

Supplier and External Manufacturer Requirements Manual



Introduction



One of the core values of Ardent Mills is nourishing people and ensuring that our food and animal products keep people and animals safe. We require full cooperation and support from our suppliers and external manufacturers (SEMs), in order to meet the expectations of our customers. This requires Ardent Mills to ensure our SEMs are aligned with our values and operate in full compliance with Ardent Mills' food/feed safety, quality and regulatory requirements. It is Ardent Mills' desire to partner with SEMs to share best practices in the areas of food/feed safety, quality, regulatory compliance and continuous improvement.

Our Supplier and External Manufacturer Management Process or SEM Process allows us to verify that our suppliers and external manufacturers can provide safe, healthy finished products and ingredients. The current scope of the SEM Process is human and animal food finished products, ingredients, food contact packaging, and food contact processing aids.

This manual is designed for use by our SEMs and provides information on (i) food/feed safety, quality and regulatory compliance requirements for SEMs and (ii) Ardent Mills qualification and management processes for SEMs.



Ardent Mills Required Programs

To be an SEM for Ardent Mills a facility must first meet applicable Legal and Regulatory Requirements and implementation of Codex Pre-requisite Programs and HACCP. The list below outlines the specific programs that Ardent Mills expects all SEMs to have in place.

Required elements for Food Safety program:

1. **HACCP or equivalent risk based process controls** – Risks in the process and from all inputs must be evaluated and controlled.
2. **Food Safety and Quality Management System** – The Quality management system shall manage regulatory compliance, customer complaints, internal auditing, and, shall involve a cross functional team.
3. **Management of Change** – Any changes to the process or facility must be analyzed for risk and documented.
4. **Control of Documents and Records** – All documents that are part of the processing and quality control of the product shall have a method to ensure that completion and changes are tracked.
5. **Supplier / External Manufacturer Qualification** – The use of outside companies by the SEM for ingredients, co-packing, or production of finished products will be evaluated for risk and controlled. All SEMs must have approval and monitoring programs for their own suppliers which, at a minimum, consist of a combination of appropriate programs, specifications, policies and procedures described in this document.
6. **Facility Security and Product Defense** – The facility must control access and have plans for emergency situations.
7. **Training** – All employees, permanent and temporary, will have job specific safety and quality training that has regular refreshers
8. **Environmental Monitoring / Pathogen Testing** – If applicable based on risk, the program will monitor microorganisms and ensure product is not contaminated.
9. **Foreign Material Control** – Metal, glass, and brittle plastics will be controlled in the facility to prevent their entry into the process.
10. **Personal Hygiene** – There will be a formal list of personal hygiene practices to prevent employees and visitors from bringing contaminants into the process.
11. **Allergen Control** – All allergens appropriate for the country of consumption will be included in the raw ingredient evaluation and their presence in the facility will be controlled. All employees must be aware of these allergens even if they are not present in the facility.
12. **Pest Control** – A program must be in place to prevent and control pests. This includes those entering the facility from outside and those that may be present in the raw ingredients.
13. **Manufacturing records** – All records that monitor the process will be included in the document control program and monitored by management for accuracy.
14. **Rework, Reprocessing, Reconditioning and Waste Management** – If any product is removed from the process for rework or for waste it must be treated in a way that it does not pose a risk to the final product or facility sanitation.
15. **Calibrations** – All equipment that monitors final product quality/food safety including in process and in the laboratory shall be regularly calibrated by a qualified person/company.
16. **Maintenance** – All equipment in the facility must be on an inspection and maintenance cycle. Also a system must be in place to find and fix equipment breakdowns in a timely manner. Any temporary fixes shall not compromise food safety and shall also be fixed in a timely manner.
17. **Cleaning and Sanitation** – Based on the risks identified in the process there will be a program to remove materials from the equipment and facility that controls these risks.
18. **Product Traceability and Labeling** – Every step of the process shall be labeled so that there is complete traceability from raw ingredient to finished product. Final product labels and packaging shall be checked for accuracy on a regular basis.
19. **Receiving, Storage, and Shipping** – All incoming and outgoing products must be inspected for quality. Any finished or in process product shall be inspected on a regular basis to prevent contamination while in storage.
20. **Good Laboratory Practices** – Systems must be in place to ensure reliability of laboratory results for testing done on products or materials manufactured for Ardent Mills. This includes use of recognized test methods, documented procedures, trained and competent technicians, calibrated and maintained equipment.

