

June 2022

FSMA and Preventative Controls Statement

Ardent Mills takes food safety and compliance with laws and regulations relating to food safety very seriously. Accordingly, this letter is to inform you of important food safety information regarding our products pursuant to the Food Safety Modernization Act (FSMA), and Final Rule 21 CFR 117 - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, we are providing some important food safety information about our products.

The Food Safety Modernization Act (FSMA) requires processors/manufacturers of products, such as flour, to:

- (1) identify hazards that can be found in the processing or manufacturing of ingredients where the process does not control for such hazard;
- (2) notify Customers that the product is produced without this preventative control; and
- (3) obtain confirmation that the Customer has received such notification. [CFR Title 21, Chapter 1, Subchapter B, Part 117.136].

Accordingly, pursuant to 21 CFR §117.136, this letter serves as Ardent Mills notification that the products indicated below are processed or manufactured without the preventative controls set forth below, and our request for written confirmation that you received this notification.

Affected Products

The following products marketed by Ardent Mills are sold to Customers without controlling for identified hazards.

Examples include:

Wheat Flour, including standard flour, whole wheat flour, semolina, durum, rye, wheat bran, germ, and Sustagrain®, oats and Aleurone. Specialty grains and seed flours / blends including without limitation chickpeas, and quinoa.

Ardent Mills further makes this notification on product labels, specifications, and/or every certificate of analysis (COA) delivered with the product.

Identified Hazards Requiring Preventive Controls

Ardent Mills processes and sells a wide range of ingredients that are all derived from raw agricultural products such as grains or seeds. There are several possible pathogens such as *Salmonella* sp., pathogenic *E. coli* and *Listeria monocytogenes* that can be sourced from the environment where grains or seeds, such as wheat, are grown, harvested and stored. These pathogens may be found in soil, water, vegetation and from wildlife and the environment. As a result, there can be an unavoidable risk that the raw agricultural products could contain these environmental pathogens.

In our standard supply chain, Ardent Mills does not process our food ingredients made from raw agricultural products to control pathogens. These ingredients are intended to be further processed to significantly minimize or prevent the risk of pathogens. This is often accomplished with a lethality step such as baking, cooking, frying or boiling.

For the products listed above, Ardent Mills conducted a hazard analysis on these products and identified the following hazards for which it cannot implement a preventive control to minimize or prevent the hazard from occurring. Foodborne microbial pathogens that have been noted by our hazard analysis for flour as an ingredient include: *Salmonella* sp., pathogenic *E. coli* and/or *Listeria monocytogenes*.

If you have questions regarding the FSMA rules, we refer you to 21 CFR 117.136. and reference the most recent updates that FDA made in January 2018 and advise you to consult your own regulatory and legal group(s) for more information. Additional information can also be found as noted below:

The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules. see- (Federal Register 80 FR 57784 August 24, 2016) and Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety and/or Foreign Supplier Verification Programs: Guidance for Industry January 2018 (83 FR 598).

There are two misconceptions regarding flour and food safety. The first is that pathogens such as *Salmonella* sp., pathogenic *E. coli* and *Listeria monocytogenes* are of minor importance in low moisture ingredients because the ingredient does not support growth of microorganisms. Pathogens have been documented at low levels in low moisture foods; and these do not need to grow/replicate to cause illness. Also, flour products may be added to environments that are more receptive to growth, such as batters and mixes.

The second misconception is that sample testing is a reliable means to assure food safety of raw product. Microbiological testing of a production lot of food does not guarantee the lot to be pathogen free. Accordingly, when testing for pathogens the probability of acceptance based on incident rate is important. Microbial contamination is not homogeneously distributed, which may result in negative results when the chance of contamination may exist.

	For lots where 5% of samples are contaminated	
n	Probability of acceptance of lot	Probability of rejection of lot
1	95%	5%
15	46%	54%
300	< 0.5%	99.5%



If you would like to learn more about Ardent Mills validated heat treatment process with up to a 5- log reduction SafeGuard® flour, please contact your sales representative.

We ask that you countersign this letter where indicated below and return a copy to us at FSMA117_136confirmation@ArdentMills.com to confirm that you have received this information, as required by FSMA regulations. Nonetheless, by continuing to purchase our products, you confirm that you received this food safety notification.

If you have any questions relating to the content of this letter, please contact one of us or your sales representative.

Thank you,

Ardent Mills, LLC

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Subject: Food Safety Modernization Act Letter

ACKNOWLEDGED and AGREED TO

this ___ day of _____, 20___.

Company: _____

By: _____

Title: _____