Vanderbilt Law Review

Volume 24
Issue 5 *Issue 5 - October 1971*

Article 1

10-1971

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VANDERBILT LAW REVIEW

VOLUME 24 OCTOBER 1971 NUMBER 5

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I. INTRODUCTION

In October 1969, the artificial sweetener cyclamate was banned from sale in the United States by Secretary of Health, Education, and Welfare Robert Finch. To justify his action legally Finch chose to rely[1] on the so-called Delaney Anticancer Clause of the Food, Drug, and Cosmetic Act of 1938. Consequently, the Delaney Clause, with its requirement that any substance producing cancer in animals be removed from the American food supply,[2] became an immediate center of controversy. The Secretary himself criticized the Clause as an undue restriction on administrative decision making and as an unscientific limitation on scientific discretion.[3] When asked if the Delaney Clause should be modified, Food and Drug Administration Commissioner Charles C. Edwards reflected Secretary Finch's view in replying:

> I think the scientific community is rather well split on this issue. There are those who feel that it is just what it ought to be right now. My personal view and that of the FDA is that we have to have more flexibility of interpretation or we are put into the position we were with cyclamates—all or nothing.[4]

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1. "I have acted under the provisions of . . . the so-called Delaney Amendment, enacted eleven years ago, which states that any food additive must be removed from the market if it has been shown to cause cancer when fed to humans or animals . . . because I am required to do so." Announcement of cyclamate ban, Press Release of Secretary Finch, Oct. 18, 1969, at 3.

2. "[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, § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) (1964).

3. "But who is to say that using Fresca or some other diet drink . . . isn't better for you than the problems of overweight or diabetes." *Finch Takes Position Against Delaney Clause,* FOOD CHEMICAL NEWS, Nov. 10, 1969, at 3.

4. Interview with Charles C. Edwards, Commissioner, Food & Drug Administration, in U.S. NEWS & WORLD REPORT, Apr. 19, 1971, at 52.

The contrary point of view was reported to the Surgeon General in 1970 by an eight-member committee of scientists with a staff of six senior scientists from the National Cancer Institute. After reviewing the state of cancer research and its relation to the Delaney Clause, the committee stated:

> It is essential to recognize that no level of exposure to a carcinogenic substance, however low it might be, can be established to be a 'safe level' for man. . . . The current legislation in the field of food additives, with its 'anti-cancer clause', is based on this principle.[5]

Although the Delaney Clause has faced criticism from some quarters, careful analysis of the Clause reveals that it seems to serve well as a vehicle for the proper balancing of administrative discretion and scientific independence on one hand with public protection on the other; because of the analogous policy conflicts that arise in many areas of consumer concern, the Clause represents a valuable model for all environmental protection legislation.

II. The Structure of Protection Under the Food, Drug, and Cosmetic Act of 1938

Prior to the enactment of the Food, Drug, and Cosmetic Act of 1938, a food was considered adulterated, and therefore excluded from interstate commerce, if it contained any added poisonous or deleterious ingredient that might render it injurious to health.[6] This state of the law proved to be unacceptable because, before a food could be barred from the national market, the Government had the obligation of showing affirmatively that it contained an added poisonous or deleterious substance which might be harmful under normal conditions of use.[7] In passing the 1938 Act to alleviate this problem of proof, Congress altered food protection law in two ways, changing both essential definitions and basic operating procedures. First, section 402(a) redefined adulteration:

> A food shall be deemed to be adulterated. . . . (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406. . . .[8]

An unsafe substance was defined in section 406(a):

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5. National Institutes of Health & National Cancer Institute, Evaluation of Environmental Carcinogens, Apr. 22, 1970 (Report to the Surgeon General, USPHS, by the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens).

6. Food and Drug Act of 1906, ch. 3915, §§ 2, 7, 34 Stat. 768.

7. 1933 FDA Ann. Rep. 14.

