Part Three. Pesticide Law and Regulation

1. Laws and Regulations

- Legal control over pesticides in the U.S. is predominantly the responsibility of the federal government. However states have the legal authority to set standards that are more rigorous than federal requirements, as California has done. Before the U.S. Environmental Protection Agency was created in 1969, the Department of Agriculture was primarily responsible for pesticide licensing.
- The USDA was created to help nurture the agricultural sector in the U.S., including providing a diversity of technologies to help protect crop and livestock production and profitability. Half a century later, the USDA's institutional support for agribusiness and pesticides is as strong as it has ever been.
- Many of the same chemicals that the USDA approved in the 1950s and 1960s are still in the marketplace, such as chlorpyrifos, 2,4-D, alachlor, atrazine, dicamba, and parathion.

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- The USDA did not require scientific analyses of a pesticide's environmental fate or effects, nor did they consider the pesticide's potential for human exposure and health loss.
- Nearly all of the data regarding chemical safety were provided to the federal government by manufacturers seeking licenses. No independent testing was required, so chemical companies argued repeatedly that no evidence of chemical persistence, mobility, exposures, or significant risk existed.
- T*his claim was interpreted by government regulators to mean that the absence of evidence of chemical danger is evidence of its safety.*
- This distorted logic led the USDA to issue more than 50,000 pesticide product registrations by 1960, and nearly 10,000 separate tolerances, or legal limits, for separate chemical residues to exist in our nation's food supply, approved by the FDA and the EPA.
- Manufacturers' data for these compounds supported corporate claims of effectiveness in managing pests, yet in most cases, the data were either nonexistent, or poor in quality.
- Thus, the EPA has spent much of its 50-year life reevaluating the hazards of previously approved chemicals and products. Normally, as pesticides are more carefully studied, scientists generally discover that their dangers are more extreme than previously believed.
- *Complete bans have been rare events in the history of U.S. pesticide regulation.* More likely than bans are regulations that restrict certain uses of a particular pesticide that has been shown to have harmful effects.
- Federal regulators complain that their limited budgets slow their pace of chemical-by-chemical reviews. The reregistration process has rarely occurred in less than a decade following original licensing.

- EPA officials in the 1990s quipped that the agency's decision-making delays were akin to putting the pesticides in a regulatory parking lot, often due to manufacturers' objections to tighter regulations.
- Manufacturers understand that delays in the re-registration process can extend the market lives of their products to get beyond the 20-year proprietary patent life that prevents the introduction of generic brands by competitors.
- By contrast, manufacturers are anxious to bring new chemicals to market quickly to recover their research, development, and regulatory compliance costs.
- These findings should require immediate adjustments in allowable uses of pre-approved products, more cautionary labels, restricted application methods, or worker training requirements. Instead, original uses have normally continued for decades before EPA has taken more rigorous regulatory action.
- The laws and regulations that pertain to pesticide residues in foods are even more complicated because they are spread across three federal agencies: the EPA, the FDA, and the USDA. This division of authority impedes effective regulations since these agencies do not easily share data, expertise, budgets, or legal authority.
- The EPA, FDA, and USDA have very different missions and political will, when it comes to pesticide uses and the protection of human health from pesticide exposures.

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2. Registration and Licensing of Pesticides

- Although the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (FIFRA) still provides the backbone of U.S. laws governing pesticides, it is now the EPA that registers products containing pesticides.

The USDA did not have the scientific expertise to demand or review technical studies relevant to judge human health threats, nor did they monitor environmental contamination.

