

Import requirements for romaine lettuce from the United States (2021)

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1. Introduction

Romaine lettuce imported from the United States have been associated with several outbreaks of foodborne *E. coli* 0157:H7 illnesses in Canada and the U.S. Food safety investigations from U.S. authorities have identified a recurring geographical area as the source of the outbreaks. This area encompasses the California Salinas Valley counties of Santa Cruz, Santa Clara, San Benito, and Monterey.

To decrease the risk associated with *E. coli* in romaine lettuce, the CFIA is implementing temporary *Safe Food for Canadians* (SFC) licence conditions for the importation of romaine lettuce originating from the U.S. Between September 30 and December 31, 2021, importers of romaine lettuce and products containing romaine lettuce from the U.S. must:

- declare that the product does not originate from counties of Santa Cruz, Santa Clara, San Benito and Monterey in the Salinas Valley, California, U.S., or

- submit an attestation form and Certificates of Analysis for each shipment to demonstrate that the romaine lettuce does not contain detectable levels of *E. coli* 0157:H7

The complete details on the SFC licence conditions and other existing import requirements are outlined in this document.

The temporary SFC licence conditions are in addition to other existing [import requirements](#).

2. Requirements at time of import

If importers and the products they import comply with other Canadian legislation, the CFIA will allow the importation of romaine lettuce and products containing romaine lettuce from the U.S. if they comply with the temporary SFC licence conditions and other import requirements, as follows:

1. the importer provides a Proof of Origin indicating the state and county where the romaine lettuce was harvested if the romaine lettuce is from outside of the California counties of Santa Cruz, Santa Clara, San Benito and Monterey
2. romaine lettuce or products containing romaine lettuce from the California counties of Santa Clara, Santa Cruz, San Benito and Monterey is accompanied by an attestation (using form [CFIA/ACIA 5961](#)) that sampling was conducted according to the temporary SFC licence conditions and by the Certificate of Analysis demonstrating that the product does not contain detectable levels of *E. coli* 0157:H7
3. if a Proof of Origin of the romaine lettuce is not available, the attestation and Certificate of Analysis must be provided
4. romaine lettuce grown in California has been handled by a certified member of the California LGMA
 - [California LGMA Certified Members List](#)

5. romaine lettuce grown in Arizona has been handled by a shipper that is a certified member of the Arizona LGMA

- [Arizona LGMA Certified Members List](#)

3. Temporary SFC licence conditions

Temporary licence conditions pursuant to section 20 (3) of the *Safe Food for Canadians Act* will be in force for the period from September 30 to December 31, 2021.

During this period, the Canadian Food Inspection Agency will require importers of leafy greens to provide proof that romaine lettuce does not originate from counties of Santa Cruz, Santa Clara, San Benito, and Monterey in the Salinas Valley of California, U.S.

Alternatively, importers who import romaine lettuce or products containing romaine lettuce from the counties of Santa Cruz, Santa Clara, San Benito, and Monterey in the Salinas Valley of California, U.S., or who import products without a valid Proof of Origin, must conform with the following:

- a. The licence holder's preventive control plan includes a written procedure describing how the sampling and testing requirement outlined below is implemented.
- b. Each shipment is accompanied by an attestation by the importer, in the form provided by the CFIA (CFIA/ACIA 5961), attesting that: they have an official Certificate of Analysis for each romaine-lettuce product in the shipment; sampling and testing was conducted according to the temporary SFC licence conditions (points d., e., and f. below); and *E. coli* 0157:H7 was not detected.
- c. Each shipment is accompanied by the Certificates of Analysis issued for the romaine products in the shipment.
- d. The imported product was sampled and tested for *E. coli* 0157:H7 according to one of the two sampling options

described below and the testing conditions outlined in points e. and f. below:

Option 1: Finished-product sampling

- Sampling and testing is conducted after all post processing and handling steps are completed, but before the product is imported into Canada.
- A sampling lot is one type of romaine-lettuce product and a size no larger than the equivalent of 1 truckload of product (no more than 20,400 kilograms/45,000 pounds).
- For each sampling lot, the minimum sampling and testing requirement is a total sample weight of 1,500 g consisting of 60 individual random sample units of 25 g each.

Option 2: Pre-harvest sampling

- Sampling of romaine lettuce in the field is conducted no more than 7 days before harvest.
- A sampling lot is a 2 acre field or less of homogeneous romaine lettuce crop that has been exposed to homogeneous agricultural conditions.
- For each sampling lot, the minimum sampling and testing requirement is a total sample weight of 1,500 g consisting of 60 individual random sample units (grab specimens) of 25 g each.
- This sampling option can be used for romaine lettuce that will be field-packed at the time of harvest. This option is also acceptable for romaine lettuce destined to further processing before export (for example, chopped or mixed with other products) if product is to be processed in separate batches, and a link can be established and documented between the Certificate of Analysis of the product sampled in the field and the finished product at the time of import.

- e. Testing with both screening and confirmation methodologies must be performed in a laboratory accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) as conforming to the requirements of ISO/IEC 17025:2017 for specific tests. The chosen method must be on the laboratory's scope of accreditation. The "application" section of the method chosen must be appropriate for the intended purpose.
- f. A presumptive positive result from a screening method is treated as a positive result for *E. coli* O157:H7 unless a confirmation test is performed on the original enrichment broth within 24 hours of the first test and produces a negative result (i.e. not detected). The confirmation test is a cultural method that is compatible with the screening method.

