IFS Global Markets – Food v2 guideline

Typical assessor questions and advice for IFS Global Markets – Food

The single requirements of the program are partly difficult to interpret. The interpretation always depends on the situation of the single company.

But the IFS is keen on improving the implementation process and the assessment quality by supporting the company and the assessor to come to a minimum performance for IFS Global Markets assessments. This guideline shall be used as implementation help and understanding providing support as well as a tool for assessors to perform the assessment correctly in terms of the IFS.

Guideline provided by the GFSI was mainly included here directly in cursive letters.

Focusing on products

The IFS Global Markets – Food assessment is focused on products/processes. Therefore any objective evidences are closely related to products and processes. The product(s) that the assessor choose(s) for the questioning during the assessment are important. If the assessed company can prove with objective evidences that these products – selected by the assessor – are produced according to the agreed specification in a safe manner, it provides a reliable assessment of the assessed company. The listed typical questions in the guideline are closely linked to the checks of products. The assessor should ask these questions in order to get a maximum of information about a representative sample of products (retailer branded products) and about the assessed company.

Incompleteness

The listed questions are just examples and can't give the assessor a complete survey. The assessor shall adapt his assessment to the specific situation of the company case by case. The assessment is not automatically complete if the assessor asks every question of the list.

It establishes just a minimum survey the assessor should fulfil.

Improvements

The IFS is dedicated for improving the guideline continuously. Therefore IFS would like to give the assessors as well as the Certification Bodies/Assessment Service Provider and the assessed companies the opportunity to support IFS. If you have comments or ideas on the basis of own experiences that could help IFS to improve the guideline please do not hesitate to contact the IFS offices.

Basic	Intermediate

no.	IFS Global Markets – Food v2	Guideline
A. Food safety and quality management system		
B.A 1	**Specifications including product release**	
	The business shall ensure that product specifications are adequate, accurate and ensure compliance with relevant safety, legislative and customer requirements. The business shall prepare and implement appropriate product release procedures.	*WHAT DOES IT MEAN?* *a) Specifications on all product ingredients should be appropriate to ensure compliance with relevant safety, legislative and customer requirements.* *b) Specifications will be managed and controlled by a designated person and should be up-to-date, clear, communicated within the business and with customers to ensure transparency.* *c) A clear procedure for product release should be documented, communicated and implemented to ensure released product meets the agreed specifications.* *WHAT DO I NEED TO DO?* *a) You need to ensure there is an accountable person who is responsible for the control of specifications, which should be up-to-date, appropriate and communicated to relevant people. This person will also manage all changes.* *b) The specifications for all ingredients should meet relevant safety, legislative and customer requirements and be agreed with each supplier.* *c) Finished product specifications should be available so that the documented product release procedure ensures the product is either properly released or held back due to being out-of-specification.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Discuss the control of specifications with the accountable person.* • *Check that specifications for all ingredients and finished products are appropriate, clear and ensure conformance with relevant safety, legislation and customer requirements.* • *Check that the specifications are up-to-date and clearly communicated to relevant people with responsibility for food safety and quality.* • *Discuss the product release procedure with relevant people to ensure that their actions establish effectively whether a finished product is either acceptable or out-of-specification.*

no.	IFS Global Markets – Food v2	Guideline
B.A 1.1	Are specifications available for all product inputs (raw materials, ingredients, additives, packaging materials, rework) and finished products?	Specifications for all product inputs shall be current, adequate, accurate and compliant with relevant safety and legislative requirements and customer requirements. • Are there specifications for all final products? • Are specifications available for all raw materials, ingredients, additives, packaging materials and rework? • What assurance is given that specifications are followed? <proof of specification compliance, e.g. lab results> • Who writes, checks and approves specifications? • If specifications come from suppliers, is there a competent person who reviews them internally?
B.A 1.2	Are the available specifications compliant with relevant safety, legislative and customer requirements? Do they consider vulnerability to food fraud?	The competent person drafting specification is aware of the means of obtaining legislative requirements. Systems are in place to ensure finished product released to customers complies with agreed requirements. • How are specifications compiled, checked and approved? • What assurance is given that specifications are in conformance with legal requirements? • Are weak points where fraud has greater chances to occur taken into consideration? • Are all materials and connected risks in regard to fraud known (history, economic factors, geographical origins, physical state, emerging issues)? • Are suppliers (manufacturer, broker, history) and the relevant supply chain known (length, complexity, supply & demand arrangements, ease of access)? • Are measure taken to decrease vulnerability to a certain type of adulteration in the given supply chain? • Are measures and specifications modified, if applicable in the event of changes within the supply chain?
B.A 1.3	Does for all packaging material which could have an influence on products, certificates of conformity exist, which comply with current legal requirements? Is there evidence available to demonstrate that packaging material is suitable for use, in the event that no specific legal requirements are applicable? Does this apply for packaging material which could have an influence on raw materials, semi-processed and finished products?	• How is it ensured that packaging material complies with current relevant legislation? • Who develops, reviews new packaging material? • Are specifications available for all packaging materials used? • How is it ensured that packaging materials have no negative effects on the product?

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B.A 1.4	Are specifications up to date, unambiguous and available to relevant staff?	Formulas, recipes and specifications are available for relevant stuff. Are they up-to-date, clear, communicated within the business and with customers to ensure transparency. • How are up to date specifications recognizable? • Who has access to specifications?
B.A 1.5	Are changes to all specifications clearly communicated both internally and externally? Is the communication process regulated and known?	The person responsible for specifications communicates with the business's suppliers. Relevant modifications of formulas, recipes and specifications are promptly communicated to the customer (e.g. changes in regard to the labelling of allergens). • Who communicates and how changes of specification internally and externally? • Who writes, amends, checks and approves specifications?
B.A 1.6	Is there a designated person with responsibility for controlling specifications?	• If specifications come from suppliers, is there a competent person who reviews them internally? • Who reviews and ensures that specifications are met in the event of recipe or processing changes? • Who controls specifications? <job description>
B.A 1.7	Are recipes and formulas up to date, valid and in line with specifications?	• What assurance is given that specified recipe is followed? • How is recipe compliance checked?
B.A 1.8	Is there a documented product release procedure in place? Does it effectively ensure that the final product (incl. packaging and label) meets the specification, meaning internal requirements, customer specification (incl. agreed formulas) and legislation of destination country?	• Who quarantines or releases products? <job description> • How are quarantined products identified? • Are there any clearly defined criteria for product release?

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B.A 2	**Traceability**	
	The business shall establish a traceability system which enables the identification of product lots and their relation to batches of raw materials, primary and final packaging materials, processing and distribution records. Records shall include: • Identification of any out sourced product, ingredient or service. • Records of batches of in process or final product and packaging throughout the production process. • Records of purchaser and delivery destination for all products supplied.	*WHAT DOES IT MEAN?* *a) Food manufacturers are obliged to prove to the authorities the source and buyers of the raw materials used to produce each of their products.* *b) The source and destination of any packaging materials that come into direct contact with the product shall also be proven.* *WHAT DO I NEED TO DO?* *a) All locations should have documented procedures to maintain traceability throughout all phases of product conversion from receiving incoming materials through production, packaging and dispatch. This includes hold orders, rework etc.* *b) Labelling of lots, including those that are partially finished, should be made during actual packing to ensure clear traceability.* *c) Where goods are also labelled later, there should be specific lot labelling for temporary batches.* *d) The batch sizes that are selected depends on your readiness to assume risk in the case of quarantine or a recall.* *e) Legal and customer requirements can be satisfied if you are able to provide credible, controlled documents as evidence.* *f) In the event of a product recall you have a duty to inform the authorities and provide complete documentation quickly.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Inspect your traceability system expecting to see effective and documented procedures from receipt to dispatch.* • *Review whether the effectiveness of the system can be proven using documented test runs.* • *Use current or retained samples to establish whether all responsible persons are delivering traceability procedures.* • *Look for evidence that there is complete labelling of all batches, partial batches, raw materials, etc.*

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B.A 2.1	Is a documented traceability system in place that meets regulatory and customers requirements for every product?	The frequency of traceability record keeping shall be appropriate. Personnel responsible for traceability are trained adequately. The person responsible for development and maintenance of the traceability system obtains knowledge of legislative requirements. The responsible person ensures other colleagues are aware of their obligation with respect to traceability and record keeping. • Is the supplier of the each raw material used to produce each of their products known and traceable? • Is the buyer of each product produced including the amount trackable? • How is traceability ensured? <traceability procedures> • What products come from which supplier? • Is there a list available with all current suppliers? <supplier list>
B.A 2.2	Is the traceability system, including work in progress, post-treatment and rework, fully operational and effective?	Intermediate products manufactured at the own site has to be labeled sufficiently (min. production date/best before or with otherwise clear identification). • What percentage of total amount was traced? • How big is a lot (The batch sizes that are selected depends on your readiness to assume risk in the case of quarantine or a recall)? • Can rework be completely traced? <results from rework traceability test> • How is rework documented? • How is a lot defined?
B.A 2.3	Are records enabling product identification available through all production stages: stock/inventory, work in progress, post processing and rework. Are records available from purchase through production and to immediate destination for all raw materials and packaging materials?	Traceability records are legible, genuine and easily accessible. • Are all traceability records prove compliance with the specifications agreed by the customer? • Is the source and destination of any packaging materials that come into contact with the product proven?

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B.A 2.4	Are there clear labelling procedures that ensure continuous identification of the product through all stages of production and delivery?	The product through all production stages, and finished product is clearly labelled or identified. Individual finished products are coded clearly allowing identification. Dispatch documents include finished product codes. • When is lot labelling done? • What is the lot labelling code? <lot labelling example> • When are labels applied to product units? • How is shelf-life calculated? <shelf-life example> • How are mix of products controlled ? **Note:** identification during process could be made by using labelling on products or specific containers.

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I.A 2	**Traceability**	
	The business shall establish a traceability system which enables the identification of product lots and their relation to batches of raw materials, primary and consumer unit packaging materials, processing and distribution records. The business shall ensure the traceability system is tested at least annually and updated as necessary. Records shall include: • Records of annual testing of the traceability system. • Records of updating the system as applicable.	*WHAT DOES IT MEAN?* *a) The goal is to test the traceability program and identify elements which might limit the effectiveness or efficiency of a recall.* *b) Effective lot identification as a part of a functional traceability program provides a cornerstone in controlling and minimising both food safety risks and the financial impact of product withdrawals and recalls.* *WHAT DO I NEED TO DO?* *a) At least annually, simulated recalls are required to ensure that the traceability program works and testing should include:* *· Identification of item traced (e.g. ingredient or finished product).* *· Time for completion and percentage of product traced, according to both regulatory or customer requirements.* *· Key learnings, gaps, system improvement opportunities.* *· Receipt and dispatch discrepancy and reconciliation.* *b) All staff are to be trained in the procedures and improvements that are identified and implemented.* *c) The results should be summarised and reported to provide evidence of system verification.* *d) The expectation is that key findings, gaps and improvement opportunities are addressed.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Inspect your full traceability program throughout the assessment process.* • *Expect that the documents will show a traceable process that is tested systematically.* • *Review whether the effectiveness can be proven using documented test runs.* • *Use either current or retained samples to establish whether responsible people are delivering traceability procedures.*
I.A 2.5	Is the traceability system tested at least annually? Is the system updated as necessary and records maintained?	The traceability system is checked risk oriented annually for products supplied to the customer. It has to be amended if necessary. • When was the last traceability test in both directions done? <traceability test results>

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I.A 2.6	If required by customer, are identified samples representative for the manufacturing lot stored appropriately and kept until expiration of the "Use by" or "Best before date" of the finished product and if necessary for a determined period beyond this date?	• Is a sample bank implemented? • Are samples stored according to their forseeable use?
B.A 3	**Incident management**	
	The business shall demonstrate the ability to withdraw and recall affected product, contact relevant customers and maintain records of these incidents.	*WHAT DOES IT MEAN?* *a) An incident is an event that has occurred which results in the production or supply of unsafe, illegal or non-conforming product.* *b) A procedure should be defined, implemented and maintained for the management of incidents and of resulting emergency situations that impact food safety, legality and quality.* *c) This includes as a minimum: The nomination and training of a crisis team, an alert contact list including suppliers and customers, sources of legal advice, the availability of internal contacts and a communication plan that includes information to consumers.* *WHAT DO I NEED TO DO?* *a) A person of the business, with the authority to initiate the incident management process, should be permanently available.* *b) Records to be available:* · *Product involved, sizes, manufacturing location.* · *Quantity of product affected.* · *Details of product affected—codes, lots, pallets, batches.* · *Production and quality control records.* · *Quantity distributed and location.* *c) Updated emergency contact details (such as names and phone numbers of suppliers, customers and competent authorities) should be available.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Inspect the relevant process throughout the entire assessment.* • *Use current or retained samples to identify whether responsible people are engaged with the relevant procedures.*
B.A 3.1	Can the business withdraw and recall affected product?	Recall procedures assure prompt take-back of supplied products.
B.A 3.2	Are records of incidents maintained?	

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I.A 3	**Incident management**	
	The business shall have an effective incident management procedure for all products including reporting, communicating with customers, product withdrawal and recall. Records of annual review, testing and verification of the system shall be available.	*WHAT DOES IT MEAN?* *a) An incident is defined as any situation, which, if not properly managed, has the potential to develop into a crisis.* *b) If a crisis or an incident occurs (e.g. food product contamination, illegal ingredients or negative reporting in the press), it is important that you are able to do the following:* *· To survey the situation in your business as fast as possible.* *· To reach all persons (internal and external) who are able to help solve the problem.* *· To communicate effectively, including making sure that only named representatives speak for the business (note: serious incidents attract the press in no time. Any of your people may be approached for comment). Frequent, clear and accurate communication can pre-empt or reduce the scale or complexity of a crisis.* *c) The feasibility, effectiveness and timeliness of implementation of the withdrawal procedure should be subject to regular internal testing, based on hazard analysis and assessment of associated risks but carried out at least once a year.* *d) This should be carried out in a manner to ensure the effective implementation and operation of the procedure.* *WHAT DO I NEED TO DO?* *a) There are two stages in defining a threat: first in terms of its severity and imminence, second in terms of its topic. No matter how insignificant an event seems, it could develop into a major, business-threatening crisis if it is ignored. It is important that every incident is treated as a full-blown crisis until you can be certain that it is not.* *b) To develop, implement and maintain a crisis management procedure to include the following:* *· Detail about the steps to be taken to manage a crisis.* *· The nomination and training of a crisis team, an alert contact list, sources of legal advice (if necessary), contacts availability, customer information and a communication plan, including information to your people, customers and consumers.* *c) Communications is not a tactical option, it's a strategic necessity and a core responsibility of the Crisis Team. Controlling and targeting of information to internal audiences can make or break a crisis. Colleagues need to be informed and external stakeholders need to be notified and reassured.* *d) The incident management system should be tested at least annually. It is important that these processes are reviewed, practiced and mastered with a broad base of employees.*

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		WHAT WILL THE ASSESSOR DO? *The Assessor will:* • *Check for a procedure that describes the approach to such situations* • *Review the emergency contact list of all relevant persons. Check it is up to date and available to all that need it.* • *Interview people to establish that they are aware of their responsibility, at least in part (e.g. when serious process failures occur, instant information to superiors, receipt of serious complaints, and instant information to the crisis team).*
I.A 3.3	Is a documented incident management system in place that addresses incident reporting, product withdrawal and product recall?	• How are incidents managed? <crisis management procedures> All relevant staff are aware of their obligations in case of incident management.
I.A 3.4	Is an effective communication plan in place with a designated, responsible person identified to provide information to customers, consumers and regulatory authorities?	A competent person is responsible for all internal and external communication. Recall concerned emergency information is available. • Who is informed when an incident occurs? • When and who informs customer? <alarm plan> <phone list> • Who is responsible for communication with customers, press/media and authorities?
I.A 3.5	Is the incident management system reviewed, tested and verified at least once a year?	Procedures in relation to incident management are regularly reviewed by a competent person. Incidents which could lead to unsafe or non conforming product are recorded and assessed in a timely manner to establish their severity and consumer risk. • How is effectiveness of withdrawal and recalls tested? • How often is effectiveness of withdrawal tested? <withdrawal test results> At least annually, simulated recalls are required to ensure that the traceability program works and testing should include: • Identification of item traced (e.g. ingredient or finished product). • Time for completion and percentage of product traced, according to both regulatory or customer requirements. • Key learnings, gaps, system improvement opportunities. • Receipt and dispatch discrepancy and reconciliation.
I.A 3.6	Are all incidents recorded and assessed to establish their severity and consumer risk?	

