

Summer 1997

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Recommended Citation

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THE FOOD QUALITY PROTECTION ACT OF 1996: DOES THE DELANEY CLAUSE EFFECTIVELY PROTECT AGAINST CANCER OR IS IT OUTDATED LEGISLATION?

ERIN E. MORAN*

INTRODUCTION

In 1973, Jack M. Setzer began work at a cardboard container facility where he had to handle a variety of chemicals.¹ In April of 1975, Setzer began experiencing severe abdominal pain, vomiting, aching pains, difficulty in breathing, numbness in his arms and chest, dizzy spells and nausea.² After losing over forty pounds, Setzer checked into the hospital in June of 1987.³ Doctors diagnosed Setzer with pancreatic cancer, and he died on January 18, 1988.⁴

Thousands of people in a situation similar to Jack Setzer's unknowingly contract the deadly disease of cancer through exposure to carcinogens⁵ in the environment.⁶ For over a decade, the

* J.D. Candidate, 1998.

1. *Setzer v. Boise Cascade Corp.*, 473 S.E.2d 431, 432 (N.C. Ct. App. 1996).

2. *Id.*

3. *Id.*

4. *Id.* Setzer's wife subsequently filed suit against her husband's employer, alleging that exposure to formaldehyde caused her husband's cancer. *Id.* at 432-33. Plaintiff's expert doctor testified that a causal relationship existed between cancer of the pancreas and exposure to industrial chemicals. *Id.* The doctor also testified that studies showed the rate of pancreatic cancer was significantly higher in employees in the paper industry. *Id.* The appellate court remanded the case to determine if there was competent evidence to support the Industrial Commission's findings of fact and conclusions. *Id.* at 434.

5. A carcinogen is a substance that causes the development of cancer. *MOSBY'S MEDICAL, NURSING, AND ALLIED HEALTH DICTIONARY* 183 (4th ed. 1996). An environmental carcinogen is defined as any natural or synthetic substance that can cause cancer. *Id.* at 402. These substances can be divided into chemical agents, physical agents, hormones and viruses. *Id.* Some environmental carcinogens include arsenic, asbestos, uranium, vinyl chloride, ionizing radiation, ultraviolet x-rays, and coal tar derivatives. *Id.* Although chemical carcinogens create effects that are delayed as long as 30 years, other

scientific community has agreed that environmental factors, such as chemical pollutants that exist in the air, water and food supply cause most cancer.⁷ Without these environmental factors, the incidence of cancer in this country could be reduced by as much as eighty to ninety percent.⁸

The U.S. Department of Health and Human Services has reported that cancer rates in this generation have increased when compared with prior generations.⁹ Men are at a two hundred percent higher risk than their grandfathers were for developing cancer, and women are at a fifty percent higher risk than their grandmothers were.¹⁰ These findings strongly suggest that cancer can be prevented by eliminating harmful environmental exposures.¹¹ In fact, studies show that farmers, welders, metal workers, plasterers, textile dyers and fertilizer workers are at a higher risk for developing cancer than workers who are not exposed to environmental pollutants.¹²

By the year 2000, the leading cause of death in America will be cancer.¹³ Based on current estimates, one in every three Ameri-

carcinogens produce more immediate effects. *Id.* Eighty percent of all lung cancer involves carcinogens in tobacco smoke. *Id.* Several factors, including heredity, affect an individual's susceptibility to cancer-causing agents. *Id.*

6. The facts of Jack Setzer's situation are similar to the facts in *Joint E. & S. Dist. Asbestos Litig. v. United States Mineral Prod. Co.*, 52 F.3d 1124 (2d Cir. 1995). In that case, John Maiorana was exposed to an asbestos spray on his job site in the fall of 1969 and spring of 1970. *Id.* at 1126. In January of 1983, doctors diagnosed Maiorana with colon cancer, and he died six months later at the age of 40. *Id.* The court reinstated the jury verdict in favor of the plaintiff, concluding that the plaintiff had presented both epidemiological studies in support of a causal connection between colon cancer and asbestos as well as clinical evidence of his own history and medical records. *Id.* at 1127, 1139.

7. Frederica P. Perera, *Molecular Epidemiology: Insights Into Cancer Susceptibility, Risk Assessment, and Prevention*, 88 J. NAT'L CANCER INST. 496 (1996).

8. *Id.* Genetics, age, sex, ethnicity, immune function and level of nutrition are all factors which influence a person's cancer risk from exposure to environmental carcinogens. *Id.* Genetic predisposition alone, contrary to popular belief, is responsible for no more than five percent of all cancers in the United States. *Id.* When it comes to the food supply, researchers generally assume foods which do not go through much processing are safe—it is man's additions to foods, such as the chemicals used to produce and preserve food, that are the main source of cancer risk that endanger human health. Richard A. Merrill, *Reducing Diet-Induced Cancer Through Federal Regulation: Opportunities and Obstacles*, 38 VAND. L. REV. 513, 514 (1985).

9. Kara Smigel, *Top Cancer-Related News Stories Focus on Fraud, Breast Cancer, And the Hope of Early Detection*, 87 J. NAT'L CANCER INST. 12 (1995).

10. *Id.*

11. *Id.*

12. Mustafa Dosemeci, et al., *Farming and Prostate Cancer Among African-Americans in the Southeastern United States*, 86 J. NAT'L CANCER INST. 1718 (1994).

13. 51 METROPOLITAN LIFE INSURANCE CO., *Cancer Risk and Prevention*

cans will become a victim of cancer.¹⁴ Cancer still baffles the scientific community, despite significant progress in research over the years. In 1993, cancer and heart disease combined were responsible for approximately fifty-six percent of all deaths.¹⁵ Children are especially at risk for cancer because their youth makes them more susceptible to diseases.¹⁶ Therefore, there exists a need for strict regulation of cancer-causing agents. However, recent changes in the law are evidence that the standards for carcinogen risk assessment are being relaxed.

One such change in carcinogen risk assessment resulted with the passage of the Food Quality Protection Act of 1996.¹⁷ The Environmental Protection Agency (EPA) regulates pesticide residues on food under the Federal Food, Drug and Cosmetic Act (FFDCA).¹⁸ The EPA also regulates the registration and licensing procedures for pesticides¹⁹ under the Federal Insecticide, Fungicide

Update, STAT. BULL. 21, (1992). Between the years of 1950 and 1987, cancer death rates increased six percent in the United States. *Id.*

14. 74 METROPOLITAN LIFE INSURANCE CO., *Trends in Urinary Tract Cancer Deaths*, STAT. BULL. 28 (1993).

15. 45 U.S. DEP'T HEALTH & HUM. SERVS., MORBIDITY AND MORTALITY WKLY. REP. 161, (1996). Doctors will diagnose an estimated two million women in the United States with breast and cervical cancer during the 1990's alone. *Id.* at 484. Approximately 54,900 persons will die from colorectal cancer this year. *Id.* at 107. In the United States, colorectal cancer is the third most common cancer. *Id.*

16. Arguing for pesticide reform, Albert Meyerhoff of the Natural Resources Defense Council (NRDC), cites the following statistics: cancer kills more children than any other childhood disease; brain cancer in children has increased by 38% since 1973; childhood leukemia has increased by 20% since 1973. *The Food Quality Protection Act: Hearings on S.1166 Before the Senate Comm. on Agriculture, Nutrition and Forestry*, 104th Cong., 2d Sess. 1996 WL 332994, at *7 [hereinafter *Meyerhoff Statement*].