4. Guidance on the temporary SFC licence conditions

a. Scope

The temporary SFC licence conditions apply to all U.S. import shipments of romaine lettuce and products containing romaine lettuce, sold in bags, in bulk, or combined with other food items, in a fresh state. It applies to all varieties of mature and baby romaine.

b. Proof of Origin

Shipments of romaine lettuce and products containing romaine lettuce from the U.S. but outside the California counties of Santa Clara, Santa Cruz, San Benito, and Monterey, must be accompanied by a declaration from the exporter on an official company letterhead which includes:

- the signature of the exporter
- the date the letter was signed by the exporter
- the state and county where the romaine lettuce was harvested

c. Certificate of Analysis

A Certificate of Analysis issued by the laboratory that conducted the test must be provided for each romaine product in an import shipment, demonstrating that the test result for *E. coli* 0157:H7 is negative. The Certificate of Analysis must identify:

- the date of sample collection
- the certificate number
- the laboratory that analysed the sample
- the client
- a product description
- the methodology
- the sample weight and number of units
- the test result
- the test date

d. Sampling

The sampling level is based on International Commission on Microbiological Specifications for Foods (ICMSF) recommendations for *E. coli* 0157:H7. The two sampling options are considered of similar value in achieving the required sampling level. The sample units must be collected aseptically and be representative of the lot being tested.

Refer to [Appendix C: Pre-harvest Product Sampling and Testing Protocol \(Version 8/27/2021\)](#) from the Western Growers Association for guidance on how to carry out the sampling option 2: Pre-harvest sampling.

Important: please note that to comply with the temporary SFC licence conditions, the following metrics must be met: sampling is conducted

within 7 days of harvest; sampling size is 2 acres or less; and the number of sampling units is minimum 60 (grab specimens) for a minimal total mass of 1,500 g per designated lot.

Examples of appropriate sampling for Option 1: Finished-product sampling

When to sample:

- A. Field packaged romaine hearts can be sampled after cooling and just before they are loaded into a transport truck destined for Canada
- B. Bulk romaine lettuce can be sampled just before it is loaded into a transport truck destined for Canada
- C. Mixed salad sold in bags can be sampled during the packaging process at the processing facility or before it is loaded into a transport truck destined for Canada

Sampling lots:

- A. A shipment of 800 cartons of pre-packaged romaine hearts, 50 cartons of wrapped iceberg lettuce and 169 cartons of mixed bagged salad containing romaine lettuce:

This shipment should be considered 2 sampling lots. One (1) sampling lot is 800 cartons of pre-packaged romaine hearts. The other sampling lot is 169 cartons of mixed bagged salad containing romaine lettuce.

- B. A shipment of bulk romaine lettuce with a weight of 14,000 kilograms. The shipment will be delivered to numerous clients in Canada after import to Canada:

This shipment should be considered 1 sampling lot.

- C. An importer purchases 1,500 cartons of pre-packaged romaine hearts weighing less than 20,400 kilograms. This product will be shipped to Canada in 4 shipments headed to various distribution centers in Canada:

This product can be considered 1 sampling lot. The importer's preventive control plan must include a system for tracking all shipments that are associated with the Certificate of Analysis.

All packages, cases or containers in the sampling lot must be equally represented in the sample. For example, a shipment of 800 cartons should have no more than 1 piece taken in a carton, and the 60 cartons sampled should be selected from various parts of the shipment. A shipment of 10 cartons should be sampled by collecting 6 pieces per carton. Product sampled during the packaging process should be sampled at the beginning, middle and end of the sampling lot.

Examples of appropriate sampling for Option 2: Pre-harvest sampling

When to sample:

- A. Sampling is conducted as close as possible to harvest day, but not more than 7 days before harvest. If the 7-day window is missed, the sampling lot can be re-sampled before harvest or the finished product can be sampled later according to Option 1: Finished-product sampling.

Sampling lots:

- A. A 3-acre plot of romaine lettuce intended for packaged romaine hearts:

Two (2) sampling lots must be taken as the field size from which the romaine lettuce was harvested exceeds the maximum 2-acre sampling size.

- B. A shipment of bulk romaine lettuce with a weight of 14,000 kilograms. The bulk romaine is from two farms:

This shipment should originate from at least two sampling lots (at least one from each farm). The number of sampling lot from each farm depends on field size from which romaine lettuce was harvested (maximum 2-acre sampling size).

C. A shipment of 169 cartons of mixed bagged salad containing romaine lettuce:

This shipment could originate from one pre-harvest sampling lot provided all of the romaine lettuce was harvested from one field not exceeding 2 acres. The product must be processed in batches separate from other product with a clear break between production lots. A link must be established and documented between the Certificate of Analysis of the product sampled in the field and the finished product at the time of import.

5. Legislative authority

The licence conditions are based on the following legislative authority.

Section 20(3) of the *Safe Food for Canadians Act* states: "The Minister may make a registration or licence subject to any additional conditions that the Minister considers appropriate."

The import requirements are based on the following legislative authority.

Section 8 of the *Safe Food for Canadians Regulations* and Section 4 of the *Food and Drugs Act*.

Section 8(1) of the *Safe Food for Canadians Regulations* states:

"Any food that is sent or conveyed from one province to another or that is imported or exported

- a. must not be contaminated
- b. must be edible
- c. must not consist in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; and

- d. must have been manufactured, prepared, stored, packaged and labelled under sanitary conditions"

Section 4 of the *Food and Drugs Act* states: "No person shall sell an article of food that:

1. has in or on it any poisonous or harmful substance;
2. is unfit for human consumption;
3. consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
4. is adulterated; or
5. was manufactured, prepared, preserved, packaged or stored under unsanitary conditions."

Failure to comply with the temporary licence conditions and import requirements may result in enforcement action taken by the CFIA.