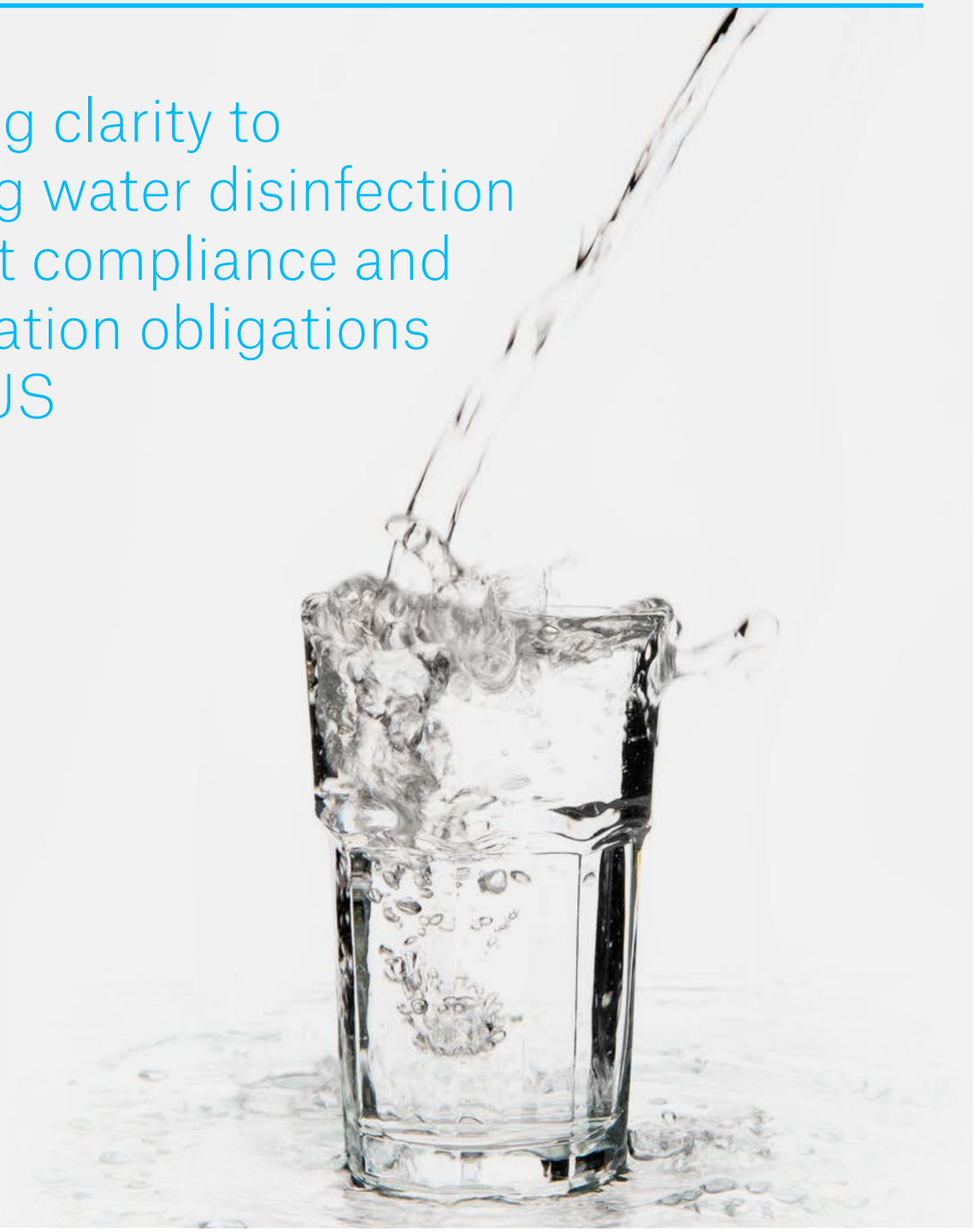
in focus

Bringing clarity to drinking water disinfection product compliance and certification obligations in the US



