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Setting an Anti-Cancer Policy: Risk, Politics, and the Food Quality Protection Act of 1996

Part 1

by

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NOTES

SETTING AN ANTI-CANCER POLICY: RISK, POLITICS, AND THE FOOD QUALITY PROTECTION ACT OF 1996

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I. INTRODUCTION

On August 3, 1996, President Clinton signed into law the Food Quality Protection Act (FQPA) of 1996,[1] initiating "the most sweeping changes to pesticide laws since 1978."[2] Coming at the height of that election year's political season, the FQPA represented a remarkable act of cooperation among Members of Congress of both parties; the Act passed through the House and Senate without a single recorded dissenting vote.[3] More importantly, however, the legislation revised a health and safety doctrine that stood famously—or infamously—at the center of the regulation of pesticide residues in food: the Delaney Clause.[4]

Although the Clause, a provision of the Federal Food, Drug and Cosmetic Act (FFDCA),[5] applied to only a limited class of pesticide residues, by early 1990, it was poised to have a powerful impact on pesticide regulation. The Clause, which is the only enacted "zero risk" ban in U.S. health, safety, and environmental regula-

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[1] Pub. L. No. 104-170, 110 Stat. 1489 (1996); The President's Radio Address, 32 WEEKLY COMP. PRES. DOC. 1399 (Aug. 3, 1996).

[2] David Hosansky, *Rewrite of Laws on Pesticides On Way to President's Desk*, CONG. Q., July 27, 1996, at 2101.

[3] The legislation passed through the House by a vote of 417-0. *See id.* The House Commerce Committee reported the bill out by a margin of 45-0. *See* H.R. REP. NO. 104-669, pt. 2, at 33 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1272. There was no vote in the House Agriculture Committee. *See* H.R. REP. NO. 104-669, pt. 1, at 75 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1208, 1250. The bill passed through the Senate Agriculture Committee 18-0, and then the full Senate by a voice vote. *See* Hosansky, *supra* note 2, at 2101.

[4] *See* Federal Food, Drug, and Cosmetic Act § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) (1994). This Note focuses on the Delaney anticancer clause applicable to food additives. Similar versions of the Delaney Clause apply to color additives (FFDCA § 721(b)(5)(B), 21 U.S.C. § 379e(b)(5)(B)) and animal drugs (FFDCA § 512(d)(1)(I), 21 U.S.C. § 360b(d)(I)).

[5] 21 U.S.C. §§ 301-395.

tions, rests on the assumption that no safe level of exposure to a carcinogen exists. As interpreted by the Ninth Circuit in a key case, *Les v. Reilly*,[6] the Delaney Clause served to ban absolutely the presence of those carcinogenic pesticide residues falling under its purview.

With the Food Quality Protection Act, Congress instituted two key changes to carcinogenic pesticide regulation. First, the FQPA rendered Delaney inapplicable to carcinogenic pesticide residues. Second, Congress substituted a new standard to govern the regulation of carcinogenic pesticides in place of Delaney's flat ban. The new law permits what can be thought of as a "negligible" risk of exposure to carcinogenic pesticides. Although the Delaney Clause remains in place for food additives, color additives, and animal drugs, the FQPA weakened the significance of the Clause by eliminating its application to pesticide residue in food.

This narrowing of the Delaney Clause marks a critical shift in the regulatory response to a set of competing dynamics lying at the heart of food safety policy. As the House Commerce Committee has acknowledged, "[t]he legal requirements for [pesticide] registration recognize that pesticides are both necessary and potentially harmful."[7] Like other chemicals added to food, pesticide residues are products of intentional application.[8] The use of synthetic pesticides, together with widespread use of synthetic fertilizers, bears a large measure of credit for the rapid expansion of food production in the years since the Second World War.[9] Although debate over pesticide use is spirited, even those most publicly opposed to pesticide use do not sup-

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[6] 968 F.2d 985 (9th Cir. 1992), *cert denied*, National Agr. Chemicals Ass'n v. Les, 507 U.S. 950 (1993).

[7] H.R. REP. NO. 104-669, pt. 2, at 30 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1269.

[8] Exposure to pesticides does not result exclusively from the consumption of food. "For chemicals in the environment the three major routes [of exposure] are *ingestion* (the oral route), inhalation, and *skin contact* (or *dermal* contact)". JOSEPH V. RODRICKS, CALCULATED RISKS 16 (1992); *see also* Pamela A. Finegan, Note, *FIFRA Lite: A Regulatory Solution or Part of the Pesticide Problem?*, 6 PACE ENVTL. L REV. 615 (1989) ("The food we eat, the air we breathe, the water we drink, the homes we live in, the clothes we wear, the lawns our children play on, and the offices we work in may contain pesticides.").

[9] Indeed, the House Commerce Committee has defined pesticides as "chemicals used to control pests (such as weeds, rodents, and insects) that *hinder the production of an abundant, affordable, and varied food supply.*" H.R. REP. NO. 104-669, pt. 2, at 29 (1996) (emphasis added), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1268. For brief discussions of the development and use of pesticides, see RODRICKS, *supra* note 8, at 5-11; Finegan, *supra* note 8, at 618-22; Paul A. Gillan, Jr., *Laying Ax to the Delaney Clause: Reform of the Zero Tolerance Standard for Carcinogenic Food Additives*, 5 U. BALT. J. ENVTL. L. 14, 17-19 (1995).

port the elimination of all pesticides from production agriculture.[10] Unlike most other additives to food, however, pesticides kill or disrupt the functioning of living organisms.[11] Pesticides pose risks to human health, including cancer or injury to the nervous, reproductive, endocrine or immune systems.[12]

Seen in this light, the shift from Delaney's zero-risk approach to the FQPA's negligible-risk standard represents a change in attitude toward health risks in the food supply. This Note will focus upon the competing conceptions of risk embodied in the FFDCA in its pre- and post-1996 incarnations. Part II of the Note provides background, describing the regulatory framework established before and after passage of the FQPA. Part III focuses upon the policy and science surrounding the different notions of risk. From a scientific perspective, the new law reflects growing confidence in the abilities of scientists and regulators both to measure and manage health risks in the food supply—including carcinogenic risks. Politically, Congress faced heavy pressure to reconceptualize its response to carcinogenic risk because the Delaney Clause had begun to matter; hundreds of millions of dollars were potentially at stake if Delaney's scope remained defined by *Les v. Reilly*. Finally, Part IV describes how the political environment in 1996 was

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[10] See, e.g., the response of Jay Feldman, Executive Director of the National Coalition of the Misuse of Pesticides, when asked by Representative Michael Bilirakis, "[I]s your organization opposed to the use of all pesticides?"

> No.... Congress and the Government should seek to make available to people the safest possible technologies to assist in a productive and profitable food production system, and the question is, how do you define safety.... We have in our membership people... who believe that cancer-causing pesticides are not necessary to a profitable and productive food supply.... We simply want to get to a point where farmers are using the safest possible tools.

Food Quality Protection Act of 1995: Hearings on H.R. 1627 Before the Subcomm. on Health and the Env't of the House Comm. on Commerce, 104th Cong. 111-12 (1995) [hereinafter *1995 FQPA Hearings*].

[11] The Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Food Quality Protection Act, defines a pesticide in part as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer." FQPA § 105(a)(2), FIFRA § 2(u), 7 U.S.C. § 136(u) (Supp. II 1996). Before a pesticide may be approved for sale, a manufacturer must demonstrate that it will "*perform its intended function* without unreasonable adverse effects on the environment." FIFRA § 3(c)(5)(C), 7 U.S.C. § 136a(c)(5)(C) (1994) (emphasis added).

[12] *See* COMMITTEE ON PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN ET AL., PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 1 (1993) [hereinafter CHILDREN AND PESTICIDES REPORT].

particularly conducive to the compromise necessary for passage of the FQPA.

II. THE LEGISLATION

Before a pesticide may be used on a food crop, its manufacturer or distributor must satisfy the requirements of two laws: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[13] and the Federal Food, Drug and Cosmetic Act (FFDCA).[14] FIFRA authorizes the EPA to set the terms and conditions under which the pesticide may be used in the field, and the FFDCA limits the levels of pesticide residues on food crops. Two chief provisions of the FFDCA apply. Prior to passage of the FQPA, section 408 of the FFDCA regulated pesticides on raw foods and certain pesticides on processed foods.[15] Section 409 of the FFDCA, which includes the Delaney Clause, regulates food additives; until 1996, this section only applied to pesticide residues on processed foods not covered under section 408.

A. Pre-FQPA Pesticide Residue Law

1. FIFRA

Before a pesticide may be distributed, regardless of whether it is intended for use on a food crop, it first must be registered for a particular use under FIFRA.[16] The potential registrant must dem-

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[13] FIFRA §§ 2-31, 7 U.S.C. § 136 (1994).

[14] 21 U.S.C. §§ 301-395 (1994).

