

# ENVIRONMENTAL LAW REVIEW

## NOTE

### INERT INGREDIENTS AND PESTICIDE REGISTRATION DATA REQUIREMENTS: EPA'S COMPLACENCY COMPOUNDS FIFRA'S INADEQUACIES

#### INTRODUCTION

One of the more difficult regulatory balancing tests currently facing the Environmental Protection Agency (EPA)\* is to control the deliberate release of pesticides into the environment. Pesticide use results in both the taking and the saving of life, and it occurs in virtually every facet of society, including the home, the farm, and the workplace.<sup>1</sup> When society determines that a particular organism is undesirable, and thus a pest,<sup>2</sup> technology is generally

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\* As a reference guide, the following common acronyms are used throughout this note:

CBI - Confidential Business Information

CFR - Code of Federal Regulations

EP - End Use Product

EPA - Environmental Protection Agency

FDA - Food and Drug Administration

FIFRA - Federal, Insecticide, Fungicide, and Rodenticide Act

GAO - General Accounting Office

OPP - Office of Pesticide Programs

MP - Manufacturing Use Product

TSCA - Toxic Substances Control Act

USDA - United States Department of Agriculture

1. MacIntyre, *Why Pesticides Received Extensive Use in America: A Political Economy of Agricultural Pest Management to 1970*, 27 NAT. RESOURCES J. 533, 536 (1987). In 1974, the distribution of pesticides in the market place was estimated to be: 15% residential use; 30% industrial, governmental, and institutional use; and 55% agricultural use. *Id.* at 536.

2. See 7 U.S.C. § 136(t) (1988) (definition of pest). Common definitions of pests include any organisms detrimental to humans. See, e.g., WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1689 (1971). As a result, such a broad term yields a similarly broad definition for

used to develop a chemical application to eradicate or regulate the organism. Pesticides are applied to protect a variety of targets, including food, fiber, home, and health.

While pesticide use benefits the user and society,<sup>3</sup> it also poses health and environmental risks. Because the scope of pesticide use is so broad, the risks of pesticide exposure to people and the environment are great. In an attempt to balance these risks against the benefits, Congress mandated that pesticide manufacturers register their products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),<sup>4</sup> no pesticide may be distributed in commerce unless the product is registered with the EPA.<sup>5</sup> Registrants<sup>6</sup> must submit data describing both the effectiveness of a pesticide for a particular use and its corresponding short and long term effects on people and the environment.<sup>7</sup> The EPA balances the economic, social, and environmental benefits against the respective burdens and will grant a registration if no "unreasonable adverse effects"<sup>8</sup> will result from the use of the pesticide.

Pesticides are formulated by combining specific amounts of different chemicals. The EPA's pesticide registration data scheme divides component chemicals into two categories based upon their use within a pesticide formulation.<sup>9</sup> These two categories are "active" and "inert" ingredients. "Active" ingredients include those chemicals that interact directly with the target pest and cause the intended effect.<sup>10</sup> "Inert" ingredients include all other chemicals present in a formulation that are not "active."<sup>11</sup> This regulatory distinction causes the EPA to require less stringent data to describe the effect of the inert ingredients on both human health and the environment.

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pesticide: anything used to eradicate or regulate pests. See 7 U.S.C. § 136(u) (1988).

3. MacIntyre, *supra* note 1, at 536. Agriculturally, a 2.2 billion dollar per year investment increases crop output 9% for an average return on investment of 400%. *Id.*

4. FIFRA is codified at 7 U.S.C. §§ 136-136y (1988).

5. See *infra* notes 17-32 and accompanying text.

6. A "registrant" is a person who has registered any pesticide pursuant to the provisions of this subchapter. 7 U.S.C. § 136(y) (1988). For purposes of this note, an applicant is a person attempting to secure a registration for a pesticide product by submitting the relevant required data.

7. See *infra* notes 58-73 and accompanying text.

8. 7 U.S.C. § 136a(c)(5) (1988). See generally *infra* notes 38-49 and accompanying text.

9. See *infra* notes 50-57 and accompanying text.

10. 7 U.S.C. § 136(a) (1988).

11. *Id.* § 136(m).

"Inert" ingredients are integral components of a pesticide and are often more toxic than their companion "active" ingredients.<sup>12</sup> Some ingredients classified as inert by the EPA are carcinogenic and mutagenic. These may cause brain disease, central nervous dysfunction, and liver, kidney, and lung damage.<sup>13</sup> Yet, the registration scheme treats most inerts as if they were, in fact, biologically inert. Neither the name "inert," nor the meager testing required for inerts, adequately reflect the potential health risks posed by this component of a pesticide product. Instead, the data required for inert ingredients reflect a regulatory perception that these chemicals do not affect organisms or interact with other substances. The active/inert distinction is an illogical basis for evaluating a pesticide product's potential toxicity.

This note reviews the pesticide registration data requirement scheme promulgated by the EPA. It principally focuses on the current regulation of inert ingredients in pesticide formulations and recent attempts by the EPA to assess more accurately the chronic toxicity of inerts. The note proposes both a comprehensive amendment and a more economically practical amendment to the present data requirements. Both proposals would allow the EPA to fulfill more effectively its responsibilities under FIFRA. Section I discusses the historical context and present state of pesticide regulation. This section reviews the general statutory framework. It also analyzes the registration data requirement scheme and the regulatory distinction between active and inert ingredients. Section I suggests that the requirement that toxicological data be based upon a chemical's intended use instead of its toxic propensity provides an incomplete picture of the potential of a pesticide to cause "unreasonable adverse effects."<sup>14</sup>

Section II confirms that inert ingredients are conclusively toxic and cause human and environmental damage. Section III presents attempts by the government to remedy the inadequacies of pesticide and inert ingredient regulation. This section discusses the statutory hurdles that hamper regulatory efforts by the EPA. It also reviews a 1987 Federal Register policy notice issued by the EPA to address the regulatory problems. Section III determines that the policy changes proposed by the EPA are inadequate. Fi-

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12. See *infra* notes 113-45 and accompanying text.

13. See *infra* notes 134-45 and accompanying text.

14. 7 U.S.C. § 136a(c)(5)(C)-(D) (1988).

nally the note concludes in Section IV that the EPA can not reasonably declare that a pesticide will not cause "unreasonable adverse effects on the environment"<sup>15</sup> without chronic toxicity data describing either the entire pesticide formulation or each of the inert ingredients present.

## I. PESTICIDE REGULATION UNDER FIFRA

### A. Historical Context of Pesticide Registration

Federal regulation of pesticides began under the 1910 Insecticide Act<sup>16</sup> which placed the regulatory authority in the Department of Agriculture (USDA). In 1947, Congress enacted the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) which repealed the 1910 Act.<sup>17</sup> FIFRA expanded the labeling requirements of the 1910 Act.<sup>18</sup> In addition, FIFRA required that pesticides be registered with the USDA before they could be sold in interstate commerce.<sup>19</sup> Applications for the registration of pesticides posing acute<sup>20</sup> exposure dangers were denied under the Act.<sup>21</sup> This registration process marked the first time the federal government sought to protect public safety from dangerous pesticides.<sup>22</sup> During the 1950's and 1960's, society became increasingly aware of the deleterious environmental effects and chronic<sup>23</sup> health problems attributable to pesticides.<sup>24</sup> As a result, Congress

15. *Id.* § 136a(c)(5)(c)-(d).

16. Act of Apr. 26, 1910, ch. 191, 36 Stat. 331, *repealed by* Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947, ch. 125, 61 Stat. 163, 172. Essentially, the 1910 act was a labeling law. W. RODGERS, JR., ENVIRONMENTAL LAW 846 (1977).

17. Federal Insecticide, Fungicide, and Rodenticide Act of 1947, ch. 125, 61 Stat. 163, *amended by* Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973 (codified as amended at 7 U.S.C. § 135 (1988)).

18. Comment, *The Federal Environmental Pesticide Control Act of 1972: A Compromise Approach*, 3 ECOLOGY L.Q. 277, 278 (1973). These labeling requirements were intended to provide minimum safety instructions for proper use. *Id.*

19. FIFRA, § 4(a), 61 Stat. 167 (1947). Registration was designed to insure that only reasonably effective products would be marketed. Comment, *supra* note 18, at 278.

20. "Acute" is defined to mean "characterized by sharpness and severity . . . having a sudden onset, sharp rise, and short course." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 23 (1971).

21. U.S. GENERAL ACCOUNTING OFFICE, PESTICIDES: EPA'S FORMIDABLE TASK TO ASSESS AND REGULATE THEIR RISKS, Pub. No. GAO/RCED-86-125, 11 (1986) [hereinafter FORMIDABLE TASK].

22. *See id.*

23. "Chronic" is defined to mean "marked by long duration, by frequent recurrence over a long time, and by slowly progressing seriousness." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 402 (1971).

24. FORMIDABLE TASK, *supra* note 21, at 11. *See also* CARSON, SILENT SPRING (1962).

amended FIFRA repeatedly<sup>25</sup> and vested in the Food and Drug Administration additional administrative authority.<sup>26</sup>

Despite these Congressional efforts, the pesticide registration scheme still did not provide the broad regulatory coverage that the federal government thought necessary.<sup>27</sup> Three fundamental events occurred in the early 1970's which expanded the protections of FIFRA. First, in 1970, the primary authority over pesticide regulation was transferred from the USDA to the newly created Environmental Protection Agency.<sup>28</sup> Second, in 1971, the United States Court of Appeals for the District of Columbia transferred to the manufacturers the burden of proof if substantial questions of safety arose about a pesticide.<sup>29</sup> Finally, in 1972, Congress amended FIFRA in its entirety.<sup>30</sup> Instead of focusing restrictions on ineffective or acutely dangerous pesticides, Congress broadened the regulatory focus to include pesticides posing unreasonable adverse effects on people or the environment.<sup>31</sup> These events culminated the evolution of FIFRA from a "primarily consumer protection and product performance" statute to a "public health and environmental protection" statute.<sup>32</sup>

### *B. Federal Insecticide, Fungicide, and Rodenticide Act*

The primary mechanism of FIFRA for regulating pesticide use is a registration requirement. Pesticides may not be distributed or sold to any person unless the pesticide is registered with the

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25. For example, amendments in 1959 increased the scope of FIFRA to include defoliants. Pub. L. No. 86-139 § 2, 73 Stat. 286 (1959). Amendments in 1964 further restricted registrations of both new and currently registered pesticides. Pub. L. No. 88-305 § 2, 78 Stat. 190 (1964).

