



BRC GLOBAL STANDARDS SELF-ASSESSMENT TOOL

Module 9 – BRC AuditOne

Welcome to the BRC Global Standards Self-Assessment tool

We hope that you will find this useful when preparing your site for an audit against the BRC Global Standard for Packaging and Packaging Materials Issue 5 and AuditOne requirements. This tool will be applicable for all BRC Global Standard for Packaging and Packaging Materials issue 5 audits in the High Hygiene Category when using the AuditOne module.

How to use the BRC Global Standards Self-Assessment tool

This tool is designed to help you assess your operation against the requirements of the Standard and the Module and help prepare you for your certification audit. Module requirements are denoted in tinted boxes.

The checklist covers each of the requirements of the Standard and the Module and may be used to check your site's compliance with each of these requirements. The checklist also allows you to add comments or identify areas of improvement in the empty boxes provided at the end of each section.

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.

Training

The BRC Training Academy has courses available to improve the understanding of the requirements for the BRC Global Standard for Packaging and Packaging Materials issue 5 and may be useful for the person using the BRC Global Standards Self-Assessment Tool. For further information on the courses available please visit www.brctrainingacademy.com

Further Information

If you have any further questions about this self-assessment tool or Issue 5 please do not hesitate to contact the BRC Global Standards team.

Email – enquiries@brcglobalstandards.com

Telephone – 020 7854 8939

Ref.	Clause	
1	Senior Management Commitment	
1.1	Senior Management Commitment and Continual Improvement	
SOI	The company's senior management shall demonstrate that they are fully committed to the implementation of requirements of the Global Standard for Packaging and Packaging Materials. This shall include provision of adequate resources, effective communication and systems of review to ensure continual improvement. Opportunities for improvement shall be identified, implemented and fully documented.	
1.1.1	The site shall have a documented policy which states the site's intention to meet its obligation to produce safe and legally compliant products to the specified quality, and confirms its responsibility to its customers. This shall be: <ul style="list-style-type: none"> signed by the person with overall responsibility for the site communicated to all staff. 	
1.1.2	The site's senior management shall establish clear objectives to maintain and improve the quality, safety and legality of products manufactured, in accordance with the product safety and quality policy and this Standard. These objectives shall be: <ul style="list-style-type: none"> documented and include targets or clear measures of success clearly communicated to relevant staff monitored, and the results reported at a suitable predetermined frequency to the site's senior management reviewed at least annually. 	
1.1.3	The company's senior management shall provide the human and financial resources required to effectively implement the processes of the quality management system and product safety programme and maintain compliance with this Standard.	
1.1.4	The company's senior management shall have a system in place to ensure that the site is kept informed of and reviews: <ul style="list-style-type: none"> scientific and technical developments industry codes of practice all relevant legislation applicable in the country of manufacture and, where known, the country where the product will be used any changes to the Standard or protocol published by the BRC. 	
1.1.5	The site shall have a genuine, current hard copy or electronic version of the Standard available.	
1.1.6	Where the site is certificated to the Standard, it shall ensure that recertification audits occur on or before the audit due date indicated on the certificate.	

1.1.7	The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for the Global Standard for Packaging and Packaging Materials certification. Relevant departmental managers or their deputies shall be available as required during the audit.	
1.1.8	The site's senior management shall ensure that the root causes of non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence. A system shall be in place to close out non-conformities raised in internal, second-party and third party audits, with consideration of the root cause.	
Notes		
1.2	Management Review	
SOI	The site's senior management shall ensure that a management review is undertaken to ensure that the product safety and quality system is both fully implemented and effective, and that opportunities for improvement are identified.	
1.2.1	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals; as a minimum annually.	
1.2.2	The review process shall include the evaluation of: <ul style="list-style-type: none"> • previous management review documents, action plans and timeframes • results of internal, second-party and third-party audits • customer performance indicators, complaints and feedback • review of the hazard and risk management (HARM) system • incidents, corrective actions, out-of-specification results and non-conforming materials • resource requirements • the site's performance against the Standard and the objectives set • the effectiveness of root cause analysis and corrective actions. 	
1.2.3	The meeting shall be documented and used to revise the objectives. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed timescales.	
1.2.4	The site shall have a demonstrable system in place which enables product safety, legality and quality issues to be brought to the attention of senior management and allows for the resolution of issues requiring immediate action.	

Notes		
1.3	Organisational structure, responsibilities and management authority	
SOI	The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality, regulatory compliance and quality.	
1.3.1	The site shall have a current organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure product safety, quality and legality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.	
1.3.2	Clear communication and reporting channels shall be in place to report on and monitor compliance with the Standard.	
1.3.3	The site's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instructions.	
Notes		
1.4	Business recovery plan	
SOI	The company's senior management shall ensure that the continuing operation of the company is assured through a business recovery plan	
9.1.4.1	Electronic files, records, data and systems shall be suitably protected and backed up. A test of the system shall be carried out at least once per year, or when any significant changes are made to the system.	
2	Hazard and risk management system	
2.1	Hazard and risk management team	
SOI	A multidisciplinary hazard and risk management team shall be in place to develop and manage the hazard and risk management system and ensure the system is fully implemented and evaluated for its effectiveness.	
2.1.1	The hazard and risk management system shall be developed, reviewed and managed by a multidisciplinary team that includes those responsible for quality, technical, engineering/maintenance, production operations and other relevant functions. In the event that the site does not have the appropriate expertise in-house, external expertise may be used to analyse any hazards and the risk of them occurring, and/or	

	develop and review the hazard and risk management system. However, the day-to-day management of the system shall remain the responsibility of the site.	
2.1.2	The multidisciplinary team shall have a designated team leader who shall be suitably trained and able to demonstrate competence and experience of hazard and risk analysis.	
2.1.3	The team shall be able to demonstrate competence in hazard and risk analysis principles and be kept up to date with factory changes and customer requirements as they occur.	
Notes		
2.2	Hazard and risk analysis	
SOI	A documented hazard and risk management system shall be in place to ensure that all hazards to product safety, quality and legality are identified and appropriate controls established.	
2.2.1	The scope of the hazard and risk analysis shall be clearly defined and documented and shall cover all products and processes included within the intended scope of certification.	
2.2.2	The hazard and risk analysis team shall maintain awareness of and take into account: <ul style="list-style-type: none"> • historical and known hazards associated with specific processes, raw materials or intended use of the product (where known) • known likely product defects that affect safety or quality • relevant codes of practice or recognised guidelines • legislative requirements. 	
2.2.3	A full description of the product shall be developed, which includes all relevant information on product safety, quality and integrity. As a guide this may include: <ul style="list-style-type: none"> • composition (e.g. raw materials, inks, varnishes, coatings and other print chemicals) • origin of raw materials, including use of recycled materials • intended use of the packaging materials and defined restrictions on use; for example, direct contact with food or other hygiene-sensitive products, or the physical or chemical conditions. 	
2.2.4	A flow diagram shall be prepared for each product, product group or process. This shall set out each process step from the receipt of raw materials to dispatch to the customer. As a guide this shall include, as relevant: <ul style="list-style-type: none"> • receipt and approval of artwork • receipt and preparation of raw materials such as additives, inks and 	

