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REGULATION OF FOOD ADDITIVES NEVER ADDED: AN ODD MIXTURE OF SCIENCE AND LAW

Mary M. Krinsky

Several federal and state laws regulate additives, hazardous substances and insecticides in foods to safeguard public health. Since 1906, when the first comprehensive federal act to protect against adulteration of food was passed, scientific and technological developments have led to profound changes in the methods of manufacturing and selling foods and the methods of analyzing substances in foods. In response to these developments, the laws have been changed and amended.

The Federal Food, Drug and Cosmetic Act of 1938 as amended is currently the primary federal law which controls food impurities. The Act broadly prohibits the introduction or delivery for introduction into interstate commerce of any adulterated food, the adulteration of any food in interstate commerce, the receipt and delivery or proffered delivery of any adulterated food in interstate commerce, and the manufacture of adulterated food.¹ There are three types of proceedings brought by the Government for violations of the Act: seizure or libel actions, criminal proceedings, and injunctions.² In a seizure or libel action, the Government prefers charges of adulteration against a certain consignment of food in a U.S. District Court where the shipment is located and asks for condemnation. If the food is found to be adulterated, it is destroyed; if not, it is returned to the owner or (if unclaimed) sold or delivered to a public institution. Violations of the Act are a misdemeanor and a second offense is a felony; fines or imprisonment, or both, may be imposed upon conviction. Injunction proceedings may be brought to restrain future violations.

The Montana Food, Drug and Cosmetic Act enacted in 1967, which regulates food impurity on the state level, is substantially identical to the Federal Act. The Act broadly prohibits the manufacture, sale, delivery, holding or offering of adulterated food in Montana.³ Three types of proceedings may be brought by the state: detention or embargo of adulterated food or food suspected of being adulterated,⁴ criminal penalties (misdemeanor fines up to \$500 or

1. 21 U.S.C. § 331.

2. 21 U.S.C. § 334 (seizures); 21 U.S.C. § 333 (criminal proceedings); 21 U.S.C. § 332 (injunctions). During the first twenty years after the Act was passed, more civil actions (seizures and injunctions) were filed each year under the Act than under any other federal statute, and the number of criminal cases was also high. See 1 TOULMIN, LAW OF FOODS, DRUGS AND COSMETICS § 6.1 at 95 (2d ed. 1963).

3. REVISED CODES OF MONTANA (1947) [hereinafter cited as R.C.M. 1947] § 27-703.

4. R.C.M. 1947, § 27-706.

imprisonment up to six months or both),⁵ and injunctions to restrain prohibited acts.⁶

DEFINITION OF FOOD ADDITIVE

Both the federal and state statutes define a food additive as:

a substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food . . . , if the 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 . . . to be safe under the conditions of its intended use: except that this term does not include . . . a pesticide chemical in or on a raw agricultural commodity [or] . . . a color additive⁷

Under both Acts, food is "adulterated" if it contains an "additive" as defined.⁸ The adulterated food containing the additive may be seized and destroyed and the violation prosecuted as outlined above.

Note that the statute prohibits substances if they are not recognized as safe by scientific experts or excepted from the definition. This definition is not consistent with scientific usage of the term "food additive", which has been defined as:

a substance or a mixture of substances, other than a basic food stuff, which is present in food as a result of any aspect of production, processing, storage or packaging.⁹

The scientific usage includes only substances directly or indirectly added by the food industry. The statutory definition of "additive", on the other hand, is not limited to substances used in food production, processing, storage or packaging, and even includes substances naturally occurring,¹⁰ but specifically excludes pesticides on raw agricultural commodities and color additives. Therefore the statutory term "additive" is really a misnomer since it includes substances never added (incidental or accidental contaminants and naturally present toxins) but excludes many that are intentionally added. Yet, while the statute requires this artificial concept of an

5. R.C.M. 1947, § 27-705.

6. R.C.M. 1947, § 27-704.

7. R.C.M. 1947, § 27-702(t) and § 201(s) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(s).

8. R.C.M. 1947, § 27-710.

9. National Academy of Sciences definition. See Oser, *Food Additives*, 21 FOOD, DRUG COSM. L.J. 616, 618 (1966).

10. See, for example, a discussion of mercury in swordfish, Note, *Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish*, 85 HARV. L. REV. 1025 (1972).

