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Food Safety Requirements for Vendors

Global Document Taste & Wellbeing

Document status

[Validated]

This document is intended to be used internally and externally

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History of changes

Date	Author	Change description	Validated by*
2015-10-01	Gl. H. VQP	First Issue	Global Food Safety
2017-07-11	Gl. H. VQP	2.6.5.6: Consideration of Preventive controls and prerequisites as to SAHCODHA items; 2.6.13 Requirements as to Food Fraud added	Global Food Safety
2021-06-24	Gl. H. VQM	Changed former title "General Food Safety Requirements" Adaption of current design/layout requirements; editorial changes; New 2.4.5.7 Preventive Controls (Verification of kill steps for pathogens)	Global Food Safety

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1 Introduction

This document is an appendix to the **Global Vendor Requirements and Expectations Policy** in its current version.

As an industry leader, GIVAUDAN is committed to provide safe flavouring ingredients of consistent quality that meet our customer expectations while adhering to high ethical standards in our business conduct. This means we are committed to comply with all applicable laws and regulations, as well as with company policies and procedures in our relations with customers, suppliers, shareholders, fellow employees, competitors, government agencies and the communities in which we work.

The undermentioned requirements apply to all vendors who deliver food or food ingredients and represent Food Safety related elements, which we expect from all vendors to the GIVAUDAN Taste & Wellbeing Division. The implementation state of the requirements will be checked by GIVAUDAN auditors during announced on-site, virtual/remote audits or with documented proof in paper assessments.

For the purpose of this document, the term 'Vendor' will apply to any company that delivers raw materials, ingredients and packaging materials also referred to as a supplier, manufacturer, co-packer, re-packer or licensee as well as toll manufacturers.

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2 Food Safety Management System

2.1 Food Safety Management System Certification

It is expected that vendors maintain certification to a GFSI recognised Food Safety Standard such as 'FSSC 22000' (or equivalent, ie. IFS, BRC, SQF) or are actively seeking such certification or maintain an 'in-house' Food Safety Management System (FSMS) that is equivalent.

The FSMS must ensure compliance with these General Food Safety Expectations, all legal and regulatory requirements and GIVAUDAN specifications for the materials supplied.

Where a choice exists, preference will be given to vendors with such certification.

2.2 General Requirements

2.2.1 Resources

Adequate resources shall be provided for the implementation and continuous maintenance and update of the Food Safety Management System.

2.2.2 Leadership and Authority

An organisational structure, identifying employees with responsibility and authority for the Food Safety Management System and describing their interrelationship shall be in place. This organisational structure shall be dated, reviewed and updated periodically, and communicated within the organisation.

2.2.3 Food Safety Policy

A Food Safety Policy signed and dated by senior management shall be developed and maintained.

The Food Safety Policy shall be:

- Communicated throughout the organisation
- Supported by measurable objectives
- Compliant with regulatory and customer requirements
- Reviewed for continued suitability

2.2.4 Review and Records

The Food Safety Management System shall be reviewed on a regularly-scheduled basis to verify that it remains adequate to comply with all requirements and incorporates the most recent information on the controlled food safety hazards. The

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review shall include assessing opportunities for improvement and the need for change. Sufficient records shall be maintained to show effective implementation of the Food Safety Management System. Records must be legible, readily identifiable and retrievable. The Food Safety Management System shall clearly set out the records that must be maintained.

2.2.5 Internal Audit / Self Inspections

Documented auditing methods shall be established, which include the identification of employees responsible for scheduling and conducting internal audits to verify the effectiveness of the Food Safety Management System. This also includes factory inspections to verify and continually improve prerequisites programmes and HACCP plans.

An internal audit schedule should be prepared detailing the scope and frequency of audits. Internal audits should include, but are not limited to, process controls, sanitation, methods for prevention of cross-contaminations and personal and operational practices.

Audit results shall be communicated to relevant management employees and staff responsible for implementing and verifying corrective actions. Records shall document all deficiencies, investigations, resolutions, and corrective actions resulting from the internal audits.

2.2.6 Service Providers

A documented programme to qualify/approve providers of services that can impact product quality or food safety shall be established and maintained. The programme shall cover, but is not limited to:

- Carriers
- Toll (or Contract) Manufacturers
- External warehouse and distribution centres
- Calibration / verification
- External laboratories
- Pest control contractors
- Laundries and cleaning companies
- Maintenance and engineering

This programme must include the criteria of qualification for each service, a periodic monitoring of services and performance measurement principles to ensure their compliance with specified requirements.

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2.3 Hazard Analysis and Critical Control Points (HACCP)

HACCP principles shall be applied to identify and control food safety hazards on each step of the process. Documented procedures shall be established and maintained as appropriate.

