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The Food Quality Protection Act of 1996: Replacing Old Impracticalities with New Uncertainties in Pesticide Regulation

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NOTES

The Food Quality Protection Act of 1996: Replacing Old Impracticalities with New Uncertainties in Pesticide Regulation

It is our alarming misfortune that so primitive a science has armed itself with the most modern and terrible weapons, and that in turning them against the insects it has also turned them against the earth.[1]

I. INTRODUCTION

The pesticides that concerned Rachel Carson over thirty years ago still remain in our environment in large quantities. According to 1991 estimates, farmers in the United States use 700 million pounds of pesticides every year.[2] Because these chemicals are designed to kill living organisms, they present a risk not just to pests but also to people, wildlife, and the environment.[3] Pesticides contribute to a number of health problems, including birth defects and cancer, and can prove fatal.[4]

Although potentially deadly, pesticides provide significant benefits to society. By controlling pests that threaten crops, pesticides increase crop yields, leading to a better agricultural economy and lower food prices.[5] They also ensure the availability of a well-balanced diet and control disease-carrying pests.[6] Because of these benefits, pesticides play an important role in modern agriculture, but their dangers necessitate government regulation.

In regulating pesticides, the Environmental Protection Agency ("EPA") generally takes into account their risks and benefits.[7] The

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1. RACHEL CARSON, SILENT SPRING 297 (1962).

2. *See* RESOURCES, COMMUNITY, AND ECON. DEV. DIV., U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-92-32, PESTICIDES: BETTER DATA CAN IMPROVE THE USEFULNESS OF EPA'S BENEFIT ASSESSMENTS 16 (1991) [hereinafter GAO, BETTER DATA].

3. *See id.*

4. *See id.*

5. *See id.*

6. *See id.*

7. This type of analysis is called risk-benefit analysis. *See generally* Richard Zeckhauser, *Measuring Risks and Benefits of Food Safety Decisions*, 38 VAND. L. REV. 539, 545-49 (1985) (describing risk-benefit analysis within the context of food safety regulation).

two major laws under which the EPA regulates pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")[8] and the Federal Food, Drug, and Cosmetic Act ("FFDCA"),[9] both contain risk-benefit standards.[10] Until recently, a notable exception to the use of risk-benefit standards was a provision in FFDCA prohibiting, in processed food, pesticide residues that carried *any* risk of inducing cancer.[11] Known as the Delaney Clause,[12] the provision proved impractical and subjected pesticides used on processed and unprocessed foods to inconsistent standards.[13] In response to these problems, in 1988 the EPA adopted a policy excepting from the Delaney Clause pesticides with insignificant cancer risks,[14] but in 1992 a federal court of appeals ruling overturned the EPA's policy for violating the plain meaning of the Clause.[15]

After several failed attempts,[16] Congress finally reformed the Delaney Clause by passing the Food Quality Protection Act of 1996

8. 7 U.S.C. §§ 136-136y (1994), *amended by* Food Quality Protection Act of 1996, Pub. L. No. 104-170, §§ 101-305, 501, 110 Stat. 1489, 1489-1513, 1536-38. For a description of FIFRA, see *infra* notes 30-37 and accompanying text.

9. 21 U.S.C. §§ 301-95 (1994), *amended by* Food Quality Protection Act §§ 401-07, 110 Stat. at 1513-36. FFDCA governs pesticide residues in food. For a description of FFDCA, see *infra* notes 38-64 and accompanying text.

10. FIFRA instructs the EPA, prior to the registration of a pesticide, to consider its "risk to man or the environment, taking into account the economic, social, and environmental costs and benefits" of its use. 7 U.S.C.A. § 136(bb) (West Supp. 1996); *see* 7 U.S.C. § 136a(c)(5) (1994). FFDCA requires pesticide residues in raw food to be "safe," taking into account "the necessity for the production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b) (1994), *amended by* Food Quality Protection Act § 405, 110 Stat. at 1514-35.

11. *See* 21 U.S.C. § 348(c)(3)(A). The provision prohibited carcinogenic food additives, and prior to the Food Quality Protection Act's amendments, FFDCA defined pesticide residues in processed food as food additives. *See* 21 U.S.C. § 321(s) (1994), *amended by* Food Quality Protection Act § 402(b), 110 Stat. at 1513. For a discussion of the Food Quality Protection Act's changes to FFDCA's food additives definition, see *infra* notes 140-41 and accompanying text.

12. The Clause was named for Representative James Delaney, who championed its inclusion in FFDCA. *See* Douglas T. Sheehy, *A De Minimis Exception to the Delaney Clause: A Reassessment of* Les v. Reilly, 50 FOOD & DRUG L.J. 257, 260-61 (1995).

13. *See infra* notes 65-80 and accompanying text (describing the problems created by the Delaney Clause).

14. *See* Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104, 41,104 (1988) [hereinafter Delaney Policy Statement]; *see also infra* notes 81-92 and accompanying text (describing the EPA's policy).

15. *See* Les v. Reilly, 968 F.2d 985, 990 (9th Cir. 1992); *see also infra* notes 95-100 and accompanying text (describing *Les*).

16. For a discussion of the congressional attempts to reform the Delaney Clause prior to the enactment of Food Quality Protection Act, see *infra* notes 101-135 and accompanying text.

("FQPA").[17] The Act creates a risk-benefit standard for all pesticide residues in food,[18] thereby negating the problems caused by the Delaney Clause's zero-risk standard. However, risk-benefit analysis is subject to the uncertainties involved in measuring risks and benefits,[19] and many of the new requirements that FQPA places on the EPA's tolerance-setting process may add to those uncertainties.[20]

This Note explores the context, meaning, and significance of FQPA, focusing on its new risk-benefit standard for all pesticide residues in food. Part II describes the pre-FQPA federal regulatory framework for pesticides,[21] the problems caused by the Delaney Clause's zero-risk standard for carcinogenic pesticide residues,[22] administrative and judicial interpretations of the Clause,[23] and the congressional efforts to reform it, culminating in FQPA.[24] Part III explains FQPA's provisions, particularly the new uniform standard for pesticide residues in raw and processed foods.[25] Finally, Part IV analyzes FQPA's risk-benefit standard, providing background on risk-benefit analysis[26] and discussing the uncertainties involved in assessing pesticide risks and benefits.[27]

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17. Pub. L. No. 104-170, 110 Stat. 1489 (codified at 7 U.S.C.A. §§ 136-136y and 21 U.S.C.A. §§ 301-382 (West Supp. 1996)); *see also infra* notes 136-64 and accompanying text (describing FQPA).

18. *See* 21 U.S.C.A. § 346a(b)(2) (West Supp. 1996); *see also infra* notes 142-56 (describing FQPA's risk-benefit standard).

19. *See infra* notes 248-320 and accompanying text (discussing potential problems with FQPA's risk-benefit standard). The issues surrounding risk-benefit assessment are germane to many other areas of environmental law besides pesticide regulation because risk assessment is a common regulatory tool in the environmental field. For a general discussion of the use of risk assessment under other federal and state laws, see March Sadowitz & John D. Graham, *A Survey of Residual Cancer Risks Permitted by Health, Safety and Environmental Policy*, 6 RISK: HEALTH, SAFETY, & ENV'T 17 (1995). Most environmental laws other than those concerned with pesticides only consider health risks and do not use risk-benefit analysis. *See* Amy Montemarano, Note, *The Delaney Paradox Resurfaces: Regulating Pesticides as Food Additives Under Federal Law*, 25 RUTGERS L.J. 433, 457-58 n.116 (1994) (citing Clean Water Act, 33 U.S.C. §§ 1251-1387 (1988 & Supp. IV 1992); Safe Drinking Water Act, 42 U.S.C. §§ 300f to 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)).

20. *See infra* note 246 (listing the new requirements creating added uncertainty). As this Note was being published, the EPA issued guidelines detailing how it plans to implement FQPA's requirements. *See infra* note 332.

21. *See infra* notes 30-64 and accompanying text.

22. *See infra* notes 65-80 and accompanying text.

23. *See infra* notes 81-100 and accompanying text.

24. *See infra* notes 101-35 and accompanying text.

25. *See infra* notes 136-64 and accompanying text.

26. *See infra* notes 170-240 and accompanying text.

27. *See infra* notes 241-320 and accompanying text.

II. HISTORY BEHIND THE FOOD QUALITY PROTECTION ACT

FQPA amends portions of two important pesticide laws: the Federal Insecticide, Fungicide, and Rodenticide Act[28] and the Federal Food, Drug, and Cosmetic Act.[29] FIFRA regulates pesticides in general, while FFDCA regulates pesticide residues in food. Together, FIFRA and FFDCA form the regulatory framework for pesticides used on food products. FQPA is the culmination of years of failed congressional attempts to reform one of FFDCA's controversial provisions, the Delaney Clause.

A. Federal Pesticide Regulation

1. The Federal Insecticide, Fungicide, and Rodenticide Act

Congress enacted FIFRA in 1947,[30] but it did not create the Act's major regulatory provisions until 1972.[31] FIFRA's foremost provision is its registration system for all pesticides in use in the country.[32] Under FIFRA, a pesticide must be registered with the EPA before it may be sold or distributed.[33] A registration applicant must submit certain information with its application, including a statement of claims about the pesticide's proposed use, the data upon which those claims are based, the pesticide's formula, and a request for classification.[34] The EPA Administrator must approve the registration request if the required submissions are complete, the pesticide is accurately labeled, and the Administrator judges that the pesticide will not cause "unreasonable adverse effects on the environment."[35] In mak-

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28. 7 U.S.C. §§ 136-136y (1994), *amended by* Food Quality Protection Act of 1996, Pub. L. No. 104-170, §§ 101-305, 501, 110 Stat. 1489, 1489-1513, 1536-38.

29. 21 U.S.C. §§ 301-95 (1994), *amended by* Food Quality Protection Act §§ 401-07, 110 Stat. at 1513-36.

30. Pub. L. No. 80-104, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C.A. §§ 136-136y (West 1980 & Supp. 1996)).

31. *See* Federal Environmental Pesticide Control Act, Pub. L. No. 92-516, 86 Stat. 973 (1972) (codified as amended at 7 U.S.C.A. §§ 136-136y (West 1980 & Supp. 1996)).

32. *See* 7 U.S.C. § 136a (1994), *amended by* Food Quality Protection Act §§ 105-06, 210, 222-24, 231, 250, 110 Stat. at 1490-92, 1493-1502, 1503-07, 1508, 1510-11.

33. *See* 7 U.S.C. § 136a(a). FIFRA contains civil and criminal penalties for violations of the Act: The Administrator may impose a civil penalty of up to $5000 for each violation, and knowing violators may receive a criminal penalty of up to $50,000 in fines and one year in prison. *See id.* § 136*l*.

34. *See id.* § 136a(c)(1), *amended by* Food Quality Protection Act §§ 210(b), 250(1), 110 Stat. at 1494-95, 1510-11. FIFRA exempts certain types of pesticides from its application requirements, including experimental pesticides, *see id.* § 136a(b)(2), and pesticides used by any state or federal agency in an emergency, *see id.* § 136p.

35. *Id.* § 136a(c)(5)(C). Upon approval, the Administrator must classify a pesticide

ing her determination, the Administrator must weigh "the economic, social, and environmental costs and benefits" of the pesticide's use.[36] This type of analysis is called risk-benefit analysis—balancing a pesticide's health and environmental risks against the benefits of its use.[37]

2. The Federal Food, Drug, and Cosmetic Act

While FIFRA governs pesticide use, FFDCA regulates pesticide residues in food. FFDCA, passed in 1938, prescribes requirements for the labeling and contents of food and food additives, drugs, and cosmetics.[38] The EPA has authority over FFDCA's application to pesticides.[39] Under FFDCA, the Administrator must establish "tolerances" for the chemical residues left on food products from pesticide spraying.[40] Food containing a pesticide residue for which the Administrator has not approved a tolerance is deemed "adulterated" and is prohibited by the Act.[41] EPA regulations also prohibit the registration of a pesticide under FIFRA until the EPA establishes all necessary tolerances for the chemical under FFDCA.[42]

Prior to FQPA's changes, FFDCA regulated pesticide residues

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for either general or restricted use. *See id.* § 136a(d)(1). If classified for restricted use, a pesticide may only be used "by or under the direct supervision of a certified applicator." *Id.* § 136a(d)(1)(C)(i). FIFRA empowers the EPA to establish training and examination requirements for certified applicators. *See id.* § 136i. The Administrator may change a pesticide's classification, or suspend or cancel its registration in the event that she finds that the pesticide is no longer safe. *See id.* § 136d(b)-(c), *amended by* Food Quality Protection Act §§ 102, 233, 110 Stat. at 1489, 1509.

36. *Id.* § 136(bb), *amended by* Food Quality Protection Act § 230(a), 110 Stat. at 1508.

37. *See* Zeckhauser, *supra* note 7, at 545-49.

38. *See* Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C.A. §§ 301-95 (West 1972 & Supp. 1996)).

39. *See* Delaney Policy Statement, *supra* note 14, at 41,106 n.2 ("Under Reorganization Plan No. 3 of 1970, which established EPA, the authority to set tolerances for pesticide chemicals . . . was transferred from FDA to EPA.").

