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An Agricultural Law Research Article

**Regulating Pesticide Pollution in California
Under the 1986 Safe Drinking Water and
Toxic Exposure Act (Proposition 65)**

Part 1

by

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REGULATING PESTICIDE POLLUTION IN CALIFORNIA UNDER THE 1986 SAFE DRINKING WATER AND TOXIC EXPOSURE ACT (PROPOSITION 65)

*Michael W. Graf**

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INTRODUCTION

Proposition 65,¹ enacted to keep toxic chemicals out of drinking water and to require businesses to warn citizens whenever they expose them to such chemicals, represents an important potential tool for the regulation of pesticide manufacture and use. Despite opposition from industry, the initiative, also known as the "Safe Drinking Water and Toxic Enforcement Act of 1986," passed with an overwhelming 62% margin. The simple promise of Proposition 65 and its overwhelming approval by the voters tends to overshadow the Statute's complexity and uniqueness. Proposition 65 may be the only environmental statute to adopt the precautionary principle in regulation, which it does by placing the burden on industry to show that the release of a toxic chemical is not harmful and by imposing protective health-based standards to guide that determination.² Proposition 65 also furthers the public's right to know about toxic chemicals to which it is exposed by requiring responsible companies to disclose exposure information in the form of warnings.³ Finally, Proposition 65 offers a unique means of enforcing these protective standards by not only allowing private parties to bring their own enforcement actions when the state declines to participate, but by offering financial incentives in the form of 25 % of the significant potential penalties.⁴

1. See CAL. HEALTH & SAFETY CODE § 25,249.5 *et seq.* (West 2000). This Article will from time to time refer to Proposition 65 as the "Statute."

2. See CAL. HEALTH & SAFETY CODE §§ 25,249.9–25,249.11 (West 2000); see *infra* notes 35–77 and accompanying discussion.

3. See CAL. HEALTH & SAFETY CODE § 25,249.6 (West 2000); *infra* note 10.

4. See CAL. HEALTH & SAFETY CODE § 25,192(a)(2) (West 2000).

A very different regulatory picture is presented by the federal and state laws that currently address the use of pesticides in California. Under these laws, the burden of showing that a pesticide is "harmful" to the environment lies with the enforcement agency or, more commonly, citizens groups. The safety standards for pesticide pollution are not exclusively health based, but rather involve a deliberate risk-benefit balancing, in which the food production benefits of pesticide use are compared to the risks posed to the public and the environment by a particular pesticide product.⁵ In direct contrast to the public disclosure required by Proposition 65, information on the timing of pesticide use and occurrence of exposures is inaccessible, held primarily in the hands of an often under-enforcing governmental agency and not available to the public.⁶ Finally, these pesticide laws offer the public minimal opportunities to influence enforcement levels. Instead, citizens generally are limited to lobbying federal and state agencies to carry out their discretionary enforcement authority, often to little effect.

This article will compare the regulation of pesticides under Proposition 65 with the regulatory regime currently in place in California. Sections I and II of the article provide an overview of Proposition 65 and current law regarding pesticide regulation. Section III evaluates the possibilities for application of the Statute to pesticide use in California. Section IV addresses issues impacting the future of pesticide regulation and concludes that, in contrast to traditional command and control environmental statutes, Proposition 65 could effectively address the non-point source pollution characteristic of pesticide use by focusing on the end exposure or release instead of the release mechanism. Listing of pesticides under Proposition 65 has the potential to force manufacturers and users to internalize pesticide pollution costs currently borne by society, leading to more accurate societal choices regarding the amount and types of pesticides we are willing to introduce intentionally into the environment.

5. See *infra* notes 96-100 and accompanying discussion.

6. See *infra* notes 138-154 and accompanying discussion.

OVERVIEW OF PROPOSITION 65

Proposition 65 adopts a dual-pronged regulatory approach based on protection and information.⁷ The Statute accomplishes these twin objectives by prohibiting any “person in the course of doing business”⁸ from knowingly discharging or releasing a listed toxic chemical into a source of drinking water (“discharge prohibition”)⁹ or from knowingly and intentionally exposing any individual to such chemicals without first providing a warning (“warning requirement”).¹⁰ These provisions apply to all toxic chemicals listed under the statute as “known to the state to cause cancer or reproductive toxicity.”¹¹

This section discusses Proposition 65’s structure, particularly as it relates to the control of non-point source air

7. This approach is derived from the original ballot argument that drinking water should be protected from toxic chemicals and persons should be informed whenever they are exposed to such chemicals. See Ira Reiner, Art Torres & Penny Newman, *Argument in Favor of Proposition 65*, CALIFORNIA BALLOT PAMPHLET: GENERAL ELECTION 54 (Nov. 4, 1986). The California Supreme Court has taken the people’s mandate at face value, holding that the protective purposes of Proposition 65 are to be broadly construed. See *People ex. rel. Lungren v. Super. Ct. (American Standard, Inc.)*, 14 Cal. 4th 294, 314 (1996).

8. Consistent with its stated intention to focus on large corporate polluters, Proposition 65 does not apply to government agencies, operators of public water systems, or small businesses (less than 10 employees). See CAL. HEALTH & SAFETY CODE § 25,249.11(b) (West 2000) (defining a “person in the course of doing business”).

9. The discharge prohibition states:

No person in the course of doing business shall knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into any source of drinking water, notwithstanding any other provision or authorization of law except as provided in Section 25249.9.

CAL. HEALTH & SAFETY CODE § 25,249.5 (West 2000).

10. The warning requirement states: No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25,249.9. CAL. HEALTH & SAFETY CODE § 25,249.6 (West 2000).

11. See CAL. HEALTH & SAFETY CODE §§ 25,249.5, 25,249.6 & 25,249.8 (West 2000). A chemical will be considered to be a carcinogen or reproductive toxicant if the state lead agency (the Office of Environmental Health Hazard Assessment (“OEHHA”)) makes such a determination based on well-accepted, scientifically valid testing, or if a state or federal agency, or other “body considered to be authoritative” reaches a similar conclusion. See CAL. HEALTH & SAFETY CODE § 25,249.8(b) (West 2000); *infra* notes 237-243 and accompanying discussion. Not surprisingly, given the high stakes involved, the listing of chemicals under the Statute is typically a highly contentious process, in which citizen groups, industry and OEHHA staff wrangle over testing protocols and risk analyses. See *infra* notes 244-261 and accompanying discussion.

and water pollution. Proposition 65's dual goals—prohibiting discharges of toxic chemicals into sources of drinking water and requiring a warning for individual exposures—make the statute an ideal vehicle to combat the types of non-point source pesticide pollution that have thus far escaped the more conventional command and control statutes protecting air and water. Enforcement of the statute is carried out through provisions for injunctive relief¹² and monetary penalties,¹³ which may be enforced by the state Attorney General, local government attorneys, or private parties where no state or local enforcement action is occurring.¹⁴ The Statute allows a private enforcing party to keep 25% of the monetary penalty, thus creating a strong incentive for private enforcement actions¹⁵ and leading many

12. CAL. HEALTH & SAFETY CODE § 25,249.7(a) (West 2000).

13. CAL. HEALTH & SAFETY CODE § 25,249.7(b) (West 2000) (stating that "any person who has violated § 25,249.5 or § 25,249.6 shall be liable for a civil penalty not to exceed \$2500 per day for each violation in addition to any other penalty established by law.")

14. See CAL. HEALTH & SAFETY CODE § 25,249.7 (West 2000). In order to prosecute a Proposition 65 violation, a private party must first give 60 days notice to the Attorney General and the local district or city attorney in whose jurisdiction the violation is alleged to have occurred. The private party's action may only be commenced if neither the Attorney General nor the local district or city attorney chooses to prosecute the alleged violation itself. CAL. HEALTH & SAFETY CODE § 25,249.7(d)(2) (West 2000). Depending upon the circumstances, the AG's office often will allow a private party to maintain the suit where it has done the majority of the preliminary work to bring the case. Assistant Attorney General Craig Thompson, personal communication [hereinafter *Thompson, pers. comm.*]; Brief for Amicus Curiae People of the State of California in Opposition to Defendants' Motion for Judgment on the Pleadings on Standing Grounds at 6, Natural Resources Defense Council et. al. v. Lucky Stores, Inc. (Los Angeles Super. Ct. August 10, 1999) (No. 190090) [hereinafter, *AG Brief*] ("participation and assistance of private plaintiffs in a complex and technical case . . . enables the Attorney General to spread [its] resources over a wider field, thus enhancing enforcement of the statute"); Letter from Roderick E. Walston, Chief Assistant Attorney General, to Fred H. Altshuler, Altshuler, Berzon, Nussbaum, Berzon & Rubin 1 (Sept. 16, 1997) (on file with author) ("certainly there is room for broad cooperation between the Attorney General and private parties in carrying out their enforcement responsibilities under Proposition 65").

15. In addition to being allowed to keep 25% of the penalty award, private parties may also be entitled to attorney's fees under CAL. CODE OF CIVIL PROC. § 1021.5. Historically, private parties also were able to obtain disgorgement of unlawfully obtained profits under California's Unfair Competition Act. See CAL. BUS. & PROFESSIONS CODE §§ 17,203, 17,204 (West 1997); *People v. Thomas Shelton Powers, M.D., Inc.*, 2 Cal. App. 4th 330, 341-343 (1992) (holding that even in the absence of direct victims, illicit profits may be disgorged to party in a position to use them to correct, as much as possible, the harm caused by defendant's action and to prevent the wrongdoer from retaining the benefits of an illegal act). The ability of private plaintiffs to bring such actions has since been limited to class action suits by the Supreme Court's decision in *Kraus v. Trinity Mgmt. Servs.*, 23 Cal. 4th 116, 137 (2000). Since many environmental cases do not create a distinct "class" of injured

industry representatives to characterize Proposition 65 as a "bounty hunter" statute.¹⁶ The variety of novel and influential enforcement cases brought by private parties is testament, however, to the importance of private enforcement to the overall effectiveness of the statute.¹⁷

A. Standards of Liability and Burden Shifting

The basic structure of all Proposition 65 litigation involves a two step process. To prove liability, a plaintiff must first establish a knowing discharge, or a knowing and intentional exposure, of a "detectable amount" of a listed chemical. If a plaintiff can make this showing, the burden shifts to the defendant to establish that the discharge or exposure was insignificant or "de minimis."

1. Plaintiff's Burden to Establish a Knowing Discharge or Exposure

A plaintiff initially establishes a knowing discharge or exposure by showing that the defendant was aware of its release of a listed chemical into the environment,¹⁸ and that the

parties, it seems likely that this decision will significantly limit the ability of private parties to bring actions for unlawful environmental business actions.

16. See, e.g., Bart Jansen, *Businesses Across Country Rail Against Proposition 65 'Bounty Hunters'*, ASSOCIATED PRESS, October 28, 1999; Jeffrey B. Margulies & Thomas J. Graves, *Environmental Bounty Hunting: Private Enforcement of Prop. 65 Violates California Constitution*, 10 PROP 65 NEWS, June 1996, at 4. The Attorney General's Office has laid the blame for this characterization on "a few unscrupulous private attorneys." Testimony of Edward G. Weil, California Deputy Attorney General, before the House of Representatives Committee on Small Business, October 28, 1999, at 2 [hereinafter "Weil Testimony"].

17. Private enforcers have brought successful Proposition 65 challenges to the release of toxic chemicals from products such as leaded ceramic tableware, brass plumbing, drinking fountains, water coolers, cigars, pipe tobacco, calcium supplements, mini-blinds, and typewriter correction fluids, and from such activities as the sterilization of medical equipment, oil and gas storage and sale, biotechnology production, defense contracting, polyurethane manufacturing, and diesel truck and brass foundry operations, to name a few. Such actions reduced the amount of discharges of and/or exposures from such toxic chemicals as chloroform, methylene chloride, ethylene oxide, lead, and diesel exhaust. See Weil Testimony, *supra* note 16, at 5-7; Michael Freund, *Proposition 65 Enforcement: Reducing Lead Emissions in California*, 10 TUL. ENVTL. L.J. 333 (1997); Attorney General, Proposition 65 Litigation, May 1, 1996 [hereinafter *AG Prop. 65 List*].

18. See CAL. CODE REGS. tit. 22, § 12201(d) (2001) ("knowingly" does not mean that the defendant had knowledge that the discharge, release or exposure was unlawful). The regulations do not define "intentionally," but it is generally assumed that a "knowing" violation will also be considered "intentional." See, e.g., *Nicole-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 659 (1991) (stating that the term "knowingly and intentionally expose" suggests some degree of human activity which results in toxins being added to the environment); Reiner, Torres & Newman, *supra*

discharge or exposure was a foreseeable consequence of the defendant's act.¹⁹ A defendant cannot avoid liability by simply pleading ignorance, since it may be charged with constructive knowledge of both Proposition 65's chemical list and of the potential health risks presented by its commercial operations.²⁰

A plaintiff may meet its burden of showing a measurable discharge or exposure by detecting any amount—even a single molecule—of a toxic chemical²¹ according to an approved “method of analysis.”²² The regulations set forth a hierarchy of four approved analytical methods, beginning with methods “adopted or employed” by state agencies and descending in order of authority to methods used by federal agencies, methods generally accepted within the scientific community, and, if none of the other three categories are applicable, a “valid scientific method.”²³ A plaintiff will most easily meet its burden if it uses a detection method already “adopted or employed” by a state²⁴ or federal agency. For many types of discharges or exposures, however, no agency approved detection method has been adopted.²⁵ In these cases, a plaintiff must argue that its selected detection method is “generally accepted” or “scientifically valid,” often in the face of withering critique from defendant's experts.²⁶

note 7 (statute applies “only to businesses that *know* they are putting one of the [known carcinogenic] chemicals out into the environment”) (italics in original).

19. Statement of Reasons for CAL. CODE REGS. tit. 22, § 12601(d), at 39-40 (“Use of the term foreseeable’ is intended to define the limits of that constructive knowledge and of exposures for which businesses can reasonably be held responsible”).

20. See, e.g., Statement of Reasons for CAL. CODE REGS. tit. 22, § 12601(d) at 39 (“The Agency interprets the requirement that exposures be “knowing and intentional” to include exposures about which there is constructive knowledge.”). See also Statement of Reasons for CAL. CODE REGS. tit. 22, § 12601(b), at 9 (“It was not the Agency’s intention that [the foreseeable language] apply only to reasonably intended exposures.”).