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B.A 4	Control of non-conforming product	
	The business shall ensure that any product which does not conform to requirements is clearly identified and controlled to prevent unintended use or delivery.	*WHAT DOES IT MEAN?* *a) Standard operating procedures are required to ensure that substandard material or finished product is labelled and controlled so that it does not contaminate other products or get released for sale or consumption.* *WHAT DO I NEED TO DO?* *a) Establish and document procedures for the management of non-conforming materials or finished product.* *b) Ensure that relevant people understand the procedure and that there are defined responsibilities for making decisions about the use or disposal of non-conforming product, as appropriate to the issue.* *c) These procedures would include reporting, labelling, isolation, disposal and corrective actions.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Review documents and compare records to establish that procedures exist and are followed when appropriate.* • *Look for evidence that non-conforming product is effectively identified and segregated pending decisions on use or disposal.*
B.A 4.1	Is a documented procedure in place to identify and manage all non-conforming raw materials, product inputs, semi-finished and finished products, processing equipment and packaging materials?	Incoming goods control is conducted and documented. Legal and specification concerned requirements (if any) are complied with. Handling and labelling procedures for non-conforming ingredients and products are regulated. • What procedures exist for non-conforming products management? • How are non-conforming products identified? • What rules exist for product quarantine procedures?
B.A 4.2	Is the control of non-conforming product managed by competent people?	• Who is responsible for putting non-conforming products into quarantine? <quarantine tickets> • Who may release quarantined products? <quarantine tickets> • How is it ensured that only authorized persons release quarantined products? <quarantine tickets>

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B.A 5	Corrective action	
	The business shall ensure that corrective action be undertaken as soon as possible to prevent recurrence of non-conformity.	*WHAT DOES IT MEAN?* *a) When an issue occurs regarding non-conforming materials, finished products or procedures, a process is followed to understand the root cause of the non-conformity and actions are taken to correct the problem so that there are no further occurrences.* *WHAT DO I NEED TO DO?* *a) Establish and document procedures for identifying non-conformities and problem solving activities to determine how the non-conformities occurred.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Review documentation that corrective action procedures exist, are effectively communicated and followed when required.*
B.A 5.1	Is a documented corrective action procedure in place to analyse any complaints and investigate non-conformities to prevent reccurrence? Are responsibilities and the timescales for corrective action clearly defined? Is the documentation securely stored, and easily accessible?	There is a competent person responsible for analysing and investigating non-conformities to establish the procedure to avoid reoccurrence. Records of all customer complaints, investigations and corrective actions are maintained. A documented system is in place to manage corrective actions. The responsibilities of individuals and timescales for corrective actions are clearly defined and documented. • All documents and records relating to corrective actions are in place. • What are corrective actions procedures? <corrective actions procedures> • Where are corrective actions documented? <model corrective action procedures>
B.A 5.2	Are corrective actions (i.e. release, rework, quarantine, rejection/disposal) identified and effectively implemented to eliminate the cause of a detected deviation or non-conformity or other undesirable situation?	There is a competent person responsible for monitoring and effectiveness of the completion and performance of the agreed corrective actions. There is a system of complaint analysis which facilitates the implementation of corrective actions to prevent reoccurrence. • Who is responsible for corrective actions? • How long may it take to implement corrective actions? • How are corrective actions verified? • How corrective actions are decided (e.g. root cause analysis), to avoid further occurrence?

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B.A 6	**Management responsibility**	
	The business shall ensure there is management commitment to provide the resources to develop, implement and comply with their food safety and quality program including customer requirements.	*WHAT DOES IT MEAN?* *a) There should be clear accountability for the production management team.* *b) The team should demonstrate commitment to provide the appropriate amount of resources to develop, implement and ensure compliance with the food safety program.* *c) Although development of many of these activities may be conducted by quality assurance and food safety people, the production management team should be actively involved in the support and leadership of these activities.* *d) The food safety program should not be a "Quality owned activity". Instead, management should show active leadership to ensure a food safety culture.* *WHAT DO I NEED TO DO?* *a) The production management team should have systematic documented discussions about the food safety and quality program as part of its periodic staff meetings where non-conformance trend analysis, resources allocation, corrective action and strategy for continuous improvement will be actively discussed.* *b) Management should show that food safety and quality is as important as production and people's health and safety and operates with an adequate budget.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check for evidence that the food safety and quality program elements are discussed and documented in production management team staff meetings, looking for prominent discussions and follow-up activities.* • *Interview the quality team about management commitment for appropriate resources, support for their activities and to ensure that those employees with responsibility for food safety activities are held accountable for compliance.* • *Ask production operations people about management commitment, seeking to establish whether management are receptive to continuous improvement suggestions*

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B.A 6.1	Is there evidence that management is committed to provide the resources to implement and comply with their food safety and quality program including customer requirements?	consider: • performance indicators for customers, complaints and withdras/recalls, • incidents, corrective actions, results out of specifications and non confomring materials, • process performance and product compliance, • evolutions of scientific information related to products, • improvement of quality system efficiency anf production process, • improvement of product, related to customer requirements, • needs in ressources (including investments). • How were the necessary resources defined? <budget plan> • What criteria are used to ensure process control? • What is done to ensure that processes are known to relevant personnel (incl. permanent staff and temporary/seasonal workers)?
I.A 6	**Management responsibility**	
	The business shall ensure there is management commitment to provide the resources to develop, implement and comply with their food safety and quality program. The business shall establish a clear organizational structure with job descriptions, responsibilities and reporting relationships of at least those staff whose activities affect product safety, legality and quality.	*WHAT DOES IT MEAN?* *a) In addition to those items already identified in Requirement B.A.6, production management should document the organizational structure which supports the food safety program and the activities that impact product safety. Documented job descriptions and reporting relationships should be included.* *WHAT DO I NEED TO DO?* *a) A clear organizational chart should be created and kept updated.* *b) Employees whose activities and responsibilities support the food safety program should be identified.* *c) These documented responsibilities should be shared with and discussed with relevant employees to ensure understanding of their accountabilities.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check for evidence of production management's commitment to the food safety program* • *Check to ensure the organizational chart is up-to-date and will look for documents (such as job descriptions) which define indivuals responsibilities that support the food safety program.* • *Discuss how production management supports and has communicated the responsibilities.*

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I.A 6.2	Is an up-to-date organizational chart outlining the business' structure available?	• Is an organisation chart available? • How is the organisation structured? <Organisation chart>
I.A 6.3	Are documented, clearly defined responsibilities regarding product safety, quality and legality available and communicated to staff?	The responsibility of Quality Assurance Department, and to whom QA Department reports shall be particularly taken into account. Must cover the absence for key staff. Responsibilities for hygiene and food safety are clear. • For which positions do written job descriptions exist? • What is regulated in the job descriptions? • What is the content of the job descriptions? • For which positions do job descriptions exist? • How is it ensured that employees know their responsibilities regarding product safety, quality and legality? • How does senior management ensure that employees know their responsibilities regarding product safety, quality and legality? • For which positions do written job descriptions exist? What is regulated in the job descriptions? Who, for example substitutes QA manager during his absence? <Responsibility description for important key staff "dedicated to a specific person", e.g. QA Manager, Production Manager, Shift Leader …>
I.A 6.4	Are employees with influence on product requirements aware of their responsibilities, and are they able to demonstrate their understanding of their responsibilities?	• How is relevant information transmitted to concerned persons? • How is it ensured that employees know their responsibilities? • How does senior management ensure that employees know their responsibilities? • Interview of at least: QAM, person responsible for labelling, person responsible for product development, person responsible for production, person responsible for monitoring CCP's

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B.A 7	Record keeping requirements	
	The business shall ensure that records are available to prove the business is complying with the food safety and quality system which includes all relevant regulatory, customer and food safety requirements.	*WHAT DOES IT MEAN?* *a) The business needs to prove it is meeting both regulatory and customer requirements that apply to its product and process.* *b) Records provide legal proof that you did what you said you were going to do to manufacture, store and distribute products.* *c) You need to identify when records will be completed and who will complete them.* *d) These records are kept for a period of time (this is 'record retention'). The period of time will be mandated by law or by customers and will depend on the type of products, processes and product liability.* *e) Identify which of these time periods is longest to decide on your record retention policy.* *f) You can set the same retention policy for all of your records or have different time periods for specific records.* *g) These records can be in paper form or they can be electronic and should be factual and genuine.* *WHAT DO I NEED TO DO?* *a) You need to identify the requirements within the food safety and quality system for which you need to prove compliance, including both customer and regulatory.* *b) Some of these records may come from your suppliers (e.g., letter of conformity, specification, etc.).* *c) You will also need to create forms which will allow you to record your own information.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check whether you have identified the records that you need to retain and set the timescales for retention.* • *Review a sample of your records to prove they exist and that they are available for the set period of time.*
B.A 7.1	Are records available to support the compliance of the business with the food safety and quality system which includes all regulatory, customer and food safety requirements that apply?	• What records exist? • Are the records complete? • Are the records available? • Are records plausible? • Are records legible? • What kind of assurance is given that records cannot be subsequently manipulated?

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B.A 7.2	Has the business set timescales for record retention which comply with regulatory or customer requirements?	• Where are records stored? • Who stores records? • How long are records kept? On what basis were record storage times defined?
I.A 7	**General documentation requirements**	
	The business shall establish and implement procedures to ensure that all documents are maintained and kept up to date.	*WHAT DOES IT MEAN?* *a) Documents provide instruction for people so they can do their job and deliver a safe and consistent product.* *b) Documents also provide records so that the business is able to collect data and provide evidence to show that it is meeting customer and regulatory requirements as well as the requirements of this checklist.* *c) They should be maintained, kept up to date and controlled so to ensure that only correct documents are used.* *d) Usage of out of date documents by people may not only resulting a product that is out of conformance with specifications but also that the appropriate data to prove compliance is not gathered.* *WHAT DO I NEED TO DO?* *a) You need to document and implement a procedure for keeping documents up to date and assuring out of date documents are not used.* *b) You should appoint an individual to be responsible for documents with accountability for approving documents.* *c) Only authorised people are able to replace existing documents so they should be protected against unauthorised change.* *d) As procedures change there should be a way to control and archive obsolete documents.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check there is a procedure there has been implemented effectively for document control.* • *Check procedures and forms during the assessment looking for correct usage including issues such as dates, signatures and frequency of recording.*

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I.A 7.1	Is a written documentation procedure in place and effectively implemented?	• Where is documentation concerning the quality system for quality assurance and food safety retained? <procedure for document control> • How is document validity identified? • How is it ensured that only valid documents are in circulation? • Procedures should cover the control of documents and their revisions • Confidential documents shall be defined and access to them shall be limited • What rules exist regarding document control? • Do the documents have an identification code? • How is the identification code structured? • How can a revision be identified? • Who is responsible for changes?
B.A 8	**Control of measuring & monitoring devices**	
	Measuring and monitoring devices critical to food safety, quality (including customer requirements) and regulatory requirements shall be reliable.	*WHAT DOES IT MEAN?* *a) The business should identify the critical control points in their process that may create a food safety issue.* *b) Once those points have been identified you should have a means to measure and monitor the process using appropriate devices.* *c) Those devices should be verified on a regular basis to ensure their reliability.* *d) For example, to ensure destruction of all pathogenic microorganisms in raw milk, time and temperature combinations of the pasteurization process should be regulated. A manufacturer will need to ensure that the device used to measure and monitor the time and temperature is accurate and reliable.* *WHAT DO I NEED TO DO?* *a) Create a master list of all measuring and monitoring devices required to control the food safety and quality of your food and list the method and frequency for calibration and maintenance.* *b) Each measuring and monitoring unit should have a unique identifier and the acceptable variance range identified.* *c) Examples of measuring and monitoring devices critical to food safety and quality include thermometers and metal detectors* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *check that the measuring and monitoring device is accurately measuring the required parameters* • *select a measuring and monitoring device and check that there is evidence that it is calibrated.*

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B.A 8.1	Are measuring and monitoring devices critical to food safety, quality (including customer requirements) and regulatory requrements reliable?	To be checked examples: Functional controls of used thermometers are proceeded. For final product calibrated balances are used. • What kinds of monitoring devices exist? <monitoring devices list> • What is demanded of monitoring devices? • What monitoring device is adequate for which kind of measurement? • How are monitoring devices identified? <identification stickers on monitoring devices> • Do calibrated devices exist? <monitoring devices list> • How is measuring devices check organized? <calibration procedures> • Are measuring devices regularly calibrated? <calibration protocol> • Who is responsible for calibration? • How is calibration done? Where is it documented? <calibration records> • Is calibration up to date? <calibration certificate>

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I.A 8	**Control of measuring & monitoring devices**	
	The business shall identify measuring and monitoring devices critical to food safety and quality (including customer requirements), ensure that they are calibrated and traceable to a recognised national or international standard.	*WHAT DOES IT MEAN?* *a) In addition to those items already identified in requirement B.A 8, the business shall ensure that calibration of measuring and monitoring devices that are critical to food safety and quality is undertaken against a recognised national or international standard.* *WHAT DO I NEED TO DO?* *a) Create a master list of all measuring and monitoring devices, ensure there is unique identification for each and that the acceptable variance range is identified.* *b) Examples of measuring and monitoring devices critical to food safety include: Thermometers, Metal detectors, X-Ray units, pH and water activity meters, scales, oven speeds and other important processing measuring and monitoring units.* *c) Develop Standard Operating Procedures (SOP) for each listed device to provide detailed, written instructions that will achieve uniformity of performance.* *d) Each SOP should list what the device is, why it is needed, how it is used, who is authorised to use it and when it is to be calibrated.* *e) Each SOP should include requirements for documented corrective action and remediation in the event of deviation to standards.* *f) Maintain and retain records of the following activities: calibration, service providers with contact information; maintenance records, monitoring frequency signed by approved operator, deviation and corrective action.* *g) Implement a training program to ensure all relevant people are adequately trained.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check for procedures for the operation of measuring and monitoring devices critical to food safety.* • *Check the calibration and maintenance log to validate that devices are maintained and calibrated against in recognised national or international standard as recommended by the manufacturer.* • *Review samples of signed operator logs for accuracy and to verify corrective action and remediation for any documented deviations.* • *Check training records for the relevant people, looking for evidence that they have been adequately trained.*

