PURDUE PESTICIDE PROGRAMS

Purdue University Cooperative Extension Service

PESTICIDES AND WATER QUALITY

PRINCIPLES, POLICIES, AND PROGRAMS

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INTRODUCTION

Today we face challenges concerning water resources, both in our own communities and nationwide. Proponents of economic development and supporters of environmental conservation debate the use of water. As the turn of the century approached, there was no debate over water as a *renewable* and *limited* resource; rather, its availability was generally assumed to be *unlimited.* Rivers and streams were viewed as cheap, dependable sources of water in support of the national surge in manufacturing, construction, and employment; and they often served as prime avenues for the disposal of waste materials.

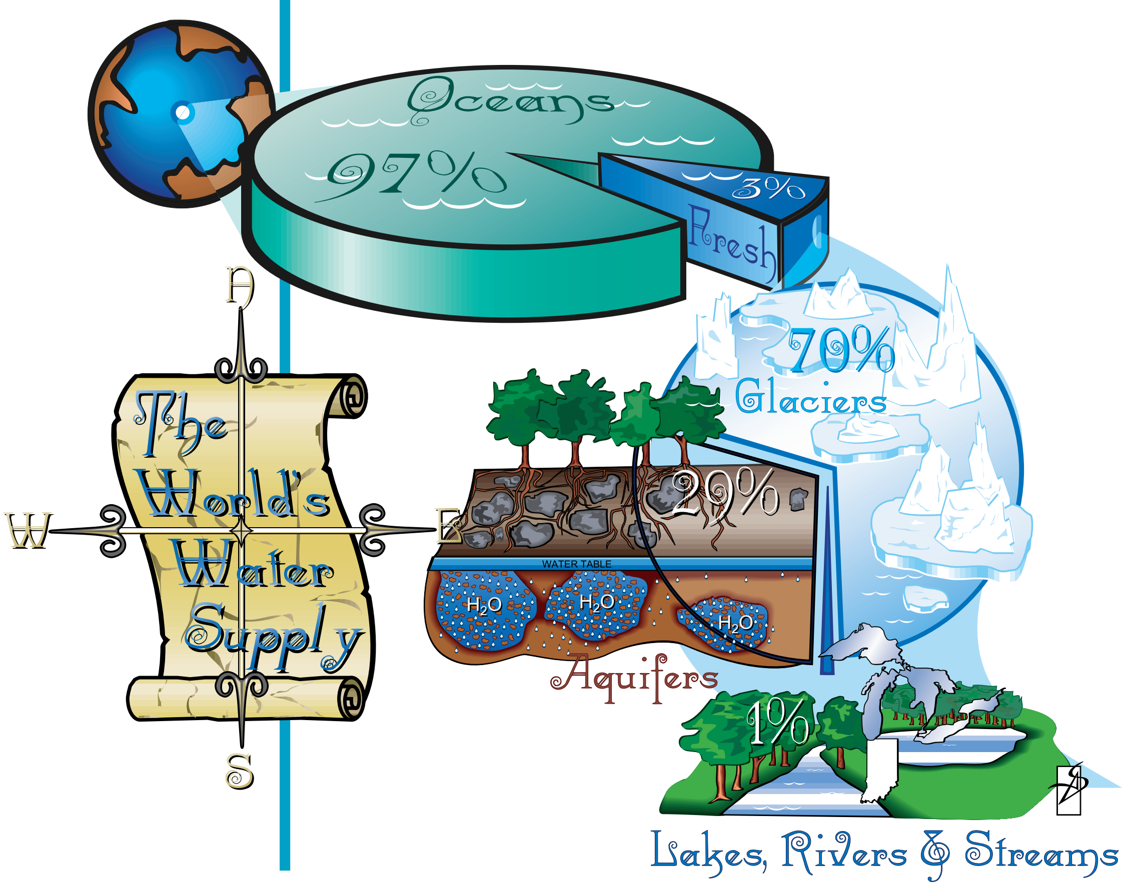
By the turn of the century, the oppression of surface water was evident; and the dumping of sewage effluent and by-products of manufacturing and agriculture had become associated with the terms *contamination* and *pollution*. Rivers and streams once considered pristine were tainted from the repeated introduction of waste. Several contamination incidents received significant media attention, sparking public concern for water quality. Some evoked such emotional outrage that public coalitions demanded legislative attention. The resulting multitude of new laws—both state and federal— specified policies and goals for establishing water quality, placing the responsibility for compliance squarely on the cities and industries (including agriculture) releasing pollutants into water.

Protecting water quality is a top environmental priority as we approach the twenty-first century. However, the pendulum of public debate has shifted from government regulation to one of cooperation among groups with divergent viewpoints. This shift evolved as factions began to view a community’s prosperity as a function of its development of water policies that blend both economic goals and environmental incentives. While cooperation is now common, major differences still exist among public, industrial, regulatory, and environmental groups. Ideas presented and solutions offered may differ, but there is universal agreement that water resources must be pollution-free and abundant if the nation is to prosper economically.

Pesticides and Water Quality

Using pesticides effectively while maintaining water quality presents an important challenge. As citizens, we must recognize the significant role of pesticides in maintaining a high quality of life. We must acknowledge that the effective production of food and fiber relies on pesticides to control weeds, insects, and plant diseases that interfere with the growth, harvest, and marketability of crops. As pest control operators and homeowners—rural as well as urban—we must acknowledge the importance of pesticides in controlling pests in our homes, restaurants, hospitals, parks, ornamental plantings, golf courses, etc. But at the same time we must be aware that pesticide applications can affect water quality. Human and environmental health may be threatened when excessive concentrations of pesticides enter surface or ground water.

‘Pesticides and water quality’ is a complex subject, both technically and politically; but if current and future expectations for community life, agriculture, industry, wildlife, and natural habitats are to be met, input from an educated public is essential. A basic knowledge of the subject is important to allow informed participation in the ongoing debate. This publication presents information on water science, environmental fate, and public policy to assist the reader in developing an understanding of the issues surrounding pesticide use and water quality.

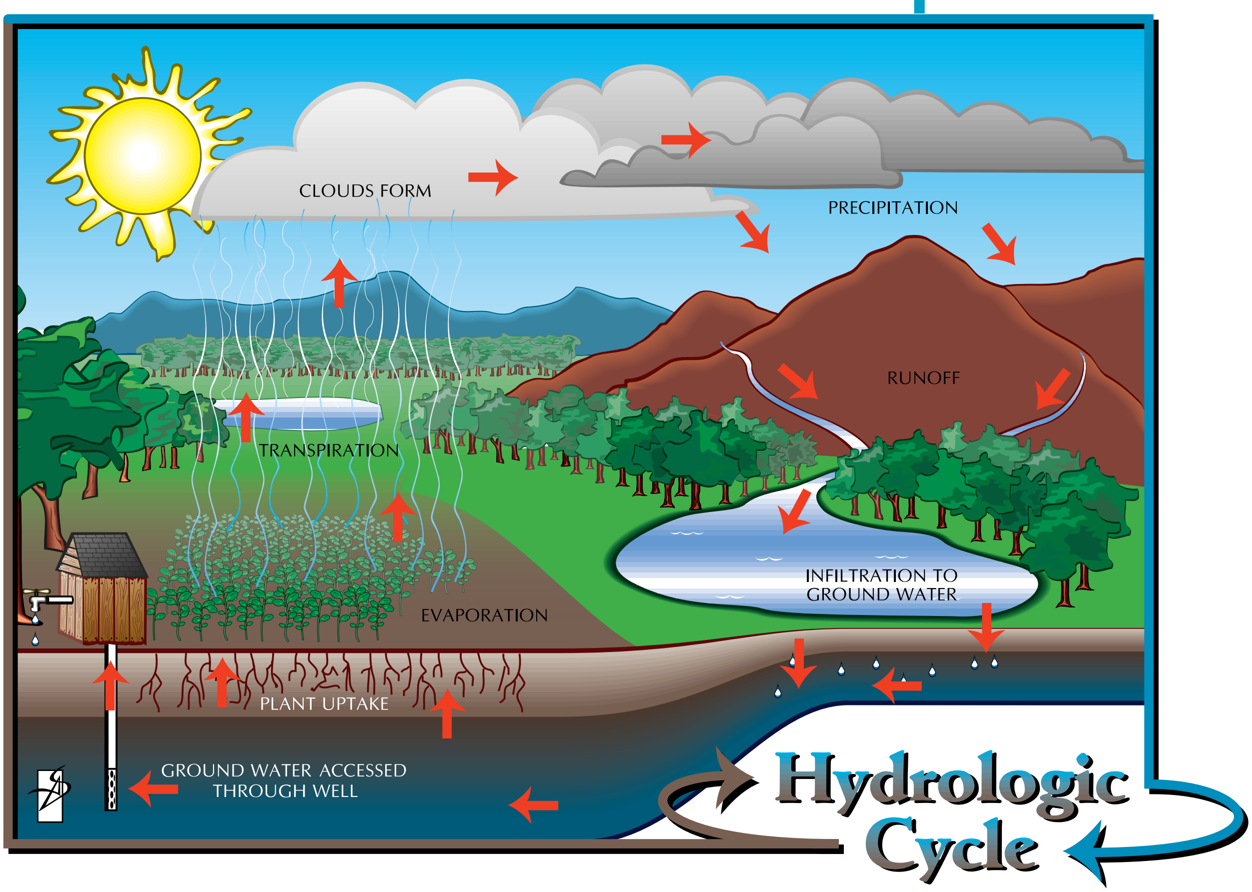


THE EARTH'S WATER CYCLE: NATURE'S OLDEST RECYCLING PROGRAM

Oceans contain 97 percent of the world's water supply. The remaining three percent is fresh water, of which approximately 70 percent is stored as ice in glaciers. Nearly all of the unfrozen fresh water on the planet occurs in aquifers below ground; only one percent is stored in lakes, streams, and rivers.

Water drawn from rivers and tapped from deep within the earth's aquifers is not 'new'. It has been continuously recycled between land and atmosphere for thousands of years through intricate processes of evaporation, transpiration, precipitation, overland runoff, and infiltration. Together these processes are linked as the hydrologic (water) cycle.

The sun energizes the hydrologic cycle. Solar energy converts surface water to atmospheric water vapor through the process we know as *evaporation.* Plants absorb water from the soil and can release it



into the atmosphere by *transpiring* (giving off) water vapor from leaves. Water vapor rises, then condenses in the cooler atmosphere to form clouds; water stored in clouds is eventually returned as *precipitation* in the form or rain, hail, sleet, and snow which can fall directly into rivers, streams, lakes, ponds, and wetlands. Water also can move into these bodies by *overland runoff* or *percolation* below ground. Water entering the soil can *infiltrate* deeper to reach ground water which, in turn, can discharge to surface water or arrive back at the surface through wells, marshes, and springs. Once on the surface, water is again energized by the sun to repeat the evaporation and transpiration processes that provide water vapor for cloud formation and continuation of the hydrologic cycle.

Ground Water: The Hidden Resource

Ground water is a widely distributed natural resource found beneath the earth's surface. Many people have the mistaken impression that ground water occurs as underground rivers and reservoirs. However, most ground water occurs in tiny voids (spaces) between grains of sand and gravel, between silt and clay, or in cracks and fractures in bedrock.

Geology of Ground Water

The geology of a particular location dictates the depth and volume of ground water. Usable ground water available to supply wells and springs comes from geologic formations called aquifers, which may be shallow (near the earth's surface) or very deep (hundreds of feet below the surface). As a general rule, fresh water aquifers tend to lie 60–300 feet below ground.

Aquifers are composed of various materials such as rock, sand, and gravel that reflect local geology. Some consist of unconsolidated (loose) deposits of sand, clay, silt, or gravel containing water in the voids between particles and rock fragments. Other aquifers occur as cracks in bedrock or consolidated (solid) materials such as igneous rock (granite, basalt), sedimentary rock (limestone, siltstone, sandstone), or metamorphic rock (slate).

Aquifers are characterized as either confined or unconfined. Confined aquifers lie below a layer of less permeable clay or rock—a confining layer—which greatly slows the vertical movement of water. The water in confined aquifers can be recharged from water that moves into the water-bearing zone from distant areas where there are no confining layers.

Unconfined aquifers do not have a confining layer and are 'open' to water moving down from surfaces directly above. The water surface of unconfined aquifers—the water table—fluctuates with changes in atmospheric pressure, rainfall, and other factors. Unconfined, unconsolidated aquifers are particularly vulnerable to contamination because, typically, they are quite shallow and surface water can infiltrate quickly down to the water table (ground water) in certain soils.

Downward Movement of Water

Between top soil and water-saturated soils, voids of unconsolidated materials fill with water and air, forming the vadose (unsaturated) zone. The portion of the vadose zone near the soil surface is where plants root, vegetation decays, and animals burrow; it is in this area that most terrestrial plants and soil organisms reside. The lower portion of the vadose zone hosts less biological activity.

Precipitation either runs off sloping land or infiltrates only the upper few inches of soil, then percolates downward and permeates the upper vadose zone. As water enters soil voids, a variety of physical processes pull it into the vadose zone, replacing air. The water table is defined as the area that separates the vadose and saturated zones. Water below the water table is ground water.

All soils can store water in voids. A soil's ability to store and transfer water downward in saturated or unsaturated conditions is a function of numerous interrelated processes and features. For example, the nature of soil particulates and the way they aggregate influence features such as porosity and how water is attracted to soils. Soils with small voids can store more water than those with larger voids. Under saturated flow, porosity and the pull of gravity greatly influence water movement. Under unsaturated conditions, attraction of water to soil surfaces (matrix potential), movement along a maze-like flow path, and very small pores (capillaries) influence water movement.

Natural ground water movement is often (but not always) in the direction defined by local topography. Horizontal flow of ground water generally is slow and is measured in inches per day or feet per year, depending on the porosity and the permeability of the materials making up the aquifer.

Surface Water: The Visible Water Resource

Surface water is water stored or flowing at the earth's surface: natural bodies of water such as rivers, lakes, and wetlands, as well as constructed (artificial) water reservoirs such as canals, man-made lakes, and drainage ditches. The quantity and quality of surface water is important for many activities: consumption, recreation, transportation, waste assimilation, agricultural production, and industrial use.

Movement of Surface Water

Surface water is linked to both ground water and atmospheric water through the hydrologic cycle. Surface water moves into ground water by infiltrating the soil and percolating downward; it also enters the atmosphere through evaporation and transpiration. Likewise, water from the atmosphere and ground water can recharge surface waters. Atmospheric water falls as precipitation: rain, sleet, hail, and snow. Ground water that moves to the earth's surface contributes to the base flow of streams, lakes, wetlands, and other waterways.

Rainfall and melting snow initially infiltrate the top layers of the soil at a rate commensurate with the soil's porosity and initial water content, as well as the intensity and duration of precipitation. Continuing precipitation may saturate the upper few inches of the soil, temporarily exceeding its capacity to hold water; water begins to accumulate on the land surface and perhaps flow overland to lower elevations. This movement, termed *overland flow* or *surface runoff,* may occur across a small or large area, depending on the amount and intensity of precipitation and on the local terrain. Soil type, land slope, and vegetative cover are contributing factors. A gentle rain lasting all day may result in only moderate runoff; but an intense summer thunderstorm producing a large amount of rainfall in a short time may yield significant runoff. The amount of runoff produced by a storm also is influenced by the moisture level of the soil prior to the storm, and by local topography. Runoff also can result from miscalculated timing, intensity, and duration of irrigation.

Runoff flows down slope until it reaches a storage area (e.g., a stream, pond, or low spot); and when the storage/infiltration capacities of that area are exceeded, runoff will flow even farther down slope. Flooding occurs when precipitation exceeds the storage capacity of surface depressions and bodies of water for a given area. Large amounts of runoff for an extended time raise stream levels, spilling water onto adjacent land—the flood plain.

