

1962

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Minn. L. Rev. Editorial Board

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Recommended Citation

Editorial Board, Minn. L. Rev., "Federal Food, Drug, and Cosmetic Act: Recent Amendments" (1962). *Minnesota Law Review*. 2780.
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Federal Food, Drug, and Cosmetic Act: Recent Amendments

The Food Additives Amendment of 1958 and the Color Additive Amendment of 1960 significantly expand the role of government in the food, drug, and cosmetic industries. The author of this Note discusses the reasons leading to the enactment of this legislation, describes the mechanics of its operation, and examines some of the resulting administrative problems. He concludes that while the Amendments were necessary, certain changes in language and administration are required if their original objectives are to be realized.

INTRODUCTION

In 1946, a frozen food packer discovered that thiourea, a chemical, would retard the growth of mold on peaches while improving their color. Without further investigation, he applied thiourea to a batch of his peaches. The Food and Drug Administration (FDA), by a fortuity, learned of the packer's thiourea treatment before the peaches were shipped. It fed a sample of the treated peaches to laboratory rats. The following morning the rats were dead.¹

The extensive use of substances, such as thiourea, in foods, drugs, and cosmetics—a development occurring near the end of World War II—allowed industry to utilize new production and marketing techniques.² This development also benefited the con-

1. The purpose of this description is to illustrate the chemical additive problem, not to deliver a precise, accurate, factual rendition of the thiourea incident. In fact the "story" varies with each source reporting the incident. See Delaney, *Peril on Your Food Shelf*, American Magazine, July 1951, p. 18; Brecher, *The Chemicals We Eat*, Nation, June 23, 1951, p. 584; see also H.R. REP. No. 2356, 82d Cong., 2d Sess. 6 (1952).

2. A United Nations committee, comprised of members from both the Foreign Agriculture and the World Health Organization issued a report on the use of additives in foods in 1956. For the purpose of this report, "food additives" were defined as "nonnutritive substances added intentionally to food, generally in small quantities, to improve its appearance, flavor, texture, or storage properties." The report explains that additives perform a variety of beneficial functions and enumerates four technical purposes for their use. Food additives should be used: (1) to maintain the nutritional quality of food, (2) to enhance stability and reduce wastage of food, (3) to improve the appearance of food, and (4) to aid in food processing. *Report of the Joint FAO/WHO Committee on Food Additives: General Principles Governing the Use of Food Additives* 4, 6-8 (1956).

sumer. As the thiourea incident suggests, however, these advantages were sometimes accompanied by adverse and dangerous side effects.³ Though not required to do so, most processors were prudent enough to pretest these substances before distribution and to market only those which would not endanger the consumer.⁴ However, an irresponsible minority continued to market products which contained untested additives. The dangers created by this practice, though infrequent, did not escape congressional scrutiny. While Congress was aware of the advantages additives made available to industry, it was most concerned with the inadequate consumer protection provided by the 1938 Food, Drug, and Cosmetic Act.⁵ In 1950 Congress formed the Delaney committee to investigate the use of chemicals in food products with a view toward determining whether new legislation was needed to provide more adequate consumer protection and, simultaneously, to facilitate progress in food technology.

The activities of the Delaney committee stimulated an active interest in the additive problem—at least among contributors to popular magazines. Many articles published in a variety of magazines favored new legislation.⁶ Usually, by stressing the failure of the 1938 Act to require pretesting and by recapitulating occurrences such as the thiourea incident, these articles advocated increased regulation, including mandatory pretesting, of all additives. A typical contributor was the committee's chairman, Representative James J. Delaney. In 1951 he wrote:

Our food supply is being doctored by hundreds of new chemicals whose safety has not yet been established. . . .

* * *

3. The United Nations committee, see note 2 *supra*, also enumerated four purposes for which food additives should not be used: (1) to disguise the use of faulty processing and handling techniques, (2) to deceive consumers as to quality of the product, (3) to reduce foods' nutritive value, and (4) to substitute for sound, economically feasible, manufacturing practices. *Id.* at 9-10.

4. Peters, *The Scientific Significance of the Amendment to the Food-Manufacturing Industry*, 13 FOOD DRUG COSM. L.J. 800 (1958); Rankin, *Establishing Tolerances for Food Additives*, 13 FOOD DRUG COSM. L.J. 641, 644 (1958).

5. H.R. REP. NO. 2284, 85th Cong., 2d Sess. (1958); S. REP. NO. 2422, 85th Cong., 2d Sess. (1958); 104 CONG. REC. 17412-24 (1958).

6. See, e.g., Delaney, *Peril on Your Food Shelf*, American Magazine, June 1951, p. 18; *Tighter Food & Drug Law*, Business Week, Feb. 23, 1952, p. 162; Consumer Reports, July 1951, p. 326; Brecher, *The Chemicals We Eat*, Nation, June 23, 1951, p. 584; *Need Laws to Guard Food*, Science News Letter, Nov. 19, 1949, p. 327. *Contra*, Dunbar, *Are Chemicals Poisoning Our Food?*, Today's Health, Oct. 1952, p. 39. See also Gosnell, *Food-Additive Legislation—A Review of Fundamentals*, 12 FOOD DRUG COSM. L.J. 369, 370-71 (1957).

This potentially lethal situation is due to a curious loophole in our present laws—a tragic legal joker that permits us to become a nation of 150,000,000 guinea pigs guilelessly testing out chemicals *that should have been tested adequately before they reached our kitchen shelves.*⁷

Some alteration of the 1938 Act was clearly necessary. That this need was as urgent as Delaney and others suggested, however, was not clear. Those who expressed opposition to basic alteration of the 1938 Act insisted that advocates of more regulation were alarmists exaggerating the danger of chemical additives.⁸ These writers argued that with food scarcity fast becoming a real global threat, legislation requiring pretesting would be cumbersome and would substantially impede the one industry most in need of encouragement.

This Note will examine two recent amendments to the 1938 Food, Drug, and Cosmetic Act—the Food Additives Amendment of 1958⁹ and the Color Additive Amendment of 1960.¹⁰ The object of this Note is to discuss the Amendments' significant provisions, the mechanics of their operation, and several controversial problems they present. Generally, these Amendments represent an effort to adjust the 1938 Act to the advent of chemical additives. They also demonstrate that the objectives of the original congressional committee—to provide more adequate consumer protection and to facilitate progress in food technology—are not entirely compatible.

