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The Delaney Paradox Resurfaces: Regulating Pesticides as Food Additives under Federal Law

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THE DELANEY PARADOX RESURFACES: REGULATING PESTICIDES AS FOOD ADDITIVES UNDER FEDERAL LAW

I. INTRODUCTION

Cancer has been the most longstanding public health concern of modern society,[1] its causes and cures remaining elusive for decades. During the early to mid-twentieth century, emerging scientific evidence showing that some forms of cancer were likely caused by dietary additives sent Congress scrambling to enact strict food safety laws.[2] The culmination of this legislative activity was the 1958 enactment of a relatively low-profile provision of the Federal Food, Drug and Cosmetic Act[3] (Food & Drug Act) called the Delaney clause.[4] The Food & Drug

1. According to the National Cancer Institute, one in three Americans will develop cancer in their lifetimes. While death rates from cancer have declined in the last half-century, the incidence of cancer in the United States, excluding lung cancer, has increased more than 22.6%, including sharp increases in cancer of the brain, colon, liver, bladder, and thyroid; total cancer incidence has increased 36.6% if lung cancer is included. During this period, cancer among children under the age of 14 has increased 21.5%. Each year in the United States more than one million Americans develop cancer and 500,000 die from it. Cancer may cost the nation as much as $100 billion each year in medical expenses, lost production and income, and research resources. AMERICAN CANCER SOCIETY, CANCER FACTS AND FIGURES (1993) [hereinafter CANCER FACTS AND FIGURES].

A recent study published in the Journal of the American Medical Association says that "baby boomer" white males develop cancer at twice the rate their grandfathers did, and women develop cancer at one and a half times the rate of their grandmothers. These figures take into account today's longer life spans and do not include smoking-related cancers. The authors indicate that the occurrence of unspecified chemicals in the environment have contributed to the rise. Devra L. Davis et al., *Decreasing Cardiovascular Disease and Increasing Cancer Among Whites in the United States From 1973 Through 1987*, 271 JAMA 431 (1994).

2. The Federal Food and Drug Act of June 30, 1906 was completely revised by the enactment of the Federal Food, Drug, and Cosmetic Act of June 25, 1938. CHARLES W. DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD (1938) (reprinted 1987, Food and Drug Institute). From 1938 to 1972, the Federal Food, Drug, and Cosmetic Act was amended 28 times. *Id.*

3. 21 U.S.C. §§ 301-394 (1988 & Supp. IV 1992). The Food & Drug Act is designed to ensure the safety of our food supply by prohibiting the sale of "adulterated" food. § 331(a). "Adulterated" food is defined as food containing, inter alia, any unsafe food "additive," § 342(a)(2)(C), which is defined in turn as "any substance the intended use of which results or may reasonably be expected to result . . . in its becoming a component

Act prohibits the sale of any food containing an "unsafe" additive, and the Delaney clause declares that any additive which is a carcinogen shall automatically be deemed unsafe: "[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 . . . ."[5] The clause rests on the assumption that absolutely no risk of cancer is acceptable in the food supply as long as the scientific community cannot

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. . . of any food." § 321(s). A food additive is deemed unsafe unless there is a specific exemption for the substance or a regulation prescribing the conditions under which it may be used safely. § 348(a).

4. In 1950, the House of Representatives created the Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics, chaired by New York Congressman James J. Delaney. The "Delaney Committee" was charged with investigating the effects of chemicals and pesticides in food production on the health and welfare of consumers. H.R. REP. No. 2356, 82d Cong., 2d Sess. 1 (1952).

The committee concluded that the increasing use of chemical additives created a "serious public health problem" that existing federal laws failed to adequately address and proposed a "chemicals in food amendment" to the Food & Drug Act which would require safety determinations for all chemical food additives. *Id.* at 25. This report led to the Food Additives Amendment of 1958, codified as § 409 of the Food & Drug Act, requiring testing of all chemical food additives to prove their safety for human use and consumption. Congressman Delaney authored and introduced his anticancer provision, which was incorporated into the 1958 amendment. S. REP. No. 2422, 85th Cong., 2d Sess. (1958), *reprinted in* 1958 U.S.C.C.A.N. 5300 [hereinafter SENATE REPORT].

For commentary on "the most famous federal health statute" from a former chief counsel to the FDA, see 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 (1988).

5. 21 U.S.C. § 348(c)(3). There actually are three parallel Delaney clauses which apply to different classes of food constituents: (1) food additives, the subject of this Note (§ 348); (2) color additives (§ 376); and (3) animal drug residues (§ 360b).

The Senate, perhaps underestimating the sweeping implications of the Delaney clause, described its purpose this way:

> We applaud Congressman Delaney for having taken this, as he has every other opportunity, to focus our attention on the cancer-producing potentialities of various substances, but we want the record to show that in our opinion the bill is aimed at preventing the addition to the food our people eat of any substances the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability.

SENATE REPORT, *supra* note 4, at 5309-10.

accurately determine a safe dose for carcinogens in humans.[6] It is a clear and unambiguous congressional mandate that no cancer risk will be tolerated, no matter how negligible, and its ultimate goal is to provide a national food supply free from added carcinogens.[7]

This provision, although fairly innocuous at its birth, has proven its might for over thirty years. As scientific accuracy in determining the carcinogenic potential of a substance has increased,[8] the clause has become ever more powerful, creating confusion in both its administration[9] and its justifications.[10] Federal regulators argue that Congress in 1958 could not have anticipated the scientific advances in cancer detection methods; therefore, the Delaney clause now regulates off the market chemicals that are carcinogenic at minute levels, but considered by the scientific community to be safe for human consumption.[11] Accordingly, federal agencies such as the United States

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6. Section 409 Food Additive Regulations; Order Responding to Objections to EPA's Response to Petition Requesting Revocation of Food Additive Regulations, 56 Fed. Reg. 7750, 7772 (1991) [hereinafter Section 409 Food Additive Regulations].

7. *Id.*; *see also infra* note 13.

8. "Since the law went into effect, . . . researchers have developed exquisitely sensitive techniques for sniffing out compounds. Today these tests can detect one part per quintillion—roughly the same as a tablespoon of liquid in all the Great Lakes combined." Christine Gorman, *Getting Practical About Pesticides*, TIME, Feb. 15, 1993, at 52.

9. Since Congress enacted the Delaney clause, courts have had considerable difficulty articulating its scope. *See, e.g.*, Rhone-Poulenc, Inc. v. FDA, 636 F.2d 750 (D.C. Cir. 1980) (declining to decide whether DES is still an exception to Delaney clause after FDA revoked "approved" test method without approving any method to replace it); Chemetron Corp. v. HEW, 495 F.2d 995 (D.C. Cir. 1974) (administering carcinogen, DES, to cattle prior to slaughter is exception to Delaney clause because no DES residue is found in edible portion of slaughtered animal through "approved" test method even though new scientific techniques prove otherwise); Environmental Defense Fund, Inc. v. HEW, 428 F.2d 1083 (D.C. Cir. 1970) (Delaney clause does not apply "full force" to pesticide chemicals, but if evidence demonstrates DDT is a carcinogen, HEW must explain why any DDT tolerance is "safe" regardless of lack of scientific basis for determining a "safe" residue level for a known carcinogen).

10. The former chief counsel to the FDA noted:

> Implementation of this [clause] might have engendered little controversy if the universe of "food additives" had remained well-defined, if few compounds had displayed the capacity to "induce cancer" in laboratory animals, and if no food constituents shown to cause cancer had gained popularity among consumers or producers. However, experience has frustrated both the Clause's opponents and its defenders.

Merrill, *supra* note 4, at 20.

11. *See infra* notes 47-51 and accompanying text.

Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) insist that the Delaney clause must be construed to contain a de minimis exception for some carcinogenic chemicals.[12]

The Delaney clause's farthest felt and most controversial impact has been in the area of pesticide regulation.[13] The use of pesticides and other chemicals has increased dramatically in this country since the end of World War II.[14] The EPA, the federal agency charged with regulation of the pesticide industry, is required to register every pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[15] In addition to FIFRA registration, pesticides used on food crops, whether for human or animal consumption, are treated as food additives and subject to the provisions of the Food & Drug Act.[16] EPA regulators argue that conflicting standards and requirements contained in these two

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12. *See infra* notes 52-63 and accompanying text.

13. Congress enacted the 1958 bill at least in part as a response to the FDA's decision to allow a known carcinogen, the pesticide Aramite, to be used as a food additive. *Food Additives: Hearings Before a Subcommittee of the House Committee on Interstate and Foreign Commerce*, 85th Cong., 1st & 2d Sess. 171 (1958).

Congressman Delaney responded to the FDA's approval for sale of foods containing small quantities of Aramite:

> 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 anticarcinogen provision.

Id. at 498.

14. One commentator explained:

> Of all interventions into the natural order, perhaps none has stirred so much debate as the creation and use of chemical pesticides in agriculture. Starting with the biochemical revolution after World War II, alchemists have brewed as many as 50,000 new concoctions in America alone. The use of pesticides has increased dramatically, now approaching three billion pounds a year.

Al Meyerhoff, *No More Pesticides for Dinner*, N.Y. TIMES, Mar. 9, 1993, at A19.

15. 7 U.S.C. §§ 136-136y (1988 & Supp. IV 1992). FIFRA defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance . . . intended for use as a plant regulator, defoliant, or desiccant," § 136(u), and "pest" as "any insect, rodent, nematode, fungus, [or] weed." § 136(t).

