

PAS 223

Prerequisite programmes on food safety for design and manufacture of food packaging – Specification

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Foreword

This Publicly Available Specification (PAS) has been prepared by the British Standards Institution (BSI) to specify requirements for prerequisite programmes to assist in controlling food safety hazards. This PAS is intended to be used in conjunction with BS EN ISO 22000 to support management systems designed to meet the requirements specified in BS EN ISO 22000. The development of this PAS was sponsored by SSAFE (Safe Supply of Affordable Food Everywhere).

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Publishing information

This PAS comes into effect on xxxxx

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This PAS is not to be regarded as a British Standard, European Standard or International Standard. In the event that this PAS is put forward to form the basis of a full British Standard, European Standard or International Standard, it will be withdrawn.

Use of this document

It has been assumed in the preparation of this PAS that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The provisions of this PAS are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is “shall”.

Commentary, recommendations, explanation and general informative material are presented in smaller italic type, using the heading NOTE, and do not constitute normative elements.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with this PAS does not in itself confer immunity from legal obligations.

0 Introduction

BS EN ISO 22000 sets out specific food safety requirements for organizations in the food chain. One such requirement is that organizations establish, implement and maintain prerequisite programmes (PRPs) to assist in controlling food safety hazards (BS EN ISO 22000:2005, **Clause 7**). This PAS is intended to be used to support management systems designed to meet the requirements specified in BS EN ISO 22000, and sets out the detailed requirements for those programmes.

This PAS does not duplicate requirements given in BS EN ISO 22000 and is intended to be used in conjunction with BS EN ISO 22000, not in isolation. For example, traceability requirements are covered by BS EN ISO 22000.

Requirements for design have been included in this PAS because of the potential food safety risk that can arise if the packaging is not suitable for the intended use. It is essential that the proposed use(s) of the packaging are fully understood to ensure that any food safety risks can be identified and addressed through correct packaging design.

1 Scope

This Publicly Available Specification (PAS) specifies requirements for establishing, implementing and maintaining prerequisite programmes (PRPs) to assist in controlling food safety hazards for design and manufacture of food packaging.

This PAS is applicable to all organizations, regardless of size or complexities, that manufacture packaging either for direct food contact or for indirect food contact where there is a potential food safety risk due to migration or other transfer mechanism.

NOTE This PAS can be applied to a wide range of packaging types, subject to meeting the above criteria. For example in the case of crates, if filled glass bottles are transported in the crates, then the crates are not in direct food contact (and there is no risk of migration) for this particular application. However, if foodstuffs are stored directly in crates, then the crates would be considered to be direct food contact packaging.

The provisions within this PAS are for implementation by food packaging manufacturing operations. This PAS is not designed or intended for use in other parts of the food supply chain.

Food packaging manufacturing operations are diverse in nature, and not all of the requirements specified in this PAS apply to an individual establishment or process.

NOTE Where exclusions are made or alternative measures implemented, these need to be justified by a hazard assessment. Any exclusions or alternative measures adopted should not affect the ability of the organization to comply with these requirements.

This PAS is not a management system standard and is intended to be used by food packaging manufacturers that wish to implement PRPs in such a way as to address the requirements specified in BS EN ISO 22000:2005, **Clause 7.2.3**.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN ISO 22000:2005, Food safety management systems – Requirements for any organization in the food chain, **Clause 7**.

3 Terms and definitions

For the purposes of this PAS, the following terms and definitions apply.

The terms and definitions given in BS EN ISO 22000:2005 also apply.

3.1 contamination

introduction or occurrence of a contaminant in food or food environment

[Adopted from Codex Alimentarius, 2.3]

NOTE In the context of this PAS, "contamination" may also refer to the introduction of non-intentionally added substances (NIAS).

3.2 contaminant

any biological or chemical agent, foreign matter or other substances not intentionally added to food which may compromise food safety or suitability

[Adopted from Codex Alimentarius, 2.3]

NOTE Measures for prevention of malicious contamination are outside the scope of this PAS. For further information and guidance on approaches to the protection of food businesses from all forms of malicious attack, see PAS 96.

