http://inspection.gc.ca/food/general-food-requirements-and-guidance/preventive-controlplans/for-importers/eng/1480084425374/1480084519065

A guide for preparing a preventive control plan – for importers

Although the <u>Safe Food for Canadians Regulations</u> (SFCR) came into force on January 15, 2019, certain requirements are being phased in over the following 12 to 30 months. For more information, refer to the <u>SFCR timelines</u>.

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Introduction

As an importer, it's your responsibility to make sure the <u>food</u> you <u>import</u> is safe and that it meets Canadian requirements. This guide is intended for food importers that are required to have a <u>preventive control plan (PCP)</u> under the <u>Safe Food for</u> <u>Canadians Regulations (SFCR)</u>. A PCP is a written plan outlining how you ensure that imported food is safe and fit for consumption in Canada and conforms to Canadian consumer protection requirements, as applicable. This document describes the <u>preventive control plan</u> contents for import <u>licence</u> holders only. If you are licenced to conduct other activities (for example packaging or labelling food that will be sent between provinces or exported) your preventive control plan will need to include additional elements that are described in other guidance documents. More information on preventive control plan requirements for domestic food businesses or businesses that export food can be found in <u>A Guide for Preparing a Preventive</u> <u>Control Plan: Domestic Food Businesses</u> and the <u>Exporting food: A step by step guide</u>.

<u>Preventive controls</u> are an internationally accepted approach to prevent, eliminate or reduce to an acceptable (safe) level <u>hazards</u> associated with food products. They are based on the <u>Codex Alimentarius General Principles of Food Hygiene CAC/RCP 1-1969 – PDF (179 kb)</u>.

Preventive control plans are not a new concept for many food importers. For example, some fish importers already have a system in place called the Quality Management Program for Importers (QMPI) that is comparable to a preventive control plan because they are based on a Codex approach. In addition, many food importers have food safety plans in place that align with voluntary codes of practice that are also consistent with Codex principles.

It's your choice

You may use other preventive control plan approaches that have been developed by other food safety authorities, industry associations, international partners, or academia. Always ensure that the information in your preventive control plan is tailored for your particular business, foods, foreign suppliers and market requirements. You are responsible for ensuring that your written preventive control plan meets the requirements of the Safe Food for Canadians Regulations.

In addition to the preventive control plan requirements described here, importers have several other <u>record</u> keeping requirements under the SFCR. For example, importers are required to keep records related to receiving and responding to complaints, <u>recall</u> and <u>traceability</u>. While these records are not required to be part of the preventive control plan, you may still choose to include these records with your plan. More details regarding these additional record keeping requirements can be found in <u>Importing Food: A step by step guide</u>.

A) Developing your preventive control plan

The required components of a preventive control plan are described in specific parts of section 89 of the SFCR and described further in <u>Regulatory requirements:</u> <u>Preventive control plan (PCP)</u>. The parts of section 89 that apply to import licence holders are:

- 89(1)(a) and (b) description of consumer protection and packaging and labelling controls
- 89(1)(c)(i) description of hazards and associated control measures
- 89(1)(c)(vi) procedure for verifying that the preventive control plan is
 effective
- 89(1)(c)(vii) documents showing that the preventive control plan has been implemented
- 89(1)(e) supporting documents to show evidence of the above information
- 89(4) description of foreign supplier food safety controls and procedures

Each of the above requirements is described in more detail below.

Keep in mind

We have created the following tools related to the PCP requirements that may apply to you:

- 1. The <u>Preventive control plan interactive tool</u> tool will help you determine if you need to prepare a written preventive control plan.
- 2. A series of <u>infographics on food hazards and preventive controls</u> will give you a basic overview of key elements that need to be included in your preventive control plan.
- 3. <u>Preventive Control Plan Templates</u> have been developed for importers to help further illustrate what a PCPincludes.