8. Food, Drug, and Cosmetic Act of 1938, ch. 675, § 402(a), 52 Stat. 1040.

> 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) of section 402(a). . . .[9]

Secondly, procedures were prescribed that for the first time allowed poisonous or deleterious substances to be added to the food supply if the amount was within tolerances promulgated as safe by the Secretary.[10] The new definition of adulteration, however, did not resolve the chronic burden-of-proof problem. Under the 1938 Act the evidentiary issue was simply moved back one step, and the Food and Drug Administration (FDA) found itself compelled to show affirmatively in the first instance that a particular chemical was poisonous or deleterious.[11]

The difficulty in the application of section 406's test to various chemical substances arose because the drafters of the section attempted to define an acceptable level of human risk by utilizing the constructs "safe" and "unsafe." From the legislative history of the Act it clearly is demonstrable that by using the words "poisonous" and "deleterious"[12] Congress sought to designate all unsafe substances. Understood in this way, sections 402 and 406 form a legal non sequitur.

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9. *Id.* § 406(a).

10. Food, Drug, and Cosmetic Act of 1938, § 409, 21 U.S.C. § 348 (1964). In approaching the problem of control from this angle, one Senate Committee Report stated: "[T]he amount of added poisons can be so allocated to different foods, in accordance with the practical necessities, that on the basis of the probable consumption of the various foods consumers will not receive an aggregate quantity of poisons sufficient to jeopardize health." S. REP. No. 493, 73d Cong., 2d Sess. 4 (1934); *see* C. DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT 113 (1938). In addition, the Senate Committee Report commented on the tolerance provisions as follows: "In promulgating such regulations this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article, as for example, poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substanees. This authorization will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessities of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount of poison in a particular food to [very] small quantities, or to eliminate it completely. It will likewise afford adequate control of those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add dangerously toxic substances to foods, as, for example, the addition of maleic acid to fats and oils to prevent rancidity when preservation can be accomplished by observance of sanitary conditions in manufacture and packaging and by use of refrigeration for the finished product." S. REP. No. 493, 73d Cong., 2d. Sess. 4 (1934).

11. "Under the law as it was . . . [after 1938] the FDA could not stop the use of a chemical simply because it was questionable, or had not been adequately tested. It was necessary to be able to prove in court that the chemical was poisonous or deleterious." T. CHRISTOPHER, CASES AND MATERIALS ON FOOD AND DRUG LAW 468 (1966).

12. WEBSTER'S NEW INTERNATIONAL DICTIONARY (2d ed. 1957) defines "poisonous" as "[h]aving the properties or effects of poison;" *i.e.*, "[a]ny agent which, introduced . . . into an organism, may chemically produce an injurious or deadly effect." It defines "deleterious" as "hurtful," "noxious;" *i.e.*, "unwholesome."

The circular nature of the food protection device becomes evident when the word "unsafe" is substituted for the terms "poisonous" or "deleterious" as they occur in the Act. Section 402(a)(2) would read: "A food shall be deemed to be adulterated . . . if it bears or contains any added unsafe substance which is unsafe within the meaning of section 406." Section 406 would read: "Any unsafe 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 the purposes of the application of clause (2) of section 402(a)." Manifestly, Congress attempted to devise a formula for establishing tolerances for poisonous—unsafe—ingredients in food. Just as clearly, however, by defining circularly the term "unsafe," Congress forced the FDA to prove in each instance the poisonous or deleterious nature of the chemicals. Often this placed the FDA in the position of attempting to answer legally, scientific questions unanswerable in the laboratory. The Food Safety Panel of the 1969 White House Conference on Food, Nutrition, and Health underscored the problem, stating: "It is not possible to determine with absolute certainty the safety of the ever-increasing number of chemicals added to or present in our foods."[13] Because of its definitional difficulties, the 1938 Act, like its predecessor, proved to be ineffective and food protection problems increased.[14]

Faced with the nearly impossible task of establishing safety for every controversial chemical, the FDA once again sought changes in the law. Between 1950 and 1953 New York Congressman James J. Delaney conducted a series of hearings into the nature and use of chemicals added to the food supply.[15] From these hearings three major pieces of legislation resulted: the Pesticide Amendments of 1954;[16] the Food Additives Amendment of 1958,[17] of which the Delaney Clause is

13. WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, FINAL REPORT 130 (1969).

14. The definitional problems could have been obviated if the section had been drafted without reference to the notion of safety. For example, it could have read "no chemical substance shall be added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice." The tolerance-setting procedure under this language would be used to determine whether a chemical was avoidable or was required in food production. This was apparently the very concept that Congress intended to introduce into the law. At this stage the FDA could defer to scientific judgments of safety when they existed.

