

# FOOD SAFETY POLICY: PROBLEMS, PERSPECTIVES, AND POSSIBILITIES

**Sherwin Gardner\*/\*\*\***  
**Timothy Larkin\*\***

## INTRODUCTION

The evolution of federal food (and drug) safety legislation can be characterized as a series of forcing events producing major advances followed by comparatively lengthy periods of quiescence. Thus, after many years of inconclusive debate and study in Congress, the 1906 Food and Drugs Act<sup>1</sup> came about largely because Upton Sinclair's novel, *The Jungle*, with its graphic descriptions of unhygienic meat processing practices, shocked the American people into demanding action.<sup>2</sup> As Sinclair later put it, "I aimed at America's heart, and instead hit it in the stomach."<sup>3</sup>

The latest forcing event might well be described as what happens when a decision aimed at American's brain ends up by hitting it in its sweet tooth. This event consists of the consequences of the March 9, 1977, announcement by the Food and Drug Administration (FDA) of its intention to ban saccharin from human food based upon evidence that the sweetener was an animal carcinogen.<sup>4</sup>

This announcement produced an unprecedented outpouring of public disapproval,<sup>5</sup> leading to a congressionally mandated moratorium on FDA action against saccharin.<sup>6</sup> More importantly, however, the uproar concerning saccharin focused attention on the whole structure and philosophical basis of the nation's food safety policy. National attention to food safety standards was reinforced in July, 1978 by the prospect of regulatory action against nitrites, widely used

\*Sherwin Gardner was formerly the Deputy Commissioner of Food and Drugs from June 1972 to December 1979. He is now Vice President for Science and Technology with the Grocery Manufacturers of America, Inc. (GMA).

\*\*Timothy Larkin is a special assistant to the Commissioner of the FDA.

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1. Federal Food and Drugs Act of 1906, ch. 3915, § 7, 34 Stat. 768 (1906) (repealed 1938).
2. J. Young, *The Medical Messiahs* 34 (1967).
3. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 Law and Contemp. Prob. 1, 9 (1933) and Sinclair, "What Life Means To Me," *Cosmopolitan*, Oct. 1906, at 594.
4. 42 Fed. Reg. 19,996 (1977).
5. Consumer Reports, July 1977, at 410 for a representative sample.
6. 21 U.S.C.A. 343(o) and (p)(West Supp. 1978). The moratorium expired in May 1979; another bill extending the moratorium until June 30, 1981 was passed in the House of Representatives (H.R. 4453, 96th Cong., 1st Sess. (1979); Senate action has not been taken.

as a preservative to prevent meat from becoming dangerously tainted with the toxin produced by *C. botulinum*.<sup>7</sup>

The Saccharin Study and Labeling Act directed the Secretary of Health, Education and Welfare to arrange for separate studies of the safety and benefits of saccharin and, more importantly, also to explore the more fundamental question of the adequacy of current laws regulating food safety. The Institute of Medicine of the National Academy of Sciences completed its studies on both subjects on November 6, 1978 and March 1, 1979.<sup>8</sup>

The forcing events of the saccharin decision together with the debate over the introduction of legislation concerning nitrites were intensified by certain features of the political environment and by a series of other actions regarding food and food additives, many of which were also controversial.

There is an ongoing debate about the value to society of regulation, including questions about whether regulation is not subjecting society to greater cost than the benefits of such regulation warrant.<sup>9</sup> There are two kinds of regulation: economic and health; the latter encompassing environmental, occupational, and product safety regulations, including those products regulated by FDA. As pointed out by Alfred E. Kahn in a speech to the American Bar Association, health regulation is different in principle from economic regulation:

No one in his or her right mind could argue that the competitive market takes care of protecting the environment. In the presence of such externalities, and in the absence of regulation, competition becomes rivalry in the degradation of the environment, unless the government intervenes, producers and consumers will have no incentive to hold down the costs that they can slough off to others. As a result, they will refrain from making any expenditures, no matter how small, to cut down on those costs, no matter how large. Although there are some important differences in the cost of occupational and product safety, the fact remains that we as a society are unwilling to leave those to the operation of the free market.<sup>10</sup>

The national debate about the value of regulation in our society carried on in newspaper editorials and magazine articles is frequently at a high level of generalization where such distinctions are not made. The overall result is to intensify the pressure for a legitimate and long overdue evaluation of public policy in the food safety area. In regard to the form of regulation exercised by the FDA, the perception that their regulation is out of touch with the real world is heightened by the realization that there are major inconsistencies in the way the law regulates various substances.<sup>11</sup>

7. Due to the health risks attendant upon any sudden elimination of nitrates, on March 30, 1979, the Carter Administration sent to Congress proposed legislation to establish a one year moratorium on any action to ban nitrates. Under the terms of the proposal, should nitrate be shown not to be safe, the moratorium would be followed by a gradual nitrate phaseout, contingent on development of commercially feasible alternative preservatives. Congress has not acted on the proposal.
8. Committee for a Study on Saccharin and Food Safety Policy, Institute of Medicine and the National Research Council, Assembly of Life Sciences, National Academy of Sciences, Washington, D.C., Part I, *Saccharin: Technical Assessment of Risks and Benefits* (1978); Part II, *Food Safety Policy: Scientific and Societal Considerations* (1979).
9. Lyons, *Up-to-Date Technology, Out-of-Date Regulations*, N.Y. Times, Dec. 31, 1978; Porter, *Big Brother Approach Ends in Consumer Protection*, Wash. Star, Dec. 24, 1978; Rattner, *Regulating the Regulators*, N.Y. Times Mag., June 19, 1979; Weidenbaum, *Measuring the Costs of Regulation*, Wash. Post, Feb. 3, 1979; Schuck, *Regulation: Asking the Right Questions*, Nat. J., April 4, 1979 at 711; 125 Cong. Rec. S. 3327 (daily ed. March 26, 1979) (Presidential Message to Congress on Regulation Reform).
10. Remarks of Alfred E. Kahn before the American Bar Association, "The Role of Regulatory Reform in an Anti-Inflation Program," Dallas, Texas (August 15, 1979).
11. Joyce C. Lashof, "Food Safety at the Crossroads," keynote speech to Annual Meeting of the Food Safety Council, Washington, D.C. (December 14, 1978).

