

task” (Ref. 54). Therefore, we consider the words “qualified” and “competent” in proposed § 111.13 and § 110.10(d), respectively, should be considered synonymous.

Another comment to the ANPRM questioned making supervisors responsible for ensuring compliance by all personnel with all CGMP requirements. The comment stated that absolute compliance with each and every CGMP requirement cannot be ensured, but that requiring a supervisor to be responsible may make the supervisor personally liable in the event of noncompliance.

Proposed § 111.13(a) would require that manufacturers assign responsibility to qualified supervisory personnel. Doing so will help ensure that the CGMPs are followed. In general, if the proposed rule is finalized, manufacturers, packagers, and holders would be responsible for complying with these CGMP requirements and for ensuring that they assign responsibility to qualified supervisors. We consider many factors when we take enforcement action, and so the facts surrounding a CGMP violation will influence the type of enforcement action we take. The manufacturer is responsible under § 111.13(a) for ensuring that qualified supervisory personnel are assigned to oversee the implementation of these CGMPs.

C. Physical Plant (Proposed Subpart C)

Proposed subpart C consists of provisions intended to help prevent contamination from your physical plant. These provisions are similar to the food CGMP requirements found in §§ 110.20, 110.35, and 110.37 which pertain to buildings and facilities.

We have not proposed requirements similar to the food CGMP requirements found in § 110.20(a) for keeping the grounds bordering your physical plant in a condition that protects against contamination of components, dietary ingredients, or dietary supplements. In order to limit the burden to manufacturers, FDA is not proposing such requirements. However, we invite comment on whether such requirements should be included in a final rule. Section § 110.20(a), identifies several methods necessary for adequate ground maintenance, such as:

- Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of your physical plant so that it does not attract pests, harbor pests, or be used by pests for breeding;
- Maintaining roads, yards, and parking lots so that they do not

constitute a source of contamination in areas where food is exposed;

- Adequately draining areas that may contribute to the contamination to food by seepage, filth, other extraneous materials, or by providing a breeding place for pests; and

- Adequately operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

For example, rodents, insects, and other pests may be attracted to garbage, and if you do not take adequate steps to remove or dispose of garbage, you may be risking contamination from those rodents, insects, or other pests. Rodents, insects, and other pests are sources of feces, hair, and other potential contaminants (Refs. 55 and 56). We invite comment on whether we should require, in a final rule, that you take these steps and/or other steps to protect against contamination.

1. What Sanitation Requirements Apply to Your Physical Plant? (Proposed § 111.15)

Proposed § 111.15(a), like § 110.35(a), would require that you keep your physical plant in a clean and sanitary condition and in sufficient repair to prevent contamination of components, dietary ingredients, dietary supplements, or contact surfaces. For example, holes in your physical plant's walls or windows could allow pests or contaminants to enter, so proposed § 111.15(a) would require that you repair those holes.

Proposed § 111.15(b) pertains to cleaning compounds, sanitizing agents, and pesticides you use. The proposal is similar to § 110.35(b) and, in essence, would require that you use cleaning compounds and sanitizing agents that are free from microorganisms of public health significance and are safe and adequate under the conditions of use. By saying that the cleaning compounds and sanitizing agents should be “free from microorganisms,” we mean that your use of those cleaning compounds and sanitizing agents should not contaminate your components, dietary ingredients, dietary supplements, or contact surfaces with microorganisms. We are proposing this requirement because microorganisms, if present in your cleaning compounds or sanitizing agents, can contaminate your contact surfaces or deactivate the sanitizing agent and, as a result, adulterate your components, dietary ingredients, dietary supplements, or contact surfaces. We advise that you should verify that cleaning compounds and sanitizing agents are free from contamination by

microorganisms of public health significance and are safe and adequate under their conditions of use. Such verification may include buying these substances under a supplier's guarantee or certification or you may examine them for contamination.

Several comments on the industry outline published in the ANPRM objected to the idea that compliance “may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination.” The comments stated that such language is unnecessary and may be interpreted as too restrictive and that manufacturers should be able to determine the appropriate means of assuring compliance.

We agree with the comments that you may determine the appropriate means of assuring compliance with this regulation. The proposed rule would not require that you follow any particular method for assuring compliance; instead, the proposal would give you the flexibility to decide how to ensure that your cleaning compounds and sanitizing agents are free from contamination and are safe and adequate under the conditions of use.

Proposed § 111.15(b)(2) would require that you not use or hold toxic materials in a physical plant in which contact surfaces, components, dietary ingredients or dietary supplements are manufactured or exposed, unless those toxic materials are necessary:

- To maintain clean and sanitary conditions,
- For use in laboratory testing procedures,
- For maintaining or operating the physical plant or equipment, or
- For use in the physical plant's operations.

If at least one of the listed conditions is not met, you must not use or hold the toxic material because there would be no reason to risk contamination from exposure to such material if it is not necessary to your operations.

Proposed § 111.15(b)(3) would require that you identify and hold toxic cleaning compounds, sanitizing agents, pesticides, and pesticide chemicals in a manner that protects against contamination of components, dietary ingredients, dietary supplements, and contact surfaces. You must take steps to store your toxic materials in a way that prevents them from contaminating your dietary ingredients and dietary supplements. If such products were stored in manufacturing areas or where dietary ingredients or dietary