

Sampling and Testing Protocol for Canadian Flaxseed Exported to the European Union

Update: March 2018

1. Purpose

The purpose of this protocol is to describe the system of sampling, testing, and documentation pertaining to the presence of FP967 (CDC Triffid) in shipments of Canadian flaxseed to the European Union (EU).

2. Background

In July 2009 a commercial laboratory in the EU detected a low level presence of genetically modified (GM) material in a shipment of Canadian flaxseed to the EU. In September 2009 the Canadian Grain Commission (CGC) confirmed a trace amount of GM material in some Canadian flaxseed shipments.

There are currently no varieties of GM flaxseed registered in Canada. FP967, a GM flaxseed variety, received regulatory feed and environmental safety authorizations in 1996, and food safety authorizations in 1998, but was never released for commercial production. No varieties of GM flaxseed have received regulatory approvals in the EU. EU regulations allow zero tolerance of non-approved GM events.

3. Commercial Handling System Procedures

a) Producer Delivery Samples - A sample will be taken by grain handling company personnel from each producer delivery into the commercial handling system. Samples will be retained for a period of no less than six months from the date of delivery. The CGC provides guidance on sampling methods to the Canadian grain industry in its official *Sampling Systems Handbook and Approval Guide*.

b) Composite Railcar Samples and Testing – All flaxseed moves from primary elevators to port position by railcars. At time of loading, each railcar will be sampled, and composite samples representing not more than 5 railcars will be prepared. The CGC provides guidance on sampling methods to the Canadian grain industry in its official *Sampling Systems Handbook and Approval Guide*. These composite samples will be tested for the presence of FP967 by a laboratory on the list of “*Laboratories Approved for Testing Flaxseed Shipments to the European Union*” using the method described in 6b. If a composite sample tests positive for the presence of FP967, all railcars testing positive represented by that sample will be diverted from the EU flaxseed supply. Individual grain handling companies will retain documentation pertaining to each rail shipment and test result.

c) Commercial Segregation and Quality Management Systems – All Canadian grain handling companies exporting bulk flaxseed to the EU are either ISO or HACCP certified. Companies will employ internal quality management systems and practices to guard against cross contamination of positive flaxseed and negative flaxseed lots.

4. Requirements for Testing Laboratories

Laboratories undertaking testing for the commercial handling system may only be designated if they operate and have been assessed in accordance with the ISO 17025 standard on ‘General requirements for competence and testing and calibration laboratories’ and if the proposed test method falls within the scope of the above assessment.

The CGC will maintain a list of “*Laboratories Approved for Testing Flaxseed Shipments to the European Union*” on its website. Laboratories designated on this list will handle and prepare samples in accordance

with ISO 17025 accredited procedures. Laboratories will employ the construct-specific method verified by the European Union Reference Laboratory.

5. Procedures for Exports: Sampling and Sealing Silos

a) Prior to Railcar Unloading

- Grain handling company personnel will seal all silos in the elevator containing flaxseed not tested under this Protocol or that has tested positive using a uniquely numbered seal, and record the silo and seal numbers.
- Grain handling company personnel will provide to the CGC a list of silos in the elevator designated for negative flaxseed destined to the EU and confirm those silos are empty prior to use.

b) Unloading Railcars, Sealing Silos, Sampling and Testing

- Grain handling companies will provide a list of the rail cars that test negative to the CGC and the CGC will compile and maintain that list.
- Grain handling company personnel will sample all railcars unloading flaxseed destined for export to the EU with an approved automatic diverter-type sampler in accordance with the official *Sampling Systems Handbook and Approval Guide*.
- For lots of flaxseed exceeding 500 metric tons, a minimum sample size of 50 kilograms will be taken. For lots between 50 metric tons and 500 metric tons, a sample equal to 0.01% of the lot size will be taken. For lots less than 50 metric tons, a minimum sample size of 5 kilograms will be taken. These sample sizes are in accordance with European Commission Recommendation 2004/787/EC¹.
- Grain handling company personnel will monitor grain flow from each railcar unload to each designated silo. Grain handling company personnel will seal full silos with a uniquely numbered seal and record the silo and seal number.
- Grain handling company personnel will prepare two 2.5 kilogram composite samples for each silo. One sample will be forwarded to an ISO 17025 accredited laboratory on the list of *“Laboratories Approved for Testing Flaxseed Shipments to the European Union”*.
- ISO 17025 laboratories will test the sample in accordance with the procedures outlined in section 6 of this Protocol, and notify the grain handling company whether each silo tests positive or negative for the presence of FP967. Any silo for which the composite sample tests positive will be diverted from the EU flaxseed supply.