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I.A 8.2	Are measuring and monitoring devices critical to food safety, quality (including customer requirements) and legality identified, calibrated and traceable to recognised standards and are they effectively controlled?	• What kinds of monitoring devices exist? <monitoring devices list> • What is demanded of monitoring devices? • What monitoring device is adequate for which kind of measurement? • How are monitoring devices identified? <identification stickers on monitoring devices> • Do calibrated devices exist? <monitoring devices list> • How is measuring devices check organized? <calibration procedures> • Are measuring devices regularly calibrated? <calibration protocol> • Who is responsible for calibration? • How is calibration done? Where is it documented? <calibration records> • Is calibration up to date? <calibration certificate>
I.A 8.3	Are actions taken and recorded when measuring and monitoring devices are found to be outside of specified limits?	Current instruments should be in calibration. Appropriate actions shall consider all product produced since last good calibration as non-confirming product. Procedures exists if tolerances of measuring devices exceed. • What corrective actions are taken when a tolerance deviation is found? <corrective actions> <calibration protocol> • What actions are taken when measurement results are uncertain? • How are embargoed measuring devices identified? <identification stickers> • How is calibration status of measuring device identified? <measuring devices list>

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B.A 9	Training	
	The business shall ensure that all people are adequately trained in food safety, quality and practices according to their job responsibilities.	*WHAT DOES IT MEAN?* *a) All new people performing work that affects product safety, legality and quality shall have the required competence by education, work experience and training, that matches their work, based on risk assessment.* *b) Training should address both personal health and safety as well as relevant food safety issues with a focus on avoiding contamination.* *c) All people (management, full-time, part-time, or temporary) shall receive relevant training.* *d) Each qualification or competency related to best practise and food safety shall be systematically "refreshed" and confirmed.* *WHAT DO I NEED TO DO?* *a) Ensure that people are aware and understand the consequences of improper food handling.* *b) Make sure that induction training of new employees is targeted towards their future duties in your business.* *c) For members of the management team, create an induction program that takes into account all relevant processes and departments.* *d) Training should be conducted regularly and the contents should be adapted to current business conditions such as incidents, improvements and current legal situation.* *e) For simple tasks create a check list with relevant topics that can be efficiently communicated.* *f) You will need to provide evidence about training topics, including hygiene and safety in the workplace, with participating employees and refresher training.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check whether you can prove that all your people have undergone relevant training, with special attention to induction for temporary and part-time people.* • *Interview people and ask them about the training they have received and how appropriate it was for the job that they must do.* • *Check that you can prove that you have delivered refresher training to all relevant people.* • *Review whether the refresher training content has been adapted to current business conditions such as incidents, improvements and current legal situation.*
B.A 9.1	Have all new people been effectively trained?	
B.A 9.2	Have all relevant people received refresher training?	

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I.A 9	Training	
	The business shall implement a system to ensure that all people are adequately trained, instructed and supervised in food safety principles and practices that matches their work.	*WHAT DOES IT MEAN?* *a) All people performing work that affects product safety, legality and quality should have the required competence by education, work experience and training, that matches their work, based on hazard analysis and risk assessment.* *b) A training program should apply to all people, including part-time and temporary workers.* *c) Before starting work, they should be trained in accordance with the training program.* *d) Each qualification or competency related to best practice and food safety should be systematically "refreshed" and confirmed.* *e) This program should be documented and implemented according to a predefined plan.* *WHAT DO I NEED TO DO?* *a) The business should implement a training program relevant to the product requirements and the training needs of the people which should include:* *· training content* *· training frequency* *· people's tasks* *· relevant language* *· qualified trainer* *· evaluation methodology* *b) There should be a procedure that proves the effectiveness of training.* *c) The contents of the training program should be reviewed and updated systematically to take into account specific issues, food safety, food related legal requirements and product and process modifications.* *d) You will need to prove what training topics have been delivered for each individual.* *e) Training topics include HACCP, hygiene and safety in the workplace.* *f) Develop a refresher training program where activities, roles and responsibilities are defined.* *g) Training activities should be documented.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check for evidence that there is a training program and that all people have undergone relevant training.* • *Will interview people and ask them about the training they have received and how appropriate it was for the job that they do.*

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		• *Will examine training records for individual people to verify that the training program has achieved its objectives.* • *Will pay special attention to the training of all new employees, temporary workers and part-time employees.* • *Will check that the procedure for review of the training program is implemented and results in improvements.* • *Check the documentation of the refresher training program to confirm that planned training is delivered and the outcomes are monitored.* • *Assess the efficacy of this program through a comparison of the procedures and the records.*
I.A 9.3	Is a people training program, including refresher (update and repetition), in place and effectively implemented?	• How often are training sessions held? <training schedule> • How are training contents reviewed? <review test> • When are training contents reviewed? • When was the latest training content update done? • What was the content of the latest update? <audit results> specific issues: non-conformities, failure, complaints, etc. • Who is responsible for training? <training proof> • What are the evidences for the trainer's qualification? • What was the content of the last training session? <training program> • How are foreign employees trained/instructed? • Who participates in the training sessions? • How are the instruction necessities for each employee determined? • How often are training sessions held? <training schedule> • Are prospective employees (incl. seasonal and temporary workers) trained/instructed upon employment? • Which employees are trained/instructed upon employment? What is the content of these instructions? <training proofs> • Which training courses are undertaken? • Are there any special training courses? • How often are hygiene training sessions held? • What was the content of the last hygiene training session? <training proofs>

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I.A 9.4	Is a HACCP training program in place?	*WHAT DOES IT MEAN?* *a) Those responsible for the development and maintenance of the HACCP plan should have an internal team leader and received adequate training.* *b) The production people in charge of the monitoring of CCP's should have received specific training.* *c) All training should be documented and managed through a HACCP training program where content, frequency, tasks and evaluation methodology are defined.* *WHAT DO I NEED TO DO?* *a) The business should ensure the training program includes HACCP training for relevant staff.* *b) The training content should be reviewed and updated regularly with consideration of business specific issues, food safety, food related legal requirements and product and process modifications.* *c) You will need to prove what training topics have been delivered for relevant people.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check for evidence that those responsible for the development and maintenance of the HACCP plan have undergone a HACCP training program.* • *Interview people and ask them about the HACCP training they have received and how appropriate it was for the job that they do.* • *Look for evidence of training topics and participating employees.* • What is the content of a HACCP training course? <HACCP training proofs> • When was the last HACCP training course held? <training proofs> • Who participated in the HACCP training course? <training proofs>

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I.A 9.5	Are adequate training records available?	*WHAT DOES IT MEAN?* *a) There should be evidence that training has been carried out.* *WHAT DO I NEED TO DO?* *a) Records should be available of all training events, stating:* · *list of participants (this should include their signature)* · *date* · *duration* · *contents of training* · *name of trainer/tutor.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check the availability, accuracy and adequacy of the training records.* • Are training courses documented? • What has been documented? • Have participants signed the training proofs?

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I.A 10	**Procedures**	
	The business shall prepare and implement detailed procedures and instructions for all processes and operations having an effect on product safety, quality and legality.	*WHAT DOES IT MEAN?* *a) Procedures are controlled documents that provide instruction for people so they can consistently deliver the particular process as defined.* *b) A procedure may include instructions on using particular equipment, how to carry out specific tests, follow a recipe, repair equipment or other essential steps in manufacturing a product.* *c) Procedures are important training tools as new staff members are inducted or for refresher training.* *d) Procedures can be made available for staff either as paper copies, in a reference manual or in electronic format.* *WHAT DO I NEED TO DO?* *a) Ensure all processes and instructions used to manufacture, test, store and ship the product have been documented in paper or electronic format, that relevant staff are trained against these and always have them available.* *b) Ensure that procedures are communicated in a consistent manner, either because they are new or because they have been changed or as a part of refresher training. This can happen during production meetings, management review meetings etc.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Collect a sample of procedures, check how people use them through observation or interview and determine whether actual usage reflects the stated intentions.*
I.A 10.1	Are detailed procedures developed and effectively implemented for all processes and operations that affect food safety, quality and legality?	To be checked examples: • Common principles of handling goods (fifo) are implemented and documented. • Best before/used by dates are fulfilled and checked regularly. • Frozen products are defreezed appropriate. • The cool chain isn't interrupted. • Intermediate cooling of pre-produced food is carried out promptly. • Heating temperatures (limits) are known and are complied with.

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I.A 10.2	Are procedures clearly communicated to relevant people?	Documents shall be legible and clearly written to be understood by staff Relevant staff should be able to demonstrate knowledge of procedures pertinent to their work area or job responsibilities All involved person are sufficiently informed and know their responsibilities. • Are all documents legible? • Are the documents unambiguous? • Are the documents available at the right places? Also after office hours? • How do relevant employees have access to documents? • How are document changes communicated to relevant employees? • Are there any distribution lists for documents? <Examples>, <procedure>, <distribution lists> • How is it ensured that employees know their responsibilities? • How does senior management ensure that employees know their responsibilities? • What criteria are used to ensure process control? • What is done to ensure that processes are known to relevant personnel (incl. permanent staff and temporary/seasonal workers)?

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B.A 11	Complaint handling	
	The business shall prepare and implement an effective program for the management of customer and consumer complaints. Data shall be controlled and managed to ensure that there are corrective actions for legal and quality compliance and food safety issues.	*WHAT DOES IT MEAN?* *a) Customer and consumer complaints can identify whether the finished product achieved the specification requirements or otherwise resulted in non-conformance.* *b) The business needs to ensure the complaint and its cause is resolved which may require further investigation using root cause analysis (which is a process of solving the fundamental causes of an incident).* *c) Once the non-conformance is accurately understood, corrective action can be taken so that the risk of recurrence is minimised.* *WHAT DO I NEED TO DO?* *a) Complaints should be recorded, investigated and resolved. Resolution is also referred to as corrective action.* *b) Create a method of requesting, capturing and investigating customer complaints.* *c) Ensure staff are made aware of their responsibilities for handling the complaints and investigations.* *d) Ensure that complaints, their investigations and resolutions are recorded.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Will check that a procedure is in place for receiving, documenting and acting on customer complaints.* • *Check if records of complaints are readily available.* • *Will select a sample of records of complaints and compare them against the procedure from receipt to resolution.* • *Interview those with responsibilities in the complaints process.* • *Will look for evidence of resulting activities which may be affected. These may include staff training, testing, management of non-conforming product, etc.*
B.A 11.1	Is a documented complaint management program in place and effectively implemented?	• How are complaints handled? <complaint handling procedure> • Who ponders about complaint significance? • Who defines the actions to be taken? • Within what time frame must actions be taken?

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B.A 11.2	Are records of all customer and consumer complaints, investigations and corrective actions maintained?	• Who ponders about complaint significance? • Who defines the actions to be taken? • Within what time frame must actions be taken? • Are complaints analysed, e.g. by sources and causes? • If applicable, are the customers informed about the implemented corrective actions?
B.A 12	**Product analysis**	
	The business shall implement a test plan to ensure that analysis of products and ingredients is systematically undertaken for issues that are identified as being critical to food safety and legal requirements as well as customer specifications. Results of analysis shall be achieved via recognized and validated methods.	*WHAT DOES IT MEAN?* *a) You need to be able to provide evidence that the food safety, legality and customer issues that you have identified during a risk assessment are being critically analysed for compliance with agreed limits.* *b) The business should have a risk based procedure to ensure that you are analysing relevant issues.* *WHAT DO I NEED TO DO?* *a) The test methodology that you use will need to ensure the accuracy and precision of the results obtained.* *b) The tests should be carried out to produce credible and accurate results.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Will check your risk assessment to see whether your testing procedure has successfully in a review to demonstrate that you meet food safety, legal requirements and customer specifications.* • *Will review whether your testing has been done via recognized and validated methods.*
B.A 12.1	Is a test plan available for internal and external analysis to ensure that all specified product requirements are met, including legal requirements and customer specifications throughout the whole shelf life? Are the test results documented?	• Does an inspection plan exist? <inspection plan> • Who organizes inspection plan? Which products are encompassed by inspection plan? (raw materials, half-finished and finished products, packaging materials, environmental tests?) <inspection plan> • Is inspection plan based on risk analysis? <risk analysis> • Where are test results documented? <test results>

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I.A 12	**Product analysis**	
	The business shall implement a program to ensure that analysis of products and ingredients is systematically undertaken for issues that are identified as being critical to food safety and legal requirements as well as customer specifications. The business shall ensure that the methods used provide valid results (e.g. by procedures set forth in ISO 17025 and/or industry recognised methods).	*WHAT DOES IT MEAN?* *a) You need to be able to provide evidence that the food safety, legality and customer issues that you have identified during a risk assessment are being critically analysed for compliance with agreed limits.* *b) The business should have a risk based procedure to ensure that you are analysing relevant issues.* *WHAT DO I NEED TO DO?* *a) This procedure will ensure that you are able to demonstrate you are evaluating and meeting food safety, legal requirements and customer specifications.* *b) The test methodology that you use will need to ensure the accuracy and precision of the results obtained.* *c) You should determine which are the relevant tests that complement your HACCP plan and its associated prerequisite programs to ensure you are meeting food safety, legal requirements and customer specifications.* *d) The tests should be carried out to produce credible and accurate results.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Will check your risk assessment to see whether your testing procedure has successfully in a review to demonstrate that you meet food safety, legal requirements and customer specifications.* • *Will review whether your testing has been done by laboratories with ISO 17025 certification or instead you can provide credible evidence of industry recognised methods.*

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I.A 12.2	Are analysis procedures in place to ensure that all specified product requirements are met, including legal requirements and customer specifications throughout the whole shelf life?	Microbiological, physical and chemical analysis required for that purpose shall be performed internally or subcontracted to a qualified service provider. The analyses and the frequency with which they are carried out, shall be based on risk and may include microbiological and chemical factors such as pH and aw. • Which physical, chemical or microbiological analyses are made or subcontracted? <analyses results> • Does an inspection plan exist? <inspection plan> • Who organizes inspection plan? Which products are encompassed by inspection plan? (raw materials, half-finished and finished products, packaging materials, environmental tests?) <inspection plan> • Is inspection plan based on risk analysis? <risk analysis> • Where are test results documented? <test results> • Are analysis which are critical to food safety/conformity carried out by laboratory(ies) whose methods are ISO 17025 accredited?
I.A 12.3	Are methods, relevant for food safety, used to provide valid results (e.g. by procedures set forth in ISO 17025 and/or industry recognised methods)?	If the analyses are performed by a factory internal or non-accredited laboratory, the results shall be verified on a regular basis by an accredited laboratory. Results of non accredited internal analyses, have to be verified by accredited laboratories regularly. • Is there an analytical laboratory on site? Is it working under ISO 17025 procedures and/or accredited under ISO 17025? <accreditation evidence> • If not accredited, are ring tests regularly performed by accredited laboratory? • Are internal lab results verified by an accredited lab? • Which external laboratories are used? Are these accredited under ISO 17025? <accreditation evidence> • How is it ensured that internal analytical methods are appropriate? • Are ring tests performed? <ring test performance evidence>
B.A 13	**Contract agreement and purchasing**	
	The company ensures that contractual agreements regarding food safety and quality are followed.	