Thus, it seemed anomalous, if not absurd, for the Food and Drug Administration to propose disrupting commerce and personal habits to ban a popular food additive regarded as a weak carcinogen while contemplating no such action in regard to what most people, including the Surgeon General of the U.S., consider to be a strong carcinogen, cigarette smoking.<sup>12</sup>

Meanwhile, there were other FDA actions regarding food and food additives which often revolved around obscure or complex problems or dealt with possible threats to health rather than actualized ones (as most FDA actions do), and appeared to subject industry to major loss without tangible compensating gain.<sup>13</sup> These actions gave support to those who questioned either the logic being followed by the Agency in carrying out the requirements of food safety policy as required by law<sup>14</sup> or indicated that if FDA actions were indeed a logical extension of law, then these actions were in fact a regulatory *reductio ad absurdum* and therefore, clearly indicating that the law itself, in regard to food safety policy, should be changed. The purpose of this article is to define the scope of the problem, to review options available for food safety policies, and to suggest which among them might better satisfy contemporary goals of rationality and safety.

### DEFINING THE SCOPE OF THE PROBLEM

Because many of the most controversial proposals or actions by the FDA resulted from scientific studies revealing that various substances possess carcinogenic capacity, the primary target of suggestions concerning changes in food safety policy has been the so-called Delaney Clause, named for Congressman James J. Delaney of New York, Chairman of a House Committee created as a result of House Resolution 207. The Delaney Clause, which called for

12. On its face, this is a logical and reasonable question to explore. The fact that tobacco and foods are treated differently in our laws answers why no action is taken by the FDA against tobacco, but does not explain why our laws are designed this way or whether they should be more alike – one way or the other. As a matter of fact, FDA *can* regulate cigarettes – as a drug, if health claims are made by the manufacturer. For the most recent decision regarding the FDA's denial of a petition to have the FDA assert jurisdiction over cigarettes containing nicotine (or nicotine separately) as a "drug," see *Action on Smoking v. Califano*, (1978-79 Transfer Binder) Food Drug Cos. L. Rep. (CCH) paragraph 38, 219 (D.D.C. Jan. 16, 1979) *appeal docketed*, No. 79-1397 (D.C.Cir. Apr. 18, 1979).
13. "Background noise" from a number of continuing controversies added to the feeling that all was not well with the way the nation had designed its food safety policy. See particularly the matters of cyclamates and Aspartame, both artificial sweeteners. Cyclamate was initially banned by the FDA in 1970, but reapproval hearings and their sequelae continued in late 1979. Aspartame was initially approved by 1974, but objections were raised about whether it induces brain tumors in rats or contributes to mental retardation, brain damage or other undesirable effects. The FDA decided then to convene a Board of Inquiry (a mechanism designed to help the FDA Commissioner resolve scientific issues; it is an alternative to a formal evidentiary hearing before an administrative law judge) but postponed it when an investigation of Searle scientific studies on some drugs raised questions about the reliability of other studies conducted by/for the company, including the Aspartame studies. In December 1975, the FDA stayed Aspartame's approval pending a comprehensive review of the studies, and put in abeyance its intention to convene the Board of Inquiry. Since the review has been completed, the FDA decided to go ahead with the Board of Inquiry proceedings. Another controversy revolved around the question of whether minute traces of the cancer-causing substance, nitrosamine, are found in some malt beverages and Scotch whiskey. Finally, there has been an ongoing and highly technical controversy surrounding the decision by the FDA in September 1977 that acrylonitrile copolymer beverage bottles are food additives and could not be approved as safe under Section 409 of the Food, Drug and Cosmetic Act.
14. There are some who say "... that a one-molecule-hit-on-one-cell can cause irreversible cancer. If that were so we would all be doomed, because unless Avogadro was weak with numbers, I estimate that if you were to rid all food of any carcinogens, down to the threshold of analytical detection, say, one part per *trillion*, every meal would still expose you to several *trillions* of carcinogenic molecules or ions. That, my friends, is one of the great benefits of knowing something about Introductory Chemistry. It compels you to abandon the concept of an Absolute Zero Risk, and brings you to the only intellectually honest proposition: Relative Risk." Congressman Martin, James G., from a speech delivered to the 22nd Educational Conference of the Food and Drug Law Institute, Washington, D.C., (December 5, 1978).

investigation of the use of chemicals in food products was introduced on May 9, 1949.<sup>15</sup>

Hearings held by the Delaney Committee ultimately resulted in three laws: the Pesticide Residues Amendment,<sup>16</sup> the Food Additives Amendment<sup>17</sup> and the Color Additive Amendment<sup>18</sup> to the Food, Drug and Cosmetic Act (FD&C Act).<sup>19</sup> The Food Additives Amendment contained an absolute prohibition against approval of a food additive by the FDA if that additive had been shown to be carcinogenic.<sup>20</sup> This is what is ordinarily meant when non-experts refer to the Delaney Clause. The fact is there are actually three separate Delaney Clauses, two of which prohibit, on slightly different grounds, approval of food and color additives that are cancer causing; the other, contained in the Animal Drug Amendments of 1968,<sup>21</sup> prohibits approval of cancer-causing drugs in food producing animals. The latter clause, however, contains a qualification designed not to ban carcinogens completely, but to establish the conditions under which they may be used.

