3.7 Requirements for Registration of Aquatic Herbicides

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This section discusses the changes in pesticide regulation in the US over the past 50 years when the new US Environmental Protection Agency (EPA) developed an emphasis on evaluating the registration and use of pesticides based on research on human health and environmental concerns.

History of pesticide regulation

A pesticide is defined as any product that claims to control, kill or change the behavior of a pest. The United States first started regulating pesticides in 1910. The 1910 Federal Insecticide Act was intended to protect farmers from adulterated products and false labeling claims. With the continuous increase in pesticide development and use after World War II, Congress passed the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) in 1947. This act, which would be amended through the years, required that all pesticides be registered with the Department of Agriculture before they could be shipped in interstate commerce. The same federal agency responsible for agricultural production in the United States was now responsible for the regulation of pesticides on agricultural crops. FIFRA established procedures for the registration and labeling of pesticides but dealt mainly with the efficacy or effectiveness of pesticides and did not regulate pesticide use. Almost anyone could use a pesticide for any purpose and there was no legal recourse if a pesticide was not properly used. In addition, FIFRA did not allow for the denial of a pesticide registration request.

In 1962 Rachel Carson published “Silent Spring”, which drew widespread public attention to the indiscriminate use of pesticides with unknown human health and environmental effects. Many of the pesticides were persistent in the environment and were transferred from one animal to the next upon being eaten (a phenomenon known as bioaccumulation). As a result, some pesticides were ultimately ingested by humans and other nontarget animals, including wildlife. Very little was known at the time about the fate of pesticides in the environment and the potential effects of their residues on man and wildlife.

The Environmental Protection Agency (EPA) was created in 1970 and the responsibility for regulating pesticide use and labeling was transferred from the USDA to this new agency. This marked the beginning of a shift in the focus of federal policy from the control of pesticides for reasonably safe use in agricultural production to the control of pesticides for the reduction of unreasonable risks to man and the environment. In 1972 Congress passed the Federal Environmental Pesticide Control Act, which amended FIFRA and set up the basic American system of pesticide regulation to protect applicators, consumers and the environment that we have today. This Act gave the EPA greater authority over pesticide manufacturing, distribution, shipment, registration and use. EPA could now, among other things:

1) require additional data as necessary;
2) suspend or cancel the registration of existing pesticides;
3) prohibit the use of any registered pesticide in a manner inconsistent with label instructions;
4) require that pesticides be classified for specific uses;
5) deny a registration request;
6) provide penalties (fines and jail terms) for violations of FIFRA;
7) provide states with the authority to regulate the sale or use of any federally registered pesticides in that state as long as state rules were at least as strict as federal guidelines.

In 1988 Congress once again amended FIFRA by requiring the EPA to reregister all pesticides registered before November 1984 and to ensure that the database was current and in accordance with modern science. The development of the Food Quality Protection Act (FQPA) in 1996 amended both the FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). This Act set a single health-based standard for residues of pesticides in food and required the EPA to reevaluate all tolerances for pesticides and their inert ingredients.

Registration

Pesticide regulations are continuously under review and revision as scientific methods and knowledge increase. The following parts of this section will discuss pesticide registration and enforcement of pesticide laws, which are just a portion of the EPA's overall responsibility to protect the environment. It costs $30 to $60 million or more, and 8 to 10 years, to introduce a new pesticide to the market. Pesticides that are destined for use in aquatic systems in the US must be registered by the federal government through the EPA and by the state in which the pesticide will be used. The product may only be used in accordance with the label accepted by the EPA and any other applicable state regulations as long as the state regulations are at least as restrictive as the federal label. A pesticide may occasionally be registered by a state based on a special local need. In such circumstances, the active ingredient of the pesticide must be registered by the EPA and the appropriate tolerances in fish, shellfish and irrigated crops must be established by the EPA. This federal agency has overall responsibility for pesticide regulation even in states with small but locally important pest control needs.