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B.A 13.1	Are requirements which are defined between the contract partners established, agreed upon and reviewed concerning their acceptability before a supply agreement is concluded? Are all clauses related to quality and food safety known and communicated to each relevant department?	• What assurances are given that customer requirements and own specifications are in accordance with each other? • Do written supply agreements with customers exist? • Do specific customer requirements for purchased products exist? • Who checks and approves specifications? • Who ensures that the proper raw materials are available whenever needed?
B.A 13.2	Are changes of existing contractual agreements documented and communicated between the contract partners?	• How is it ensured that customers are informed about product changes? • Who checks and approves specifications?
I.A 13	**Contract agreement and purchasing**	
	The business shall control purchasing processes to ensure that all externally sourced items and services conform to written requirements.	*WHAT DOES IT MEAN?* *a) A food business relies on its suppliers because achieving both product safety and deliveries on time depends on their level of conformance to your requirements, which should be written and mutually agreed through specifications and contracts.* *WHAT DO I NEED TO DO?* *a) Your purchasing procedures should include agreed specifications for raw materials, ingredients, packaging and services which may impact the safety and quality of the product.* *b) Determine which risks are relevant to the product or service. With this information, decide the relevant criteria for evaluating each supplier and implement appropriate procedures for quality control and service level (Service level is a calculation of the volume of goods provided to specification against goods ordered, expressed as a percentage).* *c) Inform your suppliers both systematically and reactively on their performance, highlighting issues where they can make improvements.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Review your specifications, ensuring these are up-to-date and looking for evidence of approval such as signatures or e-mails.* • *Check your quality control records and compare them with your procedures for product and service evaluation.* • *Review how you have dealt with supplier non-conformance, from receipt to resolution.* *Incoming good are controlled appropriately, to ensure safety and conformity to product specifications.*

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I.A 13.3	Is the control of outsourced process that impact food safety and quality ensured? Is control of such outsourced processes identified and documented within the food safety and quality management system?	
I.A 13.4	Do purchased products and services meet current specifications and contractual agreements?	Organic-certificates or other relevant certificates are available. • How is it ensured that purchased products and services conform to specifications? • How are purchased products and their specifications reviewed? <incoming product check-list> <lab tests> • Does a test schedule exist? <test schedule>
I.A 14	**Supplier approval and performance monitoring**	
	The business shall operate procedures for approval and monitoring of all its suppliers whose products or services may affect product safety and quality. The results of evaluations and follow-up actions shall be recorded.	*WHAT DOES IT MEAN?* *a) A risk based program should be developed and implemented to effectively manage and monitor the approval of suppliers.* *b) The resulting activities related to each supplier should be based on your risk assessment, such as supplier capability assessments, supplier visits, quality control for incoming materials, etc.* *c) If visiting isn't practical, alternative means of capability assessment would include the up-to-date evidence of certification to a food safety management scheme.* *d) Monitoring their performance against your requirements will provide you with data to assess their performance and ongoing capability.* *WHAT DO I NEED TO DO?* *a) There should be a supplier management program in place for the approval and monitoring of suppliers who may have an impact on food safety and quality.* *b) The program should be able to demonstrate that it is effective, with evidence that objective decisions are made about supplier capability.* *c) For approved suppliers there should be evidence that there is an ongoing systematic approach to maintain approval.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Will evaluate the procedures of the supplier management program to determine the effectiveness of the approval and monitoring process.* • *Confirm that there is evidence that the relevant procedures are implemented and reviewed.* • *Check your approved supplier list looking for evidence that you have considered and assessed their capability and that you have a systematic approach to maintain approval.*

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I.A 14.1	Is a documented supplier approval program in place and effectively implemented?	• Does an approval procedure exist for new suppliers and co-packers? <supplier procedures> • How are supplies monitored? • Are suppliers graded? <supplier grading systems> • Have suppliers been barred? • How is a barred supplier identified? • How is the qualification of suppliers ensured? <product entry monitoring> <supplier audits> <lab tests> • Are there any co-packers? <co-packers list> • How are co-packers monitored? • Are co-packers certified/assessed according to IFS Food 6, another GFSI recognized scheme or IFS Global Markets successfully? <certificate or report flyleaf>
I.A 14.2	Is a documented supplier monitoring program in place and effectively implemented?	• Records of effective monitoring should be kept • How often are external audits made? <external audit plan> • Which criteria are consulted for supplier assessment? • Which supplier has analysis certificates? <analysis certificates> • How was the risk analysis for supplier approval performed? <risk analysis> • Who reviews the results of supplier assessments? • How often are the results of supplier assessments reviewed? • What actions are taken after reviewal of the results for supplier assessments? <audit results>

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B. Good manufacturing practices (GMPs)		
B.B 1	Personal hygiene	
	The business shall ensure the implementation of appropriate hygiene practices for all its people and visitors. Such practices shall result in sanitary handling and delivery of safe and quality products to customers. The Codex Alimentarius Commission's recommendation on personal hygiene shall be followed.	*WHAT DOES IT MEAN?* *a) All food businesses should manage and control the personal hygiene requirements of its people and visitors to the site.* *b) There should be documented personal hygiene requirements to include the following: the use of protective clothing, hand washing and disinfection, eating and drinking, controls over smoking, actions to be taken in case of cuts or skin abrasions, control over fingernails, jewellery, perfume, personal belongings and the control of hair and beards.* *c) The resulting procedures must match any legal requirements.* *WHAT DO I NEED TO DO?* *a) A risk analysis should be conducted to determine the appropriate personal hygiene requirements. The outcomes of this analysis should be implemented as appropriate to your product and process.* *b) The resulting procedures that will enforce the personal hygiene requirements should apply to all relevant people, contractors and visitors, all of whom should be made aware their responsibilities.* · *Hand cleaning should be performed on entry to the production areas and that the frequency that is appropriate to minimise the risk of product contamination.* · *People with infectious diseases should not enter the production areas.* · *People who have been in contact with others with infectious diseases should identify themselves and may be excluded from entering production areas.* · *Visible jewellery, including piercing and watches, should not be worn.* · *Any exceptions that may be granted should have been comprehensively evaluated by hazard analysis and assessment of associated risks in relation to product and process.* · *Cuts and skin abrasions should be covered by a coloured plaster or bandage that shows a different colour to the product and where appropriate contains a metal strip to enable metal detection.* · *For hand injuries, in addition to a plaster or bandage, a single use glove should be worn.* · *Protective clothing, which should not leave the site, should be provided and used by all people and visitors.* · *In production areas where wearing headgear and beard snood (coverings) is required, the hair should be covered completely so that product contamination is prevented.*

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		c) All of these procedures should be enforced by a qualified person within the business. *d) Compliance should be effectively managed and checked systematically.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check for a risk analysis and the related implementation of appropriate procedures.* • *Interview people to evaluate their understanding and implementation of the personal hygiene requirements.* • *Check that there is a procedure for systematic review of the outcomes with appropriate testing.*
B.B 1.1	Are personal hygiene requirements in place and applicable to all relevant people, contractors and visitors?	• The personal hygiene requirements are monitored for compliance by a competent person. • Personnel, contractors and visitors shall wash their hands; · Upon entering food handling or processing areas · After each visit to the toilet · After using a handkerchief · After handling wash down hoses or contaminated material · After sneezing or coughing; · After smoking, eating or drinking · After handling raw food or any contaminated material, where this could result in contamination of other food items. • How is the hygiene policy communicated? <hygiene rules for employees> • Are personnel hygiene rules also followed by external service providers/workmen and visitors? <hygiene rules for visitors> • How is it assured that external persons know the relevant hygiene rules? <hygiene rules for visitors> • How are employees monitored during work? <hand swab tests, etc.> • Is employee compliance to hygiene rules checked on a regular basis? <minutes site inspection>, <list of identified failures>, etc. • Are hygiene inspections performed? <minutes of personnel hygiene inspection>

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B.B 1.2	Are personal hygiene requirements compliant with legal requirements, if applicable?	The personal hygiene requirements are developed by a competent person. These requirements are regularly checked for compliance against the local regulatory requirements. • What is the policy regarding personal hygiene? <hygiene rules for employees> • The rules regarding personnel hygiene include hand cleaning, food and beverages, smoking, handling of injuries, finger nails and jewellery, hair and beards? • Are the rules based on a risk analysis? <risk analysis> • Where is it allowed to smoke? • How should lesions be treated/covered? • What kinds of hair restraints are needed in which areas? Example of result from the hazard analysis and assessment of associated risks: if gloves are used, then hand disinfection is not required for low risk production.
B.B 1.3	Are communication procedures in place for people, contractors and visitors addressing actions to be taken in the case of an infectious disease?	The requirements in relation to control of infectious diseases cover medical examination, where applicable. • How shall personnel and visitors behave in case or suspicion of an infectious disease?
B.B 1.4	Is a qualified person responsible to decide if individuals with a suspect illness may enter food areas and how these individuals are controlled?	Conditions which shall be reported to management/supervisory staff in order to access the need for medical examination and/or possible exclusion from food handling include: · Jaundice · Diarrhoea · Vomiting · Fever · Sore throat with fever · Visibly infected skin lesions · Discharges from ears, nose or throat • How is it ensured that personnel and visitors know the guidelines? <personnel hygiene rules> <visitors hygiene rules> • Who verifies records of verification and formal acceptance of hygiene rules?

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B.B 1.5	Are people, contractors and visitors aware of and complying with the personal hygiene requirements?	To ensure that those who come directly or indirectly into contact with food: • Maintain an appropriate degree of personal hygiene; • Behave and operate in an appropriate manner. Protective clothing has to be changed daily and if necessary more often. Washing temperature should be in min. 60 °C. Personal items and clothes are prohibited in the production area. • How is the hygiene policy communicated? <hygiene rules for employees> • Are personnel hygiene rules also followed by external service providers/workmen and visitors? <hygiene rules for visitors> • How is it assured that external persons know the relevant hygiene rules? <hygiene rules for visitors> • How are employees monitored during work? <hand swab tests, etc.> • Is employee compliance to hygiene rules checked on a regular basis? <minutes site inspection>, <list of identified failures>, etc.
B.B 1.6	Are people, contractors and visitors aware of and complying with the requirements for the wearing and changing of protective clothing in specified work areas?	There is the provision of sufficient, appropriate, suitable, clean and protective clothing. This is worn only on site. The entrance of contractors and visitors to the production area is allowed in protective clothing, only and in accompany of a member of staff. • What are the rules regarding protective clothing? <personnel hygiene rules> • Are the protective clothing rules based on risk analysis? <risk analysis> • When must protective clothing be changed? <personnel hygiene rules> • Examples of areas: catering, changing rooms, smoking area, toilets, high risk areas, etc.

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B.B 2	**Facility environment**	
	The business facilities shall be located and maintained so as to reduce the risk of contamination and enable the production of safe and legal products with required quality.	*WHAT DOES IT MEAN?* *a) Facilities where food ingredients, raw materials, packaging materials, semi-processed products and finished products are stored should be designed and constructed so that food safety is ensured.* *WHAT DO I NEED TO DO?* *a) Inspect the storage areas, considering contamination risk: temperature fluctuations, humidity, pests, dusts, odours, splintering objects (wood pallets, glass, etc.).* *b) Optimize the storage conditions. If necessary, arrange for structural alterations or new facilities.* *c) Walls should be designed and constructed to prevent the accumulation of dirt as well as to reduce condensation and mould growth.* *d) The surfaces of walls and floors should be in good condition, impervious, wear resistant and easy to clean.* *e) The junctions between walls, floors and ceilings should be easy to clean.* *f) Waste water and other liquids should reach drainage easily with no possibility of puddles.* *g) In food handling areas, machinery and piping should be arranged so that waste liquids go directly into a drain.* *h) Drainage systems should be in good condition, easy to clean and designed to minimise the risk of product contamination (e.g. ingress of pests, etc.).* *i) Ceilings (or, where no ceilings exist, the inside of roofs) and overhead fixtures, such as piping, cables and lighting, should be constructed to minimise the accumulation of dirt and should not pose any risk of physical or microbiological contamination. Where false ceilings are used, access to the void should be provided to allow cleaning, maintenance and pest control inspections.* *j) Windows and other openings should be designed and constructed to avoid the accumulation of dirt.* *k) Where there is risk of contamination, windows and roof glazing should remain closed and fixed during production.* *l) Where windows and roof glazing are designed to be opened for ventilation purposes, they should be fitted with easily removable, good condition pest screens or other measures in order to prevent contamination.* *m) In areas where unpackaged product is handled, windows should be protected against breakage.* *n) Doors and gates should be in good condition and easy to clean (e.g. no splintering parts, flaking paints or corrosion).*

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		o) External doors and gates should be constructed to prevent the entry of pests. If possible, they should be self-closing. *p) All working areas should have adequate lighting.* *q) All lighting equipment should be protected by shatter proof covers and installed to minimise the risk of breakage.* *r) Adequate natural and/or artificial ventilation should exist in all areas.* *s) If ventilation equipment is installed, filters and other ingredient which require cleaning or replacement should be easily accessible.* *t) Air conditioning equipment and artificially generated airflow should not lead to any product safety or quality risks.* *u) Dust extraction equipment should be installed in areas where considerable amounts of dust are generated.* *v) Water which is used as an ingredient in the production process, or for cleaning, should be of potable quality and supplied in sufficient quantity. This also applies to steam and ice used within the food handling area. A supply of potable water should be available at all times.* *w) Recycled water which is used in the process should not pose a contamination risk. In such cases, the water should comply with applicable legal requirements for potable water; records of compliance testing should be available.* *x) The quality of water, steam or ice should be monitored following a risk based sampling plan.* *y) Non-potable water should be transported in separate, properly marked piping. Such piping should not be connected to the drinking water system, or allow the possibility of flowing back to contaminate potable water sources or the food handling area environment.* *z) The surrounding areas of the facility should be maintained and kept free of waste and accumulated debris. This will help to minimise risk of pest activity.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check the adequacy of the storage facilities for ensuring food safety and if every food, ingredient, raw material, semi-processed and finished product is stored under conditions ensuring food safety and quality.* • *Inspect the fabrication of the facility both externally and internally, looking for any risks of contamination that may adversely affect the production of quality, safe and legal finished products.*

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B.B 2.1	Is the facility located, designed, constructed and maintained to ensure product safety, legality and quality?	There is no evidence of any activities carried out near the location of the site that could compromise food safety. The design and layout of the facility lends itself to effective maintenance, cleaning and disinfection. Grounds and area surrounding the facility are well maintained and kept free of waste or accumulated debris. The site is located, planned, constructed and maintained to ensure product safety and cross contamination. To be checked examples: • doors and gates: are opened not exceeding a minimum level. • windows to open: are equipped with an intact Mosquito Net (in production area, storage and staff rooms, respectively connected rooms) • ventilation: exist sufficiently, its easy to clean, what is regularly done. • receipt of goods: good is protected against weather influence. Disposal of waste has not to take place simultaneous at the same location. • Does a location investigation exist? Can location have a negative influence on product quality? <location analysis> • What protective measures have been established if potentially damaging materials/substances are nearby? <protective measures> <corrective actions> • Is efficiency of protective measures regularly reviewed? • How is efficiency of established protective measures reviewed? • Are factory exteriors tidy? • How is it ensured that cross-contamination is avoided? <waste elimination plan> <personnel flow plan> <materials flow plan> <process flow plan> <hydraulic plan> • Are there "dirty" and "clean" areas? • Are there appropriate storage rooms? • Can dirt accumulate on window sills?

