Reducing Pesticide Risks: A Half Century of Progress

Susan Wayland and Penelope Fenner-Crisp

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The EPA Alumni Association (EPAA AA) has developed this and six other web-based subject matter essays in support of its Half Century of Progress project. An integrated summary based on these materials is contained in Protecting the Environment: A Half Century of Progress, which is available on the Association website. The Association has developed these materials to inform high school and college students and other members of the public about the major environmental problems and issues encountered in the United States in the latter half of the 20th century, as well as the actions taken and progress made in mitigating these problems.

A number of retired EPA program managers and subject matter experts worked together to produce each of the essays. This document was reviewed by the EPA AA Board of Director and members of the association. We welcome comments on this document, which you may submit to the EPA Alumni Association.

Reducing Pesticide Risks: A Half Century of Progress

BEFORE 1970

In the beginning of the 20th century, pesticides were viewed primarily as the farmers' friend. The first law regulating pesticides, passed in 1910, was all about protecting farmers

from fraudulent claims. The U.S. Department of Agriculture (USDA) was required to ensure the quality and effectiveness of products, but little or no concern was given to the potential effects on humans, wildlife, or the environment in general.

Then in World War II, soldiers were protected from disease by the "miracle" pesticide DDT, which killed insects really well. Its wartime benefits soon spread widely to virtually all aspects of civilian American life,



including use on a large variety of food crops, in the home, and as a weapon against insects that carried disease. DDT was celebrated as a wonderful weapon against bugs that was harmless to people, as illustrated in this ad from *TIME* magazine in 1947:



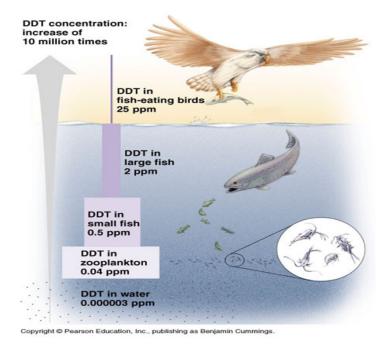
That same year, Congress passed the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which required the federal government to approve (or *register*) products before they entered the marketplace. Again, society at large was not focused on the potential adverse effects of the ballooning number of pesticides entering everyday life.

But then! Rachael Carson, a marine biologist by training, shook up the world in 1962 with the publication of *Silent Spring*. Referring to work being done by the U.S. Fish and Wildlife

Service and others, Ms. Carson described the negative effects of DDT on wildlife. She warned that continued heavy use of pesticides could someday lead to a spring without birdsong. This was a major wakeup call regarding the potential unintended effects of pesticides on living things.

The scientific evidence began to mount. DDT and the products that DDT broke down into were found to be very long lasting in the environment. Organisms at the bottom of the food chain stored it in their tissues, and as animals higher in the food chain fed on them, the levels of DDT in their bodies concentrated and increased (a process called "biomagnification," depicted in the figure below). Birds of prey in particular accumulated high levels of the pesticide, leading to thinning of eggshells and a sharp decline in the birth and survival of baby birds.

At the top of the food chain, humans were becoming exposed through their diets and the air they breathed. DDT was found to accumulate in human fat tissue, to expose developing babies before they were born, and to occur in mothers' milk.



Moreover, evidence was building that DDT caused tumors in mice, and thus could be a potential cause of cancer in humans. The science about cancer effects was controversial, since the scientific community was just beginning to develop testing methods to identify potential human carcinogens (cancer-causing agents).

In the meantime, other pesticides chemically similar to DDT were being developed and used widely in agriculture, as well as in homes, schools, and other public buildings.

THE ESTABLISHMENT OF EPA IN 1970

As other essays in this Half Century of Progress series have illustrated, by the end of the 1960s there was mounting evidence of pollution across air, land, and water, and a demand for action from the public. Public awareness and outrage led to the establishment of EPA and the passage of critical new laws across the board. USDA's pesticide duties were transferred to EPA when the Agency was created in 1970.

