

**Petition:**

Action requested: Amendment of the Food Allergen Labeling and Consumer Protection Act (FALCPA) to include barley, and rye in the list of common allergens requiring disclosure on packaging.

Statement of grounds: It has been shown that celiacs are not just sensitive to wheat, but are also sensitive to the gluten of rye and barley. For a good reference listing these grains and their products as bad for celiacs, one need only refer to page 20 of Gluten-Free Diet edition 2006, by Shelley Case, BSC (nutrition & dietetics), RD (registered dietitian).

A list of research articles supporting this follows:

1. Clin Chim Acta. 1991 Dec 31;204(1-3):95-107.

**Cellular and humoral responses in coeliac disease. 1. Wheat protein fractions.**

Penttila IA, Devery JM, Gibson CE, LaBrooy JT, Skerritt JH.

2. Am J Clin Nutr. 2008 Feb;87(2):405-14.

**Sensitive detection of cereal fractions that are toxic to celiac disease patients by using monoclonal antibodies to a main immunogenic wheat peptide.**

Morón B, Cebolla A, Manyani H, Alvarez-Maqueda M, Meqías M, Thomas Mdel C, López MC, Sousa C.

3. Aliment Pharmacol Ther. 2006 May 1;23(9):1307-14.

**Barley and rye prolamins induce an mRNA interferon-gamma response in coeliac mucosa.**

Bracken SC, Kilmartin C, Wieser H, Jackson J, Feighery C.

4. Int Arch Allergy Immunol. 1995 Feb;106(2):134-8.

**Antibody response against wheat, rye, barley, oats and corn: comparison between gluten-sensitive patients and monoclonal anti gliadin antibodies.**

Vainio E, Varjonen E.

Abstracts of all of the above articles are available at the National Library of Medicine's database at [www.pubmed.org](http://www.pubmed.org). The above are just a small fraction of the articles concerning rye and barley and their relation to celiac disease. As of this date (07/17/2008) if one queries that database using the words "(rye OR barley) celiac", one receives back a list of 173 references to articles that mention either rye or barley (or both) in conjunction with celiac disease. If one queries the

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database with the words "(rye OR barley) dermatitis" one also gets another list of 56 articles. And incidentally if one queries the database with the words "(rye OR barley) asthma" one gets another 145 articles, including one entitled, "Rye flour allergens: an emerging role in baker's asthma."

It has been estimated that one in 133 persons in the U.S. have actual celiac disease with demonstrable villous atrophy in the small intestine. (Reference: Arch Intern Med. 2003 Feb 10;163(3):286-92.

Related Articles Comment in:

- Gastroenterology. 2004 Jan;126(1):359-61; discussion 361.
- Gut. 2003 Jul;52(7):1070-1; author reply 1071.

### **Prevalence of celiac disease in at-risk and not-at-risk groups in the United States: a large multicenter study.**

Fasano A, Berti I, Gerarduzzi T, Not T, Colletti RB, Drago S, Elitsur Y, Green PH, Guandalini S, Hill ID, Pietzak M, Ventura A, Thorpe M, Kryszak D, Fornaroli F, Wasserman SS, Murray JA, Horvath K.

An excellent source for information about celiac disease, and its various associated conditions is at: <http://www.csaceliacs.org/GreatMimic.php>

Celiac disease is found almost exclusively in those who have the following genetic haplotypes: HLA DQ2 (haplotypes DR-17 or DR5/7) and, to a lesser extent, DQ8 (haplotype DR-4). (Reference: <http://www.emedicine.com/ped/topic2146.htm> under Pathogenesis). According to Wikipedia at [http://en.wikipedia.org/wiki/HLA\\_DQ#HLA\\_DQ2](http://en.wikipedia.org/wiki/HLA_DQ#HLA_DQ2), 13.1 percent of Americans have DR-17 haplotype and 11.1 percent of Americans have the DR7 haplotype. And according to Wikipedia at <http://en.wikipedia.org/wiki/HLA-DQ8>, DQ8.1 is the most common DQ8 type, with an incidence of 10.5 percent for U.S. Caucasians, and 4.5% for African Americans in the Southeast U.S. Other genetic haplotypes have also been implicated in gluten sensitivity. Consider all these percents together, and you may get an idea of the real possible total size of the gluten sensitivity-celiac continuum. Most of those who do not have actual gastrointestinal symptoms will remain undiagnosed.

Many gastroenterologists believe therefore that actual celiac disease with villous atrophy is just the tip of the gluten sensitivity iceberg. There are many persons without villous atrophy, and even without any blood antibodies to gluten, who nevertheless show gluten antibodies in their fecal smears. (Reference: <https://www.enterolab.com/StaticPages/EarlyDiagnosis.htm>).

