

## Definition of the “Purity Protocol” for Producing Gluten-Free Oats

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## ABSTRACT

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Several oat processors in the United States and Canada operate under what is referred to as a Purity Protocol for the provision of gluten-free oats. This term is derived from a Health Canada position statement that indicated that pure oats, which they defined as oats that are harvested, transported, stored, processed, and manufactured under good manufacturing practices (GMPs) to minimize the presence of gluten, can safely be consumed by some persons with celiac disease. While proprietary

definitions of the appropriate GMPs have been used in industry for many years, no independent definition of the requirements to make a Purity Protocol claim has been published. This paper provides a consensus definition of the Purity Protocol requirements based on input from the four largest Purity Protocol oat processors in North America. This definition provides transparency to gluten-free consumers and allows for auditing of a Purity Protocol claim.

In 1995, Health Canada issued their first ruling on the voluntary labeling of gluten-free foods. The current version of this ruling, part of the Canadian Food and Drug Regulations (Minister of Justice 2016), states:

*B.24.018: It is prohibited to label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food if the food contains any gluten protein or modified gluten protein, including any gluten protein fraction, referred to in the definition “gluten” in subsection B.01.010.1(1).*

Subsection B.01.010.1 defines gluten as follows:

(a) any gluten protein from the grain of any of the following cereals or the grain of a hybridized strain created from at least one of the following cereals:

- (i) barley,
- (ii) oats,
- (iii) rye,
- (iv) triticale, or
- (v) wheat, kamut or spelt; or

(b) any modified gluten protein, including any gluten protein fraction, that is derived from the grain of any of the cereals referred to in subparagraphs (a)(i) to (v) or the grain of a hybridized strain referred to in paragraph (a). (gluten)

While not all countries define oats as a source of gluten, the inclusion of oats as a gluten source is in line with the Codex Alimentarius definition (Codex Alimentarius 2015) in Section 2.2.1 Gluten, which reads as follows:

*For the purpose of this standard, “gluten” is defined as a protein fraction from wheat, rye, barley, oats<sup>1</sup> or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl.*

Footnote 1 states, “Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level.”

The inclusion of the footnote about oat consumption was backed by references from the European Commission given during the comments period of the revision of the Codex Standard for Gluten-Free Foods, many of which concluded that uncontaminated oats (defined as “oats not contaminated by wheat or other Triticum species, rye or barley”) could safely be eaten by persons with celiac disease (Codex Alimentarius 2006).

Following the release of the 1995 regulation, Health Canada continued to investigate the safety of oats for persons with celiac disease, and in 2007 released a position statement based on an extensive review of the literature (Health Canada 2007). The conclusion from this review was that some patients with celiac disease can tolerate moderate amounts of pure oats in their diet, but that further investigation was needed regarding those people who demonstrated sensitivity to pure oats. It was also concluded that the definition of “pure oats” required refinement. The definition provided in the position statement reads:

*At present in Canada, pure oats may be identified at the source to meet or exceed the purity standards of Foundation #1 as defined by Canada’s Seeds Act or equivalent level of purity obtained by current available methods. Pure, uncontaminated oats shall be harvested, transported, stored, processed and manufactured under Good Manufacturing Practices to minimize the presence of wheat, including spelt and kamut, barley, rye or triticale, or any part thereof, so as not to exceed the action level of 20 ppm of gluten as detected using current available methods.*

The Foundation level that is mentioned in this statement refers to the definition of Foundation Seeds provided in the Canadian Seeds Regulations (Minister of Justice 2015b). Schedule I, Table II of this regulation further states that for Foundation number 1 oats, only one seed of another crop is allowed per kilogram of oat seed stock.

After this position statement was released by Health Canada, some Canadian oat processors began marketing “pure oats” with a claim that they were grown under a “purity protocol” that had requirements for seed stock purity as well as criteria for harvesting, transport, storage, processing, and manufacturing. In 2015, Health Canada issued a market authorization (Minister of Justice 2015a) allowing gluten-free claims on gluten-free oats, stating:

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*Regular oats that have not been specially produced or processed to be gluten free should not be eaten by people with celiac disease or other gluten-related disorders.*

Rather than the Foundation number 1 definition of “pure oats” used in the 2007 position statement, the 2015 market authorization defined gluten-free oats only as those specially produced or processed to contain less than 20 ppm of gluten from wheat, rye, barley, or their hybridized strains.

Oat processors that claim to be operating under a “purity protocol” are stating that their production processes meet the definition of specially produced or processed oats. While some manufacturers have described the specific practices used in their facilities (Armour and Perry 2005; Perry and Armour 2006; Montana Gluten Free Processors 2016), there has been no published definition of the minimum requirements that must be met in order to make a “purity protocol” claim. Without a universal definition of the requirements of this protocol, consumers and buyers cannot be sure that every oat supplier using this term is operating according to industry-accepted or uniform best practices. This paper states the minimal process requirements that will be accepted by the Gluten Intolerance Group of North America (GIG) to meet the definition of a “purity protocol.”

