

**KATHLEEN E. LES; FRANCES LES THOMAS; MANUEL JESUS PEREZ MORALES;
DAVID R. PEREZ; MANUEL R. PEREZ, PETITIONERS,
AFL-CIO; NATURAL RESOURCES DEFENSE COUNCIL, INC.; PUBLIC CITIZEN,
PETITIONERS-INTERVENORS,
v.
WILLIAM K. REILLY, ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION
AGENCY; UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENTS,
NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, ET AL., RESPONDENTS-
INTERVENORS.**

United States Court of Appeals, Ninth Circuit.

968 F.2d 985; Decided July 8, 1992.

Before: CHAMBERS, SCHROEDER, and BEEZER, Circuit Judges.

SCHROEDER, Circuit Judge:

Petitioners seek review of a final order of the Environmental Protection Agency permitting the use of four pesticides as food additives although they have been found to induce cancer. Petitioners challenge the final order on the ground that it violates the provisions of the Delaney clause, 21 U.S.C. 348(c)(3), which prohibits the use of any food additive that is found to induce cancer.

Prior to 1988, EPA regulations promulgated in the absence of evidence of carcinogenicity permitted use of the four pesticides at issue here as food additives. In 1988, however, the EPA found these pesticides to be carcinogens. Notwithstanding the Delaney clause, the EPA refused to revoke the earlier regulations, reasoning that, although the chemicals posed a measurable risk of causing cancer, that risk was "de minimis."

We set aside the EPA's order because we agree with the petitioners that the language of the Delaney clause, its history and purpose all reflect that Congress intended the EPA to prohibit all additives that are carcinogens, regardless of the degree of risk involved.

Background

The Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301-394 (West 1972 & Supp. 1992), is designed to ensure the safety of the food we eat by prohibiting the sale of food that is "adulterated." 21 U.S.C. 331(a). Adulterated food is in turn defined as food containing any unsafe food "additive." 21 U.S.C. 342(a)(2)(C). A food "additive" is defined broadly as "any substance the intended use of which results or may reasonably be expected to result . . . in its becoming a component . . . of any food." 21 U.S.C. 321(s). A food additive is considered unsafe unless there is a specific exemption for the substance or a regulation prescribing the conditions under which it may be used safely. 21 U.S.C. 348(a).

Before 1988, the four pesticide chemicals with which we are here concerned - benomyl, mancozeb, phosmet and trifluralin - were all the subject of regulations issued by the EPA permitting their use.[FN 1] In October 1988, however, the EPA published a list of substances, including the pesticides at issue here, that had been found to induce cancer. Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed.Reg. 41,104, 41, 119 (Oct. 19, 1988). As known carcinogens, the four pesticides ran afoul of a special provision of the FFDCA known as the Delaney clause, which prescribes that additives found to induce cancer can never be deemed "safe" for purposes of the FFDCA. The Delaney clause is found in FFDCA section 409, 21 U.S.C. 348. That section limits the conditions under which the Secretary may issue regulations allowing a substance to be used as a food additive:

No such regulation shall issue if a fair evaluation of the data before the Secretary - (A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: Provided, That no additive shall be deemed to be safe if it is found 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).

FN 1. The EPA permitted use of these chemicals as food additives under the following regulations (sections in Title 21 were redesignated to Title 40 in 1988): 21 C.F.R. 193.30 (1987) and 40 C.F.R. 185.350 (1989) (benomyl on raisins and tomato products); 21 C.F.R. 193.460 (1987) and 40 C.F.R. 185.6300 (1989) (mancozeb on raisins as well as bran and flour of barley, oats, rye and wheat); 21 C.F.R. 193.275 (1987) and 40 C.F.R. 185.3950 (1989) (phosmet on cottonseed oil); and 21 C.F.R. 193.440 (1987) and 40 C.F.R. 185.5900 (1989) (trifluralin on peppermint and spearmint oils).