Legal and Regulatory Requirements

4 Steps to Qualification of SEMs



Outline of Qualification Process

The initial qualification of SEMs has four basic components: Step 1: initial information and document request, audit and/or verification, Step 2: pre-qualification corrective action plans, Step 3: determination and communication of food/feed safety status and Step 4: plant trials (if applicable).

STEP 1: Initial Information, Document Request, Audit and/or Verification

Each prospective SEM must undergo a food/feed safety, quality and regulatory compliance review. Ardent Mills will designate a person to collect and evaluate information on the SEM to determine if their programs are sufficiently managing risk. Below is a list of the possible documents or visits the SEM might be requested to provide. Based on the risk posed by the material and SEM facility to Ardent Mills one or any number may be needed before qualifying an SEM.

- A Questionnaire on facility Programs
- Product food safety documents (e.g. MSDS, letter of guarantee, country of origin, etc.)
- 3rd Party audit certificates, reports and corrective actions (GFSI preferred)
- Ardent Mills 2nd party audit of manufacturing facility
- Ardent Mills 2nd party targeted audit or visit
- Product samples, testing, or trials
- Review of specifications and/or packaging

Step 2. Pre-Qualification Corrective Action Plans

If Ardent Mills identifies any failure to comply with the outlined Food/Feed Safety Requirements in Step 1, the SEM must develop a proposed Corrective Action

Plan, including timelines for approval. The Ardent Mills employee assigned to the SEM will work with them to evaluate corrective actions and implementation dates.

Step 3. Determination and Communication of Initial SEM Food Safety Status

Ardent Mills will determine and communicate the initial Food Safety Status of an SEM following completion of the initial phase and, as appropriate, development and/or implementation of a Corrective Action Plan. Food Safety Status will be specific to SEM product(s)/material(s)/service(s), production line(s), and/or plant(s). Note: this determination is of SEM FOOD SAFETY STATUS ONLY. It does not guarantee the SEM has actually been or will be awarded the final business.

The statuses include Approved, Conditionally Approved, Pending, Not Approved, and Disqualified. Food Safety status will be specific to a specific SEM location.

Approved: This status represents an SEM that has no pending Major Non-conformance(s). They can have Minor Non-conformance(s) of food safety system components to address, however a corrective action plan has to be developed and approved by assigned Audit Specialist.

Conditionally Approved: This status represents an SEM that has no pending Major Non-conformance(s) but has Minor Non-conformance(s) stemming from an SEM audit that have not been verified as corrected by the assigned Audit Specialist but an action plan has been formed with agreed upon timeline for implementation. The SEM may be used prior to completion and verification of corrective action.

This status can also represent an SEM that has been inherited from a legacy parent company (Horizon Milling and/or ConAgra Mills). They are referred to as grandfathered suppliers and have been given conditional approval based on historical performance. These suppliers

will be required to complete the full SEM process as defined in the SEM Strategy.

Ardent Mills can use materials from Approved, and Conditionally Approved suppliers.

Pending: This status represents an SEM that is currently being evaluated with the SEM review process. These suppliers will be required to complete the full SEM process as defined in the SEM Policy before usage of the location for sourcing material is allowed.

Not Approved: This status represents an SEM that has any pending Major Non-conformance(s) or multiple Minor Non-conformances that pose a significant food safety risk as determined by the SEM team. An SEM assigned this status can submit a corrective action plan for re-evaluation by the SEM team. This could include additional documentation up to including a re-audit.

