



OatPure™ Guaranteed  
<10ppm Gluten Oats

**OatPure**  
Your Gluten-Free Guarantee

# Are Gluten-Free Oats Truly So?

- Oats are naturally gluten free, but a product must contain <20ppm gluten by FDA requirement to be considered free of gluten allergens
- Many concerns are raised around gluten-free oats in the marketplace
  - **Growing and Harvesting:** Are the source seeds free from gluten contamination? How about the land and its surroundings? The harvesting equipment? Storage? Transport? Is every aspect gluten free?
  - **Processing:** Is the plant hygienic and does it only process oats? Is mechanical/optical sorting by large millers of conventional oats to remove stray gluten-containing grains “good enough” to assure gluten-free confidence?
  - **Testing:** How reliable is the required ELISA R5 Mendez test in accurately gauging gluten levels within a margin of error? How robust are a supplier’s testing practices?
  - **Bottom line:** Is a supplier’s <20ppm oat ingredient acceptable to ensure your finished product remains under <20ppm gluten or could your product still be contaminated?



# Gluten Contamination Can Be Dangerous and Expensive

- Consumer illness or death is possible in severe cases. In addition to the human toll, expensive lawsuits are likely.
- Use of gluten contaminated oats can lead to expensive recalls and a loss of brand reputation –General Mills with its Cheerios brand
  - Top blogger Gluten Free Watchdog has blogged extensively on the Cheerios recall
- To avoid risks to consumer health, to brand reputation, and to your bottom line, you need unquestionable assurance your oats are gluten free

## FDA Investigates Complaints Associated with Cheerios Labeled Gluten Free: General Mills Voluntarily Recalls Affected Lots

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### What is the problem and what is being done about it?

The U.S. Food and Drug Administration is investigating reports of adverse reactions associated with eating original Cheerios and Honey-Nut Cheerios labeled as gluten-free and working with General Mills to facilitate their voluntary recall of these products. We recognize the importance of this issue to people with celiac disease, wheat allergy, and gluten sensitivity, and we will continue to provide updates and advice as needed.

After learning of these adverse reactions, the FDA tested 36 samples of Cheerios products labeled as gluten-free from different manufacturing facilities and lots. Although most of the samples met the definition for "gluten-free," one sample of General Mills Honey Nut Cheerios labeled as gluten-free contained 43 parts per million (ppm) of gluten. This exceeds one of the criteria for FDA's [gluten-free definition](#), that the food contain less than 20 ppm of gluten.

General Mills has voluntarily recalled 13 production lots of Honey Nut Cheerios labeled as gluten-free and 4 production lots of original (yellow box) Cheerios labeled as gluten-free due to the presence of wheat flour (an undeclared allergen). As with all recalls, the FDA will work to ensure the recall is effective and the underlying cause is identified and addressed.

### Who is at risk?

People with celiac disease or wheat allergy are at risk. People who are sensitive to gluten may also want to be aware.



# Our Gluten-Free Plant Nutrition Portfolio Continues to Expand with Gluten-Free Oats



# OatPure™ Guaranteed <10ppm Gluten Oats

## Protect Your Brand and Customers from Risk

### OatPure

- + Superior OatSecure™ 14- step gluten-free supply chain
- + Superior gluten-free processing in an oat-only facility
- + Superior gluten-free product – color, appearance, flavor, and <10ppm gluten guaranteed
- + Grown and processed entirely in Ireland, renowned for ideal growing conditions for superior oats



### OatPure gives you

- + Utmost security with absolute assurance of no gluten allergen risk at <10ppm gluten
- + Pathogen-free assurance through 4.6-log validated kill step
- + Longer shelf life from a higher quality product (18 months vs. 9-12 for competitors)



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Federación  
de Asociaciones de  
Celíacos  
de España



