



## Information for Canadian Exporters to the U.S. about the Foreign Supplier Verification Program (FSVP)

Updated June 2018

Under the newly implemented U.S. *Food Safety Modernization Act* (FSMA), U.S. importers of food are responsible for verifying that the food imported into the United States has been produced in a manner that meets applicable U.S. food safety standards. The requirements that importers must follow and document are governed by the FSMA *Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals*.

The U.S. importer is required to:

- perform risk assessments to identify and rank potential food safety risks that may be associated with produce coming from a foreign supplier
- undertake activities and/or secure documentation from the supplier to confirm that identified risks are being managed by the supplier.

The evidence that the importer requests from a foreign supplier may vary, depending on the results of their individual risk assessments. The assurances must be provided by the operation that produces the food and/or is responsible for packing. As the Foreign Supplier, **there may be a number of different ways** that you can demonstrate to the importer that food safety risks are being managed in accordance with applicable FSMA requirements.

### FSVP Modified Requirements

In May of 2016, the FDA recognized Canada as having a Comparable Food Safety System to the U.S. The arrangement was signed at a meeting of the FDA-CFIA Health Canada Joint Committee on Food Safety. This means when importing produce from Canada, importers may not be subject to the complete FSVP requirements, but only modified FSVP requirements. For the modified requirements to be applicable, **the importer would need to verify that the Canadian Supplier's operations are overseen by and are in good compliance standing with the Canadian Food Inspection Agency (CFIA)**. The FSVP recognizes two methods of demonstrating that operations are in good compliance standing:

- (1) Appears on the current version of a list, issued by the food safety authority of the country in which the Foreign supplier is located and which has regulatory oversight of the supplier, of food producers that are in good compliance standing with the food safety authority; or
- (2) Has otherwise been designated by such food safety authority as being in good compliance standing.

These FSVP Modified Requirements only apply to food that is not destined for further processing/manufacturing and raw agricultural commodities that will not be commercially processed further before consumption.

Once CFIA has the appropriate mechanism(s) in place, demonstrating to the importer that your operations are overseen by and in good compliance standing with the CFIA may be all that is required to meet the importer's FSVP responsibilities. The importer is further required to continue to monitor your good compliance standing. Prior to the licensing regime being made available under the newly promulgated *Safe Food for Canadians Regulations (SFCR)*, registered produce establishments in Canada are in a position to demonstrate their compliance standing with CFIA.

Canadian operations that are not registered are strongly encouraged to complete the online enrolment of a 'My CFIA' account. CFIA is currently exploring these and other mechanisms for Canadian operations to provide assurance to U.S. customers that they are under CFIA oversight and in good compliance standing. At the very least, setting up your company profile now on 'MyCFIA' will facilitate licensing of your operation as quickly and efficiently as possible when the *SFCR* comes into force in January 2019. In the meantime, doing so will increase your company's visibility to CFIA, which is an important element in responding to U.S. importer requirements. Further information about My CFIA can be found at <http://www.inspection.gc.ca/about-the-cfia/about-my-cfia/eng/1482205903342/1482205903815>

When the *Safe Food for Canadians Regulations* come into force in January 2019, Canadian operations will simply need to be licensed to show that they are under regulatory oversight. "In good compliance standing" is expected to mean that CFIA has not suspended or revoked a license. All operations that fall under the *Safe Food for Canadians Regulations* are subject to CFIA inspection regardless of whether a license is required; that includes fresh fruit and vegetable growers and harvesters.

Certification to the CanadaGAP program may be another effective way to demonstrate to your U.S. customer(s) that you are meeting current Canadian regulatory requirements. The CanadaGAP Program is fully recognized by the Canadian Government under the Food Safety Recognition Program, which means that CanadaGAP has been assessed by CFIA to ensure the program is fully aligned with Canadian regulatory standards. Confirmation and further details about CanadaGAP's Government Recognition can be found at the following links:

CFIA website: [https://www.canada.ca/en/food-inspection-agency/news/2017/09/government\\_of\\_canadacongratulatescanadagapforfoodsafetyachievement.html](https://www.canada.ca/en/food-inspection-agency/news/2017/09/government_of_canadacongratulatescanadagapforfoodsafetyachievement.html)

CanadaGAP website: <https://www.canadagap.ca/wp-content/uploads/English/Publications/Communiqués/2017/CanadaGAP-communique-Government-Recognition-March-2017-ENG.pdf>

Although the effective date of FSVP implementation for most companies was March 19, 2018, there are still many details to be worked out between FDA and CFIA around implementing the modified FSVP requirements. As a result, officials have indicated that delays are expected before FDA begins actively enforcing the FSVP Rule for U.S. importers. Inquiries are being made about whether FDA will share an enforcement timeline publicly so that industry is aware of expectations around compliance. This document will be updated as more information becomes available. Please contact the CanadaGAP office if you are getting requests from your U.S. customers about FSMA or FSVP compliance; we will help to relay this information to government so they are aware of market pressures.

## FSVP Full Requirements

**If you are unable to demonstrate that your operations are under the oversight and in good compliance standing with CFIA**, the U.S. importer will require you to provide evidence that food safety risks are being managed in accordance with the applicable FSMA Produce Safety Rule and/or the Preventive Controls Rule. The following are examples of the types of evidence that the importer may require you to provide:

- The audit results from annual on-site audits of the supplier's facility. The audit must be performed by a qualified 3<sup>rd</sup> party auditor and must consider applicable FDA food safety regulations (Produce Safety Rule and/or Preventive Controls Rule).
- The written results of an FDA inspection of the foreign facility.
- Copies of relevant food safety records.
- Results of testing and/or sampling.
- Written assurances.
- Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.
- Records relating to your food safety history relevant to the produce you supply.
- Corrective Action records.

If you feel that your operations already comply with provisions of the FSMA Produce Safety Rule and/or Preventive Control Rule, and you wanted to have your operations audited as a means of satisfying FSVP demands that known and reasonably foreseeable hazards are being controlled, there is currently limited opportunity for Canadian suppliers to do so. For the audit results to be recognized as a means of verifying legal compliance, the audit would need to be performed by a third party auditor accredited by the U.S. Food and Drug Administration (FDA). The FDA is currently working on the mechanisms to accredit third parties. Contact your certification body to determine their accreditation status with FDA.

In guidance documents the FDA addresses the potential for leveraging third party audits as part of its overall compliance strategy. The agency indicates its intent to do this, in part, by building on current private audit activity and by working with industry, other governments, and private partners to strengthen the rigour and reliability of private third party audits.

The FSVP Rule and guidance documents can be viewed on the US Food and Drug Administration (FDA) website <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm>