**Global Standard START! Issue 2 - Intermediate**

F916b: Auditor Checklist and Site Self-Assessment Tool-with Key changes

**Welcome to the BRCGS Auditor Checklist and Site Self-Assessment tool**

We hope that you will find this useful when preparing your site for an audit against the BRCGS Global Standard for START! Issue 2 – Intermediate requirements.

**How to use the BRCGS Auditor Checklist and Site Self-Assessment tool**

This tool is designed to help you assess your operation against the requirements of the Start Programme at the Intermediate level and help prepare you for your certification audit.

The checklist covers each of the requirements of the Programme applicable to sites at the ‘Intermediate’ level. The checklist also allows you to add comments or identify areas of improvement in the empty boxes provided at the end of each section.

Changes from Issue 2 have been highlighted in red text.

New clause highlighted in red with “NEW “

While we hope that this tool is useful in helping you prepare for your audit it should not be considered as evidence of an internal audit and will not be accepted by auditors during an audit.

**Further Information**

If you have any further questions about the BRCGS Self-Assessment Tool or the BRCGS Global Standard START! Issue 2, please do not hesitate to contact the BRCGS team.

Email – [enquiries@brcgs.com](mailto:enquiries@brcgs.com)

Change log:

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| Version no. | Date | Description |
| 1 | 17/03/2023 | New for Issue 2 |
| 1.1 | 24/03/2023 | Small formatting changes made to the document. |
| 2 | 02/05/2023 | Key changes from START! Issue 1 to Issue 2 added to F916b: Auditor Checklist & Site Self-Assessment Tool (Intermediate level) |

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| **1** | | **Senior management commitment and continual improvement** | | |
| 1.1 | | Senior management commitment and continual improvement | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The site’s senior management shall demonstrate they are fully committed to the implementation of the requirements of the START! programme and to processes which facilitate continual improvement of food safety and quality management and the site’s food safety and quality culture. |  |  |
| **1.1.1** | | The site shall have a documented policy which states the site’s intention to meet its obligation to produce safe, legal and authentic products to the specified quality, and its responsibility to its customers. This shall:   * be signed by the person with overall responsibility for the site * be communicated to all staff * include commitment to continuously improve the site’s food safety and quality culture. |  |  |
| **NEW 1.1.2** |  | The site’s senior management shall define and maintain a clear plan for the development and continuing improvement of a food safety and quality culture. The plan shall include measures needed to achieve a positive culture change. |  |  |
| **NEW 1.1.3** | | The site’s senior management shall ensure that clear objectives are defined to maintain and improve the safety, authenticity, legality and quality of products manufactured, in accordance with the food safety and quality policy and the START! programme. |  |  |
| **NEW**  **1.1.4** | | Management review meetings attended by the site’s senior management shall be undertaken at appropriate planned intervals, annually at a minimum, to review the site performance against the START! programme and objectives set in clause 1.1.3. |  |  |
| **1.1.7** |  | The company’s senior management shall provide the human and financial resources required to produce safe, authentic, legal products to the specified quality and in compliance with the requirements of the START! programme. |  |  |
| **1.1.8** | | The company’s senior management shall have a system in place to ensure that the site is kept informed of and reviews relevant food safety legislation applicable to the production site and as applicable in the country where the product is intended for sale. |  |  |
| **1.1.11** |  | The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for certification to the START! programme. Relevant departmental managers or their deputies shall be available as required during the audit. |  |  |
| **NEW**  **1.1.12** |  | The site’s senior management shall ensure that the root causes of any non-conformities against the START! programme identified at the previous audit have been effectively addressed to prevent recurrence. |  |  |
| **NEW**  **1.1.14** | | Where required by legislation, the site shall maintain appropriate registrations with the relevant authorities. |  |  |
| **1.2** | | Organisational structure, responsibilities and management authority | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality and quality. |  |  |
| **1.2.1** | | The company shall have an organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure food safety, authenticity, legality and quality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person. |  |  |
| **1.2.2** | | The site’s senior management shall ensure that all staff are aware of their responsibilities and work in accordance with site policies, procedures, work instructions and existing practices for activities undertaken. |  |  |
| **NEW**  **1.2.4** | | If the site does not have the appropriate in-house knowledge of food safety, authenticity, legality or quality, external expertise (e.g. food safety consultants) may be used; however, the day-to-day management of the food safety systems shall remain the responsibility of the company. |  |  |