3.3 establishment

any building or area in which materials or packaging are handled, and the surroundings, under the control of the same management

[Adopted from Codex Alimentarius, 2.3]

3.4 cleaning

removal of solvents, grease or lubricant, ink residues or other objectionable matter

3.5 direct food contact material

surfaces or materials that are in contact (i.e. physically touching the food or in contact with the headspace) or will be in contact with the food during normal use of the packaging

3.6 indirect food contact material

surfaces or materials that are not in direct contact with the food during normal use of the packaging, but where there is the possibility for components of the surface or material to transfer into the food

3.7 raw material/packaging specification

detailed documented description or enumeration of parameters, including permissible variations and tolerances, which are required to achieve a defined level of acceptability or quality

3.8 certificate of analysis (COA)

document provided by the supplier which indicates results of specific tests/analysis, including test methodology, performed on a defined lot of the supplier's raw material

3.9 certificate of conformance (COC)

document that confirms conformance to relevant specification or regulations.

NOTE This is sometimes referred to as a certificate of compliance or declaration of compliance (DOC).

3.10 label

printed matter that is part of the finished package conveying specific information about the contents of the package, the food ingredients and any storage and preparation requirements

NOTE This includes the package itself, printed matter attached to the package or a sticker used for over-labelling.

3.11 packaging recall

removal of nonconforming packaging from the market, trade and warehouses, distribution centres and/or customer warehouses because it does not meet specified standards

3.12 packaging

physical final output of any kind of production process that takes place in the packaging industry

NOTE This is also sometimes referred to as "finished packaging".

3.13 intermediate

physical output of part of the production process which still requires further processing to create finished packaging

3.14 migration

Partition- and diffusion-controlled transfer process of small molecules (approx. <1,000 Dalton) from the food contact material or article into food or food stimulant

NOTE The transfer of packaging ink components can take place eby migration through the substrate, by set-off to the reverse side and subsequent migration into food, or by gas phase transfer.

3.15 set-off

transfer of substances from one side of a material or article to the other side through direct contact between these different sides caused by the stacking or reeling of the materials

3.16 non-intentionally added substance (NIAS)

impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product

3.17 end product

product that will undergo no further processing or transformation by the organization

NOTE In the context of this PAS, "organization" means the food processor or food manufacturer.

3.18 waste

any substance or object which the holder discards or intends or is required to discard.

4 Construction and layout of buildings

4.1 General requirements

Buildings shall be designed, constructed and maintained in a manner appropriate to the nature of the manufacturing operations to be carried out, the food safety hazards associated with those operations and the potential sources of contamination from the plant environs. Buildings shall be of durable construction that presents no hazard to the packaging.

NOTE For example, roofs should be self-draining and not leak.

4.2 Environment

Consideration shall be given to potential sources of contamination from the local environment.

NOTE Local environment should include consideration of both internal and external areas.

The effectiveness of measures taken to protect against potential contamination of the packaging shall be periodically reviewed.

4.3 Locations of establishments

The site boundaries shall be clearly identified.

The site shall be kept in a condition that will protect against the contamination of packaging.

5 Layout of premises and workspace

5.1 General requirements

Internal layouts shall be designed, constructed and maintained to facilitate good hygiene and manufacturing practices. The movement patterns of materials, packaging and people and the layout of equipment shall be designed to protect against potential contamination sources.

5.2 Internal design, layout and traffic patterns

The building shall provide adequate space, with a logical flow of raw materials, intermediates and finished packaging and personnel through the manufacturing process.

NOTE Examples of physical separation may include walls, barriers or partitions, or sufficient distance to minimize risk.

Openings intended for transfer of raw materials, intermediates and finished packaging (e.g. transport hoses, conveyors) shall be designed to minimize entry of foreign matter and pests.

