

# Teknisk specifikation

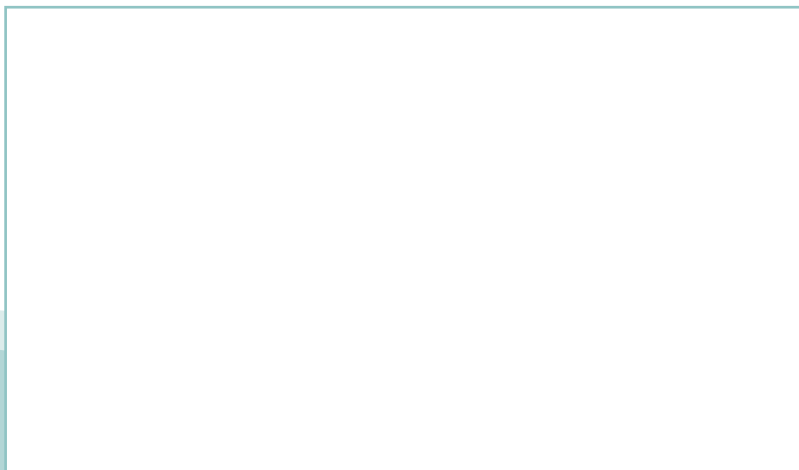
## SIS-ISO/TS 22002-4:2016

Publicerad/Published: 2016-03-18  
Utgåva/Edition: 1  
Språk/Language: engelska/English  
ICS: 67.040; 67.100

---

### **Grundförutsättningar för livsmedelssäkerhet – Del 4: Tillverkning av livsmedelsförpackningar (ISO/TS 22002-4:2013, IDT)**

### **Prerequisite programmes on food safety – Part 4: Food packaging manufacturing (ISO/TS 22002-4:2013, IDT)**



# Standarder får världen att fungera

*SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.*

## Delta och påverka

Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

## Ta del av det färdiga arbetet

Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standardpaket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

## Utveckla din kompetens och lyckas bättre i ditt arbete

Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

**Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på [www.sis.se](http://www.sis.se) eller ta kontakt med oss på tel 08-555 523 00.**



# Standards make the world go round

*SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.*

## Take part and have influence

As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

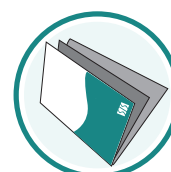
## Get to know the finished work

We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

## Increase understanding and improve perception

With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

**If you want to know more about SIS, or how standards can streamline your organisation, please visit [www.sis.se](http://www.sis.se) or contact us on phone +46 (0)8-555 523 00**



Denna tekniska specifikation är inte en svensk standard. Detta dokument innehåller den engelska språkversionen av ISO/TS 22002-4:2013.

This Technical Specification is not a Swedish Standard. This document contains the English version of ISO/TS 22002-4:2013.

© Copyright/Upphovsrätten till denna produkt tillhör SIS, Swedish Standards Institute, Stockholm, Sverige. Användningen av denna produkt regleras av slutanvändarlicensen som återfinns i denna produkt, se standardens sista sidor.

© Copyright SIS, Swedish Standards Institute, Stockholm, Sweden. All rights reserved. The use of this product is governed by the end-user licence for this product. You will find the licence in the end of this document.

*Uppllysningar om sakinnehållet i detta dokument lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om nationell och internationell standard.*

*Information about the content of this document is available from the SIS, Swedish Standards Institute, telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about national and international standards.*

Dokumentet är framtaget av kommittén för Livsmedel och foder, SIS/TK 435.

Har du synpunkter på innehållet i det här dokumentet, vill du delta i ett kommande revideringsarbete eller vara med och ta fram standarder inom området? Gå in på [www.sis.se](http://www.sis.se) - där hittar du mer information.

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Generic PRPs</b> .....	<b>4</b>
4.1 Establishment .....	4
4.2 Layout and workspace .....	4
4.3 Utilities .....	6
4.4 Waste disposal .....	7
4.5 Equipment suitability, cleaning and maintenance .....	7
4.6 Management of purchased materials and services .....	8
4.7 Measures for prevention of contamination .....	9
4.8 Cleaning .....	10
4.9 Pest control .....	11
4.10 Personnel hygiene and facilities .....	12
4.11 Rework .....	14
4.12 Withdrawal procedures .....	14
4.13 Storage and transport .....	14
4.14 Food packaging information and customer communication .....	15
4.15 Food defence and bioterrorism .....	15
<b>Annex A (informative) Comparison of food packaging design and development relevant items</b> .....	<b>16</b>
<b>Bibliography</b> .....	<b>17</b>

## 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](http://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](http://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,<sup>[1]</sup> and
- EN 15593:2008.<sup>[2]</sup>

## 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.