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| **2** | | The food safety plan – HACCP | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The company shall have a fully implemented and effective food safety plan incorporating the Codex Alimentarius HACCP principles. |  |  |
| 2.1 | | The HACCP Food Safety team (equivalent to codex Alimentarius Step 1) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **2.1.1** | | The HACCP or food safety plan shall be developed and managed by a multi-disciplinary food safety team that includes those responsible for quality assurance, technical management, production operations and other relevant functions (e.g. engineering, hygiene).  The team leader shall have an in-depth knowledge of Codex HACCP principles (or equivalent) and be able to demonstrate competence, experience and training. Where there is a legal requirement for specific training, this shall be in place.  The team members shall have specific knowledge of HACCP and relevant knowledge of products, processes and associated hazards. |  |  |
| **2.2** | | Prerequisite programmes | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **2.2.1** |  | The site shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal food products (prerequisite programmes).  As a guide these may include the following, although this is not an exhaustive list:   * cleaning and disinfection * pest management * maintenance programmes for equipment and buildings * personal hygiene requirements * staff training * supplier approval and purchasing * transportation arrangements * processes to prevent cross-contamination * allergen management.   The prerequisite programmes for the particular areas of the site shall take into account the production risk zoning.  The control measures and monitoring procedures for the prerequisite programmes shall be clearly documented and shall be included within the development and reviews of the HACCP or food safety plan. |  |  |
| **2.3** | | Describe the product (equivalent to Codex Alimentarius Step 2) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **2.3.1** | | A full description for each product or group of products shall be developed, which includes all relevant information on food safety. As a guide, this may include the following, although this is not an exhaustive list:   * composition (e.g. raw materials, ingredients, allergens, recipe) * origin of ingredients * physical or chemical properties that impact food safety (e.g. pH, *aw*) * treatment and processing (e.g. cooking, cooling) * packaging system (e.g. modified atmosphere, vacuum) * storage and distribution conditions (e.g. chilled, ambient) * maximum safe shelf life under prescribed storage and usage conditions. |  |  |
| **2.4** | | Identify intended use (equivalent to Codex Alimentarius Step 3) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **NEW**  **2.4.1** | | The intended use of the product by the customer, and expected alternative uses, shall be described, defining the consumer target groups, including the suitability of the product for vulnerable groups of the population (e.g. infants, elderly, allergy sufferers). |  |  |
| **2.5** | | Construct a process flow diagram (equivalent to Codex Alimentarius Step 4) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **2.5.1** |  | A flow diagram shall be prepared to cover each product, product category or process. This shall set out all aspects of the food process operation within the HACCP or food safety plan scope, from raw material receipt through to processing, storage and distribution.  As a guide, this should include the following, although this is not an exhaustive list:   * plan of premises and equipment layout * raw materials, including introduction of utilities and other contact materials (e.g. water, packaging) * sequence and interaction of all process steps * outsourced processes and subcontracted work * potential for process delay * rework and recycling * low-risk/high-risk/high-care area segregation * finished products, intermediate/semi-processed products, by-products and waste. |  |  |
| **2.6** | | Verify flow diagram (equivalent to Codex Alimentarius Step 5) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **NEW 2.6.1** |  | * The HACCP food safety team shall verify the accuracy of the flow diagrams by on-site audit at least annually, and whenever there are changes to the process, to ensure any changes have been considered as a part of the HACCP or food safety plan. Records of verified flow diagrams shall be maintained. |  |  |
| **2.7** | | List all potential hazards associated with each process step, conduct a hazard analysis and consider any measures to control identified hazards (equivalent to Codex Alimentarius Step 6, Principle 1) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **2.7.1** | | The potential hazards that are reasonably expected to occur at each process step in relation to product, process and facilities shall be identified and recorded. This shall include hazards present in raw materials, those introduced during the process or surviving the process steps, and consideration of the following types of hazard:   * microbiological * physical contamination * chemical and radiological contamination * fraud (e.g. substitution or deliberate/intentional adulteration) (see section 5.4) * malicious contamination of products (see section 4.2) * allergen risks (see section 5.3). * It shall also take account of the preceding and following steps in the process chain. |  |  |
| **2.7.2** | | A hazard analysis shall be conducted to identify the significant hazards (i.e. those hazards that are reasonably likely to occur at an unacceptable level), which need to be prevented, eliminated or reduced to acceptable levels. Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented. Consideration shall be given to the following:   * likely occurrence of hazard * severity of the effects on consumer safety * vulnerability of those exposed * survival and multiplication of micro-organisms of specific concern to the product * presence or production of toxins, chemicals or foreign bodies * contamination of raw materials, intermediate/semi-processed product, or finished product. |  |  |
| **2.7.3** | | The control measures necessary to prevent or eliminate a food safety hazard or reduce it to an acceptable level shall be considered. Consideration may be given to using more than one control measure. |  |  |
| **2.8** | | Determine the critical control points (CCPs) (equivalent to Codex Alimentarius Step 7, Principle 2) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **2.8.1** | | For each hazard that requires control, control points shall be reviewed to identify those that are critical.  This requires a logical approach and may be facilitated by use of a decision tree. Critical Control Points (CCPs) shall be those control points which are required in order to prevent or eliminate a food safety hazard or reduce it to an acceptable level. If a hazard is identified at a step where control is necessary for safety but the control does not exist, the product or process shall be modified at that step, or at an earlier step, to provide a control measure. |  |  |
| **2.9** | | Establish validated critical limits for each CCP (equivalent to Codex Alimentarius Step 8, Principle 3) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **2.9.1** | | For each CCP, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be:   * measurable wherever possible (e.g. time, temperature, pH) * supported by clear guidance or examples where measures are subjective (e.g. photographs). |  |  |
| **2.9.2** | | The HACCP food safety team shall validate each CCP, including critical limits.  Documented evidence shall show that the control measures selected and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level. |  |  |
| **2.10** | | Establish a monitoring system for each CCP (equivalent to Codex Alimentarius Step 9, Principle 4) | | |
| **Clause** | | **Requirements** | **Conforms** |  |
| **2.10.1** |  | A monitoring procedure shall be established for each CCP to ensure compliance with critical limits.  The monitoring system shall be able to detect loss of control of CCPs and, wherever possible, provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list:   * online measurement * offline measurement * continuous measurement (e.g. thermographs, pH meters).   Where discontinuous measurement is used, the system shall ensure that the sample taken is representative of the batch of product. |  |  |
| **2.10.2** |  | Records associated with the monitoring of each CCP shall include the date, time and result of measurement, and shall be signed by the person responsible for the monitoring and verified, when appropriate, by a suitably competent and authorised person. Where records are in electronic form, there shall be evidence that records have been checked and verified. |  |  |
| **2.11** | | Establish a corrective action plan (equivalent to Codex Alimentarius Step 10, Principle 5) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **2.11.1** | | The HACCP food safety team shall specify and document the corrective actions to be taken when monitored results indicate a failure to meet a control limit, or when monitored results indicate a trend towards loss of control. This shall include the action to be taken by nominated personnel with regard to any products that have been manufactured during the period when the process was out of control. |  |  |
| **2.12** | | Validate the HACCP plan and establish verification procedures (equivalent to Codex Alimentarius Step 11, Principle 6) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **NEW**  **2.12.1** | | HACCP or food safety plans shall be validated prior to any changes which may affect product safety, to ensure that the plan will effectively control the identified hazards before implementation.  For existing HACCP or food safety plans, this may be achieved using the established processes detailed in clauses 2.12.2 and 2.12.3. |  |  |
| **2.12.2** | | Procedures of verification shall be established to confirm that the HACCP or food safety plan, including controls managed by prerequisite programmes, continues to be effective.  Examples of verification activities include:   * internal audits * review of records where acceptable limits have been exceeded * review of complaints by enforcement authorities or customers * review of incidents of product withdrawal or recall.   Results of verification shall be recorded and communicated to the HACCP food safety team. |  |  |
| **2.12.3** |  | The HACCP food safety team shall review the HACCP or food safety plan and prerequisite programmes at least annually and prior to any changes which may affect food safety.   * As a guide, these may include the following, although this is not an exhaustive list: * change in raw materials or supplier of raw materials * change in ingredients/recipe * change in processing conditions, cleaning and disinfection procedures, process flow or equipment * change in packaging, storage or distribution conditions * change in consumer use * emergence of a new risk (e.g. known adulteration of an ingredient or other relevant, published information, such as the recall of a similar product) * review following a significant product safety incident (e.g. a product recall) * new developments in scientific information associated with ingredients, process, packaging or product.   Appropriate changes resulting from the review shall be incorporated into the HACCP or food safety plan and/or prerequisite programmes. Changes shall be fully documented, and the validation shall be recorded.  Where appropriate, the changes shall also be reflected in the company’s product safety policy and food safety objectives. |  |  |
| **2.13** | | HACCP documentation and record-keeping (equivalent to Codex Alimentarius Step 12, Principle 7) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **2.13.1** | | Documentation and record-keeping shall be sufficient to enable the site to verify that the HACCP and food safety controls, including controls managed by prerequisite programmes, are in place and maintained. |  |  |