5.3 Internal structures and fittings

Walls and floors shall be washable or cleanable, as appropriate for the food safety hazards associated with the packaging. Walls and floors shall be resistant to the cleaning system applied.

Standing water shall be avoided in areas where food safety may be impacted.

NOTE If packaging and/or raw materials are stored outside, appropriate measures should be in place to manage any risk from standing water.

Drains shall be trapped and covered.

Ceilings and overhead fixtures shall be designed to minimize build-up of dirt and condensation and shall be accessible for inspection and cleaning.

External opening doors, windows, roof vents or fans in production and storage areas shall be closed or screened (e.g. insect screened, air curtains provided).

NOTE External openings should be avoided wherever possible. Where this is not possible, keeping these openings closed is the preferred option.

5.4 Location of equipment

Equipment shall be designed and located to facilitate good hygiene practices and monitoring.

Equipment shall be located to permit access for operation, cleaning and maintenance.

5.5 Laboratory facilities

Inline and online test facilities shall be controlled to minimize risk of packaging contamination.

5.6 Temporary/mobile structures

Temporary structures shall be designed, located and constructed to avoid pest harbourage and potential contamination of packaging.

5.7 Storage of raw materials, intermediates, chemicals and finished packaging

Facilities used to store raw materials, intermediates and finished packaging shall provide protection from dust, condensation, drains, waste and other sources of contamination.

Storage areas shall be dry and well ventilated. Monitoring and control of temperature and humidity shall be applied where specified.

Storage areas shall be designed or arranged to allow segregation of raw materials, work in progress and finished packaging. Raw materials, intermediates, chemicals and packaging that are suitable for food contact shall be segregated from those that are not.

All packaging, intermediates and raw materials shall be stored off the floor and with sufficient distance from the walls to allow inspection and pest control activities to be carried out.

The storage area shall be designed to allow maintenance and cleaning, prevent contamination and minimize deterioration.

Cleaning chemicals, chemicals and other hazardous substances shall be fit for purpose, suitably labelled, secured in closed containers and used in accordance with manufacturers' instructions.

6 Utilities – air, water, energy

6.1 General requirements

The provision and distribution routes for utilities to and around production and storage areas shall be designed to minimize the risk of packaging contamination.

6.2 Water supply

The supply of water shall be sufficient to meet the needs of the production process(es).

Water (including ice or steam) used in contact with packaging shall meet specified quality and food safety requirements relevant to the packaging.

Water for cleaning or applications where there is a risk of packaging contact shall meet specified quality and food safety requirements relevant to the application.

Non-potable water shall have a separate supply system, labelled, not connected to the potable water system and prevented from reflux into the potable system.

6.3 Air quality and ventilation

The organization shall establish requirements for air used for direct packaging contact and shall monitor accordingly.

Suitable and sufficient ventilation (natural or mechanical) shall be provided to remove excess or unwanted steam, dust and odours.

Room air supply quality shall be controlled to minimize risk from airborne microbiological contamination, as applicable to the packaging type.

NOTE Packaging such as paper and board could potentially support microbiological growth if appropriate controls are not in place.

Ventilation systems shall be designed and constructed such that air does not flow from contaminated areas to clean areas. Systems shall be accessible for cleaning, filter changing and maintenance.

Exterior air intake ports shall be examined periodically for physical integrity.

6.4 Compressed air and other gases

Compressed air and other gas systems used in manufacturing shall be constructed and maintained so as to prevent contamination.

Gases intended for direct or incidental packaging contact (including those used for transporting, blowing or drying raw materials, packaging or equipment) shall be of a suitable standard to avoid contamination of the packaging.

Oil used for compressors shall be food grade wherever there is a potential contamination risk to the packaging.

Requirements for filtration, humidity (RH%) and microbiology shall be specified as applicable for the process and packaging type.

NOTE Filtration of the air should be as close to the point of use as is practicable.

6.5 Lighting

The lighting provided (natural or artificial) shall allow correct operation of processes.