Critical analyses of food safety policy seem, generally, to follow an interesting metamorphosis, beginning with an initial concentration on the multi-dimensional Delaney Clause as the root of the problem.<sup>22</sup> Finally, analyses end with a realization that modification or elimination of any or all of the Delaney Clauses can have no major impact on, or change the course of, food safety policy; indeed, the Delaney Clauses have rarely served as the basis for FDA decisions regarding additives<sup>23</sup> and even then have been a vehicle of convenience rather than necessity. FDA action against carcinogenic substances is fully provided for by "general safety standards" of the FD&C Act.

These standards, to which the Delaney Clauses are appended, requires that food and color additives and animal drug residues be shown to be safe before they may lawfully be added to food. Under the general safety standard,<sup>24</sup> a substance cannot be approved for use in food unless the FDA is satisfied that it has been shown that the additive can be used with a "reasonable certainty of no harm to consumers." This standard is the definition of safety established

15. H.R. Res. 207, 81st Cong., 1st Sess., 95 Cong. Rec. 5927 (1949).

16. 21 U.S.C. §§ 321, 342, 346 (1976).

17. 21 U.S.C. §§ 321, 331, 346, 348 (1976).

18. 21 U.S.C. §§ 321, 331, 333, 342, 343, 346, 351, 352, 361, 362, 371, 376 (1976).

19. 21 U.S.C. §§ 301 *et. seq.* (1976), hereafter cited as FD&C Act.

20. "... 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 . . . ." 21 U.S.C. § 348(c)(3)(A) (1976).

21. 21 U.S.C. §§ 321, 322, 331, 342, 351, 352, 357, 360(b), 381, 392 (1976).

22. Thomasson, *Delaney Clause is the Culprit*, Wash. Post., July 1, 1979 (reprinted from Atl. Monthly, June, 1975).

23. "In practice, the FDA has rarely relied solely on the Delaney Clause in attempting to ban or restrict exposure to carcinogenic good ingredients. Between the early 1950's and 1977, the agency forbade the use of 14 food constituents on the grounds 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." Footnote 51 of a detailed analysis of food safety issues by Richard A. Merrill (formerly Chief Counsel of the U.S. Food and Drug Administration and now Daniel Caplin Professor of Law, University of Virginia School of Law) in *Regulating Carcinogens in Food: A Legislators Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 Mich. L. Rev. 171 (1978).

24. "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*, . . . " (There follows the Delaney Clause cited in note 18 *supra*.) 21 U.S.C. § 348(c)(3)(A) (1976).

by the legislative history. Since the Delaney Clause was first enacted in 1958, the FDA has consistently maintained that it would not be possible to conclude with "reasonable certainty" that a substance will cause no harm if it has been shown to cause cancer in man or laboratory animals. Hence, as a general matter, a substance shown to cause cancer in animals would not comport with the general safety standard even if there were no Delaney Clause. While it may be argued that the existence of the Delaney Clause virtually eliminates the Agency's option not to act on carcinogens, it should be pointed out that, in a sense, the general safety standard is more rigorous than the Delaney Clause. The Delaney Clause requires a finding that a substance actually causes cancer, but it is possible for FDA to ban, and the Agency has in fact banned, substances under the general safety standard that were only *suspected* of causing cancer.<sup>25</sup>

The example of Oil of Calamus,<sup>26</sup> illustrates an issue that often confuses discussions of the law and, particularly, of the food additive provisions of the law. This stems from the fact that the statute defines food additives in a highly restrictive way.<sup>27</sup> In fact the Act applies to seven categories of substances added purposely or accidentally to foods, but only one of these is classified by the Act as a "food additive." In addition to substances classified as food additives under this definition, these categories are: environmental contaminants; GRAS (generally recognized as safe) substances; prior sanctioned substances; color additives; animal drugs and feed additives; and pesticide residues on raw commodities.

*Environmental contaminants*, a category created administratively by FDA includes not only industrial chemicals that accidentally get into food, such as polybrominated biphenyls, and industrial effluents, such as mercury and polychlorinated biphenyls, but also substances of biological origin that are by-products of food production or storage, such as the potent liver carcinogen,

25. Prior to the enactment of the original Delaney Clause, two artificial sweeteners thought to be carcinogens – Dulcin and P-4000 – were removed from the food supply because the FDA regarded them as "poisonous substances which have no place in any food." 15 Fed. Reg. 321 (1950). Then, in March 1954, the FDA announced that any food containing coumarin added as such, or as a constituent of tonka beans or tonka extract, would be regarded as adulterated on the grounds that it contained an added poisonous or deleterious substance in violation of 21 U.S.C. § 342(a)(1) (1976). This action, too, was based upon a finding that coumarin is carcinogenic. 19 Fed. Reg. 1239 (1954). Other actions concern, respectively: DES in poultry (Bell v. Goddard, 336 F.2d 177 (7th Cir. 1966)); Safrole (25 Fed. Reg. 1241 (1960); Oil of Calamus (33 Fed. Reg. 6967 (1968)); Cyclamate (34 Fed. Reg. 17063 (1969)); DES in cattle and sheep (37 Fed. Reg. 3060 (1972) and 37 Fed. Reg. 15426 (1972)); Diethylpyrocabonate (38 Fed. Reg. 10116 (1973) and 38 Fed. Reg. 33072 (1973)); Mercaptins (38 Fed. Reg. 9077 (1973)); Violet No. 1 (41 Fed. Reg. 5823 (1976)); FD&C Red No. 2 (41 Fed. Reg. 15029 (1976)).