# Introduction: Glanbia Agribusiness - AgriFood



- + Leading Agribusiness in Ireland, 450 employees covering 16 counties
- + Key linkage with Glanbia's 1,400+ Irish grain farmers and 5,000+ Irish dairy farmers
- + Full range of farm inputs and hardware to cater for all the requirements of our milk and grain producers
- + Largest supplier and user of native Irish grain. Intake approximately 200kt.
- + Adding value to Irish grain from feed to food and beverages



# Ireland's Capacity to Produce High Quality Oats

## Irish Oats platform which can be scaled for growth

- + Ireland's climate and soil types suit the growing of oats
- + Irish production varies between 120kt and 170kt per annum
- + As only 25% of the Irish oat production is used in food production presently, there is significant scope for Glanbia to increase production of gluten-free oats
- + Greater control, visibility, traceability of oats
  - + Contracts
  - + Drying in Glanbia locations

# OatSecure™ Closed Loop Gluten-Free Supply Chain



OatPure™ Oats are Gluten-Free from the seed to bag.

## Our Closed Loop Supply Chain

- The risk for contamination for wheat or barley is present at every step
- Glanbia is involved in every step of our supply chain to eliminate that risk
- Every step of the OatSecure supply chain is gluten-free and oat-only.
- We have eight steps before the gluten-free seed is even sown
- Large millers only get involved in the gluten-free supply chain at our Step 14, at the very end.
- NSF Certificate of Compliance to the QAI/NSF Protocol P404-Gluten Free



## Only Gluten-Free Barra Seed is Used

- + Selected 18 months in advance of planting with 100% oats only seed storage
- + Seed that passes all inspections is harvested and transported by dedicated gluten-free machinery
- + Seed testing has zero tolerance for gluten contamination from other grains
- + Larger grain than US/Canadian grains with better appearance and uniformity
- + We use one variety for a consistent crop every time. North American suppliers use multiple cultivars, inviting inconsistencies.



**Selected based on location, crop rotation, farmer competence and ability to engage wholeheartedly in gluten-free farming**

- + Rigorous selection and training process before approval
- + Work with Glanbia expert agronomists to ensure fields are gluten-free ready
- + We verify only land on the correct rotation is used
- + For full traceability we note the GPS coordinates of each field of the crop
- + Buffer land required to eliminate cross contamination from wheat or barley



## Agronomy Program

### Crop management from planting to harvest

- + Gluten-free seed is planted with gluten free equipment
- + We have a specific process for the positive release of field pre-sowing
- + Our agronomists support farmers throughout the growing season
- + Regular visits and detailed crop inspections are conducted to monitor the health and oat-only status of the crop



## Only crops which have passed final inspection are harvested

- + Crops are harvested at <20% moisture
- + The oats are transported by gluten-free trucks
- + Every trailer has an ID to identify it as gluten free and can be traced back to each individual oat grower



## Intake and Processing

- + Drying takes place within three days of harvest to significantly reduce opportunities for pathogen and mycotoxin growth
- + Our new ultra-modern, state-of-the-art food safe Buhler equipped Oat Mill in Portlaoise Ireland is one of the most technologically advanced facilities of its kind in the world
- + Our NSF-certified gluten-free inspection program also sets a new standard, giving maximum confidence in our gluten-free guarantee



# Ahead of the Rest

## Glanbia's treatment of oats differs from other countries

- + Ireland's moist growing conditions requires that all food grade oats undergo a drying process post harvesting to manage the higher moisture contents of grain
- + Delivered directly to our drying and storage location where each trailer is inspected, positively released and introduced to our drying system in sequence to retain full traceability
- + Drying on convection @ >167°F (75°C) reduces moisture to <14% and also is effective in denaturing naturally occurring pathogens in grain such as Salmonella
- + In addition to controlling field pathogens this drying process is also a critical control for grain storage mycotoxins
- + Countries with a continental type climate such as Canada, Sweden, Australia put oats direct into storage as typically it is harvested at 13% moisture or lower without any shock heat to manage the pathogen risk and toxin development
- + Our methods add to the length of typical oats shelf life (9-12 months) to a full 18 months

# Portlaoise: Food Safety and Quality Focus

Glanbia has developed a Food Safety & Quality Management System in our oat milling facility, setting a new standard for the starch milling industry across all aspects of our operation. This heightened Risk Assessment approach has been publicly acknowledged by industry, leading retailers and customers alike.

