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FIFRA—Chemical Testing Issues

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This Article introduces the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[1] and describes chemical substances for which testing must be conducted under FIFRA, other chemical testing that could be required, persons required to conduct the tests, data compensation procedures, and associated legal issues.

I. FIFRA

Since 1972, the U.S. Environmental Protection Agency (EPA) has regulated pesticide products and devices under FIFRA, a 1947 federal statute. Under FIFRA, EPA requires original applicants to conduct chemical testing to obtain a registration or register a new use. During registration, EPA uses the data submitted by the applicant to determine whether the pesticide or new use will pose an unreasonable risk to human health or the environment. If EPA determines that it will not, EPA will grant the applicant a registration or allow the new use. Testing requirements do not end with registration, however. EPA requires registrants to conduct additional testing to reregister certain pesticides or in response to a data call-in (DCI) to ensure original testing requirements keep pace with evolving science standards. FIFRA requires that pesticides registered before November 1, 1984, be reregistered to ensure they meet current scientific and regulatory standards. If there are gaps in the database, EPA will require registrants to submit additional data to reregister the pesticide. If EPA obtains new information that it believes suggests a pesticide could pose human health or environmental effects that were not known at the time the pesticide was first registered, EPA may issue a DCI, requiring registrants either to conduct additional testing or face the cancellation of their registrations. The testing results could impose limitations on the manufacture, distribution, and/or use of the pesticide.

II. Chemical Substances

While all pesticide products must be registered, EPA uses different processes and requires different data to review registration applications for conventional pesticides, antimicrobials, and biopesticides.[2] FIFRA defines a pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."[3] EPA regulations further define a pesticide as: "[A]ny substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest. . . ."[4]

Under FIFRA, an antimicrobial pesticide is defined as a pesticide that meets two criteria:

> It is intended to:
>
> "disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms"; or
> "protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime"; and
>
> In the intended use, it "is exempt from, or otherwise not subject to," tolerance requirements or Food and Drug Administration (FDA) food additive regulations.[5]

EPA's regulations specify several products that are included within the definition of antimicrobial pesticide, including certain chemical sterilant products, other disinfectant products, other industrial microbiocide products, and other preservative products not specifically excluded by the definition of antimicrobial pesticide.[6] The regulations specifically exclude from the definition:

> Wood preservative or antifouling paint products for which a claim of pesticidal activity other than or in addition to claims applying to antimicrobial pesticides are made;

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1. 7 U.S.C. §§136-136y, ELR Stat. FIFRA §§2-34.
2. U.S. EPA, *Registering Pesticides*, *at* http://www.epa.gov/pesticides/regulating/registering/index.htm (last visited Aug. 4, 2004).
3. FIFRA §2(u); 40 C.F.R. §152.3. FIFRA also defines the term "active ingredient," in pertinent part, to mean "an ingredient which will prevent, destroy, repel, or mitigate any pest." FIFRA §2(a)(1).
4. 40 C.F.R. §152.15.
5. *See* FIFRA §2(mm)(1). Tolerances are established under 21 U.S.C. §346(a) and food additive regulations are promulgated at 21 U.S.C. §348.
6. *See id.* §2(mm)(3); *see also* U.S. EPA, Pesticide Registration (PR) Notice 98-2, Liquid Chemical Sterilant Products 1 (1998), *available at* http://www.epa.gov/opppmsd1/PR_Notices/pr98-2.html (last visited Jan. 13, 2005) (exempting certain liquid sterilants from EPA jurisdiction and classifying them as "medical devices" regulated by the FDA).

> Agricultural fungicide products; or
> Aquatic herbicide products.[7]

These products may still be considered pesticides, however, if they meet the FIFRA definition of pesticide.

Biopesticides are derived from natural materials, such as animals, plants, bacteria, and certain minerals. EPA groups biopesticides into three classes: (1) microbial pesticides consisting of a microorganism (e.g., a bacterium, fungus, virus, or protozoan) as the active ingredient; (2) plant-incorporated protectants (PIPs), which are pesticidal substances that plants produce from genetic material that has been added to the plant; and (3) biochemical pesticides, which are naturally occurring substances that control pests by nontoxic mechanisms.[8] EPA's FIFRA regulations explicitly define eucaryotic microorganisms (including protozoa, algae, and fungi), procaryotic microorganisms (including bacteria), and viruses as biological control agents.[9] EPA defines a PIP as "a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance."[10] Biochemical pesticides include substances that interfere with mating, such as insect sex pheromones, as well as substances that attract insect pests to traps, such as various scented plant extracts.[11] Because of the difficulty in determining whether a substance meets the criteria for classification as a biochemical pesticide, EPA established a special committee to make such decisions.[12]