[15] For alternative discussions of pre-FQPA law, see H.R. REP. NO. 104-669, pt. 2, at 29-32 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1268-71; COMMITTEE ON SCIENTIFIC AND REGULATORY ISSUES UNDERLYING PESTICIDE USE PATTERNS AND AGRICULTURAL INNOVATION, ET AL, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX 23-30 (1987) [hereinafter DELANEY PARADOX]; Carol S. Curme, *Regulation of Pesticide Residues in Foods: Proposed Solutions to Current Inadequacies under FFDCA and FIFRA*, 49 FOOD & DRUG L.J. 609, 610-20 (1994); 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, 3-6 (1988) [hereinafter Merrill, *Repudiation*]; Amy Montemarano, *The Delaney Paradox Resurfaces: Regulating Pesticides as Food Additives Under Federal Law*, 25 RUTGERS L.J. 433, 440-43 (1994); Scott Douglas Bauer, Note, *The Food Quality Protection Act of 1996: Replacing Old Impracticalities with New Uncertainties in Pesticide Regulation*, 75 N.C. L. REV. 1369, 1372-77 (1997); Gail Kachadurian McCallion, Note, *From the Source to the Mouth: What Can You Reasonably Expect to Find in Your Mouth*, 5 FORDHAM ENVTL. L.J. 189, 195-206 (1993). For a helpful flowchart explaining the process for granting a food use tolerance under the pre-FQPA Food, Drug, and Cosmetic Act, see GAO, GAO/RCED-94-57, PESTICIDES: OPTIONS TO ACHIEVE A SINGLE REGULATORY STANDARD 3 (1994).

[16] "Except as provided . . ., no person in any State may distribute or sell to any person

onstrate to the EPA that its product meets standards of effectiveness and labeling, and will not cause "unreasonable adverse effects on the environment."[17] When examining whether a pesticide will have adverse effects on the environment, the EPA is directed to consider "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.*"[18] Accordingly, FIFRA is a "balancing statute;"[19] it directs the EPA to consider both the possible risks and benefits of pesticide use.

2. *FFDCA Section 408*

If a registrant wants its pesticide to be available for use on a food crop, it must also satisfy the tests of the FFDCA.[20] Under section 408 of the Act, commodities containing pesticides are considered adulterated, and thus prohibited by the FFDCA,[21] unless the EPA has granted either a "tolerance" or an "exemption" for the pesticide use on a particular agricultural community.[22] Tolerances are the workhorse of the FFDCA scheme, for they embody

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any pesticide that is not registered." FIFRA §3(a), 7 U.S.C. 136a(a) (1994). The Act makes exceptions for experimental or emergency uses. "A single pesticide can have many registered uses, including application of a pesticide product on a particular food crop." Curme, *supra* note 15, at 611 (citing DELANEY PARADOX, *supra* note 15, at 18). The FQPA enacted several changes to FIFRA, but for purposes of this Note, the fundamentals of registration remained the same.

17 FIFRA § 3(c)(5)(A)-(D), 7 U.S.C. § 136a(c)(5)(A)-(D). Potential registrants must also meet certain data and procedural requirements. *See* FIFRA § 3(c), 7 U.S.C. § 136a(c); *see also* 40 C.F.R. §§ 158, 162 (1996). Meeting these tests can be both expensive and time-consuming. The House Commerce Committee recently reported that a typical registration takes five years and $8 million to complete, in addition to basic research costs. *See* H.R. REP. NO. 104-669, pt. 2, at 31 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1270.

18 FIFRA § 2(bb), 7 U.S.C. § 136(bb) (emphasis added). This balancing act is especially visible when the EPA is considering canceling a registration for a pesticide that may have been on the market for some time. Congress directs the EPA to examine potential adverse environmental effects, but also to consider the removal of the chemical from the market on production agriculture and consumer prices. *See* FIFRA § 6(b), 7 U.S.C. § 136d(b)(2).

19 *See* DELANEY PARADOX, *supra* note 15, at 24.

20 Petitions for tolerances may be submitted only if a pesticide has been registered, or if a registration application has been submitted. *See infra* text accompanying notes 43-46 (coordination policy text).

21 *See* FFDCA § 402(a)(2)(B), 21 U.S.C. § 342(a)(2)(B) (1994).

22 *See id.*; FFDCA § 408(a), 21 U.S.C. § 346a(a). Prior to passage of the FQPA, the FFDCA directed the EPA to grant an exemption if "a tolerance is not necessary to protect the public health." FFDCA §402(a)(1), 21 U.S.C. 346a(1). The FQPA amendments to the FFDCA direct the EPA to grant an exemption only if the exemption is determined to be "safe." The term "safe" is defined as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." FQPA § 405(c)(2)(A)(i)-(ii), FFDCA § 408(c)(2)(A)(i)-(ii), 21 U.S.C. § 346a-(c)(2)(A)(i)-(ii) (Supp. II 1996).

the fundamental premise of the pesticide regulatory structure: used in limited quantities, pesticides may be beneficial, but used in excess, the chemicals may be harmful. Under the tolerance-setting scheme, the EPA establishes a legal limit on the amount of pesticide residue that may be present on raw or processed foods. If pesticide residue levels exceed the established tolerance, food will be considered adulterated and subject to FDA enforcement action.

Prior to the FQPA's enactment, in considering whether to issue a tolerance regulation, the EPA, under section 408, considered: (i) "the necessity for the production of an adequate, wholesome, and economical food supply;" (ii) ways in which consumers may be affected by the same or similar chemicals; and (iii) whether the pesticide has been certified as useful by the EPA.[23] Section 408, like FIFRA, thus balanced health risks against economic benefits of a pesticide on raw food.[24]

3. FFDCA Section 409

Under pre-FQPA law, a registrant was further obligated to demonstrate whether its pesticide also required a tolerance under the food additives provision (section 409) of the FFDCA.[25] The Delaney Clause applied to those pesticides regulated under section 409, a provision enacted four years after section 408.

The first issue to determine under section 409 was whether the pesticide triggered application of this section: was the pesticide a food additive? Under pre-1996 law, pesticides on raw foods were excluded from regulation under section 409—and hence, the Delaney Clause—through an interpretation of the FFDCA's food additive definition. The pre-FQPA Act defined food additives broadly at the outset, encompassing "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[26] The FFDCA then narrowed the food additive definition, exempting several potential candidates for food additives status, including pesticides in or on

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[23] *See* FFDCA § 408(b), 21 U.S.C. § 346a(b)(1994).

[24] In practice, however, the EPA rarely considered benefits under section 408. *See* DELANEY PARADOX, *supra* note 15, at 32.

[25] *See, e.g.*, 40 C.F.R. § 158.202-.240 (1997) (establishing residue chemistry data requirements); Curme, *supra* note 15, at 614-15. By the mid-1980s, the EPA had established 7,372 tolerances under section 408 and 122 tolerances under section 409. *See* DELANEY PARADOX, *supra* note 15, at 19. Section 409 tolerances are listed at 40 C.F.R. pt. 185.

[26] FFDCA § 201(s), 21 U.S.C. §321(s) (1994).

raw food commodities.[27] Pesticides on processed foods—foods not meeting the definition of a raw food[28]—thus by implication fell into regulation under section 409. Congress had explicitly exempted pesticides on raw foods from food additive regulation; this implied that only pesticides on processed foods required a section 409 (food additive) tolerance.[29] Not all pesticide residues on processed foods were subject to regulation under section 409, however. Under the Act's "flow-through" provision, if the pesticide in the processed food did not concentrate as a result of processing, the pesticide was excluded from section 409.[30] Accordingly, a pesticide residue that ordinarily would have to be regulated under section 409 could escape the requirements of the food additive provisions, including the Delaney Clause, so long as the residue did not concentrate.[31]

4. Sections 408 and 409 Compared

A determination that a pesticide residue was a food additive had a broad impact on the regulation of that residue. To begin with, section 409 embodied a more stringent approval standard than section 408: section 408 established a risk-benefit standard, while section 409 set a purely risk-based, i.e. no benefit consideration, approach.[32] The EPA did not consider benefits when setting section 409 tolerances but examined only the *safety* of the residue food

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[27] *See* FFDCA § 201(s)(1)-(2), 21 U.S.C. § 321(s)(1)-(2).

[28] Current and prior law define a "raw agricultural commodity" as "any food in a raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing." FFDCA § 201(r), 21 U.S.C. § 321(r). The FQPA adds a definition of "processed food" to the Act: the term means "any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing such as canning, cooking, freezing, dehydration, or milling." FQPA § 402(c), FFDCA § 201(gg), 21 U.S.C. § 321(gg) (Supp. II 1996).

[29] For an argument that Section 408 applied equally to processed foods, see Edward Dunkelberger & Richard A. Merrill, *The Delaney Paradox Reexamined: Regulating Pesticides in Processed Foods*, 48 FOOD & DRUG L.J. 411, 434 (1993).

[30] The tolerance-seeker need also have demonstrated that the residue on the raw commodity had been "removed to the extent possible in good manufacturing practice" to take advantage of the flow-through exemption. FFDCA § 402(a)(2)(C), 21 U.S.C. § 342(a)(2)(C) (1994). Curme provides an example of the flow-through provision at work: "[I]f an apricot with a tolerance of ten parts per million (ppm) of captan residue for the RAC [raw agricultural commodity] is processed by dehydration and the concentration of residue on the dried apricot exceeds ten ppm, the processed apricot is adulterated absent a tolerance under section 409." Curme, *supra* note 15, at 614.

[31] The question of pesticide residue concentration was thus an important one; see the discussion of the EPA's concentration policy *infra*.

[32] *See* DELANEY PARADOX, *supra* note 15, at 26.

additive without regard to possible economic benefits of a pesticide.[33]

Section 409 classified carcinogens or noncarcinogens under different standards. Noncarcinogens were regulated under what was termed the "general safety standard."[34] A pesticide was considered safe under the general safety standard if there was "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[35] This "negligible risk" standard permitted small amounts of noncarcinogenic pesticides in food, although the same pesticide would cause adverse health effects at higher doses.

