



**GFSI** TECHNICAL EQUIVALENCE  
GFSI GUIDANCE DOCUMENT VERSION 7.2

# PART III - L PRODUCTION OF (BIO) CHEMICALS

# Part III - L Production of (Bio) Chemicals

## Certification Programme Scope and Key Elements

This section is the third part of the GFSI Benchmarking Requirements, which has been developed and published by the Global Food Safety Initiative (GFSI) to specify the requirements for the recognition of food safety Certification Programmes.

The objective of **Part III – L – Production of (Bio) Chemicals** is to define:

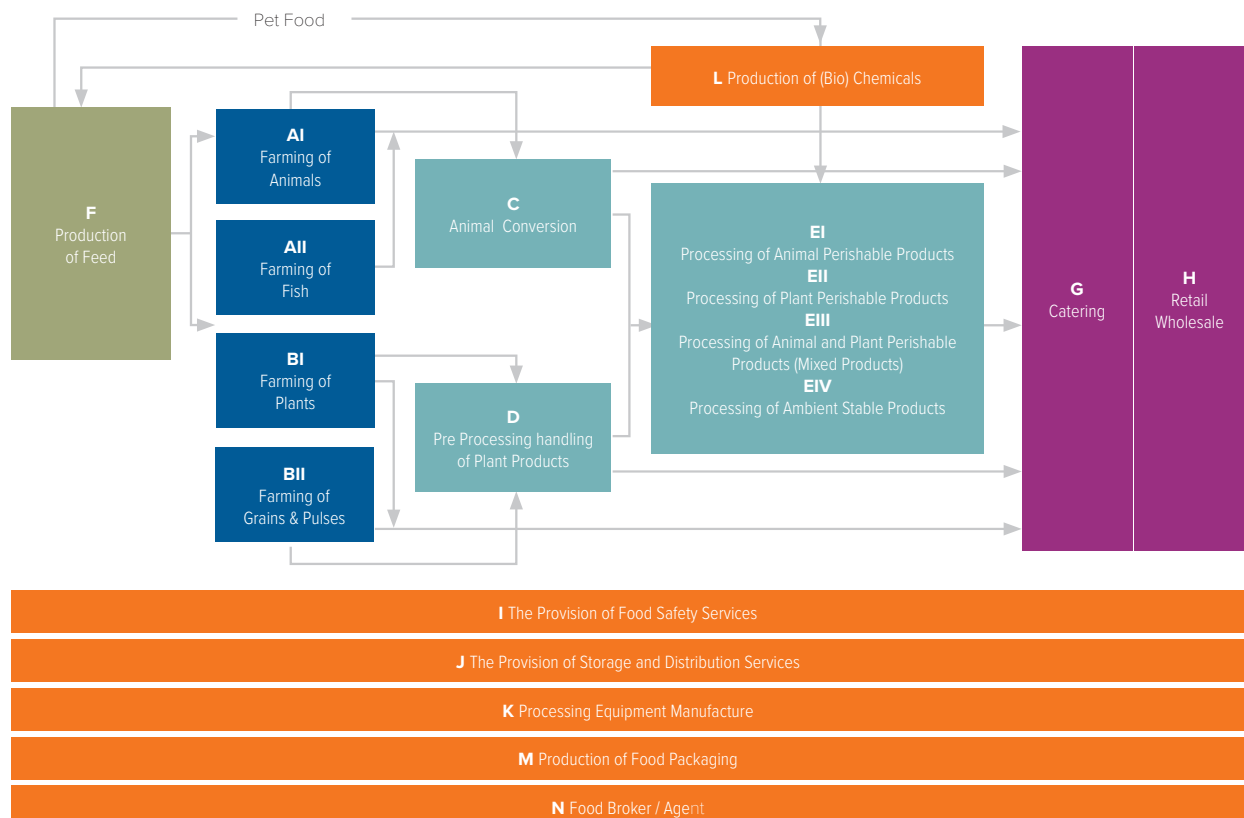
- the requirements for the Food Safety Management Systems to be in place in the Certification Programme's standard for GFSI scope of recognition **L – Production of (Bio) Chemicals**,
- the requirements for the Good Practice requirements to be in place in the Certification Programme's standard for GFSI scope of recognition **L – Production of (Bio) Chemicals**,
- the requirements for Hazard Analysis and Critical Control Points (HACCP) or HACCP based

requirements to be in place in the Certification Programme's standard for GFSI scope of recognition **L – Production of (Bio) Chemicals**.