In 1972, Congress passed major amendments to FIFRA that required the newly formed EPA to assess the potential <u>risks</u> of pesticides to humans, wildlife, and the environment, and to

take action against pesticides whose risks were found to exceed their <u>benefits</u>. Pesticides already needed to be approved before being federally registered and sold on the market. Another earlier law, the Federal Food, Drug, and Cosmetic Act, required that residues of pesticides remaining on food needed to be approved with the establishment of specific numerical limits ("tolerances") for each pesticide and crop combination.

In 1972, EPA banned (or "cancelled") virtually all uses of DDT in a landmark decision made by the first EPA Administrator, William Ruckelshaus. Then during the late 1970s, EPA began the process to ban pesticides chemically similar to DDT (called organochlorines), including aldrin, dieldrin, chlordane, heptachlor, toxaphene, and mirex. The early decisions were highly visible and controversial, with many in the agricultural community predicting dire consequences for food production. Many pesticide proponents raised alarms about epidemics of insect-borne diseases and questioned the practice of feeding animals high doses of chemicals to determine cancer-causing potential.

However, alternatives to the cancelled pesticides were developed, and agricultural production has continued to thrive over the decades. Not only is there ample food to feed our own population, but also agricultural exports have steadily increased, reaching a record \$140.9 billion in 2013 according to USDA.

But in 1972, when the law was amended and DDT was banned, it was abundantly clear that the scientific data upon which comprehensive risk assessments could be made were woefully lacking for most pesticides. As a result, an extensive effort was begun to "call in" scientific studies. Pesticide registrants, primarily the pesticide manufacturers, were responsible for conducting the testing. Informed by the new data, EPA was required by law to decide whether each pesticide sold in the United States should continue to be marketed (through a process known as "reregistration"), and whether the benefits of each use pattern exceeded the risks.

Pesticide *risk* is determined by factoring in potential *adverse effects* with potential *exposure*. This was particularly challenging, as EPA scientists, with peer review from the scientific community, had to first develop the testing guidelines and protocols for a broad range of potential risk effects. Tests needed to provide information on hazard and exposure, including acute toxicity (the extent to which the chemical caused immediate effects), birth defects, cancer, and environmental fate.

At the same time, the ability to detect pesticides in food and the environment in smaller and smaller quantities was advancing. In the early days of modern agriculture, pesticides could be detected only at parts per million levels. Later, pesticide residues in the range of parts per billion could be found. Analytic methods now can detect parts per trillion or less. A part per trillion is so small it is equivalent to one bad apple in two *billion* barrels.

CONCRETE AND MEASURABLE ACTIONS

There are hundreds of examples of how EPA has moved to protect the public and the environment from pesticide risks. This essay illustrates two such stories: DDT and the bald eagle, and pesticide reregistration.

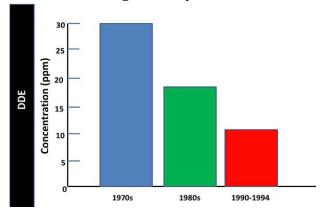
Bald Eagle on the Brink

Our nation's symbol, the majestic bald eagle, was on the verge of extinction because of the eggshell thinning caused by accumulation of DDT and the chemicals that resulted from its breakdown in the environment, such as the formation of DDE

(dichlorodiphenyldichloroethylene), and human activity in nesting and roosting areas. EPA's ban on DDT was critical to the recovery of the bald eagle, the brown pelican, and the peregrine falcon. Protections afforded by the Endangered Species Act, administered with the U.S. Fish and Wildlife Service, also aided in recovery.

It took years of scientific study, trial-like administrative hearings, and review by the courts before DDT and its chemical cousins were no longer released to the nation's air, land, and water. Even after the ban, it took years—even decades—before residue levels declined significantly. EPA's DDT actions were aggressively challenged, with predictions of gloom and doom for crop production and disease control. The procedural and public opinion controversies swirled for years. But Administrator Ruckelshaus stood firm, the courts backed EPA up, and the results proved the correctness of the EPA decisions.