26. 67 Stat. 631 (1954). 21 U.S.C. §§ 301-392 regulates maximum acceptable levels of pesticide residues in foods. 21 U.S.C. §§ 301-392 (1988).

27. See Spector, *Regulation of Pesticides by the Environmental Protection Agency*, 5 *Ecology L.Q.* 233, 233 (1976).

28. Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (1970), amended by Pub. L. No. 98-80, §§ 2(a)(2), (b)(2), (c)(2)(C), 97 Stat. 485 (1983), reprinted in 5 U.S.C. app. at 1343 (1988). This change reflected expectations that the EPA would be more concerned with long term risks associated with pesticide use than would the USDA. Spector, *supra* note 27, at 234.

29. *Environmental Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 593 (D.C. Cir. 1971).

30. 7 U.S.C. §§ 136-136y (1988).

31. *Id.* § 136a(c)(5).

32. *FORMIDABLE TASK*, *supra* note 21, at 11.

EPA.<sup>33</sup> The sale of unregistered pesticides is unlawful<sup>34</sup> and FIFRA provides civil and criminal penalties for non-compliance.<sup>35</sup> Congress granted the EPA the authority to prescribe interstitial regulations to effectuate the stated goals and provisions of the Act.<sup>36</sup> With respect to federalism concerns, FIFRA expressly allows states to regulate the sale and use of pesticides in a more stringent manner than the minimum requirements set forth by the Act.<sup>37</sup> As a result, the registration data requirements of FIFRA are the minimum constraints placed upon the introduction of pesticides into the environment.

Congress directed the EPA to grant an applicant's registration if its pesticide product meets four criteria.<sup>38</sup> First, the pesticide must prove effective in eradicating the target pest.<sup>39</sup> Second, the labels of the pesticide must provide adequate minimum safety instructions.<sup>40</sup> The remaining two criteria proscribe the use of pesticides which will cause "unreasonable adverse effects on the environment" either when performing its "intended function"<sup>41</sup> or when used "in accordance with widespread and commonly recognized practice."<sup>42</sup>

33. 7 U.S.C. § 136a(a) (1988).

34. *Id.* § 136j(a)(1).

35. *Id.* § 136l. Civil penalties range from not more than five hundred dollars for first time, private applicator offenses, to not more than five thousand dollars for any registrant, commercial applicator, wholesaler or other distributor who violates any provision of the act. *Id.* § 136l(a). Criminal penalties provide for fines up to twenty five thousand dollars and imprisonment up to one year. *Id.* § 136l(b).

36. *Id.* § 136w. The Act states that the regulations should account for differences in agricultural and non-agricultural pesticides. *Id.* § 136w(a)(1). The Administrator has the express authority to declare certain plant and animal life as pests and to determine particular substances as pesticides. *Id.* § 136w(c)(1)-(2). The Administrator also has the express authority to exempt certain pesticides from regulation. *Id.* § 136w(b).

37. *Id.* § 136v.

38. *Id.* § 136a(c)(5). Before approving a pesticide's registration, the Administrator must determine that:

- (A) its composition is such as to warrant the proposed claims for it;
- (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
- (C) it will perform its intended function without unreasonable adverse effects on the environment; and
- (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

*Id.*

39. *Id.* § 136a(c)(5)(A).

40. *Id.* § 136a(c)(5)(B).

41. *Id.* § 136a(c)(5)(C).

42. *Id.* § 136a(c)(5)(D).

The Act defines "unreasonable adverse effects on the environment" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."<sup>43</sup> In addition, the term environment is defined to include "water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these."<sup>44</sup> Congress intended the "unreasonable adverse effects" standard to impose a "cost-benefit" type of analysis on the EPA.<sup>45</sup> This balancing test is the foundation upon which the EPA makes all registration decisions under FIFRA.<sup>46</sup>

Congress gave the EPA the authority to specify the data requirements necessary to evaluate a pesticide's application for registration.<sup>47</sup> The EPA then uses this data to determine whether application of the pesticide will cause "unreasonable adverse effects to the environment." Congress expressly instructed the EPA to consider economic factors in the development of these data requirements.<sup>48</sup> As a result of this economic instruction, the EPA must undertake a dual cost-benefit analysis. The EPA must first balance the cost to industry of generating each data requirement against the contribution the data will make to the "unreasonable adverse effects" assessment.<sup>49</sup> Second, the EPA must balance the overall

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43. *Id.* § 136(bb).

44. *Id.* § 136(j).

45. W. RODGERS, JR., *supra* note 16, at 858. In making his or her determinations, the Administrator should reject an application for pesticide registration if adverse effects are found, "unless there are overriding benefits from the use of a pesticide." *Id.* (citing Senate Comm. on Commerce, Federal Environmental Pesticide Control Act of 1972, S. Rep. No. 970, 92d Cong., 2d Sess. 11 (1972)).

46. FORMIDABLE TASK, *supra* note 21, at 12.

47. 7 U.S.C. § 136a(c)(2)(A) (1988).

48. *Id.* The EPA considers cost effectiveness in terms of the economic impact on large and small pesticide producing and formulating firms, governments, and pesticide users. 47 Fed. Reg. 53,199 (1982). The EPA also considers the cost of data generation and pesticide registration as a percent of total development cost of a new pesticide product, which includes research, development, registration, plant construction, production, marketing, and other expenses. *Id.* For instance, when commentators suggested the levels of impurities required for identification and disclosure by the manufacturer should be low enough to have effectively identified the TCDD contamination in 2,4,5-T, the EPA ultimately disagreed. *Id.* Even where this was achievable, the Agency decided it was prohibitively expensive and often not cost effective. *Id.*

49. 7 U.S.C. 136a(c)(2)(A) (1988). Any changes to the pesticide registration data requirements scheme requires an "economic impact analysis" (EIA) to be prepared. W. RODGERS, JR., *supra* note 16, at 885. This helps to insure that the EPA considers the economic ramifications and food and fiber needs of the nation. *Id.* The emphasis on economic impact is particularly clear in the case of pesticide registration suspensions. If a pesticide must be suspended to prevent "imminent hazard[s] to human health," normally required consulta-

costs posed by use of the pesticide against the resulting benefits.

*C. Statutory and Regulatory Distinctions Between Active and Inert Ingredients*

In order to make regulatory judgments about the risks and benefits of a proposed pesticide product, the EPA developed a Data Requirements for Registration scheme.<sup>50</sup> Different data describing the product formulation and its ingredients are required in order to register a pesticide. Within this regulatory scheme emerges the primary regulatory distinction between active and inert ingredients. FIFRA, by its own terms, makes no distinction between active and inert ingredients under the "no unreasonable adverse effect" standard for registration. Though FIFRA expressly defines active and inert ingredients, it provides no statutory directive for the regulatory differentiation with respect to data requirements that the EPA administers. In fact, the sole provision of FIFRA relating to inert ingredients pertains to trade secret protection.<sup>51</sup>

FIFRA defines an active ingredient as "an ingredient which will prevent, destroy, repel, or mitigate any pest."<sup>52</sup> The Act then states that any ingredient which is not active is an inert ingredient.<sup>53</sup> These definitions do not relate to an ingredient's propensity to cause chronic health effects. The EPA defines active ingredient in a manner identical to the definition found in FIFRA.<sup>54</sup> The agency, however, expands the definition of inert ingredient to include the qualification that the ingredient must be intentionally added.<sup>55</sup> The EPA's active and inert ingredient distinction is based

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tions with the Scientific Advisory Panel and the USDA are waived but an EIA is, nevertheless, still required. 7 U.S.C. § 136d(b) (1988).

50. See 40 C.F.R. Part 158 (1989).

51. 7 U.S.C. §§ 136-136y (1988). Inert ingredients are defined in § 136(m) and then mentioned only once more in the statute, in § 136h(d), Protection of Trade Secrets and Other Information. Congress exempts from required submission "the identity or percentage quantity of any deliberately added inert ingredient of a pesticide" unless the chemical poses an unreasonable risk of injury to health or environment. *Id.* § 136h(d).

52. *Id.* § 136(a). Plant regulators, defoliants, and desiccants, which accelerate or retard aspects of plant growth or development, are also included within the scope of the definition. *Id.*

53. *Id.* § 136(m).

54. 40 C.F.R. § 158.153(a) (1989).

55. *Id.* § 158.153(f). In effect, this places other chemicals, which are not intentionally added, but not active, such as impurities, degradates, and metabolites, all of which are potentially toxicologically significant, into regulatory limbo. The Agency also broadens the def-

upon its obsolete data registration policy that assumes that the active ingredients found within a pesticide formulation will be the only ones that will cause unreasonable adverse chronic health effects.<sup>56</sup> The EPA has expressly recognized that the assumptions upon which its initial policy was based are no longer valid.<sup>57</sup>

#### *D. EPA Data Requirements for Pesticide Registration*

The data required to support a pesticide registration application depends upon the type of registration sought, the intended use for the pesticide product, and whether the EPA requires additional testing. FIFRA provides the following types of registrations: new "general use" pesticide registrations,<sup>58</sup> reregistrations of previously registered pesticides,<sup>59</sup> "minor use" pesticide registrations,<sup>60</sup> and "experimental use" pesticide registrations.<sup>61</sup> The data requirement profiles, which include all required data to support a pesticide registration, will vary for each of the different registration types. Because the EPA's treatment of the active and inert ingredient distinction is unrelated to the particular type of registration sought by an applicant, the different data required for active and inert ingredients remains consistent with each type of registration's data profile. As a result, this note's discussion of the EPA's treatment of active and inert ingredients will focus on new "general use" registrations and assume that the conclusions drawn can be extended to the other registration types.

Applicants seeking new "general use" pesticide registrations must identify the intended use of their product given only nine categories or "general use patterns."<sup>62</sup> Based on the specific in-

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initiation of an inert ingredient to include "a group of structurally similar substances if designated by the Agency." *Id.*

56. See *infra* notes 75-112 and accompanying text.

57. See *infra* notes 176-210 and accompanying text.

58. 40 C.F.R. § 158.20(b)(3) (1989).

59. *Id.*

60. *Id.* § 158.60.