GFSI scope of recognition **L – Production of (Bio) Chemicals** includes the following products, services, or methods of production:

- Additives, Vitamins, Minerals, Biocultures, Flavourings, Enzymes and processing aids.

GFSI has worked closely with food industry experts to clearly define the requirements that shall be in place to provide food safety assurance in specific sectors of the food industry and for organisations providing services to the food industry. Although the principles are the same, these requirements differ from sector to sector of the food supply chain.



A Certification Programme's standard and other guidance shall provide sufficient detail to ensure that the GFSI requirements in the following tables are met and that, within the benchmarking process, objective evidence of compliance can be found. The requirements for individual Certification Programme standards must be independently developed based on industry practice and it is not expected that a Certification Programme's standard shall be a direct copy of the GFSI requirements.

GFSI expects all benchmarked Certification Programmes to meet the Food Safety Management, Good Industry Practice, and HACCP requirements for the applicable sectors outlined in Part III.

However Certification Programmes requiring Certification Bodies to operate to ISO / IEC 17021-1 must also

ensure that they meet or exceed the requirements of ISO 22000.

For those Certification Programmes, where there is any divergence between the requirements of the GFSI Benchmarking Requirements and ISO 22000, the requirements of ISO 22000 shall prevail.

Certification Programmes requiring Certification Bodies to operate to ISO / IEC 17065 shall meet the requirements for applicable sectors outlined in Part III.

The following sections and tables identify the GFSI requirements for this scope. Certification Programme Applicants must ensure that all requirements are considered for all scopes included in the application. This may include requirements from more than one Part III document.

## SECTION 1: HACCP OR HAZARD BASED REQUIREMENTS

Table I: HACCP Requirements

## SECTION 2: FOOD SAFETY MANAGEMENT REQUIREMENTS

Table I: Food Safety Management Requirements

## SECTION 3: GOOD INDUSTRY SECTOR PRACTICE REQUIREMENTS

Table I: Good MANUFACTURING Practice Requirements

# SECTION 1: HACCP OR HAZARD BASED REQUIREMENTS

Table I: HACCP

CLAUSE NUMBER	CLAUSE NAME	REQUIREMENTS
HACCP L 1.1	Hazard Analysis and Critical Control Point (HACCP)	The standard shall require that the organisation has in place a Hazard Analysis and Critical Control Point system (HACCP) to identify and control all food safety hazards including allergens, to demonstrate food safety management.
HACCP L 1.2	Hazard Analysis and Critical Control Point (HACCP)	The standard shall require that the HACCP system shall be systematic, comprehensive and thorough and shall be based on the Codex Alimentarius HACCP principles.

HACCP L 1.3	Hazard Analysis and Critical Control Point (HACCP)	The standard shall require that the HACCP system shall be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.
HACCP L 1.4	Hazard Analysis and Critical Control Point (HACCP)	The standard shall require that the scope of the HACCP system shall be required to be defined per product / product category and per process line / process-location.

## SECTION 2: FOOD SAFETY MANAGEMENT REQUIREMENTS

**Table I: Food Safety Management Requirements**

CLAUSE NUMBER	CLAUSE NAME	REQUIREMENTS
FSM L 1	Food safety management general requirements	<p>The standard shall require that the elements of the organisation's Food Safety Management System be documented, implemented, maintained and continually improved. The food safety management system shall:</p> <ul style="list-style-type: none"> <li>a) identify the processes needed for the food safety management system,</li> <li>b) determine the sequence and interaction of these processes,</li> <li>c) determine the criteria and methods required to ensure the effective operation and control of these processes,</li> <li>d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,</li> <li>e) measure, monitor and analyse these processes and implement actions necessary to achieve planned results and continuous improvement.</li> <li>f) include a procedure for verification of the food safety management system to confirm that the system continues to be effective.</li> </ul>
FSM L 2	Food safety policy	The standard shall require the organisation have a clear, concise and documented food safety policy statement and measurable objectives specifying the extent of the organisation's commitment to meet the safety needs of its products.

