Schwan's Company is committed to creating advocates for our brands and company by providing safe, high-quality, consistent food to consumers and customers.

- **Safe & Compliant**
- **Driving to Zero**
- **Consistent Value**

To accomplish this imperative, it is crucial that we partner with companies who share common values and goals.

The purpose of Schwan's Company's "Manufacturing Food Safety & Quality Expectation Manual" is to ensure all business partners are aligned to industry-leading practices and full regulatory compliance.

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1. *Facility Food Safety & Quality Approval*

All facilities producing finished products, ingredients, or packaging materials for Schwan's Company must be approved through Schwan's Food Safety & Quality Department.

A. The manufacturing facility will be requested to supply to following documentation for initial approval review:

i. Schwan's supplier information form (SIF).

ii. Schwan's supplier evaluation form (SEF).

iii. Global Food Safety Initiative (GFSI) qualifying audit certificate and corrective action log or a Schwan's second-party audit. Schwan's qualifying audits include:

- BRC – British Retail Consortium (Global Standard for Food Safety)
- SQF – Safe Quality Foods (Level 2 or 3)
- Dutch HACCP
- IFS – International Food Standard
- FSSC 22000
- Schwan's Second-Party Audit

iv. HACCP or HARPC plan summary.
v. Plant layout and process-flow diagram.
vi. Product specification(s).
vii. Facility allergen profile to include all aspects of the operation and not just Schwan's specific products or lines.
viii. Further documentation may be required for the initial approval process.
ix. Approvals are based at the facility level, companywide approvals will not be granted.

B. Ongoing facility approval status is maintained through compliance to regulatory standards, annual qualifying food safety audit performance review, acceptable product performance, and Schwan's goal attainment.

C. Approved manufacturing facilities must allow Schwan's representatives on site for 2nd party auditing as requested with appropriate lead time and notice provided.

Schwan's Audit Expectations can be found as part of the vendor expectations manual: https://www.schwanscompany.com/pdf/supplier/expectations/supplier-expectations-manual.pdf

D. Any facility approval requirement deviations must be approved by Schwan's Director of Food Safety & Regulatory Affairs.

2. *Quality Policy & Management Support*

All manufacturing facilities will have a written quality policy that outlines a fundamental commitment to food safety, regulatory compliance, and product quality.

A. The quality policy will be communicated and clearly understood by all appropriate levels across the manufacturing facility and organization.

B. The quality policy must receive senior management review and approval at least annually.

C. Annual review and approval of the quality policy must be documented and available for review.

3. ***Food Safety Plan***

Each manufacturing facility must operate under a written food-safety plan, either HACCP or HARPC, as appropriate to that facility to mitigate food-safety risk. Risk assessments shall be in place for each step of the manufacturing process to identify all potential hazards and apply appropriate preventative action.

A. All food-safety plans will meet appropriate regulatory compliance standards.

B. Food-safety plans must 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.

C. A list of current prerequisite programs and supporting documentation should be available for review in conjunction with the established food safety plan to assure all areas of risk are identified and managed.

D. A facility food-safety team shall be established and be comprised of a cross-functional group of subject-matter experts from all appropriate facility departments. Food-safety team members will be knowledgeable in HACCP and/or HARPC with documented annual training on each specific food-safety plan for the facility.

E. 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 will be available for review by Schwan's during site audits.

4. ***Good Manufacturing Practices (GMP)***

Each approved facility will have a written GMP policy for all that enter the facility including employees, contractors, and visitors. The GMP policy will outline the required expectations of the facility while also meeting current regulatory and industry expectations. The policy must be presented in the appropriate language to each individual prior to them entering the facility production areas.

A. All personnel entering a production area of the facility are required to follow standing GMP requirements, including but not limited to:

i. Individuals infected with, exposed to or are a carrier of a communicable disease must 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 will not be allowed to contact product or product contact surfaces without adequate protection.