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B.B 2.2	Is the facility effectively maintained, cleaned and disinfected to prevent physical, chemical and microbiological product contamination?	Sufficient and appropriate actions are taken to avoid physical, chemical and/or microbiological products contamination. • Maintenance schedules and records are available. • Maintenance schedules and records are appropriate. • How is cross-contamination avoided within factory premises? <process flow-diagram> • Are walls mouldy? • How often are floors cleaned? <cleaning schedule> <cleaning evidence> • How often are ceilings cleaned? <cleaning evidence> <cleaning evidence> • Can dirt accumulate on window sills? • What areas are cleaned and disinfected? <cleaning schedule> • How often are areas cleaned and disinfected?
B.B 2.3	Is the lighting of the appropriate intensity and design to ensure that food safety and quality practice is effective?	• What is the assurance that all working areas are adequately illuminated? • Are all fly killing units and lamps protected by splinter shields? <lighting protectors>
B.B 2.4	Are structures, surfaces and materials, particularly those in contact with food, easy to maintain, clean and, where appropriate, disinfected?	Windows and doors are designed and constructed to prevent the ingress of pests or other contaminants. Ventilation and extraction are adequate to provide optimum product storage and processing environments to prevent condensation or excessive dust. To be checked examples: • floors: easy clean- and disinfect, impervious, water-repellent, wear-resistant, slip resistant and with sufficient drainage systems (these are covered, clean, smell and back-water resistant). • Walls: easy clean- and disinfect, free from surface cavities. • Ceiling and roof internals: hygienic, designed and constructed to to prevent accumulation of dirt, to reduce condensation and mould growth. Nesting opportunities for pest should excluded. • doors and windows: robust, in good condition, easy clean- and disinfect, smooth, water-repellent and light • How often are walls cleaned? <cleaning schedule> <cleaning evidence> • Are wall-floor junctions and corners rounded? • Are equipments suitably designed and were they checked before start up? <start up protocol> • What rules exist for start up of new equipments? • Were new equipments immediately considered in maintenance plan? • Does an equipment installation plan exist? <machinery installation plan> • How is effective prevention of dust and condensation accumulation ensured? • Are floors cleanable? • How often are floors cleaned? <cleaning schedule>,<cleaning evidence> • Are doors damaged?

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B.B 2.5	Is the equipment positioned to ensure that there is no compromise to food safety, legality and quality from waste water or drainage?	• How is waste water disposal ensured? • How often are gullies cleaned? <cleaning evidence> <drainage schedule> • Are there water or other liquid puddles on the floors of production areas? • Where is machinery which produces a large amount of waste water located? <machinery lay-out>
B.B 2.6	Are the grounds and surrounding areas of the facility maintained and kept free of waste and accumulated debris?	• Are factory exteriors tidy? • Are grounds within the factory premises in good condition? • Is natural drainage sufficient? • If natural drainage is insufficient, has a suitable drainage system been installed? • Are goods stored outdoors? • What is stored outdoors? • What rules exist for outdoor storage? • Is outdoor storage based on risk analysis? <risk analysis> • Are floors cleanable? • How often are floors cleaned? <cleaning schedule> <cleaning evidence>

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B.B 3	Cleaning & disinfection	
	The business shall ensure appropriate standards of cleaning and disinfection shall be maintained at all times and throughout all production stages.	*WHAT DOES IT MEAN?* *a) The business should ensure that raw materials, ingredients, packaging materials and finished products are stored in a sanitary environment so that the finished product will be safe and legal. To achieve this, the aim is to at all times operate and maintain a clean and hygienic environment, using clean equipment and with an expectation and understanding of hygiene and cleanliness from your people.* *b) An unsanitary environment will result in finished products that are not safe, not suitable for consumption and with reduced shelf-life.* *c) Put simply, a food facility that does not constantly strive to achieve the highest level of cleanliness is a risk to its owners, its people, customers and its consumers.* *d) A systematic cleaning program with comprehensive cleaning instructions and schedule will be required. There should be procedures, a definition of acceptable cleaning, well-trained people and the appropriate resources and equipment. Monitoring of sanitary standards will provide evidence of compliance and identify areas for improvement.* *WHAT DO I NEED TO DO?* *a) You need to document and implement a cleaning program and schedule. The program will consist of cleaning instructions (Standard Sanitary Operating Procedures [SSOPs]) that provide comprehensive detail about everything that is cleaned including equipment and the environment (e.g., floors, walls, ceilings, etc.). It will also include a cleaning schedule.* *b) The SSOPs will be used to train people and will include details of the materials that are used, the personal protective equipment that must be worn, who is responsible for cleaning and for checking before the area is used for production.* *c) The program will establish cleaning thresholds, training procedures including health and safety, supervision controls, records to be maintained, monitoring checks and a process for review.* *d) The program will establish how to deal with significant changes in production process or equipment.* *e) The cleaning schedule will identify what is to be cleaned, when, by whom and to which SSOP.* *f) The business needs to ensure specified chemicals and cleaning equipment are suitable for their intended use and properly stored.*

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		g) Specified chemicals should be appropriate for the application and not pose a risk of contamination such as having strong odours or leaving any residue after rinsing. *· They should come with a safety data sheet which addresses how to safely handle the chemical and steps to take in the event of accidental exposure.* *· They should be stored in labelled containers and have instructions on their safe and proper use in a food production application.* *· They should be stored safely to minimise risk of reaction with other chemicals, avoid contamination of product, ingredients or equipment and not put people at risk.* *h) Verification activities are those which prove the cleaning and sanitation activities have been carried our as per the specified procedure.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Observe the production, handling and storage environment and inspect the production and cleaning equipment.* • *In the event that production is in progress during the assessment, the assessor will look for physical evidence that a production area and its equipment is being maintained in a sanitary state.* • *Check documents including the cleaning program, schedule, training records, cleaning records and SSOPs procedures, monitoring records and employee training records.*

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B.B 3.1	Are documented cleaning and disinfection procedures in place and effective, including verification activities, to ensure the cleanliness of the facility, utilities and equipment?	The procedure makes reference to: • Personnel responsible for cleaning • Defined items and areas to be cleaned • Frequency of cleaning • Methods of cleaning • Cleaning materials to be used and instructions for use Cleaning and disinfection procedures are developed and monitored by a competent person. Cleaning records are available for all items and areas. A cleaning and disinfection concept including a cleaning plan and documentation exist. The general impression regarding hygiene is good. • Who is in charge of cleaning and disinfection? <cleaning schedule> • What kind of cleaning products and disinfectants are used? <up to date cleaning products and disinfectant list> • What must be observed when using different cleaning products and disinfectants? <product instructions> • What areas are cleaned and disinfected? <cleaning schedule> • How often are areas cleaned and disinfected? • Where are cleaning and disinfection procedures documented? <cleaning procedures documentation> • Do hazard symbols exist? • Does a contract exist for external service provider? <external services contract> • How are cleaning and disinfection controls performed? <cleaning controls> • Who performs these controls? <cleaning controls> • How often are cleaning and disinfection controls performed? <cleaning controls> • Where are cleaning and disinfection controls documented? • When are corrective actions executed? <corrective actions> • Who executes corrective actions? • Who reviews effectiveness of corrective actions? • Where are corrective actions documented? • Are material safety data sheets available for all cleaning chemicals? • Are these no older than two years? • Are cleaning chemicals instructions up to date? • How are instructions transmitted to personnel in charge of cleaning procedures? • Where and when can the instructions be inspected?

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B.B 3.2	Are cleaning equipment, utensils and chemicals clearly marked, stored in a segregated area away from product, equipment, packaging and suitable for intended use?	The personnel who cleans and disinfects is aware of his/her responsibility and the cleaning procedures. Only suitable cleaning- and disinfection agents are used. This has to be demonstrably. Cleaning- and disinfection agents are stored separately from food products and in closed and leak-proof containers. Appropriate cleaning and disinfection materials and items for instruments and equipment exist. Cleaning- and disinfection agents are labelled clearly. • How are cleaning utensils and chemicals recognizable? <chemicals list> • Where are cleaning utensils and chemicals stored? <chemicals storage list>
B.B 3.3	Are qualified, trained people used for cleaning and disinfection?	Relevant staff has knowledge in regard to properly cleaning and disinfection. During cleaning and disinfection food product are kept away. • Are cleaning personnel qualified? <training proof> • How often are they trained? • Who trains them? • Are these trainings documented?
B.B 4	**Product contamination control**	
	The business shall ensure appropriate facilities and procedures are in place to minimise the risk of physical, chemical, or microbiological contamination of product.	*WHAT DOES IT MEAN?* *a) The business should have in place procedures to prevent, control and detect contamination. Measures to prevent physical, allergen and microbiological contamination should be included.* *b) Allergens are a known component of food which causes physiological reactions due to an immunological response, such as nuts or shellfish.* *WHAT DO I NEED TO DO?* *a) All production and processing procedures should be systematically analysed to identify any potential hazards (physical, chemical and biological) that could occur with consideration of the susceptibility of the raw materials, ingredients and the final product. The hazards should be described and the most appropriate preventive and corrective actions implemented. In particular, consider these issues:* *b) Microbiological:* · *Separation of raw from finished or ready to eat products.* · *Structural segregation such as physical barriers, walls and separate buildings.* · *Access controls with requirements to change into required work wear.* · *Traffic patterns within the production area and equipment segregation: people, materials, equipment and the use of dedicated tools.* · *Air pressure differentials.*

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		c) Allergen: · *Products should be protected from unintended allergen cross contact by effective cleaning and comprehensive line change-over practices and product sequencing.* · *The manufacturing of products which contain allergens that require labelling should be carried out as to ensure cross contamination is minimized.* *d) Metal:* · *Where metal detectors are required, they should be installed to ensure maximum efficiency of detection and to avoid any subsequent contamination.* · *Detectors should be subjected to regular maintenance and calibration to avoid malfunction.* *e) Glass:* · *Remove glass wherever possible from production facilities.* · *Create a complete glass register, including location.* · *Inspect or glass locations systematically and record all breakages.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Inspect areas where there is potential for microbiological cross contamination due to airborne or traffic patterns within the production facility.* • *Check the use of chemicals, looking for evidence that they are suitable for their intended use.* • *Will assess the potential for foreign material contamination from glass, metal, wood and plastic as well as the controls that are in place to minimise risk.* • *Examine procedures for line changeover, looking for evidence that contamination risks between different products or through cleaning processes have been addressed with appropriate procedures for control that will minimise risk.* • *Interview people to establish whether they understand about contamination hazards and have been trained on how they can reduce risks.* • *Look for the presence of allergens within the facility and if present, examine evidence of how they are controlled and contamination risks are minimised.*

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B.B 4.1	Are physical barriers or effective procedures in place to reduce and avoid the risk of any potential physical, chemical or microbiological contamination?	Inspections are conducted by a competent person to ensure that the facility remains in good condition. Potential foreign body sources are identified i.e. personnel, raw materials, packaging materials, packaging aids, utensils, machine components, hazardous chemicals. Product contamination procedures are developed and monitored by a competent person. The facility's process flow and design, i.e. from receipt to dispatch, ensures that contamination of raw materials, packaging, semi-processed and finished products is avoided. An effective foreign body management exist. (e.g. knifes, sieves, etc. are undamaged and complete). • How is cross-contamination avoided within factory premises? <process flow-diagram> • What kinds of foreign bodies may be found? • Where foreign body sources identified through risk analysis? <risk analysis> • Are staples used? • How are contaminated products handled? <segregation records> • What is done in case of glass breakage? <glass breakage prevention procedures> • What shall be considered when glass fixtures are replaced? <glass handling procedures>
B.B 4.2	Are working systems in place to reduce the risk of any potential physical, chemical or microbiological contamination?	Product contamination control procedures are developed and monitored by a competent person. Procedures are in place in relation to the breakage of glass, including glass packaging and similar material. • How is cross-contamination avoided within factory premises? <process flow-diagram> • What kinds of foreign bodies may be found? • Where foreign body sources identified through risk analysis? <risk analysis> • Are staples used? • How are contaminated products handled? <segregation records> • What is done in case of glass breakage? <glass breakage prevention procedures> • What shall be considered when glass fixtures are replaced? <glass handling procedures> • Has the company implemented procedures for avoiding contamination risk during process (e.g. in case ustensils are off the floor, when product is loose during sampling, etc.)?

