




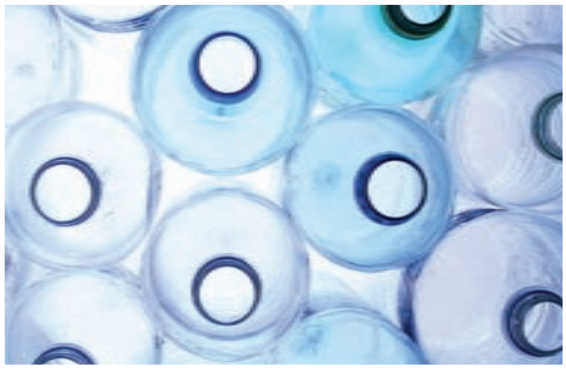

PAS 223:2011

Prerequisite programmes and design requirements for food safety in the manufacture and provision of food packaging

Publishing and copyright information

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Contents

Foreword

This Publicly Available Specification (PAS) has been prepared by the British Standards Institution (BSI) to specify requirements for prerequisite programmes and design to assist in controlling food safety hazards in the manufacture and provision of food packaging.

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). A Steering Group, consisting of leading global packaging and food manufacturing companies (listed below), was led by Neil Marshall on behalf of SSAFE. The technical authors for PAS 223 were Tracy Burton and Nancy Schouppe of The Coca-Cola Company.

Acknowledgement is given to the following organizations that assisted with the development of this PAS through membership of the Steering Group:

- Alpla
- Amcor Flexibles
- Danone
- Foundation for Food Safety Certification (FSSC)
- Institute of Packaging Professionals/FSAP (Food Safety Alliance for Packaging)
- Kraft Foods
- Nestlé
- Owens-Illinois
- ProCert
- Rexam
- Tetra Pak
- The Coca-Cola Company
- Unilever

BSI, SSAFE, the Technical Authors and the Steering Group greatly appreciate the considerable input during the consultation phase of the development of this PAS from numerous individuals and organizations around the world.

Publishing information

This PAS comes into effect on 1 July 2011.

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is put forward to form the basis of a full British Standard, European Standard or International Standard, it will be withdrawn.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.

Introduction

BS EN ISO 22000 sets out specific food safety requirements for any organization in the food chain. One such requirement is that organizations establish, implement and maintain prerequisite programmes (PRPs) to assist in controlling food safety hazards.

This PAS is intended to be used by food packaging manufacturing organizations to support management systems designed to meet the requirements for PRPs specified in BS EN ISO 22000, and it sets out the detailed requirements for those programmes.

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

1 Scope

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

This PAS is applicable to all organizations, regardless of size or complexities, that manufacture food packaging. This PAS is not designed or intended for use in other parts of the food chain.

Food packaging manufacturing organizations are diverse in nature, and not all of the requirements specified in this PAS apply to an individual organization. Each organization is required to conduct a documented food safety hazard and risk assessment that includes each requirement. Where exclusions are made or alternative measures are implemented, these need to be justified by the food safety hazard and risk assessment.

This PAS is not a management system standard and is intended to be used by food packaging manufacturing organizations that wish to implement PRPs in such a way as to address the requirements specified in BS EN ISO 22000.

This PAS is intended to be used in conjunction with BS EN ISO 22000, not in isolation.

NOTE *For the purpose of this PAS, the term food includes beverages.*

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, *Food safety management systems – Requirements for any organization in the food chain*

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 also apply.

3.1 certificate of analysis (CoA)

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

3.2 certificate of conformance (CoC)

document that confirms conformance to relevant specifications or regulations

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

3.3 cleaning

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

3.4 contaminant

any biological or chemical agent, foreign matter or other substance not intentionally added to the product that may compromise its safety or suitability

[Adapted 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,* 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.