## KEY TECHNOLOGIES

Foreign Material Control

Advanced Optical Sorting

- + Removal of damaged oats, immature oats, impurities, etc.

Process Quality Monitoring

- + Raw material evaluation
- + Particle size testing
- + In Process deviation trending / Live process and intel processing for FS and QM
- + Validated 5-log reduction heat treatment similar to Sioux Falls' MicroSure™ Plus process

Final Product

- + 3rd party Laboratory Analysis
- + Physical and sensory positive release

## STATE-OF-THE-ART OAT FACILITY

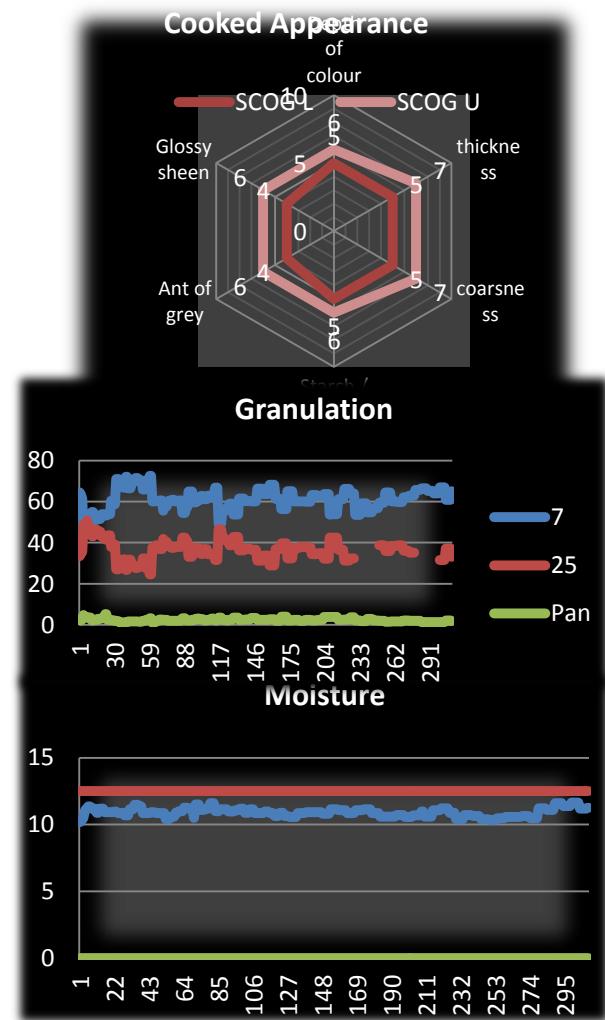
- + Dedicated oat-only mill
- + Commissioned Q4 2013
- + GFSI-Audited Plant Network
- + Gluten-free certification
- + Kosher
- + Non GM certified
- + BRC Grade AA



OatPure  
Your Gluten-Free Guarantee

# Focus On Quality

Bespoke Glanbia methods of evaluating raw material oats have been developed and these assessment results are directly linked to our processing parameters; therefore plant adjustments are dialed in before the product comes online. This ensures consistency in processing and outright adherence to world class specification tolerances.