A list of infectious disease symptoms and blood born pathogen risks should be kept as part of the facility policy and trained up with appropriate staff.

ii. Consumption of personal food and drink are allowed only in designated areas and not in processing or storage areas.

iii. Gum, smokeless tobacco, candies, etc., are *not* allowed in processing or storage areas.

iv. 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.

v. False fingernails, false eyelashes, excessive perfume/cologne, nail polish, or other personal items that could create risks are not allowed. Fingernail length shall not exceed a length that poses risk of harborage.

vi. Decorative tooth jewelry requires a single elastic-banded, dust-type mask or beard restraint to be worn.

vii. Personal medication must be managed under an existing plant program to ensure the risk of product contamination is eliminated.

viii. Smoking is permitted only in designated areas away from production and storage areas.

B. Schwan's GMP policy minimum requirements for approved clothing and attire are:

i. For anyone in the facility, personal clothing is to be clean and free from foreign-object risk.

ii. Company provided clothing is to 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.

iii. Company-provided work wear should be color-coded for designated risk levels such as floor cleaning, ready to eat area work, or pre-lethality step designation.

iv. Exterior clothing should fashion with snaps or ties instead of buttons. Exterior clothing should also be free of tears or frays that could present foreign-object risk.

v. Footwear shall be designed to minimize risk of contamination. Footwear should be constructed of non-absorbent material and have cleanable exterior surfaces. Footwear must be kept in an acceptable level of cleanliness.

vi. A captive footwear program is required unless risk analysis indicates that additional mitigation steps are in place to fully manage cross-contamination risk.

vii. Work wear designated for specific areas should be kept in those areas per facility procedures and policies.

viii. No items shall be stored in pockets above the waist.

ix. No clothing adorned with ornaments (i.e. sequins, beads, charms, etc.) is to be worn into production or storage areas.

x. Hair restraints (including beard nets) are required to be worn in processing and storage areas. Hair restraints should effectively contain all hair present.

xi. Hair restraints that become stretched, worn, or damaged and do not effectively contain all hair should be replaced immediately.

xii. Highly visible and metal-detectable bandages will be utilized along with a documented detection verification program.

C. Schwan's GMP policy minimum requirements for hand sanitization are:

i. The company will provide sufficient hand-washing facilities to comply with all federal, state, and local requirements as well as GFSI audit requirements.

ii. Hand-washing facilities and signage shall be located where it is easy to monitor compliance with the local policy. Specifically, 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.

iii. Each hand wash facility shall be designated as "Hand Wash Only."

iv. Hand-washing facilities shall be constructed in such a way as to eliminate the possibility of re-contamination after washing and drying.

v. Hand-wash supply water will be 100 degrees F within 15 seconds.

vi. Proper hand-washing procedure training must be provided to all employees and new hires. This training also must be a part of the visitor/outside-contractor training program.

vii. Personnel working in microbiologically sensitive areas will wear latex-free gloves. All gloved hands must be washed at the same cleaning frequency that hands are required.

viii. Employee hands are required to be washed at the following times:

1. Directly before exiting the bathroom.
2. Upon entering the work area at the beginning of the shift.
3. Prior to beginning work activity that involves direct food contact.
4. When returning to the work area for any reason.
5. Prior to putting gloves on.
6. Upon touching any non-sanitary material or surface (floor, nose, hair, etc.).
7. Any time the hands become soiled for any reason.

D. Documentation of GMP training and knowledge verification with applicable groups will be maintained.

5. ***Employee Training***

The company shall ensure that all personnel performing work that affects product safety, legality, and quality are demonstrably competent to carry out their activity through training, work experience, or qualification.

A. Training program minimum requirement must 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. Where personnel are performing critical-control point or process preventative-control related tasks, those individuals will have been formally trained on the task and have received competency assessment.

iii. The facility shall maintain a training matrix which clearly defines the required training for employees and 3rd party groups.

iv. All training records shall be kept for possible review. Included in the records should be date of training, individuals trained, name of trainer, knowledge verification and full training material.

v. Failures to correctly execute trained upon tasks by personnel should result in a retraining of the individual or group.

6. ***Recall & Traceability Program***

The company shall have a written recall and traceability procedure that details the ability to trace product, packaging, work in progress, and processing aids one step back to the supplier through all stages of processing, and one step forward to customer shipment. The company must be able to complete this test within 4 hours.

A. The recall and traceability program minimum requirements will include:

i. The facility must have an established recall team. Recall team contact information must be provided to Schwan's Director of Food Safety and Regulatory.

ii. All finished products, ingredients, packaging components, and processing aids must have unique identifying numbers that can be tracked from receiving through all stages of processing and to customer shipment to ensure full traceability.

iii. Production records will 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 must 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 must be kept and maintained in such a manner that they are accessible in a timely fashion.

vi. The recall program is required to be operable at all times.