61. *Id.* § 158.20(b)(2). In addition, based upon the data submitted, the Administrator must classify the pesticide for general use, restricted use, or both. 7 U.S.C. § 136a(d) (1988). This determination leads to restrictions in labeling and application. *Id.* FIFRA also confers upon the Administrator the authority to issue experimental permits, suspensions, cancellations, and conditional registrations. *Id.* §§ 136c-d. In each case, deviations in the data requirements may occur. Finally, FIFRA provides for the reregistration of all pesticides already registered prior to the regulation's promulgation "in the most expeditious manner practicable." *Id.* § 136a(g).

62. See 40 C.F.R. § 158.340 (1989). These categories include food crop and non food

tended use, the EPA promulgates a unique data requirement profile. FIFRA expressly instructs the EPA to account for differences in pesticide uses and environmental risks when deriving registration data requirements.<sup>63</sup> Despite the different data requirement profiles promulgated for each of the nine general use categories, the EPA continues to treat active and inert ingredients consistently throughout.

Notwithstanding the registration type and the intended use of the pesticide, the EPA reserves the right to require additional testing from an applicant.<sup>64</sup> The EPA expects that the information generally required for pesticide registration will be sufficient in most cases.<sup>65</sup> Where the EPA determines the required data is not sufficient, the Administrator may, on a case-by-case basis, require additional testing.<sup>66</sup> If the EPA determines additional testing is necessary, the data required to support the pesticide registration application will subsequently vary.

Generally, the data requirements for new general use pesticide registrations can be separated into three categories:<sup>67</sup> (1) product identity, analysis, and certification of limits (category I data);<sup>68</sup> (2) physical and chemical characteristics (category II data);<sup>69</sup> and (3) efficacy, health, and environmental impact data requirements (category III data).<sup>70</sup> The first and second categories of data are required for all general use patterns.<sup>71</sup> The efficacy, health, and environmental impact data requirements differ for each of the nine

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terrestrial uses, food crop and non-food crop aquatic uses, food crop and non-food crop greenhouse uses, forestry, domestic outdoor and indoor general uses. *Id.* A Use Pattern Index is included in Appendix A to the Data Requirements for Registration to aid in classifying "unique or ambiguous cases." 40 C.F.R. Part 158, App. A (1989).

63. 7 U.S.C. § 136w(a)(1) (1988).

64. 40 C.F.R. § 158.75 (1989).

65. *Id.* § 158.75(a).

66. *Id.* § 158.75(b). An explicit and definitive standard, by which the EPA decides if data is sufficient, is unavailable.

67. These categories have been created by the author to facilitate discussion of the data requirements.

68. *Id.* § 158.120. This first type of data is summarized in *id.* §§ 158.155-158.180.

69. *Id.* § 158.190. This second type of data is contained entirely in one table. *See id.*

70. *Id.* §§ 158.202-158.740. This data is tabulated in seventeen matrices in Subpart D of 40 C.F.R. Part 158 and includes residue chemistry (*Id.* § 158.240), environmental fate (*Id.* § 158.290), toxicology (*Id.* § 158.340), reentry protection (*Id.* § 158.390), spray drift (*Id.* § 158.440), wildlife and aquatic organisms (*Id.* § 158.490), plant protection (*Id.* § 158.540), nontarget insect (*Id.* § 158.590), product performance (*Id.* § 158.640), biochemical pesticides (*Id.* § 158.690), and microbial pesticides-product analysis (*Id.* § 158.740).

71. *See id.* §§ 158.120, 158.190.

general use patterns<sup>72</sup> and include notes listing qualifications for conditionally required data.<sup>73</sup> Review of these three categories of data reveals EPA's differential treatment of active and inert ingredients.<sup>74</sup>

### E. Regulation of Active and Inert Ingredients

The EPA requires new general use pesticide registrants to submit data concerning each of the three data categories. The data required is generated by using a particular test substance expressly mandated by the EPA. Any test substance, or combination of test substances, may be required by the EPA to be used to generate

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72. See *id.*, §§ 158.202-158.740.

73. See *id.*

74. Data requirements for each of these nine general use patterns are tabulated in a uniform manner throughout 40 C.F.R. Part 158. Each table presents the data requirements in matrix form. See 40 C.F.R. §§ 158.240-158.740 (1989). The first column identifies the kind of data required. See, e.g., *id.* § 158.340. The next nine columns correspond to the nine general use patterns. *Id.* Under each general use pattern, each particular data will be either required, conditionally required, or usually not required. *Id.* Whether the data is required, conditionally required, or usually not required depends on the general use pattern, the physical and chemical properties of the product, the expected human and environmental exposure, and/or the results of previous testing. 47 Fed. Reg. 53,193 (1982).

In all cases where a data type is required for a particular use pattern, the registrant must generate data to support both the pesticide's end use product (EP) and its manufacturing use product (MP). 40 C.F.R. § 158.102 (1989). An EP is a pesticide product used with directions for controlling pests or managing the growth of plants and is not used to manufacture or formulate other products. *Id.* § 158.153(b). An MP is "any pesticide product other than an end use product." *Id.* § 158.153(h).

All matrices in 40 C.F.R. Part 158 include test substance columns for both MP and EP in order to identify the material the registrant must use to generate each particular data. *Id.* § 158.102(a). "The test substance column specifies which substance is to be subjected to testing." *Id.* What substance is to be used to support the registration of MP or EP is often the active ingredient and not the MP or the EP. See *id.* §§ 158.240-158.740.

It is important to note the importance of the test substance used to generate data. Conclusions drawn from this data relate to whether the product will be granted registration or not. Yet the data used to accept or deny registration describes only the test substance used to generate the data and not the product actually sold and used. The manner and logic the EPA uses to proceed from data results of test substances to conclusions of effects and impacts of the pesticide product are crucial to insuring no unreasonable adverse effects to man or the environment will occur. From these matrices, one can determine whether a formulation or its inert ingredients are used to generate any data to support the contention that a pesticide product presents no unreasonable adverse effects on people or the environment.

Most of the standards, definitions, lab protocols, and other guidance for the tests and data described in this part are not specified in 40 C.F.R. Part 158. Instead, the information is available in advisory documents called Pesticide Assessment Guidelines (PAG) and is cross referenced with the appropriate data requirements matrices. *Id.* § 158.108.

data.<sup>75</sup> Test substances required by the EPA are almost exclusively one of the following: the manufacturing use product (MP),<sup>76</sup> the end use product (EP),<sup>77</sup> the technical grade active ingredient (TGAI),<sup>78</sup> or the pure active ingredient (PAI).<sup>79</sup> Inert ingredients alone are not required test substances for any of the efficacy, health, and environmental impact data requirements.<sup>80</sup>

The data generated by the test substance will only reflect the composition of the test substance. In those cases where the test substances required are EP's or MP's, the data generated will reflect the presence of inert ingredients because they are component ingredients in the EP or MP formulation. Conversely, where the test substance is a TGAI or a PAI, neither of which contain concentrations of inert ingredients, the data generated characterizes only the effects of the active ingredient and fails to describe the potential effects of the inert ingredient relative to that specific data type. Thus, the data generated by a TGAI or PAI test substance only demonstrates whether the active ingredient poses no unreasonable adverse effects. It does not, however, describe the effects of the entire formulation.

The EPA's current data requirement policy fails to address the synergistic effects of active and inert ingredients when combined within a particular pesticide formulation. Even if the EPA requires registrants to also test inerts, but continues not to test the EP, the data may not reveal how the inert ingredients interact with the active ingredients to change or increase the overall toxicity of the EP formulation. For example, two pesticides which have identical compositions, except for the substitution of one inert for another, would result in identical data submission for their registrations. Yet, if the substituted inert slows the degradation or evaporation of the active ingredients present, it may increase the severity of the resulting effects due to the increased exposure time.<sup>81</sup> By not using the EP formulation to generate chronic and

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75. 40 C.F.R. § 158 (1989).

76. *Id.* § 158.153(h).

77. *Id.* § 158.153(b).

78. A TGAI is defined to mean any material which contains an active ingredient produced commercially or on a pilot plant scale with no intentionally added impurities. *Id.* § 158.153(k).

79. No definitions are provided for PAI. *Id.* § 158.153.

80. *Id.* §§ 158.240-158.740.

81. For example, Omite-30W and Omite-CR are similar miticides that differ only with respect to their inert ingredients. Omite-CR, a newer version, provides for better wetting,

sub-chronic testing data,<sup>82</sup> either the EPA is overlooking the potentially significant synergistic effects of combining active and inert ingredients, or the Agency is disregarding these synergistic effects as negligible or irrelevant.<sup>83</sup>

The data required of inert ingredients found within a pesticide formulation is limited to category I data. Specifically, the EPA requires product composition information for each inert ingredient in a pesticide, including the following:<sup>84</sup>

- (1) The chemical name of the ingredient according to the Chemical Abstracts Society (CAS) nomenclature, the CAS Registry Number and any common names. If the identity or composition is unknown to the applicant because it is proprietary or trade secret information known only to the producer of the ingredient, the applicant must ensure that the producer submit this information to the EPA,<sup>85</sup>
- (2) The nominal concentration of the product;<sup>86</sup>
- (3) The upper and lower certified limits;<sup>87</sup> and
- (4) The purpose of the ingredient in the formulation.<sup>88</sup>

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longer exposure times, and slower degradation of the active ingredients. While the amount and identity of the active ingredient remained unchanged and the inert ingredient did not form new compounds with the active ingredient, the synergistic effects of the new proportions of inerts increased the adverse effects of the new pesticide's use upon people and the environment when compared to the old miticide's use. By testing only the active ingredients in the formulation, these changes in the effects go unnoticed due to the interaction of the pesticide's ingredients. R. Ames, R. Jackson, J. Knaak & L. Saunders, *Outbreak of Omite-CR-Induced Dermatitis Among Orange Pickers in Tulare County, California*, 29 *J. of OCCUPATIONAL MED.* 409 (1987).

82. See 40 C.F.R. § 158.340 (1989).

83. Consumer use through the sale of pesticides in interstate commerce serves as the actual testing because pesticide formulations are not tested for chronic type data prior to pesticide product registration, and, hence, prior to their sale. Chronic type effects of certain pesticides, such as ALAR and DDT, that are demonstrated through consumer use, compel the EPA to react by using its suspension and cancellation procedures, but only after humans and the environment have suffered unreasonable adverse effects. Chronic type effect testing through consumer use appears to be contrary to FIFRA's directives, and thus may be illegal.