40. *See* 21 U.S.C. § 346a (1994), *amended by* Food Quality Protection Act § 405, 110 Stat. at 1514-35. A tolerance "is the maximum amount of pesticide residue that is allowed by law to remain in or on raw agricultural commodities." RESOURCES, COMMUNITY, AND ECON. DEV. DIV., U.S. GEN. ACCOUNTING OFFICE, GAO/T-RCED-92-33, FOOD SAFETY: DIFFICULTIES IN ASSESSING PESTICIDE RISKS AND BENEFITS 3 (1992) [hereinafter GAO, FOOD SAFETY]. The Administrator may establish a tolerance in response to a petition from a pesticide manufacturer or user, *see* 21 U.S.C. § 346a(d), *amended by* Food Quality Protection Act § 405, 110 Stat. at 1514-35, or on her own initiative, *see id.* § 346a(e), *amended by* Food Quality Protection Act § 405, 110 Stat. at 1514-35.

41. *See* 21 U.S.C. § 342(a), *amended by* Food Quality Protection Act § 404, 110 Stat. at 1514. FFDCA prohibits the sale of adulterated food. *See id.* § 331(a).

42. *See* Pesticide Registration and Classification Procedures, 40 C.F.R. §§ 152.112(g), 152.113(a)(3), 152.114(c) (1996).

in raw and processed food under different schemes. Section 408, added to FFDCA in 1954, regulated residues in raw food.[43] It provided that the Administrator should set tolerances for residues "to the extent necessary to protect the public health," taking into consideration "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."[44] This section also established a risk-benefit comparison similar to the one in FIFRA by instructing the Administrator to consider "the necessity for the production of an adequate, wholesome, and economical food supply" when deciding whether to approve a tolerance.[45] FFDCA section 409, added in 1958, applied to pesticide residues in processed food.[46] This section regulates food additives, and prior to the enactment of FQPA, FFDCA defined pesticide residues in processed food as food additives.[47] Section 409 directed the Administrator to establish "safe" tolerances for residues in processed food.[48] When setting these tolerances, the Act instructed the Administrator to consider cumulative exposure to residues and appropriate safety factors.[49] Unlike section 408, section 409 did not expressly provide for the consideration of a chemical's benefits, but the EPA interpreted the general safety clause as allowing such a consideration.[50] The EPA implemented FFDCA sections 408 and 409 in accordance with its "coordination policy," under which the EPA would not grant a section 408 raw food tolerance for any pesticide residue failing to qualify for a section 409 processed food tolerance.[51]

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43. *See* Miller Pesticide Amendments, Pub. L. No. 83-518, § 3, 68 Stat. 511, 511 (1954) (codified as amended at 21 U.S.C.A. § 346a (West 1972 & Supp. 1996)).

44. 21 U.S.C. § 346a(b), *amended by* Food Quality Protection Act § 405, 110 Stat. at 1514-35.

45. *Id.*

46. *See* Food Additives Amendment of 1958, Pub. L. No. 85-929, § 4, 72 Stat. 1784, 1785-89 (1958) (codified at 21 U.S.C. § 348 (1994)).

47. *See* 21 U.S.C. § 321(s), *amended by* Food Quality Protection Act § 402(b), 110 Stat. at 1513. The Act's definition of food additive excluded pesticide residues in raw food, but not pesticide residues in processed food. *See id.*

48. *See* 21 U.S.C. § 348(c)(3)(A).

49. *See id.* § 348(c)(5).

50. *See* Delaney Policy Statement, *supra* note 14, at 41,106 ("The general safety clause . . . has been construed by the Agency to allow the weighing of benefits and risks when issuing food additive regulations.").

51. *See* Section 409 Tolerances; Response to Petition Requesting Revocation of Food Additive Regulations, 55 Fed. Reg. 17,560, 17,562 (1990) [hereinafter Section 409 Tolerances]. The EPA referred to this policy as the coordination policy in later notices. *See, e.g.*, Pesticides; Request for Comment on Petition to Modify EPA Policy on Pesticide Tolerances, 58 Fed. Reg. 7470, 7473 (1993) [hereinafter Request for Comment]. The

Not all pesticide residues in processed food required tolerances under section 409. According to FFDCA's "flow-through" provision,[52] a residue from a pesticide applied prior to processing did not require a section 409 tolerance if the residue was "removed to the extent possible in good manufacturing practice" and "the concentration of such residue in the processed food when ready to eat [was] not greater than the tolerance prescribed for the raw agricultural commodity [under section 408]."[53] In interpreting FFDCA's flow-through provision, however, the EPA focused on the *fact* that a residue's concentration increased during processing, rather than the *level* of concentration.[54] The Agency required a section 409 tolerance whenever the concentration of pesticide residues in raw food increased during processing, even if the concentrated level of those residues did not exceed the section 408 tolerance level.[55]

FFDCA section 409 contained the Delaney Clause, prohibiting carcinogenic food additives, including pesticide residues.[56] The

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EPA justified the coordination policy on the grounds that if the Agency approved a pesticide residue under section 408 for raw food, but not under section 409 for processed food, it would cause "uncertainty in the marketplace"—farmers would not know whether they could use the pesticide because they would not know in advance whether their crops eventually would be sold raw or processed. *See* Section 409 Tolerances, *supra*, at 17,562. Some commentators criticized the coordination policy, claiming that it violated the standards established under FFDCA section 408, conflicted with the plain language of the flow-through provision, and ignored the legislative history of section 409. *See, e.g.*, Edward Dunkelberger & Richard A. Merrill, *The Delaney Paradox Reexamined: Regulating Pesticides in Processed Foods*, 48 FOOD & DRUG L.J. 411, 430-38 (1993); *see also* Request for Comment, *supra*, at 7470-75 (containing the EPA's response to a petition to change its coordination policy).

52. *See* 21 U.S.C. § 342(a), *amended by* Food Quality Protection Act § 404, 110 Stat. at 1514. Flow-through is the term used to refer to this provision by both by the EPA, *see, e.g.*, Request for Comment, *supra* note 51, at 7472, and commentators, *see, e.g.*, Dunkelberger & Merrill, *supra* note 51, at 414.

53. 21 U.S.C. § 342(a), *amended by* Food Quality Protection Act § 404, 110 Stat. at 1514.

54. *See* BOARD ON AGRICULTURE, NAT'L RESEARCH COUNCIL, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX 28 (1987) [hereinafter NRC, REGULATING PESTICIDES].

55. *See id.* Processes applied to raw food, like drying, milling, or juicing, may cause pesticide residues in the raw food to concentrate in the food's processed form. *See id.* The EPA set section 408 tolerances according to the highest possible levels of residues on raw food, but actual residue levels at harvest are often lower because of lower application rates and dissipation. *See id.* Therefore, pesticide residues might concentrate during processing, yet still not exceed the tolerance levels set under section 408. *See id.* Some commentators criticized the EPA's approach as overly strict. *See, e.g.*, Dunkelberger & Merrill, *supra* note 51, at 415. The EPA's approach differed from that of the FDA prior to 1970, when the FDA had jurisdiction over sections 408 and 409. *See id.* at 427-28. The FDA focused on the level of concentration, exempting from section 409 pesticide residues in processed food lower than the section 408 tolerance level. *See id.* at 427.

56. *See* 21 U.S.C. § 348(c)(3)(A). FFDCA contains two other provisions similar to

Clause stated:

> [N]o additive shall be deemed to be safe [under section 409] 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.[57]

The Delaney Clause had a significant impact on pesticide regulation. Because the Clause barred the EPA from issuing a tolerance under section 409 for a carcinogenic pesticide residue that concentrated in processed food, the EPA, under its coordination policy, also declined to set a section 408 raw food tolerance for such a chemical.[58] The EPA essentially "read the Delaney Clause into section 408,"[59] in contradiction to section 408's risk-benefit standard.[60] Furthermore, in accordance with EPA regulations,[61] without a tolerance under FFDCA the EPA would not register the chemical under FIFRA,[62] although FIFRA also instructed the EPA to base its registration decisions on a risk-benefit calculation.[63] Thus, for a carcinogenic pesticide, the Delaney Clause controlled FIFRA's registration process as well.[64]

The practical ramifications of FFDCA's old pesticide regulation system were as follows:

• A pesticide used on raw food that was never processed only required a section 408 tolerance. When deciding whether to approve a tolerance, FFDCA instructed the EPA to take into account the pes-

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the Delaney Clause; one bars carcinogenic color additives, *see id.* § 379e(b)(5)(B), and the other bars animal drugs, *see id.* § 360b(d)(1)(I), in food.

57. *Id.* § 348(c)(3)(A).

58. *See* Section 409 Tolerances, *supra* note 51, at 17,562.

59. Dunkelberger & Merrill, *supra* note 51, at 430.

60. Section 408 directed the Administrator to set tolerances for pesticide residues in raw food "to the extent necessary to protect the public health," taking into consideration "the necessity for the production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b), *amended by* Food Quality Protection Act of 1996, Pub. L. No. 104-70, § 405, 110 Stat. 1489, 1514-35; *see supra* text accompanying note 45 (discussing risk-benefit standard set by section 408 prior to FQPA).

61. *See* Pesticide Registration and Classification Procedure, 40 C.F.R. §§ 152.112(g), 152.113(a)(3), 152.114(c) (1996).

62. *See* Section 409 Tolerances, *supra* note 51, at 17,562.

63. The Administrator must determine that a pesticide will not cause "unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5) (1994), 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," *id.* § 136(bb), *amended by* Food Quality Protection Act § 230(a), 110 Stat. at 1508; *see supra* notes 35-37 and accompanying text (discussing FIFRA's risk-benefit standard).

64. *See* Section 409 Tolerances, *supra* note 51, at 17,562.

ticide's dietary risks and its benefits.

• A pesticide used on raw food that might be processed, but that did not concentrate during processing, also only required a section 408 tolerance. Again, FFDCA instructed the EPA to base its decision on section 408's risk-benefit comparison.

• A pesticide used on raw food that might be processed, and that did concentrate during processing, required both section 408 and section 409 tolerances. If the pesticide was noncarcinogenic, FFDCA instructed the EPA to use risk-benefit comparisons under both sections, and the Delaney Clause did not apply. However, if the pesticide was carcinogenic, the Delaney Clause prohibited the EPA from establishing a section 409 tolerance for it, regardless of its level of risk or its benefits. Furthermore, the EPA's coordination policy prevented the Agency from setting a section 408 tolerance for the pesticide, and EPA regulations directed the Agency to cancel the pesticide's FIFRA registration.

• A pesticide used on food during or after processing required a section 409 tolerance. FFDCA instructed the EPA to use a risk-benefit comparison to decide whether to approve the tolerance. However, if the pesticide was carcinogenic, the Delaney Clause prohibited the EPA from setting a tolerance for the residue, and Agency regulations directed the EPA to cancel the pesticide's registration.

B. Criticism of the Delaney Clause

The Delaney Clause received much criticism.[65] One set of criticisms stemmed from the regulatory inconsistency the Clause created—the "Delaney Paradox."[66] Because of the Delaney Clause, FFDCA established differing standards for carcinogenic pesticide residues in raw and processed foods: While the EPA was able to set

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65. For general criticism of the Clause, see NRC, REGULATING PESTICIDES, *supra* note 54, at 40-43; Sheehy, *supra* note 12, at 275-79; Montemarano, *supra* note 19, at 435-39. Opinions of the Delaney Clause were not universally negative. Proponents praised it for "lack[ing] the compromised and ambiguous form normally associated with an act of Congress," William H. Rodgers, Jr., *The Seven Statutory Wonders of U.S. Environmental Law: Origins and Morphology*, 27 LOY. L.A. L. REV. 1009, 1014 (1994), and credited it with "bringing down DDT and putting in motion a worldwide social revolution against the serious problem of pesticide pollution," *id.* at 1011. Additionally, proponents claimed that the Clause brought "toxicology, epidemiology, and other sciences . . . to bear in the real world of risk assessment." *Id.* at 1018. Some contend that the Clause would be workable if the EPA used a strict scientific standard to determine whether a pesticide induces cancer. *See, e.g.*, Frederick H. Degnan & W. Gary Flamm, *Living With and Reforming the Delaney Clause*, 50 FOOD & DRUG L.J. 235, 248-55 (1995).

66. *See, e.g.*, NRC, REGULATING PESTICIDES, *supra* note 54, at 40-43; Sheehy, *supra* note 12, at 278-79; Montemarano, *supra* note 19, at 437.

tolerances for carcinogenic residues in raw food under section 408's risk-benefit approach, section 409 fixed a zero-risk standard for such residues in processed food.[67] A 1987 study of the Delaney Clause was "unable to identify any sound scientific or policy reason for regulating pesticides present in or on raw commodities differently than those present on processed foods."[68] In addition, the Clause prevented farmers from replacing older, more dangerous pesticides with newer, safer alternatives. Older pesticides underwent more primitive scientific testing that may have failed to detect their carcinogenicity, while subsequent advances in science have allowed researchers to identify more minute levels of carcinogens in newer pesticides.[69] Consequently, new pesticides with very small levels of risk nonetheless violated the Delaney Clause, forcing farmers to continue to use older and potentially more dangerous pesticides.[70]

Critics also contended that the Delaney Clause might have a negative effect on public health. They feared it might significantly reduce the number of available pesticides, resulting in increased farming costs and reduced crop yields.[71] These restrictions in the food supply would cause higher food prices and reduced food availability, preventing consumers from obtaining the foods necessary for a well-balanced diet.[72]

Finally, a 1987 National Research Council ("NRC") report indicated that the Delaney Clause was not the most effective way to reduce carcinogenic risk from pesticide residues in the food supply.[73]

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67. *See* Montemarano, *supra* note 19, at 437-38. For a description of the differing requirements of FFDCA sections 408 and 409, see *supra* notes 43-64 and accompanying text.