B. Mock recall exercises will be performed on a frequency no less than twice annually to ensure compliance to the recall and traceability procedure.

i. The mock recall exercises should be carried out by the recall team. The recall team should be comprised of subject matter experts and have multiple individuals identified as being able to lead the recall process.

ii. Mock recall exercises are required to cover finished product, packaging, and ingredients.

iii. Mock recalls are expected to identify and capture 100% +/- 2% of product or materials affected within four hours.

iv. The mock recall exercise and 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 materials within the four- hour window.

v. Mock recall exercises are required to be led by a minimum of two different individuals throughout the year to assure proper coverage of the function within the organization.

7. *Material Handling Program*

The facility shall have a written receiving, storage, and shipping program to assure the food-safety and quality of materials.

A. The facility will have established goods-receiving protocols to include, but not limited to:

i. All raw materials, packaging materials, and third-party services must be sourced from approved suppliers. The facility is required to keep an active log of approved suppliers for verification of source acceptability.

ii. All received materials shall be verified as meeting specification requirements through an established quality management program.

iii. A protocol will be in place to outline requirements of incoming transport vehicles including cleanliness, trailer-seal verification, trailer inspection, mixed load restrictions, and trailer-identification tracking.

iv. A documented trailer seal program failure protocol must be available to manage risk assessment of missing, mislabeled, or broken trailer seal on incoming transportation vehicles. All findings are required to be documented.

v. Incoming transport vehicles will be inspected for proper temperature requirements based on material specifications. Documentation of transport vehicle temperature tracking is required.

vi. Conditions identified as not meeting established requirements must result in notification to designated personnel for risk assessment and disposition decision.

B. Documented procedures will 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 must 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 must 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, is unacceptable at all times.

iii. Storage areas must follow industry best practice GMPs. Product is not allowed to be stored on the floor; there must be an 18-inch border along the exterior of all storage areas; and the storage area itself must provide protection from contamination.

iv. Specific storage plans for sensitive ingredients must be established in an effort 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 must be justified through risk assessment.

vi. Storage areas must be maintained in a clean and sanitary manner with documented cleaning records.

vii. Storage materials must not be allowed to 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 will 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 must be in place. Included must be a procedure for verification and documentation of temperature setting of the trailer or container based on product specifications. Temperature verification must be documented prior to, during, and at the end of the loading process.

iv. Loads must be secured so they do not shift during the transportation process.

v. A trailer seal-program that is compliant to Schwan's Company requirements will be utilized for the shipping of all Schwan's products.

vi. Shipping materials must not be allowed to present foreign-object risks. Pallet inspections are required.

8. ***Allergen Control***

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

A. Acceptable allergen control programs will 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 must be communicated to Schwan's prior to implementation.

iii. The allergen program will include labeling guidelines for incoming raw materials, work in progress materials (WIP), and finished goods. The program must clearly identify points where raw materials and labeling will be verified as correct for usage as well as finished product label verification for accurate allergen content.

iv. Cross-contamination risk mitigation steps must 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 must 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 must implement a sanitation-validation process to ensure their cleaning program is capable of removing allergen materials from production equipment, areas, and tools. This validation should be repeated when any process or sanitation changes are implemented.

ii. An annual effectiveness verification of allergen cleaning is also required for all lines and areas that produce Schwan's Company products. This verification will 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 must receive allergen-risk training followed by a knowledge check prior to working in an allergen-risk area. Individuals should refresh their training annually. All training must be documented.

9. ***Maintenance Quality & Food Safety***

The manufacturing facility will have a fully integrated 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 must exist and be in compliance with federal, state, and local regulatory codes.

ii. Training of personnel to perform the maintenance PM must 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 is to be included in the PM procedure.

v. Records of all PM work and corrective actions will be kept for tracking purposes.

vi. Programs are to be in place to ensure compliance to the PM program and be reviewed by appropriate management team members on a set frequency.

B. Requirements must 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 must 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 must be accounted for. The area must also be designated for appropriate cleaning prior to release of the area for further production. The release process should 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.