16. The EPA has been delegated responsibility for regulating pesticides that are considered food additives under the Food & Drug Act. *See* Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104, 41,106 n.2 (1988) [hereinafter Delaney Paradox Policy Statement].

statutes create an unworkable regulatory scheme, which they fondly call the "Delaney paradox."[17]

The paradox arises from two mutually exclusive standards under which the EPA must determine whether a given pesticide is safe. The agency is authorized to license a pesticide under FIFRA for use on food crops after weighing its benefits to consumers and the agricultural industry against the potential risks to public health and the environment.[18] The EPA uses the same risk/benefit standard under section 408 of the Food & Drug Act to determine whether to allow certain levels of pesticide residue, called "tolerances," to remain on raw agricultural commodities, even if the pesticide is a carcinogen.[19] However, pesticide residues which concentrate in processed foods above the level authorized to be present in their parent raw commodities are treated as food additives under the Food & Drug Act and subjected to stricter requirements.[20] The FDA and EPA may set allowable levels for food additives only after a determination that such levels are proven

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17. *See* discussion *infra* part I.

18. 7 U.S.C. § 136a(c)(5).

> The Administrator shall register a pesticide if he determines that . . . —
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> . . . .
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> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.
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> The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide.

Id.

19. 21 U.S.C. § 346a(b) (1988).

> The Administrator shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized . . . as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Administrator shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion submitted with a certification of usefulness under subsection (l) of this section.

§ 346a(b).

20. 21 U.S.C. § 321(s); *see also* United States v. Ewig Bros., 502 F.2d 715, 723 (7th Cir. 1974) (subjecting pesticide chemical in a processed food to regulation as a "food additive" under § 409 of Food & Drug Act), *cert. denied*, 420 U.S. 945 (1975).

"safe."[21] These levels for processed food are called "food additive regulations" and are authorized to be issued by section 409 of the Food & Drug Act.[22]

Section 409 also contains the Delaney clause, which prohibits *any* consideration of benefits for a food additive that is carcinogenic—it is a strict risk-only test. Thus, the EPA must consider a pesticide's benefits when registering it for use or setting a tolerance for its residue on raw foods, but it is strictly forbidden from considering these benefits if the pesticide concentrates in processed foods and has been shown to cause cancer. While some argue that this shift in standards properly protects against the cumulative effect of carcinogens in our food supply,[23] the EPA and the pesticide industry argue that it is unreasonable and burdensome.[24]

It is EPA policy to deny FIFRA registration for any food-use pesticide that cannot meet the requirements for a raw food tolerance or food additive regulation under sections 408 and 409 of the Food & Drug Act.[25] Therefore, when a pesticide manufacturer petitions the EPA for a new pesticide registration, the agency must first predict whether use of that pesticide may leave residues in processed food above the level that would be found on raw food. If the pesticide has been shown to cause cancer in laboratory animals and is likely to so concentrate, the EPA must deny the registration for that pesticide even if the agency considers it safe for human consumption.[26]

The EPA argues that this switch from a risk/benefit test to a risk-only test, coupled with Delaney's roadblock effects, is illogical and

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21. 21 U.S.C. § 348(c) (1988).

(1) The Secretary shall—

(A) by order establish a regulation . . . prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used . . . .

. . . .

(3) 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 . . . .

21 U.S.C. § 348(c).

22. 21 U.S.C. § 348(c).

23. *See* discussion *infra* text accompanying notes 88-90; *see also infra* part III.C.

24. *See infra* notes 38-51, 55-56 and accompanying text.

25. Pesticide Registration and Classification Procedures, 40 C.F.R. §§ 152.112(g), 152.113(a)(3), 152.114(c) (1993).

26. *Id.*

unjustified by Delaney's evolving overprotection of the interests it was designed to serve.[27] This regulatory scheme arguably leads to a stronghold on the market by older and more dangerous pesticides that have not yet been retested under modern scientific techniques,[28] erects barriers to entry for newer, possibly safer, pesticides,[29] and results in different regulatory treatment of similar pesticides based solely on the form of food in which they will remain as residue.[30] Because of these inconsistencies, strict application of the Delaney anti-cancer clause in these situations could lead to greater overall health risks—thus, the Delaney "paradox." Accordingly, the EPA has never invoked the Delaney clause to prohibit the use of a pesticide that it has found to pose only a negligible risk of harm.[31]

Despite repeated expressions of agency frustration, the Delaney clause has been upheld as a clear and unambiguous statement of congressional intent to remove carcinogenic additives at any level from our food supply. Courts have rejected the FDA's de minimis interpretation in *Public Citizen v. Young*[32] and, more recently, the EPA's de minimis treatment of pesticide residues in *Les v. Reilly*.[33] While acknowledging the existence of the Delaney paradox, the court in *Les* found that the clear language of the clause and its legislative history and design unambiguously require literal application. *Les* reignited the controversy over the Delaney paradox, by forcing the EPA, against its scientific judgment, to cancel pesticide registrations. The *Les* decision also sent a clear message to Congress to reevaluate its original rationale behind enactment of the Delaney clause, a message to which Congress and the Clinton administration have recently reacted.

This Note discusses the implications of the Delaney paradox and the legislative reform proposals under current debate in Congress. Part II addresses agency arguments that enforcement of the Delaney clause leads to absurd results in pesticide regulation.[34] Part III reviews the de minimis doctrine used by agencies to interpret the Delaney clause and

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27. *See generally* Delaney Paradox Policy Statement, *supra* note 16.

28. *See infra* note 48 and accompanying text.

29. *See infra* note 48 and accompanying text.

30. *See infra* notes 43-47 and accompanying text.

31. Delaney Paradox Policy Statement, *supra* note 16, at 41,108.

32. 831 F.2d 1108 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988); *see* discussion *infra* part III.B.1.

33. 968 F.2d 985 (9th Cir. 1992), *cert. denied sub nom.* National Agric. Chems. Ass'n v. Les, 113 S. Ct. 1361 (1993); *see* discussion *infra* part III.B.2.

34. *See infra* notes 38-51 and accompanying text.

judicial rejection of this doctrine.[35] Part IV examines the significance of *Les v. Reilly* for Congress and federal agencies,[36] and Part V discusses aspects of legislative reform.[37]

II. APPLICATION OF THE DELANEY CLAUSE

Under the Food & Drug Act, pesticide residue may remain in or on raw agricultural commodities, such as fresh produce, as long as the EPA scientifically determines that the level of residue is safe for human consumption, whether or not that pesticide has been shown to be a carcinogen.[38] The statute also has a "pass-through" provision, which permits the same level of pesticide residue to remain once that food is processed (e.g., canned, milled, frozen, cooked).[39] However, if

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35. *See infra* notes 52-96 and accompanying text.

36. *See infra* notes 97-114 and accompanying text.

37. *See infra* notes 115-39 and accompanying text.

38. The statute itself does not define "safe," merely noting that it has "reference to the health of man or animal." 21 U.S.C. § 321(u) (1988 & Supp. IV 1992).

FDA regulations state that:

> (i) *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:
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> (1) The probable consumption of the substance . . .
>
> (2) The cumulative effect of the substance in the diet . . .
>
> (3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and drug ingredients, are generally recognized as appropriate.

Food Additives, 21 C.F.R. § 170.3(i) (1993).

39. The relevant statute states:

> . . . [W]here 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 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, 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) (1988).

carcinogenic pesticide residue concentrates during processing, or if carcinogenic pesticides are added during processing beyond the level allowed in the food's raw counterpart, the Delaney clause prevents the EPA from issuing a food additive regulation allowing that pesticide on the processed food.[40] Thereafter, the EPA must deny a tolerance for use of that pesticide on raw food, which necessitates denial of registration for that pesticide for that particular food use.[41] Under the statute, raw food is "adulterated" and, therefore, subject to federal seizure and condemnation, if it contains pesticide residue for which a tolerance has been denied.[42]

Thus, when presented with an application for registration of a pesticide for a particular agricultural use, the EPA must first determine if that pesticide's residue will remain on the crop when it is harvested.[43] Then the agency must establish a tolerance for that residue on the crop

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40. "For example, if fruit bearing a residue of 7 parts per million of DDT permitted on the raw agricultural commodity is dried and a residue in excess of 7 parts per million of DDT results on the dried fruit, the dehydrated fruit is adulterated . . . ." Food Additives, 21 C.F.R. § 170.19 (1993).

41. *See supra* note 25 and accompanying text.

42. 21 U.S.C. § 342(a)(2)(B) (1988). An exemption may be granted when a tolerance "is not necessary to protect the public health." § 346a(c).

The FDA and the United States Department of Agriculture (USDA) monitor foods for levels of pesticide residues and enforce the Food & Drug Act. *See* Delaney Paradox Policy Statement, *supra* note 16, at 41,106 n.2. They do this by sampling food shipments in interstate commerce, through cooperative schemes with various states, and through the FDA's "Total Diet Study" program. In its Total Diet Study, FDA investigators "shop" at various grocery stores in 12 cities four or five times a year and fill their shopping carts with over 200 carefully selected foods, including infant formulas and baby food, meat and vegetables, fruit and candy bars, and beer and soda pop. The perishable groceries are then packed in ice and rushed to the FDA laboratory in Kansas City, Missouri where chemists and technicians test them with equipment capable of detecting residues at one part per billion. The ready-to-eat items are tested on the spot; the rest of the ingredients are tested after they are cooked into stews, roasts, and other dishes. James S. Benson, *An FDA View*, EPA J., May-June 1990, at 10.

