Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safequards for Children

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RISK ASSESSMENT: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children

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In 1996, Congress reaffirmed its commitment[1] to quantitative risk assessment ("QRA")[2] as an important regulatory tool by passing the much publicized Food Quality Protection Act of 1996 ("FQPA").[3] At the time of

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1. In the last eleven years, Congress has passed a multitude of legislation based on quantitatively assessing environmental risks. *See* Safe Drinking Water Act, 42 U.S.C. §§ 300f to 300j-26 (1994 & Supp. III 1997) (carcinogenic contaminants); Clean Water Act, 33 U.S.C. §§ 1251-1387 (1994 & Supp. III 1997) (industrial discharges of carcinogens); Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901-87 (1994 & Supp. III 1997) (hazardous waste characterizations); Toxic Substances Control Act, 15 U.S.C. §§ 2601-29 (1994 & Supp. III 1997) (approval of new commercial chemicals); Clean Air Act, 42 U.S.C. §§ 7401-7671q (1994 & Supp. III 1997) (hazardous maximum emissions); Solid Waste Disposal Act, 42 U.S.C. §§ 6901-92k (1994 & Supp. III 1997); Robert R. Keuhn, *The Environmental Justice Implications of Quantitative Risk Assessment*, 1996 U. ILL. L. REV. 103, 104 (noting that "Congress is the force behind the current move toward greater reliance on risk assessment . . .").

2. Risk assessors use a four-step process known as quantitative risk assessment ("QRA") to scientifically quantify the level of risk from an environmental contaminant and to regulate its presence in the human environment. *See* NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 19-33 (1983) [hereinafter NAS REDBOOK]. The National Research Council was organized by the National Academy of Sciences and it has become the chief operating arm of the National Academy of Sciences.

3. Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended in various sections of 7 U.S.C. and 21 U.S.C.) [hereinafter FQPA]. The FQPA amends the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (1994 & Supp. III 1997) [hereinafter FFDCA] and the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136 et seq. (1994 & Supp. III 1997) [hereinafter FIFRA]. FIFRA regulates the registration of pesticides for all uses and FFDCA regulates their use on food. This article only examines changes that the FQPA made to the FFDCA.

its passage, the FQPA was called "one of the most significant environmental and public health bills passed in 20 years, [which] indeed may distinguish itself in time as the most significant."[4] Consumer groups and politicians hailed the FQPA as a victory because it established a single safety standard for processed and raw foods and contained special safeguards for children. For the first time, the FQPA requires the Environmental Protection Agency ("EPA") to consider the special susceptibilities of children to pesticides when setting legal limits on the amount of pesticide residues allowable on food.[5] Additionally, the FQPA requires the EPA to quantitatively assess the risks of individual pesticide residues on all types of food and set tolerances so that the risk to humans is negligible.[6]

The reality of the post-FQPA era is that the EPA is not strictly implementing many of the Act's protections for children.[7] This article considers whether the QRA process plays a part in the EPA's failure to implement the FQPA mandate to protect children, and the larger question of whether QRA is an effective tool for environmental health regulations in general. Major criticisms about the QRA process loom large in the face of Congress' recent willingness to rely on QRA as the basis for FQPA, as well as other environmental legislation.[8] These criticisms include questions about the accuracy of QRA and about whether the executive branch of government can rationally and apolitically apply a scientific framework to regulate environmental toxins.[9]

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4. Frank B. Cross, *The Consequences of Consensus: Dangerous Compromises of the Food Quality Protection Act*, 75 WASH. U. L.Q. 1155, 1155 (1997) (quoting Letter from Charles Benbrook, former Director of the National Academy of Sciences Agricultural Board, to Mike Thompson, California State Senator (July 31, 1996) (alteration in original)); *see also* Rick Weiss, *Clinton Signs New Standards on Food Safety; President also Ratifies Gambling Commission*, WASH. POST, Aug. 4, 1996, at A21 (noting that the Act was intended to "revamp the regulation of pesticides").

5. *See* 21 U.S.C. § 346a(b)(2)(C) (1994 & Supp. III 1997).

6. *See id.*

7. *See infra* notes 195-226 and accompanying text. *See generally*, DAN FAGIN & MARIANNE LAVELLE, TOXIC DECEPTION: HOW THE CHEMICAL INDUSTRY MANIPULATES SCIENCE, BENDS THE LAW AND ENDANGERS YOUR HEALTH (1996) (asserting that EPA does not strictly implement many of the FQPA's protections for children).

8. *See* statutes cited *supra* at note 1; *see also infra* notes 133-152, and accompanying discussion. In 1983, the National Research Council published the seminal report on QRA in an attempt to create uniform standards for the process. *See* NAS REDBOOK, *supra* note 2, at 28-33.

9. *See infra* notes 133-152 and accompanying discussion. As this article goes to press, Representative Richard Pombo (R-Calif.) has sponsored a bill to amend the FQPA, The Regulatory Fairness and Openness Act of 1999, H.R. Res. 1592, 106th Cong. (1999). *See Bill Would Require Transition Analysis of FQPA Tolerance Decisions*, PESTICIDE AND TOXIC CHEM. NEWS, May 6, 1999, available in 1999 WL 9623717. This Bill would require the EPA to conduct a "transition analysis" to describe the scientific or other basis on which certain pesticide regulations are based. *See id.* The bill has been welcomed by the chemical industry. *See id.*

Additionally, the FQPA and statutes based on QRA, which have their roots in risk management, create no incentives for reducing environmental pollution; instead, these regulations are more likely characterized as "command and control" regulations.[10] These types of regulations attempt to quantify the desired environmental condition or, as here, an acceptable level of risk from environmental toxins, and demand that those creating the risk stay within this level.[11] Regulatory action based on QRA thus attempts to quantify and manage,[12] rather than reduce, risks from environmental pollutants.

As an example of an agency's efforts to apply QRA to manage environmental risks, this article examines the EPA's implementation of the FQPA to date and a recent controversy under the FQPA in which the Natural Resources Defense Council ("NRDC") has filed a challenge to EPA action which asserts that the EPA is not implementing the FQPA to protect children.[13] In the context of the NRDC's challenge, this article develops the argument that QRA in pesticide regulation does not provide scientific certainty in terms of health effects, but instead, only obfuscates the political nature of decisions which are claimed to be based exclusively on science.

Part I of this article reviews the legislative history and scientific backdrop of the FQPA, all of which evidence a clear congressional intent to increase protections from pesticides for children. Part II of this article describes the methodology and shortcomings of QRA and how Congress incorporated QRA into the FQPA. Part III analyzes and critiques the EPA's use of QRA and accompanying scientific analysis and considers the NRDC's challenge[14] to the EPA's enforcement of the FQPA thus far. Part IV discusses the reasons why science is the basis for so many environmental health regulations. Part V discusses alternatives to pollution management regulations, proposes future pesticide legislation consistent with a pollution prevention approach to environmental regulation, and makes suggestions for

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10. *See* Michael P. Vandenbergh, *An Alternative to Ready, Fire, Aim: A New Framework to Link Environmental Targets in Environmental Law*, 85 KY. L.J. 803, 824-41 (1996-97); *infra* notes 333-334 and accompanying text.

11. *See* Vandenbergh, *supra* note 10, at 842-49.

12. "Risk management is the process of evaluating alternative regulatory options and selecting among them. A risk assessment may be one of the bases of risk management." NAS REDBOOK, *supra* note 2, at 38.

13. *See* EARTHJUSTICE LEGAL DEFENSE FUND AND NRDC, WRITTEN OBJECTIONS TO VINCLOZOLIN TOLERANCE FOR SNAP BEANS SUBMITTED ON BEHALF OF NRDC ET AL. 1 (September 15, 1997) (on file with author) [hereinafter VINCLOZOLIN CHALLENGE]; EARTHJUSTICE LEGAL DEFENSE FUND, REVISED HEARING REQUEST ON VINCLOZOLIN TOLERANCE FOR SNAP BEANS SUBMITTED ON BEHALF OF NRDC ET AL. 1 (Mar. 31, 1998) (on file with author) [hereinafter REVISED HEARING REQUEST].

14. *See* VINCLOZOLIN CHALLENGE, *supra* note 13.

current enforcement of the FQPA in accord with congressional intent to improve protections for children.

I. OVERVIEW OF THE SCIENTIFIC AND POLITICAL HISTORY OF THE FOOD QUALITY PROTECTION ACT

A. The Scientific and Historical Framework Prior to the FQPA

The EPA used QRA to regulate the use of pesticides on food before Congress passed the FQPA. In response to major scientific findings in the area of children's susceptibilities to pesticides,[15] however, Congress intended the FQPA to dramatically strengthen protections for children by requiring consideration of these special susceptibilities in the risk assessment process.

1. Tolerance Setting Prior to the FQPA

The FQPA amends the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA")[16] and the Federal Food, Drug and Cosmetic Act ("FFDCA"),[17] both of which regulate the use of pesticides on food crops in the United States. FIFRA requires that a pesticide must be registered for use.[18] Before a pesticide may be registered for a food use, however, the EPA must establish a legal limit on a pesticide residue,[19] known as a tolerance,[20] or an exemption from a tolerance, pursuant to the FFDCA.[21]

Prior to the FQPA, the EPA set tolerances largely without regard[22] to the special susceptibilities of children to pesticides. For pesticides for which the

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15. *See infra* notes 38-65 and accompanying text.

16. 7 U.S.C. §§ 136 et seq. (1994).

17. 21 U.S.C. §§ 321 et seq. (1994).

18. *See* 7 U.S.C. §§ 136a(a) (1994).

19. A pesticide residue is a trace quantity of a pesticide, or its breakdown product, either on or in foodstuffs. *See* NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 13 (1993) [hereinafter DIETS OF CHILDREN].

20. *See* 21 U.S.C. § 342 (1994 & Supp. III 1997) *and* 21 U.S.C.§ 346a(a)(1)(A) (1994 & Supp. III 1997).

21. *See* 21 U.S.C. § 346a(a)(1) (1994 & Supp. III 1997).

22. *See Spotlight Story Interview: Author Explores Cancer-Environment Links*, AMERICAN POLITICAL NETWORK GREENWIRE, July 23, 1997, *available in* Westlaw, APN-GR database; *The Food Quality Protection Act: Hearings on S. 1166 Before the Senate Comm. on Agric., Nutrition and Forestry*, 104th Cong. 218 (1996) (testimony of Dr. Bruce Alberts, President of the National Academy of Sciences and Chairman of the National Research Council); *see generally* JOHN

EPA could determine a safe level of exposure,[23] the tolerance setting process generally involved using data provided by pesticide registrants.[24] Using this data, the EPA defined a level of pesticide residue on the food which would be reasonably safe for an adult[25] and then divided this level by an uncertainty factor of one hundred to make the risk estimate more conservative.[26] This traditional hundred-fold factor, still used in most situations,[27] is based on two assumptions.[28] The first is that humans are ten times more susceptible to the effects of pesticides than animals, and the second is that some humans are more susceptible to the effects of toxins than others.[29] Practically, the hundred-fold margin of safety means that if the EPA determines that a certain level of pesticide residue is safe for adults, it then divides this level by one hundred so that this safe level, also known as a threshold level, has an increased margin of safety.[30] The risk assessor thus gives himself room for error because his adjusted threshold level is at least 100 times more conservative than what he actually believes the level to be. The EPA then

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WARGO, OUR CHILDREN'S TOXIC LEGACY (1996) (discussing the regulation of pesticides and related risks immediately before the passage of FQPA).

23. Pesticides for which the EPA determines a safe level of exposure are generally those involving only non-cancer risks. For cancer risks, the EPA has assumed that no level of a carcinogenic substance is safe. The EPA appears to be moving away from this thinking, however, and may soon establish levels at which particular carcinogens pose "no risk."

While the true risk of agricultural pesticide use is unknown, numerous studies have linked pesticides to cancer and the EPA has estimated that "sixty-two percent of all pesticides in use [are] . . . potentially carcinogenic." John C. Kluge, *Farming by the Foot: How Site-Specific Agriculture Can Reduce Nonpoint Source Water Pollution*, 23 COLUM. J. ENVTL. L. 89, 93 (1998); *see also* John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 YALE J. ON REG. 277, 282 (1992).

24. *See infra* notes 225-226 and accompanying discussion.

25. This threshold level is known as the "'no observed adverse effect level'" or the "NOAEL." Scott D. Bauer, *The Food Quality Protection Act of 1996: Replacing Old Impracticalities with New Uncertainties in Pesticide Regulation*, 75 N.C. L. REV. 1369, 1394 (1997).

26. *See* Vinclozolin: Pesticide Tolerance, 62 Fed. Reg. 38,464, 38,471 (1997) (to be codified at 40 C.F.R. pts. 180, 185, 186); SCIENTIFIC ADVISORY PANEL, EPA, A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE AGENCY IN CONNECTION WITH THE USE OF FQPA 10X SAFETY FACTOR TO ADDRESS SPECIAL SENSITIVITY OF INFANTS AND CHILDREN TO PESTICIDES 24 (May 5, 1998) (visited Nov. 9, 1999) <http://www.epa.gov/opp0001/sap/1998/march/fqpa_10x.htm> [hereinafter SAP ON 10X FACTOR].

27. For a discussion of why the EPA is still using the hundred-fold safety factor, see *infra* notes 205-206, 238-242 and accompanying discussion.

28. *See* 62 Fed. Reg. at 38,471 (the interspecies factor); Letter from Representative Henry Waxman to Carol Browner, EPA Administrator 1 (Nov. 18, 1997) (citing H.R. REP. NO. 669, 104th Cong., 2d Sess., pt. 2 at 41 (1996)).

29. *See* 62 Fed. Reg. at 38,471 (the intraspecies factor).

30. *See* DAVID WALLINGA, NATURAL RESOURCES DEFENSE COUNCIL, PUTTING CHILDREN FIRST: MAKING PESTICIDE LEVELS IN FOOD SAFER FOR INFANTS & CHILDREN 41 (Apr. 1998).

compares this adjusted threshold estimate[31] to estimates about consumers' maximum exposure to the pesticide residue from consumption of the food on which it will be used.[32] If the estimated potential exposure is less than the adjusted threshold level, then the EPA will most likely approve the tolerance.[33]

For pesticides for which the EPA is not able to define a safe level of exposure to the residue, generally those involving cancer risk, the EPA also has used and continues to use data largely provided by pesticide registrants[34] to assess the riskiness of the pesticide.[35] Based on the data provided, the EPA classifies the pesticide into one of five groups, ranging from group A, carcinogenic in Humans, to group E, evidence of non-carcinogenity in Humans.[36] If the EPA classifies a pesticide as a likely carcinogen based on the available information, the EPA proceeds to assess the risk of the chemical based on the information it used originally to classify the pesticide,[37] and determines if the carcinogenic risks fall within acceptable limits. The interesting aspect of this process is that, prior to the FQPA, there was no requirement for the EPA to consider the broad range of a pesticide's potential effects on infants and younger animals, and therefore, no requirement for pesticide registrants to perform tests and submit data on these effects. Thus, prior to the FQPA, the statutory framework allowed the EPA to assess cancer and all other risks without particular consideration of the unique susceptibilities of children.

2. Dangers to Children

a. Summary of NRC Findings

In 1993, the National Research Council ("NRC")[38] released a highly publicized report entitled *Pesticides in the Diets of Infants and Children*,[39]

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31. The adjusted risk estimate is known as the "Acceptable Daily Intake ('ADI')" or the "Reference Dose ('RfD')." Bauer, *supra* note 25, at 1394.

32. *See id.*

33. *See id.*

34. *See* NAS REDBOOK, *supra* note 2, at 126; WALLINGA, *supra* note 30, at 25.

35. *See* WALLINGA, *supra* note 30, at 25.

36. *See* Bauer, *supra* note 25, at 1395.

37. *See id.* at 1395-96.

38. In 1988, the U.S. Congress asked the National Academy of Sciences to convene a committee within the National Research Council to consider the scientific and policy issues concerning pesticides and children. Five years later, the National Research Council issued its report on pesticides in the Diets of Children Report calling attention to the dangers of pesticides in the diets of infants and children. *See* DIETS OF CHILDREN, *supra* note 19.

and seriously questioned the practice of treating children and adults alike in setting pesticide tolerances. The report summarized growing epidemiological evidence that children are not as capable of warding off the dangers of pesticides because of their developing systems and smaller physical size.[40] The NRC urged that to protect children adequately, an additional tenfold margin of safety should be used when data with regard to a pesticide showed developmental toxicity after birth and when data was incomplete with regard to toxicity for children.[41] The NRC report concluded: "[i]n the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children."[42] Lawmakers and scientists were alarmed by the NRC report [43] and the growing body of data indicating that children are generally more susceptible to the toxic effects of pesticides than adults.[44]

b. Why Pesticides Are More Dangerous for Children[45]

The NRC considered the special characteristics of children and the effect these characteristics have on the toxicity of pesticides to them.[46] The report found that physiological and biochemical differences between adults and children influence the quantity absorbed and effect of pesticide residues on them.[47] The NRC found that children have higher metabolic rates[48] and consume more food and water[49] per pound of body weight than adults.[50] In

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39. *See id.*

40. *See id.* at 23-44.

41. *See id.* at 9.

42. *Id.*

43. The NRC Report was labeled a "wake-up call" for legislators. *No Action Taken on Pesticide Regulation*, CONG. Q. ALMANAC 229, 230 (1993) (quoting Representative Henry A. Waxman); *see also* DIETS OF CHILDREN, *supra* note 19, at 4.

44. *See* DIETS OF CHILDREN, *supra* note 19, at 4.

45. The following sections, I.A.2.b. and I.A.2.c., are partially adopted from Valerie J.Watnick, *Who's Minding the Schools: Toward Least Toxic Methods of Pest Control in Our Nation's Schools*, 8 FORDHAM ENVTL. L.J. 73 (1996).

46. *See generally* DIETS OF CHILDREN, *supra* note 19.

47. *See id.* at 43.

48. *See id.* at 38; *accord* Cynthia. F. Bearer, *Environmental Health Hazards; How Children Are Different from Adults*, 5 THE FUTURE OF CHILDREN (The Center for the Future of Children), Summer/Fall 1995 at 11, 15.

49. *See* Bearer, *supra* note 48, at 15 (indicating that children absorb more air than adults per pound of body weight). It follows that if the food, air or water is contaminated with toxins, children will receive a larger dose of toxins than adults who ingest the same food, air or water.

50. *See* DIETS OF CHILDREN, *supra* note 19, at 38; *see also* PHYSICIANS FOR SOCIAL RESPONSIBILITY ET AL., PESTICIDES AND CHILDREN: WHAT THE PEDIATRIC PRACTITIONER SHOULD KNOW 1 (1995) [hereinafter PESTICIDES AND CHILDREN] (citing U.S. Dept of Agriculture National Food Consumption Surveys, and indicating that children consume three times more food per unit of body weight than adults and are thus exposed to a high level of pesticides through the food they eat).

addition to asserting that children eat more food and drink more liquids than adults relative to their weight, the NRC also urged that children tend to eat a less varied diet than adults.[51]

Additionally, the NRC's report considered the differences between human children and immature animals—such as rats—on which the bulk of toxicology studies are performed.[52] The NRC concluded that there are substantial differences between these animal populations in terms of their maturity at birth and their rate of growth after birth when compared to human children.[53] For example, "the rate of maturation and growth of the mouse or rat after birth is relatively more rapid than that of the human."[54] A difference of one day, in terms of the introduction of toxins to the immature rat, may change the affect the toxin will have on the young organism.[55] The report stressed that these differences complicate interspecies comparisons for reactions to toxins.[56]

c. The Effect of Pesticides on Children's Health

The Report by the National Research Council concluded that the potential for short-term and long term toxicity of pesticides in the developing child [57]

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51. *See* DIETS OF CHILDREN, *supra* note 19, at 196. Other scientific evidence has also suggested that children take in more toxins from their environment than adults. *See* Bearer, *supra* note 48, at 15, 18; HERBERT L. NEEDLEMAN & PHILIP J. LANDRIGAN, RAISING CHILDREN TOXIC FREE 122 (1994); Richard A. Fenske et al., *Potential Exposure and Health Risks of Infants Following Indoor Residential Pesticide Application*, 80 AM. J. PUB. HEALTH 689, 699 (1990); *accord* Susan Cooper, *The Pesticide Problem: Is Any Amount Safe?*, PTA TODAY, Apr. 13, 1991, at 13; *see also* SCIENTIFIC ADVISORY PANEL, EPA, A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE AGENCY IN CONNECTION WITH POST APPLICATION EXPOSURE GUIDELINES: SERIES 875-GROUP B 35 (May 5, 1998) (visited Nov. 22, 1999) <http://www.epa.gov/oscpmont/sap/1998/march/postapp.htm> [hereinafter SAP ON POST APPLICATION EXPOSURE].