2.3.1 Food Safety / HACCP Team

A Food Safety / HACCP team shall be appointed and trained in HACCP principles. This team shall have a combination of multidisciplinary knowledge and experience in developing and implementing the Food Safety Management System.

Records shall be maintained to demonstrate that Food Safety / HACCP team has the required knowledge and experience.

2.3.2 HACCP Plan

A reviewed and validated HACCP plan based on the seven 'Codex Alimentarius' principles shall be in place to identify and control hazards associated with the material and/or process.

1. Conduct a hazard analysis
2. Identify Critical Control Points (CCPs)
3. Establish (validated) critical limits
4. Establish a system to monitor the control of each CCP
5. Establish corrective actions to be taken when monitoring indicates that a CCP is out of control / a critical limit exceeded
6. Establish verification procedures
7. Establish a documentation concerning all procedures and records associated with the implementation of HACCP

Vendors should provide a copy of the HACCP plan to GIVAUDAN upon request.

At a minimum, vendors shall provide the HACCP flow chart of the process and allow GIVAUDAN to view the manufacturing line(s) at the vendor's facility when needed.

2.3.2.1 Identification of Critical Control Points (CCP)

Following the hazard analysis appropriate control measures shall be selected that are capable of preventing, eliminating or reducing the identified food safety hazards to defined acceptable levels. The effectiveness of the selected food control measures shall be validated.

Those control measures that are managed by the HACCP plan as process steps, at which the applied control can effectively prevent or eliminate the identified food safety hazard or reduce it to the acceptable level are Critical Control Points (CCPs).

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The identification of a CCP can be facilitated by the application of a decision tree, which indicates a logic reasoning approach.

2.3.2.2 Critical limits

Critical limits shall be determined and established to ensure that the acceptable level of the specific food safety hazard is not exceeded for the product. Critical limits shall be validated, i.e. it shall be demonstrated that they have been selected to achieve the desired level of control.

2.3.2.3 CCP Monitoring

A monitoring system shall be established for each CCP. Monitoring procedures and records shall include, but are not limited to: employees responsible for monitoring activities, how the activities are performed (method), and how often the activities are performed (frequency). Monitoring method and frequency must be capable of determining when the critical limit has been exceeded in time for corrections to be taken.

Corrective actions have to be taken when a deviation from the critical limit occurs.

The HACCP plan shall specify the corrections and corrective actions to be taken when critical limits are exceeded to ensure that the cause is identified the CCP is brought back under control and reoccurrence is prevented. Procedures shall ensure that potentially unsafe products are not released until they have been confirmed as suitable for release.

2.3.2.4 Verification Procedures

Verification procedures shall be established to determine the HACCP plan is effectively implemented. Examples of verification activities include e.g.:

- Planned internal audits / inspections to confirm Prerequisite Programmes (PRPs), the
  HACCP Plan and related procedures are implemented and effective
- Review of food safety related internal non-conformities
- Review of food safety related customer complaints, withdrawals and recalls
- Review of internal / external audit findings related to food safety
- Review of training activities and their effectiveness

The HACCP plan shall be reviewed at least annually or when the process, product, equipment, and/or other food safety related areas are changed.

Results of verification activities shall be recorded, reported to management and used as input for updating the Food Safety Management System.

2.3.2.5 Record Keeping

The HACCP system documentation shall be current and updated regularly.

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2.4 Prerequisites Programmes (PRPs)

Documented Prerequisite Programmes (PRP) shall be in place to ensure a hygienic environment, suitable for the production and handling of food products. These PRPs shall include the following:

a) Hygienic Engineering Requirements
b) Hygiene Zoning
c) Maintenance Programme Elements for Food Safety
d) Cleaning and Sanitation Programme
e) Programmes for Prevention of (Cross-) Contamination
f) Pest Management Programme
g) Food Safety Aspects of Waste Management Programme
h) Personal Hygiene Practices including regulations for medical screening, communicable diseases and injuries
i) Food Safety Training
j) Receiving, Storage and Transportation Programmes
k) Rework Control
l) Food Defence Programme
m) Food Fraud Prevention and Monitoring

2.4.1 Hygienic Engineering Requirements

2.4.1.1 Design and constructions of buildings, premises and workspace

Facility design and construction shall be adequate to ensure production of safe and high quality materials. The facility, including utility areas, shall be designed to prevent potential contamination sources from affecting the products produced or handled, based on a hygiene zoning concept. Facility grounds must be maintained to address food defence considerations. The location and design of waste bins, toilets and hand washing, drying and sanitising facilities shall be adequate to comply with hygiene zoning and operational practices.

2.4.1.2 Equipment design standards

Equipment shall be designed and constructed of materials that are easy to clean and do not contribute to a food safety risk (hard / brittle plastic materials and wood should be avoided). Each new installation or modification to existing equipment design shall undergo a sanitary design review by a cross-functional team (e.g. quality, production, maintenance). This review shall address but is not limited to: ease of cleaning, functionality, and material selection.

2.4.1.3 Provisions for the quality of utilities (air and other gases, water/steam/ice)

An effective programme shall be in place for the management and control of the following utilities:

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Water

Water used as an ingredient or used to clean equipment, shall meet all applicable federal, state, and local laws and regulatory requirements for drinking water. This includes ice and steam with product contact. An effective programme shall be in place to control microbiological and chemical quality of water and to verify that water meets specified requirements. The programme should include regular monitoring to assure it remains effective.

The usage of non-potable water shall be controlled such that:

- There is no cross-contamination between potable and non-potable water lines
- Non-potable water piping and outlets are clearly identified
- Back-flow devices are installed in non-potable water lines

Water treatment devices (e.g. boilers, softeners) shall be designed, installed and operated to assure water receives an effective treatment and complies with drinking water standards.

Steam

Only steam of the correct quality and purity to meet process and usage needs shall be used. For direct contact with products and food contact surfaces, steam shall be produced from purified water in a dedicated clean steam generator. Only food grade boiler chemicals shall be used.

Air

Room air shall not provide a source of microbiological contamination and shall be filtered in areas of open product handling. Where relevant the microbiological quality of air in production areas shall be monitored, specially were microbiologically sensitive materials are handled and do not receive a subsequent kill step.

Compressed Air

Air used for general applications shall be dry, oil free, and filtered to remove foreign particles. When using compressed air in contact with products, packaging, or product contact surfaces (e.g. during cleaning), a filter must be installed as close as possible to the point of the use. The filter and all downstream air piping shall be corrosion resistant (e.g. stainless steel).

If oil lubricated compressors are used for product and/or product contact surfaces, the air distribution system shall have oil and oil vapour filters installed before the air comes into contact with products and/or product contact surfaces. The lubricants shall be food grade.

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2.4.1.4 Provisions for the quality of food contact materials

Materials that are used in the construction of utensils and food-contact surfaces must not allow migration of harmful substances or impair colour, odour, or taste of food product. Under normal conditions of use they shall be resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

Product contact materials shall, under the entire operating conditions, be:

- Inert and corrosion resistant to the product as well as to detergents and antimicrobial chemicals (sanitizers)
- Mechanically, thermally and chemically stable during installation and operation
- Smooth, with no cavities where organic material cold remain
- Free of edges and noses
- Easy to clean and disinfect and easy to dismantle
- Non-toxic, not absorbent against products and detergent / chemicals

Materials which shall not be used in contact with food include: zinc, lead, cadmium, antimony, plastics (containing free phenol, formaldehyde or prohibited plasticisers), wood, copper, brass, and bronze.

2.4.2 Hygiene Zoning

Hygiene zoning shall reduce the potential for product contamination from the environment by preventing the transfer of food safety hazards such as micro-organisms and foreign material into areas, where product is exposed. The concept shall cover:

- The identification of potential sources of product contamination from the processing environment and through personnel or material flows appropriate controls for each zone, based on risk assessment
- Periodic evaluation of compliance with hygiene zoning requirements and their effectiveness. This includes, but is not limited to, environmental testing including pathogen testing, GMP audits, and routine pre-operational and operations inspections

2.4.3 Maintenance Programme Elements for Food Safety

A programme must be in place to ensure maintenance is performed in a manner that minimises the risk of product, packaging, or equipment contamination. The programme shall include, but is not limited to, preventive maintenance, installation, and repairs. A preventive maintenance schedule to cover building, premises and equipment critical to food safety shall be maintained.

The programme shall include procedures to protect from contamination due to line maintenance work. String, wire or tape shall not be used to fix or hold equipment as part of a temporary repair. All contractors and suppliers shall meet the personal hygiene requirements while working on the premises.

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When maintenance activities are completed, tools shall be accounted for and debris removed. A hand-over procedure to prevent operation of equipment after maintenance activities before cleaning and sanitising are completed shall be in place.