<b>FSM L 3</b>	Food safety manual	The standard shall require the organisation have a Food Safety Manual or documented system having a scope appropriate to the range of business activities to be covered, including documented procedures or specific reference to them and describing the interaction of the related process steps.
<b>FSM L 4</b>	Management responsibility	The standard shall require that the organisation establishes a clear organisational structure, which unambiguously defines and documents the job functions, responsibilities and reporting relationships of at least those staff whose activities affect food safety.
<b>FSM L 5</b>	Management commitment	The standard shall require that the organisation's senior management provides evidence of their commitment to establish, implement, maintain and improve the food safety system.
<b>FSM L 6.1</b>	Management review	The standard shall require that the organisation's senior management review the verification of the food safety system and HACCP Plan at planned intervals, to ensure their continuing suitability, adequacy and effectiveness.
<b>FSM L 6.2</b>	Management review	The standard shall require that the HACCP Plan and food safety programs (or PRPs) shall also be reviewed in the event of any change that impacts food safety. Such a review shall evaluate the need for changes to the food safety system, including the food safety policy and food safety objectives.
<b>FSM L 7</b>	Resource management	The standard shall require that the organisation's senior management determines and provides, in a timely manner, the qualified resources (including suitably qualified personnel) needed to implement, maintain and improve the food safety system.
<b>FSM L 8.1</b>	General documentation requirements	The standard shall require that the required documentation is in place and maintained to demonstrate compliance with the standard.
<b>FSM L 8.2</b>	General documentation requirements	The standard shall require that documented procedures are in place to ensure that all records required to demonstrate the effective operation and control of its processes and the management of food safety are securely stored.

<b>FSM L 8.3</b>	General documentation requirements	The standard shall require that the documented procedures described under FSM L 8.1 and FSM L 8.2 are securely stored for the time period required to meet customer or legal requirements, effectively controlled and readily accessible when needed.
<b>FSM L 9.1</b>	Specified requirements	The standard shall require that the organisation ensures that, for all inputs to the process, items and services (including utilities, transport and maintenance) that are purchased or provided and have an effect on product safety, documented specifications are prepared, maintained, securely stored and readily accessible when needed.
<b>FSM L 9.2</b>	Specified requirements	The standard shall require that a specification review process is in place.
<b>FSM L 10</b>	Procedures	The standard shall require that the organisation establishes, implements and maintains documented and detailed procedures and instructions for all processes and operations having an effect on food safety.
<b>FSM L 11</b>	Internal audit	The standard shall require that the organisation has an internal audit system in place to cover all activities within the scope of the scheme.
<b>FSM L 12</b>	Corrective action	The standard shall require that the organisation has procedures in place for the determination and implementation of corrective action in the event of any significant non conformity relating to food safety.
<b>FSM L 13.1</b>	Control of non conformity	The standard shall require that the organisation has effective processes in place to ensure that any product which does not conform to food safety requirements is clearly identified and controlled to prevent unintended use or delivery.
<b>FSM L 13.2</b>	Control of non conformity	The standard shall require that the processes described under FSM L 13.1 shall be defined in a documented procedure that is securely stored and readily accessible when needed.
<b>FSM L 14</b>	Product release	The standard shall require that the organisation prepares and implements appropriate product release procedures.

