

**\*\*\*DRAFT - NOT FOR FILING\*\*\***

**901:3-1-01**      **Incorporation by reference.**

The federal food safety regulations housed in Title 21 of the Code of Federal Regulations part 117 (2017) are adopted in their entirety with the exception of those provisions amended or deleted by this chapter.

All food processing establishments as defined in section 3715.021 of the Revised Code, including processors of intoxicating beverages, shall comply with the rules of this chapter to determine that food has been manufactured under such conditions that render the food safe, unadulterated, and not misbranded.

**901:3-1-02**      **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.

(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."

**901:3-1-03**      **Deleted regulations.**

Pursuant to rule 901:3-17-01 of the Administrative Code, following sections of the 21 C.F.R. 117 are deleted in their entirety and shall not become rules of the Ohio department of agriculture:

(A) 21 C.F.R. 117.1

(B) 21 C.F.R. 117.251

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[\(C\) 21 C.F.R. 117.254](#)

[\(D\) 21 C.F.R. 117.257](#)

[\(E\) 21 C.F.R. 117.260](#)

[\(F\) 21 C.F.R. 117.264](#)

[\(G\) 21 C.F.R. 117.267](#)

[\(H\) 21 C.F.R. 117.270](#)

[\(I\) 21 C.F.R. 117.274](#)

[\(J\) 21 C.F.R. 117.277](#)

[\(K\) 21 C.F.R. 117.280](#)

[\(L\) 21 C.F.R. 117.284](#)

[\(M\) 21 C.F.R. 117.287](#)

**901:3-1-04**      **Modifications.**

Pursuant to rule 901:3-17-01 of the Administrative Code, the following sections of the 21 C.F.R. 117 are amended to read as follows:

(A) 21 C.F.R. 117.320 delete existing language and insert:

"All records required by this part must be made promptly available to a duly authorized representative of the director of the Ohio department of agriculture for official review and copying upon oral or written request."

(B) 21 C.F.R. 117.325 delete existing language and insert:

"Records obtained by the Ohio department of agriculture in accordance with this part are subject to disclosure pursuant to chapter 149 of the Ohio Revised Code."

(C) 21C.F.R. 117.5(a) delete existing language and insert:

"Subparts C and G of this part do not apply to a qualified facility unless the FDA has withdrawn the qualified facility exemption. Qualified facilities are subject to the modified requirements in 21 C.F.R. part 117.201."