You may ask, "What is the problem if gluten sensitivity is not causing actual villous atrophy (celiac disease)?" In the words of Dr. Alessi Fasano, "Gluten causes a whole lot more than just celiac disease." Celiac disease can trigger a

large variety of other autoimmune diseases, neuropathy, and even cancer. However, even without actual villous atrophy, persons with the DQ8 and DQ2 haplotypes are more prone to these same problems. I will not list all the references for this, for there are multitudes of studies, available at [pubmed.org](http://pubmed.org) which anyone can find by searching under the relevant haplotype together with such terms as autoimmune diabetes, lupus, dermatitis, Hashimoto's thyroiditis, Grave's disease, autoimmune hepatitis, scleroderma, arthritis, Sjogren's etc. You will discover that there is a documented increased incidence of these conditions and a proven increase in certain autoimmune antibodies (for DQ8 these include antiribosomal P antibodies, anti-topoisomerase I, and anti-apolipoprotein H, also known as anti-  $\beta$ 2GP1) in persons with these haplotypes.

A good discussion of the 2 main theories surrounding the comorbidity of celiac disease with other autoimmune diseases is at:

[http://www.medscape.com/viewarticle/547107\\_2](http://www.medscape.com/viewarticle/547107_2) (Medscape requires a free registration to access this article). If the first theory discussed is correct, then untold pain and suffering has resulted from the consumption of gluten by persons having the DQ8 or DQ2 genes, even if they do not have gastrointestinal effects. Of course, in actual celiac disease the adverse affects of gluten on the intestinal tract is already proven. The malabsorption that results accounts for many of its side effects such as osteoporosis, neuropathy, growth retardation in children, unusual bruising or bleeding, nutritional deficiencies, weight loss, and the other things listed at [http://www.csaceliacs.org/celiac\\_symptoms.php](http://www.csaceliacs.org/celiac_symptoms.php).

It has been shown that as little as 10 mg of gluten per day can trigger autoimmune effects in persons with celiac disease. (Reference: Aliment Pharmacol Ther. 2008 Jun 1;27(11):1044-52. Epub 2008 Feb 29

**Systematic review: tolerable amount of gluten for people with coeliac disease.**

Akobeng AK, Thomas AG.

(A link to this article is at <http://www.ncbi.nlm.nih.gov/pubmed/18315587> .)

We are talking about a very small quantity here. One cubic centimeter of water has a mass of 1 gram. Ten mg is 1/100 of that! That is why the contribution of gluten from rye and barley becomes so important.

So what does this mean from a practical standpoint for a person with celiac disease or gluten sensitivity? It means that right now, we are not able to buy any of the products in the grocery store that have the words: "Flavor", or "Natural Flavor" because these may actually be barley malt extract/syrup, and there is no requirement for the company to reveal it as a barley product or list "(from barley)" as a modifier. We also are not able to buy products listing "modified food starch" for the very same reason. And what about maltodextrin? It has to show "wheat maltodextrin" if it comes from wheat. But what does malt usually come from? Barley! And producers do not have to reveal its source as a barley product! Here

is another: "Dextrin". If it comes from wheat that must be shown, but how do we know if it comes from rye or barley? And how about "Rice syrup"? Occasionally it is made with barley malt enzymes which may contain residual gluten, but again it gets by without source labeling!

I challenge you to go to the store and try to find soups, rice mixes, entrees, sauces, dinner kits, salad dressings and other products that have none of the words "Flavor," "Natural Flavor," "Modified Food Starch," "Maltodextrin," "Dextrin," or "Rice syrup" in them. You will find next to nothing. It is very possible that those products are not derivatives of rye or barley, but there is no way for me to know, so I cannot buy them. If you are not a celiac or gluten sensitive then you can not imagine all the wasted hours I have spent in the grocery store reading labels only to find repeatedly that they have one or more of these questionable items. Try also to imagine all the hours of cooking labor added to each week from not being able to use any "convenience items" and instead having to cook everything from scratch.

The downside of this argument from the food producer's point of view is that there will be some initial expenditure to change its labels. There will also be some expenditure if a producer does not currently know the derivation of some of its ingredients, in researching that issue. Possibly there will be instances in which a producer decides to change its ingredient brands in order to assure a gluten-free end product. The advantage for the producer is that there will be many products which we on gluten-free diets have been avoiding due to the nagging question of whether they contain rye or barley, and we will find out that many of them do not, and we really CAN buy them after all! There will also be some cases where revenues from products drop because of the new labeling. However, can FDA justify having known celiacs eat rye and barley just in order to keep up revenues?

Environmental impact: none known.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and view on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.

Identifying information:

All persons wishing to participate in this petition must show (FDA requirements):

Full Name: Hallie Jane Davis

Full address: [REDACTED]  
[REDACTED]

Phone number: 

Please, print this out, fill it out, and mail to:

Food and Drug Administration  
Dockets Management Branch  
Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857