Although both FIFRA and EPA's regulations define pesticides quite broadly, exclusions include[13]:

> Drugs used to control diseases in humans or animals are not considered pesticides and are regulated by FDA[14];
>
> Fertilizers, nutrients, and other substances used to promote plant survival and health are not considered plant growth regulators and thus are not pesticides regulated under FIFRA[15];
>
> Biological control agents, except for certain microorganisms, are exempt from regulation by EPA[16]; and
>
> Products containing certain low-risk ingredients, such as garlic and mint oil, are exempt from federal registration requirements, although state regulatory requirements may still apply.[17]

III. Chemical Testing

A. General Data Requirements for Registration

Under FIFRA, EPA reviews data submitted as part of a registration application to ensure that the pesticide will "perform its intended function without unreasonable adverse effects on the environment" and that, "when used in accordance with widespread and commonly recognized practice," the pesticide "will not generally cause unreasonable adverse effects on the environment."[18] To reach these conclusions, EPA requires registrants to submit a wide range of data in a variety of categories, including product and residue chemistry, environmental and mammalian toxicity, and reentry exposure.[19] EPA uses these data to evaluate whether a pesticide has the potential to cause harmful effects in humans, wildlife, fish, and plants, including endangered species and nontarget organisms.[20] EPA also requires data regarding the possible contamination of surface water or groundwater from leaching, runoff, and spray drift.[21] According to EPA, an application to register a new pesticide or a new use for a registered pesticide requires more than 100 different scientific tests and studies to be submitted.[22]

Not all applicants are required to conduct testing to meet all the data requirements described in EPA's regulations, however. Where EPA already has in its files data pertaining to a substantially similar or identical product, FIFRA provides the new registrant (often referred to as a "follow-on registrant") with a choice of either repeating all or some of the original test battery, or employing a "data citation" alternative as to tests not repeated.[23] In other cases, applicants may be able to obtain a data waiver, such as when EPA previously granted a data waiver and the applicant is able to satisfy EPA that the prior waiver should apply to the applicant's product.[24] An applicant may also be able to obtain a new waiver of a data requirement by submitting a written request to EPA.[25] Given the complexity of the data requirements and the expense of testing, applicants are encouraged to consult the appropriate EPA Product Manager to resolve questions relating to the test protocols or the data requirements before undertaking extensive testing.[26]

EPA requires the following types of data to register a pesticide product[27]:

> *Residue Chemistry:* EPA uses these data to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances for pesticide residues in food or feed.[28]
>
> *Environmental Fate:* EPA uses data generated by environmental fate studies to assess the poten-

7. *See* FIFRA §2(mm)(2).
8. U.S. EPA, *What Are Biopesticides?*, *at* http://www.epa.gov/pesticides/biopesticides/whatarebiopesticides.htm (last visited Nov. 3, 2004).
9. 40 C.F.R. §152.20(a)(3).
10. *Id.* §152.3; *see also* U.S. EPA, *Plant Incorporated Protectants*, *at* http://www.epa.gov/pesticides/biopesticides/pips/ (last visited Aug. 10, 2004).
11. U.S. EPA, *What Are Biopesticides?*, *supra* note 8.
12. *Id*.
13. U.S. EPA, *About Pesticides*, *at* http://www.epa.gov/pesticides/about/index.htm (last visited June 17, 2004).
14. *See* 40 C.F.R. §152.6(c), (d).
15. *See id.* §§152.6(g), 152.8(a).
16. *See* FIFRA §2(t); *see also* 40 C.F.R. §152.6(d).
17. *See* 40 C.F.R. §152.25(f).
18. FIFRA §3(c)(5)(C), (D).
19. *See* 40 C.F.R. pt. 158.
20. U.S. EPA, *Data Requirements*, *at* http://www.epa.gov/pesticides/regulating/data.htm (last visited June 13, 2003).
21. *Id*.
22. U.S. EPA, *Pesticides: Regulating Pesticides*, *at* http://www.epa.gov/pesticides/regulating/index.htm#eval (last visited Oct. 4, 2004).
23. FIFRA §3(c)(1)(F).
24. 40 C.F.R. §152.91(a).
25. *Id.*. §§152.91(b), 158.45.
26. *Id.* §158.35(a).
27. U.S. EPA, *Data Requirements*, *supra* note 20.
28. *See* 40 C.F.R. §158.202(c).