	<p>adhesives</p> <ul style="list-style-type: none"> • each manufacturing process step • in-line testing or measuring equipment • the use of rework and post-consumer recycled materials • any subcontracted processes • customer returns. <p>The accuracy of the process flow shall be validated by the hazard and risk analysis team.</p>	
2.2.5	<p>The hazard and risk analysis team shall identify and record all potential hazards that are reasonably expected to occur at each step in relation to the product and process. The hazards considered shall include, where relevant:</p> <ul style="list-style-type: none"> • microbiological • foreign objects • chemical contamination (e.g. taint, odour, allergen, component transfer from inks, varnishes and glues) • potential problems arising from the use of recycled materials • legality • defects critical to consumer safety • hazards that may have an impact on the functional integrity and performance of the final product in use • potential for unintended migration of substances from the packaging material into food or other hygiene-sensitive product • potential for malicious intervention. 	
2.2.6	<p>The hazard and risk analysis team shall identify control measures necessary to prevent, eliminate or reduce each hazard to acceptable levels.</p> <p>Controls for identified hazards to product quality shall be appropriately managed through the prerequisite programme, as set out in section 5.</p> <p>Where control is through prerequisite programmes these shall be reviewed to ensure they adequately control the risk identified and, where necessary, improvements implemented.</p>	
2.2.7	<p>For each hazard that requires control, other than by an existing prerequisite programme (as set out in sections 4–6), the control points shall be reviewed to identify those that are critical. This process shall include an assessment of the risk level for each hazard based on the likelihood of the occurrence and the severity of the outcome.</p> <p>Critical control points shall be those control points that are required to prevent, eliminate or reduce a product safety or integrity hazard to acceptable levels.</p> <p>Where a control point is not classified as critical and control may be achieved through a prerequisite programme, a programme shall be developed that is sufficiently specified to effectively control the identified hazard(s).</p>	
2.2.8	<p>For each critical control point, 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</p>	

	measurable, where possible, and the rationale for their establishment clearly documented. Relevant legislation and codes of practice shall be taken into account when establishing the limits.	
2.2.9	For each critical control point, a monitoring system shall be defined in order to ensure compliance with critical limits. Records of the monitoring shall be maintained. Documented procedures relating to the monitoring of critical controls shall be included in internal audits against the Standard (see clause 3.3).	
2.2.10	The corrective action that shall be taken when monitored results indicate a failure to meet the control limit shall be established and documented. This shall include the procedures for quarantining and evaluating potentially out-of-specification products to ensure they are not released until their safety, quality and legality can be established.	
2.2.11	<p>A review of the hazard and risk management system and prerequisite programmes shall be carried out at least once per year and following any significant incidents or when any process changes.</p> <p>The review shall include a verification that the hazard and risk analysis plan is effective and may include a review of:</p> <ul style="list-style-type: none"> • process changes • product composition changes • complaints • product failures • finished product recalls from consumers (including system tests) • product withdrawals • results of internal audits of prerequisite programmes • results from external and third-party auditors • new developments in industry associated with materials, process or product. 	
Notes		
2.3	Exemption of requirements based on risk analysis	
SOI	The hazard and risk analysis study shall be fully supported by the implementation of the prerequisites set out in requirements clauses 4 to 6. However, the hazard and risk analysis may indicate that some of the requirements may be exempted.	
2.3.1	Exemptions shall be documented and regarded as proposed exemptions for review at audit. Acceptance or rejection of the proposed exemptions shall be recorded in the auditor's report.	
2.3.2	The site shall keep recorded exemptions to the Standard under review and provide	

	documented evidence of this review at subsequent audit.	
Notes		
3	Product safety and quality management	
3.1	Product safety and quality management system	
SOI	The site's processes and procedures to meet the requirements of this Standard shall be documented to allow consistent application, facilitate training, and support due diligence in the production of a safe and legal product.	
3.1.1	The site's documented procedures, working methods and practices shall be collated in a navigable and readily accessible system, with consideration being given to translation into appropriate languages.	
3.1.2	The system shall be fully implemented, reviewed at appropriate planned intervals and improved where necessary.	
9.3.1.3	The site shall define and document how new procedures, working methods and practices are communicated to relevant personnel.	
Notes		
3.2	Documentation Control	
SOI	An effective document control system shall ensure that only the correct versions of documents, including recording forms, are available and in use.	
3.2.1	The company shall have a documented procedure to manage documents which form part of the product safety and quality system. This shall include: <ul style="list-style-type: none"> • 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. 	
3.2.2	Where documents and records are in electronic form these shall be suitably protected to prevent loss or malicious intervention.	

Notes		
3.3	Record keeping	
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, appropriately authorised, retained in good condition, and retrievable. Where records are in electronic form these shall be suitably backed up to prevent loss.	
3.3.2	Any alterations to records shall be authorised and justification for the alteration shall be recorded.	
3.3.3	The company's senior management shall ensure that documented procedures are established and implemented for the organisation, review, maintenance, storage and retrieval of all records relating to product safety, legality, regulatory compliance and quality.	
3.3.4	The period of retention for records shall relate to the usable life of the packaging and products it is designed to contain and shall respect any customer requirements.	
9.3.3.5	A policy shall state that Production records and all other records associated with product safety, quality and legality shall be written indelibly. Any alterations to records shall be authorised and justification for the alteration shall be recorded.	
Notes		
3.4	Specifications	
SOI	Appropriate specifications shall exist for raw materials, intermediate and finished products, and for any product or service which could affect the quality of the finished product and customer requirements.	
3.4.1	Specifications shall be suitably detailed and accurate, and shall ensure compliance with relevant product safety and legislative requirements.	
3.4.2	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that they have taken steps to put an agreement in place.	

3.4.3	<p>A declaration of compliance shall be maintained which enables users of the packaging materials to ensure compatibility between those materials and the product with which they may be in contact.</p> <p>The declaration of compliance shall contain as a minimum:</p> <ul style="list-style-type: none"> • the nature of the materials used in the manufacture of the packaging • confirmation that the packaging materials meet relevant legal requirements • the inclusion of any post-consumer recycled materials. <p>This shall identify any limitations of use of the product and the usable life of the packaging material (where relevant).</p> <p>Products shall meet at least minimum legal requirements in the country of manufacture, and use, where known.</p>	
3.4.4	The presence of manufacturer's trademarks or logo on packaging materials shall, where appropriate, be formally agreed between relevant parties.	
3.4.5	A specification review process shall be operated where product characteristics change or at an appropriate predetermined interval.	
3.4.6	Where specifications are in electronic form these shall be suitably protected to prevent loss or malicious intervention.	
Notes		
3.5	Internal audits	
SOI	The company shall be able to demonstrate that it verifies the effective application of the requirements of the Global Standard for Packaging and Packaging Materials through internal audits.	
3.5.1	<p>There shall be a scheduled programme of internal audits throughout the year with a scope which covers the hazard and risk management system, prerequisite programmes and all procedures that have been implemented to achieve this Standard. All activities shall be covered at least annually.</p> <p>The internal audit programme shall be fully implemented.</p>	
3.5.2	The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance.	
3.5.3	Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be sufficiently independent from the process being audited to ensure impartiality (i.e. they must not audit their own work).	
3.5.4	<p>Internal audit reports shall identify conformity as well as non-conformity.</p> <p>Results shall be notified to the personnel responsible for the process audited. Root</p>	

	cause analysis shall be used to determine appropriate corrective actions. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.	
Notes		
3.6	Supplier approval and performance monitoring	
SOI	The company shall operate effective, documented procedures for approval and monitoring of its suppliers.	
3.6.1	<p>The site shall have a documented supplier approval procedure and continual assessment programme in place, based upon risk analysis. These shall apply to suppliers of:</p> <ul style="list-style-type: none"> • materials • subcontracted processes <p>to the site and ensure that materials and services procured conform to defined requirements, where there is a potential impact to product safety, quality or legality.</p>	
3.6.2	<p>The procedures shall include clear criteria for the assessment and approval of new suppliers. Assessment may take the form of:</p> <ul style="list-style-type: none"> • supplier certification with a scope covering the products supplied (e.g. against the appropriate BRC Global Standard, or other GFSI benchmarked scheme) • supplier questionnaires • supplier audits. <p>The site shall have an up-to-date list of approved suppliers.</p>	
3.6.3	Records of supplier assessment and necessary actions shall be maintained and reviewed.	
3.6.4	<p>The procedures shall define how exceptions are handled; for example, the use of products or services where audit or monitoring has not been undertaken. Assessment (on a batch or delivery basis) may take the form of:</p> <ul style="list-style-type: none"> • certificate of analysis • declaration of compliance. 	

Notes		
3.7	Management of subcontracted processes	
SOI	Where any process steps in the manufacture of the packaging material are subcontracted to a third party or undertaken at another site, this shall be managed to ensure it does not compromise the quality, safety or legality of the product.	
3.7.1	The use of subcontractors and the status of the subcontractor with respect to the Standard shall be notified to the brand owner and/or customer.	
3.7.2	Where any processes are subcontracted, including artwork or pre-press activity, the risks to the quality and safety of the product shall form part of the hazard and risk analysis and the company's evaluation of the system shall be held on record.	
3.7.3	Clear specifications shall be agreed for all work outsourced to a subcontractor.	
3.7.4	Where any process steps in the manufacture of the packaging or packaging material are subcontracted, final release of the product shall remain the responsibility of the site. Controls shall be in place for checks on finished work to ensure product safety and quality meets specification prior to dispatch to the final customer.	
Notes		
3.8	Management of suppliers of services	
SOI	The company shall be able to demonstrate that where services are outsourced, the service is appropriate and any risks presented to product safety, quality or legality have been evaluated to ensure effective controls are in place	
3.8.1	There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services may include, but are not limited to: <ul style="list-style-type: none"> • pest control • laundry services • transport and distribution • storage and dispatch 	

	<ul style="list-style-type: none"> • sorting or rework • laboratory services • calibration services • waste management. <p>Providers of utilities such as water, electricity or gas may be excluded on the basis of risk.</p>	
3.8.2	Documented agreements shall exist with the suppliers of services which clearly define service expectations and ensure potential risks associated with the service have been addressed.	
Notes		
3.9	Traceability	
SOI	The site shall be able to trace and follow all raw materials through processing to the distribution of the finished product (packaging material) to the customer and vice versa.	
3.9.1	The site shall have a system which has the ability to trace and follow all raw materials from the supplier through all stages of processing and distribution of the finished product and vice versa. Where continuous processes are used or raw materials are in bulk silos, traceability shall be achieved to the best practical level of accuracy.	
3.9.2	Identification of raw materials, intermediate products, finished products, non-conforming product and quarantined goods shall be adequate to ensure traceability.	
3.9.3	An appropriate system shall be in place to ensure the customer can identify a product or production lot number for the product, for the purposes of traceability.	
3.9.4	<p>The system shall be tested to ensure traceability can be determined from raw materials to the finished product and vice versa. Records shall be retrievable in a timely manner.</p> <p>This shall take place on a predetermined frequency, at least on an annual basis, and results retained for inspection.</p>	
3.9.5	Where rework or any reworking operation is performed, traceability shall be maintained.	

Notes		
3.10	Customer Focus and Contract Review	
SOI	The company's senior management shall ensure that processes are in place to determine customer needs and expectations with regard to quality, safety and legality, and ensure these are fulfilled.	
3.10.1	The company shall clearly identify those job titles responsible for communication with customers and shall have an effective system for communication.	
3.10.2	Customer needs and expectations shall be documented and reviewed on a suitable frequency. Any changes to existing agreements or contracts shall be agreed, documented and communicated to appropriate departments.	
3.10.3	Where customers have set particular performance criteria or indicators for monitoring, these requirements shall be communicated to relevant staff, adhered to, and reviewed at appropriate intervals.	
Notes		
3.11	Complaint handling	
SOI	Customer complaints relating to product hygiene, safety or quality shall be handled effectively and the information used to reduce complaint levels.	
3.11.1	All complaints shall be recorded and investigated (including root cause analysis) and the results of the investigation documented. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.	
3.11.2	Complaint data shall be analysed to identify significant trends. Where there has been an increase or repetition of a complaint type, 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.	
9.3.11.3	All complaints regarding raw material defects identified by the site shall be recorded and investigated (including root cause analysis) and the results of the investigation documented.	

Notes		
3.12	Management of product withdrawals, and incidents and product recalls	
SOI	The site shall have a plan and systems in place to effectively manage any product withdrawals or returns from customers, incidents and product recalls in order to ensure that all potential risks to the hygiene, quality, safety or legality of products and the final consumer are controlled.	
3.12.1	<p>A product withdrawal procedure shall be documented and shall include as a minimum:</p> <ul style="list-style-type: none"> • identification of the key personnel involved in assessing potential product withdrawals or returns, with their responsibilities clearly defined • a communications plan including methods of informing customers • root cause analysis and corrective action to implement appropriate improvements as required. 	
3.12.2	The withdrawal procedure shall be capable of being operated at any time and will take into account notification to the supply chain, stock return, logistics for recovery, storage of recovered product and disposal.	
3.12.3	The designated manager shall be responsible for ensuring that root cause analysis is used to determine and implement preventive action and improvements as necessary.	
3.12.4	The company shall provide written guidance and training for relevant staff regarding the type of event that would constitute an incident. A documented incident reporting procedure shall be in place.	
3.12.5	The company shall determine and document the activity required to effectively manage an incident to prevent release of product where hygiene, safety or quality may have been affected.	
3.12.6	<p>A procedure to manage product recalls initiated by the brand owner or specifier shall be documented and shall include as a minimum:</p> <ul style="list-style-type: none"> • identification of the key personnel involved in assessing potential recalls, together with clearly defined responsibilities • a communications plan that includes methods of informing customers and (where necessary) regulatory bodies in a timely manner • corrective action and business recovery • review of any recalls in order to conduct root cause analysis and implement appropriate improvements as required. 	
3.12.7	Where a site's products are involved in a product recall, the site shall assist with provision of information (such as traceability) as required.	

3.12.8	<p>The product withdrawal procedure shall be tested, at least annually, in a way that ensures its effective operation. Results of the test shall be retained and shall include timings of key activities.</p> <p>The results of the test, and of any actual withdrawals, shall be used to review the procedure and implement improvements as necessary.</p>	
Notes		
4	Site Standards	
4.1	External standards	
SOI	<p>The site shall be of suitable size and construction, in a suitable location, and maintained to an appropriate standard to reduce the risk of contamination and facilitate the production of safe and legal products.</p>	
4.1.1	<p>Consideration shall be given to local activities and the site environment, which may have an adverse impact on the safety or quality of the finished product or raw materials, and measures shall be taken to prevent contamination. Where measures have been put in place to protect the site, they shall be regularly reviewed to ensure they continue to be effective (e.g. flood controls).</p>	
4.1.2	<p>The external areas shall be maintained in good order. Any grassed or planted areas surrounding buildings shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced to avoid contamination of the product.</p>	
4.1.3	<p>The building fabric shall be maintained to minimise potential for pest entry, ingress of water and other contaminants. External silos, pipework or other access points for the product and/or raw materials shall be appropriately sealed and secured. Where possible, a clean and unobstructed area shall be provided along the external walls of the buildings used for production and/or storage.</p>	
4.1.4	<p>Where natural external drainage is inadequate, additional drainage shall be installed. Drains shall be properly protected to prevent entry of pests.</p>	
4.1.5	<p>Where external storage of raw materials is necessary, these shall be protected in order to minimise the risk of contamination.</p>	
9.4.1.6	<p>Where production and storage areas are surrounded by grassed or planted areas, there shall be a vegetation free zone around the buildings.</p>	

Notes		
4.2	Building fabric and interiors	
SOI	The internal site, buildings and facilities shall be suitable for the intended purpose and shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.	
4.2.1	Walls, floors, ceilings and pipework shall be maintained in good condition and shall facilitate cleaning.	
4.2.2	Where suspended ceilings exist they shall be constructed, finished and maintained to prevent the risk of product contamination, and accessible for cleaning and inspection for pests unless the void is fully sealed.	
4.2.3	All internal drain openings shall be suitably protected against the entry of pests and designed to minimise odour.	
4.2.4	Where they constitute a risk to product, and based on the likelihood and risk of contamination, windows and roof glazing shall be protected against breakage.	
4.2.5	Where they constitute a risk to product, and based on the likelihood and risk of non-production glass contamination, all bulbs and strip lights, including those on flying-insect control devices, shall be adequately protected.	
4.2.6	Suitable and sufficient lighting shall be provided to ensure a safe working environment, correct operation of processes, effective inspection of the product and cleaning.	
4.2.7	Suitable and sufficient ventilation shall be provided.	
Notes		
4.3	Utilities	
SOI	All utilities to and within the production and storage areas shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.	
4.3.1	All water used in the processing of the products or equipment cleaning shall be	

	potable or suitably treated to prevent contamination.	
4.3.2	Based on risk assessment, the microbiological and chemical quality of water, steam, ice, air, compressed air or other gases which come into direct contact with packaging shall be regularly monitored. These shall present no risk to product safety or quality and shall comply with relevant legal regulations.	
Notes		
4.4	Security	
SOI	Security arrangements shall be assessed to ensure the integrity of products and processes.	
4.4.1	The company shall undertake a documented risk assessment of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled. Identified security arrangements to reduce risks shall be documented, implemented and reviewed at least annually.	
4.4.2	Measures shall be in place to ensure only authorised personnel have access to production and storage areas, and access to the site by employees, contractors and visitors shall be controlled. A visitor reporting system shall be in place. Staff shall be trained in site security procedures and encouraged to report unidentified or unknown visitors.	
4.4.3	External storage tanks, silos and any intake pipes with an external opening shall be sufficiently secure to prevent unauthorised access.	
Notes		
4.5	Layout and product flow	
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 all relevant legislation.	
4.5.1	There shall be a plan of the site which defines:	

	<ul style="list-style-type: none"> • access points for personnel • travel routes • staff facilities • process flow • storage areas. 	
4.5.2	The process flow from intake to dispatch shall be arranged to minimise the risk of contamination or damage to the product.	
4.5.3	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe and hygienic conditions.	
4.5.4	Sorting or other activities involving the direct handling of the product shall take place in areas that have, as a minimum, the same standards as production areas.	
4.5.5	Activities that could produce a contamination risk, such as the removal of outer packaging, shall be carried out in a designated, segregated area.	
4.5.6	If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials.	
4.5.7	Where possible, all facilities shall be designed and positioned so that movement of personnel is by simple, logical routes.	
Notes		
4.6	Equipment	
SOI	Equipment shall be suitably designed for the intended purpose and shall be maintained and used so as to minimise the risk to product safety, legality and quality.	
4.6.1	Equipment shall be designed for the intended purpose and shall minimise the risk of contamination to the product. Equipment shall be constructed of suitable materials and be designed to ensure it can be effectively cleaned and maintained.	
4.6.2	Newly installed equipment shall be properly specified before purchase. New equipment shall be tested and commissioned prior to use and a maintenance and cleaning programme established.	
4.6.3	Wooden equipment including desks, chairs, tables, etc. shall be properly sealed to enable effective cleaning. This equipment shall be kept clean, in good condition and free from splinters or other sources of physical contamination.	
4.6.4	Notices on equipment shall be cleanable and secure.	

9.4.6.5	Lubrication points and application methods of any lubricant shall not be able to contaminate the product.	
Notes		
4.7	Maintenance	
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	A documented programme of maintenance shall be operated, covering all items of production equipment and plant, to prevent contamination and reduce the risk of breakdown.	
4.7.2	A condition-based or preventive maintenance programme shall be in place, covering all items of equipment and plant that are critical to product safety, legality and quality.	
4.7.3	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment failure or damage, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken.	
4.7.4	Maintenance work shall not place product safety, quality or legality at risk. Maintenance work shall be followed by a documented clearance procedure which records that contamination hazards have been removed and equipment cleared to resume production.	
4.7.5	Tools and other maintenance equipment shall be cleared away after use and appropriately stored.	
4.7.6	Temporary repairs/modifications using tape, cardboard, etc., shall only be permitted in emergencies and where product contamination is not at risk. Such modifications shall be subject to a time limit and shall be recorded and scheduled for correction.	
4.7.7	Engineering workshops shall be controlled to prevent transfer of engineering debris to production or storage areas (e.g. by provision of swarf mats).	
4.7.8	Contractors involved in maintenance or repair shall be suitably monitored by a staff member who shall be responsible for their activities.	

Notes		
4.8	Housekeeping and cleaning	
SOI	Housekeeping and cleaning systems shall be in place which ensure that appropriate standards of hygiene are maintained and that risk of contamination to the product is minimised.	
4.8.1	Good standards of housekeeping shall be maintained, which shall include a 'clean as you go' policy.	
4.8.2	<p>Documented cleaning procedures shall be in place and maintained for buildings, equipment and vehicles. The frequency and methods of cleaning shall be based on risk. Cleaning schedules and procedures shall include the following information:</p> <ul style="list-style-type: none"> • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning • cleaning materials to be used • cleaning record and responsibility for verification. 	
4.8.3	<p>Cleaning chemicals shall be fit for purpose, suitably labelled, and used in accordance with manufacturers' instructions. They shall be stored in a secured, designated location, in closed containers. Chemicals that are strongly scented or could give rise to taint and odour contamination shall not be used.</p> <p>Cleaning equipment shall be kept in a suitable designated location.</p>	
4.8.4	Materials and equipment used for cleaning toilets shall be segregated from those used elsewhere.	
9.4.8.5	The conditions required in production and storage areas shall be specified. There shall be a regular documented check that conditions match those required, and activity undertaken where required.	
9.4.8.6	The site shall ensure that equipment, in-process and finished articles are subject to sufficient segregation to reduce the risk of mixing.	