I. DEFECTS IN THE 1938 ACT

The Food, Drug, and Cosmetic Act of 1938,¹¹ though frequently amended, has retained much of its original vitality and still provides the framework for all food, drug, and cosmetic law. It is often referred to as the "basic act."

A. INADEQUATE CONSUMER PROTECTION

1. *Food Additives*

In 1958 adherents of the Delaney view persuaded Congress that the 1938 Act failed to provide the consumer with adequate pro-

7. Delaney, *supra* note 6, at 19, 112. (Italics in original.) Delaney did incidentally concede that many large firms pretested additives without being required to do so.

8. See, e.g., H.R. REP. No. 2356, 82d Cong., 2d Sess., pt. 1, at 34-39, pt. 2, at 1-6 (1952) (minority report); Dunbar, *Are Chemicals Poisoning Our Food?*, *Today's Health*, Oct. 1952, p. 39.

9. 72 Stat. 1784 (1958) (codified in scattered sections of 21 U.S.C.).

10. 74 Stat. 397 (1960) (codified in scattered sections of 21 U.S.C.).

11. 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301-92 (1958).

tection from dangerous food additives.¹² They based their arguments on two related facts which, in isolation, provided rather persuasive evidence of the inadequacy of the 1938 Act.¹³ (1) The Act did not ordinarily allow the FDA to reach dangerous additives until sold or consumed. (2) The Act required the FDA to sustain the burden of proving that a particular additive was, in fact, unsafe. Actually, to the extent that the FDA could inspect factories¹⁴ and obtain injunctions,¹⁵ additives could be "reached" prior to distribution. But the availability of either of these enforcement tools did not dispense with the arguments based on the FDA's burden of proof because neither would be sought without some reason to suspect a violation. Two arguments were advanced to support the position that the FDA's burden of proof resulted in insufficient consumer protection. First, it was difficult to marshal sufficient evidence; testing of additives suspected as unsafe often took as long as two years and, in the meantime, the additive's use continued.¹⁶ Second, cases were often tried by a lay jury; the FDA ran the risk of the jury's failure to comprehend the technical evidence required to establish a violation of the act.¹⁷

Despite the Delaney position, a consideration of the practicalities of the food industry itself suggests that the 1938 Act may have provided adequate consumer protection. Food suppliers have always depended on favorable publicity and a readily available market for their products. Their margin between financial success and failure has always been tenuous. Therefore, they could ill afford adverse publicity resulting from either injury to consumers

12. See note 5 *supra*.

13. See Rankin, *Establishing Tolerances for Food Additives*, 13 FOOD DRUG COSM. L.J. 641 (1958); Larrick, *The New Food-Additives Law*, 13 FOOD DRUG COSM. L.J. 634 (1958); Dunn, *The Federal Food, Drug, and Cosmetic Act of the United States*, 13 FOOD DRUG COSM. L.J. 407 (1958).

14. Section 704, 52 Stat. 1057 (1938), as amended, 21 U.S.C. § 374 (1958). It is estimated that 80% of the violations of the act have been detected by this method. *Hearings before the Committee on Interstate and Foreign Commerce on H.R. 2769, H.R. 3551 and H.R. 3604*, 83d Cong., 1st Sess. 2 (1953).

15. Section 302, 52 Stat. 1043 (1938), as amended, 21 U.S.C. § 332 (1958).

16. See 104 CONG. REC. 17413-14 (1958); Rankin, *Establishing Tolerances for Food Additives*, 13 FOOD DRUG COSM. L.J. 641 (1958).

17. See Dunn, *The Federal Food, Drug, and Cosmetic Act of the United States*, 13 FOOD DRUG COSM. L.J. 407, 412 (1958). The FDA was allowed only 25 dollars per day for expert witnesses. It has been argued that this weak bargaining position increased the FDA's disadvantage in the court room. See Harvey, *Administration of the Food, Drug, and Cosmetic Act*, 10 FOOD DRUG COSM. L.J. 441, 443 (1955). However, the availability of government experts in the FDA itself would seem to have minimized this burden.

or enforcement¹⁸ of the 1938 Act. That Act, which primarily sought to prevent adulteration and misbranding of food,¹⁹ was enforceable through seizure,²⁰ injunction,²¹ fine,²² and imprisonment.²³ Thus, notwithstanding the FDA's inability to reach defective goods prior to sale or consumption, it might be argued that the threat imposed by potential civil liability and the FDA's arsenal of civil and criminal sanctions may have resulted in sufficient consumer protection.

Even assuming that the various sanctions imposed a sufficient threat to the producer, it did not necessarily follow that the 1938 Act provided adequate consumer protection.²⁴ To the extent that the Act's regulatory scheme in fact operated as a deterrent, only willful violations were curtailed. The 1938 Act itself, which required no proof of criminal intent to establish a violation,²⁵ suggested that the food industry was peculiarly susceptible to the innocent misuse of innovations. The thiourea incident demonstrates that the use of food additives is such an innovation; therefore, the real justification for the additional consumer protection provided by the Food Additives Amendment would seem to lie in the threat posed by the likelihood of innocent violations.

2. Color Additives

Since the 1938 Act failed to recognize that natural colors are as hazardous, potentially, as synthetic (coal-tar)²⁶ colors, there was little dispute over the need for more adequate consumer pro-

18. For a thorough discussion of administrative and judicial enforcement of the 1938 Act, see Developments in the Law, *The Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 673-722 (1954).

19. *Id.* at 640-59.

20. Section 304, 52 Stat. 1044 (1938), 21 U.S.C. § 334 (1958).

21. Section 302, 52 Stat. 1043 (1938), 21 U.S.C. § 332 (1958).

22. Section 303, 52 Stat. 1043 (1938), 21 U.S.C. § 334 (1958).

23. *Ibid.*

24. In fact much of the evidence accumulated by the congressional committee tended to show that consumer health was inadequately protected. See *Hearings Before the House Select Committee to Investigate the Use of Chemicals in Food Products*, 82d Cong., 1st & 2d Sess., pts. 1-4 (1952); *Hearings Before the House Select Committee to Investigate the Use of Chemicals in Food Products*, 81st Cong., 2d Sess. (1950).

25. See § 301, 52 Stat. 1042 (1938), as amended, 21 U.S.C. § 331 (1958); see also Developments in the Law, *The Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 694-96 (1954).

26.

The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived.

