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Comment

CARCINOGEN ROULETTE: THE GAME PLAYED UNDER FIFRA

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that all pesticides be registered by the Environmental Protection Agency (EPA) and prohibits the EPA from registering pesticides that have "unreasonable adverse effects on the environment." Once registered, pesticides are subject to continuing review by the EPA, in part because many pesticides already on the market may have been registered when data about their impacts on health and the environment were very limited. To determine whether it should cancel the registration of a pesticide, the EPA again must apply an unreasonable-adverse-effects standard to balance the harm to public safety and the environment against the economic benefits of continued usage. FIFRA authorizes the EPA to suspend a pesticide's registration during cancellation proceedings if the Administrator "determines that action is necessary to prevent an imminent hazard" to human health. Nevertheless, the EPA is reluctant to invoke the imminent-hazard standard, as illustrated by the example of the pesticide daminozide (Alar).

2. Id. § 136a(a).
3. Id. § 136a(c)(5)(C).
4. See id. § 136a-1(a); see also id. § 136d(a).
6. 7 U.S.C. § 136d(b) (1988). "[A]mong those factors to be taken into account [are] the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy . . . ." Id.
7. Id. § 136d(c)(1).
8. "Daminozide, sold under the trade name Alar, is a growth regulator used predominantly in the apple industry." Note, Daminozide and the New England Apple Crop: A National Definition of "Safe", 12 Vt. L. Rev. 181, 181 n.1 (1987). Although daminozide is useful to growers, it is widely thought to pose substantial health risks. See Natural Resources Defense Council, Intolerable Risk: Pesticides in Our Children's Food (1989) [hereinafter NRDC] (describing NRDC efforts to determine whether pesticide residues are a health risk to preschool children). In September 1985, the Environmental Protection Agency (EPA) proposed a ban on its use. Note, supra, at 186. But in January
tion proceedings, a potentially dangerous chemical may continue to be used, thereby posing health risks to unsuspecting consumers.

This Comment will explore the controversy over the cancellation of pesticides. It will consider how significant the risk to human health must be before an intermediate suspension as well as an eventual cancellation can be effectuated. It also will consider whether the registrant or the EPA should bear the burden of proof after some threshold finding has been made as to the danger of a registered pesticide. These are especially timely issues because the EPA’s difficulty in removing harmful pesticides from the market under the current version of FIFRA increasingly undermines public confidence in the Agency’s ability to protect public health and safety.

Part I of this paper introduces FIFRA by describing the complicated and often inconsistent history of pesticide regulation. Part II, using the Alar controversy as a case study, shows the great difficulty that the EPA has had in removing “unreasonably dangerous” pesticides from the market. Part III then evaluates whether this difficulty is a necessary evil of according due process to manufacturers when the EPA attempts to remove a pesticide from the market under a risk-benefit balancing statute such as FIFRA. Finally, Part IV analyzes ways in which Congress could amend FIFRA to promote greater public safety without sacrificing the due process owed to pesticide registrants.

I. A BRIEF HISTORY OF PESTICIDE REGULATION

Beginning with the enactment of the Federal Insecticide, Fungicide, and Rodenticide Act in 1947, pesticide manufacturers were required to register their products prior to sale or movement in interstate commerce. FIFRA required that manufacturers ade-

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1986, the EPA rescinded its proposal in the face of opposition from a major daminozide manufacturer and an expression of concern from the EPA’s Scientific Advisory Panel (SAP). Id. at 186-87. Interim measures allowed “the continued use of daminozide pending further study [with registration] conditioned on a number of measures.” Note, supra, at 193.


10. See 1947 U.S. CODE CONG. SERV. 1200, 1201. Today, the law stipulates that “[e]xcept as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter.” 7 U.S.C. § 136a(a) (1988).
quately label pesticides as to their proper application and content before they were marketed—an attempt by Congress to make pesticides both safe and effective.\footnote{\textsuperscript{12}} By limiting its reach to labeling, however, this initial attempt to curtail the hazards of pesticides was modest at best.

The registration requirement did force the pesticide manufacturer to file with the Secretary of Agriculture a complete copy of the label displayed on the pesticide,\footnote{\textsuperscript{13}} including directions for its use and all claims made about the product.\footnote{\textsuperscript{14}} The United States Department of Agriculture (USDA) also could order a description of the results of tests conducted on the pesticide and a complete description of its formula.\footnote{\textsuperscript{15}} If the Secretary found the product unacceptable, either because it failed to live up to its manufacturer’s claims or because it did not meet the registration requirements, the Secretary had to notify the registrant, “so as to afford the registrant an opportunity to make the corrections necessary.”\footnote{\textsuperscript{16}} The registrant could refuse to make corrections and request registration despite the Secretary’s concerns.\footnote{\textsuperscript{17}} In that event, “the Secretary [had to] register the article, under protest,”\footnote{\textsuperscript{18}} and such registration [had to] be accompanied by a warning . . . to the registrant of the apparent failure of the article to comply with the provisions of [the] Act.”\footnote{\textsuperscript{19}}

It was not until 1964 that Congress amended FIFRA to require USDA approval before a pesticide product could legally be marketed.\footnote{\textsuperscript{20}} The 1964 amendments also provided that the Secretary of

\begin{footnotes}
\footnote{11. \textsuperscript{11} FIFRA broadened the regulation of pesticides previously regulated under The Insecticides Act of 1910, 36 Stat. 331 (1910). 1947 U.S. CODE CONG. SERV. 1200.}
\footnote{12. The goal of FIFRA registration was to insure that pesticides carried labels bearing information sufficient to make product use safe, easy, and effective. Comment, \textit{The Federal Environmental Pesticide Control Act of 1972: A Compromise Approach}, 3 ECOLOGY L.Q., 277, 279 (1973); see H.R. REP. NO. 313, 80th Cong., 1st Sess. 3, \textit{reprinted in} 1947 U.S. CODE CONG. SERV. 1200.}
\footnote{15. \textit{id.} at §§ 4a(b), 4b, 61 Stat. at 167-68.}
\footnote{16. \textit{id.} § 4c, 61 Stat. at 168.}
\footnote{17. \textit{id.}}
\footnote{18. The USDA only issued a few products under “protest”—almost all were approved by the USDA before being registered. See Ferguson & Gray, \textit{1988 FIFRA Amendments: A Major Step in Pesticide Regulation}, 19 [News & Analysis] Env’tl L. Rep. (Envtl. L. Inst.) 10070, 10072 n.22 (Feb. 1989).}
\footnote{19. FIFRA, Pub. L. No. 80-104, § 4c, 61 Stat. at 168.}
\footnote{20. Ferguson & Gray, \textit{supra} note 18, at 10072 n.22; see FIFRA amendment, Pub. L.}
\end{footnotes}
Agriculture could suspend the registration of a pesticide found to pose an "imminent hazard," thereby halting its sale in interstate commerce pending conclusion of cancellation proceedings.21

A. The 1972 Amendments

In response to growing concern over the hazards associated with pesticide use as exemplified by the dichlorodiphenyl trichloroethane (DDT) controversy,22 Congress extensively amended FIFRA in 1972.23 These amendments shifted the focus of pesticide registration away from verification-of-label claims to concern over public health and environmental protection.24 The Federal Environmental Pesticide Control Act of 1972 (FEPCA)25 continued to use "product registration as a basis for control, but it greatly expand[ed] registration, cancellation, and suspension criteria to include consideration of factors beyond the mere efficiency of the label."26

As a result of the 1972 amendments, a manufacturer can regis-

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22. In Environmental Defense Fund v. Hardin, 428 F.2d 1093, 1097 (D.C. Cir. 1970) (court considered availability of judicial remedy when administrative agency fails to act promptly) and Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 590 (D.C. Cir. 1971) (statute requires Secretary of Agriculture to determine whether regulation should be cancelled when there is substantial question concerning safety of pesticide), the Court of Appeals for the District of Columbia Circuit granted environmental groups standing to sue the EPA Administrator for his inaction on requests for suspension and cancellation of dichlorodiphenyl trichloroethane (DDT). "The court recognized that... the statute's minimum regulatory effectiveness could be rendered nonexistent through the Administrator's discretionary power to refuse to take action" absent some provision for consumer input. Comment, supra note 12, at 284-85.
fter a pesticide only if the label bears complete, clear, and truthful information as to the capabilities of the product and directions for its use\textsuperscript{27} and the manufacturer shows that the pesticide "can both 'perform its intended functions' and be 'used in accordance with widespread and commonly recognized practice' without causing 'unreasonable adverse effects on the environment.' "\textsuperscript{28} In applying this unreasonable-adverse-effects standard, the Administrator in determining whether to grant registration must take into account the "economic, social, and environmental costs and benefits of the use"\textsuperscript{29} based on information requested by the EPA.\textsuperscript{30} The Administrator also has the option of registering a product for restricted use only.\textsuperscript{31} If the pesticide "may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator,"\textsuperscript{32} the Administrator may impose additional limitations on the product's use, such as permitting only certified applicators to apply the product.\textsuperscript{33} Whether the administrator denies registration entirely or changes the product's classification, however, the applicant or other interested persons are entitled to a hearing, which can be a lengthy and cumbersome process.\textsuperscript{34}