10. ***Sanitary Design***

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

A. Equipment will be designed so that it can be effectively cleaned and does not create potential harborage.

B. Product contact and adjacent equipment will be constructed of appropriate materials that will not breakdown creating foreign object or microbiological harborage risks and remain a fully cleanable surface.

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.

i. Plant structure and flow shall provide adequate physical separation to prevent cross-contamination risk of allergens, foreign objects, or microbiological contaminants.

ii. Exterior facility grounds shall be maintained to prevent pest infestation or attraction.

iii. The manufacturing facility must maintain the structural facilities and equipment in a way that prevents contamination risks.

iv. The facility will have available a record of sanitary-design standards for the company and records of completed sanitary-design assessments for the facility.

11. ***Sanitation Processes***

The facility will have a fully developed 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.

i. The facility sanitation program includes master sanitation schedules (MSS), sanitation standard operating procedures (SSOP), proper cleaning compound usage, documented employee training, cleaning effectiveness checks, and proper chemical and equipment storage.

ii. Cleaning and monitoring trends are reviewed by the food-safety team or appropriate members of the management team at set intervals. A fully developed environmental monitoring program (EMP) is required to serve as a verification tool of sanitation effectiveness.

B. MSS programs will encompass all required non-routine cleaning programs in the facility.

i. SSOPs for proper completion of all MSS task are required.

ii. Documentation of completion for all MSS tasks will be in place to ensure program compliance.

iii. MSS program effectiveness shall be verified and reviewed by applicable management team members at a set frequency. Documentation of the review should be available for review.

C. Documented SSOPs must exist for all cleaning tasks.

i. Included in each SSOP must be:
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 utilized.

5) Appropriate chemical strength ranges either in volumes or ppm.
6) Cleaning equipment to be utilized.
7) Detailed descriptions of each individual cleaning step.
8) Steps to assure contamination does not occur during the sanitation steps.
9) Prescribed verification of cleaning effectiveness activities.

ii. SSOPs are to be established for new equipment or areas prior to the beginning of use.

iii. SSOPs should be readily available to sanitation staff to reference, but treated as a controlled document that is unable to be modified by unauthorized individuals.

iv. SSOPs will be reviewed on a routine basis by appropriate members of the management team. Documentation of the SSOP review should be available for review.

D. Sanitation verification and validation steps shall be in place to ensure the effectiveness of the overall sanitation program as well as each sanitation cycle.

i. Preoperational inspection shall be performed by trained individuals on all applicable equipment and areas prior to use in production. Formal preoperational inspection training records and knowledge verification should be available for review.

ii. Corrective actions taken based on failed preoperational inspections must be documented for review.

iii. Repeat failures to meet acceptance criteria must 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 will include, but are not limited to: CIP charts, chemical concentration checks, COP charts, cleaning checklist and preoperational inspection.

E. Sanitation good manufacturing practices are required throughout the production facility for all sanitation related activities.

i. The appropriate cleaning program must 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. All employees involved in the sanitation process are fully trained and approved to perform the required cleaning procedures. Training of the employees should be conducted prior to performing the cleaning tasks and repeated at a regular frequency with documentation.

viii. Chemical usage personal protective equipment is properly stored to assure they do not become a potential source of contamination.

ix. Follow proper procedures with cleaning tools to prevent them from being a potential source of contamination:

1. All tools must be stored properly when not in use (e.g. not on the floor).
2. Mops, squeegees, scrapers, or other tools must not have wooden components.
3. Handles that are hollow and allow for liquid or debris entry will not be used.
4. Color coding will be used to segregate cleaning tools when facility zoning includes ready to eat (RTE) and non-ready to eat (NRTE).

F. Clean-in-place (CIP) and clean-out-of-place (COP) systems are managed to ensure proper function and effectiveness.

i. All CIP/COP functions are to have a written SSOP that outlines the proper processing steps required to successfully complete each cleaning cycle.

ii. All employees performing CIP/COP functions will receive documented training on the established CIP/COP SSOPs.

iii. Each CIP/COP function will have set documented operating parameters that have limited access for modification.

iv. Any change to operation parameters of a CIP/COP system must be approved by authorized individuals and the effectiveness of that change must be verified and documented.

v. Routine verification of CIP/COP systems will be conducted on a regular frequency to assure optimal cleaning function.

vi. Regular CIP/COP component calibration programs will be implemented to ensure proper operation of the systems (e.g. flow meters, level sensors, thermometers, etc.)

