



Scope of PathShield™ Pesticide Registration with U.S. Environmental Protection Agency

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OVERVIEW

In 1996, Congress unanimously passed the Food Quality Protection Act (FQPA) that amended the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)¹, both of which fundamentally changed the way the U.S. Environmental Protection Agency (EPA) regulates pesticides. The FQPA and amended FIFRA now provide a protective regulatory scheme for pesticide regulation grounded in science and places the burden of proof of safety on product registrants. This report provides a concise resource to better understand essential elements associated with FIFRA and EPA pesticide regulation. More specifically, A S Filtration™ has successfully addressed all of the product chemistry, toxicity, environmental fate and ecotoxicity data requirements of FIFRA in order to offer PathShield™ Antimicrobial Filter Media. PathShield™ is an “antimicrobial pesticide” product registered by EPA in full compliance with FIFRA requirements for its intended uses. PathShield™ media provides for the reduction and control of coliform bacteria in stormwater, industrial waste, and municipal waste water applications. Refer to ASF Tech Reports 13.1, 13.2 and 13.3 for additional information about PathShield™ treatment

applications and performance capabilities as supported by both independent laboratory testing and field demonstrations.

In broad terms, the expansive body of pesticide law in this country is a product of the ongoing effort to strike an appropriate balance between the many benefits derived from the use of pesticides and mitigation of any corresponding potential hazards to human health and the environment.² FIFRA controls the manufacture, sale and use of a broad range of chemical and biological pest controls. State, tribal, and local regulations also govern pesticide products. The burden of satisfactorily addressing all FIFRA data requirements are borne by pesticide manufacturers and formulators since they are a practical point of control and enforcement.

DEFINITION OF PESTICIDE

“Pesticide” is defined under section 2(u) of FIFRA as “(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, [and] (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant...” A “pest” is defined as: “(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the [EPA] Administrator declares to be a pest...” Thus, FIFRA defines pesticide in terms of the inherent intent underlying the use of a substance as opposed to the inherent characteristics of a substance.

EPA has adopted regulations providing that a pesticide is “any substance (or mixture of substances) intended for a pesticidal purpose.”^{2,3} Three factors to be addressed in determining whether a substance is intended for pesticidal purposes are:

1. Whether the person who distributes or sells the substance claims that it has a pesticidal

purpose or use or contains an active ingredient that can be used to manufacture a pesticide,

2. Whether the substance contains an active ingredient and has no commercial value other than for the pesticidal purpose, and
3. Whether the person who distributes or sells the substance has actual or constructive knowledge that the substance will be used or is intended for pesticidal purposes.

DEFINITION OF DEVICE

Congress authorized EPA to designate devices that shall be subject to provisions of FIFRA §§ 2(q)(1) (labeling requirements) and 7 (establishment registration).² Devices are also subject to, but are not limited to, FIFRA Sections 8 (books and records), 9 (inspection of establishments), 12 (violations), 13 (enforcement), 14 (penalties), and 17 (imports and exports).

FIFRA §2(h) defines “device” as: “any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.”⁴

PESTICIDE REGULATION FEATURES

The major features of pesticide regulation include, but are not limited to, the following:

- **Pesticide Labeling.** All pesticides must bear an EPA-approved label that describes the pesticide’s active ingredient, hazards it poses, and its proper use, storage, and disposal.
- **Pesticide Registration.** With limited exceptions, no one may sell or distribute a pesticide product in the U.S. unless it has been registered both with EPA and the states

in which it is commercialized. FIFRA gives EPA great leverage over all aspects of pesticide experimental use, manufacture, distribution, labeling, product claims, and use.

- **Regulation of Use.** Using a pesticide in a manner not described on the label is illegal.
- **Recordkeeping and Reporting.** After EPA registers a pesticide, any new information learned by the registrant concerning unreasonable adverse effects on the environment from the pesticide must be reported.
- **Enforcement and Other Authorities.** FIFRA and state regulations provide for civil penalties, administrative actions, and criminal penalties to enforce its provisions.
- **Import and Export Requirements.** FIFRA includes special requirements applicable to import and export of pesticides and devices.⁴

REGISTRATION STANDARDS

FIFRA provides that EPA shall register a pesticide if it determines that it works as claimed, the materials submitted with the registration application, including the labeling, comply with FIFRA requirements; and, expected use of the product will not cause unreasonable environmental harm.

EPA Pesticide Registration (PR) Notice 2000-1 (March 6, 2000) cites examples of types of claims for a treated article that would lead to a requirement to register the article as a pesticide product such as, but not limited to, the following:

- Antibacterial,
- Bactericidal,
- Germicidal,
- Kills pathogenic bacteria,
- Effective against *E. coli* and *Staphylococcus*,
- Provides a germ-resistant or bacteria-resistant surface,
- Surface kills or controls common, or both, gram positive and negative bacteria.

