Quality, GMPs & Food Safety Principles
Corporate Quality and Product Safety.... Our Commitment

As a global company, with production sites around the world, we commit ourselves to continuously improve our quality and food safety (Q&FS) programs within the entire supply chain together with our employees and customers.

The supply chain includes producing, handling, warehousing and distributing all Chr. Hansen’s products; including design, construction and maintenance of the facilities, processes and equipment.

The purpose of this brochure is to provide mandatory Chr. Hansen requirements and guidance on Quality, GMPs and Food Safety principles. These guiding principles are based on the Global Food Safety Initiative requirements as related to FSSC 22000, PAS 220, ISO 22000, Codex Alimentarius Food Hygiene, Basic Texts, FAMI-QS or GMP+ for Animal Health plus our customers’ and our own demands concerning food hygiene and food safety.

Each production and warehouse site must maintain local GMPs and Food Safety procedures which define how the plant/facility complies with the Chr. Hansen Corporate Q&FS standards as defined in this brochure. All facilities must comply with local regulations.
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Infrastructure

1.1. Layout of Premises and Workspace

Each production site must establish a program that monitors the external and internal building structure including floors, walls and ceilings. The program must include environment/vegetation controls, perimeter restrictions, parking lot maintenance, control of standing water and potential contaminations from the local environment (air, water, chemicals). The program must include temporary structures.

1.1.1 Exterior Controls
Each facility must maintain the building and building perimeter to avoid any potential for product contamination from the local environment.

1.1.2 Interior Layout
Each facility must maintain the walls, ceilings and floors to prevent potential contamination. Each facility must establish traffic patterns for product and personnel to minimize the potential for product contamination.

1.1.3 Laboratory Layout
All laboratories must be separated from production and must have restricted access. Microbiology laboratories must not open directly into production.

1.1.4 Temporary Structures
Prior to release for use, a risk assessment must be conducted, appropriate controls identified and applied.

References
ISO 22000:6.3, 7.2; PAS 220:4.0/5.0

1.2 Utilities

All production sites must have an established program for the handling and use of water, electricity/lighting, boilers/steam, gas and compressed air. The program must include the monitoring, maintenance and documentation.

1.2.1 Air Handling
Heating, ventilation and air conditioning, positive/negative pressure rooms, clean rooms*, filters, ventilation, testing of air, exterior air intake, etc. if applicable, must be monitored and recorded. All clean rooms where open product is handled must have positive pressure to avoid airborne contamination.

1.2.2 Water Usage
Potable and non-potable water usage must be monitored to minimize contamination risk. Potable water must be tested annually and comply with local regulation or WHO. Treated, chlorinated and deionized water must comply with local regulations regarding quality and microbiological requirements. Where applicable, back-flow preventors must be in place. Dead-end piping should be avoided, if in use, must be cleaned and monitored and must be included in the environmental program. Steam (culinary water) supply used for products or product surfaces must be potable and comply with local regulations regarding quality and micro-biological requirements.

1.2.3 Lighting
The lighting must be sufficient enough to maintain hygienic conditions. Fixtures must be protected to prevent breakage. Bulbs must be safety coated or non-breakable. Each facility must have a glass breakage procedure.

1.2.4 Gas/Compressed Air
Oil free compressors are preferred; if not applicable oil must be food grade** or oil should not come in contact with the air. The compressor systems must be maintained to prevent contamination per the Preventive Maintenance (PM) Program.

1.2.5 Boiler Chemicals
Boiler chemicals must be approved food-grade chemicals per local regulation. The chemicals must be stored separately; see section on chemical control.
Definitions

*Clean Room specifications:
1) Contaminants must not be introduced into the controlled environment from the outside.
2) The equipment within the controlled environment must not generate or otherwise give rise to contaminants (for example as a result of friction, chemical reactions, or biological processes).
3) Contaminants must not be allowed to accumulate in the controlled environment.
4) Existing contaminants must be eliminated to the greatest extent possible, and as rapidly as possible.
5) Some clean rooms are kept at a positive pressure so that if there are any leaks, air leaks out of the chamber instead of unfiltered air coming in. Limits and positive/negative pressure in the clean rooms are determined by the Food Safety Team.

**Food Grade: Safe for human consumption and must meet local regulation as defined by Corporate Regulatory.

References
ISO 22000: 7.2; PAS 220:6.0

1.3 New Equipment

All new equipment must be selected based on food grade requirements and performance. Validated sanitation procedures, preventive/corrective maintenance must be established for all new equipment prior to release to production. This includes measuring and monitoring equipment.

