

**International
Standard**

ISO 22002-1

**Prerequisite programmes on food
safety —**

**Part 1:
Food manufacturing**

*Programmes prérequis pour la sécurité des denrées
alimentaires —*

Partie 1: Fabrication des denrées alimentaires

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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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2.

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT).

This document was prepared by Technical Committee ISO/TC 34, Subcommittee SC 17, *Management systems for food safety*.

This first edition cancels and replaces ISO/TS 22002-1:2009, which has been technically revised.

The main changes are as follows:

- the requirements in this document are applicable to food manufacturing only;
- common requirements for the food, feed and packaging supply chain have been moved to new part of the series, ISO 22002-100, which is a requirement of this document.

A list of all parts in the ISO 22002 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body.

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 (PRPs) to assist in controlling food safety hazards.

This document 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 document does not duplicate the requirements given in ISO 22000 and is intended to be used in conjunction with ISO 22000 and ISO 22002-100.

Prerequisite programmes on food safety —

Part 1: Food manufacturing

1 Scope

This document specifies, in conjunction with ISO 22002-100, requirements for establishing, implementing and maintaining prerequisite programmes (PRPs) to control food safety hazards in food manufacturing.

This document is applicable to all organizations, regardless of size or complexity.

This document does not apply to other parts of the food supply chain.

Exclusions to requirements can be supported by a sufficient justification that ensures that the exclusion does not adversely impact food safety.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 22002-100, *Prerequisite programmes on food safety — Part 100: Requirements for the food, feed and packaging supply chain*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 22002-100 and the following apply.

ISO and IEC maintain terminology databases for use in standardization.

3.1 cleaning in place CIP

cleaning of equipment by circulation of flowing chemical solutions, cleaning liquids and water rinses into, onto and over surfaces in equipment without dismantling and designed for the purpose

[SOURCE: ISO 14159:2002, 3.3, modified — “impingement or” deleted and “or systems” deleted before “dismantling”.]

4 Construction and layout of buildings

4.1 Boundaries of the site/facility

The requirements in ISO 22002-100 shall apply.

4.2 Environment

The requirements in ISO 22002-100 shall apply.

4.3 Construction and layout

The requirements in ISO 22002-100 shall apply.

Drains shall not pass over processing lines.

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

5 Design and layout of facilities and workspaces

5.1 General

The requirements in ISO 22002-100 shall apply.

5.2 Internal structures and fittings

The requirements in ISO 22002-100 shall apply.

5.3 Location of equipment

The requirements in ISO 22002-100 shall apply.

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

The requirements in ISO 22002-100 shall apply.

6 Utilities

6.1 General

The requirements in ISO 22002-100 shall apply.

6.2 Water, ice and steam

The requirements in ISO 22002-100 and the following shall apply.

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, tests shall ensure that the residual chlorine level at the point of use remains within limits given in relevant specifications.

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

6.3 Air and ventilation

The requirements in ISO 22002-100 shall apply.

6.4 Compressed air and other gases

The requirements in ISO 22002-100 shall apply.

6.5 Light

The requirements in ISO 22002-100 shall apply.

6.6 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.

7 Pest control

7.1 General

The requirements in ISO 22002-100 shall apply.

7.2 Pest control programmes

The requirements in ISO 22002-100 shall apply.

7.3 Preventing access

The requirements in ISO 22002-100 shall apply.

7.4 Harborage and infestations

The requirements in ISO 22002-100 shall apply.

7.5 Monitoring and detection

The requirements in ISO 22002-100 shall apply.

7.6 Control and eradication

The requirements in ISO 22002-100 shall apply.

8 Waste, FLW management and recycling

8.1 General

The requirements in ISO 22002-100 shall apply.

8.2 Recycling and/or reuse of materials

The requirements in ISO 22002-100 shall apply.

8.3 Waste containers

The requirements in ISO 22002-100 shall apply.

9 Equipment suitability and maintenance

9.1 General

The requirements in ISO 22002-100 shall apply.

9.2 Equipment capability

The requirements in ISO 22002-100 shall apply.

9.3 Maintenance

The requirements in ISO 22002-100 shall apply.

10 Management of purchased materials

The requirements in ISO 22002-100 and the following shall apply.