1. Hazard identification and associated control measures

The SFCR requires that imported <u>food</u> be subject to the same level of <u>hazard</u> analysis and preventive food safety controls as food prepared in Canada. We recognize that you, as an importer, are likely not present in the foreign food establishments from which you source your imported food and that you do not have direct control over the food safety control measures applied in those food establishments. For this reason, assessment of your foreign supplier is critically important in ensuring that hazards are identified by the foreign supplier and effective control measures are in place to deal with these hazards. There are several strategies an importer can use to obtain these assurances. Some examples of these strategies are provided in this document. You may choose to use other strategies as appropriate for your import business model to meet the hazard identification and <u>control measure</u> requirements.

Hazard identification

For each type of food you <u>import</u>, you need to ensure that the hazards (biological, chemical and physical) that may reasonably be expected to contaminate the food have been identified and described. Complete <u>hazard analysis</u>requires you to consider both the hazards inherent to the food and hazards that may be caused by the foreign supplier's processes and procedures. As such, the hazard identification and analysis section of your <u>PCP</u> should include the following:

- a description of all inherent hazards that are reasonably expected to occur in the food as well as any process related hazards that are known to be associated with the type of food you are importing; and
- a description of your assurances that your foreign supplier has identified all the relevant inherent hazards in the food and has identified any process related hazards that are specific to their establishment and operation

Keep in mind

You may choose to use the expertise of a trade or professional association or a consultant to help you analyze potential biological, chemical and physical hazards, and develop your PCP.

The <u>Reference Database for Hazard Identification (RDHI</u>) is also available to help you identify potential hazards in food processing.

Demonstrating hazard identification in your PCP

The following are examples of how you may demonstrate in your PCP that you have adequate assurances that all relevant hazards in the food to be imported have been identified and analyzed:

- conducting on-site audits of the foreign supplier to identify and document all hazards associated with the food to be imported. These audits may be conducted by you or by a technically competent third party acting on your behalf
 - In this case, your PCP would need to include information related to inputs (ingredients and packaging), processing steps and traffic flows and a description of the hazards identified from this information.
- sourcing from a foreign supplier who is subject to internationally recognized third party evaluations
 - In this case, you should request from your foreign supplier <u>evidence</u> that the audit includes identification and analysis of all hazards associated with the food to be imported along with evidence that the foreign supplier is in good standing with the certification body.
- sourcing food footnote1 from a foreign supplier that is in a country that has a food safety recognition arrangement with Canada. This means that the CFIA recognizes that the foreign country oversight has hazard analysis and food safety requirements in place that provide the same level of public health protection as Canada
 - In this case, your preventive control plan should include documentation showing the imported food was sourced from a foreign supplier in a country with a recognized food safety system and evidence that the supplier is in good standing with the competent authority in that country. See <u>Importing from specific countries</u> for information on which countries have specific food safety recognition arrangements currently in place.

Example:

You are importing spices. Regardless of your foreign supplier's operational procedures, you should identify in your preventive control plan the common hazards in spices associated with potential on farm contamination, such as pathogenic microorganisms (for example, Salmonella spp.), viruses (for example, Hepatitis A virus), fungi, yeast, moulds and mycotoxins (for example, aflatoxin). You should also ensure your foreign supplier has identified and analyzed these hazards.

There are also process related hazards for spices such as contamination with pathogenic microorganisms due to failure to clean tools/equipment, improper employee hygiene or improper separation of raw/untreated product from treated product. These are examples of hazards you would want to ensure your foreign supplier has identified and addressed.

Control Measures

Your <u>preventive control plan</u> needs to include evidence that there are control measures in place that are effective in controlling all hazards associated with the food you import. In most cases, the hazards associated with imported foods are controlled by the foreign supplier at the time the food is manufactured, prepared, stored, packaged or labelled in the foreign establishment.

Demonstrating effective control measures in your PCP

Similar to the strategies described above for the identification of hazards, there are several strategies that can be used to demonstrate that each of your foreign suppliers is implementing effective control measures. For example:

- conducting on-site audits of the foreign supplier to identify and document control measures for each of the identified hazards. You may choose to conduct these audits yourself or hire a technically competent third party to conduct them on your behalf. As is required for domestic food manufacturers, your PCP should include the following information from these audits:
 - 1. what a description of the tasks involved
 - 2. how details of how the task is carried out
 - 3. when the frequency of the task
 - 4. who the person responsible for carrying out the task
 - 5. records any forms your foreign supplier uses for the day-to-day collection of information used to record the delivery of tasks and controls
 - 6. any additional documentation that demonstrates the foreign supplier's control measures are effectively managing the hazards
- sourcing from a foreign supplier who is subject to internationally recognized third party assessment or audit. In this case, you should request from your foreign supplier information regarding their third party oversight certification program, including evidence that the program includes assessment of the supplier's implementation of food safety control measures. You should also obtain evidence that the foreign supplier is in good standing with the certification body.
- sourcing food content from a foreign supplier that is in a country that has a food safety recognition arrangement with Canada. This means that the CFIA recognizes that the foreign country oversight has hazard analysis and food safety requirements in place that provide the same level of public health protection as Canada. This includes having requirements and oversight in place for the implementation of food safety control measures
 - In this case, your PCP should include documentation showing the imported food was sourced from a foreign supplier in a country with a recognized food safety system and evidence that the supplier is in good standing with the competent authority in that country.

Verifying that the control measures are effective

In addition to the above strategies for demonstrating that your foreign supplier is implementing control measures, you must verify the effectiveness of these control measures. The following actions would provide assurance that your control measures are effective:

- sampling and testing imported food from each of your suppliers at a regular frequency. The frequency of your sampling and testing should be consistent with the food safety risk associated with the food and should take into consideration the history of the foreign supplier. For example, you may want to test product more frequently when sourcing from a new supplier until they establish a reliable history
- obtaining a certificate of analysis from your foreign supplier with each lot. The information accompanying the certificate may include:
 - the sampling procedure(s) and analytical method(s) used to perform the testing
 - the date of sampling and analysis, product identification (such as brand name and lot code number), name of the analyst
 - verification that the lot was recently tested, that the record of analysis matches the shipment and the food was stored under appropriate conditions to prevent any changes after testing

2. Foreign supplier controls and procedures

Under subsection 89(4) of the SFCR you are required to include in your <u>PCP</u> a description of your assurances that each of your foreign suppliers has:

- <u>preventive controls</u> in place that are the same as those described in sections 47-81 of the SFCR, or if the preventive controls of the foreign supplier are different from those in 47-81, they need to be equally effective at managing the food safety risks; and
- a food safety system in place that is consistent with the requirements of 89(1)(c)(i) to (vii) of the SFCR. For example, a system that is based on the principles of the <u>Codex Alimentarius General Principles of Food Hygiene</u> <u>CAC/RCP 1-1969 – PDF (179 kb)</u>

Your PCP must demonstrate that your foreign supplier has taken the following steps as applicable to their operation:

- hazard identification and analysis
- implementation of control measures
- identification of critical control points (CCPs)
- verification

Verifying that critical control points are implemented

Similar to the strategies above, there are several options you may want to consider to demonstrate that your foreign suppliers are implementing the <u>critical control</u> <u>points</u> and <u>verification</u> steps described in 89(1)(c)(ii) to (v). For example:

- conducting on-site audits of your foreign supplier. You may choose to conduct these audits yourself or hire a technically competent third party to conduct them on your behalf. These audits should include:
 - identifying and documenting any preventive controls implemented by your foreign supplier. These preventive controls should be consistent with those in section 47-81 of Part 4 of the SFCR
 - identifying and documenting any CCPs and describing the critical limits for each of them
 - documenting the monitoring procedures for each CCP that ensure the critical limits are met, and
 - documenting the <u>corrective action</u> procedures when critical limits are not met
- sourcing from a foreign supplier who is subject to internationally recognized third party evaluations. In this case, you should request from your foreign supplier information regarding their third party oversight certification program, including <u>evidence</u> that the program includes assessment of the supplier's identification of CCPs, a description of the critical limits, <u>monitoring</u> procedures for each CCP and corrective action procedures when critical limits are not met. You should also obtain evidence that the foreign supplier is in good standing with the certification body
- sourcing food connect from a foreign supplier that is in a country that has a food safety recognition arrangement with Canada. Where a food safety recognition arrangement is in place, the CFIA recognizes that the foreign country food safety requirements are based on Codex principles and are consistent with the requirements of 89(1)(c)(i) to (vii)
 - In this case, your preventive control plan should include documentation showing the imported food was sourced from a foreign supplier in a country with a recognized food safety system and evidence that the supplier is in good standing with the competent authority in that country.

