



531 GETTY COURT, SUITE C  
BENICIA, CALIFORNIA 94510

P: 707-590-7010  
F: 510-263-5778



## FOOD SAFETY PLAN: FSMA PREVENTIVE COMPLIANCE STATEMENT

**Effective Date:** 11/30/17

**Review Date:** 01/02/22

**Revision Date:** 1/02/22

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. To implement the law, the Food and Drug Administration (FDA) has developed seven regulations, each with varying applicability and compliance dates. Edison Grain Incorporated (Edison Grain) is committed to complying with all applicable FSMA requirements and regulations.

Edison Grain has determined that it is subject to the following regulations under FSMA:

- **Preventive Controls for Human Food Rule (PCHF).** Edison Grain is in full compliance with the PCHF Rule (21 CFR Part 117):
  - Edison Grain follows Current Good Manufacturing Practices (cGMPs).
  - Edison Grain has three trained Preventive Controls Qualified Individuals (PCQIs) on staff. Team members receive required training and are qualified individuals as defined by the rule.
  - Edison Grain has a **Food Safety Plan** with the following elements:
    - Hazard Analysis
    - Preventive Controls (Process, Sanitation, Allergen, and Supply-Chain)
    - Recall Plan
    - Monitoring, Verification, Validation
    - Corrective Actions
    - Edison Grain complies with PCHF record keeping requirements.
- **Foreign Supplier Verification Program (FSVP).** Edison Grain meets the obligations of the FSVP through its compliance with the PCHF rule (see 21 CFR 1.502(c)). Edison Grain complies with section 1.509 of the FSVP.
- **Mitigation Strategies to Protect Food Against Intentional Adulteration (IA).** Edison Grain's compliance date under the IA rule was July 27, 2020. Edison Grain currently has a Food Defense Plan in place, and will ensure that it fully meets the requirements of the IA rule.

Jeffrey E. Barnes  
President  
Edison Grain Incorporated



531 GETTY COURT, SUITE C  
BENICIA, CALIFORNIA 94510

P: 707-590-7010  
F: 510-263-5778



## FOOD SAFETY PLAN: FSMA PROCESSING CONTROLS STATEMENT

**Effective Date:** 11/30/15

**Review Date:** 1/02/22

**Revision Date:** 1/02/22

Edison Grain Incorporated (Edison Grain) is in compliance with the requirements of 21 CFR Part 117, the Preventive Controls for Human Food (PCHF) rule. Edison Grain conducted a hazard analysis of its products and processes to identify biological, chemical, and physical hazards. While our products are generally low risk, we identified hazards that require preventive controls, including biological hazards such as Salmonella and pathogenic E. coli, chemical hazards such as allergens and mycotoxins, and physical hazards such as metal and agricultural debris.

Edison Grain has implemented a Food Safety Plan that includes the following preventive controls to address identified hazards:

**Supply-Chain Preventive Controls.** Edison Grain has developed a robust supply-chain program, as many identified hazards require a supply-chain-applied control. We approve suppliers before receiving products, and update documentation and approval annually. Supplier verification activities include:

- **Product Testing** – Each lot of incoming product is sampled and sent to an independent ISO 17025 accredited laboratory for microbiological and gluten testing. Microbiological tests conducted include Aerobic Plate Count, Coliform, E. coli, L. monocytogenes, Salmonella spp., Yeast & Mold.
- **Onsite Audits** – Our suppliers are 3<sup>rd</sup> party certified for food safety, and most are certified under GFSI-recognized schemes such as SQF, BRC, and FSSC. We review 3<sup>rd</sup> party onsite audit reports (including corrective actions) upon initial supplier approval and periodically thereafter to verify ongoing compliance. Based on our hazard analysis, we have determined that it is necessary to review 3<sup>rd</sup> party audit reports on an annual basis for our ready-to-eat products.