For carcinogenic pesticides concentrating in processed foods, there was a very different treatment. Under section 409's Delaney Clause, no additive was to be deemed safe "if it is found to induce cancer when ingested by man or animal."[36] As interpreted by the EPA until 1988, and by the courts in the 1980s and early 1990s,[37] Delaney embodied a zero-risk approach: regardless of the level of risk involved, the carcinogenicity of a pesticide required that it be considered unsafe and hence unable to be the subject of an FFDCA tolerance.[38] The Clause's impact on regulatory policy was clear. Under EPA policy, the agency automatically denied tolerance petitions for new section 409 carcinogenic pesticide residues, "without further analysis."[39] By June 1986, the EPA had established 2,525 section 408 tolerances for pesticides believed to be carcinogens, and 31 section 409 tolerances for carcinogenic pesti-

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[33] In practice, this had little impact on non-carcinogenic pesticides. *See* Dunkelberger & Merrill, *supra* note 29, at 415.

[34] *See* DELANEY PARADOX, *supra* note 15, at 26.

[35] 21 C.F.R. § 170.3(i) (1997).

[36] FFDCA § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) (1994). The relevant provision of the FFDCA reads in full:

> No such [food additive] regulation shall issue if a fair evaluation of the data before the Secretary—(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. . . .

Id.

[37] *See infra* text accompanying notes 118-44.

[38] *See, e.g.*, Les v. Reilly, 968 F.2d 985, 989 (9th Cir. 1992) ("Throughout its 30-year history, the Delaney clause has been interpreted as an absolute bar to all carcinogenic food additives.").

[39] DELANEY PARADOX, *supra* note 15, at 35.

cides;[40] these latter tolerances had been established before scientists discovered evidence that the pesticide residues were carcinogenic in humans or animals.[41]

This differing treatment for carcinogenic and non-carcinogenic pesticides, on the one hand, and raw and processed foods on the other, came to be termed the "Delaney Paradox." A non-carcinogen in raw food would be regulated under the risk-benefit standard of section 408. A single carcinogenic pesticide residue on a given crop that was present in processed food was subject to two standards: a balancing approach for carcinogenic pesticides on raw foods regulated under section 408, and the zero-risk approach for carcinogens concentrated on processed foods falling under section 409.[42]

5. *Coordination and Concentration Policies*

Two non-statutory EPA requirements—the so-called coordination and concentration policies—gave the Delaney Clause even greater significance. The coordination and concentration policies together ensured that the Delaney Clause reached more pesticide residues than a strict reading of the FFDCA would have suggested. As will be discussed in Part III.A of this Note, it was in part the growing significance of the Delaney Clause that contributed to Congressional attempts to narrow the scope of the clause.

Under pre-FQPA law, the regulation of pesticides and their residues in foods was a complex matter involving three tightly interconnected and varied regulatory provisions. The EPA developed the coordination policy to manage the regulatory process more effectively and to ensure greater consistency under its various mandates.[43] In short, the policy had two components. The first component required that before a pesticide intended or expected to be used on food could be registered under FIFRA, the registrant must have received tolerances under sections 408, 409, or both, as necessary.[44] The second component required the EPA to deny section 408 tolerances to pesticides that failed to meet the

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[40] *See id.* at 36.

[41] *See id.* at 35-36.

[42] *See id.* at 40. The Committee identified another two standards that might apply to the same crop if it were used for processed and nonprocessed animal feeds. *See id.*

[43] *See, e.g.*, Pesticides; Request for Comment on Petition to Modify EPA Policy on Pesticide Tolerances, 58 Fed. Reg. 7470, 7473 (1993) (discussing coordination policy); Pesticide Tolerances; Partial Responses to Petition to Modify EPA Policy, 60 Fed. Reg. 31,300, 31,302 (1995) (discussing coordination policy).

[44] *See* 40 C.F.R. §152.112(g) (1997).

food additive petition requirements of section 409, even if the pesticide met the statutory demands of section 408.[45] In practice, the coordination policy intensified the importance of the pre-FQPA Delaney Clause. If a pesticide residue were carcinogenic, and thus had failed to pass through Delaney's screen, the coordination policy would have required that the same pesticide be barred from registration under FIFRA or from receiving a tolerance under section 408. This result led to a consistency of administrative treatment but an inconsistency between the three standards that might regulate a pesticide. A pesticide might be sufficiently safe to pass scrutiny under FIFRA or section 408 of the FFDCA, but the Delaney Clause, coupled with the coordination policy, demanded that the chemical be banned.[46]

The second policy that gave greater significance to the Delaney Clause for pesticide residues was the EPA's "concentration policy." Because of the FFDCA's "flow-through" exception, section 409 and the Delaney Clause only applied to pesticide residues that had *concentrated* in processed foods above the tolerances set under section 408. Thus, determining concentration became key to whether a residue would be regulated under section 409.

The EPA's concentration policy took a "concentration in fact" approach,[47] focusing upon the simple *fact* that a pesticide had con-

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[45] The EPA explained the policy as follows:

> EPA's coordination policy is an expression of EPA's intent to take into account all of the applicable provisions governing pesticides in taking action under any one of the three. EPA's view has been that it should not be approving pesticide uses under one of the three provisions if an approval needed under one of the other provisions cannot be obtained.

Partial Responses, 60 Fed. Reg. at 31,302. Or put another way, "if farmers use a pesticide lawfully on their crops, the food made from those crops should not be rendered illegal because of the presence of pesticide residues." The Pesticide Coordination Policy; Response to Petitions, 61 Fed. Reg. 2378, 2379 (1996).

[46] In 1992, several food industry trade groups, including the National Food Processors Association, petitioned the EPA to repeal or revise the coordination policy. The agency declined to do so. *See id.* The aspect of the policy coordinating FIFRA and the FFDCA survived the FQPA. As will be discussed *infra*, the FQPA removed pesticide residues from the purview of section 409. Accordingly, there is no need to coordinate sections 408 and 409.

[47] *See, e.g.,* Request for Comment, 58 Fed. Reg. at 7473 (discussing concentration in fact analysis); Partial Responses, 60 Fed. Reg. at 31,302 (discussing concentration in fact analysis). As articulated by a National Academy of Sciences Committee, the central question in determining when a residue had concentrated was to ask whether it was the *level* of concentration that mattered, or the *fact* of concentration. *See* DELANEY PARADOX, *supra* note 15, at 28. If regulators were to look at the level of concentration, a residue actually might concentrate slightly but still not exceed the section 408 tolerance. Thus, despite the fact that a pesticide had concentrated, it could remain at a level "not greater than the tolerance prescribed for the raw agricultural commodity." FFDCA § 402(a)(2)(C), 21 U.S.C.

centrated, regardless of the *quantum* of that concentration. If a pesticide residue had concentrated at all, the EPA would regulate the residue under section 409.[48] Under this approach, the Delaney Clause might thus apply to a pesticide residue, although the residue might not have concentrated above the level proscribed by the section 408 tolerance. A concentration in fact policy was thus an administratively convenient method of ensuring that tolerance petitioners also applied for section 409 tolerances.[49]

B. The Food Quality Protection Act

1. Rendering the Delaney Clause Irrelevant to Pesticides

The FQPA rendered much of the complex structure regulating pesticide residues in food largely irrelevant, particularly the interplay between sections 408 and 409.[50] The FQPA removes pesticides from the reach of the Delaney Clause with one easy stroke: all pesticide residues, whether for raw or processed foods, are specifically excluded from the FFDCA's definition of a food additive.[51] Congress explicitly stated that the FQPA is intended to ensure that pesticide residues—for raw and processed foods—are regulated solely under FFDCA sections 408(a) and 402(a)(2).[52]

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§ 342(a)(2)(C)(1994). In such a case, the FFDCA's flow-through provision would obviate the need for a section 409 tolerance, as the Delaney Clause would not apply.

[48] The EPA justified its approach on the grounds that pesticide residues on raw agricultural commodities "may be at or near the section 408 tolerance level.... [S]ection 408 tolerance levels are established based on actual field trials and designed to be set no higher than necessary." Partial Responses, 60 Fed. Reg. at 31,302. Indeed, the agency grounded the concentration policy in language in FIFRA regulations requiring that a tolerance "will not exceed that figure which the Administrator of the Environmental Protection Agency states, in his opinion, reasonably reflects the amounts of residue likely to result." 40 C.F.R. § 180.4 (1997). Since the EPA expected that actual residue levels would approach the section 408 tolerance, the agency could reasonably expect that a concentrating residue would likely exceed the section 408 tolerance.

[49] The EPA reconsidered its concentration policy in 1995, altering the means by which it determined to what extent a residue concentrated, thereby lessening the impact of section 409 as a whole. For instance, the EPA said that it would consider information "pertaining to the averaging of residues during processing." Partial Responses, 60 Fed. Reg. at 31,303. The FQPA made the concentration policy irrelevant, by creating a uniform standard for tolerances in a new section 408.

[50] The FQPA has a broad impact on both FIFRA and the FFDCA, but since this Note focuses upon the tolerance-setting process and the shift from the Delaney Clause to a negligible-risk approach, a comprehensive analysis of the entire bill is beyond its scope.

[51] *See* FQPA § 402(b), FFDCA § 201(s), 21 U.S.C. § 321(s) (Supp. II 1996). For an alternative description of the FQPA, see Bauer, *supra* note 15, at 1386-90.

