

# EPA Pesticide Registration: *Our Safety in the Balance?*

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*"EPA registered — your assurance of safety."*

*"Are these pesticides safe for my children and pets?  
Anything less and they wouldn't have EPA's  
registration approval."*

With statements such as these, some in the pesticide industry assure us that the products they manufacture, market, and apply have been judged safe by the Environmental Protection Agency (EPA). In reality, the registration process through which virtually all pesticides must pass prior to sale in the United States offers no such assurance, nor was it ever intended to do so.

The registration process is not a straightforward health and environmental impact assessment, but rather an attempt to balance the adverse impacts of pesticide use against its perceived benefits. EPA's efforts to strike such a balance have been seriously deficient, relying, as they have, upon inadequate and mismanaged data on pesticide composition and toxicity.

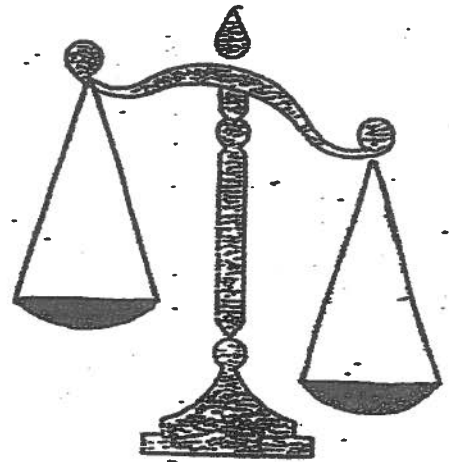
Registration is not dependent upon a finding of safety

Pesticides are regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) which sets the standard for pesticide registration. Under FIFRA, EPA must register a pesticide if the Administrator determines that the pesticide will perform its intended function *without any unreasonable adverse effect on the environment*.<sup>1</sup> Under the law, "unreasonable adverse effect on the environment" is defined as "any unreasonable risk to man or the environment taking into account the economic social and environmental costs and benefits of its use."<sup>2</sup> This term defines the registration process as a balancing act.

To make that clear, federal regulations prohibit any claim on a pesticide label that the pesticide is safe, non-toxic, or harmless, even if that claim is limited to use of the pesticide in accordance with label directions.<sup>3</sup> Thus, registration of a pesticide by EPA carries no assurance that the pesticide is safe for human health and the environment.

Other laws administered by EPA offer substantially greater levels of protection to the public. The Clean Air Act, for example, directs the EPA Administrator to regulate hazardous air pollutants at a level "adequate to protect the public health . . . with an ample margin of safety."<sup>4</sup> This establishes a health protective standard far more stringent than FIFRA.

The difference in the philosophies between these two federal laws lies in the fact that the pesticide law, FIFRA, was originally agricultural legislation. First enacted in 1947 and administered by the U.S. Department of Agriculture, FIFRA was primarily



designed to protect farmers from products which would not control the target pest, not an environmental protection law. A secondary intent of the law was to protect farm workers from gross poisoning and injury, consistent with the general state of toxicological knowledge and occupational health practices of the time. Instead of mandatory tests for new products, USDA personnel handled their registration on a case-by-case basis, requiring tests as they saw fit.<sup>5</sup>

Early testing requirements have been judged inadequate

In 1970, administration of FIFRA was transferred from the USDA to the newly-formed EPA. Along with the responsibility came many of the same USDA staff and the practices they had followed in previous years. By 1972 Congress recognized the need for more demanding and standardized testing requirements including tests for toxic effects on humans, environmental fate and impacts. Thirteen years later, in 1985, EPA finally responded to that Congressional mandate with new rules prescribing a more stringent battery of tests for new products just coming to market.<sup>6</sup>

Unfortunately, by that time there were already some 50,000 products on the market which had never been evaluated under the new requirements.<sup>7</sup> Since 1985, the number of registered products has dropped to between 20,000 and 25,000. To address those products, EPA is now reviewing the data available on them, demanding that new tests be performed and the results submitted for EPA's evaluation. This reregistration process is moving ahead slowly and will not be completed until well into the next century. In the meantime the products registered years ago, under protocols deemed inadequate by current standards, remain on the market and are readily available.

The reregistration process, flawed as it is, has not been an empty gesture. Numerous products have been removed from the market, either by EPA's mandate, or voluntarily by the registrants when faced with the prospect of data demands to satisfy the more stringent guidelines. In many other instances, uses of particular pesticides have been restricted, and their availability to the general public reduced. (Continued on page 22.)