43. Under FIFRA, a pesticide is registered for use on particular sites (e.g., specific crops, ornamental plants) at specified doses. For each proposed use the applicant must supply the EPA with extensive testing data, which the EPA uses to determine whether the proposed pesticide use will "perform its intended function" when "used in accordance with widespread and commonly recognized practice" without causing "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(B)-(D) (1988).

These adverse effects are defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb). This standard requires a finding that the benefits of use of the pesticide outweigh the public health risks of its use, when the pesticide is used in compliance with the terms and conditions of registration, or in accordance with commonly recognized practices. *Id.*

that the agency determines is safe for human consumption.[44] The next step is to determine if any portion of the crop to be treated with that pesticide will end up in a processed food.[45] If processing is likely, EPA must also ascertain whether any pesticide residue will concentrate during processing.[46] If so, then the pesticide will be regulated as a food additive and any benefits that were taken into account during the registration process or the setting of the raw food tolerance are no longer relevant in light of Delaney's risk-only standard. If the pesticide has been shown to cause cancer then its registration will be denied, even when the risk of cancer is negligible.[47] Under this regulatory scheme, the criteria for allowing pesticide residues in food depends on the form of the food—whether it is raw or processed. This is arguably an unjustifiable distinction for the purposes of protecting public health.

One result of literal application of the Delaney clause is the roadblock it places on new entrants to the pesticide market. Pesticide manufacturers have no incentive to commit the resources necessary for testing and marketing new products, especially if the products' chemical formulas contain known carcinogenic elements. The EPA argues that this effectively blocks newer and probably safer pesticides from entering the market while older pesticides remain in heavy use because they tested negative for carcinogenicity under the cruder scientific techniques of the 1960s and 1970s.[48]

The clause takes on its greatest import, however, when it is applied retroactively to the hundreds of pesticides currently in use. The EPA is in the process of retesting all registered pesticides for carcinogenicity using modern scientific techniques.[49] If the clause is strictly interpreted

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44. *See supra* note 19.

45. *See supra* note 20 and accompanying text.

46. *See supra* note 20 and accompanying text.

47. *See supra* note 26 and accompanying text.

48. Delaney Paradox Policy Statement, *supra* note 16, at 41,109. The EPA also points out the undesirable result of interference with free market competition. Two similar pesticides with similar risks can be treated very differently under this regulatory scheme. One may be banned from the market if used on food that will be processed while the other may be allowed if only used on raw foods; this may be true even if the latter's risk is significantly higher. *Id.* at 41,108.

49. All pesticides first registered before November 1, 1984 must be re-registered. 7 U.S.C. § 136a-1. "There is at least 'limited evidence' of carcinogenicity (virtually all from animal studies) for 66 or more of the approximately 350 food-use pesticides already approved for use . . . . EPA expects this number to become somewhat larger as it receives and evaluates more studies on the food-use pesticides." Delaney Paradox Policy Statement, *supra* note 16, at 41,108.

and applied, then the EPA will be forced to ban every pesticide that retests positive for carcinogenicity no matter how negligible the risk.[50] The EPA argues that such a blanket ban would be absurd, no matter how clear the language, and that Congress could not have foreseen or desired the magnitude of Delaney's prohibitions after thirty-five years of scientific advances in cancer testing.[51]

III. AGENCY INTERPRETATION AND JUDICIAL APPLICATION

A. The De Minimis Doctrine

In regulating food additives and pesticides pursuant to the Delaney clause, the EPA and FDA have attempted to interpret the clause to implicitly contain a de minimis exception.[52] They contend that federal regulatory agencies have inherent authority to avoid applying the terms of a statute literally to situations that are trivial in nature in order to conserve agency resources for important matters and to avoid "absurd or futile results."[53]

The absurd results the agencies postulate include the creation of disincentives for newer, safer pesticides, the regulatory distinction made between raw and processed foods, and the prospective industry-wide ban on many popular pesticides.[54] The EPA points out that such a ban would lead to a reduction in crop yields essential to the human diet, a corresponding increase in national food prices, an increase of natural toxins in the food supply,[55] and the use of potentially more toxic, albeit

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50. EPA Administrator Carol M. Browner recently issued a list of 35 commonly-used agricultural chemicals which would be prohibited from the market as a result of the strict application of the Delaney clause upheld in Les v. Reilly, 968 F.2d 985 (9th Cir. 1992), *cert. denied sub nom.* National Agric. Chems. Ass'n v. Lees, 113 S. Ct. 1361 (1993). The EPA does not believe that the listed pesticides pose an unreasonable risk to public health. Tom Kenworthy, *EPA Issues List of 35 Suspect Pesticides*, WASH. POST, Feb. 3, 1993, at A4.

51. Delaney Paradox Policy Statement, *supra* note 16, at 41,108.

52. The complete Latin phrase is *de minimis non curat lex*, meaning "[t]he law does not concern itself about trifles." BLACK'S LAW DICTIONARY 431 (6th ed. 1990).

53. Section 409 Food Additive Regulations, *supra* note 6, at 7753. *See generally* Margaret Gilhooley, *Plain Meaning, Absurd Results and the Legislative Purpose: The Interpretation of the Delaney Clause*, 40 ADMIN. L. REV. 267 (1988) (recognizing the primacy of legislative purpose over plain meaning in statutory interpretation in order to account for unforeseen events and prevent absurd results).

54. *See supra* notes 38-51 and accompanying text.

55. The EPA has found "some evidence" that the use of synthetic pesticides permits the cultivation of crop varieties which contain lower levels of their own natural toxins.

non-carcinogenic, pesticides.[56] The EPA argues that Delaney's risk-free food supply does not justify such drastic economic and public health effects.

The EPA and FDA generally consider a de minimis risk to be one in which seventy years of individual exposure would produce no more than a one-in-one-million chance of cancer, and, therefore, implicitly allowed by the Delaney clause.[57] As scientific methods for detecting carcinogenicity improve, the Delaney clause increasingly overprotects the interests it seeks to safeguard. The EPA urges that a de minimis exception is necessary to reconcile the clause's original purpose and its unanticipated effects.

The agencies generally find their authority to read de minimis exceptions into statutes from *Alabama Power Co. v. Costle*.[58] In

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Section 409 Tolerances; Response to Petition Requesting Revocation of Food Additive Regulations, 55 Fed. Reg. 17,560, 17,565 (1990).

56. The Delaney clause does not protect against pesticides which are toxic but not carcinogenic. *Id.*

57. *See* Proposed Guidelines for Risk Assessments, 49 Fed. Reg. 46,294 (1984); D & C Green No. 6 Listing as Color Additive in Externally Applied Drugs and Cosmetics, 47 Fed. Reg. 14,138, 14,143-45 (1982). The EPA commonly expresses risk estimates as probabilities (e.g., one in one million (1 x 10-6)), and illustrates them as lifetime cancer risks (e.g., a one-in-one-million risk is a risk that there may be one additional cancer case for every one million persons over the course of a 70-year life span). Section 409 Food Additive Regulations, *supra* note 6, at 7755.

The EPA acknowledges that there are no definitive criteria for establishing negligible risk. *Id.* at 7757. It generally bases its one-in-one-million threshold on its past assessments and those of sister agencies for acceptability of cancer risks, as supported by public notice and comment and judicial review. *Id.* at 7756-57. The EPA also notes that Congress itself enacted a one-in-one-million cancer risk tolerance into the Clean Air Act Amendments of 1990. *Id.* at 7757.

58. 636 F.2d 323 (D.C. Cir. 1979) (permitting the EPA to establish regulations under the Clean Air Act Amendments of 1977 exempting de minimis violations). "Unless Congress has been extraordinarily rigid, there is likely a basis for an implication of *de minimis* authority to provide [an] exemption when the burdens of regulation yield a gain of trivial or no value." *Id.* at 360-61.

Courts also have permitted de minimis exceptions to provisions of the Food & Drug Act. In an opinion written in the same year as *Alabama Power*, the D.C. Circuit considered whether acrylonitrile in beverage containers was a "food additive" as defined in § 201(s) of the Food & Drug Act. Monsanto Co. v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979). The court found that the FDA had discretion to exclude a chemical from the statutory definition if "the level of migration into food . . . is so negligible as to present no public health or safety concerns." *Id.* at 955. However, *Monsanto* did not involve a Delaney clause.

In a later case involving the carcinogenity of a chemical impurity found in a color additive, the Court of Appeals for the Sixth Circuit held that the color additives Delaney clause did not apply to constituents of a color additive when the additive as a whole had not been found to cause cancer in test animals, and, therefore, the FDA had discretion to allow de minimis amounts of the impure chemical to migrate into food. Scott v. FDA, 728

Alabama Power, the Court of Appeals for the District of Columbia imposed three prerequisites for agency invocation of the de minimis doctrine: (1) the problem that would be addressed by regulation must in fact be so trivial that no real benefit would result from regulation;[59] (2) Congress has not been extraordinarily rigid in expressing its intent;[60] and (3) a de minimis exception comports with the legislative design.[61] According to the EPA, the food additives Delaney clause satisfies these criteria because new technologies can detect carcinogenic potential that is truly de minimis—risks so small that Congress in 1958 could not have anticipated our ability to detect them nor would have intended to prohibit their use.[62] The agency also argues that the clause has long been regarded as allowing the EPA to exercise scientific judgment and discretion in deciding whether a food additive "induces cancer" in animals—thus, the legislative design leaves room for the EPA to do just that by way of a de minimis exception.[63]

B. Judicial Enforcement

1. *Public Citizen v. Young*: Color Additives

Appellate courts have flatly rejected the de minimis exception to the Delaney clause, holding it to be contrary to the clear language and purpose of the statute and refusing to recognize agencies' policy justifications for it. In *Public Citizen v. Young*,[64] the United States Court of Appeals for the District of Columbia Circuit considered a challenge under the color additives Delaney clause to the FDA's approval of two color additives, Orange No. 17 and Red No. 19, which the FDA concluded posed trivial cancer risks after appropriate scientific

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F.2d 322, 325-26 (6th Cir. 1984). The EPA calls this the "constituents policy" and uses it to justify granting food additive regulations which contravene the Delaney clause. Delaney Paradox Policy Statement, *supra* note 16, at 41,107.

