

# Supplier Food Safety & Quality Expectation Manual

Raw Ingredient/Co-Manufacturer/Packaging

Dear SFC Global Supply Chain, Inc. Supplier,

SFC Global Supply Chain, Inc. (hereinafter "Schwan's") is committed to cultivate ONLYONE culture that ensures safe and quality foods. We intend to achieve this goal through consistent programs and continuous improvement of food safety and quality. Schwan's relies on strong, confidence-based supplier relationships, in order to meet our commitment of delivering safe, quality foods to our customers and consumers. Schwan's requires our business partners to comply with applicable regulatory requirements and align to industry-leading practices.

It is Schwan's stance, that all Raw Material Suppliers, Packaging Suppliers, and Co-Manufacturers (hereinafter "Supplier") understand our Food Safety and Quality requirements, so we partner with companies who share common values and goals. Suppliers who apply our standards and best practices to their processes, reduce the consumer's overall food safety risk and improve the business prospects, for all parties. The expectations outlined in this document are essential to effectively manage food safety and quality, to our standards at Schwan's. The expectations which are NOT relevant for packaging suppliers are preferred but not required. Packaging requirements are specific to branded and non-branded packaging for human food use. In order to accomplish this imperative, we at Schwan's believe we shall work together with our suppliers to ensure our customers receive a great tasting, safe product. We look forward to partnering with you.

# Contents

Evaluation and Qualification of Supplier	5
Specification	5
Document Request Initial Information and/or Audit	5
Third-Party Food Safety and Quality Accreditation	5
Pre-Qualification Corrective Action Plan	5
Internal Audit Program	5
Management Commitment	6
Food Safety and Quality Management Systems	6
Document Control	6
Notification of Changes	7
Document Requirements	7
Regulatory Requirements	7
Quality Requirements & Process Capability	8
Supplier Qualifications	8
Case Label Requirement	9
Pallet Requirements	9
Weight Control	9
Food Safety Plan or HACCP/HARPC	10
Non-Conforming Product Control	10
Complaint Management	11
Traceability	11
Crisis Management	12
Data Coding	12
Material Handling Program	12
Food Defense	14
Allergen Management	14
Employee Training	15
Good Manufacturing Practice (GMP)	15
Personal Hygiene Practices	15
Approved Clothing/Attire	16
Hand Sanitization	16
Sanitary Design - Facility and Grounds	17
Sanitary Design - Equipment and Utensils	17
Maintenance Quality & Food Safety	17
Calibration	18
Cleaning and Sanitation	18
Chemical Control	20
Pest Management	20
Environmental Monitoring	21
Microbiological Testing	21
Good Laboratory Practice and Testing	22
Waste Disposal	22
Water, Air, Ice and Gas	22
Foreign Material Prevention	23
Plant Zoning	24
Animal Welfare & Social Responsibility	24
Packaging Suppliers	25
Packaging Manufacturing	25
Printed Material Management: Schwan's Labeled Packaging Materia	l 25
Transfer of Constituents from Food Contact Material	25
Transfer of Constituents from Plastic Materials	25

Transfer of Constituents from Paper and Board Materials	26
Metal in Contact with Packaging	26
Recycled Post-Consumer Material	26
Odor and Taste Transfer Testing	26
Residual Solvents	26
Printing Inks	26
Printing in Direct Contact with Food	27
Packaging Material Ingredients and Processing Aids Derivative/Sources	27
Environmental Impact of Packing	27
Minimization of Heavy Metals, and Other N-Classified Substances	27
Undesired Substances	27
Packaging Information/Specification Sheets	27
Schwan's Safety and Quality Status Classification	28
Supplier Ongoing Monitoring and Management	29
Continuous Improvement	29
Triggering Event Management	29
Exceptions	29

# **Evaluation and Qualification of Supplier**

Schwan's welcomes new and innovative ideas. All companies interested in joining the Schwan's supplier network shall understand that they shall go through an approval and contracting process prior to manufacturing, packing, or filling any product. Suppliers formally agree to Schwan's expectations and applicable regulatory requirements by signing a Master Service Agreement (MSA). To ensure that safe quality food is produced, approval is conducted at the manufacturing facility level. Technical and process capabilities may be assessed, and improvement programs required. If approved, the supplier shall be required to subscribe to our company's preferred management software.

## **Specification**

Product specifications shall be agreed upon between the Supplier and Schwan's. Systems shall be established and implemented to demonstrate that product released meets the requirements specified in the agreed upon specification.

## Document Request, Initial Information, and/or Audit

- A. Each prospective facility shall undergo a food safety, quality, and regulatory compliance review. Schwan's, among other things, utilizes questionnaires, review of FSQ documentation, government data, GFSI or 3<sup>rd</sup> Party Food Safety Audits & Certifications, Schwan's 2<sup>nd</sup> Party On-site facility audits, product testing and review of specification conformance capability to assess Supplier's ability to meet our requirements.
- B. Supplier 2<sup>nd</sup> Party On-site facility audits conducted by Corp FSQ shall be based on material risk, preventive control measures and supplier's reputation.

## Third-Party Food Safety and Quality Accreditation

- A. Schwan's requires that Supplier maintains certification for a Food Safety Certification Program recognized by the Global Food Safety Initiative ("GFSI") and a minimum acceptable score shall be either "Good" or ≥86. Non-GFSI Audit Schemes shall have a minimum acceptable "Pass" score that is <15 Minor NCs or <2 Major NCs. If an Audit Score is below the minimum acceptable score, Schwan's is to be notified within 3 days, of the completed audit. The audit with corrective actions and certificate shall be provided to Schwan's, on an annual basis. GFSI Certification is "preferred" but not required for Non-Food Contact Packaging Suppliers, only.
- B. Once accreditation is achieved, Schwan's shall be notified immediately, if certification lapses.

#### **Pre-Qualification Corrective Action Plans**

If a Supplier is unable to fully comply with key Schwan's safety and quality requirements during the verification phase of approval, the Supplier shall develop a corrective action plan prior to manufacturing products for Schwan's. Schwan's shall review the corrective action plan for effectiveness. Failure to effectively close non-conformances, may result in a "disqualification" status by Schwan's.

## **Internal Audit Program**

- A. The facility shall conduct internal audit, at planned intervals at their facility based on risk, to determine compliance with their food safety, quality, and regulatory programs. The program shall include monitoring and completion of corrective and preventive actions from internal audit findings, that have been reviewed by the designated members of the Management Team.
  - I. Verification of compliance to GMP guidelines.
  - II. Compliance to established quality system standards.
  - III. Regulatory requirement compliance

## **Management Commitment**

- A. The facility producing goods for Schwan's shall have a documented policy that states the facility's fundamental commitment to producing safe, quality and legal food.
- B. Senior management shall have clear objectives that support a food safety and quality culture. Management shall meet annually to review their facility's food safety and quality programs. Meetings notes shall be taken along with the inputs and outputs of the meeting. The scope of the meeting includes but is not limited to:
  - i. Results of internal and external audits
  - ii. Customer complaints
  - iii. Incidents
  - iv. Effectiveness of the Food Safety Plan or HACCP
  - v. Resource requirements
- C. Management shall be present at the opening and closing of Schwan's Audits. They shall provide resources to ensure gap closures and continuous improvement plans are achieved for Schwan's products.
- D. The facility shall ensure responsibilities are defined, documented and communicated within the company. They shall ensure that programs are established and shall continue in the event of personnel or company changes.

## **Food Safety and Quality Management Systems**

A Food Safety and Quality Management System shall be developed and managed by a multi-disciplinary food safety and quality team having specific knowledge of the type of Food Safety and Quality Management System being applied, based on the requirements of the region it operates in as well as knowledge related to the product, processes, and associated food safety hazards. The system shall include:

- A. Establish, implement, document and maintain food safety and quality management systems.
  - i. Food safety plans shall be reviewed prior to any process, ingredient, equipment or personnel changes to assure no unforeseen risk addition. Food-safety plans are also required to be reviewed at a frequency of no greater than 12 months.
  - ii. A list of current prerequisite programs and supporting documentation shall be available for review in conjunction with the established food safety plan to assure all areas of risk are identified and managed.
  - iii. Documented employee education on the facility food safety plan is required for new hires and all existing employees on an annual basis. Records of required training shall be available for review by Schwan's during facility audits.
- B. Demonstrate programs are effective via documented processes, controls measures, and audit results.
- C. Facility shall have a current Organizational Chart that is signed and dated and available for review, if requested.

#### **Document Control**

The company shall utilize an effective document control system to ensure only current and correct versions of documentation are available for use in the facility and establish the controls instituted for identification, storage, retrieval, retention, and disposition of records.

