaminants are considered "poisonous or deleterious" because they are toxic at some level of exposure. Some, such as PCBs, have been shown to be carcinogenic in test animals. Aflatoxins are acknowledged animal carcinogens and are strongly suspected of causing human cancers as well.

The FDA characterizes these and other environmental contaminants as "unavoidable,"⁶⁷ but it uses this term in a special sense. A person who wants to eat swordfish cannot avoid finite quantities of mercury, which apparently contaminates all of the species. But one could "avoid" mercury by not eating swordfish (or other foods) that are contaminated by it.⁶⁸ The FDA's characterization thus subsumes the desirability or value of some foods containing environmental contaminants, and measures instead the ability of manufacturers and processors to eliminate the contamination. Under the agency's interpretation, the degree to which such a contaminant may be "avoided" depends not only on the levels at which it occurs but on the practicability of the various methods by which contaminated food can be identified and prepared for distribution or consumption.⁶⁹

While the FDA's interpretation of the "unavoidability" criterion of section 406 may be entirely consonant with Congress's expectation, its approach to environmental contaminants should be contrasted with the Act's treatment of direct food additives.

67. See, e.g., *Poisonous or Deleterious Substances in Food*, 39 Fed. Reg. 42,743 (1974).

68. Hutt, *The Basis and Purposes of Government Regulation of Adulteration and Misbranding of Food*, 33 FOOD DRUG COSM. L.J. 505, 533-34 (1978). See Hutt, *Unresolved Issues in the Conflict Between Individual Freedom and Government Control of Food Safety*, 33 FOOD DRUG COSM. L.J. 558, 585-87 (1978).

69. See, e.g., *Polychlorinated Biphenyls (PCBs)*, 42 Fed. Reg. 17,487 (1977); *Aflatoxins in Shelled Peanuts and Peanut Products Used as Human Foods*, 39 Fed. Reg. 42,748 (1974).

The FDA has prudently concluded that Congress would not expect it to ban the distribution of peanuts in order to prevent human exposure to aflatoxins, but the food additive provisions make no allowance for the fact that saccharin is currently an essential ingredient of low calorie soft drinks. Banning saccharin will effectively prevent the marketing of such products altogether. Similarly, saccharin can be viewed as at least as indispensable in the production of low calorie soft drinks as pesticides are in the production of most agricultural commodities, the very circumstance for which Congress devised section 406.

This analysis is not simply a linguistic game. The classification of PCBs, for example, as an unavoidable environmental contaminant permits the FDA to avoid the strictures of the Delaney Clause. The agency has concluded that the Delaney Clause does not apply to such "unavoidable" food contaminants for two reasons.⁷⁰ First, although it considers environmental contaminants "added" substances within the meaning of the first clause of section 402(a)(1),⁷¹ it acknowledges that they could not be approved as "food additives" because they serve no purpose in food. A food additive must perform a functional purpose, *e.g.*, a preservative must preserve, before it can be approved.⁷² Second, the FDA has assumed that Congress did not intend section 409 to reach constituents whose addition to, or presence in, food cannot be fully controlled by human intervention. The Food Additives Amendment was designed to regulate ingredients used to make food and constituents, such as packaging materials, that become part of

70. Such contaminants could fit within the Act's broad definition of "food additive," 21 U.S.C. § 321(s) (1976), although little in the legislative history suggests that Congress contemplated this result, and some evidence suggests the contrary. The House Commerce Committee report on the 1958 Food Additives Amendment stated that "accidental" additives were not included in the terms of the legislation.

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

H.R. REP. NO. 2284, 85th Cong., 2d Sess., 3-4 (1958).

71. 21 U.S.C. § 342(a)(1) (1976).

72. 21 U.S.C. § 348(c)(4) (1976). See 39 Fed. Reg. 42,743, 42,744 (1974).

food through intentional use for other purposes.⁷³ The FDA has therefore regulated "unavoidable" food contaminants under other provisions of the Act, either section 402(a)(1) or section 402(a)(2) augmented by section 406. As the following discussion indicates, the interrelation of these three provisions, enacted simultaneously in 1938, poses difficult problems of interpretation. FDA's current construction represents an attempt to distill a unified policy out of language that defies consistent interpretation.⁷⁴

1. Section 402(a)(1)

As was observed in Part II, section 402(a)(1) applies a more rigorous standard to added contaminants of food than to naturally occurring poisons. The statute provides that a food is adulterated "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health"⁷⁵ The addition, in the next clause, of the "ordinarily injurious" standard addressed specifically to naturally occurring deleterious substances makes inescapable the inference that the initial clause applies only to added toxicants.⁷⁶

The "may render injurious" standard was carried over from the 1906 Act.⁷⁷ Indeed, the Supreme Court's opinion in *United States v. Lexington Mill & Elevator Co.*,⁷⁸ a case decided under the older law, is still the authoritative interpretation of this phrase. In *Lexington Mill*, the FDA sought to condemn flour which had been treated with nitrogen peroxide gas, small quantities of which remained on the food. The Supreme Court affirmed a lower court ruling that the jury had been erroneously instructed that the addition of a poisonous substance in any quantity would render food adulterated. The Court's opinion made clear that the "may render" standard applies not to the added constituent it-

73. The House Commerce Committee report on the Food Additives Amendment states: "The legislation covers substances which are added intentionally to food . . . [and] substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food." H.R. REP. No. 2284, 85th Cong., 2d Sess. 3 (1958). See also statement quoted in note 70 *supra*.

74. See *Poison or Deleterious Substances in Food*, 39 Fed. Reg. 42,743 (1974).

75. 21 U.S.C. § 342(a)(1) (1976).

76. There is little discussion in the 1938 legislative history about the application of § 402(a)(1) to "added" substances. In its consideration of this section, Congress was mainly concerned about the language it should use to reach naturally occurring dangerous substances. See note 59 *supra*.

77. Compare Federal Food, Drug, and Cosmetic Act of 1938, *supra* note 8, § 402(a)(1) (codified at 21 U.S.C. § 342(a)(1) (1976)) with Food and Drugs Act of 1906, ch. 3915, § 7, 34 Stat. 768 (repealed 1938).

78. 232 U.S. 399 (1914).

self, but to the food that contains it; it is the food which the government has the burden of showing "may be injurious" to consumers. The Court also made clear, however, that the FDA need not prove conclusively that a food containing an added poison would cause injury for that food to be condemned. Any significant possibility that the food would be injurious would satisfy the "may render" test. Consideration could be given to the various uses of the food and to the vulnerability of individuals to whom it might be fed, e.g., the sick, the young, or the aged. If food, because of an added substance, "may possibly injure the health of any of these," the statute is satisfied. If, on the other hand, "it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such [food], though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act."⁷⁹

Congress consciously sought to carry over this interpretation when it incorporated the first clause of section 402(a)(1) in the 1938 Act.⁸⁰ The key issue under the "may render injurious" standard is the quantity of the added substance in the food. In *United States v. Commonwealth Brewing Corp.*,⁸¹ the court acknowledged that in toxicology quantity is important in determining whether or not a deleterious substance may be harmful and therefore concluded that "quantity would be the test under [section 402(a)(1)]."⁸² An inquiry into level of exposure would appear to be essential under the "ordinarily injurious" standard as well. The two adulteration standards in section 402(a)(1) appear to be distinguished chiefly by the greater probability of harm the government must show to restrict a natural constituent and by its ability, under the "may render" standard, to take account of specially vulnerable segments of the population. Under either standard, the government must prove that the food itself probably will, or may, injure health, not merely that it contains a poisonous substance. If the substance is not added, it must be present in such quantities that the food is likely to be injurious under ordinary conditions of use. If any likely use of a food con-

79. 232 U.S. at 411. The Supreme Court has ruled that the language interpreted in *Lexington Mill* survived in the § 402(a)(1) test for adulteration. *Flemming v. Florida Citrus Exch.*, 358 U.S. 153, 161 (1958).

80. See *Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 530-32 (1934).

81. No. 7926 (D. Mass. May 22, 1945) (reported in V. KLEINFELD & C. DUNN, *FEDERAL FOOD, DRUG AND COSMETIC ACT: JUDICIAL AND ADMINISTRATIVE RECORD 1938-1949*, at 310, 313 (Food Law Institute Series 1949)).

82. V. KLEINFELD & C. DUNN, *supra* note 81, at 313.

taining an added toxicant would pose a risk of harm, the food is adulterated.

Because the statute imposes a more rigorous standard for "added" substances, the FDA has historically interpreted that term broadly. In regulations published in final form in 1977, the agency reiterated that any substance, including natural environmental contaminants such as mercury, that is not an "inherent" constituent of a food may be regulated as an "added" substance.⁸³ Furthermore, the FDA asserted, if the quantity of a constituent exceeds the amount that would naturally be present, *e.g.*, because of additional absorption from the environment, the excess quantity is an "added" substance under section 402(a)(1).⁸⁴ Any substance incorporated in or added to a food, or used intentionally in proximity to food in a fashion that results in migration, would obviously also fall in this category. In short, in the agency's view, the first clause of section 402(a)(1) applies to most of the deleterious substances that may occur in human food.

It should be emphasized that the first clause of section 402(a)(1), like the clause applicable to naturally occurring adulterants, is a prohibitory standard, not a licensing provision. To enforce section 402(a)(1), the FDA ordinarily must locate contaminated food, conduct chemical analyses, find witnesses prepared to testify that the amount of the contaminant is potentially harmful to some portion of consumers, and prove these facts in court. By itself, the provision gives the agency no authority to

83. See *Poisonous and Deleterious Substances in Food*, 39 Fed. Reg. 42,743 (1974), 42 Fed. Reg. 52,814 (1977). The legislative history is compatible with this position. Testimony during hearings on the 1938 Act indicates that any substance not "normal" or "natural" to a food, or that was added by "artifice" in manufacture, was considered to be "added." *Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 529-30 (1934). The courts have generally accepted this broad reading of "added." In *United States v. 1,680,000 Pounds of White Corn*, No. T-4173 (D. Kan. Dec. 18, 1970), the court found aflatoxin mold on corn to be an "added" substance because it is "not a natural constituent of corn." Similarly, in *United States v. An Article of Food Consisting of Cartons of Swordfish*, 395 F. Supp. 1184 (S.D.N.Y. 1975), the court agreed with the FDA's contention that "the test for determining whether a substance is added is whether it occurs naturally in the food," citing House hearings preceding the 1938 Act to support this conclusion. Accordingly, the court held mercury in swordfish to be an "added" substance because it "is not naturally produced by [the] fish, but is acquired through its external food supply." 395 F. Supp. at 1186. Cf. *United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151 (N.D. Fla. 1978) (Although some mercury may occur naturally in swordfish, the substance is "added" because about two thirds of the amount present in swordfish is the result of pollution.)