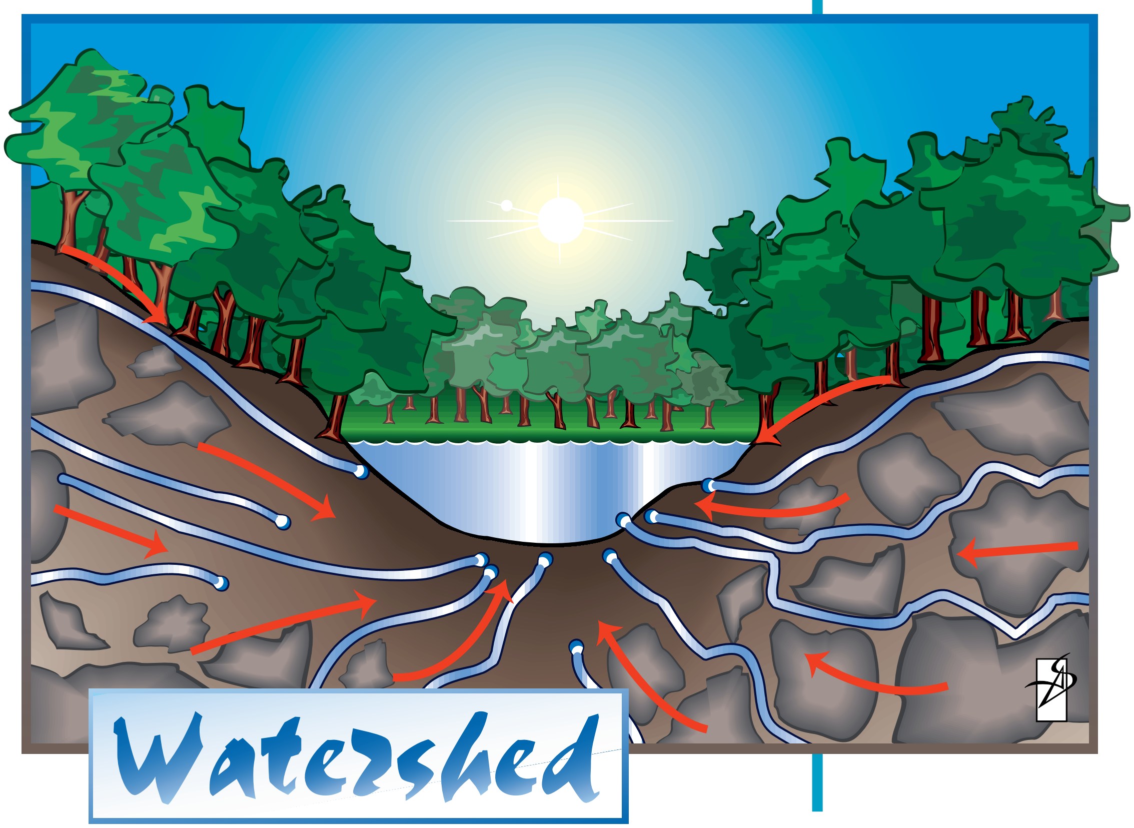
Erosion and Sedimentation

Surface water flows in defined channels such as streams and rivers. The amount and rate of flow vary primarily with precipitation, channel substrate and geometry, and gradient.

Flowing water can carry dissolved pollutants and others adsorbed to suspended sediment. Suspended sediment comes from eroded soil, which is carried in runoff, and from the channel's sides and bottom. The distance it travels varies, depending on the size and surface characteristics of the materials and the water flow rate. When flowing water meets stored water, such as when a stream enters a pond, the flow rate is greatly decreased and much of the coarser, larger, heavier sediment settles to the bottom; finer, smaller, light-weight materials such as clays may stay in suspension for longer periods of time. Generally, sediment is deposited, resuspended, and redeposited by flowing water. Conversely, storage waters tend to host pollutants for longer periods of time although, because of dilution, concentrations may be lower than in a stream.

The Surface Water System

A surface water system is characterized by its watershed or drainage basin. A watershed is the area of land draining to a specific river; the watershed boundary is defined by a region's topography. Watersheds vary in size and can be nested within other watersheds of increasing size, similar to a family genealogy or the branching of a tree. For example, the entire Mississippi River watershed draining into the Gulf of Mexico is a large area encompassing most of the central United States; it consists of thousands of



smaller subwatersheds, each contributing to the total water volume flowing into the Gulf.

The watershed concept is important because it links land area to bodies of surface water along a sequence of increasing scale. Land use within a watershed largely determines the quality of the local surface water. The quality of water leaving a watershed can, in turn, affect the cumulative quality of water far downstream. For example, pesticides detected in a city's drinking water supply could come from lawn and other urban uses *or* from an upstream watershed where agriculture is predominant. The potential exists for compounds to move off site and travel downstream through the surface water system; however, many biological, physical, and chemical processes affect the fate of pesticides in the environment.

Within a watershed, surface water occurs in a network of storage and flow areas; e.g., soil constitutes a large internal catchment (storage body) for water within a watershed. Catchments can *cycle* their water; in other words, a 'new' volume of water can replace the 'old' volume. The storage time of water—also known as hydrological residence time— depends on the hydrologic characteristics of the catchment. The mean hydrological residence time, stated as a ratio of the average volume to the average flow, represents how long it takes to replace an 'old' volume of water with a 'new' volume.

THE FATE OF PESTICIDES IN THE ENVIRONMENT

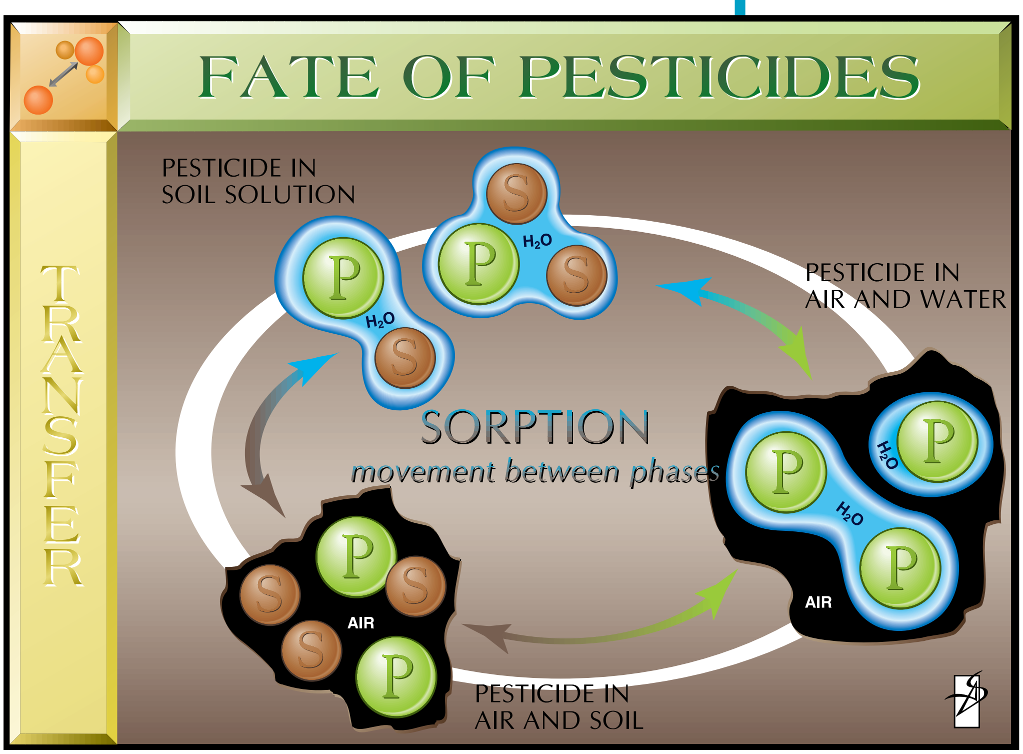
The interaction of pesticides with soils, surface water, and ground water is complex. Pesticide fate is controlled by numerous simultaneous biological, physical, and chemical reactions. Comprehending the fate of pesticides requires an understanding of certain processes: *transformation; transfer;* and *transport. Transformation* refers to biological and chemical processes that change the structure of a pesticide or completely degrade it. *Transfer* refers to the way in which a pesticide is distributed between solids and liquids (e.g., between soil and soil water), or between solids and gases (as between soil and the air it contains). *Transport* is the movement from one environmental compartment to another, such as the leaching of pesticides through soil to ground water; volatilization into the air; or runoff to surface water.

When a pesticide is applied to a field, certain reactions follow. Foliar-applied pesticides stick to leaves, where they are absorbed. But rainfall inevitably washes some of the chemical off the leaf surface onto the soil below; and some may be transformed by sunlight. Soil-applied pesticides generally interact first with moisture around and between soil particles, influencing how the chemical ultimately will react in the environment. Thus, a ‘soil solution’ can be viewed as a chemical staging area for most reactions controlling environmental fate. For instance, sorption processes (transfer), degradation by microbial and chemical reactions (transformation), volatilization to the atmosphere, leaching into deeper soil profiles, and overland flow (transport) all occur predominantly from soil solution.

Sorption

Sorption is a transfer process by which pesticides are dispersed between solid matter and water, in soil; it is important in regulating the concentration of pesticides in soil water. One important environmental sink (retention or storage site) for many pesticides is organic matter. The transfer—called ‘partitioning’—of a pesticide into organic matter in soil is a somewhat nonspecific mechanism.

Much organic matter (humus) is made up of a series of organic polymers (long chains or mats of molecules)



and generally consists of two systems: a hydrophilic (water-loving) surface; and a hydrophobic (water-hating) interior. The convention of 'like dissolves like' holds for pesticide interactions with organic matter in soil. Nonionic (noncharged or neutral) pesticides escape from soil solution into the hydrophobic interior and, as a result, a pesticide equilibrium is set up between organic matter and soil solution. Pesticides move between organic matter and water in soil. Also, pesticides may undergo an aging process, over time, whereby the chemical moves deeper into organic matter and becomes unavailable to move back into soil solution. Pesticides that are water soluble tend to remain at the surface of soil organic matter, while those that are insoluble will penetrate to the hydrophobic interior.

The amount of pesticide sorbed is largely a function of the total amount of organic matter (sorption regions) in the soil. Sorption to clay mineral particles also occurs but usually is less significant than sorption to organic matter in determining environmental fate, unless the soil has very low organic matter content.

Many pesticides develop a charge as the result of soil solution pH (a measure of acidity); i.e., neutral pesticide molecules can become ionic (charged) and more reactive. If the pH-induced charge is positive, the pesticide can bind to negatively charged soil. If the induced charge is negative, the pesticide may actually be repelled from the negatively charged surfaces of soil solids.

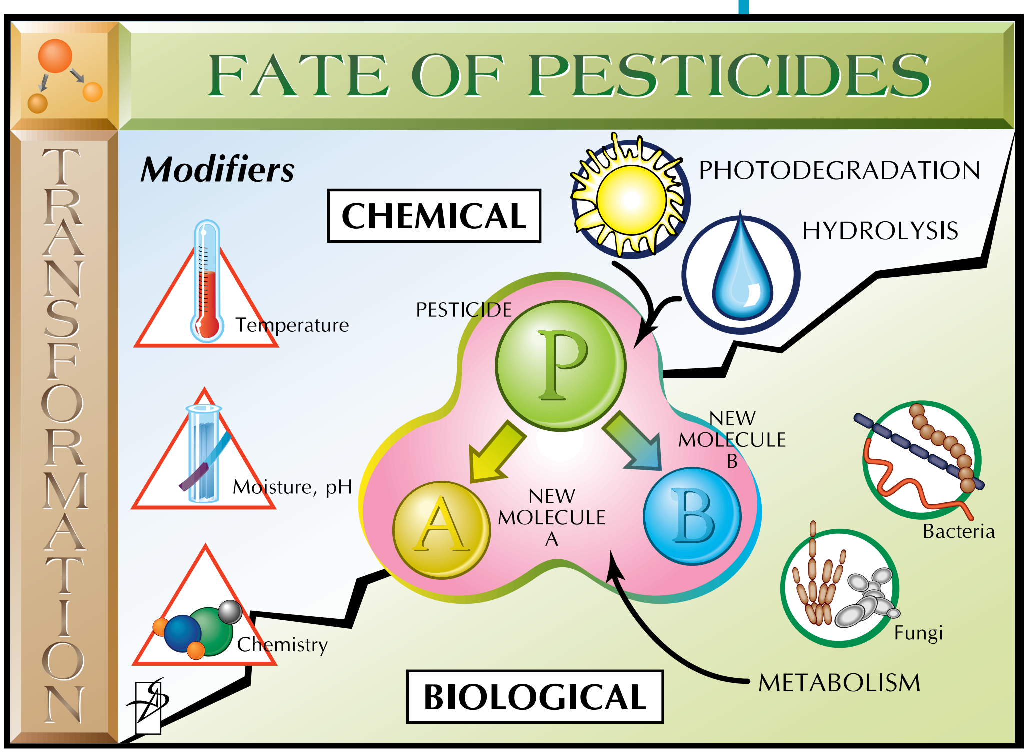
Sorption to soil particles is also dependent on soil water content because water is necessary for chemical movement; and water molecules will compete with pesticide molecules for attachment sites on clay and organic matter. Therefore, pesticide sorption tends to be greater in dry soils than in wet soils. Decreased soil water content forces the pesticide to interact with soil surfaces; however, the amount of sorption also depends on the *type* of clay and organic matter content.

The bond between a pesticide molecule and a soil particle determines, to a large degree, the environmental fate of the pesticide. For instance, pesticides that are tightly sorbed to soil particles have decreased mobility and are less likely to contaminate ground water. The bond may decrease the rate at which the pesticide is degraded by soil microbes, leading to longer environmental persistence. Pesticides strongly sorbed to soil particles may travel primarily with eroded soil and enter surface water, while weakly sorbed pesticides that are more water soluble may be released into soil water solution and enter surface water as runoff.

Microbial Degradation

Communities of soil microorganisms are very diverse. For example, researchers have estimated that between 5,000 and 7,000 different bacterial species may exist in a single gram of fertile soil. Populations of bacteria can often exceed one hundred million individuals in one gram of soil, and populations of fungal colonies can exceed ten thousand.

Microbial degradation is a transformation process that results when soil microorganisms (bacteria and fungi) either partially or completely metabolize (break down) a pesticide. Microorganisms can cause changes in a pesticide when this activity occurs; in the presence of oxygen it is termed *aerobic* metabolism, and in the absence of oxygen, *anaerobic* metabolism. Most microorganisms inhabiting the soil profile where oxygen is plentiful degrade pesticides via aerobic metabolism. As a pesticide undergoes aerobic metabolism, it is normally transformed into carbon dioxide and water. Under anaerobic metabolic conditions, microorganism degradation may produce additional end products such as methane. Those microorganisms using anaerobic metabolism for breaking down pesticides are typical of the microbes inhabiting waterlogged soils in terrestrial systems or living in the bottom sediments of ponds, lakes, and rivers. These organisms are also present in ground water and, to some extent, in the soil profile.



Pesticides, along with many other naturally occurring organic molecules, may serve as a source of food or energy for soil microbes. Because they occur at very low environmental concentrations, however, it is unlikely that their capacity to serve as a food source is adequate to sustain high numbers of microbes. Pesticides are more apt to serve as *incidental* food sources for microbes also drawing from other food sources.

Most soil microbes are associated in colonies on the soil surface, not free in soil solution. A pesticide in soil solution has to move to these microbial colonies and cross the microbial cell membrane into the cell to metabolize. Some microbes produce enzymes which are exported from the cell to predigest pesticides that are poorly transported. Once inside an organism, a pesticide can metabolize via internal enzyme systems. Any energy derived from the breakdown of the chemical can be used for growth and reproduction; any portion not fully degraded to carbon dioxide or incorporated into cells is released back into soil solution as intermediate chemical metabolites.

