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Dead But Not Forgotten: California's Big Green Initiative and the Need to Restrict State Regulation of Pesticides

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DEAD BUT NOT FORGOTTEN: CALIFORNIA'S BIG GREEN INITIATIVE AND THE NEED TO RESTRICT STATE REGULATION OF PESTICIDES

Gregory J. Mertz

The use of pesticides¹ to aid crop production has grown significantly in the United States over the past sixty years. In 1930, United States pesticide manufacturers' sales totaled only twenty million dollars.² By 1950, the figure had grown to one hundred fifty million dollars,³ and by 1988, sales had reached nearly five billion dollars.⁴ Worldwide, pesticide use doubled between 1977 and 1988.⁵

Farmers in this country have come to depend on pesticides to ensure adequate crop yields. Some researchers estimate that without

1. For purposes of this Note, pesticides are defined as chemicals used to prevent, destroy, repel, or mitigate unwanted infestations of insects (insecticides); fungi, including mushrooms, molds, mildews, and rust (fungicides); plants and weeds (herbicides); and rodents and related species (rodenticides).

2. U.S. INT'L TRADE COMM., INTERIM REPORT TO THE PRESIDENT ON INVESTIGATION NO. 332-292, CALIFORNIA PESTICIDE RESIDUE INITIATIVE: PROBABLE EFFECTS ON U.S. INTERNATIONAL TRADE IN AGRICULTURAL FOOD PRODUCTS 2-1 (1990) [hereinafter ITC INTERIM REPORT].

3. *Id.*

4. *Id.*

5. Mariam Burros, *New Urgency Fuels Effort to Improve Safety of Food*, N.Y. TIMES, May 7, 1990, at A1.

pesticides, farmers' crop production could drop by up to thirty percent.⁶ This drop would cause annual consumer food costs to increase by \$228 per household, bringing food-price inflation to double-digit levels.⁷ In addition, without pesticides, America's average export volume of major grains could drop nearly fifteen percent by the mid-1990s.⁸

Despite pesticides' important role in modern agricultural production, the increased use of these chemicals has generated growing public concern about the safety of the nation's food supply.⁹ Recent highly publicized pesticide scares have exacerbated this trend,¹⁰ raising questions about the adequacy of existing federal food safety standards.¹¹

These concerns have prompted state laws and proposals that exceed federal standards¹² for pesticide risk assessment and residue tolerance.¹³ California's Proposition 128,¹⁴ a sweeping environmental initiative popularly known as "Big Green," was one dramatic

6. *The Future of Chemicals in the Food Industry*, CHEM. PURCHASING, Mar. 1983, at 58.

7. R. KNUTSON ET AL., ECONOMIC IMPACTS OF REDUCED CHEMICAL USE (unpublished study, on file with the author). The authors of this study based results on seven chemical-use reduction scenarios, including no herbicides, no insecticides and fungicides, and different combinations of these and other pesticides. *Id.*

8. *Id.*

9. See *Etcetera*, AM. DEMOGRAPHICS, May 1, 1990, at 17 (stating that Maritz Marketing Research estimates that nearly 80% of all Americans are concerned about pesticides in produce); see also Mike Duff, *Produce*, SUPERMARKET BUS., Sept. 1989, at 199-204 (noting the supermarket industry's reaction to mounting consumer food-safety concerns); Mike Duff, *Supermarkets Face High Noon as Pesticide Issue Looms*, SUPERMARKET BUS., Dec. 1988, at 21 (stating that pesticides and chemical residues in food have undermined consumer confidence in food safety); Ellen Goldbaum, *The Pesticide Scare: Changing Public Perception*, CHEM. WEEK, May 3, 1989, at 28-30 (detailing the food industry's reaction to public fears about exposure to pesticides in food); Mary Ann Linsen, *The Produce Safety Snafu*, PROGRESSIVE GROCER, June 1, 1989, at 21 (acknowledging that produce safety is one of the biggest challenges facing the food industry in light of public fears about pesticide residues).

10. Melinda Beck, *Warning!*, NEWSWEEK, Mar. 27, 1989, at 16 (discussing recent food scares); Janet Key, *Seeds of Debate over Food Safety*, CHI. TRIB., Mar. 19, 1989, at C1 (commenting on growing debate over food safety in the United States and the Chilean grape controversy); Molly Sinclair, *Debate over Food Safety Launched by Cranberry Scare of '59*, WASH. POST, Nov. 26, 1980, § 3, at 1 (tracing growing consumer fears about safety to a 1959 cranberry scare related to the spraying of carcinogenic pesticide aminotriazole).

11. More than 30 food-safety bills were brought before Congress during the spring 1990 session, setting a record for a congressional session. Burros, *supra* note 5, at A1.

12. See, e.g., *infra* notes 14-17 & 99-109 and accompanying text; see also, Randy Abramson, *Bush Unveils Proposals to Protect Food Supply*, L.A. TIMES, Oct. 27, 1989, at A4 (discussing lawmakers' reactions to the alar apple scare and opposition to federal proposal to preempt state pesticide laws); Carole Sugarman, *California's Consumer Alert: New Law Goes Beyond Federal Standards for Toxic Substances*, WASH. POST, Mar. 2, 1988, at E1 (discussing California's efforts to regulate pesticides more stringently than EPA).

13. Pesticide risk assessment refers generally to scientific measurements of the risks associated with ingestion of pesticides. Residue tolerances establish the maximum acceptable level of pesticide accumulation on food products. For a more detailed discussion of these regulatory concerns, see *infra* notes 49-89 and accompanying text.

example of this trend. Big Green sought to ban the use of dozens of pesticides¹⁵ in California, and to set stringent pesticide residue tolerance levels for foods grown and processed in California, as well as for foods imported into the state.¹⁶ California voters rejected the measure on November 6, 1990.¹⁷

Although Big Green failed in California, the effort highlights a potentially serious weakness in current federal legislation. Under existing federal law, states have limitless authority to exceed federal standards for pesticide registration and residue tolerances.¹⁸ This authority enables states to restrict or even prohibit the availability of federally approved pesticides, although they cannot authorize the sale or use of pesticides that the federal government has disapproved.¹⁹ As a result of this federal regulatory scheme, states may ban a chemical product on the basis of political pressure and unfounded consumer fears, rather than on a scientific finding of risk to the population.²⁰

14. California Environmental Protection Act of 1990, Initiative Stat. No. 480 [hereinafter Big Green].

15. See *id.* sec. 3, § 26901(a); see also ITC INTERIM REPORT, *supra* note 2, at app. G (listing pesticides Big Green may have affected). Big Green attempted to regulate not only pesticides, but also off-shore drilling, deforestation of the California redwoods, auto emissions, and global warming. See Big Green, *supra* note 14, sec. 14 (emissions and global warming reduction provisions); *id.* sec. 15 (ozone layer protection provisions); *id.* sec. 17 (redwood forest protection provisions); *id.* sec. 21 (bay and ocean protection provisions).

16. See Big Green, *supra* note 14, sec. 3, § 26901. The food-safety provisions of Big Green are discussed more fully *infra* notes 92-98 and accompanying text. See *infra* notes 130-63 and accompanying text for a comparison between the standards proposed by Big Green and current federal standards.

17. See, e.g., Andrea Stone, *Big Green's Big Pricetag Proves Liability*, USA TODAY, Nov. 7, 1990, at 4A. In the future, California could readily resurrect portions of the package in the form of individual legislative initiatives. The food-safety measure presented under those circumstances, either before the legislature or as a referendum, would face greater likelihood of success. See Greg Anthan, *Chemical Fertilizer Industry Tries to Influence Farm Bill*, GANNETT NEWS SERV., Sept. 9, 1990 ("But even if Big Green is defeated, it will return. The concerns which spawned it will not go away."); Vlae Kershner, *Fewer Initiatives Expected in Next Election*, S.F. CHRON., May 6, 1991, at A1 (asserting that Big Green was overly broad and proposing a bill in response to Big Green that would require provisions of future California initiatives to be interrelated with existing laws); Jay Mathews, *Golden State in Dry Dock: Forget the Drought, California's Ideas and Trends Aren't Selling Like They Used To*, WASH. POST, Mar. 10, 1991, at D1 (discussing the pitfalls of ballot initiatives as epitomized by Big Green's overly complex and cumbersome provisions); Joseph Petulla, *It Isn't Easy Being Green—The Proposition 128 Fight*, S.F. CHRON., Dec. 10, 1990, at A17 ("Everything Big Green aspired to could be assimilated much better over time, using the same organizing principles environmentalists have used for the past 20 years: one issue at a time; public input and organizing; political pressure.").

18. This authority stems from a provision in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) § 24, 7 U.S.C. § 136v(a) (1988). This section reads as follows: "A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter."

19. *Id.*

20. Big Green is an extreme example of this power. During the battle over Big Green, a commercial featuring former United States Surgeon General C. Everett Koop urged voters to reject the initiative. Koop's message: "Public policy should be based on sound science, not scare tactics." Jay Mathews, *Tide is Turning Against Big Green*, L.A. TIMES, Oct. 30, 1990, at A5. A coalition of 150 scientists and health care officials concurred in that view, arguing that hysteria over traces of potentially carcinogenic chemicals is apt to produce bad laws that ban vital low-risk pesticides, ultimately leading to a

Permitting states to enjoy such autonomy in pesticide regulation threatens both national and international trade in food products. For example, economists and researchers stated that, if enacted, Big Green could have:

1. cut California's production of some fruits and vegetables in half;²¹
2. resulted in the loss of over 100,000 jobs;²²
3. led to annual revenue losses of up to twelve billion dollars for state and local governments;²³
4. caused a one to two percent cut in the state's economic growth;²⁴
5. promoted fragmentation of American regulatory standards, thereby complicating interstate and international commerce and trade;²⁵
6. endangered efforts to develop international sanitary and phytosanitary standards under the General Agreement on Tariffs and Trade (GATT) Uruguay Round negotiations;²⁶
7. reduced the competitiveness of American agricultural exports;²⁷
8. invited retaliatory actions by other countries regarding American agricultural and nonagricultural products, thereby restricting access to foreign markets for American exporters;²⁸
9. disrupted the nation's food supply by forcing the removal of

reduction in the quantity of available fresh produce. *Id.* The extreme reaction to the Chilean grape scare in 1989 further illustrates this hysteria. Grocery stores across the country refused to stock grapes imported from Chile after media reports revealed that inspectors had isolated cyanide residues on Chilean grapes. See Christine Russell, *A Year After Alar: The Pesticide Scare Grows*, WASH. POST, Feb. 27, 1990, at Z12. Despite the furor, only two grapes were found to contain cyanide poisoning. *Id.*

21. See Jay Mathews, *'Big Green' Initiative Holds High Stakes for California Agriculture*, WASH. POST, Oct. 3, 1990, at A3.

22. *Id.* One industry report estimated that as many as 189,000 jobs could be lost. See *id.*

23. *Id.*

24. *Id.*

25. See *International Trade: 'Big Green'-style Pesticide Laws Could Endanger Uruguay Round, EC Warns U.S.*, Daily Rep. for Executives (BNA) No. 156, at A-7 (Aug. 13, 1990) [hereinafter *International Trade: 'Big Green'-style*]; see also Deal & Essaye, *International Aspects of Nutrition Labeling Act*, N.Y. L.J., Dec. 6, 1990, at 6 (stating that inconsistencies between state and federal law posed by Big Green-style legislation can produce trade barriers). For a discussion of trade implications stemming from restrictive state pesticide regulations, see *infra* notes 110-29 and accompanying text.

26. See *International Trade: 'Big Green'-style*, *supra* note 25; see also *infra* notes 125-29 and accompanying text (discussing the potential negative effects of restrictive state regulations on international trade negotiations and agreements).