NOTE The intensity of the lighting should be appropriate to the nature of the operation.

Where there is a food safety risk, light fixtures shall be protected to ensure that raw materials, intermediates, packaging or equipment are not contaminated in the case of breakages.

7 Waste management

7.1 General requirements

Systems shall be in place to identify, collect, remove and dispose of waste materials in a manner that prevents contamination of the packaging, production or storage areas.

7.2 Containers for waste substances

Containers for waste or hazardous substances shall be:

- a) clearly identified for their intended purpose;
- b) located in a designated area;
- c) constructed of impervious material that can be readily cleaned;
- d) closed when not in immediate use, and locked if hazardous, where the waste may pose a risk to the packaging.

7.3 Waste management and removal

Provision shall be made for the segregation, storage and removal of waste.

Waste shall not be allowed to accumulate in production or storage areas.

Raw materials or packaging designated as waste shall be disfigured or destroyed so that that trademarks cannot be reused. Removal and destruction shall be carried out by approved disposal contractors. The organization shall retain records of destruction.

7.4 Drains and drainage

Drains shall be designed, constructed and located so that the risk of contamination of raw materials, intermediates and finished packaging is avoided.

8 Equipment suitability and maintenance

8.1 General requirements

Equipment shall be designed to minimize the risk of contamination to the packaging.

8.2 Hygienic design

All parts of equipment coming into contact with the finished packaging shall be designed and constructed to facilitate cleaning and maintenance.

Equipment shall meet established principles of hygienic design, including:

- a) smooth, accessible, cleanable packaging contact surfaces;
- b) self-draining (for wet processes);
- c) use of construction materials compatible with intended packaging, lubricants and cleaning or flushing agents.

Piping and ductwork shall be cleanable and drainable, with no dead ends, and shall not cause condensation or leakage that could contaminate the packaging.

Valve connections and controls shall fail-safe to prevent contamination.

Equipment components containing metals of known toxicity (e.g. mercury) shall not be allowed where they could compromise the food safety of the packaging.

8.3 Packaging contact surfaces

Packaging contact surfaces shall be constructed from raw materials suitable for the intended use, to prevent contamination.

8.4 Irradiation control and monitoring equipment

Equipment used for irradiation processes shall meet the provisions given in relevant packaging specifications.

Equipment shall provide for the monitoring and control of the process.

8.5 Preventive and corrective maintenance

A preventive maintenance programme shall be in place.

The preventive maintenance programme shall include all devices used to monitor and/or control food safety hazards.

NOTE Examples of such devices include screens and filters (including air filters), magnets, metal detectors and X-ray detectors.

Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination.

Maintenance requests that impact packaging food safety shall be given priority.

Temporary fixes shall not put packaging food safety at risk. A request for replacement by a permanent repair shall be included in the maintenance schedule.

The procedure for releasing maintained equipment back into production shall include clean-up and pre-use inspection.

9 Management of purchased materials and services

9.1 General requirements

Purchasing of raw materials and services that impact food safety shall be controlled such that the suppliers used have the capability to meet the specified requirements. The conformance of raw materials and services to specified purchase requirements shall be verified.

NOTE Services may include (but are not limited to) third-party storage and rework by sub-contractors.

9.2 Selection and management of suppliers

There shall be a defined process for the selection, approval and monitoring of suppliers, including:

- a) assessment of the supplier's ability to meet quality and food safety expectations, requirements and specifications;
- b) description of how suppliers are assessed. The method used shall be justified by hazard assessment, including the potential risk to the final packaging. The assessment shall be conducted by competent personnel;

NOTE Examples of a description of how suppliers are assessed include:

- a) *audit of the supplying site prior to accepting raw materials for production;*
- b) *appropriate third-party certification.*
- c) monitoring the performance of the supplier to verify continued approval status.

NOTE Monitoring may include conformance to raw material or specifications, meeting COA requirements and satisfactory audit outcomes.