Recent studies have revealed that multiple organisms often are involved in the degradation phenomenon. Previous notions that single species are solely responsible for microbial degradation of a pesticide probably are not correct. Different species have different capabilities, and together they can form a 'pool of talent' resulting in degradation of the pesticide. The likelihood that the chemical will be completely degraded is decreased if any of the microbes are missing from the pool. The ability of microbes to degrade a pesticide is related to their metabolic capacity and the complexity of the molecule, and to environmental factors that regulate microbial activity (water content, temperature, aeration, nutrients).

Abiotic Degradation

Abiotic (chemical) degradation is the breakdown of pesticides by *nonbiological* reactions (i.e., without the involvement of living organisms) occurring in soil solution and on the soil surface. Factors which affect abiotic degradation include the chemical nature of the pesticide as well as its temperature, water content, and pH. Hydrolysis (reaction with water) is important for the degradation of many pesticides, as is photodegradation (reaction with sunlight); these two processes generally are the most important abiotic mechanisms involved. Abiotic degradation results in less transformation of a molecule than does biological degradation.

Hydrolysis is a common chemical reaction—a process by which a pesticide reacts with a water molecule. Hydrolysis reactions generally substitute an hydroxyl (OH) group from water (HOH or H_20 is the chemical structure of water) into the structure of the pesticide, displacing another group. Reaction with water breaks apart the molecule, and the extent of breakdown is pH dependent.

Photodegradation (photolysis) involves the breakdown of organic pesticides by direct or indirect energy from sunlight. Light energy can be absorbed by the pesticide or by secondary materials (e.g., organic matter) which become ‘activated’ and, in turn, transfer energy to the pesticide. In either case, pesticides absorb energy from sunlight, become unstable or reactive, and degrade. Photolysis can occur in water, in air, or on surfaces such as soil or a plant leaf. Photolytic reactions occur near the surface of the ground (in the top few hundredths of an inch) or near water surfaces, where light can penetrate.

Volatilization

Volatilization is the process whereby a solid or liquid evaporates into the atmosphere as a gas. The process provides a significant pathway of transfer for some pesticides. In principle, volatilization is an escape mechanism. Compounds with high vapor pressure and low water solubility have a tendency to volatilize. The tendency of a pesticide to volatilize from water is approximated by the ratio of its vapor pressure to its aqueous solubility. The same is partially true for soils, but the tendency for a pesticide to volatilize from soil also can be inversely proportional to its potential to bind to soil.

Specific environmental factors that tend to increase volatilization include high temperature, low relative humidity, and air movement. A pesticide that is tightly sorbed to soil will have a lower solution concentration and be less likely to volatilize. That is, less volatilization occurs from drier soils because the lack of water allows the pesticide to sorb onto soil particles. Volatile pesticides usually are incorporated (plowed into the soil) after application to reduce loss into the atmosphere. However, it has also been shown that pesticide volatilization from soil is complex and highly dependent on the movement of water to and from the soil surface.

Once a pesticide enters the atmosphere as a gas, it can become ‘diluted’ in water droplets and, as a result, highly susceptible to long-range transport from the application site. Within the atmosphere, the pesticide may undergo reactions with light (photolysis) and water (hydrolysis) and sorb to suspended materials such as dust particles. Pesticides in a gaseous state may dissolve in atmospheric water and be transferred back to the soil surface during rainfall.

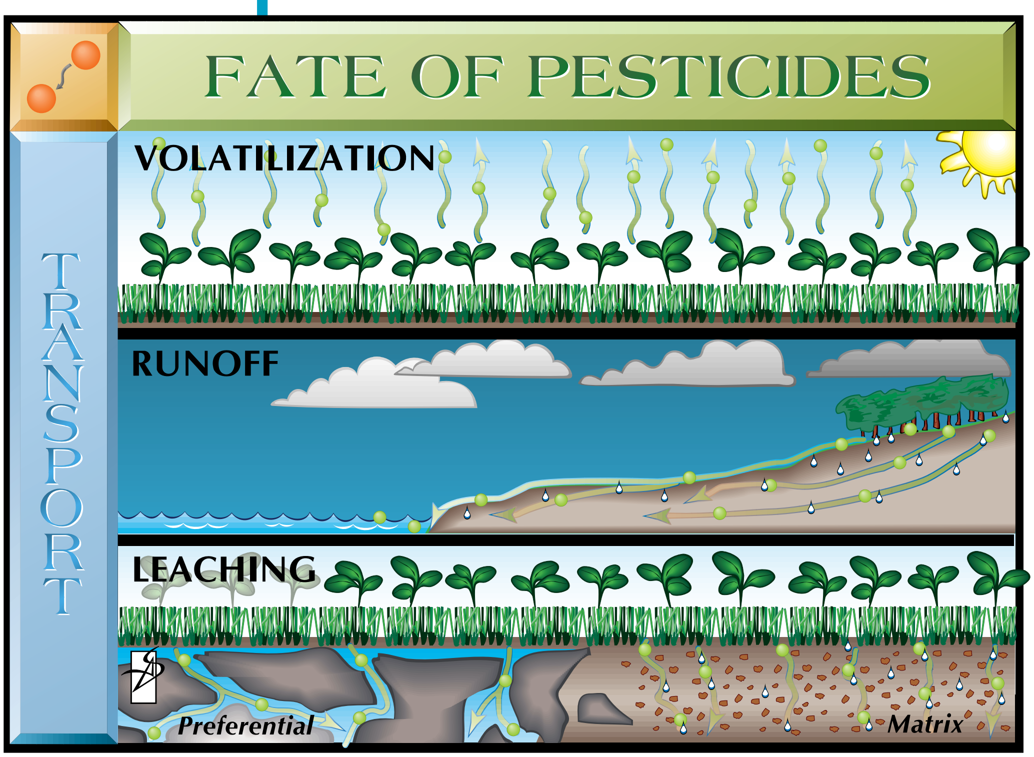
Leaching

Leaching is the term for the transport process of downward movement (infiltration) of pesticides in water. Two kinds of phenomena are associated with leaching: *preferential* flow, and *matrix* flow.

Preferential flow allows pesticide molecules to move rapidly through a section of the soil profile, with reduced likelihood that the molecules will be retained by soil particles or degraded by microbes. Preferential flow is characterized by water that flows rapidly through worm holes, root channels, cracks, and large structural voids in soil.

Matrix flow results in a slower migration of water and chemical through the soil structure; the pesticide moves slowly with water into small pores in soil and has more time to contact soil particles.

The potential for volatilization and photolysis diminishes considerably as the pesticide infiltrates the first few hundredths of an inch of soil. As the pesticide moves lower into the root zone, there is generally less organic matter, more compaction, and lower biotic activity. Once the pesticide leaches past the root zone, abiotic degradation reactions frequently become more important than biotic reactions because microbial



populations generally are smaller below the root zone. In fact, microbes in deeper soils operate under ‘starvation’ and are less energetic due to a lack of carbon and nitrogen. In addition, pesticides rarely reach deep into the soil profile; so microbes, therefore, are not adapted to degrade them quickly.

The most important factors in determining whether a pesticide will leach are its degradation (persistence) capabilities, its sorption characteristics, and its inclination to release rapidly into soil solution once it is sorbed. Pesticides that are weakly sorbed by soil and resist degradation are more likely to leach to ground water than are those that remain bound to soil. Factors such as soil type, topography, and rainfall also may impact the leaching potential of a pesticide; and factors such as application rate, frequency, and type (foliar, pre- and post-emergence) need to be considered.

The fate of pesticides in aquifers is unclear. Studies have shown that degradation will occur in the capillary fringe (the region above the aquifer) and in ground water. Subsurface rates of degradation tend to be lower than those in surface soils, perhaps reflecting smaller microbial populations, limitations in essential secondary nutrients, or lack of adaption (of microbial populations) to use the compound.

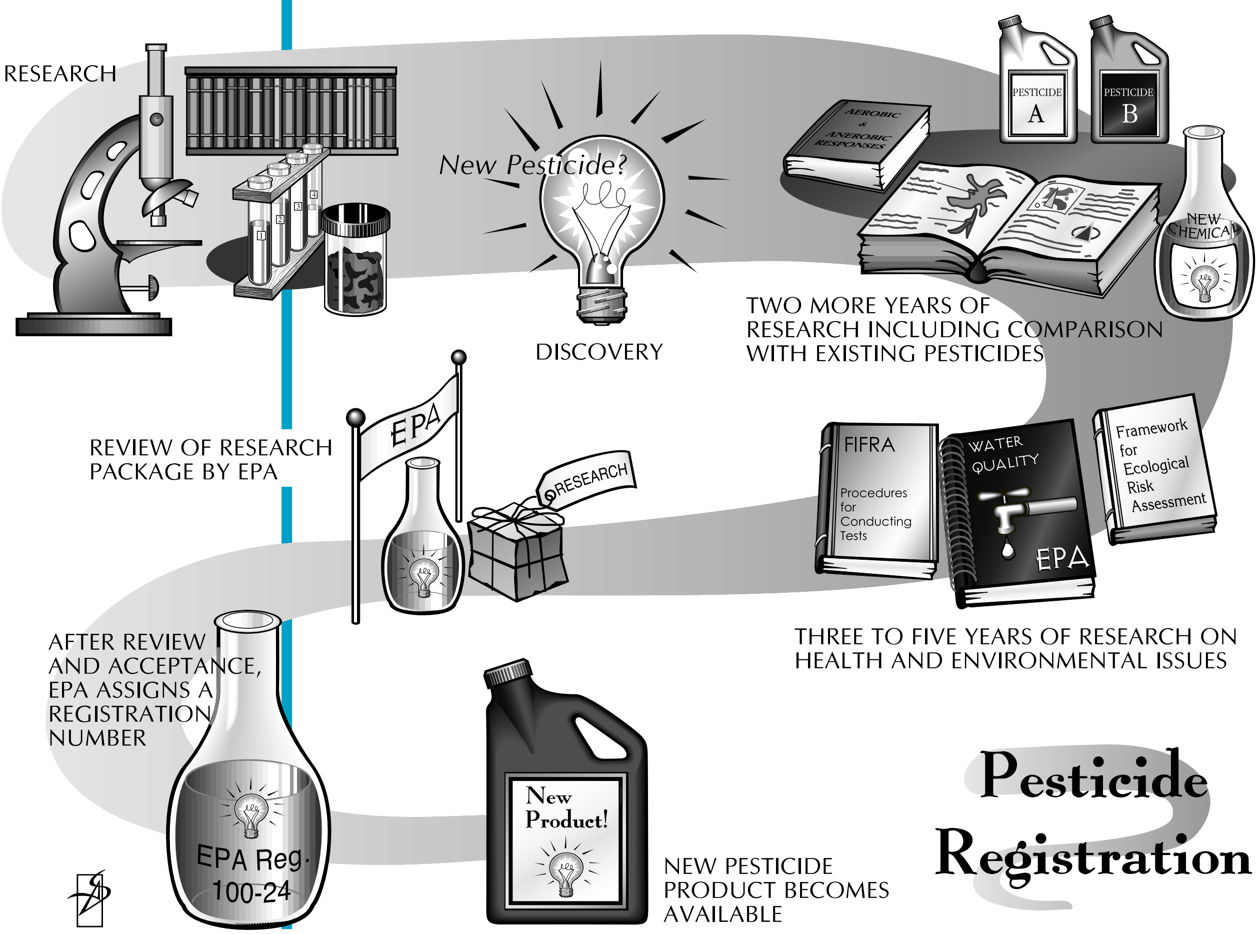
Runoff and Erosion

Runoff—movement of water across the soil surface—occurs when water collects (due to rainfall, irrigation, or melting snow) at a rate faster than it can infiltrate the soil. As rain falls, small soil particles become dislodged and are carried laterally by water in a process known as erosion. Because pesticides are applied directly to the soil, large amounts eventually end up there; and as water runs off and soils erode, dissolved and sorbed pesticides go along. Runoff and erosion have the potential to move more pesticide off site than leaching, due to the fact that runoff is a surface phenomenon. Surface runoff and erosion move pesticides and other pollutants laterally from points of higher elevations to collection points (streams, rivers, ponds, lakes) at lower elevations. Climatic factors such as rainfall timing, duration, and intensity, and surface features such as slope length and grade, soil permeability, and surface cover greatly influence the degree to which pesticides are mobilized by runoff and erosion. Similarly, pesticide management factors may significantly affect runoff; for example, a soil-incorporated pesticide is less likely to run off site than the same compound applied to the soil surface.

THE PESTICIDE TESTING PROCESS

The goal of modern pesticide chemistry is to produce pesticides that are effective in smaller quantities, more target-specific, and less persistent in the environment. Pesticide structures are developed to mimic—and therefore substitute for—specific molecules in targeted biological reactions; i.e., the pesticide mode of action is unique to the targeted pest. Such specificity is achievable with complex chemical structures which disrupt target-specific biological processes to effect the desired control and yield less persistence in the environment.

Pesticide products new to the marketplace began the registration journey seven to nine years earlier in a research laboratory. After development, two years of exploratory research are needed by the manufacturer to define the chemical's biological and environmental characteristics and to make comparisons with existing products. Pesticides identified as commercially viable are studied for an additional three to five years to



ensure that they meet the health and environmental criteria established by company philosophy and policy, and government regulations. During this additional testing period, an average of 120 studies are completed to satisfy testing mandates as specified by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) administered by the U.S. Environmental Protection Agency (EPA). Typically, the development and registration of a new pesticide costs between $40 million and $50 million; and upon completion, the entire research package is submitted to EPA for review.

The EPA review process takes two or more years, followed by assignment of an EPA registration number (a legal requirement that must be met before the new product can be sold to the public). Under FIFRA, a product may be granted a registration number only if supporting data indicate that its potential benefits to society outweigh the probability of risk to people, wildlife, and the environment when used as directed in its labeling. Recouping development costs from years of research and subsequently generating profits for the company to reinvest in new pesticide research hinge on the ability of the product to compete successfully with others in the marketplace.

Because of the time lag between discovery and product registration, manufacturers must foresee any effects which imminent environmental regulations might have on current research data. Failure to anticipate changes in environmental regulations could lead to additional years of research prior to registration.

Development of Environmental Fate Data

Discovery of ‘environmentally acceptable’ pesticides requires researchers to unravel the complexities of chemical behavior in the environment. Experiments designed to do so are time-consuming and costly and require expertise from numerous scientific disciplines.

Discovery Phase

Most manufacturers employ a screening process to identify promising compounds for further study and unfavorable ones to be discarded. Primary screens are used to pinpoint chemicals with pesticidal properties. Their impact on growth, development, behavior, and mortality of pest insects, weeds, and diseases is carefully observed and recorded. It is important that the process uncover novel modes of action rather than generating copycats of those already in the marketplace. From a marketing standpoint, chemicals lacking distinct advantages in terms of efficacy and selectivity are unlikely to generate revenues sufficient to support the significant costs associated with development, registration, and field support.

Pesticides entering the screening trials may be synthesized with specific targets in mind or produced by microorganisms inhabiting the soil. Others may be discovered by examining structural activity relationships coupled with molecular modeling. New pesticides originate from industrial manufacturing waste streams and from by-products of other industries; these sources provide about 30,000 chemicals annually for inclusion in pesticide screening programs.

Fewer than 200 of the 30,000 chemicals per year display the kind of activity on pests that warrants further evaluation. Most compounds are excluded from additional testing because they are not sufficiently selective, the cost to the manufacturer is unacceptable, the potential market is too small, or they demonstrate unacceptable hazards. In order to be economically viable, the pesticide must be used commercially for one or more major crops (corn, soybeans, wheat, or cotton).

Secondary screening (on compounds which have survived primary screening) involves the use of proven, reliable predictors of biological and environmental properties to identify negative chemical attributes. Biological, environmental, and economic questions pertinent to the commercial potential of these chemicals are listed below.

