

Quick Guide for Disinfectant Products for Drinking Water Use by Public Water Systems



Understanding Your Responsibility under FIFRA and How FIFRA Approval Relates to SDWA

Purpose:

The U.S. Environmental Protection Agency (EPA) has developed this quick reference guide to provide clarity for applicants seeking approval for disinfectant products for drinking water use. Pesticide products that bear a drinking water disinfection label claim are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These products may also be used by public water systems (PWSs) that are regulated under the Safe Drinking Water Act (SDWA).

Comparing the Two Statutory Programs, FIFRA and SDWA:

The objective of FIFRA is to protect human health and the environment through regulation of pesticide distribution, sale and use. All pesticides distributed or sold in the U.S. must be registered (licensed) by EPA, unless exempt. Registration ensures that pesticides are properly labeled and that, if used in accordance with their approved labeling, they will not cause unreasonable adverse effects on the environment or human health.

The SDWA is the primary federal law that protects public drinking water supplies throughout the nation. Under the SDWA, Congress directs EPA to set national drinking water standards to protect public health but allows states, tribes and territories to seek EPA approval for

primary enforcement responsibility to implement and enforce these regulations (called “primacy”). EPA maintains oversight of the states’, tribes’ and territories’ drinking water programs, including independent federal enforcement authority. The SDWA generally imposes requirements on PWSs, not on product manufacturers. As a result, there is no disinfectant product approval, registration or license under the SDWA. However, some states, tribes or territories may have such requirements.

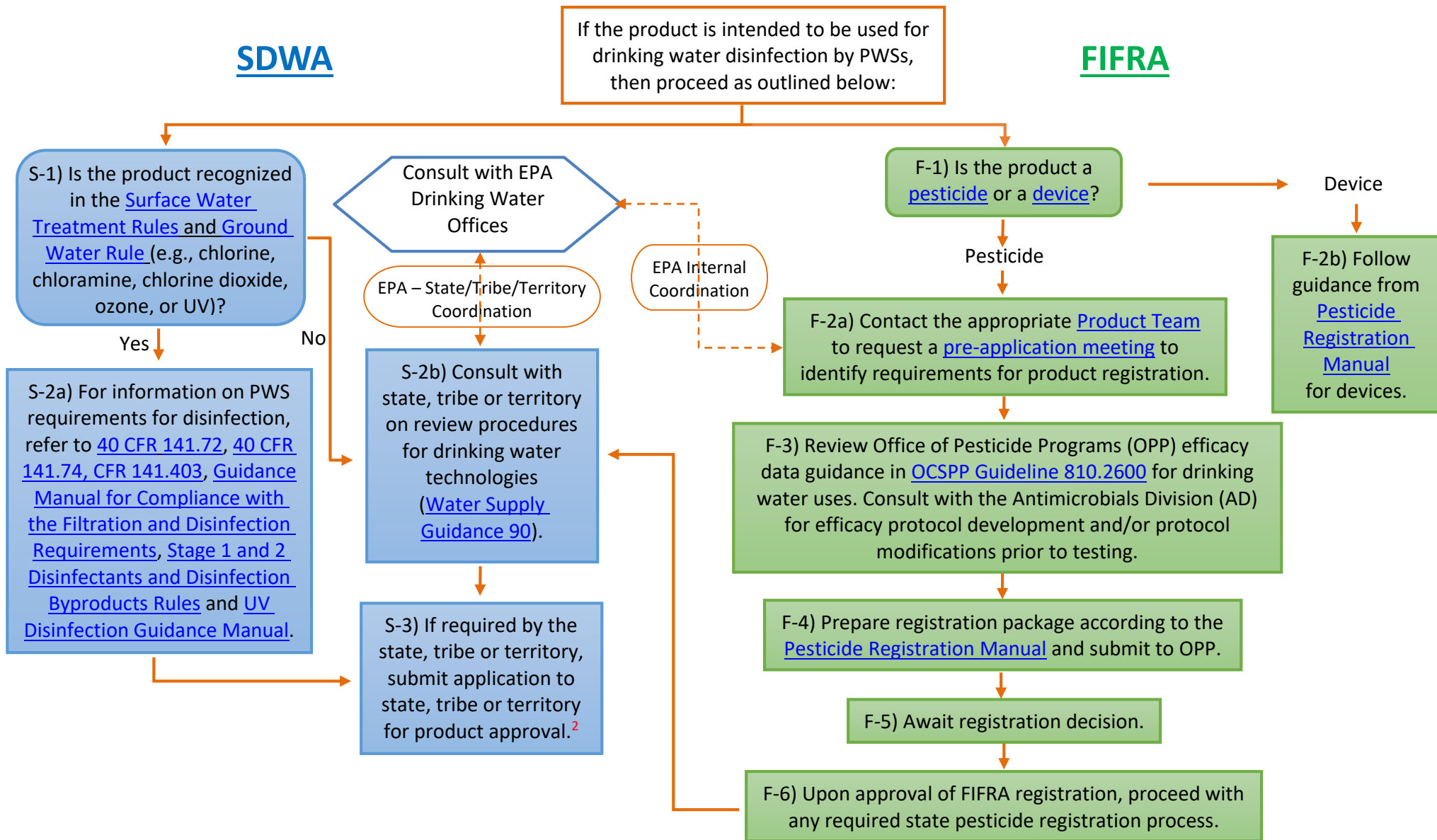
Registration of a pesticide product or regulatory compliance of a pesticide device under FIFRA does not mean that it meets the requirements of other environmental and public health protection statutes, including the SDWA, or vice versa. Furthermore, FIFRA registration does not mean that the product meets state, tribal or territorial laws regarding drinking water products for use by PWSs.