- A. The facility shall maintain an active document register which lists all current forms, procedures, policies, and other documents.
- B. All documents shall have an indicator of version, update date, and an individual responsible for the document.
- C. A system shall be in place for the replacement of existing documents when updated.
- D. Schwan's documents shall be maintained for shelf life of the product plus one year.

## **Notification of Changes**

- A. Supplier shall conform to Schwan's Change Management procedures and utilize the Schwan's Change Management Form. This includes notifying Schwan's of any changes or modifications to the production location, product specifications, product inputs, and/or process steps that would have an impact on the quality of the delivered product.
  - i. Risk assessment for plant projects that have the potential to affect food safety or quality shall be conducted by the food-safety team in conjunction with others from the facility who have knowledge of plant construction, equipment design, plant operations and microbiological risk factors.
  - ii. Any process deemed to have an elevated microbiological risk due to the opening of floors, equipment, ceilings, walls, etc., are required to have increased microbiological testing of the environment conducted during and after the project is completed, as well as, before production resumes.
  - iii. Management of change risk assessments and project planning requires food-safety team review and approval.
- B. Any changes that would potentially affect the food safety or quality of Schwan's products shall be communicated to Schwan's Corporate Food Safety & Quality contacts for internal management of change consideration prior to implementation. Applicable notification required changes include, but are not limited to:
  - Finished product facility of manufacture shift.
  - Critical equipment design change.
  - Processing technique modification.
  - Process flow modification.
  - · Packaging related changes.
  - Raw material source shift.
  - Raw material state change (i.e. fresh vs. frozen).
  - Variety/species variation.
  - Any change that would affect the consumer experience.

#### **Regulatory Requirements**

- A. It is the facility's responsibility to assure supply chain compliance with applicable laws and regulations. Suppliers may be required to comply with certification requirements (e.g. Organic, Kosher, Halal) for specific products or regions of the world.
- B. Management at the facility shall ensure that employees are trained to manage regulatory inspections and that Schwan's Corporate Food Safety & Quality is immediately notified if product released into commerce does not comply with regulatory requirements.
- C. Supplier shall have a regulatory inspection procedure that outlines requirements if Schwan's production samples are pulled for testing:
  - i. Product shall be placed on "Hold" status pending results of the required testing and Schwan's Corporate Food Safety and Quality shall be notified within 24 hours.
  - ii. If a regulatory authority collects environmental samples, consideration shall be given to how the testing could impact the acceptability of product produced for Schwan's. Product shall be placed on "Hold" status and Schwan's Corporate Food Safety and Quality shall be contacted for further direction.
  - iii. Detailed records of all regulatory inspections, findings, and corrective actions shall be kept on facility.

## **Quality Requirements & Process Capability**

Supplier shall have programs and processes in place to ensure products are made to meet regulatory guidelines and Schwan's specifications, as well as, provide verification of compliance for incoming raw materials, in process materials, packaging components and finished products.

- A. Specifications for finished products, raw materials, and packaging components shall be accessible in facility and receive formal review at a frequency of no greater than 36 months.
- B. Approved visual factory pictures and/or color charts for finished product and critical in process inspection steps are to be accessible on the production line for Schwan's production.
- C. Raw material acceptance programs shall be implemented to verify compliance to specification through either COA analysis or routine internal critical attribute testing. This analysis may be based on risk assessment to determine appropriate levels of verification activities required.
- D. The facility shall ensure that product meets Schwan's specification requirements for taste, texture, odor, and appearance (size, shape, color, etc.), includes product and packaging. It is recommended that sensory checks are conducted throughout each production run.
- E. In process monitoring of critical attributes, product characteristics, and packaging conformance shall be in place to ensure compliance to applicable regulatory guidelines and Schwan's specifications.
  - i. Process capability data shall demonstrate that products always achieve specification compliance for labeling content, physical attributes, sensory descriptions, and packaging acceptability as outlined by Schwan's product specifications. Process capability data shall be available for review upon request.
  - ii. In process testing, plans shall represent the entire run including start up, shutdown, and a maximum of every 60 minutes as part of the sampling set.
  - iii. Statistical process control systems are preferred.
  - iv. Packaging verification for lines producing over 100 pieces per minute shall have an electronic verification system of the line, an approved multi-level verification plan, or plans to implement electronic verification within the next 24 months.
- F. Finished product evaluations for Schwan's products are required to ensure full compliance to specification. Finished product evaluations shall include verification of physical and sensory attributes and packaging conformity as described in the product specification.
  - i. Any abnormalities, packaging failures, or attributes that do not meet specification shall result in a product hold and notification to a Schwan's Food Safety & Quality representative for disposition decision.
- G. The responsibility and methods for releasing products shall be documented and implemented.

#### Supplier Qualifications

Supplier shall have an effective supplier qualification program that includes the approval and monitoring of suppliers based on any potential risks from raw materials or packaging to the safety, legality, and quality of the final product.

- A. The supplier approval process shall include a risk-based analysis of the supplier, the manufacturing or collection process, microbiological risk, physical hazard risk, chemical hazard risk, and radiological risk as well as transportation factors and the location from which the goods would be received. The result of the risk analysis shall apply a rating of risk associated with that raw material or packaging component.
- B. Risk levels applied to each raw material or packaging component shall classify the required steps for acceptance of that material such as microbiological verification testing, certificate of analysis, certificate of compliance, or physical inspection.
- C. Approved suppliers shall be approved based on manufacturing location. GFSI qualifying audit or appropriate third-party food safety audit from each supplier location shall be reviewed and kept on file.
- D. The company shall have an established supplier quality verification program in place to monitor product quality from each supplier and show trending of key indicators to ensure continued compliance to

- specification and food safety standards.
- E. A list of approved suppliers per facility shall be kept on file.
- F. Raw materials, packaging materials, and third-party services may only be sourced from approved suppliers. An emergency plan for the acceptance of goods or services from a non-approved supplier which includes risk assessment shall also be in place.
- G. All approved supplier emergency contacts shall be kept on file for immediate access to supplier facility management teams.
- H. All raw material and packaging materials shall meet the applicable regulatory guidelines pertaining to the material.

#### **Case Label Requirements**

For product identification purposes, the label shall contain:

- Supplier business name
- Manufacturer address and business name
- Commercial and technical name of products
- List of ingredients in decreasing order of concentration
- Allergen Declaration
- Certification Symbols (Kosher, Halal), if applicable
- Recommended Storage Conditions
- Country of Manufacture
- Sub components Country of Manufacture
- Date of manufacture and date of expiration of product
- Product Lot number
- EST # (if applicable)
- Special claims (if applicable)

#### **Pallet Requirements**

- A. Supplier shall have a pallet management program that includes inspection for damage, infestation, mold, splinters, etc.
- B. Grade A pallets should be used and if Supplier is not able to comply with this requirement, Supplier shall be required to provide alternate measures to ensure food safety of ingredients/finished products on the pallets for evaluation.
- C. The use of slip sheets is required for finished product pallets.
- D. Pallets imported to the United State shall be heat treated and be stamped with HT.

#### Weight Control

- A. Procedures shall be documented and implemented to assure that the stated weight, volume, or count claim on the package correctly states the contents in accordance with regulations and/or guidelines appropriate to the country or region of the intended sale of the product.
- B. In no case shall packages which are outside of allowable regulatory or customer limits or guideline be shipped. Packages not meeting requirements shall be reworked or discarded.
- C. All equipment used to check weights, volumes and/ or count shall be calibrated regularly.

## HACCP/HARPC

Each manufacturing facility shall have a fully implemented and effective HACCP/HARPC, that complies with Schwan's and applicable regulatory requirements. The HACCP/HARPC shall be verified annually or when any material changes occur.

- A. The facility shall have a documented food safety and quality manual detailing facility specific policies, methods, and programs. Required documentation shall be controlled and available upon request.
- B. The facility shall have an established food safety team and be comprised of a cross-functional group of subject-matter experts from all appropriate facility departments who are trained in HACCP/HARPC and have relevant knowledge of the products and processes.
- C. A list of current prerequisite programs shall be established, maintained and available for review including but not limited to: training, purchasing, maintenance, sanitation, pest control, storage, transportation, and allergen controls.
- D. A process flow diagram shall be completed.
- E. A hazard analysis shall be completed that evaluates and identifies potential hazards that are reasonably expected to occur at each step of the flow diagram. Control measures shall be put into place to prevent or eliminate identified hazards.
- F. A hazard analysis shall be completed for raw materials including packaging (primary, secondary, and tertiary).
- G. Monitoring, verification, and validation (as applicable) activities shall be in place for critical control points and/or preventive controls.
- H. Product descriptions shall be on file for each product or product category. Product descriptions shall include shelf life, storage and transportation, ingredients, packaging and intended customer.
- I. The facility shall have a minimum of one qualified individual such as PCQI.
- J. Documented employee education on the facility food-safety plan is required for new hires and all existing employees on an annual basis. Records of required training shall be available for review by Schwan's during facility audits.