17. The Food Quality Protection Act of 1996, Pub. L. No. 104-170 (1996) (codified as 21 U.S.C. § 346 et. seq.).

18. Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104 (1988). See also Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C.A. § 301-395 (West 1972 & Supp. 1997) (regulating the use of pesticides in the food supply). The FFDCA is designed to ensure that the food supply the American public consumes is safe. *Les v. Reilly*, 968 F.2d 985, 986 (9th Cir. 1992). In order to ensure that the food supply is safe, the FFDCA prohibits the sale of food that is adulterated or contains any unsafe food additive. *Id.* A food additive is a substance that will become a component of any food. *Id.* Pesticides are therefore governed by the FFDCA because they ultimately end up being components in the food supply that Americans consume. *Id.*

19. Pesticides are used widely in U.S. agriculture, and can kill pests, including weeds, insects, fungi, bacteria and rodents. NAT'L RES. COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND YOUNG CHILDREN 13 (1993) [hereinafter NAT'L RES. COUNCIL]. Pest control from the use of chemicals has contributed to dramatic increases in most major fruit and vegetable crops and has improved the quantity and variety of the U.S. diet. *Id.* at 18. However, many pesticides are harmful to the environment and humans. *Id.* They can increase the incidence of cancer, cause reproductive dysfunction and can pos-

and Rodenticide Act (FIFRA).²⁰ While the Food Quality Protection Act of 1996 broadly amends both the FFDCA and FIFRA, this Comment addresses just one of the changes: the amending of the standard set forth in the FFDCA as it applies to pesticide tolerances for processed foods. The change is from a zero-risk of cancer standard²¹ to a standard of "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue."²² Under the Delaney Clause, if an additive was found to cause cancer in animals or humans, it could not be used on processed foods though a risk-benefit analysis was permitted for pesticides used on raw foods.²³ With the new law, the produce industry may use

sibly cause damage to the immune and endocrine systems. *Id.* The human diet is a basic source of exposure to pesticides. *Id.* The trace amounts of pesticides that are present in the food supply are called residues. *Id.* Residue levels stand for the amount of a pesticide that is applied to a crop, the time that has passed since its application, and the rate of evaporation of the pesticide. *Id.* American infants and children consume pesticides on a regular basis. *Id.* In order to protect the American public from the harmful effects of pesticides, the U.S. Congress has enacted food safety legislation to regulate residue exposures, including the Federal Food, Drug and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). *Id.* Concern in recent years that the food safety statutory scheme is inadequate to protect the health of children led Congress in 1988 to request the National Academy of Sciences (NAS) to appoint a committee to study the effects of pesticides on children. *Id.* at 14. The National Research Council of the NAS presented the results of its study in 1993, and the Food Quality Protection Act of 1996 was enacted with the purpose of employing the NRC's recommendations. *Id.*

20. 7 U.S.C.A. § 136 (West 1980 & Supp. 1997). See Carol S. Curme, Esq., *Regulation of Pesticide Residues in Foods: Proposed Solutions to Current Inadequacies Under FFDCA and FIFRA*, 49 FOOD & DRUG L.J. 609 (1994) (discussing the weaknesses existent in the FFDCA and FIFRA.) The EPA establishes the legal limits for pesticide residues, reviews the registration data of manufacturers and researches the environmental implications of pesticide residues. *Id.* at 610. The EPA will not approve a pesticide unless it has granted a tolerance for the residues. *Id.* at 612. A "tolerance" is defined under the FFDCA as "the maximum quantity of a pesticide residue allowable on a raw agricultural commodity . . . and in processed food when the pesticide has concentrated during processing." NAT'L RES. COUNCIL, *supra* note 19, at 18. The EPA will reduce a tolerance level if it determines that exposure would endanger human health. Curme, *supra*, at 612.

21. Federal Food, Drug, and Cosmetic Act of 1958, 21 U.S.C.A. § 348(c)(3) [hereinafter The Delaney Clause]. The Delaney Clause provides: "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal . . ." *Id.*

22. The Food Quality Protection Act of 1996, 21 U.S.C.A. § 346a(b)(2)(ii).

23. See Allison D. Carpenter, *Impact of the Food Quality Protection Act of 1996*, 3 ENVTL. L. 479 (discussing the effects of the Food Quality Protection Act of 1996 on the Federal Food, Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act). The Delaney Clause prohibited the existence of any residue which was found to cause cancer at any detectable level. *Id.* at 482. However, the Miller Amendment to the FFDCA (Pub. L. No. 83-518, 68 Stat. 511 (1954)) allowed tolerances for raw fruits and vegetables to be based on a risk-benefit analysis. *Id.* Further, the Delaney Clause took only

pesticides on processed foods even if the EPA finds that the pesticides cause cancer in animals. The EPA must only determine, to a reasonable certainty, that no harm will result from the use of the pesticide or that the pesticide's benefits outweigh the risks involved.²⁴ In effect, the Food Quality Protection Act of 1996 abolishes the Delaney Clause with respect to pesticide tolerance setting.²⁵

Part I of this Comment details the fight to replace the zero-risk standard that resulted in the Food Quality Protection Act of 1996. Part II analyzes the implications of this new law which has relaxed the standards of pesticide tolerance²⁶ for cancer-risk. This Comment argues that the Act's flexible standards for cancer-risk assessment for pesticides may potentially result in devastating effects on the health of Americans, particularly their children. Finally, Part III discusses how the new law will encourage America's reliance on pesticide use and proposes that the country move more in a direction towards the use of alternative agricultural techniques. Part III also proposes that Congress reassert the zero-risk standard of the Delaney Clause for regulating the setting of pesticide tolerances on all foods.

I. THE FIGHT TO REPLACE THE DELANEY CLAUSE

Since the enactment of the Delaney Clause²⁷ of the Federal Food, Drug and Cosmetic Act in 1958, the courts have interpreted the clause as an absolute bar to the use of any carcinogenic food additive.²⁸ The Delaney Clause sets forth a zero-risk standard for

cancer risks into account, which resulted in the usage of pesticides on processed foods that were prohibited on raw foods because of a non-cancer risk. *Id.* The two different approaches for raw and processed foods became known as the Delaney Paradox. *Id.* The Food Quality Protection Act establishes a single standard for residues on all types of food. *Id.* at 484. It is the position of this Comment that the Delaney Clause standard of a zero tolerance for cancer risk should apply to pesticide residues on all types of foods, both processed and raw.

24. The Food Quality Protection Act of 1996, 21 U.S.C.A. § 346a(b)(2)(B)(iii)(I) & (II) (West 1972 & Supp. 1997).

25. *Food For Thought Pesticide Bill Shows Progress is Possible*, COLUMBUS DISPATCH, Aug. 14, 1996 at 8A [hereinafter *Food For Thought*].

26. Pesticide manufacturers conducted field trials basing tolerance concentrations on their results. NAT'L RES. COUNCIL, *supra* note 19, at 18. Then, the manufacturers design the tolerance concentrations to reflect the highest residue concentrations likely in normal agricultural practice. *Id.* Therefore, tolerances are based not on considerations of human health, but on good agricultural practice. *Id.* Tolerances are the single most important tool by which pesticide residues are regulated in food. *Id.*

27. 21 U.S.C.A. § 348(c)(3) (West 1972 & Supp. 1997).

28. *Les v. Reilly*, 968 F.2d 985, 989 (9th Cir. 1992). The EPA's refusal to ban pesticides that posed only a *de minimis* risk of causing cancer was contrary to the provisions of the Delaney Clause, which prohibits food additives that induce cancer. *Id.* at 988. The court further held that the statute unambi-

any food additive that causes cancer in animals.²⁹ In other words, prior to The Food Quality Protection Act, if a pesticide was found to cause any cancer in animals, it could not be used. The Delaney Clause stands for the proposition that no risk of cancer should exist in the American food supply. The courts have consistently interpreted the legislative intent behind the clause to prohibit even a negligible risk of cancer in the food supply.³⁰

For years, the stringent standard that the Delaney Clause set forth in 1958 has been a controversial issue.³¹ Proponents of amending the Delaney Clause argue that it is outdated because risk levels can be detected at a very minute level today, as opposed to 1958 when Congress enacted the Clause.³² Therefore, the same proponents argue that additives which pose only minute risks should not be banned from usage. Delaney Clause supporters, on the other hand, argue that the Clause strictly protects the public against cancer and is therefore one of the most important safety features that exist in the current food safety statutes.³³

guously provided that pesticides which concentrated in processed food were to be treated as food additives which were governed by the Delaney Clause. *Id.* at 989. "If pesticides which concentrate in processed foods induce cancer in humans or animals, they render the food adulterated and must be prohibited." *Id.*

29. See 21 U.S.C.A., § 348(c)(3) (applying to food additives); see also 21 U.S.C.A., § 376(b)(5)(b) (applying to color additives as well).

