

September 30, 2022

Edward Messina
Director
EPA's Office of Pesticide Programs
William J. Clinton Bldg.
1200 Pennsylvania Ave, NW
Washington DC, 20460

RE: Modernizing FIFRA Compliance for Water Filtration Systems

Dear Director Messina,

On behalf of the Water Quality Association (WQA), International Association of Plumbing and Mechanical Officials (IAPMO), and more than 30 Coalition Partners, we would like to discuss an effort to modernize the enforcement of regulations pertaining to certain water filtration systems under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). We respectfully request a meeting to further review the EPA's interpretation of the statute and discuss a proposal for creating an alternative compliance pathway for manufacturers to adhere to this regulation.

Since 1976, the EPA Office of Pesticide, under FIFRA, has treated water filtration systems that inhibit bacteria, viruses, and other microorganisms in drinking water as pesticides and pesticidal devices. Although the EPA has good intentions, the agency's ambiguity, and inconsistent enforcement of FIFRA on water filtration systems in recent years have caused significant delays and detrimental impacts on the water filtration industry. Ultimately, this has a cascading effect on consumers, safety, and the economy. Additionally, EPA has continued to require manufacturers to comply with rigorous mandates including labeling, registration, and other requirements that often have little bearing on human health and environmental safety. This can be costly, time-consuming, and with little guidance from EPA, confusing. In response to these concerns, a coalition came together to review the regulation with the purpose of crafting a revised compliance pathway that better aligns with the original intent of FIFRA to protect human health and the environment.

When the agency first began to regulate water filtration systems as pesticides and pesticidal devices, third-party certification standards did not exist. Over the last half-century, national consensus-based standards, such as those developed by ANSI process, have far surpassed the scope of what the EPA requires and are at the forefront of meeting emerging water quality issues. These standards already cover performance in addition to having strict requirements for material safety, structural integrity, and literature. The coalition recommends that EPA consider modernizing its interpretation of the regulation to instead rely on third-party certification since the current enforcement guidelines can prevent the deployment and increase costs of water filtration systems that are being used to protect Americans, including many from disadvantaged and underserved communities, from a host of new, and emerging threats impacting drinking

water quality (e.g., Lead, PFOA/PFOS, legionella, disinfection by-products (DBPs), chromium-6, etc.).

Proposal for Compliance: Considering advancements made over the last 45 years, WQA, IAPMO, and our Coalition Partners propose that water treatment devices would comply with FIFRA if they meet the requirements of an alternative path of compliance which consists of these devices being independently certified to meet national standards associated with the claims being made for performance. These national standards, such as those created through the ANSI consensus-based process, have been developed with the participation of all interested and affected stakeholders. This includes manufacturers, non-profits, advocacy organizations, representatives of government (such as the EPA), and academia. These national standards are regularly updated to address emerging threats and to incorporate the latest science. This alternative path of compliance would also require the certification of such products by an independent Certifying Body (CB) accredited to ISO/IEC 17065 by a signatory to the International Accreditation Forum Multilateral Recognition Arrangement (IAF MLA) such as the American National Accreditation Board (ANAB). Compliance with FIFRA under the current EPA regime would still be an option for products that have not obtained certification to national standards.

This proposal addresses specific residential drinking water filters that fall under the term “pesticidal devices”¹ and water treatment devices that contain a bacteriostat to protect the device itself:

Pesticidal Devices: Applicable standards would include ANSI standards (e.g., NSF/ANSI 53, 55, 58, 62, 244), other consensus-based standards as determined by the EPA Administrator, and the U.S. EPA Purifier Guide Standard² that covers performance for the anti-microbial claims provided the device was also certified to a consensus standard that covers material safety, structural integrity, and literature. Devices certified to NSF P231 would technically meet these requirements by default, even though it’s not a consensus standard, since it is a combination of the U.S. EPA Purifier Guide Standard and the NSF/ANSI standards referenced above.

Pesticides: Currently under FIFRA, bacteriostatic agents that are used to protect the product itself from fouling are considered exempt under treated articles. However, that has not been consistently applied by regulators in the field. The exemption is described under FIFRA as *an article or substance treated with or containing a pesticide to protect the article itself*. It is worth noting that, any bacteriostatic agents which are used to protect the product itself from fouling (such as silver-impregnated carbon, media, and copper-zinc media.) are evaluated for material safety under the existing standards listed above. This would include products that make a bacteriostatic claim under NSF/ANSI 42. Any product which makes anti-microbial claims for protection of the end user based on

¹ As defined in FIFRA Section 2(h) (CFR 152.5000)


² *Guide Standard and Protocol for Testing Microbiological Water Purifiers*, U.S. Environmental Protection Agency, 1987.

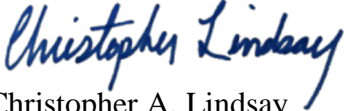
an active anti-microbial agent would not fall under this exemption and would still require FIFRA registration.