84. *United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151, 1155 (N.D. Fla. 1978).

evaluate or approve the safety of a substance before it is "added" to food.⁸⁵

2. Section 402(a)(2)(A) and 406

The two clauses of section 402(a)(1) theoretically provide a comprehensive framework for regulating food safety. Together they cover all substances, indigenous and added, that may render food unsafe, but they are inadequate in two important respects. First, neither clause authorizes the FDA to assess the safety of a constituent or of a food *before* consumers are exposed. Both standards are enforced after the fact. Second, section 402(a)(1)'s "may render injurious" standard does not appear to allow any consideration of the benefits of an added substance or of the costs of removing from food a substance whose occurrence producers cannot easily control.

Although the legislative history is not fully illuminating, Congress obviously was sensitive to this second difficulty when it enacted the 1938 Act, for it designed two other provisions to permit the FDA to establish tolerances for added poisonous or deleterious substances that provide some benefit—either because they cannot be avoided in some foods that are considered important or because their use contributes significantly to food production. The first, section 402(a)(2)(A), specifies that a food shall be deemed adulterated

if it bears or contains any added poisonous or added deleterious substance . . . which is unsafe within the meaning of section 406⁸⁶

And the second, section 406, provides:

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 manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a); 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, and any quantity exceeding the

85. It is true that in recent years the FDA has sometimes undertaken to issue regulations defining a substance as an adulterant under § 402(a)(1) or announcing the quantity of a toxicant present in food that will trigger regulatory action under this standard—a so-called "action level." In this fashion the agency has attempted to reduce the burden of demonstrating a hazard in each individual enforcement proceeding. *See United States v. Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974). Compare *United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151 (N.D. Fla. 1978).

86. 21 U.S.C. § 342(a)(2)(A) (1976).

limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a). . . . In determining the quantity of such added substances to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.⁸⁷

This language satisfies the requirements of section 402(a)(2), but it does not cure the problem posed by section 402(a)(1)'s prohibition of any "added" poisonous substance that "may render" food injurious to consumers. Congress therefore added the following additional caveat to section 406:

While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a).⁸⁸

As with many other provisions of the 1938 Act, section 406's legislative history only intimates the kinds of "added" toxicants Congress expected the FDA to set tolerances for.⁸⁹ Pesticides were obviously the primary candidates. It is questionable whether

87. Federal Food, Drug, and Cosmetic Act of 1938, *supra* note 8, § 406, as amended by Food Additives Amendment of 1958, *supra* note 9, § 3(c) (codified at 21 U.S.C. § 348 (1976)).

88. Federal Food, Drug, and Cosmetic Act of 1938, *supra* note 8, § 406 (codified at 21 U.S.C. § 346 (1976)).

89. The legislative history suggests that two major concerns motivated Congress to modify the approach of the 1906 Act. While Congress recognized that some potentially deleterious ingredients in food were ubiquitous, it wanted to enhance FDA control over consumer exposure to poisonous substances in food from all sources. Agency officials complained that the 1906 Act only allowed them to consider the consequences to health of an added poison in a single commodity. Congress wanted to allow the FDA to include in its consideration the extent to which consumers were exposed to a deleterious substance from other sources as well. *Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 17-19 (1933). FDA officials also complained about the burden imposed on the agency whenever it attempted to enforce the 1906 Act's prohibition against added poisonous substances. That law required the FDA to show that the particular lot of food subjected to the enforcement proceeding contained enough added poison to present a genuine risk to health. In each case the government had to summon outstanding toxicologists to testify that the quantity of added poison in the food was harmful—a cumbersome, expensive, and unpredictable process. *Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 596 (1934).

To remedy these drawbacks, Congress chose simply to declare a good to be adulterated, and thus subject to enforcement under § 402(a)(2), if it contained *any* added poisonous or deleterious substance. The quantity of the substance and the extent to which the food might be harmful were immaterial. The agency would only have to prove that the substance was poisonous and that it was "added." It could then set tolerances for those substances that were important or unavoidable in food production.

Congress imagined that the FDA might, as it has done, use section 406 to control environmental contaminants without flatly proscribing the marketing of contaminated foods under section 402(a)(1).⁹⁰ The point is somewhat academic, for the FDA never attempted to establish formal tolerances for any "added" poison until well into the 1970s. The agency attempted to control pesticide residues on raw commodities through informal administrative tolerances—levels that would cause it to initiate regulatory action under section 402(a)(1).⁹¹ These administrative tolerances were apparently known to producers and distributors of foods but were never published, much less made the subject of public rule-making.⁹²

90. Legislative history about which substances would qualify for the "required" or "unavoidable" exceptions—and thus be eligible for tolerances—is again scanty. A Senate Report described these exceptions by example, noting that "poisonous sprays for fruits and vegetables to protect them against insects or fungus diseases" might be required for food production and that unavoidable contaminants might be tolerated "where purification processes cannot entirely eliminate a contaminant of raw materials, or where some contaminant is unavoidably introduced in factory operations." S. REP. No. 646, 74th Cong., 1st Sess. 3 (1935). Obviously, Congress was principally concerned about pesticide residues on raw agricultural commodities. Throughout the hearings and floor debates, representatives of apple-producing states expressed their fear that the FDA would prescribe excessively stringent tolerances. See, e.g., 79 CONG. REC. 4848 (1935); 83 CONG. REC. 7783-86, 7894-98 (1938). The FDA's Campbell made clear that pesticide residues would fall within the agency's tolerance-setting authority because they were required in food production. He asserted that many pesticides were "regarded as absolutely essential in the production of our supply of fruits and vegetables." *Foods, Drugs, and Cosmetics: Hearings on S.5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce, 74th Cong., 1st Sess. 59 (1935)*(statement of Walter G. Campbell).

Nothing in the legislative history reveals which other substances might be eligible for tolerances. The other examples of "added" poisonous substances that the FDA wanted authority to control included items that were not required for production or that good manufacturing practice could avoid, such as arsenic that contaminates sugar by blowing through open windows. *Id.* However, when pointedly asked whether the authority to establish tolerances was chiefly directed at residues of pesticide sprays, Campbell replied,

Not at all They are not alone. There are a great many products in which added deleterious substances may be found. They are being discovered every day. We never know where we are going to find them. They may be found where least suspected, due, sometimes to careless manufacturing operations, such as using lead manufacturing equipment, and such as the deliberate addition of ethylene glycol to frozen eggs. . . .

Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce, 73d Cong., 2d Sess. (1933), reprinted in C. DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 1251 (1938).

91. See *Poisonous or Deleterious Substances in Food: Notice of Proposed Rule Making*, 39 Fed. Reg. 42,743, 42,744, (1974).

92. *Id.* On a casual reading §§ 402(a)(1) and (a)(2)(A) of the Act appear redundant. Section 402(a)(1) provides that an added poison will adulterate food only if present in quantities that may pose a risk to health. It contemplates that the FDA must establish the requisite degree of danger for any good by evidence in court. By contrast,

In 1954, Congress enacted section 408, which explicitly empowered the FDA to establish tolerances for pesticide residues on raw agricultural commodities.⁹³ With this amendment, section 406 lost its importance⁹⁴ until the recognition of widespread environmental contamination of basic foods by compounds such as PCBs, mercury, and various mycotoxins convinced the FDA that it needed a statutory mechanism to control consumer exposure to

§ 402(a)(2)(A), read in conjunction with § 406, prohibits the addition to food of *any* poisonous substance—regardless of the quantity or the degree of risk the substance poses. To establish that a food is adulterated under § 402(a)(2)(A), the FDA need only prove that the substance is added and that it is capable of producing toxic effects. Section 406 authorizes the FDA to relax this unequivocal prohibition for a substance that cannot be avoided by good manufacturing practice that is necessary to the production of a food. Together, these last two provisions appear to create a system requiring FDA “licensure” or approval—in the form of a tolerance—for any added poison.

It is puzzling why Congress retained the first clause of § 402(a)(1) when in §§ 402(a)(2)(A) and 406 it created a more comprehensive system for regulating added food constituents. The legislative history of the 1938 Act does not resolve the puzzle, although it suggests a possible explanation for what, in retrospect, seems an oversight. Until final House passage, § 402(a)(1) did not differentiate between added and naturally occurring substances; it declared a food adulterated if it contained any poisonous or deleterious substance that might render it “dangerous to health.” One objective of the new legislation was to enable the FDA to regulate foods whose natural constituents posed a risk to health. Since earlier versions of the bill contained a provision similar to § 402(a)(2), which dealt explicitly with added substances, it would have been possible, perhaps natural, to read earlier versions of § 402(a)(1) to apply only to naturally occurring poisons. However, when the House added the second clause of § 402(a)(1)—establishing the “ordinarily injurious” standard for naturally occurring poisons—it thereby implied that the first clause applied to *added* substances.

As a result of this legislative handiwork, the FDA may in theory proceed in either of two ways against a food that contains an added poisonous substance—under the “may render injurious” standard of § 402(a)(1) or under § 402(a)(2)(A), which prohibits any added poison for which no tolerance has been set. The agency has usually relied only on § 402(a)(1). At first blush, it is difficult to see why the FDA would ever invoke this section, which appears to impose on it a heavier burden of proof. Perhaps the agency has wanted to avoid having to explain why, in the face of the word “shall” in § 406, it has not established a single tolerance for an unavoidable or necessary added poisonous substance. In addition, agency enforcement personnel may have quickly concluded, since most seizures are uncontested, that making a case was as easy under § 402(a)(1), and that relying on this provision did not call into question its administrative authority. Until the late 1960s, the FDA relied almost exclusively on court enforcement and never fully explored the range of administrative powers open to it.