30. *Les*, 968 F.2d at 989. See, Amy Montemarano, *The Delaney Paradox Resurfaces: Regulating Pesticides as Food Additive Under Federal Law*, 25 RUTGERS L.J. 433, 434-35 (1994) (stating the purpose of the Delaney Clause continues to remain legitimate). *Id.* at 463. The American people desire to be protected against cancer-causing agents in the food that they eat. *Id.* Montemarano argues that the problem with the Delaney Clause is that it places the protection against cancer too far down the line of food production. *Id.* Instead of encouraging pesticide reliance, revisions to the food safety statutes should foster the development of alternative pest control methods. *Id.*

31. For discussions on 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); Sherry Booth Mastrostefano, *The Delaney Clause: Still No "De Minimis" Exception*, 57 GEO. WASH. L. REV. 1306 (1989); Richard A. Merrill, *Reducing Diet-Induced Cancer Through Federal Regulation: Opportunities and Obstacles*, 38 VAND. L. REV. 513 (1985); Frederick H. Degnan and W. Gary Flamm, *Living With and Reforming the Delaney Clause*, 50 FOOD & DRUG L.J. 235 (1995).

32. *Food For Thought*, *supra* note 25, at 8A. Today, scientific technology is so advanced that cancer causing potential can be measured in parts per billion or trillion. *Id.* Proponents of the new law argue that application of the Delaney Clause to pesticides was necessary in 1958 but that today it is not necessary because of the advancements of technology. *Id.* Proponents also argue such minuscule risks that are detectable today should not call for the banning of pesticides by imposing the strict standard of the Delaney Clause because doing so would result in the banning of dozens of useful pesticides that pose only a negligible risk. *Id.*

33. *The Food Quality Protection Act: Hearings on S.1166 Before the Senate*

In the past five years alone, the House Agriculture Committee held fourteen hearings on issues affecting pesticide laws.³⁴ Congress finally abolished the Delaney Clause's zero tolerance analysis and replaced it with the Food Quality Protection Act's risk-benefit analysis.³⁵

As section A discusses, the EPA attempted to set a negligible risk standard in the past despite the mandates of the Delaney Clause. Section A also looks at how the courts struck down the EPA's interpretation of this "negligible risk," reasoning that the Delaney Clause did not allow for it. Section B discusses how supporters of anti-Delaney legislation finally achieved a victory with the Food Quality Protection Act, which changes the standard set forth in the Delaney Clause from a zero-risk to a negligible risk.

A. *The EPA's Attempts to Apply a Negligible Risk Standard to the Pesticide Industry Prior to the Passage of the Food Quality Protection Act of 1996*

In October of 1988, the EPA published a new interpretation of the Delaney Clause proposing to permit use of cancer-causing pesticides as long as they posed only a *de minimis* risk of causing cancer.³⁶ The EPA attempted to set a negligible risk standard, or a cancer risk of less than one in a million over a seventy year life-span.³⁷

The courts subsequently struck down the EPA's interpretation of the Delaney Clause. In *Les v. Reilly*,³⁸ the Ninth Circuit Court of Appeals held that the EPA exceeded its authority when it allowed the use of four pesticides as food additives because the chemicals posed only a *de minimis*³⁹ risk of causing cancer.⁴⁰ The

Comm. on Agriculture, 104th Cong., available in 1996 WL 332992, at *2 (1996) (testimony of Philip J. Landrigan, Professor and Chairman of the Department of Community Medicine and Director of the Division of Environmental and Occupational Medicine of the Mount Sinai Inc. School of Medicine, N.Y. City) [hereinafter *Landrigan Statement*].

34. Pat Roberts, *Letters to the Editor: Flexible, Rational Rules for Protecting Our Food*, WALL ST. J., Sept. 26, 1996 at A13.

35. The Food Quality Protection Act of 1996, 21 U.S.C.A. § 346.

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

37. H.R. REP. NO. 104-669(II), at 32 (1996), reprinted in 1996 U.S.C.C.A.N. 1269, 1271.

38. 968 F.2d 985 (9th Cir. 1992).

39. *Id.* at 986. A *de minimis* risk is the equivalent of negligible risk. *Id.* at 988.

40. *Id.* at 990. Even though the EPA found the four pesticides at issue to be carcinogens in 1988, the EPA, notwithstanding the Delaney Clause, refused to revoke earlier regulations which permitted the use of the four pesticides (in the absence of carcinogenicity). *Id.* at 987-88. The EPA reasoned that although the chemicals posed a measurable risk of causing cancer, that risk was only *de minimis*, and therefore the pesticides were safe for use. *Id.* at 988. The court disagreed, however, and ruled against the EPA. *Id.* at 990.

court reasoned that the Delaney Clause prohibited the use of any carcinogenic additives, regardless of the degree of risk involved.⁴¹ This case established that the Food and Drug Administration could not, under any circumstances, change the strictness of the Delaney Clause by interpreting any sort of exception.⁴² The Delaney Clause prohibited an additive's use if it caused cancer in animals, even if the risk was only negligible, and allowed no administrative discretion.⁴³ Changing the statutory scheme of food safety laws was not the function of the court or the EPA, but rather the function of the legislature.⁴⁴ The court then cited several bills which were pending before the House and Senate at that time which would allow the level of risk to be considered in setting tolerances.⁴⁵

The Food Quality Protection Act of 1996 amends the regulation of pesticides under the FFDCA.⁴⁶ The new law alters the zero-risk standard of the Delaney Clause as it applies to pesticides, which is essentially what the EPA had been trying to do in *Les v. Reilly*.⁴⁷ Though the EPA experienced a loss in *Les*, it experienced a victory with the Food Quality Protection Act. After years of de-

The court reasoned that the intent of the Delaney Clause was to prohibit all additives that are carcinogens, regardless of the degree of risk involved. *Id.* at 988-89. This rationale for rejecting the *de minimis* exception rests on the legislative intent of the Delaney Clause which was to establish an absolute prohibition to the use of cancer-causing agents. Margaret Gilhooley, *Plain Meaning, Absurd Results and the Legislative Purpose: The Interpretation of the Delaney Clause*, 40 ADMIN. L. REV. 267, 268 (1987). Gilhooley sees the Delaney Clause as an example of interpreting a statute according to its plain meaning and thereby achieving absurd results (outlawing a substance no matter if the risk caused is only trivial or *de minimis*.) *Id.* Supporters of the Food Quality Protection Act see the result of the Delaney Clause in relation to pesticides as being absurd as well and therefore are pleased to see the Delaney Clause abolished with respect to pesticide tolerance setting. *Id.*

41. *Id.* at 276.

42. Mastrostefano, *supra* note 31, at 1307.

43. Gilhooley, *supra* note 40, at 267.

44. *Id.*

45. See *Public Citizen v. Young*, 831 F.2d 1108, 1123 (D.C. Cir. 1987) (holding that the Delaney Clause of the Color Additive Amendments to the Federal Food, Drug, and Cosmetic Act does not contain an implicit *de minimis* exception for carcinogenic dyes with trivial risks to humans).

46. Telephone Interview with Dr. Richard Hill, Science Advisor in the Office of the Assistant Administrator for Prevention, Pesticides, and Toxic Substances, the Environmental Protection Agency (Oct. 2, 1996). The Food Quality Protection Act repeals the Delaney Clause only with respect to its application to pesticides. *Id.* In the opinion of Dr. Hill, "the new law is marvelous". *Id.* The Delaney Clause was an absolute standard which did not allow for the consideration of risk. *Id.* For example, if a pesticide was found to pose a risk whereby one out of one trillion persons would likely get cancer, the Delaney Clause prohibited its use. *Id.* Banning a pesticide which posed such a minimal risk made no sense, according to Dr. Hill, when there are not even one trillion people in the world. *Id.*

47. *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992).

bate, Congress passed the Act in August of 1996.

B. A Victory for Anti-Delaney Supporters

Congress had been dealing with the issue of the Delaney Clause for fifteen years, and the Food Quality Protection Act of 1996 marks the first victory for supporters of anti-Delaney legislation.⁴⁸ Upon signing the Food Quality Protection Act into law in August, 1996, President Clinton referred to the Bill as the "peace of mind act."⁴⁹ The president believed that the old pesticide laws, though written with the best of intentions, no longer adequately protected the nation's food supply.⁵⁰

The Food Quality Protection Act has been called a "rare legislative compromise in which all sides can declare a measure of victory."⁵¹ While now affecting consumers of raw and processed foods, the Act amends the FFDCa Delaney Clause standard of zero-risk tolerance to a standard of "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue."⁵²

48. The White House: Remarks by the President at the Food Quality Protection Act Bill Signing, M2 Press-wire, M2 Communications, Aug. 5, 1996.