[52] *See* H.R. REP. NO. 104-669, pt. 2, at 38 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1277. Section 402 stipulates that foods termed unsafe under section 408(a) are deemed adulterated—and are therefore prohibited.

Section 409, and thus the Delaney Clause, no longer applies, since pesticide residues are not defined as food additives. The effect is not to eliminate the Delaney Clause, but to narrow its scope. Indeed, the FQPA does not amend section 409.[53] The universe of substances reached by the Delaney Clause has shrunk both numerically and in terms of significance, however.

2. *A New Section 408*

In place of the old statutory scheme interweaving sections 408 and 409, Congress substituted a rewritten section 408. This new section applies a unified regulatory standard to pesticide residues on raw and processed foods, whether or not they are carcinogens.[54]

a. *Safety*

Like the old statutory language, the amended section 408 requires that registrants seek exemptions or tolerances establishing safe levels of exposure to a pesticide in or on food.[55] The new language defines "safe" as a determination that there is "*a reasonable certainty that no harm will result* from the aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[56] The House Commerce Committee Report reveals that Congress intended that the EPA determine the safety of carcino-

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[53] *See id.* at 39 n.1.

[54] Specifically, a food is now to be considered adulterated under the FFDCA if it contains a pesticide residue not meeting the section 408(a) safety standard. *See* FQPA § 404, FFDCA § 402(a)(2)(B), 21 U.S.C. § 342(a)(2)(B) (Supp. II 1996).

[55] *See* FQPA § 405, FFDCA § 408, 21 U.S.C. § 346a. An interesting issue potentially looming on the horizon is whether the EPA must set tolerances for "unavoidable residues" on food crops. An unavoidable residue might result from a previously banned pesticide or its degradation product (such as DDT and DDE) lingering in the environment and contaminating food crops grown without the intentional application of the banned agrichemical. According to the FQPA, "if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator *may establish* a tolerance for the pesticide chemical residue." FQPA § 405(*l*)(4), FFDCA § 408(*l*)(4), 21 U.S.C. § 346a(*l*)(4) (emphasis added). In establishing such a tolerance, the Act directs that the EPA shall consider those factors applicable to new pesticide tolerances. *See id.* At issue is the important question of the EPA's discretion in setting tolerances for unavoidable residues. If the EPA were required to set tolerances for unavoidable pesticide residues, it would cramp an already resource-limited tolerance-setting process. Furthermore, tolerances for unavoidable residues might have the potential to render many crops unsafe under the FFDCA.

[56] FQPA § 405(b)(2)(A)(ii), FFDCA § 408(b)(2(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added).

genic pesticides with reliance on EPA practices under section 408 before enactment of the FQPA.[57]

Consistent with the congressional intent to give effect to then-current EPA practice, the Commerce Committee Report indicates that the Committee expected that the "reasonable certainty of no harm" standard would have a different interpretation depending on whether the pesticide residue was associated with "non-threshold" or "threshold" effects in animals.[58] Thus, although the same statutory standard applies to carcinogens and non-carcinogens, the distinction between threshold and non-threshold chemicals has resulted in different applications of the new section 408 standard.

The threshold and non-threshold distinction is, put crudely, a distinction between carcinogens and other kinds of toxicants. Scientists generally understand a threshold dose of a chemical to be "that immediately above which responses caused by the chemical begin to manifest themselves."[59] If a chemical is said to exhibit a threshold effect in animal studies, scientists have determined that there is a level below which the chemical does not cause or contribute to the biochemical steps necessary to induce cancer. In other words, below the threshold level, it is believed that exposure to the chemical embodies no health risk; from a health perspective, it is as if there were no exposure.[60] While there is no absolute consensus in this area, scientists, generally assume that the threshold model is probably appropriate "[f]or all toxic effects except carci-

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[57] *See* H.R. REP. NO. 104-669, pt. 2, at 40-41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1279-80. This applied to the determination of safety only; as shall be discussed, the new legislation makes a number of new requirements for the types of exposures that must be considered. The standard also echoes 1958 congressional intent concerning the standard of proof necessary to demonstrate safety. *See infra* note 173. The House Commerce Committee Report is the chief source of legislative history for the FFDCA amendments.

[58] "The Committee has adopted the standard of 'reasonable certainty of no harm' based on EPA's current application of the standard. The Committee understands that the Administrator currently applies this standard differently to threshold and nonthreshold effects." H.R. Rep. 104-669, pt. 2, at 40-41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1279-80. The EPA has the authority to alter its risk-assessment practices. *See id.* at 41, *reprinted in* 1996 U.S.C.C.A.N. at 1280.

[59] RODRICKS, *supra* note 8, at 166.

[60] Central to the notion of a threshold level is the concept of a no-observable effect level: "There are data from thousands of experiments in which doses were identified as having *no observable adverse effect on health*. The maximum dose at which 'no-effects' are observed is called the NOEL: the no-observed effect level." *Id.* at 166-67. The NOEL is identical to a threshold level, however. Joseph Rodricks notes that "observable" is a key part of NOEL; "it reflects the fact that scientists can only report that effects were not observed under the specific study conditions, not that they are producible under other conditions." *Id.* at 167.

nogenesis and perhaps mutagenesis."[61] For threshold effects of a pesticide residue, i.e., noncarcinogenic effects, the House Commerce Committee Report defines "reasonable certainty of no harm" as embodying the requirement that the EPA set a tolerance at a level "lower by an ample margin of safety" than the level at which the residue is found not to cause any adverse effects.[62]

Under the non-threshold effect theory, no safe exposure level has been identified before a toxicant induces carcinogenic effects. Many scientists believe that carcinogenic chemicals fall under the scope of the non-threshold model,[63] although some carcinogenic chemicals appear to display thresholds.[64] Joseph Rodricks explains the non-threshold effect theory as follows:

> Any amount of a DNA damaging chemical that reaches its target (the DNA) can increase the probability of converting a cell to a neoplastic [pre-tumorous] state. This does not mean that every such event will cause a neoplastic conversion, but only that the probability, or risk, of that occurrence becomes greater than zero as soon as the effective target-site concentration of the gene-damaging chemical is reached .... Proponents of the 'no-threshold' hypothesis are not contending that all doses greater than zero 'cause' cancer (though some extremists do). Rather they postulate

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[61] *Id.* at 169. Mutagens cause chemical damage to a cell's DNA and may be carcenogenic, although not necessarily. *See id.* at 151.

[62] H.R. REP. NO. 104-669, pt. 2, at 41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1280. The Commerce Committee Report suggests that this safety margin be a 100-fold factor. *See id.* In translating a NOEL to a tolerance level, the EPA uses two safety factors, which together create a 100-fold factor. The first 10-fold factor takes account of the difference in size and sensitivity between the laboratory animals, in which dose-response testing is occurring, and humans. The second factor reflects differences in sensitivity among humans. *See* DELANEY PARADOX, *supra* note 15, at 32.

[63] *See, e.g.,* Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104, 41,118 (1988) ("Cancer ordinarily is treated as a non-threshold effect, because of a lack of evidence to refute the assumption that the carcinogenic response in humans to low doses is approximately proportional to the response in animals to high dose").

[64] EPA Assistant Administrator Lynn Goldman told congressional leaders that the agency would regulate under the threshold effect standard those chemicals "classified as Category C carcinogens with no quantification of risk." Letter from Lynn R. Goldman, Assistant Administrator, EPA, to Richard Lugar, Chairman, U.S. Senate Committee on Agriculture, Nutrition, and Forestry (July 23, 1996) (on file with author). The EPA has also noted that a Category C carcinogen, a "possible human carcinogen," is a chemical "with limited evidence of carcinogenicity in animals in the absence of human data." Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 34,000 (1986). Also of note, in April, 1996, the EPA proposed to replace its letter-based carcinogen categorization system with narrative descriptors, such as "known/likely." *See* Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. 17,960, 17,961 (1996).

> that all doses above zero *increase the risk* of cancer occurring.[65]

The Commerce Committee envisions a different regulatory policy for pesticide residues falling into this non-threshold category. Before a residue of a non-threshold chemical may be deemed safe, it must be found to pose only a *negligible risk*; the Committee expects the EPA to continue to interpret "negligible" to mean a one-in-a-million lifetime risk of harm.[66]

This position reflects a congressional decision about an acceptable level of risk from carcinogenic chemicals. Since scientists are not able to determine whether there is an effect level for a non-threshold chemical, policymakers must determine what risk level is acceptable. The Delaney Clause embodied a requirement that a zero-risk level was appropriate. As the Commerce Committee Report suggests, the FQPA would define that risk level as a one in a million lifetime-risk of harm.[67] The implications of this change will be explored in Part III.B of this Note.

b. Consideration of Benefits

Under the new statutory language, the EPA may consider benefits of a pesticide when setting tolerance levels, but only for a limited class of chemicals ("eligible pesticide chemical residues") and only under closely-defined risk levels.[68] To qualify as an eligible pesticide chemical residue, several criteria must be met. To begin with, the class of eligible pesticide residues is comprised only of residues that fail to meet the safety requirement ("reasonable certainty of no harm") of the new section 408.[69] Thus, if a pesticide residue on or in food can be found to be safe, the revised law explicitly forbids the EPA from considering possible benefits of use.[70] This means that once a tolerance is set at a level deemed to be safe

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[65] RODRICKS, *supra* note 8, at 156, 168.

[66] *See* H.R. REP. NO. 104-669, pt. 2, at 41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1280. In practice, a one-in-a-million risk level means that when an average adult is exposed to the maximum permitted level of a chemical daily over a lifetime, there is a one-in-a-million (or $1x10^{-6}$) chance that exposure to the chemical will cause cancer.

