

High-Risk Management

Applying High Risk Concepts for Food Microbiology Risk Management

Development

To define detail, scope and purpose.

Development

This information can be used to develop food safety and quality programs that meet the requirements of modern Regulatory, Customer and Industry Standards:

- We take the time to explain the expectations and requirements of food safety and quality compliance as these relate to your food safety and quality programs.
- You may choose to use our Premium Resources to build, enhance or upgrade your food safety and quality program.
- We encourage you to share this webpage with any food compliance associates and peers you believe may benefit from our commitment to providing our users with user friendly information and resources to achieve superior Food Compliance Culture.
- We welcome your suggestions for additions of general or specific content through the haccp.com Contact Page.

Key Definitions for High-Risk Management

- Airlock: A small enclosed space with two interlocked doors that controls the movement of people, materials or air between areas of different hygiene status.
- Captive Equipment: Equipment, tools, bins and other items that are designated to one area, remain within it, and are not moved to other areas of the site without a validated cleaning and sanitation step.
- High-Care: An area designed to a high standard where practices relating to personnel, ingredients, equipment, packaging and environment aim to minimise product contamination by pathogenic microorganisms. See High-Care Management.
- High-Risk: A physically segregated area, designed to a high standard of hygiene, where practices relating to personnel, ingredients, equipment, packaging and environment aim to prevent product contamination by pathogenic microorganisms.
- HPP: High-Pressure Processing, also called High Hydrostatic Pressure Processing or High-Pressure Pasteurisation, uses ultra-high pressures to destroy pathogens without heat that can damage the taste, texture and nutritional value of the food.
- Lower Risk Area: An area of the site where food is processed to a lower hygiene standard than the High-Risk area, such as raw material handling or cooking areas that precede the High-Risk area.
- Ready to Eat: Commonly abbreviated as RTE, Ready to Eat products (in the High-Risk context) include items that are ready to consume without further preparation.
- Ready to Reheat: Commonly abbreviated as RTRH, Ready to Reheat products (in the High-Risk context) include items that are ready to consume following a prescribed heating process that is known to render that food safe and edible.
- Transfer Point: A controlled location, such as a hatch, airlock, conveyor, pipe or sanitation bath, through which people, materials or equipment move into a High-Risk area from a lower risk area.

High-Risk Management Development

When considering the development, documentation, and implementation of High-Risk Management within food safety and quality management systems, the following information should be considered to ensure effective outcomes:

About High-Risk Management

The terms High-Risk and High-Care are often used in conjunction with each other. The two terms are similar in their applications into food businesses; the main difference between the two is the fact that High-Risk is more stringent; High-Risk aims to prevent product contamination by pathogenic microorganisms; High-Care aims to minimise product contamination by pathogenic microorganisms.

High-Risk systems and premises rely on heightened levels of food safety management to achieve the anticipated outcomes of safe foods and rely on the effective development, documentation, and implementation of pre-requisite programs that are genuinely maintained on an ongoing basis. Because of the potential public health risks that can occur from contaminated High-Risk foods, the premises, equipment, and surroundings must be constructed and maintained to a high standard.

Key Considerations of High-Risk Management

Products intended to be consumed as Ready to eat (RTE) or Ready to reheat (RTRH) need to be manufactured within facilities that have specialised controls for microbiological safety. The requirements for High-Risk production facilities should reflect Food Industry 'Best Practice', as this reduces risk for consumers, and by proxy, for the businesses manufacturing such products.

Ready-to-eat products are relevant for the application of High-Risk practices due to their status. Ready to reheat items are relevant as consumers may not always follow instructions for storage and use, which can result in foodborne illness.

Product Design and Development

Procedures for product design and development must be developed, documented, and implemented to ensure the process yields appropriate outcomes. The product design and development should include structured consideration of HACCP, production trials, specifications, packaging, labelling, and shelf-life consideration for microbiological, chemical, physical, and organoleptic parameters including challenge testing where applicable.

It is important to consider within any Product Design and Development flow process that stages are linked in a logical order of dependency. Each stage of the Product Design and Development process contains a set of prescribed and concurrent activities incorporating industry best practices. The activities during a stage are generally run concurrently rather than one after another. This ensures that they are carried out quickly and effectively. Process stages must be cross-functional to allow all areas of the food business to contribute.

