General Mills Global Ingredient Supplier Manual

XQM – External Quality Management
Version 1.4
(December 27th, 2018)
As part of the ongoing focus on our supplier food safety, regulatory and quality assurance program, the General Mills Incorporated (GMI) Global Ingredient Supplier Manual has been revised to bring clarity to key program requirements.

The Global Ingredient Supplier Manual is intended to guide current and prospective new suppliers of ingredients to ensure that their own food safety, regulatory and quality systems meet GMI requirements.

In this manual, you will find an overview of quality, food safety requirements, expectations around communication of changes and exceptions.
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GMI SUPPLIER COMMUNICATION OF CHANGES

All facilities shall have a program that assures appropriate and timely communication to General Mills of any change that may affect the General Mills product specification, food safety or composition. GMI approval shall be granted prior to implementation.

For example:
- Facility Critical Control Point (CCP) change
- New allergens introduced to previously approved producing lines for GMI
- New producing line or location
- Company name change (GMI Notification Only)
- Formulation or label change

GMI SUPPLIER APPROVAL AND MAINTENANCE

As part of the GMI Supplier Management Program an assessment is required for new Production Location/line and/or transfer stations to ensure our suppliers meet GMI requirements.

GMI Global External Quality Management (XQM) Team is responsible for all initial approvals for vendor/supplier producing locations and/or transfer stations.

The initial assessment is an integrated part of the overall vendor/supplier approval. Completion of a Supplier Survey as well as return of supporting documentation is required.

Required supporting documentation includes:
- CCP Matrix or Food Safety Plan
- Flow Diagram
- Allergen Plan
- 3rd Party Audit Report, Certificate and Corrective Action Report. General Mills has a preference for GFSI schemes (e.g. IFS, FSSC, BRC, SQF).

These may be sent to supplier.documentation@genmills.com for GMI North America or XQM.Support@genmills.com for other regions. Upon review, an audit of the facility will be conducted with approval for specific products at each producing location by line.

All approved vendor/supplier producing locations for GMI will be re-audited on a risk based frequency along with requests for ongoing maintenance documentation.

All approved vendor producing locations for GMI are required to provide General Mills with a third party audit report annually.
REGULATORY COMPLIANCE

All GMI ingredients shall be food grade. Ingredients shall be produced and shipped in compliance with applicable local, state, federal and international regulations. It is General Mills’ policy to comply to the fullest extent of the laws which govern and regulate the food industry.

For Suppliers shipping to the United States, please refer to the FSMA Section of the Manual.

FACILITY REGISTRATION

All ingredient Vendors/Suppliers Producing Locations must be in compliance with the local, state, federal and international licensing and registration requirements. Owners, operators, or agents in charge of facilities that manufacture, process, pack, or hold food for human or animal consumption are required to register the facility under applicable laws and regulations.

REGULATORY CONTACTS

- All GMI suppliers shall have a written policy detailing the procedures and responsible persons associated with a regulatory contact and facility inspection.
- The facility shall keep accurate records detailing regulatory agency visits and the resolution to all findings documented by the regulatory agency.
- All GMI suppliers shall notify GMI Global External Quality Management (XQM) Team when any significant regulatory findings (e.g. adulterations injurious to health noted on a FDA Form 483 and comparable forms globally) are made.

REGULATORY SAMPLING

- Duplicate samples shall be taken anytime regulatory samples are pulled along with clear documentation of what is to be tested. This may include duplicates for finished product testing for pathogens, pesticide testing, environmental sampling, etc.
- A hold and positive release program shall be in place to accompany regulatory sampling with written clearance by the sampling agency prior to disposition. If a hold and positive release program is not feasible, GMI shall be notified in advance and a written approval from Quality personnel at the receiving plant shall be obtained.
- Supplier’s product that has been sampled and partially shipped or in regulatory hold while in transit to GMI must be communicated to the appropriate GMI contact immediately to ensure hold and clearance prior to use.

Food Safety and Quality takes several established precautions to ensure complete compliance and cooperation in any case when a raw ingredient, either owned by or being shipped to General Mills U.S., is sampled by the Food and Drug Administration (FDA).

Accordingly, we are requesting that General Mills Food Safety and Quality Contact or auditor be informed promptly and completely of all FDA inspections of your facilities which involve the sampling of any material being shipped to General Mills. This includes occasions where the FDA asks to see shipping orders and/or seeks to confirm that specific shipments have been made to General Mills. In all cases possible, we would like to have the lot numbers of ingredients involved in either the actual sampling or the shipping orders observed.
IMPORT REGULATORY REQUIREMENTS

Where GMI is purchasing ingredients directly from a foreign supplier, the supplier should comply with all applicable laws, regulations or ordinances of any governmental authority that regulates the import or export of goods and services provided by the supplier, and all reasonable requests from GMI as to the form and manner of such compliance. Such compliance activities shall include, but not be limited to, proper marking of the country of origin of goods, proper labeling, provision of all documentation requested by GMI or as otherwise needed for compliance (such as country of origin certificates, complete product descriptions on invoice, organic import certificates) and other compliance measures as required.

In countries where GMI requirements are stricter than defined in local regulations, GMI’s requirements outlined in this Manual and specifications shall take precedence.

CUSTOMS TRADE PARTNERSHIP AGAINST TERRORISM (CTPAT) (**SUPPLIERS TO N.A.**)

As a partner in the Customs Trade Partnership Against Terrorism (CTPAT) program, General Mills requires that all ingredients purchased directly from a foreign source with General Mills as the importer of record (IOR) be shipped in accordance with the guidelines outlined under the CTPAT program.

Import operations manages the initial set up of foreign suppliers shipping products to General Mills in the U.S. when GMI is designated as the importer of record. Supplier requirements under the CTPAT program will be communicated as a part of that process and a foreign supplier security questionnaire will be provided for completion. Upon receipt back, Corporate Security will assess the current status of that supplier’s supply chain security procedures under the program and provide recommendations for further action as needed to meet minimal security requirements. Suppliers who are not currently certified under the CTPAT program can expect to be placed on a continuing review schedule and should expect and plan for an on-site security assessment to verify the security information provided and the adequacy of site security and logistics programs.

Where ingredients are purchased from a foreign source and General Mills is not the importer of record the supplier must still comply with all applicable GMI standard requirements and ensure the safety and security of the product in accordance with General Mills policy.

Further information on the program is available by accessing the Customs and Border Protection website at www.cbp.gov and clicking on the CTPAT link under Quick links.

PRODUCT CONTROL, TRACEABILITY AND RECALL REQUIREMENTS

All suppliers shall have:

- An effective traceability program that includes identification, code dates, lot numbers, and documentation for ingredients, packaging, premiums, finished product, and rework.
- A documented and effective product recall, market withdrawal, and stock recovery program.
• Ability to identify, stop distribution, and notify customers and consumers by code date within 24 hours of obtaining knowledge of significant marketplace food safety or regulatory issues that would lead to a product recall or product withdrawal.
• Ability to trace one step back from receipt and one step forward from shipping.
• An annual mock recall program that includes summary results of mock recall (% recovery, time for completion, etc.), key learnings, system improvement needs and identified gaps with documented corrective action taken.
  o Includes ingredients, finished product, and food contact packaging

FDA REPORTABLE FOOD REGISTRY (SPECIFIC NORTH AMERICA)

• Companies are required to report adulteration that would present a serious adverse health consequence such as death, permanent injury, or irreversible harm.

Steps in the process to determine whether to report:
1. Determine scope of issue and, most importantly, perform full risk assessment with this frame of mind
   1. Would situation lead to a serious adverse health consequence?
   2. Is it exempt from reporting if:
      (a) the adulteration originated with you (i.e., not a supplier);
      (b) you detected the adulteration prior to any transfer of your product to another person; and
      (c) you corrected the adulteration or destroyed your adulterated product.
2. Discuss with impacted customers & suppliers
   1. General Mills expects discussion prior to reporting (if needed, use 24 hours contact line 763-764-2310)
   2. Decision resides with you
3. Report issue into food registry within 24 hours of determining reportability
   1. Make sure to retain issue number for communication to others
   2. Expect near immediate action from FDA
   3. GMI available for assistance

HOLD PROGRAM

All suppliers shall have:
• A documented hold program that effectively identifies, isolates, and maintains control of any substandard product due to potential quality or food safety issues.
• A hazardous hold (product on hold due to food safety issues) procedure that includes 2 levels of controls for product security (physical and electronic), physical inventory counts (it is recommended at least weekly) and procedures for witness destruction.
• An effective disposition process that ensures only authorized personnel disposition hold products, disposition instructions are followed, and documentation is maintained.
• A procedure for handling products that are on hold for multiple reasons.
GOOD MANUFACTURING PRACTICES AND SANITATION

Ingredients supplied to GMI shall be of food grade and in all respects in compliance with all applicable regulations for the country of manufacture and country of sale. All products shall be processed and packed under strict sanitary conditions in accordance with FDA current Good Manufacturing Practices, or equivalent based upon the country of manufacture and country of sale. Facilities must develop and implement an effective, documented sanitation and GMP program to ensure regulatory compliance, food safety and sanitary conditions of the facility.

