
**Prerequisite programmes on food
safety —**

**Part 1:
Food manufacturing**

Programmes prérequis pour la sécurité alimentaire —

Partie 1: Fabrication des aliments

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2009

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 Construction and layout of buildings	4
5 Layout of premises and workspace	5
6 Utilities – air, water, energy	6
7 Waste disposal	8
8 Equipment suitability, cleaning and maintenance	9
9 Management of purchased materials	10
10 Measures for prevention of cross contamination	11
11 Cleaning and sanitizing	12
12 Pest control	13
13 Personnel hygiene and employee facilities	14
14 Rework	16
15 Product recall procedures	17
16 Warehousing	17
17 Product information/consumer awareness	18
18 Food defence, biovigilance and bioterrorism	18
Bibliography	19

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 22002-1 was prepared by Technical Committee 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*

This Technical Specification is based on BS PAS 220:2008^[5].

Introduction

ISO 22000:2005 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, Clause 7). This Technical Specification is intended to be used to support management systems designed to meet the requirements specified in ISO 22000:2005, and sets out the detailed requirements for those programmes.

This Technical Specification does not duplicate requirements given in ISO 22000:2005 and is intended to be used in conjunction with ISO 22000:2005.

Prerequisite programmes on food safety —

Part 1: Food 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 (PRP) to assist in controlling food safety hazards.

This Technical Specification is applicable to all organizations, regardless of size or complexity, which are involved in the manufacturing step of the food chain and wish to implement PRP in such a way as to address the requirements specified in ISO 22000:2005, Clause 7.

This Technical Specification is neither designed nor intended for use in other parts of the food supply chain.

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

Where exclusions are made or alternative measures implemented, these need to be justified and documented by a hazard analysis, as described in ISO 22000:2005, 7.4. Any exclusions or alternative measures adopted should not affect the ability of the organization to comply with these requirements. Examples of such exclusions include the additional aspects relevant to manufacturing operations listed under 1), 2), 3), 4), and 5) below.

This Technical Specification specifies detailed requirements to be specifically considered in relation to ISO 22000:2005, 7.2.3:

- a) construction and layout of buildings and associated utilities;
- b) layout of premises, including workspace and employee facilities;
- c) supplies of air, water, energy and other utilities;
- d) supporting services, including waste and sewage disposal;
- e) suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance;
- f) management of purchased materials;
- g) measures for the prevention of cross-contamination;
- h) cleaning and sanitizing;

- i) pest control;
- j) personnel hygiene.

In addition, this Technical Specification adds other aspects which are considered relevant to manufacturing operations:

- 1) rework;
- 2) product recall procedures;
- 3) warehousing;
- 4) product information and consumer awareness;
- 5) food defence, biovigilance and bioterrorism.

NOTE Measures for prevention of malicious contamination are outside the scope of this Technical Specification.

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 22000:2005, *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 22000:2005 and the following apply.

3.1

contamination

⟨food safety⟩ introduction or occurrence of a **contaminant** (3.2) in food or food environment

NOTE Adapted from CAC/RCP 1:2003^[1], 2.3.

3.2

contaminant

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

[CAC/RCP 1:2003^[1], 2.3]

3.3

establishment

⟨food safety⟩ any building or area in which food is handled and the surroundings under the control of the same management

[CAC/RCP 1:2003^[1], 2.3]

3.4

materials

⟨food safety⟩ general term used to indicate raw materials, packaging materials, ingredients, process aids, cleaning materials and lubricants

3.5

cleaning

(food safety) removal of soil, food residue, dirt, grease or other objectionable matter

NOTE Adapted from CAC/RCP 1:2003^[1], 2.3.

3.6

product contact

all surfaces that are in contact with the product or the primary package during normal operation

3.7

material specification

product specification

(food safety) 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

food grade

lubricants and heat transfer fluids formulated to be suitable for use in food processes where there may be incidental contact between the lubricant and the food

3.9

disinfection

(food safety) reduction, by means of chemical agents and/or physical methods, of the number of microorganisms in the environment, to a level that does not compromise food safety or suitability

NOTE Adapted from CAC/RCP 1:2003^[1], 2.3.

