ADMINISTRATIVE CODE

CHAPTER 420-3-16-A
APPENDICES

420-3-16-AS **Appendix S - Aseptic Processing and Packaging Program and Retort Processed After Packaging Program.**

The Aseptic Processing and Packaging Program is designed to include all Grade "A" low-acid (21 CFR Part 113) aseptically processed and packaged milk and/or milk products.

The Retort Processed after Packaging Program is designed to include all Grade "A" low-acid (21 CFR Part 113) retort processed after packaged milk and/or milk products.

Note: Retort processed after packaging low-acid milk and/or milk products as addressed in the definition of Milk Products of these rules shall be considered to be Grade "A" milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in the definition of milk products of these rules or if they are labeled as Grade "A" as described in Section 4 of these rules.

Inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products shall be conducted by the Health Officer in accordance with these rules and the information provided below at least once every six (6) months. The milk plant's APPS or RPPS, respectively, as defined by these rules, shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of these rules and shall comply with the applicable portions of 21 CFR Parts 108, 110, and 113. The milk plant's APPS and/or RPPS, respectively, shall be inspected by the FDA, or the State Health Officer when designated by the FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110, and 113 at a frequency determined by FDA.

When the APPS, as defined by these rules, is utilized to produce aseptically processed and packaged low-acid milk and/or milk products and pasteurized and/or ultra-pasteurized milk and/or milk products, the APPS shall be inspected and tested by the Health Officer in accordance with the requirements cited in Section 7 of these rules.

ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CFR/*GRADE "A" PMO* COMPARISON SUMMARY REFERENCE

PMO, Section 7 Items	**Aseptic Program/ Retort Program**	**Authority**
1p. Floors - Construction	Floor drains are not required in storage rooms for aseptic processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products.	PMO
2p. Walls and Ceiling - Construction	Ceiling requirements are exempt in aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products dry storage rooms. (Same as for dry milk or milk products.)	PMO
3p. Doors and Windows	None	PMO
4p. Lighting and	None	PMO
5p. Separate Rooms	Fabrication of containers and closures for aseptic processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or milk products within the APPS and/or RPPS, respectively, is exempt.	PMO
6p. Toilet - Sewage Disposal	None	PMO
7p. Water Supply*		PMO/CFR

	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	
8p. Handwashing Facilities	None	PMO
9p. Milk Plant Cleanliness	None	PMO
10p. Sanitary Piping*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
11p. Construction and Repair of Containers and Equipment*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR. Paper, plastics, foil, adhesives, and other components of containers and closures used in the packaging of milk and/or milk products that have been aseptically processed and packaged or retort processed after packaged are not required to comply with Appendix J of the PMO; are not required to originate from an IMS Listed Source; and are subject to the requirements of the CFR.	PMO/CFR
12p. Cleaning and Sanitizing of Containers and Equipment*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
13p. Storage of Cleaned Containers and Equipment*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
14p. Storage of Single-Service Containers, Utensils, and Materials	None	PMO
	The APPS and/or RPPS, respectively, is	PMO/CFR

15p.(A) Protection from Contamination*	exempt, but shall comply with the CFR.	
15p.(B) Protection from Contamination - Cross Connections*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR. APPS and/or RPPS equipment is exempt from the separation requirements of the PMO in relationship to instrumented steam blocks between milk and milk products and cleaning and/or chemical sanitizing solutions.	PMO/CFR
16p. Pasteurization and Aseptic Processing and Packaging (A) through (D)*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR. The Health Officer is not required to conduct the quarterly equipment testing and sealing of aseptic and/or processing equipment. Records and recording charts are not required to be reviewed during routine inspections, ratings or check ratings.	CFR
17p. Cooling of Milk and Milk Products*	The APPS and/or RPPS, respectively; aseptic processed and packaged low-acid milk and/or milk product storage; and retort processed after packed low-acid milk and/or milk product storage is exempt, but shall comply with the CFR.	PMO/CFR
18p. Bottling, Packaging, and	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	CFR
		CFR

19p. Capping, Container Closure, and Sealing and Dry Milk Product Storage*	The APPS and/or RPPS, respectively, is exempt, but shall comply with the CFR.	
20p. Personnel-Cleanliness	None	PMO
21p. Vehicles	None	PMO
22p. Surroundings	None	PMO

***Note**: In areas of the milk plant where these items are dedicated only to the APPS and/or RPPS, respectively, as defined by these rules, these Items shall be inspected and regulated in accordance with the applicable FDA regulations (21 CFR Parts 108, 110, and 113).

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