21. See CAL. HEALTH & SAFETY CODE §§ 25,249.10(b)(1), 25,249.11(c) (West 2000) (“significant amount” includes “any detectable amount” of a listed chemical).

22. CAL. CODE REGS. tit. 22, § 12901(g) (2001) reads “For purposes of [the discharge provision and the warning requirement], no discharge, release or exposure occurs unless a listed chemical is detectable as provided in this section.”

23. CAL. CODE REGS. tit. 22, § 12901(b)-(e) (2001).

24. CAL. CODE REGS. tit. 22, § 12901(b) (2001). This group includes local air pollution control districts and regional water quality control boards.

25. For example, no state or federal agency has formally adopted a method of testing the amount of lead that leaches into faucet water from leaded brass plumbing fixtures.

26. See also *People v. Venegas*, 18 Cal. 4th 47, 85 (1998) (“‘General acceptance’ . . . means a consensus drawn from a typical cross-section of the relevant, qualified scientific community”); *People v. Kelly*, 17 Cal. 3d. 24, 31 (1976). A defendant may not overcome a plaintiff's showing of validity by showing the existence of another “preferred” method of analysis within the same categorical tier. Instead, a defendant must show that the plaintiff's detection method is either invalid or not

The stakes of this debate are raised by the regulatory allowance of modeling as an appropriate method of analysis.²⁷ Using modeling techniques, for example, a plaintiff may establish a detectable amount of a toxic chemical without actually measuring the exposure or discharge in question, based on modeling estimates derived from initial release data.²⁸

2. Defendant's Burden to Show that Discharge or Exposure is Insignificant

If a plaintiff establishes a knowing discharge of or exposure to a listed chemical, the defendant can avoid liability only by showing that the amount of the discharge or exposure is insignificant or "de minimis."²⁹ By placing this burden on the defendant, Proposition 65 creates a strong incentive for businesses to ensure that de minimis levels, below which they will have no liability, are established.³⁰ The agencies have responded by establishing such "safe harbors" for approximately one-third of the listed carcinogens and for three reproductive

generally accepted, or has been displaced by a detection method from a higher tier. See CAL. CODE REGS. tit. 22, § 12901(d)-(e) (2001) ("When more than one method of analysis [exists within the same tier], each may be utilized as the method of analysis.").

27. CAL. CODE REGS. tit. 22, § 12901(f) (2001). The regulatory history of Proposition 65 further demonstrates that the Statute does not require "actual detection" of a listed chemical, but only that the chemicals be present in a detectable amount. See Statement of Reasons for CAL. CODE REGS. tit. 22, § 12901, at 15 ("regulation only requires that the listed chemical be 'detectable,' not actually detected"); *infra* notes 321-328. Modeling intensifies the debate between the parties' experts as to the validity of the underlying science.

28. See James T. Dufour, *Proposition 65 Exposure Assessments: Look at the Science Before You Leap to Judgments*, 9 PROP 65 NEWS, June, July & Aug., 1995, parts 1-3. The use of modeling to establish Proposition 65 violations was upheld by the Napa County Superior Court. See *Ruling on Cross Motions for Summary Judgment and Plaintiff's Motion for Summary Adjudication, Citizens for a Better Env't v. Sawyer of Napa* (Napa County Super. Ct. Dec. 13, 1991) (No. 61687). Since that time, modeling has been an accepted part of Proposition 65 enforcement. See, e.g., Freund, *supra* note 17.

29. Proposition 65 does not regulate discharges of or exposures to amounts of carcinogens posing "no significant risk" or amounts of reproductive toxicants having "no observable effect" at 1000 times the measured exposure. CAL. HEALTH & SAFETY CODE §§ 25,249.9, 25,249.10(c), & 25,249.11(c) (West 2000). See *infra* notes 42-58 and accompanying discussion. Under the discharge prohibition, the defendant must also show that the discharge complies with all laws regulations and permits. See CAL. HEALTH & SAFETY CODE § 25,249.9(b)(2) (West 2000). Thus, if a defendant's discharge is out of compliance with any applicable law or permit, a plaintiff may successfully claim a Proposition 65 violation based on any detectable amount of discharge or release.

30. See David Roe, *An Incentive-Conscious Approach to Toxic Chemical Controls*, 3 ECON. DEV. Q. 179, 180-81 (1989).

toxicants.³¹ Industry may rely on these levels to avoid liability, but they do not limit the defendant's ability to present its own risk assessment at trial to show that a particular exposure or discharge exceeding a safe harbor level is nevertheless safe.³² Through this innovative—and controversial³³—approach, Proposition 65 has largely avoided the delays in regulatory risk assessment and standard-setting that characterize other environmental laws which defer liability until a specific risk level is established by the appropriate agency.³⁴

B. The Preventative Approach of Proposition 65: Risk Assessment and the Discharge Prohibition

The drafters of Proposition 65 were aware that a liability-oriented approach to environmental protection, in which businesses are only responsible for their own chemical discharges,³⁵ could fail to protect citizens from the many potential sources of toxic chemicals unless conservative assumptions were built into the Statute. These conservative assumptions, which form the basis of Proposition 65's protective regulatory approach, underlie the Statute's risk assessment procedures and its determination of liability under the discharge prohibition. According to the California Supreme Court, these provisions are to be "broadly construed" in order to further the protective purposes of the Statute, and to implement the will of the voters to protect themselves from toxic contamination.³⁶

31. See CAL. CODE REGS. tit. 22, § 12705 (2001) (safe harbor levels for carcinogens); § 12805 (safe harbor levels for reproductive toxicants). The three reproductive toxicants with safe harbor levels are lead, ethylene oxide and toluene.

32. CAL. CODE REGS. tit. 22, §§ 12701(a), 12801(a) (2001). As a general matter, defendants have tended not to challenge OEHHA's regulatory safe harbor levels.

33. Critics have referred to the burden of proof shift as the "guilty until proven innocent provision." Frank Clifford, *State Curbs on Household Chemicals Under Attack*, 9 PROP 65 NEWS, Mar. 1995, at 5, 9.

34. By March 1995, the Office of Environmental Health Hazard Assessment had set exposure limits for over 40% of the toxic chemicals on the Proposition 65 list, while the federal EPA had established safe limits for only two dozen toxic chemicals. See Roe, *supra* note 30; Weil Testimony, *supra* note 16, at 5-7; Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303, 311 n.36 (1996); see also David Roe & Gilbert Omenn, *California Has Successful Model of Regulatory Risk Assessment*, 10 PROP 65 NEWS, Mar. 1996, at 10.

35. See CAL. CODE REGS. tit. 22, §§ 12721(a), 12821(a) (2001).

36. See *People ex. rel. Lungren v. Super. Ct. (American Standard, Inc.)*, 14 Cal. 4th 294, 314 (1996).

1. Protective Risk Assessment Under Proposition 65

Risk assessment plays an especially crucial role under Proposition 65 since liability depends not on a showing of actual injury or detection of a pollutant concentration exceeding a pre-determined regulatory standard but rather on whether an exposure or discharge exceeds a specific risk level.³⁷ Proposition 65's risk assessment requirements are specifically designed to address carcinogens and reproductive toxicants, and the Statute adopts a conservative approach to both these toxic chemical groups. For carcinogens, which are assumed to pose a *chronic risk* to human health that generally increases over time, Proposition 65 assumes a *lifetime exposure* at the level of chemical concentration in the relevant environmental medium (such as air or water).³⁸ For reproductive toxicants, which may pose an *acute risk* dependent on the amount of a single dose, Proposition 65 assumes an exposure at *one thousand (1,000) times the actual exposure level*.³⁹ These conservative statutory assumptions assure that discharges or exposures are assessed in a preventative manner, in effect taking into account—albeit in an approximate fashion—the cumulative effect of the different sources of toxic chemicals to which persons will be exposed.⁴⁰

a. Risk Assessment For Carcinogens: The No Significant Risk Standard and the Assumption of Lifetime Exposure

Proposition 65 defines a “de minimis” exposure or discharge as one presenting “no significant risk.” The regulations define the “no significant risk level” (“NSRL”) as “one excess case of cancer in an exposed population of 100,000,⁴¹ assuming a 70-year

37. By assessing liability based on risk assessment rather than actual injury, Proposition 65 distinguishes itself from common law tort. See *infra* note 265.

38. CAL. HEALTH & SAFETY CODE § 25,249.10(c) (West 2000).

39. *Id.*

40. See Roe, *supra* note 30; *infra* notes 66-71 and accompanying discussion, regarding the different ways these conservative assumptions are implemented under the warning requirement and the discharge prohibition.

41. The one in 100,000 risk factor for carcinogens was adopted in 1988 by OEHHA's predecessor, the Health and Welfare Agency, as a compromise between business and public health interest groups. See Rechtschaffen, *supra* note 34, at 309. The factor was not as stringent as federal risk assessment guidelines in effect at that time, and has since been superseded by the one in one million risk factor employed by federal and state agencies under a number of statutes. See, e.g., Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41104 (1988) (EPA's *de minimis* policy for carcinogens adopts a one in one million standard); 42 U.S.C. §§ 7412(f)(2)(A), 7412(c)(9)(B)(i) (1994) (regulating hazardous air pollutants under Clean Air Act); Water Quality Standards, 63 Fed. Reg.

lifetime exposure at the level in question.⁴² The regulations define "lifetime exposure" as the "reasonably anticipated rate of exposure for an individual to a given *medium* of exposure measured over a lifetime of seventy years."⁴³ Thus, the appropriate "daily" exposure level is determined by multiplying the listed chemical concentration in the environmental medium of exposure (typically air or water) by an individual's anticipated daily rate of exposure to that medium.⁴⁴ A defendant may challenge the regulatory assumptions regarding a person's daily exposure to a given environmental medium⁴⁵ but not the statutory assumption of lifetime exposure to the measured chemical concentration contained within the medium.⁴⁶ This assumption of lifetime exposure means that, although in some cases an individual will almost certainly *not* be exposed to the same release or discharge over an extended period of time,

16,182, 16,184 (1998) (adopting one in one million standard for assessing risk of PCBs under Clean Water Act); California State Water Board Enclosed Bays and Estuaries Plan, approved November 6, 1991; OEHHA, Public Health Goals (PHGs) for Chemicals in Drinking Water; Health Risk Information for Public Health Goal Exceedance Reports, June 10, 1998. EPA regulation under the 1996 Food Quality and Protection Act also adopts the one in one million standard for carcinogens. See *infra* note 128.

42. CAL. CODE REGS. tit. 22, § 12703(b) (2001). The regulations define the "level in question" as "the chemical concentration of a listed chemical for the exposure in question." CAL. CODE REGS. tit. 22, § 12721(a) (2001).

43. CAL. CODE REGS. tit. 22, § 12721(b) (2001) (emphasis added). This language clarifies that the "reasonably anticipated rate of exposure" over the course of a lifetime refers to a person's general exposure to the environmental medium in question (such as air or water) and *not* to the reasonably anticipated rate of exposure to the particular contaminant level in question.

44. CAL. CODE REGS. tit. 22, § 12721(c) (2001). An individual is assumed, for example, to ingest two liters of water per day. CAL. CODE REGS. tit. 22, § 12721(d)(1)(A) (2001). Thus, under the regulations, if an individual were exposed to a given contaminant at a concentration level of 5 micrograms per liter, the *daily exposure* would be 10 micrograms per day. The regulations also set anticipated daily rates of exposure from air (20 cubic meters per day), CAL. CODE REGS. tit. 22, § 12721(d)(1)(B) (2001), but leave daily exposure rates to other media—such as wine—up to the fact finder. For consumer products, the regulations assume an anticipated rate of exposure based on the average user of the consumer product. CAL. CODE REGS. tit. 22, § 12721(d)(4) (2001).

45. CAL. CODE REGS. tit. 22, § 12721(d) (2001).

46. Many commentators have criticized the idea that Proposition 65 would allow for the "averaging" of exposures to environmental media without also averaging concentrations of carcinogens in such media, where the concentrations could reasonably be expected to decline or fluctuate over time. See, e.g., NOSSAMAN ET AL., NAVIGATING PROPOSITION 65 IN THE 1990S: A GUIDE TO THE SAFE PASSAGE THROUGH THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 134-35 (1993). This critique ignores, however, the language of the Statute and its purpose of protecting public health and safety through a preventative approach that assumes a lifetime exposure to the "level in question." CAL. HEALTH & SAFETY CODE § 25,249.10(c) (West 2000). See *infra* notes 348-350 and accompanying discussion.

Proposition 65 will still apply long term risk assessment in establishing liability.⁴⁷

While this statutory intent seems clear enough, the ultimate parameters of the “lifetime exposure” assumption remain unsettled.⁴⁸ The Statute does not provide guidance, for example, on how a court should treat a momentary “exposure” to a listed carcinogen—diesel exhaust from a passing car’s tailpipe, for example—or intermittent exposures that occur on an annual or biannual basis but are well above the regulatory no significant risk level for *daily* exposures. The regulations vary the calculation of lifetime exposure for consumer product and occupational exposures,⁴⁹ but do not otherwise address the averaging question.⁵⁰ As a practical compromise, the Attorney General’s Office has unofficially adopted a one-year average to calculate daily exposure in most instances.⁵¹ Shorter “averaging” periods, however, could be justified by the literal language of the Statute and the regulations.⁵²

47. Thus, for example, even for carcinogenic exposures of limited durations, such as releases from a child’s toy product, or emissions from a year-long construction or resource extraction project, the statutory lifetime exposure *assumption* would still mandate risk assessment based on a 70-year exposure.

48. The Proposition 65 regulations are also vague on whether exposure to an environmental medium such as air or water is directly correlated with exposure to the listed chemical. The regulations allow a defendant to introduce “more specific” data regarding an individual’s anticipated “rate of exposure,” which may overcome regulatory assumptions. CAL. CODE REGS. tit. 22, § 12721(d) (2001). The regulations are unclear, however, whether this provision would allow a defendant to argue, for example, that indoor air is distinct from the outdoor air, or that an exposure should be reduced by the *actual* amount of chemical contaminant that poses a risk, such as the percentage of fine particulate that actually reaches the inner portions of the lung where cancer may occur. The statutory “lifetime exposure” assumption would appear to preclude these types of exposure reductions.