68. NRC, REGULATING PESTICIDES, *supra* note 54, at 40.

69. *See id.* at 41. These advances also have improved researchers' ability to detect increases in pesticide concentrations in food during processing, making it more likely that the EPA will recognize the need for section 409 tolerances. *See id.*

70. *See* Sheehy, *supra* note 12, at 278; Montemarano, *supra* note 19, at 439. For some time, the EPA avoided this negative public health consequence of the Delaney paradox by excepting from the Clause carcinogenic pesticides with insignificant health risks. *See infra* notes 81-92 and accompanying text.

71. *See* Sheehy, *supra* note 12, at 275. In 1985, the EPA estimated that 53 of the 289 pesticides then used on food were potentially carcinogenic, and therefore might violate the Delaney Clause. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 50-51.

72. *See* Sheehy, *supra* note 12, at 276-78 (collecting and summarizing epidemiological studies and showing links between dietary factors and cancer).

73. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 100-17. In 1985, the EPA asked the NRC to study the impact of the Delaney Clause on pesticide regulation. *See id.* at 1. The EPA was particularly concerned about the ramifications of strictly applying the Clause to the large numbers of potentially carcinogenic pesticides already in use. *See id.* at 2; *see also id.* at 50-51 (indicating that 53 of the 289 pesticides then used on food were

Using the same risk analysis procedure employed by the EPA,[74] the NRC estimated the dietary risk posed by twenty-eight of the fifty-three carcinogenic or potentially carcinogenic pesticides then in use.[75] Comparing the Delaney Clause to an alternative uniform standard that would bar pesticide residues with more than a 1/1,000,000 risk of inducing cancer in both raw and processed foods, the NRC found that the Delaney Clause only reduced dietary cancer risk by approximately 55%,[76] while the uniform standard would reduce dietary risk by 98%.[77] Furthermore, applying the Delaney Clause to all potentially carcinogenic pesticides already in use would revoke 51% of existing tolerances, while the uniform standard would only revoke 32% of existing tolerances.[78] The NRC explained these significant differences by reasoning that the uniform standard would operate more efficiently, targeting the pesticide residues causing the highest dietary risk in both raw *and* processed food.[79] The results of its study led the NRC to recommend a uniform "negligible risk standard" for all pesticide residues.[80]

C. *Administrative and Judicial Interpretation of the Delaney Clause*

1. The EPA's De Minimis Exception

In response to the NRC's 1987 report, the EPA announced in 1988 that it would begin to apply a de minimis exception to the Delaney Clause.[81] The EPA observed that an agency may "avoid applying the terms of a statute literally when to do so would yield

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potentially carcinogenic). The 1987 report is the result of the NRC's study. *See id.* at 1.

74. For a description of the EPA's risk assessment procedure, see *infra* notes 170-240 and accompanying text.

75. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 50-83 (explaining the study's methodology). These 53 pesticides were chemicals that had been approved in the past, under more primitive scientific testing, but that the EPA had identified in 1985 as being potentially carcinogenic. *See id.* at 50.

76. *See id.* at 108-09.

77. *See id.* at 112.

78. *See id.*

79. *See id.* Because the uniform standard applied to all pesticide residues, not just residues on processed food, it would affect pesticides used on 38% of all crops, as opposed to the mere 20% affected by the Delaney Clause. *See id.* However, the NRC judged this difference to be "modest." *See id.* at 114.

80. *Id.* at 12-14.

81. *See* Delaney Policy Statement, *supra* note 14, at 41,104. De minimis is shorthand for *de minimis non curat lex*, meaning "the law does not concern itself with trifles." Public Citizen v. Young, 831 F.2d 1108, 1112 (D.C. Cir. 1987) (characterizing the doctrine as "spar[ing] agency resources for more important matters").

pointless results."[82] Citing the problems with a literal interpretation of the Delaney Clause,[83] the EPA stated that it would approve, under FFDCA section 409, any pesticide with a cancer risk of less than 1/1,000,000, and might approve riskier pesticides if their benefits outweighed their risks.[84]

In adopting this change, the EPA acknowledged that in *Public Citizen v. Young*,[85] the Court of Appeals for the District of Columbia Circuit had recently overturned the Food and Drug Administration's ("FDA") attempt to read a similar de minimis exception into FFDCA's zero-risk standard for carcinogenic color additives.[86] The *Public Citizen* court held that the FDA's de minimis exception violated the "rigid" language of the statute.[87] The court found that the provision's legislative history indicated congressional intent that the standard be strictly applied.[88] Furthermore, the court indicated that the zero-risk standard reflected public concern about cancer coupled with a perception that color additives lacked "any great value."[89]

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82. Delaney Policy Statement, *supra* note 14, at 41,107.

83. *See id.* at 41,108-09; *see also supra* notes 65-80 and accompanying text (discussing the criticisms of the Delaney Clause).

84. *See* Delaney Policy Statement, *supra* note 14, at 41,112.

85. 831 F.2d 1108 (D.C. Cir. 1987).

86. *See id.* at 1123. In 1960, Congress added the color additives provision to FFDCA. *See* Color Additives Amendments of 1960, Pub. L. No. 86-618, § 103, 74 Stat. 397, 398-403 (codified as amended at 21 U.S.C. § 379e (1994)). Like section 409, the color additives provision prescribed factors for determining if an additive is "safe," stating that an additive would not be deemed safe if "found . . . to induce cancer when ingested by man or animal." 21 U.S.C. § 379e(b). While the EPA had jurisdiction over section 409, the FDA enforced the color additives provision. *See* Degnan & Flamm, *supra* note 65, at 248. For a discussion of the FDA's implementation of the Delaney Clause's color additives provision, see Margaret Gilhooley, *Plain Meaning, Absurd Results and the Legislative Purpose: The Interpretation of the Delaney Clause*, 40 ADMIN. L. REV. 267, 274-75 (1988); 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, 6-9 (1988).

In 1986, the FDA approved two color additives for use in cosmetics, even though they posed slight cancer risks. *See* Listing of D&C Red No. 19 For Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28,346, 28,348 (1986) [hereinafter Red No. 19]; Listing of D&C Orange No. 17 for Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28,331, 28,345 (1986) [hereinafter Orange No. 17]. The risks of the two dyes causing cancer were 1/9,000,000 and 1/19,000,000,000 respectively. *See* Red No. 19, *supra*, at 28,360; Orange No. 17, *supra*, at 28,345. The FDA stated that the risks were "so trivial as to be effectively no risk," and concluded that the additives were safe. *See* Red No. 19, *supra*, at 28,360; Orange No. 17, *supra*, at 28,344. The FDA also indicated that as a general rule, it would regard any risk less than 1/1,000,000 as de minimis and except it from the color additives provision's zero-risk standard. *See* Red No. 19, *supra*, at 28,362; Orange No. 17, *supra*, at 28,344.

87. *See Public Citizen*, 831 F.2d at 1113.

88. *See id.* at 1113-17.

89. *Id.* at 1117.

Significantly, the court limited its holding to the color additives provision.[90] In a footnote to its opinion, the court stated that "the operation of the food additive Delaney Clause raises complex issues distinct from those of this appeal."[91] In creating its de minimis interpretation of section 409, the EPA relied on the *Public Citizen* court's distinction between FFDCA's food additives and color additives provisions.[92]

2. *Les v. Reilly*

Shortly after the EPA adopted the de minimis exception, a group of organizations and individuals petitioned the Agency to revoke several tolerances for carcinogenic chemicals.[93] Reiterating its new interpretation of the Delaney Clause, the EPA refused the petitioners' request for revocation of several of the tolerances listed in the petition on the grounds that the chemicals posed only a negligible risk of cancer.[94] In *Les v. Reilly*,[95] the Court of Appeals for the Ninth Circuit overturned the EPA's de minimis standard.[96] The court based its decision on the "clear and mandatory" language of the Delaney Clause, as well as the Clause's legislative history.[97] In its opinion, the court agreed with the D.C. Circuit's reasoning in *Public Citizen*, and concluded that a de minimis exception to the Clause was " 'contrary to law.' "[98] The court noted that the Clause "was enacted in response to increasing public concern about cancer" and that its authors "intended to ensure that no carcinogens, no matter how small the amount, would be introduced into food."[99] The EPA argued that its de minimis standard was a more sensible approach to pesticide regulation, but the court replied that it was up to Congress, not the EPA or the courts, to reform the law.[100]

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90. *See id.* at 1120 ("[W]e deal here only with the color additive Delaney Clause, not the one for food additives."). Noting the greater importance of food additives and its uncertainty regarding section 409's legislative history, the court stated that although FFDCA's color additives and food additives provisions "have almost identical wording, the context is clearly different." *Id.*

91. *Id.* at 1118 n.13.

92. *See* Delaney Policy Statement, *supra* note 14, at 41,107.

93. *See* Section 409 Tolerances, *supra* note 51, at 17,560.

94. *See id.* at 17,563-69.

95. 968 F.2d 985 (9th Cir. 1992).

96. *See id.* at 990.

97. *Id.* at 988-89.

98. *Id.* (citing *Public Citizen v. Young*, 831 F.2d 1108, 1123 (D.C. Cir. 1987)).

99. *Id.* at 989.

100. *See id.* at 990 ("If there is to be a change, it is for Congress to direct.").

D. Legislative Efforts to Reform the Delaney Clause

Soon after *Les v. Reilly* the EPA indicated that it would have to revoke tolerances for numerous widely used pesticides.[101] In response to this pressure, Congress began to consider a number of proposals to change the nation's pesticide laws. However, it took Congress several years to pass FQPA. A number of factors contributed to Congress' inability to act. First, members of Congress felt pressure from the general public, who feared that pesticide reform would threaten their health.[102] Attempting to reconcile the varying interests of chemical manufacturers, farmers, environmentalists, and consumer advocates was also very difficult.[103] Furthermore, pesticide regulation involved scientific and technical complexities that were difficult to grasp, and pesticide reform covered a wide range of issues.[104] Finally, jurisdiction over pesticide laws spanned eight congressional committees and four federal agencies, so coordinating reform efforts was complicated and sometimes resulted in turf battles.[105]

Congressional efforts to amend the Delaney Clause actually predated *Les v. Reilly*. Prior to the enactment of FQPA, the last significant revision of federal pesticide law was the Federal Insecticide, Fungicide, and Rodenticide Act Amendments ("FIFRA") of 1988.[106]

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101. *See* Sheehy, *supra* note 12, at 275 ("[The] EPA announced that about thirty-five pesticides with a multitude of uses would be affected by the decision," representing "over ten percent of the roughly 300 pesticides used on food crops in the United States."). The EPA anticipated that the expected number of tolerance revocations would increase as additional pesticide testing data became available. *See id.*

102. *See Pesticide Rules Remain Unchanged*, 48 CONG. Q. ALMANAC 212, 212 (1992).

103. *See id.*

104. *See id.*

105. *See id.* The Senate committees "with jurisdiction included: Agriculture; Foreign Relations; Labor and Human Resources; Environment and Public Works; and Commerce, Science and Transportation." *Id.* The House committees were: Agriculture; Energy and Commerce; and Foreign Affairs. *See id.* The four federal agencies with jurisdiction were the EPA, the FDA, the Department of Agriculture, and the Department of Commerce. *See id.*

106. Pub. L. No. 100-532, 102 Stat. 2654 (codified as amended at 7 U.S.C.A. §§ 136-136y (West 1972 & Supp. 1996)). *See generally* Pamela A. Finegan, Comment, *FIFRA Lite: A Regulatory Solution or Part of the Pesticide Problem?*, 6 PACE ENVTL. L. REV. 615, 628-41 (1989) (describing and critiquing the 1988 FIFRA Amendments); *Congress Speeds Up Pesticide Testing*, 44 CONG. Q. ALMANAC 139, 139 (1988) (describing the background and legislative history of the 1988 Amendments). The main thrust of the 1988 FIFRA Amendments was to speed up the EPA's re-registration efforts. As of 1988, less than two percent of the older chemicals in use had been subjected to modern testing. *See Congress Speeds Up Pesticide Testing*, *supra*, at 139. The Amendments established a schedule, consisting of five phases spanning a total of seven to nine years, for re-registering any pesticides "containing any active ingredient contained in any pesticide first registered before November 1, 1984." Federal Insecticide, Fungicide, and Rodenti-

Soon after the passage of the 1988 FIFRA amendments, lawmakers turned their attention to the Delaney Clause. In 1989, Senator Edward Kennedy introduced Senate Bill 722,[107] which would have replaced FFDCA's regulatory structure, including the Delaney Clause, with a negligible risk standard for pesticide residues in both raw and processed foods.[108] The bill would have directed the EPA to consider only health risks when setting pesticide tolerances, and it would have allowed states to set stricter standards for pesticide residues.[109] The Senate Labor and Human Resources Committee approved the bill in 1990, but Bush Administration objections to the measure prevented it from progressing any further.[110] The Administration wanted to allow the EPA to consider a pesticide's benefits, as well as its risks, and it also wanted to prevent states from setting standards that differed from federal standards.[111]

In 1993, the year following *Les v. Reilly*, Congress considered three alternative proposals to reform the Delaney Clause.[112] Senator Edward Kennedy and Representative Henry Waxman introduced a

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cide Act Amendments § 102, 102 Stat. at 2655-63 (codified as amended at 7 U.S.C.A. § 136a-1 (West Supp. 1996)).

107. Food Safety Amendments of 1989, S. 722, 101st Cong. *See generally Pesticide-Residue Regulation Shelved*, 46 CONG. Q. ALMANAC 358, 358 (1990) (describing the bill and its legislative history).