49. *Id.*

50. *Id.* For the past two decades, bills containing provisions similar to the provisions of the Food Quality Protection Act failed to win Congressional approval. *Food For Thought*, *supra* note 25, at 8A. Opponents of the Delaney Clause claimed it was inconsistent in its application to raw and processed foods, citing, as a ridiculous result, a situation where a substance was safe when used on tomatoes sold as fresh produce but was unsafe when used on tomatoes sold for ketchup. *Id.* See Barbara Kennedy Kahn, *New Developments in Pesticide Regulation*, 13 TEMPLE ENVTL. L. AND TECH. J. 309, 317 (1994) (arguing that the negligible risk standard applies a consistent standard to pesticide residues in foods regardless of whether they are processed or raw). John Cady of the National Food Processors Association argues that there is no such thing as zero-risk. John Cady, *FDA Reform: The Need for a Sound Science-Based Approach*, 51 FOOD & DRUG L.J. 407, 409 (1996). "Those who establish food safety laws must have the power to determine whether or not a substance poses a true risk in real-world conditions of use, and if the risk it poses is insignificant, whether or not to allow its use." *Id.*

51. Gary Lee, *In Food Safety Changes, Victories for Many*, WASH. POST, July 28, 1996 at A4. According to the EPA, new sensitive technology can locate extremely small cancer-causing levels in a substance. *Id.* Such a minute level may not be harmful to consumers. *Id.* Therefore, the Delaney standard, an absolute bar to the use of a cancer-causing agent regardless of the degree of risk involved, is outdated and inappropriate. *Id.* In other words, the standard banning pesticide residue that causes cancer in animals is outdated because this standard does not take into account the level of risk posed. *Id.* Whether the risk was minimal or large, the Delaney Clause prohibited it, which the EPA argued was inappropriate because with the technology of today, minimal or trivial risks can be detected. *Id.* Since the risks that some pesticides pose are so slight, their use should not be banned by the absolute prohibition of the Delaney Clause. *Id.*

52. The Food Quality Protection Act of 1996, 21 U.S.C.A. § 346(b)(2)(ii). Before the Food Quality Protection Act, a weighing of risks and benefits was permitted for raw commodities, but processed commodities were subject to the

The law allows cancer-causing chemicals to be used if they pose a risk of causing cancer in less than one-in-a-million people over the course of a typical life-span.⁵³ Proponents of the new law argued that the Delaney standard was obsolete and in need of updating, because Congress enacted this standard using scientific knowledge available in 1958 and failed to adjust to advances in today's technology and medical knowledge.⁵⁴

Under the new law, the EPA must consider the benefits of pesticides as the development of an adequate, wholesome, and economical food supply in determining what is an acceptable level of risk.⁵⁵ Opponents of the new law cited studies which connect cancer to vulnerable persons exposed to pesticides, such as farmers and children, who are specifically at risk due to the amount of pesticide exposure in relation to their body structure.⁵⁶ Opponents further cited numerous reports supporting the reduction of overall pesticide use,⁵⁷ instead of the passage of legislation which allowed

Delaney Clause, with no weighing of risks and benefits. NAT'L RES. COUNCIL, REGULATING PESTICIDES IN FOOD: THE DELANEY PARADOX 40 (1987). The source of exposure, either raw or processed, seemed irrelevant, and thus the Food Quality Protection Act now calls for the weighing of benefits and risks for processed foods as well. *Id.* at 40-41. A Food Safety Advisory Committee, formed by the EPA to assist with the implementation of the Food Quality Protection Act, held its first meeting with the EPA in Washington, D.C. on Thurs. Sept. 26, 1996. Environmental Protection Agency Press Advisory, *EPA's Food Safety Advisory Committee to Hold Meeting on Sept. 26*, Sept. 23, 1996, at *1, available in 1996 WL 535388. Members of the advisory committee came from the general public, public interest groups, environmental groups, the chemical industry, agriculture and other pesticide user groups, food processors, and federal and state governments. *Id.*

53. Lynn Graebner, *Pesticide Law Comes to Relief to Farmers*, 13 BUS. J. SACRAMENTO 15 (1996). Proponents of the new law argue that it allows for more flexibility in allowing the EPA to consider all potential health risks, such as inadequate nutrition, instead of only focusing on the potential risk of causing cancer. *Id.* The law allows the EPA to apply the same negligible risk standard to pesticides in both raw and processed foods. *Id.* The new law passed unanimously in both the House of Representatives and the Senate. *Id.*

54. Julie Rovner, *Congress Moves to Repeal Controversial Delaney Clause*, THE LANCET, July 27, 1996 at B6. When the Delaney Clause was enacted in 1958, science could only detect pesticide residues in parts per million. *Id.* Today, however, science can do so in parts per trillion. *Id.* Proponents of the new law claim the Delaney standard has therefore kept new and even safer pesticides off of the market. *Id.*

55. The Food Quality Protection Act of 1996, 21 U.S.C.A. § 346a(b)(2)(B)(iii)(I) & (II) (West 1972 & Supp. 1997). The new law provides for the consideration of the pesticides use if the "use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply." *Id.*

56. *Meyerhoff Statement*, *supra* note 16, at *7. Tumors that are appearing in the general population are beginning to appear more and more like those tumors found in farmers who were exposed to carcinogenic pesticides. *Id.* at *6.

57. *Id.* at *8-9. Sweden, Denmark, and the Netherlands have adopted al-

for increased pesticide use.⁵⁸ With regard to cancer risks, the drawbacks of the new law far outweigh the benefits, especially at a time when the U.S. continues to rely increasingly on pesticide use.

II. IMPLICATIONS OF THE FOOD QUALITY PROTECTION ACT

Producers of pesticides design pesticides so that they kill living organisms.⁵⁹ Every year, America's farmers apply over one billion pounds of chemical pesticides to farms, forests and ultimately the food supply.⁶⁰ Living organisms that attack crops die once farmers use pesticides on the crops. However, because humans are ultimately exposed to these pesticides, destroying the pests could backfire and destroy humans.⁶¹

The Food Quality Protection Act requires the EPA to set tolerances for processed pesticides at a level where the risk to consumers of the food which contains the pesticide is negligible.⁶² However, Congress did not create a quantitative standard to define a negligible risk.⁶³ The law gives the EPA a great deal of flexibility in setting a tolerance which the agency determines is reasonably adequate to protect public health.⁶⁴ The EPA can even

ternative agriculture programs that have been successful in maintaining adequate levels of crop production while reducing the use of and dependence on pesticides. *Id.* If the pesticides that the United States used in just one year were placed in five pound bags laid next to one another, "they would stretch . . . three times around the earth." *Id.* at *10. Meyerhoff argues for "comprehensive pesticide reform - not just tinkering with Delaney. . . ." *Id.* at *5. Reports have repeatedly found that the United States pesticide laws are "fundamentally flawed, archaic, anachronistic, and singularly ineffectual in protecting both human health and our natural environment." *Id.*

58. *Id.* at *5. Supporters of the Food Quality Protection Act of 1996 are quick to point out that "support for Delaney reform does not mean that Congress is in favor of cancer or health risks for children, as some will portray it. Nor is it a frontal assault on our nation's environmental laws. Instead, it means an improvement in environmental policy." *The Food Quality Protection Act of 1996: Hearings on S.1166 Before the Senate Comm. on Agric., Nutrition and Forestry*, 104th Cong., available in 1996 WL 332988, at *2 (comments of Dean Kleckner, President American Farm Bureau Federation) [hereinafter *Kleckner statement*]. An improvement in environmental policy in the eyes of some is seen as a step backward in the health of our nation in the eyes of others.

59. John Carlucci, *Reforming the Law on Pesticides*, 14 VA. ENVTL. L.J. 189 (1994). The risks and benefits of pesticide use are not distributed evenly in American society when it comes to who actually bears the risks and who reaps the benefits. *Id.* at 190. Pesticides benefit society and also harm it. *Id.* An Integrated Pest Management approach to agriculture decreases the need to use chemical pesticides. *Id.* at 191.

60. *Id.* at 189.

