TECHNICAL SPECIFICATION

ISO/TS 22002-1

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Prerequisite programmes on food safety —

Part 1: Food manufacturing

Programmes prérequis pour la sécurité alimentaire —

Partie 1: Fabrication des aliments

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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

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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.

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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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.