1.3.1 Equipment Design
Equipment must be of hygienic design with approved food contact surfaces*.

1.3.2 Sanitation
Sanitation procedures must be defined by either the manufacturer or per a sanitation validation program.

1.3.3 Preventive Main-tenance (PM)
A Preventive Maintenance (PM) Program must be established for all equipment; see Equipment Preventative Maintenance section (page 6).
1.3.4 Measuring and Monitoring Equipment

Equipment, including scales, that measures or monitors quality or food safety of related processes or products, including laboratory equipment, must have a documented validation, verification and/or calibration schedule established**. Scales must be calibrated at minimum annually or per local requirement. The frequency for re-validation and verification must be defined based on the equipment, use, and manufacturer recommended frequency.

1.3.5 New Equipment Release

The corporate new equipment release form must be used for release to production and filed with supporting equipment documentation.

Definitions

* Approved Food Contact Surfaces: Stainless steel, new and repairs, must be a minimum of 1.4404 for food grade steel; resin/plastic per EU and US regulations and corporate procedure; gaskets must be for food grade use; filters, fabric, coated metals must be for food grade use.

** Validation: Quality assurance process of establishing evidence that a product, service, or system accomplishes its intended requirements and documenting that a process or system meets its pre-determined specifications and quality attributes.

Verification: Quality control process that is used to evaluate whether a product, service, or system complies with regulations, specifications, or conditions imposed at the start of a development phase, scale-up, or production, including support departments.

Calibration: Calibration is accomplished by a formal comparison to a standard which is directly or indirectly related to national standards, international standards, or certified reference materials.

References

ISO 22000: 7.2, 8.3; PAS 220:8.0

1.4 Maintenance

All production sites must have an established Facility Preventive Maintenance Program. Each production site must have an established preventive/corrective maintenance program, temporary repairs procedure, reconciliation of tools/utensils and release to production.

1.4.1 Facility Preventive Maintenance

A Facility Preventive Maintenance (FPM) Program must be established for the maintenance of the building, exterior and interior, at a required frequency based on the facility, age and environmental conditions. A facility inspection must be conducted at least annually and corrective actions must be documented to support the FPM Program and food safety requirements.

1.4.2 Equipment Preventative Maintenance

An Equipment Preventive Maintenance (EPM) Program must be established for all food contact, monitoring and measuring equipment. An EPM Program, as defined by the manufacturer or maintenance/engineering department, must be established for all product related equipment that may have an impact on quality and food safety. The program must include frequency, replacement inventory requirements, release requirements for preventive and corrective maintenance and allowable temporary repairs based on the EPM criteria per equipment. The release must include a reconciliation of tools* used for the EPM.

1.4.3 Temporary Repairs

Temporary repairs must follow release-to-production criteria per equipment. Temporary repairs of the facility must follow release criteria. A description of the repair, a risk assessment and corrective action must be documented. The release must include a reconciliation of tools used for the repair.

1.4.4 Maintenance Personnel Training

Authorized maintenance personnel must be trained or licensed to perform in the maintenance and technical areas. Training records must be documented and available for review.

Definitions

*Reconciliation of tools: The maintenance responsible must account for all tools used during the PM or temporary repair of equipment, assure that no tools remain behind and all tools are returned to the appropriate maintenance storage location.

References

ISO 22000: 6.3, 6.4, 8.3; PAS 220: 8.0
Employee Awareness

2.1 Employee Awareness

Personnel performing work affecting the quality and food safety of our ingredients, finished products and packaging must have the appropriate combination of education, training and experience for their assigned tasks. All employees must be trained in GMPs and food safety.

2.1.1 GMPs/Behavior
To protect food ingredients from contamination, protective apparel such as head, face, hand, and arm coverings must be worn as appropriate to the duties performed. Plain prescription glasses and medic alert identification* are allowed. Jewelry, visible piercings and other loose items, including those in pockets above the waistline, must be removed (plain wedding bands are allowed). Only authorized personnel are allowed to enter those areas of the buildings and facilities designated as limited access areas. Each production employee must have access to a personal locker in a locker room. Employees must maintain separation of personal and work related clothing and items.

2.1.2 Personnel Hygiene/Health
Hand washing stations must be available in production areas, appropriate clothing/shoes must be worn, and designated smoking and/or eating areas must separate from production and storage areas, health assessments must be conducted due to location regulations. Personnel must practice good sanitation and health habits. Any person known or suspected to have an illness or open lesions that could impact food safety (by either medical examination or supervisory observation) must be excluded from direct contact with raw materials, packaging components, intermediates and finished products until the condition is corrected or determined by competent personnel not to jeopardize the safety or quality of the food ingredient.