61. *Id.*

62. H.R. REP. NO. 104-669(I) § 405 (1996), reprinted in 1996 U.S.C.C.A.N. 1208, 1235.

63. *Id.*

64. *Id.*

set a tolerance level above the "reasonable certainty of no harm" standard if the EPA determines the risk is reasonable after considering the health risks avoided through pesticide use (such as an abundant crop supply of cancer-preventative fruits and vegetables) and the benefits obtained through an "adequate, wholesome and economical food supply."⁶⁵

The Food Quality Protection Act changed the EPA's method of measuring harm resulting from pesticide use. Section A of this Part analyzes the new law's allowance of a risk-benefit analysis in determining the amount of cancer-causing substances allowed to enter the food supply. Section B examines how America's reliance on pesticides has increased tremendously over the years and how The Food Quality Protection Act will further encourage reliance on pesticides. Finally, this Part details what the use of carcinogenic pesticides coupled with the overall increase in pesticide use will mean to the health of Americans. Section C discusses the new law in relation to the impact of pesticides on those most at risk from our food supply, specifically children. Section D explores how the new law will be detrimental to the health of men and women.

A. *The Impact of a Risk-Benefit Analysis*

The Food Quality Protection Act of 1996 abolishes the Delaney Clause.⁶⁶ Without the passage of the Food Quality Protection Act of 1996, the recent court decision of *Les v. Reilly*⁶⁷ would have forced the EPA to ban the use of certain chemicals on crops, specifically all chemicals that cause cancer in animals, regardless of the degree of risk posed.⁶⁸ Congress passed the new law because, proponents argued, the continued use of the Delaney Clause would hamper the ability of farmers to meet the demands of America's fast growing population without the use of pesticides that pose a negligible risk.⁶⁹ In other words, Congress decided that

65. *Id.*

66. *Food For Thought*, *supra* note 25, at 8A. Congressional incumbents did not want to lose their seats. *Id.* They wanted the new law to be something that the public would see as an accomplishment, and failure to enact the new law would have given challengers for their seats an issue upon which to criticize them. *Id.*

67. 968 F.2d 985 (9th Cir. 1992).

68. *Id.* at 989.

69. *Food For Thought*, *supra* note 25, at 8A. Some members of the Senate argued that the new law would enhance consumer health through pesticide uses that resulted in minimal risks to consumers while allowing an affordable and abundant food supply. *The Food Quality Protection Act of 1995: Hearings on S.1166 Before the Senate Comm. on Agric., Nutrition and Forestry*, 104th Cong., available in 1996 WL 332982, at *3 (comments of John R. Cady, President and Chief Executive Officer of the Nat'l Food Processors Assoc.). The EPA would have created a crisis if it were forced to revoke the many pesticide tolerances it had previously granted if the new law was not passed. *Id.* at *4. The EPA had to decide by April of 1997 to allow or deny the use of 40 pesti-

producing an abundant food supply through the use of pesticides is necessary, even if it means that Americans will be exposed to cancer-causing pesticides. To take this a step further, Congress decided that cancer in a few people is worth the benefits that the rest of the world will reap due to an abundant food supply.

Congress failed to set forth an acceptable numerical risk level in the new law to define what constitutes a negligible risk standard.⁷⁰ Instead, the law allows the EPA to use its "expert" judgment in using a risk-benefit analysis unhindered by a "numerical straight-jacket."⁷¹ The new law allows the EPA to loosen regulations if enforcement of them would take potentially healthy foods off the market and create an interference with proper nutrition.⁷² Critics claimed that under the Delaney Clause, U.S. farmers suffered grave economic losses due to decreases in crop production; specifically, apple, citrus, grape and plum growers collectively would have suffered a \$111 million loss each year.⁷³ These critics argued that the Delaney Clause and the cases, such as *Les v. Reilly*,⁷⁴ that interpreted the clause would continue to endanger the abundance of our nation's food supply.⁷⁵ Enforcement of *Les* would force the EPA to ban the use of thirty-five pesticides, amounting to more than ten percent of the pesticide ingredients

cides which the EPA considered to be safe but which the Delaney Clause prohibited. *Id.* at *6. If the new law was not passed, the EPA would have likely had to revoke many of the pesticides, most of which had no adequate substitutes. *Id.* Further, the EPA had to revoke 13 food additive tolerances for pesticides which posed only a negligible risk. *Id.* Under the new law, the EPA will likely be able to withdraw the revocation orders on many of the tolerances which in the past had to be revoked due to the Delaney Clause mandates.

70. The Food Quality Protection Act of 1996, 21 U.S.C.A. § 346 (West 1972 & Supp. 1997).

71. *The Food Quality Protection Act: Hearings on H.R. 1627 & Pesticide Regulation Reform Before the House Commerce Subcomm. on Health and Env't*, 104th Cong., available in 1995 WL 337345, at *3 (written statement of the Nat'l Assoc. of State Dep't of Agric.). This statement in favor of the new law argued that the current debate over reforming the manner in which pesticides are regulated boiled down to an argument between "sound science and emotionalism." *Id.*

72. *Food For Thought*, *supra* note 25, at 8A.

73. Graebner, *supra* note 53, at 15. The new law will most likely allow the use of some chemicals that are currently under EPA review that would have been lost under the zero-risk standard of the Delaney Clause. *Id.* Jack King, head of the California Farm Bureau Federation, believes such chemicals which will likely be able to be used again include Benlate, which is the pesticide used on tomatoes, grapes, and rice, and mancozeb, which is used on apples and wheat. *Id.*

74. 968 F.2d 985 (9th Cir. 1992).

75. *The Food Quality Protection Act: Hearings on H.R. 1627 Before the Subcomm. on Dep't Operations and Nutrition Comm. on Agric.*, available in 1994 WL 267064, at *20. (statement of William D. Gullickson, Jr., Chairman Chemical Producers and Distributors Assoc.) [hereinafter *Gullickson Statement*].

used in agriculture today.⁷⁶

Congress chose a policy creating an abundant food supply over a policy promoting a cancer-free food supply. This is precisely why the Delaney Clause should remain applicable to pesticide tolerance setting. No abundance of food supplies can justify an increase in cancer rates. Further, Congress failed to acknowledge that there are other methods of alternative agriculture, which do not utilize pesticides, that producers can use to achieve an abundant food supply.

The Food Quality Protection Act gives the EPA the authority to permit the use of a pesticide even if it exceeds the established standard tolerance levels, as long as the benefits to the crop outweigh the possible health risks involved.⁷⁷ A pesticide tolerance can be set at a level which presents more than a negligible risk if the EPA determines that the risk is reasonable because: (1) the use of the pesticide protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue, or (2) the use of the pesticide is necessary to avoid a significant disruption in the production of an adequate, economical, and wholesome food supply for consumers.⁷⁸

The new law allows pesticides in an amount that will cause one new case of cancer in a million children, or two new cases of cancers if the pesticide provides very important benefits.⁷⁹ In ad-

76. *Id.* The *Les* ruling would have led to the revocation of numerous tolerances that were set by the EPA from 1989 to 1992 under its' interpretation of the Delaney Clause, and an estimated 100 crops would have been affected. Carpenter, *supra* note 23, at 483. Supporters of the Food Quality Protection Act argued that this result would have had "serious impacts on consumers and the economies of agricultural states." *Id.* In support of the new law, Gullickson argued that the zero-risk standard of the Delaney Clause prevented the implementation of risk evaluation, which was necessary. *Gullickson Statement, supra* note 75, at *20. He further argued that the American Cancer Society recommends that Americans need to double the amount of farm grown products they consume, such as fruit and vegetables, in order to reduce their chances of contracting cancer. *Id.* at *21. Delaney, with its zero-risk standard would therefore increase the incidence of cancer across the country because it would lead to fewer pesticides and therefore a decrease in the supply of fruits and vegetables. *Id.* C. Everett Koop, the former Surgeon General and a supporter of reforming the Delaney Clause, testified that there was "no scientific evidence showing that residues from the lawful application of pesticides to food have ever caused illness or death." 139 CONG. REC. E871-01 (daily ed. Apr. 1, 1993)(statement of Rep. Lehman). He reasoned that the Delaney Clause must be repealed because the abundant and affordable food supply of America was in danger due to this zero-risk standard. *Id.*

