SLOVENSKI STANDARD
SIST EN 15593:2008

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Embalaža - Obvladovanje higiene v proizvodnji embalaže za živila - Zahteve

Packaging - Management of hygiene in the production of packaging for foodstuffs - Requirements

Verpackung - Hygienemanagement bei der Herstellung von Lebensmittelverpackungen - Anforderungen

Emballages - Management de l'hygiène dans la fabrication des emballages destinés aux denrées alimentaires - Exigences

Ta slovenski standard je istoveten z: **EN 15593:2008**

ICS:

55.020	Pakiranje in distribucija blaga na splošno	Packaging and distribution of goods in general
67.020	Procesi v živilski industriji	Processes in the food industry

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EUROPEAN STANDARD

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EN 15593

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English Version

Packaging - Management of hygiene in the production of packaging for foodstuffs - Requirements

Emballages - Management de l'hygiène dans la fabrication des emballages destinés aux denrées alimentaires - Exigences

Verpackung - Hygienemanagement bei der Herstellung von Lebensmittelverpackungen - Anforderungen

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN 15593:2008) has been prepared by Technical Committee CEN/TC 261 “Packaging”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2008, and conflicting national standards shall be withdrawn at the latest by September 2008.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

All manufacturers of food packaging recognize the increasing need to demonstrate and provide adequate evidence of their ability to identify and control hygiene hazards related to their products.

Packaging hygiene is a joint responsibility that is principally assured through the combined efforts of all the parties participating in the chain.

Communication along the food packaging chain is essential to ensure that all relevant packaging hygiene hazards are identified and adequately controlled.

This European Standard is based on the principles of hazard analysis and risk assessment.

This European Standard provides for the definition of the appropriate level of controls and measures for each stage in the manufacturing process.

The most effective food packaging hygiene systems are designed, operated and updated within the framework of a structured management system and incorporated into the overall management activities of the organization. This provides maximum benefit for the organization and interested parties.

This European Standard has taken due consideration of the provisions of the EN ISO 9000 series in order to enhance the compatibility of the two standards.

This European Standard may be applied independently from other management system standards. Its implementation can be aligned or integrated with existing related management system requirements while organizations may utilize existing management system(s) to establish a food packaging hygiene management system that complies with the requirements of this European Standard.

This European Standard is a document describing both management system and hygiene practices for packaging manufacturers considering themselves as an organization within the food chain as described in EN ISO 22000.

This European Standard does not purport to address the compulsory conformity of packaging to food contact regulations.

It is expected that the user of this European Standard has knowledge of applicable food contact regulations.

1 Scope

This European Standard specifies requirements for a hygiene management system for manufacturers and suppliers of food packaging including storage and transportation.

This European Standard enables an organization to:

— plan, design, implement, operate, maintain and update a hazard analysis and risk assessment system that ensures the production of food packaging materials conforming with the hygiene requirements;

— demonstrate conformity with agreed customers' hygiene requirements;

— demonstrate the effectiveness of the system;

— help food manufacturers to provide adequate evidence to compliance with food and packaging safety regulations;

— ensure that it complies with its stated hygiene policy;

— demonstrate such compliance to other interested parties;

— seek registration or certification of its food packaging hygiene management system by an external organization.

This European Standard can be applied to all organizations wishing to implement an adequate and effective hygiene management system in the field of food packaging manufacturing including producers and suppliers of materials and services to the packaging manufacturers.

It is intended that this European Standard be applied in conjunction with a quality management system such as EN ISO 9001.

It may be appropriate to apply this European Standard to other articles and items coming into contact with food and to packaging of products other than food.

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.

EN ISO 9000:2005, *Quality management systems – Fundamentals and vocabulary (ISO 9000:2005)*

EN ISO 22000:2005, *Food safety management systems – Requirements for any organization in the food chain (ISO 22000:2005)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 9000:2005, EN ISO 22000:2005 and the following apply.

3.1
contaminant
any biological (including microbiological) or chemical agent or foreign matter or other substances not intentionally added which may compromise product safety or suitability

3.2
contamination
introduction or occurrence of a contaminant

3.3
hazard
biological, chemical or physical contaminant in the product, or a condition of the product that may cause an adverse health effect or a nonconformity to the hygiene requirements for that product

3.4
hygiene
set of measures taken to ensure the safety and suitability of a product that might otherwise become hazardous or harmful

3.5
incident
event that may potentially compromise the safety and suitability of a material or product

3.6
outsourced activity
any activity subcontracted by an organization to an external organization

3.7
packaging
any kind of product or material used by the packaging industry to wrap, pack, protect, handle or transport its own product

3.8
product
physical final output of any kind of production process that takes place in the packaging industry.