When considering the implementation of Product Design and Development elements for High-Risk processes and products, additional emphasis must be placed on the microbiological status of raw materials. This is because the management of microbiological risks within a High-Risk scenario relies heavily on the assumption of microbiological limits of process inputs. A lack of consideration of raw material microbiological status can result in a significant microbiological non-conformance.

As with any risk-based activity, implemented Product Design and Development protocols need to follow the established steps, including Development, Documentation, Implementation, Monitoring, Corrective Action, Verification, Validation and Skills, and Knowledge.

About Premises and Equipment Design and Construction Standards

The physical facilities and structure of a food establishment must be properly designed, constructed, installed, operated, and maintained to allow the receipt, storage, production, and dispatch of safe food. The design and construction of the premises and the items within it have a direct link to the control of the entry of pests and potentially their harbourage and ability to cause contamination of processes or products. The design and construction of premises and equipment are also directly related to the control of cross-contamination by staff and visitor traffic flows, process flows and waste flows.

Many factors are important to premises and equipment design being supportive of food safety including:

- Water supply, sewage, and water waste disposal;
- Garbage and recyclable matter storage;

- Ventilation;
- Lighting;
- Construction of floors, walls, and ceilings in an appropriate manner, and of correct materials;
- Correct installation and allowance for cleaning of fittings and equipment;
- Availability of designated hand-washing facilities;
- Storage areas that are appropriate for the items being stored within them, and in the correct vicinity related to food areas. For example, chemicals are stored away from food ingredients and food packaging;
- Food transport vehicles are constructed and maintained to reduce food contamination risk;
- Provision of designated eating, drinking, and smoking areas.

The internal and external design and layout of food establishments should permit good food hygiene practices, including protection against cross-contamination during and between food production operations. This may include a defined one-way product flow, the segregation between high and low-risk areas, and entry to high-risk areas via specially designated and managed changing facilities.

Sanitary facilities such as toilets should not be adjoined to operational areas within any food business. As a minimum, a double door and airlock between the sanitary facilities and low-risk production areas would be acceptable.

Adequate suitably designed and constructed facilities should be provided for cleaning food utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where required.

High-Risk 'Zones'

High-Risk 'zones' within a food business usually refer to the areas of the site flow process following a microbiological kill step. High-Risk based controls are implemented until the foodstuff is fully packaged. Items that undergo a final microbiological kill step or microbiological reduction step while contained within their fully sealed packaging may not be classed as High-Risk.

It is generally considered best practice for High-Risk 'processes' to be identified as such within HACCP documentation, such as the process flow diagram. High-Risk 'zones' should also be clearly defined within site floor plans and layouts.

Where a food business cannot fully meet the expected requirements for design and construction of High-Risk areas and facilities, the business must provide substantial evidence of effective, validated implementation of microbiological controls.

High-Risk is the more stringent standard. High-Risk status items may be used within a High-Care area because they have had a higher level of microbiological intervention, whereas High-Care status items entering a High-Risk area require additional controls to manage the related risks.

High-Risk Transfer Points

The methods and facilities used to transfer items to and from High-Risk areas require thorough risk assessment to confirm they control microbiological risk. Common methods include:

- Travelling heat treatment equipment, such as an oven or fryer, that is loaded in the Lower Risk area and unloaded in the High-Risk area;
- Heat treatment through a double door system fitted with an airlock, loaded in the Lower Risk area and unloaded in the High-Risk area;
- Transfer of heat-treated materials through piping from the Lower Risk area to the High-Risk area;
- Tipping heat-treated foodstuffs from the Lower Risk area to the High-Risk area over a defined control barrier;
- Transfer of fully packaged, appropriately heat-treated items into the High-Risk area via a sanitation process, such as a flume, conveyor or bath. The sanitation process must be validated and verified to ensure its ongoing effectiveness, including time, temperature and chemicals where applicable;
- Transfer of fully packaged, double bagged items from a High-Risk supplier into the High-Risk area via a sanitation process. This may include scenarios in which blanching, UV treatment, irradiation, chemical sanitation or HPP (High-Pressure Processing) has been used by the supplier;

- Transfer of produce into the High-Risk area via a validated sanitation process, such as a flume or bath, where the process is designed to reduce microbiological load;
- Transfer of bulk materials, such as pH-controlled liquids, through piping from the Lower Risk area to the High-Risk area.