Disqualified: This status represents SEMs that have pending non-conformance(s) that have been recorded and the SEM has indicated they are not interested in correcting. SEMs assigned this status shall not be allowed to re-apply for SEM approval without written permission from the Director of Regulatory and Strategy.

Ardent Mill's shall not use materials from Pending, Not Approved or Disqualified suppliers.

Step 4: Plant Trials

If an SEM is required to complete a plant trial, this requirement will be communicated to the SEM during the qualification process. A plant trial may not occur in an Ardent Mills or an SEM facility until the SEM has been assigned an acceptable Food/Feed Safety Status. The results of a plant trial may or may not change a SEM's Food Safety Status.





Ongoing Management of Supplier and External Manufacturer Relationship

The ongoing management of SEMs has five components: (i) communication of changes (ii) periodic audit and/or verification of compliance, (iii) ongoing monitoring, (iv) triggering event management, (v) post-qualification Corrective Action Plans and (vi) updates to Food Safety Status. They are listed below so you as the SEM can be aware of your ongoing roles and responsibilities in the ongoing partnership.

- i. **Management of Change** – SEMs must not change the location, specification, production process, inputs or material without prior notice to and approval by Ardent Mills.
- ii. **Periodic Audit and/or Verification of Compliance** – SEMs must permit Ardent Mills to review records and obtain retained samples pertaining to that Product, Material or Service. Each SEM must permit Ardent Mills upon reasonable advance notice, to audit and inspect the facilities used to manufacture Product or Material for Ardent Mills and/or provide Services to Ardent Mills.
- iii. **Monitoring Performance** – As part of its SEM program, Ardent Mills may also monitor SEMs ongoing performance through various means. Ardent Mills will advise each SEM of those documents and other information it will require for its monitoring from the SEM. Monitoring requirements may change from time to time depending on an SEMs Food Safety Status, performance, regulatory changes and other factors. Some examples of the type of documentation and other information that may be required are listed below:
 - a. Product Data (e.g., protein, fat, fiber, ash, MDF, moisture)
 - b. Microbiological testing results
 - c. Monthly reports on Key Performance Indicators,
 - d. Third Party Audits
 - e. Product Material Safety Data Sheet
 - f. Complaints regarding Ardent Mills products
 - g. Management of Change records
 - h. Batch records
 - i. Process Control Chart (Target / Range)
- iv. **Triggering Event Management** – A “Triggering Event” is an event or circumstance that would require Ardent Mills to communicate with you to determine if there is an impact to the business.

Examples of triggering events include, but are not limited to, the following:

- a. Product Retrieval Incidents – e.g., Recall, Withdrawal
 - b. Plant, Ingredient or Process Change at the SEM or Ardent Mills
 - c. Specification Change by SEM or Ardent Mills
 - d. Industry/Economic/Media Events
 - e. Change in Regulations or Regulatory Enforcement
 - f. Trends in Key Performance Indicators
 - g. Breach of Supplier Code of Conduct
 - h. Audit Results
 - i. Ownership or Financial Change
- v. **Post-Qualification Corrective Action Plans**– If Ardent Mills identifies any failure to comply with Food Safety Requirements as a result of a periodic audit and/or verification, ongoing monitoring or a triggering event, the SEM must promptly develop a proposed Corrective Action Plan, including timelines for approval.
- vi. **Updates to Food Safety Status** – If the results of a periodic audit and/or verification, ongoing monitoring or a triggering event investigation reflect that an SEM is not meeting Ardent Mills Food Safety Requirements, this may change an SEMs’ Food Safety Status. If the SEMs’ Food Safety Status changes from Approved or Approved with Conditions to Not Approved or Disqualified, Ardent Mills has the right to immediately terminate use of the SEM and its contract with the SEM with no liability. If, for any reason, it is appropriate to change the SEM designation, Ardent Mills will promptly notify SEM of that change.

Requesting Variances

In rare cases, Ardent Mills may permit SEMs to deviate from one or more of the outlined Food/Feed Safety Requirements set forth in this manual. Any such deviation must be approved by Ardent Mills, in writing.