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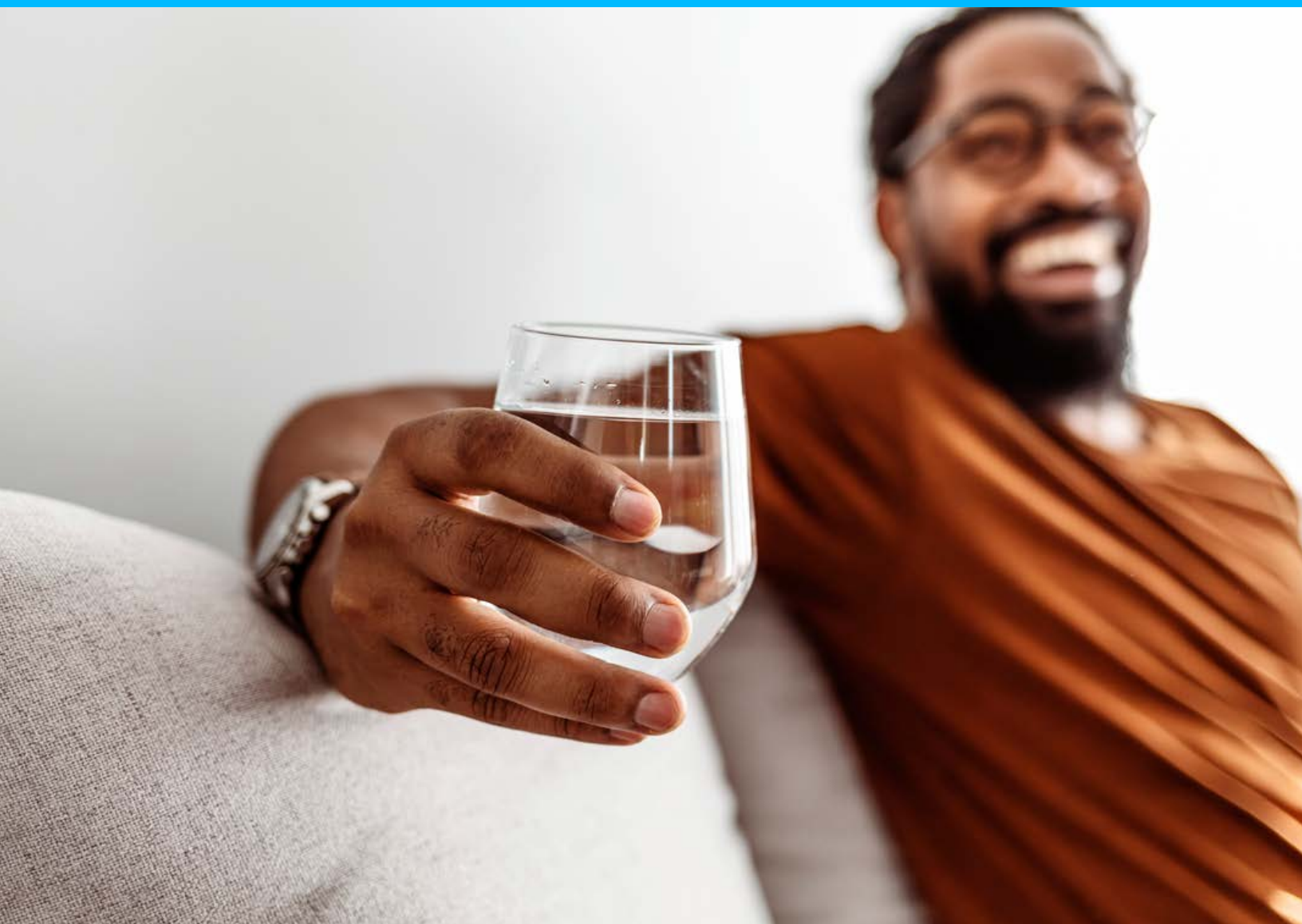
US compliance and certification obligations for drinking water disinfection products and technologies are stringent and robust. They can also be hard to navigate due to complex requirements at both the federal and state levels. In this paper, we look at national and state registration prerequisites for water disinfection products classified as pesticides or pesticidal devices (including those that do not make direct pesticidal claims). We also explain how this fits with certification requirements for drinking water chemical and device standards. Our goal is to help manufacturers of drinking water disinfection products and technologies understand their full regulatory and compliance obligations.