93. Pesticide Residues Amendment of 1954, *supra* note 9 (codified at 21 U.S.C. § 346a (1976)).

94. Although the FDA never invoked its formal authority, § 406 theoretically remained an important part of the agency’s statutory armament, for § 408 did not deal with the problems of pesticide drift or persistence, which can contaminate foods on which no pesticide is used or intended to remain. Furthermore, prior to 1958, when the Food Additives Amendment was passed, without § 406 the statute would have afforded the FDA no basis, other than § 402(a)(1), to regulate the occurrence of pesticide residues in processed food at levels above the tolerance established for the raw commodity.

contaminated foods.⁹⁵ Since the early 1970s, section 406 has provided the legal framework for FDA regulation of environmental contaminants and other “unavoidable” by-products of modern food production, such as lead in the solder used to seal tin cans.⁹⁶ It therefore is pertinent to examine this provision’s criteria.

Most notably, section 406, which is enforced through section 402(a)(2)(A), does not unequivocally preclude the marketing of food that contains an added carcinogenic substance. Indeed, the section does not mention or differentiate among specific risks to health. The FDA has taken the position that it may establish a tolerance for a contaminant shown to be carcinogenic—and thus “approve” its presence in food in quantities below the tolerance—if the criteria of section 406 are met.⁹⁷ To be eligible for a section 406 tolerance, a substance must be unavoidable despite good manufacturing practice or “necessary in the production” of a food.⁹⁸ In establishing a tolerance, the FDA must by statute consider two criteria: (1) the level at which consumption of the food will not pose a risk to public health, taking into account other ways in which consumers may be exposed to the substance, and (2) the extent to which good manufacturing practice can reduce the substance.⁹⁹ If careful processing or storage can achieve lower levels of a contaminant than health considerations might otherwise dictate, the agency presumably must establish any tolerance at such lower levels.¹⁰⁰

Read literally, section 406 presents the FDA with an insoluble dilemma. The section specifies that the agency “shall” establish a tolerance for any added poisonous substance that cannot be eliminated through good manufacturing practice. At the same

95. It should be noted that § 406 does not enable the FDA to control the *occurrence* of contamination. To the extent that environmental contaminants of food are unavoidable, as is the case with mercury in swordfish, the establishment of a tolerance can have no effect on the levels that occur in the environment. What a § 406 tolerance does, in theory, is limit human exposure to the contaminant by eliminating foods containing higher levels from the food supply.

96. See *Poisonous or Deleterious Substances in Food: Notice of Proposed Rule Making*, 39 Fed. Reg. 42,743, 42,744 (1974).

97. *Aflatoxins in Shelled Peanuts and Peanut Products Used as Human Foods: Proposed Tolerance*, 39 Fed. Reg. 42,748 (1974). See *Poisonous or Deleterious Substances in Food: Notice of Proposed Rule Making*, 39 Fed. Reg. 42,743, 42,745 (1974).

98. I have previously adverted to the potential flexibility of these requirements, and to the FDA’s solicitude for familiar constituents of the food supply. See text at notes 67-69 *supra*.

99. 21 U.S.C. § 346 (1976).

100. Once the FDA has established a tolerance, a food containing the contaminant in concentrations that exceed the tolerance is unlawful without further inquiry into the health hazard it may pose. See 21 U.S.C. §§ 342(a)(2)(A), 346 (1976).

time it implies that no tolerance may exceed the highest level that poses no risk to health. However, the lowest achievable levels of some environmental contaminants undoubtedly exceed the levels that can confidently be called safe. For a contaminant, such as aflatoxin, that has been proved an unequivocal animal and probable human carcinogen, most scientists would agree that *no* level of exposure can be judged safe for all individuals. Yet section 406 does not appear to contemplate that, in such a circumstance, forbidding marketing of the contaminated food is an appropriate alternative.

The FDA has essentially ignored this textual dilemma. The agency has never acknowledged that it must establish tolerances for all "unavoidable" contaminants of food regardless of the risks posed to consumer health. At the same time, it has declined to adopt the "no threshold" rationale for regulating carcinogenic contaminants of important food products, most notably peanuts contaminated with aflatoxin. In effect, the agency has interpreted section 406 as permitting consideration of the food's value, as well as the contaminant's toxicity and the extent to which its occurrence can be controlled. Such consideration is seldom explicit and often conducted under the guise of assessing the practicability of storage or processing procedures designed to reduce the substance.

A third criterion, while not explicitly sanctioned by the Act, is nonetheless considered by the FDA in establishing a section 406 tolerance: the capability of analytical methods to measure the contaminant.¹⁰¹ No agency can enforce a tolerance below the level that practicable analyses can detect. The capability of chemical analysis may be a primary determinant of a tolerance for a toxic contaminant if, for example, the best method available is not sufficiently sensitive to measure levels that theoretically are avoidable.¹⁰² If no method could measure the level considered necessary to protect public health, the agency would face having to establish a tolerance it could not enforce. One alternative—to

101. *Cf.* Poisonous or Deleterious Substances: Final Rule, 42 Fed. Reg. 52,814, 52,816 (1977) (in establishing tolerances, the Commissioner will establish the method of detection to be used). *See also* Letter from Donald Kennedy, Commissioner of Food and Drugs, to J.B. Cordaro, Group Manager, Food Group, Office of Technology Assessment (Jan. 22, 1979) (copy on file with the *Michigan Law Review*).

102. In 1974, when the FDA first confronted the need to determine the marketability of PBB-contaminated foods produced in Michigan, it initially established its "action level" (a form of "tentative" tolerance, *see* note 85 *supra* and accompanying text) at the lowest level measurable by the best available analytical methods. Hearings on Polybrominated Biphenyls in Lansing, Michigan (May 29, 1975) (testimony of Dr. Albert Kolbye).

conclude that no tolerance could be established—would be pointless, because the FDA could not prove a violation of section 402(a)(1) or (2)(A) if it could not detect the ostensibly “unlawful” contaminant. In such a case, the FDA would set the tolerance at the current limit of detection by the best practicable method of analysis.

The Act’s elaborate procedure for establishing tolerances under section 406 partially accounts for the FDA’s failure to make use of this section for many years.¹⁰³ The agency must first publish a proposed tolerance and invite public comments. After evaluating the comments, the agency must publish a “final order” after which objections and requests for a formal evidentiary hearing may be filed. Such a filing stays the FDA’s tolerance pending the hearing.¹⁰⁴ Following the formal administrative proceedings, including an administrative law judge’s initial decision and any appeal to the Commissioner of Food and Drugs, the agency issues an order establishing the tolerance, which is subject to review in the courts of appeals.¹⁰⁵

Partly because of the expense and duration of that procedure, the FDA has devised an informal system for setting “action levels” for environmental contaminants of food. An action level specifies the quantity of an added poisonous substance that will move the FDA to initiate court enforcement action against a food under section 402(a)(1).¹⁰⁶ It represents a formalized exercise of the agency’s prosecutorial judgment, although it does not carry the same authoritative weight in enforcement proceedings as a formal 406 tolerance.¹⁰⁷ The FDA regulations state that the

103. 21 U.S.C. § 371(e) (1976). See Hamilton, *Rule Making on a Record by the Food and Drug Administration*, 50 TEXAS L. REV. 1132 (1972).

104. 21 U.S.C. § 371(e)(2) (1976). A tolerance that is stayed by objections and a request for a hearing serves as an “action level” for FDA enforcement during the pendency of the hearing. See note 85 *supra* and accompanying text; Poisonous or Deleterious Substances: Final Rule, 42 Fed. Reg. 52,814, 52,818 (1977).

105. See 21 U.S.C. § 371(f) (1976).

106. See Poisonous or Deleterious Substances: Final Rule, 21 C.F.R. § 109.4(b) (1978); Poisonous or Deleterious Substances in Food: Notice of Proposed Rule Making, 39 Fed. Reg. 42,743 (1974).

107. For example, in the case of aflatoxin contamination of corn, a United States district court in Georgia refused to enjoin a distributor of grain from shipping corn containing a quantity of aflatoxin in excess of the FDA’s informal action level of 20 parts per billion (ppb). *United States v. Boston Farm Center*, No. 77-42 (M.D. Ga. Dec. 7, 1977), *rev’d.*, 590 F.2d 149 (5th Cir. 1979). Instead of accepting the FDA’s determination that the presence of 20 ppb aflatoxin rendered the corn injurious to health, the district court examined the evidence and concluded that aflatoxin-contaminated corn was not injurious to health unless the quantity of aflatoxin present exceed 100 ppb. The district court’s ruling was reversed by the Court of Appeals for the Fifth Circuit, which concluded that

agency will establish an action level for a contaminant, rather than initiate proceedings to establish a formal tolerance, when data on safe levels of exposure are incomplete or when the levels at which the contaminant occurs appear to be in flux.¹⁰⁸ The same criteria ostensibly govern the setting of action levels as apply to the establishing of formal 406 tolerances.

As noted previously, for many years the FDA regulated pesticide residues on raw agricultural commodities through a system of informal administrative tolerances which served the same function as the current action levels. However, because of the current interest in environmental contaminants and the controversiality of judgments about the safety of levels of exposure and about the ability of food manufacturers to reduce them,¹⁰⁹ the FDA now provides an opportunity, albeit a limited one, for public participation in the setting of action levels. When the agency identifies a contaminant that should be controlled, *e.g.*, mercury in fish, it announces in the Federal Register the action level at which it will initiate court enforcement. Simultaneously, the agency makes available for public examination whatever toxicity and human exposure data underlie its initial determination. Interested persons may submit comments on the exposure level approved, and the agency may respond to the comments if persuaded that the level initially announced should be revised.¹¹⁰ This procedure represents a modest advance beyond the agency's older practice, in which action levels were not publicly announced, but it falls short of permitting effective debate over the agency's judgment about safety, avoidability, and the value of the food.

"the facts in this case are so one-sided that any finding of non-adulteration for amounts of aflatoxin between 20 ppb and 100 ppb would be clearly erroneous." 590 F.2d at 151. The court of appeals did not, however, rule that it was in principle inappropriate for the lower court to reexamine the FDA's action level.

108. See *Poisonous or Deleterious Substances: Final Rule*, 42 Fed. Reg. 52,814, 52,817 (1977); *Poisonous or Deleterious Substances in Food: Notice of Proposed Rule Making*, 39 Fed. Reg. 42,743, 42,745 (1974).

109. See, *e.g.*, Letter from Donald Kennedy, Commissioner of Food and Drug Administration, to Congressman William M. Brodhead (Aug. 12, 1977) (denying petition to lower action levels for polybrominated biphenyls) (copy on file with the *Michigan Law Review*).

