INGREDIENT SUPPLIER MANUAL

Version 1.6

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General Mills

External Quality Management

GENERAL MILLS GLOBAL INGREDIENT SUPPLIER MANUAL CONTENT

As part of an ongoing focus on supplier food safety, regulatory and quality assurance, General Mills Incorporated (GMI) Global Ingredient Supplier Manual has been revised to bring clarity to key program requirements.

The Global Ingredient Manual states the minimum requirements that shall be followed to ensure that food safety, regulatory and quality standards of current and prospective ingredient vendors for human and animal food meets GMI requirements.

In this manual, you will find an overview of our food safety, regulatory and quality requirements and our 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 changes that may affect General Mills product specification, food safety and quality or composition of the ingredients that are supplied. GMI approval shall be granted prior to implementation of changes. Examples of these changes include:

- New producing line or location.
- Changes to a facility Critical Control Point (CCP).
- Introduction of new allergens to previously approved producing lines for GMI.
- 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 a new production location/line and/or transfer stations to ensure the supply location/line can meet GMI requirements and demonstrate an effective food safety culture.

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 integral part of the overall vendor/supplier approval. To enable XQM team to perform this initial assessment, suppliers should complete a GMI Supplier Survey for each line that is intended to manufacture ingredients for GMI. This document should be returned to GMI along with other requested supporting documents which includes but not limited to:

- 3rd party audit report along with corresponding corrective action report and certificate. GMI has a preference for GFSI schemes. Refer to link in Appendix A.
- For pet food ingredient suppliers, 3rd party certifications such as GFSI schemes (BRC, IFS, SQF, FSSC) are recommended but not required
- Food safety plan or CCP matrix*
- Flow diagram*
- Allergen management program*
- Samples for food safety and quality testing are required for pet food suppliers and will be requested as needed for human food.

* These documents may not be required from pet food ingredient suppliers.

Above mentioned documents can be sent to one of the following email addresses:

North America (human food ingredient suppliers); supplier.documentation@genmills.com

Outside North America (human food ingredient suppliers); XQM.Support@genmills.com

Pet food ingredient suppliers; supplier.documentation@bluebuff.com

After initial review, an audit of the facility will be conducted. Approvals are granted at each producing location for specific products by line. All approved vendor/supplier producing locations for GMI will be re-audited on a risk-based frequency. Suppliers shall provide updated documentation at any point of time when it is requested by GMI.

All approved vendor producing locations are required to provide General Mills with a copy of the third-party audit report with corrective actions and the audit certificate annually to demonstrate effective food safety programs and food safety culture. For pet food vendor producing locations an annual report may not be required.

REGULATORY COMPLIANCE

All GMI ingredients for human consumption shall be food grade. All GMI ingredients for pet consumption shall minimally be feed 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. Pet food ingredient suppliers shall comply with AAFCO requirements.

There are additional regulatory requirements for vendors that are supplying to Canada, the United States or US territories under FSMA (Food Safety Modernization Act) and SFCR (Safe Food for Canadians Act). These requirements can be found in FSMA sections of this manual and Appendix B.

FACILITY REGISTRATION

All ingredient 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 food safety contact when any significant regulatory findings are made (e.g., adulterations injurious to health noted on a FDA Form 483 and comparable forms globally).
- Regulatory contact training shall be documented and shall occur on a frequency that ensures appropriate individuals have an understanding of current, local, and corporate procedures for managing regulatory contacts.

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 pathogen testing, pesticide testing, environmental sampling, claims verification, 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 GMI food safety contact 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 food safety contact immediately to ensure hold and clearance prior to use.

When an ingredient, either owned by or being shipped to General Mills, is sampled by any regulatory/government agencies at any point during production, storage, or transportation the General Mills food safety contact shall be informed. In all these events, General Mills shall be notified of the lot numbers of materials that were sampled by the regulatory/government agency. If any documents showing General Mills as a customer is shared with the regulatory/government agency, General Mills shall be notified of the documents reviewed and additional information that is relevant to these documents (e.g. Lot codes, PO #'s etc.).

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 food safety and regulatory requests from GMI as to the form and manner of such compliance. Such compliance activities shall include, but not be limited to, accurate marking of the country of origin of goods, accurate 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 (C-TPAT) (SUPPLIERS TO NORTH AMERICA)

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 C-TPAT program.

General Mills Import Operations Team 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 C-TPAT program will be communicated as a part of that process and a foreign supplier security questionnaire will be provided for completion. Suppliers who are not currently certified under the C-TPAT program may need additional verification of 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 https://www.cbp.gov/border-security/ports-entry/cargo-security/ctpat.

PRODUCT CONTROL, TRACEABILITY AND RECALL REQUIREMENTS

All suppliers shall have:

- An effective traceability program that includes identification, code dates, lot numbers, and documentation throughout all points in the supply chain from incoming raw materials through product shipment to customers. This includes but not limited to ingredients, hold stock, rework, work in progress, destroyed product, processing aids (or any other substances that may come into contact with product), packaging, premiums, and finished product. Pet food ingredient suppliers must be able to demonstrate full traceability on boiler additives and denaturants.
- A documented and effective product recall, market withdrawal, and stock recovery program.
- Ability to identify, stop distribution, and notify customers and consumers by traceability code within 24 hours of obtaining knowledge of significant marketplace food safety or regulatory issues that would lead to a product recall or product withdrawal.
- An annual mock recall/traceability test program that includes summary results of mock recall (items traced, time for completion, % recovery. GMI's recommendation is a completion time of maximum 4 hours and 100% recovery of raw materials and finished good), key learnings, system improvement needs and identified gaps with documented corrective action taken. Traceability exercise shall include ingredients, finished products and food contact packaging.

FDA REPORTABLE FOOD REGISTRY (NORTH AMERICA SPECIFIC)

Food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States that are required to be registered with the FDA must report when there is

a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

Note: General Mills requires a discussion prior to any supplier reporting product concerning General Mills (contact General Mills food safety contact, or if needed, use 24 hours contact line 763-764-2310).

Reporting is required within 24 hours from identification of the situation to Reportable Food Registry. See Appendix C for process to determine whether to report.

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 procedure for products that are on hold due to food safety issues. Products that are on hazardous hold shall have a minimum of 2 of the following 3 movement controls; electronically secured, physically secured/locked, and manually isolated/segregated. A physical inventory and procedure for witness destruction shall be developed. Recommended inventory counts for hazardous hold materials is at least once a week.
- An effective disposition process that ensures only authorized personnel can disposition on 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 for human consumption shall be of food grade. Ingredients supplied to GMI for pet consumption shall be of food or feed grade and in compliance with AAFCO standards. Ingredients shall be 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 (GMP), or equivalent based upon the country of manufacture and country of sale. Facilities shall develop and implement effective and documented Good Manufacturing Practices and Sanitation Programs to ensure they are compliant with local regulatory requirements and meet or exceed the requirements in this manual.

The following practices state the minimum requirements to be followed unless applicable laws or regulations have more stringent requirements, General Mills requirements shall supersede local customs or practices.

PERSONNEL PRACTICES (EMPLOYEES, CONTRACTORS, TEMPORARIES, VISITORS)

The management team shall develop effective personnel and hygiene practices and procedures for the facility. The management team shall be accountable for ensuring all personnel comply with the requirements of the developed standards. Facility personnel, including contractors and temporary employees, shall receive documented personnel practice and hygiene training prior to performing any work or services and refresher training at a regular basis (recommended once per year). Completion of training for each person shall be documented. Facility disease control procedures shall comply with applicable laws and regulations.

OPERATIONAL AND STORAGE PRACTICES

- All ingredients and packaging materials shall be adequately protected and stored to prevent contamination at all stages of handling.
- Where applicable, personnel wearing gloves for food contact (i.e., plastic or rubber gloves) shall ensure they are maintained in an intact, clean, and sanitary condition.
- Containers and utensils shall be designed, identified, used, and cleaned to prevent them from becoming a source of contamination.
- Any container used for edible products shall be dedicated for this use only and shall not be used for storage of equipment or inedible materials.
- For unitized material, 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.
- Waste materials shall be identified and adequately controlled.