**Process Preventive Controls.** To control for metal hazards, Edison Grain passes finished products through metal detection. To enhance our ability to control all physical hazards as well as mycotoxin hazards and allergen cross-contact hazards inherent in agriculture, we installed a dry mechanical cleaning process featuring vibratory sifter, rare earth magnet, optical laser color sorter and free flow metal detector. All Edison Grain and Edison Grainery finished product undergoes additional metal detection and a QC inspection prior to being released into the stream of commerce.

**Allergen Preventive Controls.** While Edison Grain is an allergen-free facility and our production equipment is free from the Big 9 allergens, a milk allergen is present in our pasta and cheese products: Edison Grainery Organic Q Mac<sup>®</sup> Quinoa Pasta & Cheese and Edison Grainery Organic Rice Pasta Shells and Cheese. These products are processing on dedicated exclusively to the manufacturing of these products.

We have established allergen preventive controls to prevent undeclared allergens in food labeling and to ensure protection of food from allergen cross-contact. Cross-contact controls are present at multiple steps including receiving, storage, production, and shipping.

**Sanitation Preventive Controls.** Sanitation is an obsession at Edison Grain. We have established sanitation preventive controls to prevent microbiological cross-contamination, recontamination with environmental pathogens, and allergen cross-contact. Preventive controls include hygienic zoning practices and sanitation procedures for our production equipment, production rooms, and equipment wash area. We utilize extensive ATP swabbing to verify the cleanliness of food contact surfaces after cleaning. Our deviation protocol include AllerSnap swabbing should we discover and remove an errant grain during our mechanical cleaning processing. Our environmental monitoring program verifies the effectiveness of hygienic zoning and sanitation procedures to control Salmonella and Listeria.





531 GETTY COURT, SUITE C  
BENICIA, CALIFORNIA 94510

P: 707-590-7010  
F: 510-263-5778



## FOOD SAFETY PLAN: FSMA ALLERGEN PC STATEMENT

**Effective Date:** 11/30/15

**Review Date:** 01/02/22

**Revision Date:** 01/02/22

Edison Grain Incorporated (Edison Grain) recognizes that millions of people have allergic reactions to food that can sometimes be life-threatening, and that many – including our family -suffer from Celiac disease or are gluten-intolerant. So that our customers may purchase our products with confidence, we have established a robust allergen and gluten program.

**Gluten-Free:** Edison Grain is proud to be a gluten-free facility. We carry no gluten-containing grains, which are defined as wheat (e.g., durum, spelt, Kamut, emmer, einkorn), rye, barley, or their cross-bred hybrids such as triticale.

- Each and every incoming lot of every product is tested by a 3<sup>rd</sup> party laboratory for the presence of gluten to verify that cross-contact has not occurred in the field or at earlier processing steps.
- The FDA has established a gluten limit of less than 20 parts per million (ppm) for foods that carry the gluten-free label. All of our products meet or exceed that standard and carry the “Verified Gluten Free” logo. **Our threshold is <10ppms with an average of <5ppms**
- Certificates of Analysis are available on our website: <http://edisongrain.com/products/> as well on the individual product page: <https://edisongrainery.com/products/>

**Allergens:** Edison Grain recognizes the “Big 9” major food allergens as identified in the Food Allergen Labeling and Consumer Protection Act of 2004 and FASTER Act (Food Allergy Safety, Treatment, Education, and Research Act) of 2021: Milk, Eggs, Fish, Crustacean shellfish, Tree nuts, Peanuts, Wheat, Soybeans and Sesame.

While the cheese powder in our Organic Pasta & Cheese products contains a milk allergen, the cheese sachets are assembled on dedicated equipment for the exclusive production.

Protocols to ensure protection of food from allergen cross-contact and misbranding include:

- We require our suppliers to provide allergen statements so we have full knowledge of their allergen profile, and we verify that they employ sound allergen management practices.
- Cheese packets are received and stored separately within our warehouse.
- Strict sanitation practices are maintained for cleaning equipment and utensils – used exclusively for process pasta & cheese products.
- Employees practice good hygiene, and traffic flow is managed between allergen and non-allergen areas of the facility.
- Allergen labeling verification prevents undeclared allergens.