These requirements reflect the minimum expectations but do not supersede any Local or National regulatory requirements:

PERSONNEL PRACTICES (EMPLOYEES, CONTRACTORS, TEMPORARIES, VISITORS)

- Consistent and regular GMP training and education program
- Compliance with GMPs
- Health policy shall be in effect to prevent spread of infectious or communicable diseases
- Compliance with general cleanliness practices and wear clean outer garments
- Compliance with documented personnel practices

OPERATIONAL AND STORAGE PRACTICES

- Waste materials shall be identified and adequately controlled
- Containers and utensils shall be designed, identified, used and cleaned so as to prevent contamination
- Packaging and raw materials shall be received, stored and used so as to prevent contamination
- Adequate perimeter shall be maintained in warehouse and storage areas to allow inspection and cleaning (Recommended space: 18” /45 cm)
- Physical storage conditions shall be maintained to ensure material integrity
- Storage surfaces and racking shall be clean and in good condition
- Packaging, raw materials and finished goods shall be stored separately

FACILITIES AND UTILITIES

- Grounds and exterior structure shall be designed and maintained to provide protection from environmental elements, pest entry and harborage
- All openings shall be properly sealed and/or screened at all times
- Roof shall be accessible and well maintained
- Interior structures shall be designed and maintained to be impervious and cleanable
- Facility shall be maintained to be free from loose paint, rust and/or other debris that may contaminate product zones
- Water leakage and/or condensation shall be controlled to prevent product contamination or microbiological hazards
- Traffic patterns of people, machines and materials shall be controlled to prevent contamination
• Hand wash stations shall be accessible and maintained in good repair
• Facility shall use potable water that meets applicable laws and regulations. World Health Organization Backflow prevention shall be in place to ensure the integrity of the potable water system tested minimum of once per year
• Compressed air and steam in contact with food products or injected during processing shall meet all applicable regulations (including use of food grade boiler additives)
• Ventilation system shall be adequate to minimize condensation, mold development and prevent pest entry

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EQUIPMENT AND MAINTENANCE
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• Equipment shall be designed and maintained to prevent product contamination
• An effective preventive and corrective maintenance program shall be in place
• Procedures should be in place to ensure adequate tool controls as well as appropriate cleaning and sanitizing prior to production
• Product zones and adjacent areas shall be thoroughly cleaned and inspected following completion of equipment/system maintenance or repair (e.g., duel sign off, etc.)
• Temporary repairs shall be documented and effectively managed
• A calibration program shall be in place for all sensitive equipment

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SANITATION
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• An adequate, documented cleaning program shall be in place to cover daily and non-daily tasks of production and non-production areas (including drains)
• Procedures should be in place to verify effectiveness of cleaning procedures
• Facility shall have a program in place to ensure utensils used for production are distinguished from utensils used for cleaning
• For facilities utilizing CIP system, CIP sanitation process shall be validated. Key requirements of the validated CIP process (time, temperature, concentration, and flow rate) shall be documented for every CIP cycle. Program shall include a list and description of key process components and controls

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INTEGRATED PEST MANAGEMENT
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• An effective, documented pest control program (rodents, insects, birds and wildlife) shall be in place
• Program shall be supported by a licensed, certified applicator, and include only certified pesticides in compliance with country regulation
• Toxic bait shall not be used inside where prohibited by law (e.g., in production areas, warehouse, maintenance shop, etc.)
• Monitoring results, trends analysis and findings shall be evaluated to determine effective short term and long term corrective actions and proactive prevention
• When mechanic stations and glue boards are used, an increased monitoring frequency is recommended
FACILITY ASSESSMENT

- Internal inspections shall be performed to assess compliance with all regulatory and food safety requirements. Findings and corrective actions shall be documented.
- A 3rd Party shall complete annual audits at the facility and a corrective action plan shall be documented for all audit findings.

CHEMICAL STORAGE AND USAGE

- Documented chemical control program shall be in place including approved chemical list, inventory control, preparation and usage (chemicals for sanitation, maintenance and stored pesticides).
- Lubricants used in food processing equipment shall be food grade and adequately controlled and labeled. Food grade lubricants shall be stored separately from non-food grade lubricants.

TRANSPORTATION AND LOGISTICS

Transportation vehicles and containers used for transporting GMI ingredients shall comply with GMI requirements and applicable laws and regulations to assure the safety and quality of the contents during all phases of transportation.

Prior to loading and shipping, transportation vehicles and containers used to transport GMI ingredients shall be thoroughly inspected and cleaned as necessary to protect product integrity. The inspection shall be documented.

General Mills follows the GS1 guidelines on pallet level bar code labeling and expects the same from suppliers for ingredients, packaging materials, finished goods, semi-finished goods and supplies. (Refer to Appendix B for details).

VEHICLE AND CONTAINERS ACCEPTABILITY

- The ingredient supplier shall be responsible for the sanitary condition and acceptability of the vehicle when loaded and ensure compliance to GMI requirements.
- Transportation vehicles and containers (Sea going containers, direct contact bulk vehicles and containers, temperature controlled vehicles, dry good trucks) including pipes and loading/unloading equipment shall be:
  a. In good, safe, and lawful operating condition (e.g., free from structural defects, etc.) for transportation of only food grade merchandise,
  b. Clean, dry, odor free and leak proof
  c. Free of contamination and infestation
  d. Made of food grade materials for direct food contact surfaces
  e. Capable of being tightly sealed to adequately protect the contents and prevent contamination
  f. Fully functional to maintain specified temperature (if temperature controlled vehicle)
• Repaired or reconditioned direct contact bulk vehicles and containers shall be cleaned, dried and inspected prior to use for GMI.
• When present, valves, unloading pipes and ports of bulk liquid/dry cars and tanker trucks shall be purged/blown before loading. It is recommended that air be blown through bulk trucks and all pipes and valves a minimum of 5 minutes prior to loading. This is especially important after a wash, but a generally good practice between loads.
• Transportation vehicles and containers transporting bulk liquid ingredients shall be washed in compliance with food safety, regulatory and religious certification requirements on a risk based frequency to ensure integrity and quality of the product. Transportation vehicles and containers (including hoses) used to ship different bulk liquid materials shall be washed between each load. A “Wash Certificate” for all liquid loads and “Dry Clean” certificates for all dry bulk loads which includes the date cleaned and the name of previous product transported, shall be available from the driver upon request.
• Roll top, soft sided or open top trucks shall not be used for shipment of food products or ingredients to GMI, with the exception of commodity type purchased ingredients as designated in the specification and/or the purchase order. Allowances may vary by region with approval by XQM Team based upon risk assessment.
  • If roll top, soft sided, or open top trucks are used, the shipper shall consult with XQM designate to minimize product safety risk.
  • Roll top or soft sides shall be in good condition without any holes.
  • In these cases, alternate methods may be employed to secure the load and visually inspect the goods for food defense.

VEHICLE AND CONTAINERS INSPECTION

• Each vehicle must have a documented inspection prior to loading to verify the required vehicle and container acceptability criteria is met.
• If the bulk container will be top loaded, they must ensure documentation of the following criteria:
  o Only same materials into same materials
  o Vehicles must be secured under appropriate seals to ensure integrity of container and cleanliness
• Transportation vehicle and container openings (hatch covers, valves, hoses, doors, and latches, etc.) shall be inspected for cleanliness, integrity, closing ability, and shall be properly purged and cleaned prior to loading.

VEHICLE LOADING, CLOSING AND SHIPMENTS

• Bulk Railcar & Bulk Trucks opening and access points shall be protected to prevent contamination at all times, including vehicle loading, unloading and aeration. Hatches shall be covered with a heavy plastic liner (min 2 mm thickness) prior to closing to prevent leaks and contamination.
• All vehicles and containers shipping GMI ingredients shall be properly loaded and immediately sealed in order to minimize the risk of contamination or tampering of the load.
• Food ingredients shall not be shipped in mixed loads with other non-food materials where contamination of the food ingredient may occur due to foreign substances, toxic materials, off-odors or other conditions, which may render the food ingredient unacceptable.
In order to assure food safety, traceability, and quality, the following documentation shall be provided:

**Bill of Lading (BOL) or equivalent shipping documentation, minimum requirement:**
- Seal numbers of each security seal attached to the vehicle
- Vehicle information including transportation company and vehicle number
- Origin and destination points (name and address)
- Load description (e.g. name of product, GMI ingredient code, weight, etc.)
- Code Markings or Lot identification
- Quantity of each Lot/Code Marking
- GMI purchase order number or invoice number
- Scheduled date of arrival
- Temperature requirement and verification at time of shipment (for temperature controlled loads only)
- Fumigation dates and dosage (for in transit rail fumigation only)
- Hazardous Nature of Material, with rules and regulation governing shipping/handling of such material (e.g. MSDS for flammable flavors, etc.)
- For import into the US when General Mills is considered the importer: The GMI DUNs # MUST be included: 00-625-0740

Note: Missing or inaccurate BOL information may be cause for rejection.

- Kosher or Halal Symbol or other documentation as required
- Purchase, transit and delivery documentation that shall identify organic ingredient as organic.

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**VEHICLE AND INGREDIENT SECURITY**

- The seal shall be a tamper evident style. The tamper evident seals' specific style and strength is the suppliers' choice, in contrast to the cable seals required on bulk rail and truck carriers. For shipping to North America, seals on rail cars shall be sealed with wire cables ISO PAS 17712 compliant (recommended a minimum of 3/16” wire cables). The seals on bulk/tank trucks shall be a minimum of 1/16” wire cables that are ISO PAS 17712 compliant. Seals on bulk trucks may be plastic tamper evident style by exception if appropriate risk considerations such as distance, no driver changes, no overnights and dropped trailers are taken into account. A broken or missing seal is still a cause for rejection at the shipper’s liability.
- The seals are to be placed to reveal unauthorized access.
- Suppliers are not required to seal common carrier LTL’s (less than truck load) not shipped under their control. However, containers shipped on a non-sealed carrier must have individual unitization that is tamper evident.
- If a truck seal must be broken for any reason (e.g. border crossing, weigh station) on a sealed vessel while in transit, the carrier must note the time, date, location, and reason of removal on the BOL. As soon as practically possible, the container must be resealed with the new seal number, time, date, and location of resealing noted on the BOL.
- The carrier must inform both the shipping location and receiving location of this change and receive their acceptance prior to continuing on to the GMI facility for unloading. Where possible, the agency breaking the seal should reseal the container with their agency specific seal. It is the suppliers’ responsibility to ensure the carrier is aware that the seal can only be broken at the receiving facility by an authorized General Mills employee or designate, except as noted above.
FUMIGATION

- The ingredient supplier is responsible to assure compliance with fumigation specifications and applicable laws and regulations including communication with the carrier at the time of loading, during transit, and upon arrival at the receiving location.
- Fumigation cannot be done without prior written authorization between the shipper and the GMI receiving plant to assure proper procedures are in place at the receiving end to allow for fumigant handling and aeration.
- Railcars can be in transit while under fumigation. Proper procedures must be in place at the receiving location to allow for proper fumigant handling and aeration.