[67] *See* H.R. REP. NO. 104-669, pt. 2, at 42 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1280.

[68] *See* FQPA § 405(b)(2)(B), FFDCA § 408(b)(2)(B), 21 U.S.C. § 346a(b)(2)(B) (Supp. II 1996).

[69] *See* FQPA § (b)(2)(A)(iii), FFDCA § 408(b)(2)(A)(iii); 21 U.S.C. § 346a(b)(2)(A)(iii).

[70] *See id.* More specifically, a tolerance issued under the general "safety" standard (FFDCA § 408(b)(2)(A)) may not be granted a tolerance under the provisions considering benefits (FFDCA § 408(b)(2)(B)).

by the EPA, the tolerance may not be increased to account for possible benefits to farmers, processors, or consumers that might result from more intensive pesticide applications.

The FQPA established several other criteria narrowing the class of residues for which the EPA may consider benefits when calculating tolerance levels. First, an eligible residue must have an already-set tolerance level; the EPA may not evaluate benefits when setting a tolerance for a new chemical.[71] Second, the pesticide residue at issue must be associated with a non-threshold effect;[72] thus, the legislation limits consideration of benefits to carcinogenic residues.[73] Third, the registrant must demonstrate: (i) that there is a need for the pesticide;[74] (ii) that the lifetime risk posed by exposure to the residue has been "appropriately assessed by quantitative risk assessment;"[75] and (iii) that the level of risk associated with the pesticide falls within a certain order of magnitude from the "reasonable certainty of no harm" standard.[76]

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[71] *See* FQPA § 405(b)(2)(B)(ii), FFDCA § 408(b)(2)(B)(ii), 21 U.S.C. § 346a(b)(2)(B)(ii).

[72] For example, a residue for which there is no "level of exposure . . . at which the residue will not cause or contribute to a known or anticipated harm to human health." FQPA § 405(b)(2)(B)(i)(I), FFDCA § 408(b)(2)(B)(i)(I), 21 U.S.C. § 346a(b)(2)(B)(i)(I).

[73] *See supra* text accompanying notes 59-62. If a residue has a threshold effect (and thus is considered to be a non-carcinogen), any tolerance for that effect must satisfy the FFDCA's new definition of "safety," without reference to any benefits. *See* FQPA § 405(b)(2)(B)(i)(III), FFDCA § 408(b)(2)(B)(i)(III), 21 U.S.C. § 346a(b)(2)(B)(i)(III).

[74] Need is measured either by a showing that use of the residue will protect consumers from even greater risks to human health (e.g., a statutorily unsafe fungicide prevents the growth of the fungus that produces aflatoxin, an extremely powerful liver carcinogen), *see* H.R. REP. NO. 104-669, pt. 2, at 42 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1281, or that use of the pesticide "is necessary to avoid a significant disruption of an adequate, wholesome, and economical food supply." FQPA § 405(b)(2)(B)(iii)(II), FFDCA § 408(b)(2)(B)(iii)(II), 21 U.S.C. § 346a(b)(2)(B)(iii)(II).

[75] FQPA § 405(b)(2)(B)(i)(II), FFDCA § 408(b)(2)(B)(i)(II), 21 U.S.C. § 346a(b)(2)(B)(i)(II).

[76] *See* FQPA § 405(b)(2)(B)(iv), FFDCA § 408(b)(2)(B)(iv), 21 U.S.C. § 346a(b)(2)(B)(iv). Under the risk requirements, the annual risk from the non-threshold effect cannot exceed 10 times the annual risk that would be allowed under the "reasonable certainty of no harm" safety standard. Furthermore, the *lifetime* risk posed by the health effect cannot be more than twice the lifetime risk allowed under the general safety standard. The presence of the lifetime-risk limitation ensures that to the extent that the tolerance exceeds the "safe" annual-risk level, the tolerance will be phased out after "the period encompassing the permitted lifetime risk." Edward Dunkelberger & Clausen Ely, Jr., Covington & Burling, Analytical Summary of Selected Provisions of H.R. 1627, The Food Quality Protection Act of 1996 (July 26, 1996) (on file with author). The FQPA directs the EPA to examine, after five years, whether an eligible residue still meets the conditions posed by the benefit-considering provisions. *See* § 405(b)(2)(B)(v), FFDCA § 408(b)(2)(B)(v), 21 U.S.C. § 346a(b)(2)(B)(v). If EPA is presented with a new pesticide that poses a lower risk than a similar eligible pesticide the agency must consider whether the higher-risk pesticide still meets the benefits provisions. *See* FQPA § 408(d)(4)(C),

Although the EPA is authorized to consider benefits, in practice, the criteria for eligible residues are sufficiently stringent that the standard for tolerance approval will be exclusively risk-based. Indeed, both the Commerce Committee report and statements by EPA officials suggest that the benefits provisions will come into play only rarely.[77] It bears noting, however, that the replacement of the Delaney Clause with a "reasonable certainty of no harm" standard impliedly assumes that carcinogenic pesticides meeting the new safety standards offer sufficient benefits to justify a negligible risk.

c. Exposures to Infants and Children

Environmentalists and public health advocates sought, and won, a requirement in the FQPA that the EPA consider the special susceptibility of infants and children when setting tolerance levels.[78] In enacting this requirement, Congress heeded the advice of a 1993 National Academy of Sciences Committee that urged consideration of the "fundamental maxim of pediatric medicine . . . that children are not 'little adults.'"[79]

The new legislation requires the EPA to specifically "assess the risk" posed by a residue to infants and children when establishing, modifying, or revoking a tolerance.[80] The agency is to consider (i) whether consumption patterns of this subpopulation render it

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FFDCA § 408(d)(4)(C), 21 U.S.C. § 346a(d)(4)(C). The EPA must review the lower-risk pesticide in an expedited fashion. *See id.*

[77] The House Commerce Committee expressed the intention that the benefits provisions be used only in "exceptional situations." H.R. REP. NO. 104-669, pt. 2, at 42 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1281. Shortly after passage of the FQPA, EPA Assistant Administrator Lynn Goldman told a pesticide industry conference that the EPA would consider benefits only in cases demonstrating a "clear national need." Lynn Goldman, Speech at a Conference Presented by the American Crop Protection Association and McKenna & Cuneo, L.L.P. on Food Safety and FIFRA Amendments of 1996 (Sep. 10, 1996).

[78] EPA officials have suggested that these provisions codify what had been existing practice at the agency: "This provision is consistent with current Agency risk management practices." Letter from Goldman to Lugar, *supra* note 64. An EPA analysis of the legislation suggests that the agency had attempted to implement consideration of infants and children into its pesticide program, but had been hampered by "[l]ack of funding." ENVIRONMENTAL PROTECTION AGENCY, FOR YOUR INFORMATION: MAJOR ISSUES IN THE FOOD QUALITY PROTECTION ACT OF 1996 4 (1996).

[79] CHILDREN AND PESTICIDES REPORT, *supra* note 12, at 3. The Committee found "quantitative and occasionally qualitative" differences in the toxicity of pesticides between children and adults, and lack of information on child exposure to pesticide residues. *Id.* at 3, 5. For the Committee's recommendations, see e.g., *id.* at 7-12.

[80] *See* FQPA § 405(b)(2)(C)(i), FFDCA § 408(b)(2)(C)(i), 21 U.S.C. § 346a(b)(2)(C)(i) (Supp. II 1996).

more likely to be exposed to the residue than the rest of the population; (ii) whether infants and children are "specially susceptible" to the residue, including with regard to neurological differences and effects of *in utero* exposure, and (iii) whether—and to what extent—this subgroup faces differing cumulative effects from residues and other substances that share a common mechanism of toxicity.[81] After these factors have been considered, the EPA must ensure that any tolerance will guarantee "that there is a reasonable certainty that no harm will result [to infants and children] from aggregate exposure" to the residue.[82] If data are incomplete and existing data suggest that there are "potential pre- and post-natal toxicity" concerns posed by the residue, the legislation gives the EPA discretion to add an additional ten-fold safety factor when setting the tolerance level.[83]

Although the overall effect of the infants and children provision remains to be seen, the additional sensitivity of this subpopulation and the additional safety factors make it likely that these new requirements will result in stricter tolerances.[84]

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[81] *See* FQPA § 405(b)(2)(C)(i)(I)-(III), FFDCA §408(b)(2)(C)(i)(I)-(III), 21 U.S.C. § 346a(b)(2)(C)(i)(I)-(III).

[82] FQPA § 405(b)(2)(A)(ii), FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii).

[83] FQPA § 405(b)(2)(C), FFDCA § 408(b)(2)(C), 21 U.S.C. § 346a(b)(2)(C). The agency, however, may use a "different" safety factor if such a factor would be safe for infants and children. *See id.* The language of the Act and the House Commerce report do not specify what is meant by "different," although EPA officials speaking at a meeting of the American Crop Protection Association meeting appeared only to consider the possibility of lower safety factors, rather than factors higher than ten-fold. In setting the safety factor, an EPA official has indicated that the agency will consider:

> data submitted [by the registrant] in compliance with EPA testing requirements, available data published in the scientific literature, and any other data . . . meeting general scientific standards. Where reproductive and developmental data do . . . not indicate potential pre or postnatal effects of concern, the additional tenfold margin of safety would not be applied.