49. CAL. CODE REGS. tit. 22, § 12721(d)(3) (2001) (lifetime “occupational” exposure based on 40 year period multiplied by average work week); CAL. CODE REGS. tit. 22, § 12721(d)(4) (2001) (lifetime “consumer product” exposure based on average rate of exposure for average user of consumer product). One way to reconcile these regulatory assumptions with the statutory 70-year lifetime exposure assumption is to consider workplaces and consumer products as “mediums of exposure,” for which such averaging is permitted.

50. The Final Statement of Reasons rejects the notion of a 70-year averaging of the concentration “level in question” of a listed carcinogenic chemical. See Final Statement of Reasons for CAL. CODE REGS. tit. 22, § 12721, at 62.

51. Attorney General Ed Weil, personal communication (October 9, 2001).

52. See *infra* notes 348-350 and accompanying discussion regarding the practical effects of conservative risk assessment assumptions in furthering Proposition 65’s goal of protecting public health.

b. Risk Assessment For Reproductive Toxicants: The No Observable Effect Level and 1,000-Fold Safety Factor

Proposition 65 defines a “de minimis” discharge or exposure level for reproductive toxicants as one producing “no observable effect assuming exposure at 1,000 times the level in question.”⁵³ The statutory 1,000-fold safety factor is a conservative hedge, applied to account for the uncertain risk that arises when one is exposed to a reproductive toxicant, even for short duration.⁵⁴ While the use of safety factors in assessing risks from toxic chemicals with complex modes of action—characteristic of reproductive toxicants—is not unusual, the 1,000 fold factor is far more stringent than other risk assessment statutes and has been criticized as unnecessarily conservative.⁵⁵ This criticism, however, misses the larger point that the effects of reproductive toxicants are poorly understood and may pose synergistic threats to human health—threats that Proposition 65 is committed to combat.⁵⁶

Proposition 65’s risk assessment regulations for exposures to reproductive toxicants differ from those for carcinogens in an

53. CAL. HEALTH & SAFETY CODE § 25,249.10(c) (West 2000). The no observable effect level (NOEL) is defined as “the maximum dose level at which a chemical has no observable reproductive effect,” expressed in milligrams of chemical per kilogram of body weight per day. CAL. CODE REGS. tit. 22, §§ 12801(c), 12803(a)(1) (2001). See *infra* notes 256-257 and accompanying discussion of what constitutes a “reproductive effect” in listing a chemical as a reproductive toxicant and in setting the NOEL level. The regulations add that, where available data do not allow a determination of a NOEL, the lowest observable effect level (LOEL) shall be divided by 10 to establish a NOEL for purposes of assessment. CAL. CODE REGS., tit. 22, § 12803(a)(7) (2001).

54. The 1,000-fold safety factor may be considered as a product of three separate factors. First, a 10-fold factor accounts for the difference between animal test data and potential effects on humans. Second, an additional 10-fold factor accounts for the different sensitivities among individuals. Finally, a third 10-fold “uncertainty” factor accounts for the general lack of knowledge and data on the effects and mode of operation of reproductively toxic chemicals.

55. See, e.g., James R. Coughlin & F. Jay Murray, *The 1,000-Fold Uncertainty Factor: Scientific Advances Demand a Reappraisal*, 8 PROP 65 NEWS, Oct. 1994, at 4. At least one major federal statute, the Food Quality and Protection Act of 1996, has adopted a similar standard to establish pesticide residue tolerances on food products consumed by children and other sensitive subgroups. See 21 U.S.C. § 346a(b)(2)(C)(ii)(III) (1996).

56. See *infra* note 106. Some commentators have suggested replacing the automatic 1000-fold safety factor with a similarly protective presumption, which could be overcome by companies based on valid scientific evidence. See Rick Lovett & Roger Carrick, *Easy Fix Possible for 1,000-Fold Safety Factor Problems*, 11 PROP 65 NEWS, Oct. 1997, at 3. The 1996 Food Quality and Protection Act has adopted a presumptive 1000-fold safety factor when there is incomplete data on the effects and exposures of developmental toxins on infants and children, which the EPA may reduce on a case by case basis. See 21 U.S.C. § 346a(b)(2)(C)(ii) (1996).

important respect. As discussed, exposures to reproductive toxicants may pose acute, as opposed to chronic, risks. To protect against such acute risks, the Statute imposes a high margin of safety for the single exposure, but does not assume a long term exposure to the environmental medium containing the listed reproductive toxicant. Instead, the regulations allow for the averaging of the “exposure level” to a reproductive toxicant over a time period that is relevant to the reproductive effect in question.⁵⁷ Thus, for reproductive toxicants with longer term, chronic exposure risks, Proposition 65 may permit some averaging of contaminant concentrations over time.⁵⁸

2. *Protection of Drinking Water Sources under Proposition 65’s Discharge Prohibition*

The discharge prohibition of Proposition 65 also adopts a preventative approach to protecting California’s drinking water.⁵⁹ Assuming the discharge is not otherwise unlawful,⁶⁰ liability depends on whether a defendant has discharged a “significant amount” of a listed chemical into a “source of drinking water.”⁶¹

a. *Defining the “Significant Amount” Standard: Treating a Discharge Like an Exposure*

Proposition 65’s risk assessment provisions for listed carcinogens and reproductive toxicants define a “significant

57. CAL. CODE REGS. tit. 22, § 12821(b) (2001). For example, an exposure of short duration would be a relevant measurement for a chemical that causes birth defects, whereas longer exposure periods might be used for a chemical that retards fetal growth, or adversely affects healthy development of reproductive functions among individuals.

58. The Attorney General has adopted a general presumption that the appropriate period for averaging the concentration levels of reproductive toxicants is 24 hours. Weil, personal communication, *supra* note 51. The AG’s approach is based on Proposition 65’s policy of placing the burden of uncertainty on business and on the Statute’s preventative mandate, interpreted in light of the overall lack of knowledge regarding the mode of action for many reproductively toxic chemicals. Under the regulations, a business would have the right to overcome the 24-hour averaging presumption.

59. For the discharge prohibition text, see *infra* note 9; CAL. HEALTH & SAFETY CODE § 25,249.5 (West 2000).

60. See *infra* notes 79-209 and accompanying discussion regarding the laws applicable to pesticide manufacturers and users.

61. As discussed above, a defendant’s discharge will be exempt from liability only if it can show that 1) the discharge “will not cause any *significant amount* of the discharged or released chemical to *enter any source of drinking water*,” and 2) the discharge complies with all other laws and applicable permits. CAL. HEALTH & SAFETY CODE § 25,249.9(b) (West 2000) (emphasis added).

amount" of discharge as "any detectable amount⁶² except an amount which would meet the exemption test in subdivision (c) of Section 25249.10: "if an individual were exposed to such an amount in drinking water."⁶³ Thus, through these statutory provisions, Proposition 65 regulates discharges that "enter any source of drinking water" as if the discharge were to be consumed by an individual *in drinking water*.⁶⁴ As a result, discharges into a source of drinking water under Proposition 65 are evaluated under the same risk analysis provisions applicable to exposures.⁶⁵

While the discharge prohibition and the warning requirement share similar risk assessment standards, they differ in several important respects. First, the discharge prohibition does not permit the release of a significant amount of toxic pollution, whether or not a warning is provided.⁶⁶ Second, the discharge prohibition does not require actual proof of an exposure. Instead, the Statute recognizes that many potential sources of contamination ultimately affect drinking water quality and thus regulates discharges of contaminants at the source, where they "enter any source of drinking water."⁶⁷ This conservative approach is necessary to prevent contamination of what the

62. As discussed in notes 18-28, *supra*, plaintiffs have the burden of establishing the existence of a "detectable amount" of discharge according to an approved method of analysis. CAL. CODE REGS. tit. 22, § 12901 (2001).

63. CAL. HEALTH & SAFETY CODE § 25,249.11(c) (West 2000) (emphasis added).

64. The three statutory provisions are CAL. HEALTH & SAFETY CODE §§ 25,249.9(b)(1) (West 2000) (exemption provision), 25249.11(c) (definition of "significant amount"), and 25249.10(c) (risk assessment).

65. In other words, in defining a "significant amount", CAL. HEALTH & SAFETY CODE 25,249.11(c) assumes, hypothetically, that an individual has been "exposed" to the "amount" discharged into a source of drinking water, and then incorporates the risk analysis specified in § 25249.10(c).

66. The discharge prohibition is similar in some ways to the "total maximum daily loads" ("TMDLs") that states are required to establish to meet their water quality standards under the federal Clean Water Act. See 33 U.S.C. § 1313(d) (1994). Pursuant to this requirement, States must allocate the TMDL for each pollutant among the different point and non-point source dischargers. See *infra* notes 205-209 and accompanying discussion.

67. CAL. HEALTH & SAFETY CODE § 25,249.9(b)(1) (West 2000). Thus, a defendant may be in violation of the discharge prohibition even if it can show that the ultimate "exposure" to any individual is well below the significant amount level, if detectable at all. The language of the discharge prohibition itself further supports this interpretation by prohibiting significant discharges "onto land, where such chemical . . . will probably pass into any source of drinking water," thus implicitly supporting the modeling of surface runoff without necessarily requiring measurement of the actual discharged amount. See *infra* notes 321-328 and accompanying discussion.

Supreme Court characterized as the “broad zone of protection” for drinking water sources.”⁶⁸

In addition, the two provisions differ in how they calculate risk. Consider a company discharging 10 liters over a 24 hour period with an average chemical concentration of 5 micrograms per liter. Under a normal “exposure” analysis, the appropriate risk level is determined by multiplying the chemical concentration in the water times an individual’s anticipated daily rate of water intake, which is two liters under the regulations.⁶⁹ Thus, if an individual were exposed to the chemical at a concentration level of 5 micrograms per liter, the *amount* of daily exposure would be 10 micrograms per day.

The discharge prohibition differs from the analysis set forth above by simply prohibiting the discharge into a source of drinking water of any amount of a listed toxic chemical that would exceed the statutory risk assessment level.⁷⁰ Since the risk assessment levels are set forth as daily exposure *amounts*, the key measurement for purposes of evaluating liability is the amount of chemical discharged into a source of drinking water over a 24 hour period. In this case, the amount of discharge under the discharge prohibition would be 50 micrograms, the result of 10 liters containing 5 micrograms per liter, not the 10 micrograms resulting from the typical exposure analysis, as described above.

Proposition 65 assumes that an individual will be exposed to the entire amount of toxic discharge, irrespective of the chemical concentration in the water and notwithstanding the regulatory assumption that an individual ingests two liters of water per day. By focusing on the *amount* of toxic discharge rather than a concentration level, “Proposition 65 precludes a defendant from escaping liability by diluting the chemical concentration of its discharge.”⁷¹ Through this preventative approach to protecting

68. *People ex. rel. Lungren v. Super. Ct. (American Standard, Inc.)*, 14 Cal. 4th. 294, 307 (1996).

69. See CAL. CODE REGS. tit. 22, §§ 12721(c), 12821(b), 12721(d)(1)(A) (2001). Accordingly, the pre-determined safe harbor levels for various carcinogens and reproductive toxicants set forth in the regulations are stated in terms of *micrograms per day* of exposure. CAL. CODE REGS. tit. 22, §§ 12705, 12805 (2001).

70. See CAL. HEALTH & SAFETY CODE § 25,249.11(c) (2001). In other words, in contrast to typical exposure risk assessment, which assumes a “level” of contaminant concentration in an environmental medium, then analyzes an individual’s exposure to that *medium*, the discharge prohibition simply evaluates the “amount” of toxic chemical that has been discharged into a source of drinking water.

71. The discharge prohibition precludes the dilution of contaminant waste streams by applying risk assessment to the *amount* of discharged chemical

drinking water, the discharge prohibition offers a potent weapon in combating non-point source surface and ground water pollution caused by pesticides.

b. Interpreting "Source of Drinking Water"

Proposition 65 defines "source of drinking water" expansively, as "either a present source of drinking water or water which is identified or designated in a water quality control plan adopted by a regional board as being suitable for domestic or municipal uses."⁷² The California Supreme Court endorsed a broad reading of this statutory language in 1996, holding that the Act creates "a broad zone of protection for drinking water before it comes out of the tap, outlawing all toxic discharges that will have the probable consequences of contaminating" the water supply and delivery system, from the "mountain stream to the faucet."⁷³

The expansive interpretation of a "source of drinking water," coupled with Proposition 65's conservative risk assessment for discharges, creates in the discharge prohibition a formidable enforcement tool with the potential to displace the intricate statutory and regulatory framework that comprises state regulation of water quality. Perhaps fearing this result, the State Water Resources Control Board ("SWRCB") has several times proposed a "Point of Application" policy that establishes "mixing

contamination, rather than to a hypothetical "level" of contamination that could be lowered by simply adding clean water to the waste stream.

72. CAL. HEALTH & SAFETY CODE § 25,249.11(d) (West 2000). In 1988 the State Water Resources Control Board ("SWRCB") adopted a policy that "all surface and ground waters of the State," should be so designated, subject to several limited exceptions. See State Water Resources Control Board Resolution No. 88-63, Adoption of Policy Entitled "Sources of Drinking Water," May 19, 1988. The exceptions are 1) for surface and ground waters that a) have high amounts of total dissolved solids; b) have high levels of difficult-to-remediate contamination; or c) do not provide a sustained yield of 200 gallons per day; 2) for surface waters a) in systems designed to collect or treat wastewater or storm water runoff; or b) in systems designed to convey or hold agricultural drainage waters; and 3) ground waters that are regulated as geothermal energy producing sources or as underground injection wells. *Id.*

73. American Standard, 14 Cal.4th at 303, 307. The Court observed that "one of the predominant purposes of the Act . . . was to protect drinking water from toxic contamination." *Id.* The Court also held that water within the water distribution system—including the household plumbing system—constituted a "source of drinking water" under the Statute. *Id.* The decision resolved whether plumbing components containing and leaching lead fell within the scope of Proposition 65 and has resulted in a transition within the plumbing industry from leaded brass to unleaded products. See Cliff Rechtschaffen, *How to Reduce Lead Exposures With One Simple Statute: The Experience of Proposition 65*, 29 ENVTL. L. REP. 10,581 (1999).

zones” for inland surface waters and estuaries.⁷⁴ Mixing zones are not considered sources of drinking water for purposes of regional water plans and thus are not subject to otherwise applicable waste discharge standards.⁷⁵ The question of whether a mixing zone would immunize a discharger of toxic pollutants from Proposition 65 is, however, a complicated matter. Arguably, the Statute allows the state to designate whole bodies of water as something other than a “source of drinking water.”⁷⁶ The division of a connected water body into drinking water “sources” and “non-sources,” however, defeats the purposes of the Statute by allowing for the very dilution forbidden by the discharge prohibition in the first place.⁷⁷

II

OVERVIEW OF PESTICIDE REGULATION

The sale, labeling and use of pesticide products are currently regulated primarily under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), which requires all pesticides to be

74. See, e.g., State Water Resources Control Board, *Draft Water Quality Control Policy Defining Point of Application of Water Quality Objectives*, December 28, 1988. [hereinafter “Point of Application Policy”]. The Point of Application Policy defines a mixing zone as a “designated volume of a receiving water body where waste waters and receiving waters mix.” *Id.* at 2. Mixing zones have been adopted by several Regional Water Quality Control Boards. See, e.g., CENTRAL VALLEY REGION, CALIFORNIA WATER QUALITY CONTROL BOARD, THE WATER QUALITY CONTROL PLAN (BASIN PLAN) FOR THE CALIFORNIA WATER QUALITY CONTROL BOARD CENTRAL VALLEY REGION: THE SACRAMENTO RIVER BASIN AND THE SAN JOAQUIN RIVER BASIN IV-16.00 (4th ed. 1998) (explaining the Regional Water Board’s authority to designate mixing zones).