The burden of proof to show that a pesticide will not cause unreasonable adverse effects on man and the environment rests with the registrant (the company that develops or labels the pesticide). The registrant is responsible for testing the active ingredient and the end use product (the final formulated product offered for sale) for potential harm to man and the environment. The EPA requires between 84 and 124 different studies to satisfy this requirement. These studies include toxicity and exposure tests on laboratory animals that measure the possible effects of the pesticide on human

health – to applicators and to the general public – through direct exposure and through residues in food. These studies also determine the fate of the pesticide once it is introduced into the environment and the effect of the pesticide on nontarget organisms. The EPA reviews these studies and determines the appropriate labeling for the use of each pesticide. Label precautions may include user safety information (protective clothing, reentry intervals or specific hazards), environmental safety warnings, container disposal and pesticide classification. In addition, all labels must provide appropriate directions for use (see "Pesticide Labeling" below).

The EPA regulates pesticide use from occupational (applicator/worker), residential and dietary standpoints and determines the potential effects of acute (immediate or short term), intermediate and chronic (long term) exposure to humans. If the use of a pesticide results in a residue of the pesticide in food or feed, it is necessary to establish a tolerance (maximum legal residue) level for that pesticide under the FFDCA. The EPA also evaluates residues in drinking water and must determine whether pesticide residue levels found in drinking water, fish, shellfish and any other food or feedstock meet the safety standard of the FQPA. In short, the EPA verifies that there is a reasonable certainty that no harm will result from the residues of the pesticide in food or feed. The FQPA is a risk-based statute and does not provide for the analysis of risks vs. benefits. Examples of some of the studies required before a product can be used as a pesticide are listed below. More detailed information is available at https://www.epa.gov/pesticide-registration/about-pesticide-registration.

Toxicity studies (how dangerous is the pesticide to humans?)

•Acute toxicity: study the immediate/short term effects of exposure to determine appropriate user precautions
•Sub-chronic toxicity: examine intermediate toxicological effects to identify the risks of less than lifetime exposure
•Chronic toxicity: evaluate long-term toxicity effects to determine possible problems associated with a lifetime of exposure
•Oncogenicity: determine whether the product causes cancer
•Developmental and reproductive toxicity: identify any effects on development and reproductive function

Chemistry studies (what is the pesticide?)

•Chemical identity, physical and chemical properties
•Disclosure of manufacturing process and all inert ingredients
•Determine chemicals of concern including the active pesticide and inert components
•Develop analytical methods for determining concentrations of the pesticide in plants, soil, water and food
•Determine the amount of pesticide left on plants, soil, water and food as a result of use

Environmental fate (what happens to the pesticide after it has been applied?)

•Hydrolysis: establish the significance of chemical breakdown in water
•Photolysis: determine the interaction of the pesticide under natural light
•Degradation: determine when the pesticide breaks down and what it breaks down to (metabolites) in water, soil and air
•Metabolism: examine the breakdown of the pesticide by organisms in the soil and water under both aerobic and anaerobic conditions
•Mobility and bioaccumulation: determine how the pesticide moves in the environment and whether it accumulates up the food chain
•Field dissipation: test and monitor how the pesticide and any major metabolites behave under realistic conditions

Ecological toxicity (how dangerous is the pesticide to fish, birds, mammals, invertebrates/pollinators, and plants?)

•Acute toxicity: study the immediate effects on wildlife
•Chronic dietary toxicity: examine the effects of a lifetime of exposure in birds
•Reproduction studies
•Toxicity to plants

Because the EPA relies on data submitted by the registrant, it carries out a laboratory audit program. This program sends EPA scientists and enforcement personnel to laboratories that conduct studies on pesticides. These personnel are responsible for reviewing the testing procedures to ensure that they are carried out in accordance with EPA regulations for conducting accurate laboratory studies. These conditions, known are Good Laboratory Practices, include strict guidelines on how studies are conducted and documented. In addition, the EPA requires that the registrant submit to them any data concerning adverse effects associated with the use or new testing of the chemical. These data are immediately reviewed by the EPA and any corrective action (label changes, use deletions or product cancellation) is taken as deemed necessary by the agency.