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| **3** | | **Food safety and quality management system** | | |
| 3.1 | | Food safety and quality manual | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The company’s processes and procedures to meet the requirements of the START! programme shall be documented to allow effective, consistent application, facilitate training, and support due diligence in the production of a safe product. |  |  |
| **3.1.1** | | The site’s procedures, working methods and practices shall be collated in the form of a printed or electronic quality manual. |  |  |
| **3.1.2** | | The food safety and quality manual shall be fully implemented and the manual or relevant components shall be readily available to relevant staff. |  |  |
| **3.1.3** |  | All procedures and work instructions shall be clearly legible, unambiguous, in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff. This should include the use of photographs, diagrams or other pictorial instructions where written communication alone is not sufficient (e.g. there are issues of literacy or foreign language). |  |  |
| **3.2** | | Document control | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The company shall operate an effective document control system to ensure that only the correct versions of documents, including recording forms, are available and in use. |  |  |
| **3.2.1** | | The company shall have a procedure to manage documents which form part of the food safety and quality system.  Where documents are stored in electronic form these shall be:   * stored securely (e.g. with authorised access, control of amendments, or password protection) * backed up to prevent loss.   The procedure to manage documents which form part of the food safety and quality system shall also include:   * a list of all controlled documents indicating the latest version number * the method for the identification and authorisation of controlled documents * a record of the reason for any changes or amendments to documents * the system for the replacement of existing documents when these are updated. |  |  |
| **3.3** | | Record completion and maintenance | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The site shall maintain genuine records to demonstrate the effective control of product safety, legality and quality. |  |  |
| **3.3.1** | | Records shall be legible, maintained in good condition and retrievable. Any alterations to records shall be authorised and justification for the alteration shall be recorded. Where records are in electronic form these shall also be:   * stored securely (e.g. with authorised access, control of amendments, or password protection) * suitably backed up to prevent loss. |  |  |
| **3.3.2** | | Records shall be retained for a defined period with consideration given to:   * any legal or customer requirements * the shelf life of the product.   This shall take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer (e.g. by freezing).  At a minimum, records shall be retained for the shelf life of the product plus 12 months. |  |  |
| **3.4** | | **Internal audits** | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The company shall be able to demonstrate that it verifies the effective application of the food safety plan, and the implementation of the requirements of the START! programme and the site’s food safety and quality management system. |  |  |
| **3.4.4** | | There shall be a separate programme of documented inspections to ensure that the factory environment and processing equipment are maintained in a suitable condition for food production. At a minimum, these inspections shall include:   * hygiene inspections to assess cleaning and housekeeping performance * fabrication inspections (e.g. doors, walls, facilities and equipment) to identify risks to the product from the building or equipment.   The frequency of these inspections shall be based on risk but will be no less than once per month in open product areas. |  |  |
| **3.5** | | **Supplier and raw material approval and performance monitoring** | | |
| **3.5.1** | | Management of suppliers of raw materials and packaging | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The company shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials (including primary packaging) to the safety, authenticity, legality and quality of the final product are understood and managed. |  |  |
| **3.5.1.2** | | The company shall have a documented supplier approval procedure to ensure that all suppliers of raw materials, including primary packaging, effectively manage risks to raw material quality and safety and are operating effective traceability processes.  The approval procedure shall be based on risk. |  |  |
| **NEW**  **3.5.1.3** | | There shall be a documented process for ongoing supplier performance review, based on risk and defined performance criteria. The process shall be fully implemented. |  |  |
| **NEW**  **3.5.1.4** | | The site shall have an up-to-date list or database of approved suppliers. This may be on paper (hard copy) or it may be controlled on an electronic system.  The list or relevant components of the database shall be readily available to the relevant staff (e.g. at goods receipt). |  |  |
| **3.5.2** | | Raw material and packaging acceptance, monitoring and management procedures | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Controls on the acceptance of raw materials (including primary packaging) shall ensure that these do not compromise the safety, legality or quality of products and, where appropriate, any claims of authenticity. |  |  |
| **3.5.2.1** |  | The company shall have a procedure for the acceptance of raw materials and primary packaging on receipt based upon the risk assessment. A list of raw materials (including primary packaging) and the requirements to be met for acceptance shall be available.  The parameters for acceptance and frequency of testing shall be clearly defined, implemented and reviewed. |  |  |
| **3.5.3** | | Management of suppliers of services | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI**  **NEW**  **3.5.3.1** | | The company shall be able to demonstrate that where services are outsourced, the service is appropriate and any risks presented to food safety, authenticity, legality and quality have been evaluated to ensure effective controls are in place. |  |  |
| Examples of services to consider:   * pest control * laundry services * contracted cleaning * contracted servicing and maintenance of equipment * transport and distribution * off-site storage of ingredients or packaging (other than at the supplier’s facilities) prior to delivery to the site * off-site packing of products * laboratory testing * catering services * waste management * providers of product safety training * product safety consultants. |  |  |
| **3.5.4** | | Management of outsourced processing | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Where any intermediate process step (including production, processing or storage) in the manufacture of a product is outsourced to a third party or undertaken at another site, and subsequently returned to the site, this shall be managed to ensure it does not compromise the product safety, authenticity, legality or quality. |  |  |
| **3.5.4.1** | | The company shall be able to demonstrate that, where part of the production process (i.e. any intermediate process step) is outsourced or undertaken off site, and subsequently returned to the site, this has been declared to the customer and, where required, approval granted. |  |  |
| **3.5.4.5** |  | Any outsourced processing operations shall:   * be undertaken in accordance with established contracts which clearly define any processing requirements * maintain product traceability. |  |  |
| **3.6** | | Specifications | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Specifications shall exist for raw materials (including primary packaging), finished products and any product or service which could affect the integrity of the finished product. |  |  |
| **3.6.1** | | Specifications for raw materials and primary packaging shall be adequate and accurate and ensure compliance with relevant safety and legislative requirements.  The specifications shall include defined limits for relevant attributes of the material which may affect the quality or safety of the final products (e.g. chemical, microbiological, physical or allergen standard). |  |  |
| **3.6.2** | | Accurate, up-to-date specifications shall be available for all finished products. These shall include key data to meet customer and legal requirements and assist the user in the safe usage of the product. |  |  |
| **3.6.3** | | Where the company is manufacturing customer-branded products, it shall seek formal agreement of the finished product specifications. Where specifications are not formally agreed, the company shall be able to demonstrate that it has taken steps to ensure formal agreement is in place. |  |  |
| **3.7** | | Corrective and preventive actions | | |
| **Clause** | | **Requirements** | **Conforms** |  |
| **SOI** | | The site shall be able to demonstrate that it uses the information from identified failures in the food safety and quality management system to make necessary corrective actions and prevent recurrence. |  |  |
| **3.7.1** | | The site shall have a procedure for handling and correcting issues identified in the food safety and quality management system. The site procedures shall include the completion of root cause analysis and implementation of preventive action. |  |  |
| **3.7.2** |  | Where a non-conformity places the safety, legality or quality of products at risk, or where there is an adverse trend in quality, this shall be investigated and recorded including:   * clear documentation of the non-conformity * assessment of consequences by a suitably competent and authorised person * the corrective action to address the immediate issue * completion of root cause analysis to identify the fundamental cause (root cause) of the non-conformity * Root cause analysis shall also be used to prevent recurrence of non-conformities, and to implement ongoing improvements when analysis of non-conformities for trends shows there has been a significant increase in a type of non-conformity. |  |  |
| **3.8** | | Control of non-conforming product | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The site shall ensure that any out-of-specification product is effectively managed to prevent unauthorised release. |  |  |
| **3.8.1** |  | There shall be procedures for managing non-conforming products. These procedures shall include:   * the requirement for staff to identify and report a potentially non-conforming product * clear identification of a non-conforming product (e.g. direct labelling or the use of IT systems) * secure storage to prevent accidental release (e.g. physical or computer-based isolation) * referral to the brand owner where required * defined responsibilities for decision-making on the use or disposal of products appropriate to the issue (e.g. destruction, reworking, downgrading to an alternative label or acceptance by concession) * records of the decision on the use or disposal of the product * records of destruction where a product is destroyed for food safety reasons. |  |  |
| **3.9** | | Traceability | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The site shall be able to trace all raw material product lots (including primary packaging) from its suppliers through all stages of processing and dispatch to its customers and vice versa. |  |  |
| **NEW**  **3.9.1** | | The site shall have a documented traceability procedure designed to maintain traceability throughout the site’s processes. At a minimum this shall include:   * how the traceability system works * the labelling and records required. * Where applicable, the traceability system shall meet the legal requirements in the country of sale or intended use. |  |  |
| **3.9.2** | | Identification of raw materials (including primary packaging), intermediate/semi-processed products, part-used materials, finished products and materials pending investigation shall be adequate to ensure traceability. |  |  |
| **3.9.3** | | The site shall test the traceability system across the range of product groups to ensure traceability can be determined from the supplier of raw material (including primary packaging) to the finished product and vice versa.  For food raw materials and finished products (i.e. including printed packaging and labels with food safety and legal information), the test of the traceability system shall include a quantity check/mass balance. |  |  |
| **3.9.4** |  | Where rework or any reworking operation is performed, traceability shall be maintained. |  |  |
| **3.10** | | Complaint-handling | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Customer complaints shall be handled effectively and information used to reduce recurring complaint levels. |  |  |
| **3.10.1** | | All complaints shall be recorded and investigated, and the results of the investigation of the issue recorded where sufficient information is provided. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff. |  |  |
| **3.10.2** | | Complaint data shall be analysed for significant trends. Where there has been a significant increase in a complaint, or a serious complaint, root cause analysis shall be used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff. |  |  |
| **3.11** | | Management of incidents, product withdrawal and product recall | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The company shall have a plan and system in place to manage incidents effectively and enable the withdrawal and recall of products should this be required. |  |  |
| **3.11.1** | | The company shall have procedures designed to report and effectively manage incidents and potential emergency situations that impact food safety, authenticity, legality or quality. This shall include consideration of contingency plans to maintain product safety, authenticity, legality and quality. Incidents may include:   * disruption to key services such as water, energy, transport, refrigeration processes, staff availability and communications * events such as fire, flood or natural disaster * malicious contamination or sabotage * product contamination indicating a product may be unsafe or illegal * failure of, or attacks against, digital cyber-security.   Where products which have been released from the site may be affected by an incident, consideration shall be given to the need to withdraw or recall products. |  |  |
| **3.11.2** | | The company shall have a documented product withdrawal and recall procedure. This shall include, at a minimum:   * identification of key personnel constituting the recall management team, with clearly identified responsibilities * guidelines for deciding whether a product needs to be recalled or withdrawn and the records to be maintained * an up-to-date list of key contacts (including out-of-hours contact details) or reference to the location of such a list (e.g. recall management team, emergency services, suppliers, customers, certification body, regulatory authority) * a communication plan including the provision of information to customers, consumers and regulatory authorities in a timely manner * details of external agencies providing advice and support as necessary (e.g. specialist laboratories, regulatory authority and legal expertise) * a plan to handle the logistics of product traceability, recovery or disposal of affected product, and stock reconciliation * a plan to record timings of key activities * a plan to conduct root cause analysis and to implement ongoing improvements, to avoid recurrence.   The procedure shall be capable of being operated at any time. |  |  |
| **3.11.3** | | The incident management procedures (including those for product recall and withdrawal) shall be tested, at least annually, in a way that ensures their effective operation. Results of the test shall be retained and shall include timings of key activities. The results of the test and of any actual recall shall be used to review the procedure and implement improvements as necessary. |  |  |
| **NEW**  **3.11.4** | | In the event of a significant food safety non-conformity (e.g. a regulatory enforcement notice) or food safety-related withdrawal, the certification body issuing the current certificate for the site against the START! programme shall be notified within 3 working days.  The company shall then provide sufficient information to enable the certification body to assess any effects of the incident on the ongoing validity of the current certificate within 21 calendar days. As a minimum, this shall include corrective action, root cause analysis and a preventive action plan. |  |  |