2.1.3 Training and Testing for Competency
All production employees must be trained and tested annually on the following topics: Food Defense Employee Awareness**, GMPs, Food Safety, Hygienic (health & behavior) training. All training must be documented indicating employee name and date of training. Qualified individuals must provide training. Management must ensure that employees are trained at sufficient frequency to ensure that employees remain familiar with applicable principles, at minimum once per year.

Definitions
* Medic alert identification tag is a small emblem or tag worn on a bracelet, neck chain, or on the clothing bearing a message that the wearer has an important medical condition that might require immediate attention. The intention is to alert a paramedic, physician, emergency department personnel or other first responders of the condition even if the wearer is not conscious enough or old enough to explain.

** Food defense employee awareness includes training on the prevention of potential acts of bioterrorism, vandalism and sabotage.
Production Principles

3.1 Supply Management

All production sites must adhere to an established program for the selection and management of supply including direct materials, food contact materials, primary packaging and services. The program must include risk assessments, testing frequency, evaluation and audit frequency, hold and release procedures, and documentation supporting the program.

3.1.1 Selection/Approval
All raw materials, traded goods, packaging suppliers and toll manufacturers must be assessed and approved based on their ability to meet Chr. Hansen quality, food safety and Corporate Social Responsibility requirements and specifications.

3.1.2 Change Management
All new suppliers and toll manufacturers and/or new raw materials, traded goods and packaging must be documented and approved through the applicable system. The process must be maintained and monitored by the designated responsible.

3.1.3 Risk Assessment/Testing Frequency/Hold and Release
Risk assessment must be conducted for each raw material, traded goods, packaging based on process and application. The CoA/CoC must be verified against the specification prior to use. Based on the risk assessment the testing frequency is determined and the hold and release criteria defined.

3.1.4 Evaluation/Audit
All direct material suppliers (toll manufacturers, traded goods, raw materials and primary packaging) must be approved prior to supply or use and thereafter reevaluated at minimum every five years. All critical (high risk) direct material suppliers must be audited and approved prior to supply or use and thereafter re-approved based on audit every three years.

3.1.5 Documentation
Documentation required for approval, risk assessment, evaluation and/or audit of a direct material supplier must be maintained and renewed throughout the approval period of the supplier by the assigned responsible function.

3.1.6 Service Contractors
Services that may impact food safety must be approved, monitored and evaluated every three years. A contract/document must be signed accepting compliance to GMP and food safety requirements.

3.1.7 Conditional Approvals
Suppliers can only be conditionally approved for supply based on a documented risk assessment with maximum one year validity. All control measures mentioned in the risk assessment must be followed during the period of conditional approval.

References
ISO 22000: 4.1, 5.6, 7.2, 7.3, PAS 220: 9.0; FSSC 22000 (1)
3.2 Storage, Warehousing and Transportation

All production sites must have established procedures for receiving inspections, transportation requirements, appropriate storage temperatures, monitoring of temperature/humidity requirements by area, separation and labeling of non-conforming materials, stock rotation, designated chemical storage, sanitation, pest control and maintenance of warehouse equipment.

3.2.1 Receiving/Shipping Procedures
Documentation of receiving and shipping vehicle inspections must be retained; verification of temperature where required, tampering inspections, etc. Receiving documents (shipping paperwork) must be verified before unloading.

3.2.2 Storage
All raw materials must be stored according to manufacturer’s recommended storage conditions or based on an accepted risk assessment in order to maintain specified quality and food safety. All our products must be stored according to product specifications.

3.2.3 Warehouse Design, Maintenance and Controls
The warehouse or designated storage areas must be designed to allow for scheduled maintenance, cleaning, pest control and inspections. The storage temperatures, where appropriate, must be monitored and documented.

3.2.4 Outside Storage Areas
Outside storage must be protected against weather and infestation. Scheduled inspections must be conducted and documented.

3.2.5 Outsourced Storage
All outsourced storage areas and warehouses must follow the standard storage requirements as described above and must be audited for compliance prior to approval for storage and per the scheduled audit plan.

3.2.6 Transportation
All transportation companies must comply with local transportation regulations. Each company must sign a food safety agreement accepting our food safety requirements.

References
ISO 22000: 7.2, 7.3; PAS 220: 5.0, 9.0, 16.0; FSSC 22000 (1)
4.1 Waste Management

Each production site must have a waste management program that includes the identification, collection and removal of waste, including drains and drainage.

4.1.1 Waste Containers
All waste containers must be appropriately identified, constructed of material suitable for the waste material, closed when not in immediate use and stored appropriately in a designated location, e.g. hazardous waste (applies to production, production offices and laboratory).

4.1.2 Waste Removal
Waste removal from production areas must be performed daily. Storage of collected waste must be stored in a designated area for collective disposal. Removal and destruction must be carried out by an approved disposal contractor. Records of destruction shall be retained. Hazardous materials must be stored and secured prior to disposal.

4.1.3 Drains/Drainage
Waste drains must not pass over process lines unless properly protected, e.g. drip pans. Open waste drains must be of appropriate design for the location to avoid contamination and must not flow to a clean area.

References
ISO 22000: 7.2, 7.3; PAS 220:7.0

4.2 Chemical Control

Each production site must have a program for the purchase, storage and use of food grade and non-food grade chemicals, including boiler chemicals.

4.2.1 Non-Food Grade
Non-food grade chemical storage must be secured and access controlled within the warehouse and stored per manufacturer’s SDS (Safety Data Sheet).

4.2.2 Cleaning
Cleaning chemicals must be for food-grade use, labeled, secured, access controlled and stored separately when not in use per manufacturer’s SDS.

4.2.3 Food Grade
Chemicals used to food contact equipment, i.e. boiler chemicals and lubricants must be food grade and stored according to manufacturer’s SDS.

4.3 Cleaning and Sanitation Program

Each production site must validate and monitor cleaning and sanitation processes (facility, equipment, tools and utensils).

4.3.1 Zone 1 Validation
Validation Zone 1*: Sanitation of production areas and equipment must be validated based on the appropriate cleaning program for the specific production area and the equipment (manufacturer). The validation must be based on established ATP** baselines, or equivalent, and microbiological analysis and must be documented. The validation must be verified at least annually and documented. This includes CIP (clean-in-place) and SIP (steam-in-place).

4.3.2 Documentation
Each production area and related equipment must have a documented sanitation procedure identifying frequency, chemical used, application method and visual inspection prior to ATP swabbing or equivalent.

4.3.3 Verification
An ATP swabbing plan or equivalent must be established for each production area and related equipment. Verification frequency and results must be documented.
4.3.4 Production Tools
Production tools and utensils must be of hygienic design and maintained to prevent contamination.

4.3.5 Non-Production Areas
Non-production area procedures, e.g. warehouse and zone 4 areas must be established and documented for cleaning and sanitizing program including frequency, chemicals used and application methods.

4.3.6 Color Coding
Cleaning tools must be color coded according to use and documented in the local cleaning and sanitation program.
4.4 Environmental Monitoring Program

The Environmental Monitoring Program must be established and documented as part of the Food Safety Program. Sampling locations based on zoning classification, frequency and corrective actions must be defined and documented. The program must include the frequency for testing and monitoring all zones.

4.4.1 Zone 2, 3 and 4
The Environmental Program must include zones 2, 3 and 4*. The program must include frequency of swabbing/air sampling, microbiological testing must be defined by area, number of samples and composite sampling identified. If pathogens are identified, immediate investigation, root cause and corrective action must be implemented. Only validated methods must be used (ATP** or equivalent, BAM***).

4.4.2 Reporting & Corrective Actions
The Environmental Program must be reviewed and documented. The site appointed responsible manager must implement a corrective action where needed.

Definitions
*Zone 2: Non-product contact equipment within 12 inches/ 30 cm such equipment supports, external surfaces, etc.

Zone 3: All areas within the processing area, non-food contact surfaces, such as floors, drains, forklift wheels, etc.

Zone 4: All areas outside of the processing area such as hallways, warehouse, locker rooms, etc.

Note: Zone 2 and zone 3 can be merged based on a documented risk assessment that must take customer requirements into account.

**ATP:
2. ATP Assays Point Way to Greater Safety :: Article - Food Quality
www.foodquality.com/.../ATP_Assays_Point_Way_to_Greater_Safet...

*** BAM:
1. Bacteriological Analytical Manual (BAM)

References
ISO 22000:7:4: PAS220: 10.0, 11.0

4.5 Pest Control

The pest control program must be provided by a licensed service company. The program should include description of services provided, list and labeling of chemicals, reporting and corrective action documentation.

4.5.1 Pest Control Service
Each facility must use an authorized external pest control service only. The pest control program must be documented, including frequency of methods by target areas, control procedures and documented training. The chemicals used must be approved for use and documented. Poison must not be used inside the premises.