52. *See* DIETS OF CHILDREN, *supra* note 19, at 25

53. *See id.*

54. *Id.*

55. *See id.* at 29.

56. *See id.* at 25-43.

57. In the same era as the NRC Report, multiple studies also concluded that children who are exposed to pesticides on a regular basis have a greater risk of contracting leukemia and cancers than other children. *See* Jack Leiss & David Savitz, *Home Pesticide Use and Childhood Cancer: A Case-Control Study*, 85 AM. J. PUB. HEALTH 2 (1995) (associating yard treatments with a 4 times increase in soft tissue cancers and strongly associating pest strips with between a 1.7 to 3 times increase in leukemia in children); NEEDLEMAN & LANDRIGAN, *supra* note 51, at 63, 114; *see also* Marla Cone, *Human Immune Systems May Be Pollution Victims*, L.A. TIMES., May 13, 1996, at A1 (discussing children in former Soviet Union, in village highly contaminated with pesticides, who were afflicted with two to five times more lung infections than those in less contaminated areas and eighty percent showed abnormal T cell counts or other immune deficiencies). "[S]ome experts suggest that widespread, low-level exposure to pesticides in the environment may be contributing to

was greater than that in adults.[58] The NRC noted a paucity of data with regard to the toxicity of pesticides to developing children,[59] but recommended that future regulatory action consider the fact that toxicity is age related, and that there exists a need for standard testing proposals and assessment techniques in immature animals.[60]

In March 1996, just prior to the passage of the FQPA, the World Resources Institute also issued a significant report which concluded that a large body of evidence suggests that exposure to pesticides damages the immune system and that pesticide-induced suppression of the immune system is a substantial public health risk.[61] The World Resources Institute found that because children have immature immune systems, their systems may be

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rising rates of some cancers in the general population." PESTICIDES AND CHILDREN, *supra* note 50, at 4 (citing Davis et al., 271 JAMA 431-37 (1994)).

These studies were consistent with epidemiologic evidence showing that "the [i]ncidence of the two most common childhood cancers is rising: between 1990 and 1993, the incidence of brain and nervous system cancer increased by 32.6% and the incidence of acute lymphocytic leukemia increased by 27.4% while at the same time our use of pesticides appears to be rising." *Id.* at 4 (citing data collected by U.S. Surveillance, Epidemiology, and End Results Program of the National Cancer Institute); *see also* Mike Mitka, *Environmental Health Center Aims at Children*, JAMA, July 21, 1999 (noting that chemicals in the environment pose a unique danger to children; that asthma rates for children doubled in the last decade; and that, since 1972, the incidence of childhood cancer increased by 35%); Gary Gardner, *IPM and the War on Pests*, WORLDWATCH, Mar. 13, 1996, *available in* 1996 WL 13656279 (noting that despite the global interest in reducing the use of pesticides, their use rose in 1994 at the fastest rate in ten years).

58. *See* DIETS OF CHILDREN, *supra* note 19, at 105-10.

59. More recently, the Environmental Working Group released a well publicized report again confirming that children face inordinate risks from pesticides, particularly from exposure to unsafe levels of a class of pesticides known as organophosphate pesticides. *See* RICHARD WILES ET AL., ENVIRONMENTAL WORKING GROUP, OVEREXPOSED, ORGANOPHOSPHATE INSECTICIDES IN CHILDREN'S FOOD (Jan. 1998); *see also infra* notes 378-387 and accompanying text; Curt Anderson, *EPA Pledges Pesticide Review, Residue Taints Fruits, Vegetables, Researchers Say*, SUN-SENTINEL, Jan. 30, 1998; George Anthan, *Chemicals on Foods Putting Our Kids at Risk*, DES MOINES REGISTER, Feb. 8, 1998; *EPA Warns of Insecticide Overexposure*, CHEM. WEEK, Feb. 4, 1998, *available in* 1998 WL 8248916; Louis Freedberg, *1 Million Kids a Day Get Unsafe Doses of Pesticides, Group Says Risk of Damage to Nervous System from Tainted Fruit*, SAN FRANCISCO CHRONICLE, Jan. 30, 1998, at A4; Jeff Jardine, *Watchdog Group Takes on Pesticides: Environmental Working Group Claims Many Harmful to Children, Wants Them Banned by Federal Government*, FRESNO BEE, Jan. 30, 1998, at C1; Jennifer Owens, *Study: Baby Food Has Unsafe Pesticide Levels*, SUPERMARKET NEWS, Feb. 9, 1998, *available in* 1998 WL 9412430; Steve Yozwiak, *Ban Is Sought on 5 Pesticides to Protect Kids 22,000 Arizonans Affected, Report Says*, ARIZONA REPUBLIC, Jan. 29, 1998, at B2.

60. *See* DIETS OF CHILDREN, *supra* note 19, at 109.

61. *See* ROBERT REPETTO & SANJAYS BALIGA, WORLD RESOURCES INSTITUTE, PESTICIDES AND THE IMMUNE SYSTEM (Mar. 1996); *see also* ALEX GARCIA ET AL., PUBLIC CITIZEN'S CONGRESS WATCH, CITIZEN ACTION OF PENNSYLVANIA, CONTAMINATED CLASSROOMS: AN INVESTIGATION OF PEST CONTROL PRACTICES IN PHILADELPHIA AREA SCHOOLS 9 (Oct. 1991); Charles Marwick, *"Provocative" Report Issued on Use of Pesticides*, 275 JAMA 899 (1996).

particularly susceptible to immuno-suppression and that this susceptibility called for immediate precautionary action.[62]

In the wake of this growing body of scientific evidence, including the NRC report [63] and the World Resources Institute report,[64] Congress moved forward to reform pesticide laws so that the EPA would set tolerances at safer levels for children.[65]

B. Legislative History of the FQPA

1. The Delaney Clause and the *de Minimis* Exception

The Delaney clause, passed in 1958, as part of the FFDCA, became a bargaining chip[66] in the effort to gain regulatory protection for children from pesticides.[67] The famously known Delaney clause[68] specifically limited

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62. *See* REPETTO & BALIGA, *supra* note 61, at 59, 63; Marwick, *supra* note 61, at 899; Timothy Noah, *Uniroyal Chemical to Partially Ban Use of Pesticide*, WALL ST. J., Apr. 8, 1996, at B6. Researchers posit that children regularly exposed to pesticides are thus at risk for immune suppression and would be more likely to have infectious diseases of the respiratory tract and to be absent from school. *See* REPPETTO & BALIGA, *supra* note 61, at 59, 63.

Additional research suggests that pesticides are also powerful neurotoxins that can affect a child's learning and long term nerve function. *See* John F. Wasik, *Organic Food: Is It Worth the Higher Price?*, CONSUMERS DIGEST, Nov. 21, 1995, at 29. Organophosphate and carbamate pesticides "[i]nterfere with the normal functioning of the nervous system by blocking the action of cholinesterase, an enzyme essential for degrading the neurotransmitter acetylcholine." PESTICIDES AND CHILDREN, *supra* note 50, at 3. Recently, the FIFRA Scientific Advisory Panel to the EPA met to consider the common mechanism of action of organophosphate pesticides. The SAP defined mechanism of toxicity narrowly to include only the particular molecular interaction resulting in the inhibition of acetyl cholinesterase, an effect potentially harmful to the central nervous system. SCIENTIFIC ADVISORY PANEL, EPA, A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE AGENCY IN CONNECTION WITH COMMON MECHANISM OF ACTION OF ORGANOPHOSPHATES 1 (1998) (visited Nov. 22, 1999) <http://www.epa.gov/oscpmont/sap/1998/march/commop.htm> [hereinafter SAP ON COMMON MECHANISM OF OGANOPHOSPHATES]. The fact that pesticides may affect the nervous system is consistent with concerns that pesticides are linked to an increased occurrence of attention deficit disorder. *See* Wasik, *supra* at 13. Acute effects from organophosphate and carbamate pesticides can involve diarrhea, muscle twitching, visual disturbances, hypertension, mood swings, respiratory distress and death. *See* PESTICIDES AND CHILDREN, *supra* note 50, at 3. Long-term effects may involve permanent damage to the nervous system. *See id.*

63. DIETS OF CHILDREN, *supra* note 19.

64. *See* REPETTO & BALIGA, *supra* note 61.

65. *See EPA May Ban Pesticides Used on Pears*, PORTLAND OREGONIAN, Feb. 3, 1998.

66. *See* Erin Moran, Note, *The Food Quality Protection Act of 1996: Does the Delaney Clause Effectively Protect Against Cancer or Is It Outdated Legislation?*, 30 J. MARSHALL L. REV. 1127, 1131 (1997).

67. *See No Action Taken on Pesticide Regulation*, *supra* note 43, at 230.

conditions under which the EPA could allow use of a substance as a food additive[69] and resulted in differing treatment of raw and processed foods.[70] Specifically, the Delaney clause provided that regulations allowing uses of food additives had to be safe; if a substance was found to induce cancer, it could not be designated as safe and thus could not be added to processed foods.[71] This standard was known as a "zero tolerance" standard.[72] Raw agricultural commodities were considered "adulterated" and thus unsafe for use unless a tolerance or exemption was in place for a pesticide residue found on that food.[73] Unlike the case of processed foods, where carcinogenic food additives could not be added to the food, pesticide registrants could obtain tolerances and exemptions for use of carcinogenic pesticides on raw agricultural commodities if the risks were minimal.[74] This section of the FFDCA also allowed the EPA to consider the benefits of a pesticide when setting tolerances for raw agricultural commodities.[75] And finally, where the EPA had established a tolerance or exemption for a pesticide used on a raw food, the FFDCA contained "flow-thorough" provisions whereby a food subject to processing, such as freezing, canning or cooking, could contain some of the carcinogenic pesticide residue as long as: 1) the level of such residue did not concentrate in processing beyond the level permitted by the tolerance for the raw food; and 2) the residue was

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68. *See* 21 U.S.C. § 348 (1994 & Supp. III 1997).

69. The term "food additive" did not include a pesticide chemical in or on raw agricultural commodities. *See* 21 U.S.C. § 321(s)(1) (1994 & Supp. III 1997), *amended by* FQPA, Pub. L. No. 104-170, 110 Stat. 1489, 1513 (1996); 21 U.S.C. 321(s)(2) (1994 & Supp. III 1997), *amended by* FQPA, Pub. L. No. 104-170, 110 Stat. 1489, 1513 (1996); Moran, *supra* note 66, at 1132.

Food additives were then defined to include any substance, including pesticide chemical residues in processed foods, which became or were intended to become part of food. *See* 21 U.S.C. § 321(s) (1994 & Supp. III 1997), *amended by* FQPA, Pub. L. No. 104-170, 110 Stat. 1489, 1513 (1996); *Les v. Reilly*, 968 F.2d 985, 987 (9th Cir. 1992).

70. This disparate treatment of raw and processed foods was often called the "Delaney Paradox." *See* Douglas T. Sheehy, *A De Minimis Exception to the Delaney Clause: A Reassessment of Les v. Reilly*, 50 FOOD & DRUG L.J. 257, 278-79 (1995).

71. *See* 21 U.S.C. § 348(c)(3) (1994 & Supp. III 1997); *The Regulatory Improvement Act: Testimony on S. 981, The Regulatory Reform Act of 1998 Before the Senate Comm. on Govt. Affairs*, 105th Cong. 12 (1998) (statement of Bruce Alberts, Chairman of the National Academy of Sciences) [hereinafter *Regulatory Improvement Act Testimony*].

72. *See* 21 U.S.C. § 348(c)(3) (1994 & Supp. III 1997).

73. 21 U.S.C. §342(a)(2)(B) (1994 & Supp. III 1997), *amended by* FQPA, Pub. L. No. 104-170, 110 Stat. 1489, 1514 (1996); 21 U.S.C. §346a (1994 & Supp. III 1997), amended by FQPA, Pub. L. No. 104-170, 110 Stat. 1489, 1514-35 (1996).

74. 21 U.S.C. § 346a(b) (1994 & Supp. III 1997), *amended by* FQPA, Pub. L. No. 104-170, 110 Stat. 1489, 1515-20 (1996).

75. *See* Bauer, *supra* note 25, at 1374.

"removed to the extent possible in good manufacturing practice."[76] The EPA interpreted this flow-through provision to mean that if the substance concentrated during processing and it was carcinogenic, it was to be treated as an unsafe food additive[77] barred by the Delaney clause.[78]

The practical application of the Delaney clause caused problems because it prohibited any carcinogenic substance in processed food if it concentrated during processing, even if it only posed what the EPA considered a *de minimis* risk. Given scientists' current ability[79] to detect certain chemicals in extremely minute amounts[80] (which those in favor of the abolition of Delaney[81] argued were only negligibly harmful[82]), scientists and politicians urged that the Delaney clauses' zero tolerance standard for carcinogenic food additives needed revision.[83] Moreover, the EPA urged that Delaney's flow

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76. 21 U.S.C. §§ 342(a) (1994 & Supp. III 1997), *amended by* FQPA, Pub. L. No. 104-170, 110 Stat. 1489, 1514 (1996); *Les*, 968 F.2d at 987.

77. *See* 21 U.S.C. § 348 (1994 & Supp. III 1997).

78. *See* 21 U.S.C. § 348(c)(3) (1994 & Supp. III 1997). Moreover, the EPA's "coordination policy" prevented the EPA from establishing a tolerance for a pesticide used on a raw agricultural commodity if the pesticide concentrated during processing. *See* Bauer, *supra* note 25, at 1376 (citing Section 409 Tolerances; Response to Petition Requesting Revocation of Food Additive Regulations, 55 Fed. Reg. 17,560, 17,562 (1990)). This policy essentially "grafted" the Delaney clause, intended to regulate only processed foods, into the regulation of tolerances for certain raw agricultural commodities. *See* Bauer, *supra* note 25, at 1376.

79. *See* David Hosansky, *Future Battles Expected over Pesticide Bill*, 54 CONG. Q. WKLY. REP. 1759, 1759 (1996) [hereinafter Hosansky, *Future Battles Expected*].

80. At the time the Delaney clause was passed, the amount of pesticides detected in food was discussed in terms of parts per million. *See id.* Today, scientists can detect pesticide residues in parts per billion. *See id.*

Prior to the passage of the FQPA, however, much was written about the Delaney clause and the fact that it was outdated given science's ability to detect such small amounts of toxic substances in food that they could not possibly be harmful. *See supra* notes 66-88 and accompanying discussion. One interesting proposal however, suggested that Delaney's zero tolerance be adopted across the board for both raw and processed foods, but that tests sensitive to minute amounts of pesticide residues might not be appropriate for an evaluation of food safety. *See* Paul A. Gillan, Jr., *Laying Ax to the Delaney Clause: Reform of the Zero-Tolerance Standard for Carcinogenic Food Additives*, 5 U. BALT. J. ENVTL. L. 15, 48 (1995).

81. In *Public Citizen* v. *Young*, the Food and Drug Administration ("FDA") had argued unsuccessfully that the Color Additives Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 (codified at 21 U.S.C. § 379e (1982)), prohibiting carcinogenic substances in color additives, should be interpreted to allow carcinogenic color additives where the risk was "'so trivial as to be effectively no risk.'" Public Citizen v. Young, 831 F.2d 1108, 1111 (D.C. Cir. 1987) (citing 21 U.S.C. § 379e (1982) as amended). The court of appeals rejected the FDA's argument, noting that the legislative history of the Delaney Clause made clear that Congress had intended the clause to be "'extraordinarily rigid'" even in instances of "trivial risks" to humans. *Public Citizen*, 831 F.2d at 1122.

82. *See* Sheehy, *supra* note 70, at 278-79; Moran, *supra* note 66, at 1132; Gillan, *supra* note 80, at 47-48.

83. *See Regulatory Improvement Act Testimony*, *supra* note 71, at 17 (testimony of Bruce Alberts). Alberts noted that when the regulatory options were considered in a study done by the

though provisions allowed certain carcinogenic pesticide residues that did not concentrate during processing, while other less dangerous substances were impermissible simply because they did concentrate during processing.[84]

In an effort to surmount these practical problems in 1992, the EPA proposed a new interpretation of the Delaney Clause in *Les v. Reilly*.[85] The EPA argued that the Delaney Clause should be interpreted to allow carcinogenic pesticide residues which concentrated during processing in excess of the tolerance for the raw agricultural commodity, as long as the particular substances posed only a *de minimis* risk of causing cancer.[86] The Ninth Circuit rejected this argument and held that the Delaney clause was "clear and mandatory;"[87] it unambiguously provided that when carcinogenic pesticides concentrate during processing beyond the level permissible on raw foods, they are treated as food additives subject to the zero tolerance standard.[88]

2. Reform Efforts

The Ninth Circuit's decision in *Les v. Reilly*[89] further invigorated the controversy surrounding the Delaney clause,[90] and the Report by the National

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National Academy of Sciences, the option that produced the best result was one that called for a negligible risk standard for raw and processed food alike. *See id.* He urged that this standard would virtually eliminate the potential dietary cancer risk. *See id.* In contrast, Alberts stressed, the absolutist bar of the Delaney Clause, with a zero risk standard for processed foods, only reduced the cancer risk by half when considered in the study. *See id.* Congress ultimately adopted this negligible risk standard in the FQPA. *See infra* notes 163-75 and accompanying discussion.

In support of Delaney, others have hailed it as direct in intent and clear in application. *See* Moran, *supra* note 66, at 1147-50. One author has said that at least the Delaney clause recognized the inherent uncertainty in science. *See* Dominic P. Madigan, *Setting an Anti-Cancer Policy: Risk, Politics, and the Food Quality Protection Act of 1996*, 17 VA. ENVTL. L.J. 187, 224 (1998).

84. *See* Les v. Reilly, 968 F.2d 985, 988 (9th Cir. 1992); *see also* Sheehy, *supra* note 70, at 278. Similarly, the old regulatory regime allowed older pesticides that were suspected carcinogens to remain in use, but prohibited current approval of newer, safer, pesticides that were considered to be minimally carcinogenic. *See also* Sheehy, *supra* note 70, at 278. For a general discussion on the implementation of the Delaney Clause, see Richard A. Merrill, *FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?*, 5 YALE J. ON REG. 1 (1988).

85. *See Les,* 968 F.2d at 985 (explaining that the issue before the court was whether the EPA violated the Delaney Clause "by permitting the use of carcinogenic food additives which it finds to present only a de minimis or negligible risk of causing cancer").

86. *See id.* at 988.

87. *Id.*

88. *See id.* at 989.

89. 968 F.2d 985 (9th Cir. 1992).

90. For a thorough discussion of the controversial and beleaguered legislative history of the Food Quality Protection Act of 1996, see James Smart, *All the Stars in the Heavens Were in the*

Research Council[91] fueled efforts to reform the regulatory scheme to protect children.[92] For a number of years, however, Congress had faced tremendous controversy about the shape of a new regulatory scheme.[93] One major debate centered on whether to maintain a blanket prohibition, such as that found in Delaney, or to adopt a negligible risk standard, thereby placing a greater emphasis on scientifically quantifying the risks from pesticides.[94] If a negligible risk standard were to be adopted, the pesticide industry and the environmental groups would clash about the definition of "acceptable risk." The pesticide industry wanted a pesticide's economic benefits to weigh against its potential for harm,[95] while environmental groups balked at the notion that a pesticide's benefits could counterbalance human health concerns. Environmentalists also wanted to ensure that any new law would increase protections for children.[96] Additionally, the environmentalists sought a statutory definition of "negligible risk" such that it would be defined numerically as a one-in-a-million chance of occurrence.[97]

In 1993, the EPA indicated that it planned to implement the Ninth Circuit's decision in *Les*.[98] The planned implementation put pressure on the pesticide industry to accept reform proposals that were more protective of

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Right Places: The Passage of the Food Quality Protection Act of 1996, 17 STAN. ENVTL. L.J. 273 (1998).