“additive”, it also requires expert testimony on the safety of such “additives.” The legal classification of chemicals is neither scientific nor logical.

The problems which may result from this statutory definition are clearly illustrated by the recent *U.S. v. Vita Food Products* decisions.¹¹ The U.S. attempted to enjoin the distribution of fish containing some DDT. The district court reviewed the Federal Food, Drug and Cosmetic Act and decided that the pesticide residue, which had not been added in processing, was not a “food additive” within the meaning of the Act. It was, instead, a “pesticide chemical” subject to different regulations.¹² Since the food could not be considered adulterated with an unsafe food additive as a matter of law under the provisions of the Act, and as there was no showing of harm or hazard to health or adulteration with a pesticide chemical as a matter of fact,¹³ the allegations of the complaint were not sustained and the case was dismissed.¹⁴ The government appealed, and the Circuit Court of Appeals found this construction of the statute “illogical and unacceptable.”¹⁵ The Court reviewed the legislative history of the Act, cited a Senate Report showing an intent to include all incidental additives in the definition and decided the definition was broad enough to encompass pesticide chemical residues in processed food.¹⁶ Since DDT was not permitted by any tolerance regulations or generally recognized as safe, the fish were adulterated as a matter of law. The district court decision was reversed.¹⁷

These divergent views on the statutory definition of “food additive” may have an important influence on future decisions under this statute in Montana. The definitions are identical in the federal and state Acts and the Montana law specifically requires that additive regulations and safety standards in Montana conform to regulations promulgated under the Federal Act.¹⁸

11. *U.S. v. Vita Food Products of Illinois, Inc.*, 356 F. Supp. 1213 (N.D. Ill. 1973); *U.S. v. Ewig Bros. Co., Inc.*, *U.S. v. Vita Food Products of Illinois, Inc.*, 502 F.2d 715 (7th Cir. 1974), *cert. denied*, 95 S.Ct. 1324 (1975).

12. *U.S. v. Vita Food Products*, *supra* note 11 at 1219. Pesticide chemicals on raw agricultural commodities are regulated by 21 U.S.C. § 346(a). However, since the Federal Pesticide Control Act of 1972, some roles of the Secretary of Health, Education and Welfare set out in that statute have been taken over by the Environmental Protection Agency. In *U.S. v. Goodman*, 486 F.2d 847, 848 (7th Cir. 1973), DDT tolerance levels set by the Health, Education and Welfare guideline conflicted with the Environmental Protection Agency's ban on DDT. Overlapping regulation by multiple agencies can also create problems of enforcement. *See also*, 7 U.S.C. § 135 *et seq.* Pesticides are covered by the Montana Pesticides Act, R.C.M. 1947, §§ 27-213 to 27-245.

13. There is no tolerance for DDT on fish. Without a showing of harm to health, there is no adulteration.

14. *U.S. v. Vita Food Products*, *supra* note 11 at 1221.

15. *U.S. v. Ewig Bros.*, *supra* note 11 at 722.

16. *Id.* at 723.

17. *Id.* at 726.

18. R.C.M. 1947, § 27-709.

HISTORY OF FOOD ADDITIVE REGULATION

The legal definition of "additive", excluding some additives and including substances not added, was developed by Congress in attempts to remedy problems of food contamination as they arose. The demand for pure food regulation grew in the early nineteenth century with evidence of widespread food adulteration.¹⁹ The first federal legislation to broadly regulate adulteration and misbranding of food was suggested in 1879,²⁰ but a comprehensive national protection against adulteration was not secured until 1906 when the Food and Drug Act was passed.

Early court interpretations of the 1906 Act placed the burden of proof on the Government to establish that deleterious substances in food might render the article injurious to health.²¹ The Supreme Court held that, since the act was a criminal statute, creating a new offense, it must be strictly construed and applied.²² Thin silver coating on candy²³ and flour bleaching²⁴ were permitted, even though, in the latter case, the bleaching method used resulted in the formation of harmful nitrite residues. Because the Government could show no actual harm to health from consumption of the candy or flour, interstate distribution was permitted.

