



Comparison of FSMA Produce Safety Rule with CanadaGAP Program Requirements

This summary is intended to provide an overview of requirements of the Food Safety Modernization Act (FSMA) *Final Rule on Produce Safety*, in comparison with CanadaGAP program requirements. The focus of the overview is on significant differences. It is NOT intended to identify all the differences between CanadaGAP requirements and the FSMA Produce Safety Rule, but it is intended to **highlight additional items** that CanadaGAP-certified companies exporting to the U.S. may need to implement.

This summary is not intended to provide a full explanation of the Produce Safety Rule. The Rule is the final authority and readers should not rely solely on this summary information. All references below to sub-parts, sections, etc. are to the FSMA *Final Rule on Produce Safety*, published by FDA at: <http://www.fda.gov/fsma>. For more information about FSMA, and instructions to get a copy of the Rule, see the last page of this summary. It is also important to check the implementation timelines for FSMA. Consult the resource materials provided by CanadaGAP including a chart that shows when various FSMA provisions come into force.

While the CanadaGAP program applies a prescriptive approach to implementing a food safety program, the FSMA does not always provide this level of guidance. In some cases, the Produce Safety Rule will explain the requirements, but it does not necessarily explain how to meet the standard. The Rules provide you a degree of flexibility to do what is appropriate in the context of your operations.

Many of the words and phrases as defined in the CanadaGAP Glossary are also used in the Produce Safety Rule. However, in the FSMA context, the same words can have significantly different implications. It is recommended that those seeking compliance with the Produce Safety Rule are familiar with both CanadaGAP and FSMA definitions. The Produce Safety Rule definitions can be referenced in Subpart A – General Provisions, Section 112.3. The CanadaGAP definitions can be referenced in the Glossary of the CanadaGAP manuals.

While there may be exemptions, the Produce Safety Rule generally could apply to producers, packers or storage facilities who export produce to the U.S. This summary does not discuss possible exemptions or timelines for implementation. Refer to Subpart A – General Provisions, Section 112.1 for an explanation of food covered by the Rule, and Section 112.4 for an explanation of operations that are subject to the Rule. In August of 2016, the FDA produced a “Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities - Docket Number: FDA-2016-D-2373”. This guidance may be useful in determining if you are subject to the Produce Safety Rule. This document is located on the FDA website under the ‘Guidance Documents’ box and by clicking on ‘Searchable list of FSMA related Guidances’. Scroll down the page and the document can be found under the ‘Guidance for Industry and Others’ section. Note that some Canadian produce operations may instead be subject to the Preventive Controls Rule under FSMA, or **may qualify for modified requirements under the Foreign Supply Verification Program**.

CanadaGAP Section	FSMA Produce Safety Rule Requirement Additional to CanadaGAP	References
Record-Keeping (General Requirement)	<p>Records are to be dated and signed or initialed by the person who performed the activity.</p> <p>If using electronic records and signatures or initials are required, a bona fide electronic signature is required. If hand written records are used, the records must be permanent (i.e., written in ink, pencil cannot be used).</p>	<p>Subpart O Records, 112.161</p> <p>Electronic Records http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSe arch.cfm?CFRPart=11</p>
4. Manure, Compost/Compost Tea and Other By-Products	<p>Water used to make compost tea must be potable.</p>	<p>Subpart F - Biological Soil Amendments of Animal Origin and Human Waste, Section 112.51 (a)</p>
7. Agricultural Water	<p><i>Important note: U.S. FDA is reviewing the water requirements as currently set out in the Produce Safety Rule, and changes may be made before the requirements come into force.</i></p> <p>The Produce Safety Rule requirements relating to agricultural water do not apply if the water does not contact the produce or food contact surfaces.</p> <p><u>Each</u> water source must be inspected at least once annually at the beginning of each growing season and the results of the inspections must be documented. If you use CanadaGAP Appendix K to document the inspection, some modifications would be required to align with FSMA requirements. Inspections must consider the following:</p> <ol style="list-style-type: none"> 1. The nature of each agricultural water source (for example, ground water or surface water); 2. The extent of your control over each agricultural water source; 3. The degree of protection of each agricultural water source; 4. Use of adjacent and nearby land; and 5. The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your farm. <p>Testing is not required if the water is from a public water supply, and you have on file the annual test results or certificates of compliance from the public supplier that demonstrate that the supplied water is potable.</p>	<p>Subpart E – Agricultural Water, Section 112.4 (a) for inspection requirements.</p> <p>Section 112.46 for when testing is not required.</p> <p>Section 112.45 (b) for details of recognized</p>