Where equipment requires settings for the transfer of items from lower risk to High-Risk areas, it is preferable that these settings can be controlled only from the lower risk or the High-Risk side, as defined in the risk assessment. Where a system transfers items through a wall, it should be possible to clean it from both sides.

Adequate and effective storage and work-in-progress facilities must be provided within the High-Risk area for transferred items, particularly where rapid cooling is required to control spore-forming pathogens. Post heat treatment cooling temperature and time profiles must meet legal and product-specific requirements. Validation and verification of transfer methods are required on an ongoing basis. See Validation Activities and Verification Activities.

High-Risk Design and Construction



Smooth, sealed surfaces and clear floor space make a High-Risk area easier to clean and keep controlled.

Above and beyond the construction and design requirements of all food businesses, sites facilitating High-Risk processes and products require additional facilities and functions to ensure microbiological risks are controlled. Examples of High-Risk design and construction considerations are provided as follows:

- Full segregation should be facilitated, ensuring physical separation of lower risk and High-Risk Areas;
- Construction and design of High-Risk areas should not allow the use of scenarios that may encourage the harbourage, growth, or spread of microbiological concerns;
- High-Risk scenarios should be designed and constructed to allow a genuine one-way process flow where applicable;
- Drainage systems in High-Risk areas should be independent of drainage systems within, or linked to lower risk areas;
- Where drainage segregation is not available, drains must run from the High-Risk areas towards the lower risk areas;
- Anti-backflow devices must be fitted within drainage systems where practicable;
- Drainage systems, including flow direction and gradients, should be maintained and reviewed on an ongoing basis;
- Drainage channels should be smoothly constructed from non-corrodible materials to exclude any crevices, have recessed top grates and removable drainage filter baskets;
- Premises piping must be sealed, include applicable liquid and air anti-backflow devices, and have an adequate fall away from the High-Risk areas of the site;
- Flooring must be smooth and impervious and fitted to allow effective drainage without any pooling;
- Flooring on the lower risk side of High-Risk partitions, walls, or barriers must drain away from the higher risk area;
- Doors, panels, and hatches should be of solid construction, must include effective seals, and must be able to be effectively cleaned and sanitised on an ongoing basis;

- Openings into High-Risk areas should be no larger than what is required to facilitate the required task;
- Interlock or airlock doors should be fitted where practicable to control the ingress of unfiltered air into the High-Risk area;
- Equipment and other items that are not captive to the High-Risk area must undergo a validated cleaning and sanitation step before they are introduced to the High-Risk area;
- Air introduction and reticulation systems within the High-Risk areas should be filtered to an appropriate standard based on risk assessment outcomes;
- Positive pressure air systems for High-Risk areas should be implemented and verified on an ongoing basis to ensure the ingress of unfiltered air into the High-Risk area is minimised;
- Equipment sited and maintained within High-Risk areas should ideally be captive to that area and identified as such;
- Equipment sited and maintained within High-Risk areas should be constructed to avoid potential microbiological growth and harbourage;
- Where possible, equipment such as metal detectors and check weighers should be located outside of High-Risk areas;
- Where laboratories are located within the vicinity of High-Risk facilities, these laboratories must have full segregation and designated drainage and waste handling services;
- Where laundries are located within the vicinity of High-Risk facilities, these laundries must have full segregation and designated drainage and waste handling services;
- Prospective changes to the construction and design of High-Risk areas should include defined processes for how such changes are specified, commissioned, and validated in alignment with microbiological controls, and with the controls required for other relevant hazards.

Cleaning and Sanitation Procedures

Cleaning and sanitation in High-Risk areas needs additional attention to detail. The principles are set out in Cleaning and Sanitation. The following apply in High-Risk scenarios:

- Along with post-use cleaning and sanitation, High-Risk areas and equipment should be cleaned and sanitised before use using verified and validated methods;
- Where fittings and equipment may be a harbourage and growth risk because of design limitations, post-cleaning routines should include no-rinse sanitiser solutions or gels where practicable;
- Air socks and filters used in High-Risk areas must be inspected, maintained and laundered on an appropriate schedule;
- Maintenance and other tools and equipment that are not captive to the High-Risk area must be cleaned and sanitised using validated methods before entry.