## METHODS

In order to generate a definition of the requirements needed to make a “purity protocol” claim, the four primary oat processors who currently make this claim for their oats were interviewed by the GIG regarding their processing and manufacturing practices. GIG operates an independent certification program for gluten-free foods (GFCO) and thus has a vested interest in ensuring that raw materials used in certified products are safe for gluten-free consumers.

The basic outline of the protocol was established and returned to each processor for refinement. The sections that remained were those agreed upon by all of the processors as being the essential, minimal requirements they are following for manufacturing “pure” gluten-free oats.

**Purity Protocol. Definitions.** The following are definitions of terms as they are used within the protocol description:

**Aspirator:** Equipment that uses air to remove unwanted materials from the grain such as hulls and lighter feed-grade oats.

**Bagger/Filler:** A mechanical device that fills and seals bags of grain.

**Certified Pedigreed Seed:** The first generation for most open-pollinated crops (like oats), produced from Foundation seed by Canadian Seed Growers Association seed growers for sale to farmers to use in planting their commercial grain acreage, of a specific seed variety.

**Cleaned Samples:** Grain samples taken after the crop has been cleaned of unwanted materials such as foreign materials, weed seeds, or other grains and seeds.

**Crop Rotation:** The practice of growing a series of dissimilar or different types of crops in the same field or crop growing area in sequenced seasons.

**Cutter:** A machine or manual device (scythe) that is used for cutting down the grain plants (reaping).

**Extrusion Equipment:** Equipment that processes grains into uniform shapes, used for products like breakfast cereal and chips.

**Field Inspection:** A process wherein trained personnel walk the rows of the field to find any plants that bear gluten-containing grains. Field inspection processes are described under Canadian Food Inspection Agency (2016) work instructions for pedigreed seed crops.

**Gluten:** The protein fraction of wheat, rye, barley, and their hybrids and related grains, that is insoluble in water and 0.5M sodium chloride.

**Gluten-Free:** Having a uniform gluten level of less than 20 parts per million.

**Grain Cleaner:** A mechanical device used to separate fine and broken materials, large foreign material, and light low-density materials (e.g., loose hulls) from the grain. Can be portable and used in the field, or set up in a stationary location.

**Grower Agreement:** A contract that defines the growing, harvesting, and cleaning conditions expected by the packager/processor/miller. In the case of gluten-free oats, a contract guaranteeing that the grower is following the requirements of the purity protocol.

**Grower Network:** The group of growers that a packager/processor/miller relies upon to provide grain each season.

**Grower:** The individual or company that controls the fields where the grain is grown.

**Harvest Samples:** Grain samples taken in the field at harvest, before cleaning or further processing.

**Harvester/Combine:** A machine that performs crop reaping and also separates the grain from the stalks (threshing) while keeping the hulls intact.

**In-Process Tank:** Storage containers that hold grains during or in between processing steps.

**Isolation Strips:** Areas in which no crops, or only gluten-free crops, are grown. May include roads or other physical barriers that are wide enough to minimize gluten grain contamination from surrounding fields.

**Miller:** A facility that stabilizes the grain and grinds grain into flour.

**Milling Equipment:** Equipment used to grind grains into flour, such as high-pressure rollers or a stone mill. Milling operations will also use dehullers and stabilizing equipment.

**Packager:** A facility that receives bulk grain in trucks, train cars, or bulk totes and packages it into bags, totes, or other containers for retail sale.

**Pneumatic Equipment:** Equipment that uses air to move grains from one location to another.

**Processor:** A facility that changes the shape and appearance of whole grains, making items such as toasted grains, rolled grains, flakes, extruded pellets, and puffed grains. Can also refer to a milling operation.

**Purge:** The use of an inert material to push out any residue of previously processed material within a piece of equipment. Sometimes the beginning of a processing run will be discarded or diverted for a separate use and be considered purge material.

**Receiving System:** The method by which a grain delivery from a grower is taken into the packaging/processing/milling facility. These are typically in the form of a dump, in which grain is dropped into below-grade storage facilities, or conveyor/elevator leg systems that receive and move grain above ground.

**Seed:** The viable whole grain that is sowed in the field to generate a new crop; the result of harvesting before heat treatment/stabilization is applied.

**Seed Count:** A visual examination for, and enumeration of, the number of gluten-containing grains within an oat sample.