- What is the water solubility of the material?
- How mobile is the compound in soil?
- How persistent is the compound in the environment?
- What are the short-term effects on laboratory test animals such as rats?
- How toxic is the compound to man, birds, aquatic organisms, insects, and nontarget plants?
- Will the chemical be toxic to desirable nontarget plants?
- Does the material bioaccumulate (that is, does it build up in the environment)?
- What prototype formulation will be tested?
- Can the material be produced in sufficient quantity to continue testing?
- What kinds of manufacturing processes may be needed?
- Is there a market, and does it meet other commercial objectives?
- Can it be produced at a cost that will provide a product at a price that the users will pay?
- What are the strengths and weaknesses of current and expected competing products?

Research and economic development teams evaluate the relative strengths and weaknesses of each chemical and, in turn, their analyses are consolidated into product profiles. Many products are shelved because their profiles indicate undesirable health or environmental attributes, manufacturing problems, or sales potential insufficient to capture an adequate share of the market. Decisions to eliminate certain products carry an expensive price tag: two years of research costing a million dollars for each chemical in the secondary screen.

Predevelopment Phase

Chemicals which survive the secondary screening process are tested extensively to produce a database that supports EPA registration of the product. Manufacturers must conduct and analyze research and present their findings according to protocol outlined by EPA. All data submitted in support of pesticide registration must result from research conducted under Good Laboratory Practices (GLPs). GLPs are regulations issued by EPA that prescribe the procedures for extensive documentation and verification of every step of the testing process. This assures that the data were developed by appropriately trained scientists and verifies the authenticity of the data used to achieve the results. The auditing of data and reports to assure GLP compliance is a very expensive component of the product development process.

Summary of Environmental Fate Studies Required by EPA

Three basic questions on environmental fate must be answered in the data supporting EPA registration: (1) How fast and via what pathways does the pesticide degrade? (2) What are the breakdown products? (3) How much of the pesticide or its metabolites will migrate, and where will they accumulate in the environment? Environmental fate data generated from laboratory and field experiments are then used to assess the potential for negative impact on the environment. Risk assessment involves comparing effects data from various toxicological studies with fate and exposure data to predict potential health and environmental impacts—and to protect natural resources in general.

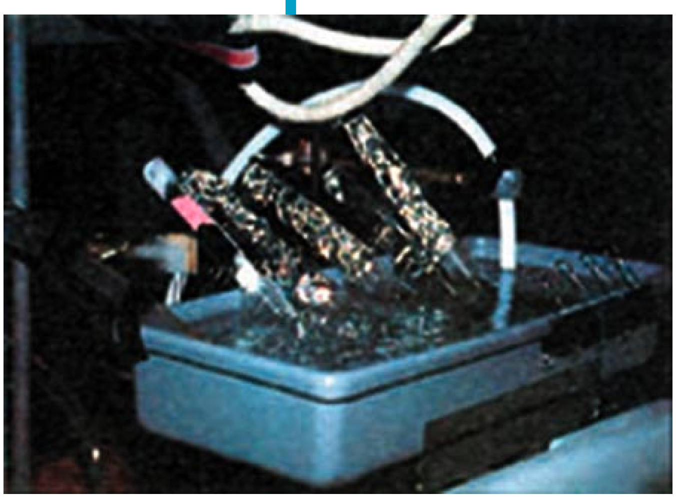
A tiered approach to testing is used to simplify the process of investigating environmental fate data for pesticide registration. The first tier of environmental fate studies addresses hydrolysis; photodegradation in water and soil; aerobic soil and anaerobic aquatic metabolism; mobility; and terrestrial field dissipation. The second tier consists of field soil studies and additional laboratory research triggered by results of first tier work.

Finally, a third tier addresses key transport mechanisms indicated (by preliminary studies) as significant in assessing the ultimate environmental impact of the product—for example, small scale ground water monitoring studies or surface water runoff evaluations. If a product's margin of safety is low in any environmental compartment, large scale surface and ground water monitoring programs and ecosystem investigations may be conducted under 'conditional' registration for the purpose of demonstrating in-use safety.

Abiotic Degradation Studies

The reactions of a pesticide with water (hydrolysis) and light (photolysis) are important in predicting a chemical's ultimate environmental fate. When a pesticide reacts with water or absorbs solar energy, either directly or indirectly, the chemical bonds holding the parent molecule together are broken. Degradation studies are conducted to document the formation and decline of the parent compound, as well as transformation products.

Controlled hydrolysis studies are conducted according to federal regulations to identify how a pesticide reacts with water. The chemical is added to water sterilized to kill pesticide-degrading microorganisms and buffered to test hydrolysis under acidic, alkaline, and neutral conditions. Pesticides containing tagged radioactive carbon-14 can be used to help scientists track the environmental fate of the chemical through its degraded products. Placement in dark incubators prevents the pesticide from reacting with light. Test samples are collected periodically for 30 days and analyzed to determine the amount of parent molecule remaining and the products generated, and to account for all of the radioactive carbon-14.

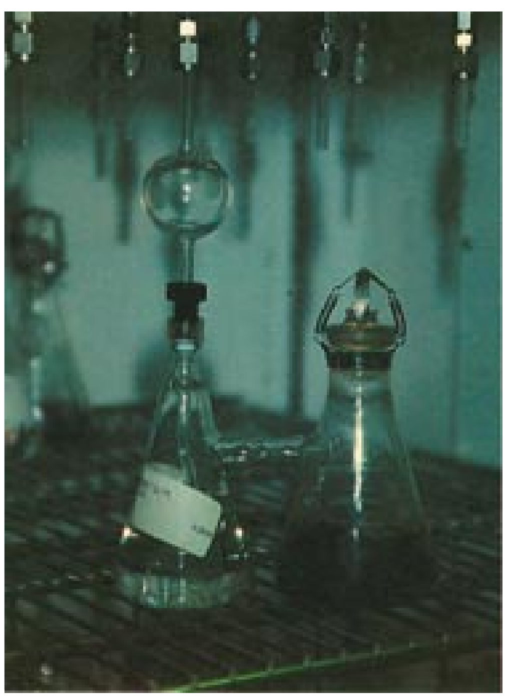


Pesticide transformation also can occur via photolysis. Studies of photodegradation in water are conducted in a manner similar to hydrolysis experiments, except that they are conducted in the presence of simulated or actual sunlight. Photodegradation on soil is studied by applying a radiolabeled pesticide to a thin layer of sterile soil. The treated water or soil is irradiated with simulated or actual sunlight and degradation is charted. Samples are collected over a 30-day period and analyzed as in hydrolysis studies. Aqueous photodegradation studies, compared to hydrolysis studies, show how sunlight affects chemical breakdown in water. Soil photodegradation studies show how soil components (e.g., clay and organic matter) affect pesticide breakdown. These data can be compared and pathways for the two systems established.

Metabolism Studies

In addition to plant metabolism and uptake studies, the biological degradation of pesticides by microorganisms in soil is examined. The term metabolism is used since most pesticides are degraded primarily by microorganisms in soil that metabolize all or part of the pesticide molecule.

Three kinds of environmental metabolism studies are required under FIFRA: a one year aerobic soil metabolism study using selected field soils; a 30-day aerobic aquatic metabolism study using sediment and



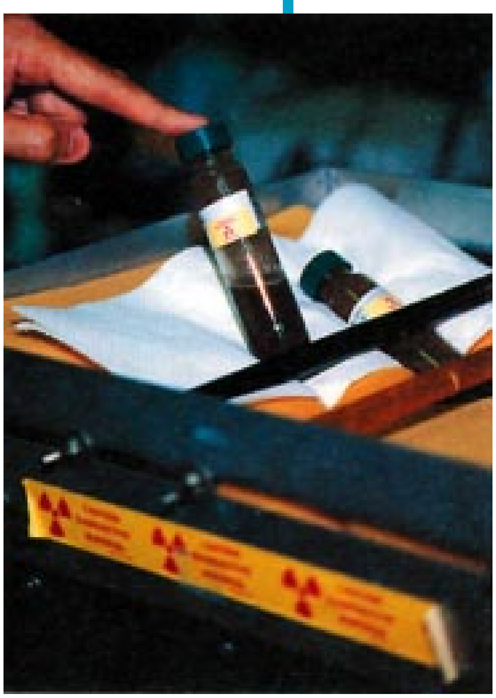
natural water; and a one-year (maximum) anaerobic aquatic metabolism study using sediment and natural water. These studies seek to determine how fast parent molecules are degraded by biological processes (mainly microorganisms) in different soils, aerobic sediment and water, or anaerobic sediment and water, and to determine what metabolites are formed. To be valid, these studies also must account for the radioactive carbon-14 used as a tracer.

Field soils known to be previously unexposed to pesticides are used in the various metabolism studies. Oxygen is maintained for aerobic metabolism studies, while anaerobic studies require that the soils or sediments be purged of oxygen. A radiolabeled pesticide is applied to the soil or sediment and, at specified intervals, researchers remove and analyze samples for the parent pesticide and any metabolites. If volatile materials and CO_2 are released, they are trapped and analyzed.

Mobility Studies

Scientists estimate potential mobility of a pesticide by first determining its sorption in soil. Soil and water are made into a slurry which is then treated with a range of pesticide concentrations. After a period of time, the slurry is centrifuged to separate the soil and water, after which the chemical concentration in each is determined.

Pesticide retention is a sorption coefficient (K_d) expressed as a ratio of the *concentration of chemical sorbed to soil* to the *concentration of chemical remaining in water:* **K_d = sorption:solution.**



The K_d is relevant to understanding pesticide transport since chemicals remaining in soil solution can leach or become available in the water of a pond or stream. Because pesticides in soil solution are subject to leaching, the extent of sorption as measured by the K_d serves as a predictor of mobility: the higher the K_d, the lower the tendency to move in soil. For example, if a K_d is lower than 2, the molecule is termed *highly mobile;* if it's between 2 and 5, the molecule is considered *mobile;* and if the K_d is greater than 5, it's deemed *immobile* with respect to leaching.

Frequently, the K_d is expressed as a K_{oc} by dividing the K_d by the fraction of organic carbon present in the soil: **$K_{oc} = K_d \div$ fraction organic carbon.** This mathematical transformation allows the potential mobility of a chemical to be compared with that of other chemicals, regardless of soil type. A K_{oc} value greater than 500 is usually associated with immobile pesticides.

Field Dissipation Studies

Terrestrial field studies are conducted to verify the integrated routes and rates of pesticide degradation and mobility demonstrated in the laboratory; the length of time required to complete the terrestrial studies is estimated from data generated in the lab. Pesticides which are persistent—those that have a soil metabolism half-life greater than 6 to 12 weeks under optimal conditions for degradation—generally require at least eighteen months per study. Field studies with less persistent pesticides often can be completed within a year.

When a pesticide is proposed for use over large areas and/or multiple crops, several field test locations and cropping scenarios are required for field dissipation studies. The test sites must be established and maintained according to best management practices for the intended crop or noncrop use. Preapplication sampling and analysis of the soil to a depth of three feet are performed to confirm that no pesticide is present. An end-use product is applied with typical application equipment at the highest rate stated on the proposed label. At timed intervals, representative samples are removed at prescribed depths and analyzed for the presence of the parent product and environmentally significant metabolites. Since terrestrial dissipation studies are most frequently conducted with unlabeled chemicals, precise method development to assure sensitive analysis of soil residues is necessary. Pesticides that are active at low rates require sophisticated and highly sensitive analytical methods for extraction and analysis of the parent molecule and significant metabolites; measurements in *parts per billion* are necessary.

Dissipation studies also must be conducted to determine the environmental fate of pesticides designated for aquatic crop and noncrop uses. Protocols for conducting aquatic studies and the timetables involved are similar to those of terrestrial field studies. Water and sediment (and sometimes animal and plant) samples are collected for analysis to detect the parent molecule and significant metabolites.

Decisions to Move Toward Commercialization

Successful development of a product requires teams of scientists working on various test components and discussing their results at every level of the testing process. Discussion on the chemical's fate and behavior, short- and long-term health effects, ecotoxicity, environmental toxicity, and production and economic information is ongoing. The benefits of the product versus its risk potential are under constant scrutiny. The project may terminate at any time during the predevelopment process if evidence suggests potential biological, environmental, or marketing problems. Only one or two chemicals out of 30,000 survive the rigors of the seven- to nine-year research and evaluation process, and those must assume the burden of recouping production costs *for all.*

Development/Registration Phase

Final internal review and discussion are conducted by the developer to ensure the validity, accuracy, and interpretative summaries of all data. Each experiment must be accompanied by complete descriptions of the procedures used, by experimental designs, and by details that allow EPA data evaluators to reconstruct the experiment. Environmental tests include qualitative and quantitative descriptions of the active ingredient and metabolites; and besides the data, per se, a summary of data, data analysis, and sufficient description to verify statistical procedures are required. Once the internal company review is satisfactorily completed, the scientific data can be forwarded to EPA as part of the registration package.

The registration package and the application for registration are processed at EPA and assigned to a Product Manager (PM) in the Registration Division within the Office of Pesticide Programs (OPP). It is the responsibility of the Registration Division to conclude whether a new pesticide product satisfies the requirements of FIFRA and should be registered. The Registration Division is supported by others within OPP in the review and evaluation of the supporting data package. The PM tracks the current status of the registration request and serves as liaison between EPA and the registrant (i.e., pesticide manufacturer). EPA has been mandated by the United States Congress to ensure that the conduct of the investigations meets scientific protocols.

Prior to the time a registration application is submitted to EPA, a company developing the product usually requests permission (in the form of an experimental use permit) to use the new pesticide under field conditions in numerous marketing areas. Prior to issuing an experimental use permit, EPA must make the decision that use will not present unreasonable adverse effects to man or the environment.

An experimental use permit is issued for finite periods of time and allows the company to develop data in support of registration that can be obtained only under normal use conditions (as prescribed by the proposed labeling). This work often is conducted by universities and consultants using farms or research field stations. Experimental use permits are required when field research is conducted on ten acres or more. Once all of the required supporting data are developed, the application for registration is submitted to EPA for review and evaluation.

EPA may meet with company representatives to discuss research methodologies or conclusions, or to request the original data. The registrant may be asked to repeat experiments, redesign research methods, or conduct additional testing. Registration ultimately will be granted only when EPA concludes that the benefits of the product (increased production, lower food costs, etc.) outweigh any potential for harm to people, wildlife, or the environment. Since pesticide registration decisions, by law, are based on benefits as well as risk assessment, all registrations are conditional; EPA may require the registrant to conduct further studies, suggest and implement strategies to minimize risks to the environment, or monitor for the presence of the pesticide and its metabolites in ground and surface water. Product registration covers only the uses and crops addressed in the studies submitted; additional studies may be required to qualify the product for expanded registration.

Product Stewardship Phase

The average cost of developing a single marketable product from among 30,000 chemicals screened is estimated at $35 million to $50 million; total expenditures might reach $150 million if the cost of manufacturing plants, etc., were factored into the equation. Moreover, nearly half of the original 17-year patent life is spent on research, development, and registration processes; and the pesticide that survives to earn an EPA registration number is *not* guaranteed success in the marketplace. Manufacturers must exercise good stewardship in maintaining and supporting their pesticide product and ensuring that its use is consistent with the label. They are required under FIFRA to report any evidence of problems relative to the use of the product which are identified after registration; as a result, additional label restrictions, suspension, or cancellation of the product might be imposed—and the manufacturer’s investment in the pesticide product might be lost in the process!

REGULATORY EVALUATION OF ENVIRONMENTAL FATE DATA FOR WATER QUALITY CONCERNS

The environmental fate studies discussed previously provide the basis for screening pesticide registration candidates for effects on water quality. Evaluations also may take place for previously registered pesticides when their use has generated water quality concerns or when their data packages need to be upgraded to current regulatory standards. The scope of the regulatory screening process focuses on two aspects of pesticide behavior which affect leaching and runoff: 1) persistence, or how long it takes for the pesticide to be transformed into an essentially harmless substance; and 2) mobility, or how easily the pesticide can be transported to ground or surface water.