110. *Poisonous or Deleterious Substances: Final Rule*, 21 C.F.R. § 109.4(b) (1978). This procedure represents a retreat from the agency's original proposal, which would have provided notice-and-comment rulemaking for the establishment of action levels, with one important difference: any "proposed" action level would be enforced in the interim. See *Poisonous or Deleterious Substances in Food: Notice of Proposed Rule Making*, 39 Fed. Reg. 42,743, 42,746 (1974). Under the procedure finally adopted, the FDA's action levels will not be the product of a public proceeding, and may therefore carry less weight in court enforcement actions. See note 107 *supra*.

C. *Intentional Ingredients of Processed Foods*

For purposes of legal analysis, this third category of food constituents must be divided into four subcategories which, although they present similar problems of safety evaluation and regulatory control, are subject to different statutory treatment. These four subcategories are artificial statutory creations; they do not correspond to functional categories in the production of food. Furthermore, the classifications themselves reflect historical distinctions that bear no relation to either functional or safety criteria. The Act's definition of "food additive," considered below, is illustrative. The four subcategories are: (1) "food additives" used as ingredients in foods, (2) ingredients that are "generally recognized as safe," (3) "prior sanctioned substances" used as ingredients in food, and (4) "color additives."

Popular misconception assumes that "food additives" are artificial substances used in food production while natural ingredients, such as salt or potatoes, are simply that—ingredients. In fact, not every artificial substance used to make food is a food additive. Moreover, the Act does not distinguish between ingredients produced by chemical synthesis and those produced naturally by agriculture. The definition of food additive, which appears in section 201(s) of the Act,¹¹¹ embraces both artificial and natural substances while simultaneously excluding several important classes of ingredients:

The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), *if such substance is not generally recognized*, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) *to be safe under the conditions of its intended use; except that such term does not include—*

(3) *a color additive; or*

(4) *any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph . . . pursuant to*

111. 21 U.S.C. § 321(s) (1976).

this Act, the Poultry Products Inspection Act . . . or the Meat Inspection Act of March 4, 1907. . . .¹¹²

The subcategory of food additives thus does not include substances whose use in food is "generally recognized as safe" by qualified experts, a category commonly referred to by the acronym GRAS. In addition, the definition excludes most ingredients that either the FDA, or, in the case of meat and poultry, the Department of Agriculture, had sanctioned for use in food prior to September 6, 1958. It also excludes color additives. Each of these exceptions is examined after a discussion of the requirements applicable to food additives.

1. *Direct food additives*

Any ingredient that is a food additive, *i.e.*, that is not generally recognized as safe, must be the subject of an approved food additive regulation before it may lawfully be used in food,¹¹³ and the FDA may not approve a food additive unless it meets certain basic criteria. Most important, the proponent of an additive must show that it will be safe under the conditions of its intended use. This requires a demonstration that, with reasonable certainty, the additive will not adversely affect the health of consumers.¹¹⁴ The Delaney Clause reinforces this requirement by flatly prohibiting the approval of a food additive that has been shown to induce cancer in man or, by ingestion or other appropriate tests, in animals.¹¹⁵

112. *Id.* (emphasis added).

113. Section 402(a)(2)(C) declares a food adulterated "if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409." 21 U.S.C. § 321(a)(2)(C) (1976). Section 409(a), 21 U.S.C. § 348(a) (1976), provides in relevant part:

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (1)(C) of section 402(a), unless—

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such as additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402(a).

114. See 21 U.S.C. § 348(c)(3)(A) (1976). See generally Freedman, *Reasonable Certainty of No Harm: Reviving the Safety Standard for Food Additives, Color Additives, and Animal Drugs*, 7 *ECOLOGICAL L.Q.* 245 (1978).

115. 21 U.S.C. § 348(c)(3)(A) (1976). Neither the Delaney Clause nor any other provision of § 409 specifically mandates that the FDA shall withdraw approval of an approved additive subsequently found to induce cancer or to be otherwise unsafe, but this requirement seems an unmistakable inference from the provisions governing initial ap-

A food additive must also be shown to be functional, *i.e.*, capable of accomplishing its intended technical effect.¹¹⁶ For example, a preservative must preserve when used in the quantities intended. If this elementary criterion is satisfied, however, the FDA may not demand any showing of the additive's broader utility or consider the availability of alternatives that would accomplish the same technical effect.¹¹⁷ The Food Additives Amendment acknowledges the "benefits" many additives can provide, and reflects Congress's judgment that the market—not the government—should determine the extent to which "safe" food additives are used.¹¹⁸

The FDA may condition its approval to assure that use of an additive will be safe.¹¹⁹ Such conditions typically include limitations on the levels of use and can include limitations on the foods in which or the purposes for which the additive may be used. Occasionally, the FDA may restrict the form in which an additive may be marketed, *e.g.*, solely as a tabletop sweetener.¹²⁰ And the

proval of food additives. The FDA has historically assumed that a clear finding of carcinogenicity ordinarily requires prompt action to terminate approval of an additive. *But see* note 56 *supra* and Culliton & Waterfall, *supra* note 56.

116. This standard is implicit in the requirement of § 409(b)(2)(C) that a food additive petition contain "all relevant data bearing on the physical or other technical effect such additive is intended to produce." 21 U.S.C. § 348(b)(2)(C) (1976).

117. *See* Saccharin And Its Salts, 42 Fed. Reg. 19,995, 20,002 (1977); Freedman, *supra* note 114, at 251.

118. Both the House and Senate reports stated:

The question of whether an additive produces such effect (or how much of an additive is required for such effect) is a factual one, and does not involve any judgment on the part of the Secretary of whether such effect results in any added "value" to the consumer of such food or enhances the marketability from a merchandising point of view.

H.R. REP. NO. 2284, 85th Cong., 2d Sess. 6 (1958); S. REP. NO. 2422, 85th Cong., 2d Sess. 7 (1958).

119. 21 U.S.C. § 348(c)(1)(A) (1976) specifies:

(1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

120. Authority to do so is less obvious than the authority to specify the foods to which

act explicitly permits the agency to prescribe labeling for the additive, apparently to provide information to commercial users.¹²¹ The FDA has on occasion, thus far without formal legal challenge, used this authority to prescribe labeling requirements for the finished foods in which an additive is used.¹²²

Because section 409 requires the FDA to verify the safety of a food additive before it may lawfully be used, a petitioner seeking approval, usually the manufacturer or a potential user, must submit to the agency data sufficient to support a finding of safety.¹²³ The FDA has developed informal standards for the toxicological tests a petitioner must submit to establish a food additive's safety.¹²⁴ The type and extent of testing required are likely to vary with the quantities in which, and the purposes for which, the additive is to be used. Although it has not always done so, the FDA reportedly now requires that any direct additive to be used at significant levels in food be tested in long-term animal feeding studies to determine whether it may induce cancer or other chronic effects. The agency also now requires testing for teratogenic effects (birth defects) and routinely suggests, though it does not require, mutagenesis testing.¹²⁵

While occasionally a petitioner may feed an additive to

an additive may be added from the language of § 409(c)(1)(A), but has been exercised occasionally. *See, e.g.,* Saccharin and Its Salts, 42 Fed. Reg. 19,995 (1977); Aspartame, 39 Fed. Reg. 27,317 (1974). The FDA's approval of aspartame, another artificial sweetener, has since been stayed. 40 Fed. 56,907 (1975)).

121. 21 U.S.C. § 348(c)(1)(A) (1976).

122. *E.g.,* BHA, 21 C.F.R. § 172.110(c) (1978); sodium nitrite, 21 C.F.R. § 172.175(b) (1978); potassium iodide, 21 C.F.R. § 172.375(b) (1978); aspartame, 39 Fed. Reg. 27,317 (1974).

123. *See* 21 U.S.C. § 348(b) (1976).

124. A petitioner can ascertain these standards by asking the agency's Division of Food and Color Additives, but they are not set forth in detail in the *Code of Federal Regulations* or any other publication. 21 C.F.R. § 170.20(a) (1978) merely states:

In reaching a decision on any petition filed under section 409 of the act, the Commissioner will give full consideration to the . . . adequacy of the methods employed to demonstrate safety for the proposed use, and the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council

The regulations governing the form and content of food additive petitions are brief and general. *See* 21 C.F.R. §§ 170.20, .22, 171.1, .6, .7 (1978).

125. Letter to the author from Joseph V. Rodricks, Ph.D., Assistant to the Director for Science Policy, Bureau of Foods, U.S. Food and Drug Administration (September 28, 1978) [hereinafter cited as Rodricks letter]. Some uncertainty remains about the extent to which the FDA routinely requires long-term testing for direct food additives, and there apparently have been exceptions to the generalization set forth in the text. A deficiency in the agency's administration of § 409 has been its failure to spell out, in regulations or some other formal policy statement, precisely what tests it regularly requires.

human volunteers¹²⁶—usually to demonstrate palatability or functionality—the data for evaluating safety are derived almost exclusively from animal experiments. The critical tests are those designed to yield probabilistic answers to broad questions, such as whether an additive causes cancer. If a food additive induces cancer in animal tests, its use may not be approved at any level. If an additive's effects do not include cancer, the agency applies a "safety factor" to determine permissible human exposure. Except in special cases,¹²⁷ the agency adheres to a safety factor of 100, dividing the dose at which no adverse effects are observed in animals by 100 to derive a dose that will, with reasonable certainty, be safe in humans. When the agency relies exclusively on short-term, or acute, studies, as it frequently does in evaluating indirect additives to which exposure is lower, it will apply a higher safety factor, usually 1000.¹²⁸

The FDA would be the first to acknowledge that this process does not guarantee that an additive may not prove harmful to some individuals. Debate continues over whether experimental animals are suitable models for evaluating the likely effects of a substance in humans. In the final analysis, a 100-fold safety factor is arbitrary, justified as much by ease of use as by any theory of comparative biology.¹²⁹ And the relatively small number of animals typically used in feeding studies weakens the statistical reliability of a finding that a particular dose produces no adverse effects.¹³⁰ The FDA's determination that an additive is "safe," therefore, suffers from several uncertainties. But the licensure process for food additives provides greater assurance of the reliability of such determinations than can be ascribed to judgments about the safety of other food constituents, such as environmental contaminants, which may have undergone very little testing and

126. See 21 U.S.C. § 348(i) (1976).

127. In 1976, the General Accounting Office sharply criticized the FDA for allowing saccharin to be used at levels corresponding to 1/30 of the "no observed effect" dose in animals. The agency acknowledged that this allowance departed from its standard practice. REPORT OF THE COMPTROLLER GENERAL OF THE UNITED STATES, NEED TO RESOLVE SAFETY QUESTIONS ON SACCHARIN 27 (Aug. 16, 1976).

128. 21 C.F.R. § 170.22 (1978); Rodricks letter, *supra* note 125.

129. Conversation with Joseph V. Rodricks, Ph.D., Assistant to the Director for Science Policy, Bureau of Foods, U.S. Food and Drug Administration (March 1977).

130. Saccharin and Its Salts, 42 Fed. Reg. 19,995, 19,998 (1977); see Page, *Chronic Toxicity and Carcinogenicity Guidelines*, 1 J. ENVTL. PATHOLOGY & TOXICOLOGY 161, 177-78 (1977); Doniger, *Federal Regulation of Vinyl Chloride: A Short Course in the Law and Policy of Toxic Substances Control*, 7 ECOLOGY L.Q. 497, 512-13 (1978) (and sources cited therein).

which the FDA must take the initiative to control.¹³¹

The statutorily prescribed process for approving or withdrawing approval of a food additive is as complex as that required for the establishment of tolerances under section 406,¹³² although the procedures are not identical. The FDA must announce in the Federal Register the filing of any petition for a food additive regulation—the equivalent of the petitioner's "proposal"—and later publish a final order of approval or disapproval.¹³³ If a petition is accepted for filing, the agency usually will approve the additive.¹³⁴ Any person adversely affected by the agency's action may file objections and request a formal evidentiary hearing.¹³⁵ Under section 409, however, the FDA need not stay its order pending that hearing; thus, the agency's approval of an additive may become effective even though it has granted a hearing on its underlying finding of safety.¹³⁶ The Commissioner's final decision following a hearing is subject to review in a court of appeals.¹³⁷ Essentially the same procedure must be followed when the FDA

131. The principal difficulty in determining the risk posed by an environmental contaminant of food, or any other constituent for which advance FDA approval need not be obtained, is the shortage of reliable safety data. No "petitioner" need seek permission to market swordfish containing mercury, and thus the burden of assembling data and, in some cases, conducting necessary additional tests falls on the government, often on the FDA or state agencies. Letter from Donald Kennedy, Commissioner of Food and Drugs, to J.B. Cordaro, Group Manager, Feed Group, Office of Technology Assessment (Jan. 22, 1979) (copy on file with the *Michigan Law Review*); Conversation with Robert S. Jackson, M.D., Assistant State Health Commissioner and Director, Office of Health Protection and Environmental Management, Virginia Department of Health (Oct. 22, 1978); Rodricks letter, *supra* note 125.

132. See text at notes 103-06 *supra*; letter from Donald Kennedy, Commissioner of Food and Drugs, to J.B. Cordaro, Office of Technology Assessment (Jan. 22, 1979) (copy on file with the *Michigan Law Review*).

133. 21 U.S.C. §§ 348(b)(5), (c)(1)-(2) (1976); 21 C.F.R. §§ 171.1(i)(2), .100 (1978).

134. Conversation with Joseph V. Rodricks, Ph.D., Assistant to the Director for Science Policy, Bureau of Foods, U.S. Food and Drug Administration (March 1977).

135. 21 U.S.C. § 348(f) (1976); 21 C.F.R. § 171.110 (1978). The FDA has construed "person adversely affected" to embrace opponents of the approval of an additive which the Commissioner has concluded is safe, as well as manufacturers or users of additives whose petitions are turned down. See Aspartame, 39 Fed. Reg. 27,317 (1974); 40 Fed. Reg. 56,907 (1975) (staying effectiveness of aspartame regulation). *Food Chemical News* reports that "FDA-ers now believe the Board of Inquiry on Aspartame probably will not begin until spring and may be delayed until summer." *All UAREP Documents on Aspartame To Be Submitted to FDA*, FOOD CHEMICAL NEWS, Nov. 6, 1978, at 36.

136. 21 U.S.C. § 348(e) (1976). More than a year elapsed between the FDA's initial approval of aspartame, 39 Fed. Reg. 27,317 (1974), and its decision to stay the effect of the food additive regulation. 40 Fed. Reg. 56,907 (1975). During that time, the successful petitioner was technically free to market the additive even though the agency had agreed to grant a formal hearing on its decision. For practical and public relations reasons, the firm chose not to do so.

137. 21 U.S.C. § 348(g) (1976).

seeks to end use of an approved food additive, even if the agency invokes the Delaney Clause.¹³⁸ The Act provides no means for abbreviating this process if a petitioner or other objectors insist on their full procedural rights. However, the statute's elaborate procedure is rarely followed in full. Most food additive petitions are eventually approved, and in twenty years only two have provoked demands for a formal hearing.¹³⁹

2. *Ingredients generally recognized as safe (GRAS)*

As noted above, the statutory definition of "food additive" excludes any ingredient that is

generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. . . .¹⁴⁰

Congress limited the coverage of the Food Additives Amendment

138. When the FDA issues a regulation on its own initiative, *e.g.*, when the agency seeks to withdraw approval or ban an additive, the Act requires that at least 30 days expire between initial publication and issuance of a final order. 21 U.S.C. § 348(d) (1976). No such requirement applies to a regulation issued in response to a food additive petition. See Saccharin and Its Salts, 42 Fed. Reg. 19,995, 20,005 (1977).

139. Both are petitions for the approval of the artificial sweeteners cyclamate and aspartame. Cyclamate was banned as an ingredient in food in 1969, following the FDA's receipt of evidence suggesting that it might be an animal carcinogen. The sweetener had not previously been regulated as a food additive, but rather was being used—with the FDA's concurrence—on the premise that it was GRAS. The new evidence destroyed its reputation as safe, thus requiring the manufacturer to obtain approval of a food additive petition before the sweetener could lawfully be used again. In 1973, such a petition was submitted, and in 1976, FDA Commissioner Alexander M. Schmidt declined to approve it on the ground that doubts about the sweetener's carcinogenicity had not been resolved. 41 Fed. Reg. 43,754 (1976). The manufacturer, Abbott Laboratories, demanded and received a formal evidentiary hearing. Its interest in pursuing the matter through the full administrative process was probably stimulated by the FDA's announcement in April 1977 that it intended to ban the use of saccharin, the only artificial sweetener currently approved for use in this country.

The second § 409 proceeding that has resulted in a request for a hearing involves aspartame, a new sweetener that appeared to be an alternative to both cyclamate and saccharin. The FDA approved the food additive petition for aspartame in 1974. 39 Fed. Reg. 27,317 (1974). Its approval provoked formal objections and a request for a hearing from an attorney associated with the consumer movement and a member of a distinguished medical faculty, both of whom contended that the agency had misinterpreted data showing that the ingredient could cause brain damage in infants and children. The FDA agreed that a hearing was justified, and subsequently persuaded the affected parties to submit the dispute to a Public Board of Inquiry, a tribunal provided by agency regulations and resembling some conceptions of a "science court." 21 C.F.R. §§ 15.1-.45 (1978). The hearing on aspartame is expected to occur sometime in 1979.

140. 21 U.S.C. § 321(s) (1976).

in this fashion principally to forestall ostensibly needless testing of ingredients, such as salt, sugar, and other familiar substances, which had long been used in foods without evident harmful effect.¹⁴¹ The GRAS exception thus represents a rough congressional judgment about the priority for the FDA's evaluation of the safety of food ingredients.¹⁴²

Numerous cases have construed the basic criteria for finding that an ingredient is GRAS.¹⁴³ As the statute itself indicates, there are two classes of such ingredients: (a) those *currently* recognized by experts as safe on the basis of their common use in food prior to 1958 (usage alone after 1958 cannot support general recognition of safety),¹⁴⁴ and (b) those generally recognized by experts as safe on the basis of toxicological tests, whether such tests were conducted before or after 1958.¹⁴⁵ Experts need not be unanimous in their recognition of an ingredient's safety, but there must be a substantial consensus.¹⁴⁶ The FDA will reject a claim

141. See *Food Additives: Hearings on Bills To Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food Before the Subcomm. on Health and Science of the House Comm. on Interstate and Foreign Commerce, 85th Cong., 1st & 2d Sess. 442, 460-65 (1957-1958)*(statement of George P. Larrick, Commissioner of Food and Drugs).

142. As the cyclamate experience demonstrates, GRAS status affords an ingredient no protection comparable to that provided by a "grandfather clause," which usually permanently exempts existing activities or marketed products from new statutory requirements. See *Cyclamic Acid and Its Salts*, 34 Fed. Reg. 17,063 (1969).

143. Most of these decisions, it should be noted, have involved drugs intended for use in humans or in animals. The Act requires premarket proof of safety and effectiveness for any "new" human or animal drug, see 21 U.S.C. §§ 355, 360b (1976), and defines a "new drug" as one whose safety or effectiveness is not "generally recognized [by qualified experts]." 21 U.S.C. § 321(p)(1), (w) (1976). Accordingly, many of the decisions interpreting the criteria for premarket approval of drugs are relevant to interpreting the criteria for GRAS status. Moreover, several of the pertinent drug decisions involve drugs intended for use in food-producing animals, which may become components of human food. See, e.g., *United States v. Articles of Food & Drug, Coli-Trol 80 Medicated*, 372 F. Supp. 915 (N.D. Ga. 1974), *affd.*, 518 F.2d 743 (5th Cir. 1975); *United States v. 1,048,000 Capsules More or Less*, 347 F. Supp. 768 (S.D. Tex. 1972), *affd.*, 494 F.2d 1158 (5th Cir. 1974).

144. See *United States v. Naremcu, Inc.*, 553 F.2d 1138 (8th Cir. 1977).

145. For an ingredient to be eligible for GRAS status under this leg of the exception, the FDA requires essentially the same quantity and quality of scientific evidence as would be needed to support the approval of a food additive. 21 C.F.R. § 170.30(b) (1978).