tial for toxicity to humans from exposure to pesticide residues remaining after application, the presence of widely distributed and persistent pesticides in the environment, and the potential environmental exposure of other nontarget organisms, and to estimate expected environmental concentrations of pesticides in specific habitats where threatened or endangered species or other wildlife populations at risk are found.[29]

Degradation Studies: EPA uses data from hydrolysis and photolysis studies to determine the rate of pesticide degradation and to identify pesticides that may harm nontarget organisms.[30]

Metabolism Studies: EPA uses data generated from aerobic and anaerobic metabolism studies to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide.[31]

Mobility Studies: EPA uses data regarding leaching, adsorption/desorption, and volatility of pesticides to obtain information on the mode of transport and eventual destination of the pesticide in the environment.[32]

Dissipation Studies: EPA uses data generated from dissipation studies to assess potential environmental hazards under actual field use conditions.[33]

Accumulation Studies: EPA uses accumulation studies to evaluate the pesticide residue levels in food supplies that originate from wild sources or from rotational crops.[34]

Hazard to Humans and Domestic Animals: EPA derives data to assess hazards to humans and domestic animals from a variety of acute, subchronic, and chronic toxicity tests, and tests to assess mutagenicity and pesticide metabolism.[35]

Reentry Protection: EPA uses studies on toxicity, residue dissipation, and human exposure to derive data to assess hazard to farm employees resulting from reentry into areas treated with pesticides. EPA uses monitoring data generated during exposure studies to determine how much pesticide people may be exposed to after application and to establish how long workers must wait before re-entering a treated area.[36]

Pesticide Spray Drift Evaluation: EPA uses studies of the range of droplet sizes and spray drift field evaluations to evaluate pesticide spray drift.[37]

Hazard to Nontarget Organisms: EPA derives the information required to assess hazards to nontarget organisms from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, subacute, reproduction, simulated field, and full field studies arranged in a hierarchical or tier system that progresses from the basic laboratory tests to the applied field tests.[38]

Product Performance: EPA requires data on product performance to ensure that pesticide products will control the pests listed on the label and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products.[39]

B. Data Requirements for Antimicrobial Registration

To date EPA has not issued final regulations regarding the data requirements for antimicrobial pesticides. On September 17, 1999, EPA issued proposed regulations, which differ in some respects from data requirements for other pesticides.[40] According to EPA, these differences occur in part because the pests are invisible disease-causing microbes, rather than insects or rodents that may be harboring disease organisms.[41] Further, evaluating human and ecological risks from exposure to antimicrobial pesticides requires a different approach than the approach needed for pesticides largely applied to crops and other plants.[42] Additional efficacy data requirements apply to antimicrobial pesticide products used for public health purposes, such as to kill microorganisms in hospitals, schools, restaurants, and homes. As a result of increased concern regarding whether public health products work as claimed, and because public health products are crucial for infection control, EPA has begun conducting preregistration confirmatory and post-registration enforcement testing of certain public health products.[43] EPA has published a number of guidance documents summarizing current efficacy-related requirements.[44] EPA has stated that it does not require the submission of efficacy data for nonhuman health-related antimicrobial pesticides.[45] All antimicrobial registrants are required to maintain product efficacy data in their files, however.[46]

C. Data Requirements for Biopesticides

In general, since biopesticides are believed to pose fewer risks than conventional pesticides, EPA typically requires less data to register a biopesticide than to register a conventional pesticide.[47] EPA stresses, however, that while it may require less data for biopesticides, "EPA always conducts