The FFDCA also contains special provisions which regulate the occurrence of pesticide residues on raw agricultural commodities. Section 402 of the FFDCA, 21 U.S.C. 342(a)(2)(B), provides that a raw food containing a pesticide residue is deemed adulterated unless the residue is authorized under section 408 of the FFDCA, 21 U.S.C. 346a, which allows tolerance regulations setting maximum permissible levels and also provides for exemption from tolerances under certain circumstances. When a tolerance or an exemption has been established for use of a pesticide on a raw agricultural commodity, then the FFDCA allows for the "flow-through" of such pesticide residue to processed foods, even when the pesticide may be a carcinogen. This flow-through is allowed, however, only to the extent that the concentration of the pesticide in the processed food does not exceed the concentration allowed in the raw food. The flow-through provisions are contained in section 402 which provides:

That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title [FFDCA section 408] and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title [FFDCA sections 406 and 409], not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity.

21 U.S.C. 342(a)(2)(C). It is undisputed that the EPA regulations at issue in this case allow for the concentration of cancer-causing pesticides during processing to levels in excess of those permitted in the raw foods.

The proceedings in this case had their genesis in October 1988 when the EPA published a list of substances, including these pesticides, that were found to induce cancer. 53 Fed.Reg. 41, 104, App.B. Simultaneously, the EPA announced a new interpretation of the Delaney clause: the EPA proposed to permit concentrations of cancer-causing pesticide residues greater than that tolerated for raw foods so long as the particular substances posed only a "de minimis" risk of actually causing cancer. 53 Fed.Reg. at 41,110. Finding that benomyl,

mancozeb, phosmet and trifluralin (among others) posed only such a de minimis risk, the Agency announced that it would not immediately revoke its previous regulations authorizing use of these substances as food additives. Id. at 41,105, 41,120-23.

Petitioners filed an administrative petition in May 1989 requesting the EPA to revoke those food additive regulations. Following public comment, the EPA issued a Notice of Response refusing to revoke the regulations. Response to Petition Requesting Revocation of Food Additive Regulations, 55 Fed.Reg. 17,560, 17,567 (benomyl), 17,568 (mancozeb), 17,569 (trifluralin) (Apr. 25, 1990).[FN 2] After the petitioners filed objections to that response, the EPA published its final order denying the petition to revoke the food additive regulations. Order Responding to Objections to EPA's Response, 56 Fed.Reg. 7750 (Feb. 25, 1991). This petition for review pursuant to 21 U.S.C. 348(g)(1) followed.

FN 2. Originally, the EPA indicated that it would cancel the phosmet regulation. 56 Fed.Reg. at 17,568. Thereafter, however, the registrant contested the proposed cancellation and the EPA reversed its decision to cancel. See 56 Fed.Reg. at 7752.

Discussion

The issue before us is whether the EPA has violated section 409 of the FFDCA, the Delaney clause, by permitting the use of carcinogenic food additives which it finds to present only a de minimis or negligible risk of causing cancer. The Agency acknowledges that its interpretation of the law is a new and changed one. From the initial enactment of the Delaney clause in 1958 to the time of the rulings here in issue, the statute had been strictly and literally enforced. 56 Fed.Reg. at 7751-52. The EPA also acknowledges that the language of the statute itself appears, at first glance, to be clear on its face. Id. at 7751 ("[S]ection 409 mandates a zero risk standard for carcinogenic pesticides in processed foods in those instances where the pesticide concentrates during processing or is applied during or after processing.").

The language is clear and mandatory. The Delaney clause provides that no additive shall be deemed safe if it induces cancer. 21 U.S.C. 348(c)(3). The EPA states in its final order that appropriate tests have established that the pesticides at issue here induce cancer in humans or animals. 56 Fed.Reg. at 7774-75. The statute provides that once the finding of carcinogenicity is made, the EPA has no discretion. As a leading work on food and drug regulation notes:

[T]he Delaney Clause leaves the FDA room for scientific judgment in deciding whether its conditions are met by a food additive. But the clause affords no flexibility once FDA scientists determine that these conditions are satisfied. A food additive that has been found in an appropriate test to induce cancer in laboratory animals may not be approved for use in food for any purpose, at any level, regardless of any "benefits" that it might provide.