These registration and classification provisions were made applicable to all pesticides, including those already on the market.\textsuperscript{35} The 1972 amendments directed the EPA to reregister all pesticides previously registered under FIFRA using the same standards applicable to new pesticides\textsuperscript{36} including the provisions regarding data

\textsuperscript{27} Id. at 292; see 7 U.S.C. §§ 136(q), 136a(c)(5) (1988).
\textsuperscript{28} Comment, supra note 12, at 292; see 7 U.S.C. §§ 136a(c)(5)(C)-(D) (1988).
\textsuperscript{29} 7 U.S.C. § 136(bb) (1988). The definition of "unreasonable adverse effects" includes these criteria. Id.
\textsuperscript{30} Id. §§ 136a(c)(1), 135a(c)(2).
\textsuperscript{31} Id. § 136a(d)(1)(A).
\textsuperscript{32} Id. § 136a(d)(1)(C).
\textsuperscript{33} Id. § 136a(d)(1)(C)(i).
\textsuperscript{35} See Spector, supra note 34, at 236. "These registration and cancellation guidelines do not apply only to new pesticides. The Act requires that all products previously registered under FIFRA be re-registered and classified under the FEPCA standards . . . ." Id.
\textsuperscript{36} 7 U.S.C. § 136a-1 (1988). Congress in 1972 did not specify how the EPA was to conduct reregistration and the only mention of it was definitional—"'[t]he term 'registration' includes reregistration.'" Id. § 136(z); see Ferguson & Gray, supra note 18, at 10073.
submission, evaluation, and approval criteria . . . . 57 Faced with the need to reregister anywhere from 30,000 to 60,000 existing products, 38 the EPA envisioned the process as requiring review of existing product labels and summary files, 39 along with any newly submitted data to determine whether the use or toxicity of the pesticide caused any unreasonable adverse effects on the environment sufficient to warrant a restricted classification or cancellation. 40 The 1972 amendments mandated completion of the reregistration and classification process between October 1974 and October 1976 41 and again every five years thereafter. 42 Needless to say, this two-year time frame was far too ambitious. 43

The task of identifying gaps in the data proved to be herculean because “the EPA lacked a usable catalogue of the various studies that had been submitted” 44 prior to 1970 when the EPA inherited FIFRA from the USDA. 45 Even if data needs were identified, the EPA’s authority under the 1972 statute to require the submission of data was unclear. 46 Moreover, the 1972 law did not specify any process for the EPA to follow in conducting an orderly reregistration of the thousands of products on the market. 47

More fundamentally, the 1972 amendments failed to address the underlying problems of FIFRA—“lack of an explicitly stated threshold danger level and agency inarticulateness.” 48 As will be discussed, the unreasonable-adverse-effects standard used to determine a pesticide’s classification or cancellation is still vague. It is uncertain how much environmental impact is necessary to create the requisite adversity and “what weight the varying factors will command in the balancing process.” 49

The imminent-hazard standard for immediate suspension is

37. Ferguson & Gray, supra note 18, at 10073 n.23; see 7 U.S.C. §§ 136a(c)(2)(A), 136a(c)(5) (1988) (data requirements and evaluation and approval of applications for registration).
38. Ferguson & Gray, supra note 18, at 10073. Estimates as to the number of products subject to classification and/or registration in 1972 “vary over this range.” Id.
39. Id.
40. Id.
41. Id. at 10072.
43. One writer termed Congress’ expectation “wildly over-optimistic.” Ferguson & Gray, supra note 18, at 10073.
44. Id.
45. See supra note 13.
46. Ferguson & Gray, supra note 18, at 10073.
47. Id.
48. Comment, supra note 12, at 297.
49. Id.
equally nebulous.\textsuperscript{50} While the standard was defined more explicitly under the 1972 amendments than it had been previously,\textsuperscript{51} imminent-hazard determinations are so discretionary that, as one commentator has remarked, "[t]he statutory standard is so vague as to amount to essentially no standard at all."\textsuperscript{52} The problem with discretionary risk and benefit standards is that they are subject to agency manipulation that may result in unnecessary delays in removing a dangerous product from the market.

\textbf{B. The 1978 Amendments: An Attempt at a More Realistic Time Frame}

The 1978 FIFRA amendments\textsuperscript{53} responded to the difficulties that the EPA encountered under the unrealistic reregistration time frame which Congress mandated in 1972.\textsuperscript{54} The 1978 amendments eliminated any specific deadline for completion of reregistration, requiring instead that it be done "in the most expeditious manner practicable."\textsuperscript{55} Moreover, the amendments gave the Agency the authority "to require data submissions, to provide for registrants to share the cost of data generation, and to suspend the registrations of products if registrants failed to respond to test data requirements in a timely fashion."\textsuperscript{56} The amendments also directed the EPA to focus on active ingredient data to expedite registrations.\textsuperscript{57} These changes in FIFRA helped to facilitate the EPA's initial review or identification of data gaps in studies conducted on approximately 200 active ingredients and allowed for the completion of data review

\begin{itemize}
\item \textsuperscript{50} See 7 U.S.C. § 136d(c)(1) (1988).
\item \textsuperscript{51} "Imminent hazard" is defined after the 1972 amendments as:
\begin{itemize}
\item [A] situation which exists when the continued use of a pesticide during the time required for [a] cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary
\end{itemize}
\item \textsuperscript{52} Spector, \textit{supra} note 34, at 235 n.13.
\item \textsuperscript{54} SPECTOR, \textit{supra} note 34, at 235 n.13.
\item \textsuperscript{55} "Imminent hazard" is defined after the 1972 amendments as:
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\end{itemize}
\item \textsuperscript{56} Spector, \textit{supra} note 34, at 235 n.13.
\item \textsuperscript{57} See \textit{supra} note 34, at 235 n.13.
\end{itemize}
and standard setting for several chemicals.\(^5^8\)

The EPA's pace identifying data gaps—approximately twenty-five products per year\(^5^9\)—was still unacceptable considering the mounting concern over discoveries of pesticide residues in food and water across the nation.\(^6^0\) A major obstacle to accelerating the reregistration process, however, was money and qualified scientists who could identify the data gaps and evaluate the data that the registrants submitted thereafter.\(^6^1\) According to one General Accounting Office study,\(^6^2\) additional resources were necessary even to continue at a rate of twenty-five initial reviews and data gap identifications per year,\(^6^3\) and the necessary government funds simply were not forthcoming.\(^6^4\)

C. The 1988 Amendments: "FIFRA LITE"\(^6^5\)

The 1988 amendments\(^6^6\) have been touted by some as "actually go[ing] to the heart of the problem bedeviling pesticide regulation . . . ."\(^6^7\) The amendments infuse more funding by allowing the EPA to levy two different fees on those manufacturers who want to reregister.\(^6^8\) The first fee is "[a] one-time 'active ingredient fee' [that] ranges from $150,000 for major food and feed use pesticides to nothing for pesticides used only for minor uses"\(^6^9\) to be paid by producers of products identified for reregistration. The other fee, one that the EPA can levy annually, is a $425 'maintenance fee' for


59. Ferguson & Gray, supra note 18, at 10075.

60. Id. at 10075 n.54.

61. Id. at 10075.

62. GENERAL ACCOUNTING OFFICE, PESTICIDES—EPA'S FORMIDABLE TASK TO ASSESS AND REGULATE THEIR RISKS 45, 86-125 (1986) [hereinafter GAO].