27. See *International Trade: Environmentalists Blast ITC Investigation on California Initiative Limiting Pesticides*, Daily Rep. for Executives (BNA) No. 133, at A-4 (July 11, 1990) [hereinafter *Environmentalists Blast ITC Investigation*].

28. See *Environmentalists Blast ITC Investigation*, *supra* note 27.

seventy-five percent of the crop protection chemicals currently used by California growers to ensure disease-free produce;²⁹ and

10. increased California fruit and vegetable prices by as much as forty to fifty percent.³⁰

This Note argues that federal legislation should be amended to ensure that state pesticide restrictions that exceed federal standards are the result of sound scientific observations of environmental risk, and not unfounded public fears. In making this argument, this Note responds to claims that the federal government does not go far enough to protect the nation's food supply from pesticide contamination. It asserts that the present federal risk-assessment standards represent a sensible compromise that ensures stable economic growth while protecting the public against chemical threats.³¹ It also stresses the importance of regulatory consistency to maintaining predictable foreign trade relations.

Part I of this Note outlines federal legislation and regulatory standards that govern pesticide registration, labeling, sale, and use. Part II discusses state regulatory activity in this area, concentrating on the potential negative economic consequences of disparate state pesticide regulation. Part III scrutinizes the federal government's food-safety standards and compares them to the more stringent model proposed by Big Green. Part III concludes that the federal standard is more desirable because it minimizes threats to human safety and the environment while ensuring that industry efforts to generate innovative agricultural control products are not stifled. Part IV proposes alternatives to the current system of state independence to regulate the sale and use of pesticides. This Note concludes that federal pesticide legislation should be amended to allow

29. *See id.*

30. Jay Mathews, *California Weighs Sweeping Environmental Plan*, WASH. POST, Apr. 26, 1990, at A6.

The costs associated with an earlier successful California initiative, Proposition 65, CAL. HEALTH AND SAFETY CODE §§ 25249.5-.13 (Deering 1988), already provide cause for alarm. This measure, which became law in 1986, *see id.*, requires that all manufacturers and producers place warning labels on substances that contain properties associated with cancer or reproductive harm. *See id.* §§ 25249.5-.13. National manufacturers wishing to sell in the California marketplace must segregate units destined for California to affix labels bearing the appropriate warning. This burden adds to the costs of inspection, production, warehousing and transportation: by some estimates, an additional \$200 million annually that consumers must absorb. Seth B. Whitelaw, *Proposition 65 v. Industry: David Against Goliath or a Misled Public Run Amok?*, 44 FOOD DRUG COSM. L.J. 677, 766-78 (1989).

31. Federal standards for food safety balance the benefits of the product to society against the risks associated with their use. *See* FIFRA, 7 U.S.C. § 136a(c)(5) (1988) (requiring EPA to conduct a risk-benefit analysis when considering whether to register a pesticide); Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(b) (1988) (listing specific risk and benefit factors for EPA to consider when enacting pesticide regulations). In assessing risks, regulators err on the side of consumer safety. *See infra* notes 33-89 and accompanying text for a discussion of the pertinent federal regulations and EPA's risk-assessment methods. This pragmatic approach recognizes the impossibility of achieving a risk-free standard, *see infra* notes 130-63 and accompanying text, but then adopts a conservative approach to registering potentially carcinogenic pesticide products. *See infra* notes 78-88 and accompanying text for a discussion of the standards for regulating potentially carcinogenic pesticides.

a state to impose pesticide standards that differ from or exceed federal standards only when the state demonstrates, based on sound science, that the federal standards are inadequate. The standard proposed, though falling short of absolute federal preemption,³² would ensure that any measures states take to restrict pesticide use will represent sound scientific policy, and not political reaction to potentially exaggerated public concerns.

I. Federal Regulation of Pesticides: FIFRA and FFDC

The federal government registers³³ pesticides and sets maximum food residue tolerance levels pursuant to two statutes: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),³⁴ and the Federal Food, Drug and Cosmetic Act (FFDCA).³⁵ FIFRA governs the registration, labeling, sale, and use of pesticides marketed in the United States. The FFDCA sets allowable pesticide residue levels in food.

A. FIFRA

Congress enacted FIFRA in 1947³⁶ primarily as a pesticide licensing and labeling statute.³⁷ The United States Department of Agriculture administered the Act at that time.³⁸ Under the original

32. Federal preemption is not appropriate because certain circumstances justify independent state authority in this area. These circumstances include unique local geographic and climatic conditions that could lead to risks not apparent in other regions. See *infra* notes 172 & 174-75 and accompanying text. This is consistent with the approach taken by negotiators in the GATT sanitary and phytosanitary discussions. See General Agreement on Tariffs and Trade (GATT) Draft Agreement on Sanitary and Phytosanitary Measures July 7, 1990, Annex II, ¶¶ 7-8. Those provisions read as follows:

Basic Rights and Obligations:

7. Contracting parties shall have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health [including, when appropriate, measures more stringent than required by international standards, guidelines or recommendations], provided that such measures are not inconsistent with the provisions of this agreement.

8. Contracting parties shall ensure that sanitary and phytosanitary measures are applied only to the extent necessary to protect human, animal or plant life or health and are consistent with available scientific evidence. Sanitary and phytosanitary measures shall not be applied in a manner which creates arbitrary, disguised or unjustified obstacles to international trade.

33. The registration process is discussed *infra* notes 44-58 and accompanying text.

34. 7 U.S.C. § 135 (1988).

35. 21 U.S.C. § 301 (1988).

36. Ch. 125, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136-136y (1988)).

37. See H.R. REP. No. 313, 80th Cong., 1st Sess. (1947), reprinted in 1947 U.S. CONG. SERV. 1200, 1201-02 (providing an overview of the scope of the Act).

38. See FIFRA, ch. 125, 61 Stat. at 164, 167-68.

scheme, however, the federal government had a limited role in regulating the manufacture, sale, and use of pesticides.³⁹

In the early 1970s, the federal government responded to mounting consumer fears about pesticide residues on food by increasing its control over agricultural pesticide safety.⁴⁰ In 1970, President Nixon created the Environmental Protection Agency (EPA), which assumed responsibility for FIFRA.⁴¹ Two years later, Congress enacted an amended version of FIFRA entitled the Federal Environmental Pesticide Control Act of 1972.⁴²

These amendments to FIFRA broadened federal power to regulate pesticides by “establish[ing] an elaborate framework for [federal] regulation of pesticide use in the United States.”⁴³ Specifically, the 1972 amendments subject to federal regulation both the intrastate and interstate use of pesticides,⁴⁴ establish a nationwide system for classifying pesticides into risk-based categories,⁴⁵ place new limits on proposed pesticide uses,⁴⁶ and create a federal system for certifying pesticide applicators.⁴⁷ The Administrator of EPA is charged with administering these requirements, and is granted authority to revise periodically the standards for pesticide registration.⁴⁸

Under the revised FIFRA, EPA must certify that products perform as their sponsors claim, and will not cause “unreasonable adverse effects on the environment.”⁴⁹ The Act defines “unreasonable adverse effects on the environment” as “any unreasonable risk to man and the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”⁵⁰ This “risk-benefit” approach seeks to strike a balance between risks to the environment and benefits to society.⁵¹

To aid EPA’s weighing of risk-benefit data, FIFRA requires a pesticide manufacturer to submit certain information to the agency. This information includes proper labeling,⁵² directions for use,⁵³ a

39. See S. REP. NO. 838, 92d Congress, 2d Sess. (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993 (discussing the limited role of the federal government under the original legislation and the effect of subsequent amendments).

40. *Id.*, *reprinted in* 1972 U.S.C.C.A.N. at 3995-4002.

41. See Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15,623 (1970).

42. Pub. L. No. 92-516, 86 Stat. 973 (1972).

43. *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988), *cert. denied*, 490 U.S. 1035 (1989).

44. See Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, § 2, 86 Stat. 973, 979 (codified as amended at 7 U.S.C. § 136v(a) (1988)).

45. See *id.* (codified as amended at 7 U.S.C. § 136a(a) (1988)).

46. See generally 7 U.S.C. §§ 136-136y.

47. See Pub. L. No. 92-516, §§ 2, 4, 86 Stat. at 975-76, 983 (codified as amended at 7 U.S.C. §§ 136(e), 136 note). “Certified applicator” is defined as “any individual who is certified under . . . this title as authorized to use or supervise the use of any pesticide which is classified for restricted use.” *Id.* § 136(e). See *infra* note 58 and accompanying text for a discussion of general versus restricted use classifications.

48. See 7 U.S.C. §§ 136a(c)(2), 136w (1988).

49. *Id.* § 136a(c)(5).

50. *Id.* § 136(bb).

51. See S. REP. NO. 838, *supra* note 39, *reprinted in* 1972 U.S.C.C.A.N. 3993, 3996 (describing the risk-benefit “balancing” approach as “wise” and “essential”).

52. 7 U.S.C. § 136(a)(c)(1)(C).

description of the purported function of the pesticide,⁵⁴ and supporting scientific and technical data.⁵⁵ By reviewing this submitted material as part of the risk-benefit analysis, EPA can determine the pesticide's risk to humans, fish, wildlife, and endangered species, as well as its behavior in the environment.⁵⁶ Human threats analyzed include acute toxic reaction, cancer, and reproductive harm.⁵⁷ EPA then classifies products approved through this process for either general use, restricted use, or both.⁵⁸

53. *Id.*

54. *See id.*; H.R. REP. NO. 313, *supra* note 37, *reprinted in* 1947 U.S. CONG. SERV. 1200, 1201-02 (discussing the original protections under FIFRA).

55. *See* 7 U.S.C. § 136a(c)(1) (1988). Specific data requirements include the following: (1) toxicological studies; (2) epidemiological studies; (3) efficacy studies; (4) studies of dietary or environmental pesticide residue; (5) toxic or adverse effect incident reports, including specific instances of toxic or adverse impact attributable to exposure to the pesticide, of residue levels exceeding established or expected levels, or of failure to perform as expected against designated target organisms; (6) failure of performance incident reports; and (7) dietary or environmental pesticide residue incident reports. *See* EPA Pesticide Programs Reporting Requirements for Risk/Benefit Information, 40 C.F.R. §§ 153.61, 153.69-.77 (1991).

For pesticides destined for use on food or feed crops (as opposed to pesticides used for lawn care or other purposes), the applicant must also petition EPA for a residue tolerance setting and submit the appropriate data so the Agency can define a safe and realistic tolerance level. *See* EPA Pesticide Programs Registration and Classification Procedures, 40 C.F.R. § 152.40 (1991). By establishing tolerance levels, EPA ensures that consumers are not exposed to unsafe pesticide residues in food.

56. *See* ITC INTERIM REPORT, *supra* note 2, at 2-5.

57. *See* 40 C.F.R. § 158.340 (1991); *see also* ITC INTERIM REPORT, *supra* note 2, at 2-5. For example, for pesticides posing a carcinogenic threat, a lifetime human cancer risk of one in a million is classified as "negligible." Regulation of Pesticides in Food: Addressing the Delaney Paradox, 53 Fed. Reg. 41,104, 41,112 (1988) [hereinafter Addressing the Delaney Paradox]. Pesticides that exceed this level of risk may still be registered if their benefits are determined to outweigh their risks. *See id.* EPA sets these tolerances pursuant to § 408 of the FFDCFA for raw agricultural commodities, 21 U.S.C. § 346a (1988), and § 409 for processed foods containing pesticidal food additives, *id.* § 348. *See infra* notes 63-89 and accompanying text.

58. 7 U.S.C. § 136a(d)(1) (1988). General use classifications apply to pesticides that "will not generally cause unreasonable effects on the environment." 7 U.S.C. § 136a(d)(1)(B) (1988). Restrictive use classifications apply to pesticides that may cause such adverse effects in the absence of certain restrictions on use by EPA. *See id.* § 136(d)(1)(C).

