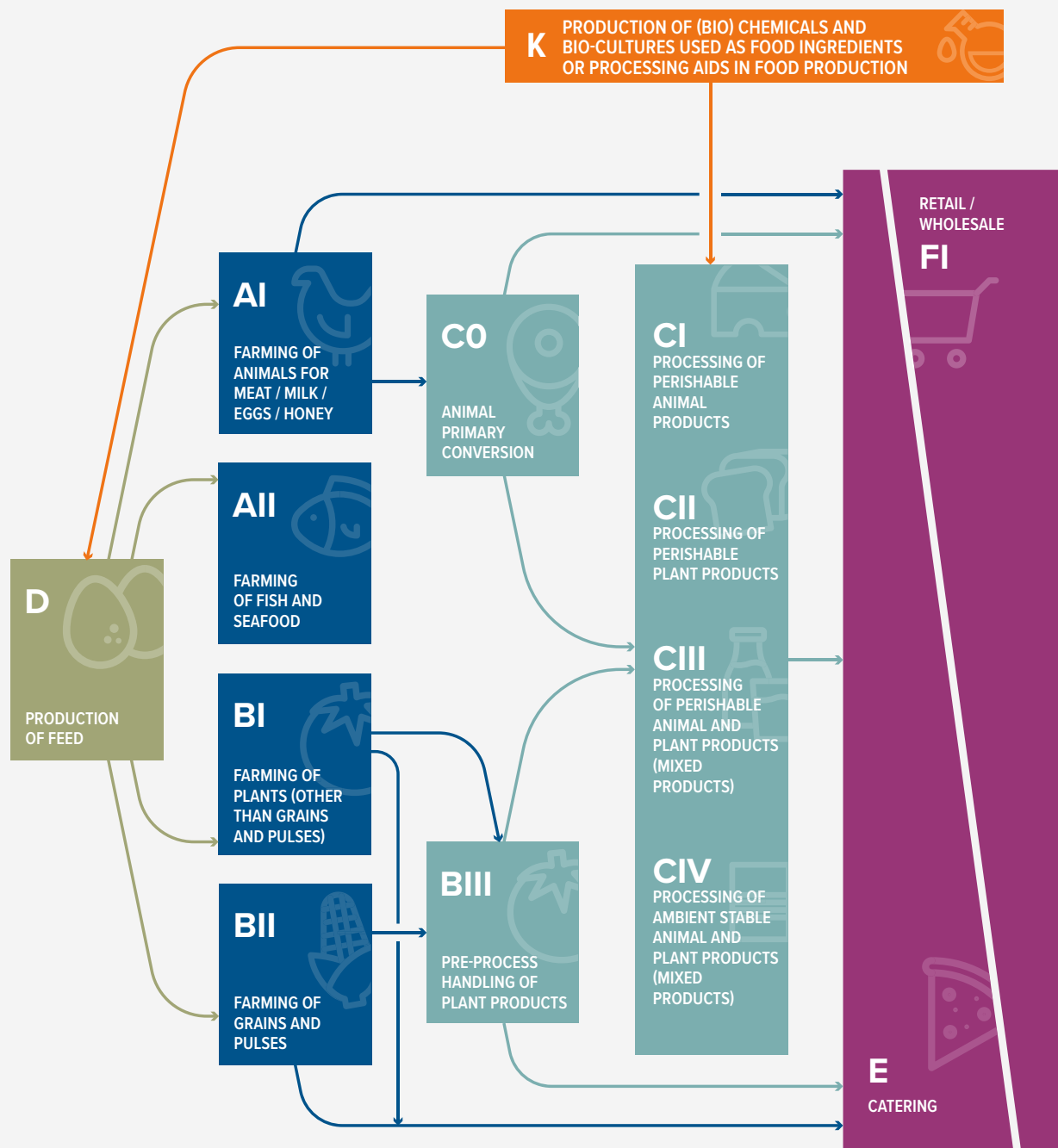




GFSI TECHNICAL EQUIVALENCE REQUIREMENTS VERSION 2020

PART III
**REQUIREMENTS
FOR THE CONTENT
OF STANDARDS**

JI Hygienic Design of Food Buildings and Processing Equipment
(for building constructors and equipment manufacturers)