Cleaning schedules for High-Risk areas should specify the areas and items to be cleaned, responsibilities, method and frequency, chemicals and dilution rates, utensils to be used and monitoring arrangements. They should be developed with specialist advice, including from your cleaning chemical suppliers where applicable.

Laundering of Uniforms



Clean protective clothing, hair covers and beard covers limit contamination from people.

Uniforms, including protective clothing, footwear and headwear, must be suitable for the intended use, made of materials that do not pose a risk to food, and changed into and out of in a designated area. Overalls should not have external pockets and should have cuffed sleeves. General requirements are set out in Personal Hygiene Standards. In High-Risk scenarios:

- High-Risk uniforms must be laundered separately from lower risk items;
- Laundering, handling and storage must be defined in documented procedures and supported by verification and validation;
- Uniform service providers should be included in the approved supplier program, and laundering chemicals must be food industry approved;
- Laundered uniforms for High-Risk areas should be protected from contamination, for example in a sealed sanitary plastic bag.

Purchased Inputs

High-Risk processes may use components that are raw or have not undergone a heat based microbiological reduction step. Where such items are used in a High-Risk environment, confidence in their microbiological safety must be based on risk assessments conducted by a technically competent individual or team. The criteria must address the specific microbiological hazards of each raw material and refer to the raw material specification, including microbiological status and relevant pathogens.

Outcomes must be documented, included in ongoing reviews of raw materials and the approved supplier program, and supported by validation and verification records. These assessments must be completed as part of product design and development, before production trials or receipt of any raw material.

Non-heat-treated items used in High-Risk scenarios should receive more scrutiny at receipt and pre-use inspection. This may include:

- Assessment at a higher frequency than lower risk items;
- Assessment at a higher sampling rate than lower risk items;
- Review of suitable Certificates of Analysis;
- Targeted microbiological testing.

Waste and Recyclables Management

Waste must not accumulate in food handling, storage or operational areas, and waste areas must be kept clean. Full requirements are set out in Waste and Recyclables Management. High-Risk applications require prompt removal of waste, recyclables and other items that may affect microbiological controls:

- Waste is commonly removed from High-Risk areas through hatches, interlock or airlock doors or designated transfer conveyors;
- Waste bins, tubs and containers should be captive to their area of use, and must not leave it without a validated cleaning and sanitation process that does not increase contamination risk;
- New containers should receive the same validated cleaning and sanitation before entering High-Risk areas;

- Out-of-specification product is waste that may need to be held until a disposal decision is made.

Poorly managed waste, particularly outside the premises, can also harbour pests. See Pest and Vermin Control.

Training, Competency, and Resources Requirements

Because of the enhanced risk in High-Risk scenarios, everyone entering or working in these areas must be trained and assessed as competent. Training should cover operational tasks as well as entry, exit and transfer to and from High-Risk areas, in addition to hygienic food handling and personal hygiene. General requirements are set out in Training, Competency and Resources Requirements. Management is responsible for ensuring all employees understand the food safety and hygiene practices important to their job.

About Chemical Control

Chemical use in High-Risk areas must promote food safety as well as the safe use, handling and storage of cleaning, sanitation, pest control and maintenance chemicals. Chemical usage procedures should be documented and available to everyone using chemicals. In High-Risk areas, chemicals should be brought in only as needed, stored away from food and packaging, and clearly labelled when decanted or diluted. See Chemical Control for full requirements.

About Food Microbiology Management

People who take part in developing, implementing and reviewing HACCP plans and finished product testing need at least a basic understanding of food microbiology. This ensures microbiological hazards are controlled and do not affect the safety or quality of finished food. See Food Microbiology Management.

Microbiological Cross Contamination

Pathogens can be transferred between foods by direct contact, food handlers, contact surfaces or air. In High-Risk areas this is controlled by:

- Physical or time separation of raw and ready to eat foods, with effective intermediate cleaning and disinfection;
- Restricted access to processing areas, normally only through a changing facility;
- Clean protective clothing, footwear and hand washing before entry;
- Thorough cleaning and, where necessary, disinfection of surfaces, utensils and equipment after raw food, particularly meat and poultry, has been handled.

About Visitor and Contractor Management



Hand washing before entry is one of the basic controls that protect High-Risk areas.