91. Referring to DIETS OF CHILDREN, *supra* note 19.

92. *See No Action Taken on Pesticide Regulation, supra* note 43, at 229; David Hosansky, *Rewrite of Laws on Pesticides on Way to President's Desk*, 54 CONG. Q. WKLY. REP. 2101, 2101 (1996) [hereinafter Hosansky, *Rewrite of Laws*]; David Hosanksy, *Long-Sought Pesticides Bill Advances Easily After Deal*, 54 CONG. Q. WKLY. REP. 2031, 2031 (1996) (discussing with surprise the bipartisan support for S. 1166, which became the FQPA) [hereinafter Hosansky, *Long Sought Pesticides Bill*].

93. *See* Annie Tin, *Pesticide Markup Is Cut Short*, 54 CONG. Q. WKLY. REP. 1962, 1962 (1996); *see also Les*, 968 F.2d at 987; Gillan, *supra*, note 80, at 15; Hosansky, *Future Battles Expected*, *supra* note 79, at 1759; Hosanksy, *Long Sought Pesticides Bill*, *supra* note 92, at 2031.

94. *See* Donald T. Hornstein, *Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 YALE J. ON REG. 369, 371 (1993); Smart, *supra* note 90, at 299. Environmental groups originally opposed legislation based on a uniform negligible risk standard, urging that Delaney's stricter standard should be adopted for all foods rather than rolled back with regard to processed foods. Ultimately, many environmental and public health advocates came to view the loss of the Delaney clause as a tradeoff. *See* Hosansky, *Rewrite of Laws*, *supra* note 92, at 2102. Ultimately, the environmentalists supported the FQPA because it was supposed to contain added protections for infants and children. *See* Hosanksy, *Long Sought Pesticides Bill*, *supra* note 92, at 2032.

95. *See* Smart, *supra* note 90, at 329-30.

96. *See id.* Additionally, industry groups did not want the endocrinic effects of a pesticide to be considered by the EPA and they wanted pesticide residues to be calculated on the basis of percent of crops actually treated, rather than on the assumption that 100% of crops were treated. *See id.* at 330.

97. *See id.* at 329-30.

98. *Id.* at 307.

children and less concerned with the benefits of a pesticide because it would have required the EPA to *reconsider* tolerances for approximately thirty pesticides.[99]

In September 1993, the Clinton Administration proposed a reform package which attempted to please the chemical industry groups and the environmentalists.[100] The proposal included[101] abolishment of the Delaney zero-tolerance standard and use of QRA to set tolerance levels that are safe for children.[102] While the Clinton proposal suggested that all tolerances pose no more than a *de minimis* risk, it did not prescribe the one-in-a-million numerical definition of *de minimis* risk sought by the environmental groups.[103] A numerical definition would have limited the EPA's discretion to increase the level of risk beyond the traditional one-in-one-million and simultaneously define the risk as *de minimis*.[104]

After the Clinton Administration made its proposal, the House and Senate Agriculture Committees of the 104th Congress held a series of hearings on pesticide regulatory reform.[105] Specific policy debates focused on questions about how to assess dietary risks to different groups of consumers, the method of assessing consumer exposure and whether and when to consider a pesticide's benefits when setting tolerances.[106] At the heart of these hearings, however, was the concern that new pesticide regulations take into account the

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99. *See id.*

100. *See id.* at 312. For a further discussion of the history of the FQPA, see Barbara Kennedy Kahn, Comment, *New Developments in Pesticide Regulation*, 13 TEMP. ENVTL. L. & TECH. J. 309 (1994).

101. *See No Action Taken on Pesticide Regulation, supra* note 67, at 230.

102. *See id.* at 230; Smart, *supra* note 90, at 312.

103. *See* Smart, *supra* note 90, at 313.

104. *See* Hosansky, *Future Battles Expected*, *supra* note 79, at 1759 (noting that some environmentalists contended that the bill's vague "negligible risk" standard left too much discretion to the EPA).

105. *See Food Qualtiy Protection Act of 1996: Hearings on S. 1166 Before the Senate Comm. on Agriculture, Nutrition and Forestry*, 104th Cong. (1996) (testimony of Albert Meyerhoff, Senior Attorney on Behalf of the Natural Resources Defense Council, and testimony of Philip J. Landrigan, Professor and Chairman of the Department of Community Medicine and Director of Environmental and Occupational Medicine of the Mount Sinai School of Medicine, New York, New York) [hereinafter *Food Quality Protection Act Hearings*]; *Regulatory Improvement Act Testimony*, *supra* note 71; *The Food Quality Protection Act of 1995: Hearings on H.R. 1627 Before the Subcomm. on Department Operations, Nutrition and Foreign Agriculture* 104th Cong. 12-27 (1995) (testimony of Lynn Goldman, Assistant EPA Administrator for Prevention, Pesticide and Toxic Substances) [hereinafter *Food Quality Protection Act Hearings of 1995*].

106. *See* Carol S. Curme, *Regulation of Pesticide Residues in Foods: Proposed Solutions to Current Inadequacies Under FFDCA and FIFRA*, 49 FOOD & DRUG J. 609, 630 (1994).

special susceptibilities of children.[107] By June of 1995, consensus had begun to develop.[108]

Many legislators agreed[109] that "the time ha[d] come to make concessions rather then [sic] fight for a perfect bill."[110] The impending election in November 1996[111] and public perception that food safety laws needed revision played roles in developing this consensus.[112] On July 11, 1996, the Health and Environment Subcommittee of the House Commerce Committee began consideration of the bill which was to become the FQPA: House of

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107. In May, 1995, Lynn Goldman, the Assistant Administrator for Prevention, Pesticides and Toxic Substances at the EPA, testified before the House Committee on Agriculture, Department Operations, Nutrition and Foreign Agriculture. *See generally Food Quality Protection Act Hearings of 1995*, *supra* note 105. She noted that the FFDCA was in need of a "single health-based standard for residues in food" which would "take into account potentially sensitive populations, especially infants and children—the most vulnerable members of our society" and reflect the recommendations of the 1993 National Academy of Sciences report on Pesticides in the Diets of Infants and Children. *See id.*, at 12. Specifically, Goldman stated that the bill should require that information about children's diets and their special susceptibility be used in developing tolerances. *See id.* at 13.

At hearings in June 1996 before the Senate Committee on Agriculture, Bruce Alberts, President of the National Academy of Sciences and Chairman of the National Research Council, testified on Senate bill 1166 (Senate bill 1166 was later passed as the FQPA) and also stressed the importance of the 1993 National Research Council Report, which had urged that "[b]asic changes [were] needed in the current regulatory system to ensure that foods eaten by infants and children are safe" and that the "[E]PA, the Food and Drug Administration (FDA) and the USDA had been paying insufficient attention to the toxicological implication of diets for infants and children." *Regulatory Improvement Act Testimony*, *supra* note 71, at 218.

Similarly, Albert Meyerhoff, Senior Attorney for the National Resources Defense Council, testified in 1996 before the Senate Committee on Agriculture, stating that his remarks would "include an analysis of whether S.1166 would accomplish its stated purpose: 'to safeguard infants and children' from hazardous pesticides." *Food Quality Protection Act Hearings*, *supra* note 105, at 190. Meyerhoff noted that the current version of the bill did not protect children against risks of cumulative exposure, nondietary intake of pesticides and that it should, but did not, eliminate the consideration of benefits as a counterbalancing factor in favor of a particular pesticide use. *See id.* Bills proposed prior to the passage of the FQPA incorporated a single negligible risk standard, but prohibited the consideration of a pesticide's's economic benefits in making a determination as to its safety. *See* Amy Montemarano, *The Delaney Paradox Resurfaces: Regulating Pesticides as Food Additives Under Federal Law*, 25 RUTGERS L.J. 433, 457 (1994).

108. *See* David Hosanksy, *Quick Work on Pesticide Laws*, 54 CONG. Q. WKLY. REP. 2032, 2032 (1996); Hosansky, *Future Battles Expected*, *supra* note 79, at 1759; *see also* Eileen Simpson, *Panel OKs Pesticide Provisions, Puts off Controversial Action*, 54 CONG. Q. WKLY. REP. 1841, 1841 (1995).

109. *See Food Quality Protection Act Hearings*, *supra* note 105, at 193 (testimony of Albert Meyerhoff of the NRDC); Moran, *supra* note 66, at 1127 (citing Gary Lee, *in Food Safety Changes, Victories for Many*, WASH. POST, July 28, 1996, at A4).

110. Hosansky, *Long Sought Pesticides Bill*, *supra* note 92, at 2032.

111. *See* Smart, *supra* note 90, at 334.

112. *See id.*, at 326; *see generally* THEO COLBORN ET AL., OUR STOLEN FUTURE (1996) (detailing the potential dangers of pesticides that disrupt the endocrine function).

Representatives Bill 1627. The bill incorporated the portion of the Clinton administration's 1993 proposal designed to ensure that tolerance levels would protect infants and children.[113] On July 17, 1996, the House Commerce Committee approved House of Representatives Bill 1627 unanimously.[114] On July 24, 1996, the child protective bill was cleared by the Senate and sent to the President for his signature.[115] President Clinton signed the FQPA into law on August 3, 1996.[116]

3. Legislative Reports on the FQPA

The House of Representatives published two reports on the new law, one from the Committee on Commerce[117] and one from the Committee on Agriculture,[118] the Committees that had shared jurisdiction over the bill.[119] These committee reports leave no doubt that the main legislative intent of the FQPA was to increase significantly protections for children by requiring that all future quantitative assessments of risks from pesticide residues consider the special susceptibilities of children.[120]

The House Commerce Committee's Report on the FQPA specifically cited the 1993 report by the NRC of the National Academy of Sciences, "Pesticides in the Diets of Infants and Children,"[121] noting that the NRC's report recommends that where there is evidence of developmental toxicity to

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113. *See* Tin, *supra* note 93, at 1962.

114. *See* Hosansky, *Long Sought Pesticides Bill*, *supra* note 92, at 2031.

115. *See* Hosansky, *Rewrite of Laws*, *supra* note 92, at 2101.

116. *See* Statement by President William J. Clinton upon Signing H.R. 1627, 32 WEEKLY COMP. PRES. DOC. 1402 (Aug. 3, 1996).

117. H.R. REP. NO. 104-669(II) (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268 (Commerce Committee Report).

118. H.R. REP. NO. 104-669(I) (1996), *reprinted in* 1996 U.S.C.C.A.N. 1208 (Agriculture Committee Report).

119. *See* Hosansky, *Future Battles Expected*, *supra* note 79, at 1759.

120. *See* H.R. REP. NO. 104-669 (II), at 42, *reprinted in* 1996 U.S.C.C.A.N. 1268, 1281 (noting that all "tolerances must be safe for children"). The Committee on Commerce stated that "[w]hen data relating to infants and children are incomplete, and also to account for potential pre- and post-natal toxicity, the Administrator is to apply, under new Section 408(b)(2)(C), an additional tenfold margin of safety for infants and children." H.R. REP. NO. 104-669 (II), at 43, *reprinted in* 1996 U.S.C.C.A.N. 1268, 1282. President Clinton also issued a statement upon signing the bill into law which said: "[m]ost importantly, H.R. 1627 contains "*special new provisions to protect America's infants and children from pesticide risks*. These protections will guarantee that every family in America has the safest food possible on their dinner table." Statement by President William J. Clinton Upon Signing H.R. 1627, 32 WEEKLY COMP. PRES. DOC. 1402 (Aug. 3, 1996) (emphasis added).

121. Refers to DIETS OF CHILDREN, *supra* note 19.

children and where toxicity data for children are incomplete, an additional margin of safety factor should be used when setting tolerances.[122]

II. QUANTITATIVE RISK ASSESSMENT: THE CORNERSTONE OF THE FQPA

A. The "Science" of QRA

QRA is scientifically defined as "'the characterization of the potential adverse health effects of human exposures to environmental hazards.'"[123] QRA is generally used for two purposes: (1) to assess the risk from an environmental hazard and then to set some upper level of acceptable risk; and (2) to assess risk from different environmental contaminants and to prioritize the regulation of those risks based on the quantitative assessment of risk.[124] In assessing the risks that pesticide residues pose to humans, the FQPA mainly calls for the EPA to use QRA for the first purpose: to assess the risk of a pesticide and to then define the upper level of acceptable risk from exposure to the pesticide residue.

QRA generally involves four steps: (1) hazard identification; (2) dose response assessment; (3) exposure pathway assessment; and (4) risk characterization.[125] The first step in QRA is for the decision maker to engage in hazard identification.[126] In this step, the researcher uses toxicology and epidemiology to characterize the hazard involved and the potential danger to humans.[127] This is the step in which the risk assessor recognizes

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122. *See* H.R. REP. No. 104-669 (II), at 43, *reprinted in* 1996 U.S.C.C.A.N. 1268, 1282. The National Academy of Sciences Report was the first to recommend that an additional tenfold margin of safety should be *consistently* used with regard to the setting of tolerances to protect the health of infants and children. *See id.* The House Commerce committee noted that the NAS had stated:"'[b]ecause there exist specific periods of vulnerability during postnatal development, the committee recommends that an uncertainty factor up to the 10-fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete.'" *Id.* (citing DIETS OF CHILDREN, *supra* note 19, at 9).

123. Junius C. McElveen, Jr. & Chris Amantea, *Legislating Risk Assessment*, 63 U. CIN. L. REV. 1553, 1579 (1995) (quoting the NAS REDBOOK, *supra* note 2, at 18).

124. *See* Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562,570 (1992).

125. *See* NAS REDBOOK, *supra* note 2, at 19.

126. *See id.*

127. *See id.*

the potential for danger from the environmental factor. Next, the assessor must engage in dose-response assessment for the substance at issue.[128]

> [This] process . . . characteriz[es] the relation between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimat[es] the incidence of the effect as a function of human exposure to the agent. . . . A dose-response assessment usually requires extrapolation from high to low dose and extrapolation from animals to humans.[129]

In this step, the risk assessor assesses the level of the hazardous substance that causes the harm and estimates the amount of times that humans will suffer the detrimental effect if exposed to the harmful agent. The third step in QRA is exposure assessment.[130] Step three requires the risk assessor to consider the manner in which people may be exposed to the identified hazard and to measure or estimate the quantity and intensity of these exposures.[131] Finally, the risk assessor must characterize the health risk to humans by combining the information gained in the first three steps of the process.[132]

Although the process appears apolitical and highly scientific, QRA has been discussed and criticized for its lack of reliability and malleability.[133] "A typical risk assessment consists of about fifty separate assumptions and extrapolations."[134] The QRA process has been compared to a "tortured spy" in that you can ultimately get it to say whatever you want by altering the assumptions on which the analysis is based.[135]

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128. *See* Jeff Gimpel, *The Risk Assessment and Cost Benefit Act of 1995: Regulatory Reform and the Legislation of Science*, 23 J. LEGIS. 61, 73 (1997); McElveen & Amantea, *supra* note 123, at 1585.

129. McElveen & Amantea, *supra* note 123, at 1584 (quoting NAS REDBOOK, *supra* note 2, at 19-20) (footnote omitted).

130. *See* NAS REDBOOK, *supra* note 2, at 20.

131. *See id.*

132. *See* Gimpel, *supra* note 128, at 74.

133. *See generally* Celia Campbell-Mohn & John S. Applegate, *Learning from NEPA: Guidelines for Responsible Risk Legislation*, 23 HARV. ENVT'L L. REV. 93 (1999) (discussing the various points of view regarding the use of QRA in legislation); Gimpel, *supra* note 128, at 89 (asserting that risk quantifications are dependent upon underlying assumptions and they are no more a sound basis for decisionmaking than are policy arguments); McElveen & Amantea, *supra* note 123, at 1579 (outlining the shortcomings of the risk assessment process—overall, it grossly overstates the risk and provides no additional protection); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1625 (1995) (assessing the complicated mix of policy and science in risk assessment decisionmaking).

134. Mark Eliot Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 413 (1995).

135. *See* Keuhn, *supra* note 1, at 103; *see also* Shere, *supra* note 134, at 413.

The National Research Council has identified two inherent limitations on the ability of agencies to perform risk assessment: "inherent limitations on the power of analysis; and practical constraints imposed by external pressures."[136] The NRC has said that the "dominant" inherent difficulty in risk analysis is "pervasive uncertainty:"[137]

> [D]ata may be incomplete, and there is often great uncertainty in estimates of the types, probability, and magnitude of health effects associated with a chemical agent, of the economic effects of a proposed regulatory action, and of the extent of current and possible future human exposures. These problems have no immediate solutions, given the many gaps in our understanding of the causal mechanisms of carcinogenesis and other health effects . . . associated with specific exposures. Because our knowledge is limited, conclusive direct evidence of a threat to human health is rare.[138]

Additionally, the NRC has identified two other major inherent limitations on risk assessment: (1) the availability of limited analytic resources to recognize and assess the potential toxins; and (2) the complexity of the assessment process once it is undertaken.[139] In addition to inherent limitations, the NRC has identified the public's concern for safety, the obvious economic interests at stake and the legislative prerogative as external limitations on the risk assessment process.[140]

The pervasive uncertainty inherent in the risk assessment process dictates that EPA scientists fill in scientific gaps, taking into account external social and economic factors, political considerations, and their own personal value judgements when making risk assessments.[141] For example, at the hazard identification and the dose response stages, a risk assessor using animal studies[142] must make certain fundamental assumptions,[143] including the

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136. NAS REDBOOK, *supra* note 2, at 11.

137. *See id.*

138. *Id.; see also* Thomas O. McGarity, *A Cost-Benefit State*, 50 ADMIN. L. REV. 7, 13 (1998) (noting that the data underlying a risk assessment is never complete and that "even risk assessments costing millions of dollars are not very accurate.").

139. *See* NAS REDBOOK, *supra* note 2, at 12.

140. *See id.* at 13-14.

141. *See* Wagner, *supra* note 133, at 1625-27 (considering the EPA's regulation of formaldehyde and noting that on the way to determining what level of formaldehyde is safe for humans in drinking water, scientists must make many jumps in analysis to account for gaps in scientific knowledge); *see also* Mohn & Applegate, *supra* note 133, at 96-97.

142. *See* Wagner, *supra* note 133, at 1613, 1625-26.

143. These inferences are also often known as "default assumptions." *See* McElveen & Amantea, *supra* note 123, at 1582 (quoting REGULATORY IMPACT ANALYSIS PROJECT, INC.,

assumption that humans and animals will react to a toxin in a similar way and that low doses on humans will yield a toxic effect similar to the effect of high doses on animals.[144] When the risk assessor is considering risks to children, the complexity is multiplied. The researcher is forced to consider whether humans would respond to a toxin in the same manner as animals, and whether children will respond in the same manner as the immature animal specimens.[145]

Similarly, when performing the exposure assessment portion of the QRA, the risk assessor must make many other assumptions. To assess the risks of an environmental contaminant found in the air, such as the pesticide methyl bromide,[146] the risk assessor must make assumptions about air dispersion patterns, the quantity of the pesticide that the wind will actually carry, human inhalation rates, and the length of exposure.[147] With regard to pesticides on food, the exposure assessment portion of the QRA requires the assessor to make assumptions about the percent of the crop treated,[148] the amount of pesticide residue that is on the product when received by the consumer, the quantity of the product that is consumed and about how and

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CHOICES IN RISK ASSESSMENT: THE ROLE OF SCIENCE POLICY IN THE ENVIRONMENTAL RISK MANAGEMENT PROCESS 26 (prepublication copy 1994) (on file with author)).

