



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

October 29, 2009

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.

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.

5. CGC Procedures for Exports: *Sampling*

- a) Sampling Method – All vessels loading flaxseed destined for the EU will be sampled by CGC personnel with an approved automatic diverter-type sampler in accordance with the *CGC Vessel Loading Work Instruction* and the official *Sampling Systems Handbook and Approval Guide*¹.
- b) Sample Size – 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/EC².
- c) Composite Samples by Vessel Hold – For all bulk shipments by vessel, CGC personnel will prepare a representative composite sample for each hold of the vessel. Typical vessel holds range in size from 4000 to 6000 metric tons. Sampling and testing by hold allows for identification and segregation of any lot that potentially tests positive.
- d) Sample Preparation and Retention – CGC personnel will reduce samples and prepare one representative 2.5 kilogram sample for testing and one identical 2.5 kilogram sample for retention and future reference. Both 2.5 kilogram samples will be sealed with official CGC seals and seal numbers will be documented. Samples will be retained for no less than six months.

6. CGC Procedures for Exports: *Testing*

- a) Testing Preparation – Samples for testing will be expedited to the CGC Grain Research Laboratory. 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 – The CGC Grain Research Laboratory 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

¹ <http://www.grainscanada.gc.ca/guides-guides/ssh-mse/sshm-mmse-eng.htm>

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:348:0018:0026:EN:PDF>

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:

The Canadian Grain Commission (CGC) officially sampled the cargo of flaxseed (Linseed) identified above and has applied the CGC seal #xxxxxx to the official sample. The CGC Grain Research Laboratory has tested the official sample with this CGC seal number. The official sample tested negative for the presence of FP967 (CDC Triffid) based on the verified testing procedures outlined in paragraph 6 (b) of the Sampling and Testing Protocol for Canadian Flax Exported to the European Union. The lab report is attached.

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.

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