H.R. REP. No. 1761, 86th Cong., 2d Sess. 6 (1960).

tection from dangerous color additives. A coal-tar color was not permitted in foods, drugs, or cosmetics unless it originated from a "batch" certified as safe after pretesting; products containing noncertified coal-tar colors were deemed adulterated.²⁷ On the other hand, there were no pretesting or certification requirements for the use of natural colors.²⁸ As a result, products polluted by dangerous natural colors could only be reached through the general adulteration provisions in the basic act.

B. TECHNOLOGICAL PROGRESS THREATENED—THE "HARMLESS PER SE" CONCEPT

Despite the fact that mandatory pretesting of additives was a concededly expensive proposition, many of the industries which would be affected supported the proposed additives legislation.²⁹ Certainly the more responsible elements, which had pretested additives before the enactment of the statutory mandate, were anxious to see their competitors bear this expense. But the primary reason for industry's support appears to have been the FDA's inflexible administration of the 1938 Act's adulteration provisions. Because of judicial construction of the previous law, the Food and Drug Act of 1906, this problem was virtually non-existent prior to 1938. With the passage of the 1938 Act, however, the FDA developed the "harmless per se" concept which threatened to impede the technological progress made possible by the use of additives. Under this standard, which was neither compelled by the language of the 1938 Act nor essential to adequate consumer protection, the use of any poisonous additive was *absolutely prohibited* even though it would be entirely safe and, perhaps, extremely beneficial at its ordinarily low level of use. Since many additives not "harmless per se" can facilitate progress in technology and even

27. See The Federal Food, Drug, and Cosmetic Act, ch. 675, §§ 402(c), 501(a)(4), 601(e), 52 Stat. 1047, 1049, 1054 (1938). See also Becker, *Courts and Food Colors*, 14 FOOD DRUG COSM. L.J. 330 (1959).

28.

It is unscientific also to differentiate between a natural source and a synthetic source of the same substance in determining whether or not such substance should be exempt from regulatory rules. All color additives should be proven harmless under conditions of intended use

Sherwood, *Scientific Problems under the Food-Additives Amendment, Illustrated by Color and Flavor Additives*, 13 FOOD DRUG COSM. L.J. 804, 808 (1958). See also *Color-Additive Amendments of 1960*, 15 FOOD DRUG COSM. L.J. 432, 436-37 (1960).

29. See 104 CONG. REC. 17413-14 (1958); H.R. REP. NO. 2284, 85th Cong., 2d Sess. (1958); S. REP. NO. 2422, 85th Cong., 2d Sess. 3 (1958).

protect public health, new additives legislation was justified even if more consumer protection were unnecessary.

1. Food Additives

The 1906 Food and Drug law prohibited the use of all food products containing "any added poisonous or other added ingredient which [might] . . . render such article injurious to health."³⁰ In *United States v. Lexington Mill & Elev. Co.*,³¹ the Supreme Court construed this adulteration clause as applying only to those substances with the established capacity to injure consumers. It overturned the government's condemnation of a "lot" of flour containing an added poisonous ingredient on the ground that the flour was not adulterated because the minute quantity added did not endanger the health of consumers.

The language of the 1938 Act seemed to permit a continuation of the *Lexington Mill* approach to food additives. The adulteration provision was almost identical to the analogous provision in the 1906 Act; it prohibited the sale of all foods "[bearing or containing] any poisonous or deleterious substance which may render it injurious to health."³² Section 406(a)³³ purported to permit, *within established tolerances*, the use of hazardous additives when required in food production or when unavoidable by good manufacturing practice. Yet *Lexington Mill* was abandoned by the FDA and replaced by the unscientific "harmless per se" concept.³⁴ For two reasons section 406(a) did not mitigate the effect of this harsh principle. First, the FDA interpreted the conditional test of section 406(a) so stringently that prior to 1954 a tolerance regulation was promulgated for only one substance.³⁵ Second, from the FDA's standpoint resort to section 406(a) was barred after the "Pesticide Chemicals" Amendment was enacted in 1954.³⁶ This section was originally designed to accommodate the frequent pres-

30. Food and Drug Act of 1906, ch. 3915, § 7, 34 Stat. 769.

31. 232 U.S. 399 (1914).

32. The Federal Food, Drug, and Cosmetic Act, ch. 675, § 402(a)(1), 52 Stat. 1046 (1938). This provision differed from the analogous provision in the 1906 Act in that it allowed the Commissioner to declare a food product adulterated if it *bore or contained* a poisonous or deleterious substance; he was no longer limited to those articles to which the hazardous substance had been *added*. This distinction has no bearing on the character of the substance that will adulterate an article.

33. Federal Food, Drug, and Cosmetic Act, ch. 675, § 406(a), 52 Stat. 1049 (1938). The present § 406 is identical to § 406(a) of the 1938 Act; the other subdivisions in the original § 406 have been repealed.

34. DUNN, LEGISLATIVE RECORD OF 1958 FOOD ADDITIVES AMENDMENT TO FEDERAL FOOD, DRUG, AND COSMETIC ACT at x (1938).

35. See 2 CCH FOOD DRUG COSM. L. REP. ¶ 3063.01 (1961).

36. *Ibid.* See also DUNN, *op. cit. supra* note 34.

ence of pesticide chemical residues in natural foods and the 1954 amendment provided for the establishment of tolerance levels for these residues.

2. *Color Additives*

Prior to *Flemming v. Florida Citrus Exch.*,³⁷ there was a dispute whether the "per se" rule applied to the use of color additives.³⁸ It was argued in that case that either *Lexington Mill* or section 406(a) permitted, at safe levels, the use of a poisonous coal-tar color in oranges.³⁹ The Supreme Court, however, approved the FDA's contention that a coal-tar color batch could not be certified unless "harmless per se" because the act required that the safeness of an additive was to be determined without regard to its effect on the health of consumers. After *Florida Citrus*, the FDA commenced a retesting program which led to the discovery that many colors listed as "harmless" were in fact toxic when highly concentrated.⁴⁰ Thus, applying the "harmless per se" test, there was a distinct possibility that many beneficial coloring agents would be decertified by the FDA. This possibility was, undoubtedly, disturbing both to Congress and to industry.

II. THE AMENDMENTS

A. EFFECT OF THE AMENDMENTS ON PRE-1958 LAW

The Food Additives Amendment of 1958 and the Color Additive Amendment of 1960, each in fact a series of amendments to

37. 358 U.S. 153 (1958), 1 B.C. IND. & COM. L. REV. 112 (1959).

38. Cf. Dohl, *Color Additives—Their Regulation*, 14 FOOD DRUG COSM. L.J. 717 (1959); Schramm, *Color Additives—Proposed Amendments*, 14 FOOD DRUG COSM. L.J. 708 (1959); Becker, *Courts and Food Colors*, 14 FOOD DRUG COSM. L.J. 330 (1959).

39. *Flemming v. Florida Citrus Exch.*, 358 U.S. 153, 157-62, 165 (1958). See Brief for Respondents other than Frank R. Schell, pp. 32-45. Though the argument based on § 406(a) would produce an eminently sensible result, it is difficult to accept analytically. Section 406(a) dealt generally with substances added to food out of industrial necessity. See text accompanying note 33 *supra*. Section 406(b) dealt expressly with coal-tar colors; it provided that "the Secretary shall promulgate regulations providing for the listing of coal-tar colors which are *harmless* and suitable for use in food . . ." (Emphasis added.) 52 Stat. 1049 (1938). Most likely this latter subsection was intended to remove coal-tar colors from § 406(a).

40. See H.R. REP. NO. 1761, 86th Cong., 2d Sess. 8 (1960). This retesting program may have provided one reason for the FDA's approval of the Color Additives measure. To remove a color from the certified list, the FDA had to establish its toxicity with extensive laboratory tests; to retest the entire list might have taken 20 years. 2 CCH FOOD DRUG COSM. L. REP. ¶ 3644 (1960).

the basic act, significantly change both the policy and substance of food, drug, and cosmetic law.

First, two fundamental policy changes may be isolated. (1) Instead of requiring the FDA to prove that an additive is in fact unsafe, these Amendments shift the entire burden of proof to industry. The producer must now establish, pursuant to pretesting requirements, the safeness of potentially unsafe additives before placing them on the market.⁴¹ (2) Except for the Delaney anti-cancer clauses which preclude the use of any additive found to induce cancer in man or animal regardless of the concentration required to induce the disease, the unrealistic "harmless per se" principle has been eliminated and replaced by the more flexible "safety in use" principle. The Secretary of Health, Education, and Welfare is permitted to establish, by regulation, tolerance levels and other restrictions as to the use of additives. Once an additive's use is sanctioned through this procedure, that substance will not "adulterate," within the meaning of the basic act, a food, drug, or cosmetic product.⁴²

Second, two changes are made in the substantive provisions of the basic act. (1) The Amendments shift the burden of proof to industry; they provide that all untested substances which qualify under the definitions of "food" or "color" additive⁴³ are unsafe.⁴⁴ Parties desiring to use these substances must assume the burden of establishing their safeness. To implement this change, the Amendments enlarge the statutory test for an adulterated food, drug, or cosmetic so as to include those articles affected by "unsafe" additives.⁴⁵ (2) The Amendments adopt the "safety in use" principle by establishing standards and procedures for determining

41. Any person holding a written guarantee of an additive's safety gains immunity from a few of the sanctions of the basic act. In most cases, however, he would be wise to pretest the additive even in this situation. See § 303(c), 52 Stat. 1043 (1938), as amended, 21 U.S.C. § 333(c) (1958); 2 CCH FOOD DRUG COSM. L. REP. ¶¶ 3572, 6327 (1960).

42. Cf. § 402(a)(2)(A), 74 Stat. 397-98, 21 U.S.C. § 342(a)(2)(A) (Supp. II, 1960).

43. The definition of "food additive" differs from the definition of "color additive" in one controversial respect. The Color Additive Amendment does not exempt from its provisions substances generally recognized as safe ("GRAS"). Compare § 201(s), added by, 72 Stat. 1784 (1958), as amended, 21 U.S.C. § 321(s) (Supp. II, 1960) (quoted note 52 *infra*, with § 201(t), added by 74 Stat. 397, 21 U.S.C. § 321(t) (Supp. II, 1960) (quoted note 60 *infra*). See notes 65-71 *infra* and accompanying text.

44. Food Additives Amendment of 1958, §§ 201(s), 409(a), 72 Stat. 1784, 1785, as amended, 21 U.S.C. §§ 321(s), 348(a) (Supp. II, 1960); Color Additive Amendments of 1960, §§ 201(t), 706(a), 74 Stat. 397, 399, 21 U.S.C. §§ 321(t), 376 (Supp. II, 1960).

45. Section 402, 52 Stat. 1046 (1938) (amended by 72 Stat. 1784 (1958) and 74 Stat. 397 (1960)), 21 U.S.C. § 342 (Supp. II, 1960).

whether an additive is safe or unsafe under the conditions of its intended use.⁴⁶ The Secretary may, on his own initiative, issue a regulation which permits an additive's use under certain tolerances and other restrictions. If the Secretary does not exercise this power, the party desiring to use the additive must petition for such a regulation. This party must first thoroughly pretest⁴⁷ the additive in question; then the petition, usually together with a sample of the additive, is filed with the FDA. This petition describes the intended use of the additive, its qualities, and the testing procedures utilized to secure the data which purport to establish its safety. The petition also recommends the appropriate restrictions as to quantity (tolerances) and methods with which the additive may be safely used. When considering the petition, the Secretary must determine whether the petitioner has proven that no harm will result from the proposed use of the additive.⁴⁸ Where the petition is adequate the Secretary will publish, in the *Federal Register*, a regulation which proposes to permit the use of the additive in question within the recommended tolerances and other restrictions. Parties "adversely affected" by either the proposed regulation or by the denial of the petition, may file objections with the Secretary requesting a public hearing.⁴⁹ If no hearing is requested, the Secretary publishes the proposed regulation in the *Code of Federal Regulations* as a final order. If a hearing is requested, the Secretary examines the record of this hearing before publishing the final order. At this point parties "adversely affected"⁵⁰ by the

46. Compare § 409, added by, 72 Stat. 1785 (1958), 21 U.S.C. § 348 (Supp. II, 1960), with § 706, added by 74 Stat. 399, 21 U.S.C. § 376 (Supp. II, 1960). "The term 'safe,' as used . . . in sections 409 and 706, has reference to the health of man or animal." Section 201(u), added by 72 Stat. 1784 (1958), 21 U.S.C. § 321(u) (Supp. II, 1960). This, of course, allows the Secretary to utilize, in framing regulations, data accumulated in tests conducted with laboratory animals.

47. Precedent for these predistribution controls is found in § 408 (Pesticide Chemicals Amendment) and § 505 ("new drug" provision) of the basic act. See also the Meat Inspection Act, 34 Stat. 674 (1907), 21 U.S.C. §§ 71-91 (1958).

48. For a detailed analysis of the criteria applied by the Secretary in evaluating petitions, see Rankin, *Establishing Tolerances for Food Additives*, 13 FOOD DRUG COSM. L.J. 641, 645 (1958). See also 2 CCH FOOD DRUG COSM. L. REP. ¶ 3562 (1960).

49. The petitioner's trade secrets, which are often contained of necessity in his detailed petition, are protected under § 301(j), 52 Stat. 1042, as amended, 21 U.S.C. § 331(j) (Supp. II, 1960), only until he requests a public hearing. Since many additives are in fact beneficial to the consumer, it does not seem unreasonable to suggest that some procedural alteration be made to allow producers to prove the safety and utility of questionable additives at these hearings without sacrificing trade secrets.

50. Which parties qualify as "adversely affected" under the Food, Drug, and Cosmetic Act is not clear. See *Reade v. Ewing*, 205 F.2d 630 (2d

Secretary's decision may appeal to a court of appeals; there the Secretary's order will be sustained if based on a "fair evaluation of the entire record."⁵¹

B. THE FOOD ADDITIVES AMENDMENT OF 1958

Since a "food additive" is *prima facie* unsafe and must be pre-tested according to the statutory procedure, the most important question for the supplier of a substance intended to be added to food is whether that substance is within the definition of "food additive." Generally, section 201(s)⁵² provides that a substance *intentionally*⁵³ added to food will be a "food additive" if, and only

Cir. 1953). *Compare* United States Cane Sugar Refiners Ass'n v. McNutt, 138 F.2d 116 (2d Cir. 1943), with *A. E. Staley Mfg. Co. v. Secretary of Agriculture*, 120 F.2d 258 (7th Cir. 1941). See also *American Lecithin Co. v. McNutt*, 155 F.2d 784 (2d Cir.), *cert. denied*, 329 U.S. 763 (1946); *Land O'Lakes Creameries, Inc. v. McNutt*, 132 F.2d 653 (8th Cir. 1943).

51. Sections 409(g)(2), added by 72 Stat. 1788 (1958), 21 U.S.C. § 348 (g)(2) (Supp. II, 1960); 706(d)(4), added by 74 Stat. 403 (1960), 21 U.S.C. § 376(d)(4) (Supp. II, 1960). This is a new standard for judicial review which replaces the previous standard of "substantial evidence on the record as a whole." The House Committee felt that this provided a fairer standard because it would restrain the court from upholding the Secretary's order on the basis of isolated evidence, "which evidence in and of itself may be considered substantial without taking account of contradictory evidence of possible equal or even greater substance." H.R. REP. NO. 2284, 85th Cong., 2d Sess. 6 (1958).

52. Section 201(s) provides:

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—

(1) a pesticide chemical in or on a raw agricultural commodity; or
 (2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(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 this Act or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).

Section 201(s), added by 72 Stat. 1784 (1958), as amended, 21 U.S.C. § 321(s) (Supp. II, 1960).

53. Additives which accidentally get into food are covered by other provisions in the basic act. 2 CCH FOOD DRUG COSM. L. REP. ¶ 3545 (1960); Rankin, *Incidental Additives*, 13 FOOD DRUG COSM. L.J. 7 (1958).

if (1) its use results, or may be reasonably expected to result, "in its becoming a component or otherwise affecting the characteristics of any food," and (2) it is not *generally recognized* among experts *as safe* ("GRAS")⁵⁴ under the conditions of its intended use. It is immaterial for the purpose of this amendment whether the substance is directly mixed in or put on the food (a "direct" additive), or migrates to the food from packaging material (an "indirect" or "incidental" additive).⁵⁵ The "grandfather clause" in section 201(s) excludes from the term "food additive" any substances approved prior to the enactment of the Food Additives Amendment pursuant to the basic act, the Poultry Products Inspection Act, or the Meat Inspection Act.⁵⁶

But even if a substance qualifies as a "food additive," under some circumstances, at least temporarily, the supplier will not be required to establish its safety. The Secretary may on his own initiative, as mentioned earlier, issue a regulation permitting the additive's use within certain appropriate restrictions. Also by regulation, the Secretary may exempt from the Amendment's provisions, products containing additives intended solely for investigation or research purposes.⁵⁷ Further, the FDA has published some lists granting an extension of time to users to prove the safety of certain enumerated additives.

C. THE COLOR ADDITIVE AMENDMENT OF 1960

The Color Additive Amendment enacted on July 12, 1960, utilizes the basic pattern set forth in the Food Additives Amendment. It consists of a "permanent" law which amends the basic act and a "temporary" law which in no way affects the basic act.⁵⁸ The "permanent" provisions will not become fully effective, for most purposes, until two and one-half years after the Amendment's enactment date. During this period the permanent provi-

54. See notes 65-71 *infra* and accompanying text. Substances used prior to 1958 can be considered "GRAS" among experts on the basis of either "common use in food," or "scientific procedures," whereas the experts may only examine substances introduced in food after 1958 on the basis of "scientific procedures." See note 52 *supra*. With respect to the FDA policy regarding "common use in food," see 21 C.F.R. § 121.1(f) (Supp. 1961); *Food and Drug Administration Answers to Questions Submitted at Conference Cosponsored by Administration and FLI at Washington on Nov. 16-17, 1959*, 15 FOOD DRUG COSM. L.J. 213, 217, 220 (1960).

55. See note 52 *supra*; 2 CCH FOOD DRUG COSM. L. REP. ¶ 3533 (1961).

56. Section 201(s)(4), added by 72 Stat. 1784 (1958), as amended, 74 Stat. 397, 21 U.S.C. § 321(s)(4) (Supp. II, 1960) (quoted note 52 *supra*).

57. Section 409(i), added by 72 Stat. 1788 (1958), 21 U.S.C. § 348 (Supp. II, 1960).

58. See 2 CCH FOOD DRUG COSM. L. REP. ¶ 3632 (1960).

sions govern only the use of "new" color additives.⁵⁹ The "temporary" provisions apply only to the previously authorized natural and coal-tar colors. These provisions provide for the provisional safe listing of these colors during the two and one-half year period before the "permanent" provisions begin to regulate the use of all "color additives."