c) Loading Lake Vessels

- Grain handling company personnel will provide to the CGC the Lake Vessel Name at time of loading.
- CGC will confirm that this vessel has not been used to transport untested or positive tested flax in the prior twelve months
- Grain handling company personnel will provide to the CGC a list of silos to be loaded to lake vessels and confirm that they have tested negative and that the seals remain intact.
- Grain handling company personnel will break the seal on each negative silo, monitor the grain flow paths and confirm to the CGC that only flaxseed from designated silos is loaded to the lake vessel during the loading of the lake vessel.
- Grain handling company personnel will confirm to the CGC that seals on positive or non-protocol flaxseed are intact prior, during and after lake vessel loading.

d) Prior to Unloading Lake Vessels

- Grain handling company personnel will seal all silos in the elevator containing flaxseed not tested under this protocol or that tested positive using a uniquely numbered seal, and record the silo and seal numbers.

¹ 1 OJ L 348, 24/11/2004, p 0018- 0026, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004H0787>

- Grain handling company personnel will provide to the CGC a list of silos in the elevator designated for negative flaxseed destined to the EU and confirm those silos are empty prior to use.
- e) Unloading of Lake Vessels
- Grain handling company personnel will monitor grain flow from each lake vessel, to each designated silo. Grain handling company personnel will seal full silos with a uniquely numbered seal and record the silo and seal number.
- f) Loading Ocean Vessels
- Grain handling company personnel will provide to the CGC a list of silos to be loaded to EU ocean vessels and confirm that they tested negative and that the seals remain intact.
 - Grain handling company personnel will break the seal on each negative silo, monitor grain flow paths and confirm to the CGC that only flaxseed from designated silos is loaded to the ocean vessel during the loading of the ocean vessel.
 - Grain handling company personnel will confirm to the CGC that seals on positive or non-protocol flaxseed are intact prior, during, and after ocean vessel loading.

6. Procedures for Exports: Testing by ISO 17025 Laboratories

a) Testing Preparation – Samples for testing will be expedited to a laboratory on the list of *Laboratories Approved for Testing Flaxseed Shipments to the European Union*². Laboratory personnel will draw four 60 gram sub-samples from the single 2.5 kilogram laboratory sample. Each 60 gram sub-sample represents approximately 10,000 individual flax seeds, which is capable of achieving a level of detection of 0.01%.

b) Testing Procedures – Laboratory personnel will test four 60 gram sub-samples taken from the single 2.5 kilogram laboratory sample. One DNA extraction will be made from each sub-sample using a DNA extraction kit that meets the performance criteria laid down in section 2.1 and 2.2 of the JRC Technical report entitled “Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing”³. Two PCR analyses will be carried out for each DNA extraction. The construct-specific method, verified by the EU Union Reference Laboratory, will be used for the qualitative PCR assay⁴.

c) Testing Results - A lot shall be considered negative when all four 60 gram sub-samples test negative.

7. CGC Procedures for Exports: Documentation

The CGC will prepare an official *Letter of Analysis* on CGC letterhead to accompany other CGC quality certification which may include a *Certificate Final* or an *Official Inspection Certificate*. The *Letter of Analysis* will be presented to the Canadian flaxseed exporter, who will in turn provide it directly to the appropriate EU authorities. The *Letter of Analysis* will include a statement as follows:

Prior to the loading of the vessel identified above, the grain handling company sampled the flaxseed (Linseed) destined to storage silos and then sealed each silo.

A sample representative of each silo was prepared and sealed by grain handling company personnel and forwarded to [Insert Laboratory Name] for testing. [Insert Laboratory Name] operates and has been assessed in accordance with the ISO 17025 standard on ‘General

² <http://www.grainscanada.gc.ca/gmflax-lingm/ltf-lal-eng.htm>

³ Available at http://gmo-crl.jrc.ec.europa.eu/doc/MPR%20Report%20Application%2020_10_2015.pdf, latest version applies

⁴ <http://gmo-crl.jrc.ec.europa.eu/flax.htm>

requirements for competence and testing and calibration laboratories', and the testing method employed falls within the scope of that assessment.

The samples, as reported by (Insert Laboratory Name), tested negative for the presence of FP967 (CDC Triffid) based on the verified testing procedures outlined in section 6 of the Sampling and Testing Protocol for Canadian Flax Exported to the European Union. The lab report is attached.

The attached silo list has been prepared by the grain handling company and designates the silos that were utilized for the shipment identified above.

8. Reporting on the Presence of FP967

Canada will share results of those controls described in this Protocol with the European Commission at regular intervals.

9. Review

The requirements of this protocol will be reviewed on an annual basis beginning in 2014 and the protocol may be terminated by mutual consent if, during that period, no detection of CDC Triffid has been reported.

10. Questions

Questions pertaining to this protocol should be directed to the Chief Grain Inspector for Canada at (204) 983-2780 or (800) 853-6705.