12. ***Foreign Material Prevention***

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.

A. The FM prevention policy will 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, will be maintained for the facility. The log must 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 will 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 must 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 must have a system validation to demonstrate the effectiveness to control the established foreign material risk.

ii. A documented verification program will be in place that details the procedures utilized to assure proper function prior to, after, and throughout the production run. Included must be a verification testing procedure. Documented training for those individuals designated to perform the verification activities is required.

iii. A detailed procedure will 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 will 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 must be in place to detail in-process 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 must 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 will 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 must be properly identified and documented within the facility. An established glass and brittle plastic control program will be in place to manage foreign-material risk.

i. A glass and brittle plastic log will 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 should 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 will be performed at a set frequency. All audits will 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) will be allowed in processing or warehouse areas.

H. Foreign-object elimination responsibility should 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 will be reviewed by the facility food safety team on a set frequency.

13. ***Zoning***

The facility shall have an established zoning plan to identify areas of elevated risk and prescribe appropriate controls to prevent cross contamination.

A. Zoning shall be a part of the hazard analysis for the facility food-safety plan.

i. The zoning plan will 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.

ii. Appropriate controls must be in place at entry points to elevated-risk areas from lower-risk areas to mitigate risk of cross contamination.

14. *Waste Disposal*

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 will at a minimum include:

i. Where licensing is required for the disposal of waste, facilities will 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 will be clearly labeled and color coded to ensure cross-contamination risks are appropriately managed.

iii. Bulk waste containers should 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 will be documented.

vi. Waste collection areas and receptacles will be properly protected to prevent pest attractant.

15. *Environmental Monitoring*

A pathogen environmental monitoring (EMP) program will be established to monitor and control the presence of pathogens within the facility environment. 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 will identify and test for the presence of all pathogens that are appropriate for the facility environment and risk factors, i.e. Salmonella, Listeria, E. coli.

B. The environmental-testing program must 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 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.

D. Facilities will 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.

E. The facility is required to conduct a full investigation into root cause for all positive findings. Documented corrective action will be applied to all positive findings along with verification testing to ensure that the corrective action was effective.

F. The log of positive test results, corrective actions, and verification of effectiveness testing results will 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.

G. Repeat EMP testing failures require documented escalation of corrective action to appropriately address findings. Seek and destroy strategies must be implemented to eliminate all risk of potential cross contamination.

16. ***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 will be conducted by an approved laboratory and follow industry recognized methods as outlined in the product specification.

i. Approved laboratories will 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 will be designated within the product specification. Any deviation in a specification-required testing method must be approved by Schwan's Company's FSQ team.

iii. Any changes to testing protocols, frequency, acceptance criteria or other modification must be approved by Schwan's FSQ team.

iv. Microbiological testing plans must include sampling that represents the entire lot of production including start up and shutdown times.

B. Pathogen testing will be conducted in an approved laboratory facility that is fully segregated from the production facility. Pathogen laboratories must 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 must follow an approved hold and test procedure.

i. All material lots involved in testing or potentially linked to tested materials must 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 must not be released for shipment to Schwan's Company until all test results are received and reviewed as acceptable.

iii. Ingredient and product contact pathogen testing should be conducted with the knowledge of the ingredient or product contact packaging supplier and should 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 will be held from shipment to Schwan's. Notification of the non-compliance must be made to Schwan's FSQ team for disposition guidance.

17. ***Non-Conforming Product Control***

The facility is required to have a protocol to control all non-conforming products so that unintended use in production or shipping does not take place.

A. Non-conforming product control programs shall at minimum include the following aspects:

i. Facilities must not accept, store, process, package, or ship product or packaging material that fails to meet 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 must include risk assessment, pictures, confirmation testing results, and written approval of release from Schwan's Company's corporate food safety & quality contacts.

iv. Documentation for destruction of non-conforming product must 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 must have a documented procedure for handling shelf life extensions which includes risk assessment, shelf life study, and approval by Schwan's Company corporate FSQ.