Tolerances

A tolerance is a residue level established by regulation which is considered a “safe level” of a pesticide and it is also an enforceable level. An “enforceable level” essentially means that when a pesticide is found in or on a food product and is either (1) not registered for use on that food product, or (2) present at a level higher than the tolerance established for that food crop, the food crop may be destroyed and investigations must be conducted to determine whether fines or other penalties are warranted. The tolerance is based on acute and chronic animal toxicity data. These data are multiplied by a 100-fold safety factor to determine an allowable residue level. The EPA does not set tolerances in drinking water as a result of pesticide use, but it does assess the safety of drinking water using the same safety standard for water as it does for food or feed before it will register the pesticide. Under the FFDCA as amended by the FQPA in 1996, a tolerance may only be established when the EPA determines that there is a reasonable certainty that no harm will result from the aggregate exposure (food, water and residential exposure) to the active ingredient and the inert ingredients in the pesticide.

Pesticides that are registered for use in a way that results in residues of the pesticide or its metabolites of concern in or on food or feed require the establishment of a tolerance under the FFDCA. Tolerances for pesticides are established under the FFDCA by the EPA. Food or feed contaminated with residues of pesticides or their metabolites of concern that do not have an established tolerance or have residues above the established tolerance level are considered adulterated and may be seized and destroyed by the Food and Drug Administration (FDA). While the EPA sets these pesticide tolerances, the FDA is responsible for enforcing them. Pesticides to be used in aquatic systems must have established tolerance levels of that pesticide and its metabolites of concern in fish, shellfish and any crops that would be irrigated with treated water.

Pesticide labeling

Pesticides are classified as either “general use”, which can be purchased and used by anyone, or “restricted use”, which may only be sold to and used by persons under the direct supervision of a certified applicator. A certified applicator must complete the appropriate federal or state training and testing. Pesticides can be used to control nuisance aquatic weeds without causing unreasonable adverse effects to man or the environment as long as label directions, precautions and warnings are followed.

The EPA regulates pesticides through pesticide labeling and determines the appropriate minimal label information required for the safe and effective use of the pesticide based on data submitted by the registrant. All labels must also include certain information; for example, all labels must carry several specific statements, including “Keep Out of Reach of Children” and a signal word (Caution, Warning or Danger). Directions for use – including application rates, number of applications allowed per season, user precautions, environmental precautions, container disposal instructions and other directions as determined by the EPA – are also required. In addition, every label must carry the statement “It is a violation of Federal law to use this product in a manner inconsistent with its labeling”. This means the pesticide can only be used in accordance with the label on the product container. The EPA stamps the label as accepted and this is the only label the registrant may place on its pesticide container before selling the product to the public. This label then becomes the principal communication between the registrant and the user. The directions for use, precautions and warnings tell the user how to use the pesticide and what precautions to take when the pesticide is used. Any changes to the labeling must be submitted to and approved by the EPA prior to marketing. For a full discussion on labeling requirements, please visit the EPA website on labeling at https://www.epa.gov/pesticide-registration/label-review-manual.

Review of registered pesticides

In 2008 the EPA completed its reregistration of all pesticides registered prior to November 1984 as required by the 1988 amendment to FIFRA. This effort took over 20 years as it required the reassessment of all products and their associated tolerances. In 2008 the EPA also initiated a Registration Review Program. This program, required by the 1996 amendments to FIFRA (FQPA), will review the registration of all registered pesticides on a continual 15-year cycle to ensure that pesticides remain in compliance with developing changes in science, public policy and pesticide use practices.

Good laboratory practices (GLP)

Working closely with the Office of Pesticides Programs, teams of investigators and scientists regularly conduct Good Laboratory Practices inspections at facilities that generate the scientific studies used in support of pesticide registrations. In addition, specific studies are randomly audited to verify adherence to identified protocols and procedures. Everything from the credentials of the researchers to the calibration of the equipment is thoroughly examined. The raw data are compared to the reported results to ensure accurate reporting. "For cause" audits of data are conducted when EPA scientists observe inconsistencies or irregularities in the studies submitted by the registrants.

