

*Oats: If Both Roads Lead to Gluten-Free,
Does It Matter Which One We Take?
DIGID BREAKFAST, FNCE 2016*

Note: This packet of information has been prepared for attendees at the DIGID breakfast. It is not intended as a stand-alone document.

Definitions

Gluten-Free Oats: Oats containing less than 20 parts per million of gluten

Purity Protocol Gluten-Free Oats: Oats produced following specific protocols to be free of gluten-containing grain beginning at the time seed is sorted for planting

Mechanically/Optically Sorted Gluten-Free Oats: Traditionally grown oats that undergo a sorting process at the mill to remove gluten-containing grain based on a variety of grain properties (e.g., size, color)

Why Oats are an Issue

Table 1. Gluten Content of Commercial Oat Products.*

Product and Lot No. or Best by Date	Gluten		
	Extraction A	Extraction B	Mean of A and B
	ppm		
McCann's Steel Cut Irish Oats, 28-oz container			
110134	12	12	12
138934	BLD	BLD	BLD
276934	24	21	23
166634	701	761	729
Country Choice Old Fashioned Organic Oats, 18-oz container			
July 11, 2004	131	138	131
Dec. 13, 2004	200	228	210
Dec. 17, 2004	116	124	120
March 12, 2005	BLD	BLD	BLD
Quaker Old Fashioned Oats, 18-oz container			
1369; Jan. 9, 2005	326	349	338
1369; Jan. 18, 2005	997	944	971
1338; Feb. 12, 2005	1861	1712	1807
1369; March 22, 2005	371	312	364

* BLD denotes below the limit of detection. The limit of gluten detection for the assay used in this analysis was 3 ppm.

In this study, regular oats (Quaker, Country Choice, McCann's) had gluten levels ranging from less than 3 ppm to over 1,800 ppm. Gluten levels were highly variable within and between brands.

Source: Thompson T. N Engl J Med 2004; 351:2021-2022
<http://www.nejm.org/doi/full/10.1056/NEJM200411043511924#t=article>

Gluten Contamination Levels of Oat Products Labeled Gluten-Free: Summary Test Results from Gluten Free Watchdog

Over the past five years Gluten Free Watchdog has tested 35 different oat products labeled gluten-free that list oats as the first or second ingredient.

Bottom line: Based on testing data from Gluten Free Watchdog, oat products labeled gluten-free are at a higher risk of gluten contamination as compared to labeled gluten-free foods as a whole.

- 28/35 or 80% of oat products tested below 5 parts per million of gluten
- 5/35 or 14% of oat products tested at or above 20 ppm of gluten
- 2/35 or 6% of oat products tested at or above 5 ppm but below 20 ppm of gluten

Note: Approximately 5% of all gluten-free foods tested to date through Gluten Free Watchdog have tested at or above 20 ppm of gluten. The percentage of oat products testing at or above 20 ppm of gluten (i.e., 14%) is higher than for gluten-free foods in general.

Products testing at or above 20 ppm of gluten [testing conducted by Bia Diagnostics, LLC using the sandwich R5 ELISA (Ridascreen Gliadin R7001) and cocktail extraction (Mendez method)]:

- Oat breadcrumbs. Extractions ranged from 9 ppm to > 84 ppm of gluten
- Rolled oats. Extractions ranged from 72 ppm to > 84 ppm of gluten
- Granola. Extractions ranged from < 5 to 50 ppm of gluten
- Hot oat cereal. Extractions ranged from 18 to 73 ppm of gluten
- Granola. Extractions ranged from 16 to 26 ppm of gluten

*Note: Based on conversations with the manufacturers of products testing at or above 20 ppm of gluten, **oats from suppliers of purity protocol oats were not being used in these five products at the time of original testing.** Four of the manufacturers have changed or are in the process of changing oat suppliers. Three of these products have been retested for gluten contamination. These products are now testing below 5 ppm of gluten. One of the manufacturers chose to stop labeling product gluten-free.*

Source: www.glutenfreewatchdog.org

For more information see <https://www.glutenfreewatchdog.org/news/gluten-contamination-levels-of-oat-products-labeled-gluten-free-summary-test-results-from-gluten-free-watchdog/>

Testing Protocols Followed by Millers of Mechanically Sorted Oats

Quaker Gluten-Free Oatmeal

Quaker uses traditionally grown oats that have been mechanically and optically sorted to be gluten-free.

- Finished product testing (as reported to Gluten Free Watchdog and confirmed July, 2016)
 - 16 pouches or tubes are pulled during a production run (approximately 1 pouch or tube every ½ hour).
 - Note: Approximately 400,000 single serving pouches are produced during a lot run; 50,000 tubes are produced during a lot run.
 - A 40-gram sample is taken from each pouch or tube.
 - The sample is homogenized.
 - Two extractions are taken from the homogenized sample and tested using the Ridascreen Gliadin R5 ELISA (R7001) Mendez Method.
 - If any single extraction from any of the 16 pouches or tubes is above 12 ppm gluten the entire lot is discarded.
 - Since beginning commercial runs, three early runs were above 12 ppm gluten and these lots were destroyed. Since taking corrective action, 25 additional lots have been run. All but one extraction from finished product gluten-free oatmeal tested below 5 ppm gluten; one extraction tested just above the lower limit of quantification of 5 ppm gluten (6 ppm).
 - UPDATE Jan 20, 2016: In email correspondence, Quaker writes, “we have continued to implement the testing protocol we shared with you for finished product. Out of our last 50 lots produced, we have had one lot test above 12 ppm; as a result, that entire lot of finished product was destroyed. All other lots produced met or exceeded our standards and were released into market.”

Source: www.glutenfreewatchdog.org

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Gluten-Free Cheerios

General Mills uses traditionally grown oats that have been mechanically and optically sorted to be gluten-free.

Finished product testing (as reported to Gluten Free Watchdog and confirmed August, 2016):

General Mills is producing gluten-free Cheerios using what they term “validated gluten-free flour.”

General Mills determines gluten-free status of a “lot” of oats via a lot mean.

General Mills defines a “lot” as a 24-hour production cycle. To arrive at a lot mean, the following protocol is followed:

1. Twelve to eighteen boxes of cereal are pulled during a production cycle
2. The contents of each individual box are ground
3. A sub-sample of ground product is taken from each box
4. The sub-samples are composited—meaning they are combined
5. The combined sub-samples are subject to additional grinding
6. A minimum of twelve extractions are taken from this combined, ground sample
7. Extractions are tested using the Ridascreen Fast Gliadin (R7002) and cocktail extraction solution

Test results

Lot means: According to General Mills lot means for Yellow Box Cheerios (finished product) are between 10 and 13 parts per million of gluten.

On August 25, 2015 General Mills advised me that, “... all the lots of Yellow Box Cheerios are testing below 15 ppm. Lots of the other Gluten Free Cheerios products are testing below 10 ppm.”

Source: www.glutenfreewatchdog.org

Grain Millers

Grain Millers uses traditionally grown oats that have been mechanically and optically sorted to be gluten-free.

Question posed to Grain Millers July 2016: “Are there any updates (or additional information) to the last information provided to me (testing one extraction every 2,000 pounds of oats with the intent of increasing this to testing in duplicate?).”

Response from Grain Millers: “... our proprietary process and overall program is significantly more complex than a simple, single ELISA test on finished product...”

The final finished product test you refer to is merely the last step of our process and is a verification that the previous steps are and have been under control throughout the entire milling process.”

Source: www.glutenfreewatchdog.org

La Crosse Milling

Questions posed to La Crosse Milling October 2015: “...can you please provide information about your sorting process and testing methodology to ensure that oats are gluten-free.”

Response from La Crosse Milling: “Gluten Free oats are sampled and tested on a per pallet basis. Finished product must test at <10ppm Gluten to make Gluten Free status.”

Additional information provided August 2016:

- There are 40,000 # per pallet
- 3 tests per pallet (first, middle and last bag)
- Test results are not averaged
- The pallet will be rejected if any sample from it comes back as over 10 ppm of gluten.

Source: www.glutenfreewatchdog.org

R-Biopharm Updated Instructions for Testing Oat Samples

In November of 2015 R-Biopharm (producers of the sandwich and competitive R5 ELISAs for gluten analysis) stated to me in email correspondence that they had updated the instructions for the sandwich R5 ELISA when testing oat samples because customers and internal experiments found that oat samples can be quite inhomogeneous.