#### **Non -Conforming Product Control**

Supplier shall have a documented program in place to prevent unintended use in production or the shipment of non-conforming Schwan's product.

- A. Non-conforming product control programs shall at minimum include the following aspects:
  - i. Facilities shall not accept, store, process, package, or ship product or packaging material that fails to meet Schwan's specification requirements.
  - ii. There shall be a protocol in place to transfer any product that is found to be out of compliance with the specification on a "Hold" status.
  - iii. Documentation for release of non-conforming product shall include risk assessment, pictures, confirmation testing results, and written approval of release from Schwan's Corporate FSQ.
  - iv. Documentation for destruction of non-conforming product shall include pictures of the product in the destruction process and a formal list of product description, code date, reason for destruction, and volume (lbs, cases, etc.).
  - v. Facilities shall have a documented procedure for handling shelf life extensions which includes risk assessment, shelf life study, and approval by Schwan's Corporate FSQ.

## **Complaint Management**

Supplier shall have a program in place to manage and trend consumer and customer complaints; as well as, respond with corrective actions at the request of Schwan's.

- A. Program shall at a minimum include:
  - i. All complaints shall be recorded for review, at Schwan's request, including the details of investigation and corrective action(s).
  - ii. Continuous improvement strategies shall be utilized with the goal to eliminate all product complaints.
  - iii. Product-complaint elimination responsibility shall be assigned to a directly responsible individual or group at the production facility.
  - iv. Foreign material (ex. Bone, Metal, Glass or Hard Plastic), alleged illness, and other food safety related complaints (ex. Mislabeling, Potential product Adulteration or Tampering) are to be given urgent status. Efforts shall be made to provide a thorough investigation and communicate critical findings within 48 hours of the initial received report.
  - v. Trending information for a customer complaint log is to be reviewed at a set frequency by appropriate members of the management team to drive improvement and evaluate the effectiveness of corrective actions.

## Traceability

The facility shall maintain a current documented product traceability and recall program through all stages of the process beginning with material receiving through product shipment. The company shall be able to complete this test within 4 hours.

- A. The recall and traceability program minimum requirements shall include:
  - i. The facility shall have an established recall team. Recall team contact information shall be provided to Schwan's Corporate FSQ.
  - ii. All finished products, ingredients, packaging components, and processing aids shall have unique identifying numbers that can be tracked from receiving through all stages of processing including customer shipments to ensure full traceability.
  - iii. Production records shall include the following key information to ensure that traceability for each production run is easily identifiable:
    - 1) Finished product name and identification number.
    - 2) Ingredient, packaging, and processing aid identification number.
    - 3) Quantities of ingredients, packaging, and processing aids utilized.
    - 4) Date of production and use for all production components.
    - 5) Date of component receipt.
    - 6) Date and destination of finished product shipments.
  - iv. Traceability shall be established at all stages of the manufacturing process including raw-material receiving, raw-material storage, in-process materials, post-production storage and shipping.
  - v. Traceability records shall be kept and maintained in such a manner that they are accessible in a timely fashion.
  - vi. The recall program shall always be operable.
- B. The program shall be tested, on a frequency no less than twice annually, for Schwan's product.
  - i. Required to cover finished product, packaging, and ingredients
  - ii. Required to identify and capture 100% +/- 2% of product or materials affected within four (4) hours.
  - iii. Results shall be reviewed by the food safety team and appropriate corrective actions applied for any failure to capture 100% +/- 2% of affected product or material within the four (4) hour window.
- C. The facility shall meet regulatory requirements related to traceability and recall/withdrawal.

#### **Crisis Management**

Suppliers shall have a documented crisis management plan, that includes a product recall/withdrawal procedure. The plan shall include the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) that can impact the facility's ability to deliver safe food, be documented by senior management outlining the methods and responsibility the facility shall implement to cope with such a business crisis, current contact information and be tested at a minimum annually. Schwan's shall be contacted promptly in the event of a product recall/withdrawal or other crisis, which may affect Schwan's product.

- A. The crisis management plan shall include at least the following:
  - i. Communication plan
  - ii. Documented contingency plan
  - iii. The nomination and training of a crisis management team
  - iv. Implementation requirements involved in crisis management
  - v. Checklist of required activities including an assessment of impact to product/facility/equipment
  - vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers
  - vii. Root cause analysis and corrective actions post incident

## **Date Coding**

All date coding information shall be clear and legible.

## **Material Handling Program**

The facility shall have a written receiving, storage, and shipping program, to comply with Schwan's specification and requirements, to assure the food safety and quality of materials and Schwan's products.

- A. The facility shall have established goods-receiving protocols to include, but not limited to:
  - A protocol shall be in place to outline requirements of incoming transport vehicles including cleanliness, trailer seal verification, trailer inspection, mixed load restrictions, and traileridentification tracking.
  - ii. A documented trailer seal program failure protocol shall be available to manage risk assessment of missing, mislabeled, or broken trailer seal on incoming transportation vehicles. All findings shall be documented.
  - iii. Incoming transport vehicles shall be inspected for proper temperature requirements based on material specifications. Documentation of transport vehicle temperature tracking is required.
  - iv. Conditions identified as not meeting established requirements shall result in notification to designated personnel for risk assessment and disposition decision.
- B. Documented procedures shall be in place to assure that the storage of finished product ingredients, work in progress, or packaging materials is such to maintain food safety and quality.
- C. Temperature controlled storage shall have a documented monitoring program assigned to ensure that acceptable conditions have been maintained for the duration of storage.
  - i. Where temperature control is required, documentation shall be provided showing the storage area meets product specifications for proper storage.
  - ii. Storage outside of the facility, where materials may be exposed to the environment, shall not be acceptable.
  - iii. Storage areas shall follow industry best practice GMPs. Product shall not be stored on the floor; there shall be an 18-inch border along the exterior of all storage areas; and the storage area itself shall provide protection from contamination.
  - iv. Specific storage plans for sensitive ingredients shall be established to prevent cross-contamination. Examples of products with special ingredients include those containing allergens or items with

- special claims (e.g. organic, gluten free).
- v. A first in, first out (FIFO) inventory system is required for all stored materials. Any variance to the FIFO system shall be justified through risk assessment.
- vi. Storage areas shall be maintained in a clean and sanitary manner with documented cleaning records.
- vii. Storage materials shall not present foreign-object risks. Pallet and other storage-area infrastructure inspections are required.
- viii. Materials that are damaged or otherwise inappropriate for use shall be clearly identified to prevent accidental usage and placed on "Hold" status until such time the material is returned to the supplier or destroyed.
- D. The following procedures shall be in place to ensure outgoing shipments meet hygienic expectations:
  - i. Each facility shall have a documented trailer inspection program with established verification checks and thresholds for acceptability.
  - ii. An established mechanism to confirm correct product and quantity of shipments.
  - iii. Documented processes to maintain quality standards for frozen or refrigerated product shall be in place. Included shall be a procedure for verification and documentation of temperature setting of the trailer or container based on product specifications. Temperature verification shall be documented prior to, during, and at the end of the loading process.
  - iv. Loads shall be secured so they do not shift during the transportation process.
  - v. A trailer seal program that is compliant to Schwan's requirements shall be utilized for the shipping of all Schwan's products. Product shipped to Schwan's shall have a seal or acceptable locking device on all trailer/vehicle openings, i.e. hatches, inspection doors, main doors, etc. The seal number shall match the number on the bill of lading (BOL). Less Than Truck Loads (LTLs) shall be locked.
  - vi. Supplier or Supplier's Carrier will be held liable for any load "rejected" due to non-compliance with Schwan's trailer seal expectations.
  - vii. Shipping materials shall not present foreign object risks. Pallet inspections are required.
- E. International suppliers shall have and provide an FDA/USDA registration number to Schwan's. The number shall be maintained and provided to Schwan's on an annual basis. All international suppliers shall comply with the Foreign Supplier Verification Program (FSVP) requirements, as outlined in the FSMA, and make all necessary evidence of compliance available to Schwan's.
- F. Schwan's requires products received from supplier to have a minimum remaining shelf life at time of receipt:
  - i. Suppliers: Product shall have 50% shelf life remaining.
- G. Schwan's conducts an inspection upon receipt of materials. Schwan's maintains the right to reject/not accept product within 72 hours of receipt and supplier shall be notified, if product is not accepted.
- H. A Certificate of Analysis (CoA), when required, shall be provided to Schwan's at time of receipt or prior to shipment, for each lot of product contained in the shipment. Each CoA shall include, at minimum:
  - i. Supplier's Name
  - ii. Manufacturing Facility Address
  - iii. Product Name
  - iv. Supplier Material Number
  - v. Lot Code
  - vi. Manufacture Date
  - vii. Expiration Date
  - viii. Schwan's Material Number
  - ix. Analytical and Microbiological Tests
    - 1) Test Results
    - 2) Test Method
  - x. Facility Quality Contact

Where the potential pathogen risk is mitigated by the supplier, CoA's shall minimally include pathogen indicator results.