Notes		
4.9	Product contamination control	
SOI	All practicable steps shall be taken to identify, eliminate, avoid or minimise the risk of foreign body or chemical contamination.	
4.9.1	Glass, brittle plastics, ceramics and similar materials control	
4.9.1.1	There shall be no unnecessary non-production glass, ceramics or brittle plastic, which may pose a risk of contamination.	
4.9.1.2	<p>All glass or brittle plastics other than the product shall be controlled and recorded on a register which shall include as a minimum:</p> <ul style="list-style-type: none"> • a list of items detailing location, number, type and condition • recorded checks of condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise potential for product contamination. <p>Glass or brittle plastics not in the production or storage areas shall be included in the register on the basis of risk.</p>	
4.9.1.3	<p>Where non-production glass or brittle plastic breakage occurs, a responsible person shall be placed in charge of the clean-up operation and shall ensure that no other area is allowed to become contaminated due to the breakage. Any product that has become contaminated shall be segregated and disposed of.</p> <p>All breakages shall be recorded in an incident report.</p>	
Notes		
4.9.2	Sharps control	
4.9.2.1	There shall be a documented policy for the control of the use of sharps.	
4.9.2.2	Sharp blades, equipment and tools shall not be left in a position that allows them to contaminate the product.	
4.9.2.3	Sharp cutting instruments used in the manufacture of packaging materials shall be	

	controlled to prevent product contamination. This shall include control into and out of the factory.	
4.9.2.4	Snap-off blade knives shall not be used.	
4.9.2.5	Where open noticeboards are present in production, packing and storage areas, loose fastenings, such as drawing pins and staples, shall not be used.	
Notes		
4.9.3	Chemical and biological control	
4.9.3.1	Processes shall be in place to manage the use, storage and handling of non-production chemicals, to prevent chemical contamination. These shall include as a minimum: <ul style="list-style-type: none"> • a list of approved chemicals for purchase • availability of material safety data sheets and specifications • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times • designated storage area with access restricted to authorised personnel • use by trained personnel only. 	
4.9.3.2	Hazard and risk analysis shall be used to identify, control and manage any potential risks from microbiological contamination and any potential allergens.	
Notes		
4.10	Waste and waste disposal	
SOI	Suitable facilities shall be provided for the storage and disposal of process and other waste.	
4.10.1	Where licensing is required by law for the removal of waste, it shall be removed by licensed contractors and records of removal shall be maintained and available for audit.	
4.10.2	Suitable and sufficient refuse and waste containers shall be provided, which shall be emptied at appropriate frequencies and maintained in an adequately clean condition.	

4.10.3	Where appropriate, waste shall be categorised according to legislative requirements based on the intended means of disposal (such as recycling), and sorted, segregated and collected in appropriate designated waste containers.	
4.10.4	Substandard trademarked materials shall be rendered unusable through a destructive process. All materials disposed of shall be recorded.	
4.10.5	If substandard trademarked materials are transferred to a third party for destruction or disposal, that third party shall be a specialist in appropriate waste disposal and shall provide records of material destruction.	
4.10.6	External storage of refuse shall be in designated areas and designed or maintained to minimise the risk of pest harbourage.	
Notes		
4.11	Pest control	
SOI	In order to minimise the risk of infestation and prevent risk to products, the whole site shall have an effective preventive pest control programme in place and the resources available to respond immediately to any issues which occur.	
4.11.1	A preventive pest control programme shall be maintained, covering all areas of the site under the site's control.	
4.11.2	The site shall either contract the services of a competent pest control organisation or shall have appropriately trained staff for the regular inspection and treatment of the site in order 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 control contractor are employed, the service contract shall be clearly defined and reflect the activities of the site.	
4.11.3	Where a site undertakes its own pest control, it shall be able to demonstrate that: <ul style="list-style-type: none"> • pest control 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 control 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 • dedicated locked facilities are used for the storage of pesticides. 	
4.11.4	Pest control equipment such as bait stations, traps or electric fly-killing devices shall	

	be appropriately located and operational.	
4.11.5	Effective precautions shall be in place to prevent pests entering the premises. The building shall be suitably proofed against the entry of all pests via doors, windows, ducts and cable entry points.	
4.11.6	In the event of infestation, immediate action shall be taken to eliminate the hazard. Action shall be taken to identify, evaluate the potential for contamination or damage, and authorise the release of any product potentially affected.	
4.11.7	In the event of an infestation, and at appropriate intervals, the site shall request a catch analysis from flying-insect control devices to help identify problem areas. In the event of increase in activity, the site shall use risk assessment to determine the activity required to eliminate the hazard.	
4.11.8	Documented procedures and detailed records of pest activity, pest control inspections and recommendations shall be maintained. These shall include as a minimum: <ul style="list-style-type: none"> • an up-to-date, signed and authorised site plan identifying numbered pest control device locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for site management and the contractor • details of pest control products used and instructions for their effective use • detailed records of pest control inspections, recommendations and of any pest infestation. <p>It shall be the responsibility of the site to ensure that all the relevant recommendations made by the contractor or in-house expert are implemented in a timely manner and monitored for efficacy.</p>	
4.11.9	Employees shall understand the signs of pest activity and be aware of the need to report any evidence to a designated manager.	
9.4.11.10	The site shall assess the suitability of its pest control programme to address variation in pest activity through different seasons, and consider any additional preventative activity required. The site shall document and implement this additional activity.	
9.4.11.11	Risk assessment and ongoing data should be used to determine whether lighting type or positioning is adversely attracting insects and/or highlighting any mitigation where required. Internal and external lighting for production and storage buildings shall be designed and constructed to avoid attracting insects through windows or other openings.	
9.4.11.12	The site shall use a documented risk and ongoing assessment to determine if double door sets are required when moving from external to internal areas. The site shall conduct ongoing assessment to determine if the closing systems are effective, where implemented.	

Notes		
9.4.12	Ambient Environment	
SOI	The site shall ensure that local environmental factors such as temperature and humidity do not affect product quality from raw materials to finished products.	
9.4.12.1	The site shall evaluate the typical local environmental conditions such as temperature and humidity on the quality and process characteristics (e.g. machine settings). Evaluation of hazards identified shall be documented, and measures established to manage this impact shall be documented and validated.	
5	Product and process control	
5.1	Product development	
SOI	Documented product development or modification procedures shall be in place to ensure the production of safe and legal products to defined quality parameters.	
5.1.1	<p>Customer requirements relating to the design, development, specification, manufacture and distribution of the product shall be documented and agreed with the customer.</p> <p>This shall take into consideration process requirements and end use, where possible.</p> <p>Any critical-use parameters shall be identified and defined; for example, barrier requirements, max/min use temperature, machine running, use of recycled materials, and testing requirements (including migration, where relevant).</p> <p>Special attention shall be paid to any materials that are required or requested to be manufactured from recycled materials, to ensure that they are both appropriate and legal.</p>	
5.1.2	<p>The site shall clearly define and document when a production trial is required.</p> <p>Where appropriate, production trials shall be carried out and testing shall validate that manufacturing processes are capable of producing a safe and legal product to the required quality.</p>	
5.1.3	The company shall ensure that production is carried out using defined operating conditions that result in safe and legal products of the prescribed quality.	
5.1.4	A technical product specification shall be prepared and, where possible, agreed with the customer or brand owner before the production process begins.	
5.1.5	Samples as agreed with the specifier shall be retained for future reference.	
9.5.1.6	A documented procedure shall be place to address the transfer of customer specification to the site's own systems. This shall include (but is not limited to):	