# Microbiological Control Across Supply Chain



- Single site/Key 72hr max between harvest and drying
- Pathogen (esp. Salmonella) and mold management, drying @ +75°C



- Specifically designed to ensure process does not add any micro load
- On-going process, people, environment assessments
- Stringent hygiene clearance system in operation
- Significant resources invested in OPRP maintenance



- Third party validated 4.6-log heat treatment kill step similar to the process used in our Next Generation Grains facility in Sioux Falls to heat treat flax and chia



- Completed daily on all product as part of positive release
- Bi annually screening of finished products targeting full sweep of bacterial, pathogenic and spore forming groups

# Heat Treatment Validation

**Microbiological assessment:** Determine the Heat Treatment Lethality of the thermal processing (Kilning) of oats towards *Salmonella* using a surrogate organism

**Project Partner selected:** Campden BRI (Chipping Campden)

- + A culture of *Enterococcus faecium* NRRL B-2354 was obtained from the Campden BRI culture collection and used to produce an inoculum following a procedure based on the Almond Board of California 'Guidelines for process validation using *Enterococcus faecium* NRRL B-2354'
- + 25 individual pods inoculated and introduced into the process pre heat step
  - + 4 hang-up, 1 outside flow rate, 20 viable pods for assessment
- + The results of this study showed that log reductions achieved in 20 of the sample pods were within the range 4.55 to >5.33 log CFU/g
- + This level of lethality would meet the minimum target log reduction of 4 log CFU/g recommended by the Almond Board of California for nuts, which is also often applied to other low moisture products such as seeds and grains

## Providing Confidence

In order to validate our OatSecure™ process we have developed a sampling and analysis program which provides confidence levels of greater than 99% that **EVERY** batch of OatPure is **GUARANTEED <10ppm** gluten.

The robustness of our programs have received further validation by an independent statistician.

In summary – **EVERY** tote produced will have an individual Certificate of Analysis from an independent laboratory.



# Microbiological Monitoring

## Period under discussion : Jan 2014 – October 2016

- + Microbiological assessments are completed daily on all product types produced
- + The scope of the screening is as follows:
  - + Aerobic Colony Counts <100
  - + Yeast and Moulds <100
  - + Presumptive Entrobacteriace <10
  - + Coagulase Positive Staph <20
  - + Bacillus Cereus <10
  - + Ecoli <10
  - + Salmonella Absent in 375g
  - + Listeria Absent
- + During this period 100% of product samples passed the Agrifood Micro screening Positive Release
- + Challenging this, for a 2 month period between November and December 2014 shadow testing was completed with another external laboratory, all results were comparable with 100% conformance

## Summary



- 100% Oats only (no equipment, storage or operational location working with other cereals)
- Clear SOP's and Stop Go metrics at all key steps
- Gluten-free seed identification
- Gluten-free seed inspection
- Seed storage and dressing requirements
- Growers selection and training
- Land suitability
- Field inspections
- Sowing
- Crop inspections
- Gluten-free harvesting and transport equipment
- Oat intake assessments
- Storage specific handling requirements
- Sampling Plans
- Certification
- Testing
- **Full Traceability**

# OatPure™ is the Guaranteed <10ppm Gluten Choice

## OatPure gives you

- + Utmost security with absolute assurance of no gluten allergen risk at <10ppm gluten through our OatSecure™ NSF-certified gluten-free supply chain
- + Pathogen-free assurance through our 4.6-log validated kill step
- + Longer shelf life of 18 months from an exceptionally higher quality product
- + Delicious, nutritious Irish oats grown with unrivalled traceability to the highest gluten-free standards