Letter from Goldman to Lugar, *supra* note 64. Prior to passage of the FQPA, the EPA used additional safety factors in considering uncertain health effects on infants and children. These factors ranged between three and ten, depending on the amount of incomplete information. *See* Letter from Lynn R. Goldman, Assistant Administrator, EPA, to Thomas Bliley, Chairman, U.S. House Committee on Commerce (July 23, 1996) (on file with author).

[84] The FQPA also includes other provisions that will shape the EPA's tolerance-setting methodology. First, the legislation directed that the EPA consider "aggregate exposure" to the pesticide residue. *See* FQPA § 405(b)(2)(A)(ii), FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii). Aggregate exposure will include dietary and non-dietary exposures such as inhalation and skin contact, and through non-food uses around the home and garden. *See* H.R. REP. NO. 104-669, pt. 2, at 40 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1279. Another FQPA provision will push tolerance levels in the opposite direction. The FQPA also directs the EPA to set tolerances based upon actual or anticipated residue levels, instead of assuming that residues were present on foodstuffs at the maximum per-

III. WHY DID CONGRESS NARROW THE SCOPE OF THE DELANEY CLAUSE?

It might appear that the replacement of the Delaney Clause was a simple legislative act, rapidly passed in the waning days of the 104th Congress, with no visible dissent. But the relative ease of the Act's formal passage through Congress in the summer of 1996 obscured the intense debate over the Clause that had raged for close to two decades. Since Delaney ensured that under certain circumstances carcinogenic pesticides would not enter the food supply, for many years, and still in many minds, the rejection of the Delaney Clause was neither a foregone nor an appealing conclusion.

I suggest that the narrowing of the Delaney Clause came as the result of two types of pressure—one political or policy-oriented, and the other based on changed notions of science and the role that science plays in regulatory decisions. The policy-based pressure was largely the result of the impact that the Delaney Clause had begun to exert on the approval of carcinogenic pesticides, and the EPA's administrative inability to escape from Delaney's strictly-interpreted mandate. In terms of science and policy, the FQPA reflects policymakers' changing conception of cancer, a growing acceptance of risk-assessment methodology, and an understanding of the appropriate roles Congress and the EPA play in assessing and managing carcinogenic risk. These issues shall be examined in turn.

A. A Change in Politics and Policy: The Clause Began To Matter

1. A Legislative Superfluity?

When Congress enacted the Food Additive Amendments of 1958, the Senate Committee responsible for the legislation and the Department of Health, Education and Welfare asserted that the

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mitted level. *See* FQPA § 405(b)(2)(E)(i), FFDCA § 408(b)(2)(E)(i), 21 U.S.C. § 346a(b)(2)(E)(i); DELANEY PARADOX, *supra* note 15, at 32. To the extent that actual residues represent a lower residue level on the food crop, tolerance levels will be raised accordingly. A third FQPA provision permits the EPA to rely on the percentage of food actually treated by a pesticide when setting a tolerance, as long as several requirements concerning the reliability of the data are met. *See* FQPA § 405(b)(2)(F), FFDCA § 408(b)(2)(F), 21 U.S.C. § 346a(b)(2)(F). Under prior EPA practice, the agency had assumed that all harvested acres of a crop had been treated with the pesticide at issue, even though "[v]ery few pesticides are used on anywhere near 100 percent of the total acreage of a crop grown in the United States, and measured residues are usually below the tolerance." DELANEY PARADOX, *supra* note 15, at 32.

Delaney Clause was, in essence, a legislative superfluity. The FFDCA already required that all food be safe; if a pesticide residue caused cancer, it could hardly be deemed safe.[85] For almost 20 years, it appeared that this early view of the Delaney Clause was correct.[86] Before the pesticide debate of the 1980s and 1990s, the Clause had been used only four times by the FDA to prevent the marketing of a substance, and the FDA had banned other carcinogens without reference to the Delaney Clause.[87]

Beginning in the late 1970s, however, the Delaney Clause began to exert real regulatory power. If Delaney had appeared to be a legislative superfluity in 1958, that view was seriously challenged on March 9, 1977, when the FDA announced that the agency was proposing to ban the use in food of the only nonnutritive sweetener on the market,[88] saccharin.[89] Citing Canadian evidence of saccharin's carcinogenicity,[90] agency officials suggested that under the Delaney Clause and the general safety standard of the FFDCA, the "FDA had no choice but to ban saccharin. The Delaney anticancer clause provides unequivocally that a substance which has been shown by appropriate tests to cause cancer in ani-

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[85] *See* S. REP. NO. 85-2422, at 11 (1958), *reprinted in* 14 LEGISLATIVE HISTORY OF THE FOOD, DRUG, & COSMETIC ACT 923 (1979). In the words of the Department of Health, Education, and Welfare:

> [I]t is the intent and purpose of this bill, even without [the Delaney] amendment, to assure our people that nothing shall be added to the foods they eat which can reasonably be expected to produce any type of illness in humans or animals. . . . In short, we believe the bill reads and means the same with or without inclusion of the clause referred to.

Id.

[86] *See, e.g.*, JAMES D. WILSON, RESOURCES FOR THE FUTURE, DISCUSSION PAPER 96-61, THRESHOLDS FOR CARCINOGENS: A REVIEW OF THE RELEVANT SCIENCE AND ITS IMPLICATIONS FOR REGULATORY POLICY 7 (1996) ("Although symbolically this language has great weight, in practice it has seen almost no use by FDA.").

[87] *See* Merrill, *Repudiation*, *supra* note 15, at 9. The real impact of the Clause was likely felt by food additives manufacturers that were dissuaded from seeking FDA "approval" for carcinogenic additives, knowing that their product would be barred by Delaney. The extent of such an impact would be difficult, if not impossible to measure.

[88] *See* HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, SACCHARIN BAN MORATORIUM, H.R. REP. NO. 95-658, at 7 (1977).

[89] *See id.* at 2, 17. The FDA published its proposal a month later. *See* Saccharin and Its Salts: Proposed Rulemaking, 42 Fed. Reg. 19,996 (1977).

[90] *See Proposed Saccharin Ban -- Oversight, Hearings Before the Subcomm. on Health and the Env't of the House Comm. on Interstate and Foreign Commerce*, 95th Cong. 41 (1977) [hereinafter *Saccharin Ban Hearings*] (statement of Sherwin Gardner, Acting Commissioner, FDA). The FDA stated that the tumorous rats had been exposed to saccharin levels equivalent to 800 cans of diet soda per day. *See* HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, SACCHARIN BAN MORATORIUM, H.R. REP. NO. 95-658, at 5.

mals may not be permitted in foods."[91] Faced with an outraged public,[92] Congress enacted a moratorium preventing the FDA from taking action based on the carcinogenicity of saccharin.[93] The public and Congress showed a willingness to make an exception to Delaney's zero tolerance mandate, realizing that some substances provide such purportedly valuable benefits that some level of carcinogenic risk is an acceptable trade-off.

2. *FDA and EPA Attempts to Escape Delaney*

Less than two weeks after the FDA proposed to ban saccharin, Acting FDA Commissioner Sherwin Gardner testified before a congressional panel that the issue had been the most controversial Delaney-related FDA action. Gardner stated: "[I]t probably will not be the last nor, as science becomes increasingly capable of identifying hazards where none were thought to exist before, will it be likely to remain the most controversial."[94] As a summary of Delaney Clause controversies through the mid-1990s, this testimony would prove to be prescient. From 1977 to 1996, the Delaney story is one of regulators seeking to evade the strict dictates of the Clause as scientists grew increasingly able to detect and identify carcinogens in the food supply.[95] Since legislative revision

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[91] *Id.*

[92] Representative Henry Waxman, later a key figure in the Delaney debate, remarked at the time that the saccharin ban "brought more protests to Members of Congress than any issue since Nixon's Saturday night massacre." *Moratorium on Saccharin Ban, Hearing Before the Subcomm. on Health and the Env't of the House Comm. on Interstate and Foreign Commerce*, 95th Cong. 65 (1977). The agency received over 40,000 letters of protest, although much of the opposition was apparently encouraged by the diet food industry. *See* HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, SACCHARIN BAN MORATORIUM, H.R. REP. NO. 95-658, at 5. The FDA conceded that public reaction had been "essentially negative." *See Saccharin Ban Hearings*, *supra*, note 90, at 42.

[93] Saccharin Study and Labeling Act, Pub. L. No. 95-203, 91 Stat. 1451 (1977). The moratorium has been reenacted repeatedly since its original imposition. *See* JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM 127 (3d ed. 1992). In essence, Congress decided that although there might be evidence of "mild" carcinogenicity, the benefits of the product justified its continued availability. *See* HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, SACCHARIN BAN MORATORIUM, H.R. REP. NO. 95-658, at 9. The legislative history of the initial saccharin ban moratorium suggests that Congress was driven in part by "disagreement among experts as to the actual risk" posed by saccharin, in part by the intense public reaction, and in part by saccharin's role in the food supply, including as a key ingredient in soft drinks and diet foods. *Id.* The House Committee overseeing the moratorium noted that 5 million pounds of the sweetener had been used in foods in 1974; the primary use was for diet soft drinks, although other uses ranged from canned fruits to tabletop sweeteners. *See id.* at 5.

[94] *Saccharin Ban Hearings*, *supra* note 90, at 42-43.