- 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 - *J1* Hygienic Design of Food Buildings and Processing Equipment (for building constructors and equipment manufacturers)

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);
- **Hygienic Design Management Systems;**
- **Good Industry Practices, Good Manufacturing Practices, Good Agricultural Practices.**

This document applies to Standard Owners applying for the scope of acknowledgement J1 - the design and construction of equipment and facilities dedicated to the production of food by the provider of such services. This scope includes the following product, services and activities:

- **Manufacturers of equipment, including any components necessary to link them together, and their utilities and utensils necessary for their operation, for farms food production facilities, food retail and wholesale operations, and packaging dedicated to food;**
- **Architects, Engineers and Designers of food handling facilities, including farm, food manufacturing, storage and retail buildings;**
- **The builders of above facilities.**

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

GFSI-recognised Standard Owners are required to address each key element outlined in this document. 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.

SECTION 1: HAZARD AND RISK MANAGEMENT SYSTEMS REQUIREMENTS

| REFERENCE | ELEMENT | THE STANDARD SHALL REQUIRE THAT |
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| HACCP 1.5 | Hygienic design process | A competent multidisciplinary team shall assess the hygienic design and risk assessment of new buildings/equipment. |
| HACCP 1.6 | Hygienic design process | The hygienic design and suitability of buildings and equipment shall be evaluated throughout their life cycle from the design concept, through construction, purchasing and during use, until the end of their intended life. |
| HACCP 1.7 | Risk assessment | A documented hygienic design risk assessment for food safety hazards on new and existing buildings/equipment shall be established, implemented and maintained. It shall include as a minimum the following considerations: intended use, food safety hazard identification, evaluation. |
| HACCP 1.9.1 | Intended use | The intended use of the building/equipment shall be specified. |
| HACCP 1.10 | Hygienic design principles | Appropriate building/equipment hygienic design principles shall be adopted based on the designated risk assessment, appropriate to their intended use and taking into consideration a user specification. |
| HACCP 1.11 | Hygienic design principles | Buildings and equipment shall be of a cleanable design, to meet all cleaning objectives. |
| HACCP 1.12 | Hygienic design principles | Buildings and equipment shall be designed and constructed to avoid favourable growth conditions (for microorganisms, pests and their harbourage), appropriate to their intended use. |
| HACCP 1.13 | Hygienic design principles | Buildings and equipment shall be designed to prevent contamination appropriate to their intended use. |

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| HACCP 1.14 | Hygienic design principles | Wherever relevant, recognised hygienic design standards/guidance shall be consulted for the design and construction of buildings and equipment, appropriate for their intended use. |
| HACCP 1.15 | Hygienic design principles | Appropriate hygienic design principles shall be adopted for the installation of new equipment and construction of buildings at sites handling food. |

SECTION 2: HYGIENIC DESIGN MANAGEMENT SYSTEMS REQUIREMENTS

| REFERENCE | ELEMENT | THE STANDARD SHALL REQUIRE THAT |
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| FSM 1.2 | Management responsibility | A clear organisational structure identifying the job functions and responsibilities of at least those employees whose activities affect Hygienic Design shall be established, implemented and maintained. |
| FSM 2.2 | Management commitment and food safety culture | Evidence of the senior management's commitment to establish, implement, maintain and continuously improve the Hygienic Design Management System shall be provided. |
| FSM 3.2 | Management review | The organisation's senior management shall review the verification of the Hygienic Design System at planned intervals, to ensure their continuing suitability, adequacy and effectiveness. |
| FSM 4.4 | Legislation | Procedures shall be established, implemented and maintained to ensure that buildings and equipment are legally compliant in the hygienic design requirements in the country of known implementation / sale. |
| FSM 5.2 | Hygienic Design Management System | A Hygienic Design Management System shall be established, implemented, maintained and continuously improved. |