Original instructions: “Homogenize well a sufficient amount (at least 5 g or 5 ml) of sample (grind it thoroughly to powder and mix well or mix well the solution respectively)...weigh 0.25 g of the homogenized sample and add 2.5 ml of the Cocktail (patented), close the vial and mix well.”

Updated instructions October 2015: “**Oat samples: gliadin may not be distributed evenly, furthermore the samples are difficult to homogenize.** Therefore, homogenize 200g, then carry out the extraction with at least the fourfold amount of reagents: weigh 1 g of the homogenized sample and add 10 ml of the Cocktail (patented), close the vial and mix well.”

Source: <http://www.r-biopharm.com/>

Must Read Study on Testing Oats for Gluten

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Researcher Contention

Oats are easily contaminated with kernels of wheat, barley, and rye. These kernels are not evenly distributed within a sample of oats and are difficult to homogenize within a sample of oats for accurate gluten testing.

Experiment One

In market survey: Commercially available gluten-free oatmeal was assessed for gluten via R-biopharm’s Ridascreen Gliadin R5 ELISA by an independent laboratory. Of the 636 samples (45 grams for a packet of oatmeal and 50 grams taken from a canister of oatmeal) tested, 10 sub-samples (based on “homogenizing” the entire sample and testing a single 0.25 gram extraction) tested at or above 20 ppm of gluten. Twenty additional sub-samples tested above the lower limit of quantification for gluten of 5 ppm but below 20 ppm of gluten. The researchers designated these samples as “positive yet compliant” meaning that they contained quantifiable gluten but the level of gluten was below the FDA’s threshold for gluten-free labeling of 20 ppm of gluten.

The lab conducted additional testing on the 20 samples of oatmeal initially testing between 5 ppm and less than 20 ppm gluten. A total of 11 (0.25 gram) extractions were tested from each of these individual samples of oatmeal. **At least 9 (and as many as 11) of these 20 samples contained on average above 20 ppm of gluten based on testing multiple extractions from each sample. This despite the fact that the first extraction tested contained less than 20 ppm of gluten.**

Experiment Two

Gluten distribution in oats spiked with wheat: One kernel of wheat was added to 12 (50 gram) samples of pure gluten-free oat groats. Each sample was ground by an independent lab to homogenize (evenly distribute) the gluten. Each ground sample was then tested in triplicate. What remained of each 50-gram sample was sent back to the researchers. PepsiCo's/Quaker's analytical team tested the entire amount of sample in 0.25-gram extractions (approximately 2,300 analysis were performed).

Results of testing were highly heterogeneous (variable) and were skewed right meaning that gluten contamination remained concentrated within a relatively small number of 0.25-gram extractions. Study authors write, "with highly skewed distributions like this, the determination of gluten content in oat groats via a single 0.25-g sample test becomes error prone. This is because a few of the 0.25-g samples possess large amounts of gluten while others have received just a fraction of it. This leads to the potential for misdiagnosis (i.e., concluding either a sample average is <20 ppm when it is not, or that all possible test results are <20 ppm when they are not, depending on one's interpretation of the 20 ppm regulatory threshold)."

Study authors used the testing data to develop probabilities for various true average gluten levels that a single 0.25-gram test result reads less than 20 ppm. They found that if the true average gluten level in a 50-gram sample is greater than 60 ppm gluten then the chance of getting a false negative result is less than or equal to 5 percent. If the true average gluten level is between 20 and 60 ppm of gluten the probability of a false negative result was about 60% for a true gluten average of 20 ppm and about 10% for a true gluten average of 55 ppm.

Source (study summary): www.glutenfreewatchdog.org

Source: Gluten-containing grains skew gluten assessment in oats due to sample grind non-homogeneity. Fritz RD, Chen Y, Contreras V. *Food Chemistry*. February 2017;216:170-175. Published online ahead of print August 12, 2016. To read the summary in full, see <https://www.glutenfreewatchdog.org/news/must-read-study-courtesy-quaker-testing-oats-gluten/>