63. Id. at 45; see also Ferguson & Gray, supra note 18, at 10075.

64. Ferguson & Gray, supra note 18, at 10075. The EPA’s pesticide program suffered greatly at the hands of those who did not want to raise taxes but did want to spend government money on other programs. In 1980, the EPA’s pesticide program had 899 employees and $45 million in expenditures. In 1985, the program was cut down to about 600 employees with $44 million in expenditures. GAO, supra note 62, at 45; see also Ferguson & Gray, supra note 18, at 10075.

65. "Critics have dubbed the changes 'FIFRA Lite' and 'another excuse to postpone important issues.' " Ferguson & Gray, supra note 18, at 10075 (arguing that the 1988 amendments will have a substantial impact).


67. Ferguson & Gray, supra note 18, at 10076.

68. Id. at 10077, see 7 U.S.C. § 136a-1(i) (1988).

69. Id. at 10076; see 7 U.S.C. § 136a-1(i)(1)-(2) (1988).
each registration.\textsuperscript{70}

The 1988 amendments also made significant changes concerning indemnification when a registration was suspended or cancelled.\textsuperscript{71} The amendments provide that indemnification no longer will be paid from the EPA’s operating budget;\textsuperscript{72} indemnification henceforth will be limited to end users and is to be paid from the “Judgment Fund,” reserved for paying claims against the federal government.\textsuperscript{73} This will unencumber the money that the EPA urgently needs for data review, and allay the fears of those who believed that “the possibility [of] having to make indemnity payments”\textsuperscript{74} out of its own operating budget would “discourage the EPA from aggressive regulation.”\textsuperscript{75}

The 1988 amendments will require registrants to conduct more preliminary work to show the ramifications of their product’s use on the environment.\textsuperscript{76} The EPA cannot take these “first cut” tests as dispositive\textsuperscript{77} and, therefore, will continue to have to conduct testing and review on its own.\textsuperscript{78} Nonetheless, the preliminary testing required of the registrants will provide the EPA with initial data from which to draw information about a pesticide before the EPA begins its review.

Some commentators have deemed these most recent amendments to FIFRA to be “extremely significant”\textsuperscript{79} and “a major step in pesticide regulation”\textsuperscript{80} because they are “designed to speed up reregistration and remove potential threats to EPA’s budget that could thwart its efforts to protect the public.”\textsuperscript{81} Nevertheless, an inefficient hearing process, the lack of any definite threshold risk level at which a pesticide should be taken off the market pending determina-

\textsuperscript{70} Ferguson & Gray, supra note 18, at 10077; see 7 U.S.C. § 136a-1(i)(5) (1988). For a detailed exposition of how, when, and on whom both the “active ingredient fee” and “maintenance fee” are to be levied, see Ferguson & Gray, supra note 18, at 10076-78.

\textsuperscript{71} See Ferguson & Gray, supra note 18, at 10078.

\textsuperscript{72} Note, however, that although the EPA was liable, “most of these claims were eventually paid from sources other than EPA’s operating budget.” \textit{Id.}


\textsuperscript{74} Ferguson & Gray, supra note 18, at 10079.

\textsuperscript{75} \textit{Id.}

\textsuperscript{76} \textit{See id.} at 10078 (1988 amendments restructure Agency’s burden, shifting many registration tasks to registrant); 7 U.S.C. § 136a-1 (1988).

\textsuperscript{77} Ferguson & Gray, supra note 18, at 10078 (the EPA must make final regulatory assessment).

\textsuperscript{78} \textit{Id.} (the EPA still must review the data to determine whether it is sufficient).

\textsuperscript{79} \textit{Id.} at 10070.

\textsuperscript{80} \textit{Id.}

\textsuperscript{81} \textit{Id.}
tions concerning potential risks, and an undue evidentiary burden on the EPA, still make FIFRA highly inadequate as a national standard to promote public health and a safe environment. The controversy surrounding the reregistration of Alar exemplifies this inadequacy.

II. ALAR AND FIFRA'S INEFFECTIVENESS

The pesticide daminozide, better known as Alar, is a growth regulator that the apple industry has used extensively since its registration on the market in 1968. While this chemical allows apples to stay on the trees longer, reduces crop loss due to preharvest dropping, prolongs the shelf life in apples, and promotes a uniform color and firmness, studies have shown that it is potentially carcinogenic, especially among young children. Daminozide, a systemic pesticide, cannot be washed or peeled off because it penetrates the meat of the apple. Moreover, the processing of apples into apple juice or applesauce converts daminozide into an even more potent carcinogen, unsymmetrical 1,1 dimethylhydrazine (UDMH).

In September 1985, the EPA first proposed banning daminozide based on studies conducted between 1973 and 1984, which revealed that daminozide had oncogenic (tumor forming) effects on laboratory rodents. The registrant, Uniroyal, however, argued

82. Daminozide was first registered under FIFRA in 1963 as a plant growth regulator for use on chrysanthemums. It also was used on peanuts, grapes, cherries, pears, and some vegetables. Schatzow, supra note 24, at 30.
83. Id. Daminozide is unique in that there is no comparably effective pesticide. Id.
84. See generally NRDC, supra note 8 (a detailed analysis of children's exposure to pesticides in food, including daminozide in apples, and the potential hazard that the residues pose to children). Pesticides pose a particularly serious threat to young children because they typically consume fruits and vegetables at a significantly greater rate than adults, and they frequently are more susceptible than adults to the effects of carcinogens. Id. at 1.
85. Note, supra note 8, at 183 (citing A. Heier, EPA Press Release 3 (Jan. 22, 1986)).
86. Id. at 185. "One expert stated that carcinogenicity studies suggest that UDMH [unsymmetrical 1,1 dimethylhydrazine] is several hundred times more carcinogenic than daminozide." Id. at 185 n.31.
87. Id. at 185. The EPA relied upon five studies conducted between 1973 and 1984 to conclude that daminozide and its metabolite UDMH are carcinogens. These studies were:
(c) Toth, B., 1977. The large bowel carcinogenic effects of hydrazines and re-
that there were too many uncertainties in these studies "to draw scientifically responsible conclusions concerning the risks of daminozide." These scientific uncertainties included data gaps in existing cancer studies and a flawed extrapolation of data over different routes of exposure.

The EPA's Scientific Advisory Panel (SAP) echoed these concerns about the studies. The SAP conceded that the studies raise concerns about the potential oncogenicity of daminozide; nonetheless, the SAP determined that the available animal studies were not a sufficient basis on which to assess human health risks. The panel, however, criticized the EPA's failure to come up with additional testing of daminozide in a more timely manner. The USDA also commented on the animal studies and the conclusions that the EPA drew from them. The USDA stated that the EPA had underestimated daminozide's benefits in its risk-benefit assessment and

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88. Schatzow, supra note 24, at 63.
89. Id.
90. The SAP is a seven-member panel of scientists, nominated by the National Institutes of Health and the National Science Foundation, empowered to advise the EPA as to the impact on health and the environment of pesticides that the EPA proposes to suspend and/or cancel. The SAP was established and empowered pursuant to 7 U.S.C. § 136w(d) (1988).
91. Schatzow, supra note 24, at 63. Curiously, the problems raised by the SAP as to the reliability of the studies were considered at length by the EPA before it proposed the cancellation of daminozide in 1985. Id. at 64. "[I]nternal deliberations . . . on exposure complexities as well as whether the oncogenicity studies from the 1970s were technically adequate grounds for a special review date back to 1978 . . . ." Id. The EPA proposed the cancellation of daminozide despite the scientific uncertainties, but later changed its position when the SAP recommended that daminozide not be cancelled because of the same scientific uncertainties. This raises the question "How much scientific uncertainty is too much [for purposes of regulating pesticides]?") Id.
92. 51 Fed. Reg. 12889 (1986); see also Note, supra note 8, at 192 (citing FIFRA SAP, Review of a Set of Scientific Issues Being Considered by EPA in Connection with the Special Review of Daminozide (Oct. 4, 1985)).
93. Id.
94. Note, supra note 8, at 192. FIFRA allows the USDA to comment on the EPA's notice of pesticide cancellation and to provide an analysis of the effect of such cancellation on the agricultural economy. 7 U.S.C. § 136d(b) (1988).
urged the EPA to reconsider the proposed cancellation.\textsuperscript{95}