84. 40 C.F.R. § 158.155(b) (1989).

85. *Id.* § 158.155(b)(1).

86. *Id.* § 158.155(b)(2).

87. *Id.* § 158.155(b)(3). Section 158.175, "Certified Limits," includes a table for calculating standard certified limits. Applicants may propose certified limits or choose to have them set by the EPA. *Id.* § 158.175. Certified upper and lower limits are the maximum and minimum concentrations of the ingredient found in the EP given variability under normal quality assurance procedures. *Id.* § 158.110.

88. *Id.* § 158.155(b)(4).

For each inert ingredient present, the EPA also requires:<sup>89</sup>

(1) Each brand name, trade name, or other commercial designation of the ingredient;<sup>90</sup>

(2) All information the applicant knows about the composition of the ingredient including specifications, data sheets, and other documents;<sup>91</sup> and

(3) If requested by the Agency, the name and address of the producer of the ingredient, or, if that information is not known to the applicant, the name and address of the supplier of the ingredient.<sup>92</sup>

The Data Requirements for Registration scheme does not require any category II or III data for inert ingredients to be submitted or that inert ingredients be used as test substances to generate any data.<sup>93</sup>

In contrast, the EPA requires considerable data under categories I, II, and III describing the "toxicological significance"<sup>94</sup> of active ingredients for pesticide registration. For example, the necessary tests designed to describe sixty-two percent of the physical and chemical characteristics found in category II require a species of the active ingredient for its test substance.<sup>95</sup> Throughout a significant majority of the category III test data, active ingredient test substances, TGAI's and PAI's, are required by the EPA.<sup>96</sup> Therefore, the differences between the pesticide registration data requirements for inert ingredients and active ingredients are dramatic.

The primary distinction of concern between the data require-

89. *Id.* § 158.160(a)(2).

90. *Id.* § 158.160(a)(2)(i).

91. *Id.* § 158.160(a)(2)(ii). Often the manufacturer does not have first hand knowledge of ingredients it uses to make a pesticide product. The EPA requires the manufacturer to submit only the information (of the types specified) that is available. No new tests for chemical composition are required. 49 Fed. Reg. 37,929 (1984).

92. 40 C.F.R. § 158.160(a)(2)(iii) (1989).

93. *See id.* § 158. Inspection of all matrices reveals that inert ingredients are never required test substances for purposes of generating data.

94. "Toxicological significance," as used by the EPA (*See, e.g.*, 40 C.F.R. § 158.155 (1989)), is purposefully ambiguous to allow the EPA discretion to require additional data whenever the situation warrants it. "Toxicological significance" is a function of both toxicity characteristics and exposure potential. Neither of these terms is easily quantified; nevertheless, the Agency finds it difficult to establish a better criterion. 49 Fed. Reg. 37,934 (1984).

95. 40 C.F.R. § 158.190 (1989).

96. *Id.* §§ 158.202-158.740.

ments for inert and active ingredients is found in the toxicological effects testing requirements for the pesticide.<sup>97</sup> The test substance required for acute toxicological effects data is the EP.<sup>98</sup> This data reflects the presence and, therefore, some effects of both the active and the inert ingredients. Conversely, the test substance used to generate data describing the chronic type<sup>99</sup> toxicological effects of the pesticide is the TGAI or the PAI.<sup>100</sup> Because no inert ingredients are found within a TGAI or a PAI, the EPA does not demand data describing the chronic type effects of inert ingredients or of the entire pesticide product formulation.

As a result, the EPA uses data describing the acute effects of the entire formulation but the chronic type effects of only the active ingredient to determine if the pesticide poses no unreasonable adverse effects to people or the environment. This registration data requirement scheme focuses on active ingredients despite the EPA's awareness that inert ingredients may pose adverse health and environmental problems.<sup>101</sup> The EPA concluded that chronic type effects are largely a function of the active ingredient rather than the formulation<sup>102</sup> despite evidence that indicates that inert ingredients in pesticides cause chronic type effects in people and the environment.<sup>103</sup> In addition, this decision runs contrary to the EPA's own policy that the entire formulation be used to generate acute effects data.<sup>104</sup>

Considerations of economics and efficiency by the EPA, coupled with the historical focus of the statute on product performance and efficacy, present a plausible explanation for the illogical reliance of the registration data scheme on active ingredients for

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97. *Id.* § 158.340.

98. *Id.*

99. For purposes of this note, "chronic type" data will include chronic, subchronic, and mutagenic data.

100. 40 C.F.R. § 158.340 (1989).

101. FORMIDABLE TASK, *supra* note 21, at 85. See also *infra* notes 151-55 and accompanying text.

102. FORMIDABLE TASK, *supra* note 21, at 24.

103. See *infra* notes at 124-37 and accompanying text.

104. W. RODGERS, JR., 3 ENVIRONMENTAL LAW: PESTICIDES AND TOXIC SUBSTANCES § 5.8(A) (1988). The Agency can not accurately evaluate the toxicological significance, persistence, absorption, synergism, cumulative effects, metabolites, or degradation products unless it uses data derived from full pesticide formulation testing. O'Brien, *But What About the Other Half?: The Fascinating Tale of (Non-)Inerts*, 1986 J. PESTICIDE REFORM 6. In fact, some authorities characterize any quantitative risk assessment conducted without information describing the full pesticide formulation as "meaningless." *Id.*

chronic effect data. With about six hundred active ingredients, twelve hundred inert ingredients, and fifty thousand pesticide product formulations,<sup>105</sup> this approach provides dramatic economic benefits to both industry and the EPA.<sup>106</sup> This focus on active ingredients may also be a vestige of the historical focus of the regulations on the efficacy of a pesticide rather than its safety.<sup>107</sup>

Another flaw in the EPA's Data Requirements for Registration scheme is that the EPA's strategy for classifying chemicals as active or inert ingredients depends not on the toxicity or "activity" of the chemical on people or the environment but instead focuses narrowly on whether the chemical prevents, destroys, repels, or mitigates the target pest.<sup>108</sup> As a result, the same chemical may be considered active in one formulation and inert in another. The classification of a particular chemical as active or inert will result in potentially significant data requirement differences.<sup>109</sup> Requiring different data for a chemical depending on its use in different formulations rather than its propensity to cause unreasonable adverse effects is illogical because a chemical which poses chronic exposure risks as an active ingredient poses the same chronic exposure risks when used as an inert ingredient. In fact, of the fifty-seven inert ingredients identified in 1987 as posing toxicological concern,<sup>110</sup> thirty were also used in other pesticide products as active ingredients.<sup>111</sup> Of those thirty dual use chemicals, five had been cancelled as active ingredients, yet the EPA still permitted their use as inert ingredients.<sup>112</sup> This inconsistent treatment of inert and active ingredients raises serious doubts about whether the EPA can fulfill its obligation to insure that a newly-registered pesticide poses no "unreasonable adverse effects." Presently, the EPA has failed to adequately protect people and the environment from the unreason-

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105. FORMIDABLE TASK, *supra* note 21, at 23.

106. The reduction in the sheer amount of data required is enormous. Obviously, whatever data must be generated by industry must also be reviewed by the EPA. In addition, it is noteworthy that chronic data testing is more expensive than acute data testing due to the period of time required for experimentation and testing.

107. W. RODGERS, JR., *supra* note 104, § 5.8(A).

108. See *supra* notes 52-57 and accompanying text.

109. See *supra* notes 75-100 and accompanying text.

110. See *infra* notes 176-84 and accompanying text.

111. NATURAL RESOURCES DEFENSE COUNCIL, MEMO ON INERTS OF TOXICOLOGICAL CONCERN (1987).

112. *Id.* Benzene, carbon tetrachloride, hexachlorophene, and DDT, chemicals banned as active ingredients, were subsequently allowed by the EPA as inert ingredients in food use pesticides. O'Brien, *supra* note 104, at 6.

able adverse effects of pesticide use.

## II. INERT INGREDIENT EXPOSURE PROBLEMS UNDER THE CURRENT REGISTRATION SCHEME

One manifestation of the inadequacies concerning the regulation of dangerous inert ingredients in pesticides is the harm that exposure to inert ingredients in pesticides has caused to people and the environment.<sup>113</sup> Congress, in FIFRA, recognized that pesticides may be harmful to people and the environment when, in 1947, it referred to pesticides as "economic poisons."<sup>114</sup> Consequently, Congress requires the EPA to deny pending pesticide registration applications and suspend or cancel existing applications if the effects of pesticide use on people or the environment are "unreasonably adverse."<sup>115</sup> Practically, however, any prediction regarding the extent of harm that must occur before the costs will outweigh the benefits of the use of the pesticide is unclear, imprecise, and unique for each pesticide.<sup>116</sup>

Despite that pesticides, in general, and inert ingredients, in particular, may cause harm, proof of causation is particularly difficult. Proof of causation becomes legally necessary if one is going to attribute certain harms to specific pesticides and if the EPA is going to include pesticide harms within the risk considerations of the regulatory balancing tests. A pesticide's potential to cause harm<sup>117</sup> varies with each exposure, which may be acute or chronic.<sup>118</sup>

The terms "acute" and "chronic" used in this context modify

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113. The deliberate release of billions of pounds of pesticides into the environment resulting in both the taking of life and the saving of life describes, in one manner, the balancing test the EPA is saddled with and what some academicians would call "the world's foremost pollution problem." W. RODGERS, JR., *supra* note 16, at 836.

114. *Id.* at 847.

115. *See supra* notes 38-49 and accompanying text.

116. *See supra* notes 38-49 and accompanying text.