59. *Alabama Power*, 636 F.2d at 361. Judge Levanthal made it clear that an agency cannot apply the de minimis doctrine merely because regulatory costs exceed regulatory benefits. *Id.*

60. *Id.* at 360.

61. *Id.* at 360 n.89. "[T]he principle is a cousin of the doctrine that, notwithstanding the 'plain meaning' of a statute, a court must look beyond the words to the purpose of the act where its literal terms lead to 'absurd or futile results.'" *Id.* (quoting United States v. American Trucking Ass'ns, 310 U.S. 534, 543 (1939)).

62. Section 409 Food Additive Regulations, *supra* note 6, at 7772-73.

63. *Id.* at 7771-72.

64. 831 F.2d 1108 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988).

testing.[65] Although the court agreed with the FDA that the dyes posed only trivial cancer risks,[66] it concluded "with some reluctance"[67] that the color additives Delaney clause did not contain an implicit de minimis exception. According to the court, all of the requirements of *Alabama Power*'s de minimis doctrine had not been met.[68] Specifically, it noted that the statutory language and legislative design

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65. The FDA listed Orange No. 17 and Red No. 19 for use in externally applied cosmetics on August 7, 1986. *Id.* at 1110.

> The [tests] considered the risk to humans from the substances when used in various cosmetics—lipsticks, face powders and rouges, hair cosmetics, nail products, bathwater products, and wash-off products. The scientific review panel found the lifetime cancer risks of the substances extremely small: for Orange No. 17, it calculated them as one in 19 billion at worst, and for Red No. 19 one in nine million at worst. The FDA . . . characterized the risks as "so trivial as to be effectively no risk" [and] concluded that the two dyes were safe.

Id. at 1110-11 (citing Listing of D & C Orange No. 17 for Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28,331, 28,344, 28,360 (1986)).

Although the FDA described its chosen testing method as "current state-of-the-art toxicological testing," industry argued that the test method was inappropriate to the evaluation of dyes and that the chosen method used in the industry would demonstrate no risk from use of the dyes. *Id.* at 1110. The FDA specifically rejected this argument after lengthy published comparisons of both methods. The court of appeals stated that the FDA's chosen test methods were accurate "for these purposes." *Id.* at 1111. The court's pointed statement implies a measure of doubt about the scientific validity of one test method over another as a means to identify exact measurable units of cancer potential. *See* discussion *infra* part IV.

66. The court noted that a consumer would face an equivalent one-in-one-million lifetime risk of liver cancer if he or she ate one peanut with the FDA-permitted level of natural aflatoxins once every 250 days or spent less than 17 hours every year in the city of Denver, with its higher than average elevation leading to higher cosmic radiation levels, rather than in the District of Columbia. *Public Citizen*, 831 F.2d at 1111. The court thought this was hardly "living dangerously." *Id.*

67. *Id.* at 1109. The court suggested a situation in which literal application of Delaney would violate the primary "human safety" goal of the Food & Drug Act, thus leading to "absurd or futile" results:

> No one contends that the Color Additive Amendments impose a zero-risk standard for non-carcinogenic substances; if they did, the number of dyes passing muster might prove minuscule. As a result, makers of drugs and cosmetics who are barred from using a carcinogenic dye carrying a one-in-20-million lifetime risk may use instead a noncarcinogenic, but toxic, dye carrying, say, a one-in-10-million lifetime risk.

Id. at 1113.

68. The court noted that one justification behind the de minimis doctrine—preserving agency resources for important matters—was of "dubious relevance" to the instant case, considering the heavy expenditure of agency resources required for elaborate animal testing and quantitative risk assessment. *Id.* at 1112.

unambiguously[69] demonstrate that the Delaney clause applies rigidly to color additives. The court declared that the "natural—almost inescapable—reading" of the clause prescribed literal application, and the legislative history strongly "strengthen[ed] the inference."[70] The court also determined that literal application was a plausible congressional policy choice given the great public concern over cancer, the low societal value of color additives, and the possibility of remedying any false scientific assumptions through reconsideration by Congress.[71] Given these findings and the absence of precedent allowing its use,[72] the court held the FDA's de minimis approach to be contrary to law,[73] and ordered the color additives to be removed from the "safe" list.

The court stressed that its opinion applied only to the *color* additives Delaney clause and that operation of the *food* additives clause "raises complex issues distinct from those on this appeal."[74] The court believed its ruling did not foreclose a de minimis interpretation of the food additives Delaney clause because of the broad social consequences that would result from literal application of that clause.[75]

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69. "The language itself is rigid; the context—an alternative design admitting administrative discretion for all risks other than carcinogens—tends to confirm that rigidity." *Id.* at 1113.

70. *Id.* The court considered the House Report on the Color Additives Amendment and noted that the committee specifically rejected all de minimis arguments that arose. Moreover, the court noted that the House Report indicated that only Congress, not regulatory agencies, should change the Delaney clause's strict mandate in the event scientific methods could establish "safe" tolerances for carcinogens. The court also determined that the questions raised in the Senate post-enactment colloquy regarding literal enforcement of Delaney were at most ambiguous. *Id.* at 1113-17.

71. *Id.* at 1117-18. "We believe that, in the color additive context, Congress intended that if this rule produced unexpected or undesirable consequences, the agency should come to it for relief. That moment may well have arrived, but we cannot provide the desired escape." *Id.* at 1122.

72. "*Monsanto* and *Scott* demonstrate that the de minimis doctrine is alive and well in the food and drug context, even on the periphery of the Delaney Clauses. But no case has applied it to limit the apparent meaning of any of those Clauses in their core operation." *Id.* at 1119. For a discussion of *Monsanto* and *Scott*, see *supra* note 58.

73. 831 F.2d at 1123. The court went so far as to warn the agency that the words "induce cancer" in the Delaney clause did not give the agency discretion "to take a finding that a substance causes only trivial risk in humans and work back from that to a finding that the substance does not 'induce cancer in . . . animals.'" *Id.* at 1121. The only discretion allowed the agency is in the *choice* of which scientific methods to use. *Id.* at 1122.

74. *Id.* at 1118 n.13.

75. The court acknowledged the argument that scientific advances made a de minimis exception to the food additives Delaney clause necessary. It reasoned that if agencies had

2. *Les v. Reilly*: Pesticides as Food Additives

Faced with the rejection in *Public Citizen* of the FDA's de minimis interpretation of the color additives Delaney clause, the EPA attempted to forestall the retroactive application of the food additives Delaney clause to the hundreds of pesticides on the market by gathering and disseminating information about the Delaney paradox and calling for legislative reform. In 1987 the Board on Agriculture of the National Research Council/National Academy of Sciences (NAS), commissioned by the EPA, published a detailed report stressing the illogical demands placed on the EPA by the conflicting standards of FIFRA and the Food & Drug Act.[76] The report also set forth recommendations for future EPA regulation of pesticide residues, including the use of the de minimis negligible risk approach.[77]

Subsequently, the EPA published a notice of proposed change in its rulemaking proceedings under section 409 of the Food & Drug Act, taking the position that the food additives Delaney clause contained a de minimis exception.[78] The agency stated that this "ideal policy"[79] would allow it to apply one uniform set of criteria under a risk/benefit standard to all FIFRA registration decisions and all section 408 tolerance and section 409 food additive regulation decisions under the Food & Drug

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to prohibit *any* food substance that causes cancer, including essential natural ingredients now shown to be carcinogenic in large doses, including "vitamins C and D, calcium, protein, and amino acids," literal application of the Delaney clause would effectively "deny the American people access to a healthy food supply." *Id.* at 1119.

The court believed that if the food additives Delaney clause were to be literally applied through an enforcement action in the judicial system, Congress would respond quickly under the threat of the consequences of banning all carcinogens from the market. *Id.* at 1120.

76. COMMITTEE ON SCIENTIFIC AND REGULATORY ISSUES UNDERLYING PESTICIDE USE PATTERNS AND AGRICULTURAL INNOVATION, NAT'L RESEARCH COUNCIL, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX (1987) [hereinafter REGULATING PESTICIDES IN FOOD].

77. These recommendations generally consisted of: (1) pesticide residues in food, whether in raw or processed form, should be regulated through one standard; (2) this standard should be "negligible risk"; (3) EPA should focus its energies on reducing risk from the most worrisome pesticides on the most-consumed crops; and (4) EPA should develop improved tools and methods to more systematically estimate overall impacts of prospective regulatory actions on health, the environment and food production. *Id.* at 11-16.