2.4.4 Cleaning and Sanitation Programme

A written cleaning and sanitation programme covering processing environment, equipment (including tankers inbound and outbound) and tools must be in place. The programme shall address:

- Sanitation schedules, methods, frequencies and responsibilities for cleaning and cleaning verification activities
- Correct use of appropriate sanitation equipment and tools
- Equipment disassembly and re-assembly
- Validation of sanitation effectiveness
- Verification procedures (pre-start up/post-cleaning inspections as a minimum; ATP or microbiological swabbing are additional means of verification ☐ environmental monitoring)
- Record keeping, record review and corrective action plans

Written sanitation instructions shall include (where applicable):

- Chemicals to be used and how they are to be used including chemical concentration, contact time, temperatures, frequencies and rinsing procedures
- Clean in Place / Clean Out of Place (CIP/COP) steps

Proper tools and materials must be used to prevent extraneous matter, microbiological and/or chemical contamination of the product. Brushes and utensils for cleaning food contact surfaces shall be clearly identified (e.g. labelled and/or colour coded) and stored separately from non-food contact tools.

2.4.5 Programmes for Prevention of (Cross-) Contamination

2.4.5.1 Allergens Management Programme

Preventive measures shall be implemented to ensure that no undeclared allergens are accidentally introduced into materials during processing and storage.

The allergens management program shall cover the food allergens listed below and any other allergen included in local regulations:

- Celery
- Cereals containing gluten (wheat, rye, barley, oats, spelt)
- Egg and egg products
- Dairy products
- Mustard
- Peanut and peanut products (Including peanut butter and partially refined peanut oil)

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- Seafood (all fish, crustaceans, mollusc and shellfish); each seafood type should be considered an allergen distinct from the other seafood allergens)
- Seeds (specifically poppy, sesame and sunflower; each seed type should be considered an allergen distinct from the other seed allergens)
- Soybean and soybean products
- Tree nuts (Brazil nut, walnut, hazelnut, filbert, cashew, chestnut, almond, pine, pistachio, pecan, Queensland nut and macadamia nut; each tree nut type should be considered an allergen distinct from the other tree nut allergens)
- Sulphites (may be a component of other materials such as wine, dried fruits or other partially compounded ingredients). Regulations require that foods, which contain 10 ppm or more of sulphites, include 'sulphite' on their ingredient statement.
- Lupines

In case GIVAUDAN requires the vendor to supply materials including one of these or other allergens the vendor must clearly declare and label them in accordance with all applicable legislation and regulation in the location in which materials are produced and the destination to which materials may be delivered.

2.4.5.2 Foreign Matter Control Programme

Foreign material is any material not intended to be part of the finished product, including, but not limited to: bones, cloth, dirt, feathers, glass, hair, insect parts, metal, paper, plastic, rocks, rodents, rust, stems and wood.

A written programme to prevent and detect foreign material must be in place.

A risk assessment shall be performed to determine potential sources of foreign material, including: raw materials, packaging materials, equipment design, plant environment (e.g. ceilings, walls, floors), processing and packaging equipment, utensils, contamination from personnel or other operations such as cleaning and sanitation, contract work, rework / work-in-process protocol, maintenance or repair of equipment, and historical information of types of foreign body previously found or reported by customer complaints.

Periodic reassessments shall be conducted, particularly following changes to the plant environment and instances of non-conformance (e.g. customer complaints, CCP failures).

A programme to control glass and hard / brittle plastic shall be in place. The programme should restrict the use of glass and hard / brittle plastic and identify equipment and areas were glass and hard / brittle plastic are used. Facilities packaging materials in glass shall properly clean the containers and provide shielding to protect materials and ingredients in event of glass or hard / brittle plastic breakage during production. Regular inspections and breakage procedure shall be implemented.

The use of wooden pallets in food handling and processing zones should be avoided whenever possible.

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Foreign Material Control Devices add an additional level of safety. These devices may detect and/or eliminate foreign material introduced through (contaminated) raw material, the processing environment or equipment (due to damage or material wear).

They shall be installed at the last possible point in order to exclude subsequent contamination risks. Terminal foreign material control devices are considered CCPs and have to be managed accordingly (refer to HACCP – CCP monitoring).

The following devices are commonly used:

- Screens, sieves or filters
- Magnets
- Metal detectors

2.4.5.3 Chemical Control Programme

A chemical approval and control programme to assure the safe use and storage of chemicals, including those used in pest control must be in place. The programme shall ensure only approved food grade chemicals are used in food and on food contact surfaces or for food contact packaging materials production.

A chemical inventory shall be maintained and shall make MSDS available for all chemicals used in the facility. Chemicals shall be clearly identified and stored in a restricted/locked area vented to the outside and accessible only by trained employees. Chemicals shall not be stored in containers that can be mistaken for raw material / finished product packaging.

Empty chemicals containers shall not be reused. Procedures for handling chemical spills shall be established.

