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# Consultation Summary: Notice of Intent to Issue a Food Marketing Authorization to Allow Gluten-Free Claims for Specially Produced Gluten Free Oats and Products Containing Such Oats

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Food Directorate

Health Products and Food Branch



Canada 

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## **Background**

On November 14, 2014, Health Canada published a Notice of Intent to inform Canadians and other interested stakeholders of the intent of the Minister of Health to issue a Marketing Authorization (MA) to allow gluten-free claims for specially produced oats that do not contain more than 20 parts per million (ppm) of gluten from wheat, rye, barley, or their hybridized strains, and for foods containing these “gluten-free oats” as ingredients when sold in Canada.

The Notice of Intent was posted on Health Canada’s website and open for public consultation for a period of 75 days from November 14, 2014 to January 27, 2015. Health Canada would like to thank stakeholders who provided input on the Notice of Intent.

The purpose of this consultation report is to provide a summary of the comments received and Health Canada’s response to these comments.

## **Summary of Consultation**

### **Participation**

Health Canada received 13 responses to the Notice of Intent from stakeholders, including industry, public health organizations and the general public. Most stakeholders expressed their support for the MA and also provided comments or sought clarification on elements of the proposed approach.

### **General Comments**

Overall, the majority of stakeholders were supportive of Health Canada’s proposed approach to allow claims for gluten-free oats. However, some stakeholders sought clarification regarding certain elements of the approach, in particular, regarding the ability to identify products containing gluten-free oats and whether different varieties of oats have a different effect on people with celiac disease.

## Comments and Health Canada Responses

The following summarizes the comments received from stakeholders as well as Health Canada's response:

**Comment 1:** Overall, Health Canada received support for the proposed changes. In particular, Health Canada received the following types of comments:

- Allows greater choice for Canadians and gives manufacturers the ability to provide more options.
- Reduces consumer confusion, introduces another nutrition filled whole grain to the gluten-free diet, and above all, recognizes the science that allows for the inclusion of oats in a healthy gluten-free diet.
- The revision will align Canada with both the USFDA and Codex standards.
- Will help identify safe foods and add variety for those following a strict gluten-free diet.

**Response 1:** Not Applicable

**Comment 2:** Concerns raised by people allergic to oats, including the "gluten-free" oats, and about the ability to identify whether a gluten-free product contains gluten-free oats.

**Response 2:** Under the proposed changes, any reference to oats on the label or in advertisements would have to indicate that they are gluten-free oats. This would enable consumers who must avoid all oats to continue to make informed choices about which foods are safe for them to consume by reading the information provided on the label.

**Comment 3:** Recommend that HC provide guidance on acceptable test methods and sampling protocols to support gluten-free claims.

**Response 3:** Currently, the most commonly used methods to detect the presence of gluten are ELISA-based methods, which use antibodies to detect proteins or specific parts of proteins (epitopes). In general, these methods are sensitive and specific to the analytes they target and can detect gluten in a wide variety of foods. However, these methods may have difficulty detecting

and/or quantifying proteins that have been hydrolyzed, fragmented or otherwise structurally altered, since the antibody will no longer react in the same manner if the epitopes have changed significantly.

Based on the most recent assessment conducted by Health Canada, methods using the Mendez antibodies (R5 antibodies) allow for the detection and quantification of gluten in most processed foods. Health Canada will continue to assess analytical methods that are specific to the detection and quantification of gluten in processed foods and will provide further guidance on the applicability of these methods.

In addition, the [\*Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten\*](#) contains a section on acceptable test methods and sampling protocols.

**Comment 4:** Suggest that the term “gluten-free” be adopted as a better descriptor than “uncontaminated oats”.

**Response 4:** The MA will require that oats which meet the criteria must be identified as gluten-free oats in any reference on the label or in advertisements. This will provide assurance to the consumer that only gluten-free oats were used in manufacturing the product.

**Comment 5:** Request that the qualifications are expanded to include products made from oats.

**Response 5:** The MA would allow gluten-free claims on gluten-free oats or foods made with gluten-free oats as long as the oats meet the requirements outlined in the MA.

**Comment 6:** Believe pure oats should qualify as “a cereal-derived ingredient which includes additional processing steps which are demonstrated to be effective in removing gluten”.

**Response 6:** Health Canada is of the opinion that oats do not qualify as a “cereal-derived ingredient which includes additional processing steps which are demonstrated to be effective in removing gluten” because oats contain the gluten-like protein “avenin”, which is still present even after the additional processing that is undertaken to remove gluten from other cereal sources.

**Comment 7 (combined):** Concerned about wording “or oats that are processed in a way that effectively removes cross-contamination by wheat, barley, rye, or their hybridized strains”.

Since research has shown that, depending on sampling procedures, results can vary significantly, more stringent requirements are needed to meet gluten-free oat status.

Recommend that footnote should only include clause: “oats that are grown, transported, stored, prepared and processed in a manner that avoids cross-contamination by wheat, barley, rye, or their hybridized strains”.

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Suggest a strict quality control program, as gluten testing is only one component of the gluten management system.

**Response 7:** The MA will specify that the oats being used must be very pure, and that they do not contain gluten from wheat, rye or barley (or hybridized strains) at levels above 20 ppm. The MA will not specify how the oats arrived at this state of purity.