- To reach the decision to register a pesticide, the EPA must find that the pesticide in question will not not cause any *unreasonable adverse effects on the environment.*[32]
- The phrase cited above requires consideration of the *economic, social, and environmental costs and benefits.* Importantly, it provides the ethical framework that has long guided pesticide licensing.
- Prior to the establishment of the EPA in 1970, the USDA registered pesticides. The USDA did not have the scientific expertise to demand or review technical studies relevant to judge human health threats, nor did they monitor environmental contamination.
- FIFRA was unclear about whether "social costs" included human health. By 1960, the USDA had granted manufacturers 10,000 different food and animal feed tolerances, and nearly 50,000 pesticide product registrations.[33]

- The USDA balanced benefits against risks when evaluating pesticides. Once the certainty of pesticides' effectiveness in increasing productivity exceeded the certainty of damage to the environment, the USDA routinely granted registrations and tolerances.

- The sheer number of different pesticide licenses guaranteed that these chemicals could be designed, sold, and used with little government oversight or interference.

- Rachel Carson's landmark book, *Silent Spring,* captured international attention and raised public concern about the environmental effects of pesticides.[34]

- Conservationists, environmentalists, and health advocates pressured Congress to pass the Federal Environmental Pesticide Control Act of 1972. The law gave the EPA broad authority to demand stronger evidence about the environmental and health effects of chemicals proposed for registration and tolerances.

- In addition, the law authorized the review of previously registered pesticides to examine the hazards they posed, using recent evidence, to ban chemicals, and to cancel or adjust food tolerances.[35]

- The EPA spent much of its first three decades reassessing the risks associated with the chemicals already approved by the USDA. Often, the EPA spent 10 or more years reviewing single chemicals, while relying on manufacturers to report the chemicals' persistence, mobility, toxicity, and health and environmental risks.

3. Inert Ingredients

- Pesticides are composed of active ingredients and inert ingredients. Some inert ingredients may be more toxic than active ingredients and can comprise 90% to 95% of the product.

- Some inert ingredients are suspected carcinogens. Other inerts have been linked to central nervous system disorders, liver and

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kidney damage, birth defects, some short-term health effects, and a range of adverse health effects.[36]

In 1996, the Food Quality Protection Act (FQPA) became federal law. Congress passed the most important statutory change in 50 years in response to a 1993 National Academy of Sciences study that found that children's health was at special risk from dangerous pesticide exposures.

- For much of the past half century, EPA has permitted more than 1,000 chemicals to be classified as inert ingredients. These are often additives, such as petroleum distillates or other solvents.
- Inert ingredients commonly make up the majority of what is released to the environment, yet neither Congress nor any regulatory agency have required chemical testing to understand their toxicity or environmental fate of these chemicals.
- Nearly 394 inert chemicals in some products are classified as active pesticide ingredients in other products. In addition, nearly 200 have been listed as hazardous wastes or pollutants under U.S. environmental laws.
- The EPA's inability to effectively review these active ingredients in a timely manner at least partly explains the neglect by the agency to address the problem of inert ingredients.[37]
- *The list of trade name inert ingredients now includes 2,632 products, registered or permitted by EPA.*[38]
- These products are often complex mixtures of chemicals that have not been tested to learn their collective toxicity. Despite this lack of testing, these chemicals are permitted to be released in agricultural, residential, commercial, educational, and recreational environments.

4. The FQPA and the Rise of Precautionary Policy

- In 1996, the Food Quality Protection Act (FQPA) became federal law. Congress passed the most important statutory change in 50 years in response to a 1993 National Academy of Sciences study that found that children's health was at special risk from dangerous pesticide exposures.[39]

- The National Academy of Sciences panel concluded that the maximum residue levels then in force were not protective of prenatal, neonatal and young children's health.[40]
- Another key finding was that variations in diet could lead to differences in pesticide exposure, and this knowledge raised special concern over residues in the diets of children.
- Children are more likely than adults to be harmed by pesticides, because of their immature organs and the rapid growth rate of their bodies.
- Children are typically more exposed than adults to environmental chemicals. Their chemical intake is higher, in terms of their lower bodyweight, higher inhalation rate, and greater skin permeability.
- The FQPA of 1996 requires that the EPA must apply an additional tenfold margin of safety for pesticide chemical residue and

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other sources of exposure for infants and children, in order to protect against underestimates and danger. The law also requires that the EPA consider how risks accumulate from exposure to other chemicals that can produce similar damaging health effects, such as cancer, neurotoxicity, or endocrine disruption.[41]

- The FQPA has now been in effect for 24 years. It was adopted by Congress three years after the National Academy of sciences warned that children were unprotected from dangerous pesticide exposures.