The Amendment is generally considered a "relief measure" from the inflexible rules which developed under the 1938 Act. It purports to liberalize the rules under which the use of a color in or on foods, drugs, or cosmetics will be authorized, and to broaden the scope of authorized uses. These objectives led to two important changes in the basic act. First, and perhaps of most significance, the definition of "color additive"⁶⁰ results in a uniform application of the Amendment to *all* colors.⁶¹ "Color additive" is defined without reference to the term "coal-tar color" which eliminates the distinction made in the 1938 Act between natural and coal-tar colors. In addition, unlike the Food Additives Amendment, this amendment contains no "GRAS" or "grandfather" clause. Second, the Amendment removes color additives from the food additives provisions⁶² and creates a new section⁶³ containing all the substantive and procedural rules for establishing the safety of colors whether used in foods, drugs, or cosmetics.

59. The two and one-half year period may be either lengthened or shortened at the Secretary's discretion. Color Additives Amendments of 1960, 74 Stat. 404; 2 CCH FOOD DRUG COSM. L. REP. ¶¶ 3620, 3633 (1960).

60.

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, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substances) 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.

Section 201(t), added by 74 Stat. 397, 21 U.S.C. § 321 (Supp. II, 1960).

61. See notes 26–28 *supra* and accompanying text.

62. Section 201(s)(3), added by 74 Stat. 397, 21 U.S.C. § 321 (Supp. II, 1960).

63. Section 706, added by 74 Stat. 399 (1960), 21 U.S.C. § 376 (Supp. II, 1960). The function of the Secretary, with respect to approving additives, is not the same under the two amendments largely because of the wider scope of the Color Additive Amendment. He may list a color additive, with appropriate tolerances and other restrictions, as safe (1) for use generally in all foods, drugs, and cosmetics; (2) for general use with a limited group of products (*e.g.*, just drugs); or (3) for a limited use (*e.g.*, for external use only). Note, however, that an additive must be listed separately for use in each of the three types of products: foods, drugs, and cosmetics.

III. TWO PROBLEM AREAS

While the interpretation and administration of these amendments has resulted in many problems, two areas seem to merit special attention. The first concerns how far the definition of "food additive" can be extended. The other problem concerns the FDA's strict application of the controversial Delaney anticancer clause. In both areas the debate takes place between industry which is seeking to protect its earning capacity and the FDA which is seeking to secure more adequate protection for the consumer. An example of this conflict in interests was seen earlier in the discussion of the "harmless per se" principle developed by the FDA when administering the 1938 Act.⁶⁴ Under the Amendments industry has been more sensitive than the FDA to the practical difficulties encountered in achieving the objectives of the Amendments and has hesitated to meet these objectives when a change, even though feasible, in the existing pattern of production and marketing is required. The FDA, on the other hand, occasionally seems to disregard the practical difficulties created by its demands for literal compliance with the statutory provisions.

A. WHICH SUBSTANCES ARE STATUTORY ADDITIVES?

1. *The "GRAS" Clause in the Food Additives Amendment*

The "GRAS" clause exempts from the Food Additives Amendment any substance having the requisite characteristics of a "food additive" if it is

generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use⁶⁵

Substances already deemed "GRAS" appear on the "white list" which is published and continually supplemented by the FDA.⁶⁶

Probably because "GRAS" represents a possible method of avoiding the Amendment's pretesting requirements, few have challenged the clause itself. The FDA's administration of this clause, however, has received continued criticism from various elements

64. See notes 29-40 *supra* and accompanying text.

65. Section 201(s), added by 72 Stat. 1784 (1958), as amended, 21 U.S.C. § 321(s) (Supp. II, 1960) (quoted note 52 *supra*). See also note 54 *supra* and accompanying text. Those qualifying as experts must have training and experience in the general areas of biology, medicine, pharmacology, physiology, toxicology, and veterinary medicine. 21 C.F.R. § 121.3(e) (Supp. 1961).

66. 21 C.F.R. § 121.101 (Supp. 1961).

of industry.⁶⁷ To determine which substances are "GRAS," the FDA consults through correspondence a group of about 800 experts. When these experts are in substantial agreement as to the safety of a substance, it is deemed "GRAS" and placed on the "white list."⁶⁸ This resort to 800 experts is challenged as being not only inefficient because of the time required to evaluate 800 diversified replies,⁶⁹ but also unauthorized by the language of the "GRAS" clause.

Some writers have urged that the FDA should consult, in most cases, a group of experts much smaller than 800. The food additives "GRAS" clause allows the FDA to permit the use of a substance without pretesting if it is generally recognized as safe among "experts qualified . . . to evaluate *its* safety." This language suggests that for each substance under consideration the FDA must consult only those experts who have already tested and studied that substance. It is argued that a comparison of the food additives "GRAS" clause with the "GRAS" clauses in the Pesticide Chemicals Amendment (adopted in 1954) and the "new drug" provision (adopted in 1938), both part of the basic act, supports this conclusion. These latter two clauses only require that the experts be qualified generally to "evaluate the *safety of pesticide chemicals*" and to "evaluate the *safety of drugs*"; they do not require the experts to be specifically qualified to "evaluate *its* safety." Since the legislative history shows no congressional intent to have the food additives "GRAS" clause administered as the FDA has administered the other two "GRAS" clauses, it is argued that this difference in language manifests a congressional intention to apply a different administrative policy to food additives. Hence the FDA could properly consult 800 experts under the Pesticide Chemicals Amendment or the "new drug" provision, but not under the Food Additives Amendment.⁷⁰

67. See, e.g., Becker, *The GRAS Clause of the Food-Additives Amendment*, 15 FOOD DRUG COSM. L.J. 444 (1960); Hutchings, *The Food-Additives Amendment As Seen By the Technologist*, 15 FOOD DRUG COSM. L.J. 17 (1960); Oser, *Current Problems Posed by the Food-Additives Amendment*, 14 FOOD DRUG COSM. L.J. 574 (1959).

68. 2 CCH FOOD DRUG COSM. L. REP. ¶ 3542 (1960). In *Merritt Corp. v. Folsom*, 165 F. Supp. 418 (D.D.C. 1958), the court interpreted the "GRAS" clause in the drug provision of the basic act. It held that whenever there was a genuine difference of opinion among the experts as to a drug's safety, it was not "GRAS." No cases interpreting this clause in the Food Additives Amendment have been discovered.