Richard A. Merrill and Peter B. Hutt, Food and Drug Law 78 (1980).

This issue was litigated before the D.C. Circuit in connection with the virtually identical "color additive" prohibition of 21 U.S.C. 376(b)(5)(B). The D.C. Circuit concluded that "[t]he natural - almost inescapable - reading of this language is that if the Secretary finds the additive to 'induce' cancer in animals, he must deny listing." Public Citizen v. Young, 831 F.2d 1108, 1112 (D.C.Cir. 1987), cert. denied, 485 U.S. 1006, 108 S.Ct. 1470 (1988). The court concluded that the EPA's de minimis interpretation of the Delaney clause in 21 U.S.C. 376 was "contrary to law." 831 F.2d at 1123. The Public Citizen decision reserved comment on whether the result would be the same under the food additive provisions as it was under the food color provisions, 831 F.2d at 1120, but its reasoning with respect to the language of the statute is equally applicable to both.

The Agency asks us to look behind the language of the Delaney clause to the overall statutory scheme governing pesticides, which permits the use of carcinogenic pesticides on raw food without regard to the Delaney clause. Yet section 402 of the FFDCA, 21 U.S.C. 342(a)(2)(C), expressly harmonizes that scheme with the Delaney clause by providing that residues on processed foods may not exceed the tolerance level established

for the raw food. The statute unambiguously provides that pesticides which concentrate in processed food are to be treated as food additives, and these are governed by the Delaney food additive provision contained in section 409. If pesticides which concentrate in processed foods induce cancer in humans or animals, they render the food adulterated and must be prohibited.

The legislative history, too, reflects that Congress intended the very rigidity that the language it chose commands. The food additive Delaney clause was enacted in response to increasing public concern about cancer. It was initially part of a bill, introduced in the House of Representatives in 1958 by Congressman Delaney, to amend the FFDCFA. H.R. 7798, 85th Cong., 1st Sess. (1957), reprinted in XIV A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments 91 (1979) (hereinafter, "Legislative History"). The bill, intended to ensure that no carcinogens, no matter how small the amount, would be introduced into food, was at least in part a response to a decision by the FDA to allow a known carcinogen, the pesticide Aramite, as an approved food additive. Food Additives: Hearings Before a Sub-committee of the House Committee on Interstate and Foreign Commerce, 85th Cong., 1st and 2d Sess. 171 (1958), reprinted in XIV Legislative History 163, 336. Of the FDA's approval for sale of foods containing small quantities of Aramite, Congressman Delaney stated:

The part that chemical additives play in the cancer picture may not yet be completely understood, but enough is known to put us on our guard. The safety of the public health demands that chemical additives should be specifically pretested for carcinogenicity, and this should be spelled out in the law. The precedent established by the Aramite decision has opened the door, even if only a little, to the use of carcinogens in our foods. That door should be slammed shut and locked. That is the purpose of my anti-carcinogen provision.

Id. at 498, reprinted in XIV Legislative History at 660. The scientific witnesses who testified before Congress stressed that because current scientific techniques could not determine a safe level for carcinogens, all carcinogens should be prohibited. See 56 Fed.Reg. at 7769. While Congressman Delaney's bill was not ultimately passed, the crucial anticancer language from the bill was incorporated into the Food Additives Amendment of 1958 which enacted section 409 of the FFDCFA into law. H.R. 13254, 85th Cong., 2d Sess. (1958), reprinted in XIV Legislative History 880, 887. Thus, the legislative history supports the conclusion that Congress intended to ban all carcinogenic food additives, regardless of amount or significance or risk, as the only safe alternative.