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 (including external air intake ports).
- 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 or 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.

- Facilities shall have adequate wash stations that are maintained and located appropriately for their specific purpose (i.e., equipment washing, hand washing).
- Facilities shall provide a sufficient supply of potable water that meets applicable laws and regulations and World Health Organization requirements.
- Water supply equipment shall be installed with backflow prevention devices to prevent back siphonage and backflow. Backflow prevention devices shall be tested annually, replaced as needed, and documentation maintained.
- 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 and airborne contamination from aerosols or fumes and prevent pest entry.
- Facilities shall provide adequate natural and/or artificial lighting that meets applicable laws and regulations and enables personnel to operate in a safe and sanitary manner. This includes sufficient lighting in areas where food is processed, stored, or examined; equipment and utensils are cleaned; and in handwashing areas, locker and dressing rooms.

EQUIPMENT AND MAINTENANCE

- Equipment shall be designed and maintained to prevent product contamination.
- Equipment shall be made of materials designed to withstand the environment of its intended use, and applicable cleaning compounds and sanitizing agents. Product contact surfaces shall be constructed from non-toxic materials that are designed for food use.
- 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. This cleaning and inspection shall be recorded.
- Temporary repairs shall be documented and effectively managed.
- A calibration program shall be in place for all process monitoring devices that ensure product safety and regulatory compliance.

SANITATION

- Facilities shall develop, implement, and document an effective sanitation program to ensure the food processing equipment and environment are maintained in sanitary condition. This program shall cover daily and other regular sanitation tasks of production and non-production areas.

- Facilities shall complete sanitation validation to show the documented sanitation procedure is capable of consistently achieving sanitation expectations for the targeted food safety hazards or quality criteria and does not present an increased risk to food safety or quality.
- As part of the facility's sanitation program, each vendor location shall determine the maximum production time allowed between sanitations (based on micro load or risk assessment) and additionally determine how the facility handles sanitation after extended downtimes.
- Facilities shall have an effective drain cleaning and sanitizing schedule and program to prevent drains from being a source of contamination of environmental pathogens or infesting insects and to reduce the risk of cross-contamination from drains to food processing areas or equipment. Drain cleaning/sanitizing tools shall be dedicated and properly identified.
- Sanitation tools and equipment shall be dedicated and properly identified for their intended purpose (e.g., food contact surfaces, floor, non-food contact, drains).
- For facilities utilizing circulation/closed loop cleaning (e.g., CIP or less automated CIP), sanitation process shall be validated. Key requirements of the validated circulation/closed loop cleaning process (time, temperature, concentration, and flow rate) shall be documented for every cycle. Program shall include a list and description of key process components and controls.
- For facilities utilizing semi-automated cleaning methods (e.g., COP tank, dish washer, tunnel washer, etc.), sanitation process shall be validated. Key requirements of these validated sanitation methods (time, temperature, concentration, and mechanical force (e.g., pressure, agitation, spray pattern)) shall be documented for every cycle. Program shall include a list and description of key process components and controls.
- Procedures should be in place to verify effectiveness of cleaning procedures.
- Any person involved with sanitation activities shall receive documented training on sanitation procedures specific to their facility and job function.

INTEGRATED PEST MANAGEMENT

- An effective, documented pest control program (rodents, insects, birds and wildlife) shall be in place.
- Program shall be supported by a licensed, certified applicator or trained staff and include only certified pesticides in compliance with country regulation.
- Toxic bait shall not be used inside processing areas (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 mechanical stations and glue boards are used, an increased monitoring frequency is recommended.

FACILITY ASSESSMENT

Facility's Internal/Self-Assessment Audit Program shall include GMP inspection and food safety and regulatory program verification.

Facility GMP inspections shall meet the following requirements:

- Inspections shall include observations of facility condition and employee behaviors in regard to all components of Good Manufacturing Practices
- Inspections shall be performed by knowledgeable personnel
- Inspection frequency shall be documented and occur at the minimum set frequencies (GMI recommendation is monthly for production and quarterly for other areas)
- Observations/findings/gaps and corrective actions resulted from these inspections shall be documented

Food safety and regulatory program verification shall occur on an annual basis and shall meet the following requirements:

- Program verification shall include review of the facility's written programs to assure compliance with applicable food safety and regulatory as well as GMI requirements
- Observations/findings/gaps 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 and non-food grade lubricants shall be stored separately and in a manner to avoid cross contamination.

TRANSPORTATION AND LOGISTICS

All suppliers to GMI shall be responsible for sanitary condition and acceptability of all vehicles and bulk transport containers (rail car, tankers). They shall comply with all GMI requirements, applicable laws and regulations and be in good condition to assure the safety and quality of the contents during all phases of transportation including transload locations.

RECEIVING

All products, ingredients, packaging materials shall be received in a manner that protects and assures the safety and quality of the material, complies with applicable laws and regulations, and does not introduce any product safety hazard to the receiving location.

This section states the minimum requirements to be followed as defined by General Mills unless applicable laws and regulations have more stringent requirements.

- Prior to unloading, all vehicle openings and security seals shall be inspected for damage or tampering by a trained employee or an authorized third party designate. All security seals shall be intact, and seal numbers shall be matched to the "Bill of Lading" (BOL) or "Delivery Note". Inspection and results shall be documented.
- A documented inspection shall be completed of all incoming vehicles and shipments to assure the quality and integrity of the shipment. The content and identification of the vehicle shall be verified as correct and match the Bill of Lading prior to acceptance.
- Receipt of all shipments shall be documented to include date received, shipper, vehicle numbers, and description of contents.
- All pertinent required documentation (e.g., wash certificate) shall be reviewed and retained according to the corporate records retention schedule. For kosher/halal bulk ingredients, a "kosher/halal wash certificate" or "letter of certification for dedicated kosher/halal bulk vehicle" shall be provided with receiving documentation.
- Sampling of ingredients or other materials shall be carried out in a manner which will not contaminate the material or load.

GMI REQUIREMENTS FOR VEHICLES AND CONTAINERS

Transportation vehicles and containers used for transporting GMI ingredients shall comply with applicable laws and regulations and minimum requirements defined by GMI as stated below:

- Prior to loading and shipping, all means of transportation used for transport of GMI ingredients shall be thoroughly inspected and cleaned as necessary to protect integrity. The inspection shall include the trailer and all valves, pipes, seals, hose fittings, gaskets, and transfer hoses where applicable. Exterior surfaces of the vehicle and bulk containers must be clean. These inspections shall be documented, and records retained.
- Inspection of all repaired or reconditioned direct food contact vehicles and containers shall confirm work is complete prior to cleaning. Vessel should be fully dried and re-inspected post repair and prior to use for transporting or storage of GMI ingredients.
- Transportation vehicles, tankers, containers and transfer hoses, gaskets and loading/ unloading equipment, temperature-controlled vehicles, shall be:
    - In good, safe, and lawful operating condition and free from structural defects and any kind of contamination.

    - Used only for food grade materials. Feed grade merchandise transportation is acceptable for pet food ingredients suppliers only.
    - Clean, dry, odor free and leak proof.
    - Free of contamination and infestation.
    - Made of food grade materials that can withstand cleaning and sanitizing.
    - Capable of being tightly sealed to adequately protect the contents and prevent contamination.
    - Have a fully functional and calibrated temperature gauge to maintain specified temperature (temperature-controlled vehicles only).
- For suppliers based in North America, roll top, soft sided or open top trucks shall not be used for shipment of food products or ingredients to GMI. Exceptions are available for commodity type purchased ingredients as designated in the specification and/or the purchase order, after risk assessment and approval from GMI food safety team.
- For suppliers outside of North America, roll top, open top and soft sided trucks are allowed for transportation of ingredients when integrity of the product is maintained.
- Roll top and soft sided trucks are allowed for transportation of ingredients for use in pet food products.
- Where used upon approval:
    - Roll top or soft sided trucks shall be in good condition without any holes.
    - Alternate methods may be required to secure the load of a roll top vehicle and visually inspect the goods for food defense.
- 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.
- Under no circumstances shall transportation vehicles or containers which have transported hazardous waste, as defined by applicable laws and regulations, which includes but is not limited to trash, garbage, waste, asbestos, toxic materials, and infectious or medical wastes, etc. be used for shipment of GMI's ingredients even after cleaning.