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.

11 Storage, including warehousing, and transport

11.1 Storage and warehousing

The requirements in ISO 22002-100 shall apply.

11.2 Dispatch

The requirements in ISO 22002-100 shall apply.

11.3 Transport

The requirements in ISO 22002-100 shall apply.

12 Measures for prevention of contamination

12.1 General

The requirements in ISO 22002-100 shall apply.

12.2 Microbiological contamination

Areas where potential for microbiological cross-contamination exists (airborne or from traffic patterns) shall be identified and a segregation (zoning) plan implemented with consideration of the following:

- a) separation of raw from finished or ready-to-eat 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.

12.3 Allergen control

Products shall be protected from unintended allergen cross-contact, as applicable, by:

- a) cleaning and line change-over practices;
- b) product sequencing;
- c) airflow control;
- d) additional protective clothing;
- e) use of dedicated tools/equipment;
- f) on-site catering control including vending machines.

NOTE 1 Manufacturing cross-contact can arise from either:

- traces of product from the previous production run which cannot be adequately cleaned from the product line due to technical limitations; or
- products or ingredients that are in the same or adjacent processing areas during the preparation process.

Rework containing allergen(s) shall be used only:

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

NOTE 2 For general rework requirements, see [Clause 17](#).

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

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

12.4 Physical contamination

Measures shall be put in place to prevent, control or detect potential physical contamination with consideration of the following:

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

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. Documented information on breakage shall be maintained.

12.5 Chemical contamination

Measures shall be put in place to prevent contamination of foods or food contact materials by chemicals (e.g. cleaning agents, disinfectants, lubricants, pesticides).

The organization shall ensure the chemicals used:

- a) have been approved by competent authorities, where applicable;
- b) are applied according to the product instructions (concentrations, method of application, etc.);
- c) are applied by competent personnel;
- d) are labelled;
- e) are stored separately from food and food contact materials;
- f) are stored in a key locked or secured area.

Pesticides shall be stored segregated from cleaning and disinfecting agents.

Equipment for applying pesticides and non-grade lubricants shall be specific to that use and shall be labelled.

If a potential chemical contamination occurs to food or food contact materials, employees shall take corrections and corrective actions, including communication.

13 Cleaning and disinfection

13.1 General

The requirements in ISO 22002-100 shall apply.

13.2 Cleaning agents and tools

The requirements in ISO 22002-100 shall apply.

13.3 Cleaning and disinfection programmes

The requirements in ISO 22002-100 and the following shall apply.

Cleaning and/or disinfection programmes shall specify, as appropriate for the nature of the operations:

- a) post-clean inspections; and/or
- b) pre-start-up inspections.

13.4 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).

14 Personal hygiene and employee facilities

14.1 General

The requirements in ISO 22002-100 shall apply.

14.2 Hygiene facilities

The requirements in ISO 22002-100 shall apply.

14.3 Designated eating areas

The requirements in ISO 22002-100 shall apply.

14.4 Workwear and protective clothing

The requirements in ISO 22002-100 shall apply.

14.5 Health status

The requirements in ISO 22002-100 shall apply.

14.6 Personnel cleanliness

The requirements in ISO 22002-100 shall apply.

14.7 Personnel behaviour

The requirements in ISO 22002-100 shall apply.

14.8 Visitors and external providers

The requirements in ISO 22002-100 shall apply.

15 Product and consumer information

The requirements in ISO 22002-100 shall apply.

16 Food defence and food fraud

16.1 General

The requirements in ISO 22002-100 shall apply.

16.2 Food defence

The requirements in ISO 22002-100 shall apply.

16.3 Food fraud prevention

The requirements in ISO 22002-100 shall apply.

17 Rework

17.1 General

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

17.2 Storage, identification and traceability

Stored rework shall be protected from exposure to microbiological, chemical, physical and allergen contamination.

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

Rework shall be clearly identified and/or labelled to allow traceability. Documented information for rework traceability shall be retained.

The rework classification or the reason for rework designation shall be retained as documented information (e.g. product name, production date, shift, line of origin, shelf-life).

17.3 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.

Bibliography

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- [6] CXC 80-2020, *Codex Code of Practice of Food Allergen Management for Food Business Operators*