In terms of cancer risk assessment, for example, it has been urged that a risk assessor must make ten major default assumptions. *See id.* These include assumptions that the substance that is carcinogenic in animals is carcinogenic in humans, that a highdose exposure in animals will be toxic to humans at a low dose, that the combined number of benign and malignant tumors in animals is indicative of the cancer rate in humans, and that the dose response curve is linear at low doses. *See id.*

144. *See* Wagner, *supra* note 133, at 1621, 1625-26 (identifying these assumptions as answers to trans-scientific questions that arise because of practical and theoretical limitations on scientific experimentation).

For a complete discussion of the required assumptions to perform a QRA, see McElveen & Amantea, *supra* note 123, at 1580-89; NAS REDBOOK, *supra* note 2, at 29-33 (the trans-scientific assumptions at all stages of QRA).

145. As the NRC concluded in its report, "Pesticide in the Diets of Infants and Young Children," differences in the way immature animals and humans develop exist and differences in the manner in which they respond to a stimulus are thus likely to exist. DIETS OF CHILDREN, *supra* note 19, at 25, 29.

146. Methyl bromide is commonly applied near residences and schools in California. *See* Jenifer Warren, *Opponents of Pesticide Cite Risk to Schools*, L.A. TIMES, Jan. 8, 1996, at A1. Methyl bromide is used on strawberry plants to kill fungus. *See id.* Californians are concerned about the drift of methyl bromide because it is a suspected human carcinogen, neurotoxin, and disputer of the hormone function. *See id.*

147. For a thorough discussion of this difficulty related to exposure assessment in the context of soil, air and dust, see McElveen & Amantea, *supra* note 123, at 1586-88.

148. *See* 21 U.S.C. § 346a(b)(2)(F) (1994 & Supp. III 1997) (allowing the risk assessor to reduce the assumption that one hundred percent of the crop was treated based on reliable information that does not underestimate public exposure).

whether it is actually absorbed by the consumer.[149] At the exposure assessment stage, one author has said that "almost every single number in this area may be modified, with relative impunity, by the risk assessor."[150]

The many assumptions required in the QRA process call into question the reliability of any resulting risk characterization.[151] In this regard, QRA is "almost always used to produce estimates that defy objective verification."[152] This uncertainty in the QRA process as it relates to the FQPA is discussed in Parts III.B & III.C below in the context of the EPA's current implementation of the Act.

B. The Food Quality Protection Act's Changes to FFDCA as They Relate to Infants and Children

1. Overview

Although the FQPA still calls for the EPA to use QRA to regulate pesticides, the Act effectuated three major changes in the regulation of pesticides and their use on food products.[153] First, the FQPA contains provisions specifically designed to protect the health of infants and children.[154] The most significant aspect of these protections for children is

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149. *See* McElveen & Amantea, *supra* note 123, at 1588.

150. *Id.* at 1586.

151. *See* NAS REDBOOK, *supra* note 2, 29-33 (including a lengthy list of trans-scientific junctures in the QRA process but cautioning that the list is not exhaustive or complete); Wagner, *supra* note 133, at 1625-27 (noting that trans-scientific questions must be answered with nonscientific information and that these decisions will have a profound impact on the resulting analysis).

152. Shere, *supra* note 134, at 412.

153. *See generally,* Andrew J. Miller, *The Food Quality Protection Act of 1996: Science and Law at a Crossroads*, 7 DUKE ENVTL. L. & POL'Y 393 (1997) (calling on science to go beyond traditional goals and synthesize information to allow for the quantification of risks); Kenneth Weinstein et al., *The Food Quality Protection Act: A New Way of Looking at Pesticides*, 28 ENVTL. L. REP. 10555 (1998) (asserting that QRA should prescribe the maximum amount of pesticide residue allowed in food); Allison D. Carpenter, Note, *Impact of The Food Quality Protection Act of 1996*, 3 ENVTL. LAW. 479 (1997) (finding that the FQPA will provide more protection for children).

154. In passing the bill, Representative Dingell, the ranking member of the House Commerce Committee, stated: "[s]pecifically, the legislation adopts the widely held view that special attention must be paid to dietary habits and health needs of special populations, such as children . . . ." 142 CONG. REC. H8143 (daily ed. July 23, 1996). "It contains requirements for tolerance setting which are directly responsible to the recommendations of the National Research Council's report on 'Pesticides in the Diets of Infants and Children.'" 142 CONG. REC. H8143 (daily ed. July 23, 1996) (statement of Rep. Bilirakis). And similarly, the Chairman of the Committee on Agriculture,

faithful to the NRC report.[155] It requires the EPA to quantitatively assess the risks of a given pesticide residue and use an additional ten-fold margin of safety when setting tolerances[156] for certain pesticide residues on food unless reliable data exists to suggest that some other margin will be safe for infants and children.[157] The FQPA also requires the EPA to take into account the special susceptibilities and consumption habits of infants and children in establishing, modifying or revoking all pesticide tolerances.[158]

Second, the Act requires the EPA to consider—for the first time—all of the different exposures to pesticides that adults and children face when setting tolerances for pesticide use on food.[159] This provision requires the EPA to consider a consumer's aggregate exposure to pesticide residues, including nonfood sources of exposure, such as exposure through the air and water.[160]

Third, the FQPA eliminated Delaney's zero tolerance standard for carcinogenic substances in processed foods and replaced it with a negligible risk standard for all foods. This standard requires the EPA to ensure that there is a reasonable certainly that no harm will result from aggregate exposure to a pesticide residue from food and all other exposures.[161] This standard is generally assumed to mean that there exists a one-in-one-million chance that an effect will occur.[162]

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of Sciences in 1993, EPA is required to give special consideration to infants and children when setting pesticide residue tolerances." 142 CONG. REC. S8737 (daily ed. July 24, 1996).

155. *See* DIETS OF CHILDREN, *supra*, note 19.

156. The EPA sets all tolerances for pesticide residues on food. *See, e.g.*, 21 U.S.C. § 342 (1994 & Supp. III 1997); 21 U.S.C. § 346a(a)(1)(A) (1994 & Supp. III 1997); *see also* DIETS OF CHILDREN, *supra* note 19, at 1.

157. *See* 21 U.S.C. § 346a(b)(2)(C)(ii) (1994 & Supp. III 1997); "For pesticides with threshold effects, an additional tenfold margin of safety shall be applied for infants and children, except EPA may use a different margin of safety on the basis of reliable data." 142 CONG. REC. S8737 (daily ed. July 24, 1996) (statement by Sen Lugar).

158. *See* 21 U.S.C. § 346a(b)(2)(C) (1994 & Supp. III 1997).

159. *See* 21 U.S.C. § 346a(b)(2)(A)(ii) (1994 & Supp. III 1997); Jan Hollingsworth, *Urban Application of Malathion Questionable*, TAMPA TRIBUNE, Feb. 2, 1998, available in 1998 WL 2763350; HERBERT L. NEEDLEMAN, M.D. & PHILIP J. LANDRIGAN, M.D., RAISING CHILDREN TOXIC FREE 129 (1994) ("Pesticide use needs to be minimized in all sectors of our society—in agriculture, in the home, on lawns, in gardens, and in schools and playgrounds.").

160. *See* 21 U.S.C. § 346a(b)(2)(A)(ii); 21 U.S.C. § 346a(b)(2)(D)(iv) (1994 & Supp. III 1997).

161. *See* 21 U.S.C. § 346a(b)(2)(A)(ii); Letter from Lynn Goldman, Assistant Administrator of the EPA, to Representative Henry Waxman 1 (Mar. 17, 1998) (on file with author).

162. *See* Jay Michaelson, *Rethinking Regulatory Reform: Toxics, Politics, and Ethics*, 105 YALE L.J. 1891, 1899 (1996). This negligible risk standard is intended to take into account the notion that food cannot ever be perfectly safe in that scientists currently have the ability to detect trace amounts of harmful substances in our food supply, which, it has been argued, pose only a

2. The Negligible Risk Standard for Adults and Children Alike

The FQPA thus defines two different types of pesticides: (1) those as to which the administrator cannot define a safe level of pesticide residue, generally involving cancer risk (the "nonthreshold effect"),[163] and (2) those as to which the administrator is able to identify a level at which the residue will not cause harm (the "threshold effect").[164] Notwithstanding the requirement that there be a reasonable certainty of no harm to children[165] or adults[166] from aggregate exposure to a pesticide, the FQPA allows the EPA to consider the benefits[167] of a pesticide when assessing nonthreshold effects to set or modify a tolerance.[168] Thus, the EPA may establish or modify a current tolerance for a pesticide if the pesticide is more protective of human health than it is harmful[169] or if use of the pesticide avoids a significant disruption to the domestic food supply.[170] However, in establishing such a tolerance, the FQPA limits the EPA's discretion, specifying that the yearly risk for such tolerances may not be more risky than ten times what is considered a standard negligible risk level[171] and that the lifetime risk may not be greater than twice an acceptable level of negligible risk.[172] The FQPA

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negligible risk of harm. *See* Les v. Reilly, 968 F.2d 985, 987 (9th Cir. 1992) (argument regarding trace amounts).

163. *See* 21 U.S.C. § 346a(b)(2)(B)(i)(I) (1994 & Supp. III 1997).

164. *See* 21 U.S.C. § 346a(b)(2)(B)(i)(III) (1994 & Supp. III 1997).

165. *See* 21 U.S.C. § 346a(b)(2)(C)(ii) (1994 & Supp. III 1997).

166. *See* 21 U.S.C. § 346a(b)(2)(A)(i) (1994 & Supp. III 1997); 21 U.S.C. § 346a(b)(2)(A)(ii) (1994 & Supp. III 1997). The words of the statute, "[n]otwithstanding the requirements of subparagraph (A)(1)" (the paragraph calling for safety in all tolerances) seem to contradict the main legislative intent of the statute to ensure that "[a]ll tolerances must be safe for children." H.R. REP. NO. 669, 104th Cong., 2d Sess., pt. 2, at 42 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1281; 21 U.S.C. § 346a(b)(2)(C)(ii).

167. *See* 21 U.S.C. § 346a(b)(2)(B) (1994 & Supp. III 1997). For a discussion of the appropriateness of considering the cost and benefits of environmental regulations, see generally, David M. Driesen, *The Societal Cost of Environmental Regulation: Beyond Administrative Cost-Benefit Analysis*, 24 ECOLOGY L.Q. 545 (1997).

168. *See* 21 U.S.C. § 346a(b)(2)(B)(ii) (1994 & Supp. III 1997).

169. *See* 21 U.S.C. § 346a(b)(2)(B)(iii)(I) (1994 & Supp. III 1997).

170. *See* 21 U.S.C. § 346a(b)(2)(B)(iii)(II) (1994 & Supp. III 1997). One problem with using a risk benefit analysis is that it assumes that a certain amount of risk is acceptable. Even assuming that we are willing to weigh human health against economic production figures, many would agree that the risk of any new cancers in children is a far more grave one and heavily outweighs any concern to produce food more economically. *See* Moran, *supra* note 66, at 1140-41 (citing Donella Meadows, *Pesticide Research for Tougher Laws Isn't There*, CHARLESTON GAZETTE & DAILY MAIL, Oct. 7, 1996, at 4A.); *see also infra* notes 320, 322-25 and accompanying text.

171. *See* 21 U.S.C. § 346a(b)(2)(B)(iv)(I) (1994 & Supp. III 1997).

172. *See* 21 U.S.C. § 346a(b)(2)(B)(iv)(II) (1994 & Supp. III 1997); Moran, *supra* note 66, at 1137.

does not, however, define negligible risk numerically.[173] Making the standard assumption that negligible risk generally means a one-in-one-million chance that an effect will occur,[174] yearly cancer risk could range from one-in-one-million to one-in-one-hundred-thousand if the exposure to the risk only spans one year, and from one-in-one-million to one-in-five-hundred-thousand if the exposure spans a lifetime.[175]

3. The FQPA's Specific Protections for Children

Many of the Act's specific protections for children are contained in a distinct subparagraph on standards with regard to infants and children. This subparagraph requires the EPA to "ensure that there is a reasonable certainty that no harm will result [specifically] to infants and children from aggregate exposure to the pesticide chemical residues"[176] and to publish a "determination regarding the safety of [a] particular pesticide chemical residue for infants and children."[177] In ensuring that there is a reasonable certainty that no harm will result to infants and children from the threshold effects of a pesticide, the FQPA requires the EPA to multiply the generally used hundred-fold margin of safety by an additional factor of ten where there is evidence of developmental toxicity or where exposure or toxicity data is incomplete.[178] The law only allows the EPA to forego use of the extra tenfold safety factor if, on the basis of reliable data, such margin will be safe for infants and children.[179] This provision requiring the extra tenfold safety factor to account for the special susceptibilities of children is the heart of the added protections for children in the FQPA.[180]

Additionally, in ensuring the safety of tolerances for children, the FQPA requires the administrator of the EPA to quantitatively assess the risk of a pesticide based on three child-specific factors: (1) "available information about [children's] consumption patterns . . ." that result in their consumption of a disproportionately high amount of certain foods;[181] (2) "available

173. *See* 21 U.S.C. § 346a(b)(2)(B)(iv) (1994 & Supp. III 1997). Congress, however, appeared to have understood the negligible risk standard to mean a one-in-a-million chance that an effect would occur. *See* H.R. REP. NO. 669, 104th Cong., 2d Sess., pt. 2, at 41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1280.

174. *See* Michaelson, *supra* note 162, at 1891, 1899.

175. Bauer, *supra* note 25, at 1399.

176. 21 U.S.C. § 346a(b)(2)(C)(ii)(I) (1994 & Supp. III 1997).

177. 21 U.S.C. § 346a(b)(2)(C)(ii)(II) (1994 & Supp. III 1997).

178. *See* 21 U.S.C. § 346a(b)(2)(C).

179. *See* 21 U.S.C. § 346a(b)(2)(C).

180. *See id.*

181. 21 U.S.C. § 346a(b)(2)(C)(i)(I) (1994 & Supp. III 1997).

information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticide chemicals;"[182] (3) and "available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity . . . ."[183]

The FQPA also outlines general factors that the Administrator shall consider when establishing or affecting a tolerance for a pesticide chemical residue and these factors call additional attention to the unique dangers that pesticides pose to the health of children.[184] For example, these factors require the EPA to consider the "dietary consumption patterns of consumers,"[185] available information concerning aggregate pesticide exposure levels[186] and common mechanisms of toxicity.[187] They hint at the concern that children tend to eat a less varied diet than adults,[188] and thus, might be exposed to many different pesticides with a similar toxic effect on a regular basis. Additionally, they require the EPA to consider whether the pesticide will have an effect on the human endocrine system, an effect that could be particularly damaging to a developing fetus or child.[189] Thus, for example, when setting a food use tolerance for vinclozolin on snap beans, the EPA is supposed to include in its exposure assessment, possible exposure to the pesticide in drinking water, [190] consideration of the fact that vinclozolin acts in a similar toxic manner to procymidone and iprodione[191] (two other pesticides used on food), consideration of whether it has an estrogenic effect

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182. 21 U.S.C. § 346a(b)(2)(C)(i)(II) (1994 & Supp. III 1997).

183. 21 U.S.C. § 346a(b)(2)(C)(I)(III) (1994 & Supp. III 1997); *see also* Hollingsworth, *supra* note 159.

184. *See* 21 U.S.C. § 346a(b)(2)(D) (1994 & Supp. III 1997).

185. 21 U.S.C. § 346a(b)(2)(D)(iv) (1994 & Supp. III 1997).

186. *See id.*

187. *See* 21 U.S.C. § 346a(b)(2)(D)(v) (1994 & Supp. III 1997).

188. *See* WILES ET AL. *supra* note 59, at 15.

189. *See* 21 U.S.C. § 346a(b)(2)(D)(viii) (1994 & Supp. III 1997). The FQPA also requires the Administrator to establish a screening program to study the endocronic effects of pesticides by August 3, 1999 and to report to Congress on its findings by August 3, 2000. *See* 21 U.S.C. 346a(p) (1994 & Supp. III 1997). Additionally, the Act required the EPA to publish a consumer brochure on pesticides in the diet for distribution in supermarkets nationally. *See* 21 U.S.C. § 346a(b)(o) (1994 & Supp. III 1997); *see also EPA Pesticide Brochure*, CHEM. WEEK, Jan. 28, 1998, *available in* 1998 WL 8248897 (noting that American Crop Association complained that the then current draft of the brochure was alarmist). The EPA did, in fact, publish a version of this brochure entitled EPA, OFFICE OF PESTICIDE PROGRAMS, PESTICIDES AND FOOD, WHAT YOU AND YOUR FAMILY NEED TO KNOW (undated).

190. *See* 21 U.S.C. § 346a(b)(2)(D)(vi) (1994 & Supp. III 1997).

191. *See* 21 U.S.C. § 346a(b)(2)(D)(v) (1994 & Supp. III 1997); *see infra* notes 248-249 and accompanying text.

in adults or children[192] and consideration of whether it may effect children differently than adults because of their sensitivities[193] or consumption habits.[194]

III. THE EPA'S USE OF SCIENCE AND RISK ASSESSMENT TO MAINTAIN THE STATUS QUO

A. Failure to Implement the Food Quality Protection Act's Safeguards for Children[195]

In at least three respects, the EPA has been remiss in implementing FQPA. First, in accord with the legislative requirements contained in the FQPA, the EPA is required to review the approximately 10,000 existing pesticide tolerances by the year 2006.[196] It was supposed to have reviewed 33 percent of all such tolerances by August 1999, continue to review an additional 33 percent by August 2002, and complete its review by August 2006. Pursuant to an FQPA mandate, the EPA was to review the riskiest tolerances first.[197] Yet, pursuant to its own schedule listing pesticides by risk,[198] the EPA has not completed reassessment of the riskiest pesticides first.[199] Instead, as of August 1999, the agency had mainly revoked tolerances that were no longer in use and reassessed tolerances that pose little or no risk.[200] On this basis, the NRDC and other health and civic

192. *See* 21 U.S.C. § 346a(b)(2)(D)(viii) (1994 & Supp. III 1997).

193. *See* 21 U.S.C. § 346a(b)(2)(D)(vii) (1994 & Supp. III 1997).

194. *See* 21 U.S.C. § 346a(b)(2)(D)(iv) (1994 & Supp. III 1997).

195. Another major controversy surrounding QRA is the argument that it disproportionately allocates the bulk of environmental risks to minority and poor communities because of a lack of social awareness and increased susceptibility. *See* Brian D. Israel, *An Environmental Justice Critique of Risk Assessment*, 3 N.Y.U. ENVTL. L.J. 469, 479-80 (1995).

196. *See* EPA, Raw and Processed Food Schedule for Pesticide Tolerance Reassessment; Notices, 62 Fed. Reg. 42,020, 42,020 (1997) [hereinafter Schedule for Reassassment]; Letter from Susan H. Wayland, Acting Assistant Administrator of the EPA, to Congressman Henry Waxman 1-6 (Feb. 22, 1999) (detailing the EPA's tolerance reassessment efforts).

197. *See* 21 U.S.C. § 346a(q)(2) (1994 & Supp. III 1997); Schedule for Reassessment, *supra* note 196.

198. *See* Schedule for Reassessment, *supra* note 196.

199. *See* Complaint for the Natural Resources Defense Council at 1, NRDC v. Browner, (C99-3701) (N.D.Cal. 1999) [hereinafter NRDC Complaint].