Early in the registration process, applicants may apply for and receive an experimental use permit to field-test their product, 40 C.F.R. §§ 172.2, 172.2-.7 (1991), although applicants cannot begin marketing it until EPA grants a final registration. *See* 7 U.S.C. § 136a(a) (1988) ("[N]o person in any State may distribute or sell to any person any pesticide that is not registered."); *id.* § 136c ("The Administrator may issue an experimental use permit only if the Administrator determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide under section 136a."). The registration process for a new active ingredient can take from two to three years and can cost between \$2.5 million and \$4.0 million. ITC INTERIM REPORT, *supra* note 2, at 2-5. EPA has registered approximately 50,000 pesticide products to date, H.R. REP. NO. 939, 100th Cong., 2d Sess. 28 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3474, 3477, and reviews on average 20,000 registration applications each year. Roger D. Middlekauff, *Pesticide Residues in Food*, 42 FOOD DRUG COSM. L.J. 251, 253 (1987).

In 1988, Congress amended FIFRA to require EPA to reevaluate all pesticides that contain active ingredients first registered before 1984 to ensure that they meet more

FIFRA, as amended, increases the federal government's role in the regulation of pesticides significantly. Congress has charged EPA with ensuring that no pesticide enters or remains on the market if analysis reveals its risks to be unreasonable.⁵⁹ Despite this, FIFRA preserves substantial state autonomy in the regulation of pesticides.⁶⁰ Although FIFRA explicitly prohibits states from enacting labeling requirements "in addition to or different from" federal standards,⁶¹ it permits states to impose more rigorous standards governing "the sale or use of any federally registered pesticide or device."⁶² Thus, under FIFRA, it appears that the states have the power to withhold registration of federally approved pesticides, effectively banning the distribution of those products within their borders.

B. FFDCA

Pesticides added to food must have an EPA tolerance level set before being registered under FIFRA.⁶³ EPA sets tolerances for pesticide residues on food pursuant to sections 408 and 409 of the FFDCA.⁶⁴ Section 408 pertains to raw agricultural products;⁶⁵ section 409 pertains to additives in processed foods.⁶⁶ The tolerance requirement ensures that no company can market a food pesticide before EPA establishes a safe residue standard for the product.⁶⁷

The FFDCA directs EPA to set tolerances for pesticide chemicals

recent registration criteria. *See* Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988, Pub. L. No. 100-352, § 102(a), 102 Stat. 2655, 2655 (codified as amended at 7 U.S.C. § 136a-1 (1988)). The review will cover roughly 600 active ingredients. H.R. REP. NO. 939, *supra*, at 28, *reprinted in* 1988 U.S.C.C.A.N. at 3477.

Reregistration hinges on a determination that older ingredients satisfy the unreasonable adverse effects standard of FIFRA. *See* 7 U.S.C. §§ 136a-1(a)(2) (1988) (requiring that the provisions of § 136a(c)(5) be satisfied before reregistration can occur); *id.* § 136a(c)(5)(C)-(D) (directing EPA to register only those pesticides that perform their function without "unreasonable adverse effects on the environment"). These earlier products may remain on the market pending the generation and review of the necessary data. *See id.* § 136a-1 (describing the process for reregistration and provisions for suspension or cancellation of the pre-1984 ingredients).

59. *See id.* §§ 136a(c)(5)(C)-(D), 136(a)-1.

60. *See* 7 U.S.C. § 136v(a) ("A State may regulate the sale or use of any federally registered pesticide or device in the State [unless otherwise prohibited by FIFRA].").

61. *Id.* § 136v(b) (stating that a "State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter").

62. *Id.* § 136v(a).

63. *See* 21 U.S.C. §§ 342, 346a, 348 (1988) (requiring the setting of tolerances for pesticides used on raw agricultural commodities and those resulting in food additives); *id.* § 346a(d) (discussing interaction between setting of tolerances under the FFDCA and registration under FIFRA). Provisions for registration of pesticides under FIFRA are at 7 U.S.C. § 136a (1988). *See supra* notes 36-62 and accompanying text (discussing FIFRA's registration process); *see also* Middlekauff, *supra* note 58, at 257 (stating that, for pesticides used on food, EPA will not approve pesticide registration under FIFRA until an applicant has obtained a tolerance or exemption under §§ 408 or 409 of the FFDCA).

64. Federal Food, Drug, and Cosmetic Act of 1939 §§ 408, 409, 21 U.S.C. §§ 346a, 348.

65. *See* 21 U.S.C. § 346a.

66. *See id.* § 348.

67. The FFDCA prohibits the distribution of raw or processed foods containing residues of pesticide that have not been duly registered and approved. *See* 21 U.S.C.

on raw agricultural commodities "to the extent necessary to protect the public health," taking into consideration the products' necessity for the production of an adequate, wholesome, and economical food supply.⁶⁸ EPA has interpreted this language as providing authority to balance the risks against the benefits in setting appropriate tolerances for raw agricultural commodities under section 408.⁶⁹

Under section 409, setting tolerances for food additives requires a finding that the pesticide "will be safe."⁷⁰ The statute vaguely defines "safe" as having "reference to the health of man or animal."⁷¹ Factors to be considered in determining safety to man or animal are: 1) the probable consumption of the pesticide; 2) the cumulative effect of the pesticide in the diet of man or animals, taking into account other related substances in the diet; and 3) appropriate safety factors to relate animal test data to human risk evaluation.⁷² The statute also permits EPA to consider "other relevant factors."⁷³ EPA has construed this definition to permit a risk-benefit analysis in the issuance of food additive regulations.⁷⁴

§§ 342(a)(2)(B)-(C), 346a, 348; *see also* Middlekauff, *supra* note 58, at 257 (describing the interaction between these provisions and their implications).

Section 402 of the FFDCCA defines as "adulterated" any raw agricultural commodity that contains a pesticide residue not authorized by a FFDCCA § 408 tolerance or exempted from the requirement of a tolerance. *See* 21 U.S.C. § 342(a)(2)(B). Section 408 authorizes EPA to grant an exemption from the tolerance requirement when residue chemistry and toxicity data reveal that no hazard to public health will result from the accumulation of pesticide residue on raw agricultural products. *See id.* § 346a(c).

A processed food is considered adulterated under § 402 of the FFDCCA if it contains any food additive (including any pesticide residue) not authorized by a section 409 food additive regulation. *See id.* §§ 342(a)(2)(C), 348. Processed food containing pesticide residue resulting from treatment at the raw agricultural commodity stage is excepted from this provision, provided that the residue level remaining in the processed food does not exceed the level permitted by the § 408 tolerance established for the raw agricultural commodity. *See id.* § 342(a)(2)(C); *see also* Addressing the Delaney Paradox, *supra* note 56, at 53 Fed. Reg. 41,104, 41,106 (1988) (clarifying this point).

68. *See* 21 U.S.C. § 346a(b).

69. *See* Addressing the Delaney Paradox, *supra* note 56, at 41,106.

70. 21 U.S.C. § 348(c)(4) (1988).

71. *Id.* § 321(u).

72. *See id.* § 348(c)(5); *see also* Addressing the Delaney Paradox, *supra* note 56, at 41,106 (citing these factors from the statute).

On judicial review, a court may set aside a tolerance setting if the record shows that EPA has not adequately considered all these factors. *See* National Coalition Against the Misuse of Pesticides v. Thomas, 809 F.2d 875, 881-83 (D.C. Cir. 1987) (striking down EPA tolerance setting for mangoes because the agency failed to consider all the listed factors).

73. 21 U.S.C. § 348(c)(5).

74. Addressing the Delaney Paradox, *supra* note 56, at 41,106. In the agency's view, a determination of whether a pesticidal food additive is "safe" should take into account its contribution to "an adequate, wholesome, and economical supply of food." *Id.* It has labeled this benefit analysis one of the nonenumerated "relevant factors" it has authority to consider under § 409(c)(5) of the FFDCCA. *See id.* In so doing, EPA adopts the risk-benefit approach explicitly formulated in § 408(b) but absent from § 409(c)(5).

At least one court has sanctioned a risk-benefit reading of the general safety clause. In *Continental Chemiste Corp. v. Ruckelshaus*, 461 F.2d 331, 340 (7th Cir. 1972), the

Applicants seeking a tolerance setting must submit residue and toxicity data similar to that required to register a pesticide under FIFRA.⁷⁵ EPA evaluates this data to determine whether the pesticide will result in injury to man.⁷⁶ For those pesticides that may induce cancer, the agency performs additional quantitative risk assessment tests.⁷⁷

The treatment of agricultural chemicals that pose cancer risk presents EPA with a significant regulatory challenge.⁷⁸ In most

court held that “the test of safety [contained in the general safety clause of § 409] was intended to take into account the broader concepts of safety under the intended conditions of use; the benefits of the additive were to be evaluated rather than merely its potential for harm.”

Excepted from this approach are those additives falling within the § 409 Delaney Clause, 21 U.S.C. § 348(c)(3)(A) (1988) (imposing zero risk standard for food additives that have been linked with cancer).

75. Addressing the Delaney Paradox, *supra* note 56, at 41,118 (setting forth particular data required by FFDCA); *see supra* note 55 and accompanying text (setting forth the data required under FIFRA’s registration process).

76. Middlekauff, *supra* note 58, at 255. This process is highly technical. EPA begins by establishing a “no observable effect level” (NOEL) of tolerance based on the animal feeding studies. ITC INTERIM REPORT, *supra* note 2, at 2-7; *see also* Middlekauff, *supra* note 58, at 255. This is the dosage level at which adverse effects observed at higher doses disappear. *See* Addressing the Delaney Paradox, *supra* note 56, at 41,118. This dosage level figure is then divided by a safety factor that

is intended to allow an extra margin of safety to compensate principally for 1) the scientific uncertainty inherent in the process of extrapolating human risk projections from animal data, and 2) the possibility of differing sensitivities to the pesticide in individuals or subgroups (such as children) among the general population. The magnitude of this factor may vary, depending on the toxicological data available, but a 100-fold uncertainty factor is used in most instances.

ITC INTERIM REPORT, *supra* note 2, at 2-7 (quoting EPA ENVIRONMENTAL FACT SHEET, PESTICIDE TOLERANCE 2 (Jan. 1990)).

The resulting figure represents the “acceptable daily intake” (ADI) of pesticide residue, which is the level of daily exposure that is not expected to cause appreciable risks during the human lifetime. *See* Addressing the Delaney Paradox, *supra* note 56, at 41,118. ADI is then compared to the “theoretical maximum residue contribution” (TMRC), the total hypothetical quantity of pesticide residue that might reasonably accumulate in a person’s daily diet. If the TMRC is less, EPA may grant the tolerance; if not, the petition will require further review. *Id.* Even if the TMRC is less than the ADI, the pesticide may nonetheless be rejected if subgroups within the general population, such as infants and children, appear to be at risk. *See* ITC INTERIM REPORT, *supra* note 2, at 2-7.

77. For substances that may cause cancer, the agency performs what is called a quantitative risk assessment in addition to calculating the ADI. The assessment proceeds as follows. EPA extrapolates from the results of high dose animal studies to predict worst case risks associated with the much lower levels of estimated or actual human exposure. Addressing the Delaney Paradox, *supra* note 56 at 41,118. The agency then makes a surface area adjustment to account for its premise that different sized animals are not equally sensitive to equal concentrations of a chemical. *Id.* at 41,119. “The effect of this adjustment is to increase the estimate of human risk by about thirteen-fold where data are derived from mice, and about six-and-a-half-fold when the data source is the rat as test animal.” *Id.* Based on the results of this analysis, EPA classifies chemicals into five groups: Group A—human carcinogen; Group B—probable human carcinogen; Group C—possible human carcinogen; Group D—not classifiable as to human carcinogenicity; Group E—evidence of non-carcinogenicity for humans. *Id.* at 41,118. These further assessment tests are described in more detail in EPA Policy Statement: Regulation of Pesticides in Food: Addressing the Delaney Paradox, *supra* note 57, at 41,118.