The EPA did reconsider its proposed cancellation of daminozide, postponing a final decision on the cancellation pending further study.\textsuperscript{96} Until the new data were available, daminozide remained on the market subject to certain interim regulatory measures.\textsuperscript{97} These measures included limiting the amount of daminozide that growers could apply to their apple crops and reducing tolerance levels for residues found in both raw and processed apples from thirty parts per million to twenty parts per million.\textsuperscript{98}

The ramifications of the EPA having raised serious health concerns about daminozide while allowing it to remain on the market were many. Both Maine and Massachusetts proposed setting tolerance levels on daminozide residues much lower than those set by the EPA.\textsuperscript{99} Many apple growers stopped using daminozide, decreasing Uniroyal's sales of Alar by about seventy-five percent\textsuperscript{100} and consumers became wary of apples and apple products.\textsuperscript{101} Moreover, the situation highlighted FIFRA's inconsistent and inefficient nature—had daminozide been a new chemical, it would not have been allowed on the market unless the registrant could submit additional data to show that it did not pose a health hazard.\textsuperscript{102}

In January 1989, the EPA announced that it intended to initiate cancellation proceedings for daminozide based on interim results of toxicology studies submitted by Uniroyal.\textsuperscript{103} The cancellation process ordinarily runs from eighteen months to several years, depending upon whether the registrant contests the EPA's actions.\textsuperscript{104} While the preliminary data were sufficient to warrant beginning the

\textsuperscript{95} 51 Fed. Reg. 12889 (1986).
\textsuperscript{96} Note, supra note 8, at 193.
\textsuperscript{97} Id.
\textsuperscript{98} 51 Fed. Reg. 12889 (1986). Although the EPA proposed to reduce the residue levels from 30 parts per million (ppm) to 20 ppm in April 1986, it did not actually reduce the tolerance level until January 16, 1987. 52 Fed. Reg. 1914 (1987).
\textsuperscript{99} Note supra note 8, at 186, 211-15.
\textsuperscript{100} Bad Apples, CONSUMER REPORTS, May 1989, at 288.
\textsuperscript{101} Schatzow, supra note 24, at 63.
\textsuperscript{102} Aidala, Apple Alarm: Public Concern About Pesticide Residues in Fruits and Vegetables, in CONG. RESEARCH SERVICE REP. FOR CONGRESS 7 (Mar. 10, 1989). For a new pesticide, the burden of proof is on the registrant to show that the pesticide's intended use will not pose an unreasonable risk. Cf. 7 U.S.C. § 136a(c)(5)(C), (D) (1988). Due to the fact that Alar already was registered, the burden of proof was on the EPA to show that the pesticide risked "unreasonable adverse effects on the environment." Id. § 136d(b). According to the EPA, the studies were not sufficiently reliable to meet the evidentiary threshold. Aidala, supra, at 7.
\textsuperscript{103} Aidala, supra note 102, at 7.
\textsuperscript{104} Id. at 8; see also infra note 136 and accompanying text.
cancellation proceedings, once the results were submitted in final form, in the EPA's opinion the data did not reveal an imminent hazard to human health, the standard sufficient to warrant a suspension of a pesticide's registration pending cancellation. According to a study by the Natural Resources Defense Council (NRDC), however, daminozide does pose the requisite imminent risk.

The NRDC study on pesticide residues in foods found that these residues posed an intolerable risk to children. The NRDC determined that 4700 to 6000 preschool children, out of a population of 22 million (or 240 in 1 million children), eventually will develop cancer from daminozide in their first 6 years of life. By contrast, the EPA calculated that during an eighteen-month exposure period (the average period of time needed to remove a pesticide from the market), only nine in one million children will get cancer due to daminozide, a number approximately twenty-five times lower than the NRDC estimate. The disparity between the NRDC's and the EPA's risk characterization results from different exposure periods—six years versus eighteen months—and different assumptions about dose-response and exposure levels.

The NRDC based its dose-response factor on the same tests and extrapolations that the FIFRA SAP rejected in 1985. According to the NRDC scientists, however, the studies that extrapolated a child's health risk through ingestion of daminozide from a rat's risk through inhalation of daminozide were valid. By contrast, the EPA used figures from a two-year ongoing daminozide study. According to the NRDC, the EPA's interim results greatly underestimate the actual risk because some of daminozide's effects have not yet surfaced.

For the exposure level, NRDC used a 1985-1986 USDA survey of 2000 persons to determine how many apples children eat. The EPA rejected this data because the sample was small and the re-

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105. 7 U.S.C. § 136d(c) (1988); Aidala, supra note 102, at 8.
106. Aidala, supra note 102, at 10.
107. See generally NRDC, INTOLERABLE RISK: PESTICIDES IN OUR CHILDREN'S FOOD/ SUMMARY (Feb. 27, 1989) [hereinafter NRDC/SUMMARY].
110. Id.
111. See supra note 87.
112. See supra note 87.
114. Id.
response rate was only 65 percent. Instead, the EPA used a 1977-1978 USDA food survey of 30,000 persons. The NRDC, in turn, discounted this data because fruit consumption has increased thirty percent from 1977 to 1985.

Despite the NRDC's and the EPA's disagreements as to underlying assumptions, scientifically, the two risk assessments are not far apart. "A factor of 25 difference is well within the range of what two reasonable people using similar data and reasonable assumptions might come up with." Nevertheless, for purposes of risk assessment, this disparity can mean the difference between pulling a dangerous product off the market and saving lives, or not. The nine in one million ratio was not enough for the EPA to declare that daminozide posed an imminent hazard to human health. The question remains as to how great the risk to human health must be before the EPA can suspend the registration of a pesticide pending cancellation. Must 1 in 100,000 people be at risk? 1 in 10,000? 1 in 1000? Or perhaps this should be decided on a case-by-case approach or by use of an incidence approach (for example, one case per year per source)? The level of risk at which a registration can be suspended is left largely to Agency discretion and consequently, so are human lives.

On May 24, 1989, after Uniroyal submitted its toxicological studies in final form, the EPA issued a Preliminary Determination and Draft Cancellation Notice that proposed the cancellation of daminozide food crop use registrations under FIFRA. In early June 1989, Uniroyal, the sole manufacturer of daminozide products registered for food use, signed an agreement with the EPA to "immediately stop sales and recall all stocks of food use daminozide including those held by users." The Agency considered this action along with an apple industry trade association’s public recommendation that growers cease the use of daminozide as sufficiently analogous to a final cancellation action and, therefore, proposed the reduction or revocation of all tolerances for daminozide. Although the health risks from daminozide are diminishing, the problems with FIFRA regarding reregistration of pesticides remain.

115. Id.
116. Id.
117. Id.
118. Id.
119. See supra note 51.
122. Id.
III. FIFRA's Inefficiency: A Necessary Evil?

The problems associated with FIFRA's reregistration process demonstrated by the Alar controversy include the lack of any definite threshold level at which a pesticide is deemed to pose a risk of unreasonable adverse effects or an imminent hazard and an inefficient hearing process.

A. The Discretionary Standards

The unreasonable-adverse-effects standard used to determine a pesticide's cancellation takes into account the "economic, social and environmental costs and benefits of the use of any pesticide." According to the Court of Appeals for the District of Columbia Circuit in Environmental Defense Fund v. Ruckelshaus, this standard obligates the EPA Administrator to issue a cancellation notice "and thereby initiate the administrative process whenever there is a substantial question about the safety of a registered pesticide." The unreasonable-adverse-effects standard has been described as being even less rigorous than the reason-to-believe standard (at which threshold many agencies begin enforcement proceedings) and analytically, little more than "a determination... that adjudicatory proceedings will commence." The same court, however, has declared that the Administrator need not initiate such cancellation proceedings when he or she believes that there is "scientific uncertainty as to the danger of a particular pesticide combined perhaps with the economic impact of cancellation on 'agricultural commodities, retail food prices and... the agricultural economy.'"

Similarly, the Administrator is not obligated under FIFRA to suspend a pesticide's registration when scientific opinion is divided. The imminent-hazard-to-human-health standard necessary for suspension is much more stringent than the unreasonable-adverse-affects standard used to determine cancellation, and it calls for more than a "substantial question of safety:" there must be a "substantial likelihood that serious harm will be experienced during

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124. 439 F.2d 584 (D.C. Cir. 1971).
125. Id. at 594.
127. 867 F.2d at 644 (quoting FTC, 449 U.S. at 241-42).
128. Id. at 642.
129. Id. at 644.
[the cancellation proceedings]."  

