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BSI Standards Publication

Prerequisite programmes on food safety

Part 4: Food packaging manufacturing

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National foreword

This Published Document is the UK implementation of ISO/TS 22002-4:2013.

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A list of organizations represented on this committee can be obtained on request to its secretary.

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

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 34, *Food products*, Subcommittee SC 17, *Management systems for food safety*.

ISO/TS 22002 consists of the following parts, under the general title *Prerequisite programmes on food safety*:

— *Part 1: Food manufacturing*

— *Part 2: Catering*

— *Part 3: Farming*

— *Part 4: Food packaging manufacturing*

The following part is under preparation:

— Part 5: Transport and storage

This Technical Specification is based on

— BS PAS 223:2011,[1] and

— EN 15593:2008.[2]

Introduction

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 (PRP) to assist in controlling food safety hazards (ISO 22000:2005, 7.2). In addition to addressing the requirements of ISO 22000:2005, 7.2, this Technical Specification includes communication requirements from ISO 22000:2005, 5.6.

This part of ISO/TS 22002 is intended to be used to support management systems designed to meet the requirements specified in ISO 22000, and sets out the detailed requirements for those programmes.

This part of ISO/TS 22002 does not duplicate requirements given in ISO 22000 and is intended to be used in conjunction with ISO 22000, e.g. the effectiveness of measures taken according to this Technical Specification to protect against contamination of the food packaging are intended to be reviewed.

Intended use of the food packaging needs to be fully understood so that any food safety hazard can be identified and addressed through appropriate food packaging design, which is covered in this Technical Specification under communication in 4.14 (Food packaging information and customer communication) in combination with clauses/subclauses in ISO 22000 as shown in Annex A.

Prerequisite programmes on food safety —

Part 4: Food packaging manufacturing

WARNING — The text of this Technical Specification assumes that the execution of its provisions is entrusted to appropriately qualified and experienced people, for whose use it has been produced. This Technical Specification does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application. Compliance with this Technical Specification does not in itself confer immunity from legal obligations.

1 Scope

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

This Technical Specification is applicable to all organizations, regardless of size or complexities that manufacture food packaging and/or intermediate products. This Technical Specification is not designed or intended for use in other parts or activities of the food supply chain.

NOTE 1 The organization producing its own food packaging (e.g. self-blowing of bottles and forming/filling/sealing of aseptic cartons/pouches) can decide whether or not this Technical Specification should be applied.

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

This Technical Specification is not a Management system Standard, and is intended to be used by food packaging manufacturing organizations wishing to implement PRPs in such a way as to address the requirements specified in ISO 22000.

This Technical Specification is intended to be used in conjunction with ISO 22000.

NOTE 2 For the purpose of this Technical Specification, 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.

ISO 22000, *Food safety management systems — Requirements for any organization in the food chain*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 22000 and the following apply.

3.1
certificate of analysis
COA
document that indicates results of specific tests or analysis, which may include test methodology, performed on a defined amount of material or product

[SOURCE: ISO/TS 22002-1:2009, 3.14, modified — The domain/subject has been deleted and the text of the definition has been changed.]

3.2
cleaning
removal of soil, dirt, solvents, grease or lubricant, ink residues or other objectionable matter

[SOURCE: ISO/TS 22002-1:2009, 3.5, modified — The domain has been deleted and the text of the definition has been changed.]

3.3
contaminant
any biological or chemical agent, foreign matter or other substance not intentionally added to the product which may compromise food safety

[SOURCE: ISO/TS 22002-1:2009, 3.2]

3.4
contamination
introduction or occurrence of a contaminant in the product

Note 1 to entry: In the context of this Technical Specification, "contamination" may also refer to the impurities in the materials used in, or a decomposition or reaction product formed during, the production process, which might compromise food safety.

[SOURCE: ISO/TS 22002-1:2009, 3.1, modified]

3.5
declaration of compliance
DOC
document that confirms conformance to specifications or regulations

Note 1 to entry: This is sometimes referred to as a certificate of conformance (CoC).