15. *See Hearings on H.R. 74 Before the House Select Comm. To Investigate the Use of Chemicals in Food Products*, 81st Cong., 2d Sess. (1951).

16. Act of July 22, 1954, ch. 559, 68 Stat. 511 (now 21 U.S.C. § 346a (1964)).

17. Act of Sept. 6, 1958, Pub. L. No. 85-929, 72 Stat. 1784 (codified in scattered sections of 21 U.S.C.).

a part; and the Color Additive Amendments of 1960.[18] The originally straightforward prohibition of unnecessary or avoidable poisonous or deleterious substances from food became the complicated prohibition of:

> (A) . . . any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agriculture commodity; (ii) a food additive; or (iii) a color additive) which is unsafe within the meaning of section 346 . . . or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of 346a(a) . . . or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 . . . .[19]

Each piece of inserted language, covering pesticides, food additives, and color additives, represents an involved regulatory system spelled out in detail within the Act. The administrative discretion granted by this machinery requires the FDA to weigh the value of each proposed chemical use on a scale that balances the rights of the chemical producer against those of the general public; however, proof of safety remains the objective of each part of the Act.

The pesticide, food additive, and color laws all contain essentially the same regulatory structure, consisting of a chemical-by-chemical analysis by "the Secretary." This authority has been delegated to the Commissioner of Food and Drugs for food and color additives and to the Administrator of the Environmental Protection Agency for pesticide chemicals. In each case the process begins by the filing of a petition seeking a ruling by the Secretary that either allows the chemical to be used, or bars its use, in the ways sought by the petitioner. The decision of the Secretary comes in the form of an order that specifies the ways in which the chemical may be properly used. Detailed procedural rules govern the process that the Secretary and all interested parties must follow from the time the petition is filed until the time of a final order and dictate the way in which the appeals from the final order are to be brought to the attention of the courts.[20] It should be noted that the complex statutory apparatus leaves unsolved the definitional problems inherent in the use of the word "unsafe"—the same problem that caused

18. Act of July 12, 1960, Pub. L. No. 86-617, 74 Stat. 397 (codified in scattered sections of 21 U.S.C.).

19. 21 U.S.C. § 342(a)(2) (1964).

20. 21 C.F.R. § 120 (1971) (pesticides); 21 C.F.R. § 121 (1971) (food additives); 21 C.F.R. § 8 (1971) (color additives).

the 1906 and 1938 food protection laws to founder.[21]

III. THE PROOF-OF-SAFETY PROBLEM—UNSUCCESSFUL ATTEMPTS TO SOLVE IT

The Food Additives Amendment of 1958 contains three distinct attempts to alleviate the FDA's burden-of-proof problem: (1) the Generally Recognized As Safe (GRAS) approach that resulted in the GRAS list of chemicals approved by the FDA for addition to foods;[22] (2) the Delaney Anticancer Clause that bans from food any substance which causes cancer when fed to animals;[23] and (3) the administrative structure that emanated from FDA regulations designed to evaluate item-by-item any chemicals which do not fall into either category one

21. One commentator described the Food Additives Amendment—and would probably say the same about the other 2 amendments—as "an example of law seeking to meet the problems that arise as side effects of scientific, economic and technological progress." T. CHRISTOPHER, *supra* note 11, at 130. Actually it might be more accurate to say tbat these 3 amendments are examples of legislation seeking desperately to deal with the problems created by poor legislative drafting.

22. Section 201(s) of the 1958 Act reads: "The term food additive means any substance . . . 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 . . . ." A parenthetical insert into this section set up a different standard for substanees used prior to Jan. 1, 1958, saying "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." 21 U.S.C. § 321(s) (1964). Essentially the same provision exists in both the Pesticide Amendment and the Color Additive Amendments. Section 408(a) of the 1954 Act reads: "Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals as safe for use . . . shall be deemed unsafe . . . unless . . . ." 21 U.S.C. § 346a(1) (1964). Section 606(b)(4) of the 1960 Act reads: "[A] color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in Section [321(s)] . . . ." 21 U.S.C. § 376(b)(4) (1964).