146. *United States v. Articles of Drug Labeled "Quick-o-ver,"* 274 F. Supp. 443 (D. Md. 1967). The FDA's regulations state,

(a) General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific

to GRAS status that relies on toxicological tests ("scientific procedures") that have not been published in the scientific literature, where they can be evaluated by the scientific community.¹⁴⁷

The Act does not explicitly allow any consideration of utility or benefit in determining whether an ingredient is GRAS. Thus, the fact that salt has important preservative qualities should not in theory affect the determination. However, an ingredient's utility is likely to influence even scientists' judgments about its safety if it has been used for centuries prior to 1958. In this connection, it should be emphasized that the conclusion that an ingredient is not "generally recognized as safe" does not automatically preclude its use. If a petitioner can demonstrate that the ingredient presents no risk to consumers, it may be approved as a food additive under section 409(c).¹⁴⁸

For many ingredients, general recognition of safety is conditioned upon the user's observance of specified restrictions, including limits on levels, source, purpose, and even on the foods to which the ingredient may be added.¹⁴⁹ The FDA's published list of selected GRAS ingredients specifies limitations that in many instances are comparable to those imposed on the use of approved food additives.¹⁵⁰ However, the FDA has only occasionally attempted to prescribe special labeling requirements for such an ingredient or for the foods in which it is used.¹⁵¹

Because GRAS ingredients do not fall within the definition of "food additive," they are not technically subject to the Delaney

community knowledgeable about the safety of substances directly or indirectly added to food.

21 C.F.R. § 170.30(a) (1978).

147. 21 C.F.R. § 170.30 (b) (1978):

General recognition of safety based upon procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies and other data and information.

148. A conclusion that an ingredient is not GRAS may, however, interrupt its use, for a food additive may not lawfully be used until the FDA has issued a regulation approving its use—a process that can require several months or longer. The FDA has devised a system of "interim food additive regulations" to bridge this gap where it concludes that a sudden suspension of use would have unacceptable consequences. See note 155 *infra* and accompanying text.

149. 21 C.F.R. § 170.30(h) (1978).

150. See, e.g., 21 C.F.R. §§ 182.1180 (caffeine), .1440 (magnesium stearate), .1295 (ethyl formate) (1978).

151. See Substances Added Directly to Human Food Affirmed as Generally Recognized as Safe (GRAS), 21 C.F.R. § 184.1(f) (1978); see, e.g., Sorbitol, 21 C.F.R. § 184.1835(e) (1978).

Clause. In practice, however, the Delaney principle prevents the introduction or continued use of an ostensibly GRAS ingredient that is found in appropriate tests to induce cancer in experimental animals.¹⁵² Such a finding would undermine any basis for general expert recognition of the ingredient's safety, and thereby render it a food additive requiring affirmative FDA approval—approval that the Delaney Clause would formally preclude. This analysis explains the FDA's actions in the case of cyclamate, which before 1970 had been widely used in the belief that it was GRAS.¹⁵³ A report by the principal manufacturer of cyclamate that it might be an animal carcinogen destroyed that status, making its continued use unlawful overnight.¹⁵⁴

The cyclamate episode illustrates an important distinction between ingredients that are excepted from the food additive definition because they are GRAS and ingredients that are ex-

152. Any intentional food ingredient found to cause cancer in *humans* would be banned by the FDA as a matter of course, whether it was GRAS, prior sanctioned, or a food additive. The circumstance more likely to confront the FDA with increasing frequency, however, is the discovery that a food ingredient is an animal carcinogen, as in the case of saccharin.

153. 30 Fed. Reg. 15,856 (1965); Cyclamic Acid and Its Salts, 34 Fed. Reg. 17,063 (1969).

154. Cyclamic Acid and Its Salts, 34 Fed. Reg. 17,063 (1969). See S. Plotkin, *The Cyclamate Ban: Science, Politics, and Law 9-11* (April 1978) (unpublished thesis).

The conclusion suggested by the text is not dictated by the language of the statute, which does not specify whether the FDA can weigh the benefits of an ingredient in determining whether it is GRAS. It could be argued that by creating the GRAS exception, Congress recognized the utility of commonly used food ingredients, and that the agency should consider such utility whenever new information about the risks posed by a familiar ingredient comes to light. A candidate for such an analysis might be sodium nitrite, which is widely used in preparing cured meat products and whose benefits include preservation against botulism. Surely in such a case, one might argue, the FDA should be able to consider such benefits, *i.e.*, seek to avoid the ostensibly greater risk of botulism, in deciding whether to subject the ingredient to the rigorous standards of § 409(c).

No one has ever formally espoused this approach to the FDA, but it is hinted at in one FDA proposal, though not in a context that involved a potential carcinogen. See *General Recognition of Safety and Prior Sanctions for Food Ingredients*, 39 Fed. Reg. 34,194, 34,195 (1974). Its formal adoption at this late date would be very difficult to explain, and would effectively transform the GRAS exception into a genuine grandfather clause, subject to forfeiture upon the agency's finding that the benefits of an ingredient did not justify an exception to the requirements of § 409(c). Moreover, in determining whether the Delaney Clause should apply, no valid scientific basis exists for distinguishing between food additives, which require formal FDA approval, and GRAS ingredients. As a group, GRAS ingredients are less likely to be carcinogenic, simply because of their record of safe usage. The lack of evidence of adverse effects may also be a sufficient reason for assigning them a low priority for safety evaluation. But the health risks posed by a food constituent that is shown to induce cancer in experimental animals does not depend on the regulatory category into which it falls. See Hutt, *Public Policy Issues in Regulating Carcinogens in Food*, 33 *FOOD DRUG COSM. L.J.* 541, 548-50 (1978).

empt because the FDA or USDA had sanctioned their use prior to 1958: An ingredient's general recognition as safe is always vulnerable to new evidence casting doubt on its safety. An ingredient that ceases to be GRAS automatically becomes a "food additive," and must be approved by the FDA for its use to be lawful.¹⁵⁵

The Food, Drug, and Cosmetic Act does not mention procedures for determining whether an ingredient is GRAS: the statutory definition of food additive is in a legal sense self-executing. Shortly after the passage of the Food Additives Amendment, the FDA issued, and from time to time has amended, a nonexclusive list of ingredients that the agency was prepared to acknowledge were GRAS—and which, therefore, could lawfully be used without affirmative approval.¹⁵⁶ In addition, the agency has consistently acknowledged that a food manufacturer may determine for itself whether an ingredient it is considering using is GRAS.¹⁵⁷ Should a manufacturer independently conclude that an ingredient is, he runs the risk that the FDA will disagree and initiate regulatory action against the product, but in such an action the agency would have to prove in court that the ingredient was not GRAS.¹⁵⁸ Neither the ingredient's absence from the FDA's list nor the manufacturer's failure to consult the agency in advance would be relevant.

Under this loose system, numerous food ingredients have come into common use through the assumption by manufacturers—sometimes, but by no means always, endorsed by the FDA—that they are GRAS. The FDA does not have a complete inventory of such ingredients, and it lacks reliable information

155. The Act makes no provision for the transition between the loss of GRAS status and the approval as a food additive. To bridge this gap, the FDA has established procedures for the issuance of interim food additive regulations. 21 C.F.R. §§ 180.1-.37 (1978). An interim food additive regulation may be issued for an ingredient whose safety is questioned by new evidence but whose continued use, pending the conduct of the studies necessary to resolve the issue of safety, is found to pose no significant risk to human health. Since controversy about its carcinogenicity arose in the early 1970s, saccharin has been protected by an interim food additive regulation, as have mannitol and brominated vegetable oil (BVO). 21 C.F.R. §§ 180.25, .30, .37 (1978). See Freedman, *supra* note 114, at 259-64. The interim regulation for BVO was attacked as beyond the agency's authority; and upheld, in *Jacobson v. Edwards*, [1971] Food Drug Cos. L. REP. (CCH) ¶ 56,059.10 (D.D.C. 1971), *affd.*, (D.C. Cir. 1971).

156. Now codified at 21 C.F.R. § 182 (1978). The original list was initially proposed at 23 Fed. Reg. 9511, 9516 (1958).

157. See General Recognition of Safety and Prior Sanctions for Food Ingredients, 41 Fed. Reg. 53,600, 53,603-04 (1976).

158. See *United States v. Naremc Co., Inc.*, 553 F.2d 1138 (8th Cir. 1977); *United States v. 41 Cases, More or Less (Naremc Co., Inc.)*, 420 F.2d 1126 (5th Cir. 1970).

about the extent and levels of their use.¹⁵⁹ To enhance its control over the use of GRAS ingredients and better assure their safety, the FDA has established a program for reviewing the available scientific data on all listed GRAS ingredients and has created a formal procedure for “affirming” the GRAS status of individual substances.¹⁶⁰

3. *Ingredients previously sanctioned by USDA or FDA*

The Act’s definition of food additive also expressly excludes any substance used in accordance with a sanction or approval granted prior to [the enactment of the Food Additives Amendment] pursuant to this chapter, the Poultry Products Inspection Act¹⁶¹ . . . or the Meat Inspection Act of March 4, 1907¹⁶²¹⁶³ This is a genuine “grandfather clause” for food ingredients that the FDA or the USDA had affirmatively approved before the

159. The Acting FDA Commissioner observed in 1977 that about 2,100 direct food additives have been approved and went on to describe the remainder of the universe of food ingredients and other constituents:

There are over 400 nonflavor GRAS substances; approximately 1,650 flavors and spices, some of which are GRAS and some regulated additives; about 400 regulated direct food additives and on the order of 10,000 GRAS and regulated indirect additives. Additionally, there are some 65 regulated and 52 “provisionally listed” color additives

Food Additives: Competitive, Regulatory, and Safety Problems: Hearings Before the Senate Select Committee on Small Business, 95th Cong, 1st Sess., Part 1, 44, 52 (1977)(statement of Sherwin Gardner) [hereinafter cited as *Food Additives Hearings*]. See 21 C.F.R. §§ 181, 182 (1978). The agency derives its estimates of overall exposure from a variety of sources, including USDA records of food sales and surveys conducted by the National Academy of Sciences-National Research Council.

160. See 21 C.F.R. §§ 170.30(e).35, 184 (1978). The objective of this program is eventually to produce a single, comprehensive list of ingredients which, based on current toxicological criteria, have been affirmed to be generally recognized as safe, and whose continued use can be subjected to the conditions specified in the agency’s affirming regulation. It should be noted, however, that the agency’s review embraces only those substances that appear on the published GRAS list, and that the agency has been unable to devise a procedure to force users of unlisted ingredients to seek review and confirmation of their safety. See generally *Food Additives Hearings*, *supra* note 159 (statement of Sherwin Gardner, Acting Commissioner of Food and Drugs); Conversation with Peter Barton Hutt, Former Chief Counsel, United States Food and Drug Administration (Oct. 19, 1978).