In order to assure food safety, traceability, and quality, the following documentation shall be provided. Missing or inaccurate BOL information may lead to rejection of a load.

Bill of Lading (BOL) or equivalent shipping documentation, minimum requirements as appropriate are:

- 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)
- COA requirement for the load

- Weight certificate
- 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 the GMI DUNS # of 00-625-0740 MUST be included.
- Kosher or Halal Symbol, wash certificate or other documentation as required
- Purchase, transit and delivery documentation that shall identify organic ingredient as organic.
- All bulk containers must comply with all GMI shipping requirements stated above as well as the following:
- When present, all valves, transfer hoses/unloading pipes and ports of bulk liquid/dry cars and tanker trucks shall be cleaned prior to loading to prevent cross contamination and infestation.
    - General Mills' preferred method is purging or filtered air blowing. It is recommended that filtered air be blown through bulk trucks and all pipes and valves a minimum of 5 minutes prior to loading after a wash, and between loads.
- Transloading transfer hoses, transportation vehicle and bulk container openings (hatch covers, valves, hoses, doors, and latches, etc.) shall be inspected for cleanliness, integrity, closing ability prior to loading and after loading is completed.
- Transportation vehicles and containers used for shipping or storing bulk ingredients shall be washed in compliance with GMI food safety requirements as well as food safety, regulatory and religious certification requirements (e.g. Kosher, Halal) on a risk-based frequency to ensure integrity and quality of the product. A validated system flush of the container can be used where applicable. Flushed product shall not be used for resale.
- A "Wash Certificate" for all liquid loads and "Dry Clean" certificates for all dry bulk loads shall be available from the driver upon request. This certificate shall include information such as: vendor ID, Carrier ID, Date and time of wash, tanker ID, Previous contents, wash /sanitize method. Kosher/Halal wash certificate is required where applicable claims are made.
- All bulk transportation vehicles used to ship liquid or dry ingredients from multiple vendors or to ship ingredients that have dissimilar specification criteria (e.g., dissimilar allergens, gluten free oat vs standard oat, and for Pet: ingredients containing corn, wheat and soy) shall have established sanitation procedures and inspection standards between each load. When containers are returned with any measurable amount of product remaining in the container from the previous load, the following criteria shall be followed and documented:
    - Returned container shall be secured with appropriate seals to ensure integrity of the container and its contents.
    - Only same materials are to be loaded on top of the remaining product
- Bulk Railcar and Bulk Truck openings, and access points shall be protected to prevent contamination, including and during, vehicle loading, unloading and aeration.

TRANSLOAD STATIONS

All vendors supplying or receiving bulk ingredients where a transload station is used (i.e. railcar to bulk vehicle or container) shall have a program to qualify and inspect these locations on a regular basis. As a minimum the program shall include:

- Confirmation that the transloading partner complies with FSMA Sanitary Transportation of Human and Animal Food or other local and regional sanitary transportation requirements.
- A food safety program, including all prerequisite programs.
- A foreign material control program. Based on risk assessment and material type, metal detector, screens/filters and/or magnets at the terminal end of loading are acceptable. Findings from these devices shall be visually examined and documented before the vehicle leaves the terminal. For further information on foreign object control program and devices refer to "CONTROL OF PHYSICAL HAZARDS AND FOREIGN MATERIAL".
- A transportation vehicle cleaning and inspection program including, but not limited to, hose/ valve and transfer pipe inspections.
- A documented sanitation and inspection program based on ingredient and load changeover risk assessment. This program shall include cleaning frequency, detailed list of areas and equipment to be cleaned (e.g., cleaning and inspection of transfer hoses between loads) and cleaning methods.
- Load identification.
- Scale/ flowmeter calibrations and weight certification.
- Documentation and record keeping.

For pet food ingredient suppliers, all transload stations shall be audited and approved by GMI before these stations can be used by GMI's pet food suppliers.

VEHICLE, CONTAINER AND INGREDIENT SECURITY

- 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.
- The seal shall be a tamper evident style. The tamper evident seals' specific style and strength is the suppliers' choice, but cable seals are required on bulk rail and truck carriers. Seals on bulk trucks may be numbered 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 high security seal must be affixed to all loaded C-TPAT importer containers bound for the U.S. All seals must meet or exceed the current PAS ISO 17712 standards for high security seals.
- Suppliers are not required to seal common LTL's (less than truck load) carrier that is shipped outside of their control. However, all items shipped on a non-sealed carrier shall have unitized packaging that is tamper evident.

- If security seal must be broken for any reason (e.g., border crossing, weigh station) while in transit, the carrier must note the time, date, location, and reason of removal of security seal 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.
- Where the security seal is broken while in transit, due to acceptable reasons as stated above, the carrier must inform both the shipping location and receiving location of this change and receive their acceptance prior to continuing 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 GMI employee or designate, except as noted above.
- A broken, or missing seal is a cause for rejection at the shipper's liability.

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 between the shipper and the GMI receiving plant without prior written authorization 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

Requirements noted in this section may be superseded by GMI's receiving plant needs. If a GMI plant has specific requirements it will be communicated to the supplier and it is the supplier's responsibility to know and comply with each plant's needs;

- 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 D for details).
- Prior to shipping, all shipping requirements shall be confirmed with the receiving facility (e.g. pallet type/ style)
- 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.
- Prior to use, all pallets (wood and plastic) shall be inspected to ensure they are clean and in good condition.
- Pallets shall be in compliance with applicable laws and regulations of the receiving country.
- Slip sheets shall be used for all pallets, before the items are placed on the pallet as well as when pallets are double stacked. For double stacking, slip sheets must be placed on top of lower pallet before placing the second pallet load on top.

- Total unit weight is determined by receiving facility's equipment capabilities and safety requirements. 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 legible 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 two (2) lots can be on any one pallet.
    - For pet food ingredient suppliers, no more than one (1) lot can be on any pallet and a maximum of three (3) lots can be shipped on the same truck.
- Information on minimal pallet labeling requirements for human food ingredient suppliers who send EDI 856 Advanced Shipment Notice to General Mills when shipping against a Purchase Order can be found in Appendix D. For pet food ingredient suppliers, Advance Shipment Notice shall be sent through TraceGains.
- Any shipments to GMI that does not comply with these requirements may be rejected.

CONSUMER AND CUSTOMER RELATIONS

All suppliers shall have effective processes to receive and manage customers/consumers/ GMI's feedback related to product quality, product safety, regulatory matters or technical information requests.

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

Supplier shall perform regular reviews of non-conformances received from customers. These reviews must be documented and used 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. This program shall ensure the current accurate GMI specifications are available on the company's specification database, are used at all times and are available to appropriate personnel. Suppliers that are supplying a "stock item" to GMI must have their specification available for review.

All suppliers shall provide ingredient composition information as requested by GMI food safety or regulatory team.

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. This process control plan shall also address sample retention for finished product based on risk assessment.

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 product is packed in correct packaging format with accurate labels applied. GMI will address failures of compliance to product specifications via Quality Notification and/or non-conformances process. A non-conforming product may result in an additional action by the receiving location such as partial or full rejection of the material.

PACKAGING AND LABELING REQUIREMENTS

Labeling program shall be in place to ensure all products supplied to GMI comply with regional specific regulatory and GMI requirements.

GMI labelling requirements are outlined below, however there may be additional labelling requirements outlined in each ingredient specification which shall be complied to where applicable. This includes any state labeling requirements for pet food ingredients suppliers.

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" (North America suppliers only)[#]
- 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 GMI.
[#]Does not apply to pet food ingredient suppliers.

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 its content.

CERTIFICATE OF ANALYSIS (COA)

Product shall not be shipped until they have cleared testing as required by GMI specification and supplier´s internal requirements unless GMI food safety contact's approvals have been obtained and documented.