3.6
establishment
any building or area in which raw materials, intermediate products, chemicals or food packaging are handled, and the surroundings under the control of the same management

3.7
food packaging
any product to be used for containment, protection, handling, delivery, storage, transport and presentation of food

Note 1 to entry: Food packaging may have direct or indirect 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 be transferred into the food.

The classification of the food packaging as direct or indirect food contact should be part of the hazard analysis.

3.8
food packaging hazard
biological, chemical or physical agent in food packaging, or condition of use, with the potential to cause an effect in the food leading to adverse health effects

3.9
food packaging withdrawal
removal of non-conforming food packaging from any part of the food supply chain because the food packaging does not meet specified food safety standards or requirements

EXAMPLE Any part of the food supply chain includes trade warehouses, distribution centres or customer operations and warehouses.

3.10
hygiene
set of measures taken to ensure the food safety of a product that might otherwise become hazardous or harmful

3.11
incident
event that might potentially compromise the food safety of a material or product

3.12
intermediate product
product that is not yet food packaging and will undergo further processing or transformation by the organization

3.13
migration
transfer of substances from an external source to food

EXAMPLE Examples of external sources are packaging material and environment.

3.14
outsourcing
any activity subcontracted by an organization to an external organization

3.15
packaging
any kind of product or material used to hold and protect food packaging during shipping, transport and storage

3.16
rework
reuse of internal scrap of certain production into material with the same composition

3.17
risk
probability of the occurrence of a hazard and the severity of its outcome

3.18
safety
condition of a product being free from unacceptable hazards

3.19
set-off
transfer of substances from one surface of a material or from the surface of a contiguous surface, to the food contact surface through direct contact between the surfaces caused by the stacking or reeling of the material(s)

3.20
specification
detailed description of the properties and requirements of a material, in particular in relation to its technical and specific suitability

3.21
waste
any substance or object that the organization discards or intends or is required to discard

4 Generic PRPs

4.1 Establishment

4.1.1 General requirements

The establishment 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.

EXAMPLE All openings to the outside for auxiliary devices and equipment should be suitably protected.

4.1.2 Environment

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

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

4.1.3 Location of establishment

The boundaries of the establishment shall be clearly identified.

All areas within the boundaries of the establishment shall be maintained in an appropriate condition to prevent contamination.

4.2 Layout and workspace

4.2.1 General requirements

Internal layouts shall be designed, constructed and maintained to facilitate good hygiene and manufacturing practices.

The movement patterns of materials, as well as recycled materials, if applicable, products and people and the layout of equipment shall be designed to protect against contamination sources, unintended mixing of materials or products and cross-contamination.

4.2.2 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 as appropriate to the activities taking place inside the building or area of the building.

4.2.3 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 can be impacted.

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.

In areas where routine cleaning of overhead fixtures and structures is not feasible or practical and there is a potential for introducing a food safety hazard, the 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) appropriate to the activity in the building.

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

4.2.4 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.

4.2.5 Temporary/mobile structures

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

4.2.6 Storage

Facilities used to store raw materials, intermediate products, chemicals or 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 products, chemicals or food packaging are stored outside, appropriate measures shall be in place to manage potential contamination. Storage areas shall be designed or arranged to allow segregation of raw materials, intermediate products, chemicals and food packaging. Raw materials, intermediate products, chemicals and food packaging which are suitable for food contact shall be segregated from those which are not.

All raw materials, intermediate products, chemicals and food packaging shall be stored in a manner to minimize the potential for contamination 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 shall be suitably labelled. Hazardous materials and hazardous chemicals shall be secured in closed containers and used in accordance with manufacturers' instructions.

4.3 Utilities

4.3.1 General requirements

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

4.3.2 Water supply

The supply of water of a suitable quality shall be sufficient to meet the needs of the food packaging production process and not cause a food safety hazard.

The 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.

4.3.3 Air quality and ventilation

The 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.

Where appropriate room air supply quality shall be controlled to prevent airborne microbiological contamination.

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.

4.3.4 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 organization shall establish requirements for gases used for direct food packaging contact (including those used for transporting, blowing or drying raw materials, intermediate products, 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.

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

4.3.5 Lighting

The lighting provided (natural or artificial) shall allow correct operation of the food packaging production process.