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	<p>Agricultural water in direct contact with produce during the growing process must meet minimal water quality thresholds. To demonstrate that the water meets these thresholds, a series of water test results is required. The thresholds are assessed using both a Geometric Mean (GM) and Statistical Threshold Value (STV). The GM threshold is 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water. The STV threshold is 410 or less CFU of generic E. coli per 100 mL of water.</p> <p>For untreated surface water: To establish the baseline GM and STV, a minimum of 20 samples must be taken over a minimum period of 2 years, but not greater than 4 years. After the baseline testing has been completed, 5 annual tests are required.</p> <p>For untreated ground water: To establish the baseline GM and STV, 4 samples are required to be taken during the growing season in the first year. After the first year, one annual test is required.</p> <p>After baseline values have been established, test results from new annual testing are used to recalculate the GM and STV. If the recalculated values fall below established thresholds, the baseline testing frequency is triggered to reestablish baseline values.</p>	<p>corrective actions and timelines for implementation, which must be pursued if the water quality falls below the minimum threshold values.</p> <p>Section 112.46 for detail on frequency of testing requirements.</p> <p>Section 112.44 (b) for details on GM & STV.</p>
8. Equipment	<p>If you harvest, pack or store produce that meets the Produce Safety Rule and produce that does not, food contact equipment (both production site and building) must be cleaned between changes in commodities. For example, a packer packs for two producers. Producer A is in compliance with the Produce Safety Rule and Producer B is not. All food contact surfaces would need to be cleaned between the packing of Producer A's product and Producer B's product. Records of the cleaning would need to be kept.</p>	<p>Subpart K—Growing, Harvesting, Packing, and Holding Activities 112.111 (a) & (b).</p>
11. Personal Hygiene Facilities	<p>CanadaGAP hand washing options which include the use of a hand sanitizer and/or hand wipes are not acceptable under the Produce Safety Rule. The Rule only recognizes hand washing that includes the use of soap (or other effective surfactant), running potable water and a method to dry hands thoroughly, including air hand dryers (which are not permitted for CanadaGAP certification).</p> <p>Hand washing facilities must be located in close proximity to toilets to make it practical for persons who use the toilet to wash their hands. CanadaGAP is more concerned with hand washing facilities being located close to product handling areas.</p>	<p>Subpart D – Health and Hygiene, Section 112.32 (b) (3) and Subpart L - Equipment, Tools, Buildings, and Sanitation, Section 112.129 (c).</p> <p>112.130 for required location.</p>

<i>CanadaGAP Section</i>	<i>FSMA Produce Safety Rule Requirement Additional to CanadaGAP</i>	<i>References</i>
12. Employee Training	<p>At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration. This training is additional to CanadaGAP training requirements.</p> <p>A record must be kept to identify all employees who train or supervise other employees. You must establish and keep records for all required food safety related training of employees. This includes keeping records of the training of employees who:</p> <ul style="list-style-type: none"> • Train or supervise other employees. • Clean equipment or packaging materials [training on Sanitation Standard Operating Procedures (SSOPs)]. • Monitor activities and/or equipment such as water treatment systems or temperature controls. • Calibrate equipment. <p>CanadaGAP Form C, which covers employee training for production site employees, does not address employee jewellery. The Produce Safety Rule applies to production site employees and states that hand jewellery must be removed or covered.</p>	<p>Subpart C— Personnel Qualifications and Training, Section 112.22 (c) for standardized training requirement.</p> <p>112.23 for supervisors.</p> <p>112.30 for recordkeeping requirements.</p> <p>Subpart D – Health and Hygiene, Section 112.32 (5) for jewelry.</p>
13. Visitor Policy	<p>While CanadaGAP considers only visitors entering controlled access areas, visitor requirements in the Produce Safety Rule apply to all visitors who enter the operation with your permission. You will therefore need to keep records of the training of all persons who enter your operation with your permission.</p>	<p>Subpart C— Personnel Qualifications and Training, Section 112.22 (a) (2)</p>
15. Water (for Fluming and Cleaning)	<p>The Produce Safety Rule definition for Agricultural Water includes virtually all CanadaGAP definitions for water. In the context of the Produce Safety Rule, Agricultural Water is defined as any water that is intended to, or is likely to, contact produce covered by the Rule, or food contact surfaces. This includes water used in growing activities AND in harvesting, packing, and holding activities.</p> <p>Both CanadaGAP and the Produce Safety Rule require the use of potable water for post-harvest activities where the water contacts produce or equipment.</p> <p>The Produce Safety Rule requires that each water source is inspected at least once annually at the beginning of each growing season and that the results of the inspections are documented. If you used CanadaGAP Form F. Water (for Fluming and Cleaning)</p>	<p>Subpart E – Agricultural Water, Section 112.44 (a) or water quality standard.</p>