The mandatory analyses for each GMI ingredient are designated in the specifications with a required testing frequency under the column labeled "Required in COA" (e.g., every batch). Exceptions must be approved by GMI. Each COA shall include enough information to allow

traceability (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 to which it relates.

LABEL DECLARATIONS AND CLAIMS

Supplier shall provide all ingredient labeling/composition information and other supporting documentation as required by GMI Labeling and Regulatory Compliance team or Blue Buffalo Supplier Quality Team.

For any claims the supplier shall provide required claim substantiation and supporting documentation upon request by GMI Labeling and Regulatory Compliance Team or Blue Buffalo Supplier Quality Team.

Supplier shall maintain third party certifications (e.g., Kosher/Halal/Organic) for ingredients in accordance with annual product certificate renewals and provide GMI/Blue Buffalo with updated product certificates as available.

FOOD SAFETY PROGRAM, HACCP, AND PREREQUISITE PROGRAMS

Each supplier location shall have a current, effective, and documented Food Safety Program and HACCP plans to manage food safety hazards. The HACCP program (Hazard Analysis and Critical Control Points) shall be based on the 7 commonly accepted principles of HACCP for each producing line and product type and 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 ingredients, including additives and processing aids: Vendor shall demonstrate control and verification of all additives, ensuring

regulatory limits are being met (e.g. BHT, sulfites, synthetic colors, sorbate, benzoate).
  - 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 and verification procedures, frequencies, responsible person(s), records (See Appendix F for definitions and examples of monitoring, verification, validation).

The HACCP Plan 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 by a third party or be a qualified individual based on experience and training.

The HACCP plan shall be validated initially and revalidated after 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 facililites shall have a written Food Safety Plan specific to their facility that is prepared (or overseen) by one or more preventive controls qualified individals (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 montoring 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.

All GMI suppliers shipping ingredients to the United States shall be compliant with all provisions of the law as they are implemented. Refer to Appendix E for details.

FOOD ALLERGENS –PET FOOD SUPPLIERS ONLY

This standard states the minimum requirements to be followed as defined by General Mills unless applicable laws or regulations have more stringent requirements, General Mills requirements shall supersede local customs or practices.

RISK ASSESSMENT AND MANAGEMENT

Human food allergens and associated risks shall also be identified and managed in the facilities that produce ingredients for pet food. All facilities that manufacture ingredients for pet food products shall complete a documented risk assessment for food allergens used in their manufacturing facility. The risk assessment shall be documented. If additional controls are necessary based on this risk assessment, they shall be documented.

Established good manufacturing practices and sanitation procedures, labelling, and ingredient sourcing practices are sufficient to minimize allergen risk to humans resulting from unintentional presence of an allergen in ingredients supplied for pet food products.

The facility allergen program (which includes the allergen risk assessment and management) shall be reviewed annually, or more often, if there are changes to allergen profile at the facility. The review shall be documented.

LABELING

Ingredient listing and product naming requirements shall be used to inform customers of notifiable human food allergens contained in the pet food ingredients and shall meet applicable laws and regulations including AAFCO Product Naming Requirements.

AWARENESS

Personnel (including permanent employees and temporary employees) involved with product development, ingredient sourcing, labeling, and/or manufacture of pet food ingredients shall have an awareness of the presence of human food allergens in pet food ingredients and their associated risks to humans. This includes awareness of human food allergens present in

ingredients, products, storage areas, production areas, and employee areas such as locker room, lunchrooms, and vending machines. Training shall be documented.

FOOD ALLERGENS –HUMAN FOOD SUPPLIERS ONLY

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, mango, etc.

Facility Allergen Management Program shall be a component of the HACCP program. All components of the Allergen Management Program shall be reviewed and updated on an annual basis or more frequently if there are any changes in allergen risk at the facility. Reasons for a change in allergen risk level includes change in formula, equipment, line configuration, allergen ingredient, allergen ingredient form, product, process, personnel or sanitation procedures. Based on these reviews, facility shall 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.

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.

All vendors shall manage the allergens using the following three allergen management strategies in the order presented below. Strategies shall be evaluated in priority order from Dedication to Separation and finally Cross contact labeling.

STRATEGY 1 – DEDICATION

Manufacturing location is dedicated to products containing the same allergen(s) or products containing allergens shall be produced on a dedicated line running a specific allergen or allergen combination.

STRATEGY 2 – SEPARATION

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.

STRATEGY 3 – CROSS CONTACT LABELING

Labeling should not be used in lieu of GMP practices necessary to protect against the unintended presence of a non-formulated allergen.

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.

General Mills shall 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.)

ALLERGEN CONTROL PROGRAM

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. All components of the Allergen Control Program shall be reviewed and updated on an annual basis or more frequently if there are any changes in allergen risk at the facility. Reasons for a change in allergen risk level includes change in formula, equipment, line configuration, allergen ingredient, allergen ingredient form, product, process, personnel or sanitation procedures. Based on these reviews, facility shall 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.

Facilities that handle allergens shall have an Allergen Control Program which includes the following components:

- List of allergens present in the facility.
- Allergen Management Strategies as outlined above.
- Procedures for receiving, handling, and storage of allergen ingredients and products.
- Storage practices shall be in place to prevent cross contamination of allergenic ingredients with other ingredients, etc. This may include but not limited to physical segregation, dedicated storage areas, unique labels, storing materials on the lowest level.
- Procedures for cleaning after allergen products; for detailed information refer to CLEANING AFTER ALLERGEN PRODUCTS.
- Allergen 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.

- Procedures for rework of allergen ingredients and products shall be in place. This includes procedures for rework/recoup/repack/refeed of ingredients and products. 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.
- Label verification procedures (refer to PRODUCT SPECIFICATIONS AND LABELING).
- Additional prerequisite programs that prevent allergen cross-contamination.

CLEANING AFTER ALLERGEN PRODUCTS

Cleaning after allergen products and when changing from one allergen product to another shall be part of the Facility Allergen Control Plan which is a component of the HACCP Plan. Documentation for cleaning shall meet requirements for both the Allergen Control Program and HACCP Program.

Facilities that handle allergens should have a documented Allergen Changeover Matrix that defines the cleaning methods necessary between product runs that is appropriate for the significance of the hazard.

All cleaning performed when changing from one product to another shall be adequate to protect against the unintended presence of an allergen whether or not the next product is cross contact labelled for such allergen(s).

Supplemental lighting, disassembly of equipment, or other means shall be used when necessary to assure adequate inspection of direct product contact surfaces and adjacent areas.

Direct food contact surfaces or adjacent areas where allergen product residue could lead to contamination shall be free of any visible allergen product residue. These surfaces and areas shall be determined based on risk analysis by the facility's food safety team.

Validation to confirm that cleaning procedures are adequate to protect against the unintended presence of a non-labelled allergen in the next product shall be completed. Validations shall be inclusive of all units of operation, materials of construction, methods of sanitation, and tested under worse-case or hard to clean conditions. Validations shall be completed for all of the following:

- All allergen products regardless of the type of allergen present or if the next product is cross contact labelled for the allergen.
- New allergen products being introduced to a system or line.
- Existing products where allergen risk level changed. Reasons for a change in allergen risk level include change in formula, equipment, line configuration, allergen ingredient, allergen ingredient form, product, process, personnel or sanitation procedures.

Validation shall be documented. The documentation shall demonstrate that, current sanitation procedures are adequate to control or eliminate hazards associated with allergen carryover

and the documented sanitation procedure is consistently executed in order to achieve visibly clean standards.

Documented monitoring records shall exist for any cleaning performed after a major allergen unless the subsequent product contains the exact same allergen. This record shall include the tasks/observations and the name of the qualified individual performing the monitoring.

Documented monitoring of cleaning between products that contain a major allergen and any other products containing no allergens or any other allergens shall include a dual sign-off. Dual sign-off shall be performed by two separate, trained, and qualified inspectors. These inspectors shall physically inspect the equipment to confirm it is visibly clean*.

