Ex-post Assessment of Genetically Modified (GM) Low Level Presence (LLP) in Canadian Flax

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Abstract:

Canada is the world's largest producer and exporter of flaxseed. In 2009, DNA from a deregistered genetically modified organism (GMO) CDC Triffid was detected in a shipment of Canadian flaxseed exported to Europe, causing a large decrease in the amount of flax planted in Canada and a major shift in export markets. The flax industry in Canada undertook major changes to ensure the removal of transgenic flax from the supply chain. To demonstrate compliance, Canada adopted a protocol involving testing grain samples (post-harvest) using an RT-PCR test for the construct found in CDC Triffid. Efforts to remove the presence of GM flax from the value chain included reconstituting major flax varieties from GM-free plants. The reconstituted varieties represented the majority of planting seed in 2014. This study re-evaluates GM flax presence in Canadian grain stocks for an updated dataset (2009-2015) using a previously described simulation model to estimate low-level GM presence. Additionally, losses to the Canadian economy resulting from the reduction in flax production and export opportunities, costs associated with reconstituting major flax varieties, and testing for the presence of GM flax along the flax value chain are estimated.

Keywords: CDC Triffid, *Linum usitatissimum*, seed purity analysis, seed testing, statistical methods, transgenic, reconstituted seed, testing costs, flax value chain.

JEL codes:

1. Introduction

CDC Triffid (FP967), a herbicide tolerant transgenic flax, was developed at the Crop Development Centre (CDC), University of Saskatchewan (McHughen, Rowland, Holm, Bhatty, & Kenaschuk, 1997). The Canadian Food Inspection Agency (CFIA) approved CDC Triffid for unconfined environment and feed release in 1996. Seed production was undertaken by seed growers across Western Canada from 1997 to 1999 (Booker et al., 2014). Due to concerns about the effect of production of genetically modified (GM) flax on export markets, the CFIA and the Flax Council of Canada (FCC) recalled seed of CDC Triffid in 2000 and the variety was deregistered in 2001 with no seed sold for commercial production in Canada. Approximately 4,000 hectares of transgenic flaxseed were grown across Western Canada and about 5,500 tonnes of seed were collected during the recall (Ryan & Smyth, 2012). Nearly a decade after its removal, transgenic flax seed identified as the GM flax variety CDC Triffid was detected in two 5,000 tonne shipments of flax grain in April 2009 during preprocessing in Europe. Further shipments of Canadian flax to Japan and Brazil also tested positive for the transgene (Flax Council of Canada, 2010). Offshore markets for Canadian flax have not approved GM flax and have no tolerance for its detection in grain shipments (Flax Council of Canada, 2009).

To demonstrate compliance, the Canadian industry adopted an extensive flaxseed testing protocol soon after the discovery of the transgenic flax. The protocol uses a real-time polymerase chain reaction (RT-PCR) test for the construct found in CDC Triffid and involves sampling and testing prior to planting, post-harvest, at initial receptor sites (elevators, railcars), and at grain terminals prior to export. This regulatory compliance is difficult due to the practical difficulties in detecting a very rare GM event with the current level of detection of RT-PCR assays (e.g., 0.01% or 1 GM seed in 9,999 conventional seeds) and the large sources of error inherent in taking representative and random samples in large seed lots (Begg, Cullen, Iannetta, & Squire, 2007; Lamb & Booker, 2011). The current testing protocol requires the collection of a 2 kg sample of any flax entering the handling system, and testing of four 60 g subsamples (4 × 60 g) for the presence of GM flax (Canadian Grain Commission, 2010). The sampling protocol presumably gives a 95% probability (or 5% error) of detecting 1 GM seed in 9,999 non-GM flax seeds (Remund, Dixon, Wright, & Holden, 2001; Whitaker, Freese, Giesbrecht, & Slate, 2001). Lamb and Booker (2011) demonstrate that the low levels of presumed contamination (far less than 1 in 9,999) are indistinguishable from the number of positive tests expected from a clean seed lot given the observed rates of false positives for the RT-PCR test. This study updates results presented in Booker et al. (2014) and

shows that the level of GM positive tests for seed and grain are below that expected due to testing error for the most recent testing data provided by the FCC. The estimated cost of flaxseed testing to Canadian flax producers is also provided. We advocate that continued testing for vanishing levels of GM flax must reasonably cease.