5. History of Pesticide Substitutes

- Historically, the harmful effects of different pesticides were only understood decades after their international acceptance and use. Most pesticides were later found to have unanticipated environmental and/or human health effects.

- Innovation in the chemical industry has created a number of groups of similar pesticides that include minor molecular variants. Starting in the 1940s, organochlorine pesticides replaced heavy metals and rapidly gained market share because of their ability to control a wide diversity of pests. Their unanticipated environmental persistence and toxicity led to their gradual phaseout as chemical companies introduced substitutions.

- These organochlorine pesticides were believed to be less toxic than metals, and highly effective in killing thousands of different insect species. Their danger grew from their persistence and tendency to bioaccumulate along food chains, eventually concentrating in human fat tissues.

- Long after the organochlorines were approved by governments, they were discovered in the tissues of most humans tested, as the result of their heavy usage on food supplies, and other applications.

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- Both metals and the organochlorine pesticides have similar characteristics. Although highly effective at eradicating a broad spectrum of species, they are highly persistent and they tend to be highly toxic. Together, these traits create the potential for harmful human exposures.

- The obvious lessons government should have learned from the 1950s and 60s was to phase out the most toxic and persistent pesticides. Governments' failure to do so has been repeated for decades and continues today.

- Given the chemical-by-chemical regulatory process, and the tens of thousands of pesticide products exchanged in international markets, the substitution of one entire class of chemicals for another has been gradually accomplished by private innovation in the chemical industry decisions, rather than by any rational plan by the EPA, USDA, or FDA.

- Independently funded scientific testing prior to governmental approval of pesticides is the only reliable antidote to the regrettable substitution syndrome:
  - **1870s:** metals - arsenic, lead, chromium, cadmium
  - **1940s:** chlorinated organics - DDT, aldrin, chlordane
  - **1950s:** organophosphates and carbamates
  - **1960s:** triazine herbicides
  - **1980s:** pyrethrins and pyrethroids
  - **1990s:** pesticides sold with genetically modified seeds designed to be uniquely resistant
  - **2000s:** neonicotinoids

- The slow pace of new pesticide design, testing, and registration limits the capacity of government to trade older, riskier pesticides for newer, safer ones. Safer pesticides might be as effective as older ones, but they may be less persistent and less toxic.

- A serious impediment to speeding the design and approval of less risky pesticide products is the cost to discover, produce, and register new products. CropLife America, the trade organization

