Q&A Sheet
Canada import requirements for U.S. romaine lettuce
September 15, 2021

Background:
On September 14, 2021, the Canadian Food Inspection Agency (CFIA) announced revised requirements for romaine imported into Canada from the United States. The revised requirements can be found here.

While this document attempts to answer questions related to the new requirements, it should not be construed as legal advice. If you have questions about the new requirements, you should contact CFIA or a food law attorney. The following information was prepared by the entities listed at the end of this document and may be updated as new information becomes available.

General Import Requirements

1. **What are the temporary SFC license conditions?**

   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 license 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 license conditions (points d., e., and f. below); and E. coli O157: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 O157: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.

2. Who is subject to the new CFIA requirements around US grown romaine?

The new requirements apply directly to entities who are identified as importers under the Safe Food for Canadians Regulations (SFCR) including Canadian based importers and Non-Resident Importers (NRIs) shipping from the U.S. Importers are responsible for ensuring that they import safe food. However, one can assume that companies will expect U.S. shippers and exporters to help them meet the obligations.

3. Why is CFIA imposing these requirements?

Romaine lettuce imported from the United States has been associated with several outbreaks of foodborne E. coli O157: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 during the yearly period of October to December.

4. When does this requirement go into effect and for how long?

The Proof of Origin, and, as required, certificates of analysis, would need to be provided for

all forms of romaine, including baby romaine, entering Canada beginning Thursday, September 30, 2021. The requirements are set to end December 31, 2021.

5. What are the CFIA requirements?
In addition to requiring that importers hold a "Safe Food for Canadians" license, importers of romaine must adhere to these requirements:

- provide 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.

- Romaine lettuce or products containing romaine lettuce from the California counties of Santa Clara, Santa Cruz, San Benito and Monterey be accompanied by an attestation (using form CFIA/ACIA 5961) that sampling was conducted according to the temporary SFC license conditions and by the Certificate of Analysis demonstrating that the product does not contain detectable levels of E. coli O157:H7

- If romaine is sourced from California or Arizona, the importer must only source romaine from those companies certified by the respective LGMAs.

6. What products are subject to this requirement? Is Baby Leaf Romaine included?
The requirements apply to all US shipments of romaine lettuce or 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.

7. Is indoor grown (greenhouse, CEA) romaine also included?
Yes

8. Who must provide the Proof or Origin for romaine?
The exporter must provide the Proof of Origin.

9. Is the requirement of a CoA applicable to all the U.S. romaine lettuce?
No, it is not. It only applies to the coastal California counties: Monterey, San Benito, Santa Clara and Santa Cruz. However, romaine from other regions must have a Proof of Origin. Romaine lettuce that does not have a proof of origin, or is of unknown origin, will also need to have a COA.

10. How should the geographic origin of romaine be communicated and expressed?
The Proof of Origin must be made on the exporting company's letterhead and contain the following information:

i. the signature of the exporter
ii. the date the letter was signed by the exporter
iii. the state and county where the romaine lettuce was harvested

11. What is the rationale behind the selected counties?
The four counties listed were implicated in previous outbreaks. Specifically, they were the four counties identified by FDA in the fall of 2019.

12. Can the voluntary romaine labelling program be used instead of a Proof of Origin?
No, a Proof of Origin must be provided on the letterhead of the U.S. exporter for each shipment of romaine.

Sampling and Testing Requirements

1. **Am I required to obtain pre-harvest testing results in addition to finished product testing results?**

No, CFIA is providing two options this year. 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.

2. **Is there guidance on how to conduct pre-harvest testing?**

The sampling level is based on International Commission on Microbiological Specifications for Foods (ICMSF) recommendations for E. coli O157:H7.

Refer to Appendix C (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 license 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.

3. **What does the sampling plan entail? How much needs to be sampled and tested?**

Reference Appendix C Section II, 4-6.

4. **Is there a specific protocol for the detection of *E. coli* O157:H7?**

Health Canada Compendium of Analytical Methods has a number of approved methods (immunological, PCR, RT-PCR) for *E. coli* O157:H7 detection (as long as their most recent version is used).

It appears that other internationally recognized methods will be accepted provided the lab has been accredited by signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA).

Other recognized methods would need to demonstrate that the methodology that is selected by the client and the testing laboratory is suitable, the method chosen must be successfully validated for the matrix of interest (leafy greens or lettuce for example) and the target organism (*E. coli* O157:H7) and the performance parameters of the method meet or exceed those of the reference method used. The validated protocol must be published and the method must be used under the conditions it has been validated for. Demonstration of validation status could include validations conducted by third-party independent certification entities.

5. What if there is a positive test?

It is important to have a procedure as per the SFCR requirements for handling a positive result. Things to consider include:

- Will presumptive results be confirmed?
- Who should be notified?
- What happens to the product? How is it disposed?

A presumptive positive result will be considered positive (that is, to correspond to a confirmed positive test result for E. coli O157:H7/NM) unless the sample proceeds to the confirmation method. In order for the CFIA to consider the sample as "not detected," cultural confirmation of a presumptive positive must be performed on the original enrichment broth within 24 hours of obtaining the presumptive result, and must be performed in an accredited laboratory by a recognized and compatible cultural confirmation method such as MFHPB-10 - Isolation of Escherichia coli O157:H7/NM from foods and environmental surface samples from the Health Canada Compendium of Analytical Methods.