> *Visibly clean – No remaining soil (i.e., all unwanted material) on product contact surfaces or on surfaces that could contaminate the product stream.

Verification of monitoring records shall be completed by a qualified individual as follows:

- For facilities under Food Safety Modernization Act (FSMA): within 7 days of creation of the record.
- For Non-FSMA facilities: at frequency determined by facility's food safety team.

Sanitation programs shall be verified and documented on annual basis to show effectiveness of the program to control risks from allergens on all systems running dissimilar allergens. The following criteria shall be included in verification activities:

- Review of sanitation records to ensure they are complete with no program gaps. Records include but are not limited to inspection reports, sanitation procedures, preventative maintenance program.
- Review of sanitation procedures to ensure they are current and are inclusive of all methods of cleaning and all equipment.
- Verification that any significant changes to the system have been appropriately addressed in the sanitation procedures. Significant changes may include: new production equipment, introduction of a new allergen, or new product claims.
- A detailed physical inspection to show visibly clean standards have been met.
- Other verification activities as identified on the Sanitation Validation report.

Non-conformities discovered during verification shall be assigned correction and corrective action. All non-conformities and associated corrective action shall be documented.

General Mills does not recommend the use of allergen analytical methods (e.g. ELISA testing) for verification. A (false) positive result could implicate products sold to GMI.

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 adequate monitoring procedures. Ingredients supplied to GMI shall conform to all

regulatory agencies and GMI's microbiological requirements and be safe and suitable for human food/ animal food use in accordance with Good Manufacturing Practices. Microbiological test results shall be provided to GMI upon request for review.

IDENTIFICATION OF BIOLOGICAL HAZARDS IN INGREDIENTS

As part of the HACCP program, an ingredient hazard analysis shall be conducted to determine biological hazards that must be controlled by process lethality and/or growth control (low pH or water activity). In instances that your supplier is controlling a hazard, these controls shall be verified via your Supplier Management Program and may include testing and COA verification (Note: test results are not considered a biological hazard control, but a verification of control).

PROCESSING AND FORMULATION CONTROLS

All products shall be produced in such a manner to ensure food safety and compliance with applicable laws and regulations. Growth of pathogens shall be controlled in ingredients, work in progress, and/or finished products through inherent material attributes, formulation, or time/temperature control. A pathogen lethality step (kill steps) shall be documented and supported by appropriate validation, verification and monitoring procedures as part of the HACCP program. Additional controls shall be evaluated and implemented to minimize the risk of cross contamination for microbiologically sensitive areas (e.g., hand washing, footwear control, traffic control, positive air flow, segregation of raw and processed areas and equipment and/or additional controls for construction and unique plant activities).

FINISHED PRODUCT TESTING

The biological control plan shall include procedures for finished product testing with designated sampling location(s), sample size, and frequency of testing to be conducted for each product. Specific microbiological testing including sampling requirements for GMI are detailed in each ingredient specification. Microbiological testing shall be documented and performed using standard approved test methods by trained personnel.

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. 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. 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.

PATHOGEN ENVIRONMENTAL MONITORING PROGRAM

Suppliers for human food ingredients (except commercially sterile ingredients) shall implement a pathogenic environmental monitoring program (PEMP). The PEMP shall verify that the controls put in place during the hygienic zoning assessment are effective at preventing potential cross-contamination between different hygienic zones and their finished products.

The rigor of this program depends on the product and process risk evaluation, and the likelihood of pathogen(s) to survive or grow in the supplier's finished product during storage and distribution. Raw meat suppliers supplying ingredients that are used pre-lethality may use sanitation verification and monitoring programs in place of a PEMP to verify effectiveness of their sanitation practices.

Suppliers of pet food ingredients shall comply with this requirement if the ingredient supplied is applied post-lethality. Meat rendering facilities supplying ingredients that are applied post-lethality are exempt from this requirement.

An effective PEMP shall 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.

Facility's PEMP 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). Refer to Appendix G for a recommended list of topics to be reviewed annually.

Facility's PEMP shall be documented and consists of but not limited to the following components:

- 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

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, monitoring history, facility layout, traffic flow, and construction activity. For facilities applying a microbiological reduction or lethality step to a product, the post-lethality area (Primary Pathogen Control or PPC) of the facility shall be the primary focus of the environmental monitoring program, with other areas of the plant appropriately monitored to ensure they do not present a risk to the PPC area.

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 G for hygienic area definitions (PPC/High Risk, Basic GMP, Non-Production) and examples. Pathogen environmental monitoring sites shall be more focused 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 G for sampling zone definitions (Zone 1, 2, 3, 4). The focus of the environmental monitoring program shall be zone 2 and 3.

Food Contact Surface (Zone 1) sites are not required to 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 must be 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 indicates contamination of the finished product produced on that line during the time the positive was found and between clean breaks. All products manufactured on the line during this time and between clean breaks shall be placed on hazardous hold. 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) and Frequency

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 sampling sites. It is recommended these are also documented on plant floor plan or map. Routine fixed sites shall be sampled in the exact same manner and location each time to be able to monitor trends over time. The number of sites to be sampled shall be based upon the facility size and risk assessment. The monitored plant area, hygienic area, and sampling zone for each site shall be recorded and readily available for risk assessment.
Refer to Appendix G for sampling site examples and definitions (routine fixed, routine variable, non-routine positive mitigation, non-routine event driven).

In high hygiene (PPC) areas, routine fixed zone 2 and 3 sites shall be sampled monthly. All sites in high traffic areas and major floor drains shall also be sampled monthly.

All sites that have been positive for 2 or more times after mitigation (in the last 12 months) shall be sampled monthly.

In Basic GMP areas, routine fixed zone 2 and 3 sites shall be sampled at least quarterly, however, monthly is recommended.

In addition to routine fixed sites, each facility shall have routine variable sites to actively find and address potential sources of contamination. These swabs can be chosen at random or can

be focused to ensure contamination for special events such as construction or roof leaks does not present a risk to the facility.

Zone 4 and non-production areas may be swabbed at the facility discretion but is not required by GMI.

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.

Areas that allow harborage of *Listeria* spp. are possible source of *Listeria monocytogenes* therefore General Mills recommends swabs to be tested for *Listeria* spp. instead of *L. monocytogenes*.

Facilities can use indicator organism for cleaning verification purposes. However, these testing regimes shall not be in lieu of *Salmonella* spp. or *Listeria* spp. testing.

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. Refer to Appendix G for additional details on sample collection timing.

Sampling Device

Cellulose or polyurethane sponge pre-moistened with a neutralizing buffer shall be used for environmental pathogen sampling. The neutralizing buffer shall be capable of neutralizing the sanitizer used in the plant and not interfere with the pathogen test methodology. In the case of 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. Refer to Appendix G 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:

Compositing samples is acceptable by GMI. For details on requirements refer to Appendix G.

Sample Analysis Details

Appropriate approved methods shall be used for environmental monitoring and samples shall be analyzed using a validated method. 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 G for details on sample analyzing methods, 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. The positive result escalation plan shall be more stringent in high hygiene/PPC areas and include vectoring to identify the root cause. Refer to Appendix G for details on vectoring.

Corrective and preventive actions may include:

- If the sample was a composite, re-sample individual sites before cleaning and sanitizing.
- Clean and sanitize the positive site and immediate area. Inspect the site and adjacent area for potential niches, and if identified, then repair or remove.
- Perform vector swabs as needed (required in PPC areas).
- Take measures to prevent cross-contamination from the site to other locations until fully mitigated.
- Re-swab the site and continue to vector. Samples shall be taken at least 24 hours apart, and no more than 10 days apart. Test results from the previous samples are not required before the next sample is taken.
- Identified root cause sites found through vectoring are required to be mitigated.

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

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.

Special Cause Swabbing

Additional monitoring is required during special events such as construction, roof leaks, drain backups and excessive condensation. These may be taken as part of routine variable swabs at the facilities discretion.

Seasonal Facility Swabbing

Seasonal facilities that produce finished goods for a short time of the year related to crop cycle shall have an effective PEMP 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 PEMP 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. A 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 PEMP shall receive documented training on the facility's PEMP and related procedures at least annually.