[95] Improvements in science contributing to Delaney's narrowing are discussed *infra* Part

of the Clause appeared unlikely in the late 1970s (legislators ignored proposals to revise the FFDCA),[96] any escape from the Clause had to come at the behest of the EPA and the FDA.

a. The Delaney Paradox *Report: The Clause Mattered For Pesticides*

In 1985, the EPA requested that a committee of the National Academy of Sciences (NAS) examine the EPA's tolerance setting process, especially "the current and likely future impacts of the Delaney Clause on the tolerance-setting process."[97] The resulting report (*The Delaney Paradox*), issued in 1987, convincingly demonstrated that the Clause would be a key force in the pesticide debate.[98] The Committee concluded that "over the next few years, the EPA will face bringing several hundred additional pesticide uses into compliance with section 409 of the FDC Act and the Delaney Clause."[99] For pesticides, the Delaney Clause could no longer be dismissed as a legislative superfluity.

The NAS Committee also highlighted another factor that became key to the reconsideration of the Delaney Clause: the provision's limited scope. As Professor Richard Merrill has commented, "even if one embraced the heroic view that we should allow no carcinogens to be added by human agency to food, the Delaney Clause is a pale imitation of such a policy."[100] While important to those pesticide residues to which it applied, the Clause was inapplicable to a large group of tolerances.[101] The Committee

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III.B.

[96] *See* Merrill, *Repudiation*, *supra* note 15, at 31 n.169.

[97] DELANEY PARADOX, *supra* note 15, at v.

[98] *See id.* at 4 ("[T]he Delaney Clause will be central to the EPA's decision making in future years.").

[99] *Id.* at 5. The Committee based its conclusion upon the findings that the "EPA considers a substantial fraction of all herbicides, fungicides, and insecticides to be oncogenic or potentially oncogenic . . . in animal studies," *id.* at 4, and upon the Committee's findings that (i) section 409 tolerances for 31 processed foods appeared to violate Delaney, and (ii) there were no section 409 tolerances for nearly 800 other processed foods in which registered oncogenic pesticide residues were expected to concentrate. *See id.* at 5. The Paradox Committee used the term "oncogen" to refer to substances capable of producing benign or malignant tumors, and "carcinogens" for those substances producing malignant tumors. *See id.* at 1-2.

[100] Merrill, *Repudiation*, *supra* note 15, at 75.

[101] The insight that Delaney applies to only a limited universe of residues might appear to weaken this Note's contention that Congress decided to revise the Delaney Clause in part because the Clause began to matter. That the Clause applies to a limited number of pesticides does not, however, alter the notion that the class of affected pesticides was sufficiently large to attract congressional attention. Strict interpretation of the Clause would have required the revocation of numerous tolerances, *see infra* text accompanying notes

found that "[a]t most, the Delaney Clause [without the coordination policy] could apply to processed-food residues responsible for only one-fifth of the estimated dietary oncogenic risk from pesticides."[102]

The NAS committee and other observers have pointed out a corollary to Delaney's limited scope: in some instances, a Delaney-barred pesticide might present a safer alternative to a pesticide already in use.[103] The Clause barred the use of carcinogenic pesticides, regardless of the magnitude of risk they posed, while non-carcinogenic pesticides were regulated under the more lenient general safety standard. Thus, if a pesticide did not concentrate, it was not barred even if it was a carcinogen. In another situation, the EPA might legally set a tolerance for a noncarcinogenic pesticide that posed a greater, albeit noncarcinogenic, public-health risk than a safer carcinogen. Accordingly, the differential treatment of carcinogens under the Delaney Clause theoretically permitted an increased health risk from noncarcinogenic pesticide residues.[104]

Having concluded that the Delaney Clause would become a key force in pesticide regulation despite its limited applicability, the

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94-157, a result that spurred passage of the FQPA.

[102] DELANEY PARADOX, *supra* note 15, at 5. The Committee generated this estimate by examining the distribution of oncogenic risk from 28 pesticides likely to have been revoked under Delaney. The Committee found that roughly 45% of dietary oncogenic risk stemming from pesticide residues was associated with food with no processed form (many fruits and vegetables; all meat, milk, and poultry products). Fifty-five percent of the risk came from crops consumed either in a raw or processed form. Only 20% of the risk ultimately was associated with the processed form of crops consumed in either form. *See id.* Combined with the coordination policy, another 35% of the risk would be curtailed.

[103] *See, e.g.*, Cass Sunstein, *Interpreting Statutes in the Regulatory State*, 103 HARV. L. REV. 405, 423 (1989) ("[T]he Delaney Clause almost undoubtedly increases health risks by keeping relatively safe substances off the market and by forcing consumers to resort either to noncarcinogenic substances that pose other risks or to substances that were approved by earlier administrators using the crude technology of their day."). *See also 1995 FQPA Hearings*, *supra* note 10, at 29 (testimony of Lynn Goldman, Assistant Administrator, EPA) ("Theoretically, a zero risk approach to cancer for these pesticides could lead to use of alternative pesticides with more net risk but no cancer risk. These [economic] costs [resulting from fewer available pesticides] to society buy little in the way of additional public health protection."); Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104, 41,108 (1988) ("[V]ery similar risk situations have been treated quite differently because of the inconsistent statutory provisions.").

[104] Furthermore, older pesticides might have been approved on the basis of toxicology tests that were not sensitive enough to detect carcinogens. *See* Sunstein, *supra* note 103, at 423. Finding that 90% of dietary oncogenic risk stemmed from pesticides with tolerances set before 1978, the Delaney Paradox Committee urged regulators to subject old tolerances to contemporary safety criteria. *See* DELANEY PARADOX, *supra* note 15, at 11.

NAS Committee proposed that regulators replace the Clause's zero tolerance requirement with a negligible-risk standard.[105] Based upon the axiom, *de minimis non curat lex* (the law does not concern itself with trifles), this standard would permit negligible carcinogenic risk levels; the EPA would establish tolerances that permitted the presence of carcinogenic pesticide residues at levels deemed to present a low risk (defined by the NAS Committee as one in a million), instead of flatly banning the presence of such carcinogens.[106]

Such a standard "could dramatically reduce total dietary exposure to oncogenic pesticides," said the panel, "with modest reduction of benefits."[107] A negligible-risk standard would reduce dietary oncogenic risk by ninety-eight percent, almost as much as if the scope of the Delaney Clause were broadened to apply to residues in both raw and processed foods.[108] In an illuminating finding, the Committee determined that implementing the de minimis standard for both raw and processed food would result in a dramatically lower cancer risk (ninety-eight percent versus fifty-five percent) than maintaining the status quo, where the Delaney Clause applied only to carcinogenic residues concentrating in processed food.[109]

i. De Minimis Doctrine in Non-Pesticide Contexts

Before the EPA could implement a de minimis doctrine for pesticides, it would have to grapple with judicial responses to other attempts to implement a de minimis standard in the food safety context. The de minimis exception had its genesis in a 1979 D.C.

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[105] *See* DELANEY PARADOX, *supra* note 15, at 12.

[106] *See id.* at 6, 100-35 (The Committee examined how changing the regulatory standard would affect the risks posed by 28 (or more) oncogenic pesticides to which Delaney would apply, by considering four alternative policies: (i) applying the Delaney Clause to all oncogenic pesticides, on raw and processed foods; (ii) applying a zero tolerance to all oncogenic pesticide residues in processed foods, regardless of concentration; a coordination policy would also apply; (iii) applying a negligible-risk standard to all pesticide residues, revoking tolerances when oncogenic risk exceeded one-in-a-million; and (iv) applying this negligible-risk standard to processed foods, revoking tolerances for raw foods under a coordination policy.).

[107] *Id.* at 12. While applying Delaney would forfeit all benefits from the barred pesticides since the application of the Clause would eliminate all tolerances for carcinogenic residue, *see id.* at 123, under a de minimis policy, fewer benefits of pesticides would be lost, even as risks dropped; only 32% of the tolerances under scrutiny would be revoked under this approach. *See id.* at 7.

[108] *See id.* at 7. Under the broad Delaney approach, cancer risk would drop to zero. *See id.* at 6, 119.

[109] *See id.* at 7, 119.

Circuit opinion, *Alabama Power Co. v. Costle*,[110] in which Judge Leventhal wrote that "[c]ategorical exemptions may also be permissible as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered de minimis. It is commonplace, of course, that the law does not concern itself with trifling matters . . . ."[111]

Alabama Power, however, did not deal with the direct health risks that carcinogenic food additives pose. Importantly for the EPA's purposes, though, federal courts had found statutory authority to implement a de minimis exception within the FFDCA. In *Monsanto v. Kennedy*,[112] the D.C. Circuit expressed concern that the Commissioner of the FDA was construing the FFDCA food additive provisions "in the belief that he was constrained to apply the strictly literal terms of the statute irrespective of the public health and safety considerations."[113] Further judicial support for a de minimis exception to the Delaney Clause came in a review of the FDA's "constituents policy" for color additives, which are regulated under a Delaney provision similar to that for food additives.[114] In *Scott v. Food and Drug Administration*,[115] a

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[110] 636 F.2d 323 (D.C. Cir. 1979).

[111] *Id.* at 360. The *Alabama Power* case involved a challenge to the EPA's final regulations under the 1977 Clean Air Act amendments. The EPA had allowed for some de minimis emissions in an effort to balance the costs of compliance and a concern for significant deterioration of air quality in "clean air areas."

[112] 613 F.2d 947 (D.C. Cir. 1979).