Because DDT and its "classmates" are so persistent, extensive monitoring of the environment, plants, and animals has been conducted, beginning before DDT's cancellation in 1972 and continuing to this day. Many studies show downward trends in exposure over time in many wildlife populations. For instance, in 2005 Canadian researchers¹ noted that DDT levels significantly declined in animals





and organisms in the Canadian Arctic from the 1970s to the late 1990s; and today they are generally less than half the levels of the 1970s, particularly in seabirds and ringed seals. Another study in 2005² measured declines of 4- to 7-fold in DDT levels in eggs from colonies of herring gulls from Lakes Ontario and Michigan

between 1971 and 1982. A third study³ that year reported a continuous decrease in DDT concentrations in penguin droppings over the past 50 years. Yet another study⁴

documented the decline in DDT breakdown products by 50% or more in osprey eggs in 1998 relative to 1989, with similar reductions in the fish that the ospreys eat.

And what a great end to the story! In the late 1990s and early 2000s, the bald eagle, brown pelican, and peregrine falcon were taken off (*delisted* from) the Endangered Species List because of their rebounding populations. Other bird species have been seen to stabilize and increase their numbers as well. This turnaround wouldn't have happened without EPA's groundbreaking science and strong stand in the face of controversy. It also illustrates that environmental progress doesn't necessarily happen overnight—ecological systems may need decades to recover after a decision is made.

New Scientific Standards for Old Pesticides

As mentioned earlier, EPA had to confront a mountain of pesticide decisions that had to be updated according to modern standards. EPA went about this enormous task in a strategic way. Spurred on by amendments to FIFRA in 1988, it grouped over 1,100 active ingredients used in over 40,000 products into "cases" of similar chemicals. EPA identified an order of review for those cases that would be of the most benefit to the public in the shortest amount of time. It assumed that pesticides used on food crops had the highest potential for exposure and risk, so those chemicals were reviewed first. The remaining chemicals were set for review according to other potential risks, including human risk (for example, residues in drinking water or exposure to workers in the field or in the pest control business) and risk to nontarget species (such as beneficial insects, birds, fish, and other wildlife).

Pesticides are tested more thoroughly than any kinds of chemicals other than drugs. A pesticide used on food requires over 100 different tests to determine, for example, its potential to cause cancer, birth defects, and acute poisoning; impacts on birds, fish, and other nontarget wildlife; damage to the nervous system; its residue levels in crops; its longevity in the environment; and its potential to reach ground and surface waters.

The pesticide industry had to make its own decisions about which of its registered products would be supported with new testing. Providing the test data was expensive, and over 220 cases and their associated products were dropped by industry.

And even as reregistration was moving down the track, Congress changed the requirements for review of food-use pesticides in a major way. A law passed in 1996, the Food Quality Protection Act, required that EPA review all existing 9,700 food tolerances over a 10-year period. Tolerances, as described earlier, are the maximum amounts of a pesticide or its breakdown products that can remain in food products consumed by people or animals. The Act also required that EPA add an additional safety factor to protect children, look at risks from multiple pathways of exposure, and develop a screening program to determine the effects of pesticides on hormonal systems (endocrine disruptors).

Because pesticides are used worldwide, and food is traded widely between countries, EPA had a strong interest in coordinating reviews with other countries and international bodies to develop consistent assessment guidelines and regulatory decisions. Extensive efforts were made with international organizations and trading partners to harmonize U.S. approaches. This allowed for some sharing of the workload. Even more important, harmonization also works to combat the U.S. importation of foods that could be treated abroad with pesticides banned in the United States.

The analyses required during reregistration and tolerance review represented a monumental and complex undertaking. Thousands of new scientific studies were required, submitted, and reviewed. Reregistration ultimately resulted in the elimination of hundreds of active ingredients and products, many of which were capable of causing harmful effects in humans and other organisms.

REREGISTRATION OF PRE-1984 PESTICIDES TO MODERN DATA & DECISIONS



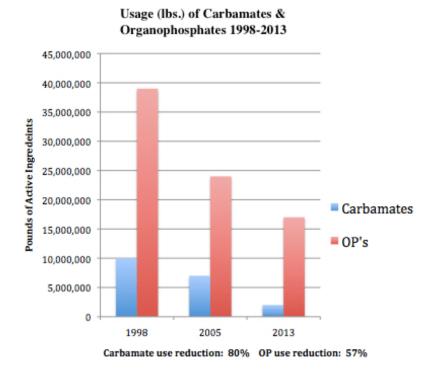
The review of the almost 10,000 old food residue tolerances was completed in 2007, and the reregistration program was completed in 2008.