Lubricants

Only food grade lubricants shall be used on equipment located over product or product conveyors. A physical separation shall be maintained of food grade and non-food grade lubricants in storage areas and cabinets. Lubricants and grease guns for food grade or non-food grade lubricants shall be clearly labelled.

2.4.5.4 Microbiological Control Programme

A microbiological control programme must be in place to ensure the microbiological safety and stability of:

- Raw materials
- Finished goods

An environmental micro-testing programme has to be established and shall include processing and ancillary equipment swabbing, pathogen monitoring (listeria, salmonella), water and air testing.

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Microbiological Testing

Microbiological testing required for materials or as part of environmental monitoring can be performed by accredited external laboratories or by on-site labs, if these comply with the following requirements:

- The laboratory must be physically segregated from production area
- The laboratory design and practices must prevent the potential for cross-contamination of pathogens by restricting access to authorised personnel
- Signs must be posted to advise that the area is restricted
- Relative air pressure shall be negative to the adjacent rooms
- The air in microbiology laboratories shall be filtered using a separate air treatment system
- Any potentially infectious material shall be sterilised prior to disposal

Environmental Monitoring

The programme shall be designed to identify the presence and extent of the potential micro contamination on processing equipment (= cleaning verification) and in the plant environment (= verification of control measures related to 'Hygiene Zoning') and describe appropriate corrective actions, as needed, to assure the elimination of potential contamination. At a minimum the programme shall define:

- How sampling sites are selected
- Target micro-organism(s)
- Frequency of sampling
- Method of sampling
- Testing methodology
- Acceptance criteria
- Corrective actions to be followed, if a result is outside the defined acceptance criteria

a) Pathogen Environmental Monitoring

The pathogen monitoring programme shall be designed to verify that control measures related to the 'Hygiene Zoning' concept are effective.

Consequently, sampling location selection should take into account personnel traffic and product flow within the production environment and be based on the potential to harbour pathogens. Sampling locations should include drains located in relevant areas and be reviewed and changed on a regular basis. Routine sampling must occur during normal operating hours, when materials are being manufactured. Site description for each sample should enable clear correlation to the sampling site within the plant environment.

b) Food Contact Surfaces / Cleaning Verification

The hygienic conditions, and thus effectiveness of cleaning activities on manufacturing and ancillary equipment respectively, shall be monitored by ATP

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testing and/or microbiological swabbing. Swab locations should be reviewed and changed on a periodic basis.

c) Water

The microbiological quality of water used as direct ingredient or for cleaning of food contact surfaces shall be monitored on regular basis. Samples shall be taken from different 'point-of-use' locations, preferably from those that are furthest from the main line. Sampling points should be reviewed and changed on a periodic basis.

d) Air

Monitoring of the microbiological air quality is important to identify the potential failure of air filtration and ventilations measures or deficiencies in cleaning and sanitation procedures ('aerosols'). The air quality shall be monitored in areas of open product handling, by sedimentation or impaction method.

Compliance to the environmental monitoring programme shall be verified and documented at least quarterly. Review of the environmental monitoring programme shall be performed when changes occur to the process, processing environment or product (e.g. new equipment installation, changed process flows, introduction of a new highly sensitive raw materials etc.)

2.4.5.5 Genetically Modified Organisms Management Program

Preventive measures shall be implemented to ensure that no undeclared GMO material is accidentally introduced into materials during processing and storage.

In case GIVAUDAN requires the vendor to supply materials including GMO materials, the vendor must clearly declare and label them in accordance with all applicable legislation and regulation in the location in which materials are produced and the destination to which materials may be delivered.

2.4.5.6 Preventive Controls (SAHCODHA Hazards Controlled by Supplier)

This paragraph is applicable for all raw materials which are imported into the US to be used in food for human or animal consumption.

For products where there is reasonable probability (i.e. historical evidence) that exposure to a known hazard will result in serious adverse health consequences or death to humans or animals (also known as SAHCODHA items under FDA legislation) the vendor must:

- Carry out a **Hazard Analysis Study** for products and production processes
- **Identify hazards** that require preventive controls
- Implement **appropriate preventive controls** to minimize or prevent the hazards
- Ensure the preventive control is **validated** for the hazard being controlled

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- **Prevent cross-contamination** during production
- Determine and document which **verification activities** are appropriate to verify adequate control of hazards and how frequently such activities must be conducted
- **Notify Givaudan** of any hazard that is **not controlled** by the vendor itself, where Givaudan would need to ensure this is part of Givaudan's risk assessment of the material