9.3 Incoming raw material requirements

Where applicable, delivery vehicles shall be checked prior to, and during, unloading to verify that the quality and safety of the raw material has been maintained during transit (e.g. seals are intact).

Where tamper-evident seals are used, a verification process shall be in place to confirm conformance to relevant customer or regulatory requirements used.

Raw materials shall be inspected, tested or covered by COA/COC to verify conformance to specified requirements prior to acceptance or use. The method of verification shall be documented.

Where incoming raw material is from a recycled source, measures shall be in place to verify food safety and traceability requirements are met prior to acceptance.

NOTE The inspection frequency and scope may be based on the hazard presented by the raw material and the risk assessment of the specific suppliers.

Raw materials that do not conform to relevant specifications shall be handled under a documented procedure that prevents their unintended use.

Access points to bulk raw material receiving lines shall be identified, capped and locked. Discharge into such systems shall take place only after approval and verification of the raw material to be received.

10 Measures for prevention of cross-contamination

10.1 General requirements

Programmes shall be in place to prevent, control and detect contamination. Measures to prevent physical, chemical and microbiological contamination shall be included.

10.2 Microbiological contamination

Where there is a risk from microbiological contamination, control measures shall be implemented to prevent or control the risk.

10.3 Physical contamination

Based on hazard assessment, measures shall be put in place to prevent, control or detect potential contamination.

NOTE Examples of such measures include:

- a) adequate covers over equipment or containers for exposed raw materials, intermediates and finished packaging;
- b) use of screens, magnets, sieves or filters;
- c) use of detection/ rejection devices such as metal detectors or X-ray.

Where glass and/or brittle material are used in production or storage areas, periodic inspection requirements and defined procedures in case of breakage shall be put in place.

NOTE Glass and brittle material (such as hard plastic components in equipment, sight glasses on storage vessels) should be avoided where possible.

Glass breakage records shall be maintained where relevant to the food safety risk.

NOTE Sources of potential contamination include wooden pallets and tools, rubber seals and personal protective clothing and equipment.

The use of loose fastenings (e.g. drawing pins and staples) shall not be allowed in production and storage areas.

There shall be a documented procedure for control of sharp items (e.g. knife blades, hard plastic).

10.4 Chemical contamination

All chemicals on site shall be suitable for the intended use, and shall be controlled, to prevent contamination of the packaging.

A register of hazardous materials shall be maintained, and measures shall be in place to prevent cross-contamination between chemicals that are suitable for food contact materials and those that are not.

NOTE Hazardous materials should include all potential migrants, hazardous chemicals or components with tainting potential.

Only approved chemicals shall be permitted on site.

Printed materials shall be stored in such a manner that transfer of substances from the printed surface to the food contact side via set-off is minimized.

Pallets shall be made of suitable raw material and be clean, dry and free from chemicals that could potentially contaminate the packaging (such as insecticides, fungicides, pesticides or other chemicals).

NOTE In some cases, treatment of pallets may be necessary to meet regulatory or customer requirements.

Where a risk of contamination from allergens has been identified, controls shall be implemented to prevent or control the risk.

NOTE Components such as inks and oils can sometimes contain or be derived from allergenic material. Information should be available from the relevant supplier to identify any such risks.

11 Cleaning

11.1 General requirements

Cleaning programmes shall be established to maintain the production equipment and environment in a hygienic condition. Programmes shall be monitored for continuing suitability and effectiveness.

11.2 Cleaning agents and tools

Facilities and equipment shall be maintained in a condition that facilitates cleaning.

Cleaning agents and chemicals shall be clearly identified, stored separately and used only in accordance with manufacturers' instructions.

Tools and equipment shall be of hygienic design and maintained in a condition that does not present a potential source of extraneous matter.

11.3 Cleaning programmes

Cleaning programmes shall specify, as a minimum:

- a) areas and items of equipment and tools to be cleaned;
- b) responsibility for the tasks specified;
- c) cleaning method and frequency;
- d) monitoring and verification arrangements.