<b>FSM L 15.1</b>	Purchasing	The standard shall require that the organisation controls purchasing processes to ensure that all externally sourced materials and services, which have an effect on food safety conform to food safety management.
<b>FSM L 15.2</b>	Purchasing	The standard shall require that where an organisation chooses to outsource any processes that may have an effect on food safety, the organisation shall ensure control over such processes.
<b>FSM L 15.3</b>	Purchasing	The standard shall require that control of processes that may have an effect on food safety shall be identified and documented in the food safety system.
<b>FSM L 15.4</b>	Purchasing (non-approved supplier)	Use of non-approved suppliers shall be acceptable in an emergency situation provided the facility has been assessed and the product meets the specification.
<b>FSM L 16</b>	Supplier performance	The standard shall require that the organisation establishes, implements and maintains procedures for the evaluation, approval and continued monitoring of suppliers which have an effect on food safety. The results of evaluations, investigations and follow up actions shall be recorded.
<b>FSM L 17</b>	Complaint handling	The standard shall require that the organisation establishes, implements and maintains an effective system for the management of complaints and complaint data in order to control and correct shortcomings in food safety.
<b>FSM L 18</b>	Serious incident management	The standard shall require that the organisation establishes, implements and maintains an effective incident management procedure, which is regularly tested for all products it supplies and covers planning for product withdrawal and product recall as required.
<b>FSM L 19.1</b>	Control of measuring and monitoring devices	The standard shall require that the organisation identifies the equipment used to measure parameters critical to ensure food safety.
<b>FSM L 19.2</b>	Control of measuring and monitoring devices	The standard shall require that the organisation identifies the measuring and monitoring devices required

<b>FSM L 19.3</b>	Control of measuring and monitoring devices	The standard shall require that the organisation identifies methods to assure that the calibration of these measuring and monitoring devices is traceable to a recognised standard.
<b>FSM L 20.1</b>	Food defence threat assessment	The standard shall require that the organisation have a documented food defence threat assessment procedure in place to identify potential threats and prioritise food defence measures.
<b>FSM L 20.2</b>	Food defence plan	The standard shall require that the organisation has a documented plan in place that specifies the measures the organisation has implemented to mitigate the public health risks from any identified food defence threats.
<b>FSM L 20.3</b>	Food defence plan	The standard shall require that the organization's Food defence plan shall be supported by the organisation's Food Safety Management System.
<b>FSM L 21</b>	Food fraud vulnerability assessment	The standard shall require that the organisation has a documented food fraud vulnerability assessment procedure in place to identify potential vulnerability and prioritise food fraud mitigation measures.
<b>FSM L 22.1</b>	Food fraud mitigation plan	The standard shall require that the organisation has a documented plan in place that specifies the measures the organisation has implemented to mitigate the public health risks from the identified food fraud vulnerabilities.
<b>FSM L 22.2</b>	Food fraud mitigation plan	The standard shall require that the organization's Food fraud mitigation plan shall be supported by the organisation's Food Safety Management System.
<b>FSM L 23.1</b>	Traceability	The standard shall require that the organisation establishes, implements and maintains appropriate procedures and systems to ensure an identification of any outsourced production, inputs or services related to food safety.
<b>FSM L 23.2</b>	Traceability	The standard shall require that the organisation establishes, implements and maintains appropriate procedures and systems to ensure that product identification that includes, as a minimum, the name and address of the producer.



FSM L 23.3	Traceability	The standard shall require that the organisation establishes, implements and maintains appropriate procedures and systems to ensure a record of purchaser and delivery destination for all products supplied.
FSM L 24	Analysis of Inputs (e.g. water, ice)	The standard shall require that the organisation prepares and implements a system to ensure that analysis of inputs critical to the confirmation of food safety is undertaken and that such analyses are performed to ISO 17025 or equivalent standards.
FSM L 25	Product Labelling	The standard shall ensure that finished product is labelled according to the applicable food regulations in the country of intended sale.
FSM L 26	Allergen Management	The standard shall require that an allergen management plan is in place in all food manufacturing facilities. This shall include a risk assessment of allergen cross contact and implemented controls to reduce or eliminate the risk of cross contact.
FSM L 27	Allergen Labelling	The standard shall require that all finished products intentionally or potentially containing allergenic materials are labelled according to the allergen labelling regulations in the country of manufacture and the country of destination.
FSM L 28	Food Safety Legislation	The standard shall require that the organisation establishes, implements and maintains detailed procedures and instructions for all processes and operations having an effect on food safety to be compliant in the country of manufacturing as well as the country of known destination.