As described previously, information on the persistence of the pesticide is obtained primarily from soil metabolism, hydrolysis, photolysis, and field dissipation studies. Information on the mobility of the pesticide is obtained primarily from sorption experiments, leaching, and field dissipation studies. A complete set of environmental fate studies generally is sufficient for identifying pesticides that have the *potential* to leach into ground water or to enter surface water as runoff.

The results of environmental fate studies are not always sufficient to estimate concentrations of a pesticide in aquifers or surface waters when the chemical is used in different geographical areas, or to define specific areas where water contamination might occur. Therefore, presumptive decisions on use restrictions or limitations must be made for pesticides with the potential to affect water quality. These decisions might be made long after registration, as cumulative information warrants; labels may be modified to be more or less restrictive, depending on the results of surface and/or ground water monitoring studies.

Although there is some interaction between surface and ground water, the primary mechanisms of pesticide entry into the two usually are quite different. Therefore, EPA addresses concerns regarding pesticide contamination of surface and ground water independently.

Screening Pesticides for Potential to Leach into Ground Water

In most cases, a period of a few months to several years is required for a pesticide to leach considerable distances through soil to reach ground water. Therefore, a pesticide generally needs to be *both* persistent and mobile to reach most aquifers.

The extent of pesticide movement through soil depends on the degree of interaction between the pesticide and soil particles, soil microorganisms, and weather. The amount of pesticide that will reach low soil depths varies dramatically with slight environmental fluctuations, making estimation difficult. A judgment can be made on the overall likelihood of ground water contamination by comparing the mobility and persistence of a chemical to those of similar pesticides previously detected in ground water at multiple use sites. Many factors affecting the environmental fate of a pesticide are not well understood. Site-specific behavior of pesticides in soils cannot be predicted unless actual field data are available for comparison.

Assessment of Comparative Leaching Potential

Several methods are used by federal and state regulators to assess a pesticide's leaching potential. Most estimates rely heavily on soil half-life and K_d as the most consequential parameters.

Modeling results should never be considered equivalent to real data. All pesticide leaching models are mathematical tools (with varying degrees of complexity and sophistication) that attempt to reduce what happens in the 'real world' to formulas. However, no formula can cover every possible contingency in the natural environment; there is still a great need to validate models by collecting pesticide residue and environmental condition data from the field. As more validation work is done, models will come closer to simulating the real world; but they probably never will be sufficiently sophisticated to completely eliminate the need for collection of field data.

Trigger Values

In this simplest of assessment methods, pesticides are presumed to have ground water contamination potential if environmental fate studies trigger multiple criteria for both mobility and persistence. Trigger values are based strictly on laboratory data. Further refinements of ground water assessment of the pesticide should consider additional field parameters such as application rate, soil, and target crops. Trigger values are determined from a group of reference pesticides which have a history of use *and* extensive ground water monitoring. The following values may be used by regulators as an initial step to identify pesticides most likely to leach to ground water:

Trigger Values Related to Persistence

1. Aerobic soil metabolism half-life of greater than two to three weeks;

2. Field dissipation half-life of greater than two to three weeks;

3. Photolysis half-life greater than one week; or

4. Hydrolysis half-life greater than 60 days in sterile water.

Trigger Values Related to Mobility

1. K_{oc} usually less than 300;

2. The pesticide is a weak to moderate acid which would not be attracted to most soil particles; or

3. Water solubility greater than 30 parts per million (ppm).

The Groundwater [sic] Ubiquity Score

The Groundwater [sic] Ubiquity Source (GUS) is another estimator model which, like trigger values, is useful for comparing the intrinsic leaching potential of pesticides. The GUS model is more sophisticated than trigger values because it uses a formula that combines pesticide mobility and persistence parameters. To calculate the GUS, average values for only two pesticide parameters are needed: the soil degradation half-life, and the soil $K_{oc.}$ Pesticides with a GUS greater than 2.8 are more likely to leach to ground water, while those with GUS values between 1.8 and 2.8 are somewhat less likely to leach. Pesticides with GUS values less than 1.8 are unlikely to leach to ground water.

The Pesticide Root Zone Model

The Pesticide Root Zone Model (PRZM) has been developed by EPA and provides site-specific leaching estimates. PRZM, like other pesticide soil fate and transport models, incorporates soil characteristics and hydrology, weather, irrigation, and crop management practices into complex mathematical formulas that estimate leaching potential. EPA uses PRZM (and similar models) to make multiple site comparisons of the leachability of a pesticide to older, reference pesticides with histories of use and extensive ground water monitoring. Models like PRZM also provide estimates of the concentration of a pesticide that will leach, but these estimates should be confirmed with actual field data.

The Pesticide Assessment Tool for Rating Investigations of Transport

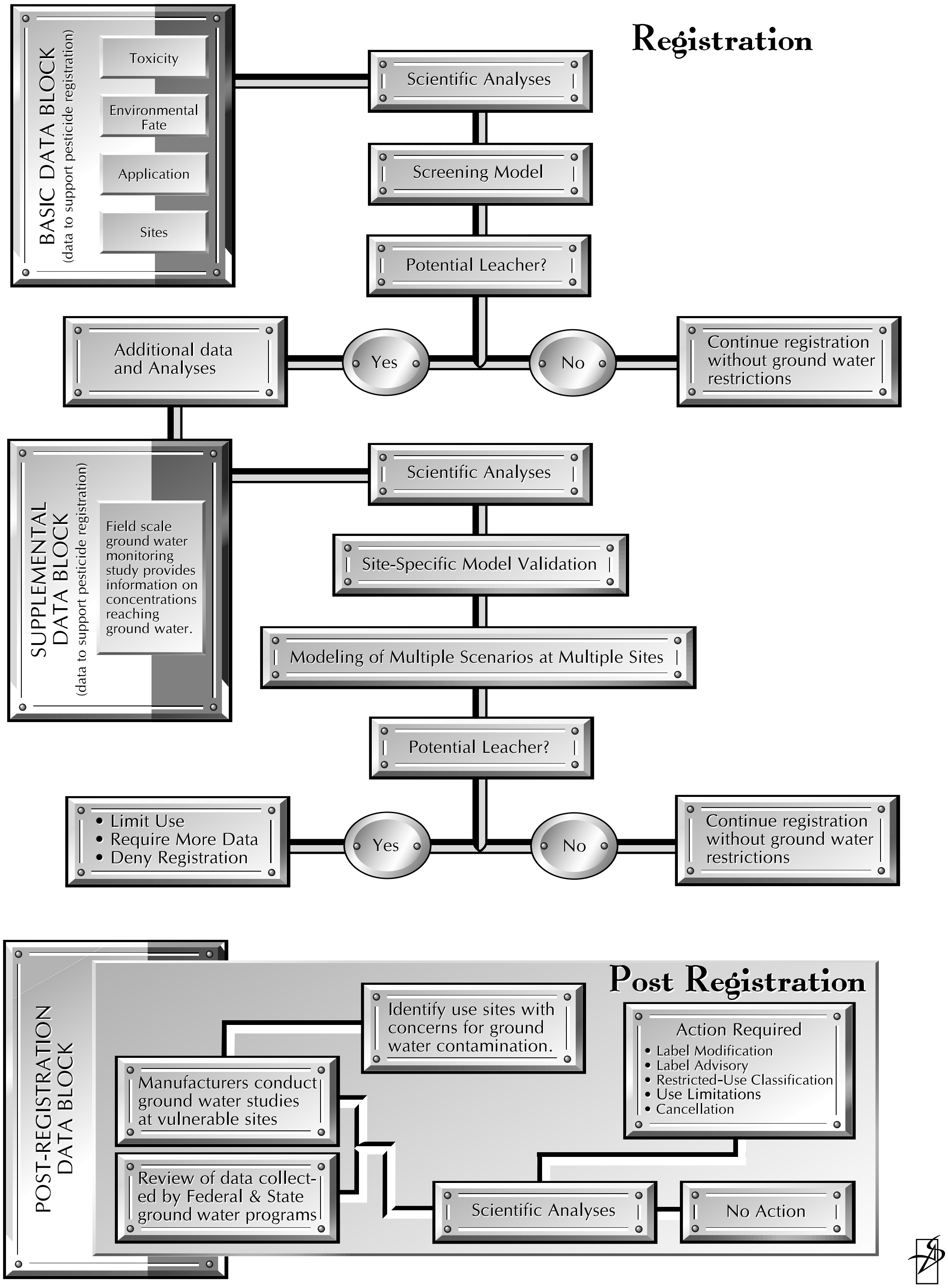
The Pesticide Assessment Tool for Rating Investigations of Transport (PATRIOT) is a site-specific screening model. That is, PATRIOT provides a quick estimation of the relative leaching potential of a pesticide at representative sites. The PATRIOT user first must select crops, geographical areas, and soil types of interest. PATRIOT automatically simulates weather, using historical records from stations with soils that closely resemble those selected for modeling; and it automatically incorporates appropriate irrigation schemes. Pesticide characteristics needed for modeling are also provided by PATRIOT; however, for newer pesticides the user must input personal estimates of the required values. Finally, PATRIOT performs simulations of pesticide leaching and provides estimates of pesticide leaching under varying conditions. Therefore, the leaching potential of a pesticide in different cropping systems or in different soil types can be evaluated with PATRIOT.

Special Studies to Evaluate Leaching Potential

When analysis of environmental fate data indicates a potential for ground water contamination, EPA may require ground water monitoring studies (called second tier studies) to determine if pesticide use limitations are necessary. Ground water monitoring studies may be required for a registered pesticide when new data (such as ground water detections at multiple sites) indicate contamination not initially anticipated. Ground water monitoring studies also may be required as a condition of registration when properties of a new pesticide fall within an area where actual field data are needed to better ascertain risks.

Before requiring a ground water study for pesticides with established uses, EPA must determine that there is a likelihood that ground water contamination at multiple sites has occurred or may result from currently registered uses. EPA also considers various environmental and toxicological effects that may be present.

Typically, field-scale studies are conducted in areas that are relatively vulnerable to ground water contamination. These studies track the movement of an applied pesticide and a tracer—a substance such as bromide used to follow the subsurface movement of water through the soil profile—into ground water. Tracer data


Registration
BASIC DATA BLOCK
(data to support pesticide registration)
Toxicity
Environmental Fate
Application
Sites
Scientific Analyses
Screening Model
Potential Leacher?
Additional data and Analyses
Yes
No
Continue registration without ground water restrictions
SUPPLEMENTAL DATA BLOCK
(data to support pesticide registration)
Field scale ground water monitoring study provides information on concentrations reaching ground water.
Scientific Analyses
Site-Specific Model Validation
Modeling of Multiple Scenarios at Multiple Sites
Potential Leacher?
• Limit Use
• Require More Data
• Deny Registration
Yes
No
Continue registration without ground water restrictions
Post Registration
POST-REGISTRATION DATA BLOCK
Identify use sites with concerns for ground water contamination.
Manufacturers conduct ground water studies at vulnerable sites
Review of data collected by Federal & State ground water programs
Action Required
• Label Modification
• Label Advisory
• Restricted-Use Classification
• Use Limitations
• Cancellation
Scientific Analyses
No Action

help analyze how readily a pesticide moves with water through the soil profile.

Soil cores (soil-water sampling devices throughout the subsoil) and the monitoring of wells which draw ground water from the upper portion of the aquifer are used to track the movement of the pesticide and tracer. Irrigation must be used as supplemental precipitation to ensure that the site receives moisture equal to that which would occur naturally in a wetter than average year.

Sampling in ground water monitoring studies is continued until the degree of ground water contamination by the pesticide, if any, is well characterized. Results from completed studies are used to evaluate the magnitude of ground water contamination that may occur over the proposed use area.

Pesticide leaching models such as PRZM may be compared to actual field study results at a given site to determine their reliability in predicting leaching potential. If found sufficiently reliable, these models then can be used to estimate the impact of a pesticide over an entire use area. The quality of data from ground water monitoring studies influences estimates of predicted behavior in the use area. Modeling based on real-world data from ground water monitoring studies is useful in evaluating the potential for pesticide exposure. Additionally, modeling may be used to develop use restrictions to mitigate the potential for pesticides to reach ground water.

Ground water monitoring data also are used by EPA to evaluate the impact of pesticide use on ground water quality in the public domain. One major effort in this area is the collection of data in the Pesticides in Ground Water Database which is maintained by EPA's Office of Pesticide Programs. The Pesticides in Ground Water Database summarizes (by state and county) monitoring data from various state entities, federal agencies, and other sources. Validated data collected from these sources according to rigorous, prescribed processes may be used by EPA to support regulatory decisions. In recent years, the U.S. Geological Survey (USGS) has greatly increased the number of pesticide analyses included in their ground water monitoring programs. USGS data often are of particular value to regulators because, traditionally, they have been central to the USGS mission to collect a full complement of hydrogeologic data to facilitate interpretation of water resources monitoring data that they collect. USDA's Agriculture Research Service also is increasingly involved in collecting monitoring data.

Even under optimum conditions, not all questions on the potential of a pesticide to impact ground water can be answered from field scale monitoring studies conducted in support of registration—or from outside monitoring studies.

Often there are some use situations where the likelihood of a pesticide leaching to ground water remains uncertain. Pesticide producers (registrants) cooperate more and more with state regulatory, agricultural, and environmental agencies to design monitoring programs to ensure that unexpected and undesirable environmental effects do not surface after a pesticide is registered. Should uncertainties remain when a product is registered, pesticide registrants may agree to conduct ongoing monitoring programs designed to provide information that can be used to head off potential ground water contamination problems.

Screening Pesticides for Runoff Potential

The runoff potential of a pesticide is influenced by three factors: type of soil; slope of terrain; and the intensity and timing (with respect to pesticide application) of rainfall. All three factors should be considered when estimating runoff potential. A nonpersistent pesticide (i.e., one which does not sorb to soil particles or organic matter) can be transported from its application site to major bodies of surface water in as little as a few minutes or hours when heavy rains occur shortly after application. A pesticide exhibiting strong sorption to soil usually will have a lower runoff potential than a pesticide exhibiting weak sorption, but it can still reach surface water if sorbed to soil particulates eroding with the flow.

Data describing persistence and sorption are used to categorize pesticides and their major degradation products into one of nine categories. These nine categories qualitatively separate pesticides according to their relative potential to contaminate surface water—in terms of both magnitude and duration of occurrence expected. Pesticides also are distinguished according to their relative propensity to occur in the dissolving or sorption phase.

In evaluating surface runoff potential, pesticides are assigned to the nine categories based on their half-lives and sorptive K_{oc}. The following criteria apply:

- **Sorptive K_{oc}**

  1. Low sorption: K_{oc} less than or equal to 1000

  2. Intermediate sorption: K_{oc} greater than 1000 and equal to or less than 10,000

  3. High sorption: K_{oc} greater than 10,000

• **Persistence (Half-Life) in Soil**

1. Short: half-life equal to or less than 2 weeks

2. Intermediate: half-life greater than 2 weeks but less than or equal to 2 months

3. Long: half-life greater than 2 months

Thus, using the prescribed criteria, pesticides can be grouped into nine categories representing each possible combination of low, intermediate, and high sorption relative to short-term, intermediate, and long-term persistence (e.g., low sorption/short persistence; or high sorption/intermediate persistence).

Persistence grouping helps predict how long a pesticide will remain in the soil and, therefore, susceptible to runoff. Such considerations are important since some mitigation procedures effective in reducing soil erosion are not necessarily effective in reducing runoff volume, and vice versa. Sorption characteristics influence how much of a pesticide dissolves in water during runoff as opposed to how much is carried into rivers, streams, ponds, lakes, etc., where it remains sorbed to sediment.

