

“sanitary concern” to the definition of microorganism. We added “sanitary” to clarify that we intend to include microorganisms of public health and sanitary concern. Although the term “sanitary” is not included in part 110, this change does not alter the generally recognized and scientific and legal meaning of the definition of “microorganism” in part 110, because part 110 is similarly concerned with sanitation. Under proposed § 111.3, *E. coli* O157:H7 would be a “microorganism” because it is a species that has public health significance. Other forms of *E. coli*, however, might not be of public health significance because not all forms of *E. coli* are pathogenic and present a public health risk. However, the presence of other forms of *E. coli* would be of sanitary concern.

One comment to the ANPRM objected to including viruses in a definition of “microorganisms” because it might imply that a manufacturer is able to demonstrate the absence of viral contamination in its dietary supplement.

We recognize that there are few effective virus detection methods and that the industry may be incapable of showing the presence or absence of specific viruses in its products. However, we have included viruses in the definition for “microorganisms” because animal tissues are used in the manufacture of dietary supplements, and the use of virus-containing tissue would adulterate the product. In order to ensure that animal tissue that may be used in or as a dietary ingredient does not contain viruses of public health significance, certain precautions may be needed to be taken in procuring and handling such tissue. We discuss in section III.A.4 of this document what precautions we are seeking comment on that manufacturers take to prevent the use of tissue that may contain viruses of public health significance for dietary ingredient or dietary supplement manufacture or to prevent the introduction of such viruses into a dietary ingredient or a dietary supplement.

Proposed § 111.3 defines “must” to indicate that you have to comply with a particular requirement. “Must” is the plain language term that replaces “shall.”

Proposed § 111.3 defines “pest” as “any objectionable insects or other animals including, but not limited to, birds, rodents, flies, mites, and larvae.” Proposed § 111.3 is similar to § 110.3(j), although the proposed definition would add “mites” to the list of pests. We added mites to the definition of “pest”

in this proposed rule because mites are capable of causing allergic reactions in persons who consume mite-contaminated foods (Ref. 44).

Proposed § 111.3 defines “physical plant” as “all or parts of a building or facility used for or in connection with manufacturing, packaging, or holding a dietary ingredient or a dietary supplement.” The proposed definition is similar to the definition of “plant” at § 110.3(k), except that we added the word “physical” before “plant” to distinguish between plants that are herbs, vegetables, and growing organisms, and buildings or facilities that are used in manufacturing, packaging, and holding a dietary ingredient or a dietary supplement. We also expanded the definition to cover the types of activities that would be subject to a CGMP rule for dietary ingredients and dietary supplements.

Proposed § 111.3 defines “quality control” as “a planned and systematic operation or procedure for preventing a dietary ingredient or dietary supplement from being adulterated.” A planned and systematic operation or procedure provides a framework of current and effective methods and procedures for each dietary ingredient or dietary supplement you manufacture that will prevent dietary ingredients and dietary supplements from being adulterated. We discuss quality control in more detail later in this document.

Proposed § 111.3 defines “quality control unit” as “any person or group that you designate to be responsible for quality control operations.” The quality control unit should consist of as many people as necessary to perform the quality control operations. Other provisions in this proposed rule address the quality control unit’s authority and responsibilities, and we discuss those provisions later in this document.

Proposed § 111.3 defines “representative sample” as “a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled.” By stating that the “sample accurately portrays the material being sampled,” we mean that it correctly represents and is typical of the material being sampled. It is important that the sample drawn accurately portrays the material being sampled because your analysis of the representative sample will be used to determine whether the material received is suitable for use in manufacturing or to determine that the dietary ingredient or dietary supplement is not adulterated and may be released for distribution. If the sample is not representative, you

risk using a contaminated component or dietary ingredient in manufacturing and you may distribute an adulterated dietary ingredient or dietary supplement.

Proposed § 111.3 defines “reprocessing” as:

\* \* \* using, in the manufacture of a dietary ingredient or a dietary supplement, clean, unadulterated components, dietary ingredients, or dietary supplements that have been previously removed from manufacturing for reasons other than insanitary conditions and that have been made suitable for use in the manufacture of a dietary ingredient or dietary supplement.

The phrase “for reasons other than insanitary conditions” means that the component, dietary ingredient, or dietary supplement was removed from manufacturing because the incorrect amount of a component was added or other reason not due to insanitary conditions. However, the component, dietary ingredient, or dietary supplement that was removed from manufacturing because it became contaminated because of insanitary conditions, that is, it became contaminated with a microorganism of public health concern or a microorganism of sanitary concern, must not be reprocessed.

Proposed § 111.3 defines “sanitize” as:

\* \* \* to adequately treat equipment containers, utensils, or any other dietary product contact surface by applying cumulative heat or chemicals on cleaned food contact surfaces that when evaluated for efficacy, yield a reduction of 5 logs, which is equal to 99.999 percent reduction, of representative disease microorganisms of public health significance and substantially reduce the numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

One comment to the ANPRM pointed out that the industry-drafted outline’s definition of sanitize differed from FDA’s *Food Code* definition of sanitization (Ref. 45).

The FDA “Food Code” is a reference that guides retail outlets, such as restaurants and grocery stores and institutions such as nursing homes in how to prevent foodborne illnesses from food that is consumed without further processing by the consumer. Because dietary supplements also are consumed without further processing by the consumer, the FDA “Food Code” definition also is appropriate for use in sanitizing contact surfaces used in the manufacture of dietary ingredients and dietary supplements. The FDA “Food Code” definition of sanitization is to apply cumulative heat or chemicals on