



**THE FOOD SAFETY MODERNIZATION ACT (FSMA) FINAL RULES & USEFUL GUIDANCE**

Final Rule Name	Issuance Date	Compliance / Effective Date	Notes & Comments	Extensions / Additional Notices																								
Information Required in Prior Notice of Imported Food  <a href="#">78 Fed. Reg. 32359</a>	May 30, 2013	May 30, 2013																										
Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements  <a href="#">79 Fed. Reg. 18799</a>	April 4, 2014	April 4, 2014																										
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for <b>Human</b> Food (HARPC)  <a href="#">80 Fed. Reg. 55908</a>	September 17, 2015	<table border="1"> <thead> <tr> <th>Business Size</th> <th>PC compliance date</th> </tr> </thead> <tbody> <tr> <td>All other business</td> <td>1 year</td> </tr> <tr> <td>Small business</td> <td>2 years</td> </tr> <tr> <td>Very small business</td> <td>3 years</td> </tr> <tr> <td>Businesses subject to the Pasteurized Milk Ordinance (PMO)</td> <td>3 years</td> </tr> </tbody> </table>	Business Size	PC compliance date	All other business	1 year	Small business	2 years	Very small business	3 years	Businesses subject to the Pasteurized Milk Ordinance (PMO)	3 years	<table border="1"> <thead> <tr> <th colspan="2">Definitions</th> </tr> </thead> <tbody> <tr> <td>All other businesses</td> <td>Businesses other than small and very small businesses</td> </tr> <tr> <td>Small business</td> <td>A business with fewer than 500 full-time equivalent employees.</td> </tr> <tr> <td>Very small business</td> <td>A business averaging less than \$1 million per year in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale.</td> </tr> </tbody> </table>	Definitions		All other businesses	Businesses other than small and very small businesses	Small business	A business with fewer than 500 full-time equivalent employees.	Very small business	A business averaging less than \$1 million per year in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale.	<p><u>Extensions:</u></p> <ul style="list-style-type: none"> <li>Extension for certain provisions concerning written customer assurances – §§ 117.136(a)(2)(ii), (3)(ii), and (4)(ii). <a href="#">81 Fed. Reg. 57784 (Aug. 24, 2016)</a>.</li> </ul> <p>Written “customer assurance” provisions occur when food safety controls are applied downstream and certain conditions are satisfied. For example, customer provisions may allow a manufacturer/processor that does not control a hazard requiring a preventive control to rely on its customer to control the hazard. The manufacturer/processor must disclose in documents accompanying the food that it is not processed to control the hazard and must obtain a written assurance from the customer that the customer will manufacture the food in accordance with applicable food safety requirements or sell only to someone that agrees to do so. This notice provides entities with the following extensions:</p> <table border="1"> <thead> <tr> <th>Business Size</th> <th>PC compliance date</th> </tr> </thead> <tbody> <tr> <td>All other business</td> <td>Sept. 19, 2018</td> </tr> <tr> <td>Small business</td> <td>Sept. 18, 2019</td> </tr> </tbody> </table>	Business Size	PC compliance date	All other business	Sept. 19, 2018	Small business	Sept. 18, 2019
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Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for <b>Animals</b> (HARPC)  <a href="#">80 Fed. Reg. 56170</a>	September 17, 2015	<table border="1"> <thead> <tr> <th data-bbox="823 1326 1038 1356">Business Size</th> <th data-bbox="1038 1326 1302 1393">cGMP compliance date</th> <th data-bbox="1302 1326 1526 1393">PC compliance date</th> </tr> </thead> <tbody> <tr> <td data-bbox="823 1393 1038 1459">All other business</td> <td data-bbox="1038 1393 1302 1459">1 year</td> <td data-bbox="1302 1393 1526 1459">2 years</td> </tr> <tr> <td data-bbox="823 1459 1038 1493">Small business</td> <td data-bbox="1038 1459 1302 1493">2 years</td> <td data-bbox="1302 1459 1526 1493">3 years</td> </tr> <tr> <td data-bbox="823 1493 1038 1560">Very small business</td> <td data-bbox="1038 1493 1302 1560">3 years</td> <td data-bbox="1302 1493 1526 1560">4 years</td> </tr> </tbody> </table>		Business Size	cGMP compliance date	PC compliance date	All other business	1 year	2 years	Small business	2 years	3 years	Very small business	3 years	4 years	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="1619 1342 2271 1372">Definitions</th> </tr> </thead> <tbody> <tr> <td data-bbox="1619 1407 1827 1469">All other businesses</td> <td data-bbox="1827 1407 2271 1469">Businesses other than small and very small businesses</td> </tr> <tr> <td data-bbox="1619 1469 1827 1536">Small business</td> <td data-bbox="1827 1469 2271 1536">A business employing fewer than 500 full-time equivalent employees</td> </tr> <tr> <td data-bbox="1619 1536 1827 1766">Very small business</td> <td data-bbox="1827 1536 2271 1766">A business averaging less than \$2,500,000 per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale.</td> </tr> </tbody> </table>	Definitions		All other businesses	Businesses other than small and very small businesses	Small business	A business employing fewer than 500 full-time equivalent employees	Very small business	A business averaging less than \$2,500,000 per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale.	<p><u>Extensions:</u></p> <ul style="list-style-type: none"> <li>Extension for certain provisions concerning written customer assurances – §§ 507.36(a)(2)(ii), (3)(ii), and (4)(ii). <a href="#">81 Fed. Reg. 57784 (Aug. 24, 2016)</a>.</li> </ul> <table border="1"> <thead> <tr> <th data-bbox="2309 1266 2613 1296">Business Size</th> <th data-bbox="2613 1266 2915 1296">PC compliance date</th> </tr> </thead> <tbody> <tr> <td data-bbox="2309 1296 2613 1330">All other business</td> <td data-bbox="2613 1296 2915 1330">Sept. 18, 2019</td> </tr> <tr> <td data-bbox="2309 1330 2613 1364">Small business</td> <td data-bbox="2613 1330 2915 1364">Sept. 17, 2020</td> </tr> </tbody> </table> <ul style="list-style-type: none"> <li>Extension for facilities that only pack and/or hold raw agricultural commodities that are produce and/or nut hulls and shells. The earliest compliance date is January 26, 2018.</li> <li>Extension for off-farm facilities solely engaged in cotton ginning that provide products (for example, cotton seed and lint) without further processing for use as animal food now have an additional 16 months to comply with applicable requirements in the CGMP and Preventive Controls for Animal Food rule. The earliest compliance date is January 28, 2019.</li> </ul>	Business Size	PC compliance date	All other business	Sept. 18, 2019	Small business	Sept. 17, 2020
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Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule)	November 27, 2015	<table border="1"> <thead> <tr> <th>Business Size</th> <th>Compliance date</th> </tr> </thead> <tbody> <tr> <td>All other farms</td> <td>2 year</td> </tr> <tr> <td>Small business</td> <td>3 years</td> </tr> <tr> <td>Very small business</td> <td>4 years</td> </tr> </tbody> </table> <p>The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions,</p> <p>Additional 2 years from applicable date above</p>	Business Size	Compliance date	All other farms	2 year	Small business	3 years	Very small business	4 years	<table border="1"> <thead> <tr> <th colspan="2">Definitions</th> </tr> </thead> <tbody> <tr> <td>All other farms</td> <td>All other farms</td> </tr> <tr> <td>Small business</td> <td>Businesses with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous 3 year period</td> </tr> <tr> <td>Very small business</td> <td>Businesses with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous 3 year period</td> </tr> </tbody> </table>	Definitions		All other farms	All other farms	Small business	Businesses with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous 3 year period	Very small business	Businesses with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous 3 year period	<p><u>Exemptions:</u></p> <ul style="list-style-type: none"> <li>• Produce that is not a raw agricultural commodity (RAC)</li> <li>• Produce commodities identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts</li> <li>• Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed)</li> <li>• Produce used for personal or on-farm consumption</li> <li>• Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less</li> <li>• Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions</li> <li>• Qualified exemption and modified requirements for certain farms</li> </ul> <p><u>Extensions:</u></p> <ul style="list-style-type: none"> <li>• Extension for operations that would be secondary activities farms except that they do not meet the ownership criterion in the definition of a secondary activities farm. The extension is applicable only to operations satisfying all of the following requirements: (1) the operation is not located on a primary production farm; (2) the</li> </ul>	
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				<p>operation is devoted to harvesting, packing, and/or holding of raw agricultural commodities; and (3) the operation is under common ownership with the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested packed, and/or held by the operation. The earliest compliance date is January 26, 2018.</p> <ul style="list-style-type: none"> <li>Extension for certain provisions concerning written customer assurances – §§ 112.2(b)(3). <a href="#">81 Fed. Reg. 57784 (Aug. 24, 2016)</a>.</li> </ul> <table border="1" data-bbox="2303 802 2915 939"> <thead> <tr> <th>Business Size</th> <th>PC compliance date</th> </tr> </thead> <tbody> <tr> <td>All other business</td> <td>Jan. 28, 2019</td> </tr> <tr> <td>Small business</td> <td>Jan. 27, 2020</td> </tr> <tr> <td>Very small business</td> <td>Jan. 26, 2021</td> </tr> </tbody> </table>	Business Size	PC compliance date	All other business	Jan. 28, 2019	Small business	Jan. 27, 2020	Very small business	Jan. 26, 2021