Procedures for verifying your preventive control plan is effective

Your <u>verification</u> procedure details what you will do to verify that your import process is consistently implemented and is effective at ensuring the import of safe and compliant food. The procedure includes details such as:

- **what:** a description of the steps you take to make sure that the food you import meet Canadian requirements. This may include,
 - o sampling and testing the imported food
 - reviewing certificates of analysis and
 - reviewing product specifications
- **when:** the frequency at which you conduct your verification steps. For example, you identify in your verification procedure that you sample and test

the first 5 shipments from a new supplier and request yearly audit results from your suppliers that are certified to an internationally recognized food safety system

• **who:** the job title of the person responsible for the conducting the verification steps

Your PCP also includes the supporting documents you used to determine your verification procedures, which may include:

- regulatory standards and guidelines
- guidelines from internationally recognized organizations, such as the Codex Alimentarius
- scientific literature
- expert opinions
- description of industry practice

3. Consumer protection requirements

Describe the measures you have in place to ensure the food you import meets the applicable consumer protection provisions such as <u>labelling</u>, <u>standards of identity and</u> <u>grades</u>, <u>packaging</u>.

B) Implementing your preventive control plan

Once you have developed your written <u>preventive control plan</u>, you need to implement it into your day-to-day operations. This involves:

- training your staff on any procedures
- following the preventive control plan as written
- generating records that show you have implemented your preventive control plan and retaining those records for at least 2 years
- verifying that your preventive control plan is implemented as written and is
 effective in preventing food safety hazards, resulting in compliance with
 the SFCR

Verifying your preventive control plan is effective

There are several options you may want to consider to demonstrate that your preventive control plan is effective in ensuring the food you <u>import</u> is safe and meets all applicable requirements of the SFCR. For example, for each type of <u>food</u> you import and/or for each foreign supplier, you may want to have a procedure in place for verifying your incoming food shipments meet Canadian requirements. The frequency and level of <u>verification</u> should be consistent with the risks associated with the imported food.

The following are measures you may want to consider implementing to verify the effectiveness of your preventive control plan:

- visually inspect the shipment to ensure the food meets specifications and Canadian requirements
- verify the packaging material is appropriate for the intended use, is used in accordance with the packaging manufacturer's instructions and meets Canadian requirements
- obtain a certificate of analysis for the lot:
 - review the certificate to ensure the sampling procedure and analytical method are appropriate
 - ensure the lot was sampled recently and stored under appropriate conditions to prevent changes to the food after sampling
 - take a representative sample at a regular frequency (for example, monthly) and analyze it to verify the accuracy of the certificates of analysis
- maintain a documented history for each supplier, indicating the supplier's adherence to specifications (for example, documenting analytical results)
- sample the lot according to a predetermined sampling plan and analyze for adherence to specifications
- conduct regular review (for example, monthly) of any complaints received about your imported food

Your preventive control plan also needs to include <u>evidence</u> that you have implemented your plan (such as, service contracts, processing records, and other day to day records).

C) Maintaining your preventive control plan

Once you have developed and implemented your preventive control plan, maintain it by reassessing it at a frequency appropriate to your food business, for example annually, and revising it as necessary.

The preventive control plan also needs to be reassessed and revised when:

- something is new or has changed (for example, you begin sourcing from a new supplier or change suppliers, your supplier notifies you of a change in a product formulation, processing or packaging)
- a problem has been identified

 (for example, deficiency or deviation observed by you or your foreign supplier
 during in-house monitoring or verification procedures, non-compliance
 identified by third party auditors, customer complaints that reveal a problem
 with the preventive control plan, food recalls, unsatisfactory laboratory results)

Reassessing your plan includes reviewing records and may include following up with your foreign supplier to ensure all hazards are being managed appropriately.

Keep in mind!

You also need to meet the investigation, notification, complaints, and recall requirements referred to in sections 82 to 85 of the <u>Safe Food for Canadians</u> <u>Regulations</u>.

More information is available in Food safety and emergency response.