Visitors and contractors, and their actions, are the responsibility of management. Those entering food production areas should wear protective clothing and follow personal hygiene provisions. A documented policy should be given to each visitor and contractor before entry. See Visitor and Contractor Management for full requirements. For High-Risk areas:

- Visitors and contractors should be signed in and identified by a badge;

- They may be required to review food safety and workplace health and safety materials before admission;
- A fresh lab coat or full uniform may be required;
- They should be accompanied by an authorised staff member at all times unless inducted and screened.
- Anyone who is unwell, particularly with vomiting or diarrhoea, should not enter High-Risk areas, and should report their illness to a manager before entry.

Visitor and Contractor Awareness

For higher risk or larger food businesses, an induction process for visitors and contractors should be developed, documented and implemented. Long term contractors who work unaccompanied should be re-inducted on a schedule, with records kept. Where labour hire companies train staff on the business's behalf, the business should verify and validate the training as part of its approved supplier of service program.

About Water and Ice Quality Standards

An adequate supply of potable water, with suitable storage, distribution and temperature control, must be available. Potable water meets the criteria of the most recent edition of the World Health Organization Guidelines for Drinking Water Quality, or a higher prescribed standard, and the potability standards of the countries where products are processed and sold. Non-potable water used for fire control, steam production or refrigeration needs a separate, identified system that does not connect with potable water. See Water and Ice Quality Standards.

Food Contact Water and Steam

Only verified potable water should be used in food handling and processing, except for non-food-contact steam, fire control and similar purposes, and certain processes such as chilling or brining where it does not create a hazard. An example is the use of clean seawater in seafood processing. Recirculated water must be treated and maintained so it poses no risk to food, and treatment processes must be documented, monitored, recorded and verified.

References

- ISO 22000:2018 Food safety management systems
- Codex Alimentarius codes of practice
- World Health Organization food safety fact sheet

High-Risk Development Key Points

- High-Risk programs must be developed to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The Senior Management of your business facilitate a commitment to ensuring adequate resources to the development of your HIGH-RISK program;
- Should you require additional resources for the development of High-Risk program elements, please discuss this with the relevant Senior Management representative;
- A properly developed High-Risk program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly-developed High-Risk program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Documentation

To establish the developed detail in a viewable format to facilitate information.

Documentation

Document: A document provides guidance and/or direction for performing work, making decisions, or rendering judgments that affect the safety or quality of the products or services that customers receive.

Documented policies, procedures, work instructions, and schedules form the basis of any food safety and quality management system. The following documentation formats may be considered to ensure ongoing compliance with specified requirements for High-Risk Management:

- High-Risk Management policy;
- High-Risk Management development procedures;
- High-Risk Management monitoring procedures;
- High-Risk Management corrective and preventative action procedures;
- High-Risk Management verification schedule;
- High-Risk Management verification procedures;
- High-Risk Management validation schedule;
- High-Risk Management validation procedures;
- High-Risk Management training procedures.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific High-Risk Management Documentation requirements in relation to their items.

You may wish to visit the High-Risk Management Templates section of haccp.com for examples of High-Risk Management documentation, record, and resource formats commonly applied within food safety and quality systems.

High-Risk Documentation Key Points

- High-Risk programs must be documented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- All documented High-Risk program elements must be controlled to ensure compliance;
- Key documented High-Risk program elements should be available to your business team at all times to ensure they can facilitate required tasks;
- A properly documented High-Risk program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly documented High-Risk program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Implementation

To facilitate the application of the documentation.

Implementation

Implementation: Implementation is the application of documented food safety and quality system elements into the actual business operation.

The implementation of High-Risk Management within any food business requires genuine commitment from senior management, staff, and visitors to ensure the nominated goals of implementation are achievable on an ongoing basis. It is a step that requires significant planning and consideration of general and specific food business circumstances to ensure the outcomes of High-Risk Management do not negatively impact the safety and quality of the food items dispatched from the business.

Implementation of High-Risk Management must include a clear definition of responsibilities and authorities for all levels of participation by senior management, staff, and visitors to the site.

