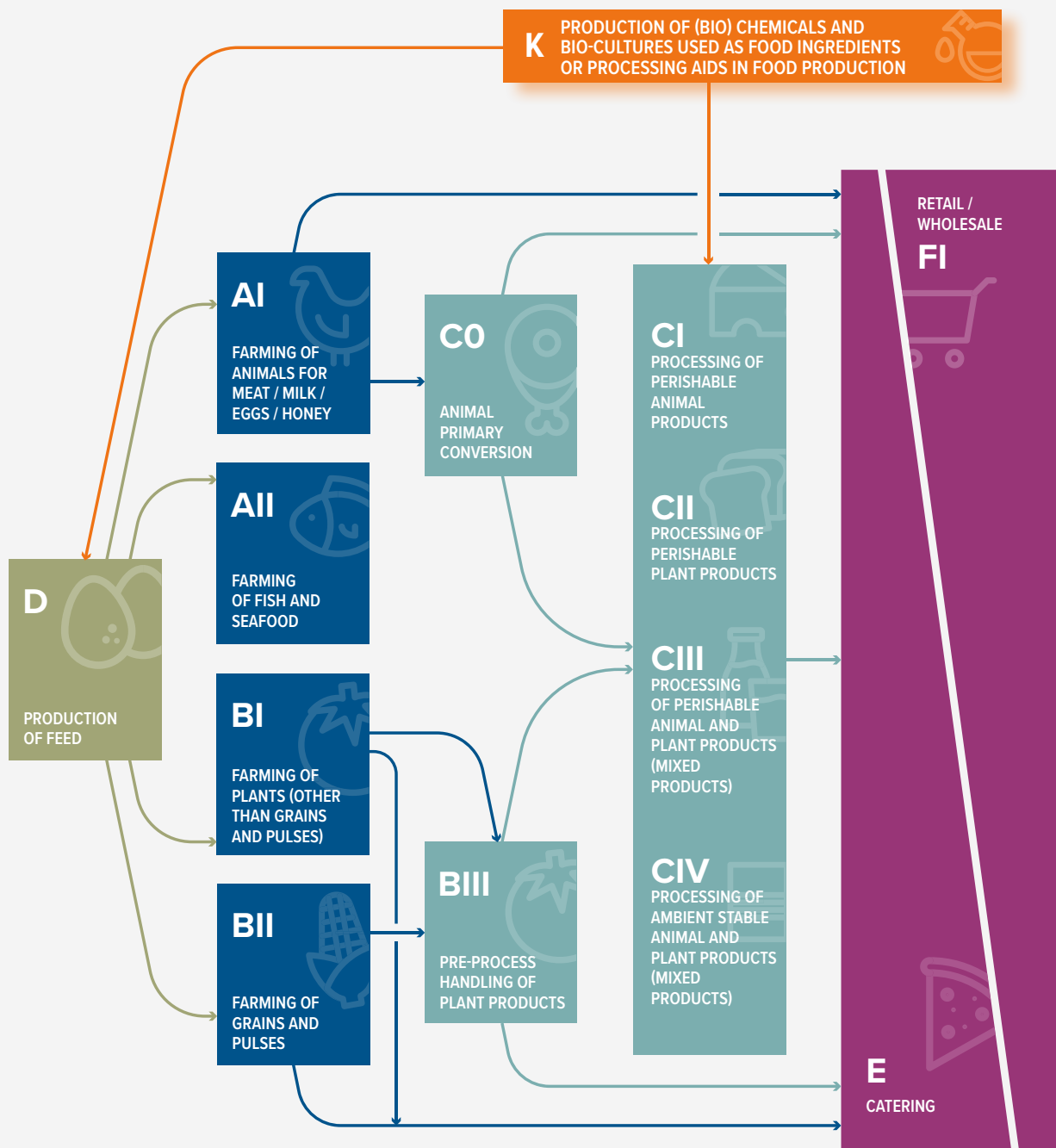




GFSI TECHNICAL EQUIVALENCE REQUIREMENTS VERSION 2020

PART III REQUIREMENTS FOR THE CONTENT OF STANDARDS

K Production of (Bio) Chemicals and Bio-Cultures Used as Food Ingredients or Processing Aids in Food Production



- FII** FOOD BROKER / AGENT
- G** PROVISION OF STORAGE AND DISTRIBUTION SERVICES
- H** PROVISION OF FOOD SAFETY SERVICES
- I** PRODUCTION OF FOOD PACKAGING
- Ji** HYGIENIC DESIGN OF FOOD BUILDINGS AND PROCESSING EQUIPMENT (FOR BUILDING CONSTRUCTORS AND EQUIPMENT MANUFACTURERS)
- Jii** HYGIENIC DESIGN OF FOOD BUILDINGS AND PROCESSING EQUIPMENT (FOR BUILDING AND EQUIPMENT USERS)

Part III - *K* Production of (Bio) Chemicals and Bio-Cultures Used as Food Ingredients or Processing Aids in Food Production

Part III of the GFSI Technical Equivalence Requirements defines the key elements required in a Standard in relation to:

- **Hazard and Risk Management Systems** (Hazard Analysis and Critical Control Points (HACCP) or HACCP based systems);
- **Food Safety Management Systems;**
- **Good Industry Practices, Good Manufacturing Practices, Good Agricultural Practices.**

This document applies to Standards applying for the scope of acknowledgement K - Production of (Bio) chemicals and bio-cultures used as food ingredients or processing aids in food production. This scope includes the following product, services and activities:

- **Production of food and feed additives, vitamins, minerals, bio- cultures, flavourings, enzymes and processing aids.**
- **Note: pesticides, drugs, fertilizers and cleaning agents are excluded.**

The requirements – named key elements – were identified by a multi-stakeholder group including industry experts to ensure relevance to this scope while ensuring harmonisation of food safety standards across industry. Although the structure of each

scope of Part III of the GFSI Technical Equivalence Requirements is aligned, some of the key elements may be specific to the industry included in this scope.

GFSI-acknowledged Standard Owners are required to address each key. The detailed content of each individual Standard must however be independently developed and is not expected to be a direct copy of the GFSI Technical Equivalence Requirements.

GFSI has defined in a Glossary terms used in key elements. Part IV, the Glossary, is an integrated part of the GFSI Technical Equivalence Requirements and definitions shall be applied accordingly in Standards. In the GFSI Technical Equivalence Requirements, food is used as an umbrella term and refers to the object of each of the scope, i.e. food, feed, packaging as applicable.

The Codex Alimentarius Guidelines on food hygiene and its HACCP annex constitutes an internationally recognised reference for food business operators and competent authorities to oversee food safety. As such, in addition to the following key elements, the Standard Owner shall ensure that the site has knowledge and align their practices to best industry practices and the Codex Alimentarius General Principles of Food Hygiene.

SECTION 1: HAZARD AND RISK MANAGEMENT SYSTEMS REQUIREMENTS

REFERENCE	ELEMENT	THE STANDARD SHALL REQUIRE THAT
HACCP 1.1	Hazard and Risk management system	A Hazard and Risk Management System including shall be implemented prerequisite programmes to identify and control food safety hazards, including allergens. This system shall be systematic, comprehensive and shall take into consideration relevant law.
HACCP 1.1.2	Hazard and Risk management system	This shall be a HACCP system, based on the Annex of Codex Alimentarius General Principles of Food Hygiene.
HACCP 1.2	Hazard and Risk management system	The scope of the Hazard and Risk Management System shall be defined per product / product category and / or per process or production step.
HACCP 1.3	Hazard and Risk management system	The Hazard and Risk Management System shall be applicable to the site's scope of activity.
HACCP 1.4	Hazard and Risk management system	The Hazard and Risk Management System shall be reviewed regularly, and in case of any change that impacts food safety.

SECTION 2: FOOD SAFETY MANAGEMENT SYSTEMS REQUIREMENTS

REFERENCE	ELEMENT	THE STANDARD SHALL REQUIRE THAT
FSM 1	Management responsibility	A clear organisational structure identifying the job functions and responsibilities of at least those employees whose activities affect food safety shall be established, implemented and maintained.
FSM 2	Management commitment and food safety culture	Evidence of the senior management's commitment to establish, implement, maintain and continuously improve the Food Safety Management System shall be provided. This shall include elements of food safety culture, at a minimum consisting of: communication, training, feedback from employees and performance measurement on food safety related activities.
FSM 3	Management review	The senior management shall review all elements of the Food Safety Management System, including the Hazard and Risk Management System HACCP plan or HACCP-based plans regularly, and in case of any change that impacts food safety, to ensure their continuing suitability and effectiveness.
FSM 4.1	Food safety legislation	Procedures shall be established, implemented and maintained to ensure compliance with applicable legislation (both countries of production and intended sale).
FSM 5	Food Safety Management system	The elements of the Food Safety Management System shall be established, implemented, maintained and continuously improved and shall have a scope appropriate to the range of business activities to be covered.
FSM 6	Food safety policy and objectives	A clear, concise and documented food safety policy statement shall be in place, as well as measurable objectives specifying the extent of the organisation's commitment to meet the food safety needs.
FSM 7.1	Food defence	A food defence threat assessment procedure shall be established, implemented and maintained to identify potential threats and prioritise food defence measures.