3.5 contamination

introduction or occurrence of a contaminant in the product or the production environment

[Adapted 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).*

3.6 establishment

any building or area in which raw materials, intermediate materials, chemicals or finished food packaging are handled, and the surroundings under the control of the same management

[Adapted from Codex Alimentarius, **2.3**]

3.7 finished food packaging

physical final output of any kind of production process that takes place in food packaging manufacturing organizations

3.8 food packaging

any product to be used for containment, protection, handling, delivery, storage, transport and presentation of food

NOTE *Food packaging may have direct, indirect and no contact with the food. Direct food contact surfaces or materials 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 food packaging. Indirect food contact surfaces or materials are not in direct contact with the food during normal use of the food packaging, but there is the possibility for substances to transfer into the food. Non-contact surfaces or materials are not in direct contact with the food during normal use of the food packaging, and there is no possibility for substances to transfer into the food. Figure 1 illustrates this concept.*

3.9 food packaging withdrawal

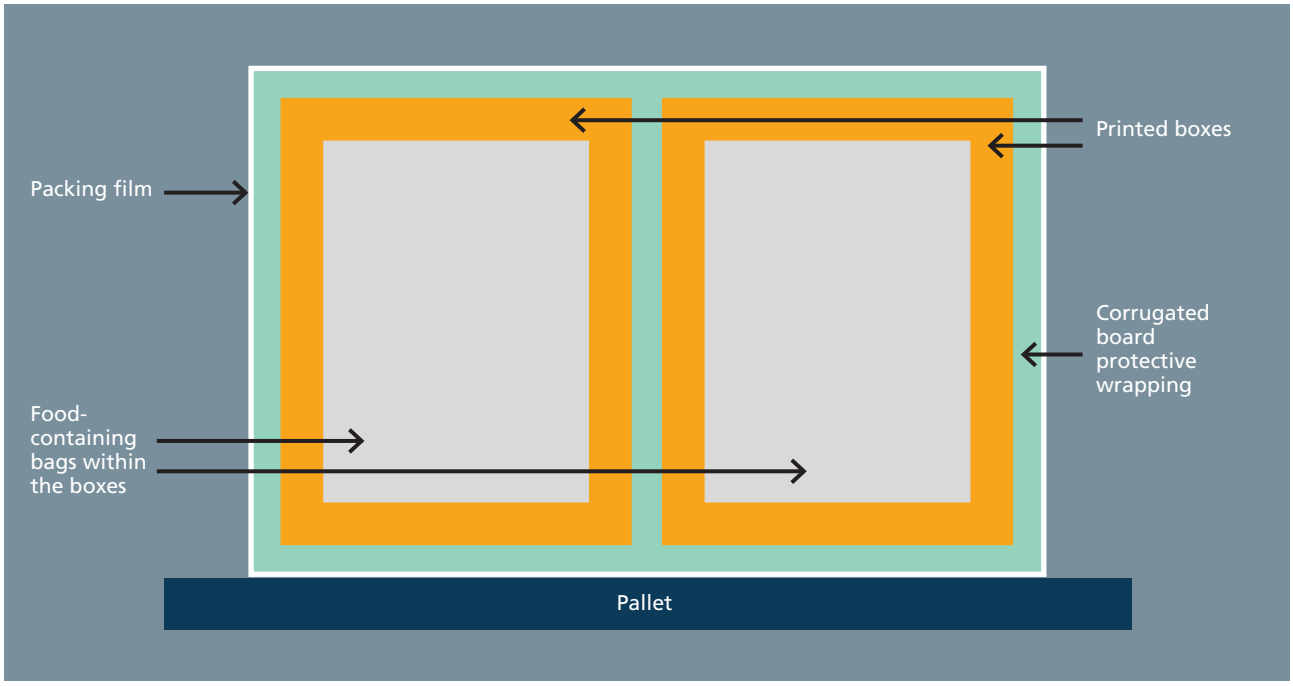
removal of nonconforming food packaging from the market, trade warehouses, distribution centres or customer operations and warehouses because it does not meet specified food safety standards or requirements

3.10 intermediate material

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

NOTE *For example, a plastic powder, granules or flakes (including "masterbatch"), ink, coating, adhesive, pre-polymer, any semi-finished material and article such*

Figure 1 – Food packaging concepts and food contact



as a film, sheet or laminate requiring further processing/reformulation steps to become a finished material or article. In short, this is any product that is not a basic chemical and not yet a finished material or article, and includes part-processed, semi-converted and converted materials.

3.11 label

printed matter that is, or is intended to be, 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 that is, or is intended to be, attached to the package or a sticker used for over-labelling.*

3.12 migration

transfer of substances from an external source (e.g. packaging material, environment) to food

NOTE *Transfer of substances can take place by migration through the substrate, by set-off to the reverse side and subsequent migration into food, or by gas phase transfer.*

3.13 non-intentionally added substance (NIAS)

impurity in the materials used in, or a decomposition or reaction product formed during, the production process

3.14 packing materials

materials used to hold and protect food packaging during shipping, transport and storage

3.15 set-off

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

3.16 specification

detailed description of the properties and requirements of a material or product, in particular its technical and specific suitability

3.17 waste

any substance or object that the food packaging manufacturing organization discards or intends or is required to discard

4 Establishments

4.1 General requirements

Establishments shall be designed, constructed and maintained in a manner fit for the nature and purpose of the food packaging manufacturing operations to be carried out, the food safety hazards associated with those operations and the potential sources of contamination.

Buildings shall be of durable construction that presents no food safety hazard to the food packaging.

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

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

4.2 Environment

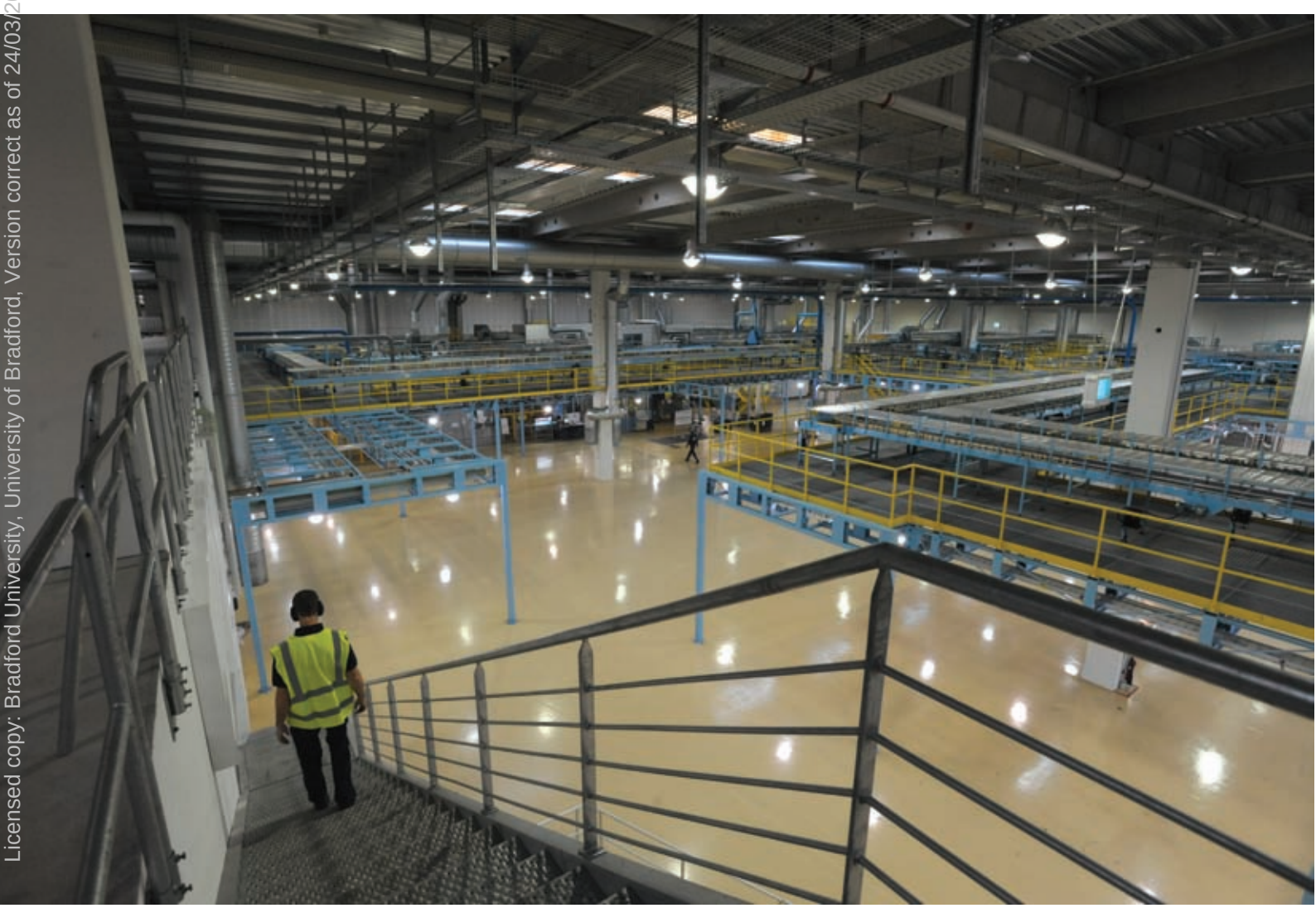
Consideration shall be given to potential sources of contamination from the local environment.

NOTE *"Local environment" includes both internal and external areas.*

4.3 Locations of establishments

The boundaries of establishments shall be clearly identified.

All areas within the boundaries of establishments shall be kept in a condition that will protect against contamination.



5 Layout 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, products and people and the layout of equipment shall be designed to protect against contamination sources and unintended mixing of materials or products.

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

5.2 Internal design, layout and traffic patterns

Buildings shall provide sufficient space to allow a logical flow of materials, products and people through the production process.

Openings intended for transfer of materials and products (e.g. transport hoses, conveyors) shall be designed to prevent 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 food packaging production.

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

Drains shall be trapped and covered.

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

In areas where routine cleaning of overhead fixtures and structures is not feasible or practical, equipment shall be covered.

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

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

5.4 Equipment

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

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

5.5 Temporary/mobile structures

Temporary structures shall be designed, located and constructed to prevent pest harbourage and contamination.

5.6 Storage

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

Internal storage areas shall be dry and well ventilated. Monitoring and control of temperature and humidity shall be applied where necessary.

If raw materials, intermediate materials, chemicals or finished food packaging are stored outside, measures shall be in place to manage contamination hazards.

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

All raw materials, intermediate materials, chemicals and finished food packaging shall be stored off the floor and with sufficient distance from the walls to allow inspection.

Storage areas shall be designed to allow maintenance and cleaning and to prevent contamination and deterioration.

Chemicals and other hazardous substances shall be suitably labelled, secured in closed containers and used in accordance with manufacturers' instructions.

6 Utilities

6.1 General requirements

The provision and distribution routes for utilities to and around production and storage areas shall be designed to prevent contamination.

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

6.2 Water supply

The supply of potable water or water suitably treated to prevent contamination shall be sufficient to meet the needs of the food packaging production process.

The food packaging manufacturing organization shall establish requirements for water (including ice or steam) used for direct food packaging contact or cleaning and shall monitor accordingly.

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

6.3 Air quality and ventilation

The food packaging manufacturing organization shall establish requirements for air used for direct food 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 prevent airborne microbiological contamination.

NOTE *Food 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.

Ventilation systems shall be accessible for cleaning, filter changing and maintenance.

6.4 Compressed air and other gases

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

The food packaging manufacturing organization shall establish requirements for gases used for direct food packaging contact (including those used for transporting, blowing or drying raw materials, intermediate materials, finished food packaging or equipment) and shall monitor accordingly.

Oil used for compressors shall be food grade wherever there is a potential for contamination.

Requirements for filtration, humidity and microbiology shall be assessed. Control and monitoring measures shall be applied as determined by the assessment.

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 the food packaging production process.

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

Where there is a food safety hazard (e.g. manufacture of containers such as jars, cans, bottles or trays), light fixtures shall be protected to prevent contamination of raw materials, intermediate materials, chemicals, finished food packaging and equipment in the case of breakages.

7 Waste

7.1 General requirements

Systems shall be in place to identify, collect, remove and dispose of waste in a manner that prevents contamination.

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

7.2 Containers for waste

Containers for waste 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.

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.

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

7.4 Drains and drainage

Drains shall be designed, located and constructed to prevent contamination.

8 Equipment suitability and maintenance

8.1 General requirements

Equipment shall be designed to prevent contamination.

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

8.2 Hygienic design

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

Equipment shall meet established principles of hygienic design, including:

a) smooth, accessible, cleanable food packaging contact surfaces;

b) self-draining (for wet processes);

c) use of construction materials compatible with the intended food packaging, lubricants and cleaning or flushing agents.

Piping and ductwork shall be cleanable and drainable and shall not cause condensation or leakage that could contaminate food packaging.

Valve connections and controls shall have fail-safes 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 food packaging.