	<ul style="list-style-type: none"> • validation of accuracy of data transferred • how changes to customer specifications are updated and communicated • how customer testing method requirements are met • evaluation of how changes made to customer specification affect the technical product specification (5.1.1) 	
9.5.1.7	New products or product changes shall be subject to suitable testing to ensure that required quality parameters can be achieved.	
9.5.1.8	The site shall determine the outputs and success criteria required from a production trial, changes and/or additions made to materials, processing characteristics or equipment.	
9.5.1.9	Settings derived from successfully qualified production trials or equipment installations shall be transferred accurately to process control documentation.	
9.5.1.10	The site's test methods used in both on-line and off-line testing shall be validated to ensure their validity, sensitivity, reproducibility and range, in addition to any other relevant criteria.	
Notes		
5.2	Graphic design and artwork control	
SOI	Artwork and all pre-press processes conducted by the site shall be managed to ensure loss of information and variation from customer specification is eliminated.	
5.2.1	<p>The site shall have a documented artwork management procedure covering the activities for which the site has responsibility. This may include, but is not limited to:</p> <ul style="list-style-type: none"> • collation of information to be included into artwork • receipt of artwork files from the customer • verification of completed artwork and approval by the customer. 	
5.2.2	<p>A process shall be in place to seek formal acceptance and approval of final product concepts and artworks by the specifier.</p> <p>The outcome shall be documented.</p>	
5.2.3	Where appropriate, print trials shall be carried out and testing shall validate that the agreed product quality and print standards can be consistently achieved.	
5.2.4	Printing equipment such as plates, silk screens, anilox rollers, cylinders and blankets shall be verified as being correct to specification and artwork version or agreed master prior to use, and fully traceable to the customer's approved origination material.	
5.2.5	Customer-approved reference material, including artwork masters and colour	

	standards used during print runs, shall be controlled to ensure minimisation of degradation and shall be returned to appropriate storage after use. The site shall have a policy to address requirements for renewal of approved masters, as necessary.	
5.2.6	The site shall have a documented procedure for managing changes to artwork and print specifications to manage obsolete artwork and printing materials.	
5.2.7	Where artwork files and approved masters are in electronic form, these shall be suitably protected to prevent loss or malicious intervention.	
Notes		
5.3	Packaging print control	
SOI	Where packaging materials are printed or decorated, procedures shall be in place to ensure that the information is fully legible and correctly reproduced to customer specification and any applicable legal requirements.	
5.3.1	An assessment shall be carried out of the pre-press activity, print process and handling of printed packaging (product) to identify: <ul style="list-style-type: none"> • risks of loss of essential information • mixing of printed product. Controls shall be established and implemented to reduce the risks identified.	
5.3.2	Printing plates, cylinders, cutting dies, print blankets and any other printing equipment shall be appropriately stored to minimise damage.	
5.3.3	Each print run shall be approved against the agreed standard (or master sample). This shall be recorded.	
5.3.4	A system shall be in place to detect and identify printing errors during the run and to sort these errors from the acceptable printed material.	
5.3.5	Where composite print is used (a mixture of different designs printed together), a process shall be in place to ensure effective segregation of differing print variants.	
5.3.6	Samples of printed packaging shall be retained together with production records for a period of time to be agreed with the customer/specifier/brand owner.	
5.3.7	Any unused printed product shall be accounted for and either disposed of or identified and appropriately stored.	
5.3.8	Lighting in print inspection cabinets and other means of print/colour checking shall be agreed with the customer or conform to accepted industry standards.	

Notes		
5.4	Process control	
SOI	Documented procedures shall be in place to ensure effective quality assurance of operations throughout the process	
5.4.1	A review of the manufacturing and, where applicable, printing process shall identify manufacturing process control points that could significantly affect the quality of the products produced.	
5.4.2	For each manufacturing process control point, machine settings or process limits shall be established and documented – the process specification.	
5.4.3	A bill of materials and process specification (including manufacturing process control points) shall be available for each batch or lot during production.	
5.4.4	Documented process checks shall be undertaken at start-up, following adjustments to equipment and periodically during production, to ensure products are consistently produced to the agreed quality specification.	
5.4.5	A documented clearance procedure shall be in place to ensure that at start-up the line is clear of all previous work and production documents.	
5.4.6	In the event of changes to product composition, processing methods or equipment, the site shall, where appropriate, re-establish process characteristics and validate product data to ensure product safety, legality and quality are achieved.	
9.5.4.7	<p>The documented line clearance procedure shall include:</p> <ul style="list-style-type: none"> • the roles of persons involved in line clearance • areas where materials can become trapped • validation of the line clearance • sign-off for continuing production <p>The line clearance procedure shall be fully implemented for each production run.</p>	
Notes		
5.5	Calibration and control of measuring and monitoring devices	

SOI	The site shall be able to demonstrate that measuring and monitoring equipment is sufficiently accurate and reliable to provide confidence in measurement results.	
5.5.1	<p>The site shall identify and control in-line and off-line measuring equipment used to monitor critical control points (where applicable) and product safety, quality and legality. This shall include as a minimum:</p> <ul style="list-style-type: none"> • a documented list of equipment and its location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration and misuse. 	
5.5.2	<p>All identified measuring equipment shall be checked and adjusted at a predetermined frequency, based on risk analysis. This shall be carried out by trained staff to a defined method to ensure accuracy within defined parameters. All results shall be documented.</p> <p>Where possible, calibration shall be traceable to a recognised national or international standard. Where a traceable calibration is not possible, the site shall demonstrate the basis by which standardisation is carried out.</p>	
5.5.3	<p>Corrective action and reporting procedures shall be established and documented in the event of the monitoring and testing procedure identifying any failure of product inspection, testing or measuring equipment. Any such failures shall be subject to an assessment of potential risk; subsequent action may include a combination of isolation, quarantine and re-inspection of products produced since the last acceptance test of the equipment.</p> <p>The site shall conduct a root cause analysis into the equipment failure and implement the appropriate corrective action.</p>	
Notes		
5.6	Product inspection, testing and measuring	
SOI	The company shall use appropriate documented procedures and facilities when undertaking or subcontracting inspection and analyses critical to product safety, legality and quality.	
5.6.1	<p>Quality checks shall be carried out to demonstrate that the finished product is within the tolerances laid down in the agreed product specification and conforms to any critical technical/legal requirements.</p> <p>The frequency of checks shall be in accordance with industry-accepted practice or customer requirements and based on risk analysis.</p>	
5.6.2	Hazard and risk analysis principles shall be used to determine the need for in-line product testing equipment to ensure product safety, quality and legality.	

5.6.3	The accuracy of in-line equipment shall be specified (with permitted tolerances), having due regard to the product parameter being controlled.	
5.6.4	The company shall establish, document and implement procedures for the operation, routine monitoring and testing of all equipment used in product inspection, testing and measurement. This shall include: <ul style="list-style-type: none"> • frequency and sensitivity of checks • authorisation of trained personnel to carry out specified tasks • documentation of test results. 	
5.6.5	Routine off-line quality checks shall be carried out at appropriate stages in production to demonstrate that the product is within the tolerances laid down in the agreed product specification. A system, which includes off-line or randomised quality checks, shall be in place to identify and remove non-conforming product from the production lot and ensure that any appropriate action is taken in consideration of the root cause.	
5.6.6	In-line testing equipment critical to product quality or safety shall incorporate a system to identify non-conforming product for removal or divert it out of the product flow.	
5.6.7	Procedures shall be in place to ensure the reliability of test results.	
5.6.8	Where the company undertakes or subcontracts analyses critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO 17025 for the test undertaken (General requirements for the competence of testing and calibration laboratories). Documented justification shall be available where accredited methods are not undertaken.	
9.5.6.9	Samples for checking in-process quality shall be selected according to customer requirements or by industry standard testing protocols.	
9.5.6.10	The site shall define how samples used for checking in-process quality are disposed of. This may be by returning to stock, re-grind/recycling, or segregation and disposal.	
9.5.6.11	Test methods, analytical methods and customer approved reference samples shall be available, kept up to date in the laboratory or where off-line testing is conducted, and shall be suitably stored to avoid degradation.	
9.5.6.12	Traceability of test data and samples to production lots shall be maintained.	
9.5.6.13	Where testing shows out of specification results, there shall be a documented procedure on how these results are investigated to determine if the cause of the out of specification results is non-conforming product or a testing failure. (Re-testing of an out of specification sample shall be done to demonstrate analytical error, not to reverse a previous result.)	
9.5.6.14	Maintenance logs shall be maintained for all off-line testing equipment. This shall include as a minimum: <ul style="list-style-type: none"> • adjustments • re-calibration 	