Compliance and certification obligations for drinking water treatment products and technologies in the United States are complex, ever changing and unforgiving. Water treatment technologies are regulated across a spectrum of federal, state and local laws.

From a federal perspective, it is commonly thought that drinking water treatment products are regulated primarily under the Safe Drinking Water Act (SDWA). Originally passed by Congress in 1974, the SDWA regulates public drinking water supplies and the rivers, lakes, reservoirs, springs, and groundwater wells that resource them. The SDWA authorizes the United States Environmental Protection Agency (EPA) to establish national health-based drinking water criteria to protect against both naturally occurring and man-made contaminants.

Importantly, the SDWA generally imposes requirements not on product manufacturers, but rather on providers of public water supplies. As there are no federal water disinfectant product approval, registration, or licensing processes under the SDWA, chemical products and other technologies that control 'pests', such as bacteria, fungi, algae, protozoa or slime in drinking water are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) administered by the EPA Office of Pesticide Programs.

Registration of products under FIFRA, however, does not mean that a disinfection product meets the requirements of other environmental and public health protection statutes. Furthermore, it does not mean that state, tribal or territorial laws allow for these products to be used by public water supplies. Chemicals used to disinfect water must be registered in every state where the product is distributed, offered for sale, or used. In addition, most US states require or strongly recommend that products used for primary or secondary drinking water disinfection be certified to NSF/ANSI drinking water standards by an accredited, third-party certification body. Therefore, it is important that manufacturers of water disinfectant chemicals and devices understand all state and federal obligations that must be met prior to distribution and sale.

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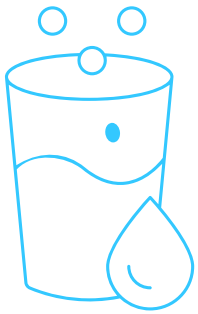


Drinking water chemical disinfectants

The water treatment industry commonly uses chemical methods to disinfect public drinking water supplies. These chemicals are considered antimicrobial products and are used to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or to protect water from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime. Chemical oxidants such as chlorine (Cl^2 or hypochlorite) and chloramines (NH^2Cl, $NHCl^2$, NCl^3) are efficient in the degradation of pathogens. Due to their rapid reaction with matrix constituents other than pathogens (including organic matter, organic nitrogen compounds and ammonia) they are most effective in matrices with relatively low disinfectant demand, such as drinking water or secondary wastewater effluents. More recently, alternative oxidants such as chlorine dioxide (ClO^2) and ozone (O^3) have increasingly been deployed for water treatment. This is largely because chlorine and chloramines are unable to inactivate harmful protozoa (e.g. *Cryptosporidium*) and have a higher propensity to generate hazardous byproducts.

Federal registration

The EPA evaluates human and environmental health risks associated with an antimicrobial product's use and determines whether it meets FIFRA's registration standard of 'no unreasonable adverse effects on man or the environment'. Registration is granted through the approval of a product label, which is needed prior to a pesticide's sale or distribution in the US.

FIFRA

FIFRA was enacted in 1947 with major amendments to the law in 1972, 1988 and 1996.

The composition, testing, registration, labeling, promotion, distribution, sale and use of pesticides and pesticidal devices are regulated under FIFRA. The Act defines, in broad terms, the process for applying for a pesticide registration. This is supplemented by the EPA through various regulations, guidelines, and other advisory documents. Pesticide registration applications undergo a review process with scientific, legal and administrative considerations. The regulations that implement FIFRA are contained in Part 40 of the Code of Federal Regulations, Sections 150-180.