FIFRA enforcement

General

Without enforcement, statutes and regulations are simply suggestions. A fair and vigorous enforcement program levels the playing field for the regulated community, removes any economic advantage of noncompliance (such as when using an unregistered pesticide on a site or crop not listed on the label) and exacts retribution as appropriate. As a result, enforcement is the exclamation point of the process that began with the registration of pesticides and the development of the labels and completes the mission of the EPA to provide a measure of consumer protection and to protect human health and the environment.

To ensure compliance with the requirements of FIFRA, federal agents and state inspectors monitor the marketplace and conduct inspections and investigations at establishments where pesticides are produced and distributed and at the facilities of commercial and private applicators where pesticides are stored. While all enforcement efforts are important, use-related inspections and investigations provide ongoing feedback to the EPA regarding the effectiveness of label requirements and accepted directions for use. This information, coupled with the requirement that registrants report all unanticipated adverse effects encountered as part of the distribution, sale and use of a pesticide, provides an impetus for additional data requirements. Mandatory label modifications may also be ordered depending on the nature of the data received.

Misuse

It is a violation of federal law for any person to use any registered pesticide in a manner inconsistent with label directions. The directions can cover all aspects of the pesticide's use, including transportation, storage, mixing, loading, application rates, target pests, use sites or crops, methods of application, personal and worker protection, environmental warnings, disposal and anything else necessary to protect human health or the environment. Federal and state inspectors conduct both routine facility inspections and "for cause" use investigations. Evidence of misuse (e.g., samples, photos, statements and records) may be used to prosecute violators in federal or state jurisdictions (or in both) depending on the circumstances of the case. Penalties can be substantial. For example, FIFRA provides for a $7,500 civil/administrative fine for each violation or count. In addition, criminal prosecutions are not unusual. While classified as misdemeanors, criminal offenses under FIFRA are considered serious environmental crimes and carry a maximum penalty of one year in jail per count plus substantial fines. Years ago, two unlicensed pest control operators in Mississippi were sentenced to 5.5 and 6.5 years in a federal penitentiary, respectively. Sentences of 2 to 3 years plus fines for the criminal misuse of pesticides are commonplace.

Product claims

As aquatic-related issues such as harmful algae blooms, unusual invasive species, and unusual environmental circumstances continue to appear, more and more creative responses to these issues arise that may require some sort of response by enforcement agencies. The EPA has tried to address some of these this in their Label Review Manual:

> For certain aquatic use products, claims to reduce sludge and unpleasant odors in water or to clean, clarify or deodorize ponds and lakes are not considered pesticidal claims; nor are claims regarding the reduction of nutrients and organic matter in water, **provided no claim is directly made or implied that the reductions will result in reduced pest populations** [emphasis added]. The claims "Reduces critical nutrients for cleaner, clearer ponds", "Ponds with algae need to reduce nutrients", and "Bacterial Product to Control Excess Nutrients for Clear, Clean Ponds" **imply pesticidal use and therefore require registration** [emphasis added].

Slime and odor control agents and other products expressly claiming control of microorganisms of economic or aesthetic significance are not considered to be public health-related but should bear accurate pesticide labeling claims. Registrants are still responsible for ensuring that these products perform as intended by developing efficacy data, which must be kept on file by the registrant.

EPA's policy does not permit the use of the terms "natural", or "naturally" in the labeling of any registered product, including biopesticide products, both microbials and biochemicals. These terms cannot be well defined and may possibly be misconstrued by consumers as a safety claim.

Aquatic dyes intended to reduce UV light or to otherwise reduce or control aquatic plants, algae or cyanobacteria are considered to be pesticides and must be registered with the EPA prior to distribution and sale.

Pesticide devices

Another area of increasing concern for EPA and state enforcement offices involves pesticide devices. In general, if an article is an instrument or contrivance that uses physical or mechanical means to trap, destroy, repel, or mitigate any plant or animal life, it is considered to be a device and is subject to regulation under FIFRA. Devices are not subject to the registration requirements that apply to pesticides under FIFRA section 3. Pesticide devices must, however, be produced in a registered pesticide-producing establishment and that number must appear on the labeling of all pesticide devices.