Hazard (examples)	Preventive Control (examples)
Biological: Salmonella spp., Listeria spp., Clostridium spp., norovirus etc. ("pathogens" or "viruses" is not acceptable)	Biological: Sterilization, Pasteurization, Environmental monitoring program
Physical: Identify the type of foreign matter: wood, glass, plastic, stones etc. In case of metal, specify type (stainless steel, ferrous, non-ferrous)	Physical: Metal detection with detection limit of 2.0 mm Ferrous, 2.0 mm non-Ferrous, 2.5 mm Stainless Steel Use of an in-line 20 mesh sieve screen
Chemical (including radiological): Allergens (specify, if from cross-contact, labelling or both) Contaminants (Agricultural residues, aflatoxins, lead, mercury, radio-nuclides etc.) ("Chemical Contamination" is not acceptable)	Chemical (including radiological): Allergen control program, allergen cleaning validation program Analytical testing programs on relevant contaminants Sourcing location considerations (radiological)

Furthermore any FDA food safety regulations that apply must be considered. This shall include review of the vendor's written food safety plan.

2.4.5.7 Preventive Controls (Verification of kill steps for pathogens)

Ingredients which are supposed be used for human consumption in their current state must have the status 'Ready-to-Use' (RTU) and must not contain any pathogenic microorganisms. Ingredient can have this status either by their nature or they have been subject to a lethality step (also known as 'kill step'; e.g. heat treatment, fumigation, irradiation, or other acceptable method).

The manufacturer shall apply control measures (micro treatment/kill step) for microbiological food safety hazards. A validated kill step is a step in the manufacturing process where a minimum of a **5-log reduction** is achieved for vegetative pathogens usually Salmonella. This reduction is validated through:

- **Validation based on literature:** In literature process conditions can be found for lethality steps. Literature studies may be used as validation criteria on the following conditions:
  - The literature is peer reviewed and from an acknowledged source (e.g. scientific journals, university etc.).
  - The study is representative for the product and process.

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        - The product has similar intrinsic properties like water activity, pH, sugar, salt, and fat content.
        - The process conditions are similar (same type of equipment).
    - No extrapolation of inactivation data to different product matrices or heating systems or extrapolating data outside the range of the experimental conditions.
    - Use a multi strain cocktail of relevant *Salmonella* species, preferably from outbreaks.
    - Based on preferably 3 independent literature sources.

- **If literature studies are not available** the preferred option is executing a validation study using a surrogate microorganism like *Enterococcus feacium* that mimics the properties of the pathogen but is not pathogenic itself.
- An alternative option is validation through laboratory experiments. The prerequisite condition for applying an experimental laboratory validation is product temperature (coldest spot) and holding time can be easily measured and monitored during production, which allows the representative simulation of pasteurization at a set temperature and holding time in a laboratory heating system (e.g. using water bath).
- Kill step that is prescribed in the countries regulations which may also be considered as a validated kill step.

There are a variety of micro treatments or kill steps possible:

- **Irradiation** refers to electron beams, X-rays or gamma rays. The irradiation dose required is 5 - 10 kGy unless validation experiments show a lower dose achieves a 5 log reduction for *Salmonella*
- **Propylene oxide or Ethylene oxide** treatment (fumigation)
- **Pasteurization:** Refers to heating of a liquid product up to 100 °C/212°F. Pasteurization only kills vegetative bacteria, spores will survive. Cooking (boiling) or blanching of fruit, vegetables, etc. can be considered as pasteurization when a temperature of minimum 90 °C is reached which is far above the minimum required temperature for high moisture foods.
- **Sterilization:** Refers to heating of a liquid product at temperatures above 100°C /212°F. Vegetative bacteria and spores are killed. Typically 121°C/250°F for 3 minutes or alternatively 145°C/293°F for 2 seconds.
- **Ultra-filtration:** Refers to filtration of a clear liquid over a micro filter of 0.2 – 0.45 µm. Reversed osmosis is accepted as an alternative.
- **Acidification:** Refers to acidifying a product to a pH < 4.5 with:
    - > 3% acetic acid
    - Vinegar equivalent to > 3 % acetic acid
    - > 5 % lactic acid
    - Acidification may be achieved through fermentation. Acid hydrolysis in the HVP manufacturing process is also considered as kill step.
- **Dry heat treated:** Refers to heating a powder typically at 65°C/149°F for several days or at 95°C/203°F for several hours. ***The treatment must be supported by a validation study using surrogate organisms.***

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- **Steam treatment:** Refers to a heat treatment in which the product usually a powder is brought into contact with steam for a short time. ***The treatment must be supported by a validation study using surrogate organisms.***

There are two exceptions, where controls of the microbiological hazards at the manufacturer are not needed:

- The pathogen control step is at Givaudan.
- Givaudan is using the ingredient in a product that is intended to be FFP "For Further Processing" (to be cooked) and the control step is at Givaudan's customer.

