

necessary, and allow them to dry thoroughly before you use them again.

Thoroughly drying equipment before it is used for manufacturing or holding dry dietary products is essential to ensure that the equipment will not change the composition of the dry product. For example, if moisture is left on equipment, the moisture will become a part of the product and may change the composition of the product. Moist surfaces can also promote microorganism growth, and microorganisms can adulterate your components, dietary ingredients, or dietary supplements.

Proposed § 111.25(e)(3) would apply if you use wet processing during manufacturing. Under the proposal, you would have to clean and sanitize all contact surfaces as necessary to protect against the introduction of microorganisms into components, dietary ingredients, or dietary supplements. Proposed § 111.25(e)(3) also would require that, when cleaning and sanitizing is necessary, you must clean and sanitize all contact surfaces before use and after any interruption during which the contact surface may become contaminated. If you use contact surfaces in a continuous production operation or in back-to-back operations involving different batches of the same dietary ingredient or dietary supplement, the proposal would require that you clean and sanitize the contact surfaces as necessary.

Proposed § 111.25(e)(4) would complement proposed § 111.25(e)(2) and (e)(3) by requiring that you clean, as frequently as necessary, surfaces that do not touch components, dietary ingredients, or dietary supplements to protect against contamination. For example, you would not have to clean your ceilings as often as you clean your contact surfaces because your ceilings normally do not touch components, dietary ingredients, or dietary supplements. However, you would have to clean your ceilings as frequently as necessary to prevent dust or other contaminants from falling onto your components, dietary ingredients, dietary supplements, and contact surfaces.

Proposed § 111.25(e)(5) would establish requirements for single-service articles, such as utensils intended for one-time use, paper cups, and paper towels. Proposed § 111.25(e)(5) would require these articles to be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that protects against contamination of components, dietary ingredients, dietary supplements, or any contact surface. For example, you would not place a paper towel dispenser over

a contact surface because persons reaching for those paper towels might drip contaminated water or other fluids onto the contact surface. Inadvertent reuse of a single-service article also could lead to contamination, so disposing of single-service articles is an important element in proposed § 111.25(e)(5).

Proposed § 111.25(e)(6) would require your cleaning compounds and sanitizing agents to be adequate for their intended uses and safe under their conditions of use. An adequate cleaning compound is one that will lower the surface tension of water so that spills can be lifted and flushed away (Ref. 60). Ordinary soap has a limited ability to solubilize fats, oils, and proteins. Inorganic alkaline detergents can dissolve food solids, such as fats and proteins, but mineral deposits will frequently require the use of acid cleaners (Ref. 60). Proposed § 111.25(e)(6) would not prescribe any particular cleaning compound. Instead, you may select cleaning compounds that are suited to your particular needs. An adequate sanitizing agent is one that has a bactericidal effect on the types of microorganisms normally present in the physical plant environment and is safe, chemically stable, and convenient for use. However, sanitizing agents can achieve their intended effect only after they are applied to a surface that has been thoroughly cleaned, and if they are applied at a proper concentration (Ref. 61).

Proposed § 111.25(e)(7) would require that you store cleaned and sanitized portable equipment and utensils that have a contact surface in locations and in a manner that protect them from contamination. This requirement is necessary to ensure that your portable equipment remains clean and sanitized until used; otherwise, if the contact surfaces on the portable equipment or utensils become contaminated, they could lead to adulteration of your dietary ingredients or dietary supplements.

We invite comment on whether we should require, in a final rule, that you establish and follow a written procedure for maintenance, cleaning, and sanitizing. Further, we invite comment on whether we should require that the person who performs the maintenance, cleaning, and sanitizing described in this section document, at the time of performance that the maintenance, cleaning, and sanitizing were performed. Those procedures may be helpful to inform you that equipment is being maintained, cleaned, and sanitized regularly and as frequently as is necessary based on the actual use, as

opposed to the planned use, of the equipment. If comments assert that written procedures are necessary, comments should include an explanation of why the requirement is necessary to prevent adulteration including how such a requirement would ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

As discussed later, proposed § 111.50(c)(4) would require that you document, in the batch production record, the date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used to producing the batch. Records that document the batch or lot number of each batch or lot of dietary ingredients or dietary supplements processed using a particular piece of equipment or a particular utensil between equipment startup and shutdown for maintenance, cleaning, and sanitizing will allow you to identify all dietary ingredients or dietary supplements that may have been manufactured or packaged with a specific piece of equipment or utensil if you later discover that the equipment or utensil was improperly maintained, cleaned, or sanitized.

Proposed § 111.25(f) would require that you keep calibration records as required by this section in accordance with the recordkeeping requirements in proposed § 111.125. Such records will verify for you and the agency that calibrations are performed. More importantly, these records will help you ensure that all calibrations are performed. If problems do occur with the production of a product, these records will help you determine whether those problems are associated with faulty calibrations. These records will help you determine which batches were produced under these conditions. Further, these records will help you train employees or adjust the calibration schedule as needed to avoid further problems.

2. What Requirements Apply to Automatic, Mechanical, or Electronic Equipment? (Proposed § 111.30)

Manufacturers of dietary ingredients and dietary supplements often rely on automatic, mechanical, and electronic