77. Graebner, *supra* note 53, at 15. However, distributors of a food product which contains a pesticide that exceeds the standard pesticide residue tolerance levels require special labeling under the new law. *Id.*

78. The Food Quality Protection Act of 1996, 21 U.S.C.A. § 346a(b)(2)(B)(iii)(I) & (II) (West 1972 & Supp. 1997).

79. Donella Meadows, *Pesticide Research for Tougher Laws Isn't There*, CHARLESTON GAZETTE & DAILY MAIL, Oct. 7, 1996 at 4A.

dition, the new law gives the EPA a dangerously flexible discretion to decide which benefits are important or very important. Americans might be willing to live with a law that risked giving cancer to one out of a million children if doing so would save an entire corn crop in the Midwest.⁸⁰ However, if Americans knew that farmers could grow continuous corn with little or no pesticide use by just rotating their crops, Americans might be less willing to let every one out of a million children get cancer.⁸¹

This law gives the EPA the ability to decide, to an even greater degree than before, just how much cancer is worth the benefits of using a pesticide.⁸² The health risks associated with pesticides are great, and the abolishment of the zero-risk standard of the Delaney Clause is a step towards valuing advances in technology over valuing human life. The reasonable certainty of no harm standard set forth in the new law is too flexible during a time when men, women and especially children are at risk for developing cancer from pesticide exposure, especially when research shows that America's reliance on pesticides continues to increase.

B. America's Increased Reliance on Pesticides

Harmful pests often quickly develop immunities to pesticides, thereby encouraging farmers to use larger and more deadly doses of pesticides.⁸³ In 1992, the United States produced pesticides at a rate 13,000 times faster than in 1962.⁸⁴ Agricultural runoff carries the residue into groundwater reservoirs and streams and then into birds and fish.⁸⁵ A 1991 study regarding the use of pesticides concluded that farmers who used natural alternatives to chemical control of pests, such as integrated pest management and crop rotation, could avoid using pesticides and herbicides without reduc-

80. *Id.*

81. *Id.*

82. Under the new law, the EPA is required to notify large grocery stores of the risks of pesticides and also give them a set of guidelines for reducing exposure to pesticides. Gary Lee, *Food Safety Plan Approved by House Comm.; Proposal Would Impose New Restrictions on Use of Chemicals in Farming, Processing*, WASH. POST, July 18, 1996 at A9 [hereinafter *Food Safety Plan*]. If the EPA decides that a pesticide is beneficial enough to leave on the market even though it does not meet the new negligible risk standard, the grocery store must inform the public of this by posting a list of foods on which those particular pesticides are used. *Id.*

83. AL GORE, *EARTH IN THE BALANCE: ECOLOGY AND THE HUMAN SPIRIT* 141 (1992).

84. *Id.*

85. *Id.* See U.S. CONGRESS, OFF. OF TECH. ASSESSMENT, *BENEATH THE BOTTOM LINE: AGRIC. APPROACHES TO REDUCE AGRICHEMICAL CONTAMINATION OF GROUNDWATER*, U.S. Government Printing Office (1990) (discussing agricultural approaches to reducing the contamination of groundwater from pesticide run-off).

ing yields, and without significant increases in the price of food.⁸⁶ Further, in the case of pesticides for which no substitute has yet been identified, the volume of chemicals used could be cut in half.⁸⁷ Since the Food Quality Protection Act grants a more flexible standard than the Delaney Clause, the country's reliance on pesticides will only increase at a faster rate than ever before. This certainly qualifies as a negative effect of the new law especially when children are at an increased risk of pesticide exposure.

C. *The Effects of Pesticides on Children*

A stated purpose of The Food Quality Protection Act is to "safeguard infants and children" from hazardous pesticides.⁸⁸ The new law requires the EPA to focus on children's diets in setting tolerances because they are especially vulnerable to pesticide exposure.⁸⁹ An analysis of this issue shows that the new law will not accomplish the stated purpose. Replacing the Delaney standard with the risk-benefit analysis of the Food Quality Protection Act puts America's children at an even greater risk of contracting cancer.⁹⁰

In the United States, the incidence of cancer in children is on the rise.⁹¹ Every year for the past twenty years, the incidence of the two most common forms of childhood cancer, leukemia and brain cancer, has increased in the U.S.⁹² These statistics, along with the following discussion of how children are the most at risk from pesticides, are evidence of the need for food safety statutes strictly prohibiting cancer-causing agents from entering America's food supply.

Children are those most at risk from the pesticides in the American food supply.⁹³ In the first six months of their lives, children drink seventeen times more water, pound-per-pound, than an

86. GORE, *supra* note 83, at 141.

87. *Id.*

88. *Meyerhoff Statement*, *supra* note 16, at *1.

89. *Food Safety Plan*, *supra* note 82, at A9. A 1993 National Academy of Sciences (NAS) study showed that chemicals are harmful to children at much lower doses than are harmful to adults. *Id.* The NAS study recommended that the food safety statutes be strengthened. *Id.* The Food Quality Protection Act purports to codify the NAS recommendation into federal law. *Id.*

90. *Meyerhoff Statement*, *supra* note 16, at *7.

91. *Landrigan Statement*, *supra* note 33, at *7.

92. *Id.*

93. *Cancer Causing Pesticides Abound in Supermarkets' Bounty: Washing, Peeling, Buying Organic Can Help*, Summer HEALTH NEWS & REV. 14 (1995). [Hereinafter *Cancer Causing Pesticides*]. As of 1995, of 300 pesticides approved by the federal government for use on food crops, 73 were "probable" or "possible" carcinogens, including some of the most frequently used pesticides. *Id.* Out of the 20 most frequently used pesticides, seven were potential carcinogens. *Id.*

average adult.⁹⁴ An average one-year old drinks eleven times more grape juice and twenty-one times more apple juice than the average adult.⁹⁵ Children are, therefore, more vulnerable to the harmful effects of pesticides because their diets expose them to larger doses of the pesticides.⁹⁶ Children also eat more food per pound of body weight than adults.⁹⁷ Not surprisingly, research indicates that children in homes which use garden pesticides are seven times more likely to develop childhood leukemia.⁹⁸

The Food Quality Protection Act eliminates the Delaney Clause standard as it previously applied to pesticides, and has therefore turned a very strict standard into a very loose one which gives the EPA too much flexibility in determining the amount of cancer causing agents that will be allowed in the food supply. The Delaney Clause, although it does not embody the latest developments in technology, has served its protective purpose by shielding several generations of American children from the harmful effects of carcinogenic pesticides.⁹⁹ Another area of concern which calls for the strictest standards of cancer risk assessment is the impact of pesticides on the health of men and women.

D. *The Effects of Pesticides on the Health of Men and Women*

Proponents of the Food Quality Protection Act cite statistics that the causes of cancer are primarily the amount of fat Americans consume, rather than the insignificant amounts of pesticide residue in the food.¹⁰⁰ It is true that many lifestyle factors are well

94. *Landrigan Statement, supra* note 33, at *2.

95. *Id.* The average one-year old eats two to seven times more grapes, bananas, pears, carrots and broccoli than the average adult. *Id.*

96. *Id.*

97. *Cancer Causing Pesticides, supra* note 93, at 14. The neurological systems of children are not matured, and they are therefore more vulnerable to health risks from chemical exposure. *Id.* The system of a child is not able to detoxify itself, as is the system of adults, because the kidneys are not fully developed. *Id.* The American Journal of Public Health reported that children from birth to age fourteen whose yards were sprayed with insecticides and herbicides had four times the risk of developing certain cancers than children whose yards were not sprayed with herbicides. *Id.*

98. *Meyerhoff Statement, supra* note 16, at *6. Children today are faced with a lifetime ahead of them of exposure to pesticides and cancer-causing agents, while the grandparents of the children of today grew up in an environment when society did not rely on pesticide use as much as it does today. *Id.* Cancer incidence is high in today's world, and it will only be higher in the future as the children of today grow up in an environment in which they are exposed to environmental carcinogens.

99. *Landrigan Statement, supra* note 33, at *2.