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B.B 5	Pest control	
	The business shall ensure controls are in place to reduce or eliminate the risk of pest infestation (including rodents, insects and birds).	*WHAT DOES IT MEAN?* *a) Pests and vermin can introduce bacteria and filth into the production and storage environment making the product unsuitable for use. They want to enter the facility to get access to food, water, bedding and to breed and should be excluded.* *b) Effective pest and vermin control is not just eliminating them once they appear. Good practice in pest control addresses a broad range of issues including attraction, places of refuge, access to the site and to food and monitoring.* *WHAT DO I NEED TO DO?* *a) The business should have an effective preventive pest control program that will minimise the risk of infestation. There should be someone with competence and responsibility. All activities will be monitored and verified. It should competently deal with any issues which occur so that risk to product is prevented.* *b) External areas should be kept free of waste, debris and food sources.* *c) A 0.5m perimeter around all buildings should be maintained that is completely clear and provides no place of refuge.* *d) Out of use equipment, construction debris and any other redundant materials should not be stored close to the site.* *e) All doors and windows are to be kept closed whenever possible and when closed should provide no gaps that would allow access.* *f) Ensure that the cleaning schedule removes all food debris with resulting proper waste containment and management.* *g) Monitor or target pest and vermin species with the appropriate equipment outside (e.g. bait stations) and inside (e.g. electronic fly killers, rodent catch traps, pheromone traps etc.).* *h) Bait stations should not be used inside the facility as there is a risk of rodents having contact with raw materials, ingredients, finished products, equipment etc.* *i) Monitoring devices should not be positioned where their operation or checking may cause contamination.* *j) A map should be maintained which shows all pest control stations, each of which should be numbered and monitored.* *k) Monitoring will provide data about typical pests in the area, with consideration for seasonality and the possibility that pests enter with incoming goods.* *l) It is good practice to appoint a third party pest control specialist that is licensed by the local regulatory authority.*

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		m) If your own people are undertaking pest and vermin control activity, they should be trained and properly licensed. *n) Check with the local regulatory authority to ensure your monitoring and corrective action are appropriate and recognised.* *o) All monitoring activities need to be identified, planned, carried out and recorded.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check the site for active infestations and evidence of pest activity (live or dead pests or vermin, droppings, etc.).* • *Check that there is someone responsible for pest control (whether internal or external) and examine evidence of their activities.* • *Look for a map identifying pest monitoring and control devices, considering whether there is proper placement and looking for evidence that each one is numbered and regularly monitored.* • *Look at records of monitoring activities and pesticide applications.* • *Check the external areas for potential refuge and breeding areas.* • *Check opportunities for pest and vermin access to the facility (doors, windows, bay doors, exhaust fans and structural deficiencies).*
B.B 5.1	Is an effective pest control program in place?	Is there evidence of pest infestation? The pest control program is in compliance with legal and customer requirements. If necessary e.g. bait boxes, cockroach- and moth traps as well as fly repellents are placed at a suitable location. A trap-plan exist. Regularly control and documentation is conducted. A negative influence of pesticides shall be definitely excluded. Up-to-date safety material data sheets are available. • How is pest control organized? <pest control procedures> • Which pests are controlled? • Which kinds of baits are used? <pest control chemicals list> • Is product contamination through baits being prevented? <bait map> • Who is responsible for pest control? • What is inspection schedule? • Where are inspections and resulting corrective actions documented? <inspection results> • Are documents signed and dated by both parties? • Which corrective actions were executed lately?

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B.B 5.2	Are the controls appropriate in relation to the product, raw material and facility?	Methods of control are reviewed by a competent person. There is no evidence of pest infestation. Raw materials, packaging, semi-processed and finished products are stored so as to minimize the risk of pest infestation. • How is pest control organized? <pest control procedures> • Which pests are controlled?
B.B 5.3	Is the inspection program undertaken by a competent person at an appropriate frequency and are findings addressed?	Detailed records of pest control inspections, recommendations and actions taken are available. Pest control is conducted properly and professionally (including the storage of pesticides). • Is pest control executed by own staff members? • Who is responsible for pest control? • What kind of training has the responsible person? <training evidence> • Is pest control executed by external services provider? • Does a written contract exist between services provider and company? <written contract> • What is the content of the contract? • What kind of training has the external services provider? <training evidence> • Where are inspections and resulting corrective actions documented? <inspection results> • Are documents signed and dated by both parties? • Which corrective actions were executed lately?
B.B 6	**Water quality**	
	The business shall ensure that the quality of water, ice or steam in contact with food product is suitable for its intended use. All food contact water, ingredient water and water used in cleaning and sanitising operations shall be from a potable source.	*WHAT DOES IT MEAN?* *a) Water, ice or steam used within your facility can be a source of microbial and chemical contamination for your equipment or product.* *b) As a food manufacturer it is your responsibility to ensure that sufficient measures are taken to ensure its suitability for use within your operation and that your procedures ensure that water, ice or steam used within your operations meet the required water quality standards.* *c) Procedures for water quality, including the identification of chemical and microbial elements that should be included in required water analysis, the frequency of analysis and sampling points should be based on a risk analysis that takes into account the water source (i.e. municipal water source, well, etc.), previous sample history and any on-site storage.*

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		WHAT DO I NEED TO DO? *a) Ensure that a risk analysis has been completed in relation to the water used within your operations which will provide the basis for your water quality procedures and policies.* *b) Ensure that water used for either the washing, thawing and treating of food or as a food ingredient complies with local, national or internationally recognised potable water quality and microbiological standards.* *c) Your sources of water, steam or ice should be tested at least annually by your local water authority or by an independent, university or government laboratory. These records should be retained.* *d) If you purchase and use ice from an outside source, you should require them to provide annual verification that the ice meets the required standards and a copy of the report should be retained.* *e) Procedures should be established to ensure that water is not a source of contamination for your facility or product.* *f) Employees should be trained to ensure they understand the procedures established in your operations.* *g) If your operations have in-house water treatment equipment you should ensure that the equipment is included in your preventative maintenance program and treated water is monitored to ensure that it meets your established standards. Maintenance and testing records should be retained.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check your procedures and policies addressing water quality* • *Examine your training documentation,* • *Review annual water quality reports for your water, ice & steam* • *Check the preventative maintenance documentation for any water treatment equipment you may use* • *Inspect the signage or other visual identification (such as colour coding) to confirm that any non-potable water piping or outlets is clearly identified.*

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B.B 6.1	Are documented procedures in place to ensure that the quality of water, steam and ice does not compromise the food safety of the finished product?	• Where does water supply come from? (City supply, well water, tanker)? • Is water demand always covered? Water quality control procedures are developed and monitored by a competent person. Procedures are in place to prevent the cross contamination of potable water by unsafe water. The water complies with nationally or internationally, i.e. WHO Guidelines for drinking water quality, recognised potable water standards. How is ensured, that water quality confirms to drinking water quality? According to a risk based sampling design microbiological drinking water quality analyses are conducted min. annually. • What for is water used in the company (social facilities, cleaning procedures, product ingredient, for washing fruits and vegetables)? • Is water treated on site (water hardness correction, chlorination, sterilization, filtration …)? • Are local legal requirements on hand? • Is water analysed according to legal requirements (own water supply, outside supply). Do results comply with standards? <several analysis results> • Is water, steam or ice used—is a station monitoring in place? <maintenance> <analysis results> • What kind of piping system exists? (Ring-pipes, water-tanks) • What is piping made from? • Is analysis and sampling plan based on risk analysis? • Are performed controls verified where the risk of contamination could be high?
B.B 6.2	Are documented procedures in place to prevent the cross-contamination of potable water by non-potable water?	• The procedure refers to the water used: · For washing, thawing & treating food · As an ingredient or food processing aid · For cleaning food contact surfaces · For the manufacture of ice · For the manufacture of steam that will come in contact with food or used to heat water that will come in contact with food • Is drinking water system completely separated from non potable water piping? <hydraulic system lay-out> • What other systems are there? (e.g. used water, cooling water, water used for fire fighting). • Are water systems properly marked and where they are? • Are reflux avoidance equipments installed wherever necessary?

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B.B 7	Staff facilities	
	The business shall ensure that staff facilities be designed and operated so as to minimise food safety risks.	*WHAT DOES IT MEAN?* *a) Staff facilities, such as toilets, changing rooms and eating areas should be designed and operated to make sure that employees using these facilities do not accidently create a food safety hazard.* *WHAT DO I NEED TO DO?* *a) Establish and document rules and procedures for staff facilities to ensure that the employee activities in these facilities are separated from the food handling area to reduce food safety risk.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Inspect the facilities to ensure they are fit for the purpose.* • *Review documentation and procedures to show that the staff facilities are regulated to minimize food safety risk.* • *Are there locker-rooms?* • *Where are the restrooms?* • *Are there bathing facilities? <plant lay-out>*
B.B 7.1	Are suitable changing rooms provided for staff?	Outdoor clothing and personal items shall be stored separately from work wear within the facility. Where high risk product the changing rooms shall be sited without direct access to the production area. Locker and sanitary rooms are appropriate. To be checked examples: • Locker and sanitary rooms: sufficient number and in clean condition. These rooms do not lead into rooms with food handling. • Locker rooms: facilitating the separate storage of outdoor and protecting clothes. Wardrobes are cleaned regularly. • Are there locker-rooms for employees and visitors with separation for outdoor and protective clothing?
B.B 7.2	Are toilets provided, operational, accessible and adequately segregated from processing and food handling areas?	Shall not open directly into storage, processing or production areas. A sufficient number of toilettes and appropriate hand washing facilities are available. They do not lead into rooms with food handling. • Do toilets open directly into production areas?

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B.B 7.3	Are suitable and sufficient hand-washing facilities provided and accessible?	At appropriate points within production areas. • Sufficient quantities of potable water provided at the appropriate temperature • Liquid soap • Single use, hands free towel dispensers or suitably designed hands free air dryers • Signs advising personnel to wash hands prior to entering food processing areas shall be prominently posted in the appropriate languages Where high risk products are handled the following requirements shall also apply: • Hands free operated taps • Hand sanitizers A sufficient number of hand washing facilities are available. Hand washing facilities aren't used for food washing. • Are there enough hand washing facilities available at the entrance to processing areas and in social areas? • Are all hand washing facilities provided with appropriate equipment for hand drying, liquid soap and disinfectant? • Are all hand washing facilities provided with running potable water at an appropriate temperature?
B.B 7.4	Are separate lunch room facilities provided away from production, packaging and storage areas?	• No food from the lunch room facilities should be taken to production, packaging and storage areas.

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B.B 8	**Waste management**	
	The business shall have a program in place for the collection and disposal of waste material.	*WHATS DOES IT MEAN:* *a) If handled incorrectly, waste materials can accumulate and become a source of contamination or a refuge for pests.* *b) Food facilities should have procedures for waste management that include the allocation of responsibility and the methods used to collect, handle and remove waste materials.* *c) These procedures should also address any legal requirements.* *WHAT DO I NEED TO DO?* *a) Establish procedures that address the responsibility for and methods used to collect handle and remove waste materials from the facility. These procedures should include the following:* *· Detailed cleaning practices associated with waste containers and waste storage areas. In both cases, these should be easy to clean, covered or kept closed (as appropriate) and included in the cleaning program.* *· Waste containers should only be used for the storage of waste.* *· Procedures for waste collection containers and waste storage areas including handling, marking, usage and colour coding.* *· The exact usage and marking or visual identification of containers that are designated to be used for inedible food waste materials.* *· Required waste management training for employees.* *· Actions to take if procedures are not followed.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Review the waste management program and associated procedures.* • *Review adherence to waste management procedures for containers including handling, markings, usage and colour coding.* • *Observe the usage and marking or visual identification of containers designated for use for inedible, waste materials or by products (e.g. animal feed)* • *Observe if signage clearly informs people about the colour code system.* • *Check training records verifying that people have been trained in waste management procedures.* • *Check sanitation records for waste containers and waste storage areas, assessing whether planned cleaning has been carried out according to procedures.*

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B.B 8.1	Are suitable provisions in place for the storage and removal of waste?	Waste shall not be allowed to accumulate in food handling, food storage and other working areas. Waste disposal has to be done in a manner (if necessary cooled) not to negatively influence food direct or indirect. • What kind of waste exists? What wastes are collected in separate containers? Can waste containers easily be cleaned and disinfected? • How often are waste containers cleaned and disinfected? <cleaning protocol>
B.B 8.2	Are containers designated for inedible products, waste or by-products clearly marked and properly utilised?	• Suitably designed • In good condition • Easy to clean and where required disinfected • Emptied at appropriate frequencies • Covered or doors kept closed as appropriate • What kind of waste exists? What wastes are collected in separate containers? How are waste containers marked? • Can waste containers easily be cleaned and disinfected? • How often are waste containers cleaned and disinfected? <cleaning protocol> • What kinds of waste disposal records exist? • Who is responsible for waste disposal? <waste disposal registry>

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B.B 9	**Storage and transport**	
	The business shall ensure that all raw materials (including packaging), semi processed product and finished product be stored and transported under conditions that protect the product.	*WHAT DOES IT MEAN?* *a) During the storage and transportation of food products all relevant contamination and deterioration parameters (such as temperature, humidity etc.) should be evaluated.* *b) All necessary measures should be taken to avoid contamination and deterioration.* *WHAT DO I NEED TO DO?* *a) Before loading food for delivery, the condition of the vehicle (e.g. odours, dust, adverse humidity, cleanliness, pests, mould) should be checked. If required, action should be taken.* *b) Adequate hygienic requirements for all transport vehicles and for the equipment used for loading and unloading should be in place. There should be records of the measures taken.* *c) Procedures to prevent contamination during transport should be implemented (food should not be mixed with other types of goods).* *d) Where goods should be transported at certain temperatures, before loading, the temperature inside the vehicle should be checked and documented.* *e) Where goods should be transported at certain temperatures, the maintenance of an adequate range of temperatures during transport should be checked and documented.* *f) Loading and unloading areas should be of appropriate construction or have equipment in place to protect transported products from contamination, adverse temperature conditions etc.* *g) In the event that food goods are transferred during their journey, there should be procedures that ensure protection against contamination or deterioration.* *h) Where a business hires a third-party transport service provider, all the requirements specified above should be defined in the respective contract.* *i) Security of transport vehicles should be appropriately maintained.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *check if the above mentioned requirements are fulfilled for minimizing any possible contamination or deterioration of food.* • *Observe arrangements for storage and transport, looking at storage areas, vehicles, loading bays and equipment.* • *Inspect third-party service contracts as relevant, assessing whether the necessary requirements for food protection are formally agreed.*

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B.B 9.1	Are there adequate facilities for the storage of food and ingredients?	Adequate facilities for the storage of food, raw material, ingredients and packaging material shall be provided. To be checked examples: • Chilling and refrigerating rooms: hygienic conditions (surfaces, walls, ceilings, floors, doors, windows), easy cleanable • Dry storage facility: hygienic conditions (surfaces, walls, ceilings, floors, doors, windows), easy cleanable • Where are raw materials, half finished products and packaging materials stored? <storage plan> • How is cross-contamination avoided? <product flow plan> • How are chemicals stored?
B.B 9.2	Are the food storage facilities constructed to effectively protect materials and finished product from contamination during storage?	Where appropriate, food storage facilities shall be designed and constructed to enable food to be effectively protected from contamination during storage. To be checked examples: • Food isn't stored on floors • Raw food, intermediate products and final products are stored separately. They shall be covered if necessary. • Are goods stored outdoors? • What is stored outdoors? • What rules exist for outdoor storage? • Is outdoor storage based on risk analysis? <risk analysis> • Where are raw materials, half finished products and packaging materials stored? <storage plan> • How is cross-contamination avoided? <product flow plan> • Where and how are packaging materials and equipment stored? <materials flow-diagram> • How is cross-contamination through packaging materials avoided? <materials flow-diagram> • How is return of packaging materials to the storeroom regulated? • What kind of storage regulations exist? • Are pests taken into account during storage? Are pallets located approximately 1 m from walls? <plant inspection protocol> • Are there baits laid out in storage rooms? <pest control schedule> • Are there sensitive products stored? • What kinds of preventive measures are in place for these goods? <preventive measures>