The history of the organophosphate pesticides in reregistration and tolerance reassessment provides a good example of public health and environmental protection. Organophosphates are highly toxic chemicals, and came under special scrutiny with the following results:

Organophosphate Decisions in Reregistration and Tolerance Reassessment Beginning of program: Cancelled Special New Restrictions Outright: on Remaining: 47 Organophosphate Active Ingredients on Market 17 To Protect Agricultural Workers To Protect the Environment To Protect Children Increased restrictive Application rate reductions Cancelled 57 Food Uses = Changes in timing of applications entry intervals 60% reduction in use Additional protective Buffer zones clothing Well setbacks Cancellation of Virtually ALL Additional protective Geographic use restrictions Home Uses equipment, e.g. respirators Measures to control spray drift

The effectiveness of the programs is also illustrated by the decrease in the use of carbamates (for example, aldicarb (Temik), carbofuran (Furadan) and carbaryl (Sevin), and organophospates (for example, parathion, malathion, chlorpyrifos, and diazinon).

In short, the conclusion of the reregistration and tolerance reassessment processes marked an enormous milestone in ensuring the safety of the U.S. food supply and the protection of human and ecological health.



THE FUTURE

One important lesson learned over the years is that science *always* moves forward—relentlessly. EPA recognized that it had to do something to make sure that future decision makers never have to face a big backlog of out-of-date determinations again. So, the 1996 Food Quality Protection Act included a provision that all pesticides must be reevaluated on a staggered, but regular, basis (every 15 years) in a process termed "registration review." This will ensure that, even as science moves forward, EPA never gets into the bind it confronted in 1972 when risk assessments on hundreds of active ingredients were decades out of date.

Emerging science in the realm of pesticide regulation presents some particular challenges, including:

• *Toxicity Testing*. In 2007, the National Research Council, an arm of the National Academy of Sciences, issued a report presenting a vision and a path forward for wholesale transformation of the traditional approaches to toxicity testing.⁵ Historically, when determining risk, scientists relied primarily on observing harmful effects in similar groups of animals exposed to relatively high doses of chemicals. This approach is expensive, time consuming, and viewed as inhumane by animal rights groups. Relatively few existing chemicals other than pesticides

have been evaluated for risk. Important facts about how chemicals interact in the real world remain unknown. The scientific community still has little information on *how* chemicals produce their effects, which is critical for understanding differences between species—or between individual human beings, for that matter.

At the core of the path forward is a shift from collecting observations in whole animals to the identification of the ways chemicals affect animal cells. This is opening the door to the use of many new tools that are providing knowledge about biologic processes and functions.

Traditional methods are being replaced by computer-based tools and short-term assays that require less or no animal tissue. Some short-term assays can be conducted by machines (robotics), so that many chemicals can be tested at multiple doses within hours to days, rather than weeks to years.

• Endocrine Disruptors. As mentioned earlier, the 1996 Food Quality Protection Act required EPA to screen pesticide chemicals for their potential to produce effects similar to those produced by the female hormones (estrogens) in humans. Endocrine systems in animals produce hormones that send "messages" to the body that affect growth, including physical, intellectual, and reproductive development. Endocrine disruptors affect how those messages are sent in animals, and some have been shown to produce effects in the offspring of exposed mothers. The law also gave EPA the authority to screen other kinds of chemicals and to include other endocrine effects. Based on recommendations from an advisory committee, EPA expanded its Endocrine Disruptor Screening Program to include male hormones (androgens) and the thyroid system, and to include effects on fish and other wildlife.

Executing a credible and efficient endocrine testing program is a formidable challenge. New methods are being developed at a rapid pace. The endocrine testing program is being propelled by more and more data from several federal programs and public concern. So far, EPA has collected estrogen screening results for 1,800 chemicals (some of which are pesticides).