PALLETIZING AND LINING

- Prior to shipping, confirm all shipping requirements with the receiving facility.
- Please note that the following requirements may necessitate being superseded by specific receiving plant needs, which will be communicated by the receiving plant. It is the supplier’s responsibility to know and comply with each plant's particular need.
- Ingredients are to be secured within the unit load. Unit shall be moveable in such a manner that the load is adequately supported and can be stacked with safety and without damage.
- Unit width should not exceed the pallet size.
- All shipments shall be slip sheeted.
- Total unit weight is predicated by receiving facility’s equipment capabilities and safety requirements. Slip-sheet must be on top of lower pallet load before placing the second pallet on top. Double-stacked product should be secured to prevent shifting and damage to the load.
- All pallets should be labeled with date of manufacture and quantity of product readable from two sides. Pallets with multiple lots are to be indicated as such and the corresponding number of units and date of production listed on the pallet as well as on the bill of lading. No more than 2 lots can be on any one pallet.
- Information on minimal pallet labeling requirements for suppliers who send EDI 856 Advanced Shipment Notice to General Mills when shipping against a Purchase Order can be found in Appendix B.

* VEHICLE SHIPMENTS NOT MEETING THESE REQUIREMENTS MAY BE REJECTED. *

RETURN OF BULK TRAILERS OR CARS (GENERAL MILLS PLANT RESPONSIBILITY)

- Suppliers should expect that all bulk carriers returning to their facility directly (without any intermediate stops) from a GMI facility will be sealed. If the returned trailers or cars are not in compliance with this requirement, please contact the shipping facility. If unavailable, GMI Global External Quality Management (XQM) Team may be contacted for support.
CONSUMER AND CUSTOMER RELATIONS

All suppliers shall have procedures in place to monitor GMI non-conformances related to product quality, food safety and regulatory matters.

Additional procedures shall also be in place to ensure issues of Quality Notifications (QNs)/Non-conformances from GMI are reviewed and addressed in a timely manner with appropriate response and documented corrective action.

Ensure documented review of non-conformances is conducted on a regular basis to identify potential product safety, regulatory, or other significant issues and trends that may require action such as further investigation or communication.

PRODUCT SPECIFICATIONS AND LABELING

All suppliers shall have a specification control program in place that includes clear accountabilities, document control and verification procedures to ensure the correct GMI specifications are used and available to appropriate personnel. Procedures shall be in place to obtain approval from GMI prior to making any changes to product, process, specifications, formulas and producing locations. A process control plan shall be in place along with a sampling plan and quality attribute testing to ensure product is produced to target specifications. A label control program shall be in place to ensure product labels contain all required and accurate information. A label verification program shall be in place to ensure right product is packed in right package with the right label. Failure to comply with these requirements will be addressed through the quality notification and non-conformances process which may result in additional action by the receiving location up to and including rejection of the material.

ADDITIONAL GMI SPECIFICATION REQUIREMENTS

The manufacturer of ingredients shall supply General Mills with a list of all the labeled individual components used in the formulation of the ingredient. This information shall be kept on file in the General Mills Food Safety and Quality Team.

For Regions outside of North America a Continuous Guarantee shall be completed, signed and returned to GMI upon request prior to ingredient first production. This document shall be re-signed and submitted after any changes to ingredient specification. When applicable, the supplier must provide additional ingredient information as requested in order to allow proper classification of ingredients for Customs or other government agency clearance and any applicable trade alliance or free trade agreement qualification.

PACKAGING AND LABELING REQUIREMENTS

Ingredient labeling program shall be in place to ensure all products supplied to GMI meet the below label requirements.

Each unit (bags, drums, boxes, etc.) shall be identified with the following information clearly legible at a distance in compliance with regulation:
• The full 10 Digit GMI Ingredient number, preceded by "GM" (GMI North America)
• The lot number, preceded by "lot" *
• The date of manufacture and/or expiry date
• The name of the manufacturer/ manufacturing location/ Brokers or Distributors
• The net weight
• The ingredient declaration of contents
• The Kosher and/or Halal symbol, if appropriate

*The term “batch” may be used in the place of “lot” if clearly identified and easily discernible on each unit and supporting documentation. In case of internal coding system, code interpretation must be provided to General Mills.

Closure: No metal clips shall be used for closing the units nor shall metal or plastic ties be used for closing bags within the unit.

Liners: Package liners must be manufactured according to “food grade” specifications and of a color that is easily distinguishable from the food packaged in it.

CERTIFICATE OF ANALYSIS (COA)

Product shall not be shipped until they have cleared testing as required by General Mills specification and supplier’s internal requirements unless Quality personnel approvals have been obtained and documented.

The items to be tested and documented on the COA are listed in the General Mills Specification under the Certificate of Analysis section. EXCEPTIONS to these requirements must be approved by General Mills. Each COA shall include enough information to allow trace back to the material tested (e.g. Supplier/vendor name, the producing location, the ingredient by GMI ingredient name and number, the results by lot number, date of shipment, and PO #). The country of origin shall also be included on the COA where applicable for regulatory and country of origin labeling (COOL) purposes.

All COA’s must arrive with or be sent to the receiving plant’s attention prior to receiving the ingredient in question.

LABEL DECLARATIONS AND CLAIMS

Proper supporting data and documentation shall be available for all General Mills ingredients as listed below:

• Religious Dietary Claims and Certification: Products bearing a religious dietary claim on packaging or in advertising shall meet the appropriate certification agency standards, applicable regulations (e.g. Kosher, Halal, Kosher Pareve, Kosher Dairy, or Kosher for Passover).
• Ingredient Free Claims: A product may bear a claim that it is “free” of a certain type of ingredient provided the claim meets applicable regulations and GMI requirements for the particular type of claim (e.g., gluten free, GMO free, lactose, etc.).
• Gluten Free Claims: GMI products with “gluten free” claims shall meet applicable regulations for labeling, substantiation, test results and documentation for the country of sale.
ORGANIC INGREDIENT REQUIREMENTS

All General Mills vendors that produce, package, store, or handle ingredients making an organic claim, or non-organic ingredients being used in finished products making an organic claim, shall provide General Mills with complete and accurate information that complies with all applicable national, state and local regulations and that meets company policies, standards and guidelines. Vendors are responsible for ensuring that organic ingredients and non-organic ingredients used in an organic product retain their integrity and avoid contamination while being stored and/or transported.

All ingredients intending to be sold, labeled, or represented as organic (i.e., “100% organic”, “organic”, or “made with organic ingredients”) shall be certified by an accredited organic certifying agency.

Organic is a labeling term that denotes ingredients produced under regulatory authority of national or regional (such as the E.U.) bodies. In the U.S., for example, the USDA’s Agricultural Marketing Services (AMS) administers the National Organic Program (NOP). “Organic” ingredients must satisfy organic production, handling, and processing requirements and be produced without the use of prohibited materials, prohibited processes, and excluded materials (e.g., GMOs).

The National Organic Program and other international equivalents also establish the specific provisions for the use of non-organic ingredients in finished products labeled “organic” or “made with organic ingredients”. For example, in the U.S., the National List of Allowed and Prohibited Substances is the federal list that identifies the natural substances and ingredients that are allowed, natural substances and ingredients that are prohibited, synthetic substances and ingredients that are allowed and synthetic substances and ingredients that are prohibited for use in organic production and handling.

ORGANIC INGREDIENT DOCUMENTATION

Suppliers shall comply with the below certification and documentation requirements. Exceptions may vary by region and may be defined by the XQM auditor or manager based upon the country of origin and intended market.

- Each operation involved in handling, processing and packing organic ingredients shall seek, receive and maintain an organic certification from an accredited certifier and must comply with all applicable organic production and handling regulations. Such operations must establish, implement, and annually update an organic production and system plan that is submitted to an accredited certifying agent for ongoing certification.
- For organic-certified ingredients, a current copy of the vendor’s organic certificate shall be presented to General Mills upon request. This certificate must contain the following:
  - Clear indication of compliance to the appropriate organic standard. For example, an ingredient to be used in a US-certified product must meet the NOP standards.
  - The specific organic ingredients sold to General Mills. Ingredients must be clearly identified on the certificate or on ancillary pages linked to the certificate.
  - All applicable processing or handling locations. If an organic ingredient is supplied to General Mills from more than one processing facility a certificate must be submitted from each location or all locations must be listed on one certificate. A handling (distributing/marketing) certificate is also acceptable, though all actual production sites must be reported to General Mills.
• An issue, expiration, or annual monitoring date. After annual compliance inspections have been successfully completed an updated, certificate shall be sent to General Mills upon request that reflects the revised date.

• Each vendor shall supply, upon request, a document indicating the exact organic percentage of an ingredient when it is not clearly indicated on their organic certificate.

CHANGE IN ORGANIC STATUS OF VENDOR OR INGREDIENT

The vendor is to notify General Mills of any and all changes in organic status that may impact the ingredients supplied to GMI. Notification shall be made when:

• Organic certification has been surrendered, revoked or suspended
• Ingredients or processing locations have been removed from the certificate
• A change in certification agencies has been made
• A change to the organic labeling classification (100%, Organic, Made with Organic) or organic percentage is made.

NON-ORGANIC INGREDIENT DOCUMENTATION

• Each operation supplying non-organic ingredients used in finished products making an organic claim may not use excluded methods, which include methods to genetically modify organisms, use of sewage sludge, and use of ionizing radiation. Additional limitations may apply to natural flavors and other items with regulatory annotated restrictions.
• For these non-organic ingredients used in organic products, vendors shall provide the appropriate documentation attesting to the suitability of those ingredients. This documentation may include supplier generated statements and/or standard forms and questionnaires provided by General Mills to the supplier to complete and return. Renewed documentation shall be provided upon request approximately every two years. Any changes to the ingredient affecting the information and conditions agreed to within the statement or questionnaire must be communicated to General Mills prior to implementation.