78. Delaney Paradox Policy Statement, *supra* note 16, at 41,107; *see* discussion *supra* part III.A.

79. Delaney Paradox Policy Statement, *supra* note 16, at 41,105.

Act.[80] The agency decided that the *Public Citizen* court's rejection of the FDA's use of this approach did not apply to pesticides because the extensive regulation of pesticides elsewhere in federal law overwhelmingly utilized a risk/benefit approach.[81] The EPA recognized possible legal concerns regarding this regulatory approach[82] and called for legislative reform officially authorizing the agency to utilize a risk/benefit approach in establishing all food tolerances and registrations.

Soon thereafter the EPA was petitioned to revoke section 409 food additive regulations for seven carcinogenic pesticides made pursuant to this de minimis policy. The EPA responded by issuing final orders in 1991 and 1992 denying the petitions[83] and reaffirming its earlier de minimis interpretation.[84] The EPA argued that Congress would not

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80. *Id.* The EPA believed this would reconcile its decisions regarding non-carcinogenic pesticides, FIFRA registrations, and § 408 tolerances for carcinogens on raw foods. Applying the "ideal policy," the EPA would approve a pesticide without regard to its benefits or efficacy if the pesticide's use would pose no risk or only a negligible risk. *Id.*

The agency also asserted authority to register pesticides that posed a greater-than-negligible risk. *Id.* at 41,109. The agency reasoned that, with respect to established food additive regulations for pesticides currently on the market, it had the authority to assess the safety of these regulations under any standard it chose to adopt as long as it was not arbitrary or capricious within the meaning of the Administrative Procedure Act, 5 U.S.C. §§ 551-706 (1982). *Id.* at 41,108.

81. *Id.* at 41,107. In the EPA's view, this satisfied the legislative design prong of the de minimis doctrine. *See supra* note 61 and accompanying text.

82. "[I]mplementing [these] approaches will be controversial and might involve the agency in protracted litigation that could cause uncertainty and make it difficult for businesses to make plans about pesticide development and pesticide use." Delaney Paradox Policy Statement, *supra* note 16, at 41,109.

83. Order Regarding Mancozeb Food Additive Regulations, 57 Fed. Reg. 20,481 (1992) [hereinafter Mancozeb Order]; *see* Section 409 Food Additive Regulations, *supra* note 6.

Of 14 food additive regulations disputed, the EPA refused the petition for four of them. The EPA stood by its de minimis determination for trifluralin on spearmint and peppermint oil, benomyl on raisins and tomato products, and mancozeb on raisins and bran of barley, oats, rye, and wheat. Phosmet, used on cottonseed oil, had not yet been definitely ruled a carcinogen. The others had already been revoked or proposed to be revoked by the EPA. Mancozeb Order, *supra*, at 20,485; Section 409 Food Additive Regulations, *supra* note 6, at 7751.

Petitioners included the State of California, Natural Resources Defense Council, Ralph Nader's Public Citizen, the AFL-CIO, a farm worker who had suffered pesticide poisoning and three young Central Valley children. Section 409 Food Additive Regulations, *supra* note 6, at 7751; Richard C. Paddock, *Attorney General Joins Suit Challenging EPA on Pesticides*, L.A. TIMES, May 26, 1989, at 3.

84. Section 409 Food Additive Regulations, *supra* note 6, at 7768-73.

knowingly have enacted a paradox regarding the regulation of pesticides and that there were fewer signs of congressional rigidity concerning the food additives Delaney clause than were noted by the *Public Citizen* court regarding the color additives Delaney clause.[85] The EPA also argued that "a court is not required to subscribe to outdated scientific notions in construing congressional intent."[86]

The EPA's arguments held little weight, however, for the Court of Appeals for the Ninth Circuit in *Les v. Reilly*.[87] The case arose as a challenge to the EPA's final orders denying revocation of food additive regulations for four pesticides: trifluralin, benomyl, mancozeb, and phosmet. In rejecting the EPA's de minimis interpretation of the food additives Delaney clause, the court succinctly stated that the language,

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The EPA argued, inter alia, that courts have frequently recognized de minimis exceptions in actions under the Food & Drug Act, pointing to judicial approval of trivial amounts of "filth" in food under a Food & Drug Act provision that condemned as adulterated a food "if it consists in whole or in part of any filthy, putrid, or decomposed substances." *Id.* at 7753 (citing United States v. Goodman, 486 F.2d 847, 855 (7th Cir. 1973); United States v. 484 Bags, More or Less, 423 F.2d 839, 841 (5th Cir. 1970)).

85. *Id.* at 7768-69. "Extraordinary rigidity would be demonstrated by showing that Congress persisted in its support for the Delaney clause despite vigorous and highly specific opposition to the clause. That is exactly what occurred in the legislative debate over the color additives Delaney clause. It did not occur in this case." *Id.* at 7769.

> Central to this determination is the absence of a congressional consideration and rejection of alternatives to the Delaney clause, the complete absence of contemplation by Congress of the effect the anti-cancer clause would have on pesticides, and the decided ambivalence of certain of the major sponsors of the bill toward the Delaney clause. In other words, Congress did not hear scientific criticism of the [food additives] Delaney clause, it did not realize that it was issuing a major law for the regulation of pesticides (moreover, a law which introduced paradoxical and irrational differences into the regulation of pesticides), and it did not speak with one voice when it approved the Delaney clause.

Id. at 7770. The EPA also noted that the legislative design of comprehensive pesticide regulation in FIFRA and § 408 of the Food & Drug Act supports weighing of benefits against risks even with respect to carcinogenic pesticides. *Id.* at 7771-72.

Indeed, to support the EPA's argument, there *is* evidence that Congress in 1958 did not place the import on it that we do today. The Delaney clause was added to the Food Additives Amendment after the bill had already been approved, and there is indication that it was added only as an honorific tribute to Congressman Delaney's work in fighting cancer. *See supra* note 5.

86. Section 409 Food Additive Regulations, *supra* note 6, at 7772. While the Delaney clause was predicated on the fact that the scientific community in 1958 could not determine a "safe" level of carcinogens, the EPA believes that scientific advancements now allow for determining carcinogenic residue levels which pose such low risks as to be considered safe. *Id.* at 7772-73.

87. 968 F.2d 985 (9th Cir. 1992), *cert. denied sub nom.* National Agric. Chems. Ass'n v. Les, 113 S. Ct. 1361 (1993).

the history, and the purpose of Delaney all reflect Congress's unequivocal goal of zero risk for cancer-causing food additives.[88] In so holding, the court noted the language of the clause was "clear and mandatory"[89] and that since its enactment in 1958 the statute had been "strictly and literally enforced."[90] The court further observed that although 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, . . . its reasoning with respect to the language of the statute is equally applicable to both."[91] The court gave weight to the fact that Congress repeatedly reenacted all three Food & Drug Act provisions containing Delaney clauses without modifying the language and with complete knowledge of their effects.[92] In light of what the court perceived as a clear demonstration of congressional intent, it was not the function of the courts or a regulatory agency to interpret the clause other than literally.[93]

In response to the argument that the Delaney clause places an unworkable risk-only test in the middle of a risk/benefit analysis, the court observed that the "pass-through" provision of section 402,[94] which allows carcinogenic pesticide residues on processed foods at levels no higher than that established for raw foods, "expressly harmonizes" the overall statutory scheme.[95] Thus, risks and benefits were properly considered throughout the process until the unacceptable event of concentration of pesticide residue in processed food. The

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88. *Id.* at 989.

89. *Id.* at 988.

90. *Id.*

91. *Id.* at 988-89.

92. *Id.* at 989-90. "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." *Id.* at 989 (quoting Federal Deposit Ins. Corp. v. Philadelphia Gear Corp., 476 U.S. 426, 437 (1986)); *see* 21 U.S.C. § 348 (amended 1960, 1962, 1984); 21 U.S.C. § 376 (amended 1960, 1970, 1976); 21 U.S.C. § 3606 (amended 1988, 1991).

93. *Les,* 968 F.2d at 990.

> 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. If there is to be a change, it is for Congress to direct.

Id. (citation omitted).

94. 21 U.S.C. § 342(a)(2)(C); *see supra* note 39 and accompanying text.

95. *Les,* 968 F.2d at 989.

United States Supreme Court refused to hear the industry's appeal of the case.[96]

C. *Is There Really a Paradox?*

Although the EPA points out that literal application of the Delaney clause creates a procedural paradox, the court in *Les* found a logical relationship between the requirements for raw and processed foods. It is clear from the risk/benefit test of section 408 that Congress recognized that our food supply would contain certain levels of carcinogens. The Delaney clause of section 409 only serves to ensure that these levels will be consistent in both raw and processed foods by allowing the "pass-through" of section 408 residue tolerances into processed foods; thus, consumers are subject to the same level of carcinogens in all foods, regardless of their form. Realistically speaking, the EPA's de minimis standard for carcinogens which concentrate in processed foods would allow a negligible level of risk *in addition* to what is already permitted on raw foods—in effect, a negligible risk on top of a negligible risk. Under this analysis, application of the Delaney clause only to processed foods does not lead to absurd results, but avoids them.

By allowing carcinogenic pesticide residue on raw foods at negligible risk levels, Congress recognized the economic and social benefits of pesticide use. This is in sharp contrast to the strict prohibition of *any* carcinogenic substance in the color additives Delaney clause construed in *Public Citizen v. Young*, where the court expressly

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96. 113 S. Ct. 1361 (1993). After the Supreme Court denied certiorari, the EPA revoked the food additive regulations for benomyl (raisins and processed tomato products), mancozeb (raisins and bran of wheat), phosmet (cottonseed oil), and trifluralin (spearmint and peppermint oil). 58 Fed. Reg. 37,862 (July 14, 1993).