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<p>Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP)</p> <p><a href="#">80 Fed. Reg. 74226</a></p>	<p>November 27, 2015</p>	<p>The date by which importers must comply with the FSVP regulations is the latest of the following dates:</p> <ul style="list-style-type: none"> <li>18 months after publication of the final rule;</li> <li>For the importation of food from a supplier that is subject to the HARPC or produce safety rules, 6 months after the foreign supplier is required to meet the relevant regulations;</li> <li>For an importer that is itself a manufacturer or processor subject to the supply-chain program provisions in the HARPC regulations, the date by which it has to comply with those provisions.</li> </ul>	<p>Additional information regarding compliance dates:</p> <ul style="list-style-type: none"> <li><a href="#">Compliance Dates for the Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals</a> (August 23, 2016)</li> </ul>	<p><u>Extensions:</u></p> <ul style="list-style-type: none"> <li>Extension for Importers Subject to FSVP for Food Contact Substances. <a href="#">81 Fed. Reg. 57784 (Aug. 24, 2016)</a>.</li> </ul> <p>Importers subject to the FSVP rule have an additional 2 years to meet the requirements for the importation of <b>food contact substances (FCS)</b>. The earliest compliance date is May 28, 2019</p> <ul style="list-style-type: none"> <li>Extension for certain provisions concerning written customer assurances – § 1.507(a)(2)(ii), (3)(ii), and (4)(ii). <a href="#">81 Fed. Reg. 57784 (Aug. 24, 2016)</a>.</li> </ul> <p>The compliance dates for these requirements for FSVP are May 28, 2019 <b>or</b> 30 months after previously announced compliance date for the relevant regulations, whichever is later.</p>								
<p>Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits</p>	<p>November 27, 2015</p>	<p>FDA intends to implement this program as soon as possible after publication of the final Model Accreditation Standards guidance, and the final user fee rule, both of which will be published separately.</p>										



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and To Issue Certifications <a href="#">80 Fed. Reg. 74570</a>		Accreditation bodies could begin to apply for recognition when the program goes into effect, and third-party certification bodies could seek accreditation after one or more FDA-recognized accreditation bodies begin accepting applications																		
Sanitary Transportation of Human and Animal Food <a href="#">81 Fed. Reg. 20092</a>	April 6, 2016	<table border="1"> <thead> <tr> <th>Business Size</th> <th>Compliance date</th> </tr> </thead> <tbody> <tr> <td>All other businesses</td> <td>April 6, 2017</td> </tr> <tr> <td>Small business</td> <td>April 6, 2018</td> </tr> </tbody> </table>	Business Size	Compliance date	All other businesses	April 6, 2017	Small business	April 6, 2018	<table border="1"> <thead> <tr> <th colspan="2">Definitions</th> </tr> </thead> <tbody> <tr> <td>All other businesses</td> <td>All other businesses</td> </tr> <tr> <td>Small business</td> <td>Businesses other than motor carriers who are not also shippers and/or receivers employing fewer than 500 persons and motor carriers having less than \$27.5 million in annual receipts</td> </tr> </tbody> </table>	Definitions		All other businesses	All other businesses	Small business	Businesses other than motor carriers who are not also shippers and/or receivers employing fewer than 500 persons and motor carriers having less than \$27.5 million in annual receipts	<u>Exemptions:</u> <ul style="list-style-type: none"> <li>• Shippers, receivers, or carriers engaged in food transportation operations that have less than \$500,000 in average annual revenue</li> <li>• Transportation activities performed by a farm</li> <li>• Transportation of food that is transshipped through the U.S. to another country</li> <li>• Transportation of food that is imported for future export and that is neither consumed or distributed in the U.S.</li> <li>• Transportation of compressed food gases (<i>e.g.</i>, carbon dioxide, nitrogen or oxygen authorized for use in food and beverage products), and FCS</li> <li>• Transportation of human food byproducts transported for use as animal food without further processing</li> <li>• Transportation of food that is completely enclosed by a container except a food that requires temperature control for safety</li> <li>• Transportation of live food animals, except molluscan shellfish</li> </ul>				
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