ORGANIC REGULATORY CONTACTS

The USDA AMS grants accreditation to state or private certifying agents, therefore all contacts made by certifying agencies must be handled according to our regulatory policy. See the “Regulatory Contacts” section in our Ingredient Manual for specific requirements.
HACCP AND PREREQUISITE PROGRAMS

Each supplier location shall have a current, effective, and documented HACCP program (Hazard Analysis and Critical Control Points) based upon the 7 commonly accepted principles of HACCP for each producing line and product type that at a minimum should include:

1) Cross functional group of HACCP trained individuals
2) HACCP training
3) CCP validation data
4) HACCP Plan which includes the following documentation:
   • List of prerequisite programs
   • Intended use of product, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product
   • Hazard Analysis including identification of potential hazards, which includes all ingredients, product contact packaging materials and finished products. The hazard analysis shall include the following:
     - Regulatory restrictions, biological, chemical and physical characteristics (including radiological and economically motivated hazards (food fraud))
     - composition of formulated ingredients, including additives and processing aids
     - origin of hazard
     - method of production
     - packaging and delivery methods
     - storage conditions and shelf life
     - preparation and/or handling before use or processing
     - food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended and unintended uses
     - utilities that contact or may have incidental food contact (e.g. steam, compressed air, nitrogen, boiler water, ice)
   • Flow diagrams that include the following:
     a) the sequence and interaction of all steps in the operation
     b) any outsourced processes and subcontracted work (as applicable)
     c) where raw materials, ingredients and intermediate products enter the flow
     d) where rework takes place (as applicable)
     e) where end products, intermediate products, by-products and waste are released or removed
   • CCPs, CCP critical limits, corrective actions and corrective procedures
   • CCP monitoring and verification procedures, frequencies, responsible person(s), records (See Appendix E for definitions and examples of monitoring, verification, validation)

The HACCP Program shall be developed, implemented and maintained by a multi-disciplinary HACCP Team that meets on a regular basis, with minimum annual review and prior to any significant changes. At least one member of the HACCP Team shall be HACCP certified or be a qualified individual based on experience and training.

The HACCP plan shall be validated initially and prior to any significant changes.
HACCP records shall be stored securely, easily retrievable and retained for the shelf life of product.

FSMA: FOOD SAFETY PLAN

Each supplier providing ingredients to GMI US facilities shall have a written Food Safety Plan specific to their facility that is prepared (or overseen) by one or more preventive controls qualified individuals (PCQI).

The written Food Safety Plan shall include:

- A written hazard analysis
- Written preventive controls (process, allergen, sanitation and supply chain applied preventive controls)
- A written supply chain program (as appropriate)
- A written recall plan
- Written procedures for monitoring the implementation of the preventive controls
- Written corrective action procedures
- Written verification procedures
- Written validation procedures for process preventive controls (CCPs)

Food Safety Plan monitoring and corrective action records shall be reviewed within 7 working days after the records are created; remaining verification records are to be reviewed within a reasonable time after records are created.

FOOD ALLERGENS

All suppliers to General Mills shall develop and maintain an Allergen Management Program that effectively controls the risks associated with these allergenic ingredients: peanuts, tree nuts, eggs, milk, fish, crustacean, soy and wheat. Additional allergens or sensitizing agents may require control as regulated in the country of manufacture or country of sale for example, mollusks, mustard, sunflower seeds, sesame, sulfites, cereals containing gluten, coconut, etc.

Allergen Management Program shall be reviewed and updated on an annual basis or more frequently if there are any changes in allergen risk.

A documented allergen training program shall be in place to educate all employees (employees, temps, support staff, management, etc.) on the basics of the major allergens and their risks. Training shall be conducted at least annually.

Allergen management program shall consider the following allergen management strategies: location/system/line dedication, separation (Physical Structures, Production Scheduling, Facility Allergen Control Program and Procedures) and cross contact labeling.

DEDICATION

Allergenic products shall be produced on a dedicated line running a specific allergen or allergen combination wherever possible.
**SEPARATION**

Wherever possible, separation and physical barrier(s) should be in place between lines and equipment running different allergenic products.

Production scheduling and allergen sequencing shall be used to minimize the risk of allergen cross contamination.

Facility Allergen Control Program shall be a component of the HACCP program and shall consider storage practices, cleaning practices, tool and container management and rework.

- Storage practices shall be in place to prevent cross contamination of allergenic ingredients, packaging materials, etc. This may include physical segregation, dedicated storage areas, unique labels, storing materials on the lowest level, etc.
- Product changeovers from one allergen to the next or to non-allergen products must be restricted to systems that have validated cleaning procedures. These systems must also have documented cleaning and changeover procedures. Part of these procedures must be verification after each cleaning and validation to confirm the cleaning procedures are sufficient to protect against the unintended presence of a non-labeled allergen in the next product. A cleaning checklist should be utilized to identify, verify and document areas that have been cleaned. Each component shall be inspected to verify that it is visibly free of residue product build-up before subsequent production. Dual sign-off is required by 2 trained and authorized personnel following an allergen clean.
- A tool and container control program shall be in place to prevent cross contamination. This may include color coding, dedicated tools, cleaning practices, maintenance procedures, segregation and storage practices.
- Plant rework policies shall be established, followed and documented. Any staging/storing of allergenic rework should be in clearly defined areas and the rework shall be clearly labeled. Rework must be “Same into Same” only and should be used during the same production run or as early as possible during subsequent production run.

**LABELING**

Labeling will not be used in lieu of cleaning practices necessary to protect against the unintended presence of a non-labeled ingredient (GMP).

All Suppliers shall label all allergens in their ingredient declarations and have a system in place to verify the accuracy of labels. Verification steps to document the accuracy of all labels must be included in all labeling strategies. Where possible the use of scanners should be utilized for verification purposes.

Controls and measures should be in place to assure to minimize the use of cross contact or may contain labeling to when and only when: the presence of major food allergens can be confirmed through visual or analytical means, the risk of major food allergen is unavoidable even when current GMPs are followed, a major food allergen is present in some not all of the products, and the presence of a major food allergen is potentially hazardous.

All suppliers to General Mills shall conduct a documented assessment as part of their HACCP program to determine which allergen control procedures are necessary at their location to protect against the unintended presence of an allergen and undeclared component of any product. The information provided to General Mills shall allow accurate allergen declaration.
General Mills must be notified as soon as possible if the allergen profile changes (e.g., when an allergen is identified in a product that was not previously labeled due to new allergen information from current supplier, addition of allergen to the “contains” or “may contain” statement due to change in formulation, etc.)

CONTROL OF BIOLOGICAL HAZARDS

A biological control program shall be in place with appropriate ingredient, environmental, processing, and finished product controls along with evaluation as part of the HACCP program and appropriate monitoring procedures. Ingredients supplied to GMI shall conform to all regulatory agencies’ microbiological requirements, and be safe and suitable for food use in accordance with Good Manufacturing Practices. Microbiological test results shall be provided to GMI upon request for review.

SENSITIVE INGREDIENT CONTROLS

As part of the HACCP program, an ingredient hazard analysis shall be conducted to identify microbiologically sensitive ingredients. Procedures should be in place to ensure safety of sensitive materials through testing and/or COA verification prior to use.

PROCESSING CONTROLS

All processes shall be in compliance with applicable government regulations and products produced in such a manner to ensure food safety. Kill steps included in the process shall be documented and supported by appropriate validation, verification and monitoring procedures as part of the HACCP program to ensure ongoing control. Additional controls shall be evaluated to minimize the risk of cross contamination for microbiologically sensitive areas:

- Effective handwashing
- Effective footwear controls
- Tool control
- Evaluation and control of traffic (personnel, materials and equipment)
- Segregation of raw and post processed areas
- Positive air flow from microbiologically sensitive areas
- Additional controls for construction and unique plant activities

FINISHED PRODUCT TESTING

The biological control plan shall include procedures in place for finished product testing with designated sampling location(s), sample size, and frequency of testing to be conducted for each product. A process shall be in place to effectively respond to microbiological results exceeding critical limits including investigation, corrective action, product disposition and customer notification as needed. Tests to be conducted shall be documented and performed using standard approved test methods by trained personnel. Specific microbiological testing including sampling requirements for GMI are detailed in each ingredient specification. A positive release program shall be in place to ensure no product is shipped until product has been cleared according to GMI specification. If product is to be shipped for clearance in transit, GMI must provide documented
approval prior to shipment. No product or lots confirmed to be positive for pathogens or out of compliance with GMI specification for micro shall be released. Product or lots testing positive for pathogens may be retested for investigational purposes only.

ENVIRONMENTAL MONITORING

All suppliers (except commercially sterile ingredients) shall have an appropriate program to monitor for microbiological environmental contamination and to reduce risk of post process contamination as part of a preventative control program. Industry experience has shown that an ongoing monitoring and control program focused on pathogens of concern as part of the site food safety plan reduces the possibility of contaminations in finished products. The environmental monitoring program shall have the capability to identify harborage niches, detect and identify microbiological contamination, establish corrective action to eliminate, and follow with procedures to verify effectiveness. The entire facility environmental monitoring program, including results and corrective actions, shall be available for review.

The environmental monitoring program (EMP) shall be documented and include:

* Program review
* Monitored plant areas
* Hygienic area designations for production areas
* Sampling zones
* List of routine-fixed sampling sites
* Frequency of monitoring routine-fixed and routine-variable sites
* Target microorganism(s) for routine sampling
* Sample collection timing
* Sampling device and method
* Compositing instructions, if applicable
* Sample analysis details: handling, shipping, laboratory, test methodology
* Actions for positive results and escalation plan
* Special cause swabbing procedures
* Seasonal facilities and plant down time
* Record Keeping
* Training

The EMP shall be reviewed annually. More frequent review may be necessary if there is a temporary or permanent microbiological risk change (e.g., construction activity, water event, observed environmental issues, change to physical layout, process/product change). Reference Appendix F for a recommended list of topics to be reviewed annually.

Monitored Plant Areas
General monitored areas should be identified within the manufacturing facility through consideration of risk factors including, but not limited to, product type, potential for contamination, past history, facility layout, traffic flow, and construction activity.

Hygienic areas
Hygienic areas should be defined and documented on a plant floor plan for all production areas based on risk for cross-contamination of ready-to-eat product. Refer to Appendix F for hygienic area definitions (PPC/High Risk, Basic GMP, Non-Production) and examples. Pathogen
environmental monitoring sites shall be more concentrated in PPC areas than in basic GMP areas and shall be selected to identify potential niches and cross-contamination points.

**Sampling Zones**
Sampling zones shall be identified for each Monitored Plant Area based on proximity to product and product contact surfaces. Refer to Appendix F for sampling zone definitions (Zone 1, 2, 3, 4).

Food Contact Surface (Zone 1) sites shall not be tested for pathogens (including Listeria species) as part of routine environmental monitoring and may be tested for hygiene indicator organisms to verify sanitation efficacy. For facilities choosing to conduct food contact surface (zone 1) testing for pathogens, additional controls shall be put in place with consideration for validated cleaning procedures, clean breaks, supporting documentation, hold and positive release program and a process to respond to positive test results. A positive pathogen result on zone 1 surfaces may implicate the finished product produced on that line during the time the positive was found and between clean breaks. Clean break is defined as a process which assures no residues or evidence of carry-over of product, chemicals, microorganisms or foreign material from one production run to another.