Prior to this revocation, the industry had unsuccessfully argued that the food additive regulations governing benomyl and mancozeb should be revoked for other reasons; the industry now contended that they were not needed because the residues did not concentrate during the processing involved. As to benomyl on raisins, the industry asserted that raisins should be classified as a raw agricultural commodity. *See* 58 Fed. Reg. 29,318 (May 19, 1993). Thus, under the industry's new position, these pesticides would have remained in use because the Delaney clause's prohibition for processed foods would have been irrelevant. However, the EPA's final revocation rendered the industry's request moot, and the pesticides were subjected to the EPA's "coordination policy" requiring the cancellation of a pesticide where the required § 408 and § 409 tolerances cannot be obtained. *See supra* text accompanying note 25. The EPA maintained its dissatisfaction with its order, pointing out that it had requested comments in February 1993, 58 Fed. Reg. 7470 (Feb. 5, 1993), on changing the way it regulated pesticides and indicating its willingness to accept suggestions regarding this "coordination policy." *Id.*

recognized that color additives had a low public utility value, and so their use did not justify even a small risk of cancer. This deliberate difference between the two Delaney clauses suggests that Congress did not overlook "unforeseen results" when it enacted section 409.

IV. THE ROLE OF QUANTITATIVE RISK ASSESSMENT IN PUBLIC POLICY DECISIONS

A. Quantitative Risk Assessment Generally

At the heart of the Delaney controversy lies the accuracy of quantitative risk assessment (QRA) methods and their validity as a foundation for important public policy decisions regarding public health. QRA is the process by which scientists quantify the risks associated with human exposure to chemicals to evaluate their respective harms to public health.[97] Risk assessment only estimates the potential adverse health consequences of exposure to chemicals; it does not determine to what extent chemicals should be regulated. This second component—called risk management—necessarily involves socioeconomic, technical, political, and other considerations.[98]

The results of QRA, like those of any scientific process, are subject to dispute. Formulations of risk necessarily rest upon unsubstantiated assumptions made by a well-informed scientific body.[99] In each step of the assessment, the strengths and weaknesses of the major assumptions need to be presented, and the nature and magnitude of uncertainties need to be characterized. The EPA issues risk assessment guidelines which incorporate agency positions, or "science policies," based on evaluation

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97. *See generally* NATIONAL ACADEMY OF SCIENCES, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983).

Risk assessment involves the following components: (1) hazard identification (how likely a chemical is to be a human carcinogen); (2) dose-response assessment (the relationship between the chemical dose given to a laboratory animal and the probability of a response in a human being); (3) exposure assessment (identification of different ways groups of people may be exposed to the chemical); and (4) risk characterization (the description of the nature and magnitude of human risk, expressed in numbers). *Id.* at 3.

98. *Id.*

99. Because many questions encountered in the risk assessment process are unanswerable given current scientific knowledge, much of risk assessment is based on inferences. *Id.* A few examples of these inferences are that effects of extremely high doses of a chemical in rodents can be accurately extrapolated to low doses in humans, that the induction of cancer in one species will translate to the induction of cancer in another, and that exposure information can be accurately predicted. Dennis J. Paustenbach, *Health Risk Assessments: Opportunities and Pitfalls*, 14 COLUM. J. ENVT'L L. 379, 386-406 (1989).

of the presently available scientific information and on the regulatory mission of the agency.[100] Since QRA is the primary tool for the formulation of pesticide tolerances and food additive regulations, these "science policies" are scrutinized and contested by industry, environmentalists, and lawmakers.

B. How Much Risk is Too Much?

Many scientists and commentators argue that current QRA methods greatly overstate actual risks. Under this view, when scientists run across uncertainties in any given test, they traditionally replace them with worst-case or extremely protective assumptions.[101] Inertia within the scientific community has derailed every attempt to replace accepted conservative assumptions with more realistic assumptions that are based on modern scientific information.[102] These scientists point out that there are more natural carcinogens in the food we eat than there are synthetic ones.[103] Despite all this, the United States has the safest, least expensive, and most plentiful food supply in the world, and to *effectively* reduce our dietary risk of cancer, we should focus instead on eating

100. *See* Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992 (1986).

101. The EPA takes the position that actual risks are probably lower than those calculated because it routinely makes conservative estimates to protect against scientific uncertainties. Section 409 Food Additive Regulations, *supra* note 6, at 7757.

The use of worst-case scenarios arose from an historical fear of underestimating risk and a general lack of acceptance of risk-based policies, coupled with a paucity of research data for improving risk assessments. Elizabeth L. Anderson, *Scientific Developments in Risk Assessment: Legal Implications*, 14 COLUM. J. ENVT'L L. 411 (1989).

One commentator illustrates this worst-case approach: "[T]he EPA standard, if used to estimate pedestrian deaths at a street crossing, would assume the crosser to be blind, lame, and deaf, [and] the [environmentalist] standard would assume him to be blind, able only to crawl, deaf, and crossing the Indianapolis Speedway on Memorial Day." MICHAEL FUMENTO, SCIENCE UNDER SIEGE 35 (1993).

102. Anderson, *supra* note 101, at 411-13.

103. Doctors Bruce Ames and Lois Gold of the University of California, Berkeley, outspoken proponents of relaxed standards in food safety laws, assert that natural carcinogens found in a cup of coffee or a handful of peanuts are more harmful than many synthetic pesticides. They posit that the vast majority of potential carcinogens in our food supply are natural chemicals that foods develop as byproducts of cooking, or natural toxins that plants secrete in self-defense—"natural pesticides." Lois S. Gold et al., *Rodent Carcinogens: Setting Priorities*, 258 SCIENCE 261 (1992); *see also* FUMENTO, *supra* note 101, at 65 (explaining that natural carcinogens in foods such as beer, mushrooms, diet cola, peanut butter, tap water, and bacon pose much higher cancer risks than the banned chemical found in Alar, a pesticide used on apples).

more fruits and vegetables and less animal fat, losing weight, and quitting smoking.[104] Therefore, congressional mandates like the Delaney clause are not based on current rational evaluations of health risks but on unreasonable presumptions bordering on paranoia. Media hype, medical hyperbole, and misguided science are to blame for society's overconcern about pesticide-related cancer.[105]

On the other hand, many argue that QRA is not too conservative. Its advocates contend that no matter how protective the underlying assumptions, they simply cannot account for all the unknown contributing factors that are found in the real-world environment.[106] For example, modern science has not yet determined the long-term or cumulative effects of exposure to low levels of carcinogens or the synergistic effects of exposure to different chemicals not only in food but in groundwater and air as well.[107] Moreover, current QRA tests do not take into account the increased risk to certain members of a population, such as infants and children who consume more fresh fruits and vegetables.[108] Given these unknowns, it is far better to err on the

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104. Gold et al., *supra* note 103, at 264. Another commentator has explained:

> [I]f we could lower the death rate directly attributable to heart disease, smoking or obesity by even a little bit, then we could increase longevity in the population by a considerable amount. Instead, we tend to spend our time worrying about things that have relatively minor effects on life expectancy. . . . Regulatory agencies such as the FDA often set as goals the elimination of risks that could reduce an exposed person's life expectancy by as little as one day.

Lester B. Lave, *Risk Assessment and Regulatory Priorities*, 14 COLUM. J. ENVT'L L. 307, 310-11 (1989); *see also* FUMENTO, *supra* note 101, at 76 ("[C]homp another double cheeseburger, wash it down with a beer, and follow it up with a cigarette, all in the blissful knowledge that you do not run the risk of ingesting a part per trillion of a pesticide sprayed on vegetables or fruits.").

105. *See, e.g.*, Elizabeth M. Whelan, *The Folly of Mouse Hysteria, reprinted in* 136 CONG. REC. 2098 (daily ed. June 22, 1990) (statement of Rep. Crane).

106. *See, e.g.*, Adam M. Finkel, *Is Risk Assessment Really Too Conservative?: Revising the Revisionists*, 14 COLUM. J. ENVT'L L. 427 (1989) (arguing that estimates resulting from QRA are not too conservative considering, among other things, the absence of consideration of any synergistic risks from combined substances); Richard A. Merrill, *Reducing Diet-Induced Cancer Through Federal Regulation: Opportunities and Obstacles*, 38 VAND. L. REV. 513 (1985) (arguing that current regulatory regime geared toward identifying individual toxins and removing them is ill-suited to modern knowledge of the relationship between diet and disease).

107. *See* Finkel, *supra* note 106, at 443-47.

108. *Frontline: In Our Children's Food* (PBS television broadcast, Mar. 30, 1993).

side of safety than to "force the public to play Russian roulette each time it eats."[109]

Critics on both sides of the issue seem to agree on at least one thing: QRA essentially is a numbers game that can be manipulated by all sides through many policy and agenda-laden assumptions. QRA methods merely measure risks; they do not answer the question of how much risk is too much—that is left to the legislators. The opinions in *Les v. Reilly* and *Public Citizen v. Young* suggest that the courts are properly refusing to leave those policy judgments to bureaucratic government agencies or to the courts themselves. Laws designed to protect public health and safety are fundamentally dependent on lawmakers who are directly accountable to the public.[110]

Les v. Reilly placed the EPA in a precarious position. By forcing the EPA into what the agency feels is an impossible situation, the case has opened the door to mistrust of agency action at a time when both Congress and the public are increasingly wary of excessive administrative control. After *Les*, the EPA must deny all food use registrations for new carcinogenic pesticides which may end up in

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109. *Not-so-tasty Decision at EPA*, WASH. TIMES, Mar. 21, 1993, at B5 (arguing that many so-called "necessary" pesticides are used merely to increase the size and appearance of produce rather than to improve taste and nutrition).