117. A pesticide's potential to cause harm is a function of three qualities: persistence, formulation, and toxicity. Lindelef, *California Farmworkers: Legal Remedies for Pesticide Exposure*, 7 STAN. ENVTL. L.J. 72, 79 (1987-88). Persistence refers to that length of time, under normal environmental and application conditions, that the chemical remains pesticidally active. *Id.* Pesticides can be categorized as nonpermanent, persistent or permanent depending on this period of activity. *Id.* Formulation refers to "composition, form, mixing technique, and method of application of a pesticide." *Id.* A pesticide's formulation relates to the method of exposure and contact, and correlates to the resulting level of toxicity. *Id.* at 79-80. Toxicity refers to a chemical's harmfulness to humans. *Id.* at 80. Finally, degradation and synergistic effects of pesticides are also relevant considerations of toxicity. *Id.*

118. *Id.* at 81.

both an instance of pesticide exposure and any resulting effects.<sup>119</sup> Acute effects of pesticide exposure provide relatively easy causation conclusions because the harm resulting from the exposure is rather immediate. However, some symptoms of acute pesticide exposure make proof of causation more difficult because they often resemble those of the common flu or cold and less often resemble those of numerous other conditions and diseases.<sup>120</sup> Proving causation in chronic exposure situations is more difficult because the effects are often less well known, long term, or latent.<sup>121</sup> Causation problems are further hampered by the ordinary epidemiological difficulties in establishing the cause of latent, chronic effects such as birth defects and cancer in future generations.<sup>122</sup> The cumulative effect of these causation problems is a less than certain probability that a nexus can be proven to exist between exposure to a pesticide and an illness or condition. Consequently, scientists are reluctant to attribute responsibility for an illness or condition to the pesticide.<sup>123</sup>

Despite these causation problems, Congress is aware that these products are potentially harmful to people and the environment.<sup>124</sup> The EPA, however, has not demonstrated the same awareness regarding the potential chronic effects of exposure to inert ingredients or the entire formulation as it has shown for chronic effects from active ingredient exposure. Recent studies demonstrate that inert ingredients in pesticide formulations can be more toxic than the active ingredients in the same pesticide.<sup>125</sup> In addition, a variety of pesticide exposure cases, where the harm is attributed to the inert ingredients, further document the toxicity

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119. Health effects and pesticide exposures can occur in both short term and long term contexts. It is not necessarily true, though, that acute exposures will lead to acute effects.

120. *Id.*

121. *Id.* Death in the event of an acute pesticide exposure is possible but rare. Acute exposure symptoms are nevertheless difficult to attribute to pesticides due to similarities with the symptoms of other diseases and conditions. Chronic exposure to pesticides is suspected of causing neurological effects, reproductive disorders, birth defects, cancer, liver and kidney tumors, and leukemia. *Id.*

122. *Id.* at 82.

123. *Id.* Conclusively establishing a nexus is complicated by problems of isolation and identification of various potential factors, latency, synergistic effects, and multiple causation. Data on pesticide effects is also incomplete; latent carcinogenic or teratogenic effects were not considered until the 1970's. Predictably, the causation problem is a frustrating one for scientists. *Id.*

124. See *supra* notes 114 & 115 and accompanying text.

125. D. MONROE, ECOTOXICITY OF SURFACTANTS USED IN VEGETATION MANAGEMENT I (Nov. 1, 1988) (unpublished memorandum).

of inerts.<sup>126</sup>

Recent studies demonstrate that surfactant inerts,<sup>127</sup> used as "carriers" or "spreaders" in pesticide applications and frequently made of diesel fuel or kerosene, cause cancer in laboratory animals.<sup>128</sup> Benzene and polynuclear aromatic hydrocarbons, known components of these surfactants, cause cancer in humans.<sup>129</sup> Other carcinogenic components in petroleum surfactants have very long or nearly permanent periods of persistence.<sup>130</sup> They "accumulate in living organisms, disperse throughout the body, and disrupt cell membrane function."<sup>131</sup> These characteristics compel scientists to suspect that surfactant inert ingredients pose hazards to human health and environmental quality.<sup>132</sup>

Most importantly, documented cases of exposure to methylene chloride,<sup>133</sup> orthodichlorobenzene,<sup>134</sup> polyoxethyleneamine,<sup>135</sup> and trichloromethane,<sup>136</sup> all inerts found in pesticides registered with

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126. See *infra* notes 133-36 and accompanying text.

127. Monroe, *supra* note 125, at 1. Inert ingredients are often used in pesticide formulations because of their cleansing, wetting, or dispersing properties. *Id.*

128. *Id.*

129. *Id.*

130. *Id.*

131. *Id.* at 2.

132. *Id.* Monroe cites the susceptibility of fish to synthetic surfactants and the effect of surfactants on trees as further evidence of the toxicity of inert ingredients.

133. A study of 27 autoworkers contends that "organic brain disease and central nervous dysfunction" may result from chronic exposure to methylene chloride. NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES, 1 TECHNICAL REPORT 4 (1986).

134. The Occupational Safety and Health Administration (OSHA) attributes liver, kidney, and lung damage to high concentrations of orthodichlorobenzene. One hundred and six worker compensation claims were filed when post office workers in Oklahoma City were exposed to high concentrations of the inert ingredient in a deodorizer. The EPA states that this chemical is registered as both an inert and an active ingredient for various pesticide uses. Curtis, *Orthodichlorobenzene: Another Pesticide Inert That Isn't Inert*, 8 J. PESTICIDE REFORM 29 (1988).

135. Japanese physicians report that polyoxethyleneamine, an inert ingredient in the popular pesticide Roundup, is over three times as acutely toxic as the active ingredient found in the same pesticide. The physicians attribute gastrointestinal and central nervous system symptoms and hemolysis to Roundup poisonings. Cox, *Roundup's "Inert" Surfactant is Poisonous*, 8 J. PESTICIDE REFORM 30 (1988).

136. Methylene Chloride and trichloromethane comprise 94.8% of a formulation of diazinon called PT-260. Symptoms from exposure to diazinon have been attributed to these inert ingredients instead of the pesticide's active ingredients. The EPA suspects methylene chloride causes adverse neurological and mutagenetic effects; yet, while the chemical has been banned by the EPA for active ingredient uses, the Agency still allows the chemical to be used as an inert in pesticides (as of 1988). In addition, trichloromethane is suspected of causing cancer in animals and is used as both an active and an inert ingredient in pesticides. Cox, *Is an Oil Spill a Convenient Hiding Place for "Inert" Chemicals?*, 8 J. PESTICIDE RE-

the EPA, further demonstrate the toxicity of inert ingredients. In addition, inerts often react with the active ingredient and create a synergistic effect making the pesticide formulation more hazardous to human health and environmental quality.<sup>137</sup>

Given documented proof that inert ingredients can cause their own unreasonable adverse effects, the present scheme of pesticide registration regulations is inadequate in a number of ways. First, the EPA determines the potential of a pesticide product for causing unreasonable adverse chronic effects by evaluating data that describes only the active ingredient. Second, the EPA's distinction between active and inert ingredients is arbitrarily based upon the chemical's purpose in the formulation.<sup>138</sup> Third, equally arbitrary and confusing is the EPA's policy that classifies the same chemical as both active and inert in different formulations.<sup>139</sup> This policy allows a chemical that is banned as an active ingredient due to its toxicity to still be used as an inert ingredient.<sup>140</sup> Finally, the current registration data requirements provide the EPA limited information,<sup>141</sup> which may not even be submitted if the inert is a proprietary secret of its producer.<sup>142</sup> This scheme is hardly sufficient to allow for an adequate evaluation of the health and environmental effects of these chemicals.

While the present registration system fails to prevent the use of pesticides containing inert ingredients that cause unreasonable adverse effects to people and the environment, the inadequacies of the data requirements create administrative problems worthy of correction. The use of incomplete or inaccurate data describing the pesticide products hinders attempts to address damage that might occur as well as attempts to remedy harms to people and the environment.<sup>143</sup> Moreover, the suspension and cancellation procedures operate in a less efficient and often mistake-plagued fashion due to

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FORM 27 (1988).

137. One example is found in the case of Omite-CR and the outbreak of dermatitis cases among 114 orange pickers due to longer degradation periods of the active ingredient when combined with a different proportion or kind of inert ingredients. Ames, Jackson, Knaak & Saunders, *supra* note 81, at 1.

138. See *supra* notes 52-56 and accompanying text.

139. See *supra* notes 108-12 and accompanying text.

140. See *supra* note 112 and accompanying text.

141. See *supra* notes 84-93 and accompanying text.

142. See *infra* note 161 and accompanying text.

143. O'Brien, *supra* note 104 at 7. For instance, if medical care is required due to exposure to an inert, proper diagnosis may be compromised when inadequate data fails to reveal potential risks.

the absence of complete toxicological data.<sup>144</sup> Finally, procedures for pesticide application in public places are often inadequate due to inaccurate or unavailable information.<sup>145</sup> Together, these problems also warrant a change in the pesticide regulation data requirement scheme.

### III. LEGISLATIVE AND ADMINISTRATIVE REACTION TO INADEQUACIES IN INERT INGREDIENT REGULATION

#### A. *Hurdles Hampering EPA Remedial Efforts*

In recent years Congress, the EPA, and state legislatures have all reacted to the perceived inadequacies of the regulation under FIFRA of pesticides in general and inert ingredients in particular. Pressure to resolve shortcomings in the Act overcame Congress's reluctance to amend FIFRA.<sup>146</sup> Congress responded by introducing a flurry of unsuccessful bills aimed at improving the regulation of inert ingredients in pesticides.<sup>147</sup> Despite the introduction of several bills<sup>148</sup> designed to increase the EPA's ability to regulate inerts, to require the labelling of inerts, and to classify harmful inerts as active, Congress failed to amend FIFRA until 1988.<sup>149</sup> Congress' concern over the backlogged reregistration process led to the 1988 amendment that largely included an accelerated reregistration plan and a limited indemnification program, but failed,

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144. Telephone interview with Ms. Gylene Basetaros, attorney for the U.S. Environmental Protection Agency (January 10, 1990). If complaints are filed with the Agency with regards to a pesticide, incomplete data impairs its ability to engage in prompt cancellation or suspension procedures. *Id.*

145. O'Brien, *supra* note 104, at 7. The amount of time that must elapse between application and safe exposure by persons may be incorrectly calculated if based on incorrect or unavailable information.