## Food Defense

All facilities are required to have an implemented food defense program and annual vulnerability assessment to meet all regulatory, state, and local requirements.

- A. The food defense program is required to identify defense vulnerabilities within the facility of operation.
  - i. Strategies to mitigate the risk of the identified vulnerabilities is required as part of the food-defense program.
  - ii. Biosecurity measures are required to be in place to meet Schwan's standards for shipping and receiving sealed trailers, less than full truck load deliveries, facility visitor, and third-party contractor work.
  - iii. Verification auditing shall be conducted to ensure compliance to the facility food-defense program.
  - iv. Training shall be conducted for new hires along with refresher training for existing employees based on a set frequency.
- B. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA.
- C. Supplier approval shall include risk assessment for the potential of product substitution and product fraud as part of the supplier approval process.

## Allergen Management

The facility shall have an established system for the management of allergenic materials which identifies and eliminates cross-contact risk or labeling inaccuracies. Schwan's shall be made aware of all allergens utilized within a facility, even if not used on Schwan's specific production lines or products.

- A. Acceptable allergen control programs shall include, but are not limited to, the following processes:
  - i. Change control of allergen content for either ingredients or finished product is integrated into the food safety plan and reviewed by the food safety team prior to changes taking place.
  - ii. All new ingredients or products are to be reviewed by the food safety team for allergen risk prior to receiving new ingredients or making new products. Changes to allergen content within the facility shall be communicated to Schwan's prior to implementation.
  - iii. The allergen program shall include labeling guidelines for incoming raw materials, work in progress materials (WIP), and finished goods. The program shall clearly identify points where raw materials and labeling shall be verified as correct for usage as well as finished product label verification for accurate allergen content.
  - iv. Cross-contact risk mitigation steps shall include scheduling of allergen materials for production, segregation of equipment, tools, employees, and all other areas of risk. Utilization of color coding or full allergen labeling is required.
- B. All allergen control policies, procedure training, and validation/verification activities shall be reviewed at a set frequency by the food safety team or designee. Documentation of this review and any changes made is required.
  - i. Each facility, with applicable allergen risk, shall implement a sanitation validation process to ensure their cleaning program is effective for the removal of allergen materials from production equipment, areas, and tools. This validation shall be repeated when any process or sanitation changes are implemented. The validation shall be reviewed by Schwan's FSQ prior to approval.
  - ii. An annual effectiveness verification of allergen cleaning is also required for all lines and areas that produce Schwan's. This verification shall at a minimum include:
    - 1) Sanitation standard operating procedure (SSOP) accuracy audits
    - 2) Full review of monitoring activity (visual inspection, swabs, etc.)
    - 3) Review of training material for adequacy

- 4) Documentation of verification and food-safety team approval
- iii. All applicable employees shall receive allergen risk training followed by a knowledge check prior to working in an allergen risk area. Individuals shall refresh their training annually. All training shall be documented.
- C. The facility shall maintain a list of allergenic items or an allergen matrix.

## **Employee Training**

The facility shall ensure that all personnel performing work pertaining to food safety, legality and quality are competent to carry out their activity through training, work experience, or qualification.

- A. Training program minimum requirement shall include:
  - i. All applicable staff including new hires, temporary staff, or third-party contractors shall be properly trained prior to performing unsupervised work tasks.
  - ii. Personnel engaged in activities relating to critical control points or preventative controls shall go through a competency assessment prior to commencing work.
  - iii. The facility shall maintain a training matrix which clearly defines the required training for employees and 3<sup>rd</sup> party groups.
  - iv. Records of training shall be maintained, and training shall be completed by a qualified individual. Records shall be available for review and include date of training, individuals trained, name of trainer, knowledge verification and full training material.
  - v. Failures to correctly execute trained upon tasks by personnel shall result in a retraining of the individual or group.

# Good Manufacturing Practices (GMP)

Each approved facility shall have a written GMP policy for all of employees, visitors, and contractors handling product for Schwan's that shall comply with current Good Manufacturing Practices (cGMPs) established by laws, regulations, and internal requirements. Building, grounds, equipment and processes shall meet cGMP requirements. The policy shall be presented in the appropriate language for each individual, prior to entering the facility's production areas. The facility shall conduct a GMP Audit at minimum, once a month, and records shall be available for review. Staff facilities shall be sufficient to accommodate the required number of personnel. The facilities shall be maintained in good and sanitary condition.

## Personal Hygiene Practices

- A. Suppliers shall maintain personal hygiene standard designed to minimize the risk of product contamination from personnel. The Codex Alimentarius Commissions recommendation on personal hygiene shall be followed.
- B. Health screenings shall be in place for new and existing employees and visitors, where permitted. Procedures in place for managing illnesses and communicable diseases shall be established and communicated throughout the company.
- C. Individuals infected with, exposed to or are a carrier of a communicable disease shall not be allowed to enter an area where finished product, raw materials, product packaging, or equipment would be at risk for contamination. Individuals with open sores or boils shall not be allowed to contact product or product contact surfaces without adequate protection. A list of infectious disease symptoms and blood born pathogen risks shall be kept as part of the facility policy and trained up with appropriate staff.
- D. Jewelry, including watches, necklaces, rings, items with decorative stones, or visible piercings, is prohibited from processing or storage areas. Plain wedding bands may be deemed acceptable at the discretion of facility management. Medical alert necklaces and wrist bands are acceptable with daily reconciliation practices.

- E. Gum, smokeless tobacco, candies, etc., shall not be allowed in processing or storage areas.
- F. False fingernails, false eyelashes, excessive perfume/cologne, nail polish, or other personal items that could create risks shall not be allowed. Fingernail length shall not exceed a length that poses risk of harborage.
- G. Decorative tooth jewelry requires a single elastic-banded, dust-type mask or beard restraint shall be worn.
- H. Consumption of personal food and drink are allowed only in designated areas and shall not be allowed in processing or storage areas.
- Personal medication shall be managed under an existing plant program to ensure the risk of product contamination is eliminated.
- J. Smoking is permitted only in designated areas away from production and storage areas.

## Approved Clothing/Attire

- A. For anyone in the facility, personal clothing shall be clean and free from foreign object risk.
- B. Company provided clothing shall be clean and in good repair with replacements readily available in the event of soiling or damage so that uniforms/covers do not become a potential source for contamination.
- C. Company-provided work wear shall be color-coded for designated risk levels such as floor cleaning, ready to eat area work, or pre-lethality step designation.
- D. Exterior clothing shall fashion with snaps or ties instead of buttons. Exterior clothing shall be free of tears or frays that could present foreign-object risk.
- E. Footwear shall be designed to minimize risk of contamination. Footwear shall be constructed of non-absorbent material and have cleanable exterior surfaces. Footwear shall be kept in an acceptable level of cleanliness.
- F. A captive footwear program is required unless risk analysis indicates that additional mitigation steps are in place to fully manage cross-contamination risk.
- G. Work wear designated for specific areas shall be kept in those areas per facility procedures and policies.
- H. No items shall be stored in pockets above the waist.
- No clothing adorned with ornaments (i.e. sequins, beads, charms, etc.) shall be worn into production or storage areas.
- J. Hair restraints (including beard nets) shall be required to be worn in processing and storage areas. Hair restraints shall effectively contain all hair present.
- K. Hair restraints that become stretched, worn, or damaged and do not effectively contain all hair shall be replaced immediately.
- L. Highly visible and metal-detectable bandages shall be utilized along with a documented detection verification program.

#### **Hand Sanitization**

- A. The company shall provide sufficient hand washing facilities to comply with all federal, state, and local requirements as well as GFSI audit requirements.
- B. Hand washing facilities and signage shall be located where it is easy to monitor compliance with the local policy. Specifically, hand-washing facilities shall be located in all restrooms and within close proximity to all work areas that contain food, food contact surfaces, or exposed packaging material.
- C. Each hand wash facility shall be designated as "Hand Wash Only."
- D. Hand washing facilities shall be constructed in such a way as to eliminate the possibility of re-contamination after washing and drying.
- E. Hand wash supply water shall be 100 degrees F within 15 seconds.
- F. Proper hand washing procedure training shall be provided to all employees and new hires. This training also shall be a part of the visitor/outside-contractor training program.
- G. Personnel working in microbiologically sensitive areas shall wear latex-free gloves. All gloved hands shall be washed at the same cleaning frequency that hands are required.
- H. Employee hands are required to be washed at the following times:
  - i. Directly before exiting the bathroom.
  - ii. Upon entering the work area at the beginning of the shift.
  - iii. Prior to beginning work activity that involves direct food contact.
  - iv. When returning to the work area for any reason.