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B.B 9.3	Is the food transport appropriate to minimize deterioration of food (e.g. by temperature and humidity control).	Where necessary, provide an environment which minimizes the deterioration of food (e.g. by temperature and humidity control). • Where are raw materials, half finished products and packaging materials stored? <storage plan>
I.B 9	**Storage and transport**	
	The business shall ensure that all raw materials (including packaging), semi processed product and finished product be stored and transported under conditions that protect product integrity. All vehicles, including contracted vehicles used for the transportation of raw materials (including packaging), rework, semi processed product and finished product shall be suitable for the purpose, maintained in good repair and be clean.	*WHAT DOES IT MEAN?* *a) The business should ensure that all raw materials (including packaging), semi processed product and finished product be transported under conditions that protect product integrity.* *b) A procedure should be implemented that assigns roles and responsibilities, control processes and a corrective action plan.* *WHAT DO I NEED TO DO?* *a) The product storage and transport procedure should provide full details so that people with responsibility will understand the relevant principles of the quality and food safety management system.* *b) The procedure will include the following:* · *identification of the required processes with a definition of the sequence and interaction* · *the criteria and methods required to ensure effective operation and control* · *the availability of information necessary to support both operation and monitoring* · *measure, monitor and analyse the procedure, implementing any necessary action to achieve planned results and drive improvement.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check the relevant procedures and the instructions concerning their implementation, compare with the associated records and assess whether the procedures are affected.* • *Interview relevant staff to confirm their understanding of the requirements for storage and transport.* • *Check training records.*

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I.B 9.4	Is there a product transport procedure and is it effectively implemented?	Practices applied during loading, transport and unloading of food are documented, implemented and designed to maintain product integrity. Procedures shall ensure that unloading is completed efficiently and core product temperatures are recorded at the beginning of, and at regular intervals during the unloading process. Prior to unloading, the load should be checked for signs of temperature abuse (thawing and re-freezing), damage or shifting during transport. • May goods be transported alongside with non food products? • How is cross-contamination prevented? • Are products which require a certain temperature being loaded? • Is vehicle temperature checked and documented before loading? <expedition inspection> • What are the procedures when vehicle temperature is not according to specifications? <expedition inspection> • How the company ensure the compliance of temperatures during transport? <"temperature indicator" occasionally placed in products> • How is ensured that products reach destination under good conditions?
I.B 9.5	Is there a transport vehicle procedure and is it effectively implemented?	Vehicles used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odours, pest, moulds or other conditions that may impact negatively on the product. Inspection records shall be available. Transport vehicles are suitable for the intended purpose. In case of subcontracting an adequate control is conducted. • What is checked before loading? <expedition inspection> • Where is inspection documented? • What corrective actions are taken? • May goods be transported alongside with non food products? • How is cross-contamination prevented? • How is it ensured that products reach destination under good conditions? • Are products which require a certain temperature being loaded? • Is vehicle temperature checked and documented before loading? <expedition inspection> • What are the procedures when vehicle temperature is not according to specifications? <expedition inspection> • How the company ensure the compliance of temperatures during transport? <"temperature indicator" occasionally placed in products> • Are vehicles equipped with thermostats and registering devices? <registering devices>

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I.B 9.6	Are there documented maintenance and hygiene procedures for vehicles and equipment used for loading and unloading? Are very effectively implemented?	Records shall include a registration number of a transport vehicle and a name of a driver. The equipment for loading or unloading shall be included in the maintenance and sanitisation program. • Are transport vehicles cleaned? • Where are cleaning procedures documented? <cleaning protocol> • What is checked before loading? • Where is inspection documented? • What corrective actions are taken? • How is maintenance organized? <maintenance plan> • Where are maintenance procedures documented? • Which equipments are subject to external maintenance?
I.B 10	**Facility and equipment maintenance**	
	The business shall implement a system of planned, preventive and corrective maintenance to ensure an adequate level of food safety and quality in the facility.	*WHAT DOES THIS MEAN:* *a) A process for maintenance and repair needs to be created and followed to ensure all critical equipment is functioning properly to maintain food safety and quality standards.* *WHAT DO I NEED TO DO?* *a) Identify the critical processing equipment and develop procedures for the inspection and maintenance of critical equipment.* *b) Maintenance programs need to be developed which inspects and repairs equipment before a food safety or quality failure occurs.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check the documentation of the preventative maintenance program, key pieces of equipment identified, frequency of inspection, inspection findings and corrective actions taken.*
I.B 10.1	Is a documented maintenance program established?	Equipment inspection frequencies should be defined. All critical equipment should be covered. Maintenance records shall be maintained. Maintenance work of equipment is conducted regularly. • How is maintenance organized? <maintenance plan> • Where are maintenance procedures documented? • Which equipment are subject to external maintenance?

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I.B 10.2	Is an effective maintenance program implemented?	• How is maintenance organized? <maintenance plan> • Where are maintenance procedures documented? • Which equipments are subject to external maintenance? • Are processing interruptions considered in maintenance planning? • Does the company follow specific indicators to ensure maintenance effectiveness (e.g. no delays in repairs, etc.)?
I.B 10.3	Is a documented hygiene and clearance procedure in place for all maintenance activities?	Must record that product contamination hazards have been removed from machinery and equipment. Must record that the area has been properly cleaned, disinfected and inspected prior to release back into production. • How is it ensured that maintenance and repair works do not affect product safety? • How are lighting fixtures repaired? • Where are repair works documented? • Are corrective actions necessary after repair works? • What rules are in place for re-activating equipment when maintenance is completed? <examples for repair works and maintenance>
I.B 10.4	Are effective hygiene procedures implemented for maintenance activities?	Effective safety and hygiene requirements for equipment including maintenance work exist. To be checked examples: • Instruments and work equipment is easy cleanable and in good condition (functioning, stainless) • Equipment which is in contact to food is easy dismantleable and mechanically stable. • Working surfaces are without depressions • How is it ensured that maintenance and repair works do not affect product safety? • How are lighting fixtures repaired? • Where are repair works documented? • Are corrective actions necessary after repair works? • What rules are in place for re-activating equipment when maintenance is completed? <examples for repair works and maintenance>
I.B 10.5	Are all materials used for maintenance and repair appropriate for their intended use?	Food grade oils, non-toxic paints, etc. Material Safety Data Sheets shall be available. • How is it ensured that materials used in maintenance or repair work are fit for intended use? • What kinds of greases are used? <grease list>

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C. Control of food hazards		
B.C 1	**Preliminary tasks**	
	The business shall identify and comply with regulatory and customer requirements related to the product and to the product category. For all products, the following shall be included: • Task 1: Establish a multi-disciplinary food safety team. • Task 2: Describe the product and product category of all ingredients (including raw materials, packaging, finished product) and the required conditions for storage and distribution. • Task 3: Describe the intended use of the product and identify the target consumer. • Task 4: Describe all of the steps taken to produce the product in a process flow diagram. • Task 5: Compare the process flow diagram with the production process to ensure it is accurate.	*WHAT DOES THIS MEAN?* *a) The effective control of food hazards require the business to fully understand their products and product categories and how they are manufactured.* *b) This understanding must be accurately described and maintained in the event of change.* *c) A multidisciplinary team with decision-making authority should be formed that can jointly research and answer the following questions:* *· What legal and customer requirements apply?* *· How is the finished product described?* *· Who will consume the specific products?* *· How are the products manufactured?* *WHAT DO I NEED TO DO?* *a) Develop and implement a procedure to check that the relevant legal and customer requirements are reviewed and that the business is in conformity with those requirements.* *b) Form a multi-disciplinary team, with knowledge and experience in manufacturing, food safety, engineering, procurement and distribution.* *c) Authorise the team to make decisions on topics related to food safety.* *d) Develop and maintain accurate and detailed descriptions of each product or groups of products that considers the following: raw materials, packaging, processes and their parameters, characteristics of product, finished product, conditions for storage and distribution, and others (see the list provided in B.C 1.3).* *e) Develop and maintain specifications about who can consume the products, how it should be used, how it should be consumed and to whom it is not recommended.* *f) Develop and maintain a comprehensive flowchart that reliably represents the processes or stages of manufacture of the products or product groups.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Check that there is a system in place to identify legal and customer requirements that apply to the products or product categories, that these are reviewed and that the business is in conformity with those requirements.*

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		• *Check that there is an internal multi-disciplinary team in place, with responsibilities defined, that they are knowledgeable and competent and have the capacity and authority to make decisions and implement change.* • *Review the detailed description of each product (as per B.C 1.3); checking that there is information about shelf life, nutritional analysis and other relevant food safety issues.* • *Check finished product labels, confirming there is identification of the intended use of the product with accompanying description of any consumer groups that may be at risk* • *Check the production flowcharts and confirmed that they compare accurately with the manufacturing process.*
B.C 1.1	Has the business identified and complied with regulatory and customer requirements related to the product and product categories?	*Supplementary guidance. You should:* • *Define the principles on which the production of a safe product is based.* • *Identify the specifications or any agreement relating to the product has been agreed with all customers.* • *Define which specific regulations are applicable and are assured by the procedure.* • *In the event of export, identify regulations of the destination country, specifically for labelling.* • *Ensure a systematic and appropriate approach to recording key information, with frequency and responsibility defined.* • *Ensure the food safety management system is reviewed on a regular basis or when changes occur.*
B.C 1.2	Has a team with different responsibilities for food safety undertaken the tasks described in this section of the checklist (Tasks 2–5)?	*Supplementary guidance. You should:* • *Developed a multi-disciplinary team with members from the following areas: food safety, production, engineering, procurement, distribution.* • *Ensure that the team member representing food safety has appropriate qualifications and can provide evidence of their education and advanced training topics.* • *In the event that there are no such qualified people, the business should have a service contract with an external expert who can provide evidence of their expertise.* • Who is the competent person or member of the HACCP team)? • Which departments/functions are included in the HACCP team or does the person has? • How was qualification for HACCP team membership or the competent person verified? <evidences for education, advanced training> • Does a contract exist with an external expert? <service contract>

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B.C 1.3	Is there a complete product description available of the product/product category including all ingredients including raw materials, packaging, finished product and conditions for storage and distribution?	*Supplementary guidance. You should:* *a) Generate an accurate and complete hazard analysis by the preparation and maintenance of comprehensive information about your products ('product descriptions') and processes ('process descriptions').* *b) The specifications designated for this purpose should include the following information:* · *Composition* · *Ingredients* · *Physical, sensory, chemical, and microbiological parameters* · *Methods of treatment* · *Packaging procedures and materials* · *Shelf life* · *Storage and transport conditions.* *c) The business should consider:* · *Allergenic ingredients* · *Genetically modified materials* · *The purpose of the product, from the point of view of the end consumer (e.g. baby food, dietary products, nutritional supplements, etc.).* *d) From the point of view of the manufacturer, it should be pre-emptively determined how the products change when used as intended. For this purpose, the business should consider:* · *list of ingredients (where applicable fresh, frozen)* · *packaging type* · *chemical analysis* · *nutritional information* · *storage information* · *warnings* · *suggestions for preparation* · *suitability of the packaging for heating or freezing* · *quantitative restrictions, e.g. for especially vulnerable consumer groups.* • There shall be a product description for each product or each type of product. • Product description shall include where appropriate: · Composition, physical/chemical structure (including aw, pH, etc.) · Processing/treatments (heat-treatment, freezing, brining, smoking, etc.) · Packaging (food contact) · Shelf life · Storage conditions · Method of distribution.

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		• Does a complete product description exist for each product? • What is included in the product description? <product description> <product specification> • What hazards are connected to the product?
B.C 1.4	Has the intended use of the product been decribed and the target consumer been identified?	*Supplementary guidance. You should:* • *Accurately document the intended use describing how it will be prepared, consumed and whether there are any guidelines required to ensure that it is safe for consumption.* • *For products where additional preparation is required, described what should be done with the product once opened, how long it can be stored and in what conditions and what are the recommended portion sizes.* • *For intended use, identify how to prevent misuse that could cause harm to the consumer.* • *Describe the target consumer. Who can consume the product and to whom it is not recommended. Consider vulnerable groups, such as children, infants, the elderly, pregnant women, people with food intolerance, allergies, diabetes etc.* • What is the intended use of the product? • The product is unsuitable for which consumer group? • Is the product suitable for children, pregnant women, senior persons? <product description>
B.C 1.5	Have all of the process steps taken to produce the product been described in a process flow diagram?	*Supplementary guidance. You should:* • *Develop and maintain a flow chart that shows all stages of the manufacturing process, including any rework.* • *Describe in the flowchart relevant inputs and outputs of each process (raw materials, ingredients, packaging material, rework, nonconforming product, process aids, finished goods, etc.)* • Are flow charts available for all products? • Are the flow charts dated? • Are all CCP's identified on the flow chart? • Have all CCP's a number? • Are all flow charts with CCP's up-to date? <flow charts for all products>

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B.C 1.6	Has the process flow diagram(s) been compared to assure it accurately reflects the process?	*Supplementary guidance. You should:* • *Having defined your flowchart, the multidisciplinary team must verify that their analysis accurately represents the manufacturing of the product.* • *The process of verification should be recorded with all team members committing in writing to the credibility of the flowchart.* • *Verification should be repeated systematically.* • *The diagram should include all steps within the product process flow* • Are flow charts available for all products? • Are the flow charts dated? • Are all flow charts up-to date? <flow charts for all products>
B.C 2	**Control of allergens**	
	The business shall ensure that there are adequate control measures in place to prevent cross contamination of allergens. All ingredients known to cause food allergies in the product shall be clearly identified and communicated to the customer.	*WHAT DOES IT MEAN?* *a) An allergen is a known component of food which causes physiological reactions due to an immunological response (e.g. nuts and others identified in the legislation relevant to the country of production or sale).* *b) Allergens can lead to allergic reactions that may pose considerable health hazards for consumers such as skin reactions, shock and even death.* *c) You should identify, manage and control all allergens that are present on the site whether as ingredients or through process cross-contamination.* *d) The labelling of allergens contained in manufactured food products should be done on the basis of the hazard analysis.* *e) The manufacturing of products which contain allergens that require labelling should be carried out as to ensure that any risk of cross contamination is minimised.* *WHAT DO I NEED TO DO?* *a) You should determine which allergens are relevant to your product or process.* *b) Once this is achieved, you will be able to determine the risk and your options to eliminate, minimise and/or control their presence.* *c) During risk identification, consider customer requirements and regulations in country of production and of sale.* *d) Once allergens are identified, develop and maintain a list of all relevant raw materials and ingredients.*

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		e) For ingredients and raw materials identified as allergens, you should write specifications that include the following: risk analysis, mitigation, control procedures and their implementation including analytical results and final product labelling. *f) For products that contain allergens requiring labelling, the manufacturing process should be carried out to minimise cross contamination with close attention to cleaning and sanitation.* *g) Finished products that contain allergens and require labelling should be declared in accordance with legal requirements in the country of sale.* *h) For any accidental and unintentional presence, the labelling of legally declared allergens should be based on hazard analysis and risk assessments.* *WHAT WILL THE ASSESSOR DO?* *The Assessor will:* • *Confirm that comprehensive and relevant risk analysis has been carried out and that its outcomes are included in relevant procedures.* • *Check if the program for allergen control is documented and implemented.* • *Assess the delivery of the program in the food handling area, examine records and review manufacturing and storage practices.*
B.C 2.1	Is a documented program in place to control allergens and prevent cross-contamination of product through all stages of production?	Procedures for allergen control are developed and monitored by a competent person. Personnel who may handle allergens or product potentially containing allergens are aware of their responsibility to control allergens. If necessary, an appropriate allergen management is implemented. • Are allergens identified in specifications? • Does a list exist that covers allergens in use? <allergen list>
B.C 2.2	Were regulations and appropriate customer requirements addressed in the development of the allergen control program?	• Has allergen status been documented in specifications? <finished product specifications> • Do customers demand that certain substances are not included in the product? • When yes, how is it managed by QA?