2. Expected Levels of False Positive Tests

The test for the GM construct has a specificity of 0.006, indicating that a false positive result can be expected in 0.6% of individual tests (Booker & Lamb, 2012; Lamb & Booker, 2011). This low rate of false positives can, however, result in substantial numbers of positive results in tests of clean seed. It is critical to determine if the number of positive tests observed is higher than the expected number of false positives given the observed false positive rate. This question was evaluated by first estimating the probability that the observed or a larger number of positive results could have arisen given the rate of false positives. A probability of ≥ 0.05 indicates that the number of observed results is not significantly different than that expected due to false positives (due to chance). This probability was calculated using the dbinom function in the R statistical package (R Development Core Team, 2014). The probability was estimated for a particular number of positive tests that could arise given the false positive rate with the total number of tests and the false positive rate as arguments. In cases where only a single test of 10,000 seeds (1×60 g) was reported per lot, a false positive rate of 0.006 was used. In cases where four tests per lot were performed (4×60 g tests), a false positive rate of 0.0238 was used (as a false positive rate of 0.006 per test means that, on average, 2.4% of clean lots will have at least one false positive test out of 4 ($0.0238=1-0.994^4$)). If the sum of the results of the dbinom function across all numbers of positive tests is greater than or equal to the observed number of positives, then the observed or a larger number of positive results could have arisen given the rate of false positives.

Test results were provided for April 1 through to March 31 of each year. For each category of seed or grain, the expected distribution of false positive results was plotted using the dbinom function. Pedigreed seed lots returned 6 out of 88, 10 out 228, 2 out of 191, 0 out of 62, 1 out of 161, and 0 out of 101 positive tests for 2009/10, 2010/11, 2011/12, 2012/13, 2013/14, and 2014/15 yearly datasets, respectively. Thus, the number of positive tests returned for Pedigreed seed was not significantly different than that presumed due to testing error or was not distinguishable from the number of positive tests returned for clean seed lots (Figure 1). Additionally, the most recent testing shows the number of positives observed from Farm Saved seed from 1 April 2013 through to 31

March 2015 (6/554 and 5/226, respectively) was not significantly different than the expected false positive rate (Figure 2). Where the number of positives returned for Farm Saved seed was greater than due to chance alone, the simulation model described in Lamb and Booker (2011) was used to estimate low level presence; results are reported in Booker and Lamb (2012) and Booker et al. (2014) and demonstrate that GM presence in sowing seed used by Canadian producers is no longer a significant source of GM contamination. For Production samples, the number of positive 4 × 60 g tests for 1 April 2013 (72/2921) through to 31 March 2015 (20/2019) were well below that expected due to the testing error rates (Figure 3). Again, the simulation model as previously described was used to estimate LLP in Canadian grain when test results from previous years indicated the level of positives returned was significantly greater than due to testing error (Figure 4).

3. Economics of Ongoing LLP Testing

The initial trade disruption costs on both sides of the Atlantic from the European Union (EU) detection of GM flax were estimated to have reached C$80 million (Ryan and Smyth, 2012). This cumulative figure includes the cargo ship quarantine costs, initial flax testing costs, and lost business opportunities within the European flax industry. As part of the resolution of the import ban that the EU placed on Canadian flax in September 2009 (when the GM flax was initially identified), Canada agreed to enact a Farm Stewardship Program for a five-year period. The objective of this program was to ensure the Canadian flax industry and international flax import markets that Canadian shipments of flax would be free of GM flax.

In the winter of 2009-2010, flax seed testing protocols were developed and an industry-wide testing program commenced. This five-year testing program concluded in February 2014. The costs of this program are presented in Table 1. Because the stewardship program was part of the Canadian Government's commitment related to the EU lifting the import ban that they had enacted in September 2009, funds to facilitate a portion of the testing costs were made available through Agriculture and Agri-Food Canada (AAFC). These funds were used to offset the cost of producer seed testing, as all seed was required to be tested prior to seeding to ensure that any GM flax was removed from the crop production cycle. The flax export industry was responsible for testing costs at the railcar to point of export, with costs estimated at $1.34 million for the 5-year testing period. Cumulative testing costs in Canada from 2009 to 2014 are estimated to have been $3.34 million.