26. 33 Fed. Reg. 6967 (1968).

27. As stated in 21 U.S.C. § 321(s) (1976): "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 this Act, the Poultry Products Inspection Act . . . or the Meat Inspection Act of March 4, 1907 . . ." (emphasis added)

aflatoxin. Indeed, the FD&C Act expressly provides authority for tolerance setting for substances meeting the standard of Section 406; risk-benefit analysis is implied by the authority to limit the amounts of substances to the extent they are required or can't be avoided "to such an extent as [the Secretary] finds necessary for the protection of public health . . . "28

The statutory definition of "food additive" excludes any ingredient that is *generally recognized as safe* (GRAS). This limitation of GRAS substances was made because Congress sought to free the FDA and manufacturers from being required to prove the safety of substances already considered harmless because of past extensive use with no harmful effect. There are actually two classes of GRAS ingredients: those generally recognized by experts as safe based on their common use in food prior to 1958, and those generally recognized as safe on the basis of toxicological tests, regardless of whether those tests were conducted before or after 1958. An ingredient that is considered GRAS can lose this status because of new evidence casting doubt on its safety, in which instance it is considered a "food additive" and must be approved by the FDA under the tests applied to other food additives.

*Prior Sanctioned Substances* include both intentional ingredients of processed foods that were approved by the FDA or the U.S. Department of Agriculture prior to 1958, and unintentional ingredients that migrate into food that were approved by those agencies before 1958. Such substances have been "grandfathered" by the Food Additives Amendment. They are therefore exempted from the food additive approval requirements, but not exempt from other food safety provisions of the Act.

*Color Additives* include all substances intentionally used for the purpose of coloring food.<sup>29</sup>

*Animal drugs and feed additives* include substances administered or fed to food producing animals that may leave residues in human food such as meat, milk, or eggs.<sup>30</sup>

*Pesticide residues on raw commodities* include substances used to control crop pests that leave residues on commodities likely to be consumed by humans without significant further processing. Pesticide residues in processed foods are

28. "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 limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of Section 402(a). 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). In determining the quantity of such added substance 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."

21 U.S.C. § 346 (1976).

29. 21 U.S.C. § 376 (1976).

30. 21 U.S.C. § 360(b) (1976).

technically food additives, which are either: (a) exempted from the requirement for food additive approval if they do not exceed the tolerance limits set for the residues on the raw commodity, or (b) subject to approval by the Environmental Protection Agency under the Food Additives Amendment if they do exceed that level. The tolerance level can be set at zero if the scientific data do not justify a higher tolerance.<sup>31</sup>

In addition to the seven categories of substances added to foods, there is an eighth category consisting of naturally occurring constituents of food. This small category consists of those substances that are inherent components of natural agricultural commodities, e.g., nitrites in spinach, saffron in nutmeg, arsenic in shrimp. Like environmental contaminants, the definition of what is in this category also is an administrative creature of the FDA. The present law concerns itself only with substances within this category that are also "poisonous or deleterious," i.e., toxic at some level of exposure but which do not ordinarily make foods containing them injurious to health.<sup>32</sup>

These categories have been laid down like successive layers of sedimentary rock over the years as various problems have emerged with amendments made to the law in response. The result is confusion; not only to the consuming public but often to lawyers, legislators, and administrators alike. There are a number of serious problems caused by this kind of uncoordinated approach to substances added to foods. For example, nitrites are regulated both as additives and as prior sanctioned substances, depending upon whether or not they were approved for use prior to the Food Additive Amendment. There are some categories of substances, the unavoidable contaminants, where the FDA may now make risk/benefit decisions, and others, food additives, where the FDA may not. Furthermore, there is no distinction as to how or at what rate a banned substance is to be removed from the market.<sup>33</sup> Perhaps the most difficult problem revolves around the ban on carcinogenic food additives whose hazards are due to small amounts of contaminating constituents or residues. In the past forty years or so there has been what might be called an analytical revolution. In that period, the minimum amount of material that can be routinely detected and quantified has diminished by as much as seven orders of magnitude. This is an enormous advance in the power of resolution, and certainly has added to our store of scientific knowledge. Unfortunately, the process also highlights areas of scientific ignorance. For when we are routinely able to detect parts per billion of a contaminant, we have to ask ourselves if we really comprehend what these minute residues mean. This is no academic

31. 21 U.S.C. § 346(a) (1976).

32. "A food shall be deemed to be adulterated - (a)(1) If it bears or contains any added or 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 . . ." 21 U.S.C. § 342(a)(1) (1976).

33. Administrative provisions for banning different classes of substances differ, e.g., a GRAS ingredient or a provisionally listed color can virtually be banned overnight by order of the Commissioner. A "permanently" listed color is subject to an evidentiary hearing before a ban can be effected. Practically, orders may undergo court challenge, and in any event, actual removal from the market is subject to enforcement discretion, based upon considerations such as degree of hazard and disruption of food supply.

question in regard to those provisions of the FD&C Act that were designed for a zero tolerance for carcinogens at a time when zero was, due to the limitations of detection, a far higher and quite possibly biologically more significant value.