4.5.2 Reporting and Corrective Actions
The Pest Control company must provide reports after each inspection identifying areas for improvement to control access to designated areas including potential access points, external openings, etc. The Chr. Hansen appointed responsible must implement a corrective action where needed.
Food Safety and Food Security

5.1 Food Safety Program

Food safety programs must be established to control, monitor and assess food safety risks per the local controls and corporate requirements. This includes microbiological, chemical and physical contaminations.

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5.1.2 Food Safety Team
The Food Safety team must assure the implementation, verification, monitoring and auditing of food safety programs.

5.1.3 Change Management
Where applicable, if a food safety process change is required, the food safety responsible must conduct a risk assessment and approve the change management cycle.

5.1.4 Corrective Action
All food safety related corrective actions (CA) must be documented and verified by the Food Safety or HACCP team.

5.1.5 Allergen Control
All allergens must be segregated and labeled according to corporate instructions and the local allergen storage procedure. Allergen processing change-over procedures must be validated and documented.

References
ISO 22000: 7.0; PAS 220: 10.0
5.2 Control of Non-Conforming Materials

Any material, including packaging, which does not conform to the Food Safety Program, quality related non-conformities and rework must be identified and controlled.

5.2.1 CCP Non-Conformity (NC)
All NCs related to a CCP must be reviewed by the Food Safety team for potential correction or action plan. Corrective action and/or action plan must be approved by the Food Safety Manager/QA Manager. All non-conforming products related to either a CCP, a regulatory non-conformity or a potential or actual food safety risk must be blocked (SAP) and separately labeled and stored in a quarantined area. Weekly stock counts are required for all these types of blocked products and must be documented.

5.2.2 Quality Non-Conformity (NC)
Quality related non-conforming product must be blocked, restricted or labeled per local procedure.

5.2.3 Rework & Returned Products
Product designated for rework must be labeled, blocked and quarantined. Use of rework must be approved by the quality responsible. Complete traceability of reworked product must be maintained. Returned products must be labeled, blocked and quarantined until evaluated and actions are decided by the quality responsible.

References
ISO 22000:7.10; PAS 220: 14.0

5.3 Food Security/Defense

Each production site must have an established food security, traceability, withdrawal, recall, crisis management, vulnerability assessment and facility access controls.

5.3.1 Traceability
All product lots, including rework, must be traceable back to the supply (one step up, one step down). Internal mock traceability must be conducted annually per product division per plant.

5.3.2 Product Withdrawal/Retrieval
Product withdrawal/retrieval must be managed and communicated by the appointed Crisis Management team.

5.3.3 Crisis Management
All facilities must establish and train a Crisis Management team. A crisis management notification/communication exercise must be conducted annually.

5.3.4 Food Security/Defense
All facilities must establish a security program to prevent potential acts of sabotage, vandalism or terrorism.

5.3.5 Visitors
Anyone not employed by the local Chr. Hansen facility is considered a visitor, excluding service contractors. Visitors must sign in, sign off on GMP rules, obtain a temporary visitor badge and be accompanied by a Chr. Hansen employee for the duration of their visit. Note: Students working on assignments with Chr. Hansen are considered to be temporary employees.

5.3.6 Service Contractors
Service contractors/providers; pest control, cleaning services, contractors, etc. must have a temporary badge. All service contractors/providers must be informed about GMPs and food safety awareness before service begins. Documentation of information given and signed acceptance must be maintained.

References
ISO 22000: 5.7, 7.9, 7.10; PAS 220: 15.0, 17.0, 18.0; FSSC 22000 (1)
6.1 Auditing

Each production site must have an established internal auditing program against the appropriate standard, scheduled frequency, auditor qualifications and corrective actions.

6.1.1 Plant and Support Department Audits
Each production site must plan and execute an internal audit program according to certification scope and customer requirements. The program must cover all certificate(s) requirements including, but not limited to, GMP, HACCP, sanitation, maintenance, equipment release etc. Each audit must be supervised by a lead auditor. It is recommended that the audit program is based on annual audit activities even if the certificates have a longer lifetime.

6.1.2 Auditor Qualifications
Each lead auditor must have prior experience and external lead auditor training to qualify as a lead auditor. Each internal auditor must have prior experience and/or internal auditor training. It is recommended that internal auditor training is conducted by an external approved trainer.

6.1.3 Corrective Actions
All non-conformities must be entered into the corrective action (CA) system, root cause determined and appropriate CA applied within 30 days, with a follow-up and verification within 90 days. CA cycle should be completed within 120 days. If exceeding 120 days, the plant manager must submit an action plan.

References
ISO 22000: 8.4