**Sampling Sites (Locations)**
A sampling site is the specific location where a sample is collected.
· The facility shall document and maintain a current list of routine fixed and routine variable monitored sites. It is recommended these are also documented on plant floor plan or map.
· The monitored plant area, hygienic area, and sampling zone for each site shall be recorded and readily available for risk assessment.
· The number of sites to be sampled shall be based upon the facility size and risk assessment.

Refer to Appendix F for sampling site examples and definitions (routine fixed, routine variable, non-routine positive mitigation, non-routine event driven).

**Frequency of Monitoring Routine-Fixed and Routine-Variable Sites**
Monthly sampling:
· All zone 2 and 3 sites in higher risk (PPC) areas
· All sites that have been positive 2 or more times after mitigation (in the last 12 months)
· All sites in high traffic areas, major floor drains, or other critical sites

Basic GMP areas must be sampled quarterly, however, monthly is recommended.
Non – Production areas are not required to be monitored but may be included at the discretion of the facility.

**Target Microorganism(s) for Routine Sampling**
*Salmonella* shall be targeted in dry environments where no wet washing occurs
*Salmonella* and *Listeria spp.* shall be targeted in wet environments, and/or dry systems where wet washing occurs

**Sample Collection Timing**
Routine environmental sampling in PPC areas shall be performed during production to assess the overall area or facility. Additional sampling may be conducted after sanitation or during pre-op inspections to verify effectiveness of sanitation procedures. Basic GMP environmental sampling may occur during production or immediately prior to start-up. Reference Appendix F for additional details on sample collection timing.

**Sampling Device**
The required environmental pathogen sampling device for most sites is a cellulose or polyurethane sponge pre-moistened with a neutralizing buffer. The neutralizing buffer shall be capable of neutralizing the sanitizer used in the plant and not interfere with the pathogen test methodology.

For very small spaces where a sponge will not fit, a cotton-tipped swab or similar device pre-moistened with a neutralizing buffer may be used for sampling. Reference Appendix F for proper swabbing method.

A separate sampling device for each organism to be tested shall be used. (i.e. if one site is to be tested for Salmonella and Listeria spp., two separate sampling devices to sample the site shall be used. If also testing for indicator organisms a third sampling device shall be used). Cutting one sampling device in half is not acceptable.

**Compositing Samples:**
The following shall occur when compositing samples:

- Up to five individual sample sponges may be composited into one test sample.
- Use a separate sponge for each location to prevent cross-contamination.
- Site selection for compositing samples:
  - The composited samples must be from sites with the same Plant Area, Hygienic Area, Sampling Zone, and Sampling Timing.
  - Do not composite samples from Zone 2 in high risk areas PPC).
  - Do not composite samples from sites with a history of positive results.
  - Compositing is not recommended during an investigation/mitigation or event.
- If a composite sample is positive for the target organism, re-sample all sites individually, preferably before making corrections or corrective actions.

**Sample Analysis Details**
Appropriate approved methods shall be used for environmental monitoring:

- Samples shall be analyzed using a validated method
  - Direct plating methods without an enrichment step are not acceptable due to lower test sensitivity.
  - If composites are tested, the test method shall be validated for composite samples.
  - Examples of organizations that validate test methods are AOAC, FDA-BAM, AFNOR, and ISO.
• If a rapid screening method is used for pathogen testing, the plant shall respond to any suspect positive results from the screening method immediately with appropriate actions, regardless of whether or not the sample will be confirmed for the pathogen. Further confirmation of the suspect positive result is optional for routine environmental samples but may be required in some mitigation situations. Refer to Appendix F for details on sample handling and shipping.

**Actions for Positive Results and Escalation Plan**
Corrective and preventive actions shall be taken to remediate a positive test result and must be documented. Corrective and preventive actions may include:

- Clean and sanitize the positive site and immediate area. If the sample was a composite, re-sample individual sites before cleaning and sanitizing, if possible.
- Take measures to prevent cross-contamination from the identified site to other locations until fully mitigated.
- Inspect the site and adjacent area for potential niches and if identified then repair or remove.

The positive result escalation plan should be more stringent in high hygiene/PPC areas.

Remediation of the positive test result shall be demonstrated with 3 consecutive negative samples from the positive site.

- Samples shall be taken no more than 10 days apart. Test results from the previous sample are not required before the next sample is taken.

Positive sites shall remain on, or be added to, the routine fixed sampling plan for at least 12 months after the most recent positive result for long term monitoring.

**Special Cause Swabbing**
Additional monitoring is required during special events such as construction, roof leaks, drain backups and excessive condensation.

**Seasonal Facility Swabbing**
Seasonal facilities that produce finished goods for a short time of the year related to crop cycle shall have an effective EMP that considers the entire facility, ensuring areas that are shut down after seasonal operations do not pose a risk to ongoing operations in other areas. A comprehensive clean and site wide EMP sampling shall be done prior to startup for each season.

**Record Keeping**
Testing result information shall be kept in an organized and accessible manner such that any trends can be easily identified. Test result documentation shall include sample site, zone, hygienic area, date the sample was collected, organism tested, test result, and any pertinent
information regarding the sampling event. In the event of a positive test result, a summary of remediation activities and subsequent follow-up testing shall be listed with the initial test result to ensure effective and timely remediation of the issue. Test results shall be trended over time to identify recurrent issues and shall be presented in a manner that is intuitive and easy to understand. Graphic representation is recommended.

**Training**
Personnel whose job function involves collecting swabs, submitting swabs for testing, recording data, responding to positive findings, reviewing data for trends, or executing other aspects of the EMP shall receive documented training on the facility’s EMP and related procedures.

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GOOD LABORATORY PRACTICES
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It is strongly recommended that microbiological testing on product be conducted at an ISO 17025 accredited laboratory. All positive pathogens testing results shall be sent to accredited outside laboratory for confirmations.

All internal laboratories shall have proper Good Laboratory Practices (GLPs) and shall have a process to validate and verify the accuracy of the results, such as check samples/ring tests, co-labs, external certification, etc.

Onsite microbiological testing shall be conducted by a trained technician.

The laboratory shall be kept clean, and equipment kept in good repair, with calibrations performed routinely. Procedures shall be in place to ensure the containment of microbiological hazards and eliminate the potential for cross-contamination to other areas of the facility (e.g., production floor). Access to the lab shall be limited to authorized personnel only. The laboratory must not open directly onto the production floor and must contain an autoclave, or other sterilization method for all hazardous waste.

Documented Standard Operating Procedures (SOPs) shall be in place for sample preparations, testing methods, and sample disposal. Quality control standards should also be established to verify the accuracy of results, and include duplicate sample analysis, use of positive and negative controls, and routine proficiency testing for all lab technicians. All methods used for analysis shall be validated and appropriate for their application, as defined by the laboratory vendor.

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**INGREDIENTS AND PACKAGING MATERIALS**

All facilities shall have a risk based supplier quality assurance program that ensures the quality and safety of all food ingredients and packaging materials along with conformance to approved specifications and all applicable government regulations.
Typical Program Requirements Include:

- New Vendors - Risk based approval process
- Current Vendors – Ongoing maintenance process
- Written specifications for all raw materials
- Continuing guarantees, or an equivalent on file (e.g. certificate to comply with country regulation for food grade ingredient or food contact packaging)
- Approved supplier list
- Procedures to handle emergency situations when a raw material must be purchased from a non-approved supplier
- Non-compliance management
- Raw material receiving procedures
- Traceability programs

----------------------------------------------- FSMA: SUPPLY CHAIN PROGRAM REQUIREMENTS -----------------------------------------------

- The facility shall have a written supply chain program for those ingredients for which they have identified a hazard requiring a supply chain control.
  - A receiving facility that is an importer, is in compliance with the foreign supplier verification program requirements
- The written supply chain program shall include (1) using approved suppliers (2) determining appropriate supplier verification activities (3) conducting & documenting the supplier verification activities (including frequency of conducting the activity).
  - For SAHCODHA (serious adverse health consequence or death to humans or animals) hazards, the facility shall use annual onsite audits as the appropriate supplier verification activity unless there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

AGRICULTURAL PESTICIDE MANAGEMENT PROGRAM

All General Mills suppliers of agriculturally based products shall have a pesticide management program in place that protects against the use of unapproved pesticides or excessive (out of tolerance) residues of approved pesticides for ingredients /products they supply to General Mills. A supplier’s pesticide program shall be comprehensive in nature including all associated pesticide risks (insecticides, fungicides, herbicides, etc.) with understanding that pesticide risks can change based on crop conditions and / or other emerging issues. Suppliers must be knowledgeable and in full compliance with the country’s applicable regulatory requirements for the country in which the ingredient will be used.

Components of this program to include:

- Knowledge and education regarding the proper use of registered pesticides by supplier or contracted growers including transport or subsequent storage of the raw material.
• Appropriate record keeping for pesticide applications including name of pesticide applied, EPA registration number (or national equivalent), formulation, amount used, location, date, pre-harvest interval, target pest, and applicator’s name with license number as required.
• When outsourcing the application of pesticides, a licensed applicator (or national equivalent) shall be used.
• Approved pesticide list including labeling information and Safety Data Sheet.
• Where a pesticide requirement is stated in the ingredient specification a Multi Residue Analysis (MRA) must be performed by a GMI approved laboratory. See appendix G for testing requirements.

A sample gathered for MRA should ideally represent a total composite from ten sample points of one production lot. If a lot or lots destined for GMI are sampled, these MUST remain on HOLD and shall NOT be shipped until results are received that assure full regulatory compliance.

General Mills ingredient suppliers are required to test and send MRA results as follows:

MRA Test Frequency described below represents the minimum requirement for reporting results to General Mills and does not define the lower test number limit of a supplier’s overall program. GMI expects the total number of MRA analyses performed for each agricultural crop to be risk based as determined by each supplier. Note General Mills will also be conducting our own verification throughout the year.