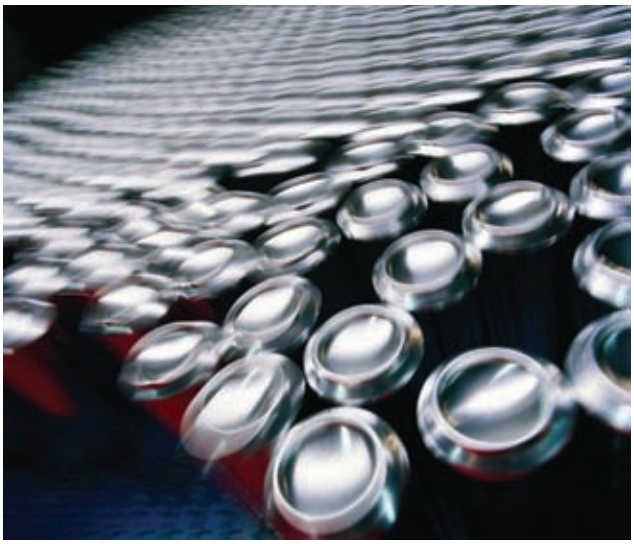
8.3 Food packaging contact surfaces

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

8.4 Testing and monitoring

Inline and online test facilities shall be controlled to prevent food packaging contamination.

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



The effectiveness of equipment used for control of food safety criteria in the production process shall be monitored and documented.

8.5 Preventive and corrective maintenance

A preventive maintenance programme shall be in place.

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

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

Corrective maintenance shall be carried out in such a way as to prevent contamination of raw materials, intermediate materials or finished food packaging on adjacent equipment.

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

Temporary fixes shall not compromise the food safety of the food packaging. 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 Purchased materials and services

9.1 General requirements

Purchasing of materials, services and subcontracted activities that may impact food safety of food packaging shall be controlled such that the suppliers used have the capability to meet the specified requirements.

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

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

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 suppliers' ability to meet food safety requirements;

b) description of how suppliers are assessed. The method used shall be justified by hazard assessment, including the potential food safety hazard to the food packaging;

c) assessment by competent persons;

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

a) audit of the supplying site prior to accepting materials for production;

b) appropriate third-party certification.

d) monitoring the performance of the supplier to verify continued approval status.

NOTE *Monitoring may include conformance to specifications, meeting CoA requirements and satisfactory audit outcomes.*

9.3 Incoming raw materials

Loads on delivery vehicles shall be checked prior to, and during, unloading to verify that food safety and safety of raw materials has been maintained during transit (e.g. seals are intact).

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

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 materials are from a recycled source, measures shall be in place to verify food safety and traceability requirements are met prior to acceptance.

Where recycled materials, plant-based materials or functional (e.g. nanotechnology) additives are used, there shall be sufficient data to enable hazard assessment for food contact and safety and conformance to applicable regulatory requirements, and all claims shall be documented.

NOTE *The inspection frequency and scope may be based on the hazard presented by the material and the hazard 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 materials receiving lines shall be identified, capped and secured. Discharge into such systems shall take place only after approval and verification of the raw materials received.

10 Contamination and migration

10.1 General requirements

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

Where external product testing is required, it shall be carried out by an accredited test facility or one that follows international test facility guidelines. Where in-house testing is carried out, calibration of equipment shall be carried out against national standards or other accurate means.

Mixing of raw or intermediate materials shall be prevented where hazard assessment reveals a food safety hazard.

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

10.2 Microbiological contamination

Where there is a potential for microbiological contamination, measures shall be implemented to prevent or control the hazard.

10.3 Physical contamination

Where glass and brittle material are used (for applications other than the food packaging production itself) in production or storage areas, periodic inspection requirements and defined procedures in case of breakage shall be put in place.

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

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

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

Other potential sources of physical contamination (e.g. wooden pallets, tools, rubber seals, personal protective clothing and equipment, knife blades, hard plastic) shall be considered.

10.4 Chemical contamination

Only approved chemicals shall be permitted on site.

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

A register of hazardous materials shall be maintained, and measures shall be in place to prevent cross-contamination between materials that are suitable for food contact.

NOTE *Hazardous materials should include hazardous chemicals or components with contamination potential.*

10.5 Chemical migration

Printed and coated materials shall be handled and stored in their intermediate and finished states in such a manner that transfer of substances to the food contact side via set-off or other mechanism is reduced to a safe level appropriate for these materials as defined by hazard assessment.

Packing materials (e.g. pallets) shall be made of suitable material and be clean, dry and free from chemicals that could potentially contaminate the food 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 there is a potential food safety hazard due to migration or other transfer mechanism, controls shall be implemented to prevent or control the hazard.

10.6 Allergen management

Where a potential for contamination from allergens has been identified, controls shall be implemented to prevent or control the hazard and to record and label accordingly.

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.