146. Stiles, *Prospects for Policy Reform in FIFRA*, 43 *FOOD DRUG COSM. L.J.* 427, 428 (1988).

147. *Id.*

148. *E.g.*, S. 309, 99th Cong., 1st Sess., 130 *CONG. REC.* S773, S786 (daily ed. Jan. 29, 1985) (expanding the definition of active ingredient to include harmful inert ingredients); H.R. 2580, 99th Cong., 1st Sess., 131 *CONG. REC.* H3611, E2388 (daily ed. May 23, 1985) (requiring labels to include biologically active "inert ingredients"); S. 1303, 99th Cong., 1st Sess., 131 *CONG. REC.* S8239, S8203 (daily ed. June 17, 1985) (same as H.R. 2580); H.R. 2482, 99th Cong., 1st Sess., 131 *CONG. REC.* H3198 (daily ed. May 14, 1985) (allowing the Administrator to require harmful "inert" ingredients to be listed on product labels); S. 2215, 99th Cong., 2d Sess., 132 *CONG. REC.* S3128, S3132 (daily ed. Mar. 20, 1986) (requiring the EPA to develop a list of 50 inert ingredients that must be controlled and increasing the EPA's authority to regulate inert ingredients); H.R. 4364, 99th Cong., 2d Sess., 132 *CONG. REC.* H1023 (daily ed. Mar. 11, 1986) (companion bill to S. 2215).

149. Pub. L. No. 100-532, Title VII, 102 Stat. 2683 (1988).

however, to address any issue relevant to the regulation of inert ingredients in pesticides.<sup>150</sup>

Notwithstanding the efforts of Congress, efforts by the EPA to improve regulatory control of inert ingredients have also proved ineffective. Although the EPA is aware that certain inert ingredients toxicologically threaten people and the environment, the Agency knows very little about the specific toxicological significance of many inerts.<sup>151</sup> In 1986, the United States General Accounting Office reported that the EPA was "beginning to reassess the safety of inerts."<sup>152</sup> The EPA, however, has been aware of the toxicological threats posed by inerts and the shortcomings of the pesticide regulatory scheme since 1975.<sup>153</sup> For instance, in 1977, the EPA identified fifty-two inert ingredients which either required immediate investigation or indicated possible health hazards.<sup>154</sup> Despite this awareness, the majority of the EPA's pesticide initiatives continue to focus on certain active ingredients rather than on entire pesticide formulations or the risks created by inert ingredients.<sup>155</sup>

Certain factors outside the EPA's control also frustrate its efforts to review the relationship between inert ingredients and the registration data scheme. For example, the EPA's ability to adequately assess the "unreasonable adverse effects" of pesticide use

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150. 54 Fed. Reg. 18,076 (1989). Accelerating reregistration, expediting certain types of registration, paying for both changes through a fee system, regulating pesticide handling, and a specifically tailored indemnity program were the primary areas of focus of the amendment. *Id.* at 18,077. Industry and environmental groups agreed after prolonged negotiations that changes in the regulation of inerts were needed and that inert ingredient regulation should emulate active ingredient regulation. The EPA disagreed with both groups and the suggestion was cut out of the bill before passage. Ferguson, *Industry-Environmental Negotiation: The FIFRA Experience*, 17 ENVTL. L. REF. (Envtl. L. Inst.) 10,249, 10,251 (July, 1987).

151. FORMIDABLE TASK, *supra* note 21, at 84.

152. *Id.*

153. U.S. GENERAL ACCOUNTING OFFICE, FEDERAL PESTICIDE REGISTRATION PROGRAM: IS IT PROTECTING THE PUBLIC AND THE ENVIRONMENT ADEQUATELY FROM PESTICIDE HAZARDS?, Pub. No. RED-76-42, 21 (1976) [hereinafter PESTICIDE HAZARDS]. In fact, as early as 1972, the EPA considered its review process for inert ingredients used on food and feed crops as "a seat of the pants operation." *Id.* at 19 (quoting an EPA internal Toxicology Branch memo dated October, 1972).

154. FORMIDABLE TASK, *supra* note 21, at 84.

155. *Id.* at 85. For instance, the reregistration process, as proposed by the EPA and accepted by Congress, allows the Administrator to review active ingredients in pesticides rather than the formulated product. The EPA is allowed to disregard the potential synergistic effects of formulations and, instead, review only the roughly six hundred active ingredients registered rather than the roughly fifty thousand pesticide formulations. *Id.* at 13.

is directly affected by the Office of Pesticide Program's (OPP)<sup>156</sup> budget. With a twenty-nine percent reduction in staff between 1980 and 1985,<sup>157</sup> the likelihood that the OPP could sufficiently review additional data was slight.<sup>158</sup>

Moreover, FIFRA itself hinders the EPA's attempts to inform the public about inert ingredients. The Act allows registrants to jointly develop data necessary to meet pesticide registration data requirements.<sup>159</sup> The Act also states that "the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person."<sup>160</sup> The confidentiality provision of FIFRA, however, prevents the EPA from divulging the identity of inerts in registered pesticide products "unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment."<sup>161</sup> Consequently, where data is required for an inert protected under the confidentiality provision, public notification is precluded and any joint data development endeavor becomes impracticable. Therefore, conflicting policies of FIFRA—protecting trade secrets of pesticide formulations and providing an equitable, practical, and efficient manner for data generation—hinder efforts by the EPA to adequately inform the public about any "unreasonable adverse effects" caused by inert ingredients.<sup>162</sup>

Notwithstanding this lack of public awareness, the confidenti-

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156. The EPA is organized into subagencies, headed by politically appointed assistant administrators. An assistant administrator manages the Office of Pesticide Programs, the Office of Toxic Substances, and the Office of Compliance Monitoring. 2 ENVIRONMENTAL LAW INSTITUTE, LAW OF ENVIRONMENTAL PROTECTION § 4.01[2] (S. Novick ed. 1989).

157. FORMIDABLE TASK, *supra* note 21, at 45. In 1980, the EPA's pesticide program had about 830 employees. In 1985, the program had dwindled to about 590 employees. *Id.*

158. For the OPP, an office with insufficient resources to handle its current workload, any new project must compete with three other primary pesticide program focuses: (1) new product registrations; (2) the special review process for existing registrations; and (3) reregistrations for products registered prior to the present data requirement scheme. Telephone interview with Lynn Bradley, U.S. Environmental Protection Agency, Office of Pesticide Programs (Oct. 12, 1989) [hereinafter Bradley telephone interview].

159. 7 U.S.C. § 136a(c)(2)(B) (1988).

160. *Id.*

161. *Id.* § 136h(d).

162. Inert ingredients in pesticides often have extensive nonpesticidal uses and are supplied to pesticide manufacturers or formulators by outside suppliers. These suppliers are often not registrants under FIFRA; instead the active ingredient manufacturers (who perform health effects and exposure testing) and product formulators (who perform acute testing of the pesticide product) are registrants under FIFRA. FORMIDABLE TASK, *supra* note 21, at 88.

ality provision also leaves other registrants and the EPA unaware of pesticide formulations.<sup>163</sup> Registrants themselves are often unaware of the composition of the inert ingredients used in their own products. For instance, the 1972 oil embargo prompted the EPA to allow registrants to purchase scarce solvents and declare alternative inerts as potential substitutes in their formulations.<sup>164</sup> Given the large number of formulations containing solvents, this substitution policy leaves the EPA potentially ignorant of the actual formulation of thousands of pesticide products. Furthermore, many confidential statements of formulation are insufficient or inaccurate<sup>165</sup> because validation of active ingredients, important impurities, and inerts is uncertain.<sup>166</sup> Accordingly, not only is the public unaware of what inerts are in many pesticides, but so are actual registrants and the EPA.

The Toxic Substances Control Act (TSCA)<sup>167</sup> is another mechanism enacted by Congress that allows the EPA to require manufacturers to submit data concerning the use of certain chemicals. TSCA, however, has not proven to be an effective regulatory mechanism when employed in the pesticide context.<sup>168</sup> Although the goal of TSCA is to close gaps that exist among already existing statutes regulating chemicals,<sup>169</sup> it is inapplicable to pesticide chemicals.<sup>170</sup> TSCA forbids the EPA to require data concerning inert ingredients if the only justification for the requirement is that the inerts are found within pesticides.<sup>171</sup> Consequently, the EPA must work solely within the FIFRA framework to obtain the inert data necessary to determine and evaluate the effects of pesticide use. Finally, beginning in 1985, significantly more legislation dealing with pesticides was proposed at the state level than in previous years.<sup>172</sup>

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163. U.S. ENVIRONMENTAL PROTECTION AGENCY, DISCUSSION PAPER ON INERTS 2 (Oct. 25, 1984) (prepared for the Administrator's Pesticide Advisory Committee, Washington, D.C.).

164. *Id.*

165. *Id.*

166. *Id.*

167. Pub. L. No. 94-469 (1976), redesignated Pub. L. No. 99-519, § 3(c)(1), 100 Stat. 2989 (1986) (codified as amended at 15 U.S.C. §§ 2601-29 (1988)).

168. FORMIDABLE TASK, *supra* note 21, at 89.

169. *Id.*

170. *Id.*

171. *Id.*

172. Stiles, *supra* note 146, at 429 n.15. This fact was disclosed by representatives of the agricultural chemical industry who monitor state legislation. See *infra* notes 214-19 and accompanying text. For instance, California passed legislation requiring pesticides to undergo state tests in response to reports of inadequate health and safety testing in FIFRA.

Industry's position on the regulation of pesticidal inert ingredients also hampers the efforts of the EPA to regulate inerts. In 1987, a National Agricultural Chemicals Association (NACA) representative stated that industry and environmentalists agree that FIFRA should regulate inert ingredients in the same way it regulates active ingredients.<sup>173</sup> The NACA now, however, states that the current regulatory scheme, unchanged since 1987, is reasonable and should not be changed.<sup>174</sup> Furthermore, other industry representatives feel that any regulation of inerts should take place under TSCA due to its broader alternatives and the extensive use of inerts outside the pesticide arena.<sup>175</sup> These inconsistent and divergent positions create a climate wherein the EPA will meet opposition regardless of its regulatory agenda.

### *B. EPA's Attempt to Evaluate Inert Ingredients*

In 1985, the EPA culminated a three year study by classifying inert ingredients according to their toxicity.<sup>176</sup> Inerts were separated into four categories according to toxicological notoriety: immediate toxicological concern (list 1), suspected toxicity (list 2), unknown toxicological concern (list 3), and innocuous (list 4).<sup>177</sup> These lists created logical priorities which the EPA used to guide its actions.<sup>178</sup> It was not until April 22, 1987 that lists 1 and 2, new

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See *infra* note 218 and accompanying text.