When implementing High-Risk Management within a food safety and quality system, you may wish to consider the following requirements before completion:

- Communication and display of the High-Risk Management policy;
- Completion of Verification and Validation of High-Risk Management development procedures;
- Availability of High-Risk Management implementation procedures and work instructions;
- Availability of High-Risk Management monitoring procedures and record templates (where applicable);
- Availability of High-Risk Management corrective and preventative action procedures and record templates (where applicable);
- Availability of the High-Risk Management verification schedule;
- Availability of High-Risk Management verification procedures;
- Availability of the High-Risk Management validation schedule;
- Availability of High-Risk Management validation procedures;
- Completion of High-Risk Management training procedures;
- Completion of product design and development requirements related to High-Risk Management;
- Completion of process design and development requirements related to High-Risk Management;
- Completion of training for team members who have responsibilities and involvement within High-Risk Management;
- Completion of competency approval for team members who have responsibilities and involvement within High-Risk Management.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific High-Risk Management Implementation requirements in relation to their items.

High-Risk Implementation Key Points

- High-Risk programs must be Implemented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Your High-Risk program must be fully implemented as per relevant documented Policies, Procedures, and Work Instructions;
- The implementation of High-Risk requires a commitment to the provision of resources by the Senior Management of your business;
- A properly implemented High-Risk program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly implemented High-Risk program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Monitoring

To review, confirm and document evidence of the implementation against documented limits.

Monitoring

Monitoring: Monitoring is the act of reviewing and confirming measurable parameters of a defined process or product status.

Monitoring requirements within food industry sectors are generally identified against limits of acceptability defined within HACCP plans, implementation procedures, and work instructions. Monitoring usually includes some element of record-keeping, which may be maintained manually or through digital systems. It is important to consider that advancements in technology have spawned many systems and processes which are self-monitored and/or self-adjusted when variances are identified. Regardless of the system used, the goal of any monitoring activity is to provide sufficient evidence that any limit of acceptability has been met.

Traditional High-Risk Management monitoring requirements include manual recording and the application of corrective actions when the results of monitoring are found to be outside acceptable limits. Corrective Actions should also generally be strongly linked to the monitoring process applied to ensure full traceability of the applied actions.

Common monitoring activities and record formats may apply to High-Risk Management:

- Pre-operational Inspection Records: These are often scheduled, conducted, and recorded to confirm that the cleaning and sanitation, premises and equipment and GMP supports to High-Risk Management have been completed as specified;
- Cleaning and Sanitation Completion Records: These are often completed by Cleaning and Sanitation team members as an indication of tasks completed. Cleaning and Sanitation completion reports are also commonly re-verified as elements of the Pre-operational Inspection Records;
- Zone entry and exit checks: These confirm that people follow changing, hand washing and protective clothing requirements before entering the High-Risk area;
- Air pressure differentials: These are recorded to confirm that positive pressure is maintained between the High-Risk area and adjoining areas;
- Transfer point controls: These records confirm that sanitation baths, airlocks, hatches and heat treatment steps operate as specified;
- Environmental swab results: These are reviewed for trends that indicate loss of microbiological control;
- Routine monitoring of GMP Prerequisite Programs for all food manufacturing premises is recommended. Daily pre-operative checks allow management and staff to ensure that all items are cleaned, sanitised and suitably stored before the commencement of daily production. If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific High-Risk Management Monitoring requirements in relation to their items.

You may wish to visit the High-Risk Management Templates section of haccp.com for examples of High-Risk Management documentation, record, and resource formats commonly applied within food safety and quality systems.

High-Risk Monitoring Key Points

- Monitoring provides real-time confirmation and evidence that your risk-based FS&Q Controls are effectively implemented;
- High-Risk programs must be monitored to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Monitoring of High-Risk must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated monitoring records for High-Risk must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly monitored High-Risk program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly monitored High-Risk program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Corrective Action and Preventative Action

To apply "real time" interventions to documented monitoring limits.

Corrective Action and Preventative Action

Corrective Action: Corrective action is mandatory action to be taken when a deviation to the Quality System occurs, particularly to a Critical Control Point.

Preventative Action: At any step in the process where a hazard has been identified, preventative action must be put into place to prevent re-occurrence.

Corrective Action and Preventative Action are implemented to ensure that any identified non-conformance issues are documented, investigated, and rectified within appropriate time frames. Corrective action is any action applied to regain control over a product, process, policy, or procedure that has been identified as being non-conforming or outside nominated limits of acceptability. Preventative action is any action applied to prevent any identified

non-conformance from reoccurring.