**Silo:** A structure for storing bulk grain.

**Sorting Equipment:** Devices that allow grains to be separated according to characteristics such as size, length, width, density, surface charge, or color. Can be mechanical, which primarily separate on physical characteristics such as size or shape, or optical, which can consider physical characteristics as well as color, pattern, opacity, or surface characteristics (matte, glossy, etc.).

**Stabilizing:** A process whereby cleaned oats are heated to about 120°C to destroy enzymes that cause rancidity.

**Totes:** Large woven grain bags that can hold 1,500–2,000 lb. of seed or processed grain material.

**Traceability:** Documentation and record-keeping that allows a crop to be traced back to the specific seed that was used and to the locations where it was grown, processed, packaged, and distributed.

*Protocol Requirements.* Purity Protocol oat packagers/processor/millers must ensure that their grower network is adhering to the following farm requirements (as specified in grower agreements):

- Seed Purity: All gluten-free oats must start from seed, either purchased or harvested from the previous crop, that is free from all gluten-containing grains as determined by seed counts.
- Crop Rotations: Growers shall follow a nongluten crop rotation, or a minimum three-year crop rotation between the last gluten-containing crop and the first pure oat crop, and document all previous crops grown.
- Isolation Strips: Isolation strips are required between adjacent gluten-containing crops or conventional oat crops and must be a minimum of 6 feet in width.
- Field Inspection: There must be inspections for potential sources of gluten cross-contamination during the growing season; these should be performed by third party inspectors trained specifically for gluten-free inspection.
- Traceability: The farm must identify the oats by land location, and document the harvesting equipment, cleaning equipment, transports, storage facilities, and final distribution for the grain from each location.
- Equipment Cleaning (trucks, cutters, harvesters, augurs, conveyors): Whenever possible, growers should use dedicated equipment. If not, they must use a validated cleaning process prior to handling gluten-free crops. Growers must also maintain documentation of the previous grains in the equipment.
- Harvest Samples: These must be visually inspected, preferably by a third party laboratory, for purity. Sometimes referred to as a “seed count.”
- Storage: Dedicated storage should be maintained for gluten-free oats.
- Cleaned Samples: Growers must visually inspect samples for gluten-containing grains prior to scheduling deliveries.

Conformance with the grower agreement must be documented either by the grower or through an audit by the purchaser. There must be validation that the grower agreement is in compliance with these requirements through documentation and inspection records. The documentation must be reviewed and verified. Samples must be visually inspected by the purchaser for purity prior to receipt or unloading at the purchaser’s facility.

Purity Protocol oat packagers/processor/millers must also ensure that they meet the following processing requirements:

- Dedicated gluten-free receiving systems.
- Dedicated gluten-free in-process tanks/silos/storage.
- Dedicated gluten-free grain cleaners, or appropriate procedures for cleaning grain-cleaning equipment and for the storage of portable grain cleaners.
- Dedicated gluten-free milling equipment.
- Dust control/collection procedures and schedules for changing or cleaning filters.
- Dedicated pneumatic equipment/aspirators.
- Dedicated extrusion equipment, or written procedures for cleaning or purging extrusion equipment, if applicable. Must document purge volume, and that purge material tests negative for gluten prior to beginning gluten-free processing.
- Dedicated baggers/fillers.
- Dedicated pre- and postprocess containers (such as totes).
- Dedicated rail cars, trucks, or transports, or procedures for the cleaning and inspection of rail cars, trucks, or transports used to deliver product to other facilities or customers.

- Sorting equipment may not be used for oats as a substitute for obtaining purity, but may be used as a supplement to the purity protocol to ensure purity.
- The final product must meet the 20 ppm threshold in order to be labeled gluten-free in the United States, Canada, Europe, and other countries following the Codex Alimentarius guidelines. The product must meet the regulations for gluten-free labeling in the country of sale.
- The final product must meet the 10 ppm threshold in order to be certified gluten-free by GFCO.

## DISCUSSION

The Purity Protocol definition for gluten-free oats is in many ways similar to existing requirements for producing non-genetically modified crops, so it is not surprising that the major Purity Protocol processors were in general agreement on the basic steps for maintaining crop purity. But given the continuing growth of the market for gluten-free products it is essential that terms like Purity Protocol be defined for both food manufacturers and consumers. While there is currently no independent verification process to ensure that an oat supplier is following the protocol provided here, the availability of this standard definition will allow the buyer to confirm that their supplier is following the accepted Purity Protocol practices, and know what documentation to request as proof.

While the requirements of the Purity Protocol are excellent for reducing the risk of gluten contamination from wheat, rye, barley, and their hybrids and related grains, these steps do not remove the requirement that the final product be verified as containing less than 20 ppm gluten in order to be labeled gluten-free, or less than 10 ppm gluten to be certified gluten-free by GFCO.

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