3.10

cleaning in place

CIP

cleaning (3.5) of equipment by impingement or circulation of flowing chemical solutions, cleaning liquids and water rinses into, on to and over surfaces in equipment or systems without dismantling and designed for the purpose

[ISO 14159:2002^[2], 3.3]

3.11

cleaning out of place

COP

system where equipment is disassembled and cleaned in a tank or in an automatic washer by circulating a cleaning solution and maintaining a minimum temperature throughout the cleaning cycle

3.12

sanitizing

(food safety) process of cleaning, followed by disinfection

3.13

sanitation

all actions dealing with cleaning or maintaining hygienic conditions in an establishment, ranging from cleaning and/or sanitizing of specific equipment to periodic cleaning activities throughout the establishment (including building, structural, and grounds cleaning activities)

3.14

certificate of analysis

COA

(food safety) document provided by the supplier which indicates results of specific tests or analysis, including test methodology, performed on a defined lot of the supplier's product

3.15
zoning

⟨food safety⟩ demarcation of an area within an establishment where specific operating, hygiene or other practices may be applied to minimize the potential for microbiological cross-contamination

NOTE Examples of practices include: clothing change on entry or exit, positive air pressure, modified traffic flow patterns.

3.16
label

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

EXAMPLE The term covers, but is not limited to:

- a) the package itself, printed matter attached to the package, or a sticker used for over-labelling;
- b) multi-packs which have an inner label on the individual product and an outer combined label for the whole contents.

3.17
product recall

removal of a non-conforming product from the market, trade and warehouses, distribution centres and/or customer warehouses because it does not meet specified standards

3.18
first expired first out
FEFO

stock rotation based on the principle of despatching earliest expiration dates first

3.19
first in first out
FIFO

⟨food safety⟩ stock rotation based on the principle of despatching earliest received products first

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 processing 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 which presents no hazard to the product.

NOTE An example of "durable construction" is self-draining roofs which do not leak.

4.2 Environment

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

Food production should not be carried out in areas where potentially harmful substances could enter the product.

The effectiveness of measures taken to protect against potential contaminants shall be periodically reviewed.

4.3 Locations of establishments

The site boundaries shall be clearly identified.

Access to the site shall be controlled.

The site shall be maintained in good order. Vegetation shall be tended or removed. Roads, yards and parking areas shall be drained to prevent standing water and shall be maintained.

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, products 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 materials, products and personnel, and physical separation of raw from processed areas.

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

Openings intended for transfer of materials shall be designed to minimize entry of foreign matter and pests.

5.3 Internal structures and fittings

Process area walls and floors shall be washable or cleanable, as appropriate for the process or product hazard. Materials of construction shall be resistant to the cleaning system applied.

Wall floor junctions and corners shall be designed to facilitate cleaning.

It is recommended that wall floor junctions be rounded in processing areas.

Floors shall be designed to avoid standing water.

In wet process areas, floors shall be sealed and drained. Drains shall be trapped and covered.

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

External opening windows, roof vents or fan, where present, shall be insect screened.

External opening doors shall be closed or screened when not in use.

5.4 Location of equipment

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

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

5.5 Laboratory facilities

In-line and on-line test facilities shall be controlled to minimize risk of product contamination.

Microbiology laboratories shall be designed, located and operated so as to prevent contamination of people, plant and products. They shall not open directly on to a production area.

5.6 Temporary or mobile premises and vending machines

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

Additional hazards associated with temporary structures and vending machines shall be assessed and controlled.

5.7 Storage of food, packaging materials, ingredients and non-food chemicals

Facilities used to store ingredients, packaging and products 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 products.

All materials and products shall be stored off the floor and with sufficient space between the material and 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.

A separate, secure (locked or otherwise access controlled) storage area shall be provided for cleaning materials, chemicals and other hazardous substances.