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

Where there is a food safety hazard, light fixtures shall be protected to prevent contamination of raw materials, intermediate products, chemicals, food packaging and equipment in the case of breakages.

4.4 Waste disposal

4.4.1 General requirements

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

4.4.2 Waste handling

Containers for waste shall be emptied at appropriate frequencies and kept in an adequate condition of cleanliness.

Waste shall be kept away from production and storage areas. Bins and containers for non-production waste shall be appropriately identified, emptied regularly and if necessary, provided with lids.

Food packaging identified and designated as waste shall be disfigured or destroyed so that

a) trademarks or food ingredient information cannot be reused;

b) it cannot enter the supply chain again.

4.4.3 Drains and drainage

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

4.5 Equipment suitability, cleaning and maintenance

4.5.1 General requirements

Equipment used in production and packaging areas shall be designed to prevent contamination.

Where relevant, equipment used for irradiation processes shall meet the provision given in relevant food packaging specifications.

4.5.2 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 and surfaces likely to constitute a source of contamination ;

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.

4.5.3 Food packaging contact surfaces

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

4.5.4 Maintenance

A system of planned maintenance shall be in place including all equipment.

Maintenance programmes shall be systematically applied to minimize the potential for contamination of product by equipment.

Priority shall be given for maintenance request where food safety is at risk.

A procedure shall be in place to remove any potential contaminant from machinery and equipment after maintenance work.

Maintenance personnel shall follow the prescribed procedures including, where appropriate, hygiene measures. Temporary engineering and modifications should be avoided, shall be controlled and shall not become permanent. Effective measures shall be implemented.

4.6 Management of purchased materials and services

4.6.1 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 can include (but are not limited to) third-party storage and rework by subcontractors.

The organization shall set clear requirements to relevant outsourced processes. There shall be a written contract.

4.6.2 Selection and management of suppliers

There shall be a documented procedure for the evaluation, approval and monitoring of suppliers in place to ensure compliance. The method used shall be justified by risk assessment and hazard analysis, including the potential food safety hazard to the food packaging.

The process includes:

a) assessment of the suppliers' ability to meet food safety requirements;

b) description of how suppliers are assessed.

Monitoring may include conformance to specifications, meeting COA requirements and satisfactory audit outcomes.

4.6.3 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 have been maintained during transit.

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

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

Sufficient data shall be available to enable hazard analysis for food contact.

NOTE 1 For example where incoming raw materials are from a recycled source or are plant-based materials, it is intended that appropriate measures be in place to verify food safety and traceability requirements are met prior to acceptance.

NOTE 2 The inspection frequency and scope can be based on the risk presented by the 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 materials receiving lines shall be identified and, if appropriate, capped and secured. Discharge into such systems shall take place only after approval and verification of the raw materials received.

4.7 Measures for prevention of contamination

4.7.1 General requirements

A hazard analysis shall be carried out. If applicable, measures to prevent microbiological, physical and chemical contamination shall be implemented.

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 products shall be prevented where hazard analysis reveals a food safety hazard.

Whenever a contamination incident occurs, the process of cleaning up or the maintenance shall be carried out under the control of a designated person. After cleaning up or maintenance a documented release procedure shall follow. Any contaminated product that cannot be effectively cleaned shall be discarded.

4.7.2 Microbiological contamination

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

4.7.3 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 and brittle materials (such as hard plastic components in equipment, sight glasses on storage vessels) shall be avoided where relevant and possible.

In production and storage areas, surfaces intended to have contact with the product shall be free from splinters and any other source of contamination. They shall be suitable for easy and effective cleaning.

A formal procedure for the use of “sharps” shall be in place. No sharp objects or loose tools shall be left in any place and on surfaces where product contamination can occur. The use of snap-off blade knives shall be forbidden.

Buildings, facilities and equipment shall be cleaned to remove dust, cobwebs, flakes and fragments to maintain an acceptable level of housekeeping.

4.7.4 Chemical contamination

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 analysis.

Chemicals, including cleaning materials and lubricants, shall be evaluated and controlled in order to prevent product contamination.

Lubricant intended to come in contact with the product shall be of a grade suitable for the intended use.