23. The Delaney Clause for food additives is contained in § 409(c)(3)(A) of the Food Additives Amendment of 1958, 21 U.S.C. § 348(c)(3)(A) (1964). It is also repeated in the Color Additive Amendments of 1960, § 706(b)(5)(B), 21 U.S.C. § 376(b)(5)(B) (1964) that reads: "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 . . . ." Whether the Delaney Clause applies to pesticide chemicals is a more difficult question about which there is considerable controversy. The Secretary's Commission on Pesticides wrote as if the clause could be interpreted to apply to pesticide chemicals; however, the definition of food additives expressly excludes "a pesticide chemical in or on a raw agricultural commodity . . . ." Food Additives Amendment of 1958, § 201(s)(1), 21 U.S.C. § 321(s)(1) (1964). Since there is no anticancer clause in the Pesticide Amendment, it would appear that pesticides do not fall under the prohibition of the Delaney Clause.

or two.[24] Each of these three legal stratagems endeavored to circumvent the problem of scientific uncertainty, but only the Delaney Clause succeeded. Before detailing the accomplishments of the Delaney Clause, the reasons for the failure of the other two mechanisms should be outlined for comparative purposes. Legislation that effectively controls chemical contamination of the environment must seek to block the use of substances that present undue risk without putting unreasonable restraints on chemicals that provide important benefits to the public. To initiate the GRAS procedure, the Food and Drug Administration asked 900 scientists to comment on the safety of the first substances proposed for the GRAS list. Rather than achieving the scientific consensus assumed possible by the GRAS theory, the FDA harvested a scattering of opinions. Of the 900 scientists questioned, 350 replied with only 194 or 21 percent of the total group ratifying the entire list. The performance of the FDA in accurately predicting the safety of specific chemicals, even after some doubt had been raised, was similarly imperfect. The FDA, for example, dismissed the complaints of a number of scientists against safrole,[25] vitamin D, and most notably cyclamate, only to find it necessary to act against the challenged chemicals in subsequent years. Thus the GRAS list mode of procedure proved to be ineffective in discriminating between safe and unsafe substances because the system presented the same problem of scientific choice that the earlier acts had been unable to deal with. Where the Agency earlier had tried to choose which chemicals and which foods were safe, it now foundered trying to choose which scientists were the best judges of safety. An FDA memorandum spelled out the guiding principle of this choice.

> In our final evaluation of the safety of a substance we have taken cognizance of the fact that all opinions are not of equal value and thus have weighed most heavily the opinions of scientifically recognized and often world-renowned experts.[26]

Under this pick and choose procedure the basic GRAS list grew to approximately 700 items with various loopholes and exceptions allowing as many as another 1,000 items to be treated as on the GRAS list by the FDA.[27] Food manufacturers, faced with a minimum of an estimated

24. This is the regulatory procedure outlined above and is essentially the same for pesticide chemicals, food additives, and color additives.

25. "Safrole" is the ingredient used for flavoring in root beer.

26. FDA Div. of Pharmacology & Food Memorandum, Sept. 2, 1959.

27. The details of this situation are spelled out in J. TURNER, THE CHEMICAL FEAST, THE RALPH NADER STUDY GROUP REPORT ON FOOD PROTECTION AND THE FOOD AND DRUG ADMINISTRATION 153-59, 162-63 (1970).

two years of study[28] before gaining permission to market a new additive, sought to achieve recognition of their chemicals through the loopholes in the GRAS list procedure. By the end of 1970 the situation had become so unwieldly that the Agency moved to revise the entire GRAS procedure by attempting to reintroduce suspect chemicals currently on the GRAS list into the chemical-by-chemical investigation.[29]

As previously noted, the chemical-by-chemical procedure relies on the ability of scientists to distinguish safe from unsafe substances. That portion of the Act authorizing this approach states: "No . . . regulation shall issue if a fair evaluation of the data before the Secretary—(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe. . . ."[30] All parties to the discussion of the 1958 Food Additives Amendment accepted the assumption that safety or the lack of it could be established in each case, and accordingly, the FDA issued a regulatory definition of safety that said, " 'Safe' means that there *is convincing evidence* which establishes with reasonable certainty that no harm will result from the intended use of the food additive."[31] Faced with reviewing the GRAS list that contained many items for which scant, controversial, or no evidence existed, the FDA, interestingly enough, moved to redefine "safe." " 'Safe' must be understood to connote that the Food and Drug Administration, after reviewing *all available evidence*, can conclude there is no significant risk of harm from using the substance as intended."[32] This second definition allows untested or only partially tested chemicals to be added to the food supply, while the former definition required the initial presentation of some convincing evidence of safety. The change in definition represents a significant erosion of the safety concept, one of the unfortunate side effects that results when a regulatory agency expected to enforce policy is required to resolve scientific conflicts. The Surgeon General's committee on low-level

28. *Hearings on H.R. 8112 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce,* 85th Cong., 1st & 2d Sess. 60 (1957-58) (remarks of FDA Comm'r Larrick).