- v. Prior to putting gloves on.
- vi. Upon touching any non-sanitary material or surface (floor, nose, hair, etc.).
- vii. Any time the hands become soiled for any reason.
- I. Documentation of GMP training and knowledge verification with applicable groups shall be maintained.

#### Sanitary Design - Facility and Grounds

Facilities shall be designed and constructed following set sanitary design principles to ensure the production of materials is completed without undue risk.

- A. The facility shall be suitable in size and location and maintained in order to facilitate the production of safe and legal products.
- B. The facility shall have reasonably designed systems in place to prevent unlawful or malicious actions from affecting the products and premises.
- C. Facility utilities are required to be adequate to prevent areas of possible contamination risks such as condensation or direct exposure to non-food grade materials.
- D. The facility layout, flow of processes and movement of personnel shall provide adequate physical separation to prevent cross-contamination risk of foreign objects, or microbiological contaminants and cross-contact risk of allergens.
- E. The interior of the facility (floors, wall, drains, ceilings, lights, etc.) shall be of suitable condition and not present a hazard to the product.
- F. Exterior facility grounds shall be maintained to prevent pest infestation or attraction.
- G. Waste shall be adequately segregated and disposed of, in a manner, that prevents contamination of the product and the surrounding environment.
- H. The facility shall have available a record of sanitary design standards for the company and records of completed sanitary design assessments for the facility.

## Sanitary Design - Equipment and Utensils

- A. Equipment & utensils shall be designed to be effectively cleaned and does not create potential harborage.
- B. Product contact and adjacent equipment shall be constructed of appropriate materials that shall not breakdown creating foreign object or microbiological harborage risks and remain a fully cleanable surface.
- C. Equipment and utensils shall be suitable for the intended purpose and of hygienic design. They shall be properly maintained and cleaned to protect the product from contamination including allergen cross contact. Cleaned and sanitized equipment and utensils shall be stored in a manner that is protected from potential contamination and allergen cross contact.

#### Maintenance Quality & Food Safety

The manufacturing facility shall have a fully integrated preventative maintenance program to deter food safety risks and ensure the production of consistently high-quality product. The program must include:

- A. Preventative Maintenance (PM) programs shall exist to achieve consistent conformance to food safety, personal safety, and quality requirements.
  - i. A schedule of facility and equipment maintenance tasks shall exist and comply with federal, state, and local regulatory codes.
  - ii. Training of personnel to perform the maintenance PM shall be completed and documented.
  - iii. Documented training and knowledge check of maintenance personnel on sanitary standards and expectations is required.
  - iv. Foreign object elimination inspection shall be included in the PM procedure.
  - v. Records of all PM work and corrective actions shall be kept for tracking purposes.
  - vi. Programs shall be in place to ensure compliance to the PM program and be reviewed by appropriate management team members, on a set frequency.
- B. Requirements shall be in place to ensure quality during repair work.
  - i. A system shall be established to notify all applicable individuals that a repair is taking place or has

- taken place during or after production hours. This also applies to new equipment, plant construction, or other activities that could potentially lead to contamination of product, ingredients, equipment or packaging.
- ii. Programs are required for tool segregation and/or a validated tool cleaning program to ensure that any risk of cross contamination is properly managed. Documented training on the tool- management program is required.
- iii. Equipment or replacement parts brought to a production area shall be visibly clean and free from soil or corrosion that could act as a harborage point for contaminants.
- iv. After completion of work tasks, all tools and parts shall be accounted for. The area shall also be designated for appropriate cleaning prior to release of the area for further production. The release process shall have a documented cleaning and inspection step to assure no aspect of the program is missed.
- v. Cleaning after all repair work shall be completed by trained individuals and follow set sanitation standard operating procedures to ensure the area or equipment is properly returned to a sanitary condition.

#### Calibration

A documented calibration program and schedule shall be in place for measuring equipment.

- A. Equipment used to measure and monitor critical aspects of the production process shall be identified and managed through a calibration program. Equipment in the calibration program shall be compared against an applicable nationally or industry recognized standard at an appropriate frequency to demonstrate consistent accuracy.
- B. All manufacturing testing equipment used for food safety and quality testing shall be calibrated against nationally or industry recognized standards at established frequencies.
- C. Calibration testing shall be completed at levels common to the required in process testing.
- D. If the measuring or monitoring devices are found to be out of calibration, previous results shall be reviewed and verified for accuracy as part of a corrective action plan.
- E. All calibration records and verification of equipment, including corrective actions, shall be maintained.
- F. Calibration training shall be documented for those individuals designated to perform routine calibration verification activities.

#### Cleaning and Sanitation

The facility shall have a documented cleaning and validated sanitation program to ensure that all equipment, tools, and infrastructure are properly cleaned and do not pose risk of product contamination.

- A. A master sanitation plan is required for all production processes, production areas, equipment, and support areas. The plan shall include the following:
  - i. Master Sanitation Schedules (MSS) shall encompass all required non-routine cleaning programs in the facility
    - 1) SSOPs for proper completion of all MSS task are required
    - 2) Documentation of completion for all MSS tasks shall be in place to ensure program compliance
  - ii. Sanitation Standard Operating Procedures (SSOP)
    - 1) Personal Safety Requirements
    - 2) Cleaning Task Description (i.e. Equipment Name or Cleaning Circuit)
    - 3) Frequency of Cleaning
    - 4) Cleaning and/or sanitizing chemicals and appropriate concentration in volumes or ppm
    - 5) Cleaning Equipment to be Utilized
    - 6) Detailed Descriptions of Each Individual Cleaning Step
    - 7) Steps to assure contamination does not occur during the sanitation steps
    - 8) Prescribed verification of cleaning effectiveness activities
  - iii. Proper Cleaning Compound Usage

- iv. Documented Employee Training
  - 1) All employees involved in the sanitation process are fully trained and approved to perform the required cleaning procedures. Training of the employees shall be conducted prior to performing the cleaning tasks and repeated at a regular frequency with documentation.
- v. Cleaning Effectiveness Checks
- vi. Proper Chemical and Equipment Storage
- vii. Cleaning and monitoring trends are reviewed by the food safety team or appropriate members of the management team at set intervals.
- viii. A fully developed environmental monitoring program (EMP) is required to serve as a verification tool of sanitation effectiveness.
- B. The facility shall perform pre-operation inspections, verify and monitor cleaning and sanitation results, and implement corrective action plan for deficiencies.
  - i. Shall be performed by trained individuals and formal pre-operational inspection training records and knowledge verification shall be available for review
  - ii. Corrective actions taken based on failed pre-operational inspections shall be documented for review
  - iii. Repeat failures to meet acceptance criteria shall result in formal procedure review by the management team followed by validation of new or modified procedures. Three failures are the recommended threshold to activate review and validation processes
  - iv. Acceptable forms of routine cleaning effectiveness verification include visual inspection and routine ATP or micro indicator testing
  - v. CIP and cleaning documentation review is to be conducted following each sanitation cycle. Reviews shall include, but are not limited to: CIP charts, chemical concentration checks, COP charts, cleaning checklist and preoperational inspection
- C. Cleaning equipment shall be properly designed and suitable for the intended purpose. It shall be stored in a clean and hygienic manner to prevent contamination.
- D. Cleaning procedure shall be validated and reviewed annually. The procedures shall be revalidated when changes occur.
- E. Sanitation good manufacturing practices are required throughout the production facility for all sanitation related activities.
  - i. The appropriate cleaning program shall be prescribed for each area of the production facility to ensure maximum effectiveness of cleaning and the prevention of contamination risks.
    - 1) Dry Cleaning
    - 2) Wet Cleaning
    - 3) CIP/COP
    - 4) Manual Teardown and Clean
  - ii. Processing equipment is kept in sanitary condition without hollow bodies, dead ends, or areas inaccessible to reach for effective sanitation.
  - iii. The facility has programs in place to ensure cleaning chemicals do not contaminate products through approved usage and adherence to prescribed chemical concentrations.
  - iv. Chemicals are labeled appropriately and stored in acceptable containers.
  - v. Chemicals are stored in a locked and restricted access area, separate from processing rooms including non-food grade cleaning and lubricant compounds. Chemicals are not allowed on the production floor at time of product manufacture.
  - vi. Chemical supplier documentation is available to confirm that the chemicals used for cleaning are appropriate for their current usage in the cleaning program and meet all local, state, and federal regulations.
  - vii. Chemical usage personal protective equipment is properly stored to assure they do not become a potential source of contamination.
  - viii. Follow proper procedures with cleaning tools to prevent them from being a potential source of contamination:

- 1) All tools shall be stored properly when not in use (e.g. not on the floor)
- 2) Mops, squeegees, scrapers, or other tools shall not have wooden components
- 3) Handles that are hollow and allow for liquid or debris entry shall not be used
- 4) Color coding shall be used to segregate cleaning tools when facility zoning includes ready to eat (RTE) and non-ready to eat (NRTE)
- Clean-in-place (CIP) and clean-out-of-place (COP) systems are managed to ensure proper function and effectiveness.
  - i. All CIP/COP functions shall have a written SSOP that outlines the proper processing steps required to successfully complete each cleaning cycle.
  - ii. All employees performing CIP/COP functions shall receive documented training on the established CIP/COP SSOPs.
  - iii. Each CIP/COP function shall have set documented operating parameters that have limited access for modification.
  - iv. Any change to operation parameters of a CIP/COP system shall be approved by authorized individuals and the effectiveness of that change shall be verified and documented.
  - v. Routine verification of CIP/COP systems shall be conducted on a regular frequency to assure optimal cleaning function.
  - vi. Regular CIP/COP component calibration programs shall be implemented to ensure proper operation of the systems (e.g. flow meters, level sensors, thermometers, etc.)