4.7.5 Chemical migration

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.

Packaging (e.g. pallets, films, containers) shall be made of suitable material and be clean and shall not contaminate the food packaging.

NOTE In some cases, chemical treatment of pallets can be necessary (such as insecticides, fungicides, pesticides or other chemicals) to meet regulatory or customer requirements.

4.7.6 Food allergen management

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

4.8 Cleaning

4.8.1 General requirements

Cleaning programmes appropriate for specific areas shall be established to maintain the production equipment and environment in a hygienic condition.

If cleaning activities are outsourced, the approved supplier shall be competent and shall maintain documentation as specified by the organization.

4.8.2 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.

4.8.3 Cleaning agents and tools

Equipment shall be maintained in a condition which facilitates cleaning.

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

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

4.8.4 Monitoring cleaning programme effectiveness

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

4.9 Pest control

4.9.1 General requirements

Appropriate measures shall be implemented to avoid creating an environment conducive to pest activity.

4.9.2 Control programmes

The 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 approved for use in specified areas of the establishment.

4.9.3 Preventing access

The establishment shall be maintained in good conditions.

Effective measures shall be in place to prevent pests from entering the establishment.

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

All external doors shall be kept in good condition and closed when not in use.

NOTE Incoming and outgoing products and materials should be checked for presence of contaminants from rodents, flying and crawling insects, birds and any other pests.

4.9.4 Harbourage and infestations

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

4.9.5 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 products, 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 analysed to identify trends in pest activity.

4.9.6 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.

4.10 Personnel hygiene and facilities

4.10.1 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.

4.10.2 Personnel hygiene, changing facilities and toilets

Personnel hygiene facilities shall be available to maintain the degree of personal hygiene required by the 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, 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/or cold or temperature-controlled water and soap or sanitizer);

b) provide an adequate number of toilet facilities of appropriate hygienic design sufficiently separated from the production area, each with hand-washing, drying and, where required, sanitizing facilities; toilet and changing facilities shall be kept clean;

c) have adequate changing and storage facilities for all personnel who work in production, packaging and storage areas.

These changing and storage facilities should be accessible without crossing the production and storage areas when coming from outside.

NOTE Where for safety or other considerations, the facilities cannot be accessed without crossing the production areas, this can be managed by using controlled or designated routes.

4.10.3 Staff canteens and designated eating and smoking areas

Staff canteens and designated areas for food storage, consumption and smoking shall be situated and appropriately managed to prevent contamination of production areas.

All food, drinks and medicines should be stored in designated areas. Procedures should be in place to control the use of medicines to prevent product contamination.

Eating (including consuming confectionery, chewing gum or chewing tobacco), drinking, other than water and smoking should only be allowed in designated areas. Where drinking water is allowed, it should be subject to control to prevent spillage and contamination.

All such areas should be kept clean. Appropriate and cleanable lidded containers should be used for disposal of waste.

Adequate containers for smokers´ waste should be provided.

4.10.4 Workwear and protective clothing

The organization shall ensure that personnel who work in or enter into production or storage areas shall wear work clothing which is fit for purpose, in good condition and which not present any potential for contamination. Work clothing shall be suitably segregated from personal clothing.

Where appropriate, work clothing or other adequate protection shall provide coverage so that hair, perspiration and loose items cannot contaminate raw materials, intermediate products, food packaging or equipment based on a food safety hazard analysis. Where gloves are used for food packaging contact, they shall be fit for purpose and in good condition.

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

4.10.5 Illness and injuries

Personnel shall follow the organization's documented guidelines for injuries and diseases.

CAUTION — Personnel infected with, or carrying, a disease or illness transmissible through food should be prevented from handling food packaging. A medical screening procedure may be in place.

All injuries, including minor cuts, shall be treated immediately and in an appropriate manner.

Dressings shall be controlled and changed at appropriate intervals. Self-adhesive plasters shall not contaminate the product. They shall be differentiated from the product (e.g. by colour).

4.10.6 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.

IMPORTANT — 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 products or food packaging. Spitting (expectorating) shall be prohibited.

Fingernails shall be kept clean and trimmed.