	<ul style="list-style-type: none"> • date of any interventions. 	
Notes		
5.7	Control of non-conforming product	
SOI	The site shall ensure that out-of-specification product is clearly identified and quarantined.	
5.7.1	Clear procedures for the control of out-of-specification or non-conforming materials shall be in place, documented and understood by all personnel. These shall include the effective identification and quarantining of materials before a decision has been made on their final disposition.	
5.7.2	Non-conforming materials shall be assessed and a decision taken to reject, accept by concession, rework or put to alternative use. The decision and reasons shall be documented.	
5.7.3	Corrective actions, root cause analysis and preventive actions shall be implemented to avoid recurrence of the non-conformity. Actions taken shall be documented.	
Notes		
5.8	Incoming goods	
SOI	Incoming goods shall be appropriately checked for contents, packaging integrity and potential contamination.	
5.8.1	The site shall document a raw materials and intermediate product intake procedure to ensure that incoming goods match purchase or product specifications. This may take the form of: <ul style="list-style-type: none"> • purchase orders • delivery notes. 	
5.8.2	Receipt documents and/or product identification shall facilitate correct stock rotation of goods in storage and, where appropriate, ensure materials are used in the correct order and within the prescribed shelf life.	
9.5.8.3	All incoming raw materials shall be appropriately validated or tested prior to use. All raw materials awaiting results of in-house testing or validation of data shall be	

	held until released for use.	
Notes		
5.9	Storage of all materials and intermediate and finished products	
SOI	The storage of all materials and products shall minimise the risk of contamination or malicious intervention, and protect product safety, quality and legality.	
5.9.1	All materials, work in progress and product shall be properly identified and protected during storage by appropriate packaging to protect the product from contamination.	
5.9.2	Storage, including off-site storage, shall be controlled to protect the product from contamination, including taint or odour and malicious intervention. Where off-site storage is used, the same site standards requirements apply as for on-site storage.	
5.9.3	In order to prevent contamination, documented procedures shall be in place to appropriately segregate raw materials, intermediate products and finished products.	
5.9.4	The site shall ensure that hazardous chemicals are handled in such a way that risk to product safety, quality and legality is minimised.	
5.9.5	Material intended for recycling shall be appropriately protected against contamination hazards.	
9.5.9.6	All raw materials shall have an expiration date defined and documented and a procedure defining how they should be handled where they exceed this date. Where raw materials have no reasonable expiration date, e.g. cullet for glass manufacture, this shall be documented.	
9.5.9.7	Warehousing equipment shall be kept in a good state of repair and cleanliness.	
9.5.9.8	Materials shall be stored away from walls to aid cleaning and inspection of production and storage areas.	
9.5.9.9	To minimise the risk of mix-ups and cross contamination, different materials shall not be stored on the same pallet unless physically segregated.	
Notes		

5.10	Dispatch and transport	
SOI	The dispatch and transport of raw materials and finished products shall be undertaken in a manner that minimises the risk of contamination or malicious intervention and maintains product safety, legality and quality.	
5.10.1	All products and materials shall be identified and either protected during distribution by appropriate external packaging or transported under conditions to protect the product from contamination. This shall include the risk of taint or odour and of malicious intervention.	
5.10.2	All pallets shall be checked. Damaged, contaminated or unacceptable pallets shall be discarded. Wooden pallets that come into direct contact with finished products or raw materials shall not be allowed to contaminate the product. Wooden pallets, if used, shall be sound, dry, clean and free from damage and contamination.	
5.10.3	All company-owned vehicles used for deliveries shall be included in the documented cleaning schedules and kept clean and in a condition to minimise the risk of product contamination.	
5.10.4	All delivery vehicles and shipping containers shall be subject to a documented hygiene-checking procedure before loading.	
5.10.5	<p>Where the company employs third-party contractors there shall be a contract or agreed terms and conditions. All the requirements specified in this section shall be clearly defined in the contract or the company shall be certificated to the Global Standard for Storage and Distribution.</p> <p>Where this is not possible, with general carriers, the packaging shall be adequate to protect the product against damage, contamination hazards, taint and odour.</p>	
5.10.6	<p>Vehicle drivers shall comply with the site rules relevant to this Standard.</p> <p>Access to the site for third-party transport personnel shall be controlled and, where possible, facilities provided to negate the need to enter storage or production areas.</p>	
Notes		
5.11	Product handling	
SOI	The handling and management of intermediate and finished products shall ensure their quality is maintained.	
9.5.11.1	Packaging used for storage or despatch of intermediate or finished products, such as pallets, shall be appropriately covered if stored outside and inspected for signs of damage or contamination prior to use.	
9.5.11.2	Finished products shall not be stored outside.	

9.5.11.3	The site shall have a system in place to validate all raw materials and intermediate products prior to introduction to the process.	
9.5.11.4	Unloading areas for bulk deliveries shall be clearly identified and designed to prevent product mix-ups.	
9.5.11.5	Finished product storage shall meet customer requirements (with regards to first-in-first-out, or FIFO, where applicable), with dispatch after quality release.	
Notes		
5.12	Product release	
SOI	The final product release to the customer shall be determined by a suitably trained and competent person.	
9.5.12.1	The site shall have a procedure that defines how the release of products shall be approved by an authorised person. This procedure shall ensure that only product meeting specification is shipped.	
Notes		
5.13	Validation and change control	
SOI	The labelling of intermediate and finished product shall facilitate identification throughout the supply chain.	
9.5.13.1	All coding applied to intermediate or finished products shall be checked for legibility and accuracy against production records.	
9.5.13.2	Labelling or any other type of identification shall be applied at the line of manufacture upon completion.	
9.5.13.3	The site shall have documented procedure in place controlling label reprints and pallet labelling.	