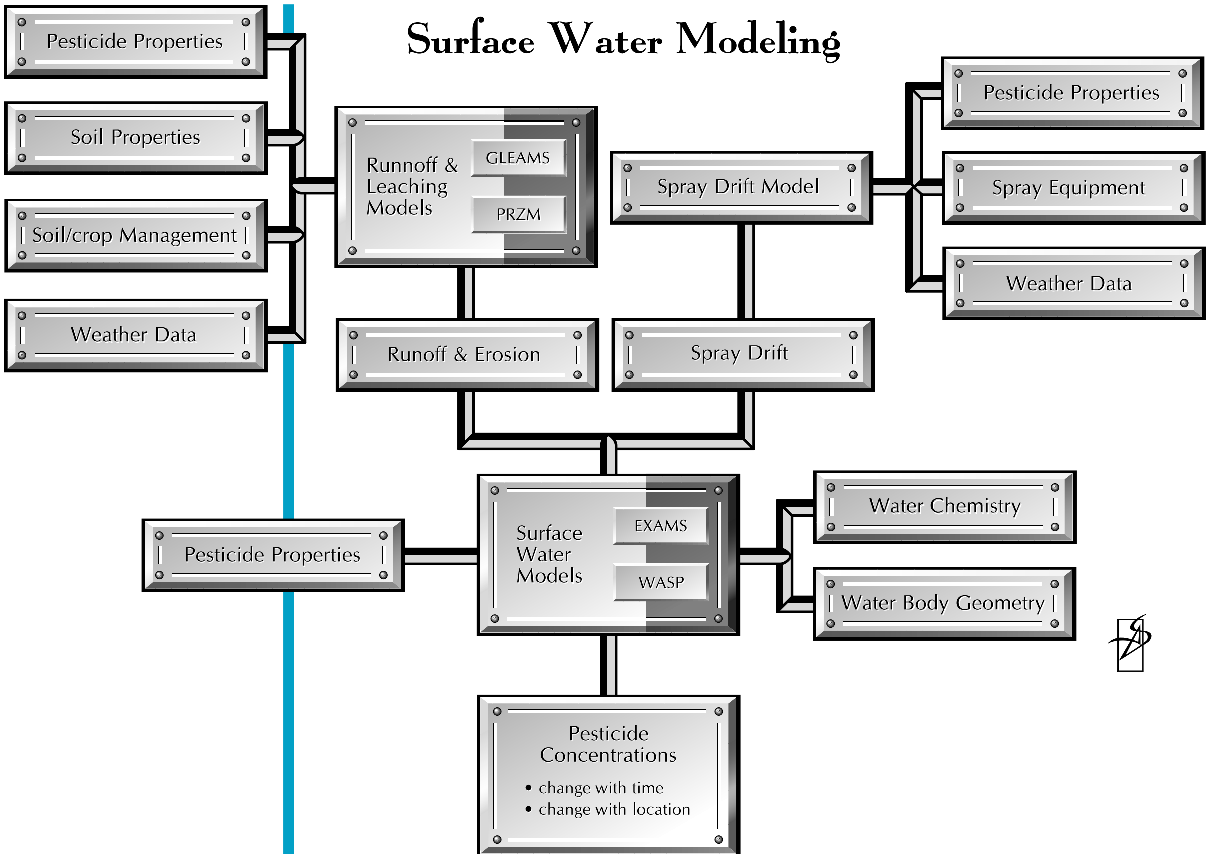
Assessment of Runoff Potential and Surface Water Contamination

The following methods may be used to assess the potential of a pesticide to enter surface water as runoff.

Surface Water Monitoring Studies and Database

EPA uses data on surface water concentrations of the widely used herbicides atrazine, cyanazine, simazine, alachlor, and metolochlor for risk assessments. For other pesticides, EPA must rely on partially validated computer modeling because data from monitoring studies are limited. In cases where risk to nontarget organisms is known or predicted to be high, EPA's Office of Pesticide Programs requires runoff and surface water studies to verify the effectiveness of mitigation in reducing amounts of pesticides reaching surface water through runoff.

EPA is developing a database for monitoring pesticide residues in surface water. It will consist of documented data which can be used in place of, or in conjunction with, modeling predictions to perform aquatic risk assessments. Data from the ongoing USGS National Water Quality Assessment Program, the multi-agency Environmental Monitoring and Analysis Program, state agencies, water supply systems, and pesticide registrants are used.



Computer Modeling

Environmental fate data can be used in computer models to predict pesticide contamination of surface water in more locations, over longer periods of time, and under more diverse conditions than are feasible from field use or monitoring studies. Runoff and surface water monitoring studies are subject to unpredictable weather factors, but computer modeling uses historical weather data gathered over long time spans and wide geographical areas.

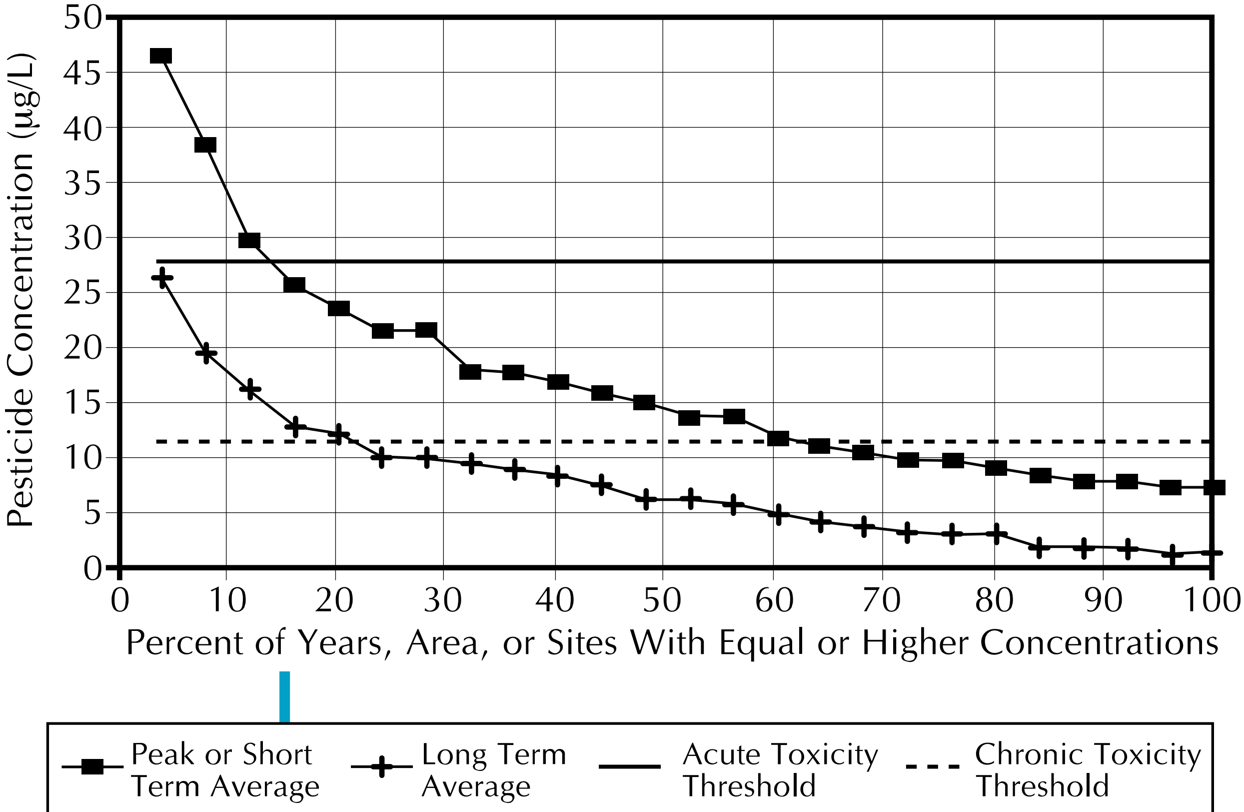
Models currently used for predicting the potential for pesticide runoff into surface water include PRZM and Ground Water Loading Effects of Agricultural Management Systems (GLEAMS). The input to both models includes pesticide fate properties, soil characteristics, management practices, and daily weather. Output from both models includes estimated runoff volumes, sediment yields, and associated pesticide concentrations at the edge of the field. Estimated pesticide runoff concentrations from PRZM or GLEAMS and estimated pesticide concentrations from spray drift are input to receiving surface water models such as the Exposure Analysis Modeling System (EXAMS) or the Water Quality Analysis Simulation Program (WASP). In addition to pesticide concentrations from runoff and spray drift, input to both EXAMS and WASP includes pesticide fate properties and receiving water characteristics. Output—described as a function of time and location—from both EXAMS and WASP includes estimated peak and varied duration average pesticide concentrations (1) present in water, (2) sorbed to suspended sediments, and (3) sorbed to bottom sediments.

Temporal and geographical distributions of pesticide concentrations based on computer estimates (or on adequate monitoring data) are used to predict where and how frequently maximum, short-term average, or long-term average concentrations will exceed acute or chronic toxicity thresholds for humans and other nontarget organisms. The temporal and/or geographical distributions of computer-estimated or measured concentrations generally are plotted as cumulative frequency curves. Such curves are created by plotting maximum, short-term average, or long-term average pesticide concentrations against the percentage of years or sites where equal or higher concentrations would be expected. Such approaches are useful because they allow scientists and regulators to better assess the likelihood of runoff and to predict when a pesticide might exceed a level of health or environmental concern.

The primary disadvantage of computer modeling is a general lack of controlled field monitoring data to validate the results. Validation with the appropriate data is needed to ensure accurate model estimates. Due to the conservative assumptions used and a knowledge of existing field and monitoring data, scientists at the Environmental Fate and Ground Water Branch of EPA are reasonably confident their modeling estimates of pesticide runoff and concentrations in surface water (using PRZM) are conservative—that is, higher than actual and therefore protective. Although some validation has been performed, additional work is needed, particularly with respect to pesticide fate modeling.

Generic Temporal and Spatial

Cumulative Exceedence Curves



Studies to Evaluate Runoff to Surface Water

Runoff studies are not routinely required under FIFRA. When available, the results of field and small scale runoff studies are used to assess the effectiveness of mitigation methods. Such results also are used to verify and to better quantify preliminary and modeling estimates of the runoff potential of pesticides and their major products of degradation.

Both field and small scale studies provide data on the amounts of water, soil, and pesticide transported in runoff from agricultural fields during and following rainfall. Small scale runoff studies are gradually gaining favor over large scale field studies because they are large enough to consider the effects of formulation, tillage, crop cover, soil type, and slope on the transport of water, soil, and pesticides from the field, yet small enough to allow the use of weather-independent rainfall simulators. Consequently, the problem of unpredictable weather patterns in field studies is eliminated. Small scale studies also are much cheaper to conduct than are field studies, so for the same cost more combinations of factors affecting runoff can be studied.

The major disadvantage of small scale studies is that the amount of water, soil, and pesticide transported by runoff from each unit area often is substantially higher than from agricultural fields. Some of this difference apparently is due to site-specific hydrological factors such as sediment deposition, ponding, and infiltration. Experimental conditions such as the use of high intensity artificial rainfall in small scale studies also may account for much of the effect in variable output.

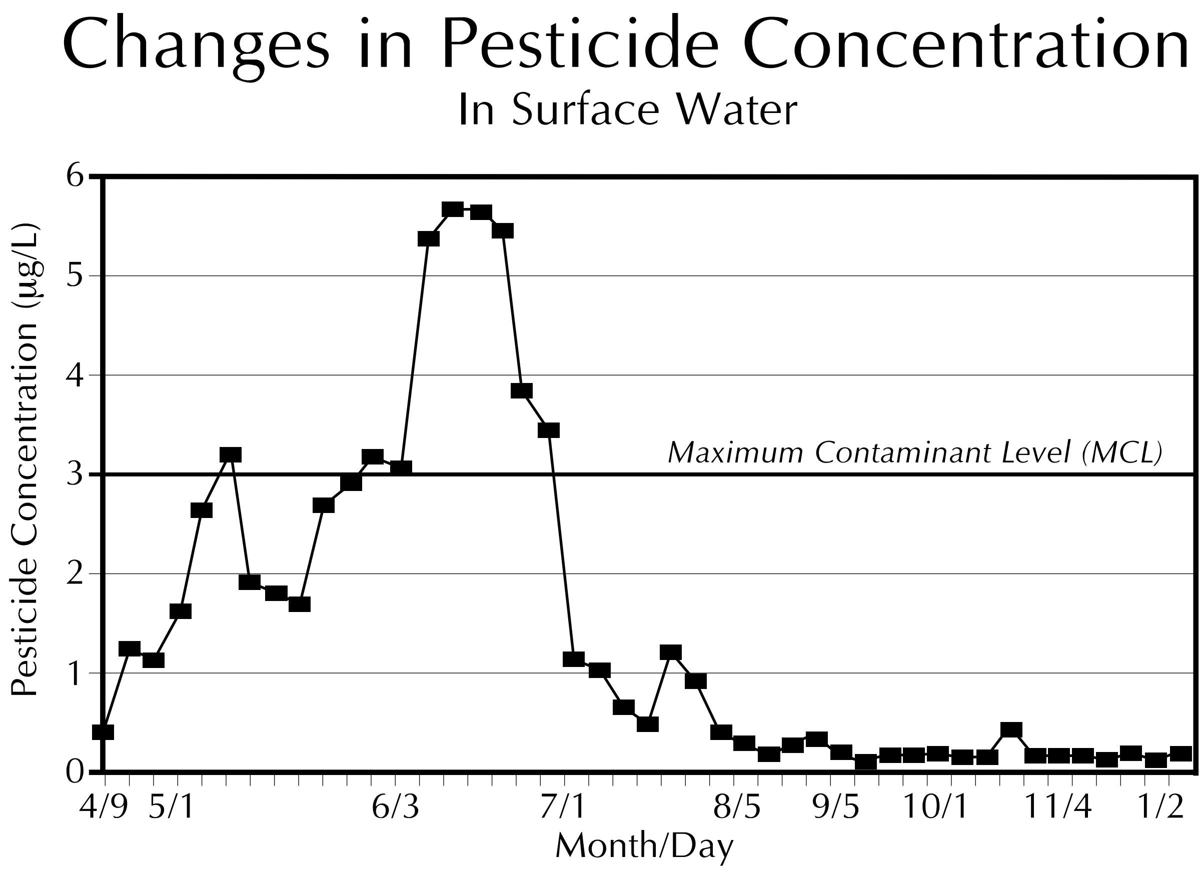
Surface Water Monitoring Studies

Surface water monitoring studies provide data on the concentration of pesticides in streams, rivers, lakes, and reservoirs. Pesticide concentrations in streams and rivers are highly seasonal, with peak concentrations occurring during the first few runoff-producing storms after application, followed by rapid decline. However, pesticide concentrations remain longer in lakes and reservoirs than in rivers and streams due to longer hydrological residence times.

Pesticide concentrations in samples collected infrequently, or in samples collected at set sampling times not coincident with significant runoff, often do not accurately reflect peak concentrations. Pesticide concentrations in samples collected from a single location can vary as much as tenfold from year to year. Consequently, surface water samples taken on only a few occasions, or over a short span of time, often do not adequately represent the source. The multitude of pesticide detection possibilities, the methods of differentiating between zero concentrations and parts per billion, and the necessity of precise, timely, repetitive sampling make surface water monitoring studies quite costly.

Spray Drift Studies

Spray drift studies and modeling also are used to estimate drift and the correlated deposition of pesticides into adjacent bodies of surface water and onto nontarget plants. The Spray Drift Task Force (SDTF), a coalition of 32 pesticide registrants formed to develop a comprehensive database of off-target drift information in support of pesticide registration requirements, has conducted spray drift studies and evaluated spray drift models. The results should afford EPA the ability to predict pesticide spray drift deposition into surface water based on distance from sites of application, and to predict the effectiveness of land buffers and application techniques in reducing pesticide spray drift to surface waters.