Exceptions for bulk or agricultural crop materials shall be documented in the food safety management system.

6 Utilities — air, water, energy

6.1 General requirements

The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination. Utilities' quality shall be monitored to minimize product contamination risk.

6.2 Water supply

The supply of potable water shall be sufficient to meet the needs of the production process(es). Facilities for storage, distribution and, where needed, temperature control of the water shall be designed to meet specified water quality requirements.

Water used as a product ingredient, including ice or steam (including culinary steam), or in contact with products or product surfaces, shall meet specified quality and microbiological requirements relevant to the product.

Water for cleaning or applications where there is a risk of indirect product contact (e.g. jacketed vessels, heat exchangers) shall meet specified quality and microbiological requirements relevant to the application.

Where water supplies are chlorinated, checks shall ensure that the residual chlorine level at the point of use remains within limits given in relevant specifications.

Non-potable water shall have a separate supply system that is labelled and not connected to the potable water system. Take measures to prevent non-potable water refluxing into the potable system.

It is recommended that water that can come into contact with the product should flow through pipes that can be disinfected.

6.3 Boiler chemicals

Boiler chemicals, if used, shall be either:

- a) approved food additives which meet relevant additive specifications; or
- b) additives which have been approved by the relevant regulatory authority as safe for use in water intended for human consumption.

Boiler chemicals shall be stored in a separate, secure (locked or otherwise access-controlled) area when not in immediate use.

6.4 Air quality and ventilation

The organization shall establish requirements for filtration, humidity (RH%) and microbiology of air used as an ingredient or for direct product contact. Where temperature and/or humidity are deemed critical by the organization, a control system shall be put in place and monitored.

Ventilation (natural or mechanical) shall be provided to remove excess or unwanted steam, dust and odours, and to facilitate drying after wet cleaning.

Room air supply quality shall be controlled to minimize risk from airborne microbiological contamination. Protocols for air quality monitoring and control shall be established in areas where products which support the growth or survival of microorganisms are exposed.

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

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

6.5 Compressed air and other gases

Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination.

Gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be from a source approved for food contact use, filtered to remove dust, oil and water.

Where oil is used for compressors and there is potential for the air to come into contact with the product, the oil used shall be food grade.

Use of oil free compressors is recommended.

Requirements for filtration, humidity (RH%) and microbiology shall be specified.

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

6.6 Lighting

The lighting provided (natural or artificial) shall allow personnel to operate in a hygienic manner.

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

Light fixtures shall be protected to ensure that materials, product or equipment are not contaminated in the case of breakages.

7 Waste disposal

7.1 General requirements

Systems shall be in place to ensure that waste materials are identified, collected, removed and disposed of in a manner which prevents contamination of products or production areas.

7.2 Containers for waste and inedible or hazardous substances

Containers for waste and inedible or hazardous substances shall be:

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

7.3 Waste management and removal

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

Accumulation of waste shall not be allowed in food-handling or storage areas. Removal frequencies shall be managed to avoid accumulations, with a minimum daily removal.

Labelled materials, products or printed packaging designated as waste shall be disfigured or destroyed to ensure 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 materials or products is avoided. Drains shall have capacity sufficient to remove expected flow loads. Drains shall not pass over processing lines.

Drainage direction shall not flow from a contaminated area to a clean area.

8 Equipment suitability, cleaning and maintenance

8.1 General requirements

Food contact equipment shall be designed and constructed to facilitate cleaning, disinfection and maintenance. Contact surfaces shall not affect, or be affected by, the intended product or cleaning system.

Food contact equipment shall be constructed of durable materials able to resist repeated cleaning.

8.2 Hygienic design

Equipment shall be able to meet established principles of hygienic design, including:

- a) smooth, accessible, cleanable surfaces, self draining in wet process areas;
- b) use of materials compatible with intended products and cleaning or flushing agents;
- c) framework not penetrated by holes or nuts and bolts.

Piping and ductwork shall be cleanable, drainable, and with no dead ends.