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The current pesticide testing guidelines occupy hundreds of pages of text, a fact often cited by the pesticide industry. These guidelines undoubtedly provide a better basis for evaluating the potential adverse effects of pesticides compared to the ones they superceded. However, these guidelines, like their predecessors, will inevitably fall behind the state of toxicological knowledge.

Significant revisions to the guidelines have already been implemented by EPA. For example, in 1987 the Attorney General of New York joined a coalition of public health and environmental advocacy groups to petition EPA to require certain tests for neurotoxicity be added to the existing battery of toxicity tests for pesticide registration.<sup>8</sup> These tests were already required by EPA for the evaluation of toxic chemicals in other regulatory programs, but were not being applied to pesticides, many of which are specifically designed to affect the nervous systems of their target organisms. In response to that petition, EPA added several new testing guidelines to the existing battery. This process will continue as our understanding of toxicology advances.

Recently, the National Academy of Sciences (NAS) reported on their study of pesticides in the diets of infants and children.<sup>9</sup> They recognized that current regulatory practices are inadequate to protect infants and children. Reminding EPA that infants and children are not just little adults, the NAS panel recommended extensive changes in toxicity testing and exposure assessment. The same problems apply to the non-dietary exposure of infants and children to pesticides.

Recognizing the inability of the regulatory program to quickly incorporate advances in science, EPA has stated that *"EPA believes that most pesticides — despite having an EPA registration — have not been adequately tested to determine their effects on people or the environment."*<sup>10</sup> Absent such a determination, how could registration possibly assure safety?

**Implementation of the registration process has been seriously flawed**

Notwithstanding the inevitable movement of science, it's fair to ask how well EPA is managing and using the data it currently receives in support of pesticide registrations. To answer this question, we need to look no further than some of EPA's evaluations of its own performance.

**Label Warnings** EPA views the label on a pesticide container as its first line of protection for the user. Each label bears warnings and use precautions prescribed by EPA, which should be readily available to all pesticide users. In order to determine the appropriate label warnings and precautions, EPA relies on its evaluation of the acute toxicity of the pesticide (i.e., its capacity to cause adverse health effects which

**"EPA believes that most pesticides — despite having an EPA registration — have not been adequately tested to determine their effects on people or the environment,"** stated an EPA report.

are manifested shortly after the exposure).<sup>11</sup> These are the types of effects which were presumably considered even in the earliest days of pesticide regulation under USDA, and those which are best understood and diagnosed by the medical community.

In 1992, the EPA Inspector General (IG) reported on an investigation of EPA's process for reviewing and approving labels for pesticide products. The IG's staff selected 95 pesticide products, studied their labels and reviewed the data files upon which the labels were supposed to be based. In the IG's own words:

*"EPA did not have either the toxicity studies, or the documentation of its review of those studies, to assure that correct precautionary statements were printed on many pesticide labels. . . Toxicity studies were unavailable for 58 of 98 pesticides reviewed."*<sup>12</sup>

*"Precautionary statements for many pesticide products we reviewed did not meet regulatory requirements. . . As a result, the labeling statements on pesticides may not adequately protect humans and the environment from unnecessary adverse effects."*<sup>13</sup>

*"The precautionary statements. . . accepted on almost half the labels evaluated were inaccurate."*<sup>14</sup>

One can't help but wonder, if 45 years of study and review of the obvious acute effects of pesticides is not translated into accurate label warning and precautions, how well can EPA evaluate the more complex issues of chronic toxicity and low level exposures?

**"Inert" Ingredients** Virtually all pesticide products are mixtures of active and so-called inert ingredients. The active ingredients are intended to control the target pest, while the "inerts" are included for a variety of other reasons, such as to dissolve or preserve the active ingredient or otherwise enhance its performance or utility. "Inert" ingredients may be highly toxic substances but, under FIFRA, manufacturers are allowed to keep their identity concealed from the public. The law directs that the information should be provided to EPA, treated as confidential business information and not released to the public.<sup>15</sup>

Presumably, although the public is kept in the dark, EPA could evaluate the potential hazards associated with the "inert" ingredients and impose appropriate precautions and restrictions. Unfortunately, we now know that EPA may also be in the dark when it comes to the "inert" ingredients in pesticide products.