In the case of daminozide, the EPA in its discretion did not regard the nine in one million ratio as a substantial enough likelihood that serious harm would result when balanced against daminozide's benefits.  

Both the unreasonable-adverse-effects and imminent-hazard standards require the EPA to conduct a risk and benefit analysis to determine how much risk is acceptable when balanced against the benefits of a pesticide—"a subjective judgment that is difficult to make even in the absence of [scientific] uncertainty." Critics of risk assessment and risk management statutes such as FIFRA argue that it is repugnant to deliberately trade off lives and health against economic costs and that the public deserves "more than 'reasonable' protection from carcinogens and other hazards." Conversely, it may be inappropriate to pull a pesticide off the market with the attendant economic consequences when the risks are uncertain and the alternatives are either untested or nonexistent. There is also the concern that twenty years down the road, the remedy may be found to be more toxic than the pesticide it replaced. To afford pesticide manufacturers the process due under FIFRA, the Administrator must take these social and economic factors into account when trying to deal with a public health hazard. Unfortunately, under the current FIFRA, the cancellation or suspension of a registered pesticide is governed by overly broad and imprecise standards that can be manipulated by political ideologies and that shift with the tide of public sentiment. The result is inconsistent and inefficient pesticide regulation that leaves the public confused and uncertain about the health risks to which they may be exposed by ordinary consumption of pesticide-treated fruits and vegetables, and suspicious of a regulatory system that sets no definite threshold on health risks imposed on the public. The same concerns voiced eighteen years ago in *Environmental Defense Fund v. EPA* are

135. 465 F.2d 528 (D.C. Cir. 1972); see *supra* note 22.
echoed today—FIFRA needs more concrete legislative guidelines.

B. The Hearing Process

An inefficient hearing process exacerbates the problem of highly subjective discretionary standards. Even if the Administrator does initiate cancellation proceedings, the process of taking a pesticide off the market can take four to eight years. After registrants submit comments and new data to the EPA for a risk and benefit balancing analysis known as Special Review (a two- to four-year process), the registrant then may request an administrative hearing to challenge the Special Review decision (another two- to four-year process). Unless the pesticide's registration has been suspended or the registrant voluntarily withdraws the pesticide from the market, the pesticide remains on the market through both of these procedures.

The registrant still may challenge the EPA's final ruling in federal court.

Due to this lengthy Special Review and cancellation process, it often has taken many years to remove a dangerous pesticide from the market. Perhaps even more disturbing is the amount of time it takes to suspend a pesticide's registration while cancellation procedures are being completed. Even if the Administrator has met the stringent burden of showing that continued use of the pesticide poses an imminent hazard to the public health when balanced against the benefits of the pesticide's continued use, the Adminis-

136. EPA, Highlights of EPA's Draft Legislative Proposal 2 (July 18, 1989) [hereinafter Highlights].
139. See id. at § 136d(a)(1).
141. Besides daminozide, these dangerous pesticides include: DBCP (dibromochloropropane), a soil fumigant used on pineapple fields that through ground water contamination can cause cancer and birth defects; carbon tetrachloride, a post-harvest fumigant used on barley, corn, oats, rice, rye, and wheat that can cause tumors and have a toxic effect on the liver and kidneys; and all pesticides containing captan, an active ingredient used in the treatment of pests on many fruits including apples, apricots, blackberries, and blueberries, and which can cause cancer. EPA, Office of Pesticide Programs, and Registration Standards in the Reregistration Program, 1-4, 1-9, 1-10 (Dec. 1989) [hereinafter Report on the Status of Chemicals in the Special Review Program]; EPA, Office of Pesticides: How Long and How Resolved (Oct. 1989) [hereinafter Special Review Suspension/Cancellation Hearings]. It took the EPA over seven years to remove each of these substances from the market; in the case of DBCP, the hearing process alone took over seven years. Report on the Status of Chemicals in the Special Review Program, supra, at 1-10.
142. See supra note 130 and accompanying text.
trator still must issue a cancellation order. To issue a cancellation order, the EPA must prepare a written assessment of the risks and benefits of a pesticide's continued use and initiate cancellation procedures. The EPA also must give the registrants an opportunity for an expedited hearing in the case of a nonemergency suspension order. As evidenced by the case of daminozide, this entire suspension process can take eighteen to twenty-four months to complete, depending upon how quickly the EPA acts.

Under FIFRA, the process of suspending or cancelling the registrations of existing pesticides unnecessarily prolongs public exposure to dangerous pesticides. Providing the opportunity for an expedited hearing prior to issuing a suspension order and retaining a pesticide on the market pending the completion of a cancellation hearing goes beyond what is required by due process. Presumably, the registrant of a registered pesticide has a property interest in that registration sufficient to invoke the protection of the United States Constitution's fifth amendment due process clause. Nevertheless, the Constitution does not create this property interest; it is created by FIFRA and the rules and regulations promulgated by the EPA pursuant to FIFRA. Just as the property interest in a welfare recipient's welfare payments, or the property interest in a horse trainer's license is created and defined in statutory terms, so too is a registrant's interest in his or her existing pesticide registration created and defined by FIFRA and the EPA. Accordingly, FIFRA and the applicable EPA regulations entitle a registrant to continued registration of a pesticide, unless that pesticide causes an imminent hazard or unreasonable adverse effects to human health or the environment.

144. Highlights, supra note 136, at 3.
146. See infra notes 148-179 and accompanying text.
147. Board of Regents v. Roth, 408 U.S. 564, 577 (1972) ("Property interests...are not created by the Constitution. Rather they are created...by existing rules or understandings that stem from an independent source such as state law—rules or understandings that secure certain benefits and that support claims of entitlements.").
148. For cases addressing the nature of property subject to due process protection, see Barry v. Barchi, 443 U.S. 55, 64 (1979) (plaintiff's property interest in a statutorily regulated horse trainer's license was sufficient to invoke due process protection); Perry v. Sinderman, 408 U.S. 593, 601 (1972) (stating that if a person's claim to a benefit is supported by rules or mutual understandings, that interest is subject to due process protection); Bell v. Burson, 402 U.S. 535, 539 (1971) (holding that driver's licenses are property interests which cannot be disposed of without due process protection).
150. Barchi, 443 U.S. at 64.
Although the opportunity to be heard usually is afforded before the Agency acts, the Supreme Court has recognized that "summary administrative action may be justified in emergency situations" such as those that create an imminent hazard to public health and safety. As one commentator noted,

When the contaminated food or a misbranded drug is about to be sold, or the gas storage tank likely to explode, the luxury of a hearing simply cannot be afforded. In the emergency case, the emergency itself is complete justification for summary action. The right to be heard must give way to the need for the immediate protection of the public.

While summary administrative action most often is allowed in situations that involve a danger to human health, the emergency exception also has been applied in tax cases due to the urgent need for the government to secure its revenues.

Under FIFRA, a pesticide registration may be suspended without a predeprivation hearing if the Administrator determines that an emergency exists. A registrant, however, is afforded the opportunity for a presuspension hearing to determine whether an imminent hazard exists when, in the discretion of the Administrator, the imminent hazard does not create an emergency situation. This imminent hazard dichotomy is unnecessary for purposes of due process; the use of a pesticide should be considered to pose an emergency situation sufficient to justify summary administrative action whenever its "continued use . . . during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment [which includes man] or will involve unreasonable adverse effects on the environment [which includes man]."

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154. Id. § 5.10, at 223.
155. Id. (citing Phillips v. Commissioner, 283 U.S. 589, 598 (1931)).
156. 7 U.S.C. § 136d(c)(3) (1988). This emergency provision was designed to provide an exception to the presuspension hearing requirement in those cases in which this hearing may take a month or more to complete. Love v. Thomas, 858 F.2d 1347, 1353 (9th Cir. 1988).
157. See Love, 858 F.2d at 1352.
ble hazard to the survival of a species declared endangered or threatened." 158 Like the statutory provision at issue in Hodel v. Virginia Surface Mining & Reclamation Association, 159 which requires immediate total or partial cessation of a surface mine operation whenever the Secretary determines that the operation "creates an imminent danger to the health or safety of the public," 160 the imminent-hazard standard under FIFRA is an attempt to reach an accommodation between the private interest affected and the "governmental interest in protecting the public health and safety and the environment from imminent danger." 161

Even in nonemergency situations, once the Administrator has determined that a pesticide meets or is likely to meet the unreasonable-adverse-effects standard sufficient to cancel a pesticide registration, the Administrator could suspend a pesticide registration during the cancellation hearing without denying due process to the registrant. The Supreme Court only infrequently has required a full evidentiary hearing prior to the deprivation of an existing property right. 162 In Matthews v. Eldridge, 163 the Court recognized that "'due process,' unlike some legal rules, is not a technical conception with a fixed content unrelated to time, place and circumstances." 164 To determine the process due an owner prior to the deprivation of his or her property right, a court must analyze the governmental and private interests affected by the deprivation. 165 The Matthews Court describes three criteria that should be considered in this analysis.