Indeed, the debate over the significance of minute traces of carcinogens has itself become a forcing event placing added pressure on present food safety policy.

While scientists agree that there is a dose/response relationship to carcinogens, i.e., the more of a carcinogen that is consumed, the greater the likelihood that cancer will result, there is disagreement about the response to very small doses or amounts of ingested carcinogens. Theoretically, some cancer will be produced by even the smallest amount, and this theory lends support to the Delaney Clause(s). There are many scientists who hold the view that, as a practical matter, there is a threshold below which minute quantities of carcinogens are biologically insignificant. The explicit prohibitions contained in the FD&C Act directed at the use of carcinogenic food and color additives, however, prevent distinguishing between carcinogens on the basis of potency or on the basis of possible thresholds and requires that all carcinogenic risks be treated equally. This latter form of scientific absolutism by legislative fiat has begun to seem less viable as risk assessment techniques have permitted some initial, rough distinctions among carcinogens on the basis of potency, extent of exposure, and other variables.<sup>34</sup>

The analytical revolution is permitting science to identify the presence of carcinogens in foods at an increasing rate. Moreover, the science of toxicology has also developed new tools and resolving power to identify carcinogenic potential in food substances. Because of these factors, if the FD&C Act were interpreted as requiring the ban of such substances, we could well endanger significant elements of the food supply.<sup>35</sup> Improved scientific processes will also have a dramatic impact on the availability of many packaging materials (especially the plastics) as it becomes increasingly possible to detect molecular migration from such materials. The inflexibility of current law will also have an impact on the availability of many chemical additives now approved, since these substances are sometimes synthesized by chemical processes that result in the presence of minute quantities of carcinogenic impurities. Modern technology in food production and distribution involves some highly complex materials and processes; chemical extraction and synthesis are commonplace activities in efficient manufacturing operations.

There are other difficulties with any of the absolutist approaches that are now beginning to emerge. For example, if a substance shown to cause cancer in laboratory animals seemed unlikely to cause cancer in humans because animals metabolize the substance in a significantly different way from humans, a literal reading of the statute would make it very difficult to employ this

34. 44 Fed. Reg. 60038 (1979).

35. "Unresolved Issues in the Conflict Between Individual Freedom and Government Control of Food Safety," a paper presented by former FDA General Counsel Peter Barton Hutt at the Conference on Public Control of Environmental Health Hazards, New York Academy of Sciences, New York, New York, June 29, 1978 and contained in *Food Safety: Where Are We?* Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, July 1979.



distincton. And, as raised in the case of nitrites, a substance suspected of causing cancer in animals may also provide an important health benefit (protection against botulism). Under current law, a balancing of these benefits against the health risks is not permitted for food additives. If this occurred with substances that are essential nutrients, it would be difficult, if not impossible, to deal with the problem under current law. Such an occurrence is not unreasonably remote. For example, Vitamins A and D have been demonstrated to be toxic under high levels of consumption. Indeed, Vitamin A is considered teratogenic at certain levels. Selenium, an essential nutrient, is associated with increased cancer-causation in laboratory tests;<sup>36</sup> other metals, essential in small amounts, may be similarly suspect as additional scientific investigation is undertaken.

There is, of course, much science does not know about carcinogens and the carcinogenic process. It is still necessary to approach any proposed addition of a carcinogen to the food supply with great caution. The task, however, is not one of choosing either/or. Rather, the task is how to retain a conservative approach to carcinogenic substances while introducing an element of flexibility and discretion sufficient to permit decisions that are scientifically sound but more realistic. This is necessary in a world where, we are discovering, it is becoming increasingly likely that foods may contain some carcinogenic constituents.

### THE PUBLIC POLICY OPTIONS

There have been a variety of proposals advanced to provide greater flexibility while still protecting the public health against the addition of carcinogens to the food supply, including: the use of quantitative risk assessment;<sup>37</sup> the recommendations contained in Part II of the Institute of Medicine/National Academy of Science Report (IOM/NAS);<sup>38</sup> and various Congressional proposals.

#### Quantitative Risk Assessment

Dr. Arthur C. Upton, the former Director of the National Cancer Institute said that quantitative risk assessment should not be used as a "primary basis" for the regulation of carcinogens.<sup>39</sup> This statement, according to Dr. Upton, does not mean that quantitative risk assessment should be regarded as worthless for evaluating the consequence of exposure to carcinogens. Neither, according to Dr. Upton, should the use of qualitative risk assessment be shunned in the

36. Selenium is an approved additive for animal feed, notwithstanding the association. The FDA reasoned that selenium caused physiological change in the liver, that this change was dose-related, and that the change led to cancer. This mechanism of cancer causation was interpreted to be different from the "induce cancer" standard of the Delaney Clause.

37. One approach, called "Sensitivity of the Method," deals with assays of drug residues in edible animals' tissue. This approach recognizes that for all assay methods the limit of detection is somewhere above zero, and that, for all cases, there will likely be some molecular amount of residue. Since it is impossible to know if and when a state of absolute zero has been attained by an animal receiving a carcinogen, the FDA had two choices: (1) not to allow use of carcinogens in food-producing animals (which is not the intent of the law); or (2) to provide an operational definition of "no residue" (the acceptable alternative). To provide this definition, the FDA sought to adopt an approach permitting it to consider the carcinogenic potency of each individual compound and require methods that can measure the level dictated by carcinogenic potency. An important element of this approach is the selection of a uniform, maximum level of risk of cancer from potential residues; a one-in-one-million lifetime risk has been proposed. Rule-making is still in process. See 44 Fed. Reg. 17070 (1979).