11.4 Monitoring cleaning effectiveness

Cleaning programmes shall be monitored, at frequencies specified by the organization, to ensure their continuing suitability and effectiveness.

12 Pest control

12.1 General requirements

Cleaning, inspection and monitoring procedures shall be implemented to avoid creating an environment conducive to pest activity.

12.2 Pest control programmes

The organization shall have a nominated person to manage pest control activities and/or deal with appointed expert contractors.

Pest management programmes shall be documented and shall identify target pests, and address plans, methods, schedules, control procedures and, where necessary, training requirements.

Programmes shall include a list of chemicals that are approved for use in specified areas of the organization.

12.3 Preventing access

Buildings shall be maintained in good repair. Holes, drains and other potential pest access points shall be sealed.

External doors, windows or ventilation openings shall be designed to minimize the potential for entry of pests.

12.4 Harborage and infestations

Raw materials, intermediates and finished packaging found to be infested shall be handled in such a way as to prevent contamination of other materials, packaging or the building.

Potential pest harborage (e.g. burrows, undergrowth, stored items) shall be removed.

Where outside space is used for storage, stored items shall be protected from weather or pest damage (e.g. bird droppings).

12.5 Monitoring and detection

Pest monitoring programmes shall include the placing of detectors and traps in key locations to identify pest activity. A map of detectors and traps shall be maintained. Detectors and traps shall be designed and located to prevent potential contamination of raw materials, intermediates, packaging or facilities.

Detectors and traps shall be of robust, tamper-resistant construction. They shall be appropriate for the target pest.

The detectors and traps shall be inspected at a frequency intended to identify new pest activity. The results of inspections shall be analyzed to identify trends.

12.6 Eradication

Eradication measures shall be put in place immediately after evidence of infestation is reported.

Pesticide use and application shall be restricted to trained personnel and shall be controlled to avoid food safety hazards.

Records of pesticide use shall be maintained to show the type, quantity and concentrations used; where, when and how applied; and the target pest.

13 Personnel hygiene and employee facilities

13.1 General requirements

Requirements for personal hygiene and behaviours proportional to the hazard posed to the packaging shall be established and documented. All personnel, visitors and contractors shall be required to comply with the documented requirements.

13.2 Personnel hygiene facilities and toilets

Personnel hygiene facilities shall be available to ensure that the degree of personal hygiene required by the organization can be maintained. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated.

Establishments shall:

- a) provide adequate numbers, locations and means of washing, drying and, where required, sanitizing hands (including wash basins, supply of hot and cold or temperature-controlled water, and soap and/or sanitizer);

NOTE Taps at handwash stations should not be hand operated.

- b) provide an adequate number of toilets of appropriate hygienic design, each with hand washing and drying;
- c) have employee toilet facilities that do not open directly onto production or storage areas;
- d) have adequate changing facilities for personnel;
- e) provide lockers for all personnel who work in production and storage areas

13.3 Staff canteens and designated eating areas

Staff canteens and designated areas for food storage and consumption shall be situated and appropriately managed so that the potential for cross contamination of production areas is minimized.

13.4 Workwear and protective clothing

Personnel who work in or enter into production or storage areas shall wear work clothing that is fit for purpose, clean and in good condition.

Where applicable to the food safety risk, workwear shall not be used for any other purpose and shall not be stored in the same locker as personal clothing.

Workwear shall provide adequate coverage so that hair, perspiration and loose items cannot contaminate the packaging.

Where gloves are used for packaging contact, they shall be clean and in good condition.

NOTE Use of disposable gloves or hand sanitizers is preferred.

Personal protective equipment, where required, shall be designed to prevent packaging contamination and shall be maintained in hygienic condition.

13.5 Illness and injuries

Employees, visitors and contractors shall be required to report relevant infections, conditions or diseases in accordance with the site requirements.

People known or suspected to be infected with, or carrying, a disease or illness transmissible through food shall be prevented from handling the packaging.