First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural require-

158. This is the definition of "imminent hazard." 7 U.S.C. § 136(l) (1988).
161. Hodel, 452 U.S. at 300.
162. See, e.g., Goldberg v. Kelly, 397 U.S. 254, 266 (1970) (recognizing that the interest of a welfare recipient in uninterrupted benefits outweighs the state's interest in avoiding the extra financial and administrative burdens of a pretermination hearing).
164. Id. at 334 (quoting Cafeteria Workers v. McElroy, 367 U.S. 886, 895 (1961)). The Matthews Court held that an evidentiary hearing was not required prior to the termination of disability benefits. Id.
165. Id. at 335.
ment would entail. 166

Under this test, Congress could permit or require that a registrant's pesticide registration be suspended pending a cancellation hearing. First, the private interest that will be affected by the suspension of a pesticide registration for the purposes of due process is the registrant's interest in the uninterrupted sale or distribution of the pesticide pending completion of the cancellation process. 167 Although suspending the registration of a pesticide during the time it takes for a cancellation hearing may impose a financial burden on the registrant, the Administrator can reimburse the registrant for losses suffered "by reason of suspension or cancellation of the registration." 168 Unlike depriving a possibly "eligible [welfare] recipient of the very means by which to live while he waits," 169 an incorrect decision regarding the suspension of a registrant's pesticide registration pending cancellation can be repaired. 170

166. Id.

167. Although the suspension or cancellation of a pesticide registration impacts the farmers who use the pesticide and the dealers and distributors who sell it, this impact is too remote; it is the registrant's interest in the pesticide registration that is a protected property interest for purposes of due process. FIFRA does provide for indemnification under certain circumstances to end users, dealers, and distributors who have suffered losses by reason of suspension or cancellation of a pesticide registration. 7 U.S.C. § 136m (1988). FIFRA also allows persons "adversely affected" by cancellation to request a hearing. Id. § 136d(b). These provisions, however, do not create an individual entitlement in a pesticide registration that cannot be removed except for cause. Absent such an entitlement, end users, dealers, and distributors do not have an interest in a pesticide registration that is protected by due process. See O'Bannon v. Town Court Nursing Center, 447 U.S. 775, 787 (1980) (Medicaid patients did not have a protected property interest in a health care facility that would entitle them to a hearing before the government could decertify that facility); Nuclear Transport & Storage, Inc. v. United States, 890 F.2d 1348, 1354 (6th Cir. 1989) (operator of facility that stored unenriched uranium feed material owned by public utilities was not deprived of property for purposes of due process by the government's decision to provide free storage of unenriched uranium under feed usage agreements).


170. After Matthews v. Eldridge, pretermination hearings are not required when monetary benefits are at stake, absent a situation involving welfare entitlements. See B. Schwartz, supra note 153, § 5.25, at 256; see also supra note 164. The Supreme Court also has held that deprivation of a property interest in a license does not require a pretermination hearing. Barry v. Barchi, 443 U.S. 55, 64 (1979); see also Keystone Cable-Vision Corp. v. FCC, 464 F. Supp. 740, 744 (W.D. Pa. 1979) (even if a property interest had been conferred by electrical permits, available postrevocation hearing procedures were adequate for purposes of due process). One might argue that the stigma of suspension cannot be readily undone and that therefore, the opportunity for a presuspension hearing should be afforded even in a nonemergency suspension; however, any stigma suffered as a result of a nonemergency suspension when the registration ultimately was not cancelled probably would not constitute a deprivation sufficient to in-
Second, the risk of erroneous deprivation of this property interest is slight. Prior to its decision to cancel, the EPA conducts a highly intensive and technical Special Review process lasting approximately two to four years.\textsuperscript{171} Rarely, if ever, has a Special Review decision to cancel a pesticide been overturned after an administrative hearing or judicial review.\textsuperscript{172}

Finally, the government's interest in suspending a pesticide registration pending the cancellation hearing is very strong. FIFRA's current practice of allowing a pesticide to remain on the market pending the completion of a cancellation hearing gives the registrant a strong disincentive to complete expeditiously the cancellation hearing. A registrant might delay the completion of a hearing to delay the pesticide's removal from the market. Therefore, to protect the public and the environment from unnecessarily prolonged "unreasonably adverse effects" and to ensure against unnecessary administrative delay and a waste of administrative resources, it is in the government's best interest to suspend a pesticide's registration pending the completion of the cancellation hearing.

Weighing the above three factors, it seems clear that when the EPA, after the process of Special Review, determines that a pesticide causes "unreasonable adverse effects" and should be cancelled, it can suspend the registration of a pesticide during a cancellation hearing without depriving the registrant of constitutional due process. Nevertheless, due process still requires some kind of post-deprivation hearing.\textsuperscript{173}

Finally, due process "does not necessarily demand all the essentials of a judicial trial in every case."\textsuperscript{174} The courts usually have employed a cost-benefit analysis "comparing the benefit of the procedural safeguard sought . . . with the cost of the safeguard"\textsuperscript{175} to determine the procedures required.\textsuperscript{176} Usually, the more serious the consequences of a property deprivation, the more formal the procedures required.\textsuperscript{177} Although the cancellation of a pesticide registration may not be as serious as a deprivation of welfare benefits,
a cancellation is a complete deprivation of a registrant's property right in that registration. As such, the procedures demanded by due process may require a meaningful evidentiary hearing with the rights to appear, to present evidence, and to call and examine witnesses. The Agency or a reviewing court may conduct this evidentiary hearing if the review is de novo. The registrant would have an interest in an expeditious resolution of the hearing because the pesticide would be suspended during the time of the hearing. It is doubtful that the registrant would request such a hearing unless there is an issue that genuinely needs to be raised.

IV. A More Responsive FIFRA

A. Proposed Amendments

As of this writing, there are several bills before Congress to amend FIFRA. These include H.R. 3153, H.R. 3292, and a proposal by the Bush administration.

1. H.R. 3153.—H.R. 3153 would amend FIFRA to allow the cancellation of a pesticide registration whenever there is a "reasonable probability that the pesticide causes unreasonable adverse effects on the environment." Furthermore, any interested person could petition the EPA for cancellation. The process of cancellation would require the EPA to give advance notice of cancellation to the USDA and to the Department of Health and Human Services (HHS) if human health concerns are involved, and there would be no deadline for consultation with either of these agencies. The bill would require publication of notice of a proposed cancellation order, a sixty-day comment period, and review by the USDA, the HHS, and SAP. Cancellation would become final upon publica-

178. See id. at 269.
179. Id. § 5.9, at 221; see Goss v. Lopez, 419 U.S. 565, 582 n.10 (1975).
184. Id. (proposed 7 U.S.C. § 136d(b)(7)(A)).
185. Id. (proposed 7 U.S.C. § 136d(b)(1)(B)).
186. Id. (proposed 7 U.S.C. § 136d(b)(1)(C), (4)).
tion of the final cancellation order in the *Federal Register*, the cancellation decision would be reviewable in federal court. While the process of Special Review occurs prior to these cancellation procedures under existing law, Special Review could occur concurrently with the cancellation procedure under H.R. 3153.

Additionally, suspension under H.R. 3153 would be allowed when the use of a pesticide generally causes unreasonable adverse effects; however, these adverse effects need not manifest themselves in the amount of time generally required for cancellation. An emergency suspension would be allowed if the Administrator determines that the use of a pesticide is likely to result in an imminent hazard. Cancellation need only be initiated within 180 days of the emergency suspension order, and an emergency suspension would be effective as soon as notice is sent to the registrant and published in the *Federal Register*. Finally, federal court review would be based on the arbitrary or capricious standard.