29. Food Additives, 35 Fed. Reg. 18,623 (1970).

30. Food Additives Amendment of 1958, § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) (1964).

31. 21 C.F.R. § 121.1(i) (1971) (emphasis added). Commenting on the safety provision, Charles Wesley Dunn, the General Counsel for the Grocery Manufacturers of America stated: "Such [a] requirement is basically a pretesting one for new food additives. . . . Whereas the FDC Act now prohibits a food that is unsafe, this prohibition normally applies after the food is sold and consumed, and its enforcement may be long delayed for various reasons. . . . [m]oreover in such an enforcement proceeding the Government has the burden of proving that the food is unsafe, whereas this requirement would instead compel the manufacturer of a food to prove in advance that it is safe." *Hearings on H.R. 8112 supra* note 28.

32. Food Additives, 35 Fed. Reg. 18,623, 18,624 (1970) (emphasis added).

carcinogens demonstrated the folly of the FDA's new safety definition. It reported that bioassays are incapable of detecting carcinogenic effects below the ten percent level, and therefore so-called negative data are grossly inadequate to give assurances of safety for man.[33] More importantly, leading scientists[34] are increasingly making this same argument about the chemicals related to genetic problems, birth defects, and mental retardation. The current FDA attempt to revise the GRAS list and its redefinition of safety concede the difficulty of giving empirical meaning to the term "unsafe" while the whole area is the subject of scientific controversy. This difficulty is further demonstrated by the FDA's new interim regulation policy.

> If after a responsible and substantial question of safety has been raised regarding a substance previously listed as GRAS the main weight of the scientific evidence still indicates safety (at least within certain limits), an interim food additive regulation will be proposed. This will permit further scientific investigations to define the conditions of safe use for a food additive regulation of indefinite duration.[35]

This statement seems to be at variance with the provision of the Act that requires that "no such regulation shall issue if a fair evaluation of the data before the Secretary—(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe . . . ."[36] The FDA, however, argues that an interim time period serves merely as one more condition of use under the law, and this interpretation has been upheld in federal district court.[37] The practice of issuing interim regulations further erodes the assumption that the food supply contains only safe chemicals.

The FDA, after 65 years of failure, still struggles to solve scientific controversies about safety with legal tools. One apparently overlooked fact underlies this struggle. When scientists agree that a chemical is either safe or unsafe, no controversy about its use erupts. Only when a scientist challenges the label of "safe" attached to a chemical or class of chemicals by other scientists does the FDA engage its balancing mechanism. Otherwise chemicals enter the food supply virtually

33. National Institutes of Health & National Cancer Institute, *supra* note 5.

34. Examples of scientists who are concerned with chemicals causing birth defects and genetic damage include Dr. Samuel Epstein of Case Western Reserve University, Dr. James Crow of the University of Wisconsin, Dr. John W. Olney of Washington University, and Dr. Marvin Legator of the FDA.

35. Food Additives, 35 Fed. Reg. 18,623, 18,624 (1970).

36. Food Additives Amendment of 1958, § 409(c)(3), 21 U.S.C. § 348(c)(3) (1964).

37. The oral opinion of Judge Gerhard Gesell was reported in FOOD CHEMICAL NEWS, July 12, 1971, at 17.

unnoticed. As a result, whenever it enters a controversy the FDA overrules one set of scientifically supported arguments with a legal or regulatory judgment.

The twisting and turning of the food and drug laws since 1906 resulted from using the word "safety" to denote two distinct concepts. First, it includes the scientific observation that a chemical additive or food does not cause damage to humans. Secondly, it includes the policy judgment that even though a chemical might cause injury to a human, the damage it causes is outweighed by the benefits it imparts. Only the Delaney Clause of the Food and Drug Act escapes this pitfall by avoiding any reference to either concept of safety. Instead, it allows scientists to ascertain the degree of risk presented by the use of a particular chemical and assigns policy makers the task of judging whether the scientifically defined risk is acceptable to society. For this reason it serves as a model for all other environmental protection legislation. Despite the simple logic underlying the Clause, and despite its ready applicability to other regulatory fields, this Clause has often been misunderstood by regulators and the public alike.