Intent of use

It is important to note that under FIFRA, products 'intended' for use as a pesticide or pesticidal device must obtain registration even if no pesticidal claims are made. If a manufacturer sells a product with the knowledge that it may be used to prevent, destroy, inhibit, or mitigate a pest, it must be registered with the EPA and in the states where it is sold.

State registration

In addition to registering with the EPA, manufacturers must register pesticide products in all states where they are sold or distributed. These registrations must be renewed as required. Most states have annual or biannual renewal cycles, though some follow a three- or five-year cycle.

NSF/ANSI/CAN Standard 60 Certification

Currently, 49 US states require that drinking water treatment chemicals are compliant with NSF/ANSI/CAN Standard 60. Manufacturers seeking certification to NSF/ANSI/CAN 60 are subject to a rigorous review process which includes a formulation review, product testing, and facility audits. Following initial certification, products are monitored annually to ensure continued compliance. It is important that end users recognize the approved product use(s), maximum use level and listing footnotes so that certified products are used as intended and adhere to any regulatory requirements (e.g. residual chlorine levels).

NSF/ANSI/CAN Standard 60: Drinking Water Treatment Chemicals – Health Effects has been updated regularly since it was initially written in the 1980s. Standard 60 was developed at the request of the EPA Office of Water as part of a larger EPA/FDA Memorandum of Understanding (MOU) under the SDWA. A consortium comprising NSF International (formerly the National Sanitation Foundation), the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the Conference of State Health and Environmental Managers (COSHEM). Voluntary at the time it came into effect, this third-party consensus standard and certification program covers all direct drinking water additives and establishes testing, evaluation and acceptance criteria that represent best practice for products added directly to water during its treatment, storage and distribution.