RISK ASSESSMENT OF PESTICIDES FOR WATER QUALITY CONCERNS

Human Risk Assessment

The Safe Drinking Water Act was implemented in 1974 to protect public water supplies from all types of contaminants. EPA's Office of Drinking Water evaluates, describes, and communicates health risks from contaminants in drinking water through Health Advisory Levels and Maximum Contaminant Levels.

Health Advisory Levels

A Health Advisory Level (HAL) is considered the maximum level of a drinking water contaminant, in milligrams per liter (parts per million, or ppm) or micrograms per liter (parts per billion, or ppb), that would not be expected to cause noncarcinogenic health risks over a given duration of exposure. This does not mean that levels above the HAL will necessarily pose health risks but, rather, that uncertainty warrants prevention of exposure above the HAL. However, HALs are nonenforceable standards.

Understanding the toxicological properties of a drinking water contaminant is necessary when calculating a health advisory. Toxicological profiles for pesticides generally are derived from animal tests because human testing is not possible. Data from human epidemiological studies can be used, but such data generally are unavailable. The Lowest Observed Adverse Effect Level (LOAEL) or No Observed Adverse Effect Level (NOAEL) are two important toxicological endpoints determined from animal tests.

The NOAEL is the maximum daily dose (of the chemical tested) per unit of body weight shown to produce no adverse health symptoms in test animals. The LOAEL is the lowest daily dose per unit of body weight confirmed to affect test animals adversely. In studies conducted for EPA, the NOAEL and LOAEL are obtained from experiments where test animals consume the pesticide through drinking water or as part of their dietary intake. The NOAEL and LOAEL represent daily doses expressed as milligrams (or micrograms) of a contaminant per kilogram of body weight: mg/kg (or µg/kg).

EPA standards for exposure differentiate between adults and children on the basis of body weight: 10 kilograms (22 pounds) for children; 75 kilograms (155 pounds) for adults. It is speculated that children might consume one liter (about a quart) of water daily, whereas an adult might drink two liters. Multiplication of the representative body weights by the NOAEL and LOAEL yields total daily doses on which to base the potential for acute and chronic adverse effects.

Since the NOAEL and LOAEL values are derived from animal testing, there is uncertainty as to whether humans might be more sensitive than test animals to the contaminant. To allow for that contingency, EPA applies ‘uncertainty factors’ which further reduce the acceptable dose for drinking water. Typically, NOAEL values for children and adults are divided by an uncertainty factor of 100 or more. If the Health Advisory is calculated from the LOAEL, an uncertainty factor of 1000 or more is used.

Thus, a HAL is based on toxicological evidence and conservative assumptions about the data. A HAL is calculated as follows:

$$\text{HAL (mg/L or } \mu\text{g/L)} = \frac{\text{(NOAEL or LOAEL) x body weight}}{\text{uncertainty factors x water consumption}}$$

Note that the HAL represents a concentration in water, which is very different from the actual dose consumed (i.e., the total mass of contaminant taken in by a person).

Duration of Exposure

HALs are derived for the following exposure periods: one day; ten days; longer-term; and lifetime. The one-day HAL is calculated for a child exposed to the drinking water contaminant for one day. The ten-day HAL provides information relative to a child drinking the contaminant for one to two weeks. The longer-term HAL is derived for both a child and an adult and assumes an exposure duration of seven years or ten percent of an individual's lifetime. A lifetime Health Advisory is derived for an adult and assumes that the individual will be exposed for a lifetime of 70 years.

Examples of Health Advisory Levels for a specific pesticide in drinking water are presented in the following table. The NOAEL and the LOAEL for this specific pesticide are 15 ppm and 150 ppm, respectively.

Exposure Duration	Population Segment	HAL (ppb)	Uncertainty Factor
1 day	child	100	100
10 days	child	100	100
7 years	child	50	100
7 years	adult	200	100
70 years	adult	3	1000

Maximum Contaminant Levels

The Safe Drinking Water Act (SDWA) directs EPA to protect human health by establishing Maximum Contaminant Levels (MCLs) for pesticides and other potential contaminants of drinking water. MCLs are *legally enforceable standards* which may not be exceeded. An MCL is the highest annual average concentration of a contaminant allowed in public water supplies. Like the lifetime HAL, the MCL is a calculated value based on the assumption that the average person weighs 70 kilograms, lives for 70 years, and drinks two quarts of contaminated water daily. Calculation of the MCL trigger value, however, also includes consideration of the costs, feasibility, and practicality of current technology to further reduce contaminant concentrations. MCLs may change as new technologies evolve, making the reduction of contaminant concentrations feasible.

MCLs for noncarcinogenic contaminants are calculated much like health advisories. The MCL is established at a level 100–1000 times lower than the lowest dose known to affect the most sensitive test animals; this ensures against the possibility that humans might prove more sensitive to the contaminant than are the animals tested.

For pesticides and other potential contaminants of drinking water that are carcinogenic, risk estimates are rated on the basis that exposure, at some level, will cause one additional cancer per 100,000 or 1,000,000 people over a lifetime of 70 years (by extrapolation of the results in animals studies where carcinogenicity was observed). For pesticides or other chemicals which are determined to be carcinogenic, MCLs must be set at the lowest level feasible.

Currently, public water utilities are required by SDWA to collect at least four samples per year from the finished water supply (tap water) for contamination analysis. If the *annual average* residue of a pesticide (as determined from the samples) exceeds the maximum contaminant level, consumer notification is required. Water utilities may have to use an alternative water supply, remove the contamination by filtration, or blend the supply with water from an uncontaminated source.

Ecological Risk Assessment

MCLs are designed to ensure that adverse human health effects do not accrue from pesticide use, but they do not address potential adverse effects on nontarget plants and animals; however, pesticide regulators are bound by legislative mandate to ensure that pesticide use does not cause adverse environmental effects. Various (plant and animal) organisms undergo a series of toxicity tests to determine what pesticide concentration levels might cause adverse effects. Some involve aquatic organisms such as fish or algae which might be exposed to pesticide residues entering streams and lakes as runoff from urban and/or rural sources.

Contact the Purdue University Cooperative Extension Service for a copy of the publication *Pesticides and Wildlife* (PPP-30) for additional information on ecological considerations.

Examples of Risk Assessments

Prevention of ground and surface water contamination is of primary concern where there is shown to be a potential for toxic effects on people, animals, and plants at concentrations which might realistically be expected to occur. See examples (page 45) of exposure and toxicity profiles for two herbicides with very different toxicological properties.

Both herbicide A and herbicide B (in the examples) tend to be more toxic to plants than to other organisms. Herbicide A is the more potent herbicide, affecting terrestrial plants at concentrations of only a few hundredths of a part per billion in irrigation water. Herbicide A residues might produce unforeseen ecosystem effects in some surface waters; thus, its use near endangered plants might be restricted.

Herbicide B is not as toxic as herbicide A but may affect certain sensitive plants exposed (through irrigation) to concentrations in surface or ground water. Herbicide B is somewhat more toxic than herbicide A to some animal species, including mammals; based on laboratory animal studies resulting in low MCLs, it is more likely (than herbicide A) to receive a restricted-use classification. Unless new data are generated and a substantial increase in the MCL is realized, herbicide B likely will receive a restricted-use classification— or cancellation—to prevent unacceptable levels in drinking water.

THE PESTICIDE LABEL

Each pesticide product is accompanied by a label bearing directions for appropriate use. The label also provides strict precautionary statements relative to the protection of human health, wildlife and its habitat, and water resources.

The intent of precautionary statements (normally found in the Environmental Hazards section of the pesticide label) is to protect ground and surface water quality for aquatic organisms and wildlife that use aquatic systems, and to prevent contamination of ground water.

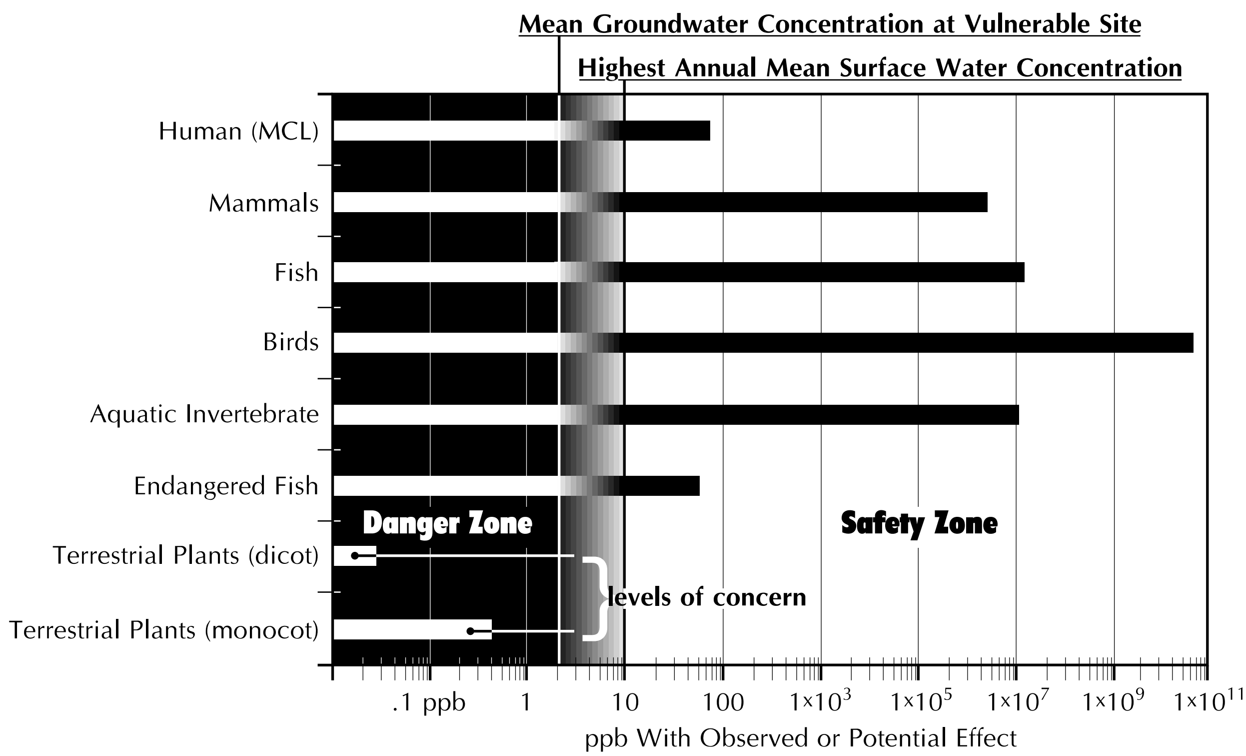
Contact the Purdue University Cooperative Extension Service for a copy of the publication *Pesticides and the Label* (PPP-24) which offers additional information on pesticide labels.

EPA-mandated instructions and precautionary statements are supported by the battery of toxicological and environmental tests required for pesticide registration. Pesticides intended for outdoor uses (other than aquatic uses) will always contain general precautionary statements. Labels on pesticides used to control weeds in aquatic environments—ponds, reservoirs, and other impoundments—contain precautionary statements relative to the use of the treated body of water.

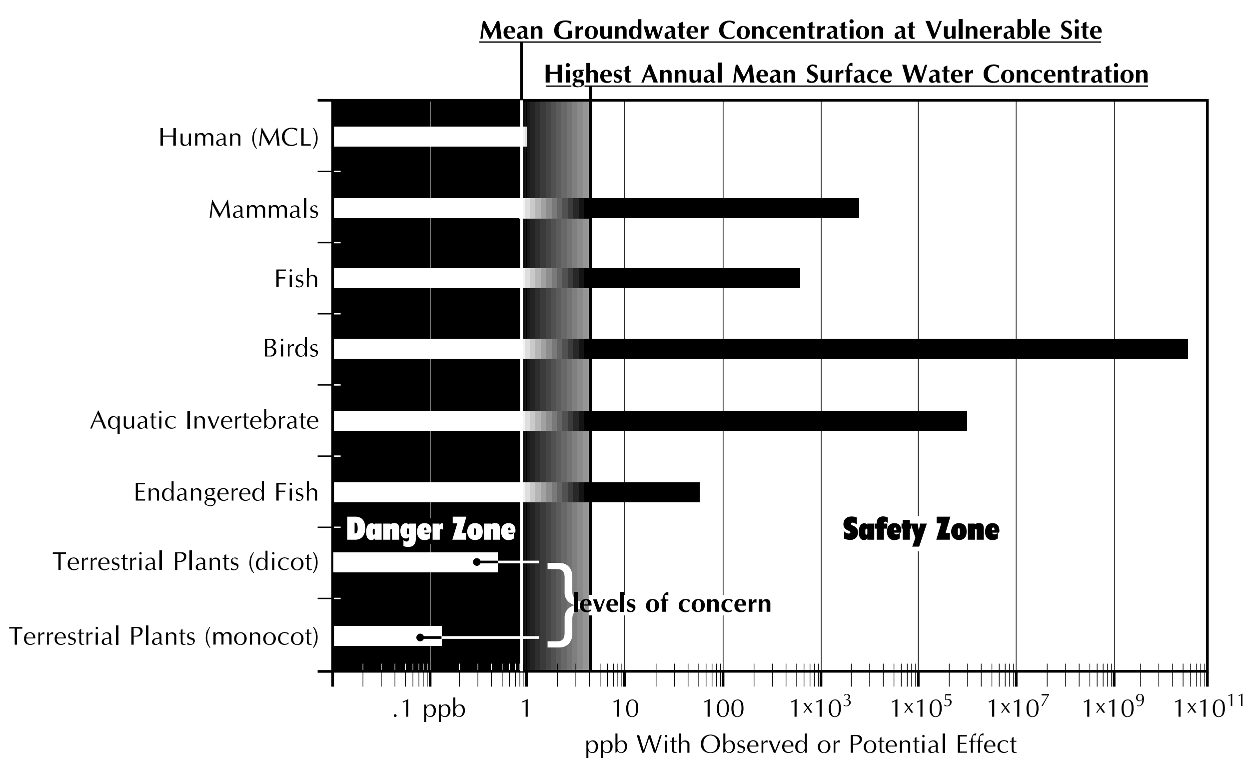
Protection of Surface Water

The Environmental Hazards section of the pesticide label may contain information concerning the impact of surface water contamination on wildlife. Example: ‘This pesticide is toxic to aquatic organisms.’ Such statements are based on the cumulative evaluation of

Exposure and Toxicity Profile Herbicide A



Exposure and Toxicity Profile Herbicide B



Examples of General Statements

'Do not apply directly to water or to areas where surface water is present, or to intertidal areas below the mean high water mark.'

'Do not contaminate water when disposing of equipment wash water or rinsate.'

Examples of Specific Statements

'Do not use fish from treated area for food or feed within 3 days of treatment.'

'Do not use water from treated area for watering livestock, for preparing agricultural sprays for food crops, for irrigation, or for domestic purposes for (a length of time is given based upon the rates applied).'

'Areas can be used for swimming twenty-four hours after treatment.'

laboratory toxicity studies and are required when 'trigger levels' have been exceeded. If the concentration in the environment is less than the level of concern, the statement is a reminder that use directions are to be followed to avoid serious consequences. If the environmental concentration exceeds the level of concern, specific label language may be mandated to prevent an even greater environmental risk.

Examples of Warning Statements Related to Toxicity

'Runoff and drift from treatment areas may be hazardous to aquatic organisms.'

'The pesticide is toxic to fish, aquatic invertebrates, and wildlife.'

'Drift and runoff may be hazardous to aquatic organisms in neighboring areas.'

'This pesticide is extremely toxic to fish and wildlife.'

Examples of Actions to Mitigate Entry into Surface Water

'Avoid over-watering since excessive watering may reduce performance and increase runoff.'

'Do not apply to turf sites that border lakes, ponds, or streams.'

'Do not apply to fairways.'

'Do not apply when weather conditions are likely to cause drift from treated area.'

'This product may not be applied aerially or by ground within 66 feet of the points where field surface water runoff enters perennial or intermittent streams and rivers.'