Congress amended the 1906 Act as defects in scope and application became apparent. Special provisions were added to prohibit fraudulent therapeutic claims (1912) and to require net weight specifications (1913) on packages, to include "wrapped meats" (1919) and butter (1923) under the Act, and to set certain standards for canned foods (1930) and seafood (1934).²⁵

Shortcomings were corrected and provisions consolidated by the 1938 Food, Drug and Cosmetic Act which broadly prohibited the addition to food of poisonous or deleterious substances, insanitary ingredients, or additives that might be injurious to health.²⁶ For the first time, attention was focused on the character of the additive. More importantly, the burden of proving the safety of the additive was shifted to the food industry. The law authorized the government to issue tolerance regulations prescribing amounts of additives that might be safely used. Pending the promulgation of such a regula-

19. An interesting, brief history (climaxed with deaths from eating peppermint lozenges) may be found in the introduction to BOYD, *PREDICTIVE TOXICOMETRICS* at 11 (1972).

20. A concise legislative history of early food adulteration laws may be found in 1 TOULMIN, *supra* note 2 in chapters 1 and 2.

21. *French Silver Dragee Co. v. U.S.*, 179 F. 824, 828 (2d Cir. 1910); *U.S. v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 402 (1914).

22. *U.S. v. Johnson*, 221 U.S. 488, 495 (1911).

23. *French Silver Dragee Co. v. U.S.*, *supra* note 21.

24. *U.S. v. Lexington Mill & Elevator Co.*, *supra* note 21.

25. 1 TOULMIN, *supra* note 2, § 1.4 at 6.

26. *Id.*, § 14.3 at 243.

tion, the addition of any poisonous or deleterious substance constituted adulteration as a matter of law.²⁷

Gradually, it became apparent that no additive could meet the test laid down. The procedure for approval of an additive was expensive and complex, as formal testing required at least two years. During the subsequent fifteen years, only one tolerance regulation was actually formulated and used.²⁸ The Food and Drug Administration controlled most additives by "suitable written notices or warnings"²⁹ rather than employing the statutory procedures. To soften the impact of a rule which established that even a trace of a deleterious substance constituted adulteration as a matter of law, courts read in the *de minimus* qualification that had existed under the previous statute.³⁰

THE FEDERAL FOOD ADDITIVE AMENDMENT OF 1958

The Food and Drug Administration recognized the problems associated with the use of the 1938 Act and, in 1950, recommended an amendment that would specifically regulate food additives.³¹ The Food Additives Amendment was passed in 1958.³² New categories of added substances, certain pesticides and "additives" were defined which, if used in food, constituted adulteration as a matter of law unless exempted. Though the food industry was still required to demonstrate that a given additive was safe before it could be used, the tolerance rulemaking procedure was simplified to correct the problems of the 1938 law. Additives generally recognized as safe by scientific experts were allowed.

Some pesticides were specifically exempt since they were covered by the Miller Pesticide Control Act of 1954.³³ Color additives were thought to warrant special attention and were handled separately.³⁴

The 1958 amendment followed six years of intensive hearings which included a considerable diversity of scientific opinions concerning the regulation of harmful additives.³⁵ As a result, the term "food additive" was defined so broadly that it included incidental and accidental additives as well as intentional additives, despite the

27. U.S. v. Ewig Bros., *supra* note 11 at 720.

28. *Id.*

29. Authorized by 21 U.S.C. § 336.

30. 338 Cartons, More or Less, of Butter v. U.S., 165 F.2d 728 (4th Cir. 1947); U.S. v. 484 Bags, More or Less, 423 F.2d 839, 841 (5th Cir. 1970).

31. See 1 TOULMIN, *supra* note 2 at chapter 22.

32. 21 U.S.C. §§ 301 *et seq.*

33. 21 U.S.C. § 346(a).

34. 21 U.S.C. § 376.

35. Post, *Food Additives: Legal Recognition of a Scientific Problem*, CLEV.-MAR. L. REV. 503, 516 (1960).

fact that no claim was made in the hearings that incidental additives were a major or even a substantial hazard to health,³⁶ and no testimony on accidental contaminants was offered. Though the term "additive" was given a statutory definition, the scientific or dictionary meaning was generally employed. The law provided that the Food and Drug Administration approve of additives "generally recognized as safe" before they be allowed in food and those so recognized be placed on an advisory list.³⁷ The general assumption that the additives amendment covered only substances actually added is evidenced by the fact that, of the petitions for listing as "generally recognized as safe" entertained by the Administration during the first eighteen months after passage of the law, only 257 involved chemicals which were incidental to processing, as contrasted with 1675 involving direct additives.³⁸ All had been added directly or indirectly to food by the food industry.