100. *Kleckner Statement, supra* note 58, at *3. Kleckner argued in support of the new law, citing a National Resource Council Report, *Carcinogens and Anti-Carcinogens in the Human Diet*, which concluded that the natural chemicals in the foods the public consumes present more of a cancer risk than the synthetic substances in those foods, but that both natural and synthetic

within the reach of Americans to change to reduce the risk of cancer. Research has shown that a low fat and high fiber diet decreases one's risk of cancer.¹⁰¹ There is further evidence that regular exercise and refraining from alcohol and tobacco use also reduces one's risk of developing cancer.¹⁰²

However, despite the knowledge about how to reduce the risk of cancer, statistics show that the incidence of breast cancer has doubled in the past fifty years.¹⁰³ Through aggressive research, the scientific community found that chemicals in the environment contribute enormously to a woman's risk of breast cancer.¹⁰⁴ The key factor in a woman's development of breast cancer is her lifetime exposure to estrogen.¹⁰⁵ Research results support the hypothesis that the increase in breast cancer is the result of pesticides in the environment.¹⁰⁶ While people cannot replace their genes or the food products they have consumed in the past, the environmental risk associated with breast cancer is something that can be changed.¹⁰⁷

chemicals are present at levels that are so low that they do not pose a significant cancer risk. *Id.* However, other reports from the National Academy of Sciences, such as Pesticides in the Diets of Infants and Young Children, are in conflict with those findings. *Meyerhoff Statement, supra* note 16, at *5. Kleckner argued that contribution of calories and fat to the human diet was a higher risk factor than individual food chemicals, both naturally occurring and synthetic. *Kleckner Statement, supra* note 58, at *3. In order to reduce cancer, Kleckner argued in favor of a diet rich in fruits and vegetables, and he argued that the presence of an abundant supply of fruits and vegetables depended upon pesticide use. *Id.* at *3, 4. If pesticides are subject to the Delaney Clause, however, the fruit and vegetable supply in the country will not be adequate. *Id.* According to this argument, the Delaney Clause discouraged healthy diets. *Id.*; See NAT'L RES. COUNCIL, CARCINOGENS AND ANTI-CARCINOGENS IN THE HUM. DIET: A COMPARISON OF NATURALLY OCCURRING AND SYNTHETIC SUBSTANCES (1996) (comparing naturally occurring and synthetic substances).

101. Phyllis Herman, *Breast Cancer and the Environment: The Deadly Link with Widespread Pesticides*, WINTER HEALTH NEWS & REV. 9 (1995).

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.* The greater a woman's exposure to estrogen, the higher her chances of getting breast cancer. *Id.* If a woman begins menstruating early, is childless, and enters menopause after age 55, her risk of breast cancer may be 25% higher than woman with a shorter menstrual history. *Id.*

106. *Id.* As far as the genetic risk factor involved in breast cancer, only two and one-half percent of breast cancer cases can be attributed to genetics. *Id.* This statistic came from a study which followed 18,000 thirty to fifty-five year old women over a 12 year period. *Id.* Environmental factors, specifically pesticide exposure, seem to be a dominant cause of the increased rate of breast cancer in the United States.

107. *Breast Cancer Study in San Francisco Area Could Produce Useful "Clues," Davis Tells Senate Group*, 39 1996 DRUG RES. REP. 7 (1996) [hereinafter *Breast Cancer Study*]. The House of Representatives has taken an interest in the San Francisco breast cancer rates, which are the highest in

Xenoestrogens, chemicals found in pesticides which are similar to estrogens, contribute to the amount of estrogen women are exposed to, and thus their risk of developing breast cancer.¹⁰⁸ Xenoestrogens are man-made substances which imitate the chemical structure of the human body's natural estrogens.¹⁰⁹ These xenoestrogens have been multiplying in the American food supply at an alarming rate due to the increased use of pesticides.¹¹⁰ With the passage of the Food Quality Protection Act, the pesticides in the food supply will multiply at an even faster rate, putting women at an even greater risk for developing breast cancer.

The language of the Food Quality Protection Act contains a provision requiring the EPA to establish and implement a screening program within three years to test pesticide chemicals for estrogenic and endocrine effects.¹¹¹ This gives the EPA overly-broad powers. For example, if a substance is found to have endocrine effects on humans, the EPA is required to take action to protect public health.¹¹² In effect, this risk-benefit analysis does little to reduce a woman's risk of breast cancer from exposure to pesticides, and instead allows the EPA to increase a woman's exposure to cancer-causing pesticides if it determines that the benefits are substantial. Further, after determining that a chemical does have an endocrine effect, the EPA is given discretion to "provide for the testing of any other substances that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substances."¹¹³ This testing should be mandatory, and the use of a pesticide found to have endocrine effects should be absolutely prohibited. If one person develops cancer as a result of exposure to such a chemical, this should be enough to ban its use without a

the world, with a focus on how environmental factors have contributed to the high cancer rate. *Id.* at 8.

108. Herman, *supra* note 101, at 9.

109. *Id.*

110. *Id.* The pesticides that are most linked to breast cancer are organochlorides, such as DDT, which is now banned in the United States. *Id.* However, DDT is still produced in the U.S. for use in Third World countries which do not regulate its use at all. *Id.* Latin America, China, and India use millions of pounds of organochlorides every year. *Id.* The animals whose fat is saturated with these chemicals as well as the sprayed fruits and vegetables are then shipped back to the U.S. *Id.* Organochlorides are stored in human fat, which may explain the link between a high animal fat diet and breast cancer. *Id.* The Food Quality Protection Act will only serve to increase the amount of pesticides to which women are exposed because the standard is more flexible in allowing cancer-causing agents with negligible risks to enter the American food supply. *Id.* Thus, the new law will likely cause the rate of breast cancer among women in the United States to increase.

111. The Food Quality Protection Act of 1996 405(p)(1), 21 U.S.C.A. § 346a(p)(1) & (2) (West 1972 & Supp. 1997).

112. 21 U.S.C.A. § 346a(p)(6) (West 1972 & Supp. 1997).

113. 21 U.S.C.A. § 346a(p)(3)(B).

consideration of other benefits the pesticide may pose.

Proof of the link between pesticides and cancer is evident in the 1990 study of breast cancer and pesticides in Israel.¹¹⁴ Israeli women had one of the highest breast cancer mortality rates in the world in the 1970's.¹¹⁵ In the ten years following 1975, however, Israel banned several pesticides, and the rate of cancer declined by twenty percent.¹¹⁶ If the United States followed Israel's steps in reducing pesticide exposure and usage, the U.S. cancer rate would similarly decline.

Studies further show that men's reproductive health is also at risk from xenoestrogens in the environment.¹¹⁷ Testicular cancer has risen between 250% and 300% in the past fifty years.¹¹⁸ Recent studies from Denmark and France show that the reproductive problems people are experiencing, including reproductive cancers, begin when they are embryos.¹¹⁹ At that stage, people are most vulnerable to pesticides.¹²⁰ Along with an increase in testicular cancer, studies show the male sperm count average has declined by two percent each year over the past twenty years and by fifty

114. Herman, *supra* note 101, at 9.

115. *Id.* Xenoestrogens increase the human body's own production of estrogen, thereby increasing the risk of breast cancer. *Breast Cancer Study*, *supra* note 107, at 8. Though some xenoestrogens are very weak, the half-life of some of the synthetic xenoestrogens is 10 years. *Id.* If a woman has only a small amount of DDT in her body but it stays there for 10 years, her cancer risk is greatly increased. *Id.*

116. Herman, *supra* note 101, at 9. Prior to the ban of certain pesticides, some of Israel's dairy products had pesticide residues as high as 500% above U.S. levels. *Id.* Further, residues in the breast milk of Israeli women were 800 times the level measured in the breast milk of American women. *Id.* This study was reported by Dr. Elihu Richter, co-author of the study, who spoke at the 1994 Forum on Breast Cancer and the Environment [which was] sponsored by the American Association for the Advancement of Science. *Id.*

117. Research has shown that xenoestrogens mimic natural hormones, and exposure to these chemicals has resulted in a decrease in the ability of animals to reproduce. Susan Zakin, *Attack on the Male of the Species: Increase Chemical Pollutants Result in Endocrine System Dysfunction*, 215 SPORTS AFIELD 56, (1996). There is a fear that the chemical exposure is now affecting human reproduction as well, causing an increase in cancer rates and a decrease in sperm counts. Catherine Dodd, *Hormone Hell: Pollutants Mimic Natural Hormones, Harming Animal Development*, 17 DISCOVER 52 (1996). Exposure to chemicals can turn male animals into females, cause a reduction in the sperm count of male animals, harm the nervous system, and cause infertility. *Meyerhoff Statement*, *supra* note 16, at *10. These chemicals should not be used. *Id.* In 1991, 21 well-known wildlife biologists, toxicologists, and cell biologists signed the Wingspread Statement, which reads: "[u]nless the environmental load of synthetic hormone disrupters is abated and controlled, large-scale dysfunction at the population level is possible." Zakin, *supra*, at 56.