Following the conclusion of the stewardship program, the Federal Government's participation through AAFC ended and testing costs have been borne by producers and industry. The Flax

Council of Canada has estimated producer testing costs at $500,000; costs to the flax industry are not known (Table 1). Given the cost ratio from previous years, it would not be expected that industry's cost would be lower than that of the producers. A reasonable estimate of the cost of testing all flax exports to the EU for the six years from initial detection to present would be in the range of $4-5 million.

Additional opportunity costs were incurred from the periodic loss of the EU market (Table 2). The decline in EU flax exports was partially offset by the addition of China as an export destination. Chinese importers knew that Canadian flax exports to the EU had declined and that Canada had flax surpluses (despite declining flax production). This allowed China to import Canadian flax at a lower price than offered by EU flax importers.

While flax production has nearly fully recovered to pre-GM flax detection levels, the EU market has not recovered. As observed for other commodity markets that have been required to contend with coexistence challenges (rice and corn), export markets typically do not recover to previous levels. Prior to GM flax detection, Canada exported an average of 80% of the flax it produced to the EU. Over the past three years, EU flax imports have, on average, represented one-third of the flax produced in Canada. The Chinese export market does not fully account for the loss of 45% of Canada's flax export market.

What is not clear is when a natural end to the flax testing will arrive. The EU has a threshold of 0.1% for unapproved events and, as demonstrated in Figure 1, GM flax occurrence rates are well below this level. Therefore, all flax exports to the EU are below the 0.1% allowance for EU unapproved GM events. Hence, the Canadian flax industry should be able to end all flax testing and stewardship program requirements.

While this make perfect sense from a logical commodity export market perspective, it does not from a politically driven perspective. There is no incentive for the EU to end their demand that every flax commodity shipment from Canada be tested to guarantee that it is free of GM flax. In fact, given the EU's recent policy change that now allows Member States to individually decide whether they will allow the production of GM crops, it is anticipated that individual Member States will be averse to allowing an end to GM flax testing.

Conversely, what incentive is there for the Canadian flax industry to end flax testing? Historically, the EU has been the single most important export market and the industry has a strong preference to see commodity trade return to pre-2009 levels. Ending the GM testing protocol could potentially make EU flax importers nervous about importing Canadian flax and drive them to seek alternative flax markets. The political sensitivity of testing has now become embedded within the flax trade between Canada and the EU and is likely to be viewed as entrenched. Therefore, this cost will likely have to be borne by producers and the flax industry going forward. Finally, the continued occurrence of false positive tests presents an ongoing challenge to flax exporters.

When LLP events are detected or coexistence thresholds exceeded, agreements to their resolution clearly need to firmly establish 'sunset clauses' or define the timeline for when the testing protocol will end; otherwise, as is evident from the situation described above, the likelihood of testing for the minute presence of GM material will continue indefinitely. Commodity export markets are not capable of providing market signals with respect to when testing protocols should end; therefore, it is crucial that those involved in the implementation of such protocols establish clear and concise timeframes regarding how long the testing period will last. Upon reaching the end of the agreed period, the testing should cease at point of export. A perfectly valid option is for the importer to incur the cost of continued testing, but the cost of such testing should no longer be borne by the exporting market.

4. Reconstituted Flax Varieties

The Crop Development Centre, University of Saskatchewan developed and applied a protocol to reconstitute commercially important flax varieties, including CDC Bethune, CDC Sorrel, and new varieties CDC Sanctuary and CDC Glas in an effort to remove GM flax from the value chain (FCC, 2012). Pedigreed seed of the re-constituted CDC varieties was available to farmers in the fall of 2013 (FCC, 2013a). The Canadian flax industry strongly encouraged renewal of farmers' seed stocks with pedigreed seed in the 2013-2014 crop year, thereby further diluting commercial flax stocks of remaining transgenic flaxseed (Figures 1-3; FCC, 2013b). The reconstituted varieties represented the majority of the planting seed in 2014 (T. Hyra, Western Canada SeCan, personnel communication). These efforts significantly contributed to returning flax production to that planted prior to the discovery of transgenic flax in Canadian flax (Table 2).