200. *See id.* at 15-16. In two tolerance decisions out of some 3000 the EPA claims to have made since Congress passed the FQPA, the EPA has reportedly banned the use of methyl parathion and limited the use of azinophos methyl. *See* Matthew L. Wald, *Citing Children, EPA Is Limiting Use of a Pesticide*, N.Y.TIMES, Aug. 3, 1999, at A1; DEPT. OF COMMUNICATIONS, EDUCATION, AND MEDIA RELATIONS, EPA, EPA ACTS TO REDUCE CHILDREN'S EXPOSURE TO TWO OLDER,

organizations have filed suit against the agency for "failing to meet statutory deadlines for protecting children, workers, the general public, and the environment from high-risk pesticides."[201]

Second, in making tolerance decisions, the EPA has not routinely or consistently applied the additional tenfold safety factor to protect children.[202] As of March 15, 1999, the EPA reported that it had made 120 regulatory decisions under the FQPA, and that it had applied the tenfold additional child safety factor in only fifteen of those 120 decisions.[203] In fifteen of the remaining 105 decisions, it has applied a threefold margin of safety, and in the remaining ninety cases, it has used no safety factor to increase protections for children.[204] The EPA generally continues to use a standard safety factor of hundred-fold[205] without taking into account the special susceptibility of infants and children to pesticides, unless specific research data exists to show that the pesticide is toxic to infants and children.[206]

WIDELY USED PESTICIDES (1999); Peter Eisler, *Toughest Decisions Still to Come in Review, Congress Wanted the Rules Updated, but Politics Slowing Process*, USA TODAY, Aug. 30, 1999, at A1. Critics charge that these two decisions, while reportedly significant, *see* Wald, *supra*, were not meaningful in that methyl parathion is already "banned in nations as diverse as Argentina and the Philippines" and that the "new azinophos methyl limits still allow higher concentrations than farmers generally use," Eisler, *supra*, at 1A.

201. NRDC Complaint, *supra* note 199, at 2. Additionally, the complaint alleges that the EPA has failed to implement an endocrine disrupters screening and testing program as required by the FQPA. *See id.* at 18-21; 21 U.S.C. § 346a(p)(2) (1994 & Supp. III 1997). The NRDC seeks declaratory and injunctive relief against the EPA and the case is currently pending in the Northern District of California.

In stark contrast to the allegations by NRDC, the American Farm Bureau Association has previously filed suit against the EPA over its implementation of the FQPA, urging that it is moving too fast in its implementation of the Act. *Farm Bureau Lawsuit Could Result in Heavy Data 'Burden' for Industry*, FOOD CHEM. NEWS, June 28, 1999, *available in* 1999 WL 9625915. Specifically, the Association seeks rulemaking as to when and how the tenfold safety factor should be applied. *See id.* The EPA has asked the court to dismiss the suit. *EPA Asks Court to Dismiss Lawsuit Concerning FQPA*, CHEM. MKT. RPTR., Sept. 20, 1999, *available in* 1999 WL 22724471.

202. *See* OFFICE OF PREVENTION, EPA, 10X SAFETY FACTOR SHEET, PESTICIDES AND TOXIC SUBSTANCES 1 (1999) (hereinafter 10X SAFETY FACTOR SHEET).

203. *See id.*; *see also* Letter from Patti Goldman, Counsel to Earthjustice Legal Defense Fund and the NRDC, to Besie Hammiel, EPA 1, 2 (Jan. 23, 1998) (noting that in the first year of the EPA's implementation, the EPA issued 90 tolerances, but only applied the tenfold safety factor in nine of those situations; and that in November 1997 alone, the EPA issued ten additional tolerances and did not apply the additional tenfold safety factor in setting any of them).

204. *See* 10X SAFETY FACTOR SHEET, *supra* note 202, at 1; *see also* Letter from Patti Goldman to Bessie Hammiel, *supra* note 203, at 1-2.

205. *See supra* notes 23-32 and accompanying text.

206. *See* Letter from Patti Goldman, Counsel to Earthjustice Legal Defense Fund, to Lynn Goldman, Assistant Administrator, EPA 2 (Sept. 9, 1998); 10X SAFETY FACTOR SHEET, *supra* note 202, at 1.

Third, although the FQPA requires the EPA to assess a pesticide for a broader range of toxic effects than previously required, the EPA has still not required prospective pesticide registrants to test for these effects in adults or children.[207] For example, the "core" or mandatory tests do not effectively require a prospective registrant to test a pesticide for effects on the adult or immature immune system or for effects on a child's developing neurological system.[208]

In August 1999, however, the EPA announced that for the first time, it will require registrants of a limited number of pesticides to conduct and submit acute, subchronic and developmental neurotoxicity studies within two years of October 1999.[209] This new requirement will call for registrants of

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207. The EPA convened a task force to provide guidance about the use of the 10X safety factor (the "10X Task Force"). On July 8, 1999, the EPA released documents describing the deliberations and conclusions of the 10X Task Force. *See generally* TOXICOLOGY WORKING GROUP OF THE 10X TASK FORCE, EPA, TOXICOLOGY DATA REQUIREMENTS FOR ASSESSING RULES OF PESTICIDE EXPOSURE TO CHILDREN'S HEALTH (1998) [hereinafter TOXICOLOGY WORKING GROUP DOCUMENT] and OFFICE OF PESTICIDE PROGRAMS, EPA, EXPOSURE DATA REQUIREMENT FOR ASSESSING RISKS OF PESTICIDE EXPOSURE TO CHILDREN (1999).

One segment of the 10X Task Force, the Toxicology Working Group, considered the core toxicology data required for assessing risks of pesticides to children, and concluded that in order to comply with the FQPA, the core toxicology data set should include a developmental neurotoxicity test to assess the potential neurological effects of pesticides on developing rodents. *See* TOXICOLOGY WORKING GROUP DOCUMENT, *supra* at 9, 11-13. As this article goes to press, however, the EPA has only begun to implement this proposed change to the core testing requirements for pesticide registration. *See infra* notes 209-212; 40 C.F.R. § 158.340 (1999) (containing the EPA's data requirements for registration of pesticides). On July 8, 1999, the EPA announced that two other science policy papers are available for public comment: OFFICE OF PESTICIDE PROGRAMS, EPA, THE OFFICE OF PESTICIDE PROGRAMS' POLICY ON DETERMINATION OF THE APPROPRIATE FQPA SAFETY FACTOR(S) FOR USE IN THE TOLERANCE-SETTING PROCESS and OFFICE OF PESTICIDE PROGRAMS, EPA, STANDARD OPERATING PROCEDURES (SOP) FOR DETERMINING THE APPROPRIATE FQPA SAFETY FACTORS FOR USE IN TOLERANCE ASSESSMENT. The Office of Pesticide Programs Policy documents discuss future plans to revise the EPA's data requirements to include neurotoxicity, immunotoxicity, and dermal studies.

208. *See* 40 C.F.R. § 158.340 (1999). Additionally, the testing guidelines, which provide detail to the laboratories performing tests as to how a test should be conducted and how extensively a pesticide chemical should be tested, do not reflect the new regulatory paradigm. *See* EPA, SERIES 870 TOXICITY TESTING GUIDELINES (1998). These guidelines have harmonized testing protocols with European testing guidelines and the Toxic Substances Control Act, but still fail to provide a reasonable certainty of no harm to infants and children. *See* WALLINGA, *supra* note 30 at 25-40.

209. *See* Karen L. Werner, *Pesticides: EPA Announces Neurotoxicity Data Call-In; Organophosphates Targeted by First Phase*, BNA CHEMICAL REGULATION DAILY, Aug. 6, 1999, at A-10; *EPA Announces Data Call-ins for Neurotoxicity Tests*, PESTICIDE & TOXIC CHEM. NEWS, Aug. 12, 1999, available in 1999 WL 9623967. This action comes at least partially in response to urging by nine national children's, educational, civic and environmental organizations. *See generally* Letter to Carol Browner, Administrator, EPA, from Learning Disabilities Association of America et al. (May 12, 1999); NATIONAL ORGANIZATIONS URGE EPA TO TEST PESTICIDES FOR IMPACT ON KIDS DEVELOPING NERVOUS SYSTEMS, May 12, 1999.

approximately 40 chemicals[210] to conduct studies to consider whether these chemicals can affect the adult nervous system and/or the development of a child's nervous system.[211] During the study period, affected registrants will be permitted to "call in" data and the affected pesticides will most likely remain on the market and available for use. This process is typically known as a "Data Call In" or "DCI."[212] It is not clear how the EPA will treat the FQPA tenfold safety factor for the affected chemicals while the studies are being conducted.[213] The EPA has stated, however, that it will use the data from the studies to address the requirement of an additional tenfold margin of safety.[214] Given this statement and the EPA's previous track record of FQPA implementation, it appears likely that the EPA will not apply the tenfold safety factor when setting tolerances on even the limited number of chemicals affected by the first phase of the DCI.[215]

This is particularly disturbing in that "core" testing requirements currently in place require pesticide registrants to perform only two tests to assess the developmental effects of a pesticide on infants and children before registering a pesticide for use.[216] These tests do not even begin to portray fully the potential effects of a pesticide on a growing child.[217] For example, one of the two required "core" tests is a prenatal developmental toxicity study in which the maternal animal is dosed with the pesticide.[218] The researcher then kills the animal before the birth of the fetus and the fetus and mother are examined to see if the pesticide affected the fetus.[219] The limits of this study are clear: it does not consider the long-term effects on the animal dosed with the pesticide prenatally.[220]

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210. *See* Werner, *supra* note 209, at A-10.

211. *See* EPA, NEW DATA WILL HELP ENSURE PROTECTION OF CHILDREN (1999) [hereinafter EPA ANNOUNCEMENT].

212. The EPA plans to conduct the DCI in phases. This process will involve approximately 140 pesticides in two phases. *See* Werner, *supra* note 209, at A-10.

213. *See* Werner, *supra* note 209, at A-10.

214. *See* EPA ANNOUNCEMENT, *supra* note 211; *see also* 21 U.S.C. § 346a(b)(2)(C) (1994 & Supp. III 1997).

215. *See* 21 U.S.C. § 346a(b)(2)(C) (referring to the Administrator's ability to depart from the tenfold safety factor).

216. *See* 40 C.F.R. 158.340 (1999); DIETS OF CHILDREN, *supra* note 19, at 145-48; TOXICOLOGY WORKING GROUP DOCUMENT, *supra* note 207, at 9, 11-13 (noting that the EPA is considering an addition to its core testing requirements to require a developmental neurotoxicity study in rodents).

217. *See* WALLINGA, *supra* note 30, at 27-38.

218. *See* 40 C.F.R. § 158.340.

219. *See* WALLINGA, *supra* note 30, at 33. Of course, if multiple fetuses are observed, they are each examined. *See* DIETS OF CHILDREN, *supra* note 19, at 145-48.

220. *See* WALLINGA, *supra* note 30, at 33.

The second required test concerning the effects on infants and children is a two generation reproductive study.[221] This study does not fill in the gaps for the developmental toxicity study discussed above. In this study, the mother rat is dosed with a pesticide.[222] The researcher then studies the reproductive function of both the maternal animal and the fetuses for approximately three months, roughly until they are at an age equivalent to a person in their late teens, and then sacrifices the animals.[223] This study does not even attempt to consider long-term reproductive effects of exposure to the pesticide, nor does it consider other effects of prenatal exposure to the pesticide, such as potential effects on heart, brain or lung function.[224]

This lack of broad and thorough testing requirements, particularly as to developmental effects on children, is troublesome in that toxicity testing is expensive[225] and the EPA typically uses data provided by registrants to quantitatively assess the toxic effects of a pesticide.[226] If pesticide registrants are not required to provide this broad range of toxicity and exposure information, the agency cannot possibly make all of the risk assessments called for by the FQPA.

B. How the EPA Uses Risk Assessment and Science To Justify Lax Enforcement of the FQPA

1. The NRDC Challenge to EPA's Lack of Enforcement

In September 1997, the Natural Resources Defense Council and other organizations (referred to hereinafter as NRDC) filed written objections challenging the Agency's failure to enforce the FQPA's child protective features in issuing a tolerance decision[227] for vinclozolin on snap beans.[228]

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221. *See* 40 C.F.R. § 158.340; WALLINGA, *supra* note 30, at 35.

222. *See* WALLINGA, *supra* note 30, at 33.

223. *See id.* at 36.

224. *See id.* at 35-36.

225. *See id.* at 25.

226. *See id.* Testing requirements consistent with the FQPA would call for testing of immature animals before and after birth for a broader range of toxic effects. *See id.* at 48-49.

227. *See* Vinclozolin; Pesticide Tolerance, 62 Fed. Reg. 38,464 (1997) (to be codified at 40 C.F.R. pts. 180, 185 & 186).

228. *See* REVISED HEARING REQUEST, *supra* note 13; VINCLOZOLIN CHALLENGE, *supra* note 13. In summary, the NRDC argued in its Challenge that the EPA should have applied the 10X safety factor because: 1) the data revealed alarming toxicity to fetuses and humans; 2) EPA's claim that it had a complete database under existing guidelines did not justify its failure to use the tenfold additional safety factor as Congress had found the existing data inadequate to protect children; and

The NRDC challenged the Agency's (1) failure to use the additional tenfold safety factor in establishing a tolerance for the use of vinclozolin on snap beans;[229] (2) failure to consider the fact that two other pesticides act in a similarly toxic manner to vinclozolin;[230] and (3) failure to use complete and traditional exposure estimates[231] in assessing the risk of vinclozolin pursuant to the FQPA.[232] Subsequent to the NRDC's petition in the VINCLOZOLIN CHALLENGE, the NRDC wrote a letter to the EPA in January 1998, noting that the EPA had failed to apply the child protective tenfold safety factor in ten additional tolerance decisions.[233] The NRDC noted:

> [b]ecause our vinclozolin objections *challenge EPA's legal interpretation of the FQPA* safety standard, and this interpretation is manifesting itself in the *vast majority of tolerances* being issued under that Act, we ask EPA to resolve our *broader challenge* to

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3) the EPA did not focus on the inadequacy of data regarding children's exposure to Vinclozolin. *See* VINCLOZOLIN CHALLENGE, *supra* note 13, at 22-26. In its Revised Hearing Request, the NRDC outlines the factual issues on which it seeks a hearing with regard to the vinclozolin tolerance decision. *See* REVISED HEARING REQUEST, *supra* note 13, at 4-17. Specifically, the NRDC reiterated its position, to wit, that the EPA did not have reliable and complete toxicity with regard to neuro-behavioral effects and the special sensitivities of infants and children to vinclozolin; that it did not consider the danger from cumulative exposure to the common metabolite vinclozolin shares with iprodione and procymidone; that the EPA did not have complete and reliable data with regard to the specific exposure patterns of infants and children; and that it did not use conservative exposure estimates. *See id.* at 5-27. The Revised Hearing Request also highlights the changes the FQPA made to FFDCA in terms of authorizing the administrative tribunal to issue subpoenas to compel production of documents or testimony. *See id.* at 2-4; *see also* 21 U.S.C. § 346a(g)(2)(B) (1994 & Supp. III 1997). And finally, the Revised Hearing Request discusses difficulties the NRDC has had in obtaining the administrative record relevant to the vinclozolin tolerance decision. *See* REVISED HEARING REQUEST, *supra* note 13, at 1-2.

229. *See* VINCLOZOLIN CHALLENGE, *supra* note 13, at 9-12, 19-27; 21 U.S.C. § 346a(b)(2)(C) (1994 & Supp. III 1997).

230. *See* VINCLOZOLIN CHALLENGE, *supra* note 13, at 12-16, 27-30; 21 U.S.C. § 346a(b)(2)(D)(v) (1994 & Supp. III 1997). Vinclozolin is a fungicide produced by the BASF Corporation and sold under the name Ronilan. *See* VINCLOZOLIN CHALLENGE, *supra* note 13, at 3. Vinclozolin has been shown to "[d]isrupt the endocrine system, which regulates the release of hormones" into the human body and controls sexual development. *See id.* at 4. In one study in which it was given to female rats, male offspring exhibited nipple development, anogenital distance and cleft phallus. *See id.* (citing Gray, Fostby & Kelce, *Developmental Effects of an Environmental Antiandrogen: The Fungicide Vinclozolin Alters Sex Differentiation of the Male Rat*, 129 TOXICOLOGY & APPLIED PHARMACOLOGY 46-52 (1994)). Additionally, Vinclozolin has been classified as a probable human carcinogen by the EPA. OFFICE OF PESTICIDE PROGRAMS, EPA, LIST OF CHEMICALS EVALUATED FOR CARCINOGENIC POTENTIAL (1997).

231. *See* VINCLOZOLIN CHALLENGE, *supra* note 13, at 10-12, 24.

232. *See* 21 U.S.C. § 346a(b)(2) (1994 & Supp. III 1997).

233. *See* Letter from Patti Goldman to Bessie Hammiel, *supra* note 203, at 3 (citing EPA tolerance decisions).

> this legal interpretation in the context of our vinclozolin objections and hearing request.[234]

In an April 1998 response to the NRDC's January letter, the EPA provided a vague response, indicating that in so far as the NRDC challenged the EPA's vinclozolin decision "on facts that apply generally to all or many tolerance decisions as well as on facts specific to vinclozolin," it would "[a]ddress all matters necessary to resolve [the NRDC's] objections."[235]

a. Failure To Use the 10X Safety Factor

The key issue raised by the NRDC in the *Vinclozolin Challenge* is that the EPA failed to use the tenfold safety factor mandated by the FQPA in the vinclozolin tolerance decision.[236] The NRDC charged that in making its decision, the EPA acknowledged that it was required to apply an "additional tenfold margin of safety for infants and children" to account for vinclozolin's identifiable toxic effects unless it determined that a "different margin of safety will be safe for infants and children."[237] The EPA proceeded to recognize vinclozolin's de-masculinizing effects on male animals *in utero* and after birth, and the basis for assuming that such effects would occur in humans. It nonetheless noted that even given these effects, the current data

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234. *Id.* (emphasis added).

235. Letter from Lynn Goldman, Assistant Administrator, EPA, to Patti Goldman, Earthjustice Legal Defense Fund (Apr. 22, 1998). Although the meaning of the EPA's response to the NRDC's broader informal challenge is not clear to date, in a later letter from Lynn Goldman, Assistant Administrator of the EPA, to Patti Goldman, Counsel to Earthjustice Legal Defense Fund and the NRDC, the EPA indicated that it had decided to apply the tenfold safety factor to one population segment, women of child-bearing age. *See* Letter from Lynn Goldman, Assistant Administrator, EPA, to Patti Goldman, Counsel to Earthjustice Legal Defense Fund and the NRDC 1 (July 31, 1998); *see also* Letter from Patti Goldman, Counsel to Earthjustice Legal Defense Fund and the NRDC, to Lynn Goldman, Assistant Administrator to the EPA 1 (September 9, 1998). In September, 1998, the NRDC replied to the EPA's decision in this regard, indicating that this change did not rectify the fact that the EPA is still not applying the FQPA's additional tenfold safety factor to protect children after birth and through adolescence. *See id.*

As this article goes to press, the NRDC's objections to the vinclozolin tolerance decision are still pending. In August 1999, the NRDC wrote to the EPA noting that it had been nearly two years since it had filed its objections and that the EPA had still not acted on its request for a hearing. *See* Letter from Patti Goldman, Counsel to NRDC, to Bessie Hammiel, EPA Hearing Clerk 1 (Aug. 20, 1999); First Declaration of Ivan Lieberburg (July 27, 1999); Second Declaration of Ivan Lieberburg (July 27, 1999). Alternatively, NRDC now requests that the EPA "expeditiously" issue a final decision regarding its objections to the vinclozolin tolerance decision. *See* Letter from Patti Goldman, Counsel to NRDC, to Bessie Hammiel, EPA Hearing Clerk 2 (Aug. 20, 1999).

236. For a discussion of the other two legal issues raised by the NRDC, see *infra* notes 245-259 and accompanying discussion.