161. Poultry Products Inspection Act, Pub. L. No. 85-172, § 2, 71 Stat. 441 (1957) (codified at 21 U.S.C. §§ 451-469 (1976)). The date of passage of this Act, August 28, 1957, fell so near the September 6, 1957 enactment of the Food Additive Amendment that very few substances qualify for exemption under its provisions. See Nitrates and Nitrites in Poultry Products, 42 Fed. Reg. 44,275, 44,376 (1977).

162. Meat Inspection Act of March 4, 1907, ch. 2907, 34 Stat. 1260 (codified in scattered sections of 5, 7, 16, 21, 43 U.S.C.).

163. 21 U.S.C. § 321(s)(4) (1976).

enactment of section 409 on September 6, 1958.¹⁶⁴ Although the FDA lacked formal authority to license food ingredients for general use prior to 1958, both it and the USDA routinely answered requests for an opinion about the safety of individual ingredients. In addition, the FDA exercised premarket control over, and thus approved, the numerous ingredients permitted to be used in foods covered by standards of identity.¹⁶⁵ The USDA had issued formal regulations describing permitted uses of many ingredients in meat and poultry products,¹⁶⁶ and in some instances the FDA formally acknowledged that the USDA had sanctioned certain substances for food use.¹⁶⁷ Though a continuing source of controversy, the kind of documentation needed to establish a "prior sanction" is principally a matter of interest for archivists, who can debate the significance of correspondence written or articles published by agency scientists in the early days of food regulation.¹⁶⁸ It need only be noted that the Food Additives Amendment excludes this class of previously sanctioned food ingredients, a class which is of uncertain size, and which enjoys a special regulatory status.¹⁶⁹

164. It is, however, a limited exception. So called "prior sanctioned" ingredients are excepted from the requirements for approval as food additives, but they are not exempt from the other food safety provisions of the Act, including § 402(a)(1). See 21 C.F.R. § 181 (1978).

165. For a discussion of FDA food standards of identity, see generally Merrill & Collier, "Like Mother Used to Make": An Analysis of FDA Food Standards of Identity, 74 COLUM. L. REV. 561 (1974). In the mid-1950s, approximately 50% of the foods purchased by American consumers were covered by standards of identity, which were designed primarily to preserve the economic quality but were also used by the FDA to restrict the use of potentially toxic ingredients. See *Atlas Powder Co. v. Ewing*, 201 F.2d 347 (3d Cir. 1952), cert. denied, 345 U.S. 923 (1953).

166. See, e.g., 9 C.F.R. §§ 319.300, 381.169 (1978).

167. See, e.g., Use of Sodium Nitrite, Sodium Nitrate, Potassium Nitrite and Potassium Nitrate, 37 Fed. Reg. 23,456 (1972).

168. See Gardner, *Sowbelly Blues: The Links Between Bacon and Cancer*, ESQUIRE, November 1976, at 112; Letter from Carol Foreman, Assistant Secretary for Food and Consumer Services, USDA, to Donald Kennedy, Commissioner of Food and Drugs (April 22, 1977) (copy on file with the *Michigan Law Review*); Letter from Donald Kennedy to Carol Foreman (July 12, 1977) (copy on file with the *Michigan Law Review*). As interpreted by the FDA, the "prior sanction" exception requires some evidence of official acquiescence, but such evidence can be very informal. No USDA regulations or FDA opinions used the magic language "sanctioned." Prior sanctions have been based on actions ranging from a scientist's publication of an article acknowledging the safety of an ingredient, to a USDA inspector's stamp of approval on processed meat, to the USDA's approval of labels bearing a statement of ingredients.

169. Because of the diverse evidence of approval accepted by the FDA, estimates of the number of ingredients that were sanctioned for one or more uses prior to 1958 are mere speculation, but persons familiar with the matter doubt the number exceeds 200. See 23 Fed. Reg. 9511, 9516 (1958); 24 Fed. Reg. 9368, 9369 (1959).

An ingredient's prior sanction status does not depend upon a contemporary evaluation of its utility or safety, but rests solely on the fact of prior approval by one of the two agencies. The FDA has historically assumed that a prior sanctioned ingredient is permanently grandfathered, *i.e.*, that it may never become a food additive so long as it is used for its sanctioned purpose, even if new evidence casts doubt on its safety.¹⁷⁰ Since the Delaney Clause only applies to food additives, an ingredient that has a prior sanction is therefore not automatically barred from use in food even if it is found to be an animal carcinogen.¹⁷¹

This does not mean that the FDA cannot restrict the use of a prior sanctioned ingredient that new evidence demonstrates is unsafe. Foods containing such an ingredient are still subject to the Act's basic adulteration provisions.¹⁷² But the agency must be able to show that the presence of the ingredient "may render" food injurious to health under section 402(a)(1). A finding that a prior sanctioned ingredient is a carcinogen would thus permit, but would not automatically require, the FDA to terminate its use.¹⁷³ Furthermore, the FDA has tentatively suggested that, in

170. See Hutt, *A Regulator's Viewpoint in HOW SAFE IS SAFE?* 116, 124 (1979).

171. In no clear instance has the FDA continued to approve the use of a prior sanctioned ingredient which has been found to induce cancer in experimental animals. The case most nearly on point is that of sodium nitrite, an ingredient used in the curing of many beef and pork products, notably including bacon. Faced with a recent finding that sodium nitrite causes cancer in laboratory rats, the FDA and Department of Agriculture are proposing to terminate all its uses but allow a phase-out period. Smith, *supra* note 56. When the Department of Justice advised that the present law did not allow the FDA to delay banning an additive found to cause cancer, the two agencies recommended to Congress that legislation be enacted to permit a phased withdrawal of nitrite from food. See Statement of Joseph A. Califano, Jr., Secretary of Health, Education and Welfare (March 30, 1979).

172. See 21 C.F.R. § 181.1(b) (1978). The exception's rationale is not difficult to fathom. Congress presumably knew of the FDA's practice of responding to manufacturer's inquiries about the safety of food ingredients, and was prepared to regard these responses as functional equivalents of food additive approvals. Furthermore, the special treatment accorded substances previously sanctioned by the USDA can be partially explained by the FDA's traditional deference to that department in the case of meat and poultry products, a deference that allowed Congress to consider such substances the USDA's concern.

173. 21 C.F.R. § 181.5(b) (1978); Prior-Sanctioned Food Ingredients, 38 Fed. Reg. 12,737 (1973); R. Kingham, *Statutory and Administrative Theories by Which FDA Avoids Applying the Delaney Clause* (Nov. 10, 1977)(unpublished manuscript on file with author). *Cf.* Use of Sodium Nitrite, Sodium Nitrate, Potassium Nitrite, and Potassium Nitrate, 37 Fed. Reg. 23,456 (1972) (in which the FDA because of its belief that certain uses of nitrites suspected of posing a carcinogenic risk were prior sanctioned, did not propose to ban those uses). The FDA might have invoked § 402(a)(1) had it not been persuaded of the benefits of nitrite. Nothing in the legislative history of the Food Additives Amendment would suggest that Congress ever contemplated the possibility that a prior sanctioned ingredient might be found to be carcinogenic. Indeed, Congress appears to

evaluating the appropriateness of regulatory action under such circumstances, it may consider *some* benefits of the ingredient's use. Thus, the agency once indicated that the capacity of sodium nitrite to prevent the growth of botulinal toxin in cured meat products may outweigh any risk of cancer from preformed nitrosamines.¹⁷⁴ This assertion is legally pertinent if sodium nitrite enjoys a prior USDA sanction under the Meat Inspection Act.¹⁷⁵ From a scientific standpoint, however, there is no reason why ingredients formally sanctioned for use by the FDA or USDA prior to September 6, 1958, should stand on a different footing, vis-à-vis Delaney, than ingredients regulated as food additives or used on the assumption they are GRAS. Nor is there any persuasive theoretical basis for permitting the FDA to consider the countervailing benefits of one class of ingredients but not of the others.

4. Color additives

Congress enacted the 1960 Color Additive Amendments¹⁷⁶ to assure the safety of substances used to impart color to foods, thereby carving out yet one more category of added food constituents to which special rules apply. While the amendments also apply to substances used to color drugs, devices, and cosmetics, the following discussion exclusively concerns colors that are used as ingredients in food. Section 201(t)(1) of the Act defines color additive broadly:

have given no thought to the possibility that some prior sanctioned ingredients might later prove to be harmful in any way.

174. See Use of Sodium Nitrite, Sodium Nitrate, Potassium Nitrite, and Potassium Nitrate, 37 Fed. Reg. 23,456 (1972); Nitrates and Nitrites in Poultry Products, 42 Fed. Reg. 44,375 (1977). See also General Recognition of Safety and Prior Sanctions for Food Ingredients, 39 Fed. Reg. 34,194 (1974). The only example the agency cited of benefits that might legitimately be considered is the antibotulinal effect of sodium nitrite.

175. In the case of a substance shown to induce cancer in laboratory animals, any opportunity to consider benefits of any kind depends on the substance's prior sanction, which shelters it against the Delaney Clause. The FDA sometimes has discovered that its assumptions about the legal status of an ingredient was mistaken. Assistant Secretary Foreman's letter to FDA Commissioner Kennedy, *supra* note 168, announcing that the USDA has not in fact sanctioned sodium nitrite for use in poultry came as a surprise, and departed from that department's informal historical position. Because it then had no evidence that sodium nitrite itself might induce cancer, the FDA was able to devise an interim solution that permitted the ingredient's limited continued use pending further scientific studies. See Nitrates and Nitrites in Poultry Products, 42 Fed. Reg. 44,375 (1977). However, confirmation that sodium nitrite is a carcinogen should, under the USDA's interpretation, automatically terminate its use in poultry products in the absence of congressional interference.