Equipment shall be designed to minimize contact between the operator's hands and the products.

8.3 Product contact surfaces

Product contact surfaces shall be constructed from materials designed for food use. They shall be impermeable and rust or corrosion free.

8.4 Temperature control and monitoring equipment

Equipment used for thermal processes shall be able to meet the temperature gradient and holding conditions given in relevant product specifications.

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

8.5 Cleaning plant, utensils and equipment

Wet and dry cleaning programmes shall be documented to ensure that all plant, utensils and equipment are cleaned at defined frequencies.

The programmes shall specify what is to be cleaned (including drains), the responsibility, the method of cleaning (e.g. CIP, COP), the use of dedicated cleaning tools, removal or disassembly requirements and methods for verifying the effectiveness of the cleaning.

8.6 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 which impact product safety shall be given priority.

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

Lubricants and heat transfer fluids shall be food grade where there is a risk of direct or indirect contact with the product.

The procedure for releasing maintained equipment back to production shall include clean up, sanitizing, where specified in process sanitation procedures, and pre-use inspection.

Local area PRP requirements shall apply to maintenance areas and maintenance activities in process areas. Maintenance personnel shall be trained in the product hazards associated with their activities.

9 Management of purchased materials

9.1 General requirements

Purchasing of materials which impact food safety shall be controlled to ensure that the suppliers used have the capability to meet the specified requirements. The conformance of incoming materials to specified purchase requirements shall be verified.

9.2 Selection and management of suppliers

There shall be a defined process for the selection, approval and monitoring of suppliers. The process used shall be justified by hazard assessment, including the potential risk to the final product, and shall include:

- a) assessment of the supplier's ability to meet quality and food safety expectations, requirements and specifications;
- b) description of how suppliers are assessed;

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

- 1) audit of the supplying site prior to accepting materials for production;
- 2) appropriate third party certification.
- c) monitoring the performance of the supplier to assure continued approval status.

NOTE Monitoring includes conformity with material or product specifications, fulfilment of COA requirements, satisfactory audit outcomes.

9.3 Incoming material requirements (raw/ingredients/packaging)

Delivery vehicles shall be checked prior to, and during, unloading to verify that the quality and safety of the material has been maintained during transit (e.g. integrity of seals, freedom from infestation, existence of temperature records).

Materials shall be inspected, tested or covered by COA to verify conformity with specified requirements prior to acceptance or use. The method of verification shall be documented.

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

Materials which do not conform to relevant specifications shall be handled under a documented procedure which ensures they are prevented from unintended use.

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

10.2 Microbiological cross-contamination

Areas where potential for microbiological cross-contamination exists (airborne or from traffic patterns) shall be identified and a segregation (zoning) plan implemented. A hazard assessment shall be carried out to determine potential contamination sources, susceptibility of the product and control measures suitable for these areas as follows:

- a) separation of raw from finished or ready to eat (RTE) products;
- b) structural segregation — physical barriers, walls or separate buildings;
- c) access controls with requirements to change into required workwear;
- d) traffic patterns or equipment segregation — people, materials, equipment and tools (including use of dedicated tools);
- e) air pressure differentials.

10.3 Allergen management

Allergens present in the product, either by design or by potential manufacturing cross-contact, shall be declared. The declaration shall be on the label for consumer products, and on the label or the accompanying documentation for products intended for further processing.

Products shall be protected from unintended allergen cross-contact by cleaning and line change-over practices and/or product sequencing.

NOTE Manufacturing cross-contact can arise from either:

- 1) traces of product from the previous production run which cannot be adequately cleaned from the product line due to technical limitations; or
- 2) when contact is likely to occur, in the normal manufacturing process, with products or ingredients that are produced on separate lines, or in the same or adjacent processing areas.

Rework containing allergen(s) shall be used only:

- a) in products which contain the same allergen(s) by design; or
- b) through a process which is demonstrated to remove or destroy the allergenic material.

NOTE For general rework requirements, see Clause 14.