173. Ferguson, *Industry-Environmentalists Negotiation: the FIFRA Experience*, 17 ENVTL. L. REP. (Envtl. L. Inst.) 10,249, 10,251 (July 1987).

174. Telephone interview with Dr. McAlister, representative of NACA (Oct. 3, 1989).

175. Telephone interview with Mr. Steve Kellner, representative of The Chemical Specialty Manufacturing Association (Oct. 4, 1989).

176. FORMIDABLE TASK, *supra* note 21, at 85. The Agency used information from the National Toxicology Program, the National Institute of Occupational Safety and Health, the International Agency for Research on Cancer, and other sources. Acute and chronic exposure data were available for those inerts that also serve as active ingredients in other pesticide products. *Id.*

177. *Id.* at 85-86. See also 52 Fed. Reg. 13,305, 13,305 (1987). List 1 inerts, inerts of immediate toxicological concern, included fifty-five chemicals identified as causing cancer, liver and kidney damage, and other adverse health effects; the chemicals include asbestos, benzene, cadmium, and carbon tetrachloride. *Id.* at 13,305, 13,306. List 2, inerts of suspected toxicity, contains fifty-one chemicals which have a chemical structure or other properties suggesting toxicity, and include toluene, xylenes, and glycol ethers. *Id.* List 4 contains 273 innocuous chemicals including foodstuffs, natural products, inorganic salts, and substances "generally regarded as safe (GRAS)" by the FDA. *Id.* at 13,307. Cf. 21 C.F.R. Part 182 (1989). Finally, List 3 contains 70% of all inerts, or between eight hundred and nine hundred chemicals. EPA lacks the health and safety data needed to establish the toxicity of these "inerts of unknown toxicological concern." FORMIDABLE TASK, *supra* note 21, at 86.

178. 52 Fed. Reg. 13,305, 13,307 (1987).

inert registrations and new food use registrations, respectively, were addressed in an Inert Ingredient Policy Statement (IIPS) issued by the EPA.<sup>179</sup> The EPA stated that available resources prevented the Agency from further regulating these categories, or even addressing lists 3 and 4 at all.<sup>180</sup> To date, the EPA has taken no further actions to address these four lists.

The IIPS issued by the EPA did change how some inerts would be treated under the FIFRA scheme.<sup>181</sup> The IIPS, however, continues to exist in notice form only and has not yet been promulgated into official regulations.<sup>182</sup> Consequently, the IIPS is not regulatory in nature and lacks legal authority.<sup>183</sup>

The IIPS focuses primarily on both new inerts and inerts of toxicological concern. For existing registrations of pesticides with inert ingredients from list 1, deviations from the then existing regulatory scheme include:<sup>184</sup> (1) that registrants are *encouraged* to substitute inerts from another category for the inert of concern;<sup>185</sup> (2) that registrants are directed to amend labels to include identification of the inerts present in the formulation; (3) that a "data call-in" is proposed that may require "as much data as would be required . . . for an active ingredient";<sup>186</sup> (4) that hearings may be held for some products to determine whether they should be cancelled; (5) that inerts used to act against a pest other than the target pest be reclassified as active ingredients;<sup>187</sup> and (6) that if an inert on list 1 has no food use application, its tolerance exemption will be revoked.

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179. *Id.* at 13,305.

180. *Id.* at 13,307.

181. *Id.*

182. *Id.* See also 40 C.F.R. Part 158 (1989). The EPA contends its goal is to subject all inerts to "tier one" data requirements but presents no plans for implementing this two and a half year old goal. Bradley telephone interview, *supra* note 158.

183. Telephone interview with Ms. Gylene Basetaros, attorney for the U.S. Environmental Protection Agency (January 10, 1990) [hereinafter Basetaros telephone interview].

184. 52 Fed. Reg. 13,305, 13,307 (1987).

185. *Id.* (emphasis added). EPA considers potential product liability as an added motivation to registrants to substitute for list 1 inerts. Bradley telephone interview, *supra* note 158.

186. 52 Fed. Reg. 13,305, 13,307 (1987). See also 7 U.S.C. § 136a(c)(2)(B)(1988); 40 C.F.R. Part 158 (1989).

187. It appears that these chemicals may continue to be classified as inerts if their purpose is not to act on pests of any kind. Therefore, the situation still exists where a chemical considered an active in a certain formulation or even banned as an active ingredient may be considered an inert ingredient in another formulation.

Although the EPA did not integrate the IIPS into its regulations, it subjects all registrants who refuse to substitute an inert from another list for a list 1 inert to a "data call-in."<sup>188</sup> The "data call-in" requires registrants to submit limited data requirements listed in the notice.<sup>189</sup> If registrants continue to refuse to substitute the inert, the "data call-in" requires registrants to submit the same data as is required for an active ingredient.<sup>190</sup> Ultimately, only five inerts of list 1 remain in registered products and the appropriate registrants are currently developing the additional data the EPA will use to evaluate toxicity and exposure effects of these chemicals.<sup>191</sup> Also, new registrations of products with list 1 inerts will generally be refused unless "the risk of unreasonable adverse effects . . . will be decreased by such a registration."<sup>192</sup>

The EPA approaches list 2 inerts in a less aggressive manner.<sup>193</sup> Review of these inerts is continuing on a case-by-case basis.<sup>194</sup> The EPA coordinates its efforts with the Office of Toxic Substances (OTS) in monitoring ongoing testing and gathering existing information.<sup>195</sup> The EPA does not require registrants to develop additional data. It will evaluate list 2 inerts as new data becomes available by other means.<sup>196</sup> If data indicates an inert should be moved from list 2 to list 1, the EPA will then initiate the procedures mentioned above for list 1 inerts.<sup>197</sup> New registrations of list 2 inerts will undergo the same closer scrutiny that existing list 2 registrations receive under this notice.<sup>198</sup>

Since 1987, the EPA has registered seven new inert chemicals that do not appear on any of the four lists.<sup>199</sup> The limited IIPS data<sup>200</sup> was required for all new inerts except where the OPP was

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188. Bradley telephone interview, *supra* note 158.

189. 52 Fed. Reg. 13,305, 13,308 (1987). The table is located in Section VI of the notice and is titled: Data Required To Evaluate Risks Posed by Inert Ingredients in Pesticide Products.

190. Bradley telephone interview, *supra* note 158.

191. *Id.*

192. 52 Fed. Reg. 13,305, 13,308 (1987).

193. *See id.*

194. *Id.*

195. Bradley telephone interview, *supra* note 158.

196. *Id.* New data can be expected to become available to the Agency through reports of accidents or exposures, and the exchange of data with other EPA offices.

197. 52 Fed. Reg. 13,305, 13,308 (1987).

198. *Id.*

199. Bradley telephone interview, *supra* note 158.

200. *See supra* notes 188-89 and accompanying text.

convinced that little or no exposure would result from the use of the pesticide product.<sup>201</sup>

The IIPS also addresses the inert confidentiality issue, but limits its scope to list 1 inerts.<sup>202</sup> First, the EPA requests the formulators of the inert to divulge the identity of the chemical to the registrant for labeling purposes.<sup>203</sup> The formulator or producer that submits the confidential information may also submit claims of Confidential Business Information (CBI) that the EPA will review.<sup>204</sup> If the EPA denies a CBI, it will inform the registrant of the identity of the chemical.<sup>205</sup> If the EPA accepts a CBI, it may still require the registrant to discover the identity of the inert.<sup>206</sup> This, in effect, forces the registrant either to persuade the formulator to reveal the identity of the inert or to substitute it with a different inert of a known identity. Once the EPA confirms that the registrant knows the identity of the list 1 inert, it will initiate further regulatory actions pursuant to the IIPS.<sup>207</sup> Finally, if a registrant attempts to register a new product with a list 1 inert, the EPA will deny the application and inform the applicant that it based the denial on the presence of the inert ingredient in the formulation.<sup>208</sup>

Although the IIPS alters the regulation of inerts under the FIFRA scheme, it fails to address those inerts of unknown toxicity. This failure is significant because inerts of unknown toxicity comprise the majority of inerts.<sup>209</sup> In addition, the policy proposes no changes to the regulation of the innocuous inerts found in list 4.<sup>210</sup> Therefore, the EPA continues to neglect its responsibility, notwithstanding the IIPS, to insure that pesticides containing inert ingredients that cause unreasonable adverse effects are not introduced into the environment.

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201. Bradley telephone interview, *supra* note 158.

202. 52 Fed. Reg. 13,305, 13,309 (1987).

203. *Id.*

204. *Id.*

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

209. *Id.* at 13,307.

210. *Id.*

#### IV. PROPOSALS FOR CHANGE IN THE DATA REQUIREMENTS FOR REGISTRATION SCHEME

##### A. Past Proposals

At the federal level, in 1986 the General Accounting Office (GAO) concluded that regulatory changes were needed. The GAO recommended that the EPA examine potential alternatives for the efficient accumulation of chronic type test data describing inerts.<sup>211</sup> The GAO called both for an easing of the confidentiality provision and for any additional authority the EPA might need to effectively assess the true chronic toxicity of pesticides.<sup>212</sup> Essentially, the GAO expressed the need to require more safety data while not eliminating all trade secret protections of pesticide formulations.<sup>213</sup> Despite this federal recognition that changes to the existing data requirement scheme are necessary, the EPA has failed to address this GAO recommendation.

In the absence of federal action to correct this problem, states are passing their own pesticide regulations.<sup>214</sup> A significant increase in state legislation proposals dealing with pesticide regulation began in 1985.<sup>215</sup> Courts have determined that states have the authority to supplement FIFRA by enacting legislation more stringent than the mandates prescribed by FIFRA,<sup>216</sup> treating the express non-preemption provision in FIFRA as a "floor" rather than a "ceiling."<sup>217</sup> One example is California's 1984 Birth Defects Prevention Act.<sup>218</sup> Enacted in response to reports of inadequate federal regulation of pesticides, this act specifically addresses chronic type effects resulting from the use of pesticides.<sup>219</sup> Most

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211. FORMIDABLE TASK, *supra* note 21, at 90.