75. The Point of Application Policy states that “a mixing zone shall not be considered a source of drinking water because all water quality standards established to protect human health may not be met in a mixing zone.” (emphasis added). Point of Application Policy, *supra* note 74, at 74.

76. See CAL. HEALTH & SAFETY CODE § 25,249.11(d) (West 2000) (incorporating SWRCB’s designation of water bodies into the statutory definition of “source of drinking water”).

77. See *supra* notes 70-71 and accompanying discussion; *infra* notes 349-350 and accompanying discussion. Such an artificial regulatory division by the SWRCB would further conflict with the will of the voters, who found that “state government agencies have failed to provide them with adequate protection” from toxic chemicals. Initiative Measure, Proposition 65, Section 1 Nov. 4, 1986; see also *Preliminary Comments by Environmental Defense Fund and Natural Resources Defense Council on “Mixing Zone” Elements of Draft “Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California,” Before the State Water Resources Control Board 2* (1997) (arguing that the SWRCB is without legal authority to exclude portions of a continuous water body from the definition of “source of drinking water” for Proposition 65 purposes).

registered with the federal government prior to use.⁷⁸ The State of California implements its own pesticide registration and regulatory program under the authority of FIFRA and the State Constitution. Several other federal and state environmental laws indirectly address pesticide pollution. This section provides an overview of the current regulatory regime and its continuing ineffective control of pesticide pollution.

A. Federal Regulation of Pesticides

1. Background on FIFRA

Federal regulation of pesticides dates back to the Insecticide Act of 1910, the precursor to the 1947 enactment of FIFRA.⁷⁹ These early federal laws required pesticides to be registered, but were primarily intended to protect farmers from ineffective products through enforceable labeling standards.⁸⁰ During the 1960s, the publication of Rachel Carson's *Silent Spring*, combined with the mounting scientific evidence that indiscriminate pesticide use damaged the environment, resulted in strong public pressure to reform the nation's pesticide laws.⁸¹ Congress responded in 1972 by passing the Federal Environmental Pesticide Control Act, which amended FIFRA by conferring additional authority on the newly formed federal Environmental Protection Agency ("EPA") to regulate pesticides.⁸²

78. In addition, the Federal Food, Drug, and Cosmetic Act (FDCA) establishes permissible tolerances of pesticide residues on food products. See 21 U.S.C. § 346a (1996).

79. See Act of Apr. 26, 1910, Ch. 191, 36 Stat. 331, repealed by Act of June 25, 1947, 61 Stat. 163, 172 (1947); Act of June 25, 1947, Ch. 125, 61 Stat. 163 (1947), as amended by the Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973 (codified as amended at 7 U.S.C. § 136 *et. seq.* (1994)).

80. Under the 1947 law, for example, the Department of Agriculture did not possess the authority to refuse registration even to a pesticide it considered unreasonably dangerous. See Marshall L. Miller, *Federal Regulation of Pesticides*, in ENVIRONMENTAL LAW HANDBOOK 284, 284-301 (Thomas F. P. Sullivan ed., 14th ed. 1997). For a good description of the origins and history of FIFRA, see CHRISTOPHER J. BOSSO, PESTICIDES & POLITICS: THE LIFE CYCLE OF A PUBLIC ISSUE (1987).

81. The passage of the 1972 FIFRA amendments was due in part to the injuries caused to wildlife by the organochlorine insecticide dichlorodiphenyltrichloroethane, otherwise known as DDT. See BOSSO, *supra* note 80, at 109-77 (describing the rise of environmental opposition to uncontrolled pesticide use).

82. See Federal Environmental Pesticide Control Act, Pub. L. No. 92-516, 86 Stat. 975 (codified as amended at 7 U.S.C. § 136 *et. seq.* (1994)). The EPA was created by Executive order in 1970. The transfer of regulatory jurisdiction over pesticide use from the Department of Agriculture to the EPA reflected a fundamental policy shift towards the regulation of pesticides based on their environmental impacts, rather than simply their ability to control agricultural pests. See BOSSO,

Chief among EPA's responsibilities was to permit only the proposed or continued registration of pesticides⁸³ that, "when used in accordance with widespread and commonly recognized practice, . . . will not generally cause unreasonable adverse effects on the environment."⁸⁴

Under FIFRA, EPA evaluates whether a potential adverse effect is "unreasonable" by balancing the "economic, social, and environmental costs and benefits" of the proposed registration.⁸⁵ To conduct this evaluation, FIFRA requires an applicant to submit testing data relating to a pesticide's effectiveness, toxicity and environmental fate.⁸⁶ A pesticide use may be classified as "general" or "restricted," according to the toxicological and exposure risks presented.⁸⁷ If additional information is uncovered indicating that a pesticide may pose "unreasonable" adverse effects on the environment, EPA may restrict or even

supra note 80, at 151-54. The opposing perspectives of the Department of Agriculture and the EPA are well illustrated by *Environmental Defense Fund v. Environmental Protection Agency*, 510 F.2d 1292, 1296 (D.C. Cir. 1975), and *Environmental Defense Fund v. Environmental Protection Agency*, 548 F.2d 998, 1002 (D.C. Cir. 1976), in which the Secretary of Agriculture was one of several parties challenging the EPA's suspension of the pesticides aldrin, dieldrin, heptachlor and chlordane for various agricultural uses.

83. Pesticides are defined as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, . . . intended for use as a plant regulator, defoliant or desiccant, . . . and any nitrogen stabilizer . . ." 7 U.S.C. § 136(u) (1994).

84. 7 U.S.C. § 136a(c)(5)(D) (1994). FIFRA defines "environment" as including "water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these." 7 U.S.C. § 136(j) (1994). The "unreasonable risk" standard has been described as "an undefined, nonzero level of risk determined on an ad hoc basis by balancing both health considerations and nonhealth concerns such as technology, feasibility, and cost." John Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy and Toxic Substances Control*, 91 COLUM. L. REV. 261, 268 (1991).

85. 7 U.S.C. § 136(bb) (1994). According to EPA, "individual decisions on initial or continued registration must depend on a complex administrative calculus, in which the 'nature and magnitude of the foreseeable hazards associated with use of a product' is weighed against the 'nature of the benefit conferred' by its use." *Envtl. Def. Fund v. Env'tl. Prot. Agency*, 465 F.2d 528, 536 (D.C. Cir. 1972).

86. See 7 U.S.C. § 136a(c)(2) (1994); 40 C.F.R. § 159 (2000).

87. 7 U.S.C. § 136a(d) (1994). In making its determination, EPA evaluates individual uses of a pesticide. Thus, a pesticide may be considered "general use" for some applications, but "restricted use" for others. 7 U.S.C. § 136a(d)(1) (1994). In practice, EPA does not classify pesticides except to restrict their use. Thus, "general use" pesticides are considered to be unclassified. See 40 C.F.R. § 152.160(a) (2000). EPA may restrict pesticides to use only by a qualified applicator, or restrict a product's composition, labeling, packaging, uses, or distribution and sale. 40 C.F.R. § 152.160(b).

cancel the registration.⁸⁸ FIFRA also confers upon EPA authority to levy fines for a variety of labeling and use violations.⁸⁹

2. *The 1996 Food Quality and Protection Act*

In recognition of growing concern regarding food quality, Congress strengthened FIFRA's application to pesticide residues with the enactment of the Food Quality and Protection Act ("FQPA"). This statute established a new health-based safety standard for pesticide residues on food products. Under FQPA, allowable "tolerances" of pesticide residues are established to ensure to a "reasonable certainty that no harm will result" from dietary and other aggregate exposures for which there is reliable information.⁹⁰ FQPA pays particular attention to the effects of pesticide residues in the diets of infants and children, requiring EPA to consider the consumption patterns and special sensitivities of this subpopulation when establishing the appropriate "safe" tolerance standard.⁹¹ These tolerance levels

88. 7 U.S.C. § 136d(b) (1994); 40 C.F.R. § 154 (2000) (providing Special Review procedures) A third party may petition EPA to initiate the Special Review process at EPA's discretion. 40 C.F.R. § 154.10 (2000). Once a pesticide is registered, FIFRA imposes a continuing obligation on the registrant to provide EPA with information regarding a pesticide's unreasonable adverse effects on the environment. 7 U.S.C. § 136d(a)(2) (1994); 40 C.F.R. §§ 159.152-159.195 (2000). Under the 1996 FIFRA amendments, pesticide registrations must be reviewed every 15 years, whether or not new data suggest environmental impacts that were not previously considered. 7 U.S.C. § 136a(g)(1)(A) (1996).

89. See 7 U.S.C. § 136j (1994) (defining unlawful acts); 7 U.S.C. § 136i (1994) (setting civil and criminal penalties). The maximum civil penalties are \$5,000 per offense for registrant, dealers, and commercial applicators, and \$1,000 per offense for private applicators. 7 U.S.C. § 136i(a) (1994). See, e.g., Kevin W. Brown, *What Constitutes Use of Pesticide in Manner Inconsistent with its Labeling, so as to Violate §12(a)(2)(G) of Federal Insecticide, Fungicide, and Rodenticide Act* (7 U.S.C. §136j(A)(2)(G)), 69 A.L.R. FED. 835 (1984) (hereinafter "Inconsistent Labeling").

90. Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended at 21 U.S.C. § 346a(b)(2)(A)(ii) (1996)). In establishing a tolerance for a pesticide chemical residue, the EPA is required to consider all "available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity," 21 U.S.C. § 346a(b)(2)(D)(v) (1996), and "available information concerning the aggregate exposure levels of consumers (and other major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances." 21 U.S.C. § 346a(b)(2)(D)(vi) (1996). Through these provisions, FQPA is thus the first federal statute to require cumulative risk assessment for chemicals sharing a common mechanism of toxicity.

91. 21 U.S.C. § 346a(b)(2)(C) (1996). Under FQPA, the EPA must consider "available information" on the cumulative effects of pesticides with common mechanisms of toxicity from all non-occupational routes of exposure. 21 U.S.C. § 346a(b)(2)(D)(iv-vi) (1996). The EPA approach to cumulative exposures is called the "risk cup." According to the EPA, "as long as the cup is not full . . . EPA can consider registering additional uses and setting new tolerances. If . . . the risk cup is full or

must then be incorporated into FIFRA's reregistration process on a phased schedule to be completed by 2006.⁹²

Under FIFRA, the exceedance of allowable "tolerances" established under FQPA constitutes an "unreasonable effect on the environment" justifying the cancellation of a pesticide's registration.⁹³ Thus, FQPA may over time have a significant impact on whether pesticides that leave chemical residues on food products continue to be registered under FIFRA.⁹⁴ Whether FQPA ultimately transforms FIFRA into a health-based, protective regulatory statute, however, is another question. The following sections discuss several factors that continue to undermine FIFRA's ability to control pesticide pollution.

3. *Evaluation of Federal Regulation of Pesticides under FIFRA: Limits of a Licensing Statute Based on Risk Assessment*

In the 1970s, the EPA used FIFRA's unreasonable risk standard to force the cancellation of a number of the most

exceeded, no new uses could be approved until the risk level is lowered." U.S. ENVIRONMENTAL PROTECTION AGENCY, 1996 FOOD QUALITY PROTECTION ACT IMPLEMENTATION PLAN 14 (1997). The EPA must also consider information relating to the endocrine disrupting effects of certain pesticides, a toxicity endpoint never before addressed by any federal statute. 21 U.S.C. § 346a(b)(2)(D)(viii) (1996). FQPA requires the EPA to set up an endocrine screening program under which the possibility of endocrine disrupting effects is tested for each pesticide according to a phased schedule. 21 U.S.C. § 346a(p) (1996). Whether this program will be successfully implemented, however, is still questionable. *See, e.g.,* Davis Balz, *Implementing FQPA: U.S. EPA and Endocrine Disruptors*, 9 GLOBAL PESTICIDE CAMPAIGNER 6 (1999). Where insufficient data exist to determine whether the impact of a reproductive and/or developmental toxin on children or infants is "safe," EPA must add up to an additional ten-fold safety factor to the tolerance level. 21 U.S.C. § 346a(b)(2)(C)(ii)(II) (1996). FQPA also requires EPA to make an assessment of the "validity, completeness and reliability" of existing data. 21 U.S.C. § 346a(b)(2)(D)(i) (1996).

92. EPA has already missed its first deadline—August 1999—to establish revised tolerances and accompanying registration revisions for the "riskiest" food residue pesticides. *See* Peter Eisler, *Toughest Decisions Still to Come in Pesticide Review*, USA TODAY, Aug. 30, 1999, at 1A. This failure has been challenged by a coalition of environmental and labor groups. *See* Complaint, Natural Resources Defense Council et. al. v. Browner (N.D. Cal. 1990) (No. 99-70946).

93. 7 U.S.C. § 136(bb) (1994).