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from a different species either to repel bugs or to resist the effects of herbicides, they fall under EPA's purview. Genetic modification of crops is a very controversial issue. Many environmental and consumer advocates are opposed to this practice, either on general principle or the argument that their safety has not been established adequately. Those advocates often cite insufficient testing to assess harm to human health or the environment. Others see biotechnology as a major step forward in feeding the world's population. There remains strong disagreement on whether the yields of genetically modified crops grown by traditional farming can or will exceed those of conventional crops grown according to the principles of sustainable agriculture. Sustainable agriculture takes into account an understanding of whole ecosystems to integrate knowledge of many natural and biological processes, and moves away from the massive one-crop-at-a-time approach.

Some countries do not allow imports of genetically modified corn or other commodities, and in the United States the term "organic" may not be applied to genetically modified produce.

Government regulators have already approved or are reviewing genetic engineering of several large volume crops, such as corn, soybean, canola, sugar beets, potato, papaya, squash, radicchio, flax, tomato, and plums. Genetic engineering is an area that will continue to grow and will demand more government scrutiny and review.

• **Decline in number and populations of species.** The World Wildlife Fund International issues a Living Planet Index, which measures more than 10,000 representative populations of mammals, birds, reptiles, amphibians, and fish. Its 2014 report notes that the total number of animals in all of these species has declined by 52 percent since 1970. Most of that change can be attributed to human activities that take more from our ecosystems than can be renewed.

Use of pesticides is implicated in being and, in some cases has been demonstrated to be, a contributing factor to this decline in species. Decline in the numbers of Monarch butterflies, honeybees, and frogs represent just *three* examples for which pesticide use does or may play a role.

Monarch butterfly: The Monarch and other butterflies are important pollinators of flowers. Milkweed is the only plant on which monarch butterflies will lay their eggs. It is the primary food source for Monarch caterpillars. Between 1995 and 2013,



milkweed decreased by 21 percent in the United States.⁶ An estimated 550 million Monarchs completed the winter migration to Mexico in 2004, but only 33 million arrived in 2013.⁷ Contributing factors to the decline include large-scale use of herbicides, increased planting of corn, loss of old forests in Mexico, adverse weather conditions, and illegal logging.⁸ In the United States, milkweed is destroyed along roadsides for aesthetic reasons and within or along the edges of crop fields, either purposefully or as a consequence of pesticides drifting away from sprayed fields. EPA and other government agencies are working together at home and also with Mexico and Canada to shed more light on these problems and to find new solutions.

Honeybees: Honeybees are critical players in the pollination of agricultural

crops. They are used to pollinate billions of dollars' worth of the nation's agricultural produce each year. Well over 125 fruits and vegetables are cross-pollinated by honeybees. Many of these crops are not self-pollinating. Commercial and wild bees are responsible for the pollination of an estimated 80% of all food crops in the United States.



But honeybee populations have been dying off at extraordinary rates in recent years, sometimes greater than 50% over a winter season. The prevailing theory among scientists in EPA, USDA, and the global scientific community is that the general declining health of honeybees is related to complex interactions among multiple factors, including:

- Pests (for example, the varroa mite), pathogens (for example, the bacterial disease American foulbrood), and viruses;
- Poor nutrition (for example, from loss of foraging habitat and increased reliance on supplemental diets);
- Bee management practices (for example, long migratory routes to support pollination);
- Lack of genetic diversity; and
- Pesticide exposure.

A class of pesticides chemically related to nicotine called "neonicotinoids" affects insects' nervous systems. The European Union has moved to limit the use of neonicotinoid pesticides for at least two years starting in December 2013; however, EPA has not proposed any cancellations or bans. While research is ongoing and some modest steps have been taken in this country, much remains to be done.

 \underline{Frogs} : Frogs and other amphibians (greater than 7,000 known species) are threatened worldwide. A recent assessment of the entire group 11 found

that nearly one-third (32%) of the world's amphibian species are threatened, representing 1,856 species. In just the last two decades, about 168 species are believed to have gone extinct, and at least 2,469 (43%) more have populations that are declining.