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

11.2 Cleaning agents and tools

Equipment shall be maintained in a condition that facilitates cleaning.

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

Cleaning tools shall be of hygienic design and maintained in a condition that does not present a potential source of contamination.

11.3 Cleaning programmes

Cleaning programmes shall specify, as a minimum:

a) areas and items of equipment to be cleaned;

b) responsibility for the cleaning tasks specified;

c) cleaning method(s) and frequency;

d) monitoring and verification arrangements for the cleaning.

11.4 Monitoring cleaning programme effectiveness

Cleaning programmes shall be monitored, at frequencies specified by the food packaging manufacturing organization, to assess their continuing suitability and effectiveness.

12 Pest control

12.1 General requirements

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

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

12.2 Pest control programmes

The food packaging manufacturing organization shall have a designated person to manage pest control activities 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, personnel training requirements.

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

12.3 Preventing access

Establishments shall be maintained in good repair. Holes and other potential pest access points shall be sealed.

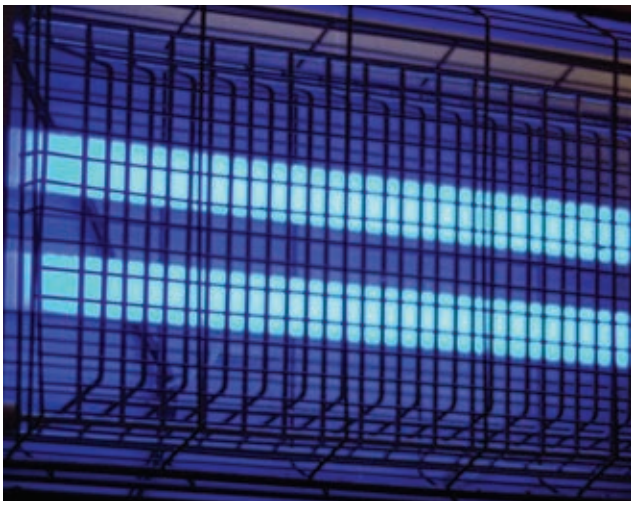
External doors, windows or ventilation openings shall be designed to prevent entry of pests.

12.4 Harbourage and infestations

Raw materials, intermediate materials or finished food packaging found to be infested shall be handled in such a way as to prevent contamination of other raw materials, intermediate materials, finished food packaging or the establishment.

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

Where external space is used for storage, stored items shall be protected from weather and 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 contamination of raw materials, intermediate materials, finished food packaging and equipment.

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

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 in pest activity.

12.6 Eradication

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

Pesticide application shall be restricted to trained personnel and shall be controlled to prevent 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 facilities

13.1 General requirements

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

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

13.2 Personnel hygiene facilities and toilets

Personnel hygiene facilities shall be available to maintain the degree of personal hygiene required by the food packaging manufacturing organization. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated.

According to their size and complexity, food packaging manufacturing organizations shall:

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

b) provide an adequate number and location of toilets of hygienic design, each with hand washing and drying facilities;

c) have toilet facilities that do not open directly onto production areas;

d) have adequate changing facilities for personnel;

e) provide lockers for all personnel who work in production, laboratory 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 to prevent contamination of production areas.

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.

Work clothing shall not be used for any other purpose and shall not be stored in the same locker as personal clothing.

Work clothing shall provide coverage so that hair, perspiration and loose items cannot contaminate raw materials, intermediate materials, finished food packaging or equipment based on a food safety hazard assessment.

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

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

13.5 Illness and injuries

Personnel, visitors and contractors shall be required to report relevant infections, conditions or diseases in accordance with the food packaging manufacturing organization's requirements.

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

13.6 Personal cleanliness

Personnel who are working in production areas shall be required to wash their hands:

a) before starting any food packaging handling activities;

b) immediately after using the toilet, eating, smoking or drinking (other than water);

c) immediately after handling any potentially contaminated material.

NOTE *Hand-cleaning products suitable for food safety (e.g. odourless) should be used.*

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

Fingernails shall be kept clean and trimmed.

13.7 Personal behaviour

A documented policy shall describe the behaviour 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 prevent hazards presented by permitted jewellery;

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

c) permissibility of having 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) control measures to restrict writing implements or loose items in areas where they could contaminate raw materials, intermediate materials or finished food packaging;

f) maintenance of personal lockers so that they are kept free from rubbish and soiled clothing;

g) prohibition of storage of food packaging contact tools in personal lockers.

