

Compliance Dates for Preventive Controls Rule for Human Food (Part 117)

Business Type	Compliance Dates				
	Subpart A-F Requirements for:		Subpart C Unique Requirements for:	Subpart G Requirements for:	
	Facilities engaged in processing activities	Facilities that: –Are solely engaged in packing and/or holding produce RACs and/or nut hulls and shells –Color RACs but would otherwise qualify as a farm –Would qualify as secondary activities farms except for ownership of the facility*	Annual written assurance from customer or subsequent entity that microbial hazards are being controlled ‡	Supply-Chain Program Receiving facilities with suppliers that are:	
Qualified Facilities* (including very small businesses ‡)	Sept 17, 2018	January 27, 2020	Not applicable	Not applicable	Not applicable
Initial attestations submitted to FDA by:	Dec 17, 2018				
Small business**	Sept 18, 2017	January 28, 2019	Sept 18, 2019	not subject to the PC or PS Rule	Sept 18, 2017
				subject to the PC or PS Rule	Sept 18, 2017 or 6 mos. after their supplier is required to comply with applicable rule, whichever is later.
All other businesses	Sept 19, 2016	January 26, 2018	Sept 19, 2018	not subject to the PC or PS Rule	March 17, 2017
				subject to the PC or PS Rule	6 mos. after their supplier is required to comply with the applicable rule.

*Qualified Facilities must retain records to support Qualified Facility status beginning January 1, 2016;

Definition of a qualified facility – a facility that is a very small business as defined in this part, or a facility to which both of the following apply: 1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and 2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was < \$500,000, adjusted for inflation.

‡ Definition of a very small business – a business (including any subsidiaries and affiliates) averaging < \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

** Definition of a small business – a business employing fewer than 500 full-time equivalent employees.

‡‡ See § 117.136 for more details concerning requirements for annual written assurances.

* A variety of business structures that may satisfy FDA's intention to require a close relationship regarding ownership of the primary and secondary activities farms but the business structures do not meet the ownership requirement as codified in the "farm" definition i.e., majority owned by the primary production farm.