38. Institute of Medicine/National Academy of Sciences Report, *supra* note 8, at 3.

39. Carter, *How to Assess Cancer Risk*, 204 Science 811 (1979).

regulatory decisionmaking process. As expressed in a September 21, 1979 joint statement by Dr. Upton, and Dr. Norton Nelson, Director, Institute of Environmental Medicine, New York University Medical Center, "Society sometimes finds itself in a situation where choices must be made between the demonstrated benefits of certain chemicals or processes and the risks they pose. Clearly, when non-carcinogenic alternatives are available the choice is clear; the dilemma arises when such options are not accessible. In such instances it is imperative that all relevant evidence be carefully analyzed and examined in respect to its weight and reliability, including, crude though they may be, quantitative estimates. The limitations of quantitative risk assessment are well recognized in the scientific community and have been discussed by one of us.<sup>40</sup> Such estimates can not be the exclusive or primary basis for the final judgement, but they contribute to the ultimate decision to the extent justified by their reliability. Valid evidence is better than pure guesses. Current procedures may not be optimal; constructive ways of improving them should be encouraged."

#### **IOM/NAS Recommendations**

In Part II of its Report,<sup>41</sup> the National Academy of Sciences surveys the area of Federal food regulation and proceeds to develop a methodology within which to discuss future modification to the system. The major areas addressed are: food safety, risk assessment, benefit assessment, current and alternative policies, and strategies.

In regard to these concerns, the Report recommends adopting:

- (1) a single safety standard for all foodstuffs, food additives, and food contaminants;
- (2) ways by which officials responsible for administering the policy may be accorded the flexibility necessary to weigh benefits and risks, including economic and social consequences;
- (3) ways by which the FDA may choose from a full range of options from no action to warning to selective to complete ban; and
- (4) a classification scheme providing a range of low, moderate, and high risk materials.

In addition, the IOM/NAS Report recommends that the Delaney Clause(s) be abandoned.

#### **Various Legislative Initiatives**

Congressman James G. Martin (R. N.C.), Congressman Thomas Foley (D. Wash.) and Senator Richard S. Schweiker (R. Pa.) have introduced bills to revise the food safety laws insofar as the regulation of food additives is concerned. The Martin Bill<sup>42</sup> which has some 30 cosponsors, would require that the risks and benefits of food additives be considered and that an additive be approved if the benefits outweigh the risks or if the risk to humans is low considering the overall safety and reliability of the food supply. Under Congressman Martin's bill, the risks of an additive would be weighed against

40. Nelson, *Comments on Extrapolation of Cancer Response from High Dose to Low Dose*, 22 *Environmental Health Perspectives* 93 (1978).

41. Institute of Medicine/National Academy of Sciences Report, *supra* note 8, at 3.

42. H.R. 3778, 96th Cong., 1st Sess. (1979).

the benefits listed in the order of priority to be given to them: (a) health risks and benefits; (b) nutritional needs and benefits and the nutritional value, cost availability and acceptability of food; (c) environmental effects; and (d) interests of the general public. Under this bill, benefits could override risks, even significant ones.

The Foley bill,<sup>43</sup> which has no cosponsors, would simply revoke the Delaney Clause. When it was introduced, Congressman Foley, Chairman of the House Agriculture Committee, stated that he had not yet decided that the clause should be revoked, but felt strongly that discussion of that possibility is important and overdue.

The Schweiker bill,<sup>44</sup> which has two cosponsors, is similar to the Martin bill. It would require risk/benefit decisionmaking and consideration of the same benefits that Congressman Martin's proposal would require (and in the same order).

#### **Implications of *Monsanto Co. v. Kennedy*.**

A recent decision<sup>45</sup> of the U.S. Court of Appeals for the District of Columbia has introduced a new element into the administration of the FD&C Act that is likely to heighten the pressure for statutory revision of food safety standards. In September 1977, FDA Commissioner Donald Kennedy decided that acrylonitrile copolymer beverage bottles were food additives and could not be approved as safe under Section 409 of the FD&C Act.

Monsanto appealed this decision, the principal issue being whether the bottles may indeed be classified as food additives. It argued (1) that in order for a packaging substance to be judged a food additive the migration from it must be toxicologically significant; (2) that in order for a packaging material to be judged a food additive migration from it must be actually detected, not merely projected; (3) that the new bottle was not a food additive; and (4) that the FDA had acted in a discriminatory and inconsistent manner in treating the acrylonitrile bottle as a food additive.

The Court rejected these and other arguments, remanded the case to provide for reconsideration by the FDA, and went on to say:

For the component element of the definition [of 'food additive'] to be satisfied, Congress must have intended the Commissioner to determine with a fair degree of confidence that a substance migrates into food in more than insignificant amounts. We do not suggest that the substance must be toxicologically significant; the aspect is subsumed by the safety element of the definition. Congress has granted the Commissioner a limited but important area of discretion. Although as a matter of theory the statutory net might sweep within the term 'food additive' a single molecule of any substance that finds its way into food, the Commissioner is not required to determine that the component element of the definition has been satisfied by such an exiguous showing. The Commissioner has latitude under particular circumstances to find migration 'insignificant' even giving full weight to the public health and

43. H.R. 12, 96th Cong., 1st Sess. (1979).

44. S. 587, 96th Cong., 1st Sess. (1978).

45. *Monsanto Co. v. Kennedy*, No. 77-2023 (D.C. Cir. Nov. 6, 1979).

welfare concerns that must inform his discretion. Thus, the Commissioner may determine based on the evidence before him that the level of migration into food of a particular chemical is so negligible as to present no public health or safety concerns, even to assure a wide margin of safety.