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| **4** | | **Site Standards** | | |
| 4.1 | | External standards and site security | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The production site shall be of suitable size, location and construction, and be maintained to reduce the risk of contamination and facilitate the production of safe and legal finished products. |  |  |
| **4.1.1** | | Consideration shall be given to local activities and the site environment, which may have an adverse impact on finished product integrity, and measures shall be taken to prevent contamination. Where measures have been put into place to protect the site (from potential contaminants, flooding etc.), they shall be reviewed in response to any changes. |  |  |
| **4.1.2** | | The external areas shall be maintained in good order. Where grassed or planted areas are located near buildings, they shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced and maintained in good repair to mitigate the risk of contamination of the product. |  |  |
| **NEW**  **4.1.3** | | The building fabric shall be maintained to minimise potential for product contamination (e.g. elimination of bird-roosting sites, sealing gaps around pipes to prevent pest entry, ingress of water and other contaminants). |  |  |
| **NEW**  **4.1.4** |  | Policies and systems shall be in place to ensure that access to the site by staff, contractors and visitors is controlled.  A visitor recording system shall be in place.  Contractors and visitors, including drivers, shall be made aware of the procedures for access to the site.  Only authorised personnel shall have access to production and storage areas. Contractors working in product processing or storage areas shall be the responsibility of a nominated person.  Staff shall be trained in site security procedures. |  |  |
| **4.2** | | Food Defence | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Systems shall protect products, premises and brands from malicious actions while under the control of the site. |  |  |
| **4.2.2** | | Where applicable, the food defence plan shall meet the legal requirements in the country of sale or intended use.  The company shall undertake a documented risk assessment (threat assessment) of the potential risks to products from any deliberate attempt to inflict contamination or damage. This threat assessment shall include both internal and external threats.  The output from this assessment shall be a documented food defence plan. This plan shall be kept under review to reflect changing circumstances and market intelligence. |  |  |
| **4.2.4** | | Areas where a significant risk is identified shall be defined in the food defence plan, monitored and controlled. These shall include external storage and intake points for products and raw materials (including packaging).  Staff shall be trained in food defence procedures. |  |  |
| **4.3** | | Layout, product flow and segregation | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The factory layout, flow of processes and movement of personnel shall be sufficient to prevent the risk of product contamination and to comply with relevant legislation. |  |  |
| **NEW**  **4.3.2** |  | There shall be a map of the site. At a minimum, this map shall define:   * production risk zones, where product is at different levels of risk from pathogen contamination – for example, high-risk, high-care, ambient high-care, low-risk and enclosed product areas (see Appendix 1) * access points for personnel * access points for raw materials (including packaging), semi-finished products and open products * routes of movement for personnel * routes of movement for raw materials (including packaging) * routes for the removal of waste * routes for the movement of rework * location of any staff facilities, including changing rooms, toilets, canteens and smoking areas * production process flows * any areas where time segregation is used to complete different activities (for example, time segregation for high-care areas). |  |  |
| **4.3.4** | | The movement of personnel, raw materials, packaging, rework and/or waste shall not compromise the safety of products. The process flow, together with the use of demonstrably effective procedures, shall be in place to minimise the risk of the contamination of raw materials, intermediate/semi-processed products, packaging and finished products. |  |  |
| **4.3.5** | | Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe hygienic conditions. |  |  |
| **4.4** | | Building fabric, raw material handling, preparation, processing, packing and storage areas | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The fabrication of the site, buildings and facilities shall be suitable for the intended purpose. |  |  |
| **4.4.1** | | Walls shall be finished and maintained to prevent the accumulation of dirt, minimise condensation and mould growth, and facilitate cleaning. |  |  |
| **4.4.2** | | Floors shall be suitably hard-wearing to meet the demands of the process, and withstand cleaning materials and methods. They shall be impervious, be maintained in good repair and facilitate cleaning. |  |  |
| **4.4.3** | | Drainage, where provided, shall be sited, designed and maintained to minimise risk of product contamination and not compromise product safety.  Machinery and piping shall be arranged so that, wherever feasible, process waste water goes directly to drain. Where significant amounts of water are used, or direct piping to drain is not feasible, floors shall have adequate falls to cope with the flow of any water or effluent towards suitable drainage. |  |  |
| **4.4.4** | | Ceilings and overheads shall be constructed, finished and maintained to prevent the risk of product contamination. |  |  |
| **4.4.7** | | Where there is a risk to product, windows and roof glazing which are designed to be opened for ventilation purposes shall be adequately screened to prevent the ingress of pests. |  |  |
| **4.4.8** | | Doors (both internal and external) shall be maintained in good condition.  At a minimum:   * external doors and dock levellers shall be close fitting or adequately proofed * external doors to open product areas shall not be opened during production periods except in emergencies * where external doors to enclosed product areas are opened, suitable precautions shall be taken to prevent pest ingress. |  |  |
| **4.4.9** | | Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of product and effective cleaning. |  |  |
| **NEW**  **4.4.10** | | Adequate ventilation and extraction shall be provided in product storage and processing environments to prevent condensation or excessive dust. |  |  |
| **NEW**  **4.4.11** | | Where plastic strip curtains are present, these shall be maintained in good condition, clean, fitted correctly (e.g. to prevent pest ingress or for temperature control), and shall not pose a food safety risk. |  |  |
| **4.5** | | Utilities – water, ice, air and other gases | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Utilities used within the production and storage areas shall be monitored to effectively control the risk of product contamination. |  |  |
| **4.5.1** | | All water (including ice and steam) used as a raw material in the manufacture of processed food, the preparation of product, hand-washing or equipment or plant cleaning shall be supplied in sufficient quantity, be potable at point of use, be fit for purpose and pose no risk of contamination according to applicable legislation. Where water is stored and handled on site (e.g. in storage or holding tanks), these shall be managed to minimise food safety risks  The microbiological and chemical quality of water shall be analysed as required by legislation or at least annually. The sampling points, scope of the test and frequency of analysis shall be based on risk, taking into account the source of the water, on-site storage and distribution facilities, previous sample history and usage. |  |  |
| **4.5.3** | | Air and other gases used as an ingredient or that are in direct contact with products shall be monitored to ensure this does not represent a contamination risk. Compressed air that is in direct contact with the product shall be filtered at point of use. |  |  |
| **4.6** | | Equipment | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | All production and product-handling equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product. |  |  |
| **4.6.2** | | Equipment that is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable. |  |  |
| **NEW**  **4.6.5** | | Food contact equipment that has been stored but is not in daily use shall be cleaned and, where necessary, disinfected prior to use. |  |  |
| **4.7** | | Maintenance | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | An effective maintenance programme shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns. |  |  |
| **4.7.1** | | There shall be a planned preventive maintenance schedule or condition monitoring system which includes all plant and processing equipment equipment. The maintenance requirements shall be defined when commissioning new equipment. |  |  |
| **4.7.2** | | In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment damage, the equipment shall be inspected at predetermined intervals, the inspection results documented and appropriate action taken. |  |  |
| **4.7.3** | | Where temporary repairs are made, these shall be documented and controlled to ensure that the safety or legality of products is not jeopardised.  These temporary measures shall be permanently repaired as soon as practicable and within a defined timescale. |  |  |
| **4.7.4** | | The site shall ensure that the safety or legality of products is not jeopardised during maintenance and subsequent cleaning operations. Maintenance work shall be followed by a documented hygiene clearance procedure.  Equipment and machinery shall be inspected by an authorised member of staff to confirm the removal of contamination hazards, before being accepted back into operation. |  |  |
| **NEW**  **4.7.5** | | Materials and parts used for equipment and plant maintenance shall be of an appropriate grade or quality. |  |  |
| **4.8** | | Staff facilities | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Staff facilities shall be sufficient to accommodate the required number of personnel, and shall be designed and operated to minimise the risk of product contamination. The facilities shall be maintained in good and clean condition. |  |  |
| **4.8.1** | | Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly (e.g. the provision of cleaning facilities for footwear). |  |  |
| **4.8.3** | | Outdoor clothing and other personal items shall be stored separately from production clothing within the changing facilities. Facilities shall be available to separate clean and dirty production clothing. |  |  |
| **4.8.4** | | Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-washing facilities shall provide, at a minimum:   * advisory signs to prompt hand-washing * a sufficient quantity of water at a suitable temperature * liquid/foam soap * single-use towels or suitably designed and located air driers. |  |  |
| **4.8.5** | | Toilets shall be adequately segregated and shall not open directly into production or packing areas. Toilets shall be provided with hand-washing facilities comprising:   * basins with soap and water at a suitable temperature * adequate hand-drying facilities * advisory signs to prompt hand-washing.   Where hand-washing facilities within toilets are the only hand-washing facilities provided before re-entering production, the requirements of clause 4.8.4 shall apply and signs shall be in place to direct people to hand-washing facilities before entering production. |  |  |
| **4.8.6** | | Where smoking is allowed under national law, designated controlled smoking areas shall be provided which are both isolated from production areas to an extent that ensures smoke cannot reach the product and fitted with sufficient extraction to the exterior of the building. Adequate arrangements for dealing with smokers’ waste shall be provided at smoking facilities, both inside and at exterior locations. Electronic cigarettes shall not be permitted to be used or brought into production or storage areas. |  |  |
| **4.8.7** | | All food brought into manufacturing premises by staff shall be appropriately stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas. Where eating of food is allowed outside during breaks, this shall be in suitable designated areas with appropriate control of waste. |  |  |
| **4.9** | | Chemical and physical product contamination control: raw material-handling, preparation, processing, packing and storage areas | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Appropriate facilities and procedures shall be in place to control the risk of chemical or physical contamination of product. |  |  |
| **4.9.1** | | Chemical control | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **4.9.1.1** |  | Processes shall be in place to manage the use, storage and handling of non-food chemicals to prevent chemical contamination. These shall include, at a minimum:   * an approved list of chemicals for purchase * availability of material safety data sheets and specifications * confirmation of suitability for use in a food-processing environment * avoidance of strongly scented products * the labelling and/or identification of containers of chemicals at all times * a designated storage area (separate from chemicals used as raw materials in products) with access restricted to authorised personnel * use by trained personnel only * procedures to manage any spills * procedures for the safe, legal disposal or return of obsolete or out-of-date chemicals and empty chemical containers. |  |  |
| **4.9.2** | | Metal control | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **4.9.2.2** | | The purchase of ingredients and packaging which use staples or other foreign-body hazards as part of the packaging materials shall be avoided.  Staples, paper clips and drawing pins shall not be used in open product areas.  Where staples or other items are present as packaging materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination. |  |  |
| **4.9.3** | | Glass, brittle plastic, ceramics and similar materials | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **4.9.3.1** | | Glass or other brittle materials shall be excluded or protected against breakage in areas where open products are handled or there is a risk of product contamination. |  |  |
| **4.9.3.3** |  | Procedures detailing the action to be taken in the event of breakage of glass or other brittle items shall be implemented and include the following:   * training of staff in the correct procedure * quarantining the products and production area that were potentially affected * cleaning the production area * inspecting the production area and authorising production to continue * changing of workwear and inspection of footwear * specifying those staff authorised to carry out the above points * recording the breakage incident * safely disposing of contaminated product. |  |  |
| **4.9.3.4** | | Where they pose a risk to product, glass windows shall be protected against breakage. |  |  |
| **4.9.3.5** | | Where they pose a risk to product, bulbs and strip lights (including those on electric fly-killer devices) shall be adequately protected. Where full protection cannot be provided, alternative management such as wire-mesh screens or monitoring procedures shall be in place. |  |  |
| **4.9.4** | | Products packed into glass or other brittle containers | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **4.9.4.2** | | * Systems shall be in place to manage container breakages between the container-cleaning/inspection point and container closure. This shall include, as a minimum, documented instructions which ensure: * the removal and disposal of at-risk products in the vicinity of the breakage; this may be specific for different equipment or areas of the production line * the effective cleaning of the line or equipment which may be contaminated by fragments of the container; cleaning shall not result in the further dispersal of fragments, for instance by the use of high-pressure water or air * the use of dedicated, clearly identifiable cleaning equipment (e.g. colour-coded) for removal of container breakages; such equipment shall be stored separately from other cleaning equipment * the use of dedicated, accessible, lidded waste containers for the collection of damaged containers and fragments * a documented inspection of production equipment is undertaken following the cleaning of a breakage, to ensure cleaning has effectively removed any risk of further contamination * authorisation given for production to restart following cleaning * the area around the line being kept clear of broken glass. |  |  |