**Current NA and Mexico suppliers:**
- One (1) MRA per base crop each year (supplier cost)
  Example: 1 MRA for strawberries; 1 MRA for tomatoes-all types; 1 MRA for milled corn-all types
- Results sent to: Supplier.Documentation@genmills.com or posted to G-GAP; include Supplier Producing Location (City, State) on copy of test result

**Current off-shore suppliers including Mexico:**
- Two (2) MRA’s per base crop each year (supplier cost)
- Results sent to: Supplier.Documentation@genmills.com or posted to G-GAP; include Supplier Producing Location (City, State) on copy of test result

**New ingredient type for existing suppliers:**
- One (1) MRA per crop as part of the FSQ new supplier approval process (GMI request and cost)

**New NA or offshore region for existing suppliers:**
- One (1) MRA per crop as part of the FSQ new supplier approval process (GMI request and cost)

**New NA (US and Canada) suppliers:**
- One (1) MRA per crop as part of the FSQ new supplier approval process (GMI request and cost)

**New off-shore suppliers including Mexico:**
• Three (3) MRA per crop (minimum one MRA per crop as part of the FSQ new supplier approval process; two subsequent MRA’s determined by Ingredient Manager (GMI request and cost)

**Current suppliers (except NA and Mexico):**

- One (1) MRA per base crop each year (supplier cost)
  - Example: 1 MRA for strawberries; 1 MRA for tomatoes-all types; 1 MRA for milled corn-all types
- Results sent to responsible auditor or XQM Manager

More frequent testing may be required as determined by the Ingredient Manager, XQM Manager or Ingredient Pesticide Manager.

Ensure no solvent-based markers (Magic Marker, Sharpie, etc.) be used on any MRA samples. Acceptable means of labeling include wax pencils, ink pen or laser/ink jet, or tags affixed with string or wire.

The most updated list of GMI approved labs can be found on G-GAP Site under the ingredient portion of the G-GAP Library.

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**CONTROL OF PHYSICAL HAZARDS AND FOREIGN MATERIAL**

All ingredient materials shipped to General Mills shall be free of hazardous foreign material and shall be in compliance with General Mills specification, local laws or regulations.

All suppliers shall have a physical hazard prevention, detection and control program. This program may include strategic placement of strainers, sifters, scalpers, filters, magnets, X-rays, visual sorters, and/or metal detectors at strategic points in the process from point of unloading throughout the process. Physical hazard detection and control devices shall not be used to clean up known contamination in ingredients or products. Terminal* product protection devices shall be present as appropriate to the material category and product type. There shall be no further processing or handling between these final product protection devices and the end of the production line. GMI will look for the product protection devices to be appropriately managed as part of the HACCP or Food Safety plan.

All physical hazard detection and control devices shall have an effective management program including:

- Immediate response to findings
- Investigation into source and root cause
- Risk assessment for product produced
- Complete documentation of checks and findings
- Retention of foreign matter through shelf life of product

Product rejected from physical hazard detection and control devices during normal operation shall not be reintroduced into the process for acceptance and/or shipment. Product may be repassed for investigational purposes only and cannot be released.

*NOTE: Terminal = last point of control*
The mesh size shall be the smallest possible while not restricting product flow.

All screening devices shall be composed of a material that can be readily detected and identified by your system.

Material of all screening devices shall be food contact approved.

All screening devices shall be inspected at an appropriate frequency for integrity and inspection results shall be documented. GMI recommends minimum weekly inspections based upon supplier's acceptable risk. If screening devices are located at the end of the line, the frequency of inspection shall be increased based on risk assessment/food safety plan.

Sifter tailings shall be examined at an appropriate frequency for evidence of foreign material contaminants, and findings and corrective actions shall be documented. GMI recommends minimum once per shift based upon supplier's acceptable risk.

In place of metal detector, filter of 50 mesh or finer (0.297mm) and sifter/scalper of 30 mesh (0.595mm) can be considered. Mesh sizes allowance may vary by ingredient category with approval by XQM team based upon risk assessment.

MAGNETS

Magnets shall be designed and configured to maximize separation capability and provide effective pull and holding capability of magnetic metal. The effectiveness shall be re-evaluated as product flow rates change.

Magnet strength shall be tested for validation and documented at the time of installation. Strength and condition of the magnet shall be verified and documented based on risk and not to exceed 5 years.

Deterioration in magnet strength or structural integrity shall necessitate evaluation of causes and magnet replacement.

Magnets shall be inspected at a minimum of once per day to identify any contaminants based upon supplier's acceptable risk as well as location of magnet and history.

Findings shall be evaluated, documented and retained for trending. Appropriate corrective actions shall be taken in a timely manner.

Magnets on bulk unloading systems should be inspected after each vehicle/vessel is unloaded.

METAL DETECTORS & X-RAYS

The final metal detector or X-Ray shall be located at the terminal end of the process and must be included as a part of the hazard analysis and risk assessment completed to determine if it is a Preventive control or Critical Control Point (CCP).

Metal detectors or X-Rays settings shall be determined and applied to achieve the most sensitive level possible to provide maximum protection from metal contamination. General Mills minimum recommended capability for the supplier metal detection verification and validation is defined in following table:
Monitoring shall occur at the beginning and end of each run, before and after changeovers, after extended downtimes and in other situations which could affect the functionality of the metal detector or X Ray device. The frequency of monitoring shall occur at minimum once per shift. The monitoring check shall include successful rejection of the applicable test pieces (stainless steel, ferrous and non-ferrous) to ensure effectiveness of the detection device, its reject mechanism, and related alarms. All product used in the monitoring process must be rerun through the metal detector or X Ray device under normal circumstances or discarded once the check is complete.

**Monitoring and verification procedures shall ensure the specific test piece is placed directly in the product zone or as close as possible to the product zone and the geometric center of the device aperture. Test pieces shall be passed through the detection device at the same speed as the product and with the product flow.**

**Metal detectors or X Rays devices shall have an automatic reject/stop mechanism along with an audio or visual alarm that must be acknowledged to clear. All detections and rejects must be documented.**

**Rejected product shall be immediately segregated from the product stream and separated from product rejected for any other reason. Rejects shall be examined immediately upon rejection to permit identification and investigation into cause.**

**All metal detector or X Ray device failures, checks and findings shall be fully documented along with risk assessment and corrective action. Findings and documentation shall be retained for the shelf life of the product.**

**Metal detector/ X Ray device set-up and effectiveness should be validated by the supplier of the detection unit upon installation, and validated at least annually. Annual validation can be performed by either 3rd party or a trained employee.**

**Additional events may require validation:**
* After relocating a metal detector
* New or changed package/size
* Changes in line speeds
* Changes in conditions (moving from conductive to non-conductive products, freezer to ambient), resolution of on-going equipment issues, including maintenance
* New products
* Significant system changes that may interfere with the metal detector/ X Ray (e.g. vibration)
* Gaps identified through monitoring and verification process
* The metal detector/X Ray device has been damaged

GLASS, BRITTLE PLASTIC AND CERAMICS CONTROL PROGRAM

Facilities shall minimize the use of glass, brittle plastic, and ceramic within processing, packaging and storage areas or any other area where materials or products are exposed. Necessary glass/brittle plastic/ceramic components (e.g. glass thermometers, panel views, control touch screens) within processing, packaging and storage areas shall be located and protected as appropriate to prevent accidental breakage.

It is required that the facility has a documented glass, brittle plastic and ceramic control program including:

- Full inventory and audit of glass, brittle plastics and ceramics on a risk based frequency, minimum annually
- Procedure for handling breakage including segregation, product evaluation, clean up, documentation, corrective action, etc.

Documented training on associated hazards and procedures for personnel who are involved with the handling of glass, brittle plastic or ceramic.

FOOD DEFENSE

All Suppliers shall have a Food Defense Program in place to effectively manage risks to protect General Mills ingredients from intentional acts of tampering.

The Food Defense Program shall include the following:

- Facility Food Defense Team responsible for food defense plan and training development, implementation and maintenance; investigation of threats or acts of intentional tampering and compliance with food defense regulations.
- Documented Food Defense Plan that includes annual self-assessment, mitigation action plan, emergency contacts, facility profile, food defense team members and FDA registration number (if making shipments to the US)
- Documented Food Defense Training for employees, contactors and temporary employees upon hiring and once per year thereafter.
- Documented personnel policies and procedures to assure persons performing work do not pose risk of intentional harm (hiring practices including pre placement background screening and drug screening, except where prohibited under local regulatory authority).
- Documented physical security policies and procedures to reduce and deter unauthorized access and to protect from exposure to or inadvertent or intentional
release of proprietary information (all access and entry points for people/product/chemicals controlled, employee and non-employee's identification, etc.)

- Documented policies and procedures that support food safety and regulatory including traceability, GMP, transportation and logistic
- Documented Contingency Management procedures shall include effective and immediate response to risk related to food defense.

**TRAINING AND QUALITY MANAGEMENT SYSTEMS**

All facilities shall have procedures in place to ensure all food safety and quality management systems are fully documented with clearly defined accountabilities. Change management procedures shall be in place to ensure review and communication of any and all changes. These shall also be accompanied by a record management program to ensure proper retention and storage of all related documentation. Records shall be easily accessible and stored in a manner to protect against loss or damage.

A documented training program shall be in place to ensure effective onboarding and ongoing awareness for quality and food safety programs. This should include an annual refresher for all employees and cover key topics such as food safety, HACCP, allergens, GMPs, food defense, regulatory compliance and other job specific topics where applicable.
APPENDIX A: DEFINITIONS, CONTACTS AND REFERENCES

DEFINITIONS

Ingredient Supplier Quality Expectations
The terms used to designate requirements and recommendations stated in this document include:
- Shall, Will (also Must) – Used to express an obligation or imperative, binding, with no exclusions (i.e., what is mandatory).
- Should – Used to express a strong recommendation among other possible options.
- May – Used to indicate an action which is permissible, but not mandatory.