78. *See generally id.* (discussing the agency’s approach to regulating carcinogenic agricultural pesticides under FIFRA and FFDCA).

cases, the agency assesses the chemicals' legitimacy using the traditional risk-benefit analysis scheme of sections 408 and 409 of the FFDCA.⁷⁹ A clause in section 409, however, explicitly bars this approach for food additives that may induce cancer.⁸⁰ Known as the "Delaney Clause," it states that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."⁸¹ This clause establishes a zero-tolerance standard for potentially carcinogenic food additives.⁸²

The language of the Delaney Clause creates an inconsistency between FIFRA and the FFDCA for potentially carcinogenic pesticides in processed foods. Products that otherwise would satisfy the FIFRA risk-benefit analysis, as well as the FFDCA section 408 tolerance setting requirements for use on raw agricultural commodities, may fail the Delaney Clause zero-tolerance standard.

EPA addressed this conflict in a policy statement entitled *Regulation of Pesticides in Food: Addressing the Delaney Paradox*.⁸³ The statement outlined EPA's revised regulatory policy aimed at achieving greater consistency in the tolerance setting process. The policy requires that food additives be divided into two analytical categories for purposes of setting tolerance levels. The first category includes food additives that have no carcinogenic impact or pose only a negligible risk of carcinogenicity. Negligible risk is classified as one or less cancer risks per million people.⁸⁴ For this category, the agency announced that it would apply the risk-benefit approach, even for those food additives requiring section 409 clearances.⁸⁵ The agency's approach in evaluating these pesticides assumes the presence of benefits that outweigh negligible risks.⁸⁶ This reflects a relaxation of the Delaney Clause zero-tolerance standard for pesticides posing only a negligible risk of cancer.

The second category consists of pesticides that pose a carcinogenic risk that is greater than negligible.⁸⁷ Pesticides in this category that require section 409 clearances will not be granted FIFRA registrations absent a convincing explanation for why, irrespective of the results of animal studies, the chemical poses no risk of cancer

79. See *id.* at 41,105-06. See *supra* notes 68-74 and accompanying text for a discussion of EPA's interpretation of §§ 408 and 409 as generally permitting a risk-benefit approach.

80. 21 U.S.C. § 348(c)(3)(A).

81. *Id.*

82. See *id.*

83. 53 Fed. Reg. 41,104 (1988).

84. *Id.* at 41,112.

85. *Id.*

86. *Id.*

87. See *id.*

for humans.⁸⁸

The FFDCA is silent on states' authority to set pesticide residue tolerances that exceed federal standards. States can exercise this power, however, pursuant to their authority to set independent registration requirements under FIFRA.⁸⁹

II. State Regulation of Pesticides and Its Implications

Increasing pesticide use and mounting consumer fears about possible chemical contamination have prompted states to take a more active role in regulating these products.⁹⁰ California has been particularly active in this area.⁹¹ Other states, however, also are moving toward regulating pesticides more stringently than the federal government. This Part describes the various forms of pesticide regulation in California and other states, and considers their implications for the nation. The impact of Big Green-style regulations receives particular attention.

A. State Regulation of Pesticides

Big Green is the most recent example of California's legislative activism in this field.⁹² The initiative's food-safety provisions are the broadest example to date of a state's potential to exceed federal standards.⁹³ Big Green would have banned *all* food pesticides shown to cause cancer or reproductive harm in animal laboratory experiments.⁹⁴ The proposal sought to achieve this ban by canceling these pesticides' registration for use on foods grown or

88. See *id.* at 41,112-13. One such convincing explanation would be a "showing that cancer was induced in animals only as secondary effect of an organic change in the animals induced by very high doses of the chemical and a showing that this effect would not occur at the low levels of human exposure." *Id.* at 41,112. Only Group C chemicals—"possible human carcinogens"—are affected by this last exception. See *id.* at 41,118. Group A and B chemicals—human carcinogens and probable human carcinogens—remain subject to the Delaney Clause exclusion in all cases unless their carcinogenic risk is proven to be negligible and thus within the *de minimis* exception outlined above. See *id.*

89. See 7 U.S.C. § 136v(a).

90. See *infra* notes 92-109; see also Anthony F. Essaye & Jill B. Deal, *International Aspects of Nutritional Labeling Act*, N.Y. L.J., Dec. 6, 1990, at 6 (noting that "the food industry has become increasingly alarmed by the recent proliferation of inconsistent state and local laws governing food products"); Carole Sugarman, *Who's Minding the State? Everybody But Uncle Sam Seems to be Setting Food Policy*, WASH. POST, Oct. 4, 1989, at E1 ("States are becoming increasingly active in drawing up their own food safety and labeling laws.").

91. See, e.g., The Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY CODE §§ 25249.5-.13 (Deering 1988) (requiring manufacturers and producers to place warning labels on all substances, including food products, that contain properties likely to cause cancer or reproductive harm) [hereinafter Proposition 65]; CAL. FOOD & AGRIC. CODE § 12811 (Deering 1988) (imposing data submission requirements on pesticide manufacturers and distributors exceeding that required under FIFRA); CAL. CODE REGS. tit. 3, §§ 6158, 6159, 6172, 6176-92, 6200 (1988) (same).

92. See Big Green, *supra* note 14.

93. See Anthony F. Essaye & Jill B. Deal, *Pesticide Law Could Have International Implications*, N.Y. L.J., June 7, 1990, at 5 (noting that Big Green went further than previous state regulation of pesticide use); Mathews, *supra* note 21, at A3 ("Proposition 128, the most stringent antipollution measure ever placed on an American ballot, would impose unprecedented curbs on pesticides [in California].").

94. See Big Green, *supra* note 14, § 26901. This zero-tolerance standard is in stark

processed in California.⁹⁵ EPA estimates that this would have affected seventy-two EPA-approved pesticides.⁹⁶ In addition, one of the most controversial provisions would have required that foods imported into the state meet the same standards,⁹⁷ thereby requiring importers to customize production to meet California's unique regulatory demands.⁹⁸

Big Green followed in the wake of another restrictive California initiative, the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65),⁹⁹ which voters enacted into law through the referendum process. Proposition 65 requires, among other things, that all manufacturers and producers put warning labels on all substances, including food products, that contain properties found to cause cancer or reproductive harm.¹⁰⁰ As of the time of this writing, legislation modeled after Proposition 65 was pending in Illinois,¹⁰¹ Massachusetts,¹⁰² and New York.¹⁰³ Citizens in Ohio had also

contrast to the federal risk-benefit standard. See *infra* Part III and accompanying text for a comparison of these two standards.

95. See Big Green, *supra* note 14, § 26901.

96. See ITC INTERIM REPORT, *supra* note 2, at app. G (EPA's list of food use pesticides that have been evaluated for carcinogenicity).

97. See Big Green, *supra* note 14, § 26910. Section 26910 of Big Green read as follows:

In order to protect the health of the People of the State of California, food produced outside of this state, foreign or domestic, which contains a residue of a pesticide which has been canceled or cannot be registered in this state because of Sections 26901 or 26903, or which is in excess of the amount permitted by Sections 26905 and 26906, is adulterated and unsafe.

98. This, in turn, would have led to major increases in production costs. See *infra* notes 115-19 and accompanying text.

99. CAL. HEALTH & SAFETY CODE §§ 25249.5-.13 (Deering 1988).

100. See CAL. HEALTH & SAFETY CODE § 25249.6 (Deering 1988); see Whitelaw, *supra* note 30, at 677-78 (noting that under Proposition 65, manufacturers must either affix the required warning labels or stop selling in the California marketplace). The list of pesticides compiled under Proposition 65 represents the first category of chemicals that would have been eliminated under Big Green. See Big Green, *supra* note 14, § 26914(l)(2) (defining chemicals "known to cause cancer" as those listed by the Governor as "known to the state to cause cancer pursuant to [CAL. HEALTH & SAFETY CODE] section 25249.8").

101. See Illinois Food Toxic Disclosure Act, S. Res. 34 (sponsor: Sen. Howard Brooks (D)) (introduced in early 1991) (requiring clear and reasonable warnings for all chemicals in food and food packaging that have been linked to cancer or reproductive toxicity).

102. See Massachusetts Consumer Right-to-Know Protection Law, H.R. Res. 1610 (sponsor: Rep. Patricia A. Walrath (D)); Massachusetts Toxic Warning Act, House Bill 2886 (sponsor: Rep. John McNeil (D)) (introduced in early 1991) (emulating Proposition 65's notice requirements for chemicals known to cause cancer).

103. New York Toxic Disclosure Act, A. Res. 477 (sponsor: Assemblyman Neil Keller (R-100)) (introduced in early 1991) (requiring clear and reasonable warnings for all chemicals known to cause cancer or reproductive harm). Officials at Grocery Manufacturers of America, Inc.—an industry group that monitors food safety laws—report that other states are awaiting the outcome of the lawsuits challenging Proposition 65 before seeking to implement similar initiatives. Telephone interview, Oct. 14, 1991. Proposition 65 has been challenged in a variety of lawsuits. See, e.g., Chemical Specialties Manufacturers Ass'n v. Allenby, 744 F. Supp. 934 (N.D. Cal. 1990) (rejecting claim that

launched an initiative to put a Proposition 65-type law on the ballot in 1992.¹⁰⁴

Numerous other states have adopted laws that either duplicate or exceed the requirements of FIFRA. For example, ten states have recently enacted laws restricting pesticide use, primarily in the form of registration, right-to-know, posting and notification statutes.¹⁰⁵ Right-to-know, posting, and notification statutes require commercial pesticide applicators to notify neighboring residents before applying pesticides to homes, lawns, public buildings, or agricultural and state lands.¹⁰⁶ One common provision requires twenty-four to seventy-two hours advance notice of pesticide application or the posting of warning signs for an extended period following spraying, or both.¹⁰⁷ Some of these laws already have been subject to federal preemption suits under FIFRA,¹⁰⁸ but the Supreme Court has indicated that such challenges are unlikely to be successful. Many states also have adopted laws that exceed federal standards governing pesticide drift.¹⁰⁹

Proposition 65 is preempted by FIFRA); *D-Con v. Allenby*, 728 F. Supp. 605 (N.D. Cal. 1989) (same); *AFL-CIO v. Deukmejian*, 260 Cal. Rptr. 479 (Cal. Ct. App. 1989) (ruling on the required contents of the Governor's Proposition 65 list of chemicals).

104. *GROCERY MFRS. OF AMERICA, INC., FACT SHEET 25* (Oct. 1991).

105. *See* CONN. GEN. STAT. ANN. §§ 22a-66a (West Supp. 1991); FLA. STAT. ANN. § 482.2265 (West 1990); IOWA CODE § 206.19 (Supp. 1991); LA. REV. STAT. ANN. §§ 3:3201 to :3214, 3:3221 to :3228, 3:3241 to :3257 (West Supp. 1991); MD. AGRIC. CODE ANN. §§ 5-201 to -211 (Supp. 1991); MASS. GEN. LAWS ANN. ch. 132B, §§ 11-15 (West 1991); N.J. ADMIN. CODE tit. 7, §§ 7:30-11.1 (1990); N.Y. ENVTL. CONSERV. LAW § 33-1001 (Consol. Supp. 1991); W. VA. CODE § 19-16A-1 to -16A-27 (1991); WIS. STAT. ANN. § 101.58-101.589 (West 1988).