14 Rework

14.1 General requirements

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

NOTE In this PAS, the term "rework" includes materials intended for onsite processing.

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

14.2 Storage, identification and traceability

Stored rework shall be segregated and protected against contamination.

Rework shall be clearly identified and 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. finished food packaging name, production date, shift, production line of origin).

14.3 Rework usage

Where rework is to be incorporated back into the production 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 raw materials, intermediate materials or finished food packaging to be contaminated with materials not intended for food contact.

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

15 Withdrawal procedures

15.1 General requirements

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

NOTE *Refer to BS EN ISO 22000, Clause 7.10.3, "Handling of potentially unsafe products", and Clause 7.10.4, "Withdrawals".*

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

15.2 Withdrawal requirements

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

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

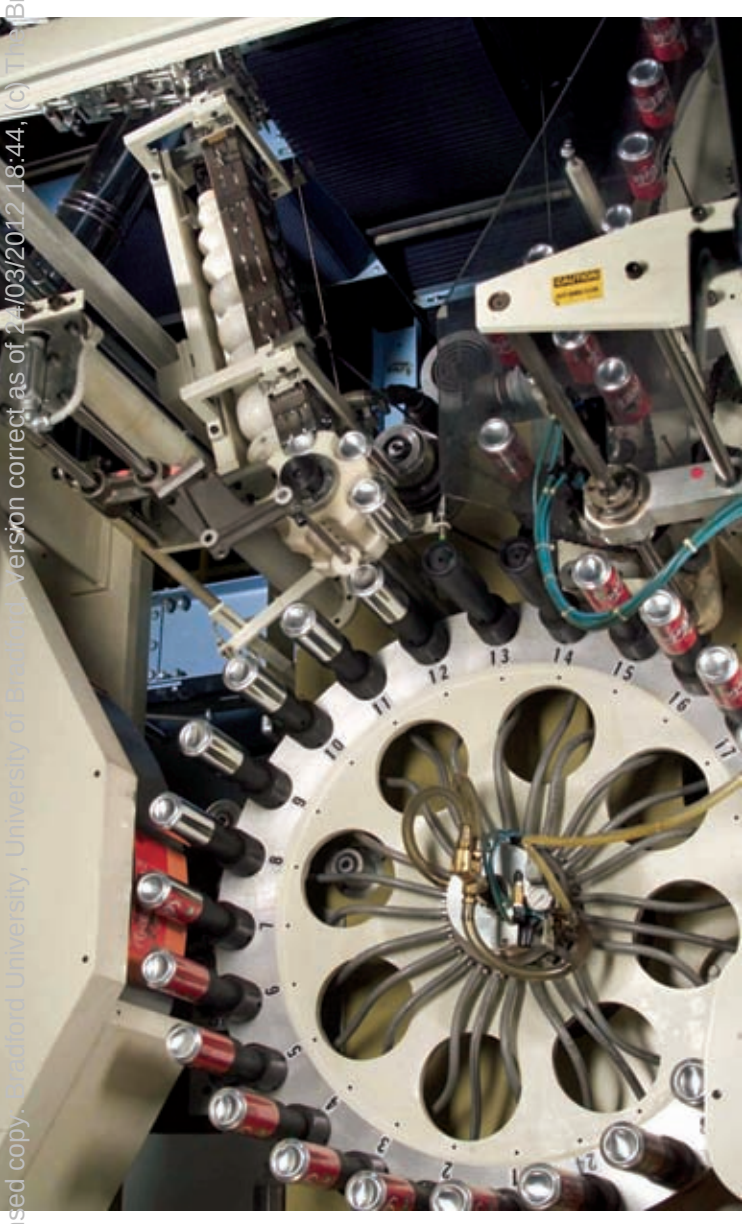
Where food packaging is withdrawn due to immediate health hazards, the food safety of other food packaging produced under the same conditions shall be evaluated.

16 Storage and transport

16.1 General requirements

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

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



16.2 Warehousing requirements

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

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

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

Specified stock rotation systems that meet customer, food safety and regulatory requirements shall be observed. Stock shall be used in the correct order and within the allocated shelf-life.

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 food packaging.

Control of temperature and humidity shall be applied, recorded and accessible where required.

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

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

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

17 Food packaging information and consumer awareness

17.1 General requirements

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

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

Controls shall be in place to prevent the use of obsolete printing media (e.g. preprinted material, printing plates).