2. *H.R. 3292.*—The requirements for cancellation under H.R. 3292 are more demanding than under H.R. 3153. While the Administrator could cancel a pesticide "to assure that the pesticide... does not generally cause unreasonable adverse effects on the environment," cancellation must be based on a validated test or some other significant evidence that raises concerns of unreasonable adverse effects. H.R. 3292 provides for an advance notice of the proposed cancellation and then a notice of proposed cancellation. The advance notice provides a sixty-day comment period while the notice of proposed cancellation provides for a ninety-day

187. *Id.* (proposed 7 U.S.C. § 136d(b)(5)(B)).
188. *Id.* (proposed 7 U.S.C. § 136d(b)(6)).
194. *Id.* (proposed 7 U.S.C. § 136d(d)(1)(A)(B)).
195. *Id.* (proposed 7 U.S.C. § 136d(d)(2)).
197. *Id.* (proposed 7 U.S.C. § 136d(b)(2)(A)).
198. *Id.* (proposed 7 U.S.C. § 136d(b)(3), (4), (6)).
comment period; an informal hearing may be held after the close of the ninety-day comment period.\textsuperscript{199} The Administrator would not be allowed to cancel a pesticide if alternatives are available to prevent the risk at issue.\textsuperscript{200} The final decision is reviewable in federal court, and the registrant or any other interested person with the registrant's permission may petition to revoke or amend a final cancellation rule.\textsuperscript{201} Like H.R. 3153, H.R. 3292 provides that the Special Review and cancellation procedures would occur concurrently.\textsuperscript{202}

Suspension under H.R. 3292 is essentially the same as that under current law.\textsuperscript{203} The process for emergency suspension under H.R. 3292, however, does not require initiation of cancellation prior to suspension; it does require that the Administrator "proceed expeditiously to issue a proposed [cancellation] rule."\textsuperscript{204}

3. The Bush Administration's Proposal.—The Bush administration proposals for amending FIFRA do not change the current unreasonable-adverse-effects standard for cancellation. The administration proposal would require a prior consultation with the USDA and HHS if human health concerns are involved and, like H.R. 3153, there would be no deadline for consultation.\textsuperscript{205} A proposed order of cancellation would be published in the \textit{Federal Register} with at least ninety days for public comment, and the EPA would have the discretion to grant an informal hearing.\textsuperscript{206} The proposed order would be reviewed by the SAP, the USDA, and if there is a human health concern, by the HHS.\textsuperscript{207} A final order would be published in the \textit{Federal Register} and the decision could be reviewed in federal court.\textsuperscript{208} It is uncertain, however, whether the period of Special Review would run concurrently with the cancellation procedures under the administration proposal.\textsuperscript{209}

The Bush proposal would allow suspension of a pesticide regis-
tration when the Administrator "has prudent concerns that the use of a pesticide results in unreasonable adverse effects on the environment." Before suspension would occur, the continued use of the pesticide during the time required for cancellation would have to pose a substantial risk to the environment or human health and exceed the risk posed by alternate pesticides or it would have to cause a significant lifetime risk that is unreasonable. The registrant or any interested party with the registrant's permission could petition the EPA within sixty days to have the suspension order reconsidered, and the suspension would be reviewable in federal court.

B. The Need for a More Definite Threshold of Safety

While H.R. 3153, H.R. 3292, and the Bush administration proposal are aimed at making FIFRA more responsive to health risk concerns, all of these proposed amendments fall short of the mark. The imminent-hazard standard is still vague and involves too much agency discretion to regulate consistently and effectively the potentially dangerous pesticides that enter the food supply. In addition, the equally vague and highly discretionary unreasonable-adverse-effects standard used for purposes of cancellation has not been adequately revised, and the public still is left wondering "how safe is safe?" when it comes to assessing the risks of pesticides under FIFRA. The EPA defends the vagueness of FIFRA's standards as a way to "preserve flexibility to allow for the development of alternatives in some cases and to accommodate changes in scientific opinion and standards for adequate testing." When pressed, however, the EPA has been able to deal with these changes in scientific opinion and testing standards when enforcing other statutes that have definite statutory or regulatory thresholds of what is safe—the EPA's new ample-margin-of-safety policy under the Clean Air Act is one such example.

In National Resources Defense Council v. EPA, the Court of Appeals for the District of Columbia Circuit required the EPA Administrator to set national emissions standards for hazardous air pollutants under section 112 of the Clean Air Act in two steps.
The Administrator first must determine a "safe" or "acceptable" level of risk considering only health factors and then must set a standard that provides an ample margin of safety considering health, costs, feasibility, and other relevant factors. The EPA has since ruled that to determine a safe level of risk, it will consider maximum individual risk (MIR): the extent of the estimated risk of contracting cancer "were an individual exposed to the maximum level of a pollutant for a lifetime." "If the risk to that individual is no higher than approximately 1 in 10 thousand, that risk level is considered acceptable and EPA then considers the other health and risk factors to complete an overall judgment on acceptability." The number of persons "estimated to suffer cancer or other serious health effects as a result of exposure to a pollutant" is an important factor in this overall judgment on acceptability. "[E]ven if the MIR is low, the overall risk may be unacceptable if significant numbers of persons are exposed to a hazardous air pollutant." The agency's judgment on acceptability also will be influenced by whether the pollutant is a known human carcinogen. Although the EPA has not created a rigid standard for judging the acceptability of MIR, it has provided a "starting point for the analysis in which a floor for the ultimate standard is set." The ample-margin-of-safety standard set at the second step is the "legally enforceable limit that must be met by a regulated facility." At this step, the EPA strives to protect the greatest number of persons possible from contracting cancer—"an individual lifetime risk level no higher than approximately 1 in 1 million." In determining the ample margin of safety, however, the EPA may consider "economic impacts of controls, technological feasibility, uncertainties and any other relevant factors" in addition to health; therefore, while the EPA may strive for a lifetime risk level no higher than one in one million, the allowable risk may be greater once all factors are considered. The EPA may not set the acceptable risk

217. Id.
219. Id.
220. Id.
221. Id. at 38045-46.
222. Id. at 38046.
223. Id.
224. Id.
225. Id.
226. Id.
higher than the maximum individual risk set in the first step of the process which is presumptively 1 in 10,000.

Regulating clean air and pesticides are certainly very different endeavors. While smoke and other emissions may be filtered so as to reduce carcinogenic particles in the ambient air, a carcinogenic pesticide usually must be removed from the market. Nevertheless, the public is as entitled to a safe food supply as it is to clean air and the standards of risk for food and air should be equally stringent and concrete. The Clean Air Act and its applicable regulations thus provide a useful framework for amending FIFRA.

When a pesticide's carcinogenicity is in question, there should be one level of suspension and the term imminent-hazard should not include a consideration of economic benefits or the availability of alternate pesticides as the EPA has proposed. Rather, FIFRA only should allow the EPA to consider health factors when determining whether a pesticide poses an imminent hazard necessitating suspension from the market pending cancellation proceedings. FIFRA should establish a threshold at which a potentially carcinogenic pesticide poses an imminent hazard to public health—if the estimated risk of contracting cancer following a lifetime of exposure to the pesticide (based on an average daily consumption rate or inhalation rate in the case of farm workers, for example) is greater than approximately 1 in 10,000, the pesticide should presumptively pose an imminent hazard to public health. The greater than 1 in 10,000 risk threshold, although strongly presumptive, need not be an absolutely inflexible standard. The EPA in its discretion could find that a risk of 1 in 10,000 or less still poses an imminent hazard to the public health when the incidence of cancer or other serious health risks and the distribution of health risks in the exposed population are considered. The strengths and weaknesses of scientific studies also should be taken into account. For example, greater weight might be accorded a known human carcinogen than those extrapolated from animal studies. These same factors may lead the