Logistical Considerations

***Note: This section is based on last year's requirements, it does not includenew specifics at the time. We will update this Q&A document continually as details are released.**

1. How will these requirements be enforced?

Shipments of romaine lacking the appropriate documentation (Proof of Origin, and as applicable, CoA) will not be permitted to enter commerce in Canada. Shipments may enter Canada for testing but may not be released until negative tests are confirmed.

2. Must the Proof of Origin be provided as a hard copy?

No. The Proof of Origin would be submitted via the single window application used by CFIA and CBSA. A company's export specialist or import broker should know what this is and how to do it.

3. How do I submit a CoA?

CoA's available before shipments are presented to CBSA should be submitted along with other paperwork through the single window portal. The recommendation is to perform a single submission with all documents. This means that you could have a CoA ready before a truck arrives at the border or have a Conditional Release form (form 5078) until a CoA is available. The idea is that a CoA gets scanned and included with all the other routine documentation, such as a bill of landing, utilizing the current submission process. Every CoA will be reviewed by CFIA before any truck is released at the border. CFIA estimates it will take roughly two hours to review CoAs.

4. Does a CoA need to be presented at the border at the time of entry?

If testing was completed in the U.S. prior to arrival in Canada, the CoA must be electronically submitted via the single window portal. If test results are still pending, submit a Conditional Release form #5078. The product will not be released to commerce until a copy of the CoA is presented to CFIA.

When a CoA is not included with other import documents, because the product will be tested in Canada, CFIA is allowing for a conditional entry at this time. The 5078 form must be completed and submitted for a conditional release. Trucks with a conditional release may enter Canada, but the product in transit will be placed on hold until a CoA is available. If testing is completed in Canada, importers are to contact the local office of the CFIA to submit the CoA of their shipment.

5. Where can the actual testing take place?

Product testing can take place in the United States or in Canada.

6. What if you get a positive result? What if product is tested in Canada and tests positive?

If a truck is in transit while a test is in progress, the FDA's Reportable Food Registry requires that product confirmed positive be reported if it has left the company's control. This applies to product that has been shipped into commerce. Also, in case of a positive result, the shipper should have procedures in place via their recall program to assure they can contact their customer to put that product on hold when it is received in order to prevent it from entering commerce.

If product in Canada with a conditional release tests positive you must advise the CFIA that you have a shipment of contaminated romaine lettuce as per the SFCR procedure. The affected lot of product must not be sold and must be returned to origin or destroyed. CFIA will oversee that product does not reach consumers in Canada. They will also inform FDA of any positive finds, and FDA will work with companies in the US.

7. What should growers and shippers do to comply?

Shippers should be working closely with their customers if they intend to comply with these rules. If a 'test and hold' program is to be devised, assess your current system and make adjustments as needed.

8. What should I consider for a test and hold program?

If this is the first time your company needs to establish, and implement, a test and hold program there are some things to consider. Below are listed some key considerations:

- Make sure sales orders are known well in advance to reduce stress on the system to avoid mistakes and errors.
- Provide a safe location, proper training, necessary tools, and equipment to sample items quickly and efficiently, while also following all required aseptic sampling techniques.
- After products have been sampled, they will then need to be put on hold in a way that physically shows they are on hold to prevent mis-picks. If the company has an electronic warehouse management system, it can also be set up to establish a positive release gatekeeper function tied to pallet and case bar coding to prevent mis-picks if the system has that capability.
- Lastly, all shipping personnel must be vigilant to not accidentally pick products that have not been released. Make sure all the documentation needed is provided with every shipment. Trucks from the coastal California counties in the notice need to submit a CoA or a conditional release (Form 5078) in order to enter Canada. All other regions from the U.S. need to provide the Proof or Origin.

9. How can successful product identification during a Test and Hold Program be ensured?

It is important to determine which products will be part of the Test and Hold Program. It could be helpful to minimize the number of products and SKUs that will be part of the program, if possible. Work with the team to determine which products will be sent to Canada or could be sent via brokers who are on the U.S. side. Once the list is confirmed, it is important that all individuals in the operation know which are the products that will be part of the Test and Hold process to avoid errors.

10. What kind of storage capacity is needed to implement the required testing?

If a test and hold procedure is used (e.g., product will not ship until after results have been received), then depending on the amount of product that needs to be tested, you will need to allocate an area where product can be securely kept on hold under optimal refrigerated conditions until the test results are available.

It is important to have a Warehouse Management System that uses bar code scanning and shipping department employees who are well trained regarding picking procedures. A dedicated area to hold product can be better managed and secured to prevent accidental mis-picks before product test results are available.

In some instances, space needs may be more than is available at the current facility. In this case you might consider using dedicated refrigerated truck units to hold product until test results are available. However, make sure your company develops procedures for how product and trucks will be managed. It is a Best Practice to prevent cubing-out a refrigeratedtrailer and ensure adequate air channels, such as a center-line loading pattern, to optimize cold chain conditions during Test and Hold intervals.

The 2020 version of this document was created by the Arizona Leafy Green Marketing Agreement, CaliforniaLeafy Green Marketing Agreement, Canadian Horticultural Council, Canadian Produce Marketing Association, Produce Marketing Association, United Fresh Produce Association and Western Growers.

Western Growers is updating the 2020 version on September 15, 2021 and will be contacting other associations and CFIA to review and finalize this 2021 version. The information contained in this document is based on an understanding of the requirements as of the date of release. This document will continue to be updated as required.