18. *Calibration*

Equipment used to measure and monitor critical aspects of the production process will be identified and managed through a calibration program. Equipment in the calibration program will be compared against an applicable nationally or industry recognized standard at an appropriate frequency to demonstrate consistent accuracy.

A. A written calibration program and schedule must be in place in all facilities.

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 should 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 must be reviewed and verified for accuracy as part of a corrective action plan.

E. All calibration records, including corrective actions, will be maintained.

F. Calibration training must be documented for those individuals designated to perform routine calibration verification activities.

19. *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.

A. The facility shall maintain an active document register which lists all current forms, procedures, policies, and other documents.

B. All documents will have an indicator of version, update date, and an individual responsible for the document.

C. A system will be in place for the replacement of existing documents when updated.

20. ***Internal Audit Program***

The facility will perform internal audits of those programs and practices which are designed to assure product quality, food safety, and regulatory compliance by industry.

A. A written procedure shall be in place to outline an internal audit program and requirements for the manufacturing facility.

i. The program will outline each area to be audited at a set frequency for the inspections.

ii. All audit results are to be reviewed by the appropriate members of the management team.

iii. Corrective action for all findings should be applied and documented along with task assignment to an appropriate directly responsible individual.

B. Minimum audit requirements must be set within the internal audit program.

i. Verification of compliance to GMP guidelines.

ii. Compliance to established quality system standards.

iii. Regulatory requirement compliance.

C. All areas of the facility must be included under the internal audit program, including production areas, maintenance areas, employee welfare areas, and facility exterior.

21. ***Change Management Program***

Facilities will have an implemented change management program to ensure that modifications to the facility, equipment, or processes are properly reviewed for food-safety-and-quality risk prior to the change implementation.

A. 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.

B. The food-safety team will provide guidance on requirements to ensure food-safety-and-quality risks are fully controlled throughout the process of all projects.

C. 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 but before production resumes.

D. Management of change risk assessments and project planning requires food-safety team review and approval.

E. **Any changes that would potentially affect the food safety or quality of Schwan's Company products must 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.

22. ***Quality Management***

Production facilities shall have programs and processes in place to ensure products are made to meet regulatory guidelines and Schwan's Company specifications at all times. Programs will provide verifications of compliance for incoming raw materials, in process materials, packaging components and finished products.

A. Specifications for finished products, raw materials, and packaging components must be accessible on site 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 Company production.

C. Raw material acceptance programs will 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. In process monitoring of critical attributes, product characteristics, and packaging conformance must be in place to ensure compliance to applicable regulatory guidelines and Schwan's specifications.

i. Process capability data must demonstrate that products achieve specification compliance at all times for labeling content, physical attributes, sensory descriptions, and packaging acceptability as outlined by Schwan's product specifications. Process-capability data must be available for review upon request.

ii. In process testing, plans must represent the entire run including start up, shutdown, and a maximum of every 60 minutes as part of the sampling set.

iii. In process compliance, data will be reviewed in duplicate by appropriate levels of management prior to product release for shipment. Any deviation to regulatory guidelines or Schwan's specifications must result in a product hold and notification to a Schwan's food safety & quality representative for a disposition decision.

iv. Statistical process control systems are preferred.

v. Packaging verification for lines producing over 100 pieces per minute must 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.

E. Finished product evaluations for Schwan's Company products are required to ensure full compliance to specification. Finished product evaluations will include verification of physical and sensory attributes and packaging conformity as described in the product specification.

i. A qualified team of individuals shall perform finished product evaluation. A minimum of two qualified individuals must conduct the finished product evaluation and approval.

ii. Product utilized for the finished product evaluation will represent the entirety of the production run. Minimum requirements include one sample from the beginning, end, and middle of the production run.

iii. Schwan's products shall be prepared per the packaging preparation instructions for product evaluation, as applicable.

iv. Finished product evaluations will be documented through written or digital records including descriptions of all findings and corrective actions. The addition of pictures is preferred. Product evaluation records should be available for review upon request.

v. Any abnormalities, packaging failures, or attributes that do not meet specification must result in a product hold and notification to a Schwan's food safety & quality representative for disposition decision.

23. ***Supplier Approval***

The company shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials or packaging to the safety, legality, and quality of final product are managed.