227. Highlights, supra note 136, at 4, 12.
228. Scientists may disagree as to how they should determine figures such as an average daily consumption rate. See supra notes 111-116 and accompanying text. The problems of scientific uncertainty may never be resolved; however, because the EPA no longer has to make indemnity payments out of its own budget for economic losses suffered by a registrant whose registration is cancelled or suspended and because the EPA will receive more money from reregistration fees as a result of the 1988 amendments, some are hopeful that the EPA will be better able to acquire the best technology and more scientific help for the testing of pesticides, thus mitigating the effects of scientific uncertainty. See Ferguson & Gray, supra note 18, at 10076.
Administrator to determine that an imminent hazard to human health does not exist although the estimated risk of contracting cancer following a lifetime of exposure to the pesticide through average daily consumption is greater than 1 in 10,000. Still, the 1 in 10,000 risk factor would be strongly presumptive, and it would be very difficult for the Administrator to conclude that a risk factor above 1 in 10,000 does not pose an imminent hazard to public health. "This presumptive level comports with many previous health risk decisions by EPA premised on controlling maximum individual risks to approximately 1 in 10 thousand and below."229

Moreover, the cancellation procedure could be initiated up to ninety days after a suspension is ordered. To initiate the cancellation procedure for a pesticide that may cause cancer in humans (a procedure that could begin either in conjunction with or completely separate from the suspension procedure as is the case under the current FIFRA), the term "potentially unreasonable adverse effects" on the public health would not include a consideration of the economic benefits of the pesticide's continued use. As in the suspension process, only health effects could be considered. Potentially unreasonable adverse effects on the public health presumptively would exist if the estimated risk of contracting cancer following a lifetime of exposure to the pesticide (based on an average daily consumption rate and inhalation rate, for example) is greater than one in one million. This greater than one in one million threshold, although strongly presumptive, would not preclude agency discretion as to what constitutes potentially unreasonable adverse effects to the public health. As in the suspension process described above, the Administrator could consider the incidence of cancer or other serious health risks, the distribution of health risks in the exposed population, and the strengths and weaknesses of the scientific studies. The one in one million risk factor should be strongly presumptive, however, and it would be very difficult for the Administrator to conclude that a one in one million risk of cancer does not pose potentially unreasonable adverse effects to the public health.

In determining whether it ultimately should cancel a pesticide's registration, the EPA would be able to consider the economic and social benefits of a pesticide's continued use, as well as its health risks. The EPA's final determination of whether a pesticide poses unreasonable adverse effects to the public health should be influenced strongly by health considerations and the threshold that

promoted the initiation of cancellation procedures. Moreover, the greater the health risk over the one in one million risk threshold, the greater the weight that should be accorded the pesticide’s risks when balanced against the benefits of its continued use.

The above proposal for amending FIFRA would be applicable only to those pesticides that are actual or possible human carcinogens. The noncarcinogenic human health risks or risks to the environment that pesticides pose should be evaluated under a nonthreshold risk-benefit approach. Under this approach, the Administrator would be able to cancel a pesticide registration to insure that the pesticide does not generally cause unreasonable adverse effects on the environment, considering both the risks and benefits of the pesticide as under the current FIFRA. An imminent hazard still would be required for suspending a pesticide registration pending cancellation; however, suspension would be allowed when the use of a pesticide generally causes unreasonable adverse effects on human health or the rest of the environment during the pendency of the cancellation. Only the risks of the pesticide’s continued use during the pendency of the cancellation would have to be considered. The decision to suspend would become effective when notice of the suspension is sent to the registrant and published in the Federal Register.

The reason for this dichotomy between carcinogenic and noncarcinogenic pesticides is two-fold. First, it may be very difficult and perhaps ridiculous to establish a risk threshold for many health and environmental hazards. For example, it would be very difficult to set a risk threshold regarding the number of fish that must die due to the run-off of a pesticide into a pond before that pesticide is declared to pose unreasonable adverse effects on the environment. It would be equally ridiculous and perhaps impossible to set a threshold on the number of severe headaches a pesticide can cause in the population before an imminent hazard to human health exists. A certain amount of discretion by the Agency in risk-benefit situations such as these is both necessary and desirable. For health risks like cancer, which the EPA has been able to quantify, a less discretionary threshold approach is more desirable; both the EPA and the public would be more aware of the “acceptable” levels of risk that can be imposed on the public health.

Second, this threshold approach is consistent with the proposed revisions of the Federal Food, Drug and Cosmetic Act, (FFDCA) which, among other things, regulates the amount of pesticide resi-
dues allowed in food. Under the Administration's plan, the level of pesticide residues that pose a cancer risk to humans, and are allowed in both raw and processed vegetables, would be set according to a negligible-risk standard. This standard would establish a flexible threshold of safety: the administration proposal has suggested a lifetime risk of one in one million for long term health risks like cancer. While a tolerance level posing greater than negligible risks may be allowed when economic impacts on consumers and producers as well as public health are taken into consideration, the negligible-risk standard would put a bit more certainty into the risk assessment process and attempt to resolve the current inconsistencies within the FFDCA.

C. A More Efficient Hearing Process

The only hearings that should be afforded a registrant during the suspension and cancellation processes are those hearings required by due process. Accordingly, there need be no opportunity for a trial-type hearing required prior to the suspension of a registered pesticide. There would be an opportunity for judicial review of the suspension only to determine if the decision to suspend was arbitrary and capricious. To prevent any unnecessary delay in cancelling or otherwise restricting the use of a suspended pesticide, cancellation procedures would be initiated within ninety days of sending the suspension notice to the registrant. The registrant would be able to request an agency hearing challenging the Administrator's final decision to cancel.

To begin the cancellation procedure (which can be conducted in conjunction with or separately from the suspension procedure), the registrant, USDA, FDA, and HHS would be given thirty-days notice before the proposed notice of intent to cancel is published to

230. See 21 U.S.C. § 346a(a) (1988). The registration process under FIFRA is closely linked with the tolerance setting process under the FFDCA.

Pesticides that are to be registered for use on food crops must be granted tolerances under the [FFDCA]. Tolerances authorize and place legal limits on the presence of pesticide residues in or on raw agricultural commodities and, in appropriate cases, processed foods. The EPA will not register the use of a pesticide on food crops unless tolerances first have been granted to cover any residues expected to remain in or on the food.


232. Id. at 48.

233. See supra notes 146-179 and accompanying text.
prepare for the notice and comment period. There would then be a notice and comment period lasting 120 days from the day that the proposed cancellation and the reasons behind it are announced in the Federal Register. During this 120-day period, the burden would be on the registrant, the USDA, and any other interested party to present information to the EPA regarding the pesticide's benefits (including social and economic factors), as well as any scientific studies or data regarding the pesticide's carcinogenic or other effects. Any interested party also could submit information regarding the risks or benefits of the pesticide's continued use. At the end of the 120-day period, the EPA would have 30 days to consider the risks and benefits of the pesticide's continued use and to publish both a written notice in the Federal Register of its intention to cancel or continue the pesticide's registration and an account of the risks and benefits considered in the decision. The registrant could challenge the final agency decision in an evidentiary hearing conducted by the Agency. If the pesticide has not already been suspended or voluntarily withdrawn from the market by the registrant, the Administrator could suspend the pesticide registration pending the final outcome of the cancellation hearing.

CONCLUSION

There are those who believe that the EPA should have as much discretion in the risk assessment process as possible (as under the current FIFRA) because it is the most realistic and sensible way to regulate potentially hazardous chemicals in the highly complex world in which we live. These people may argue that we voluntarily accept risk every day—by driving a car, smoking, or building a house on the San Andreas fault—because we realize that to live our lives, we often must balance the risks against the benefits of our actions. Accordingly, the argument goes, we should not be loath to accept a risk-benefit approach to regulating our food supply. Nonetheless, there is something inherently disturbing about having a cancer risk imposed on you by a regulatory agency that may be bowing to political pressures. It is even more disturbing that someone close to you may have had his or her life balanced away against the economic benefits of keeping the color of apples uniformly red. Picking up a fruit or vegetable at the grocery store becomes a game of carcinogen roulette in which no consumer really knows the dangers of what he or she is eating.

It may be inevitable that we must consider the economic benefits as well as health risks when determining whether a pesticide should be taken off the market. The world is a complex place in which the loss of a fruit or vegetable crop to pests even for one season could have a profound effect on the availability and prices of food in this country and a devastating effect on the farmers who grow the failed crop. To protect the public health, however, especially from diseases like cancer, there must be some safety threshold established (albeit not too rigid) as well as a more efficient way to remove dangerous pesticides from the market. These proposals are intended to facilitate more consistent and efficient pesticide regulation, to provide the Agency with a realistic and appropriate amount of discretion, and to give the public a more concrete understanding of, and more confidence in the standards and procedures that the EPA uses to protect the public health and safety from the dangers of pesticides.

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