Q&A Sheet
Canada import requirements for U.S. romaine lettuce
October 7, 2020

Background:
On October 2, 2020, the Canadian Food Inspection Agency (CFIA) announced new requirements for romaine imported into Canada from the United States. The 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. 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.

2. Why is CFIA imposing these requirements?
CFIA is implementing these requirements based on the recurrence of *E .coli* O157:H7 outbreaks associated with romaine lettuce imported from the United States during the period of October to December in the past four years.

3. 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 Wednesday October 7. The requirements are set to end December 31.

4. What are the new CFIA requirements?
In addition to requiring that importers hold a "Safe Food for Canadians" license, importers of romaine must provide a Proof of Origin (state and county) for romaine lettuce and products containing romaine lettuce from outside of the California counties of Santa Cruz, Santa Clara, San Benito and Monterey.

If romaine is sourced from California or Arizona, the importer must only source romaine from those companies certified by the respective LGMAs. Additionally, shipments of romaine sourced from the Salinas growing region (Santa Clara, Santa Cruz, San Benito and/or Monterey counties) or romaine of unknown or undeclared origin must be accompanied by a certificate of analysis (CoA) demonstrating that the product does not contain detectable levels of *E. coli* O157:H7.

5. 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.

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

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

8. 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.

9. 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

10. 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.

11. 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. When does the testing need to be completed?
Negative test results will need to be provided prior to the release for sale in Canada. However, the product may be transported and held in Canada while awaiting results. Sampling and testing can be conducted in either the US or Canada.

2. Will the results of pre-harvest testing be accepted as an alternative?
No. The requirement is clear in that only post-handling/ processing sampling and testing will be acceptable. Specifically, the requirement is to test after the harvest and postharvest handling of whole heads, hearts, or bulk-shipped topped and tailed romaine heads or following further trimming and processing in the US for packaged goods. For example, field packed romaine hearts could be sampled after cooling and just before they are loaded onto a truck destined for Canada. Bulk romaine lettuce could be sampled just before it is loaded into a transport truck destined for Canada. Bagged, mixed salad could be sampled during the

packaging process at the processor in the USA. If the romaine is to be further processed in Canada, Canadian processors do *not* need to test product after processing; romaine would need to have already tested negative and been "released" before receipt by the Canadian processor.

3. What does the sampling plan entail?

At least 60 units of 25g samples will need to be collected per lot. A lot is defined as no more than 45,000lb of the same type of *product containing romaine lettuce*. This is the typical maximum load within the same truck trailer (i.e. 53 foot). If the truck load contains multiple types of romaine-containing products (hearts, bulk, salad mix, etc.), each product represents a lot.

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 one piece (25 g sample) 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 (25 g samples) per carton. Product sampled during the packaging process should be sampled at the beginning, middle and end of the sampling lot. If a purchase order is fulfilled on multiple shipments, each shipment should be considered a lot if the importer does not have preventive controls in place to trace and identify lots efficiently.

4. How much needs to be sampled and tested?

The required number of sample units for each sampling lot is 60 units of 25 grams per lot. The sample units must be collected aseptically, be representative of the lot being tested and meet the screening methodology specifications, which in some situations may require sample units of more than 25 grams.

For each lot, a total of 1500g of romaine lettuce consisting of 60 individual sample units of 25g each must be tested. Sample units may be composited for analysis to the maximum allowable analytical portion specified in the method.

5. Does the total 1500g sample need to be tested in aliquots as large as the method permits or is a single, representative sample of the 1500 g all that is required? If a method requires a 375g sample, would 4 samples need to be tested (4 x 375 = 1500) or would 1 sample of 375 which is representative of the lot be acceptable?

The requirements stipulate that 1500g of romaine lettuce must be tested. This means that 60 x 25g analytical units must be tested. In the case of a detection method that has been validated for the matrix and target of interest for a composite size of 375g (15 units x 25g in one enrichment), it would mean that 4 different enrichments/tests would need to be performed to reach the target total analytical weight. As another example, if the method has been validated for a composite of 125g, then 12 different enrichments/tests (5 units x 25g in one enrichment) would need to be performed.

For laboratory/methodology related questions, contact cfia.labcoordination-coordinationdeslaboratoires.acia@canada.ca

6. 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.

7. 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

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 refrigerated trailer and ensure adequate air channels, such as a center-line loading pattern, to optimize cold chain conditions during Test and Hold intervals.

This document was prepared by the Arizona Leafy Green Marketing Agreement, California Leafy Green Marketing Agreement, Canadian Horticultural Council, Canadian Produce Marketing Association, Produce Marketing Association, United Fresh Produce Association and Western Growers.

The information contained in this document is based on an understanding of the requirements as of the date of release. This document was reviewed by the Canadian Food Inspection Agency (CFIA) and will continue to be updated as required.