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The American Dietetic Association (ADA) appreciates this opportunity to respond to the Food and Drug Administration (FDA) notice: Food Labeling: Gluten-Free Labeling of Foods; Public Meeting; Request for Comments published in the July 19, 2005 Federal Register (Vol. 70, No.82, pp. 41356-41358.) We support the FDA in establishing a definition of "gluten-free" that will assist Americans with celiac disease to make more informed food consumption decisions and that is, in FDA's words, "both protective of the celiac population and that uniformly applies to "gluten-free" labeling statements for foods marketed in the United States."

The ADA is the largest association of food and nutrition professionals, representing nearly 65,000 members serving the public through the promotion of optimal nutrition, health and well-being. Americans suffering from celiac disease (CD) look to registered dietitians (RDs) for dietary guidance that will resolve symptoms, heal the intestinal villi, and prevent complications that may arise as a result of untreated celiac disease. A label definition and standards for "gluten-free" will be of considerable value both to RDs in their efforts to educate and counsel individuals with celiac disease and to individuals with CD. RDs advise persons with CD to read all labels and ingredient lists for both obvious and not so obvious sources of wheat, barley, rye and triticale. Considering the number of food products on the market, this process is time intensive and not 100 percent certain, even for persons who are well educated on label reading. A standardized gluten-free label will help gluten-sensitive persons protect their health.

ADA experts review the latest scientific literature to develop and update ADA's *Nutrition Care Manual* and other professional documents that are timely to assist RDs in providing the most up-to-date, evidence-based nutrition care. These documents and expertise are the primary sources for the comments that follow.

DEFINITIONS AND PERMISSABLE USE OF “GLUTEN-FREE”

ADA acknowledges that a zero tolerance for gluten¹ in foods is both unrealistic and technically unreasonable. Thus, ADA recommends that FDA consider adopting the threshold recommendations of Codex when those standards are finalized. This approach would promote the creation of a universal, global definition of “gluten-free” and be of great benefit to persons with CD who travel outside of the United States.

ADA also encourages FDA to consider the Codex *Draft Revised Standard for Gluten-Free Food*, which is scheduled to be presented at the fall 2005 meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). This report will address thresholds of gluten tolerance in celiac disease based on the Prolamin Working Group clinical trial data. The FDA may derive important information by examining this report as the agency deliberates on the establishment of a definition for gluten-free foods.

OATS AS A SOURCE OF GLUTEN

While there is evidence that oats can be consumed safely by most persons with CD, given the many opportunities of the commingling of gluten and non-gluten containing grains throughout the growing and harvesting of these grains, celiac patients need to exercise caution. Corn, wheat, soybeans, oats and other grains are grown on the same farms in the United States and farmers use the same combines to harvest, wagons to transport, and grain bins to store these various grains. The grain elevators receiving the grains also may use the same catch basin to transport different types of grains. The grains then can be transported in containers by truck and rail that are used to transport other grains.

The USDA grade standard specifically recognizes that up to 10 percent of “other grains” can be found in corn, soybeans, wheat and canola and that up to 25 percent of “other grains” can be found in oats and barley. If the oat grain is not contaminated by wheat, barley, or rye due to crop rotation, transport, or processing, because of potential risks of consuming oats to some individuals with CD, ADA supports FDA establishing a definition for uncontaminated oats that is tied to testing and meeting the definition of gluten-free for food labels. This would be a huge benefit to persons with CD and is consistent with recommendations published in the celiac disease chapter of ADA’s *Nutrition Care Manual*² which recommends that persons with CD consume oats that are not contaminated with gluten..

Dietetic professionals play a critical role in helping consumers interpret food labels, integrate them with other tools and information, and apply them in their lives. For persons with CD, the food label is a critical partner in managing and treating their disease.

¹ In using the term ‘gluten’, we are adopting the convention of assuming that it includes a combination of prolamin proteins called “gliadins” and glutenin proteins called “glutenins” found in different wheat species, barley, rye, and their cross-bred hybrids such as triticale. Food and Drug Administration. Approaches to establish thresholds for major food allergens and for gluten in food. Available at: www.cfsan.fda.gov/~dms/alrgn.html. Accessed June 24, 2005.

² Celiac Disease. ADA Nutrition Care Manual. 2004. Available at: www.nutritioncaremanual.org. Accessed September 16, 2005.

For further information or clarification of the above comments, please contact me at 202-775-8277 or mhager@eatright.org.

Sincerely,

/s/

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