The outcomes of corrective and preventative actions should result in regained process control after effective application. Specified corrective actions are commonly linked to the HACCP Plans and the food business certification process.

Below are Corrective Action and Preventative Action examples which may be associated with High-Risk Management related non-conformance:

- Review of the High-Risk Management policy;
- Review of High-Risk Management development procedures;
- Review of High-Risk Management implementation procedures and work instructions;
- Review of High-Risk Management monitoring procedures;
- Review of High-Risk Management corrective and preventative action procedures;
- Review of the High-Risk Management verification schedule;
- Review of High-Risk Management verification procedures;
- Review of the High-Risk Management validation schedule;
- Review of High-Risk Management validation procedures;
- Review of High-Risk Management training procedures;
- Re-training in High-Risk Management;
- Review of management review activities to include High-Risk Management as an agenda item;
- Initiation of product hold procedures where safety or quality may be compromised;
- Initiation of a product recall or product withdrawal procedures where investigations show that there is a substantial safety and/or quality risk to the released product;
- Contacting stakeholders including customers regarding any confirmed or potential High-Risk Management concerns involving their product.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific High-Risk Management Corrective Action requirements in relation to their items.

You may wish to visit the Corrective Action and Preventative Action section of haccp.com for examples of best practice applications for this food safety and quality system element.

High-Risk Corrective Action and Preventative Action Key Points

- The implementation of Corrective Action and Preventative Action provides confidence that your FS&Q Program is effectively implemented and that FS&Q criteria are being met;
- Where deviations or variations are observed, Corrective Action and Preventative Actions must be facilitated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Corrective Action and Preventative Action of High-Risk must be facilitated as per relevant documented Policies, Procedures and Work Instructions;
- Records of Corrective Action and Preventative Action must for High-Risk be maintained per relevant documented Policies, Procedures and Work Instructions;
- Proper application of Corrective Action and Preventative Action for your High-Risk program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poor application of Corrective Action and Preventative Action for your High-Risk program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Verification

To review and confirm documented monitoring and corrective actions against documented parameters.

Verification

Verification: The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements.

Verification is the detailed review of all food safety and quality system elements to confirm that they are effectively developed, documented, implemented, monitored, and reviewed. All food safety and quality system elements, including documented policies, procedures, training, HACCP plans, and their operational applications must be verified on an ongoing scheduled basis. The verification process commonly includes a defined schedule for which verification activities are required, how often they are conducted, who is responsible, and detailed documented procedures for each nominated verification activity.

The general goal of an established verification process is to ensure any systemic non-conformance issues are identified and rectified within an appropriate time frame. When non-conformance issues are identified through the verification process, Corrective Actions and Preventative Actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system.

The following examples of verification activities may apply to High-Risk Management:

- Review of the High-Risk Management policy;
- Review of High-Risk Management development procedures;
- Review of High-Risk Management implementation procedures and work instructions;
- Review of High-Risk Management monitoring procedures;
- Review of High-Risk Management monitoring records;
- Review of High-Risk Management corrective and preventative action procedures;
- Review of the High-Risk Management verification schedule;
- Review of High-Risk Management verification procedures;
- Review of the High-Risk Management validation schedule;
- Review of High-Risk Management validation procedures;
- Review of High-Risk Management training procedures;
- Review of High-Risk Management performance since the last review and historically;
- Analytical testing of product or process to ensure the effectiveness of High-Risk Management;
- Review of the environmental monitoring program, including swab results and trends;
- Review of finished product microbiological results against specifications;
- Inspection of drainage, airflow and air pressure controls in High-Risk areas;
- Inclusion of High-Risk Management as an agenda item within the Management Review Process.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific High-Risk Management Verification requirements in relation to their items.

You may wish to visit the Verification Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

High-Risk Verification Key Points

- Your verification program provides evidence that your FS&Q Controls have worked;
- High-Risk programs must be verified to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The verification of High-Risk must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated verification records for High-Risk must be maintained as per relevant documented Policies, Procedures, and Work Instructions;

- A properly verified High-Risk program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly verified High-Risk program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Validation

To confirm the documented monitoring or procedural limits.

Validation

Validation: The process of gathering evidence to provide a scientific basis for the documented act of demonstrating that a procedure, process, and activity will consistently lead to the expected results. It often includes the qualification of systems and equipment.