How to Use this Guide:

The graphic on page 2 illustrates general steps for obtaining product approval for drinking water disinfection use by PWSs. Note that it is not intended to convey the steps in a strict chronological order. Depending on the applicant’s specific needs, certain steps may take place sooner than others. For more details on each step of the process, see pages 3 and 4.

Quick Guide for Disinfectant Products for Drinking Water Use by PWSs

Understanding Your Responsibility under FIFRA and How FIFRA Approval Relates to SDWA¹



¹ This process is applicable for new and existing products seeking a drinking water use label for PWS disinfection.

² FIFRA registration should be obtained before submission to state, tribe or territory.

FIFRA:

- F-1)** Applicants should first determine whether the product is a pesticide or device. Unless exempt, pesticide products and devices that make antimicrobial claims of efficacy are subject to certain EPA regulatory requirements. FIFRA defines a [pesticide](#) as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. The term pesticide includes antimicrobials (e.g., sterilants, disinfectants, sanitizers) in addition to various other substances used to control pests.
- A pesticide [device](#) is defined in FIFRA as an instrument or contrivance (without a chemical substance) that is used to destroy, repel, trap or mitigate any pest such as insects, weeds, rodents, animals, birds, mold/mildew, bacteria and/or viruses. Devices include ultraviolet light systems, ozone generators, water filters, etc. They do not include equipment used for the application of pesticides when sold separately from the pesticide.
- F-2a)** Unless exempt, products that contain a substance or mixture of substances and make a pesticidal claim must be registered by EPA prior to sale or distribution. Applicants seeking registration of an [antimicrobial pesticide](#) should contact the appropriate [Product Team](#) within the Office of Pesticide Programs' (OPP) Antimicrobials Division (AD) to request a [pre-application meeting](#) to identify data and labeling requirements for the product. Data requirements may include, but are not limited to, efficacy, chemistry, acute toxicity, chronic toxicity and environmental fate studies. Applicants are encouraged to refer to the [Label Review Manual](#) as a general guide to pesticide labeling. *Note: For new products undergoing FIFRA registration for drinking water disinfection use in PWSs, EPA will coordinate internally to ensure that requirements under both FIFRA and SDWA are addressed.*
- F-2b)** While devices are subject to certain EPA regulatory requirements, they do not require registration as pesticide products. A device is subject to the FIFRA prohibition against misbranding and must be produced in an EPA-registered establishment.
- Additional information on pesticide devices and the associated FIFRA requirements is available on [EPA's website](#) including the [Pesticide Registration Manual](#).
- F-3)** For products that claim efficacy against a public health pest, an applicant must submit data demonstrating that efficacy in order to obtain a product registration. General efficacy testing guidance for drinking water uses is available in [OCSPP Guideline 810.2600](#). Applicants should consult with OPP AD Efficacy Evaluation Team on efficacy protocol development and/or protocol modifications prior to conducting efficacy testing.
- F-4)** Once an applicant has completed the data and labeling requirements for the product (as agreed upon at the pre-application meeting), the applicant should prepare a registration package according to the [Pesticide Registration Manual](#) and submit the package to the Agency for review.
- F-5)** OPP will review the submission and maintain contact with the applicant regarding the status of the review and any deficiencies. At the completion of the review, the applicant will receive a final product registration decision from the Agency.
- F-6)** Upon approval of the federal registration, registrants should proceed with any required state pesticide registration process. States may have stricter standards than those prescribed in federal regulations. *Note: FIFRA registration for drinking water use should be obtained before submission to a state, tribe or territory for product approval under their drinking water laws.*