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B.C 2.3	Are potential causes of cross contamination identified and procedures established for the handling of raw materials, intermediate and finished products to avoid cross contamination?	The procedure makes reference to: • Physical or time segregation while allergen-containing materials are being stored, processed or packed • The use of identified, dedicated equipment for processing or cleaning • A policy for all food brought on site by personnel, contractors and visitors • The labelling of raw material , ingredients and semi finished products known to contain or potentially contain allergens The cleaning and sanitisation program is effective to remove all potential allergens from product contact surfaces. • Is a procedure in place to avoid contamination of allergen free products? • How often is effectiveness of these procedures reviewed? • Where are these proofs documented? <examples>
B.C 2.4	Are procedures relating to the cleaning and sanitation of product contact surfaces in place and effective to remove all potential allergens from food contact surfaces?	• Is a procedure in place to avoid contamination of allergen free products? • How often is effectiveness of these procedures reviewed? • Where are these proofs documented? <examples>
B.C 2.5	Is a clear labelling system in place ensuring continuous identification of the product through all stages of production and delivery?	

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I.C 3	HACCP	
	The business shall perform a hazard analysis of their food manufacturing process as a minimum step in order to determine if there are any hazards associated with the production of their food item. The business shall use the HACCP [Hazard Analysis Critical Control Point] tool to accomplish this assessment. If hazards are identified within the manufacturing process, it is expected that the business will take appropriate action necessary to develop a HACCP Plan that meets the 7 principles reflected within Codex Alimentarius.	*WHAT DOES THIS MEAN?* *a) For each manufacturer of food products, the Hazard Analysis and Critical Control Point (HACCP) concept is a fundamental element of the business's internal food safety management system.* *b) HACCP is an internationally recognised instrument for controlling food safety in the manufacturing process. It enables the recognition and control of potential consumer risks by implementing suitable preventative measures.* *c) Control measures may be identified which are critical to maintaining product safety and will minimise the potential for biological, chemical and physical hazards which if not properly controlled may produce illness, injury or death to the consumer. These will be identified as Critical Control Points (CCPs), with critical limits and monitoring processes established.* *d) Corrective actions will be established which are designed to ensure if the critical limits are violated. In such cases, the finished product does not leave the facility.* *e) There should be records of monitoring the CCPs and corrective action taken.* *WHAT DO I NEED TO DO?* *a) It is not sufficient to just define a CCP and implement inspections. An effective HACCP concept, with adequate documentation, requires:* *· a systematic approach.* *· an expert multi-disciplinary team.* *· a comprehensive analysis of all products and procedures.* *· a risk analysis with definition of CCPs and critical limits.* *· a demonstrable system for corrective measures with a regular, systematic review of effectiveness.* *b) Codex Alimentarius provides 12 steps with seven principles for implementing HACCP and the business needs to follow these.* *c) The following principles should govern your HACCP system:* *· Principle 1 – Develop a hazard analysis for each level of the flow charts.* *· Principle 2 – Determine the CCPs within the scope of your HACCP plan.* *· Principle 3 – Determine critical limit values for all CCPs.* *· Principle 4 – Develop a system for inspecting and controlling the CCPs.* *· Principle 5 – Determine corrective measures and implement them when necessary.* *· Principle 6 – Regularly review the effectiveness of your HACCP program.* *· Principle 7 – Create documentation for all steps of the concept including processes and procedures.*

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		d) Begin by defining where your process starts and where it ends. This is the scope of your system as it relates to departments and products. *e) Define the area of application by establishing which production departments, products, product and packaging lines, storage areas and transport routes should be considered, including the following:* *· Number of production lines and differentiation of product categories.* *· Existing hygiene, production, and control standards* *f) Evaluate the risk of harm to consumers as result of consumption of your food product using: literature data, objective and proven values, market observations, effects of customer complaints and assessment of residual risk.* *WHAT WILL THE ASSESSOR DO? The Assessor will:* • *Check for evidence that HACCP principles 1-7 have been developed and implemented.* • *Assess your documentation, looking to establish that it is complete, current, correct, and sufficiently known to all responsible people.* • *Check that there is an internal multi-disciplinary team in place, with responsibilities defined, that they are knowledgeable and competent and have the capacity and authority to make decisions and implement change.*
I.C 3.1	**Principle 1:** Is a hazard analysis conducted for each process step in the manufacturing of the food item?	*Supplementary guidelines. You should:* • *Consider in your hazard analysis the potential for all chemical (including allergens), microbiological, and physical hazards that could occur within the process.* • *Address the potential hazards (biological, chemical, physical) associated with the production inputs from raw materials and ingredients (including water, steam, ice or gases used as ingredients).* • *Undertake hazard analysis for each process step, considering chemical, microbiological and physical hazards each time.* • *Undertake risk analysis for all product groups including consideration of potential harm and likelihood.* • Does the HACCP plan cover all product groups and processes incl. product development and product packaging? • Which processes are performed? <product group overview>, <flow chart> • Does a hazard analysis exist for each step? <hazard analysis> • Does it include every hazard? • Which biological, physical and chemical hazards can be expected? <hazard analysis> • Does a risk analysis for all product groups including harm and likelihood exist? <risk analysis>

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I.C 3.2	Was the hazard analysis conducted by a competent team?	*Supplementary guidelines. You should:* • *Create a multidisciplinary team to include members with knowledge and experience from food safety, production, engineering, procurement and design.* • *Ensure that team members have been trained in the principles of HACCP based on Codex Alimentarius* • *Ensure that the team member representing food safety has appropriate qualifications and can provide evidence of their education and advanced training topics.* • *Ensure that in the event that there is no such qualified person, the business should have a service contract with an external expert who can provide evidence of their food safety expertise.* • Which departments/functions are included in the HACCP team or does the person has? • How was qualification for HACCP team membership or the competent person verified? <evidences for education, advanced training> • Does a contract exist with an external expert? <service contract>
I.C 3.3	**Principle 2:** If the hazard analysis indicates any significant hazards not minimised or eliminated by Good Manufacturing Practices (GMPs) that are present within the food manufacturing process, are they identified as Critical Control Points (CCPs)?	*Supplementary guidelines. You should:* • *When determining that there is a CCP, used a decision tree or other adequate method and documented the process.* • *Consider on your defined CCPs whether the existing process can be influenced to prevent, eliminate or reduce a food safety hazard.* • *Identify associated control points and existing controls that are in place.* • *CCPs are defined with consideration of many 'pre-requisite measures' that are associated with Good Manufacturing Practice, such as cleaning and training programs. When defining a CCP, such considerations should be documented.* • Which CCPs were defined? • How many CCPs exist? • Are all CCP's identified on the flow chart? • Have all CCP's a number? • Are all flow charts with CCPs up-to date? <flow charts for all products> • On the defined CCPs, can the process be influenced in order to prevent, eliminate or reduce a food safety hazard? <hazard analysis> <flow chart>, <HACCP plan>, <decision tree>

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I.C 3.4	**Principle 3:** Are Critical Limits established for each CCP?	*Supplementary guidelines. You should:* • *Apply critical limits only to the specific operation, product or groups of products being processed.* • *Only apply critical limits that have been specified and validated.* • *Define the critical limit for each CCP.* • Is a critical limit defined for each CCP? • What critical limits are defined? • How were the critical limits determined? <HACCP plan>
I.C 3.5	**Principle 4:** Are monitoring procedures established for each CCP?	Supplementary guidelines. You should: • Be able to detect a loss of control in the process through your monitoring procedures. • Ensure that your monitoring records are evaluated by a trained and competent people. • Assign a frequency that is adequate to ensure that the CCP remains in control in the event that monitoring is not continuous. • Ensure that monitoring records are signed by individuals that are conducting the monitoring and reviewing the records. • Ensure that monitoring records are documented and include: date, time, responsible person and result. • Ensure that monitoring records are retained in line with business procedures. The compliance to cooking temperatures and times is controlled and if necessary documented. Product specific cooling and freezing temperatures are complied with and documented. Cold chain in the supply of chilled and frozen goods is maintained and ensured.
I.C 3.6	Are CCPs effectively implemented?	• How are CCPs monitored? • Are the CCPs under control? • How is the monitoring of each CCP documented? • Who documents? • Are date, time, responsible employee and result/reading documented? • How long will records be stored? • Where are records stored? <CCP records>

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I.C 3.7	**Principle 5:** Are corrective actions established for each CCP in the event critical limits are exceeded?	*Supplementary guidelines. You should:* • *Ensure that any corrective actions resulting in return to control of the CCP and that affected products are disposed of in accordance with waste management procedures.* • *Ensure that product deviations and final disposal is documented.* • *Ensure that monitoring is understood as defined in Codex Alimentarius ("The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control")* • What corrective actions exist for each CCP? • When was a corrective action carried out? • Where are corrective actions documented? • Who documents the taken corrective actions? <CCP records> <corrective actions>
I.C 3.8	**Principle 6:** Are verification procedures established ?	*Supplementary guidelines. You should:* • *Ensure that the frequency of the verification procedures establishes that the HACCP system is working effectively.* • *Ensure that verification is undertaken by someone other than the people responsible for monitoring and corrective actions.* • *The frequency of the verification procedures should ensure that the HACCP system is working effectively* • *Verification should be conducted by someone other than the personnel responsible for monitoring and corrective actions* • How often is the HACCP plan verified? • What was the date of the last verification? • What was the result of the last verification? • Does the HACCP plan reflect the results of the verification? • What was the last date when the HACCP plan was changed? <audit/assessment reports or other reports for validation>

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I.C 3.9	Are verification procedures effectively implemented?	• How often is the HACCP plan verified? • What was the date of the last verification? • What was the result of the last verification? • Does the HACCP plan reflect the results of the verification? • What was the last date when the HACCP plan was changed? <audit reports or other reports for validation> • The frequency of recording is carried out continuously and/or at appropriate intervals. • The food control system is reviewed on a regular basis or when changes occur.
I.C 3.10	**Principle 7:** Are record keeping and documentation for HACCP procedures established?	*Supplementary guidelines. You should:* • *Ensure that all established HACCP procedures have been documented, including preliminary steps and pre-requisite programs.* • *Ensure that the record-keeping is effective and clearly communicated to the relevant people.* • All established HACCP procedures shall be documented • The record keeping system must be effective and clearly communicated to the appropriate personnel • What HACCP plan related documents exist? • Do these documents include processes, procedures and results? <inspection plans>, <records>, <product descriptions>, <hazard analysis>, <risk analysis>
I.C 3.11	Are all HACCP-related record-keeping and documentation procedures effectively implemented?	• Includes preliminary steps, HACCP and pre-requisite programs (bullet point) • Monitoring records must be maintained • What HACCP plan related documents exist? • Do these documents include processes, procedures and results? <inspection plans>, <records>, <product descriptions>, <hazard analysis>, <risk analysis> • How are CCPs monitored? • Are the CCPs under control? • How is the monitoring of each CCP documented? • Who documents? • Are date, time, responsible employee and result/reading documented? • How long will records be stored? • Where are records stored? <CCP records>

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I.C 3.12	Has the business implemented specific control measures for all relevant steps not identified as CCPs?	*Supplementary guidelines. You should:* • *Ensure that pre-requisite measures have been taken and documented for other control points.* • Which CPs are defind? • Which prerequisite measures were taken regarding CPs? • Which prerequisite measures are documented? • How are the measures documented? <hazard analysis> <flow chart> <decision tree> <prerequisite measures>
I.C 4	**Food defense**	
	The business shall assess its ability to prevent intentional product tampering/intentional contamination and put in place the appropriate preventive control measures.	*WHAT DOES IT MEAN?* *a) Food defence is the means of preventing, protecting, and responding to the deliberate contamination of food by bacterial agents, toxins, chemicals, radiation or a physical object.* *b) Threats to food defence might occur at any level in the business's food-supply chain.* *c) The most important aspect of a food defence program is prevention.* *d) This is a regulatory requirement for food exports into the USA.* *WHAT DO I NEED TO DO?* *a) Develop and implement a procedure for conducting a facility vulnerability assessment.* *b) Develop and implement a food defence plan based on the result of the vulnerability assessment that includes methods, responsibility and criteria for preventing food adulteration or contamination caused by deliberate acts of sabotage.* *c) The food defence plan should include the following key elements:* · *A designated member of senior management with responsibility for food defence* · *Policies and procedures for recording and controlling access to areas of the facility by employees, contractors and visitors.* · *Procedures for secure storage and transportation of raw materials, equipment, packaging material, hazardous chemicals and finished food products.* · *Facility physical security.* · *A process for managing food, packaging and equipment that has been intentionally adulterated.* · *Training program.* · *An effective recall program.*

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		WHAT WILL THE ASSESSOR DO? *The Assessor will:* • *Review your documented food defence plan.* • *Check to see that the production has conducted a vulnerability assessment and identified sensitive areas* • *Review your training program and interview people to establish their knowledge of the food defence plan.*
I.C 4.1	Have the threats to the product as a result of intentional product tampering or intentional contamination been assessed?	Intentional product tampering can include acts of sabotage, vandalism or terrorism. The assessment must be appropriate to the business, the site and the country. • What are the legal /customer food defense requirements applicable to the company? • How can the company demonstrate compliance with such requirements? • What is the process /procedure used to perform the hazard analyisis and assessment of associated risks? • Is the hazard analysis in line with legal and/or customer needs and/or expectations? • How often is a review of the food defense program performed? • What criteria does the company consider in order to determine the frequency to perform the hazard analysis, if is not done annually? • How is the company alerted of any food defense breach? • How does the company evaluate the effectiveness of the food defense program?
I.C 4.2	Have those points in the process which are vulnerable to intentional product tampering/intentional contamination been identified and subjected to additional access control?	Physical restriction of access may be through the use of locks, electronic key card or other appropriate systems. Control measures shall cover product, process, personnel, security and systems and where applicable, storage and transportation. • Based on the hazard analysis and assessment of associated risks, what areas have been identified as critical? • What control measures are in place in order to control the entrance to those areas? • How does the company maintain control over who enters to the premises and critical areas? • What are the access controls applicable to the following people? · Temporary employees · Contractors · Visitors · Employees · Carrier drivers

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I.C 4.3	Are measures in place to address what to do with the product, if prohibited access took place and the product may have been tampered with or intentionally contaminated?	Measures shall address identifying the incident, identifying potentially affected material, isolation and quarantine of the potentially affected material and appropriate disposition based on the safety of the product. • Does the company define procedures to identify tampering of raw materials, Works in Process (WIP) and final goods? • Are there means to verify if products have been tampered? • Are employees trained in the identification of tampered products? • Does the design of packaging material include the identification of tamper evident measures? • Is it required by law in the country of origin or destination? • Are there tests to verify that measures against tampering are properly applied and working properly?

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