GOOD LABORATORY PRACTICES

It is strongly recommended that microbiological testing on product be conducted at an ISO 17025 accredited laboratory. Presumptive positive results may be treated as positive without confirmation or confirmed at an accredited laboratory.

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 approved by an accredited organization (e.g. AOAC , ISO, IS, CNS) and/or General Mills and be appropriate for their application.

INGREDIENTS AND PACKAGING MATERIALS

All facilities shall have a risk-based supplier quality assurance program that ensures the quality and safety of all food (and feed) ingredients and packaging materials along with conformance to approved specifications/contractual agreement and all applicable 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

* For pet food suppliers, the facility's ongoing maintenance process shall include ongoing monitoring and verification of current vendors to ensure the quality and safety of all ingredients.

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 applied control.
- A receiving facility that is an importer shall be in compliance with the FSVP (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 AND MYCOTOXIN MANAGEMENT

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 pesticides (insecticides, fungicides, herbicides, etc.) with understanding that risk of pesticide residue 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.

All General Mills suppliers of agriculturally based products where mycotoxins are known to occur shall have a mycotoxin management program in place that protects against the presence of unsafe mycotoxin levels and/ or mycotoxin levels exceeding regulatory maximum limits for ingredients /products they supply to General Mills. A supplier's mycotoxin management program shall be comprehensive in nature including all relevant mycotoxins of concern (e.g. aflatoxins, deoxynivalenol, fumonisins, ochratoxin A, etc.) with understanding that risk of mycotoxin presence 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.

For pet food ingredient suppliers;

All new ingredients and/or existing ingredients from a new source that are supplied to Blue Buffalo will undergo a risk assessment. Based on this risk assessment and at the discretion of Blue Buffalo, a pesticide and/or mycotoxin analysis shall be performed.

For human food ingredient suppliers, components of the pesticide management program may 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.
- Whenever testing is a requirement as part of the supplier's pesticide management program, a Multi Residue Analysis (MRA) must be performed by an ISO 17025 accredited laboratory with pesticide testing as part of the accredited scope. The laboratory's pesticide screen must cover no less than 300 pesticides and pesticide metabolites. See Appendix H 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.

For human food ingredient suppliers, components of the mycotoxin management program may include:

- The supplier or contracted growers have knowledge and education regarding molds known to generate mycotoxins of concern on the raw agricultural commodity.
- Select disease-resistant varieties to minimize mold growth and mycotoxin formation.
- Evaluate climate and field conditions for risk of mold and mycotoxin formation prior to planting. These are regularly monitored for crop health during the growing season and harvest.
- Approved integrated pest management techniques are employed where appropriate to minimize mold growth; this may include the proper use of registered and approved fungicides for the specific crop.
- Effective cleaning procedures to remove broken or infected material prior to storage.
- Effective procedures to control humidity and temperature of stored material.
- Monitoring procedures for agricultural materials destined for human food or animal food (e.g., dairy farms).
- Whenever testing is a requirement as part of the supplier's mycotoxin management program, each mycotoxin of concern must be tested. At a minimum, one test must be performed by an 17025 accredited laboratory with the mycotoxin test as part of the accredited scope per year. Additional testing may be performed as needed.
- Molds known to generate mycotoxins often form as "hot spots" and are not uniformly distributed. A sample collected for mycotoxin testing should be statistically based to effectively represent the production lot. Refer to the USDA Grain Inspection Handbook Book 1 Sampling or the COMMISSION REGULATION (EC) No 401/2006 for recommended mycotoxin sampling methods in raw agricultural commodities.

GMI requirements for submitting pesticide residue and mycotoxin test results:

GMI ingredient suppliers are required to submit an MRA and/ or mycotoxin test result upon request of General Mills. GMI expects the total number of ~~MRA~~ analyses performed for each agricultural crop to be risk based as determined by each supplier. Note: GMI will also be conducting verification activities throughout the year.

More frequent testing may be required as determined by GMI food safety contact. Ensure no solvent-based markers (Magic Marker, Sharpie, etc.) are 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.

CONTROL OF PHYSICAL HAZARDS AND FOREIGN MATERIAL

All ingredient materials shipped to GMI shall be free of hazardous foreign material and shall be in compliance with GMI specification and local laws or regulations.
All suppliers shall have a physical hazard prevention, detection and control program. This program may include strategic placement of physical contamination detection devices (referred to as "devices") such as strainers, sifters, scalpers, filters, magnets, x-rays, visual sorters, and/or metal detectors at strategic points throughout manufacturing system including ingredient unloading/handling, processing, transfer, and packaging/point of load out. Devices shall meet applicable laws and regulations for licensing, installation, and operation of devices. Terminal (last point of control) product protection devices shall be present and be appropriate to the material category and product type. There shall be no further processing or handling between these final product protection devices to the point where product is protected from the environment. Final product protection devices must be included as a part of the hazard analysis and risk assessment completed to determine if they are Preventive Controls or Critical Control Point (CCP). Physical hazard detection devices shall not be used to clean-up known contamination in ingredients or products.
All physical contamination detection devices shall be documented in the facility's food safety/HACCP Plan. Each device shall have an effective management program including:

- Immediate response to findings
- Investigation into source and root cause
- Risk assessment for the rejected product and continuation of manufacturing
- Complete documentation of checks and findings
- Retention of foreign matter through shelf life of product
- Procedures to follow when the device malfunctions

Personnel whose job function involves activities related to monitoring, verification, validation, or maintenance of control devices shall have documented training to qualify them to interact with control devices. 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.

GMI recommends foreign material detection devices be as sensitive as possible knowing that more sensitive detection devices may be present in GMI receiving facilities.

Devices used for reasons other than physical contaminant detection (e.g. equipment protection) do not need to be included in the physical contaminant program and/or managed according to requirements of this standard.

SCREENING DEVICES

- Screening devices (e.g. sifters, screens, strainers, scalpers, and filters) shall be designed and sized to detect physical contaminants.
- The smallest screen size capable of detecting potential contaminants while not restricting product flow shall be used. The screen size and rationale shall be documented in physical contaminant program.

- 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.
- The integrity of all screening devices shall be inspected at an appropriate frequency and these inspection results shall be documented. Documentation of these inspections shall include screen and device condition, employee observation and confirmation that the correct screen size is in place. The frequency of these inspections shall be determined based on a risk assessment considering nature of the product, GMI recommends a minimum weekly frequency. 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 on a risk assessment.
- For liquid ingredients, if a screening device of 50 mesh (0.297 mm opening) or smaller is capable of trapping and retaining potentially hazardous metals then it may be used in place of a metal detector. For dry ingredients, acceptable mesh size to replace metal detector is 30 mesh (0.595 mm opening) or smaller. Mesh sizes allowance may vary by ingredient category with approval by GMI food safety team, based upon risk assessment.

MAGNETS

- Magnets shall be designed and configured to maximize separation capability and provide effective pull, holding capability of magnetic metal and sufficient product coverage during operation flow. The effectiveness shall be re-evaluated as product flow rates change.
- Magnet strength shall be validated upon installation. This validation shall be documented. Strength and condition of a magnet that is a terminal product protection device shall be verified on an annual basis. All other magnets in the product stream shall be verified at a frequency based on risk assessment and at a minimum of every 3 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.
- All magnets that are terminal product protection device shall be visually inspected and cleaned at a minimum of once per shift.
- Findings shall be evaluated, documented and retained for trending. Appropriate corrective actions shall be taken in a timely manner.
- Magnets on bulk loading systems should be inspected after each vehicle/vessel is loaded.

METAL DETECTORS AND X-RAYS

- Capability of each metal detector and x-ray device shall be established. If the x-ray device is used for metal and non-metal contaminants, then capability shall be

established for both metal and the non-metal hazard of greatest relevance. Facilities shall determine the smallest test pieces that the device is capable of detecting for stainless steel, ferrous, and non-ferrous. Recommended test piece materials are:
    - 316 non-magnetic stainless steel
    - aluminum for non-ferrous

- Once capability is established, then validation shall be completed to establish repeatability and reproducibility of successful detection. For GMI specific requirements on metal detector/x-ray capability determination and validation refer to Appendix I. Target capability for different test piece sizes are defined in the following table. NOTE: Metal detectors shall have the smallest possible aperture that allows product passage and maintains optimum metal detection capability and functionality.