Although the amendment had been passed to solve the problems of the older statutes, new problems developed. Subsequent decisions under the amendment demonstrated confusion about what was an "additive". Processed foods contaminated with pesticides were generally treated separately from raw foods³⁹ as proscribed by the Act, even though different tolerance standards might exist for the same pesticide. Since the food additive statute required "general recognition of safety" among experts, a zero tolerance was allowed for chemicals not on the "generally recognized as safe" list.⁴⁰ In contrast, the other statutes for pesticide residues and color additives generally did not require this "general recognition".⁴¹ Theoretically, then, under this classification scheme, if fish were considered an agricultural commodity,⁴² raw fish could contain a pesticide chemical not "recognized as safe" and prohibited by the food additives amendment, but the chemical would not be classified as an

36. Nelson, *Incidental Additives to Food: Have We Made a Prudent Judgment?*, 16 *FOOD, DRUG COSM. L.J.* 597, 599 (1961).

37. The wording of the statute resulted in an advisory list of chemicals "generally recognized as safe." See Goodrich, *Safe Additives and Additives Generally Recognized as Safe—There is a Difference*, 15 *FOOD, DRUG COSM. L.J.* 625 (1960).

38. Nelson, *supra* note 36 at 600.

39. *U.S. v. Bodine Produce*, 206 F. Supp. 201, 210 (D. Ariz. 1962); *Environmental Defense Fund, Inc. v. U.S. Dept. of Health, Education and Welfare*, 428 F.2d 1083, 1086 (D.C. Cir. 1970); *Continental Chemiste Corporation v. Ruckelshaus*, 461 F.2d 331, 340 (7th Cir. 1972).

40. An absence of scientific knowledge on the part of an expert and his colleagues was considered sufficient to show lack of general recognition of safety; see, *Continental Chemiste Corporation v. Ruckelshaus*, *supra* note 39 at 340. Disagreement among experts created a question of fact for the jury. See *U.S. v. Goodman*, *supra* note 12 at 850.

41. *Continental Chemiste Corporation v. Ruckelshaus*, *supra* note 39 at 340.

42. The parties stipulated that chubs were raw agricultural commodities in *U.S. v. Goodman*, *supra* note 12 at 850.

“additive” or subject to additive regulations. If the same fish with the same concentration of chemical were smoked, it would contain a prohibited additive because the fish would no longer be a “raw agricultural commodity”. A Michigan court has drawn this distinction,⁴³ and the court in the *Vita Foods* case also addressed it. Some courts simply inferred a “common sense dictionary definition” and defined an additive as “something to be added”,⁴⁴ a definition of additive identical to that used before the amendment,⁴⁵ but most attempted to apply the statutory definition.⁴⁶

RECOGNITION OF SAFETY

In addition to requiring a classification of a chemical as a “food additive” rather than a “pesticide chemical” or “color additive”, the statute requires “general recognition of safety”. This has also caused some confusion.

Scientific advancement has resulted in improved quantitative analyses and bioassays to detect trace chemicals. For example, an unsafe chemical might be present, though undetectable, in food, and experts would consider the food safe. In later years, the same food would be determined to be unsafe when tested with improved procedures. Mass data on the effects of food additives simply are not available.⁴⁷ Proof of reasonable certainty that no harm will result has been the criterion of safety,⁴⁸ but sometimes there is considerable disagreement about what is “safety”,⁴⁹ and about the reliability of the tests used. In fact, in the *Vita Foods* case, the method used for the analysis of DDT had up to a 25% experimental error.

Furthermore, many chemicals banned under the food additives amendment as poisons of men are actually also poisons of insects, though not *used* as pesticides, and therefore not considered “pesticides.” However, the law still distinguishes “pesticides” from other chemicals of equal or greater toxicity.⁵⁰

43. *City Smoked Fish v. Michigan Department of Agriculture, Food Inspection Division*, 47 Mich. App. 125, 209 N.W.2d 267 (1973). See also, *U.S. v. City Smoked Fish*, Mem. Op. 33669 (D.C. Mich. 1970), mentioned in Myers, *Food-Additive as Adulteration*, 21 A.L.R. Fed. 314, 337 (1974).

44. *Toilet Goods Association v. Gardner*, 278 F. Supp. 786, 790 (S.D.N.Y. 1968).