29. *See id.* §158.202(d)(1).
30. *See id.* §158.202(d)(2).
31. *See id.* §158.202(d)(3).
32. *See id.* §158.202(d)(4).
33. *See id.* §158.202(d)(5).
34. *See id.* §158.202(d)(6).
35. *See id.* §158.202(e).
36. *See id.* §158.202(f).
37. *See id.* §158.202(g).
38. *See id.* §158.202(h).
39. *See id.* §158.202(i).
40. 64 Fed. Reg. 50672 (Sept. 17, 1999). Once enacted, the regulations will be codified at 40 C.F.R. Part 158 in a new Subpart W devoted to antimicrobial registration procedures. EPA's proposed regulations are available on the Internet at http://www.epa.gov/oppad001/pdf_files/158subprtw.pdf (last visited Nov. 11, 2004).
41. U.S. EPA, *Regulating Antimicrobial Pesticides*, *at* http://www.epa.gov/oppad001/ (last visited Oct. 12, 2004).
42. *Id.*
43. U.S. EPA, *Antimicrobial Pesticide Products*, *at* http://www.epa.gov/pesticides/factsheets/antimic.htm (last visited May 19, 2003).
44. U.S. EPA, *Antimicrobial Science Policies: Disinfectant Technical Science Section (DIS/TSS)*, *at* http://www.epa.gov/oppad001/sciencepolicy.htm (last visited Dec. 22, 2003).
45. *Id.*
46. *Id.*
47. U.S. EPA, *What Are Biopesticides?*, *supra* note 8.

rigorous reviews to ensure that pesticides will not have adverse effects on human health or the environment."[48] EPA has promulgated specific data requirements for two kinds of biopesticides—biochemical and microbial pesticides.[49] According to EPA, since most biochemical pesticides are applied at very low rates, and either are highly volatile or are applied in bait, trap, or "encapsulated" formulations, which result in less exposure and thus have less likelihood of causing adverse effects, EPA has created a tiered testing scheme to ensure that only the minimum data sufficient to make scientifically sound regulatory decisions will be required.[50] Even though EPA has promulgated data requirements for microbial pesticides, EPA "encourages potential registrants to contact the Division for a preregistration submission meeting to discuss these data requirements, and the scientific rationales for study waivers."[51]

EPA has not yet promulgated specific data requirements for PIPs, although it intends to in the future.[52] Currently, when assessing the potential risks of genetically engineered PIPs, EPA requires extensive studies examining numerous factors, such as risks to human health, nontarget organisms, and the environment, potential for gene flow, and the need for insect resistance management plans.[53] Again, EPA encourages applicants to "work closely" with EPA "to determine the data requirements for their products."[54]

D. Reregistration

The intent of reregistration is to ensure that all active ingredients "meet contemporary health and safety standards and product labeling requirements, and that their risks are mitigated."[55] The result is that registrants, having met the data requirements necessary to obtain a registration, may periodically be required to conduct more testing on their products. FIFRA, as amended in 1988, requires EPA to conduct a comprehensive pesticide reregistration program, incorporating a complete review of the human health and environmental effects of older active ingredients first registered before November 1, 1984.[56] To be eligible for reregistration, the active ingredient must have a substantially complete database, and must not cause unreasonable adverse effects to human health or the environment when used according to EPA-approved label directions and precautions.[57] Where the database is incomplete, EPA will require registrants to submit additional data to maintain the uses declared not yet eligible for reregistration.[58]

The Food Quality Protection Act (FQPA) of 1996[59] amended FIFRA to require EPA to establish a program to review all pesticide registrations on a 15-year cycle.[60] The FQPA also amended the Federal Food, Drug, and Cosmetic Act (FFDCA) by establishing new safety standards for pesticide residues in food.[61] Under the new standard, EPA must consider information concerning the exposure to infants and children to pesticides in food, as well as available information concerning cumulative effects on infants and children of the pesticide residues and other substances that have a common mode of action. In addition, EPA must consider the cumulative effects of the pesticide and the aggregate exposure levels of these pesticides to the U.S. population and major subgroups of the population.[62]

EPA has incorporated the new FFDCA safety standards into its reregistration program. The result is that, due to the difficulty in accurately assessing the exposure to infants and children in food, and the complexity of determining the cumulative effects of pesticides with a common mode of action, the reregistration program has slowed considerably. For example, for pesticides that must be included in a cumulative assessment, EPA began issuing interim reregistration eligibility decisions (IREDs), instead of producing only final reregistration eligibility decisions (REDs).[63] In May 2004, EPA stated:

> EPA generally has not considered individual [organophosphate (OP)] pesticide decisions to be completed REDs or tolerance reassessments. Instead, the Agency is issuing IREDs for these chemicals at this time. EPA will complete the risk assessments and may issue REDs for 23 OP pesticides with IREDs, once the Agency completes a cumulative assessment of the OPs.[64]

EPA began issuing IREDs for OPs in 2000, and intends to issue IREDs for all OPs by September 2005.[65] Whether EPA will be able to do so remains to be seen. In fiscal year (FY) 2003, EPA completed only 13 REDs and 3 IREDs.[66]