69. See Hutchings, *supra* note 67; Hall, *Flavor Additives and the Food-Additives Amendment*, 15 FOOD DRUG COSM. L.J., 24, 28-30 (1960); Oser, *supra* note 67.

70. See Becker, *supra* note 67; see also Mulford, *Some Vexing Problems of Additives Under the New Law*, 15 FOOD DRUG COSM. L.J. 10, 11-12 (1960).

Notwithstanding these arguments, the FDA appears to have adopted a sound procedure for administering the food additives "GRAS" clause. Since a scientist can possess sufficient expertise to evaluate a substance without being previously familiar with that substance, the difference in language between the three "GRAS" clauses is not necessarily significant. The Amendments' policy of providing increased consumer protection seems to favor the consultation of a large group of experts because the use of more experts may increase the reliability of their composite judgment.⁷¹ Where only a few experts are familiar with the specific properties of a questionable substance, it is not "GRAS." The Amendment does not contemplate the clearance of largely unknown additives through the "GRAS" clause.

2. *Incidental Additives under the Food Additives Amendment*

The Food Additives Amendment applies equally to "direct" additives (those directly mixed with or put on food) and "indirect" or "incidental" additives (substances which actually migrate to food from packaging and other materials).⁷² The Amendment's effect on the suppliers of these additives has, however, been unequal. Its application to incidental additives has given rise to many problems not encountered by suppliers of direct additives. Most of the difficulty seems to stem from the FDA's unwillingness to adopt a more flexible administrative policy with respect to incidental additives.

The pretesting requirements of the Food Additives Amendment often pose a particularly onerous burden for the packaging industry because ordinarily only minute quantities of additives actually migrate to the food product. The packager is responsible not only for the actual "migrants," but also for the substances subsequently formed on or in the food as a result of the migration. The packager's problem is made more complex by the statutory requirement that a petition for the approval of an additive is insufficient if it fails to contain "a description of the practicable methods for determining the quantity" of the additive in question.⁷³ While it may be difficult to ascertain which substances in fact migrate to the food, it is often impossible to devise tests sensitive enough to determine the quantity of the additive migrating,

71. The justification for the "GRAS" clause itself depends upon this assumption.

72. See note 52 *supra*; 2 CCH FOOD DRUG COSM. L. REP. ¶ 3533 (1961).

73. Section 409(b)(1)(D), added by 72 Stat. 1785 (1958), 21 U.S.C. § 348(b)(1)(D) (1958).

the nature of the substance subsequently formed, and the quantity of that second substance.⁷⁴

But the difficulties created by the Amendment's application to incidental additives are not limited to suppliers of these additives, they are also reflected in the administration of the Amendment. Initially Congress was primarily concerned with regulating the use of direct additives. Yet petitions for the approval of incidental additives has occupied more of the FDA's time than petitions requesting the approval of direct additives.⁷⁵

It has been frequently suggested that exempting minute quantities of incidental additives from the Amendment's pretesting requirements (a "de minimis" exception) would avoid many of the difficulties which result from regulating the use of packaging materials. This proposal, which would minimize testing problems for industry and the FDA, would treat additives present in amounts below an established tolerance level as having a concentration of zero.⁷⁶ The FDA insists, however, that the language of the statute will not permit a "de minimis" exception⁷⁷ principally because minute quantities of some additives can be lethal. The FDA also argues that since the statute forbids the use of all substances not "GRAS" or otherwise exempt by regulation, the "de minimis" exception would result in the issuance of regulations which could not be practicably enforced. The FDA would not be furnished with practical methods for detection of incidental additives if small quantities could be disregarded by industry during pretesting.

Even if the FDA position is compelled by the language of the Amendment, there are several reasons why a "de minimis" excep-

74. See Nelson, *Incidental Additives to Food: Have We Made a Prudent Judgment?*, 16 FOOD DRUG COSM. L.J. 597, 600-05 (1961); Hall, *supra* note 69, at 30-31; Mulford, *supra* note 70, at 14-15; Kaufman, *Food Packaging and the 1958 Food-Additives Amendment*, 14 FOOD DRUG COSM. L.J. 649 (1959); Oser, *supra* note 67.

No attempt is made here to describe all the testing problems facing the packaging industry. It might be noted, however, that even those packagers not intentionally utilizing unknown substances in their product may be subject to the amendment. These processors must grapple with the difficult problem of proving that *no* migration occurs. Miller, *The Effect of the Food Law on Packaging Materials*, 17 FOOD DRUG COSM. L.J. 38, 40 (1962).

75. Nelson, *supra* note 74, at 599-600.

76. See, e.g., Oser, *supra* note 67, at 577-80; NATIONAL RESEARCH COUNCIL, FOOD PROTECTION COMMITTEE, FOOD AND NUTRITION BOARD, PRINCIPLES AND PROCEDURES FOR EVALUATING THE SAFETY OF FOOD ADDITIVES 8-9 (1959).

77. See Kirk, *Safety of Packaging Materials*, 15 FOOD DRUG COSM. L.J. 263 (1960); Rankin, *Incidental Food Additives*, 14 FOOD DRUG COSM. L.J. 768 (1959); Checchi, *Food-Additives Procedures and Policies*, 14 FOOD DRUG COSM. L.J. 591 (1959).

tion or something similar should be provided either by the FDA administratively, or by a change in the Amendment. The dispute between industry and the FDA appears to be largely factual. The FDA insists on strict application of the Amendment on the ground that any quantity of a migrating substance may be lethal. Industry, doubting whether the ordinarily low concentrations of packaging migrants are ever lethal, argues that even though this possibility exists the administrative policy should take into account the difficulty of detecting these substances. Until this factual dispute is resolved to the contrary, it seems at least arguable that at some point the cost resulting from strict compliance with the pretesting requirements by the packaging supplier will be out of proportion to the protection secured for the consumer.⁷⁸ This cost may also be out of proportion to whatever advantage can be gained through the use of the questionable packaging material. Where this is the case the supplier may elect either to discontinue the use of certain products or to use them in disregard of the statutory mandate. The consumer stands to lose either way. He may be denied the use of beneficial products or his health may be jeopardized by untested products.

B. THE DELANEY ANTICANCER CLAUSE

Easily the most controversial provision of the additives legislation is the Delaney anticancer clause. This provision, which is found in both Amendments,⁷⁹ forbids the Secretary to approve

78. Cf. Nelson, *supra* note 74.

79.