110. The power of public reaction to affect public health decisions regarding carcinogens is illustrated by the two following examples. In 1977, the FDA's attempt to ban saccharin as a carcinogenic food additive led to intense public protest, and, eventually, a congressional amendment exempting saccharin from Delaney's ban despite its carcinogenicity:

> [T]he Secretary—
>
> (1) may not amend or revoke the interim food additive regulation . . . applicable to saccharin . . . or
>
> (2) may . . . not take any other action . . . to prohibit or restrict the sale or distribution of saccharin . . . solely on the basis of the carcinogenic or other toxic effect of saccharin as determined by any study . . . .

Pub. L. No. 100-71, Title I, July 11, 1987 (101 Stat. 431).

In 1989, a scientific study by the environmental group Natural Resources Defense Council warning of the health effects of a pesticide, Alar, on apples was highlighted on the television show *60 Minutes*, as well as by congressional testimony by well-known actress Meryl Streep, and resulted in thousands of supermarkets pulling Alar-treated apples from their shelves and eventual EPA ban of the pesticide. *See* Margaret E. Kriz, *Poison Gamesmanship*, NAT'L J., Apr. 18, 1992, at 930. Many have criticized the Alar scare as a carefully-executed and scientifically biased public relations campaign which resulted in devastating economic injury to farmers and the prohibition of a completely safe substance. *See, e.g.*, FUMENTO, *supra* note 101, at 19-44.

processed food. At the same time, all registered pesticides must be retested for carcinogenicity under a federal agency's time constraints and limited resources. A determination of carcinogenicity potentially subjects a pesticide to the cumbersome and lengthy process of suspension or cancellation.[111] The chemical industry itself supplies the EPA with the scientific data on the carcinogenicity of specific pesticides.[112] The agency that is required to prohibit all carcinogens under the law is the same body that must verify the industry's scientific determinations regarding cancer risks, all the while being bombarded from all sides by forceful scientific and political arguments.[113] It is this pressure on the EPA that has prompted the call for congressional directives codifying the agency's "negligible risk" approach.[114]

V. LEGISLATIVE REFORM

Despite agency, industry, executive, and congressional pleas for legislative repeal of the Delaney clause, Congress has yet to produce a bill on which most members can agree.[115] Many of the proposals incorporate a single, health-based standard, which would prevent the EPA from factoring broadly defined economic benefits into a pesticide's safety determination,[116] as well as incentives for lower-risk

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111. Current cancellation and tolerance procedures involve notice and comment periods, formal hearings, and a right of appeal. 7 U.S.C. §§ 136d, 136n (1988 & Supp. IV 1992).

112. *See supra* note 43.

113. The EPA's struggle to adhere to the accepted one-in-one-million standard may be more a question of public policy rather than exact science. For example, one of the pesticides at issue in *Les*, benomyl, was first estimated in 1987 to have a very high cancer risk of one in 5000. *See* Section 409 Food Additive Regulations, *supra* note 6, at 7752. The EPA later revised that figure to a reduced risk when "more realistic exposure information was incorporated in the risk assessment," *id.*, and stated that the risk assessment would likely be further reduced by one to two orders of magnitude once actual residue information was received. *Id.*

114. For a discussion of the development of the EPA's negligible risk approach, see *supra* note 57 and accompanying text.

115. Indeed, despite the debate surrounding the Delaney paradox, Congress has reauthorized the food additives Delaney clause three times since its original enactment, most recently in 1984, without changing the strict statutory language. *See supra* note 92 and accompanying text.

116. Virtually all other environmental laws use health-based standards rather than cost/benefit tests; pesticides are the only environmental concern which are not currently health-based. *See, e.g.*, Clean Water Act, 33 U.S.C. §§ 1251-1387 (1988 & Supp. IV

pesticides or alternative pest control methods.[117] Until recently, congressional inertia and jurisdictional issues[118] have combined with

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1992); Safe Drinking Water Act, 42 U.S.C. §§ 300f-300j-26 (1988 & Supp. IV 1992); Solid Waste Disposal Act, 42 U.S.C. §§ 6901-6992k (1988 & Supp. IV 1992); Clean Air Act, 42 U.S.C. §§ 7401-7671q (1988 & Supp. IV 1992).

117. Decades of conventional pesticide use have caused contaminated water supplies, low-value soil, and new strains of resistant pests. Jim Hightower, *Sustainable Family Farming*, ISSUES IN SCI. & TECH., Fall 1989, at 26. Richard Wyles, a former scientist at National Academy of Sciences and author of REGULATING PESTICIDES IN FOOD, *supra* note 76, now president of the Environmental Exchange, argues that alternative technologies do exist that are safe and just as effective as chemical pesticides, including pheromone traps, the release of sterile male insects, and biological insecticides. Telephone Interview with Richard Wyles (Feb. 22, 1993).

For a discussion of the economic, environmental, technical, social and policy effects of alternative agriculture technologies as compared to conventional agriculture practices, see *Alternative Agriculture: Perspectives of the National Academy of Sciences and the Council for Agricultural Sciences and Technology: Hearing before the Joint Economic Committee*, 101st Cong., 2d Sess. (1990).

The EPA has embarked on a reduced-risk pesticide initiative with the primary objective of developing incentives to encourage the development, registration and use of lower-risk pest control substitutes for existing high-risk pesticides. *See* Notice, request for comment, 57 Fed. Reg. 32,140 (1992). The agency expressed a need for lower-risk pest control technologies because of the inherent risk to nontarget organisms posed by all current pesticides and the existence of some pesticides on the market that pose potential risks of some concern but were registered or allowed to remain on the market because effective alternatives were not available. *Id.* at 32,141. The EPA also predicted that some pesticides will be found in the future to have adverse effects not now recognized due to changes in scientific understanding. *Id.* Moreover, current data is not routinely available on the interactive or concurrent exposure to pesticides. *Id.* The agency suggested that such incentives might include possible reductions in required data, accelerated processing by EPA, waiving of registration and tolerance fees, and changes to existing agency policies that prohibit safety claims for pesticides. *Id.*

In January 1993, the agency implemented an interim strategy which provides for special consideration of pesticide applications demonstrating reduced risk. 58 Fed. Reg. 5854 (Jan. 22, 1993). Its long-term approach consisted of four issues:

(1) developing specific criteria for identifying lower-risk pesticides;

(2) streamlining the registration process for all products;

(3) pesticide label reform; and

(4) extending exclusive use or patent term extension incentives for lower-risk pesticides.

Id.

118. In the United States House of Representatives, the Food & Drug Act is under the legislative jurisdiction of the House Energy and Commerce Committee and FIFRA is under the House Agriculture Committee.

fear of excessive agency power[119] to stall any effective legislative reconciliation of the requirements of FIFRA and the Food & Drug Act.[120]

Prior to the Clinton administration, the most powerful proposal under consideration in Congress had been a pair of identical bills introduced by Senator Edward Kennedy and Representative Henry Waxman.[121] This proposal, the Pesticide Food Safety Act of 1993, gave the EPA authority to establish a tolerance for a pesticide chemical residue at every stage of food's useful life—at harvest, at purchase, and after processing—at a level the EPA determines "is reasonably certain to cause no harm to human health."[122] The bill allowed the EPA to set a tolerance for a carcinogenic pesticide if: (1) it does not cause adverse human health effects at the one-in-one-million cancer risk level; (2) it is the lowest level that permits the pesticide to perform its intended function; and (3) in the case of a processed food, it is the lowest level possible after compliance with good manufacturing practices.[123] The bill also required the EPA to consider children's unique susceptibility to pesticide chemicals.[124] Finally, the bill tempered the increase in EPA

In the United States Senate, the Food & Drug Act is under the legislative jurisdiction of the Senate Labor and Human Resources Committee while FIFRA is under the Senate Agriculture Committee.

119. In its final order dated February 25, 1991, the EPA stated that, in addition to finding a de minimis exception to the Delaney clause, it would allow food regulations for pesticides which posed *more* than a negligible risk of cancer where "EPA determines that current estimates most likely overestimate risk, data could be obtained that will in all probability show that the risk is de minimis, and that data are being produced expeditiously." Section 409 Food Additive Regulations, *supra* note 6, at 7774. This additional authority would give EPA discretion to allow pesticide residues to remain on foods where information about exposure and carcinogenicity is unavailable, subject to the interpretation of "expeditiously." Congress may be unwilling to grant to the EPA such broad power.

120. Members of Congress also expressed concern over how passage of the North American Free-Trade Agreement Act (NAFTA) would affect our food safety regulations. *See, e.g.*, 139 CONG. REC. H9,958 (daily ed. Nov. 17, 1993) (statement of Rep. Waxman).