Tables and Figures

Table 1: Canadian flax seed testing costs ($CAD)

Time Period	AAFC	Producers	Industry
Aug 2009 – Feb 2014	$1 million	$1 million	$1.34 million
Mar 2014 – Jun 2015	NA	$0.5 million	Unknown

Source: Don Kerr, Flax Council of Canada, personal communication.

Table 2: Canadian flax exports to China and the EU, 2005-2015 (in 000 tonnes)

Export Year	China	EU	Total Exports
2014-2015	207,900	155,900	451,200
2013-2014	124,800	153,300	381,400
2012-2013	117,500	109,300	331,700
2011-2012	124,100	17,300	256,800
2010-2011	35,000	202,300	327,100
2009-2010	220,100	265,800	617,800
2008-2009	18,100	422,700	530,200
2007-2008	0	415,400	545,200
2006-2007	0	466,100	579,700
2005-2006	0	355,000	440,600

Source: Canadian Grain Commission, 2015.

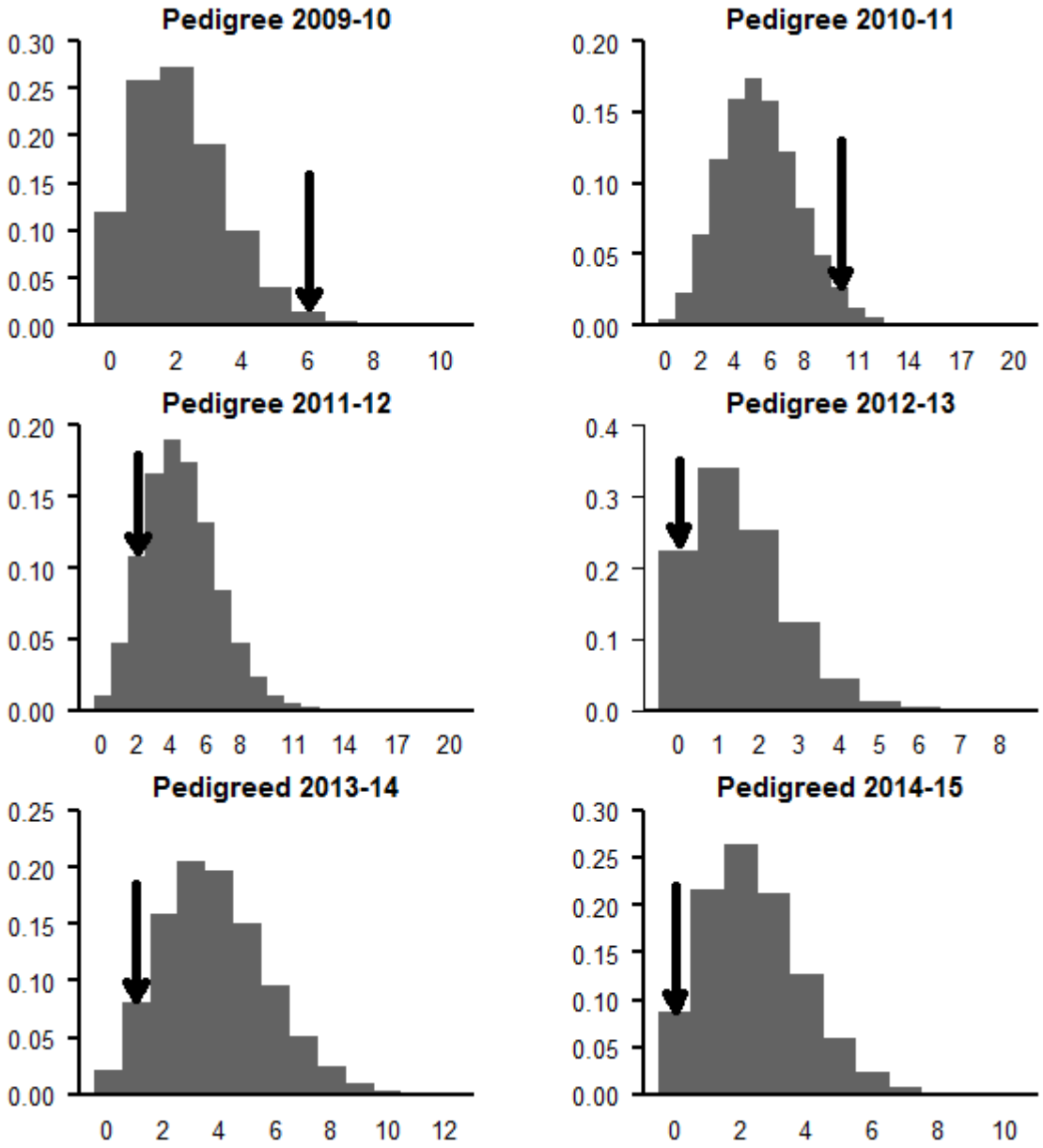

Figure 1: The expected distribution of false positive tests for each series of tests completed on data for Pedigreed seed. The arrows indicate the observed number of positive tests.

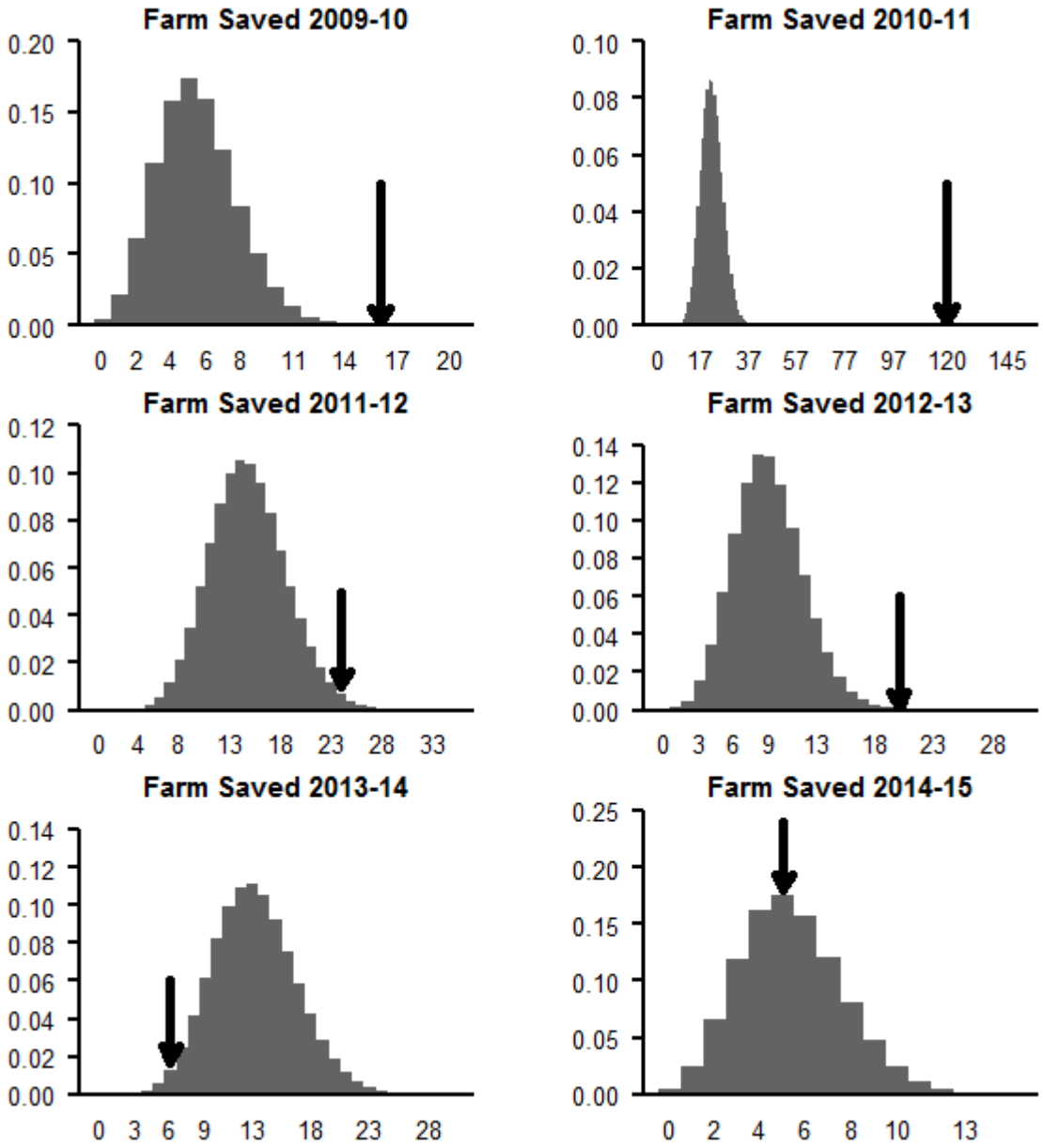

Figure 2. The expected distribution of false positive test for each series of tests completed on data for Farm Saved seed. The arrows indicate the observed number of positive tests.