118. Zakin, *supra* note 117 at 56.

119. *Id.*

120. *Id.*

percent overall since 1940.¹²¹

By passing the Food Quality Protection Act, Congress failed to consider seriously the detrimental effects that pesticides have on the rate of breast cancer in women or on men's ability to reproduce. Perhaps we will have a safe, affordable and abundant food supply. But, will anyone enjoy the benefits if the reproductive capabilities of men are gradually being destroyed and women are becoming victims of breast cancer at an increasingly higher rate?

III. THE RETURN OF A ZERO-RISK STANDARD

The Food Quality Protection Act of 1996 allows a negligible risk standard for pesticide residue tolerances in raw and processed foods, but it fails to set forth clearly what level of risk is "negligible."¹²² The new law allows risks that exceed the negligible risk standard if, in the opinion of the EPA, the benefits are greater than the pesticide's risks.¹²³ Children, women, and men are all at risk when it comes to the cancer causing effects of pesticides. Americans should be able to eat their food with certainty that the food is safe. Therefore, the broad benefits language of the new law is unacceptable in a food safety statute affecting the health of human beings.¹²⁴

The Delaney Clause standard should remain applicable to pesticides used in all foods. The increase in cancer rates that has occurred as Americans have become more dependent on chemicals to produce food is the reason federal legislation should focus on ways to prevent daily exposure to carcinogenic pesticides in the American food supply.¹²⁵ The scientific community still does not know whether humans are more or less vulnerable to carcinogens than laboratory animals.¹²⁶ Science still does not know what the cumulative impact is of the carcinogens that currently exist in the food supply and environment.¹²⁷ Furthermore, it is not necessarily the individual cancer-causing substances that Americans need to be concerned about; but rather, it is the cumulative effect of carcinogens in the environment that threaten human health the most.¹²⁸ Human diets are composed of thousands of different chemicals in minute amounts, and the scientific community does

121. *Id.*

122. *The Food Quality Protection Act: Hearings on H.R.1627 Before the Subcomm. on Dep't Operations, Nutrition and Foreign Agric.*, 104th Cong., available in 1995 WL 301485, at *6 (testimony of Lynn Goldman, M.D., Assistant Administrator for Prevention, Pesticides and Toxic Substances. U.S. Environmental Agency).

123. *Id.*

124. *Id.*

125. *Meyerhoff Statement*, *supra* note 16, at *4.

126. *Id.*

127. *Id.*

128. *Id.* at *5.

not know much about their synergy.¹²⁹

Albert Meyerhoff of the Natural Resources Defense Council said that the current tolerance-setting system is "entirely predicated on a chemical-by-chemical, crop-by-crop, risk-by-risk approach, grounded in myopia, 'managing' cancer, rather than preventing it."¹³⁰ The Delaney Clause is the strictest protection against cancer in the FFDCA, and eliminating this clause will only make the food safety statutory scheme even worse.¹³¹

America needs to move in a direction in which it does not rely extensively on chemicals to produce its food. To accomplish this goal, America needs to look into methods of alternative agriculture.¹³² Several European countries, including Denmark, Sweden and the Netherlands, have begun to implement pesticide use reduction programs.¹³³ These programs reduce dependence on pesticides while maintaining crop levels.¹³⁴ For example, the program in Sweden achieved a fifty percent reduction in pesticide use between 1986 and 1991, and the Danish program achieved a twenty-five percent reduction from 1986 to 1990.¹³⁵ In order to safeguard the health of this country's men, women and children, America needs to implement the ideas used in these countries which have succeeded in providing a safer food supply without suffering economic loss.

In the name of an affordable and abundant food supply, the American people will suffer an elevated cancer rate. The benefits considerations of the new law are overly broad, and the reasonable certainty of no harm standard is too flexible. The Delaney Clause

129. *The Food Quality Protection Act: Hearings on S.1166 Before the Senate Comm. on Agriculture, Nutrition and Forestry*, 104th Cong., available in 1996 WL 332989, at *5. (Statement of Dr. Bruce Alberts, President of the National Academy of Sciences).

130. *Meyerhoff Statement*, *supra* note 16, at *4.

131. *Id.* at *5. Members of the pesticide industry have claimed to be concerned about the large amount of pesticides that the U.S. relies on; however, attempts to discuss how to reduce pesticide use with these members have been unsuccessful. *Id.* Instead, the pesticide industry has put their energy on eliminating the few safeguards contained in the existing law, namely the Delaney Clause. *Id.* The pesticide industry seems to be more concerned with its business rather than the physical health consequences that their products will have on consumers.

132. *Id.* at *7.

133. *Id.* at *8-9. See JENNIFER CURTIS, ET AL., HARVEST OF HOPE: THE POTENTIAL FOR ALTERNATIVE AGRICULTURE TO REDUCE PESTICIDE USE, 42-58 (1991) (discussing methods of alternative agriculture available to reduce the use of pesticides between 25% and 80% on nine different cropping systems in the United States.) America needs to look to alternative methods of agriculture if it is truly interested in protecting the consumers of its food supply, rather than continuing to rely mostly on its current method of pesticide use which statistics have shown increase the rate of cancer.

134. *Meyerhoff Statement*, *supra* note 16, at *8-9.

135. *Id.* at *9.

could possibly be abolished with respect to pesticides if a standard of acceptable risk, which used state-of-the-art science, replaced it.¹³⁶ Instead, the new law replaces the Delaney standard with a weak and subjective reasonable certainty of no harm standard which gives the EPA excessive flexibility and deprives America of the best possible protection.¹³⁷

The benefits of an abundant food supply through the use of pesticides does not outweigh the devastating effects of this new law. The Delaney Clause standard of zero-risk tolerance should therefore remain applicable to tolerance setting for pesticides. The Food Quality Protection Act does not protect the quality of this nation's food, as its title suggests, but rather it places this country's population at a great risk for developing cancer due to increased exposure to pesticides.

CONCLUSION

Given that men, women and especially children are at risk from exposure to and consumption of pesticides, all possible measures should be taken to reduce the usage of pesticides in American society. However, statistics show that America's reliance on pesticides has increased tremendously. As a consequence of adopting the Food Quality Protection Act, America's produce industry will further rely on pesticides, which will prove to be detrimental to American consumers. It is the position of this Comment that the Delaney Clause standard of a zero tolerance for cancer risk should apply to pesticide residues on all types of foods, both processed and raw. Therefore, America needs to rely less on pesticides and more on alternative agriculture programs.

Through the enactment of the Food Quality Protection Act, Congress gave the EPA the ability to balance, to an even greater degree than before, America's risk of cancer and the benefits of using pesticides. The standard the EPA must use to calculate this balance is the reasonable certainty of no harm standard. This standard allows the EPA too much flexibility during a time when men, women and especially children are at a higher risk for developing cancer from pesticide exposure. A simple solution exists to combat higher cancer risk: re-establish the Delaney Clause standard of zero-risk. Although this standard does not embody the lat-

136. *Landrigan Statement, supra* note 33, at *6. The Food Quality Protection Act does not set forth an objective numerical value to the negligible risk standard which it permits. *Id.* at *6-7. This vague standard will result in increased exposure of American children to carcinogenic pesticides. *Id.* Thus, the rate of cancer among children in the U.S. will continue to increase, an effect which a food safety law, such as the Food Quality Protection Act, is not suppose to have. Rather, a food safety statute should have the effect of protecting and providing a safer food supply for its consumers.

137. *Id.* at *6.

est developments in technology, the Delaney Clause has served its protective purpose by shielding several generations of Americans from the harmful effects of carcinogenic pesticides. By passing the Food Quality Protection Act, Congress failed to consider seriously the basic detrimental effects that pesticides have on consumers of processed and raw foods.