Employees handling food should receive specific training in allergen awareness and associated manufacturing practices.

10.4 Physical contamination

Where brittle materials are used, periodic inspection requirements and defined procedures in case of breakage shall be put in place.

Brittle materials, such as glass and hard plastic components in equipment, should be avoided where possible.

Glass breakage records shall be maintained.

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

NOTE 1 Examples of such measures include:

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

NOTE 2 Sources of potential contamination include wooden pallets and tools, rubber seals, and personal protective clothing and equipment.

11 Cleaning and sanitizing

11.1 General requirements

Cleaning and sanitizing programmes shall be established to ensure that the food-processing equipment and environment are maintained in a hygienic condition. Programmes shall be monitored for continuing suitability and effectiveness.

11.2 Cleaning and sanitizing agents and tools

Facilities and equipment shall be maintained in a condition which facilitates wet or dry cleaning and/or sanitation.

Cleaning and sanitizing agents and chemicals shall be clearly identified, food grade, stored separately and used only in accordance with the manufacturer's instructions.

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

11.3 Cleaning and sanitizing programmes

Cleaning and sanitizing programmes shall be established and validated by the organization to ensure that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule, including the cleaning of cleaning equipment.

Cleaning and/or sanitizing programmes shall specify at a minimum:

- a) areas, items of equipment and utensils to be cleaned and/or sanitized;
- b) responsibility for the tasks specified;
- c) cleaning/sanitizing method and frequency;
- d) monitoring and verification arrangements;
- e) post-clean inspections;
- f) pre start-up inspections.

11.4 Cleaning in place (CIP) systems

CIP systems shall be separated from active product lines.

Parameters for CIP systems shall be defined and monitored (including type, concentration, contact time and temperature of any chemicals used).

11.5 Monitoring sanitation effectiveness

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

12 Pest control

12.1 General requirements

Hygiene, cleaning, incoming materials inspection and monitoring procedures shall be implemented to avoid creating an environment conducive to pest activity.

12.2 Pest control programmes

The establishment 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 which are approved for use in specified areas of the establishment.

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 Harbourage and infestations

Storage practices shall be designed to minimize the availability of food and water to pests.

Material found to be infested shall be handled in such a way as to prevent contamination of other materials, products or the establishment.

Potential pest harbourage (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 so as to prevent potential contamination of materials, products 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 analysed 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 operatives and shall be controlled to avoid product 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 process area or product 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 hygienically washing, drying and, where required, sanitizing hands (including wash-basins, supply of hot and cold or temperature controlled water, and soap and/or sanitizer);
- b) have sinks designated for hand washing, whose taps should not be hand operated, separate from sinks for food use and equipment-cleaning stations;
- c) provide an adequate number of toilets of appropriate hygienic design, each with hand-washing, drying and, where required, sanitizing facilities;
- d) have employee hygiene facilities that do not open directly on to production, packing or storage areas;
- e) have adequate changing facilities for personnel;
- f) have changing facilities sited to enable personnel handling food to move to the production area in such a way that risk to the cleanliness of their workwear is minimized.

13.3 Staff canteens and designated eating areas

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

Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods. Storage conditions and storage, cooking and holding temperatures, and time limitations, shall be specified.

Employees' own food shall be stored and consumed in designated areas only.

13.4 Workwear and protective clothing

Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear work clothing that is fit for purpose, clean and in good condition (e.g. free from rips, tears or fraying material).

Clothing mandated for food protection or hygiene purposes shall not be used for any other purpose.

Workwear shall not have buttons. Workwear shall not have outside pockets above waist level. Zips or press stud fastenings are acceptable.

Workwear shall be laundered to standards and at intervals suitable for the intended use of the garments.

Workwear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.

Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints unless hazard analysis indicates otherwise.

Where gloves are used for product contact, they shall be clean and in good condition. Use of latex gloves should be avoided where possible.

Shoes for use in processing areas shall be fully enclosed and made from non-absorbent materials.