Notes	
6	Personnel
6.1	Training and competence raw materials handling, preparation, processing, packing and storage areas
SOI	The company shall ensure that all personnel are adequately trained, instructed and supervised commensurate with their activity and that they are competent to undertake their job role.
6.1.1	All personnel, including temporary personnel and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period. Induction training shall include the company hygiene rules.
6.1.2	Where personnel are engaged in activities relating to product safety, quality and legality, relevant training and competency assessment shall be in place. This may include, but is not limited to: <ul style="list-style-type: none"> • product inspection, testing and measuring • calibration • printed packaging controls • operatives at manufacturing process control points.
6.1.3	The company shall routinely review and document the competencies of all staff and provide relevant training as appropriate. This may be in the form of training, refresher training, coaching, mentoring, or on-the-job experience.
6.1.4	Records of training shall be available. These shall include: <ul style="list-style-type: none"> • 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 (external or internal provider). Where training is undertaken by agencies on behalf of the company, records of the training shall be available.
6.1.5	The site shall put in place documented programmes covering the training needs of relevant personnel. These shall include as a minimum: <ul style="list-style-type: none"> • identifying the necessary competencies for specific roles • providing training or other action to ensure staff have the necessary competencies • reviewing the effectiveness of training

	<ul style="list-style-type: none"> the delivery of training in the appropriate language of trainees. 	
9.6.1.6	The effectiveness of trainers shall be monitored and verified.	
9.6.1.7	The site shall ensure that the competency of personnel responsible for laboratory testing and assessment is maintained and developed.	
Notes		
6.2	Personal hygiene raw materials handling, preparation, processing, packing and storage areas	
SOI	The site's personal hygiene standards shall be developed to minimise the risk of product contamination from personnel. These standards shall be appropriate to the products produced and be adopted by all personnel, including agency-supplied staff, contractors and visitors to the production facility.	
6.2.1	<p>The requirements for personal hygiene shall be documented and communicated to all personnel. These shall include, as a minimum, the following instructions:</p> <ul style="list-style-type: none"> watches shall not be worn jewellery shall not be worn on exposed parts of the body, with the exception of a plain wedding ring or wedding wristband and sleeper earrings (continuous loop). perfume or aftershave shall not be worn. <p>Compliance with the requirements shall be checked routinely.</p>	
6.2.2	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.	
6.2.3	Personal items and belongings, including personal mobile phones, shall not be taken into production areas without the permission of the management.	
6.2.4	Procedures and written instructions shall be in place to control the use and storage of personal medicines, to minimise the risk of product contamination.	
6.2.5	Fingernails shall be kept short and clean. False fingernails, nail varnish/polish or nail art shall not be permitted. Where visitors cannot comply, suitable control procedures shall be in place (e.g. non-handling of product, use of gloves).	
6.2.6	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue). These shall be site issued and monitored when involved in work with materials intended to come into direct contact with food or other hygiene-sensitive products. Where appropriate, in addition to the plaster, a finger stall or glove shall be worn.	

Notes	
6.3	Staff facilities
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. Such facilities shall be kept in a good and clean condition.
6.3.1	Locker rooms shall be accessed without the need to enter production areas unless appropriately segregated walkways are in place.
6.3.2	Lockers shall be provided for all personnel who work in raw material handling, processing, preparation, packing and storage areas. Lockers shall be of sufficient size to accommodate all reasonable personal items and any protective clothing required.
6.3.3	Site-issued protective clothing and personal clothing shall not be stored in the same locker or shall be effectively segregated within the locker.
6.3.4	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in locker and changing rooms.
6.3.5	<p>Suitable and sufficient hand-washing facilities shall be available to enable cleaning of hands before commencing work, after breaks, and as necessary during the course of work. Such hand-washing facilities shall provide, as a minimum:</p> <ul style="list-style-type: none"> • sufficient quantity of water at a suitable temperature to encourage hand washing • unscented liquid soap or foam • adequate hand-drying facilities • advisory signs to prompt use (including signs in appropriate languages). <p>Where materials are handled that will be in direct contact with food or other hygiene-sensitive products, hand-washing facilities shall be sited at the entrance to the production area.</p>
6.3.6	Toilets shall not open directly into storage, processing or production areas in order to prevent the risk of contamination to product. Toilets shall be provided with suitable and sufficient hand-washing facilities.
6.3.7	Facilities for visitors and contractors shall enable compliance with the site's hygiene policy.
6.3.8	All food brought into manufacturing premises shall be stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas.
6.3.9	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in the production or storage areas. If it is impractical for personnel to leave their work area, local controlled facilities (such as a

	fully walled area with hand-washing facilities) shall be provided.	
6.3.10	Drinking of water from purpose-made dispensers and/or by using disposable conical cups or spill-proof lidded containers may be allowed, provided it is confined to a designated area away from equipment.	
6.3.11	<p>Where smoking is allowed under national law, it shall only be permitted in designated controlled smoking areas which shall be isolated from production and storage areas and fitted with extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall also be provided at smoking facilities, both inside buildings and at external locations.</p> <p>The use of electronic cigarettes and associated materials shall not be permitted in locker rooms, or in production or storage areas, and shall only be permitted in designated smoking areas.</p>	
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6.4	Medical screening	
SOI	The company shall ensure that documented procedures are in place to ensure health conditions likely to adversely affect product safety are monitored and controlled.	
6.4.1	<p>Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the site shall make employees aware of the symptoms of infection, disease or condition which would prevent a person working. The site shall have a procedure for the notification by personnel, including temporary personnel, of any relevant infections, diseases or conditions with which they may have been in contact or be suffering from.</p> <p>Employees, contractors and visitors suffering from any of the above shall be excluded from work involving the handling of direct-food contact or other hygiene-sensitive product packaging for as long as the symptoms persist.</p>	
6.4.2	Where permitted by law, visitors and contractors shall be required to fill in a health questionnaire or otherwise confirm that they are not suffering from any symptoms which may put product safety at risk, prior to being allowed into production, packing or storage areas.	
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6.5	Protective clothing	

SOI	Appropriate protective clothing shall be worn in production and storage areas to minimise the risk of product contamination.	
6.5.1	<p>Hazard and risk principles shall be used to determine the need for protective clothing, including garments and footwear in raw materials handling, preparation, production and storage areas.</p> <p>Where no need for protective clothing has been established by risk assessment in a particular area, it shall be fully justified and shall not pose a contamination risk to the product.</p>	
6.5.2	<p>The company shall use risk assessment to determine, document and communicate to all employees, including temporary personnel and contractors, the rules regarding:</p> <ul style="list-style-type: none"> • the wearing of protective clothing on the journey to work • the wearing of protective clothing in raw materials handling, preparation, production and storage areas • the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, canteen or smoking areas). 	
6.5.3	Where the need for protective clothing has been determined, appropriate clean protective clothing that cannot contaminate the product shall be worn. Sufficient sets of clothing appropriate to the activities carried out shall be provided.	
6.5.4	<p>Protective clothing worn in production areas shall provide adequate coverage of the upper torso.</p> <p>Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the clothing shall have no external pockets on the upper body garments or sewn-on buttons. Changes of such clothing shall be available at all times as required.</p>	
6.5.5	Based on the assessment of risk to the product, suitable footwear shall be worn within the factory environment.	
6.5.6	<p>In production and packing areas, hazard and risk analysis shall be used to determine the need for:</p> <ul style="list-style-type: none"> • snoods for beards and moustaches • scalp hair coverings. 	
6.5.7	If gloves are used they shall be replaced regularly, be distinctive, intact and not cause a contamination risk to the product.	
6.5.8	<p>Protective clothing shall be kept clean and laundered. Laundering shall be carried out by one of the following methods:</p> <ul style="list-style-type: none"> • professional laundry service • in-house • controlled laundering facilities • self-care. 	
6.5.9	<p>Where self-care laundry is permitted, it shall be ensured that:</p> <ul style="list-style-type: none"> • employees have received written instructions regarding the laundering 	

	<p>process to be used and these shall be reinforced as part of an induction or other in-house training programme</p> <ul style="list-style-type: none"> • employees shall be provided with suitable means to safely transport washed garments from home to the workplace • there shall be a defined process within the site for monitoring the effectiveness of the system • there shall be a procedure and system for dealing with any case where employees are unable to perform self-laundry effectively, through lack of either diligence or facilities. 	
6.5.10	Clean and dirty clothing shall be segregated and controlled to prevent cross-contamination.	
6.5.11	Disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination.	
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