106. *See* statutes cited *supra* note 105.

107. The Connecticut, Florida, Maryland, and New York laws cited in note 105, *supra*, contain examples of such provisions.

108. *See, e.g., New York State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115 (2d Cir. 1989) (holding that New York statute mandating notification requirements governing the spraying of pesticides constitutes permissible state regulation of sale or use of pesticides under FIFRA). Other cases have challenged the authority of municipalities to regulate pesticides, yielding different results in different jurisdictions. *See, e.g., Professional Lawn Care Ass'n v. Village of Milford*, 909 F.2d 929 (6th Cir. 1990) (holding that FIFRA impliedly preempts municipal ordinance imposing registration, posting and notice requirements on commercial pesticide users), *vacated*, 111 S. Ct. 2880 (1991); *Maryland Pest Control Ass'n v. Montgomery County*, 646 F. Supp. 109 (D. Md. 1986) (same), *aff'd*, 822 F.2d 55 (4th Cir. 1987); *Deukmejian v. County of Mendocino*, 683 P.2d 1150 (Cal. 1984) (holding that FIFRA did not preempt voter-enacted ban on aerial spraying of certain pesticides). The Supreme Court seemingly settled the issue in *Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476 (1991), by holding that FIFRA did not explicitly nor impliedly preempt municipal ordinances regulating pesticide use.

109. *See, e.g., CAL. FOOD & AGRIC. CODE § 12972* (Deering 1988) (directly prohibiting drift); N.Y. ENVTL. CONSERV. LAW § 33-1101 (Consol. Supp. 1991) (withdrawing certain grape growing regions from spraying of pesticides); OKLA. STAT. ANN. tit. 2, § 3-84 (West 1990) (establishing process for termination of hormone-type spraying); OR. REV. STAT. § 634.212 (1990) (providing for the establishment of protected & restricted areas); *see also* CONN. GEN. STAT. ANN. § 22a-51 (West 1990) (permit requirement for experimental use pesticide); DEL. CODE ANN. tit. 3, § 1214 (1990) (permit requirement for restricted use or experimental use pesticide); LA. REV. STAT. ANN. § 3273 (West 1990) (permit requirement for generators of pesticide waste); OHIO REV. CODE ANN. § 921.03 (Baldwin Supp. 1991) (permit requirement for experimental use pesticide); R.I. GEN. LAWS § 23-29-7 (1990) (experimental use permit requirement); TEX. AGRIC. CODE ANN. § 76.048 (West 1991) (experimental use permit requirement); WASH. REV. CODE ANN. § 17.21.030 (West 1990) (permit requirement for restricted use pesticides); WYO. STAT. § 35-7-357 (1991) (experimental use permit requirement); *see also* Sarah E. Redfield,

As the above discussion indicates, state activity is accelerating in the area of restrictive pesticide regulation, and this trend shows no sign of abatement.

B. The Implications of State Regulation of Pesticides

Restrictive regulation of pesticides by individual states has national, international, and perhaps constitutional implications. For example, these regulations could lead to a disturbing patchwork of state laws¹¹⁰ that ultimately would hurt consumers by weakening the federal regulatory effort, disrupting the nationwide system of food distribution, and forcing distributors to pass on to consumers, in the form of higher food prices, the added cost of complying with multiple jurisdictional standards.¹¹¹

Even if California were the only state to adopt more restrictive measures, the impact on production, commerce, and trade could still be significant. For example, the United States Department of Agriculture's report to the International Trade Commission noted that, had Big Green become law, American tomato production would have declined by up to ninety percent and lettuce production would have declined by forty to sixty percent.¹¹² This decline would have resulted because pesticides that Big Green may have outlawed

Chemical Trespass? An Overview of Statutory and Regulatory Efforts to Control Pesticide Drift, 73 Ky. L.J. 855, 873-918 (1985) (summarizing state laws governing drift).

110. This patchwork scenario assumes that states adopt standards that differ from one another, as well as from the federal standard. If all states were to adopt the same standard, balkanization would not result. If the resulting uniform standard were to mirror Big Green, however, the economic impact would still be significant in light of that measure's zero-tolerance standard. See *infra* notes 111-17 and accompanying text. It is more likely, however, that state laws, although similar, would still vary from one another in at least subtle ways, producing at least a minor balkanization effect. Pesticide dealers would still bear the economic burden of analyzing and accommodating these differing standards, or of applying the most stringent provisions among them.

111. See Michael R. Taylor, *Federal Preemption and Food Regulation: Where We Go From Here*, 40 FOOD DRUG COSM. L.J. 221, 227 (1985).

112. See Brief Submitted by the United States Department of Agricultural at 9-10, ITC Investigation No. 332-292 (1990) [hereinafter USDA Brief]. The USDA relied on information provided by one of its sub-units, the Economic Research Service (ERS). See ERS, POTENTIAL ECONOMIC EFFECTS OF THE CALIFORNIA ENVIRONMENTAL PROTECTION ACT OF 1990 (report accompanying the USDA brief submitted on behalf of the ITC investigation of Big Green). The ERS based its estimates on statistics of California lettuce and tomato growers' dependence on pesticides that would have been banned under Big Green. See *id.* at 2-4.

For example, a short-term loss of the fungicide maneb—a potentially carcinogenic fungicide for which no equally cost-efficient replacement exists—would have cut California lettuce production by two to four percent (920,000 to 2.1 million hundredweight). *Id.* at 4. The use of alternative pesticides to replace this one chemical would have increased California lettuce growers' cumulative production costs over the short term by \$600,000-\$900,000. *Id.* Using a price elasticity figure of -0.18, which is within the range of estimates recognized by experts, the ERC calculated an average farm-level price increase of seven to sixteen percent. *Id.* at 5. This figure translates into a net increase to lettuce consumers of \$70 million to \$150 million. *Id.* Over the long term, the ERS

make it possible to cultivate crops during damp conditions, and thereby enable farmers to harvest several crops per year.¹¹³ This problem would have affected other fruits and vegetables as well, particularly cauliflower, broccoli, and berries.¹¹⁴

Furthermore, manufacturers and producers that sell to California consumers, or the consumers of any state that passes Big Green-style legislation, would be burdened severely by restrictive and inconsistent pesticide regulations.¹¹⁵ To retain those markets, manufacturers and producers would have to either take the unlikely step of establishing special production lines adapted to meet California's standards or bring their entire nationwide production into compliance with California's standards.¹¹⁶ Under this latter scenario, California's laws would become, in effect, "the national standard," usurping EPA's responsibilities and forcing industry and consumers to incur burdensome costs. This result could put the United States at a competitive disadvantage in the international market for food and agricultural products because foreign distributors that do not shoulder comparable regulatory expenses could sell their products abroad at lower prices, undermining the competitiveness of American goods.¹¹⁷

estimated that Big Green would have cost American lettuce consumers \$30 million annually. *Id.* These statistics refer to the loss caused by eliminating only one chemical product.

113. See USDA Brief, *supra* note 112, at 9-10.

114. *Id.* Another report prepared for the California Coordinating Council, SPECTRUM ECONOMICS, INC., PROPOSITION 128: IMPACTS ON CALIFORNIA AGRICULTURE OF THE FOOD SAFETY AND PESTICIDES SECTION (1990) [hereinafter SPECTRUM ECONOMICS REPORT] (submitted with the USDA Brief, *supra* note 112), gave the following estimates of possible yield losses associated with Big Green: 1) Almonds—10 to 40%; 2) grapes—minimum 10 to 20%; 3) lettuce—10 to 30%; 4) oranges—25 to 35%; 5) strawberries—20 to 50%. *Id.* at II (Executive Summary). The estimate for lettuce is based on an assumption that the growing season, normally year-round, would be shortened by at least one-third because maneb would be unavailable. *Id.* This estimate is more conservative than that made by the ERS in its report on the probable economic impacts of Big Green. See *supra* note 112.

The report also noted that the loss of sulfur-based pesticides under Big Green could have destroyed the state's entire grape crop, resulting in a loss of more than \$1 billion. SPECTRUM ECONOMICS REPORT, *supra*, at I, 7-2, 7-6. California is the country's leading grape producer, accounting for more than 90% of American production. *Id.* at 7-2. The report added that the measure would have cost Californians roughly 100,000 jobs, *id.* at II, 5-7, and would have resulted in increased consumers costs of three to five billion dollars. *Id.* at 5-4.

115. See *infra* notes 116-24 and accompanying text.

116. See Whitelaw, *supra* note 30, at 683 (discussing this phenomena in relation to Proposition 65). As noted *supra* note 110, this situation might result even under the "patchwork" scenario, where a number of states adopt unique, burdensome laws. Manufacturers might engage in a "race to the bottom," bringing their production standards into compliance with the most restrictive state measures. The economic consequences of this would still be significant. See *supra* note 110 and the text accompanying notes 116-20.

117. A state legislative scheme as comprehensive as Big Green might be susceptible in whole or in part to a constitutional Commerce Clause challenge. FIFRA appears to grant states virtually unlimited discretion to regulate the sale or use of pesticides as long as such regulation does not permit pesticide sales or uses prohibited by federal law. See 7 U.S.C. § 136v(a); see also S. REP. NO. 838, *supra* note 39, reprinted in 1984 U.S.C.C.A.N. 3993, 4021 ("[T]he intent of [7 U.S.C. § 136v(a)] is to leave to the States the authority to impose stricter regulation on pesticide use than that required under the Act."). If § 136v(a) means what it says, then no Commerce Clause challenge would succeed, given

Discussing this effect in relation to Proposition 65, one author has estimated that the cost of compliance incurred by food manufacturers under that measure will approach \$200 million annually.¹¹⁸ As he explains: "Unless a manufacturer intends to drop the California market entirely or to reformulate that portion of its product line destined exclusively for the California market, a special attention that would incur excessive costs, it must apply California's tolerances nationwide."¹¹⁹

Indeed, concerns have been expressed both at home and abroad regarding the potential negative impact on international trade that would flow from restrictive state regulations of pesticides. For example, while Big Green was pending in California, the Office of the United States Trade Representative, as well as the European Community and several Latin American countries, expressed reservations about the implications for international trade of Big Green's food-safety provisions.¹²⁰ In fact, the United States Trade Representative requested that the International Trade Commission investigate Big Green's potential international trade effects.¹²¹ The

Congress' unrestricted grant of authority to the states. See *Prudential Ins. Co. v. Benjamin*, 328 U.S. 408, 421-27 (1946) (holding that when Congress grants the states authority over certain commerce issues, no constitutional issue arises). Thus, any successful Commerce Clause challenge must establish that Congress did not permit the particular state regulation under scrutiny.

If § 136v(a) does nothing more than make clear that FIFRA does not totally strip states of the ability to regulate pesticide sale and use, a Commerce Clause challenge might be successful. The Supreme Court has stated consistently that state laws burdening interstate commerce are unconstitutional if such burdens are not outweighed by compelling local interests. See, e.g., *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662 (1981); *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970); *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824). The potential burdens of Big Green-style legislation on interstate commerce are far greater than those the Court has found intolerable in other circumstances. Compare *supra* notes 21-30 & 110-16 and accompanying text (discussing the possible effects of Big Green on interstate commerce) with *Kassel* (striking down Iowa statute that would have required trucking companies traversing Iowa to tailor all trucks to meet that state's unique standards) and *Pike* (invalidating Arizona law requiring canteloupes grown in Arizona to be packaged in Arizona-approved crates because it would have created a loss of more than \$200,000 to an Arizona grower that used California packages).

118. Whitelaw, *supra* note 30, at 677 (citing LEXECON, INC., AN ECONOMIC ANALYSIS OF THE EFFECTS OF PROPOSITION 65 ON OUT-OF-STATE CONSUMERS AND PRODUCTS 23 (1988)). This estimate was based on the following two assumptions: (1) Californians consume \$9 billion worth of imported processed foods annually, and (2) Proposition 65 would lead to a two percent rise in the cost of those out-of-state goods. *Id.* at 677 n.4.