FSM 7.2	Food defence	A documented food defence plan shall be in place specifying the measures implemented to mitigate the public health risks from any identified food defence threats.
FSM 7.3	Food defence	This food defence plan shall be supported by the Food Safety Management System.
FSM 8.1	Food fraud	A food fraud vulnerability assessment procedure shall be established, implemented and maintained to identify potential vulnerability and prioritise food fraud mitigation measures.
FSM 8.2	Food fraud	A documented food fraud plan shall be in place specifying the measures implemented to mitigate the public health risks from the identified food fraud vulnerabilities.
FSM 8.3	Food fraud	This food fraud mitigation plan shall be supported by the organisation's Food Safety Management System.
FSM 9.1	Documentation requirements	A procedure shall be established, implemented and maintained for the management and control of documented information required to demonstrate the effective operation and control of processes and the Food Safety Management System.
FSM 9.2.3	Documentation requirements	All the above-mentioned documented information shall be securely stored for the time period required to meet customer and legal requirements, or for a period exceeding the shelf-life of the packaging if customer or legal requirements are not available. It shall be effectively controlled and readily accessible when needed.
FSM 10.1	Specified requirements / Specifications	Specified requirements or specifications shall be established, implemented and maintained for all inputs to the process, including services that are purchased or provided and have an effect on food safety.
FSM 10.2	Specified requirements / Specifications	A review process of the specified requirements or specifications shall be in place.
FSM 11	Procedures	Effective procedures and instructions shall be established, implemented and maintained for all processes and operations having an effect on food safety.
FSM 12	Resource management	The resources needed to establish, implement, maintain, review and improve the Food Safety Management System shall be identified and assigned.

FSM 13.1.2	Purchasing and supplier performance	A purchasing procedure shall be established, implemented and maintained to ensure that all inputs to the process, including externally purchased materials and services which have an effect on food safety, conform to specified requirements or specifications as well as food safety and regulatory requirements.
FSM 13.2.1	Purchasing and supplier performance	A procedure for the evaluation, approval and continued monitoring of suppliers which have an effect on food safety shall be established, implemented and maintained. The procedure shall address procurement in emergency situations to ensure that food still conforms to the documented specified requirements or specifications, and the supplier has been evaluated. The results of evaluations, investigations and follow up actions shall be recorded.
FSM 13.3	Purchasing and supplier performance	Outsourced processes that may have an effect on food safety shall be identified and controlled. Such controls shall be documented in the Food Safety Management System.
FSM 14.1.1	Traceability	Procedures shall be established, implemented and maintained to ensure product identification from the supplier (minimum one step back) through any processes undertaken to the recipient of the food (minimum one step forward).
FSM 14.2	Traceability	Documented tests of the traceability system shall be undertaken to ensure this is operating effectively.
FSM 15	Product development	Product design and development procedure shall be established, implemented and maintained for new products and changes to product or manufacturing processes to ensure safe and legal products are produced.
FSM 16.1	Allergen management	An allergen management plan shall be established, implemented and maintained. This shall include a risk assessment of allergen cross contamination, implemented controls to reduce or eliminate that risk, and labelling of the food in compliance with the allergen labelling legislation in the country of intended sale.
FSM 17.1	Control of measuring and monitoring equipment / devices	The equipment / devices used to measure parameters critical to ensure food safety shall be identified.

FSM 17.2	Control of measuring and monitoring equipment / devices	The identified equipment / devices shall be regularly calibrated; calibration shall be traceable to a national or international standard or method.
FSM 18.1.1	Product labelling and product information	Finished product shall be labelled to ensure safe use of food, in compliance with the applicable food safety legislation in the country of intended sale.
FSM 19.1	Testing	A procedure shall be established, implemented and maintained to ensure that analyses of food parameters critical to food safety are undertaken by competent laboratories and using appropriate sampling and testing methods and that such analyses are performed in accordance with the applicable requirements of ISO/ IEC 17025.
FSM 20	Internal audit	An internal audit procedure shall be established, implemented and maintained; it shall cover all elements of the Food Safety Management System.
FSM 21	Complaint handling	A procedure for the management of complaints and complaint data shall be established, implemented and maintained to ensure that complaints are assessed and corrective actions implemented, when necessary.
FSM 22	Serious incident management	An incident management procedure, including product recall and withdrawal, shall be established, implemented and maintained. The recall procedure shall be regularly tested for effectiveness.
FSM 23	Product release	A product release procedure shall be established, implemented and maintained.
FSM 24.1	Control of non-conformity	A procedure shall be established, implemented and maintained to ensure that any non-conformity impacting food safety and any non-conforming products are clearly identified and controlled to prevent unintended use or delivery.
FSM 25	Corrective actions	A procedure shall be established, implemented and maintained for the determination and implementation of corrective actions in the event of any significant non-conformity relating to food safety.