176. Color Additive Amendments of 1960, *supra* note 9.

The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and

(B) when added or applied to a food . . . is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.¹⁷⁷

The FDA has adopted a regulation limiting the circumstances in which the concluding exception might apply:

For a material otherwise meeting the definition of "color additive" to be exempt from section 706 of the act, on the basis that it is used (or intended to be used) solely for a purpose or purposes other than coloring, the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color.)¹⁷⁸

The regulatory requirements for color additives resemble those for food additives, with certain important distinctions: The Color Additive Amendments require premarket safety testing and FDA approval of all substances used to color food.¹⁷⁹ The manufacturer or would-be user of a color additive may petition the agency for a regulation permitting the color to be used in food. Before it may approve, or "list," a color, the FDA must find, with reasonable certainty, that the additive poses no risk to human health, that it accomplishes its intended effect, and that its use will not deceive consumers.¹⁸⁰ The agency may impose restrictions on the use of a color to assure that these criteria are satisfied. Such restrictions may include limits on levels of use,¹⁸¹ a require-

177. 21 U.S.C. § 321(t)(1) (1976).

178. 21 C.F.R. § 70.3(g) (1978). This regulation was not designed by the FDA to subject food additives which impart color to regulation under the Color Additive Amendments, rather than under the Food Additives Amendment, although it has that effect. Rather, it was adopted as part of a since-abandoned FDA scheme to subject certain cosmetic products to premarket clearance. See *Toilet Goods Assn. v. Finch*, 419 F.2d 21 (2d Cir. 1969).

179. A food containing a color additive that the FDA has not approved is adulterated. Color Additive Amendments of 1960, *supra* note 9, §§ 102(a)(2), 103(b) (codified at 21 U.S.C. §§ 342(c), 376(a) (1976)).

180. 21 U.S.C. §§ 376(b)(4),(5),(6) (1976); Freedman, *supra* note 114, at 253.

181. 21 U.S.C. § 376(b)(7) (1976).

ment that the FDA certify individual batches of the color to assure that the color actually used in food is identical to the substance shown in experiments to be safe,¹⁸² and specification of the foods in which a color may be used.¹⁸³ The FDA has also taken the position that, in certain instances, it may require informative labeling on foods that contain a specific color additive in order to facilitate safe use by consumers.¹⁸⁴

The Color Additive Amendments contain a Delaney Clause similar in language and identical in principle to the clause that appears in section 409.¹⁸⁵ This clause precludes approval for food use of any color additive shown to induce cancer when ingested by experimental animals. The Color Additive Amendments do not recognize a category of colors "generally recognized as safe"¹⁸⁶ and do not exclude from the definition of color additive substances that were sanctioned or used prior to 1960. The Delaney Clause in section 706 thus effectively applies to *all* food coloring agents.¹⁸⁷ Accordingly, the FDA could not engage in the kind of

182. 21 U.S.C. § 376(c) (1976). Such a requirement is not authorized for food additives.

183. See 21 U.S.C. § 376(b)(8) (1976).

184. The FDA has proposed to require label declaration of FDC Yellow No. 5 when used to color foods and ingested drugs, and to prohibit its use in certain drugs for human use. This proposal springs from evidence that a substantial number of consumers are allergic to the color. 42 Fed. Reg. 6835 (1977).

185. Color Additive Amendments of 1960, *supra* note 9, § 103(b) (codified at 21 U.S.C. § 376(b)(5)(B) (1976)), which reads in pertinent part:

A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal

186. This statement requires qualification. Under § 103(b) of the Color Additive Amendments of 1960, *supra* note 9 (codified at 21 U.S.C. § 376(b)(4) (1976)), a color additive shall be deemed suitable and safe for use in food—and thus automatically eligible for listing—if the FDA has published a finding that the substance is exempt from the definition of food additive because it is GRAS. This provision does not, however, exempt any color additive from the requirement of affirmative FDA approval.

187. The obligation to be accurate demands a further qualification. As the next paragraph of the text explains, the Color Additive Amendments did authorize the FDA to "provisionally list" colors then in use and believed to be safe, pending the completion of contemporary toxicological studies necessary to support full approval. As the Color Additive Amendments are drafted, the Delaney Clause does not apply to provisionally listed colors and it would be possible, in theory, to argue that the FDA might lawfully authorize provisional listing—and continued use—of a carcinogenic color additive. But

risk-benefit analysis previously suggested for sodium nitrite as a preservative in meat in evaluating a specific color that had been shown to be an animal carcinogen.¹⁸⁸

While Congress did not "grandfather" food colors already in use in 1960, it did accord them temporary special treatment. Section 203 of the Color Additive Amendments authorized the FDA to list "provisionally" colors then in use that were believed to be safe, in order to allow manufacturers to conduct the kind of toxicological testing required to support approval under the new law's scientific standards.¹⁸⁹ The provisional list was designed to permit an orderly transition from bifurcated regulation in which some colors were subject to little effective control,¹⁹⁰ to a scheme in which *all* color additives must be licensed. The only colors eligible for provisional listing were those in use in 1960.¹⁹¹

this argument would be even more fragile in this context than in the case of a once-GRAS food ingredients. See text at notes 152-54 *supra*. The Delaney Clause clearly would preclude permanent listing of such a color, and both the text and legislative history of the 1960 amendments make clear that provisional listing was to be temporary for all colors. In general, a provisional listing would terminate no later than the end of the 2½ year period beginning on the date of enactment. However, where necessary to complete scientific testing required for a particular additive, the Secretary could extend this period with respect to a particular color additive or use, if this is consistent with the protection of the public health and with the objective of completing these tests as soon as possible. H.R. REP. No. 1761, 86th Cong., 2d Sess. reprinted in [1960] U.S. CODE CONG. & AD. NEWS 2897-98. Moreover, the FDA has left no doubt that it regards evidence of carcinogenicity as fatal to a provisionally listed food color. *Certified Color Mfrs. Assn. v. Matthews*, 543 F.2d 284 (D.C. Cir. 1976); *Food, Drug, & Cosmetic Red No. 2*, 41 Fed. Reg. 5823 (1976).

188. Sodium nitrite has been used in curing poultry to stabilize or "fix" color. Once the USDA announced that sodium nitrite was not sanctioned for use prior to the 1958 Food Additives Amendment, the FDA faced the difficult task of differentiating the uses of this substance as a food and as a color additive, and determining the applicable statutory provisions for regulating its use. See 42 Fed. Reg. 44,376 (1977).

189. Color Additive Amendments of 1960, *supra* note 9, § 203. This section is not codified in the Food, Drug, and Cosmetic Act.

190. Prior to 1960, colors derived from coal-tar dyes were subject to stringent regulation under § 406(b) of the original 1938 Act, a provision that has since been repealed. As the FDA ultimately interpreted this provision, which required the agency to certify coal-tar dyes shown to be "harmless," it forbade approval of any color that produced toxic effects at any dosage in animal experiments—an extremely onerous standard. See *Fleming v. Florida Citrus Exch.*, 358 U.S. 153 (1958). By contrast, colors other than those derived from coal-tar dyes were subject merely to the criteria of § 402(a)(1). The Color Additive Amendments were designed both to relax the stringency of the "harmless" standard to permit the use of coal-tar colors shown to be safe at the levels proposed to be used, and to bring other colors under premarketing controls for the first time. See S. REP. No. 795, 86th Cong., 1st Sess. (1959); H.R. REP. No. 1761, 86th Cong., 2d Sess. (1960).

191. This transitional authority conferred by the Color Additive Amendments was potentially open-ended in that Congress did not specify a final date by which all pre-1960 colors were either to be approved or terminated. Although Congress did prescribe an initial 30-month period, Color Additive Amendments of 1960, *supra* note 9, § 203(a)(2), it also permitted the FDA to extend this period by regulation when necessary to complete requi-

Section 203 of the amendments made no provision for adding a new color to the provisional list to permit continued use while tests of its safety are being conducted.¹⁹²

The FDA has maintained a "provisional list" of color additives for over eighteen years, deleting some colors, such as F.D.&C. Red No. 2, whose safety came under serious challenge,¹⁹³ and permanently listing others as scientific data confirmed their safety.¹⁹⁴ In 1977 the agency publicly committed itself to a timetable for completing tests and evaluation of the nearly seventy remaining provisionally listed colors.¹⁹⁵ By the early 1980s, the FDA expects that no colors will be provisionally listed; all will either have been approved or dropped from the list.

The statutory procedures for denying or withdrawing approval of a listed color additive parallel those applicable to food additives, with an important difference.¹⁹⁶ If the FDA, after publishing a proposal and receiving comments, issues a final order terminating the "listing" of a color, the filing of objections accompanied by a request for an evidentiary hearing automatically stays the agency's order pending completion of the hearing.¹⁹⁷ Thus, the FDA may not summarily ban a permanently listed

site testing. By contrast, in the 1958 Food Additives Amendment, Congress specified a two-year, nonextendable transitional period. However, the 1958 law also built into the food-additive definition the exception for GRAS ingredients which permitted the FDA to postpone definitive evaluation of many "additives" for more than 30 years. See S. REP. No. 2478, 85th Cong. 2d Sess., reprinted in [1958] U.S. CODE CONG. & AD. NEWS 5303-08.

192. On at least one occasion, the FDA restored a once provisionally listed color to the list following a brief absence. The color was FDC Red No. 4, once used by all producers of maraschino cherries. The agency deleted the color in 1966 following a controversial study that suggested it might cause teratogenic effects in dogs, but was persuaded to restore the color's provisional approval when cherry producers demonstrated how little of the substance consumers would be exposed to. In 1976, the agency once more terminated the provisional listing for Red No. 4 on the ground that the petitioners for its approval had never performed the toxicological tests necessary to resolve the earlier questions about its safety. 41 Fed. Reg. 41,852, 41,854 (1976).

193. See, e.g., 41 Fed. Reg. 5823 (1976); 21 C.F.R. § 81.10(f) (1978).

194. E.g., Ferric Ferrocyanide (Iron Blue), 43 Fed. Reg. 54,235 (1978).

195. See Color Additives: Provisional Regulations; Postponement of Closing Dates, 42 Fed. Reg. 6992 (1977).

196. See 21 U.S.C. § 376(b), (c), (e) (1976). The Color Additive Amendments contain another distinctive feature. This is a provision, 21 U.S.C. § 376(b)(5)(C), (D) (1976), that allows the petitioner for a color whose potential carcinogenicity is in issue to request that the matter be referred to a special committee selected by the National Academy of Sciences. No similar provision is made for resolving the scientific issues involving other constituents of food, with the exception of pesticide residues on raw agriculture commodities. The authority to refer a color additive to an N.A.S. committee has never formally been invoked.

197. 21 U.S.C. § 371(e)(2) (1976).