4.10.7 Personal behaviour

A documented procedure 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; the prohibition of wearing jewellery, wristwatches and visible piercings, unless they are appropriately controlled to minimize contamination. The organization shall clearly define the type of jewellery allowed to be worn as determined by hazard analysis;

b) permissibility of having personal items, such as smoking materials and medicines, in designated areas only;

c) prohibition of the use of nail polish, false nails and false eyelashes;

d) control measures to restrict writing implements or loose items in areas where they could contaminate raw materials, intermediate products or food packaging;

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

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

4.11 Rework

4.11.1 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.

4.11.2 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. food packaging name, production date, shift, production line of origin).

4.11.3 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 products or 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's requirements are maintained by following the specified rework process.

4.12 Withdrawal procedures

Systems shall be in place to ensure that products failing to meet required food safety standards can be identified, located and removed from all necessary points of the supply chain.

The system shall be recorded and tested at an appropriate frequency.

4.13 Storage and transport

4.13.1 General requirements

Raw materials, intermediate products and food packaging shall be stored and handled in such manner to avoid contamination such as dust, condensation, fumes, odours or other sources.

Subcontracted storage areas shall fulfil the requirements of this Technical Specification.

4.13.2 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.

Measures shall be in place (electronically or physically separated) to avoid non-conforming materials to be released and or delivered.

Specified stock rotation systems should be implemented.

4.13.3 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.

Where required, control of temperature and humidity shall be applied, recorded and readily available. Transport vehicles shall be checked before loading and unloading. They shall be in good usable condition, clean and free from foreign bodies, pests and undesirable odour.

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

Pallets shall be inspected before use. They shall be suitable for the intended use and clean, free from foreign bodies, pests and undesirable odours. Pallets shall not contaminate raw materials, intermediate products and food packaging.

4.14 Food packaging information and customer communication

The organization shall be able to demonstrate compliance with food safety requirements and agreed specifications.

The organization shall obtain the information necessary to determine that the food packaging to be provided is suitable for the intended use and will meet the food safety requirements. In case of changes to the food packaging, the organization shall assess any implications for food safety and compliance.

The organization shall provide and update food safety relevant information on product applicability and restrictions of use to its customers.

NOTE Information can be provided by labelling or other means, such as company websites and advertisements and may include storage, instructions applicable to the product.

Where as part of the process food safety, information is provided on the food packaging, this information shall be complete, legible and controlled to prevent misprinting.

4.15 Food defence and bioterrorism

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

A procedure shall be in place for management of security incidents.

It may include but is not limited to:

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) transport and distribution.

The site security assessment shall be kept up to date. Personnel shall be trained in site security measures.

Annex A
(informative)

Comparison of food packaging design and development relevant items

Intended use of the food packaging needs to be fully understood so that any food safety hazard can be identified and addressed through appropriate food packaging design, which is covered in this Technical Specification as specified in Table A.1.

Table A.1 — Overview ISO 22000 or ISO/TS 22002–4 and BS PAS 223

<table>
<tr><th colspan="2">ISO 22000</th><th>This Technical Specification (TS 22002–4)</th><th colspan="2">BS PAS 223</th></tr>
<tr><td colspan="2">Food packaging design and development relevant (sub)clauses:</td><td></td><td colspan="2">19 Food packaging design and development</td></tr>
<tr><td>5.6.1</td><td>External communication</td><td rowspan="12">4.14 Food packaging information and customer communication</td><td>General requirements</td><td>19.1</td></tr>
<tr><td>5.6.1</td><td>External communication</td><td rowspan="3">Communication and change control</td><td rowspan="3">19.2</td></tr>
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<tr><td>7.3.4</td><td>Intended use</td></tr>
<tr><td>5.6.1</td><td>External communication</td><td rowspan="2">Specification</td><td rowspan="2">19.4</td></tr>
<tr><td>7.3.3.1</td><td>Raw materials, ingredients and product-contact materials</td></tr>
<tr><td>8.2</td><td>Validation of control measure combinations</td><td rowspan="2">Process validation</td><td rowspan="2">19.5</td></tr>
<tr><td>8.3</td><td>Control of monitoring and measuring</td></tr>
</table>

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