2.4.6 Pest Management Programme

A documented pest management programme must be in place that covers the facility and the surrounding area effectively. The pest management programme shall include as a minimum:

- A map showing the location of pest control devices, such as indoor rodent traps, insect light traps, pheromone traps, insect glue boards, outdoor bait stations etc.
- Monitoring / inspection procedures and frequencies (schedules)
- Records of inspections including pest activity log
- Records of application of pesticides
- Analysis of records for trends in pest activity and corrective / preventive actions in case of increased activity
- Training requirements / licenses

Exclusion shall be the first line of defence and primary method of controlling pests. Next to this, an effective monitoring system shall be established to detect pest infestation at an early stage. Whenever feasible and practical, the usage of toxic baits shall be avoided in processing, storage and distributions areas.

If pesticides need to be used, they must be used in accordance with local regulations. Records shall be maintained with name, quantity, EPA number (US) or equivalent identification in other jurisdictions and lot number of the pesticide used.

All pest control activities must be performed by a trained individual, preferably a licensed pest control technician. A copy of the pest control technician's current license must be kept on file.

All pest control devices must be inspected / serviced at a frequency appropriate to identify pest activity in a timely manner.

2.4.7 Food Safety Aspects of Waste Management Programme

Waste shall be removed from the premises on a routine basis. If waste is held on site prior to disposal, this shall be done in a separate area located away from direct entry to manufacturing and warehouse areas. The area shall be kept clean and free of spillage, containers shall be covered / closed and suitably fly-proofed.

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Waste disposal equipment, waste bins, and storage areas shall be regularly cleaned and sanitised to avoid attraction of pests.

2.4.8 Personal Hygienic Practice

2.4.8.1 General Behaviour

Rules regarding the wearing and changing of protective clothing in relation to the 'Hygiene Zoning' concept shall be documented and communicated to all employees, including temporary staff.

Smoking, chewing, eating, drinking or spitting shall be prohibited in any food processing and/or handling area. If sensory evaluations occur in the food handling / contact zone, following controls shall be implemented to assure:

- Food safety is not compromised
- Authorised employees conduct all sensory evaluations
- Employees conducting sensory evaluations practice a high standard of personal hygiene
- Sensory evaluations occurs only in areas equipped for that purpose
- Equipment for sensory evaluation is sanitised after use and stored separately from processing equipment

Employees shall wash hands before beginning operations and after each absence or activity where hands are potentially soiled (e.g. using the restroom, handling dirty material, smoking, eating and drinking). Even if gloves are used for product handling, employees shall maintain good hand washing practices. Gloves shall be regularly checked and changed, whenever they are dirty or damaged or have come in contact with non-product contact surfaces.

Employees shall not wear jewellery or personal effects that present a potential contamination risk. Hairnets and beard restrains shall be used to fully cover scalp and facial hair, based on risk assessment.

Visitors and contractors shall wear suitable clothing and footwear when entering any food processing or handling area. Visitors and contractors shall enter and exit food processing and handling areas through proper staff entrance and exit points and shall comply with all hand washing and personal hygiene requirements. Documented rules for visitors and contractors shall be in place.

2.4.8.2 Medical Screening

Medical screening procedures must be in place for new and existing employees, visitors as well as contractors with respect to food safety.

2.4.8.3 Illness and Communicable Disease

Anybody afflicted with a communicable, infectious disease shall not be permitted access to processing areas. Instructions for the control of illness and communicable

diseases must be established, documented, communicated to all employees, including temporary staff, contractors and visitors. Cuts and grazes on exposed skin shall be covered with coloured, preferably metal detectable plasters.

No person shall be admitted to processing areas, if the person carries a communicable disease. Employees that cannot effectively cover a skin cut or graze shall not handle open product.

2.4.9 Food Safety Training

The food safety team and other personnel carrying out activities having an impact on food safety shall be competent and shall have appropriate technical skills. An employee training programme shall be in place. Each employee should receive at least job specific GMP personal hygiene and safety training. Training shall be provided to new employees before starting work in production. Specifically employees monitoring CCPs must receive specific instruction on monitoring, documentation, corrections and corrective actions prior to commencing work.

Refresher training shall be provided at least annually. Refresher Trainings should cover HACCP principles and prerequisite programmes as relevant.

The assessment of the employee's understanding of the key messages is of critical importance (i.e. through questioning, quizzes, tests etc.).