IV. The Delaney Clause: A Model for Environmental Protection Legislation

A. Misunderstanding the Delaney Clause

Food and Drug Commissioner Charles C. Edwards restated accurately the misunderstanding of the Delaney Clause when he said of it:

> My personal view and that of the FDA is that we have to have more flexibility of interpretation or we are put into the position that we were with cyclamates—all or nothing. And it becomes a highly emotional issue at that point, allowing no discretion on our part or anyone else's.[38]

This statement implies that but for the Delaney Clause the FDA would have allowed cyclamates to remain in the food supply in some amount even though this chemical causes cancer in rats. The Commissioner's characterization of the Delaney Amendment as a usurpation of administrative discretion is incongruous because other parts of this food protection law, although operating more slowly than the anticancer clause, also would have required cyclamates to be completely banned from the food supply. At the onset of the cyclamate controversy, the chemical was generally recognized as safe by the FDA. After a

38. See Interview with Charles C. Edwards, *supra* note 4.

substantial safety question was raised, the Secretary officially removed cyclamates from the GRAS list. At this point the law, absent the Delaney Clause, requires that the chemical be shown to be safe before a petition can be granted allowing its addition to food.[39] In view of the state of scientific knowledge about cancer causing substances, it is unlikely that cyclamate could have met this burden of proof; therefore, the chemical could have been removed from the food supply without reference to the Delaney Clause. In fact, some of the most vigorous critics of the Delaney Clause call it an unnecessary duplication of already existing authority.

When the Commissioner asks for "discretion" to decide when a chemical that causes cancer in animals can still be used in food for man, he is asking for the discretion to decide an issue that thousands of cancer researchers have been unable to resolve. The dangers of this position were put forth accurately by former Secretary of Health, Education and Welfare, Arthur S. Flemming:

> The rallying point against the anticancer provision is the catch phrase that it takes away the scientist's right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for man a safe tolerance for a cancer-producing agent.
>
> . . . .
>
> As I pointed out in my original testimony, the opposition to inclusion of an anticancer clause arises largely out of a misunderstanding of how the provision works. It allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.[40]

The fact that the country's highest food and drug officials still believe that this kind of discretion should be granted demonstrates the need for more effective policy setting by Congress.

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39. Food Additives Amendment of 1958, § 409(c)(3), 21 U.S.C. § 348(c)(3)(A) (1964).

40. *Hearings on H. R. 7624 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 86th Cong., 2d Sess. 501 (1960). The members of the committee that reported to the Surgeon General on low levels of environmental carcinogens considered the arguments made by Secretary Flemming so important that they inserted the entire statement of the former Secretary in their report. Following the statement they added this note: "The scientific basis on which the

B. *Expanding the Delaney Clause to Other Areas of Environmental Protection Legislation*

From the FDA's experience in attempting to differentiate between safe and unsafe substances, it seems apparent that in order to shield the environment from further chemical contamination, the policy issues and the scientific issues, although interrelated, must be approached separately. The report to the Surgeon General on environmental carcinogens clearly defined the problem and divided the scientific and policy responsibility. "While science can provide quantitative information regarding maximum risk levels, the task of ultimately selecting socially acceptable levels of human risk rests with society and its political leaders."[41] The role of the scientist is to describe physical phenomena—this chemical caused lesions in mouse brains under these conditions; that chemical caused cancer when fed to mice in certain quantities; those chemicals caused birth deformities when injected into chickens in designated amounts at certain ages. Scientists can offer less definite but still important scientific opinions on the degree to which damage to man can be predicted from damage to animals. Without knowing the levels of risk that society will tolerate, however, scientists cannot effectively differentiate between "safe" and "unsafe" substances.