A. Minimum requirements of a supplier approval program will include:

i. 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 should also be in place.

ii. The supplier approval process will 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 end result of the risk analysis should apply a rating of risk associated with that raw material or packaging component.

iii. Risk levels applied to each raw material or packaging component should classify the required steps for acceptance of that material such as microbiological verification testing, certificate of analysis, certificate of compliance, or physical inspection.

iv. Approved suppliers will be approved based on location and not supplier companies as a whole. GFSI qualifying audit or appropriate third-party food-safety audit from each supplier location are to be reviewed and kept on file.

v. The company will 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.

vi. All approved supplier emergency contacts must be kept on file for immediate access to supplier facility management teams.

vii. All raw material and packaging materials must meet the applicable regulatory guidelines pertaining to that material for the production of food products.

24. ***Pest Control***

The production facility is required to have a fully integrated pest-control program in place for all areas of the facility and grounds.

A. Facility pest-control programs are required to have the following minimum requirements:

i. A fully trained and licensed individual from the facility or a licensed third-party pest-control officer must 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 must be in place.

iii. Monitoring records and trending data will be kept. All records and trends must be reviewed by appropriate individuals at a set frequency.

iv. All findings from routine or non-routine pest-control-related inspections must have root-cause analysis completed and corrective actions applied. Records of both root-cause analysis and corrective actions will be available as part of the pest-control program review.

v. A map of all pest devices must 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 may only be applied by properly trained and authorized personnel.

vii. Rodenticides are only allowed on the exterior facility. Gel or block form rodenticides are 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 must be kept on site.

B. Pest-control program records must in place as assurance that the program conforms to all applicable regulatory, state, and local laws.

i. The 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. SDS forms for all pest-related chemicals must be on file and available.

iv. In the case of a third party PCO, the service agreement and insurance certificate must be included as part of the pest control program.

25. ***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 site 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 Company standards for shipping and receiving sealed trailers, less than full truck load deliveries, site visitor, and third-party contractor work.

iii. Verification auditing must be conducted to ensure compliance to the site food-defense program.

iv. Training must 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 must include risk assessment for the potential of product substitution and product fraud as part of the supplier approval process.

26. *Regulatory Inspection*

The facility is required to have a written regulatory inspection protocol to ensure compliance with regulatory requirements and efficiently manage on-site visits.

A. Regulatory inspection programs shall include:

i. Qualified individuals from the facility staff will be designated to manage the regulatory inspection processes.

ii. In the event, a regulatory inspection includes sampling of product produced for Schwan's Company, the product will be placed on "Hold" status pending results of the required testing and Schwan's corporate food safety and quality staff will be notified within 24 hours.

iii. If a regulatory authority collects environmental samples, consideration must be given to how the testing could impact the acceptability of product produced for Schwan's. Product should be placed on "Hold" status and contact made with Schwan's corporate FSQ staff for further direction.

iv. Detailed records of all regulatory inspections, findings, and corrective actions will be kept on site.

27. *Complaint Program*

A customer-complaint program will be place to receive, trend, and manage complaints.

A. Company-complaint programs shall at a minimum include:

i. All complaints shall be recorded for review. The details of investigation and corrective action are to be documented.

ii. Continuous improvement strategies shall be utilized with the goal to eliminate all product complaints.

iii. Product-complaint elimination responsibility should be assigned to a directly responsible individual or group at the production facility.

iv. Foreign material, alleged illness, and other food-safety related complaints are to be given urgent status. Efforts will 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.

28. ***Animal Welfare & Social Responsibility***

Schwan's Company 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 or 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 or 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 Company 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.

Document Change Log

Date	Supersedes Date	Section #	Section Name	Page #
09-19-17	08-25-17	21	Management Of Change	24

Addition of notification requirement. All changes that could potentially alter the consumer experience are required to be communicated for Stage Gate consideration prior to change implementation.

Date	Supersedes Date	Section #	Section Name	Page #
9-19-17	8-25-17	22	Quality Management	25

Development of quality based monitoring expectations at the facility line level. Requirements defined for raw material, in process material, finished product, and packaging verification activities to assure compliance to specification and consumer expectations.

Date	Supersedes Date	Section #	Section Name	Page #

Date	Supersedes Date	Section #	Section Name	Page #