CONTACTS FOR GMI SUPPLIERS

Use the following links for GMI 3rd Party Audit Submissions:
- GGAP system
- For North America: supplier.documentation@genmills.com
- For outside North America: XQM.Support@genmills.com

Use the following links for other inquiries on Specification:

For North America:
- GMI Specification Acceptance spec.accepted@genmills.com
- GMI Specification Rejection spec.rejected@genmills.com
- GMI Specification Change Requests spec.updates@genmills.com
- GMI Organic Documentation JFB-QRO.fax@genmills.com
- Vendor Contact Changes RMI.Ingredient@genmills.com

For LATAM:
- GMI Specification Contact Argentina SpecUpdate.Arg@genmills.com
- GMI Specification Contact Brasil SpecUpdateBrasil@genmills.com
- Vendor Contact Changes Argentina XQM.ContactArgentina@genmills.com
- Vendor Contact Changes Brasil XQM.ContactBrasil@genmills.com

For AMEA:
- GMI Specification Contact SQA.India@genmills.com
REFERENCES

GMI Global Audit Program (G-GAP):

- http://ggap.force.com

Allergens:

- Food Allergy Research and Resource Program
- FDA Food Allergens
- FDA Food Allergen Labeling
- Food Allergy and Anaphylaxis Network

Environmental Monitoring Program:

- ICMSF Book 7, Chapter 11: Sampling to Assess Control of the Environment
- GMA Salmonella Control Guidance

Food Defense:

- FDA Food Defense Awareness Training for Employees
- FDA Food Defense Training Information
- USDA FSIS Food Defense and Emergency Response
- AIB Online Training

HACCP:

- FDA HACCP Principles Application Guidelines

Organics:

- USDA National Organic Program (NOP)

Water Testing Standards:

- WHO Drinking Water Guidelines
- EPA Drinking Water Standards
APPENDIX B: GENERAL MILLS EDI/ASN SUPPLIER PALLET LABELING REQUIREMENTS (SSCC18 LABELS)

General Mills follows the GS1 guidelines on pallet level bar code labeling and expects the same from suppliers for ingredients, packaging materials, finished goods, semi-finished goods and supplies. The GS1 label guideline document is linked below.


General Mills uses and requires an SSCC18 (Serial Shipping Container Code) pallet level label for ASN transactions. The bar code style utilized is GS1-128. The bar code minimum height per GS1 guidelines is 1.25 inches and should be centered to include appropriate scan quiet space on the side margins.

The SSCC18 pallet ID barcode label schematic is shown below. The label can include human readable information in addition to the pallet level bar code. Human readable information is not required on the SSCC18 label provided General Mills required information (item code, manufacturing date, vendor lot, quantity, etc.) is visible on the material or an accompanying and affixed pallet placard.

In all cases, the information electronically associated with the pallet label (item code, manufacturing date, vendor lot, quantity, etc.) must match the physical material.

Below is a GS1 example of an SSCC18 pallet label that includes human readable information as well as additional bar codes. Such labels are acceptable for General Mills purposes so long as the SSCC18 pallet label is visible, scan-able, and positioned as the top or bottom bar code (avoid any middle position for an SSCC18 pallet label bar code).
Details for specific minimum pallet labeling requirements for EDI 856 Advanced Shipment Notification to General Mills can be found in the following site address:

APPENDIX C: REQUIREMENTS FOR GMI PURCHASED COMPONENTS FOR USE IN ANOTHER INGREDIENT

REQUIREMENTS

Regulatory Requirements: All GMI purchased components for use in GMI ingredients shall meet regulatory requirements for the country of sale.

- Imports and cross border movements shall meet applicable regulatory requirements.
- The exporting country supplier shall be responsible for ensuring the ingredient container is labeled according to the laws of the importing country.

Specifications: All GMI purchased components for use in GMI ingredients shall have a complete, accurate and approved specification from General Mills.

- Ingredient specifications shall include the following:
  - A complete description of the ingredient in terms of functional, physical, chemical, and microbial requirements.
  - Requirements for packaging, handling, shipping, storage and shelf life.
  - Analyses and/or sampling required to certify conformance to the specification.
  - Requirements for the proper identification of the ingredient including General Mills code number, date of manufacture, or lot numbers.
  - GMI approved suppliers.
  - Requirements pertaining to consumer health, worker safety, and regulatory considerations.
  - A statement requiring the ingredient to comply with all current applicable regulatory requirements.
  - Specific limitations on ingredients for pesticides, mycotoxins, foreign materials, and other materials as appropriate.

Ingredient Sourcing:

- All GMI purchased components for use in GMI ingredients shall be purchased from suppliers and locations that are approved by GMI Quality or an approved designate.
- Ingredients shall not be purchased from a supplier who does not have a current and complete specification and documented purchase agreement.
  - For example: In the US, the documented purchase agreement is the Purchase Order with Purchase Order Terms and Conditions.

Monitoring, Verification, and Handling of Ingredients: Ingredient monitoring, verification, and handling methods shall be used to assure compliance to ingredient specifications and to protect the quality and safety of ingredients. At a minimum, methods shall include:

- Maintain a database or comprehensive list of all GMI approved ingredient suppliers by ingredient.
- Communicate complaints, rejections, and claims concerning suppliers.
- Establish sampling and testing programs for ingredients, as appropriate.
For example, Pesticide Multiple Residue Analysis Program for raw agricultural commodities.

- Review and verify ingredient Certificate of Analysis (COA) based on risk assessment led by the Quality dept. at the manufacturing facility. The risk assessment process and outcome shall be documented.
- Review and verify ingredient meets all requirements per the most recent GMI specification for that raw material code.
- Document and resolve ingredient non-compliance.
- Establish effective methods of detecting product safety concerns such as foreign material in ingredients at manufacturing locations.
- Effectively manage ingredient shelf life and storage requirements at manufacturing locations.

COMPLAINT PROCEDURES

Facilities shall be responsible for following procedures as outlined in this document for substandard or questionable GMI purchased components for use in GMI ingredients received and/or used in the manufacturing process.

Supporting Documents
- Ingredient Complaint Form. Request a copy of the complete ESC complaint form at the following email address: ESCQuality.Notifications@genmills.com

Communication
- The facility shall contact the GMI FSQ Ingredient or XQM regional responsible if there is a quality or safety issue with a GMI purchased component for use in GMI ingredients.
- Any communication made between the facility and GMI supplier of the component regarding the complaint shall be made known to the GMI FSQ Ingredient or XQM regional responsible, including any visit scheduled by the supplier of the component.
- If materials are damaged in transit to the facility, the damaged materials shall be rejected at the point of receipt.

Documentation
There is one type of complaint:
- Facility filed against GMI Supplier (original ingredient supplier complaint)
  - All complaints shall be formally submitted by email to GMI FSQ Ingredient or XQM responsible at ESCQuality.Notifications@genmills.com and GBSSC.QN@genmills.com. Ingredient Complaint Form shall be used for all types of quality and food safety complaints. Attach Bill of Lading and any other supportive documentation such as core tags, pallet tags, etc.
  - While, minor quality deficiencies may appear to be insignificant when considered individually, all deficiencies shall be reported and documented. There may similar observations across multiple locations indicating a trend and cumulative quality deficiencies may also play a role in future GMI purchases/supplier selections.
o Additional reporting requirements are necessary for complaints involving significant quantities, possible shut down, extra labor/changeovers and/or total estimated costs exceeding $500. Advance approval shall be obtained from General Mills for any special charges for labor and/or handling related to the complaint.

Hold and Disposition
Defective materials shall not be used without prior approval from the GMI Quality Ingredient or XQM regional responsible. If materials need to be held, proper hold, disposition, and reconciliation procedures shall be followed to ensure the product is not used.
  • General Mills will work with the GMI supplier regarding final disposition.
  • The GMI FSQ Ingredient or XQM regional responsible will communicate specific disposition instructions to the facility Quality Manager.

Samples
  • Samples and/or photographs shall be collected for each complaint and sent to the GMI FSQ Ingredient or XQM regional responsible. Samples shall be provided to the GMI supplier, if requested.
  • Samples shall be representative of the complaint.
APPENDIX D: FSMA REQUIREMENTS FOR GMI PRODUCTS SHIPPED TO US

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule is now final, and compliance dates for some businesses begin in September 2016. See FDA website for more information. GMI suppliers shipping ingredients to the United States shall be compliant with all provisions of the law as they are implemented.

DEFINITIONS

- **Corrective Action**: If Critical Limits for PCs are not met, appropriate actions are taken to identify and eliminate the cause, to prevent recurrence, and to bring the process or system back into control.
- **Correction**: If Critical Limits for a PC are not met, the products affected are identified and controlled with regard to their use and release.
- **Food Safety Plan**: A set of written documents that is based on food safety principles; incorporates hazard analysis, preventive controls, supply chain programs and a recall plan; and delineates the procedures to be followed for monitoring, corrective actions and verification.
- **Hazard**: any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.
- **Hazard Analysis**: Analysis that identifies and evaluates known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held at the facility.
- **Ingredient Hazard Analysis**: Analysis that identifies and evaluates known or reasonably foreseeable hazards for each type ingredient received/used in the receiving facility.
- **Monitoring**: A planned sequence of observations or measurements routinely performed in order to determine whether a chemical, physical, or biological hazard is under control and to produce an accurate record.
- **Qualified Auditor**: a person who is a qualified individual and has technical expertise obtained through education, training or experience (or combination thereof) necessary to perform the auditing function as required by 117.180(c)(2).
- **Qualified Individual**: a person who has the education, training or experience (or a combination thereof) necessary to manufacture, process, pack or hold clean and safe food as appropriate to the individual's assigned duties.
- **SAHCODHA Hazard (serious adverse health consequences or death to humans or animals)**: a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals.
- **Supply Chain Applied Control**: A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.
- **Validation**: obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazard.
- **Verification**: Activities confirming a control measure has been implemented and is consistently operating as intended and establishes the validity of the food safety plan.
## APPENDIX E: HACCP MONITORING, VERIFICATION AND VALIDATION DEFINITIONS AND EXAMPLES

<table>
<thead>
<tr>
<th>Validation</th>
<th>Verification</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Validation</strong> is applied prior to an activity and provides information about the capability to deliver intended results</td>
<td><strong>Verification</strong> is applied after an activity and provides information for confirmation of conformity</td>
<td><strong>Monitoring</strong> is applied during an activity and provides information for action within a specified time-frame</td>
</tr>
</tbody>
</table>

**WHAT:** Evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling a hazard to a specified outcome.

**WHEN:** Performed at the time that a processing step or other food safety control measure is designed or significantly changed.

**EXAMPLE:** The evidence may be scientific data, published technical information, observational information, or analytical data.