EPA has identified many types of devices that are subject to FIFRA jurisdiction. Some aquatic-related devices include (but are not limited to) certain ultraviolet light systems, ozone generators, water filters and ultrasonic devices for

which claims are made to kill, inactivate, entrap, or suppress the growth of pests in various sites. Aerators, nano-bubblers, water circulators and similar products which are marketed with claims to control algae, cyanobacteria or aquatic life in general, would all be considered to be pesticide devices. It has also been noted recently that devices utilizing fire, steam and lasers along with skimmers, vacuums, and the like – all claiming to manage or control aquatic pests – are making a comeback. They are still regulated as pesticide devices under FIFRA.

Harvesters and cookie cutters and similar devices are not regulated by the EPA even though they clearly are devices intended to manage aquatic plants. These types of devices fall under an exemption from regulation because the effectiveness of the device depends more on the performance of the operator than the performance of the devices itself. A flyswatter is another good example of a pesticide device exempt from regulation because its efficacy depends on the skill of the user and not the device itself.

The EPA also regulates the labeling of pesticide devices to some degree. In brief, the device is considered to be misbranded and subject to prosecution if the labeling fails to comply with the following requirements and others not listed here:

> The labeling bears any statements, designs, or graphic representations that are false or misleading;
> The label fails to bear the establishment number of the establishment where it was produced;
> It lacks adequate directions for use; or
> It lacks an adequate warning or caution statement.

While, as stated above, no registration of the device is required by the EPA, a manufacturer is barred from making any false or misleading claims for the device. In practice, that means, should the EPA ask for it, the manufacture must be able to satisfactorily prove with scientific evidence that their product does what it claims.

Use of unregistered pesticides for commercial purposes

As indicated above, products that directly or imply claims to reduce, control or manage plants, algae or cyanobacteria populations when used are thus considered to be pesticides. And “The claims ‘Reduces critical nutrients for cleaner, clearer ponds’, ‘Ponds with algae need to reduce nutrients’, and ‘Bacterial Product to Control Excess Nutrients for Clear, Clean Ponds’ imply pesticidal use and therefore require registration”. More and more often these days, companies or individuals will use a product known to reduce nutrients and either directly or by implications as described above, make claims to customers that the treatment will control a pest such as algae or cyanobacteria. Frequently such claims are associated with alum treatments, although there are other products used as well. The original manufacturer usually is not making claims. Rather, the user is the entity implying or actually claiming pesticide activity.

FIFRA Compliance Policy No. 3.5 states, in part:

> The Agency considers any application of an unregistered pesticide for other than personal use to be distribution or sale of an unregistered pesticide, a violation under Section 12(a)(1)(A) of FIFRA. This includes applying an unregistered pesticide to another person’s property for other than monetary consideration. Furthermore, a person applying an unregistered pesticide for hire, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, would be considered a distributor and is therefore subject to the higher penalties set forth in section 14(a)(1) and 14(b)(1) of FIFRA.

The use of alum, lanthanum and other nutrient reducers, flocculants, etc., absent any additional claim, is perfectly legal and constitutes a viable option for water management. Once an expressed or implied claim to reduce, control or manage an aquatic organism has been made in association with the application, the applicator/operator is in clear violation of FIFRA. In addition, because the application of the unregistered pesticide is to, over, or near either waters of the U.S. or waters of the State, the provisions of the Clean Water Act are also triggered and compliance with that statute is also required.

Summary

The US Environmental Protection Agency was formed in 1970 and became responsible for regulating the rapidly expanding development and use of pesticides. During the course of the next 20 years, the use of some pesticides was cancelled, and testing requirements were developed to study the effects of pesticides on human health and the environment. These requirements are regularly revised to include the most recent developments in science. EPA toxicologists, chemists and biologists review proposed pesticide labels and revise label instructions as needed to ensure that human health and environmental safety will not be compromised. States may also register or approve pesticide labels for use in their jurisdictions and are allowed to add additional restrictions or requirements to the pesticide label. State guidelines cannot be less restrictive than those outlined on the federally approved label. The EPA and state regulatory agencies enforce pesticide laws regarding the purchase, use and disposal of pesticides. Pesticide labels are developed after years of research and include specific information about the pesticide and its use. The label is a legal document and all directions must be followed by those who use the product.

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