

901:3-17-02

**Amended definitions.**

As adopted in rule 901:3-17-01 of the Administrative Code, where ever used in 21 C.F.R. part 117, the following definitions are modified as follows:

(A) The definitions found in 21 C.F.R. 117.3 are amended as follows:

(1) "Audit" means "the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a food suppliers' food safety processes and procedures.

(2) "Facility" means a food processing establishment as defined in section 3715.021 of the Ohio Revised Code.

(3) "Food" means:

(a) Articles used for food or drink for humans or animals;

(b) Chewing gum; or

(c) Articles used for components of any such articles.

(4) "Lot" means

(B) The following terms found in 21 C.F.R. 117 are hereby replaced as indicated:

(1) "Establishment", with the exception of the term "retail food establishment," shall be read as "facility."

(2) "FDA" shall be read as "Ohio department of agriculture."

(3) "Section 402 of the Federal Food, Drug, and Cosmetic Act" shall be read as "section 3715.59 of the Ohio Revised Code."

(4) "Section 403(w) of the Federal Food, Drug, and Cosmetic Act" shall be read as "section 3715.60 of the Ohio Revised Code."

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under: 119.03  
Statutory Authority: 3715.02, 3715.021  
Rule Amplifies: 3715.59, 3715.60, 3715.62