212. *Id.*

213. *Id.*

214. Stiles, *supra* note 146, at 429 n.15.

215. *Id.*

216. See *National Agr. Chemicals Ass'n v. Rominger*, 500 F. Supp. 465 (E.D. Cal. 1980) (holding that FIFRA did not preempt state's right to require additional data on pesticides and additional state requirements did not constitute an unconstitutional burden on interstate commerce). Precisely how long this statutorily permitted relationship will continue is uncertain. On October 27, 1989, President Bush proposed to preempt states from regulating pesticide residues in food products in any manner more stringent than the federal government requires. *Bush Would Change Rules On Regulations of Pesticides*, N.Y. Times, Oct. 26, 1989, at A18, col. 1. See also 7 U.S.C. § 136v (1988).

217. See *Rominger*, 500 F. Supp. at 470.

218. The Birth Defects Prevention Act of 1984, CAL. FOOD & AGRIC. CODE § 13121 (Deering 1984).

219. Stiles, *supra* note 146, at 429 n.15.

state action, though, is directed at tolerance limits for food-use pesticides and applicator certification. As a result, very little state legislation addresses inert ingredient data requirements in pesticide registration.

Nevertheless, pesticide regulation would benefit more from a uniform federal regulatory system than from a "federation of state regulatory actions."<sup>220</sup> State actions would create nationwide inconsistencies and unnecessary duplication of costs. Financial, technical, and administrative constraints for many states might prevent them from adopting proper safety precautions. Pesticides marketed nationwide are best regulated with uniform rules. Chronic type effects testing is fundamental enough to the pesticide regulatory process that it should be done on a nationwide basis.

In the private arena, the Natural Resources Defense Council endorsed a proposed amendment to FIFRA that sought to clarify the statute's definitions of active and inert ingredients.<sup>221</sup> The 1988 proposal was intended to exclusively classify chemicals as either active or inert in all formulations.<sup>222</sup> This approach falls short of remedying the current situation. Chemicals labeled inert in one formulation but active in another would be reclassified active in both and be subjected to chronic type testing in both situations. Nevertheless, most other inerts would continue not to be considered in chronic effect assessments. The proposal perpetuates the classification of chemicals based upon their use or function and not their potential for toxicity. While the proposal would prevent chemicals which are banned as actives from being used as inerts, it fails to address toxic inerts never used as actives. It also fails to address potential synergistic effects of ingredient interaction in formulations.

### B. Comprehensive Proposal

An effective way to remedy the current pesticide registration data requirement problem would be to require, for all pesticide products, formulation testing for chronic, subchronic, and mutagenic effects in addition to the formulation testing currently required only for acute effects. The data collected would include not

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220. *Id.* at 431.

221. NATURAL RESOURCES DEFENSE COUNCIL, INERT/ACTIVE INGREDIENT AMENDMENT MEMORANDUM (April 6, 1988).

222. *Id.*

only chronic type effects of inert ingredients but also synergistic effects of the interaction between inerts and other chemicals in the formulation. This would eliminate the undesirable and potentially illegal method currently used by the EPA to test pesticide formulations for chronic type effects in which it allows the sale and distribution of pesticides and reacts only when unreasonable adverse effects occur. This would also eliminate any possibility that a banned active ingredient would find its way into the marketplace as an untested inert ingredient in a different formulation.

Imposing such a requirement for formulation testing would generate no trade secret problems. Formulation testing would not require disclosure of the identity of registrants or inert ingredients. Moreover, collective data generation would not apply to formulation testing because each formulation is unique to each registrant. Formulation testing would also provide the EPA with a very comprehensive data profile for each pesticide formulation. This data would enable the EPA to make an informed and accurate evaluation of the propensity of a pesticide to cause unreasonable adverse effects to people and the environment.

A major problem encountered with formulation testing for chronic effects is the increased economic burden placed both on industry for data generation and on the EPA for data evaluation.<sup>223</sup> Because formulations far outnumber active or inert ingredients, the increased economic burden would be significant. Rather than chronic testing for 600 active ingredients, chronic testing would be required for 50,000 formulations.<sup>224</sup> Generally, chronic testing for pesticide formulations costs one million dollars or more per pesticide.<sup>225</sup> Moreover, in the case of small business formulators, this type of testing lies beyond their financial capacities.<sup>226</sup>

Another problem presented by formulation testing relates to the quality assurance of the testing data. Whereas chronic testing for active ingredients is usually conducted by the chemical's manufacturer,<sup>227</sup> acute testing is usually "farmed out" by the formulator

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223. Telephone interview with Mr. Steve Kellner, representative of The Chemical Specialties Manufacturers Association (February 7, 1990) [hereinafter Kellner telephone interview].

224. See *supra* note 105 and accompanying text.

225. Kellner telephone interview, *supra* note 223.

226. *Id.*

227. *Id.*

to testing laboratories.<sup>228</sup> Additionally, there may be a shortage of laboratories that provide testing services at a quality with which industry is satisfied.<sup>229</sup> One expert suggested that the supply of reliable laboratories may be ill-equipped to handle the increased demand for testing.<sup>230</sup> On the other hand, it would appear that the market could generate the quality testing capacity to meet the new demand. Nevertheless, the question of whether reliable testing is currently available to meet the demand is not a factor in the decision regarding whether a pesticide causes unreasonable adverse effects. The economic burden on industry, though, is a factor that the EPA must consider when requiring new data for pesticide registrations.<sup>231</sup>

Industry also points out that chronic data testing of pesticide formulations will significantly delay the introduction of new pesticides into the market.<sup>232</sup> Chronic testing would also cause manufacturers to discontinue the marketing of existing pesticide products.<sup>233</sup> These are not, however, necessarily unattractive features of the proposal. The reduction of pesticide poisonings that untested pesticides would cause arguably outweighs the delay in new product development. In addition, chronic formulation testing that forces currently registered products off the market because of their unreasonable adverse effects is the primary intent of FIFRA.

Nevertheless, an industry spokesperson points out that chronic testing would result in the withdrawal of many "safe" pesticides.<sup>234</sup> It will also force many small business formulators out of business.<sup>235</sup> The result of these divergent market forces would create a less competitive market with fewer formulators and fewer product formulations. Moreover, the industry's practice of quickly changing component chemicals both to create diversification in products and to react to adverse effects of certain formulations would be stymied.<sup>236</sup> Industry's positions, however, are irrelevant to the issue of the safe regulation of pesticides because FIFRA is not a marketing enhancement statute. Nor does FIFRA presume

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228. *Id.*

229. *Id.*

230. *Id.*

231. See *supra* notes 48-49 and accompanying text.

232. Kellner telephone interview, *supra* note 223.

233. *Id.*

234. *Id.*

235. *Id.*

236. *Id.*

that more or new pesticide formulations are desirable. Instead, FIFRA presumes pesticides are harmful and should be tested before marketing to prove they do not cause unreasonable adverse effects.<sup>237</sup> Given the benefits to society from a more complete assurance of pesticide safety and the elimination of the hidden costs of remedying the chronic effects of pesticide exposures, chronic type testing of pesticide formulations should be viable.

### *C. Intermediate Proposal*

An alternative to full formulation testing of the chronic type effects is to test the inert ingredients present in a formulation in the same manner as an active ingredient is tested. Essentially, this approach eliminates any distinction between active and inert ingredients. Toxicity data requirements, both acute and chronic, would be based on the toxic propensity of a chemical and not based on the purpose of a chemical in a formulation.

This approach would account for the chronic type effects of all component ingredients present in a formulation while reducing the economic burdens that formulation testing would create. The number of inert ingredients approximates the number of active ingredients and is far fewer than the number of formulations.<sup>238</sup> As a result, chronic testing would increase from six hundred active ingredients to eighteen hundred active and inert ingredients, or 2.4% of the testing required if all formulations were tested. This intermediate approach also eliminates any possibility that a banned active ingredient could be introduced into the marketplace under the guise of the inert ingredient classification.

Despite these improvements, this approach is not as complete as formulation testing. Without testing the entire formulation for chronic type effects, the EPA cannot account for harmful, synergistic effects of component ingredient interaction. This intermediate approach also presents the conflict between the trade secret confidentiality provision and the collective data generation provision of FIFRA.<sup>239</sup> In order to create a practicable situation, Congress should amend the confidentiality provision. One approach would be to permit the disclosure of a registrant's identity when data is needed to determine the potential toxicity of an inert ingre-

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237. See *supra* notes 33-49 and accompanying text.

238. See *supra* note 105 and accompanying text.

239. See *supra* notes 159-162 and accompanying text.

dient. Some proprietary information, such as the proportion of an inert ingredient in a formulation, need not be disclosed. Alternative approaches include offering the registrant an opportunity to generate the data alone or in concert with the manufacturer of the inert ingredient. Another alternative might require that the manufacturer, rather than the registrant, provide the EPA with the test data. Nevertheless, reduced trade secret protection is required if industry is going to enjoy the economic benefits of chronic data testing of component ingredients instead of formulations. If a pesticide registration data requirements scheme is promulgated where all component ingredients are tested for chronic effects, the EPA will be better equipped to make regulatory decisions about the propensity of a pesticide to cause unreasonable adverse effects on people and the environment.

#### CONCLUSION

FIFRA requires the EPA to forbid the sale of any pesticide that may create unreasonable adverse effects. In order to assess the potential of a pesticide to cause unreasonable adverse effects, the EPA requires registrants to submit certain data describing the pesticide. The EPA data requirements describing chronic type effects of a pesticide focus exclusively on the active ingredients. Inert ingredients, however, have demonstrated conclusively their potential to also cause chronic type effects. Despite the misleading label, inerts must be considered in all aspects of testing if the EPA is to adequately measure the potential of a pesticide to cause unreasonable adverse effects. Exposure traits of inert ingredients, such as carcinogenic and mutagenic traits, make chronic type effects testing of pesticide formulations particularly appropriate. If economic constraints prohibit full formulation testing, the EPA should require component ingredient testing to assess the potential of a pesticide to cause chronic effects. The important shortcoming of this approach is the inherent disregard for potential synergistic effects of component ingredient interaction.

Regardless of which alternative is chosen, the EPA must test more thoroughly for potential chronic type effects if it is going to fulfill its obligation under FIFRA. The IIPS is an inadequate response to the problem. Distinctions between active and inert ingredients should create differential treatment only for truly innocuous inerts that pose no unreasonable adverse effects in a given registered use. By not requiring chronic testing of inert ingredients of

unknown and potentially great toxicity, the EPA either is presuming unjustifiably that the chemicals do not pose unreasonable adverse effects or is conceding that it has no intent or is unable to fulfill its obligations under FIFRA.

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