121. S. 331 and H.R. 872, 103d Cong., 1st Sess. (1993).

122. S. 331, § 3(a)(2)(B)(i).

123. S. 331, § 3(a)(2)(B)(iii)(I)-(III).

124. Under the bill, the EPA must specifically evaluate the risk to children in various age groups, from infancy through adolescence, as well as for other population groups that have special food consumption patterns. S. 331, § 3(a)(2)(E)(i)-(ix).

discretion in setting tolerances by providing specific assumptions that the EPA must use in its QRA methods.[125]

Congressional focus on the Kennedy-Waxman bill was diverted as the Clinton administration took office and began the "reinvention of government," which took a strong stance on environmental safety and protection. The new EPA Administrator, Carol M. Browner, announced that one of her first official acts as agency head would be a reevaluation of the Delaney clause.[126] In September 1993, the Clinton administration, through an interagency working group, produced its version of proposed reforms for pesticides and food safety.[127] The proposed reforms were partly a response to a recent National Academy of Sciences report concluding that current pesticide policies do not adequately protect children from exposure to pesticides in food and water.[128] The reforms essentially incorporate the provisions of the Kennedy-Waxman bill with the additional aim of reducing overall pesticide use by promoting alternative pest control methods through the development of legislative, regulatory, and administrative initiatives.[129] The reforms also require tolerances for all types of foods to be set at a health-based standard of "reasonable certainty of no harm," represented for carcinogens by the one-in-one-million upper limit.[130] The reforms

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125. For example, in estimating potential human exposure to a chemical residue in food, the EPA must assume that:

(I) all the food has the total amount of residue allowed under the proposed tolerance;

(II) all other sources of dietary exposure, including drinking water, occur; and

(III) human exposure to that residue at the tolerance level occurs for a lifetime.

S. 331, § 3(a)(2)(C)(ii). This is surely a worse-case scenario.

126. Keith Schneider, *EPA Plans to Seek Loosening of a Law on Food Pesticides*, N.Y. TIMES, Feb. 2, 1993, at A1.

127. Executive Summary of Administration Proposed Reforms for Pesticides/Food Safety, Issued Sept. 21, 1993, *in* DAILY ENV'T REP., Sept. 22, 1993, at E-1 [hereinafter Administration Proposed Reforms].

128. NATIONAL ACADEMY OF SCIENCES, PESTICIDES IN THE DIET OF INFANTS AND CHILDREN (1993) [hereinafter PESTICIDES IN THE DIET OF INFANTS AND CHILDREN].

129. One principle guiding the reforms is the "recognition of the need to work with American farmers to develop and implement improved means of pest control, to reduce use of high-risk pesticides and promote greater use of integrated pest management (IPM) techniques, including biological and cultural pest control systems and other sustainable agricultural practices." Administration Proposed Reforms, *supra* note 127, at E-1.

130. While these reforms, like the Kennedy-Waxman bill, replace the Delaney clause with the EPA's de minimis approach, they also circumscribe agency discretion by providing the EPA with specific assumptions it must use in QRA and specifically requiring

also provide special provisions for infants and children[131] and a timetable for the review of existing tolerances.[132]

One of the most significant and controversial proposals is the incentives for the development of reduced risk pesticides and support for integrated pest management (IPM). IPM involves a combination of different pest management techniques designed to de-emphasize chemical use, including biological, cultural, genetic, and physical controls, to balance environmental, economic, and social issues.[133] Following the EPA's implementation of a pesticide reduction policy,[134] the reforms call for a joint EPA-USDA chaired effort to develop community-specific pesticide use reduction goals within one year and to

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the EPA to consider sensitive populations and cumulative exposures to other pesticides, as well as the same pesticide in other media such as air and water. *See infra* note 131.

131. The EPA must issue specific findings that a tolerance is safe for infants and children. The agency also must look at multiple exposures when establishing a tolerance and must "vigorously pursu[e]" more accurate data on children's consumption habits. Moreover, the FDA must prioritize its monitoring of residues on the foods that children eat most. Administration Proposed Reforms, *supra* note 127, at E-1.

132. The EPA must review all existing tolerances for compliance with the new safety standard within seven years of enactment of the proposed statute, and special fast track provisions would be made available for pesticides which do not meet the safety standard under currently available data. These pesticides must be identified within 180 days of enactment; 75% of them must be reviewed within three years, and all of them must be reviewed within four years. *Id.*

The reforms also include a host of other proposed changes, including streamlined processes of registration, suspension, and cancellation under FIFRA and improvement in enforcement mechanisms. The reforms would also prohibit export of any pesticide that has been denied registration in the United States, thus breaking the "circle of poison" allowed under current law which permits banned pesticides to re-enter the United States' food supply as residues on imported foods. *See* 139 CONG. REC. S10,964-65 (daily ed. Aug. 6, 1993) (statement of Sen. Leahy) ("It makes no sense to reform our food safety and pesticide laws if pesticides banned in the United States end up in our food supply on imported food.").

To accommodate pesticide interests, the reforms allow for interim transitional tolerances to be set for pesticides which do not meet the new standard if "the loss of the pesticide would result in significant disruption in the food supply"—a claim sure to be advanced on behalf of every pesticide currently on the market. Administration Proposed Reforms, *supra* note 127, at E-2.

133. *See generally* Jamie C. Abrams, Research Guide, *Biological Control Agents in Integrated Pest Management: Are They Regulated?*, 8 PACE ENVT'L L. REV. 89 (1990). *But see* Gregory Aplet & Marc Miller, *Biological Control: A Little Knowledge is a Dangerous Thing*, 45 RUTGERS L. REV. 285 (1993) (warning about the unintended results that can occur from shifting the natural balance of an ecosystem).

134. *See supra* note 117 and accompanying text.

design pilot projects which would implement IPM programs for seventy-five percent of crop lands within seven years of enactment.[135]

This emphasis on the use of alternative pest control technologies, virtually unprecedented in federal pesticide policy, is certain to spark opposition from the chemical and agriculture industries.[136] Horror stories about the economic ruin of American farmers and the destruction of a safe and inexpensive food supply will dominate many discussions on the floors of Congress and committee rooms. However, similar horror stories exist about neighborhood "clusters" of cancer, birth defects, and miscarriages among farmworkers exposed regularly to pesticides[137] and about the increasing cancer rate among children in the United States.[138] Indeed, so much remains unknown about the effects of long-term, cumulative human exposure to dietary pesticides in low doses that it is socially and economically preferable to err on the side of public health and safety rather than to allow potentially dangerous pesticide risks in our food while waiting for decades of backlogged data to be verified.

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135. Administration Proposed Reforms, *supra* note 127, at E-2. The Clinton administration's proposed bill does not include a definition of IPM; the intent is to define IPM on a regional basis through regulation.

136. Industry-backed bills in the House and the Senate fall far short of the protective reforms proposed by the Clinton administration. S. 1478 and H.R. 1627, Food Quality Protection Act of 1993, 103d Cong., 1st Sess. (1993). The bills replace the Delaney clause with EPA's de minimis approach. They retain the general safety determination and risk/benefit test for pesticide residue and allow EPA to set a tolerance on raw or processed food which is "adequate to protect the public health" without distinguishing between carcinogens and noncarcinogens. S. 1478, §§ 304, 305; *see* 139 CONG. REC. S12,130, 12,139 (daily ed. Sept. 21, 1993) (statement of Sen. Lugar) ("In light of the great impact of pesticides on the Nation's good health and healthy economy, it is imperative that we allow EPA to balance the benefits and risks of pesticide use as they search for meaningful tolerance and registration regulations."). The bills provide for the dissemination of information about IPM and children's exposure to pesticide residues but leave incorporation of this information into QRA to agency discretion. They allow EPA to set a tolerance at greater than negligible risk if: (1) use of the pesticide protects against greater adverse health effects to humans or the environment; (2) use avoids greater risks from another pesticide; or (3) the unavailability of the pesticide would reduce the availability of an adequate, wholesome, and economical domestic supply of the food, and the adverse effects from the reduction would outweigh the risk posed by the residue. S. 1478, § 305. Both bills have many co-sponsors.

137. *See generally* FRED SETTERBERG, TOXIC NATION (1993); *see also Frontline: In Our Children's Food*, *supra* note 108.

138. *See* CANCER FACTS AND FIGURES, *supra* note 1; *see also* PESTICIDES IN THE DIET OF INFANTS AND CHILDREN, *supra* note 128.

If Congress and consumers genuinely desire strengthened strides toward risk reduction in our food supply in the true spirit of the Delaney clause, new pesticide laws should foster development of these lower-risk alternative pest control technologies. The Clinton administration's proposed reforms strike a well-crafted balance between economic and public health concerns. While many environmentalists see the imminent demise of the Delaney clause as a dangerous weakening of our public health laws, the fact is that the clause has become unenforced due to its own anachronistic mandates. The purpose behind the Delaney clause remains legitimate: the public wants regulatory protection against identified carcinogens in our food supply, especially for children, who are most at risk. The problem with the clause is that it places that protection too far down the line of food production. Government-backed market incentives to reduce conventional pesticide use and a shift to alternative biological pest control methods pack the regulatory punch that the Delaney clause had attempted to do for over thirty years. As EPA Administrator Browner put it: "Instead of applying countless numbers of chemicals to our food and then trying to study the effects on human health, doesn't it make more sense to grow our food safely in the first place?"[139]

VI. CONCLUSION

The Delaney paradox has remained just that for over thirty years as Congress and federal regulatory agencies have attempted to mold legislative policy around ever-changing scientific assumptions. A de minimis interpretation, while theoretically logical and administratively easy, perpetuates the use of questionable risk-assessment numbers as determinative factors between what is harmful and what is not. As Congress debates the best way to protect the nation's food supply for carcinogens, incentives for alternative and lower-risk pest control technologies should be a part of any approved bill.

Amy Montemarano

139. Carol M. Browner, Address Before the American Public Health Association, *in* PESTICIDE & TOXIC CHEM. NEWS, Nov. 3, 1993, at 8-9.