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	<p>Assessment to document the inspection, some modifications would be required to align with FSMA requirements. Inspections must consider the following:</p> <ol style="list-style-type: none"> 1. The nature of each agricultural water source (for example, ground water or surface water); 2. The extent of your control over each agricultural water source; 3. The degree of protection of each agricultural water source; 4. Use of adjacent and nearby land; and 5. The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your farm. <p>Testing is not required if the water is from a public water supply, and you have on file the annual test results or certificates of compliance from the public supplier that demonstrate that the supplied water is potable. This can be a lower standard than CanadaGAP, where depending on the use of the water, the testing of municipal water is required. For example, CanadaGAP requires that Final Rinse Water must be tested, regardless of the source or water treatment, as contamination could be introduced from your final rinse equipment.</p> <p>If you use untreated ground water, the Produce Safety Rule requires that you must initially test the water at least four times in the first year to demonstrate that the water quality is reliable. Thereafter, only one test per year is required. However, if a single test fails, you must resume testing at least four times per year. CanadaGAP requires two annual water tests, whether or not the ground water is treated.</p> <p>Both CanadaGAP and the Produce Safety Rule require that all surface water is treated before it can be used for fluming and cleaning. Two annual water tests are required by CanadaGAP to confirm that the water treatment is effective in maintaining potability. CanadaGAP requires that the water tests are taken after the operation's start date, to ensure that the test is taken during the current year.</p> <p>For recirculated water, you must establish and follow water-change schedules.</p>	<p>112.44 (a) for items that the inspections must include.</p> <p>112.46 (a) for when testing is not required.</p> <p>112.46 (c) for testing frequencies.</p> <p>112.48 (a) for recirculated water.</p>
16. Ice	No significant differences were identified, provided water potability requirements, as explained in 15. Water (for Fluming and Cleaning), are met.	
17. Packaging Materials	If you harvest, pack or store produce that meets the Produce Safety Rule and produce that does not, food contact equipment and packaging materials (both harvested product	Subpart K – Growing, Harvesting, Packing,

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	<p>and market ready) must be cleaned between changes in commodities covered by the rule and commodities excluded from the rule. For example, an operation produces both apples and peaches and the same bins are used for both. Apples are managed in compliance with the Produce Safety Rule and are exported to the U.S. Peaches are not exported. The bins would need to be cleaned after being used for peaches, before they can be used for apples. The cleaning activity would need to be documented.</p> <p>The Produce Rule defines food contact surface as any surface that comes in contact with food such as equipment and tools used during harvesting. You must inspect, maintain, and clean, and when necessary, sanitize all food contact surfaces of equipment and tools as frequently as necessary, to protect against contamination. With regards to cleaning, CanadaGAP requires that harvested product packaging materials be cleaned annually before first use.</p>	and Holding Activities, Section 112.111
<p>19. Sorting, Grading, Packing, Repacking, Storing and Brokerage 20. Storage of Product 21. Transportation</p>	Operations cannot mix produce that meets the Produce Safety Rule and produce that does not. For example, a packer receives apples from some growers who comply with the Produce Safety Rule and from some that do not. Traceability must be maintained throughout all activities. The apples that were supplied by growers who are in compliance with the Produce Safety Rule cannot be mixed with apples from growers who are not compliant with the Rule.	Subpart K – Growing, Harvesting, Packing, and Holding Activities, Section 112.111

For More Information About FSMA:

The FSMA is administered by the US Food and Drug Administration (FDA). The FDA website, <http://www.fda.gov/fsma>, provides information about the Final Rules, as well as Factsheets & Presentations, Guidance Documents, Frequently Asked Questions (FAQ) and Training Resources.

To access the full version of the *Final Rule on Produce Safety*, follow the instructions below:

- Go to <https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption>
- Move the mouse over the top icon located on the left of the page (Enhanced Content – Table of Contents)
- Scroll down the table of contents list until you find “PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION” and click on this link. This link is located near the bottom of the list.

For More Information About CanadaGAP: www.canadagap.ca

This comparison is based on Version 7.1 (2018) of the CanadaGAP food safety manuals.