| **4.9.5** | | Wood | | |
| **Clause** | | **Requirements** | **Conforms** |  |
| **4.9.5.1** | | Wood used for food contact purposes shall be fit for purpose (e.g. free from damage or splinters, free from taint; and wood treatments, where used, are used only in accordance with legislation and approved for food use).  Wood should not be used in open product areas except where this is a process requirement (e.g. maturation of products in wood). Where the use of wood cannot be avoided, its condition shall be monitored on a risk-based frequency to ensure it is in good condition and free from damage or splinters which could contaminate products. |  |  |
| **4.9.6** | | Other physical contaminants | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **NEW**  **4.9.6.3** |  | Procedures shall be implemented to minimise other types of foreign-body contamination that are reasonably expected to occur at a site but are not specifically covered in section 4.9. |  |  |
| **4.10** | | Foreign-body detection and removal equipment | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The risk of product contamination shall be reduced or eliminated by the effective use of equipment to remove or detect foreign bodies |  |  |
| **4.10.1** | | Selection and operation of foreign-body detection and removal equipment | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **4.10.1.1** | | A documented assessment in association with the food safety plan (see section 2 – The food safety plan) shall be carried out on each production process to identify the potential use of equipment to detect or remove foreign-body contamination. Typical equipment to be considered may include:   * filters and sieves * metal detection and X-ray detection equipment * magnets * optical sorting equipment * other physical separation equipment. |  |  |
| **4.10.1.2** |  | The type, location and sensitivity of the detection and/or removal method shall be specified as part of the site’s documented system. Industry best practice shall be applied with regard to the nature of the ingredient, material, product and/or packed product. The location of the equipment or any other factors influencing the sensitivity of the equipment shall be validated and justified. |  |  |
| **4.10.1.3** | | The site shall ensure that the frequency of the testing of the foreign-body detection and/or removal equipment is defined and takes into consideration:   * specific customer requirements * the site’s ability to identify, hold and prevent the release of any affected materials, should the equipment fail.   The site shall establish and implement corrective action and reporting procedures in the event of a failure of the foreign-body detector and/or removal equipment. Action shall include a combination of isolation, quarantining and re-inspection of all products produced since the last successful test or inspection. |  |  |
| **4.10.1.4** |  | Where foreign material is detected or removed by the equipment, the source of any unexpected material shall be investigated. Information on rejected materials shall be used to identify trends and, where possible, instigate preventive action to reduce the occurrence of contamination by the foreign material. |  |  |
| **4.10.2** | | Filters and sieves | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **4.10.2.1** | | Filters and sieves used for foreign-body control shall be of a specified mesh size or gauge and designed to provide the maximum practical protection for the product. |  |  |
| **4.10.2.2** | | Filters and sieves shall be regularly inspected or tested for damage at a documented frequency based on risk. Records shall be maintained of the checks. Where defective filters or sieves are identified, this shall be recorded and the potential for contamination of products investigated and appropriate action taken. |  |  |
| **4.10.3** | | Metal detectors and X-ray equipment | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **4.10.3.2** | | The metal detector or X-ray equipment shall incorporate one of the following:   * an automatic rejection device, for continuous in-line systems, which shall divert contaminated product either out of the product flow or to a secure unit accessible only to authorised personnel * a belt stop system with an alarm where the product cannot be automatically rejected (e.g. for very large packs) * in-line detectors which identify the location of the contaminant to allow effective segregation of the affected product. |  |  |
| **4.10.6** | | Container cleanliness – glass jars, cans and other rigid containers | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **4.10.6.1** | | Based on risk assessment, procedures shall be implemented to minimise foreign-body contamination originating from the packaging container (e.g. jars, cans and other pre-formed rigid containers). This may include the use of covered conveyors, container inversion and foreign-body removal through rinsing with water or air jets. |  |  |
| **4.10.7** | | Other foreign-body detection and removal equipment | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **NEW**  **4.10.7.1** |  | Other foreign-body detection and removal equipment, such as gravity separation, fluid bed technology or aspirators, shall be checked in accordance with the manufacturer’s instructions or recommendations.  Checks shall be documented. |  |  |
| **4.11** | | Housekeeping and hygiene | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Housekeeping and cleaning systems shall be in place which ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimised. |  |  |
| **4.11.1** | | The premises and equipment shall be maintained in a clean and hygienic condition. |  |  |
| **4.11.2** | | Documented cleaning and disinfection procedures shall be in place and maintained for the building, plant and all equipment.  The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.  Cleaning procedures for the processing equipment and food contact surfaces shall, at a minimum, include:   * responsibility for cleaning * item/area to be cleaned * frequency of cleaning * method of cleaning, including dismantling equipment for cleaning purposes where required * cleaning chemicals and concentrations * cleaning materials to be used * cleaning records and responsibility for verification.   The frequency and methods of cleaning shall be based on risk. |  |  |
| **4.11.4** | | The resources for undertaking cleaning shall be available. Where it is necessary to dismantle equipment for cleaning purposes or to enter large equipment for cleaning, this shall be appropriately scheduled and, where necessary, planned for non-production periods. Cleaning staff shall be adequately trained or engineering support provided where access within equipment is required for cleaning. |  |  |
| **4.11.6** | | Cleaning equipment shall be:   * hygienically designed and fit for purpose * suitably identified for intended use (e.g. colour-coded or labelled) * cleaned and stored in a hygienic manner to prevent contamination. |  |  |
| **4.11.7** | | Cleaning in place (CIP) | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **4.11.7.3** | | The CIP equipment shall be maintained by suitably trained staff to ensure effective cleaning is carried out. |  |  |
| **4.11.7.4** | | CIP facilities, where used, shall be monitored at a defined frequency based on risk. |  |  |
| **4.12** | | Waste and waste disposal | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Waste disposal shall be managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests. |  |  |
| **4.12.1** | | Where licensing is required by law for the removal of waste, it shall be removed by licensed contractors.  Records of removal shall be maintained and available for audit. |  |  |
| **4.12.2** | | Internal and external waste collection containers and rooms housing waste facilities shall be managed to minimise risk. These shall be:   * clearly identified * designed for ease of use and effective cleaning * well maintained to allow cleaning and, where required, disinfection * emptied at appropriate frequencies.   External waste containers shall be covered or doors kept closed as appropriate. |  |  |
| **4.14** | | Pest management | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The whole site shall have an effective preventive pest management programme in place to minimise the risk of pest presence, and resources shall be available to respond rapidly to any issues which occur to prevent risk to products.  Pest management programmes shall comply with all applicable legislation. |  |  |
| **4.14.1** | | If pest activity is identified, it shall not present a risk of contamination to products, raw materials or packaging.  The presence of any infestation on site shall be documented in pest management records and be part of an effective pest management programme to eliminate or manage the infestation so that it does not present a risk to products, raw materials or packaging. |  |  |
| **4.14.2** | | The site shall either contract the services of a competent pest management organisation or have appropriately trained staff for the regular inspection and treatment of the site to deter and eradicate infestation.  The frequency of inspections shall be determined by risk assessment and shall be documented.  Where the services of a pest management contractor are employed, the service scope shall be clearly defined and reflect the activities of the site. |  |  |
| **4.14.3** | | * Where a site undertakes its own pest management, it shall be able to effectively demonstrate that: * pest management operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site * staff undertaking pest management activities meet any legal requirements for training or registration * sufficient resources are available to respond to any infestation issues * there is ready access to specialist technical knowledge when required * legislation governing the use of pest control products is understood and complied with * dedicated locked facilities are used for the storage of pesticides. |  |  |
| **4.14.4** | | Pest management documentation and records shall be maintained. At a minimum, this shall include:   * an up-to-date plan of the full site, identifying pest control devices and their locations * identification of the baits and/or monitoring devices on site * clearly defined responsibilities for the site management and the contractor * details of pest control products used, including instructions for their effective use and action to be taken in the event of an emergency * any observed pest activity * details of pest control treatments undertaken.   Records may be on paper (hard copy) or controlled on an electronic system (e.g. an online reporting system). |  |  |
| **4.14.5** | | Bait stations or other rodent monitoring or control devices shall be appropriately located and maintained to prevent contamination risk to product. Toxic rodent baits shall not be used within production or storage areas where open product is present except when treating an active infestation. Where toxic baits are used, these shall be secured.  Any missing bait stations shall be recorded, reviewed and investigated. |  |  |
| **4.14.6** | | Insect-killing devices, pheromone traps and/or other insect-monitoring devices shall be appropriately sited and operational. If there is a danger of insects being expelled from a fly-killing extermination device and contaminating the product, alternative systems and equipment shall be used. |  |  |
| **4.14.8** | | In the event of infestation, or evidence of pest activity, immediate action shall be taken to identify at-risk products and to minimise the risk of product contamination. Any potentially affected products should be subject to the non-conforming product procedure. |  |  |
| **4.14.9** |  | Records of pest management inspections, pest proofing and hygiene recommendations and actions taken shall be maintained. It shall be the responsibility of the site to ensure that all of the relevant recommendations made by its contractor or in-house expert are carried out in a timely manner. |  |  |
| **4.14.12** |  | Staff shall understand the signs of pest activity and be aware of the need to report any evidence of such activity to a designated manager. |  |  |
| **4.15** | | Storage facilities | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | All facilities used for the storage of raw materials, packaging, in-process products and finished products shall be suitable for purpose. |  |  |
| **4.15.3** | | Where temperature control is required (e.g. for raw materials, semi-finished materials or final products), the storage area shall be capable of maintaining product temperature within specification and operated to ensure specified temperatures are maintained. Temperature recording equipment with suitable temperature alarms shall be fitted to all storage facilities or there shall be a system of recorded manual temperature checks, typically on at least a 4-hourly basis or at a frequency which allows for intervention before product temperatures exceed defined limits for the safety, legality or quality of products. |  |  |
| **4.15.4** | | Where controlled atmosphere storage is required, the storage conditions shall be specified and effectively controlled. Records shall be maintained of the storage conditions. |  |  |
| **4.15.5** | | Where storage outside is necessary, items shall be protected from contamination and deterioration. Items shall be checked for suitability before being brought into the factory. |  |  |
| **4.15.6** | | The site shall facilitate correct stock rotation of raw materials, intermediate products and finished products in storage and ensure that materials are used in the correct order in relation to their manufacturing date and within the prescribed shelf life. |  |  |
| **4.16** | | Dispatch and transport | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Procedures shall be in place to ensure that the management of dispatch and of the vehicles and containers used for transporting products from the site do not present a risk to the safety, security or quality of the products. |  |  |
| **4.16.1** | | Procedures to maintain product safety and quality during loading and transportation shall be developed and implemented. These may include, as appropriate:   * controlling temperature of loading dock areas and vehicles * the use of covered bays for vehicle loading or unloading * securing loads on pallets to prevent movement during transit * inspection of loads prior to dispatch. |  |  |
| **4.16.2** | | All vehicles or containers used for the transport of raw materials and the dispatch of products shall be fit for purpose. This shall ensure that they are:   * in a clean condition * free from strong odours which may cause taint to products * in a suitable condition to prevent damage to products during transit * equipped to ensure any temperature requirements can be maintained throughout transportation.   Records of inspections shall be maintained. |  |  |
| **4.16.3** | | Where temperature control is required, the transport shall be capable of maintaining product temperature within specification, under minimum and maximum load.  Temperature data-logging devices which can be interrogated to confirm time/temperature conditions, or a system to monitor and record at predetermined frequencies the correct operation of refrigeration equipment, shall be used and records maintained. |  |  |
| **4.16.4** | | Maintenance systems and documented cleaning procedures shall be available for all vehicles and equipment used for loading/unloading. There shall be records of the measures taken. |  |  |