As with the honeybee, interactions of many factors are thought to be

responsible for the declines. Likely and confirmed factors include:



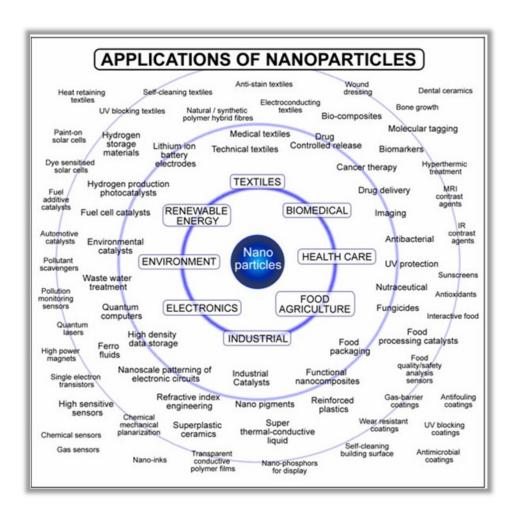
- Habitat destruction:
- Introduced (non-native) species;
- Climate change;
- Ultraviolet-B radiation;
- Disease; and...

o Chemical Contaminants: Chemical stressors (for example pesticides, heavy metals, acidification, and nitrogen based fertilizers) can harm amphibians. The effects may include death, decreased growth rates, developmental and behavioral abnormalities, decreased reproductive success, weakened immune systems, and/or gender changes. A substantial body of peer-reviewed studies in the scientific literature supports these findings. A particularly useful resource is the analysis performed to provide the European Food Safety Agency with information relating to assessment of risk to European species of aquatic and terrestrial amphibians posed by pesticide exposure. It is likely that risks in the U.S. setting would be comparable.

No amphibian-specific testing requirements exist to support the U.S. registration of pesticides. In general, EPA uses bird toxicity data as a surrogate for land-based reptiles and amphibians, and the required fish toxicity data as a surrogate for aquatic-phase amphibians. At present, no EPA research projects are directed at issues related specifically to amphibians—again, more work for the future.

Nanotechnology.

Nano-sized materials (1 to 100 billionths of a meter) can, and often do, have physical properties fundamentally different from those of their larger counterparts. Therefore, they may also possess very different toxicity characteristics and potential risks. Many different categories of products use nanoscale materials, including household appliances, automobiles, coatings, electronics and computers, food and beverage, medical devices and drugs, clothing, and personal care products. Many of these products were introduced into commerce without any prior evaluation of the potential for risk to human or environmental health.



Nanoscale materials intended to be used in ways that meet the legal definition of a pesticide are being evaluated on a case-by-case basis. EPA determines whether it is a "new" active or inert ingredient for purposes of the law, even when an identical, non-nanoscale form of the nanoscale ingredient is already registered.

As described earlier, producers of pesticide products must submit scientific and technical data for EPA review to ensure that the use of a pesticide will not cause unreasonable adverse effects on human health or the environment. However, the major challenges facing the scientific community now are the relative meager body of data characterizing the toxicity of these materials compared with their larger-sized counterparts. Validated testing protocols are lacking and need to be developed. The products that are not pesticides will be addressed through the Toxic Substances Control Act, as discussed in that essay in this series.

To date, EPA has conditionally registered only two nanomaterial pesticide products as new active ingredients for a period of four years. Again, more research and testing need to occur in the to tackle this important area of new concern.

CONCLUSION

The job is never done! EPA needs to continue to lead the way in developing measures of risks of pesticides and in determining ways to protect the public and environment from any adverse effects. As science marches on, so must the practices of regulators who guard the future of our children, wildlife, and environment.

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Authors:

Susan H. Wayland, former Deputy Assistant Administrator for the Office of Pesticides, Prevention, and Toxic Substances (now the Office of Chemical Safety and Pollution Prevention), 1992-2000.

Penelope Fenner-Crisp, PhD, former Director of the Health Effects Division, Office of Pesticides Programs, 1989-1994; Deputy Office Director, Office of Pesticides Programs, 1994-1997; and Senior Science Advisor, 1998-2000.