94. Under the authority of FQPA, for example, the EPA has instigated a comprehensive tolerance assessment of the organophosphate pesticides, which EPA considers to be the highest priority for re-review. *See* Pesticide Registration Performance Measures and Goals, 65 Fed. Reg. 37,375, 37,377 (2000); EPA, Office of Pesticide Programs, Status Summary of the Organophosphate Review Process, Feb. 1, 2000, at www.epa.gov/pesticides/op/status.htm. Pursuant to this assessment, EPA sought and negotiated with the registrant a two-year voluntary cancellation of the pesticide chlorpyrifos for household use. *See infra* note 132. Chlorpyrifos is an insecticide commonly sold under the trade names Lorsban or Dursban. It is found in hundreds of household products.

harmful organochlorine pesticides, such as DDT, aldrin and dieldrin. These regulatory victories were achieved through a combination of agency commitment, lingering public outrage over the environmental harm caused by these persistent toxic chemicals, and the perceived availability of less harmful alternatives.⁹⁵ Since that time, however, several factors have conspired to slow FIFRA's performance in protecting the human and natural environment from pesticide exposures.

a. Limits of Cost Benefit Analysis under FIFRA

A significant historical factor limiting FIFRA's success in protecting public health and the environment is the cost-benefit analysis built into the statutory "unreasonable risk" standard.⁹⁶ Amendments requiring the EPA to consider the impacts of any proposed pesticide restrictions on retail food prices and the agricultural economy emphasize this cost benefit balancing.⁹⁷ More than any of the other major federal environmental statutes passed between 1969 and 1973, FIFRA considers the costs to industry and the economy at large of proposed regulatory

95. See BOSSO, *supra* note 80, at 154-58, 194-97.

96. Congress ensured that FIFRA would not hinder market competition by adding language that prohibits the EPA from denying registration to a pesticide simply because another effective pesticide product is already on the market. 7 U.S.C. § 136a(c)(5)(D) (1994). The availability of a safer alternative pest control measure or product may be considered, however, in calculating the relative "benefits" of a particular pesticide. *Envtl. Def. Fund v. Env'tl. Prot. Agency*, 465 F.2d 528, 539 (D.C. Cir. 1972); *Env'tl. Def. Fund v. Env'tl. Prot. Agency*, 510 F.2d 1292, 1303 (1975).

97. See 7 U.S.C. § 136d(b) (1994) (originally enacted November 28, 1975, 89 Stat. 751) (EPA shall consider the impact of any proposed pesticide cancellation "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy."); see also 40 C.F.R. § 154.1 (2000) (no denial of registration or cancellation if pesticide risks can be reduced to acceptable levels or if benefits of pesticides outweigh risks). The 1975 amendments also require the EPA to submit an "agricultural impact statement" to the Department of Agriculture regarding any proposed restriction and provide the Agricultural Secretary an opportunity to comment on the proposed restriction. 7 U.S.C. § 136d(b) (1994). In adding this requirement, the Senate Agricultural and Forestry Committee noted that:

Because the basic thrust and principal responsibility of EPA are to protect the environment, the Committee does not see a need to broaden the impact statement to include the environment. There is clearly a need to consider the impact of EPA's decisions on agriculture if balance is to be achieved.

S. REP. NO. 94-452, at 9 (*reprinted in Merrell v. Thomas*, 807 F.2d 776, 780 (9th Cir. 1986)). The 1975 amendments are generally considered to be a congressional reaction to the aggressive enforcement actions taken by the EPA in the early 1970s against the organochlorine pesticides. See, e.g., BOSSO, *supra* note 80, at 195-97; Donald T. Hornstein, *The Medicare DRGs: Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 YALE J. ON REG. 369, 434-35 (1993).

restrictions.⁹⁸ As a result, many pesticides with known adverse environmental impacts continue to be registered and used in agricultural applications.⁹⁹ While FQPA adopts a tougher stance regarding food residue pesticides, it is still unclear whether FQPA's health-based standards will ultimately limit the use of toxic pesticides under FIFRA.¹⁰⁰

b. Limits of Quantitative Risk Assessment under FIFRA

The blame for FIFRA's ineffectual regulation can also be traced to the inherent limitations of the quantitative risk assessment process, and how it functions under FIFRA.¹⁰¹ For the EPA, the "hard science" of risk analysis has proven irresistible, both as a tool to guide pesticide regulation and as a

98. The federal Clean Air Act, for example, sets national primary ambient air quality standards without consideration of costs in order to "protect the public health," with an adequate margin of safety. See 42 U.S.C. § 7409(b)(1) (1994); *Lead Indus. Ass'n v. Env'tl. Prot. Agency*, 647 F.2d 1130, 1149 (D.C. Cir. 1980) ("The legislative history of the Act . . . shows the Administrator may not consider economic and technological feasibility in setting air quality standards."). The Federal Clean Water Act adopts technology-based pollution controls, 33 U.S.C. § 1311 (1994), as long as the costs are not "'wholly disproportionate' to the potential effluent-reduction benefits." *Rybachek v. United States Env'tl. Prot. Agency*, 904 F.2d 1276, 1289 (9th Cir. 1990) (quoting *Ass'n of Pacific Fisheries v. Env'tl. Prot. Agency*, 615 F.2d 794, 805 (9th Cir. 1980)).

99. See, e.g., Memorandum from James J. Jones, Office of Pesticide Programs, U.S. EPA, to Jerome R. Campbell, Supervisor of Regulation, Department of Pesticide Regulation, California Environmental Protection Agency (Apr. 30, 1999) (EPA will allow application of 150,000 pounds of a canceled pesticide based on findings under Section 18 of FIFRA that the is essential to the agricultural economy and to reducing prices for food consumers); see also 40 C.F.R. § 154.1 (2000) (no restrictions where benefits of pesticide outweigh its risks). EPA's cost-benefit balancing under FIFRA resembles the "cost-justified model," in which regulation will only be implemented if the benefits of a regulatory action clearly outweigh the costs. See generally William H. Rodgers, Jr., *Benefits, Costs, and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENVTL. L. REV. 191, 201-14 (1980).

100. FQPA adopts a health-based standard designed to ensure a "reasonable certainty" of no harm. Under FQPA, cost-benefit balancing is limited to pesticides with carcinogenic effects, and then only upon a showing that the imposition of the pure health-based standard would itself pose non-dietary health risks or would cause a "significant disruption in domestic production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b)(2)(B)(iii) (1996). FQPA limits the extent to which such cost-benefit balancing may reduce FQPA's safety standard to a factor of 10 for yearly risk, and a factor of 2 for lifetime risk. 21 U.S.C. § 346a(b)(2)(B)(iv) (1996). The federal Endangered Species Act and Safe Drinking Water Act also provide for more protective standards, with little or no account taken of cost factors. See *infra* notes 167-173 and accompanying discussion.

101. Quantitative risk assessment consists of four steps: 1) hazard identification, 2) dose-response or toxicity assessment; 3) exposure assessment; and 4) risk characterization. See *Guidelines for Carcinogen Risk Assessment*, 51 Fed. Reg. 33,992, 33,993 (1986).

political shield against the partisan battles that surround the determination of national pesticide policy.¹⁰² As many commentators note, however, there are reasons to doubt EPA's faith in the risk assessment process under FIFRA.¹⁰³ Pesticide risk assessment is extremely complex and information-intensive. It contains inherent uncertainties. An accurate assessment requires the EPA to assess the toxicity, environmental fate, exposure scenarios and resulting cumulative risks to humans and the natural environment from thousands of pesticide products. These products are themselves composed of both active and "inert" ingredients,¹⁰⁴ many of which break down into toxic metabolites when exposed to sunlight or water.¹⁰⁵ Once released into the environment, different pesticide residues may act cumulatively or even synergistically with one another—or with other substances—in ways still not well understood by

102. See, e.g., EPA Risk Assessment Council, *Guidance for Risk Assessment* 4 (Nov. 1991) (risk assessment is a process that generates "scientific information" in a manner that is credible, objective, realistic, and balanced"—without consideration of "non-scientific factors"); Hornstein, *supra* note 97, at 438-42; Mark E. Shere, *The Myth of Meaningful Environmental Risk Assessment*, 19 HARV. ENVTL. L. REV. 409, 412-13 n.11 (1995). For good discussions of pesticide regulatory politics, see BOSSO, *supra* note 80, and James Smart, *All the Stars in the Heavens Were in the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 STAN. ENVTL. L.J. 273 (1998).

103. See, e.g., John Carlucci, *Reforming the Law on Pesticides*, 14 VA. ENVTL. L.J. 189 (1994); Pamela A. Finegan, *FIFRA Lite: A Regulatory Solution or Part of the Pesticide Problem?*, 6 PACE ENVTL. L. REV. 615 (1989); Hornstein, *supra* note 97, at 438-56; Applegate, *supra* note 84.

104. The "active ingredient" is that part of the pesticide which causes the physiological harm to the pest or weed. See 7 U.S.C. § 136(a) (1994). Inert ingredients have no pesticidal effect but are used to "dissolve, dilute, deliver or stabilize" active ingredients. 7 U.S.C. § 136(m) (1994); U.S. GENERAL ACCOUNTING OFFICE, PESTICIDES: EPA'S FORMIDABLE TASK TO ASSESS AND REGULATE THEIR RISKS 23 (1986). Despite their characterization as harmless, inert ingredients include such toxic chemicals as benzene and vinyl chloride. See Finegan, *supra* note 103, at 638 n.199; SANDRA MARQUARDT ET AL., TOXIC SECRETS: "INERT" INGREDIENTS IN PESTICIDES 1987-1997 (1998).

105. See J.L. Domagalski, Abstract, *A Synoptic Study of Agricultural Pesticides and Pesticide Degradation Products: Sacramento River Basin, California, National Water Quality Assessment Program*, 75 EOS: TRANSACTIONS OF THE AM. GEOPHYSICAL UNION (Supp.) 230 (1994); James J. La Clair, John A. Bantle & James Dumont, *Photoproducts and Metabolites of a Common Insect Growth Regulator Produce Developmental Deformities in Xenopus*, 32 ENVTL. SCI. & TECH. 1453 (1998). For example, the most highly used pesticide in California, metam sodium, breaks down on contact with air or water into several degradate products, the principal of which, methyl isothiocyanate or "MITC," is also considered highly toxic. Studies of the environmental effects of this pesticide, however, routinely fail to distinguish between exposures to metam sodium and MITC. See, e.g., CAL. ENVTL. PROT. AGENCY DEP'T OF PESTICIDE REGULATION MEDICAL TOXICOLOGY BRANCH, SUMMARY OF TOXICOLOGY DATA METAM-SODIUM (1986).

science.¹⁰⁶ Finally, the adverse effects of pesticide exposures may be latent, manifesting only years later in a given population.¹⁰⁷

Even in the best circumstances, assessment of such complex and interrelated risk factors would be an overwhelming challenge, requiring enormous resources and years of study.¹⁰⁸ Pesticide regulation under FIFRA, however, has never enjoyed this kind of legislative commitment.¹⁰⁹ Instead, it has operated under severe time pressure and has been constrained by scarce resources from the beginning.¹¹⁰ The combination of

106. See, e.g., Warren P. Porter, James W. Jaeger & Ian H. Carlson, *Endocrine, Immune and Behavioral Effects of Aldicarb (Carbamate), Atrazine (Triazine) and Nitrate (Fertilizer) Mixtures at Groundwater Concentrations*, 15 TOXICOLOGY & INDUSTRIAL HEALTH 133 (1999); DAVID WALLINGA, PUTTING CHILDREN FIRST: MAKING PESTICIDE LEVELS IN FOOD SAFER FOR INFANTS & CHILDREN 15-23 (1998); D. Jonker et al., *4-Week Oral Toxicity Study of a Combination of Eight Chemicals in Rats: Comparison With the Toxicity of the Individual Compounds*, 28 FOOD CHEM. TOXICOLOGY 623 (1990); M. Ikeda, *Multiple Exposure to Chemicals*, 8 REG. TOXICOLOGY & PHARMACOLOGY 414-21 (1988).

107. See, e.g., Mary S. Wolff & Ainsley Weston, *Breast Cancer Risk and Environmental Exposures*, 105 ENVTL. HEALTH PERSP. 891 (1997); S.M. Chanda & C.N. Pope, *Neurochemical and Neurobehavioral Effects of Repeated Gestational Exposures to Chlorpyrifos in Maternal and Developing Rats*, 53 PHARMACOLOGY BIOCHEMISTRY & BEHAVIOR 771 (1996); Lorraine F. Meisner, B.D. Roloff & D.A. Belluck, *In Vitro Effects of N-Nitrosoatrazine on Chromosome Breakage*, 24 ARCHIVES OF ENVTL. CONTAMINATION & TOXICOLOGY 108 (1993); see also Beyond Pesticides/National Coalition Against the Misuse of Pesticides, *Residential Pesticide Exposure Linked to Parkinson's Disease*, 15 TECHNICAL REP. 4 (2000) (describing links between Parkinson's disease and home pesticide use and exposure); WALLINGA, *supra* note 106, at 28-30.

108. Professor Applegate notes that an inherent difficulty in a licensing statute such as FIFRA is that "the premarket phase of [product] development is the time when the least information is known about a chemical's long-term effects." Applegate, *supra* note 84, at 312.

109. For a good discussion of the difficulties encountered by EPA in conducting risk assessment in the early years of FIFRA, see Scott Ferguson & Ed Gray, *1988 FIFRA Amendments: A Major Step in Pesticide Regulation*, 19 ENVTL. L. REP. 10,070 (1989).