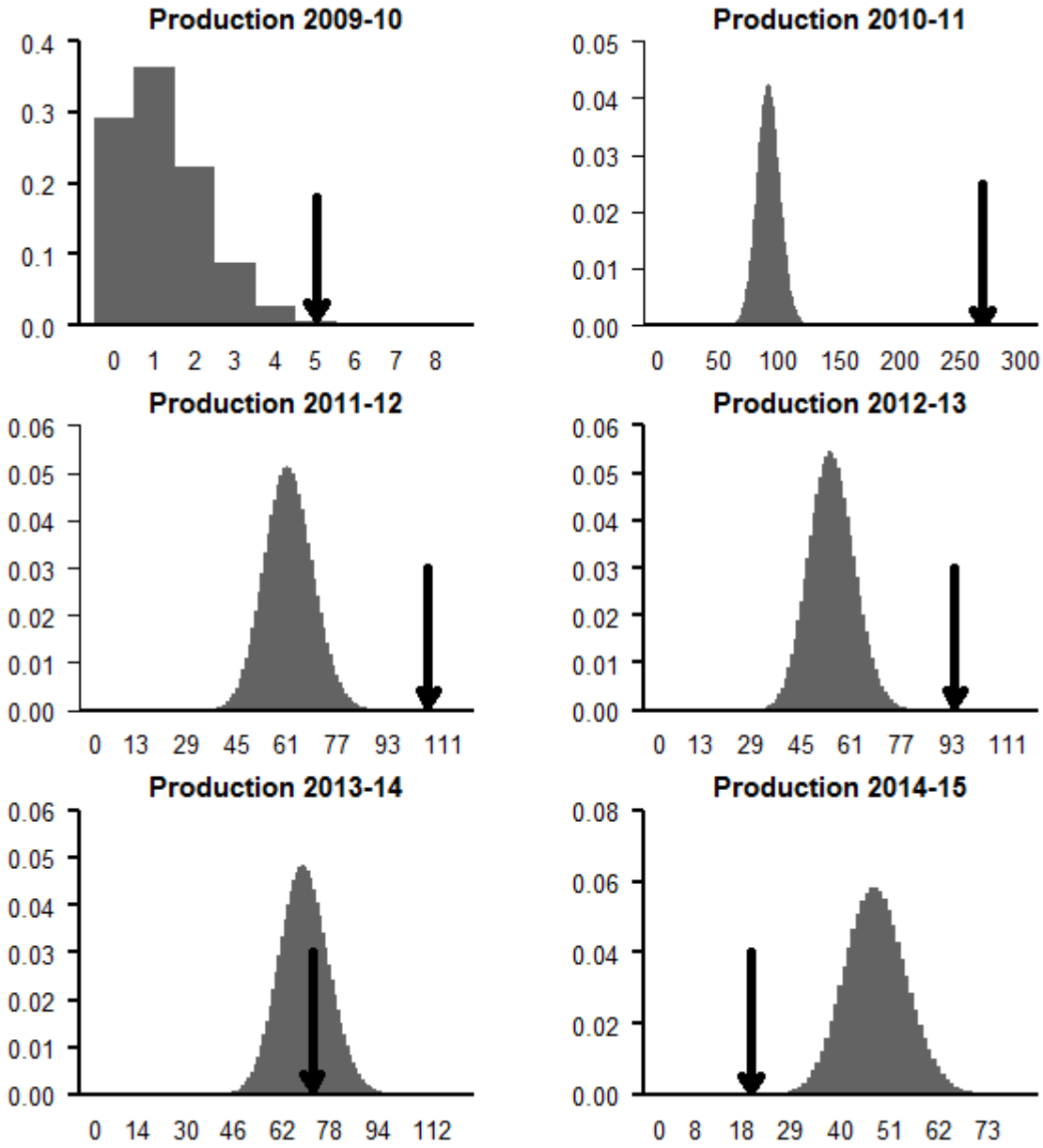

Figure 3. The expected distribution of false positive test for each series of tests completed on data for Production seed. The arrows indicate the observed number of positive tests.