Product Characteristic	Aperture Size	Ferrous Sphere Size†	Non-Ferrous Sphere Size†	Non-Magnetic 300 Series-Stainless Steel Sphere Size†
Non-Conductive Products (e.g. dry products, cereal, dry mix)	<7"(17.78 cm)	1.3 mm *	1.5 mm *	2.0 mm *
	>7"(17.78 cm)	1.5 mm *	2.0 mm *	2.5 mm *
Conductive Products (e.g. high moisture products, dough, yogurt, vegetables, pizza)		Sphere size must not exceed 3.0 mm *		

† GMI production facilities may use more sensitive metal detectors.
*** Numbers stated in this table are GMI recommended test piece sizes and are not to be mistaken as specification for allowable metal size in product.**

- Metal detectors or x-ray 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.
- All test pieces used for capability of metal detectors and x-ray devices should be certified by third party or the vendor.
- Metal detector and x-ray shall be monitored at the beginning and end of each production 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 a minimum of once per shift.
- Terminal metal detector and x-ray shall be verified annually or when factors that may impact the functionality of the device occur including new product type, change in formula, new package size, changes in line speeds, after device maintenance. Annual verification can be performed by either 3rd party or a trained employee. For GMI specific requirements on metal detector/x-ray verification refer to Appendix I.

- Monitoring and verification checks 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.
- Any product that is used for the monitoring process, must have been passed through the metal detector or x-ray device under normal circumstances before the product is used for the monitoring process. If the product that is used for monitoring process is deemed saleable, supplier shall ensure that the product does not become a source of contamination.
- 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.
- 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.
- All terminal metal detector and x-ray devices shall be validated at installation after capability is established and re-validated after device is relocated and when verification fails. Additional events that may require re-validation are as follow:
    - 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 breakage, damage, and/or product contamination.

As part of glass, brittle plastic and ceramic control program, facilities shall maintain:

- A documented inventory of necessary glass, brittle plastic, and ceramic components located and used in storage, shipping/receiving, processing, and packaging areas (including wireless/mobile devices that are used for operations).
- A documented inspection of these components shall be performed on a frequency based on a risk assessment.

- A response procedure for glass, brittle plastic or ceramic breakage or damage. This procedure shall address segregation and breakage containment, product evaluation, clean up, documentation of the event, corrective action, etc.

Personnel who are involved with the handling of glass, brittle plastic or ceramic in storage, processing or packaging areas shall receive documented training on the associated hazards and procedures.

FOOD DEFENSE AND FOOD FRAUD MITIGATION

All Suppliers shall have a Food Defense Program in place to effectively manage risks to protect GMI ingredients from intentional acts of adulteration or fraud. Suppliers shall perform a vulnerability assessment for intentional adulteration with intent to harm and for economically motivated food fraud.

The Food Defense and Fraud Mitigation Program shall include the following:

- Facility food defense team responsible for food defense plan and training development, implementation, and maintenance. This team will be responsible for 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 preplacement 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 logistics.
- Documented Contingency or Crisis Management procedures shall include effective and immediate response to risk related to food defense.
- Documented Food Fraud Mitigation plan which includes identification of potential vulnerabilities, mitigation measures for significant vulnerabilities and training requirements.

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 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.

EMERGING ISSUES

Food integrity and consumer trust are top priorities at General Mills. We actively monitor issues of interest. Below is the list of issues that we are currently monitoring and sharing with our ingredient suppliers:

Phthalates

We are concerned about reports of phthalates found in food. Phthalates are chemicals that are widely used to make plastics more pliable. While the FDA, in the US, has not yet adopted a threshold for levels of phthalates in food, we are committed that our food is handled in the safest way possible. We ask that you review your food processing equipment and develop plans to replace components containing ortho-phthalates with other inert, food-safe options.

APPENDIX A: DEFINITIONS, CONTACTS AND REFERENCES

DEFINITIONS

The following terms are used in this document to state GMI requirements and recommendations to suppliers:

- 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

Human Food Ingredient Suppliers;

Use the following links for 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 inqueries on Specification:

For North America:

- GMI Specification Change Requests spec.updates@genmills.com

For LATAM:

- GMI contact XQM.Support@genmills.com

For AMEA:

- GMI Specification Contact SQA.India@genmills.com

For AUNZ:

GMI Specification Contact specifications.au-eu@genmills.com

Pet Food Ingredient Suppliers;

Send 3rd party audit documents to supplier.documentation@bluebuff.com
For specification enquiries contact Blue Buffalo Procurement team.

REFERENCES

GMI Global Audit Program (G-GAP):

- http://ggap.force.com
- https://www.tracegains.com/ (for pet food ingredient suppliers)

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

AAFCO:

- https://petfood.aafco.org/

GFSI:

- https://mygfsi.com/

APPENDIX B: SFCR REQUIREMENTS FOR INGREDIENTS USED IN FINISHED PRODUCTS SOLD IN CANADA

To ensure compliance to SFCR, in addition to meeting all the requirements of this manual, vendors are required to provide the following information if requested by GMI food safety or regulatory contacts:

- Information on the scope of the SFCR license and the license # for the product(s) made for GMI
- Detailed information and contacts for all shipping locations
- Detailed information and contacts for all manufacturing sites (including factories, pack houses, storage sheds, cold storage, etc.)
- All required third party food safety audit certificates and audit reports for each manufacturing site and food category being exported from Canada
- Product specifications and allergen check records
- Product labels and list of legal ingredients
- Product traceability code and its interpretation
- Processing SOPs as per HACCP principles required
- Product testing reports and consumer or customer complaint corrective action reports for CFIA product investigations for consumer issues
- Information for the border clearance process with CFIA and CBSA in Canada

APPENDIX C: FDA REPORTABLE FOOD REGISTRY

Facilities registered with the FDA must report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

Reporting is required within 24 hours from identification of the situation to Reportable Food Registry. 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. **<u>General Mills expects discussion prior to reporting (if needed, use 24 hours contact line 763-764-2310)</u>**
    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

APPENDIX D: 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.

https://www.gs1.org/docs/tl/GS1_Logistic_Label_Guideline.pdf

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:

http://www.generalmills.com/en/Company/working-with-us/TradingPartners/NAHome/NA-Suppliers

APPENDIX E: FSMA REQUIREMENTS FOR INGREDIENTS SHIPPED TO US PRODUCTION FACILITIES

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule is now final, and compliance is mandatory for all businesses. 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 F: HACCP MONITORING, VERIFICATION AND VALIDATION DEFINITIONS AND EXAMPLES

Validation	Verification	Monitoring
Validation is applied prior to an activity and provides information about the capability to deliver intended results	*Verification is applied after an activity and provides information for confirmation of conformity*	*Monitoring is applied during an activity and provides information for action within a specified timeframe*
WHAT: Evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling a hazard to a specified outcome.	**WHAT**: Activities confirming a control measure has been implemented and is consistently operating as intended.	**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: Performed at the time that a processing step or other food safety control measure is designed or significantly changed.	**WHEN:** Frequency varies. May be scheduled or unscheduled.	**WHEN:** Scheduled on set frequency.
EXAMPLE: The evidence may be scientific data, published technical information, observational information, or analytical data.	**EXAMPLE:** Verification activities may include observation of monitoring activities, interview of employee understanding of monitoring activities, records review, program review (HACCP, PSE), and other.	**EXAMPLE:** Monitoring activities may include temperature data, instrument check, sanitation inspection and other.