Jeffrey E. Barnes, President  
Edison Grain Incorporated



531 GETTY COURT, SUITE C  
BENICIA, CALIFORNIA 94510

P: 707-590-7010  
F: 510-263-5778



## FOOD SAFETY PLAN: FSMA SANITATION PC STATEMENT

**Effective Date:** 11/30/15

**Review Date:** 1/02/22

**Revision Date:** 01/02/22

Sanitation is the foundation of Edison Grain Incorporated's food safety program. We have developed comprehensive Sanitation Standard Operating Procedures (SSOPs) intended to prevent food from becoming adulterated and that establish adequate and appropriate steps to protect against contamination and allergen cross-contact.

All operations, including receiving/shipping, storage, processing and packing, are conducted in accordance with sanitation principles. Our SSOPs prioritize the practice of adequately cleaning, sanitizing, and maintaining all equipment and utensils. Appropriate quality control activities are employed to ensure that our food is suitable for human consumption and that our packaging materials are safe. A team of HACCP and PQCI trained individuals are assigned various responsibilities to uphold our overall sanitation standards.

Edison Grain's sanitation program includes the following elements intended to protect against contamination and allergen cross-contact:

- Ensuring adequate facility design and maintenance;
- Sanitary facility controls for water quality, plumbing, sewage disposal, toilet facilities, hands-free washing facilities, and waste management;
- Employee hygiene standards and procedures;
- A pest control program;
- Use of equipment and utensils adequately designed for their purpose and properly maintained;
- Procedures for cleaning and sanitation of food-contact and non-food-contact surfaces;
- Use of cleaning compounds and sanitizers that are safe and adequate and that are in compliance with National Organic Program standards;

Scheduling for sanitation activities:

- A comprehensive sanitation checklist is completed daily and covers all areas of the facility including production rooms, warehouse areas, docks, bathrooms, changing rooms, and employee kitchen;
- Production room non-food-contact surfaces are cleaned and sanitized daily before production, between each new product run, and after production;
- Food-contact equipment and utensils are cleaned and sanitized between each new product run and at the end of the day in a wet clean area and allowed to dry overnight;

Use of sanitation verification activities including:

- Pre-production ATP swabbing of food contact equipment to verify sanitation effectiveness;
- Routine use of AllerSnap swabs when deviation protocol warrant,
- Quarterly environmental monitoring, with testing for Salmonella and Listeria;
- Annual air and water monitoring.

Records for monitoring, verification, and corrective actions are established and maintained to satisfy the requirements of our SSOPs.

Jeffrey E. Barnes, President



531 GETTY COURT, SUITE C  
BENICIA, CALIFORNIA 94510

P: 707-590-7010  
F: 510-263-5778



## FOOD SAFETY PLAN: FSMA SUPPLY CHAIN PC STATEMENT

**Effective Date:** 11/30/15

**Review Date:** 01/02/22

**Revision Date:** 01/02/22

Edison Grain Incorporated (“Edison Grain”) has established a risk-based supply-chain program for products identified in our hazard analysis as requiring a supply-chain applied control. Implementation of the supply-chain program will provide assurance that hazards requiring a supply-chain control have been significantly minimized or prevented.

Our supply-chain program accomplishes the following:

- Ensures that suppliers of products requiring a supply-chain applied control are approved prior to receiving food products.
- Establishes an approval process that requires the collection and review of relevant documentation to support a supplier’s status as an approved supplier.
- Establishes procedures for receiving products into our facility to ensure they are from approved suppliers.
- Establishes appropriate supplier verification activities.
- Defines the conduct and documentation of verification activities.
- Establishes corrective actions in the event of significant deficiencies.

Edison Grain has developed its supply-chain program in accordance with FDA requirements under 21 CFR Part 117 Subpart G.

Jeffrey E. Barnes  
President  
Edison Grain Incorporated