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Responding to a rising level of public concern about "inert" ingredients, EPA announced an Inerts Strategy in 1987. The Strategy was designed to eliminate the most toxic "inert" ingredients from use, require improved label disclosure of inert ingredients, and increase the toxicity testing required for "inerts." That Strategy, if effectively implemented could have enhanced the level of protection the EPA afforded the public. As revealed by another investigation by the EPA Inspector General, implementation was substantially deficient.<sup>16</sup> For example:

EPA has not ... enforced the 1987 Inert Strategy requirements for inerts with toxic effects. ... EPA identified 68 inerts as potentially toxic, and assigned them to a high priority for testing. ... EPA has no specific procedures or timetables for insuring that these inerts are reviewed."<sup>17</sup>

"EPA is not sure how many chemicals registrants are using as inert ingredients because the inerts were not accurately coded into ... [the EPA database] ... there were about 600 registrations for which ... the chemical name was not available."<sup>18</sup>

How precisely can EPA balance the risks and benefits of the use of a particular pesticide, if EPA doesn't know the identity of the chemical(s) which often make up the bulk of the product sold to the public?

**Lack of Efficacy Requirements** The presumed benefits of pesticides are used in the registration process to balance the potential adverse effects of pesticide exposures. Yet, EPA routinely examines efficacy data only for disinfectants used to protect public health and certain other products. It is EPA's general practice to demand that pesticide registrants only perform tests of pesticide efficacy, but not submit these tests to EPA for evaluation.<sup>19</sup>

Often with no data on the presumed benefits of pesticide use, and with inadequate and mismanaged data on pesticide composition and toxicity, EPA still attempts to balance the costs and benefits of the use of particular pesticides as required by law. Their own evaluation of the process is unambiguous: "EPA registration does not mean a pesticide is safe."<sup>20</sup>

We need not rely upon this registration process, with all its legal and procedural shortcomings. Alternative pest management techniques are available which use physical, mechanical, biological, and cultural means to control pests. Our safety is hanging in the balance, but with pesticides, the scales are tipped against us.

### Endnotes

- 1 7 U.S.C. §136a (a) (5).
- 2 7 U.S.C. §136a (bb)
- 3 40 CFR 162.10 (a) (5)
- 4 42 U.S.C. §7412b (1) (B)

<sup>5</sup> U.S. General Accounting Office, April 1986. "Nonagricultural Pesticides—Risks and Regulation," (GAO/RCED-86-97), p. 9-10.

<sup>6</sup> U.S. General Accounting Office, April 1986. "Pesticides—EPA's Formidable Task to Assess and Regulate their Risks," (GAO/RCED-86-125), p. 21.

<sup>7</sup> *Ibid.*, p. 22.

<sup>8</sup> "Petition to Develop Testing Methods to Assess Neurotoxic and Neurobehavioral Effects of Pesticide Active and Inert Ingredients." Submitted by Center for Science in the Public Interest, State of New York, et al. to the U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances, Feb. 12, 1987. Docket No. OPP-000247.

<sup>9</sup> National Research Council, Committee on Pesticides in the Diets of Infants and Children, 1993. "Pesticides in the Diets of Infants and Children," National Academy Press, xv & 386 pp.

<sup>10</sup> U.S. Environmental Protection Agency, February 1993. "Lawn Care Pesticides White Paper" Appendix VI, p. lxxiii.

<sup>11</sup> U.S. Environmental Protection Agency, Office of the Inspector General, "Labeling of Pesticides," Audit Report EIEPF1-05-0429-2100613, Sept. 10, 1992, p.10.

<sup>12</sup> *Ibid.*, p.9.

<sup>13</sup> *Ibid.*, p.19.

<sup>14</sup> *Ibid.*, p.20.

<sup>15</sup> 7 U.S.C. §136h (d) (1) (c)

<sup>16</sup> U.S. Environmental Protection Agency, Office of the Inspector General, Sept. 27, 1991. "Inert Ingredients in Pesticides," Audit Report EIEPF1-05-0117-1100378.

<sup>17</sup> *Ibid.*, p.3.

<sup>18</sup> *Ibid.*, p.4-5.

<sup>19</sup> U.S. General Accounting Office, May 1993. "Pesticides—Pesticide Registration May Not Be Completed Until 2006," (GAO/RCED-93-94), p.3.

<sup>20</sup> *Loc. cit.* U.S. Environmental Protection Agency, Feb. 1993.