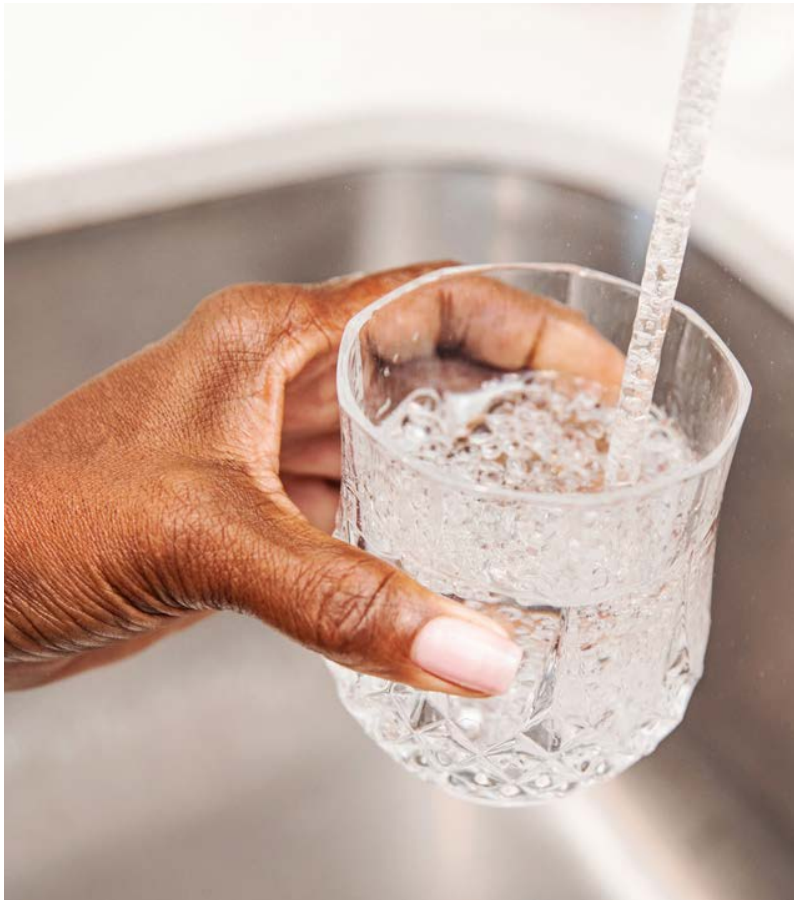
Drinking water treatment devices

Some consumers elect to further reduce exposure to potential pathogens and chemicals in treated drinking water with point-of-entry (POE) or point-of-use (POU) technologies. POE systems treat water entering a house and are usually installed near the water meter (municipal) or pressurized storage tank (well water). They include UV light disinfection systems, water softeners and whole-house chlorine filters. POU products include, but are not limited to, personal water bottles, pitchers, faucet-mount filters, and refrigerator filters.

UV light disinfection is a common, non-chemical method of killing, inactivating, or suppressing the growth of microbes, including bacteria, viruses, fungi, protozoans, and cysts. UV technology has been used commercially for some time to treat drinking water and is increasingly being used in residential applications. For instance, a UV lamp can be used to kill microbes that escape reverse osmosis membrane filtration. The effectiveness of UV treatment depends on the strength and intensity of the light, the duration of treatment, and the quantity of particles present.

FIFRA registration

FIFRA defines a pesticidal device as 'an instrument or contrivance (other than a firearm) that is used to destroy, repel, trap or mitigate (lessen the severity of) any pest such as insects, weeds, rodents, certain other animals, birds, mold/mildew, bacteria and viruses' *(FIFRA 2(h))*. EPA policy dictates that pesticidal devices include UV light systems, ozone generators, water, and air filters (except those containing pesticides), and ultrasonic devices that claim to control fungi, bacteria, or viruses (41 Fed. Reg. 51,065 (Nov. 19, 1976)).



Where these devices work by physical means (such as electricity, light, or mechanics) and do not contain a substance or mixture of substances to perform their intended pesticidal function, the EPA does not require registration of the device. However, these devices are regulated under FIFRA, meaning that they must still comply with specific reporting and labeling requirements. It is also important to note that while pesticide devices are exempt from federal registration, these products do require registration in several states and certification to the NSF/ANSI standards may still be recommended.

Barrier products

To add to the complexity of the regulatory landscape associated with water treatment device products, 'barrier products' are not subject to FIFRA registration requirements (40 CFR 152.10(c)). In order to be considered a barrier product, products must not be intended to 'prevent, destroy, repel or mitigate a pest…', must not 'make a pesticidal claim on the labeling or in connection with sale and distribution' and must be 'intended to exclude pests only by providing a physical barrier against pest access, and contain no toxicants'. Various filtration technologies such as nanofiltration, reverse osmosis membranes, carbon blocks and ceramic filters could be considered barrier products if they only provide a physical barrier to pests.

Treated articles exemption

There is some uncertainty in the water treatment industry surrounding filters or other device components that have been treated with antimicrobial materials or preservative chemicals, such as silver. The EPA exempts from FIFRA registration articles or substances treated with or containing a pesticide that is present to protect (preserve) the article or substance itself. However, in order to qualify for the exemption, the material's preservative pesticide must itself be registered for the appropriate application. For example, it would be unlawful to use an EPA registered materials preservative pesticide in a drinking water filter if the product is approved for use in textiles only. The EPA registered pesticide must be approved for use in water filters in this instance.

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Labeling claims under the treated article policy are often the source of confusion. The seller of an exempt treated article may not make implied or explicit public health claims against human pathogens. Public health claims are claims made against pathogens that can make people sick. For example, a claim that a water filter containing silver 'kills bacteria' would fall outside the treated article exemption because 'bacteria' in this instance could include bacteria that negatively impact public health. To qualify for the treated article exemption in this case, the claim would need to be changed to 'kills odor-causing bacteria' or 'bacteria that causes deterioration of the filter media'.

Corporate marketing and sales staff do not always have an appreciation or understanding of the regulatory obligations under FIFRA and, more importantly, the enforcement consequences associated with claims that are not in compliance with the treated article policy. There has been an increase in EPA enforcement in this area because it is relatively easy for EPA enforcement officials to review product labels in the marketplace and pursue companies that are making unlawful claims.