It is important to note that the court indicated that the Commissioner is *not required* to exempt a *de minimis* substance from the food additive definition; he may do so as a matter of his *discretion*. Such discretionary authority, however, is not unlimited. If a Commissioner does exercise this discretionary authority and does exempt a *de minimis* substance from the definition of food additive, it will be necessary for him to state the reasons why this limited exemption authority has been used.

In the event of a refusal to exempt a *de minimis* substance, the second limitation on his authority arises because there is a narrow, but real, power of judicial review. As the Court put it, however, "Absent a showing of bad faith or other extraordinary circumstances, a court will not consider meritorious the claim that the Commissioner has abused his discretion in declining to exercise his exemption authority for *de minimis* situations. This is an area of decision by its nature committed to the informed discretion of the Commissioner."

The essence of the Court's decision, and of the importance of that decision to food safety policy, is that while the Court did not agree with Monsanto's contention that toxicological significance must exist in order for a substance to be construed as a food additive, the FDA has discretionary authority to consider toxicological insignificance as a basis for exempting a substance from such status.

Under this interpretation of the Court, the definition of *de minimis* is extended from "very small" to "toxicologically insignificant." Whether this interpretation of law will (or can) be broadly applied has yet to be determined. It is *not unreasonable speculation*, however, that further litigation will arise if the FDA attempts to apply the approach (a challenge by supporters of a conservative food safety policy), or if the FDA declines to apply the approach (a challenge by food additive petitioners seeking its use). In short, it appears that events still in the making are building a foundation for a more realistic food safety policy; a major court test of existing law confirming the Monsanto interpretation or, ideally, a legislative initiative is needed to set the foundation in place.

### SUGGESTED APPROACHES

Whatever proposals are finally translated into legislative initiatives, it seems clear that, as a practical matter, legislation designed to put food safety standards on a realistic footing should not attempt to redo the entire universe of food policy but, rather, focus on the objectives of clarification, conservation, and continuity. Having raised the issue, it seems only fair to suggest some specific approaches.

It is obvious in regard to the present convoluted system of classification that "anyone who isn't confused, isn't thinking clearly." We have arrived at a point where complexity has become so great that the system is beginning to defeat itself. The loss of understanding has been followed by a loss of public credibility and public confidence. Resolution of this serious problem is not beyond the scope of human invention. Two types of change would be

required: redefinition of food categories and adoption of acceptable risk criteria.

The first change could be attained by establishing three simplified, mutually exclusive food categories, each with a uniform regulatory approach. Thus, it would be possible to divide food regulated by the FDA into (a) traditional foods; (b) food contaminants; and (c) food additives. The scheme should be comprehensive so that all foods would be classifiable into one of these categories.

Under this simple system of categorization, continuity of the food supply would be achieved through considering as traditional foods the basic food commodities, as well as naturally occurring poisonous or deleterious substances, i.e., harmful substances that are inherent constituents of food; both natural and artificial (i.e., synthesized and chemically indistinguishable from natural ones) spices and flavors; and essential nutrients at the levels they occur in food. This category would involve a regulatory approach in which the burden of proof would be on the government to prove risk before a substance could be banned. This approach now exists for some foods under Section 402(a)(1)<sup>46</sup> and would be continued, although redefinition of the category would be necessary to include substances not now included. A standard of "not ordinarily injurious to health" would apply to this category.

Food contaminants would include environmental and accidental contaminants that are not inherent constituents of foods and are not deliberately added to food (e.g., PCB, aflatoxin). In regard to this category, the regulatory approach would require the FDA to assess the risk and establish tolerances in the same manner as it does now for unavoidable contaminants under Section 406.<sup>47</sup> The Delaney concept would not apply because banning the substance would also ban the food.

Finally, the food additive category would include everything now classified as food additives, as well as GRAS and prior sanctioned substances, color additives, and nutrients above normal levels and synthetic foods. (Obviously, the current GRAS definition would require revision to reclassify those traditional food substances fitting the definition, e.g., salt, sugar, vinegar, coffee, etc.) The regulatory approach would require the FDA to review evidence of food additive safety before use.

With regard to the second type of change, a modified Delaney concept would apply, built on the framework of rebuttable presumption and consideration of health benefits/risks. Carcinogenic substances would be prohibited from use as additives unless a showing of acceptable risk could be made using risk assessment techniques or by showing, with appropriate scientific evidence, that the carcinogenicity of a substance in test animals may have different effects in man; or that a threshold for its effects can be shown; or that other valid scientific reasons exist for rejecting a carcinogenicity finding in laboratory tests. Further, approval of an additive could be permitted if direct health benefits could be shown for a substance that might outweigh its health risks, e.g., for preservatives that prevent botulism.

It can be argued that the suggested approach to food categories is internally inconsistent and not likely to resolve all current problems. In particular, it is held that it is not logical to distinguish between additives and contaminants or between deliberately added substances and inadvertently added substances,

46. 21 U.S.C. § 342(a)(1) (1976).