Records shall be maintained in relation to personnel training, skills and experience. A periodic evaluation shall be performed to verify the effectiveness of training programmes, e.g. through management supervision and internal auditing / inspections. Visitors and contractors shall be covered with site specific training programmes, as necessary, prior to performing activities which may affect product safety or quality.

2.4.10 Receiving, Storage and Transportation

2.4.10.1 Receiving

Incoming products and packaging materials must comply with applicable regulations and vendor specifications, including microbiological, physical, chemical criteria and residues requirements. Vendors shall establish and make available to GIVAUDAN testing requirements, parameters and specified limits to ensure food safety and quality of all raw materials, ingredients, and packaging materials.

Prior to accepting incoming materials, the vendor must verify that delivery vehicles (such as trucks or railcars) have maintained the quality and safety of the material during transit. Verification activities shall include inspection of vehicle cleanliness and structural integrity, inspection of packaging for cleanliness and seal integrity, and temperature measurement for refrigerated or frozen items.

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Tankers or railcars shall be dedicated to food only – with records available for the previous product shipped. They shall be adequately cleaned and sanitised, as applicable and cleaning records shall be checked upon receipt.

Procedures that require verification of seal integrity and seal numbers with accompanying shipping documentation shall be implemented for tankers and railcars.

Inbound loads suspected of any type of tampering shall be investigated. Records must be maintained.

2.4.10.2 Hygienic Storage

Storage areas or rooms shall be managed to prevent damage to, deterioration of or tampering with products and packaging materials. Procedures for the control of storage facilities shall be in place and include, but not be limited to:

- Stock rotation (FIFO / FEFO)
- Control of temperature and humidity (where applicable)
- Adequate protection of materials during storage
- Control of pallets (hygienic conditions)
- Segregation (allergens, GMO etc.)
- Spillage procedures
- Cleaning schedules
- Regular warehouse inspections (incl. pest control)

If third party warehouse are used to store raw materials, packaging materials, intermediates or finished products, a periodic assessment to ensure that the requirements laid down in this document are met shall be conducted.

2.4.10.3 Hygienic Transport

A transportation program shall be in place to ensure that products are maintained in good condition, clean, dry and sealed and – where applicable - properly temperature controlled at all times during transportation.

Where controlled temperatures or other specific transport conditions are mandatory to maintain the product quality, a transport validation is required.

2.4.11 Rework Control

A documented rework procedure outlining how non-conforming products have to be reworked must be implemented. At a minimum, the procedure shall ensure:

- Qualified employees supervise rework operations
- Clear identification and complete traceability of reworked product
- Clear identification of rework containing allergens and segregation as required by the
- Inspection and/or analysis of each batch of reworked product before release

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- A documented break in the rework cycle
- Compliance with all applicable regulations, including labelling requirements

2.4.12 Food Defence Programme

A food defence programme shall be established and maintained to prevent food adulteration caused by deliberate acts of sabotage, vandalism or terrorist like incidents. The programme shall include, but is not limited to:

- The appropriate management responsibility for food defence
- Methods to control and record access to the premises by people, vehicles and materials
- Access to production and storage areas should be physically restricted by use of lock, electronic card key or alternative systems
- Measures taken to assure the security of raw materials and packaging upon receiving and finished goods upon shipping (tamper evidence).

The food defence programme shall be based on results of a threat assessment.

2.4.13 Food Fraud Program

Food fraud is the deliberate and intentional adulteration of food for economic gain. It encompasses a wide range of fraudulent acts, such as the addition of non-authentic substances or removal / replacement of authentic substances as well as the deliberate mislabeling or counterfeiting of food products. .

Adulterated products can be harmful for human consumption. A well-known example is the adulteration of milk with melamine to increase the protein content.

A vendor must therefore identify related risks (**Vulnerability Assessment**) and the likelihood of becoming a victim of fraudulent activities. The assessment should consider potential **motivations** as well as **opportunities** and should consider the following:

- Supply chain mapping
- Behavioral aspects
- Geo-political and socio-economic aspects
- Historical data/evidence

Subsequently a vendor must set up mitigation strategies (**Vulnerability Control Plan**). The Control Plan should consider the following:

- Monitoring strategy (e.g. horizon scanning, market screenings)
- Origin/label verification (e.g. contractual requirements as to traceability and labelling)
- Specification management
- Supplier evaluation concepts (e.g. audits on site)
- Analytical testing strategy (e.g. advanced inspection methods and modified inspection protocols)

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Givaudan advocates the Food Fraud Vulnerability Assessment tool by SSAFE, but other approaches, e.g. Vulnerability Assessments based on the USP Food Fraud Mitigation Guidance or Threat Assessment Critical Control Point (TACCP) according to PAS 96:2014, are acceptable, too.