. . . [N]o 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;

Food Additives Amendment of 1958, added by 72 Stat. 1786, 21 U.S.C. § 348(c) (3) (A) (Supp. II, 1960).

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.

(C) (i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order . . . may

the use of any additive if, on the basis either of experience or reliable experiments, it is shown to induce cancer. The one difference between the two Amendments with respect to this clause is important only when it is invoked against a petition. The Color Additives Amendment allows the petitioner to request a review of his petition by an ad hoc expert advisory committee.⁸⁰ A similar provision was eliminated from the Food Additives Amendment shortly before its passage.⁸¹

As in other controversial areas under the two Amendments, most of the criticism of the anticancer clause is leveled at its interpretation and administration by the FDA. In interpreting this clause the FDA takes the position, not inconsistent with the language of the clause, that it is an absolute prohibition of carcinogenic (cancer inducing) substances.⁸² Thus, substances found to induce cancer will be barred regardless of the concentration required to induce the disease. In administering the anticancer clause, however, the FDA appears to have strained even this interpretation. For several types of additives the FDA seems to require proof of non-carcinogenicity.⁸³ The statute appears to prohibit the use of additives which *in fact* induce cancer;⁸⁴ it contains no prohibition of additives which *might* induce cancer. Also, the FDA appears to have adopted a strained interpretation of the word "induce." For example, there are reports that an additive which causes gall stones in test rats will be prohibited under the clause because

request . . . that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. . . .

Color Additive Amendments of 1960, § 706(b)(5)(B), added by 74 Stat. 400, 21 U.S.C. § 376(b)(5)(B) (Supp. II, 1960).

80. Section 706(b)(5)(C), added by 74 Stat. 400 (1960), 21 U.S.C. § 376(b)(5)(C) (Supp. II, 1960) (partially quoted note 79 *supra*).

81. Becker, *The Scientific Advisory Committee and the Administration of Color Additives*, 15 FOOD DRUG COSM. L.J. 801, 802-03 (1960); Oser, *Recent Developments on the Food-Additives Front*, 14 FOOD DRUG COSM. L.J. 254, 257-58 (1959). Many argue that a provision of this nature should now be added to the Food Additives Amendment. See, e.g., Gordon, *Problems Involved with the Administration of the Food-Additives Amendment*, 15 FOOD DRUG COSM. L.J. 777, 786 (1960).

82. This interpretation may well be the "plain meaning" of the clause. See note 79 *supra*. Yet, since the "safety in use" principle pervades both amendments, it might be argued that the Secretary may issue tolerance levels even for the use of carcinogens. Certainly the language does not preclude such an interpretation.

83. See Matson, *Scientific Judgment in Law and Regulation*, 15 FOOD DRUG COSM. L.J. 70, 77-78 (1960).

84. See note 79 *supra*.

the gall stones irritate the rats' gallbladders and thereby cause tumors.⁸⁵

For a number of reasons, many argue that the anticancer clause should be repealed.⁸⁶ As administered by the FDA, this clause refutes a basic policy objective of the Amendment—the "safety in use" principle. Only the Color Additives Amendment, with its provision for referral to an ad hoc committee,⁸⁷ leaves room for the exercise of scientific judgment. But since the FDA will bar any concentration of a carcinogen, the scientists will have little opportunity to exercise discretion even under the Color Additive Amendment procedure. Moreover, the clause is not conducive to efficient, predictable administration. Experts disagree as to the distinction between benign and malignant growths. There is no accepted definition of cancer. Also, there are no known practical, reliable methods for discovering carcinogenic substances.

In response, the FDA points out that since very little is known about cancer and there are no known tolerance levels any error should be made on the side of increased protection.⁸⁸ However, of all the suspected sources of cancer, the evidence gathered to indict food or color additives is the weakest.⁸⁹ The exact causes of many dangerous diseases are not established, but the statute only gives cancer special treatment.

A reasonable compromise between the FDA and the advocates of repeal of the anticancer clauses might permit the FDA to issue tolerances⁹⁰ for at least those carcinogens with known threshold levels. Some of the legislative history of this clause supports this construction. When the Food Additives Amendment was passed, many Congressmen who were aware of the "safety in use" principle thought that the Amendment's effect would be the same with or without the Delaney clause.⁹¹ Since the "safety in use" principle pervades both Amendments and permits the use of no additive which is dangerous under the conditions of its intended use there seems to be no need to isolate carcinogens.

85. See Oser, *Current Problems Posed by the Food-Additives Amendment*, 14 FOOD DRUG COSM. L.J. 574, 581-82 (1959).

86. See, e.g., Oser, *Modern Technology as Related to the Safety of Foods*, 15 FOOD DRUG COSM. L.J. 586 (1960); Oser, *supra* note 85; cf. Hagan, *The Food-Additives Amendment—Its Effect on Veterinary Drugs and Feed*, 15 FOOD DRUG COSM. L.J. 117 (1960); Ringuette, *Medicated Animal Feeds Under Food-Additives Amendment of 1958: A Case Study*, 15 FOOD DRUG COSM. L.J. 320 (1960).

87. See notes 80 & 81 *supra*.

88. See 2 CCH FOOD DRUG COSM. L. REP. ¶ 3648 (1960).

89. See Oser, *supra* note 85, at 581.

90. Cf. Depew, *Problems of Food Additive Regulation*, 16 FOOD DRUG COSM. L.J. 253 (1961); Matson, *supra* note 83.

91. S. REP. No. 2422, 85th Cong., 2d Sess. 11 (1958).

CONCLUSION

The long overdue Food and Color Additive Amendments make two significant alterations in the basic act. First, the burden of proof was shifted; industry is now required to pretest. Second, the "safety in use" principle was adopted; this permitted industry to exploit many additives previously unavailable because they were prohibited under the "harmless per se" concept. Yet the additive problem continues to warrant congressional scrutiny. Congress might now examine this legislation with a view toward simplifying its administration. The application of the "GRAS" clause, for example, might be restricted. The present practice of consulting 800 experts may prove unwieldy. Congress might also reconsider the all-inclusive "food additive" definition in light of the incidental additive problem. Finally, the administration of the anticancer clauses makes these provisions inconsistent with the basic objectives of the additives legislation; if these clauses are retained, they should be altered to incorporate the "safety in use" principle.