

example, fertilizer runoff can enter streams and contaminate surface water. Contaminants in the ground may enter a well and contaminate well water. Therefore, it is important that water from any source comply with the requirements set out in proposed § 111.15(d).

Another comment to the ANPRM suggested that a potable water standard is inappropriate for use in manufacturing dietary ingredients and dietary supplements from chemicals. The comment would limit the use of potable water to manufacturing, processing, and handling of vegetables, ready-cooked dishes, etc.

We disagree with the comment. If water is not suitable for drinking (nonpotable), the water may contain microorganisms or contaminants that will contaminate your dietary ingredients or dietary supplements. For example, water from private sources may be untreated, so it may be contaminated by pesticides due to water runoff from fields or may contain microorganisms, algae, particulates, etc. Therefore, proposed § 111.15(d) would require that you use water that is of safe and sanitary quality, regardless of whether you use natural or synthetic components to make dietary ingredients and dietary supplements.

Proposed § 111.15(d)(3) would require that you have documentation or otherwise be able to show that the water that contacts components, dietary ingredients, dietary supplements, or any contact surface meets the water quality standard in proposed § 111.15(d)(2). The proposal would not prescribe any particular type of documentation or method for showing water quality, but you should remember that water is used as a component in manufacturing dietary ingredients and dietary supplements would fall within the definition of "component," so it should meet whatever specifications you establish for component identity, purity, quality, strength, and composition. We discuss requirements for the identity, purity, quality, strength, and composition of components later in this section when we describe proposed § 111.35, "What production and process controls must you use?". Proposed § 111.15(d)(3) would be similar to a provision in the drug CGMP regulation at 21 CFR 211.48(a) and the proposed requirement in the infant formula proposed rule (61 FR 36154 at 36211), which requires that water meet EPA's drinking water requirements in 40 CFR part 141.

Proposed § 111.15(e) is similar to the plumbing requirements in the food CGMPs at § 110.37(b). Proposed

§ 111.15(e) would require your physical plant's plumbing to be adequate size and design and to be adequately installed and maintained to:

- Carry sufficient amounts of water to required locations throughout the physical plant;
- Properly convey sewage and liquid disposable waste from your physical plant;
- Avoid being a source of contamination to components, dietary ingredients, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition;
- Provide adequate floor drainage in all areas where floors are subject to flooding-cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
- Not allow backflow from, or cross-connection between, piping system that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary ingredients or dietary supplements, or cleaning contact surfaces, or for use in bathrooms and hand washing facilities.

This provision is intended to ensure that your plumbing system does not adversely effect the water in your physical plant. If the plumbing system is not adequately installed and maintained, it may contaminate your water supply and, in turn, contaminate your components, dietary ingredients, and dietary supplements through direct contact, such as when you use water to make the products, or indirect contact, such as when the contaminated water is used on a contact surface.

In addition to the water directly contaminating your components, dietary ingredients, dietary supplements, or contact surfaces, standing water can cause contamination by attracting pests or becoming a breeding ground for microorganisms. Therefore, the proposal would require your plumbing system to have adequate drainage and would not allow backflows or cross-connections in your plumbing system because backflows from a nonpotable water system to a potable water system under negative pressure conditions could contaminate your water system (Ref. 57).

A comment to the ANPRM stated that requiring a physical plant's plumbing to carry sufficient amounts of water to required locations throughout the plant was too vague. The comment stated the water is not needed in many operations in the plant, and so firms should be able to decide the location and availability of water throughout their own physical plants.

The comment may have misinterpreted the ANPRM. Proposed

§ 111.15(d) would not require water to be available in all parts of a physical plant. In areas where water is unnecessary, we would not expect you to make water available or to have any particular quantity of volume of water available. However, there are areas where water is necessary to ensure that any unadulterated dietary ingredient or dietary supplement is manufactured, packaged or held. In those areas where water is necessary, your plumbing must carry sufficient amounts to those locations.

Proposed § 111.15(f) would require that you dispose your physical plant's sewage into an adequate sewage system or through other adequate means. This proposed provision is similar to the sewage provisions at § 110.37(c). Proper sewage disposal is essential to ensure that you maintain your manufacturing facility in a sanitary condition, and this would include protecting the processing environment against pathogenic microorganisms shed in fecal material. For example, bathroom floors can become contaminated with pathogens if your sewage disposal system fails to remove fecal material. Employees using those bathrooms, in turn, can transport those pathogens into your processing areas and contaminate components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.15(g) would apply to bathrooms. Proposed § 111.15(g) would require that you have adequate, readily accessible bathrooms for your employees and require that the bathrooms be kept clean and not become a potential source of contamination to your components, dietary ingredients, dietary supplements, or contact surfaces. The proposal would require that you keep your bathrooms from becoming potential sources of contamination. You would be required to keep the bathrooms in good repair at all times, provide self-closing doors, and provide doors that do not open into areas where components, dietary ingredients, dietary supplements, or contact surfaces are exposed to airborne contamination, except where you have taken other means (such as double doors or positive airflow systems) to protect against airborne contamination.

Proposed § 111.15(h) applies to hand washing facilities. The proposal would require that you provide adequate and convenient hand washing facilities that furnish running water at a suitable temperature. Proposed § 111.15(h)(1) would require that you have hand washing facilities and, where appropriate, hand sanitizing facilities at each location in your physical plant