In production areas, personnel with wounds or burns shall be required to cover them with specified dressings. Any lost dressing shall be reported to supervision immediately.

13.6 Personal cleanliness

Personnel in production areas shall be required to wash hands:

- a) before starting any packaging handling activities;
- b) immediately after using the toilet, eating, smoking or drinking;
- c) immediately after handling any potentially contaminated material.

Personnel shall be required to refrain from sneezing or coughing over raw materials, intermediates or packaging. Spitting (expectorating) shall be prohibited.

Fingernails shall be kept clean and trimmed.

13.7 Personal behaviour

A documented policy shall describe the behaviours required of personnel in production and storage areas. The policy shall at a minimum cover:

- a) permissibility of smoking, drinking (other than water), eating and chewing in designated areas only;
- b) control measures to minimize hazards presented by permitted jewellery;

NOTE Permitted jewellery includes specific types of jewellery that may be worn by the personnel in processing and storage areas, taking into account religious, ethnic, medical and cultural imperatives.

- c) permissibility of personal items, such as smoking materials and medicines, in designated areas only;
- d) prohibition of the use of nail polish, false nails and false eyelashes;
- e) prohibition of carrying of writing implements in places where they could fall;
- f) maintenance of personal lockers so that they are kept free from rubbish and soiled clothing;
- g) prohibition of storage of packaging contact tools and equipment in personal lockers.

14 Rework and recycling

14.1 General requirements

Rework shall be stored, handled and used in such a way that packaging safety, quality, traceability and regulatory compliance are maintained.

NOTE In this section, the term “rework” includes raw material intended for onsite recycling.

14.2 Storage, identification and traceability

Stored rework shall be segregated and protected against contamination.

Rework shall be clearly identified and/or labelled to allow traceability. Traceability records for rework shall be maintained.

The rework classification or the reason for rework designation shall be recorded (e.g. packaging name, production date, shift, line of origin).

14.3 Rework usage

Where rework is to be incorporated back into the process, the acceptable quantity, type and conditions of rework use shall be specified. The method of addition, including any necessary preprocessing stages, shall be defined.

Measures shall be in place to prevent rework processes allowing food contact materials or packaging to be contaminated with materials not intended for food contact.

Validation records shall be available to demonstrate that conformance to regulatory and customer requirements are maintained by following the specified rework process.

15 Recall procedures

15.1 General requirements

Systems shall be in place to identify, locate and remove, from all necessary points of the supply chain, packaging failing to meet required food safety standards.

NOTE Refer to ISO22000 "Handling of potentially unsafe products" and "Withdrawals".

15.2 Recall requirements

A list of key contacts in the event of a recall shall be maintained and shall be accessible at all times.

A procedure shall be in place to notify affected customer(s) immediately of potential recall situations.

Where packaging is withdrawn due to immediate health hazards, the food safety of other packaging produced under the same conditions shall be evaluated.

16 Warehousing

16.1 General requirements

Raw materials and packaging shall be stored in clean, dry, well-ventilated spaces protected from dust, condensation, fumes, odours or other sources of contamination.

16.2 Warehousing requirements

Effective control of warehousing temperature, humidity and other environmental conditions shall be provided where required by packaging or storage specifications.

Waste materials and chemicals (cleaning products, lubricants and pesticides) shall be stored separately.

A separate area or other means of segregating materials identified as nonconforming shall be provided.

Specified stock rotation systems that meet customer, food safety and regulatory requirements shall be observed.

16.3 Vehicles, conveyances and containers

Vehicles, conveyances and containers shall be maintained in a state of repair, cleanliness and condition consistent with requirements given in relevant specifications and contracts.

Vehicles, conveyances and containers shall provide protection against damage or contamination of the packaging. Control of temperature and humidity shall be applied and recorded where required by the organization.

All delivery vehicles and shipping containers shall be subject to a documented hygiene and integrity check prior to loading.

Packaging shall be protected from contamination during loading operations. Where required by the organization, bulk containers shall be dedicated to a specified packaging material.