[113] *Id.* at 954. A food additive was defined, in part, as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." FFDCA § 201(s) (1976). At issue in *Monsanto* was whether a polymer, which was used to make soft drink containers, migrated into the drink in sufficient quantities to require that the polymer be regulated as a food additive. The polymer migrated into the beverage at undetectable levels, but the FDA had prohibited the use of the polymer in beverage containers. The *Monsanto* court found "latitude inherent in the statutory scheme to avoid literal application of the statutory definition of 'food additive' in those de minimis situations that, in the informed judgment of the Commissioner, clearly present no public health or safety concerns." 613 F.2d at 954. Thus, the court found that the FDA had discretion to determine that "the level of migration into food of a particular chemical is so negligible as to present no public health or safety concerns . . . ." *Id.* at 955.

[114] *See* FFDCA § 706(b)(5)(B), 21 U.S.C. § 379e(b)(5)(B) (1994).

[115] 728 F.2d 322 (6th Cir. 1984). At issue in *Scott* was the FDA's listing of D&C Green No. 5, a color additive not believed to be carcinogenic. One of the reactants used as a building block for the additive, *p*-toluidine, an acknowledged carcinogen, was inescapably present in Green No. 5. A strict application of the Delaney Clause to Green No. 5 and the residual amount of *p*-toluidine would result in the ban of the color. But instead of applying Delaney, the FDA distinguished the "additive" and the "constituent." *See* D&C Green No. 5, Listing as a Color Additive in Drugs & Cosmetics, Termination of Stay and Confirmation of Effective Date, 47 Fed. Reg. 49,628, 49,630 (1982). Since *p*-toluidine "is not intended to and does not contribute any color to Green No. 5," the FDA declined to

1984 decision, the Sixth Circuit approved the constituents policy, under which the FDA applied the Delaney Clause only to the color additive compound and not to trace levels of a carcinogenic constituent of the color additive.[116]

When the FDA sought to escape further the dictates of Delaney in the color additive context, however, the judicial response was less welcoming. In 1986, the FDA proposed to regulate carcinogenic color additives under Delaney, but with a de minimis standard in place of Delaney's zero tolerance ban.[117] In *Public Citizen v. Young*,[118] an unanimous panel of the D.C. Circuit strictly interpreted the color additive Delaney Clause, holding that the de minimis doctrine "obviously is not available to thwart a statutory command . . . ."[119] Relying on text,[120] legislative history,[121] and policy considerations,[122] the *Young* court finally rested on a separa-

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treat it as color additive. *Scott*, 728 F.2d at 323. The Delaney Clause was thus inapplicable, and the agency listed Green No. 5. *See id.* at 324. Although *p*-toluidine was a carcinogen, the FDA concluded that it presented a sufficiently low risk to pass the general safety standard. *See id.*; D&C Green No. 5, 47 Fed. Reg. 24,278, 24,279-80, 24,284 (1982); D&C Green No. 5; Listing as a Color Additive in Drugs & Cosmetics; Termination of Stay and Confirmation of Effective Date, 47 Fed. Reg. 49,628 (1982).

116 *See* Merrill, *Repudiation*, *supra* note 15, at 38-41.

117 The agency listed two color additives, Orange No. 17 and Red No. 19, as safe, despite risk assessments suggesting that the colors caused cancer in test animals. *See* Listing of D&C Orange No. 17 for Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28,331, 28,341 (1986); Listing of D&C Red No. 19 for Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28,331, 28,346, 28,357. The FDA concluded that the risks posed by the additives are so low (one in 19 billion and one in nine million, respectively) "as to be effectively no risk." *Id.* at 28,345; *accord id.* at 28,360, 28,362. The agency conceded that under its previous, strict reading of the Delaney Clause, the agency would likely have banned the two color additives. *See id.* at 28,341, 28,357. The FDA argued, however, that the legislative history of the FFDCA demonstrated that the agency had been invested with "inherent authority under the *de minimis* doctrine" to administer an exception to the Delaney Clause. *See id.* at 28,341, 28,358.

118 831 F.2d 1108 (D.C. Cir. 1987).

119 *Id.* at 1113.

120 *See id.* at 1112, 1122. The court found the "almost inescapable" reading of the Clause to be "that if the Secretary finds the additive to 'induce cancer' in animals, he must deny listing." *Id.* at 1112. Since Orange No. 17 and Red No. 19 had been found to induce cancer, Delaney applied. *See id.* Concerning the context of the Clause, the court noted that adjacent to the Clause were a "variety of factors" for the FDA to consider when deciding whether to list a color additive. *See id.* "For carcinogens, however, [the statute] framed the issue in the simplest form, 'If A [finding that cancer is induced in man or animals], then B [no listing].'" *Id.*

121 *See id.* at 1113-17.

122 *See id.* at 1113, 1117-18. These considerations included the possibility that Congress in 1960 was "truly alarmed about the risks of cancer." *Id.* at 1117. Another possible explanation was a determination that color additives "lack[ed] any great value." *Id.* Finally, the court noted that Congress had contemplated the possibility that "its no-threshold assumption might prove false and contemplated a solution: renewed consideration by Con-

tion of powers rationale: "[I]n 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."[123]

b. EPA's Pesticide De Minimis Policy

With this history in mind, and armed with the backing of the NAS Committee, the EPA in 1988 adopted a de minimis policy for carcinogenic pesticide residues in processed foods.[124] Under this de minimis policy, the EPA would apply the Delaney Clause's prohibition to carcinogenic pesticides posing a risk greater than "negligible," which in turn was defined as a one-in-a-million likelihood of developing cancer after a daily lifetime exposure to the maximum permitted level of the residue.[125] However, a unanimous Ninth Circuit panel would later strictly interpret the Delaney Clause, rejecting the de minimis doctrine for pesticides, and thereby setting the stage for the Food Quality Protection Act.[126]

The EPA took a slightly different approach in proposing a de minimis exception to Delaney for pesticide residues than the FDA had used for color additives. Only briefly noting the *Alabama Power* line of cases,[127] the EPA instead stressed the regulatory inconsistencies that resulted from the Delaney Clause's limited scope.[128] Under the coordination policy, regulators would have denied FIFRA registration and a section 408 tolerance to pesticides barred under section 409 and the Delaney Clause.[129] Application of Delaney thus would have banned pesticides otherwise allowable under the risk-benefit calculus of FIFRA or the non-Delaney provisions of the FFDCA.[130] In effect, the Agency said that Delaney had trumped FIFRA and other provisions of the FFDCA, thereby defeating congressional intent concerning pesticide registration. "Many of these [otherwise lawful] pesticides appear to pose low or negligible risks and to have substantial benefits

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gress." *Id.* at 1118.

123 *Id.* at 1122.

124 *See* Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104 (1988).

125 *See id.* at 41,107.

126 *See infra* Section III.A.2.c.

127 *See* Regulation of Pesticides in Foods, 53 Fed. Reg. at 41,107 n.5.

128 *See id.* at 41,104, 41,108-09.

129 *See id.* at 41,108.

130 *See id.* ("Very similar risk situations have been treated quite differently.").

for the production of food in this country."[131] Rather than proposing to eliminate the paradox by revising the coordination policy, the EPA contended that a de minimis (negligible risk) policy was the most satisfactory solution.[132]

The EPA cited *Alabama Power* as support for its "inherent authority to avoid applying the terms of a statute literally when to do so would yield pointless results."[133] Necessarily, the agency distinguished its pesticide policy from the *Young* court's consideration of Delaney in the color additive context.[134] Even in unveiling its administrative de minimis policy for pesticide residues, however, the EPA noted that a legislative solution "clearly would be desirable."[135] The Agency also noted that a legislative solution could be more sweeping in its revision of pesticide policy, and that this strategy could minimize "protracted litigation."[136]

c. *No Means No:* Les v. Reilly

In the end, congressional intervention to resolve this issue was more than desirable; it was essential. Seven months after the EPA

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[131] *Id.* The EPA explicitly embraced findings of the NAS *Delaney Paradox* report:

> This [then-current] approach has not necessarily resulted in lower health risks for the public. In fact, there is a strong argument that in some cases the constraints of the Delaney Clause paradoxically may have led to greater risks to the public. New pesticides that pose lower cancer risks than pesticides currently on the market have been denied registration while older, more hazardous pesticides remained in use.

Id. The introduction to the Federal Register Notice summarizes the NAS Committee's findings. *See id.* at 41,104-105; *see also id.* at 41,110-16 (responses to NAS Committee recommendations).

[132] The agency explained that it felt obliged to keep its coordination policy in place, "[d]ue to the constraints dictated by the literal approach to the Delaney Clause" and because "there is often no practical way to assure that the raw agricultural commodity at issue [otherwise eligible for a section 408 tolerance] will not be processed [thus requiring regulation under section 409]." *Id.* at 41,108. It hinted that it would not want to repeal "its long-standing policy that the lawful application of a pesticide should not result in illegal pesticide residues." *Id.* That said, the EPA did not consider a de minimis policy to be ideal. Even more preferable would have been a uniform standard applicable to FIFRA and FFDCA decision-making. *See id.* at 41,105. Such a revision would require elimination entirely of the Delaney Clause, something achievable only by Congress.

[133] *Id.* at 41,107.

[134] *See id.* at 41,107 ("The food additive Delaney Clause in section 409, adopted in 1958, was not at issue in the case."). Furthermore, the EPA noted that the *Young* court had suggested that the legislative history of the food additive Delaney Clause might allow a different outcome than in *Young*. *See id.;* Public Citizen v. Young, 831 F.2d 1108, 1120 (D.C. Cir. 1987).

[135] Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. at 41,109.

[136] *Id.*