237. Vinclozolin: Pesticide Tolerance, 62 Fed. Reg. 38,464, 38,471 (1997) (to be codified at 40 C.F.R. pts. 180, 185 & 186).

provided to the EPA was sufficient to decide that an additional uncertainty factor beyond the standard hundred-fold[238] was not necessary to ensure that the tolerance would be safe for children.[239] The EPA decided that because it had a complete database under existing guidelines, even a database that indicated developmental toxicity to infants and children, it did not have to apply the additional tenfold margin of safety in this regard[240] until it had some evidence to prove that the standard hundred-fold safety margin was not sufficient to protect children.[241] The EPA's decision in this regard—to recognize vinclozolin's toxic effects in children and to then proceed without the extra tenfold safety factor with regard to this segment of the population—conflicts squarely with the legislative intent behind FQPA: to increase, rather than maintain, the level of protections for infants and children.[242]

The NRDC urged that while the FQPA permits the EPA to use the standard hundred-fold safety factor in certain situations,[243] the EPA may only do so where the EPA has a complete database *and* where the data does not raise concerns regarding the adequacy of the standard factor.[244] The NRDC argued that, here, the data did raise concerns regarding the adequacy of the standard factor, calling for the EPA's use of the additional tenfold factor to protect children.

b. Failure To Consider Common Mechanism of Toxicity

Additionally, the NRDC charged that the EPA has not complied with the FQPA in that it failed to incorporate cumulative exposures of pesticide chemicals with a common mechanism of toxicity into its assessment of threshold effects.[245] As discussed above,[246] the FQPA requires the EPA to

238. *See supra* notes 27-29 and accompanying discussion for a discussion of the risk factors inherent in the 100-fold standard safety factor.

239. *See* VINCLOZOLIN CHALLENGE, *supra* note 13, at 10.

240. *See* 62 Fed. Reg. at 38,472.

241. *See* VINCLOZOLIN CHALLENGE, *supra* note 13, at 10.

242. The EPA did not consider the special susceptibilities of children, their special consumption patterns, or the endocronic effects of the pesticides on children all as required by the FQPA: 21 U.S.C. § 346a(b)(2)(D)(vii) (1994 & Supp. III 1997); 21 U.S.C. § 346a(b)(2)(D)(iv) (1994 & Supp. III 1997); 21 U.S.C. § 346a(b)(2)(D)(viii) (1994 & Supp. III 1997). *See* VINCLOZOLIN CHALLENGE, *supra* note 13, at 10.

243. *See* Vinclozolin; Pesiticide Tolerance, 62 Fed. Reg. at 38,471; *see also supra* note 244.

244. *See* 62 Fed. Reg. at 38,469, 38,471; VINCLOZOLIN CHALLENGE, *supra* note 13, at 10. The EPA is only permitted to circumvent the additional tenfold margin of safety when "EPA has a complete data base under existing guidelines *and* when the severity of the effect in infants or children *or* the potency *or* unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor." 62 Fed. Reg. at 38,471 (emphasis added); VINCLOZOLIN CHALLENGE, *supra* note 13, at 22.

245. *See* VINCLOZOLIN CHALLENGE, *supra* note 13, at 27.

consider the cumulative risks to children of pesticides that share a common method of harm.[247] Vinclozolin degrades into the same metabolite as iprodione[248] and procymidone, and this metabolite has been "[a]ssociated with vinclozolin's [de-masculinizing or] anti-androgenizing effects."[249] The EPA acknowledged this common mechanism of toxicity, but declined to conduct a cumulative effects analysis because it lacked the methodology to do so. In its tolerance decision, the EPA stated:

> For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific [sic] concerning common mechanism of toxicity in a meaningful way.[250]

Despite its statutory obligation to perform an analysis "concerning the common mechanism of toxicity"[251] that vinclozolin shares with these two other substances for a broad range of toxic effects,[252] the EPA proceeded to consider *only carcinogenic risks* associated with the metabolite that forms when vinclozolin, iprodione, and procymidone degrade.[253]

The EPA next acknowledged how much discretion it truly exercises in setting tolerances, concluding that although cancer risk estimates for the common metabolite were two and a half times the standard negligible risk estimate of one-in-one-million,[254] such a deviation was not significant. The EPA stated:

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246. *See supra* notes 183, 185-94 and accompanying text.

247. *See* 21 U.S.C. § 346a(b)(2)(C)(i)(III) (1994 & Supp. III 1997); 21 U.S.C. § 346a(b)(2)(D)(v) (1994 & Supp. III 1997). One commentator has correctly pointed out that this is a difficult task given that many pesticides have a common mechanism of toxicity, and may also have synergistic effects. *See* WARGO, *supra* note 22, at 274-75.

248. Iprodione has also been designated by the EPA as a probable human carcinogen. *See* WALLINGA, *supra* note 30, at 15.

249. VINCLOZOLIN CHALLENGE, *supra* note 13, at 13.

250. Vinclozolin; Pesticide Tolerance, 62 Fed. Reg. 38,464, 38,471 (1997) (to be codified at 40 C.F.R. pts. 180, 185 & 186).

251. Although difficult to do, an analysis as to the effects of exposure to multiple pesticides when the pesticides share a common mechanism of toxicity would be more reflective of the actual multiple exposures that people face in the environment everyday.

252. 21 U.S.C. § 346a(b)(2)(D)(v) (1994 & Supp. III 1997).

253. *See* 62 Fed. Reg. at 38,470.

254. In the vinclozolin decision, EPA stated the standard assumption that negligible risk means one-in-one-million, but then departed from this standard assumption. *See* 62 Fed. Reg. at 38,471. The EPA decided to allow this higher risks level even though it had itself, in the pre-FQPA era, tried to define *de minimis* risk as "a hypothetical cancer risk of less than one-in-a-million over a 70-year lifetime for food tolerances. . . ." H.R. REP. NO. 669, 104th Cong., 2d Sess., pt. 2, at 32 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1271.

> *Quantitative cancer risk assessment is not a precise science.* There are a significant number of uncertainties in both the toxicology used to derive the cancer potency of a substance and in the data used to measure and calculate exposure. Thus, EPA generally does not attach great significance to numerical estimates for carcinogenic risk that differ by approximately a factor of 2 1/2.[255]

Because so much uncertainty existed with regard to the underlying toxicology and data used to support the QRA, the Agency essentially decided that more than two-in-a-million also meant negligible risk.[256] In doing so, the EPA noted the imprecision of QRA and highlighted the height of its own discretion in that it was able to increase the risk by 250% without an accompanying analysis of why such an increase was safe.[257]

c. Failure To Use Conservative and Standard Assumptions

The NRDC also argued that the tolerance decision's assumptions were not conservative or complete because the EPA abandoned its traditional assumption that 100% of the crops that can be treated will be treated. In the past, the EPA has stated that this particular conservative assumption injects additional safety into its analysis.[258] Here, the EPA estimated the percentage of crops to be treated with vinclozolin, adjusting this percent down from 100%, thus making the final risk estimate less conservative.[259]

2. The EPA Justifies Its Policy Decisions with Science

The EPA itself acknowledged in the vinclozolin decision that a QRA requires the risk assessor to make many assumptions and that existing science

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Before passage of the FQPA, environmentalists lobbied Congress for a numerical definition of *de minimis* risks of one-in-one-million so that the EPA would not have as much discretion as it now has. *See* Smart, *supra* note 90, at 329.

255. 62 Fed. Reg. at 38,471 (emphasis added). The EPA has indicated in fact that it considers any risk below four-and-a-half parts per million to be closer to one than 10, and therefore within the negligible risk range. *See* Telephone Interview with David Wallinga, M.D., Natural Resources Defense Council (Nov. 11, 1998) [hereinafter Interview with David Wallinga].

256. *See* Vinclozolin; Pesticide Tolerance, 62 Fed. Reg. at 38,471.

257. H.R. REP. NO. 669, 104th Cong., 2d. Sess., pt. 2, at 41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1280 (noting that it was the Committee's understanding that under current EPA practice, EPA interprets negligible risk to mean a one-in-a-million lifetime risk).

258. *See* 62 Fed. Reg. at 38,469-70; VINCLOZOLIN CHALLENGE, *supra* note 13, at 11.

259. *See* 62 Fed. Reg. at 38,469. Estimating the percentage of crops treated, although less conservative an approach than assuming that all crops were treated, appears to be permissible under FQPA. 21 U.S.C. § 346a(b)(2)(F) (1994 & Supp. III 1997); VINCLOZOLIN CHALLENGE, *supra* note 13, at 11.

is not able to inform all of the assumptions[260] required to perform QRA with regard to food tolerances. Thus, risk assessors must fill in these assumptions on the basis of external factors—such as social, economic and political considerations[261]—thereby politicizing decisions that are said to be based strictly on "scientific" rational. Therefore, the result of any risk analysis is dependant on the assumptions the risk assessor makes,[262] and the EPA can "back into" a QRA analysis to reach a final standard-setting decision consistent with predetermined agency policy.[263]

Circumstantial evidence showing the EPA's attempts to back into a predetermined policy not to stringently enforce the FQPA exists. Consider, for example, the EPA's decision not to apply the additional tenfold safety factor with regard to the bulk of tolerances it has set since the Act was passed.[264] This track record is strongly indicative of an agency policy not to implement the FQPA more forcefully at the current time.

This policy was also borne out in the vinclozolin decision.[265] There, the EPA cavalierly increased the standard notion of *de minimius* risk from one-in-one-million to two-and-a-half-in-one-million[266] based on the imprecision of its own scientific risk assessment, therefore setting the vinclozolin tolerance at a higher level. This decision-making logic exemplifies the EPA's ability to justify any standard-setting decision at all: if the QRA analysis is performed and the result is as desired, the EPA proceeds. On the other hand, if the result is not acceptable, the EPA simply criticizes the scientific process it used to make the analysis, and proceeds as it intended to in the first place, despite the relevant scientific analysis. Using the imprecision of the scientific basis for its own decisions, the EPA appears able to justify any

260. *See* Wagner, *supra* note 133, at 1619 (urging that scientists cannot actually identify quantitatively the level at which a substance is harmful).

261. *See supra* notes 141-52 and accompanying text. One assumption that the EPA makes with regard to pesticide risk assessment is that the inert ingredients in pesticides do not have to be included in the risk assessment at all. *See* John Carlucci, Note, *Reforming the Law on Pesticides*, 14 VA. ENVTL. L.J. 189, 205 (1994). This assumption is particularly faulty because inert ingredients in pesticides have been found to be just as toxic, if not more toxic than their active counterparts. *See* DENNIS C. VACCO, ENVTL. PROTECTION BUREAU, N.Y. STATE DEP'T OF LAW, THE SECRET HAZARDS OF PESTICIDES: INERT INGREDIENTS 4 (Feb. 1996).

262. *See* 21 U.S.C. § 346a (b)(2) (1994 & Supp. III 1997); Shere, *supra* note 134, at 413.

263. *See* Wagner, *supra* note 133, at 1646-48.

264. *See supra* notes 203-206 and accompanying text.

265. *See* Vinclozolin; Pesticide Tolerance, 62 Fed. Reg. 38,464–74 (1997) (codified at 40 C.F.R. pts. 180, 185 & 186).

266. *See* 62 Fed. Reg. at 38,471; *see also supra* notes 203-206 and accompanying text.

number of externally and/or politically motivated tolerance decisions.[267] The EPA's decision with regard to the vinclozolin tolerance and the proceedings to date in the Vinclozolin Challenge specifically highlight the EPA's use of scientific explanations and QRA to maintain the pre-FQPA status quo in pesticide regulation and "scientifically" justify lax enforcement of the FQPA's child protective features.

3. The EPA Uses the Cover of Science To Avoid Widespread Challenge of Its Decisions

The "cloaking" of the EPA's policy decisions in science[268] also prevents the lay public from being truly informed about the nature of agency decisions and prevents the public from challenging administrative decisions. At times, the information needed for the public to question an agency decision is extremely complex and difficult to garner because some parts of the decision-making process are mired in difficult policy choices and others are obscured by high-level scientific analysis.[269] The initial information costs are so high that the general public will shy away from challenge.[270]

Professor Wagner illustrated this point compellingly with the EPA's decision not to regulate formaldehyde in the early eighties.[271] In this era, the Reagan administration attempted to weaken protective regulations concerning formaldehyde.[272] In 1982, the EPA decided not to regulate formaldehyde under the Toxic Substances Control Act because the Agency argued that there was insufficient evidence of danger to human health.[273] The EPA stated that its decision was based exclusively on science and risk assessment.[274] The EPA had, however, failed to note in its disclosures that it had used "nonstandard" scientific assumptions in reaching its decision and that this allowed it to reach a result contrary to the mounting scientific evidence that formaldehyde was indeed dangerous to human health.[275] The EPA's lack of complete candor and apparent use of science allowed it to

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267. *See* McElveen & Amantea, *supra* note 123, at 1579 (noting that the risk assessment "process is so flexible that in the regulation of carcinogens, it can be used to justify almost any result that is sought."); *supra* notes 133-52 and accompanying text.

268. *See* McGarity, *supra* note 138, at 15; Wagner, *supra* note 133, at 1674-77.

269. *See* Wagner, *supra* note 133, at 1676.

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

271. *See id.* at 1646-49.

272. *See id.* at 1645-46.

273. *See id.* at 1646.

274. *See id.* at 1646-48 (noting that there exists *some* circumstantial evidence that the EPA may have made its decision with regard to formaldehyde before performing its QRA).

275. *See* Wagner, *supra* note 133, at 1647-48.

justify and defend what was in effect a policy or political decision not to regulate formaldehyde at that juncture and made it more difficult for the public to challenge the decision.[276]

In the context of the FQPA, the EPA's tolerance decisions are also so loaded with scientific jargon and obfuscations that it is difficult for the public to realize the true nature of the EPA's decisions. In issuing the vinclozolin tolerance, the EPA deviated from standard conservative assumptions to reach its decision by assuming that less than 100% of the crops would be treated with vinclozolin.[277] In doing so, the EPA obfuscated the increased risk inherent in this assumption, by stating that this change "refined" the decision.[278]

C. Why the EPA Has Failed To Implement the FQPA

The EPA may be using the QRA process to avoid strict implementation of the FQPA,[279] to conserve administrative resources[280] and avoid politically difficult decisions.[281] In May 1998, the EPA and the United States Department of Agriculture (hereinafter "USDA") convened a tolerance reassessment advisory committee (hereinafter "TRAC") to hold a series of public meetings and to provide EPA and USDA guidance on implementing the FQPA.[282] One legal expert in this area has said, however, that the EPA will continue conducting business as usual and will not enforce the FQPA to protect children until the Courts require it to do so.[283]

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

277. *See* Vinclozolin; Pesticide Tolerance, 62 Fed. Reg. 38,464, 38,469 (1997) (codified at 40 C.F.R. pts. 180, 185 & 186).

278. *See id.* Similarly, in the vinclozolin decision, the EPA decided, as discussed above, to increase a risk factor from one-in-one-million to two-and-a-half-in-one-million because the scientific process used to quantitatively assess the risk was not reliable. 62 Fed. Reg. at 38,471. Even where the decision called into question the entire scientific basis for the agency's standard setting process, mass public challenge of the public did not occur, supporting the thesis that the lay public does not and perhaps cannot easily challenge decisions based on seemingly scientific rational. *See supra* notes 254-57 and accompanying text.

279. *See supra* notes 195-226 and accompanying text.

280. *See* Bauer, *supra* note 25, at 1401.

281. *See infra* notes 310-311, 321-322 and accompanying text.

282. *See* EPA, EPA/USDA TOLERANCE REASSESSMENT ADVISORY COMMITTEE TO HOLD PUBLIC MEETING MAY 28-29 IN ARLINGTON, VA.. (1998).

283. *See* Telephone Interview with Patti Goldman, Counsel to Earthjustice Legal Defense Fund and NRDC (Mar. 5, 1998) [hereinafter Interview with P. Goldman] (describing reasons behind the VINCLOZOLIN CHALLENGE, *supra* note 13).

1. The EPA Has Stated that It Does Not Currently Possess the Methodology or Requisite Data To Implement the FQPA

Even assuming that the EPA was willing to stringently enforce the FQPA, the EPA has stated that it lacks the methodology and data to perform fully the complex scientific analysis[284] required under the FQPA. The EPA's shortage of information on the toxicity of pesticides is not surprising given that almost all of the information used to assess the safety of a pesticide is provided by pesticide registrants.[285] In addition to the potential bias inherent in any information provided,[286] this mechanism for information gathering is not efficient. It makes common sense to assume that pesticide registrants have little motivation to provide information that casts doubt on the safety of their products and decreases their chances of registration or reregistration. And it is beyond question that pesticide manufacturers have even less "motivation to perform toxicity testing in excess of EPA's data requirements" which were drafted prior to the FQPA.[287]

The EPA's lack of available information and methodologies was illustrated by its decision in the case of vinclozolin.[288] In the vinclozolin decision, the EPA acknowledged that vinclozolin, iprodione and procymidone, two other widely used pesticides, share similar structural and chemical properties and produce a common metabolite that is associated with vinclozolin's anti-androgen effects.[289] The EPA nonetheless stated that it did not have a sufficient toxicological database or the methodology to consider

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284. *See* Vinclozolin; Pesticide Tolerance, 62 Fed. Reg. 38,464, 38,464-754 (1997) (codified at 40 C.F.R. pts. 180, 185 & 186) (noting the EPA's lack of data and insufficient methodology in the vinclozolin tolerance decision). *See also*, 64 Fed. Reg. 32,229 (1999) (notice of revised risk assessment for pesticides Bensulide and Profenofos); Ethoprop, Fenamiphos, Phorate, and Terbufos, Revised Organophosphate Risk Assessments; Notice of Public Meeting, 64 Fed. Reg. 44,920 (1999) (notice of revised organophosphate pesticide risk assessment for terbufos).

Many commentators have similarly questioned whether science is sufficiently developed to be the basis of our regulatory system. *See, e.g.*, Michaelson, *supra* note 162, at 1894 (urging that risk determination as part of the risk assessment process is a "nonscientific threshold decision about what constitutes 'acceptable' risk"); Ellen Silbergeld, *The Risks of Comparing Risks*, 3 N.Y.U. ENVTL. L.J. 405, 406 (1995) (postulating that it is almost impossible to develop methodologies or sufficient data to make sound comparative risk assessments); Wagner, *supra* note 133, at 1629 (urging that administrators engage in a "science charade" in cloaking their policy decisions in science); Wendy E. Wagner, *Congress, Science and Environmental Policy,* 1999 U. ILL. L. REV. 181, 208-09.

285. *See* WALLINGA, *supra* note 30, at 25.

286. *See* Bauer, *supra* note 25, at 1401.

287. WALLINGA, *supra* note 30, at 25.

288. *See* Vinclozolin; Pesticide Tolerance, 62 Fed. Reg. 38,464, 38,464-74 (1997) (codified at 40 C.F.R. pts. 180, 185 & 186).

289. *See id.* at 38,466; VINCLOZOLIN CHALLENGE, *supra* note 13, at 28.

the cumulative effects of these pesticide residues[290] and their common metabolite in a meaningful manner.[291] The EPA made these pronouncements even while acknowledging that it was statutorily required to consider these combined risks, and to consider exposure to the pesticide's metabolite from food, air and water. The agency proceeded to analyze only the carcinogenic risks,[292] ignoring, for purposes of the tolerance decision, all other possible effects from the three substances—iprodione, procymidone and vinclozolin—even though their common metabolite has been associated with non-cancer effects.[293]

2. The Regulatory Scheme Is Administratively Burdensome

In the context of the FQPA, QRA is also administratively cumbersome;[294] it requires an array of scientific analysis that attempts to assess many possible risks for each standard-setting decision.[295] Even assuming the EPA had complete databases regarding cumulative exposure and toxicity of all pesticides,[296] the FQPA requires the EPA to consider a myriad of factors for each toxic effect of a pesticide for which a tolerance is sought. Hypothetically assuming that the EPA could amass the vast amount of

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290. *See* 62 Fed. Reg. at 34,470; *see also* Gimpel, *supra* note 128, at 87 (noting that the EPA has found it difficult to perform rigorous quantitative risk assessments outside of cancer risks).

291. *See id.*; VINCLOZOLIN CHALLENGE, *supra* note 13, at 28.