#### **Chemical Control**

All chemicals used at the facility shall be purchased, labeled, stored and used in compliance with all applicable laws, regulations, and internal facility requirements. Each facility shall have a written chemical approval and management program. Chemicals shall be stored appropriately to prevent contamination. Safety Data Sheets ("SDS") shall be on file for all chemicals used at the facility.

#### Pest Management

The facility shall have a documented pest management process to prevent and eliminate pests. The facility shall have resources available to rapidly respond to any issues, which occur to prevent the risk to product.

- Facility pest control programs are required to have the following minimum requirements:
  - A fully trained and licensed individual from the facility or a licensed third-party pest control officer shall be designated as the directly responsible individual (DRI) for the pest control program at the facility.
  - ii. Schedules of facility inspection for infrastructure condition, pest activity, and pest control device condition shall be in place.
  - iii. Monitoring records and trending data shall be kept. All records and trends shall be reviewed by appropriate individuals at a set frequency.
  - All findings from routine or non-routine pest control-related inspections shall have root-cause iν. analysis completed and corrective actions applied. Records of both root-cause analysis and corrective actions shall be available as part of the pest control program review.
  - ٧. A map of all pest devices shall be in place at the facility. The map is required to be updated with any location or device type modification. Annual review of the device map is required.
  - vi. Pesticides shall only be applied by properly trained and authorized personnel.
  - Rodenticides are only allowed on the exterior facility. Gel or block form rodenticides are vii. approved for use while powder or granular forms are not allowed.
  - viii. All pest control-related chemicals shall be properly labeled, stored per product instructions and have restricted access to only authorized individuals. Safety Data Sheets for all pest control chemicals shall be kept on site.
- Pest control program records shall be in place as assurance that the program conforms to all applicable 20

regulatory, state, and local laws.

- i. The directly responsible individual (DRI) credentials, license, and training must be kept on file as part of the program documentation.
- ii. Pesticide use records for the previous 12 months are required to be accessible.
- iii. In the case of a third-party Pest Control Operator, the service agreement and insurance certificate shall be included as part of the pest control program.

## **Environmental Monitoring**

The facility shall have a risk based environmental monitoring program (EMP) in place to monitor and control pathogens and indicator organisms. Schwan's shall be allowed to review the environmental monitoring program prior to approval. A risk assessment demonstrating that full control is attained through other factors is required for any facility that does not employ an EMP.

- A. The EMP shall identify and test for the presence of all pathogens that are appropriate for the facility environment and risk factors, i.e. *Salmonella spp., Listeria spp., E. coli*.
- B. The environmental testing program shall feature multiple zones to fully address the risk of pathogen presence across all areas of the facility. Risk assessment of the process and facility shall dictate which zones are tested, how frequently testing is performed, and the number of sites sampled.
  - i. Zone 1 Product contact surfaces or directly above/adjacent surfaces to product or product contact surfaces.
  - ii. Zone 2 Surfaces below equipment or surfaces below but somewhat adjacent to product or product contact surfaces.
  - iii. Zone 3 Floors, walls, or other surfaces that are not above or adjacent to product or product contact surfaces including drains or other floor fixtures.
  - iv. Zone 4 Non production areas such as hallways, welfare areas, plant entrances, etc.
- C. Facilities shall have a set frequency of testing established sites or areas based on the operational risk of the process and facility. Industry best practices also include rotations for time of day and days of the week for site sampling.
- D. The facility shall conduct a full investigation into root cause for all positive findings. Documented corrective action shall be applied to all positive findings along with verification testing to ensure that the corrective action was effective.
- E. The log of positive test results, corrective actions, and verification of effectiveness testing results shall be reviewed by the appropriate members of the management team at a set frequency to identify trends and ensure the appropriate level of response is given to each finding.
- F. Repeat EMP testing failures require documented escalation of corrective action to appropriately address findings. Seek and destroy strategies shall be implemented to eliminate all risk of potential cross contamination.

## Microbiological Testing

The facility shall operate under a documented microbiological testing program by qualified means to ensure food safety and specification compliance.

- A. Microbiological testing shall be conducted by an approved laboratory and follow industry recognized methods as outlined in the product specification.
  - i. Approved laboratories shall be accredited for the required testing by a nationally recognized accreditation body or be enrolled in a nationally recognized proficiency testing program with acceptable documented results for all applicable testing.
  - ii. The required testing method shall be designated within the product specification. Any deviation in a specification required testing method shall be approved by Schwan's Corporate FSQ.
  - iii. Any changes to testing protocols, frequency, acceptance criteria or other modification shall be approved by Schwan's Corporate FSQ.

- iv. Microbiological testing plans shall include sampling that represents the entire lot of production including start up and shutdown times.
- B. Pathogen testing shall be conducted in an approved laboratory facility that is fully segregated from the production facility. Pathogen laboratories shall also have appropriate programs in place to manage cross-contamination risks.
- C. Pathogen testing performed on finished products, product contact surfaces, product contact packaging, or ingredients shall follow an approved hold and test procedure.
  - i. All material lots involved in testing or potentially linked to tested materials shall be placed on hold status and under full control of the facility or company for the duration of the testing cycle.
  - ii. Pathogen tested material shall not be released for shipment to Schwan's until all test results are received and reviewed as acceptable.
  - iii. Ingredient and product contact pathogen testing shall be conducted with the knowledge of the ingredient or product contact packaging supplier and shall include only lots that have not been previously utilized for the production of Schwan's products.
- D. Any product or material that receives test results that do not comply with product specifications shall be held from shipment to Schwan's. Notification of the non-compliance shall be made to Schwan's Corporate FSQ for disposition guidance.

## **Good Laboratory Practices and Testing**

- A. Programs shall be in place to ensure reliability of laboratory results for testing done on product or material produced for Schwan's. Schwan's shall be allowed to review and approve testing completed on products and materials.
- B. Unless agreed to in writing, suppliers shall not ship product with test results pending.
- C. Controls shall be in place to prevent potential contamination of product by laboratory personnel or laboratory reagents.
- D. Where the potential raw material pathogen risk is mitigated by the supplier, at minimum pathogen indicator test results shall be reported on the Certificate of Analysis (CoA) for each item lot shipment to Schwan's.

## **Waste Disposal**

Each manufacturing facility waste disposal shall be managed in accordance with legal requirements and completed in a way that prevents risk of contamination or pest attractant.

- A. Waste disposal control programs shall at a minimum include:
  - i. Where licensing is required for the disposal of waste, facilities shall utilize a licensed entity for waste removal and keep up-to-date licensing information on file at all times.
  - ii. Facility waste receptacles and tools shall be clearly labeled, and color coded to ensure cross-contamination risks are appropriately managed.
  - iii. Bulk waste containers shall be segregated within the layout of the facility to allow for handling that does not put other areas of the plant at risk of contamination.
  - iv. Facility traffic flows shall be maintained to limit potential exposure of product, materials, equipment, or personnel from waste collection or storage areas.
  - v. Waste collection tools, receptacles, and bulk collection areas shall be cleaned at a set frequency to prevent the risk of microbiological growth. The cleaning cycles shall be documented.
  - vi. Waste collection areas and receptacles shall be properly protected to prevent pest attractant.

# Water, Air, Ice and Gas

Water, air, ice, steam, and gas that come into contact with food product, food contact surfaces, or food packaging shall be safe and suitable for the intended use. They shall be monitored, and records shall show compliance with applicable law, regulations, and internal facility requirements.