Throughout its 30-year history, the Delaney clause has been interpreted as an absolute bar to all carcinogenic food additives. See 53 Fed.Reg. at 41,104 (announcing a shift in the EPA's position, away from reading section 409's Delaney clause "literally"). In 1958, the Department of Health, Education, and Welfare (which would be charged with administering the food additive provisions of the newly enacted Delaney clause) interpreted the clause as removing all agency discretion regarding carcinogens. See 104 Cong.Rec. 17,412, 17,415 (1958), reprinted in XIV Legislative History 866, 869. As a contemporaneous agency construction of the statute, this interpretation is entitled to great weight. See *Norwegian Nitrogen Products Co. v. United States*, 288 U.S. 294, 315, 53 S.Ct. 350, 358, 77 L.Ed. 796 (1933). Further, Congress has repeatedly ratified a strict interpretation of the Delaney clause by reenacting all three FFDCFA provisions which contain Delaney clauses without changing the Agency's interpretation. See 21 U.S.C. 348 (amended 1960, 1962, 1984); 21 U.S.C. 360b (amended 1988, 1991); 21 U.S.C. 376 (amended 1960, 1962, 1970, 1976). "When the statute giving rise to the longstanding interpretation has been reenacted without pertinent change, the congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." *Federal Deposit Ins. Corp. v. Philadelphia Gear Corp.*, 476 U.S. 426, 437, 106 S.Ct. 1931, 1937, 90 L.Ed.2d 428 (1986) (quotation omitted).

The EPA contends that the legislative history shows that Congress never intended to regulate pesticides, as opposed to other additives, with extraordinary rigidity under the food additives provision. The Agency is indeed correct that the legislative history of the food additive provision does not focus on pesticides, and that pesticides are regulated more comprehensively under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136-136y (West 1980 & Supp. 1992). Nevertheless, the EPA's contention that Congress never intended the food additive provision to encompass pesticide residues is belied by the events prompting passage of the

provision into law: FDA approval of Aramite was the principal impetus for the food additive Delaney clause and Aramite was itself a regulated pesticide. Thus, Congress intended to regulate pesticides as food additives under section 409 of the FFDCFA, at least to the extent that pesticide residues concentrate in processed foods and exceed the tolerances for raw foods.

Finally, the EPA argues that a de minimis exception to the Delaney clause is necessary in order to bring about a more sensible application of the regulatory scheme. It relies particularly on a recent study suggesting that the criterion of concentration level in processed foods may bear little or no relation to actual risk of cancer, and that some pesticides might be barred by rigid enforcement of the Delaney clause while others, with greater cancer-causing risk, may be permitted through the flow-through provisions because they do not concentrate in processed foods. See National Academy of Sciences, *Regulating Pesticides in Food: The Delaney Paradox* (1987). The EPA in effect asks us to approve what it deems to be a more enlightened system than that which Congress established. The EPA is not alone in criticizing the scheme established by the Delaney clause. See, e.g., Richard A. Merrill, *FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress*, 5 *Yale J. on Reg.* 1, 87 (1988) (concluding that the Delaney clause is both unambiguous and unwise: "at once an explicit and imprudent expression of legislative will"). Revising the existing statutory scheme, however, is neither our function nor the function of the EPA. There are currently bills pending before the House and the Senate which would amend the food additive provision to allow the Secretary to establish tolerance levels for carcinogens, including pesticide residues in processed foods, which impose a negligible risk. H.R. 2342, 102d Cong., 1st Sess. (1991); S. 1074, 102d Cong., 1st Sess. (1991). If there is to be a change, it is for Congress to direct.

The EPA's refusal to revoke regulations permitting the use of benomyl, mancozeb, phosmet and trifluralin as food additives on the ground the cancer risk they pose is de minimis is contrary to the provisions of the Delaney clause prohibiting food additives that induce cancer.[FN 3] The EPA's final order is set aside.

FN 3. The EPA contends that its regulations as to phosmet and mancozeb may nevertheless remain in place pending, for phosmet, reevaluation of the pesticide's carcinogenicity, see 56 Fed.Reg. at 7752; and pending, for mancozeb, completion of the "ongoing FIFRA cancellation proceeding against mancozeb and the other pesticides in the EBDC family." See 56 Fed.Reg. at 7773. These apparently still ongoing administrative procedures cannot countermand the application of the Delaney clause in light of the 1988 declaration, never revoked, that both of these pesticides are carcinogenic.