119. *Id.* at 683.

120. See *International Trade: 'Big Green'-style*, *supra* note 25, at A-7; see also ITC INTERIM REPORT, *supra* note 2, at app. D (summarizing the views of various international governments and organizations opposed to Big Green).

121. See ITC INTERIM REPORT, *supra* note 2, at app. A (reprinting a letter from United States Trade Representative Carla Hills to the International Trade Commission Chairman requesting evaluation of the extent to which Big Green could create major differences between California and federal standards for chemical residues in food; the volume and value of agricultural products imported through California and marketed in the state; the volume and value of agricultural products exported from California and

resulting report from the International Trade Commission, issued prior to Big Green's defeat, stressed California's importance as a food producer and importer, and summarized analyses submitted by a number of authors regarding the potential trade effects of the measure.¹²² Although several authors argued on behalf of Big Green,¹²³ "[o]pponents of the measure commenting on its international [trade] aspects outnumbered supporters by a wide margin."¹²⁴ That California's Big Green alone generated such a global protest supports the claim that restrictive state regulation of pesticides could significantly affect international trade.

Restrictive state regulation of pesticides may also undermine international trade negotiations and agreements aimed at harmonizing countries' food-safety laws.¹²⁵ The United States is currently a party to negotiations aimed at harmonizing international sanitary and phytosanitary standards among signatories of GATT.¹²⁶ State regulations that exceed federal standards for pesticides create regulatory inconsistencies at the subnational level that stand to defeat the purpose of these talks. Furthermore, state regulation of pesticides could place the United States in violation of its obligations under articles 2 and 3 of the Agreement on Technical Barriers and Trade.¹²⁷ Under that agreement, the United States is bound to ensure that its environmental regulations do not "have the effect of creating unnecessary obstacles to international trade,"¹²⁸ and to "take such measures as may be available to [the United States] to ensure that local government bodies within [its] territories comply with [the provisions of the Agreement.]"¹²⁹ These international efforts to discourage nations from enforcing health and safety laws that negatively impact international trade indicate that restrictive

through its ports; and the potential international trade implications arising from Big Green).

122. *See id.* at app. D.

123. Those supporting the measure included the Natural Resources Defense Council, the National Family Farm Coalition, the California Association of Family Farmers, and the director of the Consumer Pesticide Project of San Francisco, California *Id.*

124. *Id.* at 4-5. Organizations opposed to Big Green included the Mexican government, the California State World Trade Commission, the United Fresh Fruit and Vegetable Association, the American Farm Bureau Federation, the International Apple Institute, the American Frozen Food Institute, the National Agricultural Chemicals Association, the Asociacion de Exportadores de Chile, the National Grain and Feed Association, the American Soybean Association, the Agricultural Council of California, Professor Sandra Archibald of the Food Research Institute at Stanford University, and Professor Otto Doering of Purdue University. *Id.* at app. D. European Community officials also expressed concern that Big Green-style legislation would disrupt international trade negotiations. *See International Trade: 'Big Green'-Style, supra* note 25, at A-7.

125. *See* ITC INTERIM REPORT, *supra* note 2, at 4-5.

126. GATT, *opened for signature* Oct. 30, 1947, 61 Stat. A3, T.I.A.S. No. 1700, 55 U.N.T.S. 187. As of the date of this writing, these negotiations had only yielded a draft agreement. GATT Draft Agreement on Sanitary and Phytosanitary Measures, July 5, 1990, at Annex II.

127. Agreement on Technical Barriers to Trade of GATT, *opened for signature* Apr. 12, 1979, 31 U.S.T. 405, T.I.A.S. No. 9616, *reprinted in* GATT, THE TEXTS OF THE TOKYO ROUND AGREEMENT 1 (1986).

128. *Id.* at article 2.1.

129. *Id.* at article 3.1.

state regulations of pesticides could create liabilities for the United States in its dealings with other nations.

III. Risk Assessment: Contrasting Risk-Benefit Analysis with a Zero-Risk Approach

As discussed, EPA conducts a risk-benefit analysis in all cases involving pesticides designed for use on raw agricultural products.¹³⁰ If the agency determines that the benefits outweigh the risks, it will authorize use of the product. For chemicals that will result in residues in processed foods, EPA also conducts a risk-benefit analysis, unless the carcinogenic risk associated with the product is greater than negligible.¹³¹ For this narrow category of pesticides posing a greater than negligible cancer risk, a zero-tolerance standard applies and no registration will be granted for such pesticides.¹³²

The usual EPA method of balancing the risks of use of a pesticide against the likely benefits of such use has not been immune from criticism.¹³³ The food-safety provisions of Big Green, for example, indicate that many believe that no level of risk is acceptable for products that may cause cancer or reproductive harm.¹³⁴ This position directly challenged EPA's traditional risk-benefit approach.

Underlying the view that no level of carcinogenic risk in the food supply is acceptable is the notion that "life is priceless, not to be bartered for mere economic returns."¹³⁵ Unfortunately, in modern society, this ethic is almost never attainable and, indeed, is often subrogated to other objectives.¹³⁶ Many technologies have been

130. See *Addressing the Delaney Paradox*, *supra* note 57, at 41,104 (outlining EPA's policy of applying risk-benefit analysis under FIFRA and FFDCa). See *supra* part I for a discussion of EPA's approach to assessing risks under FIFRA and FFDCa.

131. See *Addressing the Delaney Paradox*, *supra* note 57, at 41,104. Negligible is defined as one risk of cancer per million over a lifetime exposure. *Id.* at 41,112. See *supra* notes 70-88 and accompanying text for a discussion of EPA's treatment of processed foods.

132. See 21 U.S.C. § 348(c)(3)(A). See *supra* notes 78-88 and accompanying text for a discussion of the Delaney Clause and EPA's interpretation of it.

133. See Janet S. Hathaway, *An Environmentalist's Perspective on the Magnitude of the Health Risk from Pesticide Residues in Food*, 44 *FOOD DRUG COSM. L.J.* 659 (1989); Marina M. Lolley, Comment, *Carcinogen Roulette: The Game Played Under FIFRA*, 49 *MD. L. REV.* 975 (1990); Martha McCabe, *Pesticide Law Enforcement: A View from the States*, *J. ENVTL. L. & LITIG.* 35 (1989); Samuel S. Epstein, *A National Pesticide Policy Would Be Dangerous to Our Health*, *L.A. DAILY J.*, Jan. 3, 1985, at 4; Stephen Green & Rick Rodriguez, *State Moving to Tighten Up Pesticides Program*, *L.A. DAILY J.*, Nov. 23, 1984, at 2.

134. See *supra* notes 92-98 and accompanying text. The Delaney Clause, 21 U.S.C. § 348(c)(3)(A), as interpreted by EPA, see *supra* notes 78-88 and accompanying text, impacts far fewer products than Big Green would have. Big Green sought to ban all pesticides posing a risk of cancer, regardless of whether they are negligible, or whether the pesticide residue will appear in food additives.

135. Richard Zeckhauser, *Measuring Risks and Benefits of Food Safety Decisions*, 38 *VAND. L. REV.* 539, 540 (1985).

136. *Id.* In fact, risks to the public from the use of pesticides are often greater than

pursued and accepted despite the inherent risks associated with them because society has recognized that technologies can dramatically improve, and perhaps expand, our lives.

Numerous commentators have taken issue with the prospect of achieving zero risk, and perceive risk-benefit analysis to be a necessary component to regulating food safety in a modern society.¹³⁷ One argument is that, when fundamental human values are concerned, society has a duty to engage in a reasoned risk-benefit calculation.¹³⁸ This school of thought recognizes that banning a product may produce greater risks than preserving it.¹³⁹ As one author has stated: "The use of pesticides, fertilizers, and chemical additives appears to require a cost in the form of probable hazards to life, *yet these products provide the most support for survival.*"¹⁴⁰

Another argument for allowing small amounts of additives and contaminants to remain in food products is that they serve the significant purposes of either "mak[ing] food products more appealing to consumers, . . . lower[ing] the costs of producing the products, or . . . provid[ing] nutritive or health benefits."¹⁴¹ This argument's major justification for permitting some level of contaminant is the "exceedingly high cost of removing them completely."¹⁴² Similarly, additives, which unlike contaminants, are put into the food supply intentionally, are deemed valuable because they can "assist with the production of the food itself," or "may be employed at some stage in the industrial preparation of a food to reduce its cost."¹⁴³ These benefits are passed along to the consumer in the form of lower prices.¹⁴⁴ "In determining how the world is to feed itself, it seems evident that we are confronted ultimately with the question of trading risks for benefits."¹⁴⁵

Another frequent assailment of the zero-risk approach is that it

tests are able to predict, and should properly be regarded as greater than zero. *See id.* at 557; cf. Peter B. Hutt, *The Importance of Analytical Chemistry to Food and Drug Regulation*, 38 VAND. L. REV. 479 (1985) (tracing historic advancements in analytical chemistry techniques and resulting improvements in risk detection). Methods of risk detection constantly are improving, allowing scientists to discover threats that previously went undetected. *See Hutt, supra*, at 485.

Modern analytical chemistry techniques enable detection of exceedingly low-level risks. *See Zeckhauser, supra* note 135, at 540. These techniques will continue to achieve greater precision over time. *See Hutt, supra*, at 491. Products once thought safe would fail a no-risk standard today. *Zeckhauser, supra* note 135, at 540. Thus it is likely that science will some day expose risks in chemicals, including pesticides, currently considered risk-free. *Id.* at 540, 557. Of course, once risks are detected through scientific analysis, reasonable efforts to limit their impact on society is warranted.

137. *See, e.g., Middlekauff, supra* note 58.

138. *See Samuel E. Stumpf, Social Aspects of Risk/Benefit Analysis of the Food Supply*, FOOD TECH., Aug. 1978, at 68-69.

139. *Id.* ("It would be very strange to adopt a social policy where in the name of saving life we destroy other human life.").

140. Samuel E. Stumpf, *The Moral Dimension of the World's Food Supply*, 1 ANN. REV. NUTRITION 1, 25 (1981) (emphasis added).

141. *Zeckhauser, supra* note 135, at 550.

142. *Id.* at 553.

143. *Id.*

144. *See, e.g., id.* at 554.

145. *Id.* at 582.

fixates too strenuously on the need to eliminate risk associated with individual toxicants, while ignoring the much higher threats associated with natural dietary patterns.¹⁴⁶ The Delaney Clause, which requires zero-tolerance levels for all carcinogens in food additives,¹⁴⁷ represents a prime example of this inconsistency. Commentators have argued that this use of a zero-tolerance standard is perverse.¹⁴⁸ Referencing a 1982 National Research Council Study of dietary cancer risks,¹⁴⁹ one author writes:

The law applies the most stringent test [under the Delaney Clause]—freedom from any risk of harm—to food and color additives, *whose contribution to cancer incidence the NRC Committee was unable to discern*. As a corollary, the law applies the most relaxed standard—*forbidden only if 'ordinarily injurious'*—to unprocessed foods of natural origin, many of which include high levels of constituents that pose a cancer risk which the Committee ranked the highest.¹⁵⁰

Regulators can achieve zero risk of cancer “only by eliminating all exposure to all carcinogens.”¹⁵¹ Yet, federal agencies have identified more than two thousand potential carcinogens.¹⁵² Achieving zero risk in the face of so many suspect carcinogens represents a near-impossible task.¹⁵³ Regulating even one chemical taxes agencies' time and resources greatly.¹⁵⁴ Regulatory policy should not expend these limited resources on substances that pose only a negligible risk. A better solution is to focus limited agency resources on “high risk situations.”¹⁵⁵ “Ironically, striving to eliminate all risk will provide less public health protection than a policy that defines certain small levels of risk as insignificant and acceptable.”¹⁵⁶

146. See Richard A. Merrill, *Reducing Diet-Induced Cancer Through Federal Regulation: Opportunities and Obstacles*, 38 VAND. L. REV. 513, 515 (1985). For example, high fat diets or diets high in smoked or cured foods have been linked to an increased risk of cancer. *Id.* at 516; see also COMMITTEE ON DIET, NUTRITION, AND CANCER OF THE NATIONAL RESEARCH COUNCIL, DIET, NUTRITION, AND CANCER (1982) (finding little evidence that additives contribute significantly to the overall risk of cancer in this country and concluding that many organic foods pose much higher risks) [hereinafter DIET, NUTRITION, AND CANCER].