As part of the reregistration process, EPA typically includes a DCI notice in the RED.[67] EPA has broad authority to issue DCIs, which require existing registrants to submit additional data identified by EPA as necessary to support the continued registration of a pesticide (or to seek a waiver from the data requirement if a particular use pattern warrants different treatment).[68] EPA issues DCIs to obtain data in support of an existing registration when there is no existing, reliable information available to characterize a pesti-

48. *Id.*
49. *See* 40 C.F.R. §§158.690, 158.740.
50. U.S. EPA, PR Notice 97-3, Guidelines for Expedited Review of Conventional Pesticides Under the Reduced-Risk Initiative and for Biological Pesticides 16 (1997), *available at* http://www.epa.gov/opppmsd1/PR_Notices/pr97-3.html; *see* 40 C.F.R. §158.690.
51. PR Notice 97-3, *supra* note 50.
52. 66 Fed. Reg. 37772, 37783 (July 19, 2001).
53. U.S. EPA, *Plant Incorporated Protectants*, *at* http://www.epa.gov/pesticides/biopesticides/pips/index.htm (last visited Aug. 10, 2004).
54. PR Notice 97-3, *supra* note 50.
55. U.S. EPA, *Pesticide Reregistration Facts*, *at* http://www.epa.gov/oppfead1/trac/factshee.htm (last visited Dec. 13, 2000).
56. FIFRA §4(a).
57. *Id.* §4(a); 69 Fed. Reg. 25082, 25083 (May 5, 2004).
58. *Id.* §4(f)(1)(B); 69 Fed. Reg. at 25085.
59. Pub. L. No. 104-170, 110 Stat. 1489 (1996).
60. FIFRA §3(g)(1)(A).
61. FFDCA §408(b)(2), 21 U.S.C. §346a.
62. U.S. EPA, Reregistration Eligibility Decisions and the FQPA (1996), *available at* http://www.epa.gov/oppfead1/fqpa/redsnew.htm; more information regarding the FQPA is available in Lynn L. Bergeson & Carla N. Hutton, *The Food Quality Protection Act (FQPA)—Implementation and Legal Challenges*, 34 ELR 10733 (Aug. 2004).
63. 69 Fed. Reg. at 25086.
64. *Id.*
65. U.S. EPA, *Organophosphate Review—Chemical Status*, *at* http://cfpub.epa.gov/oppref/rereg/status.cfm?show=op (last visited Nov. 30, 2004).
66. 69 Fed. Reg. at 25084.
67. FIFRA §4(g)(2)(B); 69 Fed. Reg. at 25086.
68. FIFRA §3(c)(2)(B); 40 C.F.R. §158.45(a).

cide's risk or exposure, or to otherwise complete a risk assessment.[69] EPA states: "Ideally, in response to the DCI notice accompanying the RED document, the pesticide producer, or registrant, will submit the required product-specific data and revised labeling, which EPA will review and find acceptable. At that point, the Agency may reregister the pesticide product."[70] EPA may determine during reregistration that additional data are necessary because EPA has changed and upgraded its testing requirements over the years, or because EPA identifies a particular concern that needs to be addressed with additional studies.[71]

For pesticide reregistration, EPA may require toxicity, dietary exposure, ecological effects, environmental fate, non-dietary exposure (residential and occupational), and residue chemistry studies, as well as special studies, including neurotoxicity studies.[72] To reregister specific products, EPA may issue DCIs for specific exposure scenarios such as agricultural worker exposure, turf for residential and worker exposure, and spray drift. For the 13 FY 2003 REDs completed, 4 of the pesticides were voluntarily cancelled, and EPA issued DCIs for the other 9. For each of the 9 pesticides, EPA issued DCIs requiring 31 or more product chemistry studies and 48 (4 batches/4 products not batched) to 216 (5 batches/31 products not batched) acute toxicology studies.[73] For each of the 3 IREDs, EPA issued DCIs requiring from 22 to 31 product chemistry studies and from 36 (3 batches/3 products not batched) to 852 (37 batches/105 products not batched) acute toxicology studies.[74] Although the batching allowed in the acute toxicity testing reduces the burden, the testing required is not insignificant. When EPA issues final REDs for the three pesticides that received IREDs in FY 2003, EPA may include additional DCIs in the REDs. For registrants, reregistration can be a long and uncertain process. The burden of conducting additional testing may persuade registrants to revise their labels or change how their products are marketed and sold instead. EPA believes that almost all REDs include some risk reduction measures, including:

> Voluntary cancellation of pesticide products or deletion of uses;
>
> Declaring certain uses ineligible or not yet eligible (and then proceeding with follow-up action to cancel the uses or require additional supporting data);
>
> Restricting use of products to certified applicators;
>
> Limiting the amount or frequency of use;
>
> Improving use directions and precautions;
>
> Adding more protective clothing and equipment requirements;
>
> Requiring special packaging or engineering controls;
>
> Requiring no-treatment buffer zones;
>
> Employing groundwater, surface water, or other environmental and ecological safeguards; and
>
> Other measures.[75]

Once a registrant agrees to any of the above risk reduction measures, rather than conducting additional testing, all future registrations for the pesticide will include the same risk reduction measures, unless that registrant is willing to provide the data that EPA seeks.

E. Special Review

If EPA obtains information that uses of a pesticide product "may cause unreasonable adverse effects on the environment," EPA may initiate a Special Review.[76] Risk concerns that justify a Special Review are: (1) serious acute injury to humans or domestic animals; (2) cancer, mutagenic, teratogenic, fetotoxic, reproductive, or other chronic or delayed toxic effects in humans; (3) acute or chronic hazards or adverse reproductive effects in nontarget organisms; (4) a risk to the continued existence of any threatened or endangered species; (5) potential destruction or other adverse modification of critical habitat for any endangered or threatened species; or (6) any other adverse effect to humans or the environment that may outweigh the benefits of registration.[77] During Special Review, EPA conducts an in-depth assessment of the risks and benefits of a registered pesticide that has triggered one or more risk criteria. As part of a Special Review, EPA may issue DCIs for toxicity, dietary exposure, ecological effects, environmental fate, non-dietary exposure (residential and occupational), and residue chemistry studies, special studies such as neurotoxicity studies, incident data from the American Association of Poison Control Centers, or chemistry data for a group of chemicals suspected of containing a carcinogenic chemical contaminant.[78]

A Special Review can culminate in a decision to cancel one or more uses of a pesticide, make changes to the terms and conditions of registration, or continue the registration unchanged.[79] A Special Review can be a very lengthy process and can continue for years before EPA arrives at a regulatory decision on the active ingredient under review. As in reregistration, because of the length and uncertainty of the Special Review process, registrants may agree to EPA's proposed risk reduction measures, rather than incur the cost of expensive chemical testing to defend their products.

69. U.S. EPA, *Data Call-Ins*, *at* http://www.epa.gov/oppfead1/trac/dci.htm (last visited May 17, 1998).
70. 69 Fed Reg. at 25086.
71. *See* 40 C.F.R. §158.75.
72. U.S. EPA, *Data Call-Ins*, *supra* note 69.
73. 69 Fed. Reg. at 25087-88. Regarding the acute toxicology studies, EPA states:

> In an effort to reduce the time, resources, and number of animals needed to fulfill acute toxicity data requirements, EPA "batches" products that can be considered similar from an acute toxicity standpoint. For example, one batch could contain five products. In this instance, if six acute toxicology studies usually were required per product, only six studies (rather than 30 studies) would be required for the entire batch.

Id. at 25088.
74. *Id.*
75. *Id.* at 25085.
76. 40 C.F.R. §154.1; FIFRA §3(c)(8).
77. 40 C.F.R. §154.7.
78. U.S. EPA, *Data Call-Ins*, *supra* note 69.
79. 40 C.F.R. §154.1; U.S. EPA, Status of Chemicals in Special Review 7-8 (2000), *available at* http://www.epa.gov/oppsrrd1/docs/sr00status.pdf.

IV. Guidelines and Protocols for Testing

A. Good Laboratory Practice (GLP) Requirements

EPA's regulations include GLP standards, which are intended "to assure the quality and integrity of data" submitted to EPA and apply to all studies initiated on or after October 16, 1989.[80] The standards address requirements for testing facility management; maintenance of a quality assurance unit in testing facilities; adequate facilities and equipment for testing; standard operating procedures for testing facilities; study protocols; study conduct; and recordkeeping and archives.[81] All data submitted to EPA must include one of the following statements: (1) the study was conducted in accordance with GLP standards; (2) a detailed description of all differences between the practices used in the study and GLP standards; or (3) the submitter was not a sponsor of the study, did not conduct the study, and does not know whether it was conducted in accordance with GLP standards.[82] EPA may refuse to consider reliable for purposes of supporting a registration application any data from a study that was not conducted in accordance with GLP standards.[83]