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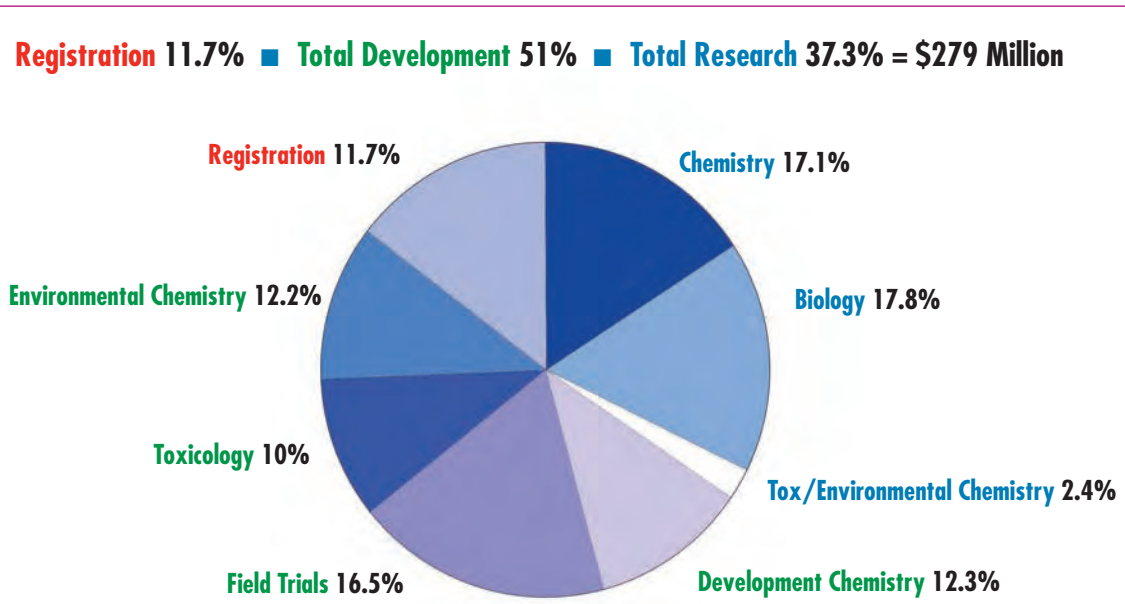
Figure 17. Chemical Company Claims of Costs to Bring New Pesticides to Market 2010-2014



Each pesticide may require hundreds of separate product registrations to permit its use in agriculture, livestock rearing, forestry, and residential, commercial, industrial, and consumer product applications, such as additives to textiles, plastics, or preserved wood.

that represents the pesticide industry, recently published the results of a survey among the world's largest pesticide manufacturers. They reported on what the average cost would be of bringing a single new pesticide to the global marketplace.[42] That cost included basic research that totaled $100 million; product development that totaled $146 million; and regulatory approvals requiring an additional $33 million, for a total average cost of $279 million per pesticide (Figure 17).

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- As costs of chemical design or discovery, testing, and gaining government licenses to market new products increase, the rate of discovery and introduction of safer chemicals has declined. The largest biochemical companies now claim that new chemical introduction

costs are nearing $300 million dollars annually, with regulatory compliance and licensing costs accounting for 11.7% of the total.

- The pesticide industry normally looks to get approvals from as many foreign nations as possible. Glyphosate, for example, is registered for use in 160 nations. The average time from chemical design to government approval is 11 years.
- In addition, the cost of developing a pesticide is so costly that it incentivizes agrochemical-biotechnology companies to find as many applications as possible. Chlorpyrifos, for example, produced initially by Dow AgroSciences, was granted 800 separate product registrations. The company also received approval for more than 100 separate agricultural crop uses, and associated tolerance limits.
- Pesticide companies are under enormous pressure to recover their research and development costs as quickly as possible within the 20-year international patent life that precludes government licensing of competitive generic brands.
- Monsanto, now part of Bayer, found a lucrative solution to extend their market domination by selling glyphosate in tandem with their corn, soybean, cotton, and other seeds that had been genetically edited to resist the damaging effects of the herbicide.
- This genetic innovation became the vehicle to carry Monsanto's profitability beyond the patent life of their pesticides. Monsanto paired their herbicide with modified grain seeds, which covered the most extensive acreage in the U.S. and many other parts of the world.

Federal law to control pesticide risks relies heavily on labeling to provide consumers with information on product ingredients, directions for safe use, specific health and environmental warnings, and acceptable methods of disposal.

6. Pesticide Labeling and Warnings

- The oldest, and still the most common, approach to pesticide risk management has been to issue consumer and user warnings about health and environmental hazards, including safe use instructions via product labels.

There are many reasons that explain why labels are ineffective in managing highly toxic substances contained within over-the-counter products.

- Federal law to control pesticide risks relies heavily on labeling to provide consumers with information on product ingredients, directions for safe use, specific health and environmental warnings, and acceptable methods of disposal. Pesticide packaging and labeling remain the excusive authority of the federal government.