110. See *id.* at 10,072-76; see generally U.S. GENERAL ACCOUNTING OFFICE, *supra* note 104, at 20-57. The 1972 amendments required EPA to review the registrations of thousands of pesticides to determine their compliance with the unreasonable risk standard under a wholly unrealistic statutory deadline of four to five years. See Federal Environmental Pesticide Control Act, Pub. L. No. 92-516, § 4(c)(2), 86 Stat. 973 (codified as amended at 7 U.S.C. § 135 *et. seq.* (1972)). In 1971, EPA stated that there were nearly 45,000 outstanding pesticide registrations for "hundreds" of substances in use over approximately five percent of the total land area of the United States. *Envtl. Def. Fund v. Env'tl. Prot. Agency*, 465 F.2d 528, 535-36 (D.C. Cir. 1972). Other sources have estimated the number of pesticide registrations subject to review at the time of the 1972 amendments to have been between 30,000 to 60,000. See Ferguson & Gray, *supra* note 109, at 10,073. In 1978, Congress extended the deadline for registration review but failed to allocate the necessary funds to complete the task. See Federal Pesticide Act, Pub. L. No. 95-396, § 3(g), 92 Stat. 819 (1978). A decade later, in 1988, impatient with the continued slow pace of reregistration and mindful of growing public concerns over inadequate health and safety data on widely used pesticides, Congress again amended FIFRA to require reregistration of all

congressional deadlines and limited budgets creates a less than optimal environment for EPA to assess pesticide risk, particularly for pesticides subject to the reregistration process.¹¹¹ Consider, for example, the generation of data upon which EPA relies to make its "unreasonable risk" determination. Since EPA lacks the resources to conduct its own testing, it must rely on pesticide manufacturers to supply the necessary data.¹¹² However, besides being extremely expensive,¹¹³ testing offers the possibility of revealing unreasonable risks posed by the tested product. Thus, a strong incentive exists for manufacturers to provide the minimum data required under the regulations and to skew or fail to provide testing results indicating unreasonable risk.¹¹⁴ While FIFRA allows the EPA to reject inadequate data

pesticides first licensed before November 1, 1984 under a phased schedule to be completed within ten years. See Ferguson & Gray, *supra* note 109, at 10075. See generally U.S. GENERAL ACCOUNTING OFFICE, *supra* note 104, at 20-57. A 1984 National Academy of Sciences Report, for example, stated that adequate health and safety data for proper risk assessments existed on only 10 percent of the pesticides in use. NATIONAL ACADEMY OF SCIENCES, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES (1984). By 1996, the job still undone, Congress mandated that EPA publish annual reports on its progress in completing the reregistration process. See FIFRA § 4(a), 7 U.S.C. § 136a-1(a) (1996); see also Ferguson & Gray, *supra* note 109; Finegan, *supra* note 103. The 1996 amendments to FIFRA also imposed significant additional review obligations on the EPA to comply with new restrictions on pesticide residues in food pursuant to FQPA, again under a tight statutory time schedule on which EPA has already fallen behind. See Food Quality and Protection Act, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended at 21 U.S.C. §346a (1996)); FIFRA § 4(l), 7 U.S.C. § 136a-1(l) (1996). This section is entitled "Performance measures and goals." The 1996 amendments requiring EPA to report on its progress were partly a response to a 1992 G.A.O. report that noted that "some 20 years after the Congress directed EPA to reregister older pesticides, only 2 of 19,000 older pesticide products have been reregistered." U.S. GENERAL ACCOUNTING OFFICE, PESTICIDES: 30 YEARS SINCE SILENT SPRING-MANY LONG STANDING CONCERNS REMAIN 3-5 (1992). In addition, EPA informed Congress during the FQPA hearings that it would need at least 8 additional years - to 2004 - to complete the 1988 reregistration program, twice the time allotment mandated by the 1988 amendments. See H.R. REP. NO. 104-669, pt. 1, 68 (1996).

111. A licensing scheme such as FIFRA creates in effect a two-tiered system, in which older chemicals are likely to be less well-tested than to those registered more recently. Applegate, *supra* note 84, at 312.

112. FIFRA's risk assessment provisions assume that EPA will review data generated by manufacturers. See 7 U.S.C. § 136a(c) (1994); WALLINGA, *supra* note 106, at 25.

113. A two-year test for carcinogenicity, for example, costs \$2 to 4 million. NATIONAL TOXICOLOGY PROGRAM, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ANNUAL PLAN FOR FISCAL YEAR 1996 (1996).

114. See WALLINGA, *supra* note 106, at 25; Hornstein, *supra* note 97, at 436-38 (discussing manipulations of data by pesticide registration applicants); Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1803-04 (1989). In addition, pesticide manufacturers may refuse to disclose the contents of non-active or "inert" pesticide

submittals and to request additional testing through the data call-in process,¹¹⁵ such diligence takes time and resources and eventually generates even more information for EPA staff to review.¹¹⁶ Exposure assessment creates a similar dilemma, since monitoring is expensive and time consuming, and detections of pesticide residues in the field trigger additional data requests to registrants, thereby further delaying the reregistration process.¹¹⁷ As statutory deadlines approach, EPA may understandably focus on completing registration review at the expense of more comprehensive inquiry.¹¹⁸

Deadlines and tight budgets also create a disincentive for EPA to enlarge, through the rulemaking process, the scope of mandatory data submissions. Additional data are necessary, however, since, under existing regulations, required data regarding a pesticide's residue potential, environmental fate, and toxicity to humans, fish and invertebrate organisms provide at best an incomplete or speculative picture of environmental impacts.¹¹⁹ Although scientific understanding of these complex

ingredients based on the theory that such chemicals constitute protected "trade secrets." See, e.g., 7 U.S.C. § 136h (1994) ("Protection of trade secrets and other information"); Tybe A. Brett & Jane E.R. Potter, *Risks to Human Health Associated with Exposure to Pesticides at the Time of Application and Role of the Courts*, 1 VILL. ENVTL. L.J. 355, 358-63 (1990). Many of these ingredients are toxic on their own, or in combination with other chemicals. See, e.g., MARQUARDT ET AL., *supra* note 104.

115. 7 U.S.C. §§ 136a(c)(2) (1994) (discussing requesting and submission of data in support of registration), 136a(g)(2) (discussing registration review), 136a-1 (discussing reregistration of registered pesticides).

116. To avoid this type of resource drain, EPA's practice in the 1970s and 1980s was to allow pesticides to be reregistered despite outstanding data gaps. See, e.g., Ferguson & Gray, *supra* note 109, at 10,074; Hornstein, *supra* note 97, at 437. As discussed *infra*, however, this process creates a problem since any subsequent restrictions on such reregistered pesticides require EPA to undertake the cumbersome special review process. See *infra* notes 141-154 and accompanying discussion. The FIFRA regulations acknowledge the limits of EPA's oversight role by only requiring confirmation that submitted data have been developed according to proper testing methodologies, but not that such data be accurate. See 40 C.F.R. § 158.80 (2000); Brett & Potter, *supra* note 114; *Burke v. Dow Chemical*, 797 F. Supp. 1128, 1135 (E.D.N.Y. 1992).

117. EPA will often identify additional data needs based on its own exposure analysis. See 40 C.F.R. § 158.101(b) (2000) (data may be designated as conditionally required depending on product's use pattern, physical or chemical properties, expected exposure of non-target organisms and/or results of previous testing).

118. See Hornstein, *supra* note 97, at 437 ("[T]he Agency openly worried that the rate at which it rejected industry studies was 'too high' because it would prevent reregistration by the new target date of 1997, or even beyond an extended target of 2002.")

119. The specific federal data requirements relating to environmental impacts are set forth at 40 C.F.R. § 158.202 (2000) and cover residue chemistry (§ 158.202(c)); environmental fate (§ 158.202(d)); hazard to humans and domestic animals (§ 158.202(e)); reentry protection (for workers) (§ 158.202(f)); pesticide spray drift

mechanisms has grown over the last decades, regulatory amendments to require additional data are years if not decades away.¹²⁰

The problem with incomplete information is that it produces uncertainty in risk assessments.¹²¹ In many situations, risk that is "uncertain" will not be considered "unreasonable," particularly when compared to the readily quantifiable economic impacts to farmers and consumers resulting from regulation.¹²² Even more significantly, uncertainty in risk assessment may substantially hinder regulation when the regulatory agency bears the burden of establishing the "risk" posed by a particular activity.¹²³ In theory, the burden under FIFRA to establish that a particular pesticide use is safe is borne by the proponent of registration.¹²⁴

evaluation (§ 158.202(g)); hazard to nontarget organisms (§ 158.202(h)); and product performance (§ 158.202(i)). Many potential impacts of pesticide use, including cumulative and/or synergistic effects, endocrine disrupting effects, effects on developing organisms, sublethal effects, and long term effects of toxic byproducts of pesticide breakdown, are not well addressed by these regulatory requirements. See WALLINGA, *supra* note 106, at 25-40; Porter, *supra* note 106; La Clair, *supra* note 105. In this sense, pesticides are one of several sources of ubiquitous chemical contaminants in our physical environment. Cynthia Carey & Corrie J. Bryant, *Possible Interrelations Among Environmental Toxicants, Amphibian Development and Decline of Amphibian Populations*, 103 ENVTL. HEALTH PERSP. Supp. 4 (1995); Rob Edwards, *Sea Sickness: Deaths of Harbour Porpoises Are Linked to PCBs and Mercury*, NEW SCIENTIST, Dec. 18, 1999, at 12.

120. During the 1990s, EPA held workshops and conducted scientific research to revamp its risk assessment data needs and procedures. See, e.g., Office of Pesticide Programs, EPA, EFED's Summary of the SAP Review of Ecological Risk Assessment Methodologies, Apr. 14, 1997. Proposed rules for these new data requirements and risk assessment methodologies, however, are not on the near horizon. See, e.g., Guidelines for Ecological Risk Assessment, 63 Fed. Reg. 26,846 (1998).

121. See, e.g., Applegate, *supra* note 84, at 264-67; Howard A. Latin, *The "Significance" of Toxic Health Risks: An Essay on Legal Decisionmaking Under Uncertainty*, 10 ECOLOGY L.Q. 339 (1982).

122. In the face of such uncertainty, a fact finder may well decide against imposing the foreseeable and tangible costs associated with a cancellation or restriction of a pesticide use. In *National Coalition Against Misuse of Pesticides v. Environmental Protection Agency*, 867 F.2d 636 (D.C. Cir. 1989), the court noted:

[The EPA Administrator] might determine after an administrative hearing (involving the expenditure of substantial administrative resources) that scientific uncertainty as to the danger of a specific pesticide (combined perhaps with the economic impact of cancellation on 'agricultural commodities, retail food prices and [] the agricultural economy' []), indicates that the registration should not be cancelled.

Id. at 642 (quoting 7 U.S.C. § 136d(b) (1982)). See also *Love v. Thomas*, 858 F.2d 1347, 1363 (9th Cir. 1988) (reviewing specific numbers on crop losses in reversing EPA's decision to cancel use of pesticide dinoseb).

123. See, e.g., Applegate, *supra* note 84, at 264-67; Latin, *supra* note 121, at 357-58.

124. See *Envtl. Def. Fund v. Envtl. Prot. Agency*, 465 F.2d 528, 532 (D.C. Cir. 1972); 40 C.F.R. §§ 154.5, 164.80(b) (2000).

In many respects, however, the mechanics of the registration process place a significant burden on the EPA to establish that a particular use is harmful. If a registrant skews testing results or submits incomplete information on a pesticide product, for example, the EPA must spend time and resources to determine that the data submitted are inadequate. If it fails to do so, EPA's subsequent registration denial, cancellation, or restriction may be overturned on judicial review as unsupported by substantial evidence.¹²⁵ EPA also bears the burden of requesting or developing fully the types of information needed to assess a pesticide's impact on human health and the environment,¹²⁶ and determining whether pesticide use in the field is causing human or environmental exposures.¹²⁷ If time or budget constraints persuade EPA to forgo such inquiries, it will be unable to establish a sufficient factual record to withstand judicial review.

EPA's burden is all the more substantial given that neither FIFRA nor its regulations establish specific standards as to when pesticide residues constitute a significant impact on public health or the environment.¹²⁸ Thus, unlike other federal

125. See *Env'tl. Def. Fund v. Env'tl. Prot. Agency*, 548 F.2d 998, 1005 (D.C. Cir. 1976); *Env'tl. Def. Fund*, 465 F.2d at 537. Even if substantial evidence is produced, the registrant may introduce its own studies contradicting EPA's results, or highlighting other factors not considered. See, e.g., *Nat'l Coalition Against Misuse of Pesticides*, 867 F.2d at 642 ("[O]ur cases holding that the Administrator satisfies his burden of proffering 'substantial evidence' of harm from respected scientific sources . . . [do not] mean that the Administrator is guaranteed victory if the proceedings are contested by the registrant and the ultimate order challenged subsequently in federal court"); *Love*, 858 F.2d at 1362 (holding that EPA's failure to consider economic impacts justifies reversal notwithstanding evidence of harm).

126. Registrants have no incentive to provide data beyond the minimum regulatory requirements. See WALLINGA, *supra* note 106, at 25. While FIFRA regulations require an applicant to submit any factual information regarding unreasonable adverse pesticide effects as part of the registration application, 40 C.F.R. § 152.50(f)(3) (2000), and after the pesticide is registered, 7 U.S.C. § 136d(a)(2) (1994); 40 C.F.R. § 159.152 (2000), nothing in FIFRA or its regulations provides any incentive for registrants to develop such information on their own.

127. See 7 U.S.C. § 136r(c) (1994) (granting EPA authority to conduct monitoring in cooperation with other federal, state and local agencies). In cases where high levels of contamination have been detected, EPA has the power to require registrants to submit monitoring and use information as part of the data call-in process. See, e.g., *Atrazine, Simazine and Cyanazine*, 59 Fed. Reg. 60,412, 60,414 (1994) (describing EPA's 1989 data requests to Ciba Geigy for ground and surface water monitoring information and use data on simazine). EPA has also negotiated with registrants to conduct their own monitoring for some newly registered pesticides. See, e.g., Office of Pesticide Programs, U.S. EPA, *Acetochlor Desk Statement* (1994), available at <http://www.epa.gov/oppefed1/aceto/index.htm> (noting that registration of acetochlor would be dependent on registrants continuous ground and surface water monitoring in areas where product will be applied.)

