

## Commentary

# Oat Consumption by Celiac Disease Patients: Outcomes Range from Harmful to Beneficial, Depending on the Purity of the Oats

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Currently, the only known treatment for Celiac Disease (CD) is adherence to a gluten-free diet (GFD) [1]. This treatment is theoretically effective but hampered in practice due to difficulty of execution, an impaired quality of life [2], side effects such as nutritional deficiencies [3] and unanswered questions regarding possible increased risk of cardiovascular disease [4].

These issues are due in part to a lack of whole grains inherent with a GFD. This limits dietary options which can then adversely affect adherence. Quality of life can then be impaired due to the reduction in food alternatives as well, and the limited dietary diversity may cause deficiencies in fiber, iron and protein.

Oats are a whole grain that is naturally gluten-free (GF). Oats are also an excellent source of fiber, iron and proteins [5], as well as being associated with a reduced risk of cardiovascular disease [6]. Thus it seems oats would be a natural addition to GFD's for CD patients. But questions exist regarding oat safety for CD patients, due to conflicting results across oat feeding studies [7].

Some theorize these inconsistent findings are due to a portion of CD patients possessing sensitivity to the oat protein avenin. Recent research suggests another possibility for the occasional observed adverse reactions to pure oats though. That is, that study subjects likely did not receive pure gluten free oats during these investigations, and therefore studies became unknowingly biased by use of oats assessed as GF but actually contaminated by gluten containing grains (GCG) [8].

The reason for the mis-assessment is that until recently, standardized, statistically valid assessment of oats as GF has not occurred. Consequently participants in prior CD feeding studies, as well as CD patients in general have been potentially consuming gluten-contaminated GF labeled oats on a regular basis. Testing of

in-market GF labeled oats in the U.S. substantiates this claim. Table 1 demonstrates recent in-market assessments of various manufacturers of GF labeled oats, wherein one in every few dozen servings is non-compliant.

The root cause for errant assessment is overlooking the subtle but profound implications of 'whole kernel' contamination. During routine harvesting and processing, oats are regularly contaminated with wheat, barley and other GCG's. Contamination thereby comes highly concentrated in pill-like form, remaining intact to the spoon in whole grain products. This 'needle in the haystack' type circumstance renders traditional sampling approaches prone to false negatives, i.e., concluding no gluten present in a production lot when in fact it is.

For instance, if the true but unknown contamination rate is 1 in 25 servings, the probability of looking at 25 servings and finding them all clean is still rather high, at 0.36. So, about 36% of production lots would be deemed GF under this scenario. Looking at just 10, instead of 25, would pass 64% of the time, and looking at three would pass nearly 90% of the time. Because of this, false negatives could have biased CD oat feeding studies to date [8], and as we have seen in Table 1, several GF oat offerings tend to have a wheat or barley kernel present in every few dozen servings, that is despite having been evaluated and dispositioned as GF by their producers.

Consequently, most servings of GF labeled oats are pure, and therefore truly GF, but these clean servings are then interrupted with some regularity by servings containing a GCG. When that occurs, say with a hard wheat kernel in a 40g serving of GF oats, the serving contains about 4 times the maximum allowed gluten under U.S. FDA requirements. This equates to gluten dosing of ~3.34mg gluten, which has been shown sufficient to affect a sizable portion of the CD patient population, when ingested on a daily basis [9].

**Table 1 - Contamination Rates for GF Labeled Oatmeal obtained from Store Shelves for Various U.S. Manufacturers**

Manufacturer of GF Labeled Oatmeal	Approach Used to Achieve GF State	Item Type	How Samples Obtained	Date of Assessment	Serving Qty. Assessed (45-50g amounts)	Lab	Test Method Used	Qty. of Non-Compliant Servings Found*	Rate of Non-compliant Servings (> 20 ppm gluten)
Major U.S. Manufacturer #1	Mechanical/ Optical Cleaning	In-Market Finished Goods	3rd Party Sample Acquisition Company	7/14 - 12/14	316	well-recognized third party analytical lab	R-Biopharm R5 ELISA RIDASCREEN Gliadin (R7001)	8	1 in 40
Major U.S. Manufacturer #1	Mechanical/ Optical Cleaning	In-Market Finished Goods			360	PepsiCo Analytical Lab		5	1 in 72
Major U.S. Manufacturer #2	Mechanical/ Optical Cleaning	In-Market Finished Goods		7/14 - 12/14	320	well-recognized third party analytical lab		2	1 in 160
Major U.S. Manufacturer #2	Mechanical/ Optical Cleaning	In-Market Finished Goods			101	PepsiCo Analytical Lab		2	1 in 51
Major U.S. Manufacturer #2	Mechanical/ Optical Cleaning	In-Market Finished Goods		8/17	150	well-recognized third party analytical lab		4	1 in 26
Major U.S. Manufacturer #3	Purity Protocol	In-Market Finished Goods		8/17	166	well-recognized third party analytical lab		5	1 in 33
Major U.S. Manufacturer #3	Purity Protocol	In-Market Groats		8/17	50	well-recognized third party analytical lab		4	1 in 13

\* - Non-compliant servings being those with >= 20 ppm gluten found.

But today we know what it takes to accurately assess oats as GF [8]. And economically viable systems to ensure this level of performance have been shown attainable [10]. Quaker for instance, has been using these published methods since 2015. Since then, 44 candidate GF groat lots have been assessed, this done via 3,000 servings-worth per lot and where all 3,000 must be found compliant to the 20 ppm regulatory limit. Ten servings total, out of the 132,000 evaluated thus far have been found non-compliant, and the ten lots from which they came routed to non-GF labeled oats streams. This performance equates to a cleaning efficiency of 1 in 13,200 servings on average containing a GCG, and this is an assessment done prior to acceptance of the oats as acceptable for GF labeled product. Purging the lots found with a non-compliant serving then provides an ‘average outgoing quality limit’ (AOQL) via attribute acceptance sampling of no worse than 1 in every 22,022 servings being contaminated. AOQL represents the maximum outgoing non-compliance rate for finished goods.

So in summary, oats as part of a CD patient diet can provide benefit or cause harm. The outcome appears dependent on the purity of the oats consumed. It remains possible some CD patients are sensitive to the oat protein avenin, explaining inconsistent clinical trial outcomes, but increasingly the evidence appears on the side of CD patients simply getting ‘glutened’ by contaminated GF labeled oats. Further clarification of observed intolerances awaits clinical trials employing stringently assessed GF oats. Regardless though, adding oats deemed GF by these new high standards to CD patient diets, may safely provide the benefit of broader dietary options, leading to improved GFD adherence and quality of life, while bolstering nutritional deficiencies and potentially aiding heart health.

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