SDWA:

S-1) EPA does not register or approve disinfection products under the SDWA, but instead imposes requirements on each regulated PWS³ to deliver water that meets specific standards to persons served by the system. Each PWS must determine what product or combination of products to use to meet the federal and any applicable state, tribal or territorial drinking water requirements. EPA's drinking water rules do provide requirements for disinfecting water supplies. Applicants with such products should consult the [Surface Water Treatment Rule](#) (SWTR), the [Long Term 2 Enhanced Surface Water Treatment Rule](#) (LT2ESWTR) and the [Ground Water Rule](#) (GWR) for treatment requirements. These rules provide criteria for establishing log inactivation by different disinfectants when applied to surface or ground water. Such products include chlorine, chloramine, chlorine dioxide, ozone and/or ultraviolet light (UV).

S-2a) For additional information on disinfection requirements for regulated PWSs under the SWTRs or GWR, applicants may refer to the following sources. For chlorine, chloramine, chlorine dioxide and ozone, applicants can refer to [40 CFR 141.72](#), [40 CFR 141.74](#), [40 CFR 141.403](#) or the [Guidance Manual for Compliance with the Filtration and Disinfection Requirements and Stage 1 and 2 Disinfectants and Disinfection Byproducts Rules](#). For UV-based products, applicants can refer to the [UV Disinfection Guidance Manual](#).

S-2b) While requirements under the SDWA do not prohibit the installation of a given technology, applicants should consult with the relevant state, tribe or territory regarding procedures for approval of new technologies in PWSs under state, tribal, or territorial law. States, tribes or territories may have standards beyond those prescribed in the SDWA and its implementing regulations. This includes the authority to approve a drinking water treatment technology to be used within the state, tribe or territory, or

to request additional data or information about the technology. States, tribes and territories and technology manufacturers can refer to EPA's [Water Supply Guidance \(WSG\) 90](#) for guidance on types of data or information that may be requested as part of the state, tribe or territory's evaluation and approval of alternative drinking water treatment technologies. Applicants are encouraged to contact the state, tribe or territory for specific guidance on procedures for approval of new products for use in a PWS.

For products and technologies not covered under the SWTRs and GWR, states, tribes and territories may consult with the EPA Drinking Water Offices (headquarters and/or regional offices), as needed. *Note: For new products undergoing FIFRA registration for drinking water disinfection use in PWSs, EPA will ensure internal coordination across relevant programs.*

S-3) After satisfying all pesticide requirements under FIFRA, applicants should consult with the relevant state, tribe or territory to determine the procedures, if any, for product approval for drinking water use in that state, tribe or territory.

Helpful Links:

SDWA

- [Safe Drinking Water Act](#)
- [Surface Water Treatment Rules](#)
- [Guidance Manual for Compliance with the Filtration and Disinfection Requirements and Stage 1 and 2 Disinfectants and Disinfection Byproducts Rules](#)
- [Ground Water Rule](#)
- [UV Disinfection Guidance Manual](#)
- [Water Supply Guidance \(WSG\) 90](#)

FIFRA

- [Federal Insecticide, Fungicide and Rodenticide Act](#)
- [Pesticide Registration Manual](#)
- [Label Review Manual](#)
- [OCSPP Guideline 810.2600](#)

³The Agency defines a PWS as "a system for the provision to the public of water for human consumption through pipes or, after August 5, 1998, other constructed conveyances, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year." 40 CFR 141.2. The criteria for a PWS can be found under [40 CFR 141.3](#).