APPENDIX G: PATHOGEN ENVIRONMENTAL MONITORING PROGRAM

Program Review

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

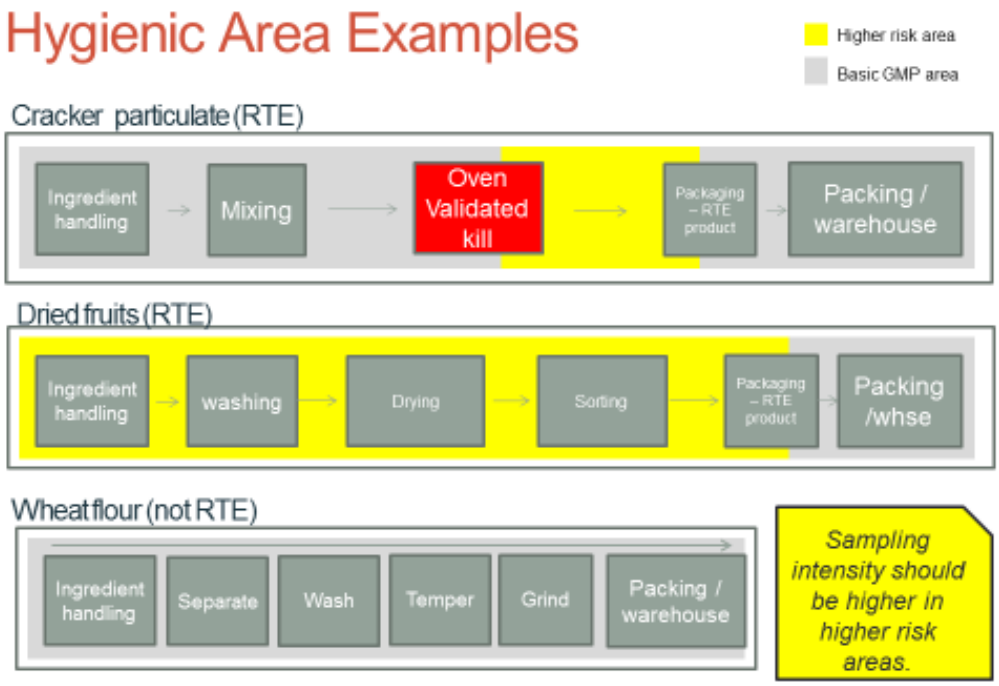
- Compliance to this manual
- PEMP results including trend analysis
- Events that affected the environment
- Physical changes to the facility or equipment
- Changes to products or ingredients at the facility that change the overall risk profile
- Changes to programs that may affect the environment (e.g. 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 Definitions

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 and Site Examples

Sampling zones are defined as following:

Sampling Zones and Site Examples		
Zone	**Definition**	**Examples of Sample Sites** *(This is not an all-inclusive list)*
1	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	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.
2	Non-product contact surfaces in close proximity to product contact surfaces	Control panels, conveyor supports, platform handrails, overhead beams or other structures adjacent to or below product zones
3	Peripheral areas of production that if contaminated with a pathogen, could lead to contamination of Zone 2 via movement of humans or machinery	Thresholds, floor drains, high traffic areas, stairs, floor/wall cracks
4	Non-Production Areas	Changing areas, restrooms, break rooms, offices, laboratories Warehouses with physical separation from production area

Increasing risk of product contamination

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

Compositing Samples:

The following shall occur when compositing samples:

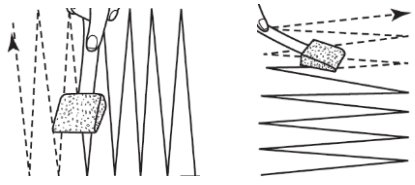
- Up to five individual sample sponges may be composited into one test sample.
- Use a separate sponge for each location to prevent cross-contamination.
- Site selection for compositing samples:
    - The composited samples must be from sites with the same Plant Area, Hygienic Area, Sampling Zone, and 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 Collection Timing

Sample Collection Timing	Purpose	Sample Details
During production	To assess the area under normal operating conditions	Samples shall be taken: ○ ≥3 hours after the start of production, or ○ At end of run / end of operational shift, or ○ 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	○ 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	○ 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 m^2 (5.4 ft^2).
- 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 Handling and Analysis Details

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.

Sample 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.

Vectoring – A Tool to Track the Sources and Flow of Pathogens in A Facility

Increasing sampling around the area where a positive is found is called "vectoring". This process involves a physical examination of an identified positive site and its surrounding area.

The following shall be considered as part of vectoring process;

- Facilities shall investigate and resample not just suspect sites, but also the surrounding areas and traffic pattern areas, for potential contamination sources.
- Investigation sites shall include sites upstream and downstream of the initial positive.
- The original *Listeria* spp. positive sample is considered to be the center of a bullseye; investigational samples are taken from around this center point using a concentric ring like pattern (if possible three dimensional).

APPENDIX H: 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. such as US-EPA, State Department of Agriculture, FSSAI, ANVISA, and any local governments or other country's applicable requlatory requirements for the country of use.

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) at least annually or according to the local regulations.

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 a comprehensive list of pesticides with an international scope. The laboratory conducting the pesticide testing for General Mills products must be ISO 17025 accredited with their pesticide screen in scope and tests for no fewer than 300 pesticides and pesticide metabolites.

MSDS: OSHA "Material Safety Data Sheet".

APPENDIX I: CAPABILITY DETERMINATION, VALIDATION AND VERIFICATION REQUIREMENTS FOR METAL DETECTOR/X-RAY

For capability determination, validation, and verification the following must occur:

- All activities for capability, validation, and verification must be recorded including date, settings, and test piece type and size.
- Testing must be conducted under normal operating conditions with normal product flow through the device.
- The type of metal used for stainless steel, ferrous, and non-ferrous test pieces must be documented. (e.g. aluminum, etc.)
- The test piece must be in or attached to product.
- Product with the test piece must pass through the least sensitive zone of the device. For metal detectors, this is directly in geometric center of the detector aperture. For x-rays, this area is determined through empirical testing.

Capability

Capability testing of metal detector/x-ray shall be performed to determine the smallest stainless steel, ferrous, and non-ferrous (aluminum recommended) test pieces that the device is capable of detecting to;

- maximize the device performance efficiency
- balance false positives and false negatives to protect the business
- enable consistent routine performance

Device capability must be determined at the installation. Facility can determine smallest size test piece that the device can detect, in the order of stainless steel (316 non-magnetic recommended), followed by ferrous, non-ferrous (aluminum recommended). For capability testing, it is recommended to use the product that is the most difficult to detect the test pieces.

Documentation must include the smallest size test pieces the device is capable of detecting and the test piece sizes that failed detection. There cannot be more than 0.5 mm difference between the test piece that passed and the test piece that failed. For example, if capability was determined to be 2.5 mm, then there must be documentation showing that a test piece less than 2.5 mm failed.

Validation

Metal detector/x-ray devices shall be validated to provide scientific data that the device is capable of consistently detecting and rejecting 3 metal types that are of the same size as identified during capability.

After the capability has been determined for all 3 metal types, validation must be completed as follows:

- The device must demonstrate the capability to detect and completely reject the test piece multiple consecutive times for each of the same size metal test pieces determined

at capability. GMI recommendation is 30 consecutive passes for stainless steel and 30 consecutive passes for ferrous and 30 consecutive passes for non-ferrous.
- Visual and/or audible alarms must indicate detection for all successful tests.
- Documentation of device settings.

If the device fails to detect or fails to reject or fails to indicate audible and/or visual alarms, then the device must be adjusted or repaired and the entire validation process must be repeated. If validation is still failing, capability must be re-established for all 3 metal types.

Verification

Metal detector/x-ray devices shall be verified to provide data that the device remains capable of detecting and rejecting 3 metal types that are of the same size as identified during capability.

During verification the device must detect and completely reject the test piece multiple consecutive times for each of the same size metal test pieces determined at capability. GMI recommendation is 10 consecutive passes for stainless steel and 10 consecutive passes for ferrous and 10 consecutive passes for non-ferrous. Visual and/or audible alarms must indicate detection for all successful tests.

If the device fails to detect or fails to reject or fails to indicate audible and/or visual alarms, then the device must be adjusted or repaired, and the entire verification process must be repeated. If verification is still failing, capability must be re-established, and validation procedures must be completed for all 3 metal types.