292. *See* 62 Fed. Reg. at 38,470-71. Originally, in a draft tolerance decision dated May 30, 1997, the EPA specifically noted that it completely ignored the cumulative effects of exposure to vinclozolin, iprodione and procymidone because it believed that the agency did not have the requisite policies and methodologies for understanding these common mechanisms of toxicity. *See id.* Ultimately, the EPA issued its final tolerance decision which only accounted for vinclozolin's common mechanism of toxicity with regard to cancer risk assessment, and not other toxic effects of vinclozolin, iprodione and procymidone, chemicals with a common mechanism of toxicity. *See id.* This result is particularly troubling because the FQPA requires the EPA to assess the effects of a pesticide chemical residue and to aggregate these effects with other substances that have a common mechanism of toxicity (21 U.S.C. § 346a(b)(2)(D) (1994 & Supp. III 1997), and to make this assessment considering the special susceptibility of infants and children (21 U.S.C. § 346a(b)(2)(C) (1994 & Supp. III 1997); 21 U.S.C. § 346a(b)(2)(D) (1994 & Supp. III 1997)).

293. *See* 62 Fed. Reg. at 38,470.

294. *See* Applegate, *supra* note 23, at 279, 285 (noting that quantitative risk assessment places extraordinary demands on agency resources and that while EPA duties had increased in recent years, the EPA's budget had not followed suit); *infra* notes 295-309 and accompanying discussion.

295. *See* Letter from Susan H. Wayland, Acting Assistant Administrator of the EPA, to Congressman Henry Waxman 6 (Feb. 22, 1999) (noting that "implementation of FQPA is "challenging" and that it "presents a great many complex scientific and regulatory problems").

296. The reality, of course, is that risk assessment suffers from a lack of reliable data. *See* Bauer, *supra* note 25, at 1400.

information required by the FQPA,[297] the EPA would then have to assess this data for each potential risk or endpoint of toxicity concern.[298]

According to a staff paper on the risk characterization process which was provided to the EPA "Tolerance Reassessment Advisory Committee" (hereinafter "TRAC") in June of 1998,[299] a complex and administratively burdensome task must be undertaken for each requested tolerance or exemption.[300] In addition to new registrations and requests for tolerances, the FQPA subjects all existing tolerances to reassessment.[301] To put this task in perspective, at the time the FQPA was enacted, there were 9728 tolerances and exemptions in effect and new requests for tolerances on a regular basis.[302] The staff paper described a risk characterization process that requires the Health Effects Division of the EPA to review exposure and toxicity studies attained from the individual seeking registration and a tolerance for a pesticide (hereinafter "the Pesticide Registrant") and establish endpoints of toxicity concern.[303] According to this staff paper, the Environmental Fate and Effects Division also evaluates the drinking water exposure and other environmental effects.[304] Next, the Science Assessment Review Committees (hereinafter "SARCS"), which includes Hazard Identification Assessment, Cancer Assessment, Mechanism of Toxicity and Reproductive and Developmental Toxicity Committees, may review the

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297. Such information would include: information about vinclozolin's toxic effects; information concerning the aggregate level of exposure for consumers; information concerning the sensitivities of "major identifiable subgroups of consumers," including children; information about the cumulative effects of its residues and other substances with which it shares a common mechanism of toxicity; information about potential non-food sources of exposure; and information about its potential endocronic effects. 21 U.S.C. § 346a(b)(2)(D) (1994 & Supp. III 1997).

298. *See id.*

299. *See* Memorandum from Stephen L. Johnson, Deputy Director, Office of Pesticide Programs, to TRAC Risk Assessment Work Members (June 16, 1998) (with attached Staff Paper, EPA's Risk Assessment Process for Tolerance Reassessment (June 17, 1998)) [hereinafter Staff Paper]. In April, 1999, seven public interest groups resigned from TRAC dealing a serious blow to the credibility of the FQPA. The groups resigned anticipating that the EPA would fail to meet the August, 1999, deadline for reassessing the riskiest tolerances. *See* Toby Eckert, *Groups Favoring Tough Pesticide Rules Quit Panel*, STATE J. REG., May 1, 1999; *see also, supra* note 197.

300. Astoundingly, the FQPA does not even require an analysis of the potential synergistic effects of the active ingredients in pesticides or *any* analysis concerning the inert ingredients in pesticides. *See* ROBERT ABRAMS, N.Y. STATE DEPT. OF LAW, ENVTL. PROTECTION BUREAU, LAWN CARE PESTICIDES: A GUIDE FOR ACTION 9, n.4 (undated). The inert ingredients in pesticides have often been found to be just as toxic if not more toxic than their active counterparts. *See id.*

301. *See* Raw and Processed Food Schedule for Pesticide Tolerance Reassessment; Notice, 62 Fed. Reg. 42,020, 42,020 (1997).

302. *See id.*

303. *See* Staff Paper, *supra* note 299, at 2.

304. *See id.*

hazard assessment and an overall risk characterization is developed for the pesticide.[305] The FQPA Safety Factor Committee then reviews this risk characterization and recommends retention, reduction or removal of the FQPA tenfold additional safety factor.[306] At this point, a final risk characterization is drafted and it is sent to the Risks Characterization Committee, another SARC, where it is reviewed for consistency.[307] The Committee next shares the risk characterization with the Pesticide Registrant. The Pesticide Registrant may respond with additional data, and the characterization is revised if appropriate.[308] The EPA then publishes a tolerance decision for the pesticide.[309] Given this administratively burdensome risk characterization process, one can envision the enormity of the task for the EPA in implementing this complex and broad statute.

3. Strict Implementation of the FQPA Would Require the EPA to Make a Myriad of Tough Policy Decisions

The manufacturers and users of pesticides represent "big business."[310] They quite obviously oppose further restrictions on the agricultural use of pesticides and bring the size of the industry to bear on the political process of regulating pesticide use. The path of least resistance is to continue setting tolerances on the basis of current data and current standards, rather than force pesticide manufacturers to provide additional data to obtain tolerances for their products and to meet stricter safety standards. Because QRA is such a flexible tool, the EPA can, in some instances, avoid making politically charged decisions which would force pesticide users and manufacturers to submit additional information to obtain a tolerance by making a political decision about how it would like outcomes to look and backing into"scientific analysis" that supports the status quo.[311]

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305. *See id.*

306. *See id.*

307. *See id.*

308. *See id.*

309. *See id.* at Appendix (EPA's Risk Assessment Process for Tolerance Reassessment).

310. WALLINGA, *supra* note 30, at 1 (explaining that "Pesticides are big business. Each year, more than 4.5 billion pounds of pesticides are used in the United States.").

311. *See supra* notes 271-276 and accompanying text concerning what appeared to have been such an analysis by the EPA in the eighties with regard to the regulation of formaldehyde.

IV. WHY ARE REGULATORY FRAMEWORKS GROUNDED IN SCIENCE IF THE QRA PROCESS IS SO UNRELIABLE?

As discussed in parts II and III above, QRA based regulatory schemes that attempt to quantify and manage environmental risks have many drawbacks in terms of reliability, accountability and in terms of long-term improvements in safety. Despite these problems, however, there are many reasons why science and QRA are featured so prevalently in our current regulatory frameworks.

A. The Courts Have Required Agencies To Support Their Decisions with a Quantitative Analysis of Risk

The rise in quantitative risks assessment as a prevalent tool began after the Supreme Court's decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*.[312] In that well-publicized case, the Supreme Court held, in a plurality opinion, that an OSHA benzene exposure standard calling for the lowest technologically feasible level of benzene in the workplace was unacceptable without some quantification of the risks.[313] "[A]gency regulators largely interpreted the case to require reliance on quantitative risk assessment even where the results are of questionable validity."[314] This judicial reliance on QRA continued in two later decisions in the D.C. Circuit, *Public Citizen Health Research Group v. Tyson*[315] and an *en banc* decision in *Natural Resources Defense Council v. EPA*.[316] In the *Public Citizen* decision, the circuit court upheld the agency decision, specifically distinguishing it from the Supreme Court's *Industrial Union* decision, stating that the agency had supported its decision with a quantitative analysis of potential harm.[317] In *Natural Resources Defense Council*, the Court "essentially mandate[d] that administrative agencies use risk assessment to translate narrative environmental standards into numeric criteria."[318]

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312. 448 U.S. 607 (1980).

313. *See id.* at 655.

314. Keuhn, *supra* note 1, at 110 (footnote omitted).

315. 796 F.2d 1479 (D.C. Cir. 1986).

316. 824 F.2d 1146 (D.C. Cir. 1987).

317. *See Public Citizen,* 796 F.2d at 1499.

318. Shere, *supra* note 134, at 421. Despite their strong stand on numerically assessing toxic risks, these judicial decisions requiring the use of QRA to support agency decisions "show almost no recognition . . . of the profound unreliability and malleability of risk assessment." *Id.*; *see also supra* notes 133-52 and accompanying text.

B. "Science-Based" Decisions Are Socially Acceptable

Another compelling reason for the prevalence of science as a basis for regulation of toxins is that there is an inherent social value in labeling an agency's decisions "science-based" rather than "policy-based."[319] Consumers feel better knowing that administrators are making rational, "science-based" decisions. It is not easily recognizable to the public that these "science-based" decisions are really value-guided policy decisions in which we allocate cancer and other toxic effects to few for the alleged greater good.[320]

In the formaldehyde example discussed above,[321] the EPA stated that its decision not to weaken protective regulations of formaldehyde was based almost exclusively on science.[322] Although unlikely to have reflected the true nature of the EPA's decision, this notion was proffered to the public in place of the less appealing, but more likely, political rationale for the decision: the Administration had decided that only a few would be harmed by formaldehyde if it were not more strictly regulated, and politically, it could not justify stricter regulations.

In the context of the FQPA, scientific decisions based on "*de minimis* risk" also allow the government to allocate harm to a few, purportedly for the greater good. Inherent in this standard are two ethical concepts: the first is that the government should be allocating harm to the public; the second is that the level at which this is done should be statistically insignificant. While not defined numerically in the FQPA, the term *de minimis* was definitively used by Congress as scientists use it, to convey negligible and "scientifically insignificant" risk levels.[323] By limiting the risks to a "scientifically insignificant" level, the *de minimis* standard avoids the first half of the ethical problem about whether the government should be in the business of allocating harm in the first instance and allows the public to move directly to the question about how much risk we as a society are willing to bear.[324]

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319. *See* Michaelson, *supra* note 162, at 1902-03.

320. *See id.* at 1899-1900.

321. *See supra* notes 271-76 and accompanying discussion; Wagner, *supra* note 133, at 1646-49.

322. *See* Wagner, *supra* note 133, at 1647-48.

323. H.R. REP. NO. 669, 104th Cong., 2d. Sess., pt. 2, at 41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268 (noting that it is the committee's understanding that under current EPA practice, EPA interprets negligible risk to mean a one-in-a-million lifetime risk).

324. *See* Alyson C. Flournoy, *Legislating Inaction: Asking the Wrong Questions in Protective Environmental Decisionmaking*, 15 HARV. ENVTL. L. REV. 327, 347 (1991); Mohn & Applegate, *supra* note 133, at 100.

If the "scientifically insignificant" risk that we are willing to bear is one-in-one-million, then the standard-setting agency uses science to set risk levels such that an estimated one-in-one-million people will suffer the toxic consequences.[325] Even though this seems like a small risk, if spread over the U.S. population for a carcinogenic substance, it "allocates 250 cancers or deaths per risk period."[326] By accepting the notion that *de minimis* or negligible risk means statistically insignificant and trivial, the public is able to avoid the initial value decision inherent in the *de minimis* standard.

Consider again the EPA's decision with regard to the cancer risks from vinclozolin.[327] In that decision, the EPA considered the cancer risks from a structurally related compound, found its risk to be two-and-a-half-in-one-million, or two hundred and fifty percent greater then that which is normally considered negligible risk, and then proceeded to approve that risk as safe.[328] Such a risk, although seemingly statistically insignificant, allocates almost 700 cancers for each risk period.[329] The scientific and statistical nature of such a decision obfuscates the true nature of the decision, which starts with a value judgement, and allows the public to avoid the ethical dilemma inherent in allocating *any* number of deaths per risk period.[330] The notion of *de minimis* risk is acceptable to the public because it is seemingly rational and scientific, not necessarily because we agree that it is appropriate for the government to allocate harm.

C. Science Is Convenient

Finally, despite its lack of reliability and malleability, the legislative reliance on QRA has become reflexive. Two major factors have contributed to the administrative and legislative reliance on QRA. The first is the court-imposed requirement discussed above: that quantitative analysis of the potential for harm supports agency standard-setting decisions.[331] The second is a lack of a better politically acceptable alternative. In the following

325. *See* Michaelson, *supra* note 162, at 1899-1900.

326. *Id.* at 1899.

327. *See supra* notes 252-257 and accompanying text.

328. *See supra* notes 254-257 and accompanying text.

329. *See* Smart, *supra* note 90, at 329.

330. *See* Michaelson, *supra* note 162, at 1899-1900; Mohn & Applegate, *supra* note 133, at 100. Some commentators have urged that it is unethical for the government to allocate some human death as an inevitable part of the QRA analysis. *See* Israel, *supra* note 195, at 480. Those making this argument would urge that the government has an obligation to ensure absolute safety from environmental contaminants or at least to state this as the obvious goal of governmental regulation. *See id.*

331. *See supra* notes 322-328 and accompanying text.

section, I argue that pesticides pose a particularly dangerous environmental threat and propose that future pesticide regulation should be streamlined to blend the best of the current science-based regulatory regime with incentive-based, prevention-oriented regulation.

V. THE FUTURE: ALTERNATIVES TO LEGISLATION BASED SOLELY ON SCIENTIFICALLY ASSESSING THE RISKS AND CURRENT IMPLEMENTATION OF THE FQPA

A. Alternatives to Legislation Based Solely on Scientifically Assessing the Risks

1. Regulations Based on Quantitatively Assessing Risks Manage Environmental Dangers, Rather than Provide Incentives for Decreased Environmental Pollution

In addition to its lack of reliability and other shortfalls discussed above, QRA is also flawed as a basis for environmental regulations because it supports regulatory schemes that attempt to manage, rather than reduce the overall risk from toxic substances.[332] Thus, the FQPA creates no incentives for pesticide users and manufacturers to reduce environmental contamination from pesticides. To the contrary, the FQPA encourages agribusiness to obtain the highest possible tolerances so that they will have an easier time staying within them.

The FQPA, rooted as it is in quantitatively identifying risks and setting upper levels for those risks, is readily characterized as a so-called "command and control" type regulation in which government sets certain pollution limits and demands compliance.[333] In addition to the fact that command and control regulations do not reduce toxins in the environment, command and control legislation has also been heavily criticized for creating litigious relationships, for its lack of efficiency and efficacy, for its susceptibility to "capture by special interests" and for its support of a stagnant scientific state.[334] To the contrary, the current trend in

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332. *See* Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 91-95 (1988); Carlucci, *supra* note 261, at 210.

333. *See* Rena I. Steinzor, *Reinventing Environmental Regulation: The Dangerous Journey from Command to Self-Control*, 22 HARV. ENVTL. L. REV. 103, 104 (1998).

334. *See* Vandenbergh, *supra* note 10, at 842-43.

environmental regulation is toward the incentive-based and source-prevention regulatory schemes discussed below.[335]

2. Future Legislation Should Retain QRA To Make Crude and Comparative Estimates of Risk, but Should Stress Pollution Prevention and Be Incentive-Based

The justification for a change in the way we regulate pesticides is two-fold. First, since it has been more than three years since Congress passed the FQPA and little has changed in terms of protection for children from pesticides,[336] changes in the way we regulate pesticides appear needed. Second, the current system, based on QRA, is extraordinarily complex. It allows agencies to shroud pure policy decisions in science and leaves them with a tremendous amount of political discretion in making standard-setting decisions aimed at controlling the level of acceptable risk. A new regulatory regime would instead be simpler and incentive-based, and aimed at a reduction in overall risk from pesticide use. [337]

a. Common Sense Justification for Pesticide Reduction

An approach based on pollution prevention, or reducing our reliance on pesticides over time, makes sense. Regulations that attempt to reduce overall risks will use less resources and be more effective than those like the FQPA, which try to consider and quantify all possible effects from particular environmental toxins, such as pesticides.[338]

In the area of pesticide regulation, the case could not be stronger for minimizing environmental risk at the outset. "[H]umans and pests 'undeniably' depend on the same food chain and are interdependent; and thus, it is axiomatic that chemicals intended to kill and destroy one come with unknown risks to the others."[339] Moreover, "[i]t is becoming increasingly clear that as pests become more and more resistant to chemical

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335. *See* Carlucci, *supra* note 261, at 210; *infra* notes 332-337, 349-368 and accompanying text.

336. Congress passed the FQPA, however, in the wake of great controversy and I, therefore, make suggestions for the current implementation of the well-intentioned FQPA in part V.B below. *See infra* notes 369-409 and accompanying text.

337. *See* Carlucci, *supra* note 261, at 211.

338. *See* Hornstein, *supra* note 94, at 387-88 (noting that the ultimate policy question in the area of environmental regulation must be about "how society might better organize itself through legal rules and public policies to avoid unnecessary trade-offs among deeply held public values.") (emphasis omitted).

339. Watnick, *supra* note 45, at 85 (citing PESTICIDES AND CHILDREN, *supra* note 50, at 6).

pest control, we will have to use stronger, more toxic pesticides in greater quantities to do the same job previously done with less chemical use."[340] Over thirty years ago, Rachel Carson correctly postulated that pesticides would infiltrate our ecosystems and our very beings.[341] More recently, in *Our Stolen Future*, the authors urge that the prevalence of pesticides is causing hormonal changes in all species and threatening our fertility and our very existence.[342] Yet, the extraordinarily complex scientific process that we use to determine the relative safety of these pesticides appears to be imprecise at best and a complete shot in the dark at worst.[343] Additionally, this process reduces accountability to the public and potentially threatens our long-term safety.[344] If the goal is to improve protections for children and adults alike,[345] we must move legislatively toward a simplified system less inclined toward managing the risk and more inclined toward reducing long-term risk[346] from pesticide use.

b. Major Components of Legislative Reform

Future pesticide legislation should have two major components. First, it should use QRA comparatively to identify those pesticides that *definitively* produce the greatest risks and to ban or reduce the use of these substances. Such an approach would simplify the regulation of pesticides and allow resources to be directed at pollution prevention. One author has said, at least with regard to carcinogenesis, "[o]btaining a rough, qualitative sense of a chemical's carcinogenic potential is a relatively manageable task."[347] Science would only be used to draw bright lines where it is possible to do so with some efficacy. This methodology would insure that the most dangerous

340. Watnick, *supra* note 45, at 98-99 (footnote omitted) (citing Carlucci, *supra* note 261, at 212); *see also* Gardner, *supra* note 57.

341. *See* RACHEL CARSON, SILENT SPRING (1962); *see also* WALLINGA, *supra* note 30, at 1 (noting that "pesticides are found in nearly three-quarters of the fruits and vegetables most commonly eaten by children" and that they are found in food, drinking water, "on toys, in households, and schools, even in children's urine.").

342. *See* THEO COLBORN ET AL., OUR STOLEN FUTURE (1996).

343. *See* Applegate, *supra* note 23, at 283; *supra* notes 123-152, 255, 265-267 and accompanying text.

344. *See supra* notes 133-152, 268-278 and accompanying text.

345. Whenever environmental regulation is considered, one must assess the overall goal of the regulatory scheme, be it efficiency, safety, increased awareness of the ethical concerns or some other goal. The author here assumes that in the context of the FQPA, the abiding goal for future reform is to increase food safety for adults and children. *See* Cross, *supra* note 4, at 1156 (discussing possible goals of environmental regulation).

346. *See* Carlucci, *supra* note 261, at 210.