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| **5** | | **Product control** | | |
| 5.1 | | Product design/development | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Product design and development procedures shall be in place for new products or processes and any changes to product, packaging or manufacturing processes to ensure that safe and legal products are produced. |  |  |
| **5.1.2** | | All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader or an authorised HACCP team member. This shall ensure that hazards have been assessed and suitable controls, identified through the HACCP system, are implemented. This approval shall be granted before products are introduced into the factory environment. |  |  |
| **5.2** | | Product labelling | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Product labelling shall comply with the appropriate legal requirements and contain information to enable the safe handling, display, storage and preparation of the product within the food supply chain or by the customer. |  |  |
| **5.2.1** | | All products shall be labelled to meet legal requirements for the designated country of use and shall include information to allow the safe handling, display, storage, preparation and use of the product within the food supply chain or by the customer.  There shall be a process to verify that ingredient and allergen labelling is correct based on the product recipe and ingredient specifications.  The company shall have a procedure for artwork approval and sign-off. |  |  |
| **5.3** | | Management of allergens | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The site shall have a system for the management of allergenic materials which minimises the risk of allergen contamination (cross-contact) of products and meets legal requirements for labelling in the country of sale. |  |  |
| **NEW**  **5.3.1** | | The site shall carry out an assessment of raw materials to establish the presence and likelihood of contamination (cross-contact) by allergens. This shall include a review of the raw material specifications and, where required, the acquisition of additional information from suppliers (e.g. through questionnaires to understand the allergen profile of the raw material, its ingredients and the factory in which it is produced). |  |  |
| **5.3.2** | | The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products, and any new product development ingredients or products. |  |  |
| **5.3.4** |  | Procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination (cross-contact) of products not containing the allergen.  These shall include, as appropriate:   * physical or time segregation while allergen-containing materials are being stored, processed or packed * the use of separate or additional protective overclothing when handling allergenic materials * use of identified, dedicated equipment and utensils for processing * scheduling of production to reduce changes between products containing an allergen and products not containing the allergen * systems to restrict the movement of airborne dust containing allergenic material * waste handling and spillage controls * restrictions on food brought onto site by staff, visitors and contractors and for catering purposes. |  |  |
| **5.3.5** |  | Where rework is used, or reworking operations are carried out, procedures shall be implemented to ensure rework containing allergens is not used in products that do not already contain the allergen. |  |  |
| **5.3.6** | | Where a justified, risk-based assessment demonstrates that the nature of the production process is such that cross-contamination (cross-contact) from an allergen cannot be prevented, a warning should be included on the label. Legislation, national guidelines or codes of practice shall be used when making such a warning statement. |  |  |
| **5.3.8** |  | Equipment or area-cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination (cross-contact) by allergens.  The cleaning methods shall be validated to ensure that they are effective and the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be identifiable and specific for allergen use, single use, or effectively cleaned after use. |  |  |
| **5.4** | | Product authenticity, claims and chain of custody | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Systems shall be in place to minimise the risk of purchasing fraudulent or adulterated food raw materials and to ensure that all product descriptions and claims are legal, accurate and verified. |  |  |
| **5.4.5** |  | Where products are labelled or claims are made on finished packs which are dependent on the status of a raw material, the status of each batch of the raw material shall be verified.  The facility shall maintain purchasing records, traceability of raw material usage and final product packing records to substantiate claims. |  |  |
| **5.4.6** | | Where claims are made about the methods of production (e.g. organic, halal, kosher), the site shall maintain the necessary certification status in order to make such a claim. |  |  |
| **NEW 5.4.7** |  | Where a product is designed to enable a claim to be made, the company shall ensure that all claims are substantiated, and product formulation and the production process are fully validated to meet the stated claim and any legal requirements (in the country of intended sale) relating to the claim.  The process flow for the production of products where claims are made shall be documented and potential areas for contamination or loss of identity identified.  Appropriate controls shall be established to ensure the integrity of the product claims. |  |  |
| **5.5** | | Product Packaging | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | Product packaging and processes for the purchase of product packaging shall be appropriate for the intended use. Packaging shall be stored under conditions to prevent contamination and minimise deterioration. |  |  |
| **NEW**  **5.5.1** | | Evidence shall be available for primary packaging to confirm it complies with applicable food safety legislation and is suitable for its intended use. |  |  |
| **5.5.2** | | Product liners and bags purchased by the company for use in direct contact with ingredients, or work in process, shall be appropriately coloured (e.g. contrasting colour to the product) and resistant to tearing to prevent accidental contamination. |  |  |
| **5.6** | | Product inspection, on-site product testing and laboratory analysis | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The company shall undertake or subcontract inspection and analyses which are critical to confirm product safety, authenticity, legality and quality, using appropriate procedures, facilities and standards. |  |  |
| **5.6.1** | | There shall be a scheduled programme of product testing which may include microbiological, chemical, physical and organoleptic testing according to risk. The methods, processes for obtaining product samples (including, where appropriate, their delivery to a laboratory), frequency and specified limits shall be documented. |  |  |
| **5.6.2** | | Test and inspection results shall be recorded and reviewed regularly to identify trends.  The significance of on-site and laboratory results shall be understood and acted upon accordingly. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends.  Where legal limits apply, these shall be understood and appropriate action taken promptly to address any exceedance of these limits.  Where applicable, the measurement uncertainty associated with laboratory test results shall be considered. |  |  |
| **NEW**  **5.6.3** | | The site shall ensure that a system of validation and ongoing verification of the shelf life is in place. This shall be based on risk and shall include sensory analysis and, as applicable, microbiological testing and relevant chemical factors such as pH and aw. Records and results from shelf-life tests shall verify the shelf-life period indicated on the product. |  |  |
| **NEW 5.6.4** |  | Pathogen testing (including pathogens tested as part of the site’s environmental monitoring programme) shall be subcontracted to an external laboratory or, where conducted internally, the laboratory facility shall be fully segregated from the production and storage areas and have operating procedures to prevent any risk of contamination of products or production areas. |  |  |
| **5.6.5** |  | Where testing laboratories are present on a manufacturing site, they shall be located, designed and operated to eliminate potential risks to product safety. |  |  |
| **5.6.6** | | Where the company undertakes or subcontracts analyses which are critical to product safety, authenticity or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO/IEC 17025, including proficiency testing where applicable. Documented justification shall be available where accredited methods are not undertaken. |  |  |
| **5.7** | | Product release | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The site shall ensure that finished product is not released unless all agreed procedures have been followed. |  |  |
| **5.7.1** | | Where products require positive release, procedures shall be in place to ensure that release does not occur until all release criteria have been completed and the release has been authorised. |  |  |

