



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

March 10, 2010

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 Community Reference Laboratory.

5. CGC Procedures for Exports: *Sampling and Sealing Silos*

- a) Prior to Railcar Unloading
 - o The CGC will seal all silos in the elevator containing flaxseed not tested under this Protocol or that has tested positive using a uniquely numbered CGC seal, and record the silo and seal numbers.
 - o The CGC will obtain 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
 - o The CGC will obtain a list of railcars from grain companies that have tested negative.
 - o CGC personnel will officially 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*.
 - o 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.
 - o The CGC will monitor grain flow from each railcar unload to each designated silo. The CGC will seal full silos with a uniquely numbered CGC seal and record the silo and seal number.
 - o The CGC 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*".
 - o ISO 17025 laboratories will test the official sample in accordance with the procedures outlined in section 6 of this Protocol, and notify the

¹ OJ L 348, 24/11/2004, p 0018- 0026

CGC whether each silo tests positive or negative for the presence of FP967. The CGC will notify terminal elevator operators of the testing results for each silo. Any silo for which the composite sample tests positive will be diverted from the EU flaxseed supply.

- c) Loading Vessels
 - o The CGC will obtain a list of silos to be loaded to EU vessels and confirm that they tested negative and that the seals remain intact.
 - o The CGC will break the seal on each negative silo, and monitor grain flow paths to ensure only flaxseed from designated silos is loaded to the vessel during the loading of the vessel.
 - o The CGC will confirm that seals on positive or non-protocol flaxseed are intact prior, during, and after vessel loading.

6. CGC 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 the *Fast ID Genomic DNA Extraction Kit*. Two PCR analyses will be carried out for each DNA extraction. The construct-specific method, verified by the EU Community Reference Laboratory, will be used for the qualitative PCR assay³.
- 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 Canadian Grain Commission (CGC) officially sampled the flaxseed (Linseed) destined to storage silos and then sealed each silo.

An official sample representative of each silo was prepared and sealed by CGC 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 requirements for competence and testing and calibration

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

³ <http://gmo-crl.jrc.ec.europa.eu/flax.htm>

laboratories', and the testing method employed falls within the scope of that assessment.

The official 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 CGC and designates the silos that were utilized for the shipment identified above.

8. CGC Investigation into the Presence of FP967

The CGC is conducting an investigation into the presence of FP967 within the Canadian flaxseed supply. The CGC will share results of this investigation with the European Commission at regular intervals.

9. Review Date

This protocol may be reviewed and revised at any time. The Government of Canada will notify European Commission officials if revisions are sought.

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.