108. Senate Bill 722 stated that:

> [A] tolerance may be established for a pesticide chemical residue in or on a raw agricultural commodity or a processed food only if the risk to human health, including the health of identifiable population groups (such as infants and other children) with special food consumption patterns, from dietary exposure to the pesticide chemical residue is *negligible.*

S. 722 § 4(b)(2)(A)(i) (emphasis added). The bill defined "negligible risk" as the level of exposure to a pesticide residue that would pose less than a 1/1,000,000 risk of inducing cancer and that would not cause any other adverse health effects. *See id.*

109. *See* S. 722; *see also Pesticide-Residue Regulation Shelved*, *supra* note 107, at 358 (noting the absence of a provision allowing consideration of benefits and of a national uniformity provision).

110. *See Pesticide-Residue Regulation Shelved*, *supra* note 107, at 358.

111. *See id.*

112. In 1992, the House Agriculture Committee's Subcommittee on Department Operations, Research, and Foreign Agriculture passed a bill containing numerous amendments to FIFRA, but no provisions related to the Delaney Clause. *See* Pesticide Safety Improvement Act of 1991, H.R. 3742, 102d Cong.; *see also Pesticide Rules Remain Unchanged*, *supra* note 102, at 212 (describing the bill and its legislative history). Among other things, the bill would have preempted local regulation of pesticides and eased requirements for minor use pesticides, which are pesticides used on crops other than wheat, corn, soybeans, cotton, or rice. *See Pesticide Rules Remain Unchanged*, *supra* note 102, at 212 (describing various sections of H.R. 3742); *see also infra* note 138 (describing minor use pesticides). Congress took no further action on H.R. 3742. *See Pesticide Rules Remain Unchanged*, *supra* note 102, at 212.

bill[113] that would have created a uniform standard for pesticide tolerances, excluded benefits considerations from the EPA's tolerance-setting process, and required special attention to children's exposure to pesticides.[114] The Clinton Administration recommended that Congress replace FFDCA's current standard with a uniform standard that, based only on health risks and not benefits, would only allow pesticide residues posing a "reasonable certainty of no harm."[115] Finally, Representative Richard Lehman introduced FQPA for the first time.[116] Like the measure's final version, the bill would have replaced FFDCA sections 408 and 409, including the Delaney Clause, with a flexible uniform standard for evaluating a pesticide's residues based on the chemical's risks and benefits.[117] Congress took little action on any of these proposals in 1993,[118] and likewise failed to pass any reform in 1994.[119]

When the new Republican-controlled Congress convened in 1995, the chairs of the House Agriculture and Commerce Commit-

113. Pesticide Food Safety Act of 1993, S. 331, 103d Cong.; H.R. 872, 103d Cong. (1993). The two bills were identical versions of the same measure. *See generally No Action Taken on Pesticide Regulation*, *supra* note 113, at 230 (describing the bills and their legislative history).

114. *See No Action Taken on Pesticide Regulation*, *supra* note 113, at 230 (referring to S. 331 and H.R. 872). The bills' language, *see* S. 331 § 3(a); H.R. 872 § 3(a), closely resembled the language in Senate Bill 722, Senator Kennedy's 1989 proposal, *see* Food Safety Amendments of 1989, S. 722, 101st Cong. § 4(b)(2)(A)(i); *see also supra* note 108 (quoting language of S. 722). The bills' special protections for children stemmed from a report concluding that children and infants faced an elevated dietary risk from pesticide residues. *See* COMMITTEE ON PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, NAT'L RESEARCH COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 3-7 (1993). This report eventually shaped FQPA's provisions for children and infants. *See infra* notes 154-56 and accompanying text (discussing FQPA's additional safety measures for children).

115. *No Action Taken on Pesticide Regulation*, *supra* note 113, at 230.

116. *See* H.R. 1627, 103d Cong. (1993). The bill's initial supporters were farmers and chemical manufacturers. *See No Action Taken on Pesticide Regulation*, 49 CONG. Q. ALMANAC 229, 230 (1993).

117. The bill would have required the Administrator to set a pesticide's tolerance at a level "adequate to protect the public health," H.R. 1627 § 305(b)(2)(A), taking into account the adverse effects prevented by the pesticide, the health risks of alternative pest controls, and the need for an adequate and economical food supply, *see id.* § 305(b)(2)(F).

118. *See id.* A joint House-Senate committee did consider the Clinton Administration's proposals, but took no action. *See id.*

119. *See FIFRA Rewrite*, 50 CONG. Q. ALMANAC 198, 198-99 (1994). The "farmer-friendly" House Agriculture Subcommittee on Department Operations and Nutrition did pass H.R. 1627, but it advanced no further in the 103d Congress. *See id.* The House passed a much narrower bill, Minor Crop Protection Act of 1994, H.R. 967, 103d Cong., merely providing for increased development of minor use pesticides, but the Senate failed to take up the measure. *See FIFRA Rewrite*, *supra*, at 198-99.

tees reintroduced H.R. 1627.[120] The House accorded joint jurisdiction over the bill to the two committees.[121] The Agriculture Committee approved portions of the bill that would have shortened the EPA's review process for potentially dangerous pesticides, required the EPA to base restrictions on "significant evidence of a chemical's health risk," and eased the registration process for certain pesticides with special applications.[122] However, the Commerce Committee failed to act on its portion of the bill, which dealt with provisions to reform FFDCA's tolerance standard, including the Delaney Clause.[123]

On June 19, 1996, the House Agriculture Committee again considered its portions of H.R. 1627 and approved them with "little debate."[124] The Commerce Committee's Health and Environment Subcommittee took up the portions of the bill relating to FFDCA's tolerance standard, but suspended its markup on July 11 to allow members to conduct additional negotiations over the measure.[125] A week later, the legislators reached a compromise that the subcommittee and the full Commerce Committee approved on July 17 "without dissent."[126] On July 23, the House passed the combined provisions

120. H.R. 1627, 104th Cong. (1995).

121. *See* David Hosansky, *Pesticides Bill Advances in Agriculture Panel*, 54 CONG. Q. WKLY. REP. 1500, 1500 (1996) [hereinafter Hosansky, *Pesticides Bill*].

122. Eileen Simpson, *Panel OKs Pesticide Provisions, Puts Off Controversial Action*, 53 CONG. Q. WKLY. REP. 1841, 1841 (1995) (referring to various sections of H.R. 1627). The special-use pesticides included minor use, antimicrobial, and public health pesticides. *See infra* note 138 (describing these types of chemicals).

123. *See* David Hosansky, *Future Battles Expected Over Pesticide Bill*, 54 CONG. Q. WKLY. REP. 1759, 1759 (1996) [hereinafter Hosansky, *Future Battles*]. At that time, H.R. 1627's standard, *see* H.R. 1627 § 405, was similar to the standard in the bill's 1993 version, *see supra* note 114, and contained neither the limitations on benefits considerations nor the heightened standards for pesticides used on foods in children's diets that FQPA's final version does. *Compare* H.R. 1627 § 405 (the standard in the 1995 version), *with* Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 405, 110 Stat. 1489, 1514-35. *See also infra* notes 140-56 and accompanying text (describing the standard in FQPA's final version).

124. Hosansky, *Future Battles*, *supra* note 123, at 1759.

125. *See* Annie Tin, *Pesticide Markup is Cut Short*, 54 CONG. Q. WKLY. REP. 1962, 1962 (1996). Congressman Waxman wanted to tighten the bill's "adequate to protect the public health" standard. *See* David Hosansky, *Long-Sought Pesticides Bill Advances Easily After Deal*, 54 CONG. Q. WKLY. REP. 2031, 2031 (1996) [hereinafter Hosansky, *Long-Sought Pesticides Bill*]. For a description of the bill's original standard, see *supra* note 114.

126. Hosansky, *Long-Sought Pesticides Bill*, *supra* note 125, at 2031. The language in the final bill instructs the EPA to approve only pesticide residue levels for which "there is a reasonable certainty that no harm will result." 21 U.S.C.A. § 346a(b)(2)(A)(ii) (West Supp. 1996); *see also infra* notes 143-47 and accompanying text (describing FQPA's standard). In addition to Congressman Waxman's position, the EPA advocated a "reasonable certainty of no harm" standard, as opposed to the standard in the original bill. *See* Steven

from both committees 417 to 0.[127] The next day, the Senate Agriculture, Nutrition, and Forestry Committee approved the language of the House bill unanimously, and the full Senate approved it by voice vote with no debate.[128]

In light of Congress's string of failed attempts to reform the Delaney Clause, FQPA's swift and easy passage was a surprise.[129] Several factors may have contributed to the Act's success. First, the *Les v. Reilly*[130] decision cast doubt on the availability of a variety of chemicals,[131] and the resulting "potential pesticide crisis" may have finally spurred Congress to act.[132] Another incentive for Congress to act may have been public opinion favoring environmental protection.[133] The Republican majority in Congress may have felt a " 'strong need for a victory in the environmental area' " going into the 1996 elections.[134] Finally, advocates on all sides of the issue may have simply been tired of debating it.[135]

III. THE FOOD QUALITY PROTECTION ACT

The Food Quality Protection Act of 1996[136] amends portions of both FIFRA and FFDCA. It revises FIFRA's re-registration process[137] and provides incentives for minor use, antimicrobial, and public

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Gibb, *'Zero Risk' Era Ends as Congress Adopts 'Safe' Pesticides Policy*, INSIDE EPA'S RISK POL'Y REP., Special Report, July 26, 1996, at 1.

127. *See* David Hosansky, *Rewrite of Laws on Pesticides on Way to President's Desk*, 54 CONG. Q. WKLY. REP. 2101, 2101 (1996) [hereinafter Hosansky, *Rewrite On Way*].

128. *See id.*

129. *See id.* (quoting a House Commerce Committee spokesperson as saying " 'I'm going to check outside because hell's got to be freezing over,' " and a Senate Agriculture Committee aide as saying " '[i]t's one of the signs of the apocalypse, I'm told' ").

130. 968 F.2d 985 (9th Cir. 1992). For a discussion of the *Les v. Reilly* decision, see *supra* notes 93-100.

131. *See* David Hosansky, *Quick Work on Pesticide Laws*, 54 CONG. Q. WKLY. REP. 2032, 2032 (1996) [hereinafter Hosansky, *Quick Work*].

132. Hosansky, *Future Battles, supra* note 123, at 2032.

133. *See id.*

134. Gibb, *supra* note 126, at 1 (quoting "Congressional sources"); *see also* Hosansky, *Rewrite On Way*, *supra* note 127, at 2101 ("GOP lawmakers were hungry for an election-year environmental bill.").

135. *See* Hosansky, *Quick Work*, *supra* note 131, at 2032 (quoting an attorney with the Natural Resources Defense Council who said that " 'a lot of people were getting sick of it' " and various interest groups that thought "this is the best deal they're going to get").

136. Pub. L. No. 104-170, 110 Stat. 1489 (codified at 7 U.S.C.A. §§ 136-136y and 21 U.S.C.A. § 301-82 (West Supp. 1996)).

137. FQPA directs the Administrator to review pesticide tolerances under FFDCA in conjunction with the EPA's re-registration review. *See* 7 U.S.C.A. § 136a-1(g)(2)(E) (West Supp. 1996). It also requires the Administrator to periodically review pesticide registrations, with the goal of reviewing registrations every fifteen years. *See id.*

health pesticide development.[138] FQPA's central feature, though, is its new, uniform standard for pesticide residues in food.[139]

FQPA does not actually repeal the Delaney Clause, but rather makes it inapplicable to pesticide residues by changing the definition of "food additive" in FFDCA.[140] While FFDCA's old definition excluded residues in raw foods, but included residues in processed foods, the amended definition excludes any "pesticide chemical residue in or on a raw agricultural commodity or processed food."[141] The new definition of "food additive" renders FFDCA section 409, including the Delaney Clause, inapplicable to all pesticide residues.

FQPA then creates a new uniform standard, replacing FFDCA section 408, the old standard for residues in raw food, with FQPA section 405, a new standard for pesticide residues in both raw and processed food.[142] Under the new standard, the EPA Administrator "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the

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§ 136a(g)(1)(A).

138. Minor use pesticides are pesticides used on small crops (300,000 total acres or less), or pesticides for which it is uneconomical to undergo the registration process. *See* 7 U.S.C.A. 136(*ll*). Essentially, minor crops are everything but wheat, corn, soybeans, cotton and rice, and include all fruits and vegetables. *See Minor-Use Pesticides*, 50 CONG. Q. ALMANAC 199, 199 (1994). FQPA creates incentives to encourage pesticide manufacturers to seek registration of minor use pesticides by extending data submission deadlines and allowing the Administrator to waive certain data requirements for minor use pesticide applicants, expediting the review of minor use pesticides, and granting minor use pesticide manufacturers prolonged exclusive use of the data submitted on behalf of their chemicals. *See* 7 U.S.C.A. §§ 136a to 136a-1. FQPA also creates a minor use program, under both the EPA and the Department of Agriculture, to coordinate efforts to develop minor use pesticides. *See id.* §§ 136w-6 to 136w-7.

Antimicrobial pesticides are chemical sterilants or disinfectants designed to eliminate bacteria, viruses, molds, and the like. *See id.* § 136(mm). FQPA facilitates the registration of these substances by exempting them from FFDCA's tolerance requirements and instructing the EPA Administrator to develop other reforms to expedite their review. *See id.* § 136a(h).

Public health pesticides are minor use pesticides that control mosquitoes, flies, rats, and other vectors, or otherwise protect public health. *See id.* § 136(nn)-(oo). FQPA directs the Administrator to weigh the risks and benefits of a public health pesticide separately from the risks and benefits of other chemicals, and to take into account the public health risks curtailed by the pesticide. *See id.* § 136(bb).