**WHAT:** Activities confirming a control measure has been implemented and is consistently operating as intended.

**WHEN:** Frequency varies. May be scheduled or unscheduled.

**EXAMPLE:** Verification activities may include observation of monitoring activities, interview of employee understanding of monitoring activities, records review, program review (HACCP, PSE), and other.

**WHAT:** A planned sequence of observations or measurements routinely performed in order to determine whether a chemical, physical, or biological hazard is under control and to produce an accurate record.

**WHEN:** Scheduled on set frequency.

**EXAMPLE:** Monitoring activities may include temperature data, instrument check, sanitation inspection and other.
APPENDIX F: PATHOGEN ENVIRONMENTAL MONITORING PROGRAM

Program Review

The Environmental Monitoring Program (EMP) shall be reviewed annually by a plant-based team and review should include all the following for the previous 12 months:

* Compliance to this standard
* EMP results including trend analysis
* Events that affected the environment
* Physical changes to the facility or equipment
* Changes to products or ingredients at the facility that change the overall risk profile
* Changes to programs that may affect the environment (e.g. sanitation methods, extended runs)
* Effectiveness of control measures to minimize cross-contamination to primary pathogen control (PPC) areas
* Other relevant information

NOTE: Example outcomes of the review may include, but are not limited to, the following:

* Additions to, or deletions from, the routine-fixed site list
* Intense environmental survey of specific plant area for more detailed understanding
* Ideas, plans, or implemented solutions for improving control measures to minimize cross-contamination to primary pathogen control areas

Hygienic Areas

Hygienic Areas Definitions:

<table>
<thead>
<tr>
<th>Area Type</th>
<th>Definition</th>
</tr>
</thead>
</table>
| High Risk Area – Primary Pathogen Control Area | Production area with higher risk of environmental cross contamination to a RTE product  
• Areas where RTE products or RTE product contact surfaces are exposed to the environment after the last validated pathogen kill step.  
• If there is no validated pathogen lethality step, then the entire process where RTE products or RTE product contact surfaces are exposed to the environment is a PPC area |
| Basic GMP Area | Production area with lower risk of environmental cross contamination to RTE and RTE-Like product  
• Non-RTE production areas  
• Sites before validated pathogen lethality step for RTE products  
• Sites where product is not exposed to environment (e.g. after it is packaged or where equipment is completely closed to the environment) |
| Non-production Area | Monitored non-production areas (e.g. warehouses, break rooms, locker rooms) |
Sampling Zones & Site Examples

Sampling zones are defined as following:

<table>
<thead>
<tr>
<th>Zone</th>
<th>Definition</th>
<th>Examples of Sample Sites (This is not an all-inclusive list)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Direct food contact surfaces and surfaces directly above food contact surfaces where the effects of gravity or normal air flow could cause contamination to the product contact surface</td>
<td>Equipment surfaces such as conveyor belts, chutes, slides, product handling utensils or areas directly above product and product zones, such as HVAC units or condensation above a freezer entrance. If product contact surfaces are moved to another location for cleaning, consider potential Zone 1 locations in cleaning area.</td>
</tr>
<tr>
<td>2</td>
<td>Non-product contact surfaces in close proximity to product contact surfaces</td>
<td>Control panels, conveyor supports, platform handrails, overhead beams or other structures adjacent to or below product zones</td>
</tr>
<tr>
<td>3</td>
<td>Peripheral areas of production that if contaminated with a pathogen, could lead to contamination of Zone 2 via movement of humans or machinery</td>
<td>Thresholds, floor drains, high traffic areas, stairs, floor/wall cracks</td>
</tr>
<tr>
<td>4</td>
<td>Non-Production Areas</td>
<td>Changing areas, restrooms, break rooms, offices, laboratories Warehouses with physical separation from production area</td>
</tr>
</tbody>
</table>
### Sampling Site definitions:

| Routine Fixed | Sites sampled routinely on a monthly or quarterly basis  
| Sites likely to harbor or transfer microorganisms  
| Sites that have been positive 1 or more times in the past 12 months |
| Routine Variable | Exploratory sites in the spirit of “find it, fix it”  
| Sites selected at the sampling team’s discretion based on observations on the sampling day  
| Sites may or may not be sampled again if results are negative  
| Number of routine variable sites depends on the program maturity and overall understanding of the facility environment. A general guideline is 5-15% of monthly swabbing sites  
| Part of routine sampling |
| Non-Routine Positive Mitigation | Swabs taken during mitigation and investigation of a positive finding. This includes repeat swabs of the positive site and additional swabs from the area for investigative purposes |
| Non-Routine Event Driven | Sites selected in response to specific activity or special event in the plant that poses a potential risk |

### Sample Collection Timing

<table>
<thead>
<tr>
<th>Sample Collection Timing</th>
<th>Purpose</th>
<th>Sample Details</th>
</tr>
</thead>
</table>
| During production       | To assess the area under normal operating conditions | Samples shall be taken:  
|                         |         | o 3 hours after the start of production, or  
|                         |         | o At end of run / end of operational shift, or  
|                         |         | o After shutdown but before cleaning.  
|                         |         | Samples may be taken during short downtimes. |
| Before start-up         | To assess effectiveness of sanitation procedures in eliminating target organisms routinely, or after a positive finding or event | o Samples shall be taken after residual sanitizer has dissipated (consult chemical supplier for timeframe), but before production begins (closer to start-up is preferred). |
| Not running             | To monitor effectiveness of containment procedures or investigate an event | o If needed, samples shall be taken around a production system that has been stopped due to a planned or unplanned event (e.g. construction or roof leak) |
Samples may be taken around a production system that is not running for an extended period.

**NOTE:** If the system is running at any time during the month, the expectation is to take routine samples during production or before start-up.

**Sampling Method**

- The total surface area to be sampled for pathogens is dependent on each site. For each location the maximum surface area swabbed should be ~0.5 m² (5.4 ft²).
- The entire area shall be swabbed in at least two different directions using both sides of the sponge. Sufficient force shall be applied to dislodge material at the site (e.g. soil, product build up, biofilms, particulates, dust).

**Sample Analysis Details**

- **Sampling Handling**
  - Samples shall be kept refrigerated (32-45°F / 0-7.2°C) during storage and shipping. The time between sampling and commencement of testing shall be <48 hrs.
APPENDIX G: AGRICULTURAL PESTICIDE PROGRAM
DETAILED PROGRAM COMPONENTS

**Integrated Pest Management:** All agricultural commodities or products produced for General Mills under contractual agreements must have written integrated pest management (IPM) plans in place. Goals of the integrated pest management plan should contain but are not limited to the following:

- A plan to minimize crop losses caused by insect, weed, and disease pests.
- A plan to deliver raw product with manageable levels of contaminants using practices that are safe, practical, and effective while being economical and environmentally sound.
- An understanding of the dynamics of the pests that pose serious potential crop loss or product contamination.
- An effective way to monitor for pest problems including pheromone traps, black light traps and visual scouting methods.
- Maximal use of natural and cultural pest control practices including weather, field selection, and crop rotation.
- Judicious, proper and safe usage of approved pesticides.

All pesticides used on agriculturally grown commodities must be approved by all applicable regulatory agencies including US-EPA, State Department of Agriculture, and local governments or other country’s applicable regulatory requirements for the country of use.

**Pesticide Approvals:** All agricultural pesticides used on any General Mills agricultural commodity or ingredient, must be approved by all applicable regulatory agencies.

**Pesticide Applicators:** All agricultural pesticides applied to General Mills raw agricultural commodities must be applied by either a “Certified Pesticide Applicator” or applied by the grower/owner operator of the agricultural commodity and meet local applicator certification requirements.

**Pesticide Usage:** All agricultural pesticides used on General Mills agricultural commodities must be applied in strict accordance with all current labels and instructions.

A copy of the current pesticide label must be kept on file and readily available at the facility receiving or contracting the agricultural commodity. Current Material Safety Data Sheet (MSDS) information for each pesticide must also be readily available or accessible at the facility where the pesticide is used or stored.

**Pesticide Record Keeping:** Agricultural pesticide application documentation for each unit (acres, field, lot) treated must accurately list the following for each pesticide application.

- EPA or equivalent national registration number
- Pesticide name (chemical and trade name)
- Quantity or dosage rate
- Formulation
- Date applied
- Pre-harvest interval (PHI)
- Site of application (field name/number)
- Target pest(s) if required by local regulations
• Pesticide applicator name with certification number (if required by local regulations).

**Pesticide Purchase:** Pesticides can be purchased from any reputable supplier if the pesticide has a current approved EPA registered label or equivalent national registration.

When a pesticide purchase is made by a grower/owner operation, information as to registration number, chemical and trade name, and appropriate rate/unit must be made available to the contracting or receiving GMI supplier facility upon request.

**Pesticide Storage and Disposal:** Agricultural pesticides used on General Mills raw commodity or ingredients shall be stored and disposed of according to the label, labeling instructions, and all regulatory requirements. Care must be taken at all times to protect the safety of people, product, and the environment during storage and disposal of pesticides. Security for pesticides and pesticide storage areas must be kept locked and maintained at the highest level.

**Pesticide Monitoring of Products and Ingredients:** All General Mills raw commodity or ingredients shall be monitored for compliance to established pesticide residues through a MRA (Multi-residue analysis).

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**DEFINITIONS**

**Agricultural Commodities:** Used here to designate unprocessed agriculturally grown grains, fruits, vegetables and some specific GMI ingredient codes where pesticide requirement is stated.

**Certified Pesticide Applicator:** A person who has passed a federally approved state test and received a registered certification number allowing purchase and use of a pesticide within a specified category or classification in the state certified (USA).

**Grower/owner operations:** Used here to designate farmers, ranchers, land owners or individual owners of the raw agricultural commodity, agriculturalist, crop lead person or manager, field supervisor, consultants or custom pesticide applicators hired by the owner of the crop, that may have direct responsibility for pesticides applications to the vegetable, fruit or grain crop.

**Integrated Pest Management (IPM):** A sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks.

**MRA:** Multi-Residue Analysis for pesticide residues on food or ingredients. Full MRA screen includes the four groups of pesticides: organonitrogens, organophosphates, organohalogens, and n-methyl carbamates. **Be sure to verify that the laboratory conducting the pesticide testing for General Mills products includes the full four group screen.**

**MSDS:** OSHA "Material Safety Data Sheet"