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| **6** | | **Process control** | | |
| **6.1** | | Control of operations | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The site shall operate to process specifications and work instructions/procedures that ensure the production of consistently safe and legal product with the desired quality characteristics, in full compliance with the HACCP or food safety plan. |  |  |
| **6.1.1** |  | Documented process specifications and work instructions/procedures shall be available for the key processes in the production of products to ensure product safety, legality and quality. The process specifications and work instructions/procedures (as appropriate) shall include:   * recipes – including identification of any allergens * mixing instructions, speed, time * equipment process settings * cooking times and temperatures * cooling times and temperatures * labelling instructions * coding and shelf-life marking * storage conditions (e.g. storage temperatures) * any additional critical control points identified in the HACCP or food safety plan.   Process specifications shall be in accordance with the agreed finished product specification.  The site shall review the process specifications and work instructions/procedures prior to any changes which may affect food safety, legality and quality. |  |  |
| **6.1.3** | | Process monitoring, such as temperature, time, pressure and chemical properties, shall be implemented, adequately controlled and recorded to ensure that product is produced within the required process specification. |  |  |
| **6.1.5** | | Where variation in processing conditions may occur within equipment critical to the safety or quality of products, the processing characteristics shall be validated and verified at a frequency based on risk and performance of equipment (e.g. heat distribution in retorts, ovens and processing vessels; temperature distribution in freezers and cold stores). |  |  |
| **6.1.6** | | In the event of equipment failure or deviation of the process from specification, procedures shall be in place to establish the safety status and quality of the product to determine the action to be taken. |  |  |
| **6.2** | | Labelling and pack control | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The management controls of product labelling activities shall ensure that products will be correctly labelled and coded. |  |  |
| **6.2.3** | | Procedures shall be in place to ensure that all products are packed into the correct packaging and correctly labelled. These shall include checks:   * at the start of packing * during the packing run (e.g. at predefined intervals and when printed packaging or labels are brought to the line during the production run) * when changing batches of packaging materials * at the end of each production run.   The checks shall also include verification of any printing carried out at the packing stage including, as appropriate:   * date coding * batch coding * quantity indication * pricing information * bar coding * country of origin * allergen information. |  |  |
| **6.3** | | Quantity – weight, volume and number control | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The site shall operate a quantity control system which conforms to legal requirements in the country where the product is sold and any additional industry sector codes or specified customer requirements. |  |  |
| **6.3.1** | | The frequency and methodology of quantity checking shall meet the requirements of the appropriate legislation governing quantity verification, and records of checks shall be retained. |  |  |
| **6.4** | | Calibration and control of measuring and monitoring devices | | |
| **Clause** | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | The site shall be able to demonstrate that measuring equipment is sufficiently accurate and reliable to provide confidence in measurement results. |  |  |
| **6.4.2** | | All identified measuring devices, including new equipment, shall be checked and, where necessary, adjusted:   * at a predetermined frequency, based on risk assessment * to a defined method traceable to a recognised national or international standard where possible.   Results shall be documented. Equipment shall be readable and be of a suitable accuracy for the measurements it is required to perform. |  |  |
| **6.4.4** | | Procedures shall be in place to record actions to be taken when the prescribed measuring devices are found not to be operating within specified limits. Where the safety or legality of products is based on equipment found to be inaccurate, action shall be taken to ensure at-risk product is not offered for sale. |  |  |