SECTION 3: GOOD INDUSTRY PRACTICE REQUIREMENTS

REFERENCE	ELEMENT	THE STANDARD SHALL REQUIRE THAT
GMP 1	Site environment	The site shall be located and maintained to enable the reception, storage, production and distribution of safe food and to prevent its contamination.
GMP 2	Local environment	All grounds within the site shall be maintained to prevent contamination and enable the production of safe products.
GMP 3	Site design, construction, layout and flow of operations	The site, both the exterior and the interior, shall be designed, constructed and maintained to minimise food safety risks. The layout and flow of operations shall be suitable for the intended purpose and designed to minimise food safety risks.
GMP 4.1	Product contamination risk and segregation	Procedures shall be established, implemented and maintained to prevent or minimise risk of contamination and cross-contamination of purchased materials, work in progress, rework, packaging and finished product covering all aspects of food safety.
GMP 5	Employee facilities	Employee facilities including hand washing and toilet facilities, and public facilities where applicable, shall be provided, designed and operated to minimise food safety risks.
GMP 6.1	Personal hygiene, protective clothing and medical screening	Documented personal hygiene standards shall be established, implemented and maintained to minimise food safety risks.
GMP 6.2	Personal hygiene, protective clothing and medical screening	Suitable protective clothing shall be provided to minimise food safety risks.
GMP 6.3	Personal hygiene, protective clothing and medical screening	A medical screening procedure shall be established, implemented and maintained to identify conditions impacting food safety and that any person affected shall immediately report illness or symptoms to management, subject to legal restrictions in the country of operation.

GMP 6.4	Personal hygiene, protective clothing and medical screening	The requirements 6.1, 6.2, and 6.3 shall apply to employees, contractors and visitors commensurate to their impact on food safety.
GMP 7	Training	Procedure shall be established, implemented and maintained to ensure that all employees are trained, and retrained as necessary to have an understanding in food safety, commensurate with their activity.
GMP 8.1.1	Housekeeping, cleaning and disinfection	Procedure of housekeeping, cleaning and disinfection shall be established, implemented and maintained. Its effectiveness in minimising food safety risks shall be verified, based on the risks associated with the product or activity. Cleaning activities shall not represent a food safety risk.
GMP 8.2	Housekeeping, cleaning and disinfection	Cleaning facilities, equipment and chemical materials shall be suitable for their intended use and shall be stored and used appropriately.
GMP 9	Rework	Rework shall be managed to minimise food safety risks and not to compromise traceability.
GMP 10	Site inspections / checks	A programme of site inspections / checks shall be established, implemented and maintained to ensure the site environment and processing equipment are maintained in a suitable condition to ensure food safety, as applicable to the activity of the site.
GMP 11	Air and water quality	Air, compressed gases, and water (including ice and steam) in any form which could impact food safety shall be regularly monitored, and adequately stored and handled in order to minimise food safety risks. Water not intended for use in food production, if available on site, shall be managed to minimise food safety risks.
GMP 12.1	Waste management	A procedure shall be established, implemented and maintained for the collection, storage and disposal of waste material, including waste water and drainage.
GMP 13	Pest control	A procedure shall be established, implemented and maintained to prevent, monitor and control or eliminate the risk of pest infestation at the site.

GMP 14	Reception of purchased materials	Appropriate procedures for the reception of purchased materials shall be established, implemented and maintained to assure that only materials that meet food safety requirements are accepted.
GMP 15	Transport	All containers and vehicles used for transportation in a way that could impact food safety shall be designed, constructed and maintained to minimise food safety risks. They shall be suitable for the intended purpose.
GMP 16.1	Storage	Food shall be held or stored in designated areas and handled under controlled conditions to minimise food safety risks.
GMP 17	Stock management	A procedure shall be established, implemented and maintained to ensure that purchased materials, work in progress and finished products are used in the correct order, and within the allocated shelf life when applicable.
GMP 18	Equipment	Equipment shall be suitable for the intended purpose. Equipment shall be designed, constructed, maintained, and used and stored to minimise food safety risks.
GMP 19	Maintenance	Effective planned maintenance shall be in place for the site and equipment to minimise food safety risks. Maintenance activities shall not represent food safety risks.