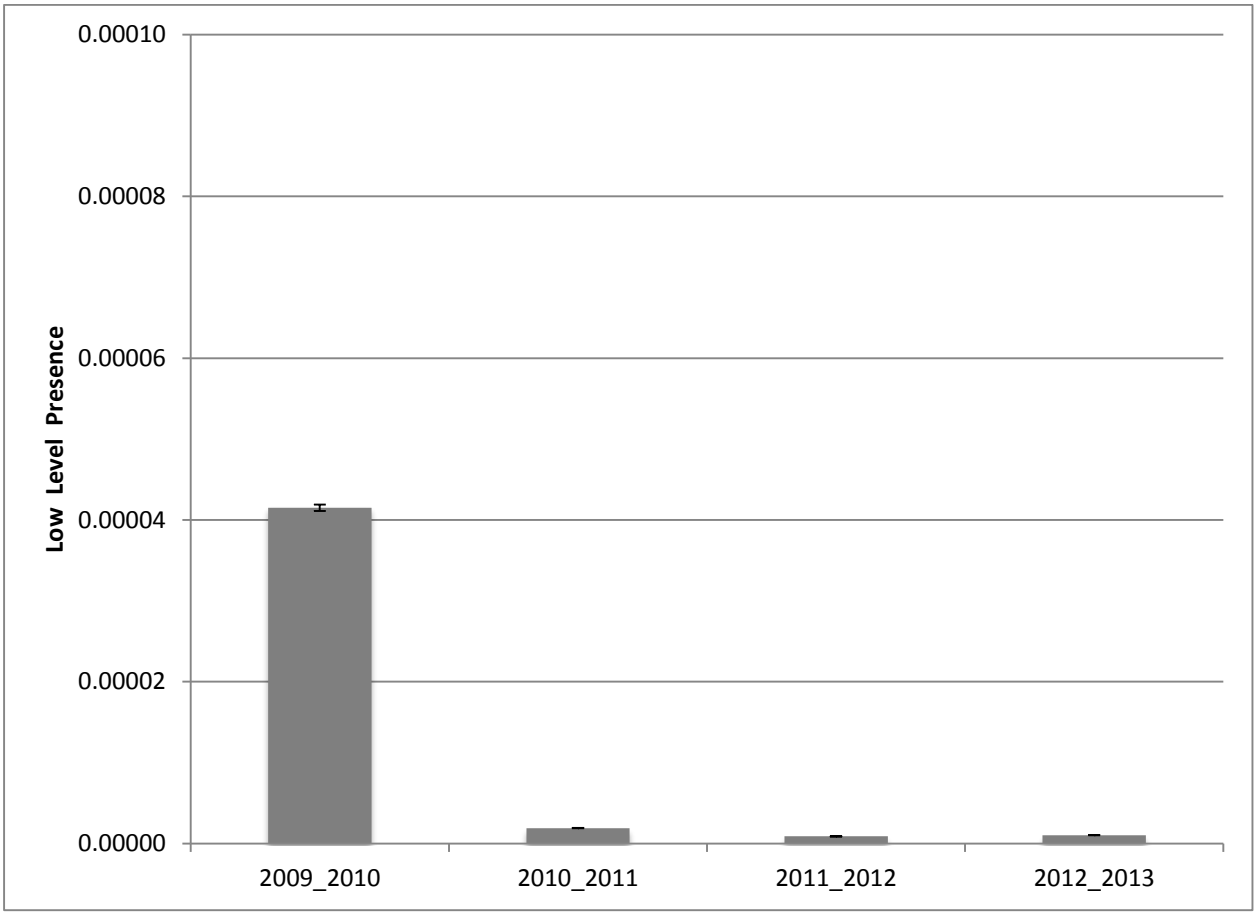

Figure 4. Estimated mean low level presence (LLP) of GM flax in production grain lots using the simulation tool. The error bars indicate a 95% confidence interval around the estimate (Source: Adapted from results presented in Booker et al. (2014), Table 1).

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