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

13.5 Health status

Subject to legal restrictions in the country of operation, employees shall undergo a medical examination prior to employment in food contact operations (including site catering), unless documented hazard or medical assessment indicates otherwise.

Additional medical examinations, where permitted, shall be carried out at intervals defined by the organization.

13.6 Illness and injuries

Where permitted by law, employees shall be required to report the following conditions to management for possible exclusion from food-handling areas: jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected skin lesions (boils, cuts or sores) and discharges from the ear, eye or nose.

People known or suspected to be infected with, or carrying, a disease or illness transmissible through food shall be prevented from handling food or materials which come into contact with food.

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

NOTE Dressings should be brightly coloured and metal detectable where appropriate.

13.7 Personal cleanliness

Personnel in food production areas shall be required to wash and, where required, sanitize hands:

- a) before starting any food-handling activities;
- b) immediately after using the toilet or blowing the nose;
- c) immediately after handling any potentially contaminated material.

Personnel shall be required to refrain from sneezing or coughing over materials or products. Spitting (expectorating) shall be prohibited.

Fingernails shall be kept clean and trimmed.

13.8 Personal behaviour

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

- a) permissibility of smoking, eating, chewing in designated areas only;
- b) control measures to minimize hazards presented by permitted jewellery, such as that worn by 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 behind the ears;
- f) maintenance of personal lockers so that they are kept free from rubbish and soiled clothing;
- g) prohibition of storage of product contact tools and equipment in personal lockers.

14 Rework

14.1 General requirements

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

14.2 Storage, identification and traceability

Stored rework shall be protected from exposure to microbiological, chemical or extraneous matter contamination.

Segregation requirements for rework (e.g. allergen) shall be documented and met.

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. product name, production date, shift, line of origin, shelf-life).

14.3 Rework usage

Where rework is incorporated into a product as an "in-process" step, the acceptable quantity, type and conditions of rework use shall be specified. The process step and method of addition, including any necessary pre-processing stages, shall be defined.

Where rework activities involve removing a product from filled or wrapped packages, controls shall be put in place to ensure the removal and segregation of packaging materials and to avoid contamination of the product with extraneous matter.

15 Product recall procedures

15.1 General requirements

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.

15.2 Product recall requirements

A list of key contacts in the event of a recall shall be maintained.

Where products are withdrawn due to immediate health hazards, the safety of other products produced under the same conditions shall be evaluated. The need for public warnings shall be considered.

16 Warehousing

16.1 General requirements

Materials and products 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 product or storage specifications.

It is recommended that where products are stacked, consideration is given to measures necessary to protect the lower layers.

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

A separate area or other means of segregating materials identified as non-conforming shall be provided.

Specified stock rotation systems (FIFO/FEFO) shall be observed.

Gasoline- or diesel-powered fork-lift trucks shall not be used in food ingredient or product storage areas.

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.

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

Where the same vehicles, conveyances, and containers are used for food and non-food products, cleaning shall be carried out between loads.

Bulk containers shall be dedicated to food use only. Where required by the organization, bulk containers shall be dedicated to a specified material.

17 Product information and consumer awareness

Information shall be presented to consumers in such a way as to enable them to understand its importance and make informed choices.

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

18 Food defence, biovigilance, and bioterrorism

18.1 General requirements

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

18.2 Access controls

Potentially sensitive areas within the establishment shall be identified, mapped, and subjected to access control.

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

Bibliography

- [1] CAC/RCP 1:2003, *Recommended international code of practice — General principles of food hygiene*. Available [2009-11-23] at www.codexalimentarius.net/download/standards/23/cxp_001e.pdf
- [2] ISO 14159:2002, *Safety of machinery — Hygiene requirements for the design of machinery*
- [3] ISO/TS 22003, *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems*
- [4] ISO/TS 22004:2005, *Food safety management systems — Guidance on the application of ISO 22000:2005*
- [5] BS PAS 220:2008, *Prerequisite programmes on food safety for food manufacturing*

