

7. What Requirements Apply to Manufacturing Operations? (Proposed § 111.65)

Proposed § 111.65 would require that you take all necessary precautions to ensure that, during the manufacturing operations, you do not create a source of possible contamination and that specifications are consistently achieved.

Under proposed § 111.65(a), you must design or select equipment and processes to ensure that dietary ingredient or dietary supplement specifications are consistently achieved. Frequently, a computer or system of computers may control many or all stages of manufacturing operations such as mixing, producing tablets, and packaging. It is important that such systems and equipment function as expected to ensure that the dietary ingredient or dietary supplement contains a homogenous mixture, a tablet that is neither too hard or too friable, and that the packaging contains the correct dietary ingredient or dietary supplement. Equipment used in dietary ingredient or dietary supplement manufacture, packaging, and label operations must be, for example, of an appropriate size and installed properly in order to produce an unadulterated product. If not designed or installed properly, the equipment can result in a variety of problems. For example, a mixer for the blending of powdered ingredients will not properly perform its function if the blade is too small relative to the size of the mixer or not properly placed inside of the mixer. Such a mixer may produce an adulterated product because the dietary supplement, for example, is not of uniform composition and therefore would not be able to meet the specifications for purity, quality, strength, or composition in the final product. Thus, equipment design and selection is critical to ensure that you manufacture an unadulterated dietary ingredient or dietary supplement.

Proposed § 111.65(b) would require that you conduct all manufacturing operations in accordance with adequate sanitation principles. We discussed the importance of having adequate sanitation earlier and related it to the use of sanitary practices for employees, physical plant, and equipment.

Proposed § 111.65(c)(1) through (c)(11) would require that you take all the necessary precautions during the manufacture of dietary ingredients and dietary supplements to prevent contamination of components, dietary ingredients, and dietary supplements.

Proposed § 111.65(c)(1) would require that you perform manufacturing operations under conditions and

controls that protect against the potential for microorganism growth and the potential for contamination. This would require that you conduct all operations in receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, sorting, and packing dietary ingredients and dietary supplements in accordance with appropriate and established sanitation procedures. Operations with poor sanitation in the production and processing environment can significantly increase the risk of contaminating components, dietary ingredients, or dietary supplements. Pathogenic microorganisms may be found on the floors and in the drains of the processing area and on all contact surfaces. Without good sanitary practices, any surface that comes in contact with components, dietary ingredients, and dietary supplements could be a potential source of microbial contamination. Thus, using appropriate sanitation procedures would provide conditions and controls to protect against potential contamination and microbial growth.

Proposed § 111.65(c)(2) would require that you wash or clean components that contain soil or other contaminants. This is a basic sanitation procedure to protect against contamination and microbial growth. Raw agricultural materials and other components that contain soil or other contaminants must be washed or cleaned as necessary. Water quality used for washing, rinsing, or conveying raw agricultural materials must be adequate for its intended use, both at the start and at the end of the processing operation, and should not contribute to the contamination of such materials.

Proposed § 111.65(c)(3) would require that you use water that meets the EPA's NPDW regulations or, where necessary, higher sanitary quality and that complies with all applicable Federal, State, and local regulations for water that is used in the manufacturing operation. If you reuse water that was used to remove soil or contaminants from components, the proposal would require that the reused water be safe and of adequate sanitary quality so that it does not become a source of contamination. Some manufacturing operations may require water of a higher sanitary quality than water that meets the NPDW regulations. For example, the fluoride or chloride levels in water meeting the NPDW regulations may interfere with certain capsule or tablet operations and a higher quality water such as distilled water may be necessary. This proposed requirement allows the manufacturer discretion in determining whether NPDW regulations

or higher sanitary quality water is necessary for a manufacturing operation.

Proposed § 111.65(c)(4) would require that you perform chemical, microbiological, or other testing, as necessary, to prevent the use of contaminated components, dietary ingredients, and dietary supplements. You should consider identifying those areas in the processing and production areas where chemical, microbial, or other forms of contamination are most likely to occur. Chemical, microbial, or other testing is necessary to identify areas where sanitation measures have not been adequate or where products may become adulterated.

Proposed § 111.65(c)(5) would require that you sterilize, pasteurize, freeze, refrigerate, control hydrogen-ion concentration (pH), control humidity, control water activity, or use any other effective means to remove, destroy, or prevent the growth of microorganisms and to prevent decomposition. The measures you decide to use to remove, destroy or prevent the growth of microorganisms on or in your components, dietary ingredients, or dietary supplements must be appropriate under the conditions of manufacture, handling, and distribution. Such measures are necessary to prevent their adulteration and misbranding. Microorganisms include pathogenic bacteria that, if present would adulterate the product. In addition, decomposition may result in a change in the component, dietary ingredient, or dietary supplement strength; the consequence of not using the appropriate measure may be that the dietary ingredient or dietary supplement no longer meets specifications, and thus, would be adulterated under section 402(g) of the act and misbranded under section 403 of the act. By including the phrase, "any other effective means," we provide you with discretion to decide which measures to use to destroy or prevent the growth of microorganisms and to prevent decomposition.

Proposed § 111.65(c)(6) would require that you hold components, dietary ingredients, and dietary supplements that can support the rapid growth of microorganisms of public health significance in a manner that prevents them from becoming adulterated.

Proposed § 111.65(c)(7) would require that you identify and hold any components, dietary ingredients, and dietary supplements, that require a material review and disposition decision, in a manner that protects the components, dietary ingredients, and dietary supplements against