128. The harm-based standards of FQPA, which are incorporated into FIFRA standards, are one exception to this general rule. See 7 U.S.C. § 136(bb) (1994)

regulatory statutes, FIFRA does not allow the EPA to ban or restrict a pesticide use based on violations of a particular emission or exposure standard. Instead, the EPA must support each individual determination with substantial evidence of "unreasonable risk."¹²⁹ Where such evidence is lacking or fragmentary, the use may be allowed to continue.¹³⁰

FQPA attempts to remedy these seemingly chronic information gaps by requiring EPA to consider a range of toxicity and exposure data in setting "safe" tolerances for pesticide residues on food products.¹³¹ As a legal matter, the provisions of FQPA provide EPA with tremendous legal authority—indeed, a statutory duty—to conduct more meaningful and informed risk assessment. The results of such in-depth review can be significant. In June, 2000 the EPA negotiated a phase-out for home and garden products containing the ubiquitous organophosphate chlorpyrifos, based on new testing demonstrating that the developing brains of infants could be more sensitive to the chemical's neurotoxic properties.¹³² Despite this and other regulatory successes, however, a question

(human dietary risk from pesticide residues not in compliance with FQPA constitutes unreasonable impact on the environment). For carcinogenic pesticides, FQPA's harm-based standard has been inferred from Congressional hearings to be EPA's historical "de minimis" standard of one in a million lifetime risk. See H.R. REP. NO. 104-669(ii), at 41 (1996). For pesticides with non-carcinogenic effects, FQPA applies a safety standard of no observable adverse effect, with the normal safety 100-fold factor to account for differences between animals. FQPA requires EPA to apply a tenfold margin of safety unless the EPA can determine "on the basis of reliable data," that a lesser safety factor will be sufficient to ensure protection. 21 U.S.C. § 346a(b)(2)(C)(ii) (1996).

129. See, e.g., *Nat'l Coalition Against Misuse of Pesticides*, 867 F.2d at 642; 7 U.S.C. § 136d(d) (1994) (holding that an EPA order denying, restricting or canceling a registration "shall be based only on substantial evidence . . . and shall set forth detailed findings of fact upon which the order is based"). FIFRA thus confers broad discretion on the EPA to determine what constitutes an unreasonable impact on the environment, but does not necessarily encourage the agency to exercise that discretion to restrict pesticide use.

130. A good example, among many, is the organophosphate chlorpyrifos, a common household and agricultural insecticide first registered in 1965 and subsequently reregistered in the 1980s. Not until the year 2000, when new test results indicated increased neurotoxic susceptibility among developing infants and children, was the use of chlorpyrifos in home, lawn and garden products phased out by EPA. See *infra* notes 132, 146 and accompanying discussion.

131. 21 U.S.C. § 346a(b)(2)(D)(i-ix) (1996).

132. See Carol Browner, EPA Administrator, Dursban Announcement: Remarks Prepared for Delivery June 8, 2000, Washington, D.C., available at http://www.epa.gov/epahome/speeches_0608.htm. A key aspect of the EPA's decision was its conclusion that the FQPA safety factor of 10 should be retained for chlorpyrifos. See EPA Office of Pesticide Programs, Overview of Chlorpyrifos Revised Risk Assessment at 3, available at <http://www.epa.gov/pesticides/op/chlorpyrifos/overview.pdf> (August 3, 2000).

remains whether the FQPA risk assessment process can translate to a reduction in pesticide exposures to humans.¹³³ Due to its focus on food residues, for example, FQPA regulates pesticides posing risks through air, water or soil contamination only on a tangential basis. Moreover, it depends upon the existence of “reliable information,” which is often not available.¹³⁴

Furthermore, FQPA is limited by its ultimate reliance on the risk assessment process for policy direction. FQPA simply adds statutory force to a risk assessment process already beset with uncertainty. The statute attempts to shift the burden of this uncertainty to pesticide manufacturers, but this is a difficult task given the contentious partisan battles that quickly envelop risk assessment debates. Instead, the strong possibility exists that FQPA will succumb to the same historical political tug of war that has so drastically limited pesticide regulation under FIFRA.¹³⁵ Under this scenario, FQPA intensifies, but does not break from the “analytical treadmill” of quantitative risk assessment.¹³⁶ Meanwhile, as discussed below, the larger

133. FQPA does not address pesticide environmental impacts that do not directly effect human beings. It seems likely that one perhaps unintended result of FQPA's emphasis on human health and food residues will be the creation, over time, of an even larger gap between what is known of the impacts of pesticides on humans and knowledge of impacts on the non-human physical environment, including wildlife.

134. See, e.g., EPA, OFFICE OF PESTICIDE PROGRAMS, PROPOSED GUIDANCE ON CUMULATIVE RISK ASSESSMENT OF PESTICIDE CHEMICALS THAT HAVE A COMMON MECHANISM OF TOXICITY 4 (2000), available at <http://www.epa.gov/fedrgstr/EPA-PEST/2000/June/Day-30/6049.pdf> (“due to limitations in currently available data and assessment methodologies . . . the data for residential/non-occupational and drinking water exposures are comparatively less”). Even if such data were available, it is not clear that EPA is prepared to utilize it in meaningful cumulative risk analysis. See EPA, *Response to Public Comments on the Preliminary Risk Assessments for the Organophosphate Pesticide Chlorpyrifos-Methyl*, Apr. 21, 2000, at 6 (“[T]he Agency acknowledges that it has not yet performed a cumulative risk assessment, because the methodology for conducting such assessments is still being developed.”).

135. Clearly, the political battle has already been joined. In June 1999, for example, the American Crop Protection Association and the American Farm Bureau Federation, groups representing pesticide manufacturers and users, filed suit claiming that EPA was making policy decisions with insufficient data. Bette Hileman, *Reexamining Pesticide Risk*, CHEM. & ENG'G NEWS, July 17, 2000, at 34. Around the same time, House and Senate bills were introduced that would have forced EPA to give pesticide manufacturers more time to present data. *Id.* Meanwhile, environmental and consumer groups sued EPA for failing to move fast enough in conducting risk reassessments and resigned in protest from EPA's Tolerance Reassessment Advisory Committee due to its failure to make meaningful progress on any significant reassessment issue. *Id.*; *supra* note 110; William Claiborne, *7 Groups Quit Food Panel*, WASH. POST, Apr. 28, 1999, at A23; see also Tim Strohshane, *U.S. Food Quality Protection Act: Will the Risk Cup Runneth Over?*, 9 GLOBAL PESTICIDE CAMPAIGNER, Apr. 1999, at 1; Peter Elsler, *Toughest Decisions Still to Come in Pesticide Review*, USA TODAY, Aug. 30, 1999, at 1A.

136. See Hornstein, *supra* note 97, at 442-43.

question of whether there may be preferable alternatives to the intensive use of chemicals to control pests remains largely unexplored.¹³⁷

c. Limits of Enforcement under FIFRA

The range of enforcement options available under FIFRA is inherently limited by its regulatory focus on registration and labeling. Unlike many environmental statutes, for example, FIFRA does not allow for citizen enforcement.¹³⁸ Instead, it confers sole enforcement authority on the EPA and its state agency delegates.¹³⁹ When an unreasonable pesticide impact occurs in the field, the EPA is limited to either initiating special review proceedings to cancel or restrict the pesticide's registration or attempting to cite users for violations of the label directions.¹⁴⁰ Neither of these options provides for a particularly effective enforcement scheme.

Given the economic interests at stake, it is not surprising that the restriction or cancellation of a pesticide registration is a procedurally complicated and often lengthy matter. The procedural hurdles strewn throughout the administrative review process¹⁴¹ require prohibitive amounts of the EPA's time and

137. See *infra* notes 155-163 and accompanying discussion.

138. See *Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983) ("legislative history [of FIFRA] confirms that Congress did not intend to create a private right of action under FIFRA"); *Almond Hill School v. United States Dept. of Agriculture*, 768 F.2d 1030, 1035-38 (9th Cir. 1985). Nor can citizens challenge registration decisions through the NEPA process. *Merrell v. Thomas*, 807 F.2d 776, 780-81 (9th Cir. 1986) (holding that registration decisions are exempt from NEPA).

139. See 7 U.S.C. § 136w-1 (1994) (granting to states "primary enforcement responsibility").

140. See, e.g., *Inconsistent Labeling*, *supra* note 89.

141. To begin the process, EPA first must privately notify the registrant that it is considering initiating special review based on observed adverse environmental impacts of the pesticide. 40 C.F.R. § 154.21(a) (2000); U.S. ENVIRONMENTAL PROTECTION AGENCY, STATUS OF PESTICIDES IN REGISTRATION, REREGISTRATION, AND SPECIAL REVIEW 11(1998), available at <http://www.epa.gov/oppssrd1/Rainbow/98rainbo.pdf> [hereinafter RAINBOW REPORT]. After an informal notice and comment process, EPA then must determine whether to initiate "special review" based on a series of criteria relating to adverse impacts on public health, non-target organisms or endangered species. 40 C.F.R. § 154.7 (2000). EPA may initiate special review upon a showing that a pesticide may cause serious acute or chronic health effects to humans or non-target organisms, or may pose a risk to the continued survival of an endangered species or adversely effect its critical habitat. 40 C.F.R. § 154.7(a)(1) - (6) (2000). If preliminary review indicates that a pesticide is having such "unreasonable" adverse impacts on the environment, EPA must publish a notice of Special Review. 40 C.F.R. § 154.25(c) (2000). This notice is known as a Position Document ("PD") 1. The notice describes the Special Review criterion of concern, the assumptions and data used in the analysis, and the strength

resources and impose a significant burden on EPA to provide factual support for its proposed action.¹⁴² These hurdles can delay enforcement for years.¹⁴³ During this time a pesticide may continue to be used unless the EPA makes a formal finding that such use constitutes an “imminent hazard” justifying immediate suspension.¹⁴⁴ Furthermore, even after a final order, the EPA must allow individual states to permit application of a canceled

of the conclusions. The notice will also announce the availability of the pre-Special Review public docket, solicit public comment and request additional information on the pesticide. RAINBOW REPORT at 11.

EPA commences special review by meeting with “interested parties” and conducting a risk-benefit analysis. *Id.* at 12. Potential risks are evaluated by considering such factors as 1) adverse impacts to health or the environment; 2) magnitude of exposure of humans and other non-target organisms; and 3) size of the population at risk. Benefits of use are evaluated by assessing the availability, efficacy and cost of alternative control methods, and impact on users, consumers, and other parties if the pesticide is canceled. *Id.* As discussed, FIFRA is explicit that EPA consider the impact of any proposed pesticide cancellation or restriction on the agricultural economy and on consumer prices. 7 U.S.C. § 136d(b) (1994); 40 C.F.R. § 154.1 (2000). Where the “benefits” of continued use are found to outweigh the perceived risks, EPA will then publish a Notice of Decision to Terminate the Special Review. This is known as a Position Document 2. RAINBOW REPORT at 12. If risks are perceived to outweigh benefits, and the registrant is unwilling to amend the registration so as to reduce such risks, EPA issues a notice of Preliminary Determination, which initiates a formal round of notice and comment. RAINBOW REPORT at 12. The Notice of Preliminary Determination is known as a PD 2/3. *Id.*

FIFRA provides a registrant the right to an evidentiary hearing on the merits. 7 U.S.C. § 136d(b) (1994); 40 C.F.R. §§ 154.15 - 154.29 (2000). As part of this process, EPA submits the Preliminary Determination, including an “agricultural impact analysis,” to the Department of Agriculture regarding any proposed restriction, to which the Agricultural Secretary may provide comments. 7 U.S.C. § 136d(b) (1996); 40 C.F.R. § 154.31(b) (2000). The Secretary’s comments must be published in the Federal Register, with appropriate responses by EPA. *Id.* At the hearing, questions of scientific fact may be referred to an outside body, the FIFRA Scientific Review Panel, whose report thereupon becomes part of the administrative record. 7 U.S.C. § 136d(d) (1996); 40 C.F.R. § 154.31(b) (1994). RAINBOW REPORT at 12. After evaluating all comments, EPA issues a Notice of Final Determination, also known as a Position Document 4, which sets forth the agency’s intention to cancel, deny or reclassify an existing registration. 40 C.F.R. § 154.33 (2000); RAINBOW REPORT at 12. Cancellation or restrictions are subject to judicial review based on the substantial evidence standard. 7 U.S.C. §§ 136d(h), 136n (1994); *see* *Envtl. Def. Fund v. Env’tl. Prot. Agency*, 465 F.2d 528, 539 (D.C. Cir. 1972); *Env’tl. Def. Fund v. Env’tl. Prot. Agency*, 510 F.2d 1292, 1303 (1975).

142. Due to the reregistration requirements and the passage of FQPA, analysis of *existing* pesticide registrations forms the vast majority of EPA’s risk assessment work. *See* Pesticide Registration Performance Measures and Goals, 65 Fed. Reg. 37,375 (2000).

143. *See, e.g.,* Hornstein, *supra* note 97, at 437-38 (describing how “informational demands of risk analysis doom the regulatory process to a perpetual state of slow motion”).

144. 7 U.S.C. § 136d(c) (1994).

or restricted use pesticide if there is the possibility of a "significant economic loss."¹⁴⁵

This process provides EPA with strong incentives to forgo cancellation or suspension proceedings in favor of less severe sanctions. For example, EPA often negotiates with registrants to place warnings and use restrictions on pesticide labels.¹⁴⁶ Incremental enforcement is encouraged by the language of FIFRA, which requires EPA to consider restrictive labeling as an alternative enforcement option at each stage of the special review process.¹⁴⁷ Restrictive labeling, however, does not necessarily translate to a reduction in risk. FIFRA's labeling provisions create enforceable standards for labeling or use directions, but impose no direct sanctions on manufacturers or users for

145. 7 U.S.C. § 136p (1994); 42 C.F.R. § 166.2(a)(2) (2000). Such "emergency" requests from the states are routinely granted. *See, e.g.*, Carbofuran; Receipt of Application for Emergency Exemption, Solicitation of Public Comment, 63 Fed. Reg. 31,464 (1998); Carbofuran; Receipt of Application for Emergency Exemption, Solicitation of Public Comment, 63 Fed. Reg. 17,177 (1998); Carbofuran; Receipt of Application for Emergency Exemption, Solicitation of Public Comment, 63 Fed. Reg. 26,592 (1998); Carbofuran; Receipt of Application for Emergency Exemption, Solicitation of Public Comment, 62 Fed. Reg. 26,313 (1997). Each of these proposals was subsequently accepted as an emergency exemption. *See, e.g., supra* note 99.

146. *See, e.g.*, Atrazine, Simazine and Cyanazine, Notice of Initiation of Special Review, 59 Fed. Reg. 60,412, 60,415 (1994) (indicating that the first special review of cyanazine resulted in restricted uses and labeling amendments); Alachlor; Notice of Intent to Cancel Registrations; Conclusion of Special Review, 52 Fed. Reg. 49,480 (1987) (indicating EPA's agreement not to cancel pesticide if registrant agrees to comply with use restrictions and label amendments.) Explaining why, after testing showed brain damage to laboratory fetal rats, EPA negotiated a multi-year phaseout rather than implementing an immediate ban on household products containing chlorpyrifos, EPA Administrator Carol Browner noted that "[t]his is the fastest possible action that we could have taken . . . If we had been forced to go through the legal process [for a recall or immediate ban] it would have taken . . . years." *EPA Limits Sales of a Common Pesticide*, S.F. CHRON., June 9, 2000, at A12.