139. *See* 21 U.S.C.A. § 346a (West Supp. 1996).

140. *See id.* § 321(s).

141. *Id.* For the old definition, see 21 U.S.C. § 321(s) (1994), *amended by* Food Quality Protection Act § 402(b), 110 Stat. at 1513.

142. *See* 21 U.S.C.A. § 346a. For old FFDCA sections 408 and 409, see 21 U.S.C. §§ 346a, 348 (1994), *amended by* Food Quality Protection Act § 405, 110 Stat. at 1514-35; *see also supra* notes 38-64 and accompanying text (discussing FFDCA's old regulatory structure).

tolerance is safe."[143] FQPA defines "safe" as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue."[144] Like FFDCA's old standard, FQPA instructs the EPA to consider "aggregate exposure" to a pesticide when setting its tolerance,[145] but while FFDCA merely defined such exposure as "the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances,"[146] FQPA is more specific. It instructs the EPA to consider dietary and all other non-occupational sources of exposure to the pesticide, as well as exposure to other chemicals with "a common mechanism of toxicity."[147]

When setting a tolerance, FQPA permits the Administrator to adjust tolerance levels if there are competing public health or economic considerations.[148] In other words, the Act establishes a risk-benefit standard similar to that in FIFRA and in former FFDCA section 408.[149] FQPA allows the Administrator to set a tolerance above the "safe" level for a residue if "[u]se of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue," or "[u]se of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply."[150] However, FQPA places several limits on when and to what degree the Administrator may relax a residue's tolerance. She may not permit residues beyond the safe level for threshold effects,[151] and she may

143. 21 U.S.C.A. § 346a(b)(2)(A)(i).

144. *Id.* § 346a(b)(2)(A)(ii).

145. *Id.*

146. 21 U.S.C. § 346a(b) (1994), *amended by* Food Quality Protection Act § 405, 110 Stat. at 1514-36.

147. 21 U.S.C.A. § 346a(b)(2)(D)(v)-(vi).

148. *See id.* § 346a(b)(2)(B).

149. *See supra* notes 35-37 and accompanying text (describing FIFRA's risk-benefit standard); *supra* text accompanying note 45 and accompanying text (describing FFDCA section 408's risk-benefit standard).

150. 21 U.S.C.A. § 346a(b)(2)(B)(iii)(I)-(II). These benefits considerations are broader than those in FFDCA's old standard, which merely instructed the EPA to consider "the necessity for the production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b) (1994), *amended by* Food Quality Protection Act § 405, 110 Stat. at 1514-36.

151. *See* 21 U.S.C.A. § 346a(b)(2)(B)(i). Threshold health effects, like birth defects, are effects for which a given level of exposure can be identified below which the effect will not occur. *See* Junius C. McElveen, Jr., *Risk Assessment in the Federal Government: Trying to Understand the Process*, 5 TUL. ENVTL. L.J. 45, 63-64 (1991). Traditionally, all non-cancerous health effects have been considered threshold effects. *See id.* at 63 ("With respect to substances that cause reversible effects, and, historically, with respect to sub-

not relax a tolerance established according to FQPA's special provisions for children.[152] Finally, the Administrator may not allow a tolerance level that either increases the annual risk of a non-threshold effect by more than ten times the level of risk permitted at the "safe" level, or that increases the lifetime risk of a non-threshold effect by more than twice the level of risk permitted at the "safe" level.[153]

FQPA creates added safety measures for children. It requires the Administrator to determine explicitly that a residue tolerance is safe for children, based on information about the consumption patterns of children and infants, their particular susceptibilities, and the results of cumulative exposure to toxins.[154] Furthermore, FQPA directs the Administrator to apply a "tenfold margin of safety" to the safe level of a residue for threshold effects.[155] The Administrator may choose an alternative margin of safety, however, if "reliable data" shows it is appropriate.[156]

FQPA directs the EPA Administrator to review all old tolerances under the new standard, setting a ten-year schedule for reviewing every tolerance issued under FFDCA prior to FQPA's passage.[157] FQPA also contains provisions aimed at harmonizing the EPA's activities under FFDCA and FIFRA.[158] Furthermore, FQPA's

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stances that caused irreversible, noncancerous effects, the assumption has been that there is a threshold below which adverse effects will not occur."). *But see id.* at 64 (describing the debate in the scientific community over whether irreversible health effects like cell death or enzyme inhibition, caused by substances like lead, should be considered threshold effects). Because exposure to any amount of a carcinogenic substance entails a risk, however slight, of inducing cancer, cancer has been considered a non-threshold effect. *See* Delaney Policy Statement, *supra* note 14, at 41,118 ("Cancer ordinarily is treated as a non threshold effect."). *But see* McElveen, *supra*, at 65 (stating that "[t]he issue of whether a 'threshold' exists for carcinogenesis is a controversial one"). This Note adopts the traditional understanding of threshold and non-threshold effects.

152. *See* 21 U.S.C.A. § 346a(b)(2)(B)(vi). For a discussion of FQPA's requirements for children, see *infra* notes 154-56 and accompanying text.

153. *See* 21 U.S.C.A. § 346a(b)(2)(B)(iv). For example, assume that the Administrator establishes the safe tolerance level for a given pesticide so that the pesticide's residues in food present a 1/1,000,000 risk of inducing cancer. She then determines that the benefits of the pesticide's use justify relaxing the tolerance. She may only relax the tolerance to the point that exposure to the pesticide's residues over the course of the following year presents a 1/100,000 risk of inducing cancer, or to the point that lifetime exposure presents a 1/500,000 risk.

154. *See* 21 U.S.C.A. § 346a(b)(2)(C).

155. *Id.* In other words, once the Administrator determines the level of exposure at which a pesticide residue causes no ill health effects, the Act requires the Administrator to set the tolerance for that pesticide at one-tenth of the safe level.

156. *See id.*

157. *See id.* § 346a(q).

158. *See id.* § 346a(*l*). FQPA's harmonization provisions essentially codify the EPA's

new tolerance standard addresses two additional issues. The first is the Delaney Clause's incompatibility with international pesticide standards.[159] When setting a pesticide tolerance, the Act directs the Administrator to determine whether a Codex maximum residue level[160] exists for the chemical, and if the FFDCA tolerance differs from the Codex level, the Administrator must "publish for public comment a notice explaining the reasons for departing from the Codex level."[161] The second issue is the dispute over national uniformity of pesticide standards.[162] FQPA prohibits states from enforcing limits on pesticide residues that differ from the EPA's tolerances, but this prohibition only applies to tolerances set at the "safe" level; states may enforce residue limits that differ from a federal tolerance adjusted due to benefits considerations.[163] Additionally, states may request permission to set different standards if local conditions so require, and they may set temporary standards in response to an emergency.[164]

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regulations making FFDCA tolerances a condition of FIFRA registration. *See* Pesticide Registration and Classification Procedures, 40 C.F.R. §§ 152.112(g), 152.113(a)(3), 152.114(c) (1996). If the Administrator revokes a tolerance under FFDCA, FQPA directs her to take "any related necessary action" under FIFRA. 21 U.S.C.A. § 346a(*l*)(1). Likewise, if she suspends or cancels a pesticide's FIFRA registration, she must also revoke that chemical's tolerance under FFDCA. *See id.* § 346a(*l*)(2)-(3). Finally, FQPA directs the Administrator to set a FFDCA tolerance in accordance with an emergency exemption registration under FIFRA. *See id.* § 346a(*l*)(6).

159. For a general discussion of the issue of harmonizing U.S. pesticide standards with international standards, which is beyond the scope of this Note, see Christina M. Markus, *International Harmonization of Pesticide Tolerances—Legal, Procedural, and Policy Issues*, 47 FOOD & DRUG L.J. 701 (1992); Bartlett P. Miller, Note, *The Effect of the GATT and the NAFTA on Pesticide Regulation: A Hard Look at Harmonization*, 6 COLO. J. INT'L ENVTL. L. & POL'Y 201 (1990). The Delaney Clause's zero-tolerance standard for carcinogenic pesticide residues in food was stricter than international pesticide tolerances, known as Codex standards, adopted under the General Agreement on Tariffs and Trade (GATT). *See* Miller, *supra*, at 216 n.117.

160. GATT adopted international pesticide tolerances known as Codex standards. *See* Miller, *supra* note 159, at 215-16.

161. 21 U.S.C.A. § 346a(b)(4).

162. A complete discussion of this debate is also beyond the scope of this Note. For a discussion of it, see Gregory J. Mertz, Note, *Dead But Not Forgotten: California's Big Green Initiative and the Need to Restrict State Regulation of Pesticides*, 60 GEO. WASH. L. REV. 506 (1992) (advocating uniform national standards for pesticides). Concern over the dangers of pesticides has prompted many states to consider standards more stringent than those in federal pesticide laws. *See id.* at 507-08 (using as an example "Big Green," a proposal in California that would have set very stringent limits on pesticide residues in food grown, processed, or imported into the state). However, differing state standards for pesticides may interfere with national and international trade. *See id.* at 509.

163. *See* 21 U.S.C.A. § 346a(n).

164. *See id.* § 346a(n)(5)-(6).

IV. ANALYSIS OF THE FOOD QUALITY PROTECTION ACT'S RISK-BENEFIT STANDARD

FQPA's most notable feature is its new standard for pesticide residues in both raw and processed food.[165] Before granting a tolerance for a pesticide, the EPA must consider the dietary health risks posed by its residues.[166] For all noncarcinogenic health effects, the EPA may only approve a tolerance level that will not induce those effects.[167] However, when determining whether the cancer risk posed by a pesticide residue is acceptable, the EPA conducts a risk-benefit analysis considering not only the level of the risk, but also the chemical's benefits.[168] This approach is a significant change from the Delaney Clause, which flatly prohibited many carcinogenic pesticide residues, regardless of their level of risk or their value to society.[169] Unfortunately, risk-benefit analysis also entails uncertainties that may complicate EPA's tolerance-setting process.

A. The EPA's Risk-Benefit Analysis Process for Pesticides[170]

The first step in risk-benefit analysis is to assess a pesticide's potential risk. Risk assessment is "the characterization of the potential adverse health effects of human exposures to environmental hazards."[171] It involves "the assembly, evaluation, and interpretation of all pertinent scientific information about the toxicity, human experience, environmental fate, and exposure to a particular chemical or

165. *See id.* § 346a; *see also supra* notes 142-56 and accompanying text (discussing FQPA's new standard).

166. FQPA directs the Administrator to determine whether the residues at the tolerance level are "safe," 21 U.S.C.A. § 346a(b)(2)(A)(i), defining "safe" as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue," *id.* § 346a(b)(2)(A)(ii).

167. For threshold effects, the Administrator must determine that the tolerance level of exposure is "safe." *See id.* § 346a(b)(2)(B)(i)(III).

168. *See id.* § 346a(b)(2)(B); *see also supra* notes 148-53 and accompanying text (discussing FQPA's benefits provision).

169. *See* 21 U.S.C. § 348(c)(3)(A) (1994); *see also supra* notes 56-57 and accompanying text (describing the Delaney Clause).

170. For a general description of risk-benefit analysis, see Zeckhauser, *supra* note 7. For general descriptions of the risk-assessment process, see COMMISSION ON LIFE SCIENCES, NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) [hereinafter NRC, RISK ASSESSMENT]; McElveen, *supra* note 151. For a general description of EPA's benefit assessment process, see GAO, BETTER DATA, *supra* note 2, RESOURCES, COMMUNITY, AND ECON. DEV. DIV., U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-91-52, PESTICIDES: EPA'S USE OF BENEFIT ASSESSMENTS IN REGULATING PESTICIDES (1991) [hereinafter GAO, BENEFIT ASSESSMENTS].

171. NRC, RISK ASSESSMENT, *supra* note 170, at 18.

physical agent."[172] When assessing a pesticide residue's dietary risks, the EPA follows the generally accepted procedure for risk assessment, which consists of four steps: 1) hazard identification; 2) dose-response assessment; 3) exposure assessment; and 4) risk characterization.[173]

Hazard identification is the process by which researchers determine whether exposure to a given substance increases the risk of an adverse health condition like cancer or birth defects.[174] Two important methods used to identify potential health hazards are human and animal studies.[175] Human studies attempt to establish an association between human exposure to an environmental hazard and the occurrence of health problems by identifying hazards to which people are exposed and looking for corresponding incidents of health problems.[176] In contrast, animal studies are controlled laboratory studies in which researchers expose animal subjects to a particular hazard, measure any response, and extrapolate the results to humans.[177] Researchers may supplement the results of human and animal studies with other evidence of health risks. For example, when attempting to determine whether a substance is carcinogenic, they may compare that substance's molecular structure with those of known carcinogens and look for similarities.[178] Also, since carcinogens are mutagenic, researchers may test to determine whether a given substance is a mutagen.[179]

Dose-response assessment uses the information revealed through hazard identification to determine the level of exposure to a hazard that will produce adverse health effects.[180] Researchers at-

172. McElveen, *supra* note 151, at 47.

173. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 19-20.

174. *See id.* at 19 ("[Hazard identification] involves characterizing the nature and strength of the evidence of causation.").

175. *See* McElveen, *supra* note 151, at 57.

176. *See* Sheldon Leigh Jeter, Note, *The Role of Risk Assessment, Risk Management, and Risk Communication in Environmental Law*, 4 S.C. ENVTL. L.J. 25, 30-32 (1995) (describing both human and animal studies); *see also* NRC, RISK ASSESSMENT, *supra* note 170, at 20-22 (stating that human epidemiological studies provide "the most convincing evidence about human risk").