347. Applegate, *supra* note 23, at 283.

pesticides would be the first to be banned. Beyond this elementary use, however, the lack of reliability of QRA makes its use close to futile.[348]

The second major component of new pesticide regulation would encourage reduction of pesticide use over the long term.[349] Such regulation would thus create economic incentives for food producers to decrease their use of pesticides, as discussed in sections V(A)(2)(c) and (d) below, concomitantly reducing overall pollution from pesticides.[350] This blended approach would salvage the most useful aspects from the current science-based regulation, and would focus on pollution prevention.

c. Integrated Pest Management as a Mechanism To Reduce Overall Pesticide Use

One pollution prevention strategy that would decrease our overall use of pesticides and increase the safety of our food supply[351] and the environment is known as Integrated Pest Management (hereinafter "IPM").[352] Legislation based on IPM would require the use of the least toxic methods of pest control, including biological methods, if possible, and the use of synthetic pesticides only as a last resort.[353] The FQPA contains a broad and somewhat vague section on IPM that requires the Secretary of Agriculture, in cooperation with the EPA Administrator, to implement programs that support the use of IPM, and requires the federal government to use and promote

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348. *See id.* ("[d]efining the precise degree of risk, however, is an enormously difficult and perhaps impossible undertaking"); *supra* notes 133-52 and accompanying text.

349. *See* Elizabeth Glass Geltman & Andrew E. Skroback, *Reinventing the EPA to Conform with the New American Evironmentality*, 23 COLUM. J. ENVTL. L. 1, 17-20 (1998).

350. *See* Hornstein, *supra* note 94, at 387-88.

351. The regulation of pesticides unquestionably affects the availability of fruits and vegetables, and high consumption of fruits and vegetables has been clearly linked with decreases in the rates of heart disease and cancer. It can thus be argued that if we reduce the number of available pesticides to farmers, food prices will go up and fruits and vegetables will be less readily available, and ultimately, public health will suffer. *See* Michael Fumento, *Pesticides Are Not the Main Problem*, N.Y. TIMES, June 30, 1998, at A23.

On the other hand, studies have shown that if we abandoned all use of pesticides, our ecosystems would return to equilibrium, with natural predators controlling pests that harm crops, and our food supply would remain virtually the same. *See* Carlucci, *supra* note 261, at 199. Moreover, there is compelling evidence that: 1) the more we rely on pesticides to control pests, the more resistant pests become to the chemicals and the more we have to use to kill them; and 2) that sustainable agriculture is actually more cost effective and efficient in the long-run. *See id.* at 197-99.

352. *See* Carlucci, *supra* note 261, at 215-16 (calling for legislative incentives for farmers to use integrated pest management to reduce use of chemical pesticides).

353. For a detailed discussion of the benefits and characteristics of Integrated Pest Management, *see generally* Carlucci, *supra* note 261.

IPM.[354] In a memorandum to Secretary Daniel Glickman and EPA Administrator, Carol Browner,[355] Vice President Gore outlined "implementation principles" for FQPA and encouraged the EPA to use "additional resources and strategies" to "expand integrated pest management strategies."[356]

Currently, the EPA has a program designed to encourage IPM called the Pesticide Environmental Stewardship Program.[357] This program creates voluntary partnerships [358] between the EPA and pesticide users to encourage reduced use of agricultural and non-agricultural pesticides.[359]

d. Incentive-Based Reform

Vice President Gore also laid down as an FQPA "implementation principle" the concept that the EPA should use "market-based and incentive-based approaches" to transition grower groups into engaging in less risky practices.[360] Additionally, Vice President Gore encouraged the EPA to "explore creative, common-sense approaches" to eliminate unacceptable risks and replace those products posing such risks with "known safe alternatives."[361]

Legislation could create economic incentives for farmers to reduce their reliance on pesticides and to practice IPM.[362] For example, the government could increase funding to train farmers about the effectiveness and efficiency of IPM.[363] Additionally, the government could pay premiums to farmers who engage in sustainable agriculture and provide increased subsidies for decreased pesticide use.[364] Of course, an impediment to government

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354. *See* 7 U.S.C. § 136r-1 (1994).

355. *See* Memorandum from Vice President Al Gore to Secretary Daniel Glickman and EPA Administrator Carol Browner (Apr. 8, 1998) (reaffirming commitment to FQPA and describing implementation principles) [hereinafter Gore Memorandum].

356. *Id.* at 2-3.

357. *See* EPA, 1996 FOOD QUALITY PROTECTION ACT IMPLEMENTATION PLAN at pt. 8.2 (Mar. 1997) [hereinafter IMPLEMENTATION PLAN].

358. *See* Geltman & Skroback, *supra* note 349, at 19.

359. *See* IMPLEMENTATION PLAN, *supra* note 357, at Part 8.2.

360. Gore Memorandum, *supra* note 355, at 3.

361. *Id.*

362. *See* Carlucci, *supra* note 261, at 215-16 (discussing legislative incentives for farmers). In 1993, the Clinton Administration announced the goal that 75% of all U.S. cropland would be farmed using IPM before the year 2000. *See* IMPLEMENTATION PLAN, *supra* note 357, at pt. 8.2.

363. *See* Carlucci, *supra* note 261, at 214-15.

364. *See id.* at 215-16. These subsidies would have to be structured so as to coincide with exiting subsidy programs which actually discourage crop rotation and planting of the most environmentally appropriate crops for a location and time period: two practices essential to an IPM program. *See id.* at 216.

incentives is funding, but funding could come from increased fees for pesticide use—particularly use of the most dangerous pesticides[365] as determined by crude QRA estimates[366]—thereby also creating negative economic incentives for use of these chemicals.

Finally, federal labeling laws should be revised to require informing consumers about growing methods, since consumers appear willing to pay more for sustainable agriculture.[367] Additionally, Congress could revise federal labeling laws to decrease emphasis on the size and appearance of raw agricultural products when grading them because products grown with sustainable agriculture are often less physically attractive than those grown using conventional pesticides.[368] These legislative changes would make sustainable agriculture more profitable and provide market incentives for reduced pesticide use.

B. Suggestions for Current Implementation of the FQPA

1. Recent Scientific Reports

The effects of pesticides on children's health and our treatment of this potential danger has been compared to the history of our study of lead poisoning in children[369] and the now outdated notion that while we suspected lead was a danger to children, we should wait until the hypothesis was confirmed before taking regulatory action.[370] History proved this to be a dangerous and inappropriate approach, and many children have suffered profound learning deficits because they were exposed to harmful levels of lead—the same levels of lead that would not have harmed adults.[371] Two major recent scientific reports, one entitled "Overexposed," by Richard Wiles et al. of the Environmental Working Group (hereinafter "EWG"),[372] and the other, "Putting Children First," by David Wallinga of the NRDC,[373]

365. *See id.* at 219-20.

366. *See* Applegate, *supra* note 23, at 283.

367. *See* Carol Baxter, *Buying Organic, Eating Organic, Why It's Important,* BIG APPLE PARENT, at 19 (Apr. 1998).

368. *See* Carlucci, *supra* note 261, at 218.

369. *See* SAP ON 10X FACTOR, *supra* note 26 (noting that the history of lead as an example of a developmental neurotoxin not originally recognized as a harmful substance to children might inform decision making about organophosphate regulation).

370. *See* WILES ET AL., *supra* note 59, at 5-6.

371. *See id.*

372. *See id.* The EWG is a consumer interest group in Washington, D.C.

373. Referring to WALLINGA, *supra* note 30.

seriously question the EPA's current approach to the regulation of pesticides—an approach which looks similar to our past regulatory history of lead.

a. The EWG Report

In "Overexposed," the EWG stressed that the situation with regard to a widely used group of pesticides known as organophosphates[374] may be worse than it was with lead because a larger cross section of children receive a daily dose of organophosphates in their food.[375] Nonetheless, the EPA has taken the position that the tenfold additional safety factor need not be applied in all risk assessments involving organophosphates,[376] and has currently put off major reassessments of organophosphate pesticide tolerances since the enactment of the FQPA.[377]

The EWG points out that the EPA has taken this approach to organophosphate pesticides in the face of forty years of research and literature with regard to organophosphate toxicity which raises grave concerns about organophosphates and their effects on the nervous systems of children.[378] These insecticides can produce "long-term behavioral and functional damage to the nervous system" even while the system appears to be functioning normally."[379] Additionally, the EWG noted that the peer-reviewed literature consistently and compellingly points to the conclusion that "fetal and neonatal animals are often more sensitive than adults to the

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374. *See* WILES ET AL., *supra* note 59, at 28-9 (using a similar analytical method to the one used by the National Academy of Sciences in its 1993 Report (DIETS OF CHILDREN, *supra* note 19)).

The term oraganophosphates pesticides is used to describe organophosphorous compounds. SCIENTIFIC ADVISORY PANEL, EPA, A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE AGENCY IN CONNECTION WITH COMMON MECHANISM OF ACTION OF ORGANOPHOSPHATES 1 (1998) [hereinafter SAP ON ORGANOPHOSPHATES].

375. *See* WILES ET AL., *supra* note 59, at 5-6.

376. *See id.* at 11.

377. *See* Letter from Susan H. Wayland, Acting Assistant Administrator, EPA, to Congressman Henry Waxman 1-6 (Feb. 22, 1999) (detailing organophosphate pesticide reassessment plans and revocations). On August 2, 1999, the EPA banned most uses of methyl parathion, a widely used organophosphate, and lowered the tolerance on azinphos methyl, another organophosphate. *See* Wald, *supra* note 200, at A1. This is the first move by the EPA specifically intended to protect children. *See id.* at A11. *But see supra* notes 200-207 and accompanying text (noting that these decisions may not have been truly significant).

378. *See* WILES ET AL., *supra* note 59, at 13. The Report described organophosphates as acetylcholinesterase inhibitors in the nervous system. *See id.* Although the EWG noted that the role of acetylcholine in the nervous system function is not completely clear, it is clear that the enzyme acetylcholine is essential to the proper functioning of the nervous system. *See id.*

379. *Id.*

toxic effects" of exposure to organophosphate insecticides.[380] The EWG concluded: (1) children suffer long term deficits as a result of low level exposure to organophosphates even in the absence of any overt signs of problems;[381] (2) "American children are routinely exposed to unsafe levels of organophosphate pesticides in the food they eat;"[382] and (3) it is probable that these pesticides alone are "[c]ausing long-term functional and learning deficits that scientists are just beginning to understand."[383]

b. The NRDC Report

In April 1998, the NRDC also published a report calling attention to the EPA's failure to implement the FQPA to protect children and making recommendations about how to make pesticide levels in food safer for children.[384] The NRDC Report highlights the EPA's failure to use the ten-fold safety factor[385] and criticizes the EPA for not updating its testing guidelines for pesticide registrants to ensure broad testing concerning neo-natal and post-natal toxicity of pesticides.[386]

2. Step by Step Implementation in Accord with the Legislative Mandate of FQPA: Common-Sense Implementation To Protect Children

Because QRA is such a flexible tool that it does not force administrators to realistically assess the dangers that most pesticides ultimately pose to children and the environment, the FQPA should be enforced currently in the

380. *Id.* at 13, 40.

381. *See id.* at 19. The EWG stressed that "[u]nlilke data generated under EPA protocol, the peer reviewed literature analyzed [in its report] show a consistent and repeated pattern of behavioral and functional deficits from low level organophosphate exposure in the absence of any overt toxic effects . . . ."*Id.*

382. Baxter, *supra* note 367, at 19. It appears that the public is concerned about pesticides in the food supply: organic food sales have increased from $174 million in 1980 to $1.9 billion in 1993, to $3.6 billion in 1996. *See id.* Additionally, numerous consumer guides exist to aid the consumer in choosing the safest food. *See, e.g.*, DAVID STEINMAN, DIET FOR A POISONED PLANET, HOW TO CHOOSE SAFE FOODS FOR YOU AND YOUR FAMILY (1990).

383. WILES ET AL., *supra* note 59, at 6. "On any given day, [the Environmental Working Group] estimate[s] that more than one million children under age six exceed federal safety standards for [organophosphates]," and that "[o]ne hundred thousand of these children exceed these same standards by a factor of 10 or more." *Id.* at 41.

384. *See* WALLINGA, *supra* note 30.

385. *See id.* at 42.

386. *See id.* at 25-40.

manner that is most protective of human health.[387] This sort of implementation calls for the EPA to presumptively use the tenfold additional safety factor in the absence of compelling toxicity and exposure data indicating that a substance does not pose a danger to infants and children.[388] Moreover, it would require the EPA to adhere to conservative assumptions, including the assumption that negligible risk mean not greater than one-in-one-million,[389] and that all crops that can be treated with a pesticide will be treated.[390] Implementation of this sort would go far toward reducing the information bias inherent in EPA tolerance decisions and would increase safety for children—even if science is not yet up to this task.[391] In the vinclozolin decision, for example, the EPA should have admitted that it lacked information about the common mechanism of toxicity that vinclozolin shares with iprodione and procymidone with regard to children, and then applied the additional tenfold safety factor.[392]

Under the guise of a lack of toxicological information and a lack of appropriate methodology, the EPA has instead adopted an approach to the implementation of the FQPA that is neither most conservative nor most protective of children's health.[393] The problem with this approach is that the FQPA specifically calls for the Administrator to utilize *existing* information and methodology to consider the cumulative effects of toxins and consumers' aggregate exposure to other pesticides and related substances[394] and to implement *additional* safety factors to account for current uncertainties with respect to exposure and toxicity for infants and children.[395]

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387. The Environmental Working Group has suggested that because reliable databases do not exist with regard to data on fetal and infant toxicity for many pesticides, the implementation of the FQPA in accord with Congressional intent must proceed on a step by step basis, and that we must view first attempts to enforce the FQPA as first steps in the process of making our food supply safer for children. *See id.*

388. *See* WALLINGA, *supra* note 30, at 48-49.

389. *See* H.R. REP. NO. 669, 104th Cong., 2d Sess., pt. 2, at 41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268.

390. *See* Vinclozolin: Pesticide Tolerance, 62 Fed. Reg. 38,464, 38,469 (1997) (codified at 40 C.F.R. pts. 180, 185 & 186); VINCLOZOLIN CHALLENGE, *supra* note 13, at 11. While the FQPA permits the EPA to deviate from the conservative assumption that all crops that can be treated will be treated, it may only do so on the basis of reliable data that does not understate exposure for any subpopulation, such as children. *See* 21 U.S.C. § 346a(b)(2)(F) (1994 & Supp. III 1997); *see supra* notes 248-49 and accompanying discussion.

391. *See supra* notes 133-152, 255-260, 342-344 and accompanying text.

392. *See* 21 U.S.C. § 346a(b)(2)(C) (1994 & Supp. III 1997); 21 U.S.C. § 346a(b)(2)(D) (1994 & Supp. III 1997); *see also* VINCLOZOLIN CHALLENGE, *supra* note 13, at 28.

393. *See, e.g.*, Vinclozolin; Pesticide Tolerance, 62 Fed. Reg. at 38,470.

394. *See* 21 U.S.C. § 346a(b)(2)(D).

395. *See* 21 U.S.C. § 346a(b)(2)(C).

Essentially, the statute was designed to shift the onus to the chemical companies so that children would receive additional protection from pesticide exposure in their diets *unless and until* the chemical manufacturer could prove that such additional safety precautions were not necessary.[396] The EPA's current implementation approach instead turns the logic of the FQPA on its head and allows higher tolerances until it has specific evidence indicating that such higher tolerances are not safe for children.[397]

The legislative history of the FQPA and the plain words of the statute make clear that Congress has not chosen a "wait and see" approach, but has authored a statute that is capable of offering broad current protection to our nation's children.

> Any delay in implementing the new child-protective provisions of the FQPA should be viewed, at best, as bare-knuckle politics. At worst, it amounts to a massive experiment on large numbers of fetuses, infants, and children, an experiment where we knowingly expose them on a daily basis to pesticide-chemicals designed to be poisonous in small amounts.[398]

While the EPA has finalized certain revised data requirements and testing guidelines, which were drafted prior to the FQPA[399] and which are more "reflective of current science" than were previous testing requirements and guidelines,[400] these guidelines do not reflect the new statutory requirement that *all* pesticide residues must be safe for children.[401] Moreover, because toxicity testing is extraordinarily expensive and pesticide manufacturers typically generate the toxicity data for the EPA's first step of QRA, hazard identification,[402] there is absolutely no incentive for pesticide manufacturers to perform toxicity testing in excess of EPA's protocols. Statements by the pesticide industry and agribusiness that we should wait until the data is complete until we implement stricter testing and data requirements are likely self-serving[403] and perpetrate the lack of knowledge about the broad range of dangers that pesticides pose to children. The EPA should thus review its

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396. *See* WALLINGA, *supra* note 30, at 41-42 (noting that the law is now clear that in the absence of reliable and complete data with regard to pre- or post-natal, infant or child toxicity, the EPA must err on the side of child safety and apply the additional tenfold margin of safety when setting food tolerances).

397. *See supra* notes 236-44 and accompanying discussion.

398. WALLINGA, *supra* note 30, at ix.

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

400. *See id.* at 48.

401. *See id.* (calling these guidelines imperfect).

402. *See id.* at 25.

403. *See id.* at 49.

exposure data and toxicity testing guidelines with children's experts to ensure that they are complete and thorough,[404] and then implement more stringent testing guidelines and requirements.

With regard to the particular danger that organophosphates pose to children's health, the EWG recommended that the EPA ban all home and other uses of organophosphates and that the EPA should immediately ban five additional high-risk organophosphates that do not meet current safety standards.[405] The EWG also urges that organophosphate uses should be banned if the food is to be used in commercial baby food.[406] Additionally, the EWG has urged that the EPA should require manufacturers to do developmental neurotoxicity studies for all remaining permissible organophosphates to gauge their effect on developing fetuses and children.[407] For organophosphates for which this information does not currently exist, the EPA should apply the required extra tenfold margin of safety.[408] Finally, the EWG suggests that food tolerances for all organophosphates be adjusted downward so that they are at least safer for infants and children.[409]

VI. CONCLUSION

Congress passed the FQPA in 1996, reaffirming its commitment to scientifically and quantitatively assessing the risk of pesticides as a basis for regulating their use on food. Although Congress passed the FQPA in the wake of growing scientific evidence that pesticides pose a unique danger to children, and it requires the EPA to implement additional safeguards for children, the EPA does not appear to be implementing the FQPA in accord with the legislative intent behind the Act.

Instead, the EPA appears to be using the complexity and malleability of the QRA process to avoid strict implementation of the FQPA. The recent challenge by the NRDC regarding the EPA's tolerance decision for the pesticide vinclozolin highlights the Agency's practice in this regard.

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404. *See* WALLINGA, *supra* note 30, at 48-49.

405. *See* WILES ET AL., *supra* note 59, at 42. These organophosphates were identified by the Environmental Working Group as "methyl parathion, dimethoate, chlorpyrifios, pirimiphos, methyl, and azinphos methyl." *Id.* The EPA has since banned most uses of methyl parathion and limited the use of azinphos methyl. *See generally* Wald, *supra* note 200.

406. *See* WILES ET AL., *supra* note 188, at 42.

407. The EPA has required current registrants of a limited number of organophosphates to submit these studies within two years; *see supra* notes 209-212.

408. *See* WILES ET AL., *supra* note 59, at 42; *See supra* notes 213-215 and accompanying text (noting that the EPA will probably not apply the tenfold safety factor while awaiting the results of developmental neurotoxicity studies.)

409. *See* WILES ET AL., *supra* note 59, at 42.

Specifically, the EPA uses QRA and "scientific methodology" to justify its failures to use the FQPA ten-fold safety factor; to consider the broad range of a pesticide's effects; or the common mechanisms of toxicity a pesticide may share with another chemical. While the reasons for the EPA's failure to implement the FQPA to protect children are unclear, its lax implementation is most likely the result of political pressures and lack of agency resources and capabilities.

The EPA's inaction in this regard has been heavily criticized. Current implementation requiring the presumptive use of the additional ten-fold safety factor would be a great step toward increasing protections for children. Additionally, stricter regulation of organophosphate pesticides is needed to protect infants and children until data exists to prove that such protections are not needed.

Congress should draft future legislation which is less heavily dependent on quantifying and managing the risks of pesticides and more focused on reducing our overall reliance on pesticides. This type of legislation would use QRA comparatively and sparingly and would be incentive based. Additionally, it would be consistent with the current trend in environmental regulation toward pollution prevention, rather than pollution management.