LABELING

EPA's labeling requirements are the fulcrum on which FIFRA turns. All registered pesticide products must bear an EPA-accepted label, which is both distinctive and highly prescribed. EPA "Stamped-Accepted" labels are the formal documentation of EPA's intense data review and a pesticide product's approval for commercialization in the U.S. The resultant labels comply with a strict format and include required statements used by EPA to both enforce safety standards and efficacy claims and to communicate risks and proper use. No substantive change can be made to a pesticide product label or labeling (e.g., advertisement claims, technical bulletins, etc.) without formal review and approval by the EPA. The distinctive pesticide product label is proof to the user that the product and its label uses and claims have been thoroughly reviewed by EPA and determined to be safe if used as directed and in full compliance with FIFRA. It is a direct violation of the statute to distribute any pesticide, registered or not, without a label that includes an ingredients statement, directions for safe use and handling, information about the manufacturer, and other basic information.

PESTICIDE CATEGORIES

The 1996 amendments to FIFRA define three pesticide categories including (a) minor use pesticides, (b) antimicrobial pesticides⁵ and (c) public health pesticides.⁶ PathShield™, being classified as an antimicrobial pesticide, is meant either to affect the growth or development of microbiological organisms or to protect inanimate objects, industrial processes, or chemical substances from contamination by such organisms. FIFRA does allow for substances to be excluded from the regulatory scheme for one of two reasons: they are not within the definition of pesticide or they are otherwise specifically exempted from the registration program. Given that PathShield™ holds EPA pesticide registration confirms that the product

is intended for pesticidal uses and is not exempt from FIFRA registration.

PUBLIC HEALTH CLAIMS

Public health claims for a pesticide cannot be made if the product's EPA-accepted label does not identify the product as a "public health pesticide." A public health pesticide means that the product is registered for use; and, is used predominantly in public health programs for vector control or for other recognized health protection uses including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria or other microorganisms on or in living man or other living animal) that pose a threat to public health.

In recent years the marketplace has experienced a proliferation of products that are treated with pesticides and bear implied or explicit public health claims for protection against bacteria, fungi and viruses, as well as specific claims against pathogenic organisms. The above-cited EPA Pesticide Registration (PR) Notice 2000-1 addresses widely used claims and references to microorganisms harmful to humans with products providing public health protection. EPA considers an article or substance to make a public health claim if any of a number of claims, whether made either explicitly or implicitly cite, but not limited to, the following:

- A claim for control of specific or classes of microorganisms that are directly infectious or pathogenic to man and/or animals that can include *E. coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and others.
- An unqualified claim of "antimicrobial" activity.
- A claim of "antibacterial," "bactericidal," or "germicidal" activity or references in any context implying public health related protection.

- A claim for the product as a sterilant, disinfectant, virucide or sanitizer regardless of the site of use and whether specific microorganisms are identified.
- A non-specific claim that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.

STATE REGISTRATIONS

All states (including tribal and territory governments and the District of Columbia) require pesticide registration for almost all (i.e., there are a few exceptions for “minimum risk pesticides”) pesticide products sold or distributed within their respective jurisdictions. Most of the state registration approvals and annual renewals rely solely on the EPA registration review process and resultant EPA stamped-accepted label. State registration application processes can include registrations for new active ingredients, significant new uses, Restricted Use Pesticide (RUP), Experimental Use Permits (EUPs), Special Local Needs (SLNs) and Emergency Exemptions (EEs) when an off label or unique use of a FIFRA registered product is needed. Unless specifically stated otherwise, all FIFRA rules pertaining to labeling, enforcement, intended uses, classification (e.g., RUP, EUP, SLN, EE), etc. apply to state registrations as well.

Antimicrobial treatment of stormwater runoff at site-specific locations may require the use an SLN permit in addition to the state’s general permit. The SLN permit application process can vary between states but typically requires state collaboration with EPA to expedite the SLN permit review process.

CONCLUSIONS

The central feature of FIFRA is its requirement that pesticides be Federally registered with EPA. EPA grants registrations only after comprehensive review of data on the pesticide while seeking to protect public health and the environment. With the exception of devices and a short list of minimum

risk active ingredient-based products, FIFRA prohibits any sale or distribution of an unregistered pesticide product. All registered pesticides must have EPA-accepted labels. All jurisdictions in the United States (as well as most other countries) require pesticide registration following a specific registration application procedure before a product can be sold or distributed in that jurisdiction. Exceptional circumstances at a local level may be grounds for special local need or emergency exemption permits to allow a unique use of a registered pesticide product.

PathShield™ Antimicrobial Filter Media holds EPA registration and an accepted label in accordance with FIFRA. Significant operational and environmental benefits can be realized through the use of PathShield™ filter media including:

- Media does not discharge, release or leach any antimicrobial agents
- Long term and high level of performance
- Does not rely on physical trapping
- No external power source or moving parts
- Media is non-corrosive and is not consumed
- Unaffected by seasonal temperature changes

REFERENCES

1. 7 U.S.C. §§136-136y.
2. Brown, E.C., et. al., 2001, Pesticide Regulation Handbook, The Environmental Law Reporter, Environmental Law Institute and Latham & Watkins, Washington, D.C., ISBN 1-58576-013-7.
3. 40 C.F.R. §152.15.
4. 7 U.S.C. §136(h).
5. 7 U.S.C. §136(mm).
6. 7 U.S.C. §136(nn).

To learn more about PathShield™, please contact A S Filtration™ at (888) 344-9044 or visit our website www.asfiltermedia.com.