177. *See* Jeter, *supra* note 176, at 31-32; *see also* NRC, RISK ASSESSMENT, *supra* note 170, at 22 ("The most commonly available data in hazard identification are those obtained from animal [studies].").

178. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 23.

179. *See id.* at 22-23. "Mutagenic" is defined as "capable of inducing mutation." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1492 (1976). A "mutagen" is "an agent . . . that tends to increase the occurrence or extent of mutation." *Id.*

180. *See* McElveen, *supra* note 151, at 56; *see also* NRC, RISK ASSESSMENT, *supra*

tempt to establish a relationship between exposure to a hazard and its impact on human health that allows them to show the degree of risk posed by various levels of exposure to the hazard.[181] The graphical representation of this relationship is the dose-response curve.[182] If researchers' data are from human studies, researchers measure the resulting health effects at the observed level of exposure and extrapolate the results to other exposure levels, while researchers using animal studies measure the different effects from various levels of exposure and extrapolate the results to humans.[183]

Exposure assessment determines the overall level of human exposure to a hazard.[184] Researchers either measure actual exposure levels, or estimate exposure levels through the use of mathematical models.[185] Researchers may also attempt to identify particular subgroups of the population, such as pregnant women, who may be especially vulnerable to a hazard.[186]

Risk characterization, the final stage of risk assessment, determines the actual health risk posed by a given hazard in the environment.[187] Having established the average amount of the hazard to which the population is exposed (exposure assessment) and the health response to various levels of exposure to the hazard (dose-response assessment), researchers combine those determinations to compute the overall health risk posed by the hazard.

While the EPA generally follows the four-step risk assessment process when assessing pesticide risks, its procedure varies somewhat depending on the nature of the health risk posed by a given chemical. For all health effects other than cancer,[188] the EPA uses dose-response assessment to determine the highest level of exposure to a

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note 170, at 19 ("Dose-response assessment is the process of characterizing the relation between the dose of an agent . . . and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent." (emphasis omitted)).

181. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 23-27.

182. For an example of a dose-response curve, see *id.* at 26.

183. *See id.* at 23-24.

184. *See id.* at 27; *see also* McElveen, *supra* note 151, at 67-72 (providing an in-depth description of the exposure assessment process).

185. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 27.

186. *See id.* at 28.

187. *See* McElveen, *supra* note 151, at 72-73; *see also* NRC, RISK ASSESSMENT, *supra* note 170, at 28 ("[Risk characterization is] the estimate of the magnitude of the public-health problem.").

188. For a general description of the EPA's risk assessment process for non-carcinogenic pesticides, see Delaney Policy Statement, *supra* note 14, at 41,118; NRC, REGULATING PESTICIDES, *supra* note 54, at 31-33.

pesticide residue resulting in no ill effect: the "no observed adverse effect level" ("NOAEL").[189] The EPA then divides the NOAEL by a safety factor, usually 100, to account for uncertainties in extrapolating health effects in animals to humans and for differences in sensitivities among individuals.[190] The adjusted NOAEL, referred to as the Acceptable Daily Intake ("ADI") or the Reference Dose ("RfD"), represents the threshold level of safety for exposure to a residue.[191] After it calculates the ADI for a pesticide residue, the EPA uses exposure assessment to identify the highest potential level of human exposure to a pesticide residue, known as the "theoretical maximum residue contribution" ("TMRC").[192] When calculating the TMRC, the EPA assumes that a pesticide is used on all crops for which the applicant seeks a tolerance and that the pesticide's residues are present on every crop at the full level of the proposed tolerance.[193] Using food consumption statistics, the EPA multiplies a residue's tolerance level for a particular food product by the amount of that food in the typical diet.[194] The EPA performs this calculation for every food product on which the applicant proposes to use its pesticide and the sum of those values is the TMRC.[195] If a residue's TMRC is less than its ADI, it is regarded as safe and the residue's tolerance is approved.[196] If the TMRC exceeds the ADI, the EPA may nonetheless approve the tolerance, depending on a pesticide's benefits,[197] or explore with the tolerance applicant ways to reduce the chemical's residues through less-frequent spraying.[198]

The EPA follows a different procedure for assessing a pesticide's cancer risk.[199] Based upon the quality, adequacy, and consistency of

189. *See* Delaney Policy Statement, *supra* note 14, at 41,118.

190. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 32.

191. *See* Delaney Policy Statement, *supra* note 14, at 41,118.

192. *See id.*

193. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 32.

194. *See* Delaney Policy Statement, *supra* note 14, at 41,118.

195. *See id.*

196. *See id.*

197. *See infra* notes 215-20 and accompanying text (describing the EPA's benefits consideration).

198. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 32-33. The EPA may also attempt to estimate more accurately the actual residue levels in foods through data on anticipated residues and the percentage of crops treated with the chemical. *See* Propiconazole; Pesticide Tolerances for Emergency Exemptions, 61 Fed. Reg. 58,135, 58,137 (1996) [hereinafter Propiconazole Tolerances].

199. For a general description of the EPA's carcinogenic risk assessment procedures, see Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992 (1986) [hereinafter Carcinogen Guidelines]. This variance in the EPA's approach to assessing risks stems

the data revealed through hazard identification,[200] the EPA classifies evidence of carcinogenicity into one of five groups: Group A—Carcinogenic to Humans; Group B—Probably Carcinogenic to Humans; Group C—Possibly Carcinogenic to Humans; Group D—Not Classifiable as to Human Carcinogenicity; and Group E—Evidence of Non-Carcinogenicity for Humans.[201] If evidence of a pesticide's carcinogenicity falls in Groups A or B, the EPA performs the remaining three stages of risk assessment on the residue.[202] If the evidence falls in Group C, the EPA judges on a case-by-case basis whether to continue the risk assessment.[203] Finally, if the evidence falls in Groups D or E, the EPA deems the evidence insufficient to justify further assessment of the residue's risk, and concludes that the residue poses no risk of cancer.[204] Once the EPA has determined to proceed with a carcinogenic residue's risk assessment, it performs a dose-response assessment of the residue. The EPA uses the information gained through hazard identification[205] to establish the dose-response relationship for the residue.[206] This relationship, the rate of additional cancer incidents for each additional level of exposure to the residue, is referred to as the residue's Cancer Potency Factor ("Q*").[207] The Q* value is the slope of the residue's dose-response curve.[208] To account for potential errors in its calculation, the EPA sets the Q* value so that 95% of the potential values within the calculation's range of error fall at or below the Q* value.[209] Furthermore, the EPA adjusts the Q* value to account for potentially greater human sensitivity to the residue.[210] A residue's Q* value is also used to estimate the cancer risk from low levels of actual human

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from the lack of a threshold level of exposure for carcinogenic effects. *See supra* note 151 (explaining threshold and non-threshold effects).

200. The EPA typically uses at least two animal test species, exposes them to various high levels of the pesticide, and measures the resulting incidents of cancer. *See* Delaney Policy Statement, *supra* note 14, at 41,118.

201. The EPA refers to this classification process as a "weight-of-evidence judgment." *See* Carcinogen Guidelines, *supra* note 199, at 33,996.

202. *See id.*

203. *See id.* The EPA usually proceeds with risk assessment for a Group C chemical. *See id.*

204. *See id.*

205. *See supra* note 200 (describing the EPA's typical hazard identification tests).

206. *See* Delaney Policy Statement, *supra* note 14, at 41,118.

207. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 54 (explaining the Q*).

208. *See id.*

209. *See id.*

210. *See* Delaney Policy Statement, *supra* note 14, at 41,118 ("The effect of this adjustment is to increase the estimate of human risk by about thirteen fold where data are derived from mice, and about 6½ fold when the data source is the rat.").

exposure to the residue.[211] Additionally, the EPA assumes that the relationship between exposure level and cancer risk is linear; that the Q* rate is constant across all levels of exposure.[212] The EPA's exposure assessment process for a residue's cancer risk is identical to its exposure assessment procedure for noncancer risks, in that the Agency assumes maximum possible exposure to the residue.[213] The EPA then multiplies the resulting exposure level by a residue's Q* value to arrive at the human cancer risk posed by a pesticide's residue in food at the proposed tolerance level.[214]

After the EPA has assessed a pesticide's risk, the next step in risk-benefit analysis is to estimate the pesticide's benefits. Prior to FQPA, when assessing the benefits of a pesticide as part of its tolerance-setting process, the EPA measured the economic impact that would result if the pesticide was not available.[215] It compared the crop losses that would be prevented by the pesticide and the pesticide's cost with the effectiveness and cost of other available chemicals.[216] The sum of the value of the increased crop yield and the pesticide's cost savings, multiplied by the total acreage treated by the pesticide represented that pesticide's overall benefits.[217] This calculation reflected the EPA's narrow definition of the "benefits" of a pesticide, focusing on "direct benefits to farmers and the food industry."[218] FFDCA's old language gave the EPA the flexibility to define benefits in this manner.[219] However, the more detailed benefits language in FQPA restricts the EPA's discretion. The Act now directs

211. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 54.

212. *See* McElveen, *supra* note 151, at 66.

213. *See* Delaney Policy Statement, *supra* note 14, at 41,118-19. The EPA assumes that all crops are treated with the highest permissible level of a pesticide. *See id.*; *supra* note 193 and accompanying text. *But see supra* note 198 (describing more accurate EPA exposure assessment techniques).

214. *See* Delaney Policy Statement, *supra* note 14, at 41,118.

215. *See* GAO, BETTER DATA, *supra* note 2, at 3.

216. *See id.* at 19. The EPA refers to these two aspects of its benefit assessment process as biological analysis and economic analysis. *See* GAO, BENEFIT ASSESSMENTS, *supra* note 170, at 2.

217. *See* GAO, BETTER DATA, *supra* note 2, app. at 19. The EPA also considered the national and regional impact of the loss of those benefits, as well as the impact that the loss would have on "inflation, unemployment, and international trade." *Id.*

218. GAO, FOOD SAFETY, *supra* note 40, at 5-6.

219. *See supra* notes 45, 48-50 and accompanying text (discussing FFDCA's old benefits provisions). Section 408 merely required the EPA to consider "the necessity for the production of an adequate, wholesome, and economical food supply," 21 U.S.C. § 346a(b) (1994), *amended by* Food Quality Protection Act of 1996, Pub. L. No. 104-170, § 405, 110 Stat. 1489, 1513-35, and section 409 allowed the EPA to consider appropriate "safety factors," 21 U.S.C. § 348(c)(5)(C).

the EPA to consider not only the need for "an adequate, wholesome, and economical food supply," but also how the pesticide "protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue."[220] Thus, the EPA may have to expand the scope of its benefit assessments to take this new language into account.

Once the EPA calculates a pesticide's risks and benefits, the Agency weighs the risks and benefits against one another to decide whether a chemical's benefits justify tolerance approval, given the health risks posed by the chemical's residues in food. The EPA "has no formula to guide the balancing of a pesticide's benefits and risks."[221] Because of the lack of a strict analytic process, the decision relies more on intuitive judgment.[222] The EPA tends to restrict or cancel pesticide uses that offer few benefits, while substantial benefits may justify significant risks.[223]

In practice, the role of risk-benefit analysis in the EPA's tolerance-setting process has been limited.[224] When evaluating pesticide residues for noncarcinogenic risks, the EPA rarely considers benefits.[225] The Agency's practice has been simply to approve a residue's proposed tolerance if the anticipated maximum level of human exposure is below the lowest level of exposure at which health effects occur.[226] If the maximum exposure exceeds the residue's safe level, the EPA may consider benefits, or it may explore ways to reduce the exposure level by changing the proposed uses of the pesticide.[227] For carcinogenic pesticides, the Delaney Clause often denied the EPA the opportunity to conduct risk-benefit analysis. Residues from carcinogenic pesticides that concentrated in processed foods were absolutely barred by the Clause, so the EPA could only use risk-benefit analysis on pesticides for raw foods that were never processed, or on pesticides that did not concentrate during processing.[228]

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220. 21 U.S.C.A. § 346a(b)(2)(B)(iii)(I) (West Supp. 1996).

221. GAO, BETTER DATA, *supra* note 2, app. at 19.

222. *See* Telephone Interview with David W. Brassard, Senior Entomologist, Office of Pesticide Programs, U.S. Environmental Protection Agency (Oct. 11, 1996).

223. *See* GAO, BETTER DATA, *supra* note 2, app. at 19. For example, the EPA approved the chemical alachlor, which had a 6/1,000,000 risk of causing cancer, because alachlor's benefits totaled between $400 and $500 million. *See id.*

224. *See id.* at 3.

225. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 32.

226. *See supra* note 196 and accompanying text.

227. *See supra* notes 197-98 and accompanying text; *supra* notes 215-20 and accompanying text (describing the EPA's benefits consideration).