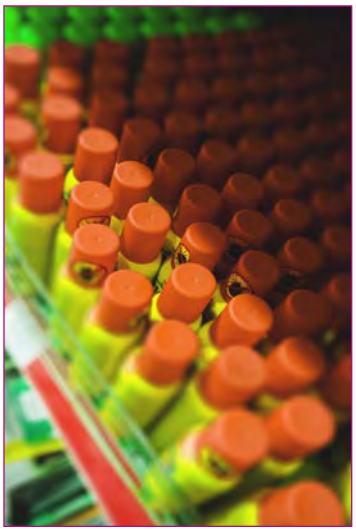
- Pesticides that are sold over the counter must contain a label that has been approved by the EPA, and which contains appropriate directions for use to prevent loss of health or environmental quality. The principle of prior warning underlies most consumer protection law. Prescription drugs, in contrast to pesticides, are more stringently regulated and need approval from physicians, pharmacists, and licensed dispensaries.

- Each separate product is given a distinctive label with a registration number that permits rapid identification in cases of accidental exposures or environmental releases. The majority of the chemical mixture in the container is not the pesticide, but rather inert ingredients that may add up to 99% of the net weight sold.

- There are many reasons that explain why labels are ineffective in managing highly toxic substances contained within over-the-counter products. These include the following:

  - Illiteracy makes it impossible for many consumers to understand warning labels.
  - Consumers, if informed, are unlikely to accurately convey warnings to those exposed.
  - Warnings are normally required only for proven adverse effects.
  - Consumers expect product safety due to EPA approval on the label.
  - Consumers also assume product safety, due to wide unregulated retail availability.
  - Consumers expect product effectiveness, with no demonstration required by governments.

- Information about adverse effects may have been withheld by manufacturers.
- Warning language is seldom updated, only following EPA reviews, and commonly after a decade delay.
- Warnings do not explain hazards and ingredients in non-technical language.
- Untrained consumers may make mistakes in mixing and applying pesticides.
- Licensed applicators may delegate authority to untrained workers.
- Residues normally persist longer than users and government regulators realize.
- Pesticides are not tested in mixtures, but they are sold and applied as mixtures.
- Pesticide packaging normally emphasizes product benefits and effectivenesss.



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- Government-required warning labels are often placed on the backs of packaging or in booklets printed in type so small that many people find them unreadable. Label instructions are expressed in scientific and technical language that is often unintelligible to untrained individuals. Products are and wrapped inside packaging that is impossible for consumers to read prior to purchase.

- Warning language is normally in English, though many farm-workers in the U.S. are immigrants for whom English is not their first language.

- Finally, pesticides produced in one nation are often exported without translation to importing nations' languages, even when the producers' countries have banned the chemicals.[43]

- Producers, formulators, and retail owners have stopped referring to chemicals as pesticides or toxins, but instead call them crop

protection products, designed to promote the health of plants and livestock.

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- Labels, warnings, and advertising fail to deliver clarity about the risks posed by pesticides. The decreasing transparency of the EPA since 2016 has reduced access to crucial data the public needs to understand the risks to themselves and their environments.
- The agency's refusal to disclose information aboout residue, exposure, and/or toxicity data prevents independent hazard assessments.

7. Fractured Regulatory Authority

- Legal authority to manage pesticides is divided among the EPA, FDA, and USDA. This impedes effective regulation since these agencies do not easily share data, expertise, budgets, legal authority, or political will to protect human health or environmental quality from pesticides. They also have widely differing institutional norms and mission priorities.
- The EPA is responsible for pesticide registration and tolerance setting for both food and water, under authority granted by three main statutes. The EPA is also required to evaluate pesticides' environmental fate and effects, patterns of human exposure, and chemical toxicity.
- Today, nearly 17,000 pesticides are registered, and nearly 9,000 maximum allowable residue levels are set as tolerances that provide legal limits for pesticide residues, chemical by chemical and food by food.[44]