## Foreign Material Prevention

The potential presence of foreign material shall be considered in all hazard analyses. All necessary steps shall be taken to prevent the introduction of foreign material into product and there shall be a documented policy to manage the risk of physical hazards and foreign materials (FM) at the facility as part of the applicable HACCP or HARPC food safety plan. Where applicable and/or available, technology options shall be used to detect foreign material.

- A. The foreign material prevention policy shall address metal, glass, hard plastic, soft plastic, gloves, belting, gaskets, or any other reasonably foreseeable material that could enter or be present in the product stream.
- B. An established method of tracking foreign material findings, both internally and from customer returns, shall be maintained for the facility. The log shall be reviewed by the applicable members of the management team at a set frequency to ensure trends are identified and proper corrective actions have been applied.
- C. Metal detection or X-ray shall be installed on lines where the risk-based, food safety plan identifies metal or other detectable material as a significant hazard that is not fully controlled by another process control function. Metal detection or X-ray units shall be installed at the farthest most possible point downstream in the manufacturing process to ensure all risk of contamination from the process can be controlled.
  - i. Each metal detection or x-ray system shall have a system validation to demonstrate the effectiveness to control the established foreign material risk.
  - ii. A documented verification programs shall be in place that details the procedures utilized to assure proper function prior to, after, and throughout the production run. Included shall be a verification testing procedure. Documented training for those individuals designated to perform the verification activities is required.
  - iii. A detailed procedure shall be in place for the handling of in process detection and rejections to assure noncompliant product is not added back to the product stream.
  - iv. For systems with a mechanical reject, a failure to either detect or reject must be considered a verification test failure.
- D. Metal control programs shall address the control of sharp metal tools including, but not limited to, equipment parts, knives, cutting blades, wires, needles, skewers, etc. Tools are required to be part of a loss reporting or set reconciliation program.
- E. When sifters, filters, or magnets are utilized to control foreign object hazard risks, a program is required to outline in-process verification testing or inspection along with documentation of results and findings. Appropriate corrective actions are required to be implemented and documented for all failures or findings.
- F. Bone elimination systems or steps are required for all protein grinding. A program shall be in place to detail inprocess monitoring as well as action thresholds and corrective actions. For areas processing whole muscle proteins in which bones are not a portion of the product, there shall be systems in place to aid in the detection and removal of bones. Examples include X-ray, lighted belts, dedicated and trained inspection personnel or other applicable steps. Documentation shall be available to prove that the program in place consistently prevents extraneous bone material from remaining in the product stream.
- G. Glass and brittle plastic materials shall be properly identified and documented within the facility. An established glass and brittle plastic control program shall be in place to manage foreign-material risk.
  - i. A glass and brittle plastic log shall be kept identifying each applicable material location within the production facility
  - ii. A written policy is required for the handling of glass or brittle plastic materials. Included shall be procedures for breakage and clean up, light-bulb changing, and use of glass containers anywhere in the facility.
  - iii. Glass and brittle plastic material audits shall be performed at a set frequency. All audits shall include confirmation of acceptability as well as any appropriate corrective actions applied to unacceptable findings.
  - iv. No unprotected glass (e.g. light bulbs or thermometers) shall be allowed in processing or warehouse areas.

- H. Foreign-object elimination responsibility shall be assigned to a directly responsible individual or group at the production facility.
  - i. Continuous improvement strategies shall be utilized with the goal to eliminate all foreign objects from the product stream.
  - ii. Foreign object prevention efforts and trending shall be reviewed by the facility food safety team on a set frequency.

## Plant Zoning

The facility shall have an established zoning plan to identify areas of elevated risk and prescribe appropriate controls to prevent cross contamination which shall be a part of the hazard analysis for the facility food-safety plan.

- A. The zoning plan shall be utilized as part of traffic flow planning including employee, visitors, product, ingredient, packaging, and waste streams to minimize potential cross contamination risk to product.
- B. Appropriate controls shall be in place at entry points to elevated risk areas from lower risk areas to mitigate risk of cross-contamination.

## Animal Welfare & Social Responsibility

Schwan's expects all livestock producers, handlers, and processors to provide safe and humane treatment to the livestock within their care. The obligation to provide the proper levels of care and husbandry to livestock is a basic expectation and requirement we place on our business partners, as it is considered an ethical obligation. This commitment is aligned with fundamental values expressed in the internationally acknowledged Five Freedoms of Animal Welfare.

- A. Animal welfare & social responsibility programs shall at a minimum include:
  - i. Freedom from hunger and thirst by ready access to fresh water and a diet to maintain full health and vigor.
  - ii. Freedom from discomfort by providing an appropriate environment including shelter and a comfortable resting area.
  - iii. Freedom from pain, injury, and disease by prevention or rapid diagnosis and treatment.
  - iv. Freedom to express (most) normal behavior by providing sufficient space, proper facilities and company of the animal's own kind.
  - v. Freedom from fear and distress by ensuring conditions and treatment which avoid mental suffering.
- B. Schwan's supports and is working with all partners to follow the fundamental nature of the 10 principles of Fair Trade as published by the WTO.
  - i. Creating opportunities for economically disadvantaged producers.
  - ii. Transparency and accountability.
  - iii. Fair trading practices.
  - iv. Payment of a fair price.
  - v. Ensuring no child labor and forced labor.
  - vi. Commitment to non-discrimination, gender-equity and women's economic empowerment, and freedom of association
  - vii. Ensuring good working conditions.
  - viii. Providing capacity building.
  - ix. Promoting fair trade.
  - x. Respect for the environment.
- C. Applicable suppliers are expected to have a written policy addressing animal welfare and social responsibility commitment. The written policy shall be signed by the appropriate level of management and available for review upon request.

# **Packaging Supplier**

All packaging materials supplied to Schwan's shall comply with all applicable laws, regulations, and Codes of Practices and Standards of the production country and the destination to which the materials will be delivered (both national and local requirements, as applicable).

#### **Packaging Manufacturing**

All food contact packaging materials shall be accompanied by a Letter of Guarantee (LOG) covering materials and conversion (e.g. inks, adhesives, coatings) and an FDA Letter of Compliance, whenever applicable, prior to the first material delivery.

Food Contact Packaging shall not be a source of biological (e.g. microbial), chemical or physical (e.g. foreign bodies) hazards. Suppliers shall demonstrate their ability to control food safety hazards in order to ensure that the packaged food is safe at the time of human consumption.

Packaging suppliers of materials with ingredient line information shall ensure that print runs items that are not mixed on a pallet.

#### Printed Material Management: Destruction or Recycling of Schwan's Labeled Packaging Material

The Supplier shall ensure that any discarded or recycled materials (including any scrap or waste) containing any Schwan's name, trademark or logo, or any other Schwan's identifying information, cannot be reused.

The supplier shall have a documented process for destruction and recycling of materials. When handled by a third-party company, responsibilities and methods for assuring the destruction of the packaging material shall be specified in contracts including the verification of destruction.

#### **Transfer of Constituents from Food Contact Material**

Packaging materials that come in direct contact with the product, either by design or by foreseeable use, are defined by Schwan's Food Contact Packaging. Under their normal or foreseeable conditions of use, materials shall not transfer their constituents, or release any antimicrobial agents, to foodstuffs in quantities that could endanger human health, cause an unacceptable change in the composition of the foodstuffs (color), or result in deterioration of the organoleptic (tainting, odor) characteristics thereof. This requirement applies to all materials and articles intended to be in contact with food, either by physical contact, by head space exchange, or by insufficient barrier, under actual, intended, or foreseeable conditions. The requirement encompasses safety and consumer acceptance during both storage and after opening (i.e., during the preparation and consumption phase).

The packaging material shall be tested under conditions related to the food type, time, and temperature that the packaged food is exposed during filling, processing, storage and preparation. The ingredients and composition of all packaging materials in a polymer shall comply with all legal safety requirements, in accordance

## A. Transfer of Constituents from Plastic Materials

Where no dedicated national food packaging legislation for plastic material exists, Schwan's requires compliance with Food and Drug Administration (FDA) (21 CFR 177), U.S. Department of Agriculture (USDA), U.S. Environmental Protection Agency (EPA) and state regulations. All corresponding raw data and documents shall be maintained and available.

For safety reasons, the residual monomer content in PVC shall not exceed 1 mg vinyl chloride per kg polymer. In addition, vinyl chloride shall not be detectable in food.

#### B. Constituents from Paper and Board Materials

Paper and board for direct food contact shall be of suitable microbiological quality. In the absence of applicable regulations, the following guidelines shall be followed: FDA's regulations in 21 CFR Part 176.

Films made of regenerated cellulose fibers shall be of food grade quality. In the absence of applicable regulations, the following references shall be followed: European regulation 2007/42/EC or U.S. 21 CFR Part 177.1200.

#### Metal in Contact with Packaging

For primary packaging intended for use with dairy products, there shall be no direct contact between the packaging and copper or any alloy containing copper. Suppliers shall take steps to ensure that primary packaging does not contact these compounds either directly or indirectly through regular machine wear.