228. *See* 21 U.S.C. § 348(c)(3)(A) (1994); *see also supra* notes 56-57 and accompanying

FQPA essentially codifies the EPA's existing practice for noncarcinogenic health effects. Under FQPA, the EPA may approve a tolerance level for a pesticide residue only if that level of the residue will not induce noncarcinogenic health effects.[229] The only difference is that now the EPA may never consider a chemical's benefits when setting tolerances for noncarcinogenic effects.[230] However, FQPA expands the role that risk-benefit analysis may play in setting tolerances for carcinogenic pesticides. The EPA is no longer constrained by the Delaney Clause and may use risk-benefit analysis for any carcinogenic pesticide residue.[231]

The procedure that the EPA adopted under its short-lived de minimis interpretation of the Clause provides insight into the Agency's possible procedure under FQPA's new standard.[232] For a pesticide residue posing less than a 1/1,000,000 risk of inducing cancer, the EPA approved its tolerance with "very little scrutiny" of the pesticide's benefits.[233] For a pesticide residue with carcinogenic risks greater than 1/1,000,000, the EPA adopted its tolerance only if a "careful scrutiny of the projected benefits" from the pesticide's use showed that the chemical's benefits outweighed its residue's risks.[234] The Agency stated that "the higher the risk, the more thorough the benefits evaluation that will be necessary."[235] The EPA followed this same process when setting tolerances for carcinogenic residues in raw food under FFDCA section 408, to which the Delaney Clause did not apply, but the Agency rarely granted section 408 tolerances for residues with carcinogenic risks greater than 1/10,000.[236] Thus, the effect of the EPA's tolerance-setting practice for carcinogenic residues was to create a range of risk between 1/1,000,000 and 1/10,000 in which

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text (describing the Delaney Clause).

229. *See* 21 U.S.C.A. § 346a(b)(2)(A)(ii) (West Supp. 1996) (stating that for threshold effects, the Administrator must determine that at the tolerance level of exposure "there is a reasonable certainty that no harm will result").

230. *See id.* § 346a(b)(2)(B)(i)(I) (stating that FQPA's benefits considerations may only be used when setting the tolerance for a pesticide residue for which "the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health").

231. *See supra* notes 140-41 and accompanying text (discussing the applicability of FQPA's new standard to all pesticide residues).

232. *See generally* Delaney Policy Statement, *supra* note 14, at 41,104 (describing the EPA's risk-benefit analysis procedure under its de minimis exception to the Delaney Clause).

233. *Id.* at 41,112.

234. *Id.*

235. *Id.*

236. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 34.

the EPA would consider a pesticide's benefits.[237]

FQPA also establishes a range of carcinogenic risk in which the EPA may consider a pesticide's benefits. However, the range is considerably smaller than that previously used by the EPA. The EPA first must determine what level of dietary exposure to a residue is "safe."[238] Then, the EPA may only adjust its tolerance level to account for a pesticide's benefits to the point that the chemical's residue poses ten times the risk at the safe exposure level over the course of a year, or two times the safe exposure level over a lifetime of exposure.[239] Indications are that for carcinogenic risk, the EPA will consider the safe level of exposure to be a level that poses no more than a 1/1,000,000 risk of inducing cancer.[240] If that is the case, the range of risk in which the EPA may adjust a tolerance is between 1/1,000,000 and 1/100,000 if exposure to the risk only spans one year, or between 1/1,000,000 and 1/500,000 for lifetime exposure to the risk.

B. Potential Problems with FQPA's Risk-Benefit Standard

FQPA's new risk-benefit standard for pesticide residues offers some advantages over FFDCA's old system. Risk-benefit analysis provides greater flexibility to the EPA when setting pesticide tolerances[241] and FQPA eliminates the problems posed by the Delaney Clause.[242] FQPA's standard applies to all pesticide residues equally, as opposed to the paradoxical results of the FFDCA's old regulatory structure.[243] Additionally, the new standard removes the threat that the Delaney Clause would eliminate a significant number of pesti-

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237. *See id.*

238. *See* 21 U.S.C.A. § 346a(b)(2)(A) (West Supp. 1996). FQPA defines "safe" as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.*

239. *See id.* § 346a(b)(2)(B)(iv).

240. *See* David Hosansky, *Pesticide Bill Highlights*, 54 CONG. Q. WKLY. REP. 2104, 2104 (1996) [hereinafter Hosansky, *Pesticide Highlights*] (stating that a " 'reasonable certainty of no harm' " is "generally interpreted to mean that there be no more than a [1/1,000,000] chance that the residue would cause cancer"). In the past, the EPA has generally viewed any risk less than 1/1,000,000 as "negligible." *See, e.g.*, Delaney Policy Statement, *supra* note 14, at 41,112.

241. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 18-19.

242. *See supra* notes 65-80 and accompanying text (discussing the problems created by the Delaney Clause).

243. *See supra* notes 66-70 and accompanying text (describing the "Delaney Paradox").

cides and thus cause lower crop yields and higher food costs.[244] Finally, the new standard may more effectively reduce dietary risks with less impact on pesticide use.[245] However, FQPA's risk-benefit standard may create some regulatory difficulties, stemming from inherent uncertainties in risk-benefit assessment that some of FQPA's new requirements may complicate even further.[246] The problems with risk-benefit analysis fall into four general categories: 1) data inadequacies; 2) methodological shortcomings; 3) disparate impacts; and 4) ethical concerns.[247]

1. Data Inadequacies

The core problem in risk assessment is a lack of reliable data.[248] The EPA has gaps in its knowledge about pesticides because information on the effects of the wide variety of chemicals in use is

244. *See supra* notes 71-72 and accompanying text (describing the Clause's threat to the food supply).

245. *See supra* notes 73-80 and accompanying text (describing a study of the effectiveness of the Delaney Clause compared to a uniform risk-benefit standard).

246. *See* Alan Schreiber, *The Food Quality Protection Act: A Trojan Iceberg*, AGRICHEMICAL & ENVTL. NEWS, August 1996, at 4 (asserting that FQPA "could ultimately have a much greater negative impact on the cost and production of food" than the Delaney Clause); *see also* Letter from Lynn R. Goldman, EPA Assistant Administrator, to Pesticide Registrants (Sept. 6, 1996) (on file with author) (providing interim guidance for tolerance applicants under FQPA and warning that "additional time will be needed to adequately review certain food use applications"). FQPA's new requirements include more detailed consideration of aggregate impacts, *see supra* notes 145-47 and accompanying text, expanded benefits considerations, *see supra* note 150 and accompanying text, and special protections for children and infants, *see supra* notes 154-56 and accompanying text.

247. For critical accounts of risk assessment, see Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562 (1992) [hereinafter Hornstein, *Normative Critique*]; Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89 (1988); Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409 (1995); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995). Suggested alternatives to risk-based regulation of pesticides include: (1) risk regulation based on priority-setting, *see* John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 YALE J. ON REG. 277 (1992); (2) Integrated Pest Management, a multidisciplinary approach to controlling pests, *see* John Carlucci, *Reforming the Law on Pesticides*, 14 VA. ENVTL. L.J. 189 (1994); and (3) a cause-oriented approach that focuses on preventing pollution rather than regulating it after its creation, *see* Donald T. Hornstein, *Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 YALE J. ON REG. 369 (1993).

248. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 6. FQPA contains provisions aimed at improving the EPA's pesticide data. *See* Food Quality Protection Act of 1996, Pub. L. No. 104-170, §§ 301-305, 110 Stat. 1489, 1511-13 (codified in scattered sections of 7 and 21 U.S.C.A. (West Supp. 1996)).

incomplete.[249] The EPA also has poor information systems to keep track of its pesticide data.[250] Furthermore, because of the Agency's scarce resources,[251] it relies on data submitted by pesticide manufacturers and users, and it has little control over the accuracy this information.[252]

Data shortages also result from uncertainties in every stage of the risk assessment process.[253] At the hazard identification stage, both human and animal studies have weaknesses. In human studies, the level of exposure and the number of people exposed is often low, creating a high level of uncertainty in the observed results.[254] The observed results also may be skewed by exposure to multiple hazards over which researchers have no control,[255] and by problems with subject recall during interviews.[256] Furthermore, the observed association between exposure to a hazard and negative health effects may be due to chance, rather than any causal connection.[257] Uncertainties in animal studies stem from the extrapolation of animal response data to humans.[258] The effects of a particular hazard on humans may be different than its observed effect on animals because of biological differences between the species.[259]

Dose-response assessment suffers from the uncertainties involved in extrapolating the results of high-level exposure to a hazard to lower levels of exposure. High-level exposure to a hazard may overload animal metabolisms, overstating the true health effects resulting from lower levels of exposure.[260] The EPA generally is unable

249. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 11-12.

250. *See* GAO, FOOD SAFETY, *supra* note 40, at 11-12. Information about pesticides is "scattered across different nonintegrated systems or kept in paper files." *Id.* at 11.

251. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 11-12.

252. *See* GAO, FOOD SAFETY, *supra* note 40, at 13.

253. The overall effect of these uncertainties in the risk assessment process is that the EPA "pile[s] uncertainty atop uncertainty," multiplying the potential inaccuracy of the Agency's risk estimates. McElveen, *supra* note 151, at 100; *see also* Shere, *supra* note 247, at 467-68 (describing the "stacking effect" of data uncertainties). For example, risk assessments of vinyl chloride showed a million-fold variation. *See id.* at 439-40. Likewise, saccharin, trichloroethylene, and polychlorinated biphenyls all had ten-million-fold variations in their assessed levels of risk. *See id.*

254. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 20-22.

255. *See id.*

256. *See* McElveen, *supra* note 151, at 57-58.

257. *See id.*

258. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 20-22.

259. *See id.* at 22-27; *see also* McElveen, *supra* note 151, at 59-61 (providing a list of the biological differences between humans and test animals).

260. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 24; *see also* Shere, *supra* note 247, at 437 (arguing that massive test doses also cause rapid cell division, which by itself

to verify the accuracy of estimates based on high-level exposure because the extremely low risks that people face from actual exposure levels are not subject to direct observation.[261] Variations in individual sensitivities also make it difficult to apply dose-response findings to the general population.[262]

Finally, exposure assessments also rely on uncertain information, including gaps in food consumption data[263] and food consumption estimates that "vary widely."[264] Plus, exposure estimates "are complicated by variations in diet and personal habits,"[265] as well as by variations in food storage and food preparation techniques.[266] FQPA may further complicate the EPA's efforts to measure exposure to pesticide residues by requiring the Agency to consider aggregate exposure to pesticides,[267] as well as the special dangers that pesticides pose for children and infants.[268] It is unclear whether the EPA will be able to assemble information about all non-occupational sources of exposure to a pesticide and all chemicals similar to it,[269] and the EPA's uncertainty about food consumption in the general population may make it difficult for the Agency to specifically account for food consumption by children and infants.[270]

The EPA's benefit assessment process also suffers from data insufficiencies which limit the effectiveness of benefit assessments in

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increases the rate of cancer and may explain the observed incidents of cancer in test animals).

261. *See* Shere, *supra* note 247, at 440.

262. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 23-27.

263. *See* GAO, FOOD SAFETY, *supra* note 40, at 7.

264. NRC, REGULATING PESTICIDES, *supra* note 54, at 57.

265. NRC, RISK ASSESSMENT, *supra* note 170, at 27.

266. *See id.*

267. *See supra* notes 145-47 and accompanying text (describing FQPA's aggregate exposure requirements).

268. *See supra* notes 154-56 and accompanying text (describing FQPA's requirements for assessing the risks of pesticides in the diets of infants and children).

269. An example of the EPA's uncertainty about aggregate exposures is its assessment of the pesticide propiconazole's tolerances in conjunction with the chemical's emergency exemption registration under FIFRA. *See* Propiconazole Tolerances, *supra* note 198, at 58,135. FQPA requires the EPA to issue a tolerance before a pesticide may receive an emergency exemption under FIFRA. *See* 21 U.S.C.A. § 346a(l)(6) (West Supp. 1996). In addition to propiconazole residues in food, people may be exposed to the chemical through groundwater contamination, or through the chemical's use as a wood preservative. *See* Propiconazole Tolerances, *supra* note 198, at 58,138. However, in assessing the risk posed by propiconazole, the EPA concluded that it lacked data on these sources of exposure to the chemical. *See id.*

270. The EPA does have testing methodologies for exploring the impacts of pesticides on infants and children. *See* Propiconazole Tolerances, *supra* note 198, at 58,138-39 (describing the EPA's "developmental toxicity studies").

Agency decision-making.[271] The EPA lacks complete information on the quantity of pesticides used on crops[272] and the effects of pest control alternatives on crop yields.[273] The EPA's tolerance-setting process under FQPA depends not only on this incomplete information about pesticide use and crop yields, but also on information about the health risks that consumers would face without a given pesticide.[274]

2. Methodological Short-Comings

Because of the data uncertainties detailed above, the EPA must make a number of assumptions throughout its risk assessment process that affect its risk estimates.[275] Because these assumptions tend to be conservative, some contend that they lead to over-burdensome requirements on pesticides.[276] However, other aspects of the EPA's risk assessment process may understate risks.[277]

In the hazard identification stage, for example, the EPA bases its evaluation of the probable carcinogenicity of a pesticide on qualitative judgments about the sufficiency of the evidence of the chemical's health effects.[278] This process involves medical judgments that may

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271. *See* GAO, BETTER DATA, *supra* note 2, at 4 (asserting that "benefit assessments are not meeting their full potential to help refine the agency's regulatory decisions").

272. *See id.* at 5. For example, estimates of ethylene bisdithiocarbamate usage, a family of fungicides, varied by 20%. *See id.*

273. *See* GAO, FOOD SAFETY, *supra* note 40, at 8 (stating that the EPA "pieces together whatever information it can"); *see also* GAO, BETTER DATA, *supra* note 2, at 5 (describing the EPA's reliance on questionable data).

274. *See supra* note 150 and accompanying text (describing FQPA's expanded benefits considerations).

275. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 28-36 (identifying a number of inferences that risk assessors must draw throughout the process); *see also* Shere, *supra* note 247, at 413 (stating that the typical risk assessment "consists of about fifty separate assumptions and extrapolations").