In summary, to more effectively protect consumers, increase safety, and remove regulatory burdens, the Coalition recommends an alternative compliance pathway under FIFRA for drinking water filtration systems if they meet national standards that require nationally recognized third-party testing and certification requirements for the claims being made. This alternate compliance pathway is similarly used to protect water quality in plumbing components in model plumbing codes, as well as in EPA's enforcement of water-related products (e.g., the WaterSense program and rule on lead-free plumbing components). Making this change to FIFRA registration requirements for water filtration systems would remove an unnecessary burden on manufacturers, importers, and the EPA.

We applaud the EPA and its efforts to ensure the health and safety of Americans and we hope to work with you to modernize the enforcement of FIFRA as it pertains to water filtration systems. Additionally, enclosed with this letter is a technical analysis that provides additional information on current FIFRA requirements vs. third-party certification. Thank you in advance for your consideration of this proposal, and we request the opportunity to meet with you to discuss these recommendations in greater detail.

Sincerely,


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Technical Analysis

FIFRA Requirements vs. Certification to National Standards

The overall aim of certifying products, processes, or services is to give confidence to all interested parties that a product, process, or service fulfills specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfillment of specified requirements by a third party. Parties that have an interest in certification include, but are not limited to:

- consumers who rely on products to meet safety and efficiency standards;
- water treatment technology manufacturers;
- government regulators;
- water authorities; and
- non-governmental organizations.

Certification of products, processes, or services is a means of providing assurance that they comply with specified requirements in standards and other normative documents. In the case of residential drinking water filters, an accredited Certification Body (CB) has developed certification schemes that include initial product testing, initial factory inspection, and compliance with the applicable health and safety product standards, including marking and labeling requirements. CBs also require annual surveillance inspections that take into account the quality management system, retesting requirements and frequency, modifications to certified products, and revisions to product standards.

Table 1: Analysis of FIFRA Requirements vs. National Standards

The table outlines the comparison of FIFRA requirements for pesticidal devices to third-party testing and certification to NSF/ANSI-accredited product standards for proposed use as an alternative compliance pathway under FIFRA.

Table Notes

- Category Column: Focuses on overarching themes present in both FIFRA & the NSF/ANSI Standards. Additional background can be found in the Appendix.
- FIFRA Requirements for Pesticidal Devices Column: Addresses the various categories and needs involved with FIFRA compliance.
- Third-Party Product Testing & Certification Requirements Column: Analyzes the requirements specified in NSF/ANSI standards for an independent CB accredited to ISO/IEC 17065.
- Rating Column: Considers the requirements of FIFRA as compared to Product Certification and NSF/ANSI Standards and assigns an assessment.

Category	FIFRA Requirements for Pesticidal Devices	Third-Party Product Testing & Certification Requirements	Rating (Certification to Standards vs. FIFRA Requirements)
Product Safety - Certified products undergo rigorous testing to ensure product safety and compliance with specific NSF/ANSI standards.	<ul style="list-style-type: none"> • Directions & Cautionary Statements • Child Resistant Packaging 	<ul style="list-style-type: none"> • Independent review of materials in contact with water • Toxicological assessment • Material safety testing 	Exceeds
Performance - To certify a product, it must undergo verification testing specifically related to claims and/or intent of the product's use.	N/A	<ul style="list-style-type: none"> • Review of health effects claims • Test microbiological performance • Test to ensure active agents (silver) do not impact water quality 	Exceeds
Structural Integrity - The purpose of testing structural integrity performance is to evaluate the materials, design, and fabrication quality of the complete water treatment system.	N/A	<ul style="list-style-type: none"> • Elevated water pressure testing • Life cycle pressure testing 	Exceeds
Product Literature – Defines user instructions for labeling, installation, maintenance, and disclosures of product limitations.	<ul style="list-style-type: none"> • General Product info: • Labeling Requirements (40 CFR Part 156) • Misbranding • Exporting Labeling Requirements 	<ul style="list-style-type: none"> • Product Literature requirements • Performance Data Sheet that is independently verified • Data Plate (label on the product itself) 	Exceeds
Surveillance – Each laboratory that certifies products shall operate a formal QA program.	<ul style="list-style-type: none"> • Pesticide Establishment Requirements (Annual Reporting) 	<ul style="list-style-type: none"> • Initial product testing, retested every several years or if changes are 	Exceeds

		<p>made to product or standard.</p> <ul style="list-style-type: none"> • Manufacturer facility inspection (annual) 	
<p>Facility Registration – Administrative requirements</p>	<ul style="list-style-type: none"> • Facility register by EPA • EPA Specific Documents • Importing; NOA (EPA Form 3540-1) • Establishment Number (EPA form 3540-8) 	<ul style="list-style-type: none"> • Facility registered through Certification Body • Manufacturer Facility Inspection (annual) • Certification Body is required to publicly list all certified companies and products • U.S. CBP able to verify compliant products with a Certification Body 	Exceeds

Testing Required Under National Standards and Third-Party Testing

NSF/ANSI-accredited product standards for water filters are developed through a consumer-driven process that includes industry experts from around the world. These standards are continually being refined to account for new water quality challenges and technologies. Whereas FIFRA requirements are largely based on a manufacturer’s own statement of compliance (self-declaration). Third-party testing and certification provide an independent non-biased way to verify product claims utilizing knowledgeable staff with proven expertise in water filtration technologies.