47. 21 U.S.C. § 346 (1976).

e.g., between adding saccharin to soft drinks and adding aflatoxin – contaminated peanuts to peanut butter.<sup>48</sup> This interpretation would classify contaminated peanuts as a food additive. Certainly, this would be a narrow and technical-legal interpretation of the term “food additive.” It would however, overlook the functionality criterion contained in the current definition of a food additive; aflatoxin, unlike saccharin, serves no function.

There is a difference, as suggested in the *de minimus* decision of *Monsanto*, in adding a substance (peanuts) containing a minute amount of a toxic, contaminating constituent (aflatoxin) and intentionally adding the constituent itself (saccharin) in relatively large amounts. We do not agree with the narrow interpretation of “food additive,” and believe the three-category approach is workable, although it is an arguable issue and one that may require modifying the definition of food additive for efficient application of the scheme. However, the three-category approach suggested satisfies a more fundamental need by providing the flexibility to approve use of additives that satisfy acceptable risk criteria.

Regardless of how one chooses to treat a substance (intentional versus unintentional additives), there would be a basis for permitting its use if it meets the standards for acceptable risk. Peanut butter, saccharin, nitrites, acrylonitrile, and most other problem substances would be readily classifiable and manageable under the scheme outlined above; approvability, of course, would depend on the standard of acceptable risk.

Doggedly following the logic of a narrow and technical interpretation of “food additive” leads inexorably to the conclusion that everything should be treated as a food additive and that there are no solutions to the present dilemma. This should not be our goal. Rather, we should seek ways to make the food safety system credible and manageable.

Certainly, an everything-is-a-food-additive result is unmanageable if the requirement for pre-clearance before marketing is to continue. Alternatively, marketing pre-clearance could be eliminated and the burdens placed on users to self-determine safe use in accordance with uniform standards and on the government to establish the standards and police compliance with them. We suspect this would be too radical a change, especially since we are still developing scientific standards and procedures for evaluating safety.

It is interesting to explore the additive definition issue with other examples, e.g., packaging materials or color additives. Substances in these categories are formulated by complex chemical processes involving materials which are converted into other forms, or which are merely intermediates serving as catalysts or extractives and which are removed from the end product. Removal or conversion usually is not complete and residual traces remain. In addition, other substances, such as reaction products, may be formed as a result. How should these trace residues or reaction products be treated? Current practice

48. See Hutt, *Hair Dye Regs: A Narrowing of FDA "No Risk" Policy*, Legal Times of Washington, (Nov. 5, 1979) and Hutt, *"Monsanto": Important for Food, Drug, Cosmetic Problems*, Legal Times of Washington, (Nov. 26, 1979.)

would treat them as additives.

Alternatively, under either current law or the proposal outlined here, they could be treated as unavoidable contaminants. A new administrative policy, an "inherent constituent" treatment, would have to be extended to man-made substances as well as those produced by nature. This would be consistent with the *de minimis* theory in *Monsanto*, and provide a risk assessment basis using the current application of Section 406 for handling some difficult problems.

In short, we believe the suggested classification scheme and risk assessment approach will make food safety regulation a manageable function and will bring rationality to an admittedly irrational and difficult enterprise.

In order to gain some flexibility while maintaining a conservative approach toward carcinogenic food additives as redefined following the new category previously suggested, it seems important to avoid making arbitrary choices disguised by the rationale of risk/benefit. It is difficult to quantify risks and benefits of foods in a meaningful and comparable way. To employ any scheme that involves generalized assessment of benefits for food additives would extend the job of regulation far beyond its present scope and far beyond what the proponents of risk/benefit consider to be the legitimate function of a regulatory agency. In this regard, it is worth noting that when the Food Additives Amendment to the FD&C Act was being considered, food industry representatives opposed any consideration of benefits beyond that of considering whether an additive achieves its intended effect<sup>49</sup> and for good reason. If the FDA were to consider benefits, it might conclude, for example, that the addition of a new emulsifier to the food supply, even in the absence of demonstrated risk, could not be accepted since the marginal benefit could not compensate for the potential risk. Indeed, an agency empowered to consider benefits as well as risks would be justified in exercising its authority into a retrospective consideration of all approved additives, eliminating those whose benefits seem questionable in the light of subsequent approvals. It is difficult to believe that at a time when government is beginning to turn away from economic regulation, economic benefit consideration would become part of the food safety regulatory process. Imposing governmental value judgments in what is a highly subjective area is simply asking for trouble. In addition, experience in administering the current statute strongly argues against the concept of generalized risk/benefit consideration.

49. Cooper, *The Role of Regulatory Agencies in Risk-Benefit Decision-Making*, 33 Food Drug Cos. L. J. 755 (1978).

Under the present system, FDA decisions involving food substances with significant economic consequences or public interest impact have been accompanied by extensive administrative proceedings and litigation. There is no reason to believe that safety decisions will become any easier to make or less controversial, that the due process associated with such decisions will be briefer, or that decisions affecting important food substances will be less contested than now. Adding a benefit dimension to the decision would simply result in more data to be evaluated and contested. The burden imposed on both government and industry would make for an extremely costly and time-consuming approval process.

### CONCLUSION

One thing should be clear: there is no practical application of absolute safety in our food regulatory scheme. Further, public and private resources for assuring food safety are limited; extensive pre-market testing of food substances already is straining our scientific and technical capacity. Therefore, we must accommodate some degree of risk. It is important that we formalize the criteria for risk acceptance in a statutory way; the issue is important and not likely to go away. Resolution is needed if we are to lessen uncertainties and put our food safety policies on a contemporary basis.