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| **7** | | | **Personnel** | | |
| **7.1** | | | Training: raw material handling, preparation, processing, packing and storage areas | | |
| **Clause** | | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | | The company shall ensure that all personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification. |  |  |
| **7.1.1** | | | All personnel, including agency-supplied staff, temporary staff and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period. |  |  |
| **7.1.2** | | | Where personnel are engaged in activities relating to control measures and critical control points, relevant training shall be in place. |  |  |
| **7.1.4** |  | | All personnel, including engineers, agency-supplied staff, temporary staff and contractors, shall have received general allergen awareness training and be trained in the site’s allergen-handling procedures. |  |  |
| **7.1.6** | | | Records of all training shall be available. These shall include, at a minimum:   * the name of the trainee and confirmation of attendance * the date and duration of the training * the title or course contents, as appropriate * the training provider   Where training is undertaken by agencies on behalf of the company, records of the training shall be available. |  |  |
| **7.1.7** | | | The company shall routinely review the competencies of its staff. As appropriate, it shall provide relevant training. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience. |  |  |
| **7.2** | | | Personal hygiene: raw material handling, preparation, processing, packing and storage areas | | |
| **Clause** | | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | | The site’s personal hygiene standards shall be developed to minimise the risk of product contamination from personnel, be appropriate to the products produced and be adopted by all personnel, including agency-supplied staff, contractors and visitors to the production facility. |  |  |
| **7.2.1** | |  | The requirements for personal hygiene shall be documented and communicated to all personnel. These shall include, at a minimum, the following:   * watches and similar wearable devices shall not be worn * jewellery shall not be worn, with the exception of a single, plain wedding ring, wedding wristband or medical alert jewellery * rings and studs in exposed parts of the body, such as ears, noses and eyebrows, shall not be worn * fingernails shall be kept short, clean and unvarnished * false fingernails and nail art shall not be permitted * excessive perfume or aftershave shall not be worn.   Compliance with the requirements shall be checked routinely. |  |  |
| **7.2.2** | | | Hand-washing shall be performed on entry to the production areas and at a frequency that is appropriate to minimise the risk of product contamination. |  |  |
| **7.2.3** | | | All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue) and contains a metal detectable strip. These shall be site-issued and monitored. Where appropriate, in addition to the plaster, a glove shall be worn. |  |  |
| **7.3** | | | Medical screening | | |
| **Clause** | | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | | The company shall have procedures in place to ensure that staff, agency staff, contractors or visitors are not a source of transmission of infections, diseases (including food-borne diseases) or conditions to products. |  |  |
| **7.3.1** | | | The site shall make staff aware of the symptoms of infection, disease or condition which would prevent a person working with open food. The site shall have a procedure which enables notification by staff (including temporary employees), contractors and visitors to the site, of any relevant symptoms, infection, disease or condition which they may have been in contact with or may be suffering from. |  |  |
| **7.3.2** | | | Where there may be a risk to product safety, visitors and contractors shall be made aware of the types of symptoms, infection, disease or condition which would prevent a person visiting areas with open food. Where permitted by law, visitors shall be required to complete a health questionnaire or otherwise confirm that they are not suffering from any symptoms which may put product safety at risk, prior to entering the raw material, preparation, processing, packing and storage areas. |  |  |
| **7.3.3** | | | There shall be procedures for employees, contractors and visitors relating to action to be taken where they may be suffering from or have been in contact with an infectious disease. Expert medical advice shall be sought where required. |  |  |
| **7.4** | | | Protective clothing: staff or visitors to production areas | | |
| **Clause** | | | **Requirements** | **Conforms** | **Comments** |
| **SOI** | | | Suitable site-issued protective clothing shall be worn by employees, contractors or visitors working in or entering production areas. |  |  |
| **7.4.1** | | | The company shall document and communicate to all staff (including agency and temporary personnel), contractors and visitors the rules regarding the wearing of protective clothing in specified work areas (e.g. production areas, storage areas). This shall also include policies relating to the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, and use of canteen and smoking areas). |  |  |
| **7.4.2** | | | Protective clothing shall be available that:   * is provided in sufficient numbers for each employee * is of suitable design to prevent contamination of the product (at a minimum containing no external pockets above the waist or sewn-on buttons) * fully contains all scalp hair to prevent product contamination * includes snoods for beards and moustaches, where required, to prevent product contamination. |  |  |
| **7.4.4** | | | Protective clothing shall be changed at an appropriate frequency, based on risk. |  |  |

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| **8** | **Production risk zones – high risk, high care and ambient high care** | | |
| **Clause** | **Requirements** | **Conforms** | **Comments** |
| **SOI** | The site shall be able to demonstrate that production facilities and controls are suitable to prevent pathogen contamination of products. |  |  |

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