B. Harmonized Test Guidelines

EPA's regulations refer to the *Pesticide Assessment Guidelines*, which contain the "standards for conducting acceptable tests, guidance on evaluation and reporting of data, further guidance on when data are required, definition of most terms, and examples of protocols."[84] In the mid-1980s, EPA began an effort to harmonize the test guidelines both within the Office of Prevention, Pesticides, and Toxic Substances (OPPTS), which oversees both the Toxic Substances Control Act (TSCA) and FIFRA, and beginning in 1990, with those of the Organization for Economic Cooperation and Development (OECD).[85] EPA intended the harmonization of the guidelines to decrease the burden on chemical producers, while at the same time reducing inconsistent and sometimes duplicative study requirements imposed by EPA and other OECD members.[86] EPA has issued a number of final *Harmonized Test Guidelines*, which update many of the test guidelines in the *Pesticide Assessment Guidelines*.[87] The *Harmonized Test Guidelines* use different numerical designations than the designations provided in the *Code of Federal Regulations* and include the following series:

Series 810—Product Performance;
Series 830—Product Properties;
Series 835—Fate, Transport, and Transformation;
Series 840—Spray Drift;
Series 850—Ecological Effects;
Series 860—Residue Chemistry;
Series 870—Health Effects;
Series 875A—Occupational and Residential Exposure: Applicator Exposure Monitoring;
Series 875B—Occupational and Residential Exposure: Post-Application Exposure Monitoring;
Series 880—Biochemical Pesticides; and
Series 885—Microbial Pesticides.

Because the documents are guidelines, mandatory requirements are not imposed. EPA has stated, however, that "they do reflect the considered judgment of the Agency and recognized experts as to what minimum steps are necessary to produce reliable data . . . . Accordingly, EPA advises that any deviations from final guidelines be fully explained and justified."[88]

V. Persons Required to Test

EPA has broad authority under FIFRA §3 to specify the kinds of information and data that it requires to support the registration of a pesticide. EPA also has an unqualified right to seek additional data if EPA determines that "additional data are required to maintain in effect an existing registration of a pesticide."[89] These data needs typically are satisfied by the technical registrants of the pesticide. If the technical registrants are disinclined to support specific data needs pertinent to end-uses of the product, however, then the end-use registrants of the pesticide would be required to support any additional data requirements pertinent to that end-use, or cancel the end-use registration. EPA registration requirements specify that each registrant is required either to certify that it is intending to produce the data, or will collaborate with others in the production of the required data. Failure to so certify would result in the suspension of the registration, and ultimately lead to its cancellation.

VI. FIFRA's Data Compensation Provisions

FIFRA provides for data compensation in two circumstances—when a registration applicant cites to studies previously submitted to EPA by other registrants, and when EPA requires current registrants to produce new data, which the registrants may individually submit, jointly develop, or share in the cost of developing.[90] Both provisions permit any involved applicant or registrant to initiate binding arbitration if the data compensation and cost-sharing issues cannot otherwise be resolved.[91] Because of the complexity of data compensation under FIFRA, only a very broad overview will be provided here.

80. 40 C.F.R. §160.1.
81. *Id.* §§160.29-.195.
82. *Id.* §160.12.
83. *Id.* §160.17(a).
84. *Id.* §158.20(c).
85. U.S. EPA, Office of Pollution Prevention and Toxics: Program Activities for Fiscal Years 1998 and 1999, at 12 (1999), *available at* http://www.epa.gov/oppt/ar98-99/opptreport.pdf.
86. U.S. EPA, Pesticide and Toxic Chemical Test Guideline and Harmonization (2004), *available at* http://www.epa.gov/oppfead1/cb/csb_page/fyi/testguid.htm (last visited Jan. 13, 2005).
87. U.S. EPA, Harmonized Test Guidelines (2004), *available at* http://www.epa.gov/opptsfrs/home/guidelin.htm (last visited Jan. 13, 2005).
88. 64 Fed. Reg. 70023, 70025 (Dec. 15, 1999).
89. FIFRA §3(c)(2)(B).
90. *Id.* §§3(c)(1)(F), 3(c)(2)(B).
91. Another provision, §3(c)(7), also often comes into play in data compensation disputes. This section authorizes EPA to grant "conditionally" registrations where some data production requirements have not yet been fulfilled by any registrant, if the follow-on registrant agrees to cite or submit that data when it is required from other registrants. Whether this provision in turn triggers an obligation under §3(c)(1)(F) or §3(c)(2)(B) has been a matter of dispute among registrants and applicants, and the issue has not definitively been resolved.