Manufacturing, rework, storage and distribution processes shall be designed and implemented to prevent mixing of food packaging with different food safety information within a given batch.

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

18 Food defence, biovigilance and bioterrorism

18.1 General requirements

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

NOTE 1 *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 unauthorized entry;

b) reference checks for personnel;

c) control of confidential information;

d) security of storage and production areas;

e) management of security incidents.

NOTE 2 *For further information and guidance on approaches to the protection of food businesses from all forms of malicious attack, see 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.

The site security assessment shall be kept up to date.

Personnel shall be trained in site security measures.

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

18.2 Access controls

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

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

19 Food packaging design and development

19.1 General requirements

All applicable food safety requirements from regulatory authorities and any additional customer requirements shall be identified and addressed in the design process.

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

19.2 Communication and change control

The food packaging manufacturing organization shall have in place a procedure to obtain the information necessary to design food packaging suitable for its intended use.

There shall be a process in place to verify that changes in requirements are communicated along the food packaging supply chain.

***NOTE** Figure 2 illustrates an example of information flows along the food packaging supply chain.*

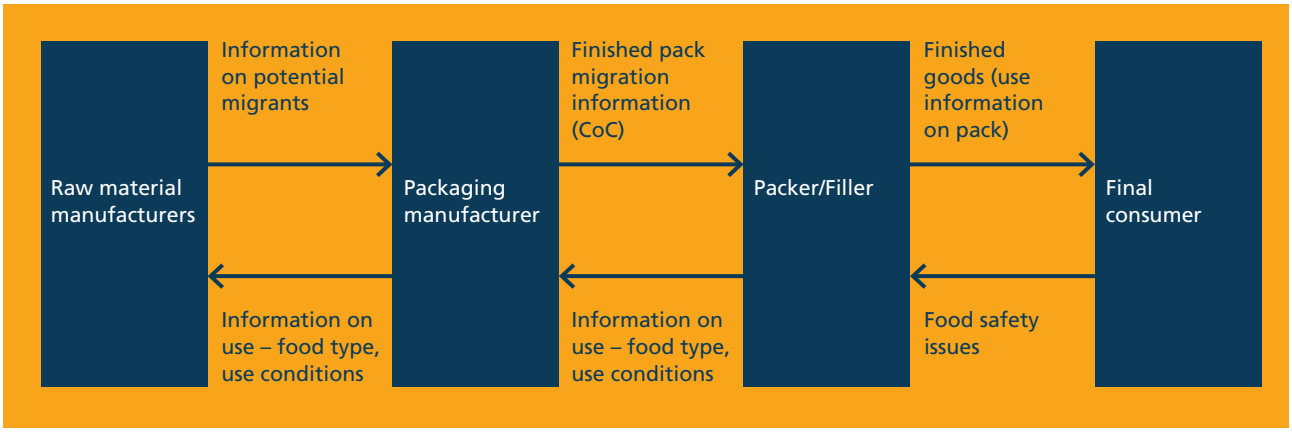
New technology and new manufacturing processes that may impact the food safety performance of the food packaging shall not be introduced without notification of the affected customer(s) in accordance with contractual obligations.

19.3 Design

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

Intermediate material composition, finished food packaging composition and migration data (where applicable) shall be available to demonstrate

Figure 2 – Information flows along the food packaging supply chain



***NOTE 1** Several materials may be used by a food packaging manufacturing organization to produce the finished food packaging (e.g. plastic film, paper, ink, adhesive).*

***NOTE 2** Several finished articles may be used by the packer/filler to produce the finished pack:*

e.g. 1. bottle, label, closure;

e.g. 2. carton box, inner liner.

conformance to relevant food safety regulatory and customer requirements in the countries where the end product is intended to be used, where known.

Compliance data (e.g. migration data) shall include the intended conditions under which the food packaging is to be used.

19.4 Specifications

Food safety requirements and specifications shall be developed and maintained, and a process shall be in place to verify that these specifications are agreed by the food packaging manufacturing organization and the customer(s).

Specifications shall include all food safety-relevant parameters.

19.5 Process validation

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

NOTE *Previous validation data may be used for new food packaging and processes if they are 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*

Other publications

Codex Alimentarius, *Recommended international code of practice – General principles of food hygiene*

Further reading

BIP 2078, *Managing food safety the 22000 way*

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*

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