Where specified by customer or regulatory requirements, outer wrapping and/or delivery vehicle shall be equipped with unique non-toxic, supplier-identifiable, tamper-evident seals (or equivalent) to indicate any violation or attempted violation.

17 Packaging information and consumer awareness

Where packaging is printed with food safety information, measures shall be in place to verify that the information is compliant with customer requirements.

NOTE Food safety information includes (but is not limited to) ingredient lists, allergen statements and instructions for use.

Controls shall be in place to prevent the use of obsolete printing plates.

Manufacturing process shall ensure that there is no mixing of packaging with different food safety information within a given batch.

18 Food defence, biovigilance and bioterrorism

18.1 General requirements

Each organization shall assess the hazard posed by potential acts of sabotage, vandalism or terrorism and shall put in place proportional protective measures.

NOTE This should include consideration of transport and distribution, as well as onsite activities. It should include points such as:

- a) *building and infrastructure design to prevent unlawful entry;*
- b) *reference checks for personnel;*
- c) *control of confidential information;*
- d) *security of storage and production areas;*
- e) *management of security incidents.*

For further information and guidance on approaches to the protection of food businesses from all forms of malicious attack, see PAS 96.

The site security assessment shall be kept up to date.

Personnel shall be trained in site security measures.

18.2 Access controls

Potentially sensitive areas (e.g. production areas, utility services) within the establishment shall be identified, mapped and subjected to access control.

NOTE Where feasible, access should be physically restricted by use of locks, electronic card key or alternative systems.

Trademarked packaging, promotional materials and/or graphics shall be secured when not in use.

19 Packaging design and development

19.1 General requirements

Food safety-related customer requirements and applicable food safety regulatory requirements shall be determined prior to commencing the packaging design.

19.2 Communication

Customer requirements shall be recorded in a manner that clearly demonstrates the packaging manufacturer has been provided with sufficient information on the intended use of the packaging, the food processing conditions and the markets in which the packaging is intended to be used.

There shall be a process in place to verify that changes in customer requirements are communicated to the packaging manufacturer.

19.3 Design

Complete and accurate supporting documents confirming the suitability of the raw materials for the intended application shall be available for all material components used to manufacture the packaging.

Packaging composition and migration data (where applicable) shall be available to demonstrate conformance to food safety regulatory and customer requirements in the countries where the end product is intended to be used.

Migration data shall cover the intended conditions under which the packaging will be used.

19.4 Specifications

Packaging specifications shall be maintained, and a process shall be in place to verify that packaging specifications are formally accepted by the packaging manufacturer and the customer(s). Packaging specifications shall include all food safety relevant parameters.

New technology and/or new manufacturing processes that may impact the food safety performance of the packaging shall not be introduced without notification of the affected customer(s) in accordance with contractual obligations.

19.5 Process validation

Validation data (such as information from production trials or testing) shall be available to demonstrate that the manufacturing process is capable of producing packaging to accepted specifications and that the transport conditions to the customer(s) do not compromise the food safety or functionality of the packaging.

NOTE Previous validation data may be used for new packaging and/or processes is similar to existing ones.

Bibliography

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Standards publications

PAS 96, *Defending food and drink. Guidance for the deterrence, detection and defeat of ideologically motivated and other forms of malicious attack on food and drink and their supply arrangements*

BS EN 15593, *Management of hygiene in the production of packaging for foodstuffs*

Other publications

Codex Alimentarius, *Recommended international code of practice – General Principles of Food Hygiene*

WHO, *World Health Organization – Guidelines for drinking-water quality*

Further reading

BIP 2078, *Managing food safety the 22000 way*

BIP 2128, *ISO 22000 Food safety – Guidance and workbook for food manufacturers*

BS EN ISO 22005, *Traceability in the feed and food chain – General principles and basic requirements for system design and implementation*

ISO/TS 22003, *Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems*

ISO/TS 22004:2005, *Food safety management systems – Guidance on the application of ISO 22000:2005*