45. *U.S. v. 1232 Cases American Beauty Brand Oysters*, 43 F. Supp. 749, 751 (W.D. Mo. 1942). This is essentially the National Academy of Sciences definition, *supra* note 9.

46. *U.S. v. 41 Cases, More or Less*, 420 F.2d 1126, 1131 (5th Cir. 1970).

47. Post, *supra* note 35 at 505.

48. Post, *supra* note 35 at 516; Mulford, *The Food Additives Amendment of 1958*, 17 *FOOD DRUG COSM. L.J.* 292, 295 (1962). Obstacles to F.D.A. decision-making include public pressures, inadequate data, difficulty in predicting future harm, and disagreement on adverse results. See Hult, *Safety Regulation in the Real World*, 28 *FOOD, DRUG COSM. L.J.* 460, 464 (1973).

49. *U.S. v. Vita Food Products*, *supra* note 11 at 1219-1220.

50. In fact, though pesticide residues have now accumulated in some places in the

The statute also prohibits some natural toxins present in food. The definition covers all substances "the intended use of which results . . . in its becoming a component . . . of food." The use is not restricted to use by the food industry; contamination may be condemned under the Act if the substance is ever used by anyone. Though swordfish have contained large amounts of mercury for centuries, the metal suddenly became an "additive" in 1970,⁵¹ as did the natural cyanide in an apple/apricot seed snack.⁵² Both were removed from the market. Yet other naturally occurring poisonous ingredients have not been made subject to regulation.⁵³

In addition, the law, though lengthy and specific, does not require an expert to take into account interactions between foods or cumulative or synergistic effects of components of various foods in the diet.⁵⁴ "Recognition of safety" under the law refers to the safety of eating only one food at a time!

CONCLUSION

The regulation of chemicals in food, actual additives as well as "food additives" never added, would be simpler if all substances in food—directly and indirectly added chemicals, pesticides, colors—were all covered by a single statute prescribing regulation by one agency promulgating one set of tolerance limits that could be used even as testing procedures are improved.⁵⁵ The piecemeal regulation of food additives has resulted in an odd mixture of science and law.

environment to levels that are catastrophic for certain animal populations, there is no report of chronic DDT poisoning recognized in man, it seldom causes illness, and it is not recognized as a serious poison for mammals. See SAPEIKA, *FOOD PHARMACOLOGY* 81, 130, 131 (1969); BROWN, *PESTICIDES IN CLINICAL PRACTICE* 446 (1966); Hodges, *The Toxicity of Pesticides and their Residues in Food*, 23 *NUTRITION REV.* 225, 226 (1965). Though DDT is stored in body fat, there was no reported increase in DDT levels in human fat between 1951 and 1962, during years of heavy DDT use. SAPEIKA at 130; Hodges at 229. In fact, most pesticide problems have resulted from improper use, accidental exposure, or deliberate ingestion. Hodges at 230. There was considerable diversity of expert opinion on DDT in the *Vita Foods* case, *supra* note 11 at 1219.

51. For a spirited protest, see Note, *supra* note 10 at 1026.

52. *Id.* at 1042.

53. Natural toxins and contaminants include solanine in potatoes; aflatoxins in peanuts; toxins in rice, SAPEIKA, *supra* note 50 at 8, 54; shellfish and ground nut meal, SAPEIKA, *supra* note 50 at 127; goitrogens in cauliflower and turnips, oxalates from spinach, cashews, almonds and cocoa; stimulants in tea and coffee; and pressor amines in bananas, pineapple, cheese and wine. A discussion of these and other substances may be found in Hall, *Toxic Substances Naturally Present in Food*, 25 *FOOD, DRUG COSM. L.J.* 387 (1970). Scientists have even whimsically speculated on the dangers of sugar consumption. Kleinfeld, *The Delaney Proviso—Its History and Prospects*, 28 *FOOD, DRUG COSM. L.J.* 556, 565 (1973).

54. Note, *supra* note 10, suggested labelling regulation to remedy this problem.

55. See, for example, the Canadian regulation. Kitchell, *Control of the Use of Food Additives in the United Kingdom*, 16 *FOOD, DRUG COSM. L.J.* 177 (1961); Pugsley, *Food Additive Control in Canada*, 15 *FOOD, DRUG COSM. L.J.* 487 (1960); Curran, *Food Additives Control in Canada*, 15 *FOOD, DRUG COSM. L.J.* 108 (1960).