276. *See* McElveen, *supra* note 151, at 100. The EPA uses conservative estimates to account for gaps in information and uncertainties about health effects. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 32. These conservative assumptions "may overstate adverse health risks by factors of ten to 1000." Carol S. Curme, *Regulation of Pesticide Residues in Foods: Proposed Solutions to Current Inadequacies Under FFDCA and FIFRA*, 49 FOOD & DRUG L.J. 609, 618 (1994).

277. For example, the Agency does not consider the risks from possible synergistic effects of a chemical. *See* GAO, FOOD SAFETY, *supra* note 40, at 5. Synergistic effects stem from the interaction of two or more chemicals, which may produce greater effects than the sum of the effects that the chemicals produce separately. *See* Shere, *supra* note 247, at 438.

278. *See supra* notes 200-01 and accompanying text (describing the EPA's "weight of evidence" evaluation).

be beyond the expertise of EPA personnel.[279]

Dose-response assessments also contain a number of assumptions. When the EPA proceeds with the dose-response assessment of a carcinogenic pesticide, it assumes that the relationship between the level of exposure to the chemical and the risk of cancer incidence is linear.[280] However, the true shape of the dose-response curve is unknown.[281] Furthermore, the EPA uses a number of safety factors for both carcinogenic and noncarcinogenic pesticides that may overstate health risks.[282] For example, the Agency adds additional uncertainty to its carcinogenic risk estimates by applying a safety factor based on the size difference between humans and test animals.[283] For noncarcinogenic pesticide residues, the EPA's hundred-fold safety factor for a residue's ADI value makes the ADI a very conservative estimate.[284] FQPA increases this safety factor even further for residues in foods commonly consumed by children.[285]

Finally, the EPA's exposure assessments assume that the highest possible level of a pesticide residue is present on every food for which the pesticide is approved.[286] However, "[s]uch high and widespread residue concentrations are rare in reality."[287] Few pesticide chemicals "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."[288] Even the EPA acknowledges the shortcomings of its theoretical maximum residue concentration assumption.[289]

The EPA's benefit-assessment methodology also contains weaknesses. When comparing a pesticide's performance and cost to alternative pest control options, the Agency only considers other pesticides, not nonchemical pest control alternatives that may be

279. *See* Shere, *supra* note 247, at 431.

280. *See supra* note 212 and accompanying text (describing the EPA's assumption).

281. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 24.

282. *See supra* notes 190, 209-10 and accompanying text (discussing the EPA's safety factors).

283. *See* Shere, *supra* note 247, at 438.

284. *See* NRC, REGULATING PESTICIDES, *supra* note 54, at 32; *see also supra* notes 189-91 (discussing ADI).

285. *See supra* notes 154-56 (discussing FQPA's safety provisions for children).

286. *See supra* notes 192-93 and accompanying text (describing the EPA's "theoretical maximum residue contribution" calculation). *But see supra* note 198 (describing more accurate EPA exposure assessment techniques).

287. Shere, *supra* note 247, at 466.

288. NRC, REGULATING PESTICIDES, *supra* note 54, at 32.

289. *See id.* at 60 ("The agency has acknowledged for a long time the shortcomings of this method.").

cheaper and more effective.[290] By doing so, the EPA may overstate a pesticide's benefits.[291] Conversely, the Agency understates benefits by not considering the possible health and environmental ramifications from the use of an alternative chemical.[292]

3. Disparate Impact

A third concern about risk assessment is that it does not reflect the potentially disproportionate risk that a hazard may pose for subgroups of the general population, particularly poor and minority communities.[293] These communities may face higher risks from hazards in the environment because they are exposed to higher levels of toxics than the general population, and they may be more susceptible to the health risks associated with that exposure.[294]

Poor and minority communities experience heightened exposure to toxics because there tend to be more sources of toxins in such areas.[295] Individuals in these communities may be exposed to a higher level of a given hazard, so an assessment of that hazard based on its risk to the general population may not accurately reflect the risk faced by members of poor and minority communities.[296] Further-

290. *See* GAO, BETTER DATA, *supra* note 2, at 8-9. The EPA believes that farmers' most likely alternatives are other pesticides. *See id.*

291. *See* GAO, FOOD SAFETY, *supra* note 40, at 6.

292. *See id.* FQPA addresses this shortcoming by requiring the EPA, when assessing a pesticide's benefits, to consider the health risks averted by the pesticide. *See* 21 U.S.C.A. § 346a(b)(2)(B)(iii)(I)-(II) (West Supp. 1996) (allowing EPA to set a tolerance above the "safe" level for a residue if public health or economical food production would be more jeopardized by not approving the pesticide).

293. *See generally* Marion Moses et al., *Environmental Equity and Pesticide Exposure*, 9 TOXICOLOGY & INDUS. HEALTH 913 (1993) (discussing the disparate impact of pesticide risks and recommending greater resources to study the problem); Brian D. Israel, Student Article, *An Environmental Justice Critique of Risk Assessment*, 3 N.Y.U. ENVTL. L.J. 469 (1995) (discussing the disparate impact of environmental risks in general). *But see* Lynn E. Blais, *Environmental Racism Reconsidered*, 75 N.C. L. REV. 75 (1996) (critiquing the environmental justice movement). FQPA attempts to address this issue by requiring the EPA to consider "the variability of the sensitivities of major identifiable subgroups of consumers" when setting pesticide tolerances. 21 U.S.C.A. § 346a(b)(2)(D)(vii). This requirement, however, may further complicate the EPA's tolerance-setting process.

294. *See* Israel, *supra* note 293, at 494-509. Migrant and seasonal farm workers, the majority of whom are people of color, face higher levels of exposure to pesticides than any other population group. *See* Moses et al., *supra* note 293, at 914. The health problems that migrant and seasonal farm workers face from disproportionate exposure to pesticides are exacerbated by limited data on their health conditions and under-reporting of pesticide poisoning. *See id.* at 915, 938-39.

295. *See* Israel, *supra* note 293, at 496-97.

296. *See id.* at 496-501.

more, members of such communities may be exposed simultaneously to higher levels of numerous hazards, multiplying the overall level of risk that they face[297] and exacerbating the hazards' synergistic effects.[298]

Members of poor and minority communities also may face higher risks because of their increased susceptibilities.[299] Population subgroups have varying genetic characteristics that may make them more sensitive to toxics.[300] Plus, repeated exposure to toxics may create characteristics that increase sensitivity.[301] The frequency of diseases like hypertension, diabetes, liver disease, tuberculosis, and asthma that may make an individual more susceptible to toxic poisoning also varies by race, ethnicity, and socioeconomic status.[302] Furthermore, problems like poor health care and nutrition that are associated with low-income communities may worsen the effect of toxics.[303] Finally, lifestyle differences like higher pregnancy rates and increased alcohol and tobacco use may make members of poor and minority communities more susceptible to environmental hazards.[304]

4. Ethical Concerns

Risk-benefit analysis entails a number of ethical concerns. The first is the extent to which non-scientific factors may influence the process. Risk assessment encounters external pressures from Congress, the general public, and the regulated community.[305] Due to the uncertainty in the risk assessment process, policy inevitably plays a role.[306] Because risk assessment "can be used to justify almost any result that is sought,"[307] it may give EPA too much discretion and

297. *See id.* at 496-97; *see also* Moses et al., *supra* note 293, at 915 ("People of color are more likely to have multiple simultaneous and sequential exposures to pesticides.").

298. *See* Israel, *supra* note 293, at 497-500. Risk assessment fails to account for synergistic effects. *See supra* note 277.

299. *See* Israel, *supra* note 293, at 503-09.

300. *See id.* at 504-05.

301. *See id.* at 505; *see also* Moses et al., *supra* note 293, at 937-38 (describing "multiple chemical sensitivity syndrome").

302. *See* Israel, *supra* note 293, at 506-07.

303. *See id.* at 507-08; *see also* Moses et al., *supra* note 293, at 915 ("Lack of access to and unavailability of adequate health care contribute significantly to the impact of environmental contamination."). Farm workers' poor living conditions intensify the effects of their exposure to pesticides. *See id.* at 921.

304. *See* Israel, *supra* note 293, at 508-09.

305. *See* NRC, RISK ASSESSMENT, *supra* note 170, at 13-14.

306. *See id.* at 48-49.

307. Junius C. McElveen, Jr. & Chris Amantea, *Legislating Risk Assessment*, 63 U. CIN. L. REV. 1553, 1579 (1995).

open up the process to political influence.[308] This problem may be particularly acute when the EPA considers a pesticide's benefits along with its risks. The fear is that the EPA may use a chemical's benefits to justify its approval regardless of the level of risk.[309]

A second ethical concern is that the results of risk and benefit assessments seem more certain than they actually are.[310] The appearance of scientific certainty may conceal the assumptions and policy decisions that underlie the process.[311] Consequently, members of the public may lose the opportunity to influence those policy decisions.[312] Furthermore, the appearance of certainty may discourage scientific scrutiny of the process's assumptions.[313]

A further concern is the dichotomy between expert and public perceptions of risk. The general public often perceives risks differently than experts do.[314] The public tends to view risks "qualitatively rather then quantitatively," and to fear risks that are involuntary, unfamiliar, or lead to "dreaded physical effects," like cancer.[315] Therefore, a level of risk that experts categorize as safe may still be unacceptable to the public.[316] This dichotomy is especially problematic when regulators compare risks, because regulators and the public may disagree over the relative seriousness of risks.[317]

Finally, risk-benefit analysis involves the very complicated matter of valuing a human life.[318] Risk assessors have several methods for

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308. *See* Curme, *supra* note 276, at 632.

309. *See id.* at 643-44 (suggesting that limits be placed on the ability of risk assessors to consider benefits). FQPA does limit the extent to which the Administrator may adjust a pesticide's tolerance based on the chemical's benefits. *See supra* notes 151-53 and accompanying text.

310. *See* GAO, BETTER DATA, *supra* note 2, at 7 (recommending that the EPA communicate the uncertainties in its risk and benefit assessment processes more effectively). *See generally* Wagner, *supra* note 247 (discussing the "science charade" in risk assessment, its causes, and its consequences).

311. *See* Wagner, *supra* note 247, at 1628-31.

312. *See id.* at 1674-77.

313. *See id.* at 1685-88.

314. *See* Jeter, *supra* note 176, at 26-28.

315. *Id.* at 27-28.

316. *See id.* at 27.

317. For a general discussion of risk comparison, see Hornstein, *Normative Critique*, *supra* note 247; Ellen K. Silbergeld, *The Risks of Comparing Risks*, 3 N.Y.U. ENVTL. L.J. 405 (1995). FQPA instructs the EPA to compare risks for certain pesticides. It directs the EPA to weigh a pesticide's risk of inducing cancer against the "adverse effects on health" that the pesticide seeks to prevent. 21 U.S.C.A. § 346a(b)(2)(B)(iii)(I) (West Supp. 1996).

318. For example, under FQPA, to compare a pesticide's risks and benefits, the EPA must place a value on the chemical's risk to human life (inducing cancer).

making this valuation. Besides simply choosing an arbitrary value, these methods include: (1) invested value, based on the total value of all resources needed to sustain a human life; (2) productive value, based on the average individual's discounted future earnings; and (3) surrender value, based on the amount of money that people are willing to pay to avoid risks.[319] All of these methods entail concerns, such as valuing life based upon a person's economic status.[320]

V. CONCLUSION

The Food Quality Protection Act of 1996 addressed a long-standing problem in federal pesticide regulation. The Act's risk-benefit standard for pesticide residues in food replaced the Delaney Clause, which prohibited tolerances under FFDCA for pesticides that might induce cancer, no matter how slight the risk or how important the chemical. FQPA gives the EPA flexibility to consider the seriousness of a carcinogenic pesticide's dietary risk, as well as the pesticide's benefits to society when making tolerance decisions.

However, FQPA's risk-benefit standard replaces the impracticality of the Delaney Clause with the uncertainties inherent in risk-benefit analysis. Informational and methodological shortcomings cast doubt on the accuracy of EPA assessments, and risk-benefit analysis raises social and ethical concerns as well. Because many of FQPA's new, more detailed requirements are subject to these same uncertainties, they may further complicate the EPA's tolerance-setting process.

FQPA's true impact is unclear.[321] The EPA is embarking on a transitional period during which it will begin to implement FQPA's requirements.[322] It remains to be seen whether the EPA can fully ad-

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319. *See* Jay Michaelson, Note, *Rethinking Regulatory Reform: Toxics, Politics, and Ethics*, 105 YALE L.J. 1891, 1916-18 (1996). Risk assessors may avoid directly valuing a human life by "(1) comparing risks to others popularly accepted, (2) regulating up to a point of diminishing returns, or (3) balancing lives saved against lives lost in regulation." *Id.* at 1913. However, these non-pricing methods are so inaccurate as to be "effectively useless in practice." *Id.* at 1916.

320. *See id.*

321. One commentator dubbed FQPA the "Trojan iceberg" because "[j]ust as 90% of an iceberg cannot be seen, so will much of the impact of the act remain unknown" until the EPA issues its regulations. Schreiber, *supra* note 246, at 4 (stating that the impact may not be known "for several years").

322. At the time of publication of this Note, the EPA had just issued its Implementation Plan for FQPA. The Plan identifies FQPA's new standard and requirements for pesticide tolerances, and summarizes the agency's initial implementation strategy for each of FQPA's major provisions. *See* PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, U.S. EPA, 1996 FOOD QUALITY PROTECTION ACT IMPLEMENTATION PLAN (1997)

dress the uncertainties surrounding FQPA so that the law truly improves pesticide regulation.

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(available on the Internet at <http://www.epa.gov/opppsps/fqpa/impplan.pdf>).