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| FSM 6.2 | Hygienic Design Policy | A clear, concise and documented Hygienic Design policy statement shall be in place, as well as measurable objectives specifying the organisation's commitments to meet the food safety needs of its products. |
| FSM 9.1.2 | 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 Hygienic Design Management System. |
| FSM 9.2.4 | 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 lifetime of buildings/equipment 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 | Procedures and instructions shall be established, implemented and maintained for all processes and operations having an effect on food safety. |
| FSM 12.2 | Resource management | The resources needed to establish, implement, maintain, review and improve the Hygienic design Management System shall be identified and assigned. |
| FSM 13.1.3 | 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 as well as regulatory requirements. |

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| FSM 13.2.4 | 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 buildings/equipment still confirms to the documented specified requirements or specification, and the supplier has been evaluated. The results of evaluations, investigations and follow-up actions shall be recorded. |
| FSM 13.3.2 | Purchasing and supplier performance | Outsourced processes or service that affect food safety shall be identified and controlled. Such controls shall be documented in the Hygienic Design Management System. |
| FSM 14.1.5 | Traceability | Procedures shall be established, implemented and maintained to ensure the ability to trace or follow a material or article critical to food safety through all stages of purchase, construction and distribution (minimum one step forward and one step backward). |
| FSM 19.4 | Testing | Where external testing of construction materials, buildings or equipment is required, it shall be carried out by an accredited testing facility or one that follows relevant international testing guidelines. |
| FSM 19.5 | Testing | Where in-house testing is carried out, calibration of equipment that is critical to food safety shall be carried out against national standards or other accurate means. |
| FSM 20.2 | Internal audit | An internal audit procedure shall be established, implemented and maintained; it shall cover all elements of the Hygienic Design 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 22.4 | Serious incident management | An incident management procedure, including product recall, withdrawal, and retrofit shall be established, implemented and maintained. The recall procedure shall be regularly tested for effectiveness. |
| FSM 23.2 | Product release | Commissioning or building/equipment release procedures shall be established, implemented and maintained. |

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| FSM 23.3 | Product release | Hygienic design construction specifications shall be verified for buildings and equipment prior to dispatch or hand-over to the customer. |
| 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 SECTOR PRACTICE REQUIREMENTS

| REFERENCE | ELEMENT | THE STANDARD SHALL REQUIRE THAT |
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| GMP 3.2 | Equipment | The building in which equipment is manufactured shall be designed, constructed and maintained to minimise any contamination of the manufactured equipment which may affect food safety. |
| GMP 4.8 | Product contamination risk and segregation | Suitable employee, contractor and visitor access requirements shall be in place such that food safety is not compromised if construction is undertaken at a site in which food is being handled. |
| GMP 4.9 | Product contamination risk and segregation | Procedures shall be in place to prevent the cross-contamination of food from hazards created by construction activities if construction is undertaken at a site in which food is being handled. |
| GMP 4.10 | Product contamination risk and segregation | Prior to building commissioning or equipment dispatch, buildings / equipment shall be cleaned by the manufacturer / constructor using appropriate methods that will remove all food safety hazards associated with the construction process. Cleaning should be recorded and verified. |

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| GMP 7.2 | Training | Procedures shall be established, implemented and maintained to ensure all employees and contractors involved in building and equipment evaluation, specification, purchase and hygienic design shall be trained in hygienic design principles appropriate to their tasks and to the hygienic design requirements of the building or equipment for its intended use. |
| GMP 7.3 | Training | Procedure shall be established, implemented and maintained to ensure all employees and contractors involved in building construction and equipment installation, undertaken at a site handling food shall be trained in food safety principles appropriate to their task. |
| 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 15.2 | Transport | Manufactured equipment shall be stored and transported to the final customer in a manner that prevents contamination of the equipment which may affect food safety. |