Congress, on the other hand, taking into consideration the certainty or relevancy of the scientific findings, must set broad policy guidelines. Several issues suggest themselves as important for the consideration of the nation's policy-makers. Which purposes served by chemicals are worth the apparently increasing risk of their use in foods? Resolving this issue involves a reassessment of the "required for" or "unavoidable in" food production concept of section 406. If additional uses of chemicals are found necessary to improve the food supply, these concepts could be expanded.[42] In addition, Congress must determine

Government's position was established in 1960 remains valid. The progress of knowledge in carcinogenesis in the last decade has only strengthened the points made in Secretary Flemming's testimony." National Institutes of Health & National Cancer Institute, *supra* note 5.

41. National Institutes of Health & National Cancer Institute, *supra* note 5, at 14.

42. The Food Safety Panel of the White House Conference suggested some additional criteria that Congress might consider: "[That] no additional chemicals should be permitted in or on foods unless: They have been shown with reasonable certainty to be safe on the basis of the best scientific procedures available for the evaluation of safety and meet one or more of the following criteria:

1. They have been shown by appropriate test to be significantly less toxic than food additives currently employed for the same purpose.
2. They significantly improve the quality or acceptability of the food.
3. Their use results in a significant increase in the food supply.
4. They improve the nutritive value of the food.

which extrapolations from animals can be made to man. In the cancer area it is policy that if a chemical affects animals it will not be given to humans.[43] This practice was adopted because under the present state of scientific knowledge a safe tolerance for man of a substance that produces cancer in animals cannot be established.[44] What chemicals should be added to the "zero tolerance" list now containing only carcinogens? Already chemicals causing birth defects and genetic damage in animals have been suggested for addition to the list. Congress must collect and review the evidence that other irreversible biological damage can be caused by chemicals and set a "zero tolerance" policy for these areas where necessary.

The Delaney Clause can serve as a model for environmental protection legislation because it delegates to scientists the responsibility for making scientific judgments and to Congress the task of making policy decisions. The scientist, after an analysis of all technical data, specifies the degree of risk that would result if any amount of known carcinogens were allowed in the nation's food supply; Congress, after considering all other relevant information, determines that the risk is unacceptable. The FDA is then charged with the responsibility of removing carcinogenic chemicals from the food supply. The procedure outlined for developing a new food protection or any other environmental protection law should not include any effort to define "safety." Rather, scientists should describe a degree of risk as accurately as science allows. Congress then should decide whether that risk is worth taking. To begin the development of a more effective food protection law, the report to the Surgeon General enunciated one additional fundamental point. "Chemicals should be subjected to scientific scrutiny rather than given individual 'rights': they must be considered potentially guilty unless and until proven innocent."[45] The authors of that report directed their comment at carcinogens, but the same observations may now be made for chemicals relating to genetic damage or birth defects.

V. CONCLUSION

The nearly uninhibited addition of chemicals to the environment for the last several decades lies at the heart of the so-called

5. Their use results in a decrease in the cost of food to the consumer." WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, *supra* note 13.

43. Food Additives Amendment of 1958, § 409(c)(3), 21 U.S.C. § 348(c)(3)(A) (1964).

44. National Institutes of Health & National Cancer Institute, *supra* note 5, at 15.

45. *Id.* at 15.

environmental crisis. To control this use of chemicals requires a new combination of scientific expertise and legal policy. The drafters of the Delaney Clause of the current food protection law were successful in writing into that legislation a proper balancing of the policy function and the scientific function. Congress heard scientists describe the level of known and unknown risk associated with cancer causing chemicals. It set the policy that no chemical known to cause cancer in animals would be allowed in the food supply. The regulatory agency was assigned the scientific task of distinguishing those chemicals that cause cancer in animals from those that do not. The Delaney Clause sets clear public policy and allows complete scientific freedom.

Congress, by setting the public policy concerning cancer causing chemicals itself and by assigning the scientific implementation of that policy to the agency that regulates food, established a procedure for effectively weighing environmental dangers and acting to prevent them. All chemicals—whether they be pesticides in or on foods, industrial chemicals that contaminate the water or air, hazardous substances that are used in the home, or any one of hundreds of other environmental pollutants used in this society—must be subjected to a rationalized policy. Congress, guided by the state of scientific knowledge, must place limits on the risks to be assumed by society; the appropriate regulatory agency, again guided by scientific research, must not allow that established risk to be exceeded. This is the principle of the Delaney Clause, and for this reason the Delaney Clause serves as a model for other environmental legislation.