147. See 21 U.S.C. § 348(c)(3)(A).

148. See generally DIET, NUTRITION, AND CANCER, *supra* note 146; Merrill, *supra* note 146.

149. DIET, NUTRITION, AND CANCER, *supra* note 146.

150. Merrill, *supra* note 146, at 525 (emphasis added).

151. Frank B. Cross, *Beyond Benzene: Establishing Principles for a Significance Threshold on Regulatable Risks of Cancer*, 35 EMORY L.J. 1, 10 (1986).

152. *Id.* (citing a number of studies).

153. See *id.*

154. See *id.* at 11.

155. *Id.* at 10.

156. *Id.* at 11. Professor Cross recommends risk thresholds of one chance per 100,000 for “average environmental risks,” *id.* at 51 (this category refers to the risk posed by general environmental hazards—ones to which most people are exposed on a continual basis—to the average person); one chance per 1,000 for “maximum individual

Courts' efforts to adhere literally to the Delaney Clause zero-tolerance standard for food additives¹⁵⁷ have been the subject of criticism.¹⁵⁸ *Public Citizen v. Young*¹⁵⁹ exemplifies the seemingly illogical consequences of this restrictive approach. In *Young*, the United States Court of Appeals for the District of Columbia Circuit held that, under the FFDCA, the Food and Drug Administration was required to ban food dyes even when the health risks associated with them were de minimis.¹⁶⁰ The court noted that the threat associated with the food dyes in question was only 1/19,000th of the incremental risk of spending one extra day each year in Denver rather than in the District of Columbia (given the carcinogenic effects of cosmic radiation at higher elevations),¹⁶¹ yet held that Congress had not authorized any deviation from the zero-tolerance standard.¹⁶² In criticizing this result, one author wrote:

The court of appeals in *Young* simply took it for granted that once the will of Congress is determined, no result is too arbitrary or absurd to question.

risks," *id.* at 53 (this category refers to the risk posed to the "most threatened individuals"); and one chance per 10,000 for "occupational risks," *id.* at 54.

For additional critiques of the zero-tolerance standard, see *id.* at 11 n.51 (quoting Anderson, *Risk Assessments and Regulatory Approaches to Carcinogens*, RISK/BENEFIT DECISIONS AND THE PUBLIC HEALTH 20 (1978) ("There are simply too many suspected carcinogens to which people are exposed to expect that the goal of zero risk could ever be implemented for each case. Such a goal would likely lead to the total banning of a few chemicals but fail to contribute significantly to the overall improvement of public health.")); see also Charles H. Blank, *The Delaney Clause: Technical Naivete and Scientific Advocacy in the Formulation of Public Health Policies*, 62 CAL. L. REV. 1084 (1974) (concluding that the Delaney Clause is irrational and inappropriate on its face); Margaret Gilhooly, *Plain Meaning, Absurd Results, and the Legislative Purpose: The Interpretation of the Delaney Clause*, 40 ADMIN. L. REV. 267 (1988) (interpreting the Clause as allowing de minimis risks, and criticizing the application of the law); Thomas O. Henteleff, "Modernizing" the Delaney Clause, 38 FOOD DRUG COSM. L.J. 147 (1983) (suggesting that more realistic low-level restrictions should be established); Middlekauff, *supra* note 58, at 259 ("Application of the Delaney Clause as an absolute prohibition of carcinogens has resulted in regulatory decisions which are unduly restrictive and not in keeping with current knowledge in the field of carcinogenesis."); Elizabeth Poliner, *The Regulation of Carcinogenic Pesticide Residues in Food: The Need to Reevaluate the Delaney Clause*, 7 VA. J. NAT. RESOURCES L. 111 (1987) (criticizing the current regulatory scheme as outdated and encouraging the adoption of a more flexible approach).

157. 21 U.S.C. § 348(c)(3)(A).

158. See Stephen F. Williams, *Book Review: Fingers in the Pie*, 68 TEX. L. REV. 1303 (reviewing JEREMY RABKIN, *JUDICIAL COMPULSIONS: HOW PUBLIC LAW DISTORTS PUBLIC POLICY* (1989)).

159. 831 F.2d 1108 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988).

160. *Id.* at 1122. EPA maintains that *Young* is not inconsistent with the adoption of a de minimis exception to pesticidal food additives posing negligible carcinogenic risks. See *Addressing the Delaney Paradox*, *supra* note 56, at 41,104, 41,107 (1988). First, the agency emphasizes that *Young* did not deal with the FFDCA § 409 Delaney Clause pertaining to food additives, but rather involved a separate FFDCA Delaney Clause regarding color additives. *Id.* Similarly, the agency points to the *Young* court's language noting that: 1) the context of the § 409 Delaney Clause bore no resemblance to that of the color-additive clause; and 2) "the operation of the food additive Delaney Clause raises complex issues distinct from those of this appeal." *Id.* (quoting *Young*, 831 F.2d at 1118 n.13). In essence, EPA refers to the *Young* court's suggestion that the legislative history of the food-additive clause could warrant a different outcome. *Id.* Neither the *Young* court nor EPA, however, has clearly explained why.

161. *Young*, 831 F.2d at 1111.

162. *Id.* at 1111, 1122.

This ruling may appear to be the reduction ad absurdum of contemporary administrative law, in which Congress is treated like some ancient oriental potentate, whose orders must be followed without question, whether they are rational or not, whether they are seriously intended or not.¹⁶³

The risk-benefit standard currently employed by EPA in most cases represents the most feasible and scientifically supportable approach to regulating food safety. The sweeping zero-risk approach advanced in the Big Green proposal for all pesticides that pose carcinogenic risk or reproductive harm is radically out of step with modern methods of production and technological development, and could actually increase, rather than reduce, food-safety hazards. Such a measure does not represent a reasoned, scientific response to health risks associated with pesticides. Inherent risks always will accompany the consumption of mass-produced food catering to modern demands. Energy is better devoted to concentrating on high-risk situations, such as risk from organic food components and general dietary patterns, than on individual low-risk additives and contaminants.

IV. Proposing a Federal Check on State Authority over the Regulation of Pesticides and Food Safety

The existing federal regulatory scheme for pesticide use enables states to regulate pesticides more stringently than the federal government. This scheme has potentially negative consequences for interstate commerce and international trade. Even if these negative consequences are ignored, EPA's current risk-benefit approach to pesticide regulation is superior to the more restrictive approaches likely to surface in the various states. These factors suggest that states ought to be limited in their ability to exceed federal regulations governing pesticides. This Part advances two alternative proposals for achieving this objective: (1) an explicit statutory grant of federal preemption authority over the registration, sale, and use of pesticides, including the setting of tolerances; or (2) a statutory requirement that states seeking to exceed federal standards governing the registration, sale, and use of pesticides bear the burden of demonstrating, on a product-specific basis founded on sound scientific principles, the inadequacy of federal regulations. This Note urges the adoption of the latter proposal.

163. Williams, *supra* note 158, at 1307 (quoting RABKIN, *supra* note 158, at 207-08); see also Zeckhauser, *supra* note 135, at 539 n.1 (critiquing the Delaney Clause by suggesting that it would "prohibit even a highly beneficial food preservative if it imposed an infinitesimal carcinogenic risk").

A. Federal Preemption Under FIFRA and the FFDCA

FIFRA grants states express authority to impose more exacting constraints on the sale or use of pesticides than those imposed by the federal government.¹⁶⁴ Moreover, although FIFRA prohibits states from enacting *labeling* requirements “in addition to or different from” federal standards,¹⁶⁵ courts have held that this provision does not necessarily preempt states from imposing *warning* requirements that exceed federal standards,¹⁶⁶ and that it does not preempt state tort claims involving failure to adequately warn despite compliance with federal labeling provisions.¹⁶⁷

The FFDCA makes no reference to state authority to set tolerances that exceed federal levels under sections 408 and 409. This would seem to leave room for EPA to declare a policy of preemption in this area by interpreting congressional intent as providing for federal preemption over inconsistent state laws.¹⁶⁸ Supreme Court opinions on preemption, however, dispel that possibility. The Court has held that, in areas of traditional state police power like food safety, federal laws can preempt state enactments only if there is “an unambiguous congressional mandate to that effect.”¹⁶⁹ Congressional silence on the matter would not meet this test. Thus, efforts by EPA to declare preemptory authority under sections 408 and 409 of the FFDCA likely would not withstand judicial review.

164. See 7 U.S.C. § 136v(a).

165. *Id.* § 136v(b).

166. See, e.g., *N.Y. State Pesticide Coalition v. Jorling*, 874 F.2d 115, 119-20 (2d Cir. 1989) (holding that FIFRA’s labeling provision is inapplicable to New York regulations requiring certain warnings); *Chemical Specialties Mfrs. Ass’n v. Allenby*, 744 F. Supp. 934, 935 (N.D. Cal. 1990) (holding that Proposition 65 warning requirements do not conflict with FIFRA labeling provisions and are not preempted); *D-Con Co. v. Allenby*, 728 F. Supp. 605, 606 (N.D. Cal. 1989) (noting that although FIFRA preempts state pesticide labeling requirements, Proposition 65 “safe harbor” warning methods do not constitute “labeling” under FIFRA). The courts in *Jorling* and *D-Con Co.* relied on *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963), in which the Supreme Court upheld a California law regulating avocados that differed from federal standards on the grounds that there existed “no inevitable collision between the two schemes of regulation, despite the dissimilarity of the standards.” *Id.* at 143.

167. See *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1539-43 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984); *Evenson v. Osmose Wood Preserving, Inc.*, 760 F. Supp. 1345, 1348 (S.D. Ind. 1990); *Arkansas Platte & Gulf Partnership v. Van Waters & Rogers, Inc.* 748 F. Supp. 1474, 1482-84 (D. Colo. 1990); *Stewart v. Ortho Consumer Prods.*, No. 87-4252, 1990 WL 36129 (E.D. La. 1990). *But see Papas v. Upjohn Co.*, 926 F.2d 1019, 1024-25 (11th Cir. 1991) (holding that FIFRA preempts state tort claims for inadequate labeling); *Hurt v. Dow Chem. Co.*, 759 F. Supp. 556, 559-60 (E.D. Mo. 1990) (same); *Fitzgerald v. Mallinckrodt, Inc.*, 681 F. Supp. 404, 407-08 (E.D. Mich. 1987) (same).

168. See *Taylor*, *supra* note 111, at 227-28 (1985) (urging the FDA to interpret at least certain provisions of FFDCA as favoring a policy of federal preemption).