147. *See* 7 U.S.C. § 136d(b) (1994) (requiring EPA, in taking any final action under Special Review process, to consider restricting a pesticide's use as an alternative to cancellation.); *see also* 40 C.F.R. §§ 154.1 (2000) (allowing formal review procedures to be skipped if "risks can be reduced to acceptable levels"), 154.31(a)(2) (requiring that a Preliminary Determination include a determination of whether "any changes in the composition, packaging, labeling, or restrictions on use of a pesticide product," proposed by a registrant, would "reduce the risk so that the use no longer would satisfy any of the risk criteria" in the FIFRA regulations). In explaining the Special Review process, the RAINBOW REPORT notes that "the ultimate goal of the Special Review process is to reduce the risks posed by a pesticide to an acceptable level while taking into account the benefits provided by the use of that pesticide. RAINBOW REPORT, *supra* note 141, at 12. In describing "Negotiated Settlements," the report also notes that "[a]t any time in the review process, a registrant may reach an agreement with the Agency to modify the terms and conditions of a pesticide registration." *Id.*

causing pesticide contamination.¹⁴⁸ This creates a regulatory dilemma because low-level contamination to air, water, soil, and food products is relatively common in agricultural applications even when pesticides are used in a manner consistent with labeling directions.¹⁴⁹ Moreover, even where a violation can be established, it may be difficult to trace the causal link between the labeling or use infraction and specific contamination. Finally, where infractions lead to enforcement actions, there is little evidence that the moderate penalties imposed cause significant changes in the patterns of intensive pesticide use.¹⁵⁰

The EPA's efforts to eliminate the harmful environmental impacts from atrazine and cyanazine, carcinogenic herbicides with a propensity for contaminating surface and groundwater, illustrate the incremental enforcement problem.¹⁵¹ The special review process for these chemicals, begun in the mid- to late 1980s, resulted in labeling restrictions but no cancellation.¹⁵²

148. See, e.g., *Oregon Environmental Council v. Kunzman*, 714 F.2d 901, 905-06 (9th Cir. 1983) (finding compliance with labeling requirements despite unrefuted allegations that spraying operations caused exposures to skin and eyes of residents).

149. See, e.g., SUSAN KEGLEY ET AL., *DISRUPTING THE BALANCE: ECOLOGICAL IMPACTS OF PESTICIDES IN CALIFORNIA* 38-66 (1999).

150. Modest labeling or use penalties, while potentially effective against egregious violators, have little impact on the heavy pesticide use patterns in agricultural states such as California. See, e.g., SUSAN KEGLEY, STEPHAN ORME & LARS NEUMEISTER, *CALIFORNIANS FOR PESTICIDE REFORM, HOOKED ON POISON: PESTICIDE USE IN CALIFORNIA, 1991-1998* (2000). For example, DPR recently noted 685 enforcement cases by 42 agricultural commissioners representing a total of \$197,432 collected, or an average of \$288 per violation. DEPARTMENT OF PESTICIDE REGULATION, CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY, COUNTY AGRICULTURAL COMMISSIONER ADMINISTRATIVE CIVIL PENALTY REPORT 2 (1999). See also *Panhandle Co-op. Ass'n, Bridgeport, Neb. v. Env'tl. Prot. Agency*, 771 F.2d 1149, 1151 (1985) (imposing a \$5,000 fine for labeling violations on a pesticide company with annual sales of \$35 million); Department of Pesticide Regulation, California Environmental Protection Agency, *Department of Pesticide Regulation Takes Action to Suspend License of Kern County Pesticide Business*, Aug. 20, 1997, available at <http://www.cdpr.ca.gov/docs/archives/pressrls/1997/inland.htm> (noting that numerous notices of violations and civil penalties had previously been filed against the applicator prior to license suspension); Department of Pesticide Regulation, California Environmental Protection Agency, *Monterey County Pesticide Applicators Fined for Pesticide Misuse*, May 17, 1996 (announcing fines, for violations of restrictions on Methyl bromide use, of only \$800 and \$3,000). In addition, penalties for use or label violations have little if any effect on pesticide manufacturers.

151. Atrazine was first registered in 1959, and cyanazine in 1971, both before the passage of FIFRA's unreasonable risk standard. See *Atrazine, Simazine and Cyanazine; Notice of Initiation of Special Review*, 59 Fed. Reg. 60,412, 60,414-16 (1994).

152. See *Atrazine, Simazine and Cyanazine*, *supra* note 151; *Cyanazine; Intent to Cancel Registrations, Denial of Applications for Registrations, Conclusion of Special Review* 53 Fed. Reg. 795 (1988). Each of these reviews concluded with application restrictions to protect handlers and applicators and label amendments warning of

The EPA reinitiated special review in 1994, however, after uncovering additional information regarding exposures to workers and the environment.¹⁵³ Nevertheless, today, despite evidence of unreasonable environmental risk dating back to the mid-1980s, both chemicals are still in use, although cyanazine is currently scheduled to be phased out of use by the year 2002.¹⁵⁴

d. *Limits of FIFRA in Promoting Non-Toxic Alternatives*

FIFRA's greatest shortcoming as a protective statute lies in its failure to promote safer, non-toxic alternatives to pesticide products. As a licensing statute, FIFRA necessarily focuses the regulatory debate on pesticide manufacturers and distributors, both of which hold strong vested interests in continuing the long-term use of chemically-based pest control.¹⁵⁵ Through its focus on pesticide "risk," FIFRA's administrative process becomes dominated by quantitative risk assessment, in which incremental risk reduction is accomplished one pesticide use at a time for individual chemicals. This approach inevitably minimizes attention on alternative forms of pesticide control that might be just as acceptable to pesticide users.¹⁵⁶ In registering pesticides, for example, the EPA is not authorized to deny a registration based solely on the existence of a preferred less

toxicity and the potential for leaching. During this time, the EPA requested data on both chemicals for additional toxicity studies, usage, ground and surface water monitoring and environmental fate and ecological effects.

153. Atrazine, Simazine and Cyanazine, *supra* note 151.

154. In 1996 EPA entered into an agreement to cancel the registration for cyanazine through a voluntary six-year phaseout period, 17 years after the initiation of the first Special Review. See Cyanazine; Notice of Final Determination to Terminate Special Review of Cyanazine, Notice of Voluntary Cancellation and Cancellation Order of Cyanazine Product Registrations, 61 Fed. Reg. 39,024 (1996). The final cancellation order was issued on January 6, 2000. Cyanazine; Cancellation Order, 65 Fed. Reg. 771 (2000). Meanwhile, over 12 years after initial "Special Review," EPA is still interpreting testing results indicating previously unrecognized routes of carcinogenicity for atrazine See FIFRA Scientific Advisory Panel, 64 Fed. Reg. 73,045, 73,046 (1999) (reviewing atrazine cancer risk assessment to provide comments on the adequacy of EPA's approach to addressing potential cancer hazard to children). EPA has also added simazine and propazine, additional triazine pesticides, to the ongoing special review process. See RAINBOW REPORT, *supra* note 141, at 28.

155. See Applegate, *supra* note 84, at 312.

156. Integrated pest management, or "IPM," combines biological, cultural, physical and chemical tools to manage pests. IPM relies on collection and interpretation of field data to determine pest infestation thresholds, protect non-target and beneficial species, and utilize predators and parasites. In emphasizing sustainability and healthy ecosystems, traditional IPM relies on chemical controls only as a measure of last resort.

harmful alternative.¹⁵⁷ In enforcement actions, FIFRA's cost benefit analysis discourages significant consideration of reduced or non-chemical methods of pest control by creating an artificial comparison between a world based on heavy pesticide use and one in which pests are uncontrolled.¹⁵⁸ As a result, FIFRA places relatively little pressure on the agricultural industry to move towards alternative technologies that do not substantially rely on toxic chemicals.¹⁵⁹ To the extent that pressure is exerted by EPA, it is borne largely by manufacturers rather than users. Thus, instead of promoting non-toxic alternatives, FIFRA establishes a regulatory environment in which manufacturers can debate the merits of various EPA risk assessments for years, fortified by a comparatively unlimited amount of time and resources, particularly for those pesticides currently in use and earning daily profits.¹⁶⁰ By the time one pesticide's registration is ultimately canceled, a company is often ready to bring a new, but not necessarily less toxic, pesticide product to market.¹⁶¹ In sum,

157. *Merrell v. Thomas*, 807 F.2d 776, 781 (9th Cir. 1986) (distinguishing FIFRA from NEPA by noting that FIFRA does not imply a preference for the less environmentally harmful alternative.).

158. The feasibility of safer alternative designs is a key criteria of risk-benefit balancing in product liability law. *Brown v. Super. Ct.*, 44 Cal. 3d 1049, 1061 (1988). In *Brown*, the Court rejected as overly narrow the defendant drug manufacturers' argument that an alternative design was impossible, based on the reasoning that possible "alternatives" such as removal of a particular drug component that may be largely responsible for the increased risk or using alternative drugs to achieve the same medical result had not been explored. *Id.* at 1062. Under FIFRA, the absence of a readily available pesticide alternative would likely prevent an EPA enforcement action. See, e.g., *Love v. Thomas*, 858 F.2d 1347, 1362 (9th Cir. 1988) (stating that EPA's "insensitivity to the local economic problems caused by its decision is unbecoming and inappropriate"); *Env'tl. Def. Fund v. Env'tl. Prot. Agency*, 510 F.2d 1292, 1302 (1975) (reviewing EPA's finding that existing pesticide alternatives are just as effective in controlling pests under substantial evidence standard).

159. Restrictive labeling neither affects the behavior of pesticide manufacturers nor creates incentives for the agricultural industry to reduce its dependence on pesticides. See *supra* note 150.

160. The length of EPA's 20-year struggle to reign in the adverse environmental impacts of the triazine pesticides, as discussed above, is wholly consistent with EPA's earlier efforts to cancel harmful pesticides in the 1980s. Actions against Captan, ethylene bisdithiocarbamates (EBCDs) and Alar took 9, 12 and 17 years respectively. See Hornstein, *supra* note 97, at 437-38 ("informational demands of risk analysis doom the regulatory process to a perpetual state of slow motion."); Marina M. Lolley, *Carcinogenic Roulette: A Game Played Under FIFRA*, 49 MD. L. REV. 975, 991 n.141 (1990).

161. See, e.g., Wendy Williams, *Pirate Fear: Controversy Heats Up About Chlorfenapyr, a.k.a. Pirate—A Pesticide Some Claim Is the Next DDT*, SCI. AM., Sept. 15, 1999 (describing a new pesticide manufactured by American Cyanamid); Department of Pesticide Regulation, California Environmental Protection Agency, *DPR Approves 20 New Chemicals in 1999, Adds Staff to Expedite Reduced Risk Registrations*, Jan. 28, 2000, available at

despite EPA's authority to push for safer chemical alternatives,¹⁶² the scope of the debate still rests tightly within the control of the pesticide industry.¹⁶³

B. Other Federal Laws Regulating Pesticide Use

FIFRA's regulatory shortcomings are particularly problematic due to the fact that commercial pesticide applications by and large escape regulation under traditional command and control statutes such as the federal Clean Water Act and Clean Air Act. The Clean Water Act specifically excludes "agricultural stormwater discharges and return flow from irrigated agriculture" from its regulatory ambit.¹⁶⁴ Many other forms of agricultural pollution are considered "non-point source" discharges and are not directly regulated.¹⁶⁵ In similar fashion, the Clean Air Act does not consider agricultural operations to be "stationary sources" subject to regulation under the hazardous air pollutant program.¹⁶⁶ Thus, aerial pesticide drift from

<http://www.cdpr.ca.gov/docs/pressrls/pmgrant2.htm>. The new 1999 registrations include 1 agricultural bio-insecticide, 2 agricultural fungicides, 2 agricultural insecticides, 1 agricultural herbicide, a turf herbicide, a mosquito larvicide, and an industrial insecticide, anti-microbial and anti-foulant. *Id.* at 2. In fact, the pace and timing of EPA's administrative review process creates market incentives of registrants to introduce new and more potent pesticide products every decade or so. See Brian Tokar, *Monsanto: A Checkered History*, 28 THE ECOLOGIST 254 (1998).

162. Newly registered pesticides by EPA often promise to replace those more environmentally damaging chemicals of the previous generation. See, e.g., Office of Pesticide Programs, U.S. EPA, *Conditional Registration of Isoxaflutole*, at <http://www.epa.gov/pesticides/chemicals/isoxaflu.htm> (Sept. 1998) (allowing use of a new conditionally registered chemical instead of atrazine, a known contaminant); Office of Pesticide Programs, *supra* note 132 (newly registered pesticide acetochlor is designed to substitute for herbicides alachlor, metolachlor, atrazine, EPTC, butylate and 2,4-D).

163. As discussed, despite its strong protective language, FQPA's fundamental reliance on quantitative risk assessment as the principal tool of regulation limits its ability to break this cycle. See *supra* notes 131-137 and accompanying discussion.

164. See 33 U.S.C. § 1362(14) (1994).

165. The Clean Water Act applies technology-based controls to "point source" discharges, see 33 U.S.C. § 1311 (1994), but largely leaves the regulation of non-point pollution sources to states based on recommended "best management practices." 33 U.S.C. § 1314(f)(2)(A) (1994) (requiring EPA to issue "processes, procedures, and methods to control pollution resulting from agricultural and silvicultural activities, including runoff from fields and crops and forest lands"); see also Nat'l Wildlife Fed'n v. Gorsuch, 693 F.2d 156, 164-166 (D.C. Cir. 1982); *infra* note 208 and accompanying discussion regarding California's regulation of non-point source pollution.

166. 42 U.S.C. § 7412(a) (1994) limits regulation of sources of hazardous air pollutants to stationary sources, which are defined in 42 U.S.C. § 7411(a)(3) (1994) as "any building, structure, facility or installation which emits or may emit any air pollutant." See also 40 C.F.R. § 61.02 (2000). Even if the EPA had created a source