Examples of tests required on Third-party certified water filters, but are not required for EPA registration:

- **Material Safety Test:** (Extraction Test, Evaluation of materials in contact with water): A toxicologist reviews the materials used in the water filter to determine the appropriate test battery. These tests involve soaking the product to ensure that there are no harmful contaminants introduced through simple contact with the water filter. If any harmful contaminants leach from the product, it is also confirmed that they come out at safe levels.

- **Structural Integrity Test:** This test helps to ensure that the products will maintain their integrity when subjected to water line pressure. The test inflates the actual pressure to simulate 20 years of the life of the product. This helps to ensure that the product will not leak under normal usage and will continue to perform over time.
- **Elective Performance Test** (based on health effects claims): If a device makes a health claim from one of the categories below, it triggers a performance test in order to qualify for certification. The test verifies that the product reduces the contaminants to requirements set forth by the NSF/ANSI standard or better. These requirements are continually being evaluated and updated to include new science and technological capabilities. Health effects performance tests are conducted with a safety factor. When a system has a performance indication device that warns a user to replace the cartridge, testing is done to 120% of water filter capacity or 200% of capacity if a performance indication device does not exist. Performance tests are completed to verify health effects claims related to the following categories:
 - Microbes (bacteria, virus, and protozoan cysts)
 - Volatile organic compounds (benzene, 1,2,3 TCP, 24D, atrazine, lindane, etc.)
 - Disinfection byproducts (bromate, trihalomethanes (THMs), etc.)
 - PFAS (PFOA, PFOS)
 - Heavy metals (lead, arsenic, hexavalent chromium, etc.)
 - Inorganic compounds (nitrates, perchlorate, etc.)
 - Emerging contaminants and compounds (pharmaceuticals, etc.)
- **Flow Verification Test:** This test helps to ensure the water filter flows at a reasonable rate - too slow and it impacts consumer satisfaction, too fast and it could impact filtration performance. Rated service flow test – ensures the product does not flow at a rate greater than where the contaminant reduction testing was performed.
- There are a number of other tests depending on the nature of the product including pressure drop testing, active agent, and performance indication device testing.

Table 2: Water Treatment Device Registration Process: EPA Pesticidal Device Registration vs. Third-Party Product Testing & Certification

This table is meant to delineate the process for pesticidal device registration under FIFRA through the EPA and the third-party certification requirements for water treatment devices. This is not meant to be a comparison of each step, however, exhibits the process participants must undergo to comply with FIFRA and CBs.

EPA PESTICIDAL DEVICE REGISTRATION PROCESS	THIRD-PARTY CERTIFICATION PROCESS
Company applies for an EPA company number	Application: Includes a list of all products the manufacturer intends to certify. The list includes detailed components, supplier information, detailed information on the production facility, and product literature (installation/operation manual, data plate, performance data sheet).
Company applies for an EPA establishment number and prints this number on the pesticidal device.	Technical Review: The Certification Body review the application information and assign specific performance testing in accordance with the performance standard.
Product labeling must comply with FIFRA section 2(q)(1) and 40 CFR Part 156 and EPA regulations on child-resistant packaging --40 CFR 157.20 – 157.36: FIFRA does not require device producers to submit any data concerning either safety or efficacy of a device prior to distribution or sale.	Manufacturing facility initial inspection: The manufacturer provides a list of all manufacturing locations. The Certification Body schedules initial inspections at all locations to ensure a minimum quality assurance plan is in place.
Importer submits to EPA a Notice of Arrival of Pesticides and Devices (EPA Form 3540-1) for each shipment.	Laboratory Testing: Testing laboratories conduct product testing per the technical review and provide test reports to the Certification Body.
Manufacturer reports annual sales of pesticidal devices (filters) to the EPA.	Final technical review / Initial Listing: Certifying Body reviews lab testing reports, factory inspection reports, and product literature to verify compliance with the performance standard and certification policies. If everything is found compliant with the certifier authorizing the use of its registered product certification mark future product production.
	Continuous compliance – ISO 17065 requires the Certification Body to perform surveillance activities to ensure the ongoing validity of the certifications. This is accomplished through periodic inspection of marked products and factory inspections to ensure the products remain compliant with the requirements in the standards. Retesting can

	be triggered through updates to the standards, product modifications, or new product claims.
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CONCLUSION

The process that an independent CB accredited to ISO/IEC 17065 undertakes to address consumer protection, public health, and transparent business operations demonstrate the higher protection offered to consumers through third-party certification. Specifically for water treatment devices, the testing, examination, and data reporting that are required to meet national standards are robust and are more stringent than the requirements specified under FIFRA by EPA. Third-party certification should be accepted as an alternative compliance pathway for FIFRA.