Table 1 outlines typical examples of drinking water treatment systems and components which make pest reduction claims and the relevant FIFRA obligations.

Water treatment system/component	FIFRA obligation
Water filter with bacteriostat agent, bacteriostatic claim	Pesticide
Filtration product with bacteriostat agent advertised to protect against growth of bacteria within product, downstream of filter	Pesticide
Water filter making a cyst claim where cyst reduction is accomplished purely by mechanical means (e.g. size exclusion)	Pesticidal Device
Filtration product with bacteriostat agent intended to prevent the media from fouling; no bacteriostat claim, bacteriostat present to protect product's durability	Treated Article, exempt from registration
Class A UV microbiological water treatment system	Pesticidal Device
Ozonator unit	Pesticidal Device
Water cooler incorporating UV or other bactericidal device (with or without making its own claims)	Pesticidal Device
Manufacturer sells finished device constructed with components, making a treatment claim	Pesticidal Device

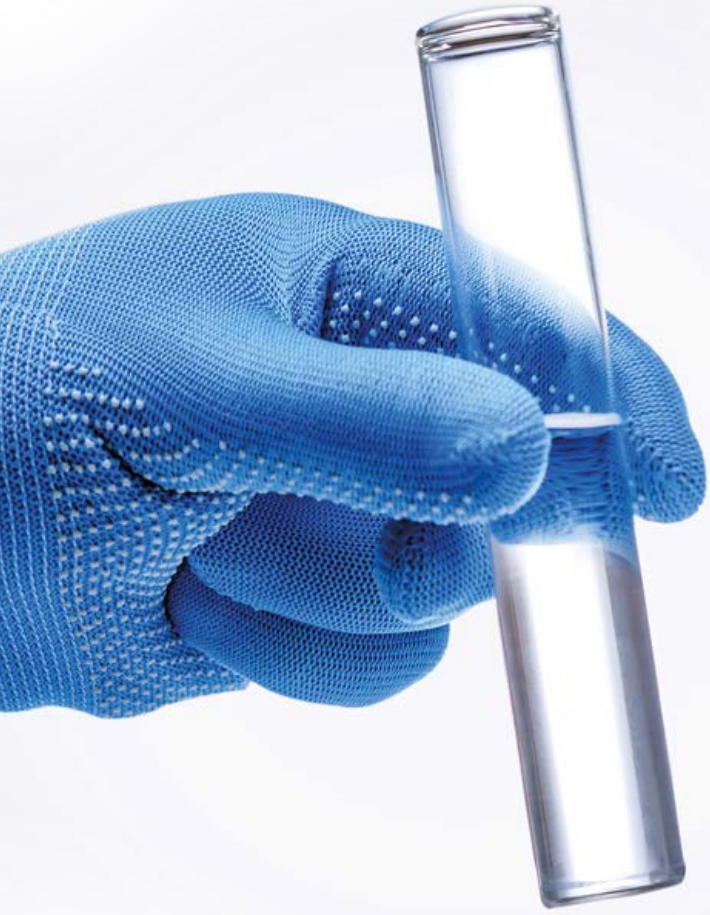
Table 1. FIFRA obligations for drinking water treatment systems making 'pest' reduction claims

NSF/ANSI water treatment device certification

Voluntary national standards for the certification of residential drinking water treatment devices have been developed through the same process as described previously for NSF/ANSI/CAN Standard 60. The standards for this equipment cover both POE and POU products.

The first NSF/ANSI standard for residential water treatment systems, NSF/ANSI 42 - Drinking Water Treatment for Aesthetics, was adopted in 1973. It covers POU and POE systems designed to reduce specific aesthetic or non-health-related contaminants (such as chlorine, taste and odor, and particulates) that may be present in public or private drinking water. The companion standard, NSF/ANSI Standard 53, addresses POU and POE systems designed to reduce specific health-related contaminants that may be present in public or private drinking water. Some products fall under the scope of Standards 42 and 53 because they make both aesthetic and health claims. In addition to NSF/ANSI Standard 53, there are several other treatment unit certification standards that evaluate products making 'pest' reduction or elimination claims. (See NSF Standards for Water Treatment Systems | NSF International for more information.)