Where the follow-on registrant chooses to cite data previously filed by another entity, compensation is required if: (1) the study was submitted after December 31, 1969; and (2) the follow-on registrant cites it within 15 years of its submission to EPA.[92] The statute does not describe the standard by which compensation should be determined when data are cited within this 15-year window, however, and EPA's implementing rules also do not describe this standard.[93] Instead, EPA's rules focus on procedural issues. They provide two methods for citing previously submitted data in support of an application. Under the "cite-all" method, the applicant may cite to "all relevant data in the Agency's possession that would satisfy any applicable data requirements."[94] Under the "selective method," the applicant may "selectively [identify] one or more studies to satisfy each individual data requirement."[95]

The failure of the statute and administrative rules to describe a standard for compensation under §3(c)(1)(F) has left considerable room for dispute. Moreover, there is no controlling judicial interpretation. While the U.S. Supreme Court twice has addressed—and upheld—the constitutionality of the data citation system, it never squarely has addressed the question of what standards should govern compensation decisions.[96]

In 2002, EPA issued a draft Pesticide Registration (PR) Notice providing guidance on how to comply with FIFRA's data citation requirements for registration of new pesticide products.[97] According to EPA, the draft PR Notice is intended to provide assistance to pesticide registration applicants and help data submitters preserve their data protection rights. The draft PR Notice establishes requirements for applicants providing offer-to-pay letters for reliance on data using the cite-all and selective cite data citation methods. EPA also clarifies that task forces that generate data may also be entitled to compensation, stating: "Each applicant for a registration action should be familiar with the data requirements to which task force data respond and should determine whether reliance on such data is required for the registration action it seeks."[98]

92. *Id.* §3(c)(1)(F).

93. *See* 40 C.F.R. pt. 152.

94. 49 Fed. Reg. 30884, 30889 (Aug. 1, 1984).

95. *Id.* Both the cite-all and the selective-cite mechanisms are codified at 40 C.F.R. §§152.86 (cite-all) and 152.90 (selective).

96. *See* Ruckelshaus v. Monsanto Co., 467 U.S. 986, 14 ELR 20539 (1984); Thomas v. Union Carbide Agric. Prods. Co., 473 U.S. 568, 15 ELR 20698 (1985).

97. U.S. EPA, PR Notice 2002-XXXX, Compliance With Data Citation Regulations (2002); 67 Fed. Reg. 68866 (Nov. 13, 2002).

98. PR Notice 2002-XXXX, *supra* note 97, at 7.

Considerably less ambiguity surrounds the determination of obligations for current registrants to develop new data. This is because FIFRA §3(c)(2)(B) deals expressly with sharing data costs, rather than compensation. FIFRA §3(c)(2)(B) states:

> If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, 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.
>
> Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification.[99]

Thus, in the §3(c)(2)(B) context, the focus is on what constitutes data production cost and on allocation of costs, while in the §3(c)(1)(F) context, more expansive theories of competitive benefit and impact can be advanced. Furthermore, §3(c)(2)(B) essentially serves as limited exception to U.S. antitrust laws, in that it authorizes registrants "to develop jointly, or share in the cost of developing, such data" upon notification to EPA. The breadth of this "exemption" has not been tested in the courts, and legal counsel have been careful in structuring arrangements to avoid overexpansive interpretations of it, however.

VII. Conclusion

Given the significant data requirements to obtain a FIFRA registration, and the potential of facing additional data requirements to maintain a registration, companies enter the pesticide market only after an extensive cost-benefit analysis. The chemical testing burdens imposed by FIFRA appear only to increase with time, as new safety standards are promulgated, requiring earlier registrants to provide new data simply to maintain all uses for their current registrations. EPA is aware of these hurdles, however, and repeatedly offers, in PR Notices and its regulations, to meet with applicants or registrants to discuss the data requirements. Applicants should meet with EPA early in the registration process, before beginning extensive testing, to see if other solutions, such as data waivers, might be available. Registrants should carefully monitor the regulatory status of their products and participate early in the reregistration and Special Review processes to ensure EPA has all data available before requiring additional testing.

99. FIFRA §3(c)(2)(B).