'If the product is applied to highly erodible land, the 66-foot buffer or set-back from runoff points must be planted to a crop or seeded with grass or other suitable crop.'

'Remove from premises or tightly cover fish tanks and disconnect aerator when applying indoors where such containers are present.'

'Keep out of lakes, streams, ponds, tidal marshes, and estuaries for waterfowl protection; do not apply immediately before or during irrigation or on fields in proximity to waterfowl nesting areas.'

'Do not apply where fish, shrimp, crabs, and other aquatic life are important resources.'

Protection of Ground Water

The Environmental Hazards section of the label may contain specific directions to prevent the occurrence of the pesticide in ground water. A product already on the market becomes subject to restrictions and advisories when it is detected in ground water. The restrictions are based on the chemical and physical properties of the compound (mobility, persistence, environmental fate) and levels of concern for human health, as well as plant and aquatic life. For instance, a new registration for a pesticide must include specific precautionary statements if the pesticide has been identified as a *potential* leacher.

Examples of Warning Statements Related to Environmental Fate

If it has been found in ground water: 'This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.'

If it has not been found in ground water but has leaching characteristics: 'This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.'

Examples of Actions to Mitigate Entry into Ground Water

'Care must be taken when using this product to prevent back-siphoning into wells, to prevent spills, and to dispose of excess pesticides, spray mixture, or rinsates appropriately.'

'Check valves or antisiphoning devices must be used on all mixing and or irrigation equipment.'

'Users are advised not to apply this product to sand and loamy soils where the water table (ground water) is near the surface and soils are permeable.'

'This product may not be mixed, loaded, or used within 50 feet of all wells, including abandoned wells, drainage wells, and sink holes.'

Restricted-Use Pesticides

Pesticides are classified for restricted use if they carry significant potential to harm people, wildlife, or the environment. Classification is based on how close estimated environmental concentrations are to levels of concern. When very near levels of concern, predicted environmental concentrations must be mitigated (as in the previous examples). Pesticides may be assigned a restricted-use classification limiting their purchase and use to certified and licensed pesticide applicators (or persons working under the direct supervision of a certified and licensed applicator).

Nearly two decades have elapsed since commercial pesticide applicators and farmers (private applicators) were first required to meet proficiency standards. EPA and state pesticide certification programs educate commercial and private applicators in the judicial use of pesticides, and applicators are continually updated on safe handling procedures. More than a million commercial and private pesticide applicators are certified and licensed, currently.

The pesticide certification process is enhanced by legal requirements for retail dealers who sell restricted-use pesticides. Dealers must meet recordkeeping requirements which include documentation of the purchaser's name, address, and current pesticide applicator license number; they also must record the name and amount of product sold. This recordkeeping system allows regulatory agencies to monitor the sale and use of restricted-use pesticides.

PUBLIC POLICY, PESTICIDES, AND WATER QUALITY

Changes in public expectations and new scientific knowledge mandate continual evaluation of pesticide use by local, state, and federal agencies. As a result, public debate surrounding the use of pesticides has driven frequent reassessment of their benefits to society versus risks attributable to their use. This shift in public policy decision relies on a framework of proposing, discussing, and drafting legislative mandates to ensure that pesticides' benefits to society outweigh their potential risks to human and environmental health.

During the 1950s, pesticide production escalated as companies began to commercialize their discoveries. The pesticide technology of the ’50s spurred federal and state governments to pass amendments to existing regulations to ensure adequate control of pesticides used in the United States. Early policies required USDA to register all pesticides and to establish standards for label content.

In the 1960s a number of issues developed, raising alarming and bothersome questions relative to environmental risks associated with pesticides. The views expressed in Rachel Carson’s *Silent Spring* in 1962 outraged, coalesced, and engaged the public. Government leaders subsequently made environmental issues a priority when assessing a pesticide for registration.

The creation of the United States Environmental Protection Agency in 1970 represented a dramatic change in the federal regulation of pesticides. Emphasis during the registration process shifted from a proposed product's *benefits* to the potential *risks* its use might pose to human and environmental health. Pesticide registration hinged on manufacturers' ability to meet stringent guidelines via increasingly comprehensive testing procedures; i.e., research data in support of specific health and environmental public policy objectives became crucial to the registration process. Pesticide labels became the conduit linking research data to user instructions designed to reduce the potential for adverse health and environmental effects.

As Americans have increasingly distanced themselves from their agricultural roots, they have become less tolerant of traditional arguments favoring the benefits of pesticides. Public concern has triggered stringent testing requirements in pursuit of product registration, and society's perception of the benefit-to-risk scenario plays a major role in determining the fate of pesticides—that is, whether or not they'll remain on the market. Legislators draft laws and regulations to reflect the desires of their constituents, and effective communication will be the key in educating the public in support of pesticide use.

Public Policy Establishes Water Quality Legislation

Public policy strategies for dealing with pesticides are decided by government. The process involves the prioritization of issues to be addressed, development of a plan, and implementation; as a unit, these steps comprise *reaction.* The speed with which government *reacts* to a pesticide issue may be influenced by local situations or by large-scale strategies orchestrated within the executive or legislative branch of the federal government. Changes may be instituted via legal decisions and interpretations rendered by courts of law. In essence, Congress passes laws (governing pesticides), and EPA establishes regulations and policies by which to enforce them. In turn, courts determine whether or not EPA enforces the intent of Congress—and the public drives the speed and direction of the overall *reaction*.

Federal and State Regulatory Responsibility

State and federal agencies are responsible for implementing and managing

- legislative statutes,
- executive branch policy decisions, and
- judicial interpretations

that deal with pesticides and their potential to impact water resources. Legislation sets goals and provides the framework which guides federal agencies in executing prescribed programs.

State and federal regulations require pesticide manufacturers, government agencies, and the general public to take certain actions relative to the manufacture, transportation, storage, application, and disposal of pesticides in order to meet statutory goals. Regulations may

- require that specific pesticides meet new registration standards,
- stipulate mandatory pesticide use education, and
- mandate environmental monitoring to determine any adverse effects on water resources.

SPECIAL INITIATIVES

Ground Water Protection Strategy. EPA continually seeks national cancellation of pesticides that pose a threat to water quality. Currently, EPA's efforts to prevent pesticides from reaching ground water include

- Predicting (on the basis of research data submitted by the manufacturer) a pesticide's potential to leach into ground water
- Establishing national label restrictions addressing concerns on leaching
- Requiring a restricted-use classification, triggering additional training requirements for users
- Providing each state the opportunity to develop and implement a State Management Plan for each pesticide identified as a potential leacher
- Cancelling pesticides known to contaminate ground water despite aversion efforts

The cornerstone to EPA's ground water protection policy is the State Management Plan (SMP), by which states can tailor their own strategies to prevent ground water contamination. The basic components of the SMP include philosophy and goals toward protecting ground water:

- Roles and responsibilities of state agencies
- Legal authority
- Resources
- Basis for assessment and planning
- Monitoring
- Prevention actions
- Response to detections of pesticides
- Enforcement mechanisms
- Public awareness and participation
- Information dissemination
- Records and reporting

Use of pesticides identified as risks to ground water are tightly controlled by EPA-approved SMPs:

- EPA determines the need for an SMP.
- EPA stipulates a time period for SMP development and approval, during which use of the pesticide may continue.
- Use of the pesticide is allowed only in accordance with the approved SMP.

Pesticide Reregistration

More than 50,000 pesticide products have been registered in the United States since FIFRA was enacted in 1947. Congress amended FIFRA in 1988 and mandated through legislative language that all pesticides registered before November 1984 would be subject to reregistration by EPA. The goal of the nine-year reregistration program was to ensure that all chemicals on the market have been fully evaluated. The amendment prescribed that each pesticide's chemistry, toxicology, and environmental effects be reexamined using current scientific, medical, and regulatory guidelines.

FIFRA amended 1988 made necessary the reevaluation of 1150 active ingredients in 45,000 formulated products. The active ingredients were assigned to 612 chemical cases (groups) of related pesticide active ingredients. The 612 chemical cases were subdivided into lists A, B, C, and D based on the ranking of various reference criteria such as the potential for adverse effects to food; drinking water; human health; plants and animals. EPA produces Reregistration Eligibility Documents (REDs) once a substantially complete set of data on a chemical case has been reviewed and no significant issues remain concerning use of the pesticide.

• 1150 active ingredients (45,000 formulations)

• 612 chemical cases (groups) subdivided into four lists (A,B,C,D) based on ranking of reference criteria:

- **potential for residues in/on food**
- **potential for drinking water contamination**
- **potential for adverse effects on human health**
- **potential for adverse effects on animals and plants**

EPA's Review After Pesticide Registration

The responsibilities of EPA and pesticide manufacturers do not end at the point of registration. Product information is continually collected, assembled, reviewed, and analyzed in cases where scientific studies and field use indicate a potential for adverse impacts on human health (such as long-term health effects and worker poisoning), environmental pollution (such as ground water contamination), and toxic effects on nontarget organisms (such as fish poisonings resulting from pesticide runoff).

Reporting Adverse Information After Registration

EPA can obtain information on the adverse impacts of pesticides via two reporting mechanisms:

• FIFRA section 6(a)(2) reporting

• Incident reporting

FIFRA states in Section 6(a)(2) that "if at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator." The 6(a)(2) reporting requirement is a legal obligation and applies solely to the registrant. Reports to EPA can originate from scientific research conducted by the manufacturer with the intention of supporting continued registration; but more often they result from data (on adverse effects) collected in field use situations. The pesticide manufacturer provides EPA information clearly identified as a 6(a)(2) report; in addition, the manufacturer must identify the newly observed adverse effect. Examples of incidents requiring 6(a)(2) reports:

• When pesticides impact aquatic organisms at a lower dose than previously shown

• When evidence from additional toxicological studies shows new types of potentially adverse effects

Incident reporting is used to measure the impact of a pesticide in the marketplace. Incident data can originate from many sources: universities, poison control centers, state and federal fish and game agencies, state departments of agriculture, EPA regional offices, or the news. Essentially, any adverse impact is subject to incident reporting.

All section 6(a)(2) and incident reports submitted to EPA are categorized and indexed on the Incident Data System—part of the Pesticide Information Network operated by EPA that is publicly available in the United States. Information concerning new, potentially adverse effects is submitted to the proper division for review and analysis to determine if an immediate EPA review is warranted. For instance, the Environmental Fate and Effects Division would examine potential impacts on wildlife, while human health concerns would be reviewed by the Health Effects Divisions within the Office of Pesticide Programs.

An EPA work group meets weekly to discuss FIFRA 6(a)(2) and incident reports. Priority is given to those pesticides with the most serious problem potential in order to expedite review, response, and remedial action. Those responsible for minimizing recurrent risk from the use of the product in question are monitored to ensure that appropriate measures are taken.

Special Review

The special review process allows EPA the regulatory flexibility to reevaluate the registration of a pesticide. A special review may be initiated when new evidence suggests that the legal use of a specific active ingredient may pose unreasonable risk to human health or the environment.

The process officially begins with an EPA letter of notification (called the Grasley-Allen letter) to the registrant, stating that the active ingredient is formally being placed under special review. The letter provides a brief summary of the reasons why.

Information pertinent to the suspected risk associated with the active ingredient is scrutinized by EPA reviewers who, in turn, prepare a 'risk review' for comparison with its projected benefits. The availability and efficacy of the pesticide, as well as the cost of alternative controls, are appraised in a benefit-to-risk analysis. Conclusions drawn from analysis are forwarded to the FIFRA Scientific Advisory Panel, to USDA, and to the general public (through the Federal Register) for comments on the scientific accuracy, data interpretation, and rationale behind proposed risk reduction measures. If after taking all comments under advisement EPA concludes that risk reduction measures are needed, there are four avenues of pursuit:

alteration of label language; classification of products containing the active ingredient for restricted use; elimination of specific uses; suspension or cancellation of the registration.

EPA’s Lower Risk Pesticide Policy

EPA has identified four areas for implementation of a voluntary reduced-risk pesticide initiative for pesticide manufacturers: developing criteria to identify lower-risk pesticides; streamlining the overall registration process; improving pesticide labels to effect well-informed choices in the marketplace; and encouraging (via statutory changes which would extend the period of exclusive use of data, or patent protection) the development of reduced-risk pesticides.

Under this voluntary approach, manufacturers of products containing a new active ingredient thought to be worthy of reduced-risk classification must submit substantiative data. Claims of reduced risk must be supported by evidence of reduced toxicity to humans and other nontarget organisms, and evidence of the environmental fate of the active ingredient must be substantiated. Incorporation of the pesticide into an integrated pest management program must be considered in comparison to alternative products. EPA will determine the sequence of application review according to these elements, as described.

EPA's intent is to promote pesticides that pose lower or reduced risks in comparison to alternative pesticides. Applications documenting lower-risk characteristics will be granted priority consideration, thereby gaining a distinct marketing advantage. In 1996, EPA will strengthen the reduced-risk initiative further by denying review of registration data for pesticides that fail the agency’s reduced-risk screen.

CONCLUSIONS

Protection of ground and surface water quality is critical to economic viability, as well as human health and environmental quality. Although pesticides are essential in the production of an adequate, economical food supply, rural (agricultural) as well as urban uses loom as possible sources of water contamination. Detection of pesticides in water aroused public interest in the environmental impact of agricultural chemicals; and the resulting heightened concern is reflected in strict legislation which impacts the pesticide industry significantly.

In the interest of minimizing risks associated with pesticides, significant public resources have been allocated for the development and implementation of rational, pesticide use policies based on solid scientific evidence. Compliance involves extensive, detailed, expensive laboratory research and field studies to determine the behavior and environmental fate of pesticides—that is, in deriving the *solid scientific evidence*—and it follows that manufacturers must commit significant financial resources to product development en route to the marketplace.

A pesticide's route and rate of entry into the environment, as well as its degradation characteristics, are key to understanding and predicting its potential impact on surface and ground water. Preregistration research data also play a significant role in determining use pattern and hazard statement language for the pesticide label. Research findings also influence the stringency of post-registration monitoring programs.

Technological breakthroughs that allow for pesticide detections at very low concentrations, combined with increased scrutiny of water resources by researchers and regulators, have increased scientific understanding of the potential for pesticides to contaminate water resources. The pesticide industry seeks to develop pesticides and pesticide management practices with the lowest possible potential for adverse environmental impact. The public interest is well served by a cooperative effort among regulators, university researchers, and industry to establish reasonable use restrictions. These efforts should ensure that, when used appropriately, pest control products will not pose a threat to water quality.

ACKNOWLEDGMENTS

Special thanks to Marty Risch, U.S. Geological Survey, for his constructive comments and ideas that aided the development of this publication.

Thanks also to R. David Jones, U.S. EPA, for the figure which appears on page 36; and to Ron Parker, R. David Jones, and Siros Mostaghimi, U.S. EPA, for the figure on page 38. Partial funding was provided by U.S. EPA, Region 5.

All complementary illustrations are the work of artist Stephen Adduci; his work is sincerely appreciated. The following individuals are acknowledged for their invaluable, thorough reviews of this document.

K. Balu, Ciba Crop Protection
Aldos Barefoot, DuPont Agricultural Products
Elizabeth Behl, U.S. EPA
Don de Blasio, U.S. EPA, Region 5
Kevin Costello, U.S. EPA
Harry Craven, U.S. EPA
Allan Felsot, Washington State University
Dick Green, University of Hawaii at Manoa
Sidney Harper, Tennessee Valley Authority
Paul Hendley, Zeneca
Scott Jackson, BASF
Henry Jacoby, U.S. EPA
William Koskinen, USDA, ARS
Dennis Laskowski, DowElanco
Terry Lavy, University of Arkansas
Mark Lenz, Bayer, Inc.
Jim Lin, Bayer, Inc.
George Oliver, DowElanco
P.S.C. Rao, University of Florida

REVIEWED: 5/01