169. *Florida Lime and Avocado Growers*, 373 U.S. at 146; see also *Hillsborough City v. Automated Medical Labs.*, 471 U.S. 707 (1985) (rejecting argument that a local ordinance requiring blood donor testing and recordkeeping requirements in excess of federal standards was preempted by federal law); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (noting that courts must presume that Congress does not intend to supercede states’ traditional police power over food regulation unless it is the “clear and manifest purpose of Congress” to do so); *Savage v. Jones*, 225 U.S. 501, 525 (1912) (“[W]hen the local police regulation has real relation to the suitable protection of the people of the State, and is reasonable in its requirements, it is not invalid . . . provided it

In light of the Supreme Court's rulings and the language of FIFRA, nothing short of an outright reversal of current state authority provisions under FIFRA, and a clear congressional statement of the need for national uniformity under the FFDCA, could displace state power to enact laws such as Big Green. An explicit rendering of federal preemption rights under these two statutes effectively would resolve the problem of balkanization of state laws and the resulting negative implications for domestic and foreign trade.¹⁷⁰ Congress likely would reject this proposal, however, given that previous efforts to preempt the states in this area have failed, and that Congress does not appear predisposed toward such a measure.¹⁷¹ Moreover, states should retain a certain degree of authority to respond to unique regional geographic and climatic circumstances that give rise to particularized local risk factors not apparent in other regions.¹⁷² In sum, federal preemption does not appear feasible or appropriate.

does not conflict with legislation enacted by Congress pursuant to its constitutional authority."'). When viewed collectively, these cases establish that, absent express preemptory language, states may impose regulations governing food, drugs, and cosmetics that exceed federal requirements so long as they do not seek to redefine or severely alter federal law.

170. See *supra* notes 110-29 and accompanying text for a discussion of the trade affects associated with the emergence of a patchwork of differing state laws governing pesticides.

171. For example, during the debate leading up to the 1988 revisions of FIFRA, Congress considered and rejected a proposal to preempt states' authority to set pesticide residue tolerances in food at levels more stringent than those set by EPA. See *House Agriculture Adopts 'Core' FIFRA Bill Addressing Fees, Indemnification, Disposal*, Daily Rep. for Executives (BNA), Sept. 14, 1988 (reporting that a congressional committee considering amendments to FIFRA dropped a provision authorizing federal preemption); *Pesticide Reform*, 19 NAT'L J. 1936, 1936 (1987) (reporting that proposed revision of FIFRA excluded provisions for state preemption that were supported by farmers and the grocery industry). Moreover, the current political climate in Congress appears opposed to preemption efforts. See Margaret E. Kriz, *Ahead of the Feds*, 21 NAT'L J. 2989, 2990 (1989) ("Congress is less inclined than it has been in the past to impose a uniform federal law on the states."); Mariam Burros, *New Urgency Fuels Effort to Improve Safety of Food*, N.Y. TIMES, May 7, 1990, at A1 (quoting Sen. Patrick Leahy, Chairman of the Senate Agriculture Committee: "I think federal preemption is probably the biggest red herring you can float around here.").

172. FIFRA's registration provision contemplates the need to allow for adaptation to local circumstances. That provision reads as follows:

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State.

7 U.S.C. § 136v(c) (1988) (emphasis added).

Although debate about the safety of the food supply is commendable and should be encouraged, legislation should not hinge on reactionary outcries such as those exemplified by Big Green's food safety provisions. Under current federal law, the threat of Big Green-style responses still lingers.

To protect against unfounded state reactions while preserving a measure of independent state autonomy, Congress should amend federal law to require states seeking to impose pesticide regulations exceeding federal standards to demonstrate, on the basis of sound science, the inadequacy of federal law. To prevail under this system, states should have to establish that the federal standard for a particular pesticide exposes people to a greater than negligible risk of harm. This risk having been shown, states could enact remedies ranging from an outright ban of the product to a reduction in the acceptable residue tolerance level. Remedial measures taken by states, however, should be no greater than necessary to protect against the risks discovered. Moreover, states should have to establish a "grace period," and permit the period to expire before enforcing the revised standards. This period would provide industry the time needed to bring products into compliance with new pesticide residue levels, thereby cushioning the potentially harsh economic consequences.¹⁷³

Under this proposal, a state that discovers that a federally-approved pesticide exposes people to greater than negligible health risks should have to determine whether this risk results from unique local climatic or biological conditions,¹⁷⁴ or from an inaccurate risk assessment by EPA. When the added risks are associated with physical conditions unique to a particular region, and only affect the population within that area, no reassessment of federal standards should be required. Implementation of stricter standards should be limited to the state or states affected by these added risks. When the tests reveal a flaw in EPA standards that affects the population at

173. This proposal could be implemented by adding a subsection to FIFRA, 7 U.S.C. § 136v (1988), stating that, where a state exercises the authority granted by this provision to implement pesticide sale or use standards that exceed federal standards, it must compile a scientific record for EPA review, demonstrating either (i) the need for a more stringent requirement because of unique regional conditions, or (ii) that the federal standard fails to insulate the public from unreasonable risks to public health and the environment. Additional subsections should define the risk-assessment standard upon which states could base more stringent standards and describe the procedures for imposing a grace period.

174. Examples of unique local conditions that might produce regionally-confined risks justifying specialized regulatory intervention would include a geographic area that already suffers from intolerable levels of a particular environmental contaminant (phosphate contamination of the Everglades resulting from over-cultivation of sugar cane, or the existence of "Love Canal"-type environmental hazards), or a region with a shallow groundwater table and loose, sandy soil through which greater leaching of chemicals into groundwater can occur (as is the case in Florida). States would still have to show that less onerous control methods, such as the use of pollution control devices to filter out contaminants as opposed to pesticide bans, either do not exist or are impracticable.

large, however, EPA should be required to revise its standards to reflect the new scientific data.¹⁷⁵

States enacting new measures under the proposed procedure should have to accept substandard imports during a grace period that would take into account practical timetables for conversion. The pertinent state agency should be required to convene a temporary panel composed of qualified, disinterested local jurists, scientists, economists, and food regulators to set this grace period on a case-by-case basis. In each case, the panel should review data hypothesizing the immediate impact of compliance on importers and local producers, and thereafter establish a realistic timetable for the implementation and enforcement of the new standards. To ensure informed analysis, the panel should solicit comments from industry officials and other interested parties in the form of written submissions or oral hearings or both.¹⁷⁶

The standards fixed by the panel should be binding and not subject to review by the state legislature. Judicial review would be appropriate, however, to determine whether the state's action violated any express congressional provision.¹⁷⁷ Once the panel had completed its work, it should be dissolved until the next effort to impose stricter pesticide laws emerged.¹⁷⁸

This proposal alleviates the flaws in the current system, while stopping short of advocating outright preemption. It preserves states' ability to monitor pesticide safety independent of federal guidelines, while ensuring that regulations emerging at the state level stand as reasoned scientific responses rather than reactionary, overreaching measures with associated threats to trade. Moreover, the imposition of a grace period between the adoption of stricter laws and their enforcement against individual producers would allow companies time to adapt. This period, in turn, would insulate

175. For example, independent tests performed at the state level might reveal that a chemical, which EPA had determined posed only a negligible risk of cancer, actually poses a risk that is greater than negligible.

176. This system would be comparable to informal rulemaking procedures required under the federal Administrative Procedures Act. See 5 U.S.C. § 553 (1988).

177. This proposal adheres closely to proposed sanitary and phytosanitary standards discussed during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). See GATT DRAFT AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES, July 7, 1990, Annex II; see also *supra* notes 125-29 and accompanying text. These discussions sought to establish guidelines that would limit member countries' ability to use health regulations as a means of blocking imports. *Id.* The spirit of these negotiations is captured in a subnational context by the proposal advanced in this section. That GATT member countries are seeking to bring their food safety standards into greater consistency with one another provides incentive to avoid subnational balkanization of food safety laws.

178. The composition of the panel could, but need not, vary each time a new one is convened. In each case, however, states should be required to select qualified individuals for service on the panel.

producers and distributors from the potentially harsh economic impact of an immediate, absolute removal of a product from the market. Affected goods already in distribution within the state could still be sold. In addition, companies could spread the cost of compliance over the span of time allotted under the grace period, rather than facing an immediate, possibly unanticipated, capital expense. These factors would help minimize the economic loss associated with enforcement of the new standards.

A potential weakness in this proposal is that it would seem to permit a balkanization of food safety standards, with the associated international trade ramifications.¹⁷⁹ Two factors, however, balance this risk. First, the proposal puts a significant check on state authority in the area. Because EPA's regulations are based on sound science, states will have difficulty establishing their inadequacy. This difficulty means that, in most cases, unique local conditions would be the only justification for stricter standards. Thus, this proposal actually would minimize the number of independent state laws likely to emerge.

Second, this Note does not argue that economic costs always outweigh the benefits associated with limiting pesticide use. Instead, it has endorsed EPA's risk-benefit analysis, which includes the economic costs associated with the banning of a chemical product as one factor to be considered when setting acceptable risk levels. If a state has relied on science to demonstrate that a chemical approved by EPA poses greater than negligible health risks, current patterns of use should be reassessed.

As a result, this proposal leaves federalism intact. It recognizes that concurrent risk-assessment efforts at the state level can multiply the likelihood of discovering harmful effects associated with certain chemicals. Moreover, it takes into account that states, in some cases, may be better equipped to uncover risks overlooked by the federal government, given administrative and bureaucratic constraints at the federal level. States will retain power to keep out injurious products. This proposal merely seeks to ensure that on a national level, pesticide laws remain approximately uniform. Uniformity will ensure predictability and cost-efficiency within the commercial market for food products, and create the most advantageous environment.

Conclusion

This Note highlights the need for greater national uniformity in the regulation of pesticides, urging the amendment of FIFRA to limit states' ability to regulate pesticide registration, sale and use. This solution preserves states' ability to respond to unique regional conditions that give rise to unique local risks, while ensuring that

179. See *supra* notes 110-11 and accompanying text. This is true of any proposal that provides room for states to act independently.

states cannot implement reactionary laws that do not adhere to sound scientific principles.

FIFRA and the FFDCA's standards establish a comprehensive means of ensuring that the nation's food supply will not be contaminated with unsafe levels of pesticide residues. The present threat of contracting cancer from pesticides, for example, is considered lower than the threat associated with general dietary patterns.¹⁸⁰ Moreover, EPA's method of balancing the benefits with the risks is the most realistic approach, given the harsh economic consequences of a zero-risk standard,¹⁸¹ and the scientific improbability of regulating away all health risks.¹⁸² Given these factors, FIFRA's provision granting states unlimited authority to exceed federal standards governing the sale or use of pesticides¹⁸³ is both unnecessary and potentially harmful, providing an opening for the implementation of unfounded regulatory impediments to pesticide products.

Big Green, Proposition 65, and restrictive pesticide regulations and proposals in other states, dramatize the urgency of this situation. Measures such as these threaten to have a negative impact on world trade in food, with substantial economic consequences both domestically and internationally. Although Big Green failed, its food safety provisions easily could resurface in the form of independent, less controversial proposals, enhancing the prospect for enactment. This legislation could set off efforts in a variety of states to adopt their own, increasingly restrictive standards. The federal government should take action to prevent this balkanization, and thereby preserve the integrity of the federal regulatory process and the health of the agricultural and food industries.

180. See Merrill, *supra* note 146, at 515 ("Finally, the risk of disease for individuals is linked closely to lifetime dietary patterns rather than to occasional encounters with individual toxicants. Under these circumstances, a regulatory regime geared to identifying individual toxicants and removing them from the food supply may seem ill-suited or at least inadequate."); see also DIET, NUTRITION, AND CANCER, *supra* note 146 (finding little evidence that additives contribute significantly to the overall risk of cancer in this country and concluding that many organic foods pose much higher risks); Doll & Peto, *The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today*, 66 J. NAT'L CANCER INST. 1192, 1235-37 (1981) (noting that chemical food additives such as pesticides are not a significant source of cancer risk).

181. See *supra* notes 110-19 and accompanying text.

182. See *supra* Part III.

183. 7 U.S.C. § 136v(a).