Q&A Sheet
Canada import requirements for U.S. romaine lettuce
October 5, 2020

Background:
On October 2, 2020, the Canadian Food Inspection Agency 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 (NRI's) shipping from the U.S. The Canadian Food Inspection Agency (CFIA) can only regulate Canadian entities, so it is ultimately the importer that is responsible for following these requirements. 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.

3. **When does this requirement go into effect and for how long?**
The declaration 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 indicate the geographical origin for romaine. 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 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 salad mixes containing romaine lettuce, sold in bags, in bulk, or combined with other food items, in a fresh state.

6. Is indoor grown (greenhouse, CEA) romaine also included?
Yes, based on our interpretation, and without additional clarification from CFIA, it appears that the requirement to provide declaration of origin would be needed.

7. Who must provide the declaration of the geographic origin for romaine?
The exporter must provide the declaration 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, other regions must have a declaration of origin. Romaine lettuce that does not have a declaration 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 declaration of origin must be made on the exporting company's letterhead and *only* contain the following information (and no additional 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 Declaration of Origin?
No, a Declaration 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?

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. 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. It appears that other internationally recognized methods (as long as their most recent version is used) will be accepted provided the lab has been accredited by signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA)

6. What if there is a positive test?

It is important to have procedures for when a presumptive or positive result has been determined. Molecular tests are diagnostic and are considered a positive evidence. Things to consider include:

- Who should be notified?
- What happens to the product? How is it disposed?

If a presumptive positive is detected by PCR, RT-PCR or an immunological technique, a culture-based test can be performed on the original enrichment broth within 24 hours of obtaining the presumptive positive result. A recognized method selected from the Health Canada Compendium of Analytical Methods must be used. If the results of the culture-based tests are negative, CFIA will consider the sample as "not detected".

Logistical Considerations

1. How will these requirements be enforced?

Shipments of romaine lacking the appropriate documentation (declaration 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 declaration of origin be provided as a hard copy?

No. The Declaration 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?

All COAs should be submitted along with other paperwork through the CFIA 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.

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. If test results are still pending, this can be indicated on the entry form. The product will not be released to commerce until a copy of the COA is transmitted to the system.

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. Based on information verbally shared by CFIA, if testing is completed in Canada, importers are to contact the area office of the CFIA and/or the National Import Service Centre to check the status of their test results.

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.

5. Where can the actual testing take place?

Product testing can take place in the United States or in Canada. A COA must be provided (via the entry portal) regardless of where testing takes place.

6. What will happen if product is tested in Canada and tests positive?

If a sample taken in Canada is confirmed positive, this will result in destruction of the affected lot of product. CFIA will inform the importer of the result and will work with them to see 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 DOO.

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 if you get a positive result?

If a truck with a conditional release tests positive, this must be communicated to CFIA.
In addition, 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.

11. 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. The document will be submitted to the Canadian Food Inspection Agency (CFIA) for review and will be updated as required, including a link to CFIA's guidance once available.