#### **Recycled Post-Consumer Material**

Schwan's favors the use of recycled materials provided that strict requirements are established to ensure food safety and that quality and performance are not compromised. Schwan's does not permit post-consumer recycled materials used for primary packages to come in direct contact with food unless proper food safety parameters have been met. If compliance with food contact material regulations can be declared, Schwan's shall make an exception for glass, metal, and specific product applications when agreed to by your Schwan's Contracting Representative and included in Schwan's Packaging Specifications.

Food contact packaging material suppliers (except for those exclusively supplying glass and/or metal) shall have a system in place to notify Schwan's of any products or materials supplied to Schwan's that contain post-consumer usage recycled material.

If post-consumer recycled material is part of a multi-component primary packaging system, but is not in the layer where it contacts the food, the use of the post-consumer recycled material shall only be permitted subject to three requirements: (1) Schwan's shall be pre-notified; (2) the Food Additive/Migration status shall be ascertained with respect to the intended use; and (3) the material shall be identified as being recycled in the Schwan's Packaging Specifications.

#### **Odor and Taste Transfer Testing**

To fulfill legal requirements and to ensure consumer acceptance, food contact materials shall not change the organoleptic properties of the packed food. Food contact packaging materials supplied to Schwan's shall comply with odor and taste transfer testing.

#### **Residual Solvents**

Food contact packaging materials supplied to Schwan's shall comply with residual solvents, if applicable.

The total residual solvents in printed and converted materials shall be kept as low as possible. The solvent shall not exceed the legally acceptable limit according to ASTM F 1884-04 "Standard Test Method for Determining Residual Solvents in Packaging Materials.

#### **Printing Inks**

Printing inks applied to the non-food contact side of a packaging shall not transfer any residues of toxicological concern. The inks shall be of high purity to ensure that there is no migration of substances that have not been toxicologically evaluated and that there is no violation of any specific migration limit imposed for other materials.

Aromatic compounds (e.g., toluene, xylene) shall not be part of the formulation added to packaging materials during the production, printing or cleaning processes. However, traces below 0.5 mg/m² are considered 'aromatic' free. In the U.S., suppliers shall have an FDA regulatory approval letter on file for approved use of specific inks used for indirect

or direct product contact. For ink layers with direct food contact see the below.

#### **Printing in Direct Contact with Food**

When packaging materials are printed on the side that shall be in direct contact with food and no functional barrier is in place, only food grade colorants can be used. Colorants shall be approved for food use in the locations where the products are produced and may be delivered. In the U.S., inks used for direct product contact shall be FDA approved food grade colorants.

This requirement applies to printings on the inner side of a package (e.g. for promotions). It also applies to outside printed packages that could be taken into the mouth or placed in close or direct contact to an unpacked food (e.g., multi component packs that comprise of packaged and unpacked food).

#### Packaging Material Ingredients and Processing Aids Derived from Allergenic and Genetically Modified Sources

Materials derived from allergenic sources shall not be used (exception: oils derived from allergenic sources which have been refined, bleached and deodorized are allowed). Allergenic sources are defined in the Food Allergen Labeling and Consumer Protection Act of 2004(FALCPA).

Schwan's shall be notified about the use of rubber-based natural latex used in adhesives or other indirect potential contact applications and about the use of any materials derived from Genetically Modified (GM) sources.

## **Environmental Impact of Packaging**

All materials supplied to Schwan's shall comply with national environmental packaging and packaging waste regulations of the production location and destination location(s) where products shall be produced, used, transported and disposed. Suppliers shall consider source reduction and prevention, including an appropriate material delivery in terms of noise, urban congestion, transportation means, quantity and volume.

#### **Minimization of Heavy Metals**

The supplier shall certify, via a Letter of Guarantee (LOG), for all packaging materials that heavy metals are not introduced into Schwan's packages or packaging components

The supplier shall certify that packaging materials supplied to Schwan's or used for any Schwan's labeled products do not contain more than a combined total of 100 ppm by weight of the following heavy metals from any source: lead, mercury, cadmium and hexavalent chromium. The supplier shall conduct periodic monitoring of materials (including adhesives, labels, inks, dyes and stabilizers) to assure compliance with this policy.

#### **Undesired Substances**

Schwan's trusts and relies on safety assessments of internationally recognized food safety authorities such as FDA, EFSA and others. At the same time, it also respects consumer preferences, therefore, Schwan's shall be notified about any materials that contain ingredients of public attention in the food contact layer.

The use of Bisphenol A (BPA), phthalates, and intentionally added per- and polyfluoroalkyl substances (PFAS), in food packaging shall be avoided or if not possible, Schwan's shall be notified.

#### **Packaging Information/Specification Sheets**

For all packaging materials produced or shipped to the U.S. or Canada, Packaging Information and/or Specification Sheet shall be provided to Schwan's. This shall occur prior to Schwan's Packaging Specification development and purchase of material by Schwan's.

# Schwan's Safety and Quality Status Classifications

A Supplier shall be awarded one of the following statuses by Schwan's. Schwan's retains the right to change a Supplier's status at any time.

## Approved

Schwan's may use a supplier who is in "Approved" status.

To be in "Approved" status, the supplier shall comply with Schwan's standards and to remain in status, the supplier shall ensure that documentation is updated as required and they are continually meeting Schwan's standards.

#### Conditionally Approved

Schwan's may use a supplier that is "Conditionally Approved" with the requirements below:

- Verification that corrective action plan has been developed and mutually agreed upon timeline for close is in place.
- An acceptable plan is developed and implemented to mitigate any perceived risk
- Supplier Quality Survey & Document Request Form
- Bioengineered Ingredient Disclosure
- GFSI or 3<sup>rd</sup> party GMP & Food Safety Audit Certificates and Reports
- Specification Sheet
- Allergen Matrix
- Label Samples with USDA Establishment Number (Meat Suppliers Only)

## **Not Approved**

Schwan's shall not use a supplier who is in "Not approved" status. A Supplier who wishes to achieve an "Approved" status shall develop and implement with a corrective action plan.

Once reviewed and approved by Schwan's, verification shall be completed to ensure compliance, this may be in the form of an on-facility audit. Schwan's shall determine, based on the corrective action plan and verification, if the supplier is ready to be moved to "Approved" status.

#### Restricted

"Restricted Status" is a direct result of unresolved issues that may put Schwan's products at risk. Continued sourcing to Schwan's is allowed; however, no new volume or new products shall be considered. A Re-audit is needed, and strategies shall be re-evaluated at a predetermined interval. To be reevaluated as a supplier to Schwan's, the supplier shall develop and fully implement a corrective action plan. Schwan's shall review the supplier corrective action plan and verify effectiveness to ensure compliance. A facility audit may be required. For a probationary period of 3 months, no non-conformities are to be observed.

#### Disqualified

Schwan's shall not use a supplier who is in "Disqualified" status. A "disqualified" status reflects that a supplier has a severe gap in its food safety and quality programs and/or does not otherwise comply with Schwan's standards. Operations are suspended and materials are placed on hold. If a supplier wishes to return an "Approved" status they shall go through the Schwan's approval process again.

# **Supplier Ongoing Monitoring and Management**

Schwan's ongoing monitoring and management of suppliers has the following components:

Periodic audits and corrective action plans; supplier performance to food safety and quality requirements and triggering event management.

#### A. Audit

Schwan's audits, as appropriate, may require corrective and preventive action plans with closure due dates.

#### B. Monitoring Performance

Schwan's shall monitor supplier ongoing performance utilizing various methods. Schwan's shall advise each supplier of the methods and other information that is required for monitoring of the supplier. Some examples of documentation and other information that may be required are listed below:

- Microbiological testing results
- Contamination testing results
- Monthly reports on Key Performance Indicators
- Third-Party Audits
- Food Safety and Quality Questionnaire/Assessments
- Management of Change records
- Complaints
- Batch Records
- Process Control charts (Targets/Ranges)

#### **Continuous Improvement**

A. Supplier shall have processes in place to improve the effectiveness of internal food safety and quality programs. Measurements shall be in place to demonstrate the results.

## **Triggering Event Management**

A "Triggering Event" is an event or circumstance that might cause Schwan's to change the Food Safety and Quality status or another component of the management of the supplier. This may be a positive or negative event. Examples of triggering events include, but are not limited to, the following:

- Product Retrieval Incident
- Repeated failure to meeting specification
- Trends in Key Performance Indicators
- Audit Results
- Change in Regulations or Regulatory Enforcement
- Escalated Complaint

#### **Exceptions**

Exceptions to the program may be made on a case-by-case basis and as be authorized and allowed by Schwan's Food Safety and Quality VP's sole discretion.