NOTE This includes products that undergo further production steps to fulfil the specification defined by the filler/packer.

3.9
recall procedure
procedure to ensure the efficient return of products identified as potentially having a nonconformity that could present a hazard

3.10
risk
function of the probability of the possible occurrence of a hazard and the severity of its outcome

3.11
safety
condition of a product being free from unacceptable risk of harm

3.12
specification
explicit or detailed description of a material, product or service including hygiene aspects

3.13
top management
person or group of people who directs and controls an organization at the highest level

4 Hygiene management system

4.1 Management responsibility

4.1.1 Top management shall define its hygiene policy which shall state its commitment to develop and implement a hygiene management system to ensure that it meets its obligations to produce safe products and shall communicate this effectively through the organization. It shall conduct management reviews at planned intervals and at least once a year and shall ensure the availability of resources in accordance with the requirements of this document.

4.1.2 The organization shall apply hazard analysis and risk assessment to every stage from procurement to delivery of the product to determine the application of this document.

4.1.3 Top management shall appoint a competent person responsible for implementing and maintaining the hygiene management system.

4.1.4 A manual defining the scope of the system including the documented procedures or references to them shall be established by the organization. The scope shall specify the products or product categories, processes and production sites that are addressed by the hygiene management system.

4.1.5 The organization shall establish documents needed to ensure the effective planning, operation and control of processes related to hygiene and to recalls.

4.1.6 The organization shall periodically review customer feedback, audit results and follow-up actions.

4.1.7 Top management shall ensure that responsibilities and authorities are defined. Duties of personnel that relate to this document shall be provided in job descriptions or other suitable documents.

4.1.8 Top management shall ensure that appropriate communication processes are in place within the organization.

4.1.9 The organization shall have a plan for cleaning and maintenance.

4.1.10 The requirements of this document shall also apply to contractors and temporary personnel.

4.2 Control of documents

4.2.1 The organization shall have a procedure to control documents and records.

4.2.2 Documents shall be properly approved, reviewed and updated with changes and current version status identified. They shall be made available at the point of use.

4.2.3 Records shall be maintained to provide evidence of the effective operation of the hygiene management system and retained for a period covering the normal and foreseeable shelf life of the packaged food.

4.3 Specifications

4.3.1 The organization shall establish and regularly review specifications for incoming materials and for products.

4.3.2 Where appropriate, the specifications shall be agreed between the organization and the interested parties.

4.4 Management of nonconformities and incidents

4.4.1 The organization shall have procedures for dealing with nonconformities and incidents and shall take action to eliminate them. Action shall be taken to eliminate the causes of nonconformities and incidents to prevent a recurrence.

4.4.2 The organization shall have written guidance to its personnel on events that could constitute an incident.

4.4.3 The nature of nonconformities and incidents and any subsequent actions taken shall be recorded. The effectiveness of the corrective action implemented shall be verified.

4.4.4 Where a nonconforming product is detected after delivery, or its use has started, the organization shall take appropriate action for all products concerned. The customer shall be informed about the nature of the nonconformity.

4.5 Traceability

4.5.1 The organization shall have procedures in place which ensure that the traceability of materials and products can be provided.

4.5.2 The effectiveness of the traceability system shall be demonstrated by an audit or by existing recall records or by a simulation of a recall.

4.6 Internal audits

4.6.1 The organization shall conduct internal audits at planned intervals to assess that the hygiene management system is effectively implemented and maintained.

4.6.2 The responsibilities and requirements for planning, conducting and reporting of audit results and maintaining records shall be specified in a procedure.

4.6.3 Auditors shall be competent and independent of the area to be assessed.

4.6.4 The manager responsible for the area being audited shall ensure that corrective actions are taken within an appropriate period.

4.6.5 Top management shall use the results of the audits for review and improvements.

4.7 Complaint management

4.7.1 The organization shall have a procedure for dealing with complaints.

4.7.2 Subsequent actions shall be proportionate to the frequency and seriousness of complaints.

4.8 Approval and monitoring of suppliers

4.8.1 The organization shall approve suppliers on the basis of their ability to supply incoming materials and services in accordance with the specified requirements. Records shall be maintained.

4.8.2 Suppliers shall be monitored in an appropriate manner. The results of the evaluation shall be recorded.

4.8.3 The organization shall establish and implement inspections or any other activities necessary to ensure that incoming materials meet specified requirements.