Validation is the provision of evidence to support the limits of control or acceptability for food safety or quality parameters nominated within systemic elements. Limits of control or acceptability are commonly included within documented food safety and quality systems elements such as procedures, HACCP plans, and specifications.

Common sources of validation include regulatory and legislative standards, finished product specifications and customer requirements, industry codes of practice and guidelines, verified and validated research, historical product, and process control outcomes, and analytical testing.

The general goal of an established validation process is to ensure any systemic non-conformance issues are identified and rectified within an appropriate time frame. When non-conformance issues are identified through the validation process, Corrective Actions and Preventative Actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system.

Validation activities are commonly defined within the verification schedules and procedures of established food safety and quality management systems.

The following examples may apply to validation of the limits of control or acceptability for High-Risk Management:

- Confirmation of nominated food safety and food quality control limits for High-Risk Management. These limits may apply to regulatory, industry, customer, or finished product specifications;
- Confirmation of analytical testing methods being used to confirm the effectiveness of High-Risk Management and ensure the accuracy of outcomes;
- Validation of heat treatment and sanitation transfer steps, including time, temperature and chemical concentration;
- Validation of cooling profiles for heat-treated product entering the High-Risk area;
- Validation of uniform laundering processes for High-Risk areas;
- Ongoing programmed and recorded Competency Verifications for team members facilitating important Microbiological Control tasks within the context of High-Risk Food Manufacturing.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific High-Risk Management Validation requirements in relation to their items.

You may wish to visit the Validation Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

High-Risk Validation Key Points

- Your validation program provides evidence that your FS&Q Controls will work;
- High-Risk programs must be validated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The validation of High-Risk must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated validation records and supporting documentation for High-Risk must be maintained as per relevant documented Policies, Procedures, and Work Instructions;

- A properly validated High-Risk program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly validated High-Risk program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Training, Competency and Resources

Skills, knowledge and competency requirements to facilitate development, documentation, implementation, monitoring, corrective action, verification and validation of every Food Safety and Quality System Element.

Skills and Knowledge

Skills and Knowledge: Skills and knowledge are attributes of human interactions commonly linked to competency within any specified job-related task.

Training and competency requirements for High-Risk Management must be ongoing, including regularly scheduled reviews to ensure the effectiveness of training and competency outcomes.

Team members who have defined responsibilities regarding High-Risk Management should have knowledge including:

- Basic High-Risk Management requirements;
- Positive outcomes of High-Risk Management;
- Negative outcomes of a lack of High-Risk Management;
- Current High-Risk Management procedures, methods, and techniques;
- General operational, corporate, and social awareness regarding High-Risk Management;
- Regulatory, industry, and customer requirements regarding High-Risk Management.

Team members who have defined responsibilities regarding High-Risk Management should have skills including:

- Competency regarding basic High-Risk Management;
- Effective application of current High-Risk Management procedures, methods, and techniques;
- The basic development, documentation, and implementation of HACCP and Prerequisite Programs within the food industry sector.

Team members who have defined responsibilities regarding High-Risk Management should have access to resources including:

- High-Risk Management training;
- High-Risk Management associations and events;
- Regulatory standards, industry and customer information and updates regarding High-Risk Management;
- Incidents within the food industry sector regarding High-Risk Management;
- Commitment to High-Risk Management by senior management;
- Suitably qualified food industry professionals with verified experience in High-Risk Management;
- Effective communication systems including email, internet, and phone through which High-Risk Management information can be sent and received within suitable timeframes.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific High-Risk Management Training, Competency, and Resources requirements in relation to their items.

You may wish to visit the Training, Competency, and Resources section of haccp.com for examples of best practice applications for this food safety and quality system element.

High-Risk Training, Skills and Knowledge Key Points

- Your Training, Skills and Knowledge program ensures all participating personnel, visitors, and contracted have the required skills and knowledge to effectively facilitate the requirements of your FS&Q Program;
- Training, Skills and Knowledge programs for High-Risk must be facilitated to meet relevant Regulatory, Industry,

and Customer standards and requirements;

- Training, Skills and Knowledge programs for High-Risk must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Training, Skills, and Knowledge records for High-Risk must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- Properly applied Training, Skills, and Knowledge programs for High-Risk will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poorly applied Training, Skills, and Knowledge programs for High-Risk will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.



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