Some current producers of pure oats use controls on the way that oats are grown, transported, stored, etc., which has proven to be effective. However, if other methods or controls are developed to effectively remove cross contamination and provide oats that meet the requirements of the MA, then this would be equally acceptable.

Oats that do not meet the strict criteria for application of the MA would not be eligible for use in foods that will be making a gluten-free claim.

The Canadian Food Inspection Agency (CFIA) will enforce the requirements of the MA and take appropriate action against any foods that make gluten free claims if the oats being used do not meet the criteria outlined in the MA.

**Comment 8:** Different varieties of oats may have different toxicity to people with celiac disease. There was only one Canadian study (Sey *et al* 2011) and that this is not sufficient to support a strong conclusion.

**Response 8:** With regards to studies that suggest different varieties of oats may have different toxicity for people with celiac disease (the first study to this effect was published by Comino *et al* in 2011), Health Canada does not have data comparing the different varieties of oats being grown in North America and Europe. The majority of recent studies about the safety of oats have shown no undesirable effects and confirm that oats which are not contaminated with gluten (the specific varieties used were not identified) are generally well tolerated.

The North American study by Sey *et al* (2011) concluded, based on a small number of participants (15) followed for 3 months, that specially prepared, non-contaminated oats were safe for individuals with celiac disease. No significant changes in the clinical or biological test scores were observed during the study period when oats were being consumed. As in most of these studies, the specific variety of oats used was not identified.

Health Canada agrees that additional studies, particularly Canadian studies, should continue to be encouraged in order to clarify the role that different varieties of oats may play in celiac disease.

**Comment 9:** There should be a national information campaign for people with celiac disease and health professionals to accompany the MA.

**Response 9:** Information will be developed and disseminated to inform Canadians about the changes, in conjunction with relevant stakeholders.

**Comment 10:** There should be a statement on the label of foods with oats that are gluten-free which says something like: “Celiac disease: consult the Health Canada web site for more information about oats and the gluten-free diet”.

**Response 10:** The suggested text was not adopted as a requirement due to its length and the resulting space requirement on the label; since gluten-free oats will be identified on the label and in any advertisements, this will provide sufficient information to consumers.

**Comment 11:** It is important for producers of pure oats to have rigorous standards in place to avoid cross contamination at all critical control points from field to plate.

Concerned that some producers will sell “gluten-free” oats without ensuring their product is safe.

Suggest providing recommended guidelines to safely produce pure oats.

**Response 11:** Some producers of gluten-free oats use controls on the way that oats are grown, transported, stored, etc., and this has proven to be effective. However, if other methods or controls are developed to effectively remove cross contamination and provide oats that meet the requirements of the MA, this would also be acceptable.

Oats that do not meet the strict criteria set out in the MA would not be eligible for use in foods that will be making a gluten free claim.

The CFIA will enforce the requirements of the MA and take appropriate action against any foods that make gluten-free claims if the oats being used do not meet the criteria outlined in the MA.

**Comment 12:** There is no threshold level for wheat allergic individuals. These individuals may expect gluten-free foods to contain zero gluten if they are not aware of the current position regarding the 20 ppm threshold for gluten in gluten-free foods. Suggest using “gluten safe” instead of gluten-free.

Suggest additional wording be required on the label to indicate that gluten-free foods may not be suitable for wheat allergic individuals.

**Response 12:** [Health Canada’s position on gluten-free claims](#) states that foods making a gluten-free claim should not contain any intentionally added sources of gluten at any level. However, gluten-free foods prepared under good manufacturing practices and which contain levels of gluten not exceeding 20 ppm as a result of cross-contamination are considered to meet the health and safety intent of section B.24.018 of the *Food and Drug Regulations*. This is consistent with the way gluten-free claims are regulated in many other countries.

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Gluten-free is the wording that has been used to help individuals with celiac disease make safe food choices for many years. It is the term individuals with celiac disease are taught to look for and is the term that will continue to be used.

Depending on their level of sensitivity, individuals with a wheat allergy may not be able to rely on a gluten-free claim to know if a food is safe for them to consume. There is no requirement for other gluten-free foods to include a disclaimer on their label stating that gluten-free foods may not be suitable for wheat allergic individuals.

Communication around the MA for gluten-free claims on oats will include information for wheat allergic individuals.

**Comment 13:** What is the application process that would be required for manufacturers that want to make a gluten-free claim on products made with pure oats?

**Response 13:** Under the MA, there will be no requirement for an application in order to make a gluten-free claim. Manufacturers who wish to make a gluten-free claim on pure oats or products made with pure oats will be responsible for ensuring that the oats meet the criteria outlined in the MA.

If a product is being marketed as gluten-free and contains oats that do not meet the criteria outlined in the MA, they will be subject to enforcement actions by the CFIA.

### Results of Consultation

Based on the feedback received in response to this consultation, Health Canada has issued a marketing authorization to allow gluten-free claims for specially produced and /or specially processed oats that do not contain more than 20 parts per million of gluten from wheat, rye, barley, or their hybridized strains, and for foods containing these “gluten-free oats” as ingredients when sold in Canada.

### Contact Information

For further information on this consultation, please contact the [Bureau of Policy, Intergovernmental and International Affairs](#)