# OatPure™ Portfolio



Gluten-Free  
Jumbo Oat Flakes



Gluten-Free  
Quick Cook Oats



Gluten-Free  
Shredded Oats



Gluten-Free  
Steel Cut Oats

# OatPure™ Portfolio

|  | Characteristics   | Applications   |
|--|---|--|
| <b>Gluten-Free Shredded Oats</b><br>     | <ul style="list-style-type: none"> <li>• Heat treated</li> <li>• Whole Grain horizontal steel cut oats</li> <li>• Long shelf life (18 months)</li> <li>• Cream to golden brown color</li> <li>• Full oaty flavor and aroma</li> </ul>   | <ul style="list-style-type: none"> <li>• Bars/breakfast cereals</li> <li>• Bakery</li> <li>• Cookie mixes and product toppings</li> </ul>  |
| <b>Gluten-Free Jumbo Oat Flakes</b><br>  | <ul style="list-style-type: none"> <li>• Heat treated</li> <li>• Whole Grain oats</li> <li>• Long shelf life (18 months)</li> <li>• Light brown to light golden color</li> <li>• Fresh and clean oaty flavor and aroma</li> <li>• Consistent flake</li> </ul>                     | <ul style="list-style-type: none"> <li>• Bars/breakfast cereals</li> <li>• Oat clusters/granola products</li> <li>• Dry snack mixes</li> <li>• Bakery</li> <li>• Foodservice</li> <li>• Yogurt/dairy products</li> </ul> |
| <b>Gluten-Free Steel Cut Oats</b><br>   | <ul style="list-style-type: none"> <li>• Heat treated</li> <li>• Whole Grain, evenly steel cut oats</li> <li>• Long shelf life (18 months)</li> <li>• Yellow brown to golden color</li> <li>• Clean oaty flavor and aroma</li> </ul>  | <ul style="list-style-type: none"> <li>• Bars/breakfast cereals</li> <li>• Granola products</li> <li>• Dry snack mixes</li> <li>• Bakery</li> <li>• Toppings</li> <li>• Yogurt/dairy products</li> </ul>                 |
| <b>Gluten-Free Quick Cook Oats</b><br> | <ul style="list-style-type: none"> <li>• Heat treated</li> <li>• Whole Grain oat flakes</li> <li>• Long shelf life (18 months)</li> <li>• White to yellow brown color</li> <li>• Clean oaty flavor and aroma</li> <li>• High water absorption</li> <li>• 2 minute cook</li> </ul> | <ul style="list-style-type: none"> <li>• Bars/cereals/clusters</li> <li>• Hot breakfast</li> </ul>   |



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## APPENDIX

# EU and FDA Definitions of Gluten-Free

- **EU regulation (EU 828 - 2014)** As of Aug 1, 2016, oats contained in a food presented as gluten-free or very low gluten must have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties and the gluten content of such oats cannot exceed 20 mg/kg. *OatPure oats are at <10ppm gluten.*
- **From the FDA web site:** “On August 5, 2013, FDA issued a final rule defining the term “gluten-free” for voluntary use in the labeling of foods. The compliance date for the final rule was August 5, 2014. In general, foods may be labeled “gluten-free” if they meet the definition and otherwise comply with the final rule’s requirements. More specifically, the final rule defines “gluten-free” as meaning that the food either is inherently gluten free; or does not contain an ingredient that is: 1) a gluten-containing grain (e.g., spelt wheat); 2) derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour); or 3) derived from a gluten-containing grain that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food. Also, any unavoidable presence of gluten in the food must be less than 20 ppm.” *OatPure oats are at <10ppm gluten.*

# Gluten Free Oat Products

There is a growing global market for **Gluten Free Oat** products.



# Consumers Driving Growth of Gluten Free Foods

In recent years, U.S. consumers have started to shun gluten, which is found in wheat, barley, rye, and hybridized strains of the same.

Typically there are 2 categories of consumer interested in removing gluten from their diets:

1. The diagnosed **Coeliac Disease Sufferer** - accounts for <5% of population
2. The consumer making a **lifestyle choice** to remove as much gluten from their diet in hopes of losing weight or gaining other health benefits.
  - *This sector of the market is not quantified at present but is a rapidly growing sector.*

Although, through greater awareness the diagnoses of CD is rising. It is marginal compared to the uptake of the **lifestyle gluten avoidance** by consumers. It is this lifestyle gluten avoidance category which is driving the growth/demand in gluten free product categories.

**# of Product Launches with On Package  
Allergen Claims**