## SECTION 3: GOOD INDUSTRY SECTOR PRACTICE REQUIREMENTS

**Table I: Good Manufacturing Practice Requirements**

CLAUSE NUMBER	CLAUSE NAME	REQUIREMENTS
GMP L 1	Facility environment	The standard shall require that the site or facility is located and maintained so as to prevent contamination and in order to enable the production of safe products.

<b>GMP L 2</b>	Local environment	The standard shall require that all grounds within the site or facility are maintained so as to prevent contamination and enable the production of safe products.
<b>GMP L 3</b>	Facility design, construction, layout and product flow	The standard shall require that premises, site and / or plant are designed, constructed and maintained, both the exterior and the interior, to control the risk of product contamination.
<b>GMP L 4</b>	Fabrication (input and material handling, preparation, product handling, packing and storage areas)	The standard shall require that the fabrication of the site, buildings and facilities is suitable for the intended purpose.
<b>GMP L 5</b>	Equipment	The standard shall require that equipment is suitably designed for the intended purpose and shall be used and stored so as to minimise food safety risks.
<b>GMP L 6</b>	Maintenance	The standard shall require that a system of planned maintenance is in place covering all items of equipment which are critical to product safety.
<b>GMP L 7</b>	Staff facilities	The standard shall require that staff facilities are designed and operated so as to minimise food safety risks.
<b>GMP L 8</b>	Physical and chemical product contamination risk	The standard shall require that appropriate facilities and procedures are in place to control the risk of physical, chemical or biological contamination of product.
<b>GMP L 9</b>	Segregation and cross-contamination	The standard shall require that procedures are in place to prevent contamination and cross-contamination of raw materials, packaging and finished product, covering all aspects of food safety.
<b>GMP L 10</b>	Stock management	The standard shall require that a system is in place to ensure that materials and ingredients are used in the correct order and within the allocated shelf life.
<b>GMP L 11.1</b>	Housekeeping, cleaning and hygiene	The standard shall require that documented standards of housekeeping, cleaning and hygiene is maintained at all times and throughout all the stages.
<b>GMP L 11.2</b>	Housekeeping, cleaning and hygiene	The standard shall require that cleaning materials shall be suitable for their intended use and stored appropriately.

<b>GMP L 12</b>	Water quality and utility management (including Ice)	The standard shall require that the quality of water (including steam and ice) that comes into contact with food is regularly monitored and shall present no risk to food safety.
<b>GMP L 13</b>	Waste management	The standard shall require that adequate systems are in place for the collation, collection and disposal of waste material.
<b>GMP L 14</b>	Pest control	The standard shall require that a system is in place for controlling or eliminating the risk of pest infestation on the site or in the facilities.
<b>GMP L 15</b>	Transport	The standard shall require that all containers and vehicles, including contracted out vehicles, used for the storage and transportation of raw materials (including packaging), intermediate / semi-processed product and finished product (including packed, fresh product in final packaging) are suitable for the purpose and maintained in good repair and be clean.
<b>GMP L 16.1</b>	Personal hygiene, protective clothing and medical screening	The standard shall require that documented personal hygiene standards based on risk of product contamination are in place and personnel trained in them.
<b>GMP L 16.2</b>	Personal hygiene, protective clothing and medical screening	The standard shall require that hand washing and toilet facilities shall be provided.
<b>GMP L 16.3</b>	Personal hygiene, protective clothing and medical screening	The standard shall require that suitable and appropriate protective clothing shall be provided.
<b>GMP L 16.4</b>	Personal hygiene, protective clothing and medical screening	The standard shall require that a medical screening procedure shall be in place to identify conditions impacting food safety.
<b>GMP L 16.5</b>	Personal hygiene, protective clothing and medical screening	The standard shall require that in all cases, the requirements described under GMP L 16.1, 16.2, 16.3 and 16.4 shall also apply to contractors and visitors.
<b>GMP L 17</b>	Training	The standard shall require that a system is in place to ensure that all employees are adequately trained, instructed and supervised in food safety principles and practices, commensurate with their activity.