As with the process for drinking water treatment chemicals, manufacturers seeking certification to NSF/ANSI standards for POE or POU water treatment devices are subject to a thorough review by an accredited third-party certification body. This includes a product review, contaminant reduction claims review, product testing (extraction, structural, contaminant reduction, mechanical reduction, chemical reduction), and facility audits. After the initial certification, products are regularly monitored (often every five years) to ensure continued compliance.



Bacteriostatic and bactericidal claims

In general, 'bacteriostatic' agents are intended to prevent the growth and reproduction of bacteria, while 'bactericidal' agents are intended to kill bacteria. As explained above, there are several industry drinking water treatment device standards that address bactericidal claims, including NSF/ANSI 53 for cyst reduction using filtration, NSF/ANSI 55 for UV systems and NSF/ANSI 42 for aesthetic effects, amongst others. The federal regulations that implement FIFRA do not recognize these industry standards and compliance with them has no bearing on whether the products are compliant with FIFRA. The claims 'bacteriostatic' and 'bactericidal' are considered pesticidal claims and products that make these claims on their packaging or any other marketing materials need to comply with the regulations under FIFRA. From an EPA registration perspective, the Agency must review and approve efficacy data to support products that make bactericidal claims. While the Agency does not routinely review efficacy data for products that make bacteriostatic claims, it reserves the right to request this data from the registrant.

Managing federal and state registration and certification responsibilities

Review of a pesticide or pesticidal device registration application by EPA or at the state level does not include consideration of a product's NSF/ANSI drinking water standards certification status. Similarly, neither federal nor state registration is a prerequisite for third-party certification to any NSF/ANSI drinking water standard.

It is important to note that these certification and registration processes are lengthy and complex. For example, the EPA review time for FIFRA registration applications ranges from six months to nearly two years depending on the formulation. However, the registration and certification processes can be pursued concurrently to improve efficiency. Manufacturers and distributors of these products need to satisfy both requirements ahead of sale or distribution in the US. Federal and state registrations, as well as NSF/ANSI/CAN certification must be maintained for as long as the products are available for sale. A recent scenario associated with a drinking water treatment chemical is highlighted in the box to the below. It demonstrates the potential for confusion and the consequences when federal and state-level registration and certification requirements are not fully understood.

In 2018, it was discovered that the disinfectant 1-bromo-3-chloro-5,5-dimethylhydantoin (BCDMH) was being used to treat some of the well water in the city of Denmark, South Carolina for naturally occurring iron bacteria. Although BCDMH had been used for approximately ten years in one of Denmark's four wells, the product was not FIFRA registered.

During the subsequent investigation, state government officials explained that they believed the BCDMH product was EPA-approved to treat drinking water based on the way the product was advertised. However, while it was certified to NSF/ANSI 60 for drinking water treatment applications, it had not been evaluated and registered under FIFRA.

In July 2018, the South Carolina Department of Health and Environmental Control (DHEC) presented the city of Denmark with two options: either find a replacement treatment chemical registered under FIFRA or remove the impacted well from service. The city notified DHEC in August 2018 that the impacted well had been taken offline while alternate treatments for iron-bacteria were considered.

How can TSG help?

The US regulatory and compliance landscape for drinking water treatment products is complex, stringent, and continually evolving. Understanding a product's status in relation to federal and state registration requirements is vital for any manufacturer of drinking water treatment products. To ascertain whether a given product is classified as a pesticide or pesticidal device, or qualifies for exemption, it is advisable to liaise directly with EPA and/or state level regulators. Here at TSG, our federal and state regulatory and scientific experts can provide strategic advice and representation in front of EPA and state agencies, as well as registration and technical assistance with EPA and the relevant states.

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